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Biosafety Regulatory Systems Overseeing the Use of Genetically Modified Organisms in the Latin America and Caribbean Region

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The development of a legal framework and the establishment of an administrative system are two fundamental elements when building a biosafety regulatory system. Further, the ability to process applications and make decisions concerning the various uses of genetically modified organisms (GMOs) are good indicators of an operational biosafety regulatory system. This study provides an update of the progress made by Latin American and Caribbean countries in the establishment of their biosafety regulatory systems, and focuses especially on the regulation of four key types of GMO use (e.g., contained use, confined use, unconfined use, and importation of GMOs or their derived products for food, feed, or processing purposes). It demonstrates that nine countries have operational biosafety regulatory systems with experience in all four types. The majority of countries, however, have little experience regulating GMOs. In fact, our study highlights common capacity deficiencies of these countries, upon which future assistance can be targeted.

Key words: administrative system, biosafety regulatory system, capacity building, genetically modified organisms (GMOs), Latin America and the Caribbean (LAC region), legal framework.

Introduction

The use of genetically modified organisms (GMOs), also called living modified organisms (LMOs), genetic engineered organisms (GEOs), transgenics, or products of recombinant DNA technologies (Kinderlerer, 2008; McHughen & Smyth, 2008) is regulated in the majority of countries around the world (Keese, 2013). Starting in the late 1970s, countries began to develop provisions to establish national biosafety regulatory systems to ensure the safe use of GMOs (Cantley, 2007; Kinderlerer, 2008; Tribe, 2012). For instance, in 1976, the US National Institutes of Health Recombinant DNA Advisory Committee published the first set of guidelines governing the safe conduct of recombinant DNA research, and in 1986 the first national biotechnology-specific legislation (The Gene Technology Act) was adopted by Denmark (Cantley, 2007).

The interest to establish national biosafety regulatory systems is a direct result of the country's vision and policy related to the role of the use of GMOs within its territory. In most developing countries, however, the establishment of national biosafety regulatory systems was an end product of the ratification and entry into force of the Cartagena Protocol on Biosafety (CPB) to the Convention of Biological Diversity (M^{c}Lean, Foley, & Pehu, 2012). The CPB is an international agreement that "aims to ensure the safe handling, transport, and use of LMOs resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health" (Secretariat of the Convention on Biological Diversity, 2000). Thus, over the last decade and more, developing countries have received international assistance through numerous capacity-building initiatives to develop or implement biosafety regulatory systems (Johnston, Mongagle, Green, & Mackenzie, 2008) as a means to implementing the CPB. To date, however, most developing countries still lack biosafety regulatory systems due to the lack of institutional capacities and professional expertise in scientific, technical, and legal disciplines for exercising regulatory oversight (Pertry et al., 2014). Further, the lack of appropriate coordination and harmonization across regulatory authorities within individual developing countries is slowing down GMO decision-making processes (Adenle, 2011, as cited by Araya-Quesada, Craig, & Ripandelli, 2012).

There is no best model for building a biosafety regulatory system because varying national priorities and interests by necessity influence each system. However, specific elements are commonly considered when building a biosafety regulatory system (Keese, 2013; M^{c}Lean et al., 2012; United Nations Environment Programme [UNEP], 2005). The first step is usually the development of a legal framework (Keese, 2013; M^{c}Lean et al., 2012; UNEP, 2005). This framework includes the adoption of a country's policy and legal instruments, such as

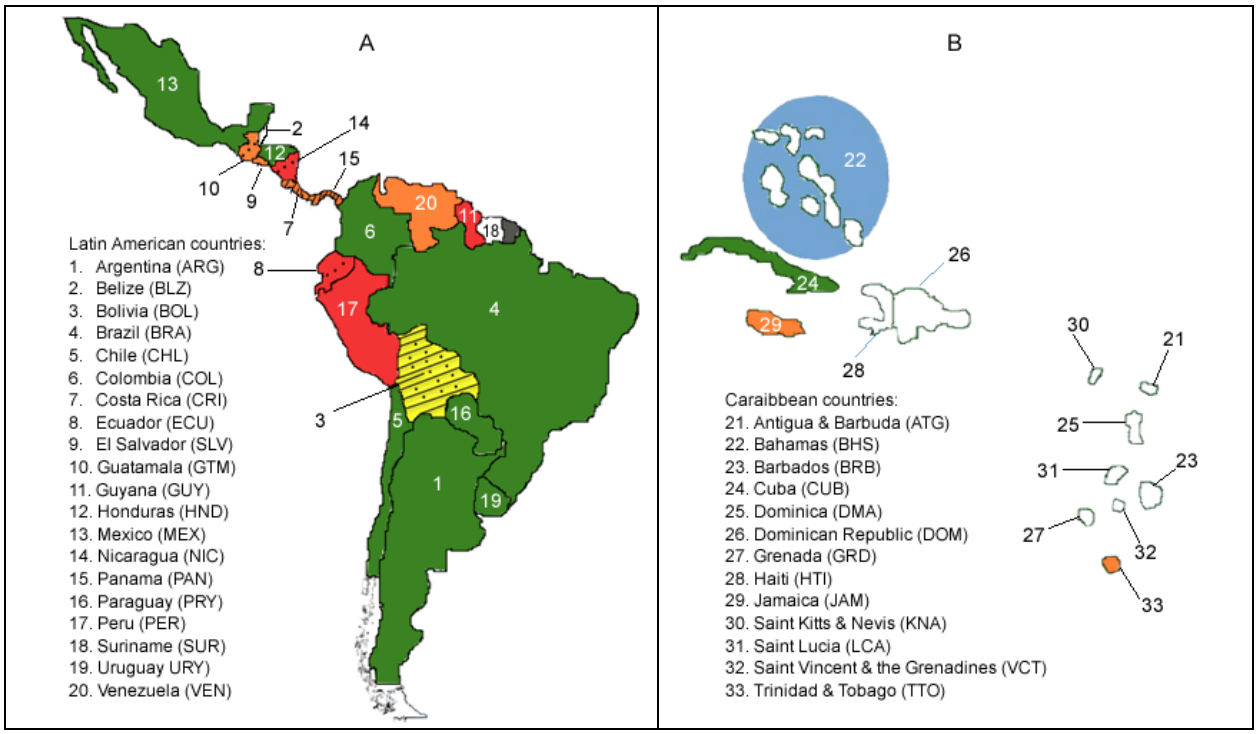

Figure 1. LAC countries with GMOs authorized for various purposes.

Note. Data compiled from Rodriguez (2016), Azurdia (2015), F. Tutillo (personal communication 2015), ISAAA (2015), MAGyP (2015), MCTI (2014, 2015), SENAVE (2015), USDA (2015a, 2015b, 2015c, 2015d), Araya et al. (2012), Comision Nacional de Bioseguridad para los Organismos Geneticamente Modificados (2012); CONARGEM (2005), SAG (1997, 2013), and Fermin et al. (2004, 2010). Maps not to scale. Categories: ■ Countries with GMOs under development in laboratory and/or glasshouse facilities (contained use); ■ Countries where CFTs of GMOs have been authorized (confined use); ■ Countries with both GMOs under development in laboratory and glasshouse facilities and authorized CFTs; ▨ Countries where the commercial-scale cultivation of GM crops has been authorized (unconfined use); ⊠ Countries where the importation of GMO or their derived products has been authorized; ■ Countries with GMOs under development in laboratory and glasshouse facilities, authorized CFTs, and where both GMOs for commercial-scale cultivation and importation has been authorized; □ No information found; and ■ Country not part of the study.

legislation and/or regulations. Then, the legal framework is put into practice by creating an administrative system, which ensures that procedures and tools are in place to support decision-making (Keese, 2013). The establishment of an administrative system involves the development of administrative procedures and tools for the lodgement and processing of applications and the making of each eventual regulatory decision. Finally, for the functioning of a biosafety regulatory system, a combination of human resources that have a biosafety technical background (including experience and qualifications in modern biotechnology and risk assessment), a legal competency in drafting and implementing legislation and hands-on experience in administrative procedures is required in each regulatory authority.

As expected, there is no "one-size-fits-all" approach to biosafety capacity building for developing countries, and understanding the specific country context (limitations and priorities) is the basis for any success from capacity-building assistance (Araya-Quesada, Degrassi, Ripandelli, & Craig, 2010; Johnston et al., 2008; M^{c}Lean et al., 2012).

In order for a country to be able to regulate the use of GMOs within its territory, it should have experience in processing applications and making decisions. However, these two activities are not the only factors that measure the degree of biosafety expertise in a country: a country can only truly generate indigenous regulatory experience through practice, and by utilizing key technical and scientific information resources (Araya-Quesada et al., 2012). As such, an operational GMO authorization process is a good indication of regulatory competency and maturity.

The first authorizations regulating the use of GMOs in Latin America and the Caribbean (LAC region) were made during the 1990s by Argentina (ARG),[1] Brazil

(BRA), Chile (CHL), Costa Rica (CRI), Honduras (HND), Mexico (MEX), and Uruguay (URY). To date, 11 countries of the LAC region, including the aforementioned countries and Bolivia (BOL), Colombia (COL), Cuba (CUB), and Paraguay (PRY), have commercially cultivated GM crops (International Service for the Acquisition of Agribiotech Applications [ISAAA], 2015; Figure 1). However, the degree of biosafety expertise available in the LAC region is quite diverse (Araya-Quesada et al., 2012). Some countries have operational biosafety regulatory systems and greater experience in authorizing the use of GMOs for multiple purposes, while others have little—or are yet to gain—experience with GMO authorization, as the majority of the latter are still lacking the legal framework that underpin a biosafety regulatory system.

Between 2009 and 2011, Araya-Quesada et al. (2012) undertook an email-based stakeholder consultation of more than 300 people intimately involved in biosafety and/or biotechnology in the LAC region. The study indicated that 19 countries had experience in processing applications and making decisions concerning the use of GMOs. Countries were categorized according to experience gained in authorizing four key types of GMOs use (regulatory activities). These four types were divided into two broad categories:

1. Research and development (R&D)
   - contained use (laboratory/glasshouse research),
   - confined use (confined field trials [CFTs]),

2. Commercial purposes
   - unconfined use (commercial cultivation), and
   - importation of GMOs or their derived products for food, feed, or processing purposes (FFPs).

Using the results of Araya-Quesada et al. (2012) as a baseline, the present study sought to provide an update of the progress, if any, made by countries in the LAC region in authorizing these four types of GMO use. The present study considered countries to have an operational biosafety regulatory system if they have experience processing applications and making decisions in all four regulatory activities. Further, specific elements for building biosafety regulatory systems are described, with examples from operational LAC national systems and common limitations identified for building a biosafety regulatory system in countries with little, if any, experience in the authorization of the use of GMOs. Finally, the present study proposes key considerations for possible capacity-building assistance in the region.

Operational Biosafety Regulatory Systems: Experience in the Authorization of the Use of GMOs for Various Purposes

Research and Development (R&D)

Contained Use. Ecuador (ECU), PRY, and Venezuela (VEN) joined the list of 20 LAC countries (Figure 2) in which GMO research is authorized in laboratory and glasshouse facilities. In 2012, ECU's Polytechnic Superior School of the Coast (ESPOL), a public university, began developing GM bananas resistant to black sigatoka, a leaf-spot disease caused by the ascomycete fungus *Mycosphaerella fijiensis*. These GM plants, however, remain in containment facilities since ECU's biosafety regulatory system prohibits field trials and commercial-scale cultivation of GM crops (US Department of Agriculture [USDA], 2015a). With the enactment of the ECU's Constitution (2008), the government has declared the country to be free of GM crops and seeds (Article 401). In fact, Article 401 also states that GM crops and seeds may enter into the ECU's territory only under exceptional conditions (applications can be submitted and processed) should these GMOs be of national interest according to the Presidency of the Republic and approved by the National Assembly. Currently there are initiatives to amend Article 401 of the Constitution in order to remove the prohibition to use GM crops and seeds (F. Tutillo, personal communication, 2015). Similarly in VEN, the University of the Andes (ULA), in collaboration with Cornell University, has been developing local GM papaya varieties resistant to ringspot virus since 1993 (Fermin et al., 2004), but the products of this research also have yet to reach the market due to the current biosafety regulatory system in VEN prohibiting the commercial cultivation of GM crops. With the recent enactment of VEN's Law of Seeds (2015), the production, import, commercialization, propagation, and use of GM seeds are prohibited in VEN's territory. In contrast, since 2013, PRY's Plant Health Inspection Service (SENAVE) has authorized nine GM crop events for research purposes: one GM maize (Organisation for Economic Co-operation and Development [OECD] Unique Identifier.[2] MON-89034-3 × DAS-01507-1 × MON00603-6 × DAS-40278-9);

1. *Official ISO 3166-1 alpha-3 three-letter country codes (see http://unstats.un.org/unsd/tradekb/Knowledgebase/Country-Code).*

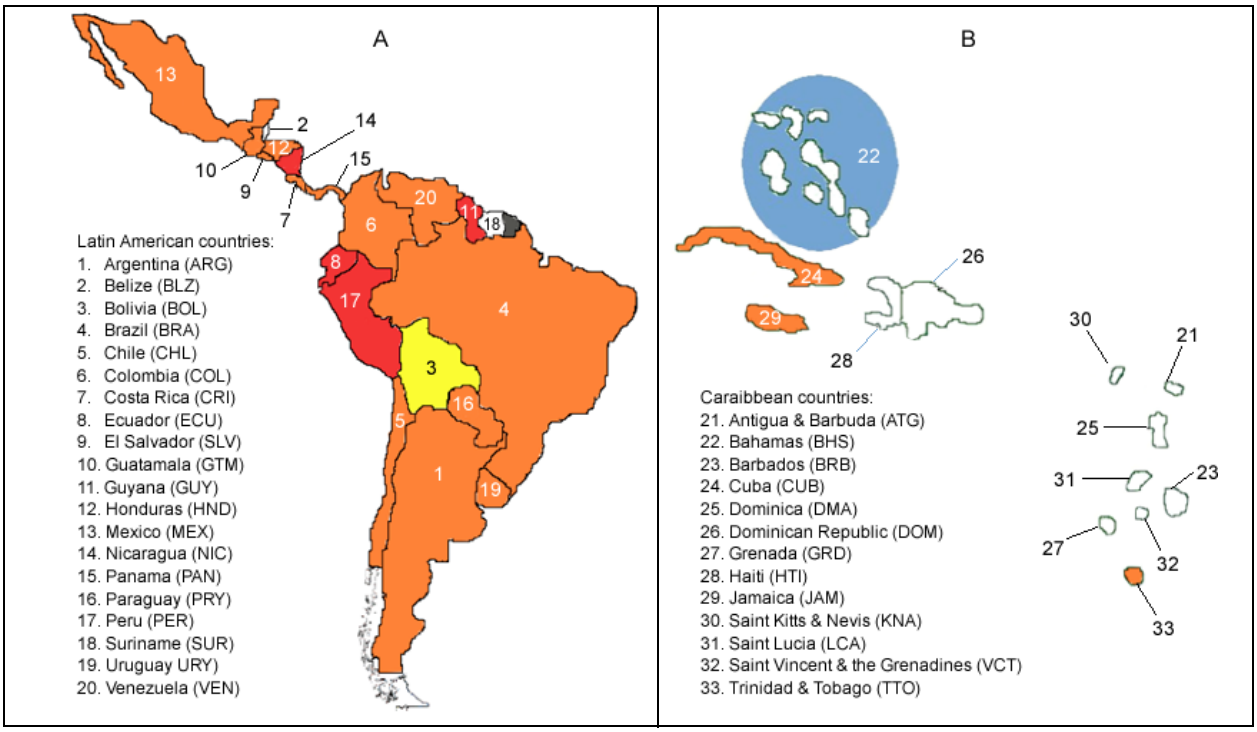

Figure 2. LAC countries with GMOs under R&D.

Note. Data compiled from Rodriguez (2016), Azurdia (2015), SENAVE (2015), USDA (2015a, 2015b, 2015c, 2015d), Araya et al. (2012), and Fermin et al. (2004, 2010). Maps not to scale. Categories: ■ Countries with GMOs under development in laboratory and/or glasshouse facilities (contained use); ■ Countries where CFTs of GMOs have been authorized (confined use); ■ Countries with both GMOs under development in laboratory and glasshouse facilities and authorized CFTs; □ No information found; and ■ Country not part of the study.

two GM cottons (MON-88913-8 and MON-88913-8 × MON-15985-7); and six GM soya beans (MON-87708-9 × MON-89788-1, DAS-44406-6, DAS-81419-2 × DAS-44406-6, ACS-GM006-4, MST-FG072-2 and MST-FG072-2 × ACS-GM006-4; SENAVE, 2015).

Confined Use

There are now 17 countries in the LAC region that have authorized CFTs of GM plants (Figure 2). New approvals for CFTs were authorized in Guatemala (GTM) and VEN. With respect to the latter two countries, in 2004, the Ministry of Agriculture, Livestock, and Food in GTM (MAGA) have approved CFTs of GM maize (MON-00810-6) and GM cotton (ACS-GH001-3); and in 2012, MAGA approved CFTs for an additional GM maize event (DAS-01507-1; Azurdia, 2015; USDA, 2015b). In 2001, ULA obtained a special permit from VEN's Ministry of Health to undertake a CFT of their GM papaya (Fermin, Castro, & Tennant, 2010). To date, none of these products are yet being produced commercially, as both countries still prohibit the commercial use of GM crops within their territories. The GTM regulatory system does not allow placing GM products on its market; the only permitted use is the propagation of GM seeds for export purposes.

Concerning CFTs of GM animals, in 2014 BRA's National Biosafety Council approved CFTs of GM mosquitoes to determine their efficacy in the control of dengue fever (Ministerio da Ciencia, Tecnologia e Inovacao [MCTI], 2014). BRA and Panama (PAN) are the only countries in the LAC region to have authorized CFTs of GM animals, with PAN approving GM salmon and GM mosquitoes, while BRA has approved only the latter (Araya-Quesada et al., 2012).

To date, R&D of GMOs is conducted in most Latin American countries (18) as opposed to Caribbean countries (three; Figure 2). In the Latin America sub-region, 13 countries have carried out activities with GMOs in

2. *A Unique Identifier is a nine-digit alphanumeric code that is given to each transgenic plant that is approved for commercial use, including planting and food or feed use (OECD, 2004).*

both containment and confinement facilities (orange; Figure 2a). ECU, Guyana (GUY), Nicaragua (NIC), and Peru (PER) have only carried out activities with GMOs in laboratory and/or glasshouse facilities (red; Figure 2a). In fact, similar to ECU, GMO R&D in PER remains in containment facilities due to PER's biosafety regulatory system prohibiting CFTs and commercial cultivation of GMOs. With the enactment of the moratorium law, PER prohibits CFTs and the commercial cultivation of GMOs for a period of 10 years (2011-2021). In the case of GUY, the country does not have a biosafety legal framework in place to oversee the development of GMOs in CFTs. Further, NIC has had a biosafety law in place since 2010 to regulate the use of GMOs, but to date its National Commission of Risk Analysis of GMOs (CONARGEM) has yet to approve any GMO for field testing (USDA, 2015c). Finally, BOL's regulatory authority has not received any request for GMO use in containment (Rodriguez, 2016), however, BOL has approved the field testing of GMOs developed outside its territory (yellow; Figure 2). With respect to the Caribbean sub-region, there are a few countries such as CUB, Jamaica (JAM), and Trinidad and Tobago (TTO) that have conducted activities with GMOs for contained and confined use (orange; Figure 2b). No information was found for the remaining 10 Caribbean countries (white; Figure 2b) and there is a strong likelihood that the majority of them are not carrying out activities with GMOs under R&D.

Commercial Purposes

Unconfined Use. In the LAC region, the main GM crops authorized for commercial cultivation are soya bean, maize, and cotton. Overall, GM crops are authorized for commercial cultivation in more Latin American countries (11) than in Caribbean countries (one: CUB; Figure 1). CHL, CRI, and PAN joined the list of countries (Figure 1) in which the commercial cultivation of GM crops has been authorized. The regulatory systems of CHL and CRI do not allow the placing of GM products on their markets, although they have both approved the propagation of GM seeds for export purposes. Since 2012, PAN has begun authorizing the commercial cultivation of GM crops, beginning with GM maize DAS-01507-1 (Comision Nacional de Bioseguridad para los Organismos Geneticamente Modificados, 2012). In addition, three new GM crops have been authorized for commercial cultivation in the region: GM eucalyptus and GM bean in BRA (MCTI, 2015) and GM potato in ARG (Ministerio de Agricultura, Ganaderia y Pesca [MAGyP], 2015).

Importation of GMOs or Their Derived Products for FFPs. To date, 13 countries in the study region have authorized the importation of GMOs or their derived products for FFPs (Figure 1). The importation of GMOs or their derived products for FFPs is authorized in more Latin American countries (12) than Caribbean ones (CUB only). Three countries (CHL, ECU, and NIC) have recently joined the list of LAC countries that have issued such authorizations. NIC has approved the import of 15 different events of GM maize (CONARGEM, 2005), while CHL has approved the import of GM maize MON-00810-6 (Servicio Agricola y Ganadero [SAG], 1997) and GM soya bean MON-89788-1 (SAG, 2013), each for use as animal feed only. Further, ECU has approved the import of food products from GM maize, soya bean, and tomato (F. Tutillo, personal communication, 2015).

Overall, countries which have authorized GMOs for commercial purposes are mainly located in the Latin America sub-region (Figure 1). In this sub-region, nine countries have authorized GMOs for both commercial cultivation and import (green and BOL; Figure 1a). ECU, GTM, and NIC have only authorized the importation of GMOs or their derived products for FFPs (black dots; Figure 1a). In fact, as previously mentioned, ECU prohibits the commercial cultivation of GM crops while GTM and NIC both have biosafety legal frameworks in place but do not yet have an operational administrative system to handle applications for commercial cultivation. Further, CRI and PAN have authorized GM crops for only commercial cultivation (black dashes; Figure 1a). In 2010, PAN's National Commission of Biosafety for GMOs received a request for the importation of GM rice for FFPs, but as of 2015 this was still under review (USDA, 2015d). Further, CRI's biosafety regulatory system prohibits the importation of GMOs or their derived products for domestic consumption. Moving to the Caribbean sub-region, CUB is the only country that has authorized the use of GMOs for commercial cultivation and import (green; Figure 1b). Further, no information was found in this respect for the remaining Caribbean countries (white, JAM and TTO; Figure 1b); in fact, these countries do not have a biosafety regulatory framework in place to oversee activities with GMOs for commercial cultivation nor import.

In conclusion, our study shows that, since the report by Araya-Quesada et al. (2012), an additional eight Latin American countries (CHL, CRI, ECU, GTM, NIC,

Table 1. Main legal instrument in LAC countries with experience in all four biosafety regulatory activities.

Country	Main legal instrument	Type of instrument	Year of enactment
ARG	Resolucion MAGYP 763/2011	Regulation	2011
BRA	Lei 11.105	Law	2005
CHL	Resolucion No.1523 establece normas para la internacion e introduccion al medio ambiente de organismos vegetales vivos modificados de propagacion	Regulation	2001
COL	Ley 740 por medio de la cual se aprueba el Protocolo de Cartagena sobre Seguridad de la Biotecnologia del Convenio sobre la Diversidad Biologica	Law	2002
CUB	Decreto-Ley 190 De la seguridad biologica	Law	1999
HND	Reglamento de bioseguridad con enfasis en plantas transgenicas	Regulation	2001
MEX	Ley de bioseguridad de los organismos vivos modificados	Law	2005
PRY	Decreto No.9699 por el cual se crea la Comision Nacional de Bioseguridad Agropecuaria y Forestal (CONBIO)	Regulation	2012
URY	Decreto 335/008. Dictense normas relativas a bioseguridad de vegetales y sus partes geneticamente modificadas y deroganse los Decretos 249/000 y 37/007	Regulation	2008

PAN, PRY, and VEN) have gained experience in the authorization of GMO use for various purposes. Together this means that 64% (21) of the countries in the LAC region now have experience in regulating GMOs (Figure 1). Of these, nine countries have operational biosafety regulatory system with experience authorizing the use of GMOs in all four regulatory activities (green; Figure 1). CHL and PRY joined ARG, BRA, COL, CUB, HND, MEX, and URY in demonstrating experience in all four of the key types of the regulatory activities of interest.

Our study indicates that the majority of LAC countries (24), mainly those in the Caribbean sub-region, do not have the full complement of GMO regulatory experience, ranging from none to three of the four key types of regulatory activities. Countries with experience in three of the four regulatory activities are CRI, GTM, and PAN (CRI and PAN have yet to authorize GMO imports for FFPs, and GTM has no regulatory experience with unconfined GMO use). Notably, though previously included in the group of countries with experience in three regulatory activities (Araya-Quesada et al., 2012), BOL now has a restrictive law that prohibits CFTs and commercial cultivation of GMOs. With the enactment of the Mother Earth Framework Law in 2012, BOL specifically prohibits the import, production, and commercialization of GM seeds and requires measures for the gradual elimination of any previously approved GM seed. In addition, eight countries have experience in one or two types of regulatory activities (two types: ECU, El Salvador [SLV], JAM, NIC, TTO, and VEN; and one type only: GUY and PER). Finally, no information was found for 10 countries located in the Caribbean sub-region (Antigua and Barbuda [ATG], Bahamas [BHS], Barbados [BRB], Dominican Republic [DOM], Dominica [DMA], Grenada [GRD], Haiti [HTI], Saint Lucia [LCA], Saint Kitts and Nevis [KNA], and Saint Vincent and the Grenadines [VCT]; white; Figure 1) and for two Latin American countries (Belize [BLZ] and Suriname [SUR]). In fact, these 12 countries have yet to acquire experience in authorizing GMOs for any use at all and are all faced with common limitations in the construction of national biosafety regulatory systems at both the legal and administrative levels. There is also an apparent insufficiency of trained human resources to process applications and make decisions in these countries.

Specific Elements for Building Biosafety Regulatory Systems

Development of Biosafety Legal Framework

Countries that lack biosafety legal frameworks initially tend to prepare a biosafety policy, which outlines their positions concerning the use of GMOs; the scope and functions of the regulatory authority(s); and the role of stakeholders, including other country departments and agencies (Keese, 2013). This policy is the basis for the development of specific legislation and regulations (M^{c}Lean, Frederick, Traynor, Cohen, & Komen, 2003; UNEP, 2005). Developing biosafety legislation may involve the amendment of pre-existing national legislation or the enactment of new laws (Keese, 2013). Some countries only enact regulations such as decrees and use resolutions to serve as the main legal instruments to regulate the use of GMOs in the absence of specific biosafety legislation (Table 1). Once the biosafety legislative framework is established, a country can

begin to develop a set of specific regulations to implement the legislation. In the LAC region, countries with operational biosafety regulatory systems have been enacting new laws and regulations since the 1990s. Table 1 lists the main current legal instrument in specific LAC countries used to regulate GMO use. Countries such as ARG, BRA, CHL, MEX, PRY, and URY have had biosafety legal instruments since the 1990s, however, these instruments have since been modified to become the instruments indicated in Table 1.

It is important to note that the elaboration of policy, legislation, and regulations must be consistent with other biosafety-related instruments, such as national legal instruments and international obligations, including treaties and agreements (e.g., CPB to the Convention on Biological Diversity and the International Plant Protection Convention) and relevant international obligations directed by the Codex Alimentarius Commission, International Organization for Standardization, World Organization for Animal Health and the World Trade Organization (Keese, 2013; M^{c}Lean et al., 2003).

Based on their biosafety legal framework, countries usually nominate and delegate functions to different regulatory authorities (e.g., specialized Ministries, agencies, and/or advisory bodies) to implement the biosafety regulatory system and also to designate the final decision-maker(s), such as the President of a Board, a Minister, an Administrator, etc. In some cases, the scope of the decision-maker varies depending on the purpose of the GMO use. Thus, some legislation states that the Minister of Agriculture is the decision-maker for applications for the use of GMOs for agricultural purposes, while the Minister of Environment is the decision-maker for environment purposes, and the Minister of Health is the decision-maker for GMOs or their derived products for FFPs. Some countries however, prefer to designate only one overall decision-maker regardless of the sector of eventual authorized use (e.g., ARG, BRA, CHL, CUB, HND, PRY, URY).

Establishment of Administrative Systems

Countries need an administrative system of procedures and tools for the lodgement and processing of applications and for making the final decision. Around the world, numerous reviews have documented a variety of established regulatory approaches to evaluate the risks associated with the use of GMOs (M^{c}Hughen & Smyth, 2008). Furthermore, key elements such as appropriate mechanisms for risk assessment, risk management, and risk communication are well established (M^{c}Lean et al., 2012). The central role of risk assessment in regulatory decision-making is well-recognized and is evident from the large amount of guidance material and training courses available (Keese, 2013).

In order to facilitate the lodgement of applications, regulatory authorities must first make application forms available, and usually directly from their website. For example, in the LAC region, application forms[3] are available on the websites of ARG's Ministry of Agroindustry and URY's Biosafety National Cabinet (GNBio). According to these two examples, and supported by Keese (2013), a model application form for commercial use will request the following information:

- the identity and address of the applicant,
- the type of licence/permit authorization applied for,
- the intended use of the GMO,
- a scientific and technical description of the GMO,
- proposed conditions to safely manage the activity with the GMO, and
- any previously granted approval(s) of the same GMO use by a foreign regulatory authority/ies.

Application forms for contained and confined use can also request information such as the technical staff responsible for carrying out the proposed activities involving the GMOs, and the facility to be used or the location for which the activity with the GMO is intended. Moreover, additional forms and requirements may be developed for the collection of specific information and made available on the regulatory authority website. For instance, requirements of risk assessments[4] are available on the website of HND's National Agriculture Health Service (SENASA) and CHL's Agricultural and Livestock Service (SAG). In addition, regulatory authorities, such as those from URY[5] also describe the payment process for application fees (if applicable).

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3. *To download the application forms from ARG and URY, see: http://www.agroindustria.gob.ar/sitio/areas/biotecnologia/solicitudes/ and http://www.mgap.gub.uy/unidad-ejecutora/direccion-general-de-control-de-la-inocuidad-alimentario/bioseguridad/procedimientodeautorizacion, respectively.*
4. *To download the guidance for risk assessment from CHL and HND, see http://www.sag.cl/ambitos-de-accion/organismos-geneticamente-modificados-ogm/1354/procedimientos, and http://www.senasa.gob.hn/index.php/sub-direcciones/sub-direccion-tecnica-de-sanidad-vegetal/depto-de-certificacion-de-semillas/formato-y-requisitos-cs, respectively.*
5. *See http://www.mgap.gub.uy/sites/default/files/multimedia/2017_tarifas_01082017_0.pdf.*

It is also common for biosafety legislation to require the publication of a notice indicating the receipt of each application (including the description of the GMO and its intended use) in the country gazette, local newspapers, or regulatory authority website for a specific period (Keese, 2013). The legislation may require this to facilitate the inviting of public comments or for legal notification purposes. ARG's Ministry of Agroindustry, MEX's Inter-secretarial Commission of Biosafety of GMOs (CIBIOGEM), and URY's GNBio all publish a summary of each application received on their respective websites in order to invite comments from the public for a specific period. Other countries, such as CHL, publish a summary of the application in the official gazette. It is also common during the application process for the applicant to be required to provide information that is considered confidential, and thus will provide reasons for it not to be made public. Some biosafety legislation also requires publishing a summary of the results of the risk assessment for public comments or legal notification purposes (e.g., ARG, BRA, COL, HND, MEX, and URY). COL (J. Bocanegra, personal communication, 2015) and HND (C. Almendares, personal communication, 2015) only publish a summary of the risk assessment on the international node of the Biosafety Clearing-House (BCH).[6]

Regarding the processing of applications, it is common for biosafety legislation to require the establishment of a Technical Advisory Committee or Council (TAC) to provide scientific and other technical advice to the decision-maker. The TAC is usually tasked to undertake the requisite risk assessment or to review the risk assessment documents lodged by the applicant. Members of the TAC are typically representatives from Ministries and agencies of regulatory authorities, universities, and the private sector, amongst others. These representatives are mostly full-time employees of their institutions and, at the same time, *ad hoc* members of the TAC. The regularity of committee meetings may vary depending on the number and type of applications received. Legislation, for example from ARG, COL, and MEX, may establish more than one TAC charged to assess applications according to specific intended uses. In addition, biosafety legislation can allow the TAC to seek advice from other national and international experts in the field or to form sub-committees.

Finally, upon receipt of the application and evaluation by the TAC, the decision-maker may either decide to approve a license or permit, to refuse it, or to approve it subject to conditions. Legislation may also require the establishment and maintenance of a publicly-accessible register of licenses and permits. In the LAC region, a public register of licenses and permits is available on the websites of ARG's Ministry of Agroindustry, BRA's National Biosafety Technical Commission (CTNBio), COL's Ministry of Health and Social Protection (MINSALUD), MEX's CIBIOGEM, and URY's GNBio. Moreover, a public register is also available in the international BCH for the aforementioned countries, including HND.

Common Limitations of Biosafety Regulatory Systems

Lack of Biosafety Legal Frameworks

Beginning in 2001, the LAC region has received technical support from the United Nations Environment Programme (UNEP), funded by the Global Environment Facility (GEF), for the development and implementation of national biosafety frameworks. To date however, 12 countries, principally located in the Caribbean sub-region, have only progressed to having drafts of their legal biosafety frameworks, and in some cases, biosafety bills (Table 2); these drafts are undergoing revision in preparation for future enactment. Further, some countries, such as ATG and KNA, are also developing regulations to support the implementation of their biosafety legislation.

In fact, according to our study, the majority of these countries have yet to gain GMO regulatory experience. Specifically, the Caribbean sub-region comprises more countries (10) in the LAC region with no GMO regulatory experience than the Latin America sub-region (BLZ and SUR only). Amongst the Caribbean countries with no GMO regulatory experience, only DOM and KNA have recently promulgated biosafety laws (Table 3). The Caribbean sub-region also includes two countries, GUY and TTO, with experience in one and two regulatory activities, respectively. In fact, these two countries make use of plant quarantine import permits to authorize the importation and introduction of GMOs. However, none of these countries have an operational biosafety regulatory framework in place to oversee the production or release of GMOs. This therefore represents a serious impediment to activities for R&D in both

6. *See https://bch.cbd.int website for more information about the BCH.*

Table 2. Description of legal framework for those LAC countries without a promulgated biosafety legal framework.

Country	Current biosafety legal status	Draft regulations
ATG	Latest 2015 draft Bill ready for finalization by the Office of Parliamentary Drafting and will be subject to another consultation	Prepared in 2015: i) import, export, and transit; ii) environmental release; iii) contained use; and, iv) labelling
BHS	Have only a draft national biosafety framework completed in 2008	None
BRB	Draft Bill prepared in 2008 and still undergoing review	None
BLZ	Draft Bill prepared in 2006 and still undergoing review	None
DMA	Latest draft Bill was finalized in 2016 and it is waiting for approval by the House of Assembly so it can be enacted	None
GRD	Biosafety Policy was approved in 2014. Latest 2014 draft Bill is ready for finalization by the Parliamentary drafter from the Ministry of Legal Affairs, after which approval for introduction will be sought	None
GUY	Latest draft of Biosafety Bill was prepared in 2015 and upon which a public consultation is currently underway	None
HTI	Have only a draft national biosafety framework which was completed in 2008	None
LCA	Latest draft of Biosafety Bill prepared in 2014 and currently undergoing further re-drafting. Both the biosafety legislation and policy are still in draft form and have yet to go before Parliament	None
VCT	Latest draft of Biosafety Bill prepared in 2015 and currently undergoing re-drafting	None
SUR	No draft bill	None
TTO	Have a draft national biosafety framework which was completed in 2015	None

contained and confined use, as well as on a commercial level (USDA, 2015e).

Clearly, these LAC countries will continue to face a *de facto* moratorium regarding the importation and use of GMOs until they have a biosafety regulatory system in place. The lack of legislative instruments can result in the complete prohibition of the use of GMOs until such time that there is sufficient political will to resolve the situation (Obonyo, Nfor, & Uzochukwu, 2011). Due to the absence of appropriate legislation, there are protracted delays in assessing GM products, and by extension, any eventual authorization. Such delays, caused by the lack of judicial and political decisions, can result in undesirable situations, such as the illegal planting of GM crops (Pelaez, 2009, as cited by Obonyo et al., 2011). For instance, there has been illegal importation of GMOs into ATG with GM seeds confiscated by the Plant Protection Agency (Black-Layne, 2016).

Absence of Administrative Systems

The majority of the LAC countries with GMO regulatory experience in less than four key types of GMO use, principally in the Caribbean sub-region, require the adoption of administrative systems for the effective functioning of their biosafety regulatory systems such that applications for GMO use can be processed and regulatory decisions made. The majority of Latin American countries and a few Caribbean countries have promulgated biosafety legal frameworks but have yet to implement an operative administrative system to handle applications for all four key types of GMO use (Table 3). Even though BOL, ECU, PER, and VEN have legal instruments in place, they also have restricted regulations that prohibit CFTs and commercial cultivation in their territories, and thus no specific administrative procedures are required for those regulatory activities. Some GMO uses, such as research activities in contained use, are however permitted in these four countries, and the importation of GMOs or derived products for FFPs is allowed in BOL, ECU and PER. These latter GMO regulatory activities will require administrative procedures to be developed. The majority of countries in the LAC region have not yet developed procedures for the lodgement, processing, and decision-making concerning applications, nor have they developed tools (e.g., application forms, guidance documents, standard operating procedures, etc.) that lay the basis for an effective administrative system.

Currently, a few LAC countries (ECU, SLV, GTM, PAN, PER, and KNA) are developing drafts of their administrative systems under their respective UNEP-GEF National Biosafety Framework Projects. However, due to the recent nature of their legislation enactment, DOM (M. Hernandez, personal communication, 2015)

Table 3. Current biosafety status of LAC countries with a promulgated biosafety legal framework but without administrative procedures for all four biosafety regulatory activities.

Country	Main legal instrument	Administrative system
BOL	Have had biosafety regulations since 1997 *(Reglamento sobre bioseguridad)*	No
CRI	Have had a biosafety law since 2006 *(Ley No.8537 Ley 740 Aprobacion del Protocolo de Cartagena sobre Seguridad de la Biotecnologia del Convenio sobre la Diversidad Biologica)*	Yes (only for contained, confined and unconfined use)
DOM	Have a recent biosafety law which was enacted in 2015	No
ECU	Have a recent biosafety regulation which was enacted in 2015 *(Acuerdo No.425 Reformar el titulo VII del libro IV del texto unificado de legislacion secundaria del Ministerio del Ambiente)*	No. Being developed under the UNEP-GEF National Biosafety Project
SLV	Have had biosafety regulations since 2008 *(Decreto No.78. Reglamento especial para el manejo seguro de los organismos modificados geneticamente)*	No. Being developed under the UNEP-GEF National Biosafety Project
GTM	Have had biosafety regulations since 2006 *(Acuerdo Ministerial No.386-2006 acuerdase establecer los requisitos para la importacion, transporte, manejo dentro del pais, establecimiento de experimentos de campo y produccion para exportacion de organismos vivos modificados – OVM, para uso agricola)*	No. Draft of administrative system was developed in 2015 under the UNEP-GEF National Biosafety Project
KNA	Have had a Biosafety Act since 2012	No. Being developed under the UNEP-GEF Regional Biosafety Project
JAM	Have The Plant (Quarantine) Act, 1997	Yes (only for contained and confined use)
NIC	Have had a biosafety law since 2010 *(Ley No.705. Ley sobre prevencion de riesgos provenientes de organismos vivos modificados por medio de biotecnologia moderna)*	No
PAN	Have had a biosafety law since 2002 *(Ley No.48. Ley que crea la Comision Nacional de Bioseguridad para los Organismos Geneticamente Modifcados y dicta otras disposiciones)*	No. Being developed under the UNEP-GEF National Biosafety Project
PER	Have had a biosafety law since 1999 *(Ley No.27104. Ley de prevencion de riesgos derivados del uso de la biotecnologia)*	No. Being developed under the UNEP-GEF National Biosafety Project
VEN	Have had a biosafety regulation since 2006 *(Decreto No.4.334, mediante el cual la se dispone que la Comision Nacional de Bioseguridad, como organism tecnico-cientifico, asesorara al Ejecutivo Nacional en las actividades que en el se senalan)*	No

and KNA (V. Woods, personal communication, 2016) have not yet developed specific regulations for the effective implementation of their legislation. Both countries are in the early stages of drafting regulations for the implementation of administrative systems. In general, the lack of administrative systems triggers delays and denials in the acceptance and processing of applications. For example, in the case of DOM, in 2006 the Regulatory Authority, the former Secretary of Environment and Natural Resources (now Ministry of Environment and Natural Resources), denied the import of GM zebra fish (GloFish®), citing the lack of regulations regarding decision-making (Secretaria de Estado de Medio Ambiente y Recursos Naturales, 2006). Other countries, such as PER, do not have specific regulations to help implement biosafety legislation and handle applications (S. Pastor, personal communication, 2015). In addition, neither GTM (C. Azurdia, personal communication, 2015) nor DOM (M. Hernandez, personal communication, 2015) offers official risk assessment guidance to support the processing of applications.

Conclusions

Our results demonstrate since Araya-Quesada et al. (2012), the establishment of biosafety regulatory systems and the degree of GMO regulatory experience are still diverse across the LAC region. Notably, there is a big difference in terms of regulatory experience in processing applications and making decisions between Latin American and Caribbean countries. The Latin America sub-region is home to eight countries with operational biosafety regulatory systems that have accumulated extensive experience in regulating GMOs for a multitude of diverse purposes. In the Caribbean sub-region, however, CUB is the only country with a wide experience in regulating the use of GMOs. The lack of biosafety legal frameworks and the absence of administrative systems, principally in the Caribbean sub-region,

are two main common limitations faced by the majority of LAC countries in establishing their biosafety regulatory systems. Therefore, these limitations create a *de facto* moratorium regarding the use of GMOs in such countries until a biosafety regulatory system is in place.

Clearly, the national priorities and interests of each country vary the scope of their GMO regulation. Based on their national biosafety legal framework, countries indicate the uses of GMOs that are permitted within their territories. In fact, capacity building assistance is most effective when provided as phased support, focusing initially on the one or two GMO uses that the countries are immediately facing (e.g., developing and implementing administrative procedures for processing applications and making decisions on limited regulatory activities, such as importation as a first step, or contained use), and then building upon that to extend to the full complement of regulated GMO use in accordance with its biosafety legal framework.

Our study suggests that capacity-building assistance in the region is best focused on efforts at the legal and administrative level. It is worth noting that those few LAC countries currently with comprehensive and operational systems have created them with minimal international assistance and have expended great efforts to improve their systems, thus gaining experience processing applications and making decisions, while the remainder (the majority) of LAC countries still do not have such systems in place, even after more than 10 years of receiving international technical and financial assistance from various donors. In fact, many countries, principally in the Caribbean sub-region, have yet to promulgate any biosafety legislation. However, further analysis is needed to investigate the extent to which insufficient political will is a key factor in the success of capacity building assistance.

In the LAC region, there are good examples of countries with competent and mature regulatory systems. The formation of strategic partnerships between such countries and others with less experience would greatly assist the harmonization of regulatory matters (e.g., drafting and implementing legislation) and administrative procedures (e.g., operational GMO authorization processes) in the region. ARG, BRA, CUB, and MEX are obvious strong candidate countries to lead such strategic partnerships.

Finally, recognizing that the cohort of personnel trained in any given capacity building project or endeavor is subjected to the fluxes of parliamentary changes, the degree of their training as well as the stability of their positions suffer, and thus until the establishment of a bona fide regulatory system is prioritized by the government and/or society, this phenomenon of insufficient trained human resources will continue to be requested in future capacity-building initiatives.

References

Araya-Quesada, M., Craig, W., & Ripandelli, D. (2012). Biosafety of genetically modified organisms in the Latin America and the Caribbean region: Main needs and opportunities for strategic capacity building. *AgBioForum*, *15*(1), 77-88. Available on the World Wide Web: http://www.agbioforum.org.

Araya-Quesada, M., Degrassi, G., Ripandelli, D., & Craig, W. (2010). Key elements in a strategic approach to capacity building in the biosafety of genetically modified organisms. *Environmental Biosafety Research*, *9*, 1-7.

Azurdia, C. (2015). *Third national report on the implementation of the Cartagena Protocol on Biosafety.* Ciudad de Guatemala, Guatemala: Biosafety Clearing-House. Available on the World Wide Web: https://bch.cbd.int/database/record.shtml?documentid=109123.

Black-Layne, D. (2016). *Third national report on the implementation of the Cartagena Protocol on Biosafety.* St. John's, Antigua and Barbuda: Biosafety Clearing-House. Available on the World Wide Web: https://bch.cbd.int/database/record.shtml?documentid=110835.

Cantley, M. (2007). *An overview of regulatory tools and frameworks for modern biotechnology: A focus on agro-food*. Paris, France: Organisation for Economic Co-operation and Development (OECD). Available on the World Wide Web: http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926623.pdf.

Comision Nacional de Bioseguridad para los Organismos Geneticamente Modificados. (2012). Resolucion CNB No.05-2012. Por la cual se recomienda a la Autoridad Nacional Competente, autorizar siembras controladas de maiz con la tecnologia Herculex I (DAS-01507-1) [Resolution CNB No.05-2012. For which it is recommended to the Competent National Authority, authorize controlled corn plantings with the Herculex I technology]. *Gaceta Oficial Digital*, *27105-A.* Available on the World Wide Web: http://gacetas.procuraduria-admon.gob.pa/27105-A_2012.pdf.

Comision Nacional de Analisis de Riesgos de Organismos Geneticamente Modificados (CONARGEM). (2005). *Conclusion final. Analisis de riesgo de eventos de maiz amarillo geneticamente modificado para uso de alimento balanceado para aves* [Final Conclusion: Risk Analysis of genetically modified yellow maize events to be used as feed for birds]. Managua, Nicaragua: Author. Available on the World Wide Web: https://bch.cbd.int/database/record.shtml?documentid=15170.

Fermin, G., Inglessis, V., Garboza, C., Rangel, S., Dagert, M., & Gonsalves, D. (2004). Engineered resistance against *Papaya ringspot virus* in Venezuelan transgenic papayas. *Plant Disease*, *88*, 516-522.

Fermin, G., Castro, L., & Tennant, P. (2010). CP-transgenic and non-transgenic approach for the control of papaya ringspot: Current situation and challenges. *Transgenic Plant Journal*, *4*(Special issue 1), 1-15.

International Service for the Acquisition of Agribiotech Applications (ISAAA). (2015). *50 Biotech bites*. Ithaca, NY: Author. Available on the World Wide Web: http://www.isaaa.org/resources/publications/50biotechbites/download/50_Biotech_Bites.pdf.

Johnston, S., Mongagle, C., Green, J., & Mackenzie, R. (2008). *Internationally funded training in biotechnology and biosafety: Is it bridging the biotech divide?* Yokohama, Japan: United Nations University Institute of Advanced Studies (UNU-IAS). Available on the World Wide Web: http://archive.ias.unu.edu/resource_centre/Internationally%20Funded%20Training%20in%20Biotechnology%20and%20Biosafety_Is%20it%20Bridging%20the%20Biotech%20Divide.pdf.

Keese, P. (2013). Building an effective biosafety regulatory systems: The nuts and bolts. *Collection of Biosafety Reviews*, *8*, 10-39.

Kinderlerer, J. (2008). The Cartagena Protocol on Biosafety. *Collection of Biosafety Reviews*, *4*, 12-65.

Ministerio de Agricultura, Ganaderia y Pesca (MAGyP). (2015). *Resolucion SAGYP No.399*. Buenos Aires, Argentina: Author.

M^{c}Hughen, A., Smyth, S. (2008). US regulatory system for genetically modified [genetically modified organism (GMO), rDNA or transgenic] crop cultivars. *Plant Biotechnology Journal*, *6*, 2-12.

M^{c}Lean, M., Frederick, R., Traynor, P., Cohen, J., & Komen, J. (2003, February). *A framework for biosafety implementation: Report of a meeting organized by ISNAR Biotechnology Service*. The Hague, The Netherlands: International Service for National Agricultural Research (ISNAR). Available on the World Wide Web: http://biosafety.icar.gov.in/wp-content/uploads/2016/03/Mclean-et-al.-2001-A-Framework-for-Biosafety-Implementation.pdf.

M^{c}Lean, M., Foley, M., & Pehu, E. (2012, June). *The status and impact of biosafety regulation in developing economies since the ratification of the Cartagena Protocol* (Joint Departmental Discussion Paper 3). Washington, DC: The World Bank. Available on the World Wide Web: http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2012/06/12/000356161_20120612021559/Rendered/PDF/698300WP0P11210egulations0final0web.pdf.

Ministerio da Ciencia, Tecnologia e Inovacao (MCTI). (2014). *Parecer tecnico No.3964/2014* [Technical comment No. 3964/2014]. Brasilia, Brazil: Comissao Tecnica Nacional de Biosseguranca (CTNBio), Secretaria Executiva, MCTI. Available on the World Wide Web: http://ctnbio.mcti.gov.br/documents/566529/1701211/Parecer+Técnico+nº%203964+-+2014+-+Mosquito+OXITEC/b5365e8c-aa92-4f01-9f97-16bb018d8cb4?version=1.3.

MCTI. (2015). *Resumo geral de plantas geneticamente modificadas aprovadas para comercializacao* [General summary of genetically modified plants approved for marketing]. Brasilia, Brazil: CTNBio, Secretaria Executiva, MCTI.

Obonyo, N., Nfor, L., & Uzochukwu, S. (2011). Identified gaps in biosafety knowledge and expertise in sub-Saharan Africa. *AgBioForum*, *14*(2), 71-82. Available on the World Wide Web: http://www.agbioforum.org.

Organisation for Economic Co-operation and Development (OECD). (2004). *OECD guidance for the designation of a unique identifier for transgenic plants* (Series on harmonization of regulatory oversight in biotechnology No. 23). Paris, France: Author. Available on the World Wide Web: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=env/jm/mono(2002)7.

Pertry, I., Sabbadini, S., Goormachtig, S., Lokko, Y., Gheysen, G., Burssens, S., & Mezzetti, B. (2014). Biosafety capacity building: Experiences and challenges from a distance learning approach. *New Biotechnology*, *31*(1), 64-68.

Rodriguez, G. (2016). *Third national report on the implementation of the Cartagena Protocol on Biosafety.* La Paz, Bolivia: Biosafety Clearing-House. Available on the World Wide Web: https://bch.cbd.int/database/record.shtml?documentid=109714.

Servicio Agricola y Ganadero (SAG). (1997). *Establece autorizacion para el consumo animal de maiz transgenico con modificacion (Bt) y resistente a glufosinato* [Establishing authorization for animal consumption of transgenic corn (Bt) and glufosinate resistance]. Santiago, Chile: Author. Available on the World Wide Web: http://www.sag.cl/sites/default/files/RES_3970_1997.pdf.

SAG. (2013). *Autoriza para consumo animal soya MON 89788* [Authorization for animal consumption of soy MON 89788]. Santiago, Chile: Servicio Agricola y Ganadero (SAG). Available on the World Wide Web: http://normativa.sag.gob.cl/Publico/Normas/DetalleNorma.aspx?id=1049559.

Secretariat of the Convention on Biological Diversity. (2000). *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and annexes*. Montreal, Canada: Author. Available on the World Wide Web: http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

Secretaria de Estado de Medio Ambiente y Recursos Naturales. (2006). *Decision para la introduccion de pez cebra geneticamente modificado* [Decision on the introduction of gentically modified zebrafish]. Santo Domingo, Dominican Republic: Author.

Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas (SENAVE). (2015). *Listado de eventos con modificacion genetica autorizados para experimentacion* [List of genetic modification events authorized for experimentation]. Asuncion, Paraguay: Author. Available on the World Wide Web: http://www.senave.gov.py/docs/servicios/bioseguridad-agricola/2015/SERVICIOS-BIOSEGURIDAD.pdf.

Tribe, D. (2012). Gene technology regulation in Australia: A decade of a federal implementation of a statutory legal code in a context of constituent states taking divergent positions. *GM Crops and Food: Biotechnology in Agriculture and the Food Chain*, *3*(1), 1-9.

United Nations Environment Programme (UNEP). (2005). *UNEP-GEF Toolkits for the development of national biosafety frameworks*. Geneva, Switzerland: Author. Available on the World Wide Web: http://www.unep.org/biosafety/Toolkit.aspx.

US Department of Agriculture (USDA). (2015a). *Ecuador agricultural biotechnology annual* (GAIN report). Washington, DC: USDA Global Agricultural Information Network (GAIN). Available on the World Wide Web: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Quito_Ecuador_7-6-2015.pdf.

USDA. (2015b). *Guatemala agricultural biotechnology annual: Efforts to strengthen the Cartagena Protocol* (GAIN report 15007). Washington, DC: USDA GAIN. Available on the World Wide Web: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Guatemala%20City_Guatemala_7-15-2015.pdf.

USDA. (2015c). *Nicaragua agricultural biotechnology annual: Agricultural biotechnology annual report* (GAIN report). Washington, DC: USDA GAIN. Available on the World Wide Web: http://gain.fas.usda.gov/Recent%20GAIN%20 Publications/Agricultural%20Biotechnology%20Annual_Managua_Nicaragua_7-14-2015.pdf.

USDA (2015d). *Panama agricultural biotechnology annual: Agricultural biotechnology annual report* (GAIN report). Washington, DC: USDA GAIN. Available on the World Wide Web: http://gain.fas.usda.gov/Recent%20GAIN%20 Publications/Agricultural%20Biotechnology%20Annual_Panama%20City_Panama_7-22-2015.pdf.

USDA (2015e). *Caribbean Basin agricultural biotechnology annual* (GAIN report CB1510). Washington, DC: USDA GAIN. Available on the World Wide Web: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Miami%20ATO_Caribbean%20Basin_7-15-2015.pdf.

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