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COMPLIANCE COMMITTEE UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Fifteenth meeting

Montreal, Canada, 8-10 May 2018

# DETAILED SUPPORTING INFORMATION FOR THE Review of consistency between information in THIrd national reports and the Biosafety Clearing-House

*Note by the Executive Secretary[[1]](#footnote-1)\**

1. The present document provides detailed information[[2]](#footnote-2) to support the review of consistency of information in third national reports and the Biosafety Clearing-House to be undertaken by the Compliance Committee at its fifteenth meeting.
2. The information contained in the annex to the document is presented in six tables, covering the following sets of information:

Table 1. Decisions taken on the intentional transboundary movement of living modified organisms for intentional introduction into the environment (Articles 7 to 10);

Table 2. Decisions taken on living modified organisms approved for domestic use, including placing on the market, and that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11, (1));

Table 3. Bilateral, regional and multilateral agreements and arrangements (Article 14(2));

Table 4. Notifications concerning unintentional transboundary movements (Article 17(1));

Table 5. Illegal transboundary movements (Article 25(3)); and

Table 6. Relevant laws, regulations and guidelines to implement the Protocol (Article 20(3)(a)).

*Annex*

ORIGINAL: English, French, Russian and Spanish

**Table 1. Decisions taken on the intentional transboundary movement of living modified organisms for intentional introduction into the environment (Articles 7 to 10)**

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|  | **PARTIES** | **Question 39.**  **In the current reporting period, how many decisions has your country taken regarding intentional transboundary movements of LMOs for intentional introduction into the environment?** | **BCH:  Number of decisions submitted by the Party to the BCH regarding intentional transboundary movementsof LMOs for intentional introduction into the environment, during the reporting period.**  **(Figures in red font indicate inconsistency of information)** | **Relevant comments in text boxes of third national report** |
| 1 | Brazil | More than 10 | 6 |  |
| 2 | Burkina Faso | More than 10 | 0 |  |
| 3 | Cameroon | Less than 5 | 0 | Within the reporting period, a total of six decisions for experimentation have been taken comprised of two (02) AIA authorizations and four (04) import authorizations. So far, all AIA decisions taken have been forwarded to the notifier but not to the BCH. The first AIA decision for the importation of GM cotton for confined field trials went beyond the ninety days timeline due to reasons beyond the control the Competent National Authority. However, with the creation of the National Biosafety Committee, the second AIA decision for the importation of GM cotton for open field trials respected the ninety days timeline. |
| 4 | Colombia | More than 10 | 8 |  |
| 5 | Costa Rica | Less than 5 | 0 |  |
| 6 | Denmark | Less than 5 | 0 | Reference is made to the submitted third national report of the European Union. Denmark is as a member of the European Union obliged to apply the legislative framework of the EU.  Furthermore, it should be noted that Denmark has only taken decisions on applications for deliberate release of LMO's for the purpose of field trials, since there is has not been and is currently no cultivation of LMO's in Denmark. |
| 7 | Guatemala | Less than 5 | 0 | Como se ha indicado antes, a falta de una ley específica de bioseguridad de la biotecnología, bajo el marco del Acuerdo Ministerial 386-2006, en el año 2012 el MAGA autorizó la liberación experimental en el medio ambiente del maíz transgénico Herculex I (identificación única DAS 1507), de la empresa Duwest; para dicha autorización, con la integración de una Comisión de Asesoría y Consulta para fortalecer la toma de decisiones, se aplicaron criterios del Acuerdo Fundamentado previo; después de eso no se avanzó más y no se tomaron decisiones para la liberación comercial, debido a que el mismo Acuerdo establece que el uso de los OVM es para la producción y exportación de semillas, no así para la siembra o consumo en el territorio nacional. En los avances posteriores en materia de normatividad de la bioseguridad de la biotecnología, en el marco del Proyecto de Desarrollo de Mecanismos para Fortalecer la Implementación del Protocolo de Cartagena en Guatemala, se propuso el Reglamento de Bioseguridad de los OVM, aún pendiente de aprobación por parte de las Autoridades Nacionales Competentes en el cual se incluye los procedimientos para dar respuesta a los diferentes usos de OVMs.En el particular de la pregunta 45 de este informe, acerca de la liberación del maíz Herculex I anotado en el párrafo anterior, previo a a la liberación, los motivos en que se basaron las decisiones tomadas por el MAGA fueron expuestas al notificador, mas no así al CIISB. |
| 8 | Honduras | Less than 5 | 2 |  |
| 9 | Indonesia | Less than 10 | 0 |  |
| 10 | Japan | Less than 5 | 1 | Under the Protocol and its relevant domestic law, biological diversity risk assessments had been carried out regarding use of three LMOs (two soybeans, one maize). Approvals for these three were given without condition during the current period by the Japanese government. Accordingly, BCH was notified to the effect that three LMOs were approved. |
| 11 | Malaysia | None | 1 |  |
| 12 | Mexico | More than 10 | 181 | Con relación a la pregunta 35 y 36, en el periodo del informe se han otorgado 157 permisos de liberación al ambiente: 88 a nivel experimental, 62 en etapa de programa piloto y siete para liberaciones al ambiente en etapa comercial.Para el caso de la pregunta 37, hasta septiembre de 2015 se han otorgado 23 permisos de liberación al ambiente en etapa experimental, que no han estado asociados a movimientos transfronterizos y uno en etapa comercial. Respecto a la pregunta 38, en total durante el periodo del informe se recibieron 273 solicitudes de liberación al ambiente, para diferentes etapas de liberación (129 experimental, 111 programa piloto y 33 comercial).Para la pregunta 39, en total se han otorgado 192 resoluciones que incluyen 157 permisos de liberación y 35 decisiones negativas. Siguen en proceso de análisis 105 solicitudes. De acuerdo a los datos actualizados al 30 de septiembre de 2015. Respecto de la pregunta 45 se respondió "Si, siempre" considerando la respuesta al notificador, sin embargo también corresponde que "Solo en algunos casos al CIISB". Se mantienen los trabajos de actualización de la información que está contenida en su totalidad dentro del Sistema Nacional de Información: http://www.conacyt.gob.mx/cibiogem/index.php/sistema-nacional-de-informacion |
| 13 | Mozambique | Less than 5 | 0 |  |
| 14 | Netherlands | Less than 5 | 0 | Decision making on transboundary movements of LMOs for intentional introduction to the environment for commercial purposes is regulated at EU level. Introduction to the environment of LMO's for experimental purposes (field trials) is regulated at national level. In the Netherlands, the procedure for obtaining authorisation for field trials is laid down in the GMO Act. |
| 15 | Norway | Less than 5 | 0 | The Advance Informed Agreement procedure of the protocol is implemented in the Norwegian legislation through the Gene Technology Act and its regulations. A GMO which has been approved by the Directive for placing on the market in the EU is also approved for that purpose in Norway, unless the competent authority in Norway considers it to constitute a risk to human health or the environment or otherwise contravene the Gene Technology Act's assessment criteria sustainability, ethics and social utility and therefore has decided to restrict or prohibit its placing on the market in Norway. This only applies to directive 2001/18/EC and not to the regulation 1829/2003/EC as the latter regulation has not been implemented in Norway. In contrast to applications for marketing of LMOs, applications for experimental release into the environment is subject to a national procedure. |
| 16 | Pakistan | More than 10 | 0 | Pakistan had approved the import of Genetically Modified (GM) cotton and corn hybrids to be planted for the assessment and evaluation of environmental safety and performance in the agro-climatic conditions of the country. The confined and Field Trials of GM corn hybrids are under way to establish the economic value of the GM corn crops and impacts on agricultural communities of the country. |
| 17 | Panama | Less than 5 | 0 |  |
| 18 | Paraguay | More than 10 | 0 |  |
| 19 | Philippines | Less than 5 | 0 | During the reporting period, the Philippines has a total of 15 approved importations, four of which is for field trial and 11 for propagation. There has been no cases of prohibiting imports. |
| 20 | Romania | Less than 5 | 0 | Romania applies its national legislative framework transposing the EU legislation instead of the Protocol's advanced informed agreement procedure.For the experimental purposes (field trials), the legal person who intends to introduce GMOs into the environment, must first obtain written authorisation from the Romanian competent authority (National Agency for Environmental Protection). The authorization is issued on a case by case risk assessment basis and is applicable only on the national territory. |
| 21 | Slovakia | Less than 5 | 1 | The Slovak Republic applies its domestic legislative framework instead of the Protocol's advanced informed agreement procedure. The authorisation procedure for intentional introduction into the environment is common for all Member States of the European Union as described in the EU 3rd national report. The experimental introduction of GMOs into the environment is decided by each Member State independently, the decision-making on placing on the market involves all EU-Member States, as authorised products are granted free movement throughout the territory of the EU. In the current reporting period Slovakia received two applications on field trials with genetically modified maize NK603 x MON810 and MON89034 x NK603 (imported also from country outside the European Union) and sugarbeet H7-1 (imported from an EU-Member State, under EU-legislation not considered as an import). |
| 22 | South Africa | Less than 10 | 3 |  |
| 23 | Spain | More than 10 | 2 | España aplica la legislación comunitaria y nacional para la autorización de organismos vivos modificados para la liberación al medio ambiente, ya sea con fines experimentales o de comercialización, legislación que se ajusta a las disposiciones del Protocolo, estableciendo un marco reglamentario nacional compatible con el Protocolo, según art. 9.3 del mismo. No obstante, tenemos diferentes autoridades competentes en función del uso final de los OVM, por lo tanto, esta información se somete a diferentes agencias gubernamentales. La recopilación de esta información puede dar lugar a algún retraso de transferencia de información ya que es un proceso lento. Véase el informe nacional de la Unión Europea. |
| 24 | Sudan | Less than 5 | 2 |  |
| 25 | Uganda | Less than 10 | 0 | All applications so far received have been for confined field trials and contained use. This is for generation of preliminary information for informed decision making in future in case we receive applications for large scale / market releases which will await the national law to be passed. |
| 26 | Uruguay | More than 10 | 6 | La introducción deliberada en el medio ambiente incluye aplicaciones referidas a producción de semilla para exportación, así como uso comercial para consumo directo y procesamiento, publicándose 15 resoluciones correspondientes al período 2012-2015. Para las aplicaciones para Investigación y Evaluación Nacional de Cultivares corresponden 12 resoluciones GNBio para el período 2012-2015. |
| 27 | Viet Nam | Less than 10 | 4 | So far in Vietnam, regulations allowing the release of GMOs into the environment have been Permit for trial of GM crops (confined trials and large scale trials) and granted Biosafety Certificate of GM crops:- The Permit for trial of GM maize with events: GA21, Bt11, NK603, MON89034, TC1507, MIR162.- Decision on granting Biosafety Certificate of GM maize events: MON89034, GA21, NK603, Bt11. |

**Table 2. Decisions taken on living modified organisms approved for domestic use, including placing on the market, and that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11, (1)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **PARTIES** | **Question 55.**  **In the current reporting period, how many decisions has your country taken regarding domestic use, including placing on the market, of LMOs-FFP?**  **(Red font indicates Parties reporting ‘none’ that nevertheless submitted decisions to the BCH)** | **BCH:**  **Number of decisions submitted by the Party to the BCH regarding domestic use, including placing on the market, of LMOs-FFP during the reporting period**  **(Figures in red font indicate inconsistency of information)** | **Relevant comments in text boxes of third national report** |
| 1 | Austria | More than 10 | 0 | Austria itself has taken national decisions to introduce safeguard measures for some LMOs to prohibit the cultivation and in some cases the import and placing on the market of LMOs according to Directive 2001/18/EC and the respective provisions of the Austrian Gene Technology Act (Para. 60). These measures are based on concerns regarding the conclusions of the risk assessments conducted at the EU-level for these applications. For an overview on these decisions see: http://www.biosafety.at/ms/biosafety/en/enbiosafety\_natdecisions/enbiosafety\_decision1/  Decisions with regard to release and placing on the market of LMOs are taken on an EU level according to its regulatory framework and are binding for all EU Member States, including Austria. |
| 2 | Belgium | More than 10 | 0 | cf EU's report |
| 3 | Bolivia (Plurinational State of) | Less than 5 | 0 |  |
| 4 | Brazil | Less than 10 | 0 |  |
| 5 | China | More than 10 | 0 | During 2012-2013, the MOA approved the import of 29 agricultural GMOs used for processing, |
| 6 | Colombia | None | 57 |  |
| 7 | Cuba | Less than 5 | 0 | El mecanismo para la toma de decisiones en materia de OVMs para uso directo como alimento humano o animal y procesamiento, es similar en cuanto al proceso de evaluación de riesgos que se necesita para su uso. En coordinación con el Registro de Alimentos de la República de Cuba, el Centro Nacional de Seguridad Biológica (CSB) ha evaluado y aprobado dos procesos, importación de maiz que contiene variedades geneticamente modificadas para consumo animal, bajo las licencias de seguridad biológica LH455-L( 36)14 y LH455-L(37)14. |
| 8 | Czech Republic | More than 10 | 0 | It has to be noted that the import of GMOs intended for direct use for food or feed or for processing, is covered by the directly applicable EU Regulations. |
| 9 | Denmark | More than 10 | 0 | Reference is made to the submitted third national report of the European Union. |
| 10 | European Union | More than 10 | 31 |  |
| 11 | Finland | More than 10 | 0 | See the EU CION report |
| 12 | Honduras | None | 1 |  |
| 13 | Indonesia | Less than 10 | 0 |  |
| 14 | Japan | More than 10 | 0 | Under the domestic law for the implementation of the Protocol, biological diversity risk assessment regarding domestic use of LMOs intended for direct use as food or feed, or for processing is carried out on the basis of the Biological Diversity Risk Assessment Report submitted by the applicant, and approval is given if it is recognized that there is no possibility of adverse effect on biodiversity. When Japanese government approved LMOs, the information of the LMOs has been notified to the BCH with relevant information. |
| 15 | Kenya | More than 10 | 0 | Decisions made were only for imports in relation to food aid and not for placing in the market. All approved products were processed/milled prior to import (Not LMOs in the definition of the Protocol). Since the approvals were products from USA, there was no mechanism to specify which particular event was in the imports rather it was a blend of all events approved in USA for corn and soybean. Our sharing of information on approved LMOs-FFP is only though the National Biosafety Clearing House portal in the NBA website www.biosafetykenya.go.ke which is linked to the international BCH. |
| 16 | Luxembourg | Less than 5 | 0 | A trois reprises, le Grand-Duché de Luxembourg, a, par le biais d'arrêtés ministériels, refusé la mise sur le marché d'OVM:- arrêté ministériel du 15 juin 2010 interdisant à titre provisoire la mise sur le marché en vue de la mise en culture de la pomme de terre génétiquement modifiée Solanum tuberosum L- lignée H92-527-1; - arrêté ministériel du 23 mars 2009 interdisant à titre provisoire la mise sur le marché en vue de la mise en culture du maïs génétiquement modifié MON810 (Zea mays L. lignée MON810); - arrêté ministériel du 7 février 1997 interdisant à titre provisoire le produit consistant en lignées pures et hybrides d'une lignée de maïs (Zea mays L.)(CG 00256-176) transformée à l'aide de plasmides |
| 17 | Malaysia | More than 10 | 10 | As of 31 July 2015, Malaysia has approved 14 LMOs-FFP. |
| 18 | Mexico | More than 10 | 36 | Respecto a la pregunta 53 a la fecha se han autorizado 146 OGM para uso directo como alimento humano y para el procesamiento. Durante el periodo de reporte han sido otorgadas 48 autorizaciones previa evaluación de riesgo a la salud humana y de análisis de inocuidad. |
| 19 | Netherlands | More than 10 | 2 | Please note that the authorisation of LMO-FFPs is regulated at EU level |
| 20 | New Zealand | More than 10 | 17 |  |
| 21 | Norway | Less than 5 | 1 | The Norwegian legislative framework addresses LMOs-FFP, and does not lay down other procedures for LMOs-FFP than for LMOs. |
| 22 | Pakistan | Less than 5 | 0 | Four applications have been received and approved recently. However, the same will be submitted to the BCH shortly. |
| 23 | Paraguay | More than 10 | 0 |  |
| 24 | Philippines | More than 10 | 0 |  |
| 25 | Republic of Korea | More than 10 | 62 |  |
| 26 | Romania | Less than 10 | 0 | Please see the EU report |
| 27 | Slovakia | More than 10 | 0 | With regard to the decisions taken for placing on the market of LMOs-FFP, it has to be noted that those decisions are taken for the whole European territory and not by the MS individually.  Only the summary reports of the risk assessment of field trials were submitted to the BCH in the current reporting period. The summary reports of the risk assessment of contained use were not submitted to the BCH. |
| 28 | South Africa | More than 10 | 0 |  |
| 29 | Sudan | Less than 5 | 0 |  |
| 30 | Swaziland | Less than 5 | 0 | The decision made on LMOs-FFP was an informal agreement made prior to the Act being operational, thus the country is still in a transition phase in the regulation of LMOs-FFP as per the Act. |
| 31 | Sweden | More than 10 | 0 | Article 11 is implemented in legislation at the EU level. |
| 32 | Turkey | More than 10 | 32 |  |
| 33 | Uruguay | More than 10 | 4 | Las decisiones de liberación para uso comercial, consumo o procesamiento de VGMs, hasta el momento han sido elaboradas conjuntamente. |
| 34 | Viet Nam | More than 10 | 18 | So far in Vietnam, Vietnam's Ministry of Agriculture and Rural development has been granted Certificate for GM maize and GM soybean satisfying conditions to be used as food, feed:- Certificate satisfying conditions to be used as food, feed for GM maize event: GA21, Bt11, NK603, MON89034, MIR162, T25, MON87427, MON87460, MON88017, MON810.- Certificate satisfying conditions to be used as food, feed for GM soybean event: MON89788, 40-3-2, MON87705, MON87701, MON87708, A5547-127, A2704-12, MON87769. |
| 35 | Zambia | Less than 10 | 0 | The system of approving LMOs-FFP intended for food, feed and processing in Zambia involves issuance of a permit by the National Biosafety Authority as provided for in the Biosafety Act No. 10 of 2007. One permit may be issued for several LMOs-FFP derived-products. |
| 36 | Zimbabwe | Less than 5 | 0 |  |

**Table 3. Bilateral, regional and multilateral agreements and arrangements (Article 14(2))**

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| --- | --- | --- | --- |
| **Parties that reported to have entered into bilateral, regional or multilateral agreements or arrangements.(Question 72 of third national report)** | | | |
|  | **Party** | **Q 74:**  **Has your country informed the Parties through the BCH of the agreements or arrangements?** | **Is the information in the BCH? (Y/N in red)**  **Document available in the BCH (name of document in black)**  **Explanation provided in free text (Questions 75 and 76) in the third national report where no document has been made available (explanation in blue)** |
| 1 | Austria | NO | NO  The Austrian Government did not enter into any bilateral, regional or multilateral agreements, other the European Union itself. The EU has determined as per Article 14(4) and 9 (2) (c) that it relies on its existing legislative framework for intentional movements of GMOs within the European Union and for imports of GMOs into the European Union. This decision has been communicated to other Parties through the Biosafety Clearing-House. |
| 2 | Belarus | YES | YES  ТR СU 021/2011 "On Food Safety"  ТR СU 022/2011 "Food products in terms of their labeling" |
| 3 | Benin | YES | YES  REGLEMENT N°007/2007/CM/UEMOA RELATIF A LA SECURITE SANITAIRE DES VEGETAUX; DES ANIMAUX ET DES ALIMENTS DANS L'UEMOA.  Loi 2012-29 du 10 Juillet 2012 portant ratification de la convention africaine sur la conservation de la nature et des ressources naturelles |
| 4 | Bulgaria | NO | NO  Bulgaria is member state of European Union. Bulgarian public bodies, analytical laboratories and academic institutions participate in the activities related to LMO on EU level, for example EFSA, EU Committees and Working Parties, European Network of GMO laboratories (ENGL), etc.  Bulgaria has been Party to the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention) since 2003 and has ratified on 6th March 2007 the amendment on GMO, adopted by the Meeting of the Parties to the Convention through decision II/1, taken at its second session (Almaty, 25-27 May 2005). |
| 5 | Burkina Faso | NO | NO  Une réglementation régionale a été adoptée par les huit (8) pays de l'Union économique et monétaire ouest africaine (UEMOA) dont le Burkina Faso fait partie. Le document final n'est pas encore disponible. Ce document devrait par la suite être adopté par les quinze (15) pays de la Communauté économique des Etats de l'Afrique de l'ouest (CEDEAO) qui incluent ceux de l'UEMOA |
| 6 | Costa Rica | YES | NO  La Iniciativa Centroamericana de Biotecnología y Bioseguridad (ICABB), es un mecanismo adscrito a voluntad por Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panamá y República Dominicana, y que no significa un compromiso vinculante, político o legal entre ellos, y su permanencia y relevancia es alimentada directamente por el trabajo en grupo, el compromiso de sus participantes y la voluntad política de sus autoridades. El ICABB tiene como objetivo formalizar y fortalecer las acciones en Biotecnología en los ámbitos nacional y regional, procurando el acceso a la biotecnología, la utilización segura de sus productos, la optimización y armonización en la gestión de los marcos legales y las políticas en Bioseguridad, procurando el beneficio de los sistemas agroalimentarios, la calidad de la vida rural, la protección del ambiente y el fortalecimiento de la economía.  El proyecto UNEP/GEF exploró la posibilidad de establecer acuerdos comerciales bilaterales entre estados parte y no parte con los cuales Costa Rica es socio comercial, y realiza movimientos transfronterizos de OVM`s, para validar la información proveniente de los análisis del riesgo, e incorporarla en decisiones según el artículo 11, sin embargo, no se logró consolidar el acuerdo por falta de voluntad política. |
| 7 | Czech Rep. | YES | NO  The Czech Republic has been a Member State of the European Union since 2004. EU is a regional arrangement with common market rules, including transboundary movements of goods. |
| 8 | Democratic Republic of the Congo | NO | NO  Dans le cadre du Marché Commun pour l'Afrique de l'Est et Australe (COMESA) auquel la RD Congo est Partie, les politiques et les directives pour manipuler les cultures commerciales génétiquement modifiées, le commerce des OVM et l'aide alimentaire d'urgence contenant les OVM ont été développées et adoptées. En ce qui concerne de manière spécifique les cultures commerciales génétiquement modifiées, ces politiques et lignes directrices ont pour objectifs de fournir aux Etats membres du COMESA un mécanisme d'évaluation régionale centralisée des OGM destinés à une culture commerciale et promouvoir les exigences harmonisées d'évaluation des risques selon des lignes directrices développées au niveau international pour les OVM. Le champs d'application de ces politiques et directives sont l'évaluation centralisée risques à travers l'opérationnalisation des sous-comités régionaux d'évaluation des risques liés aux OVM dans les pays COMESA, l'évaluation des risques pour la santé humaine ou l'environnement ainsi que les considérations socio-économiques, culturelles ou autres réalisées en accord avec les cadres nationaux de biosécurité. Les politiques et les directives COMESA reconnaissent dûment la souveraineté et l'existence de lois et des politiques nationales de biosécurité. Un comité d'experts (PoE) a été établi en tant que comité permanent de guidage des politiques au sein du COMESA pour les domaines liés aux biotechnologies et à la biosécurité. |
| 9 | France | YES | NO  France est un des 28 États membres de l’Union européenne, qui a mis en place depuis le début des années 90 un cadre réglementaire complet et centralisé visant à assurer la sécurité quant à l’utilisation des organismes génétiquement modifiés sur l’ensemble du territoire européen, comme cela est présenté dans ce même rapport à la question 21. |
| 10 | Gambia | NO | NO  The Gambia is a member of the WTO and also a signatory to the ECOWAS protocol in which the regulation of LMOs and GMOs is already taken on board. |
| 11 | Guinea-Bissau | NO | NO  Guinea-Bissau is a member of the WAEMU and CILSS and benefits from the scientific support in the context of the Common Biosafety Regulations  La Guinée Bissau fondent sa mesures de protection sanitaires et environnementales sur les normes, directives et autres recommandations internationales notamment celles du Codex Alimentarius, de l´OMC, de la CIPV, et de l´OIE. |
| 12 | Guyana | NO | NO  NAREI has signed an agreement with MS Technologies and Stine Seed Company to collect data and may develop corn and/or soya bean seed that may be applicable to commercial production in Guyana. They will train local researchers in various aspects of plant breeding and germplasm development, enhance laboratory capabilities for biotechnological research and expand operation in the intermediate savannah to include the Ebini station. |
| 13 | Hungary | NO | NO  Hungary has entered into a regional agreement (EU). |
| 14 | Indonesia | NO | NO  There has been a guidelines on risk assessment of GMO in ASEAN Region and GM Food testing Network ASEAN; Research on rice on greenhouse gas emission, tomatoes resistant to virus disease. |
| 15 | Kazakhstan | NO | YES  Технический регламент Таможенного союза «О безопасности зерна»; ТР ТС 015/2011  Технический регламент Таможенного союза «Пищевая продукция в части ее маркировки»; ТР ТС 022/2011  Технический регламент Таможенного союза «О безопасности пищевой продукции»; ТР ТС 021/2011 |
| 16 | Mali | YES | NO  Adopté en avril 2007, le Programme Régional de Biosécurité de l’UEMOA (PRB/UEMOA) qui concerne les 08 pays de l’espace UEMOA (Bénin, Burkina Faso, Côte d’Ivoire, Guinée Bissau, Mali, Niger, Sénégal et Togo) a pour objectif : «élaborer et mettre en œuvre un cadre juridique communautaire de biosécurité pour permettre aux États membres de l’UEMOA de faire face à leurs obligations vis-à-vis du Protocole de Cartagena sur la Prévention des risques liés aux OVM». |
| 17 | Malta | YES | YES  EC Accession |
| 18 | Namibia | NO | NO  Bilateral agreement with South Africa, however the scope is not limited only to LMOs. Biosafety capacity buildings are supported under this bilateral agreement. |
| 19 | New Zealand | YES | NO  The Agreement between Australia and New Zealand establishing a System for the Development of Joint Food Standards (the Treaty) was signed on 5 December 1995. |
| 20 | Niger | YES | YES   * UEMOA Guideline * Regulation Project Relating To Biosafety In West Africa * ECOWAS Regulation C/Reg.4/06/2008 On Harmonisation Of The Rules Governing Quality Control, Certification And Marketing Of Seeds |
| 21 | Norway | YES | YES   * Convention on Access to Information; Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) * Cartagena Protocol on Biosafety * European Economic Area agreement, Annex XX, Part IV, para 24-25 |
| 22 | Paraguay | NO | NO  Cooperaciòn, capacitaciòn e intercambio de informaciòn. |
| 23 | Republic of Moldova | YES | YES  ASSOCIATION AGREEMENT between the European Union and the European Atomic Energy Community and their Member States; of the one part; and the Republic of Moldova; of the other part; 30.08.2014 |
| 24 | Rwanda | NO | NO  Rwanda belongs to different organizations: CEPGL, EAC, COMESA. Members States of the EAC have an Environment Protocol which covers all aspects related to the environment in general and Biosafety. The COMESA treaty calls for member states to among others: establish a customs union; and simplify and harmonize their trade documents and procedures. Key priorities for COMESA in consolidating its strategic objectives include implementing major programs in infrastructure, trade and agriculture. The importance of regional cooperation in harnessing the technology safely and responsibly and handling of other GMO related issues is evident from the experience of other global regional blocs. In cognizance of this reality, COMESA endorsed in 2003 the implementation of the RABESA initiative (Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa) which has the objective of supporting harmonization of biosafety policies among its member states. |
| 25 | Senegal | NO | NO  Le Sénégal a adhéré au Règlement communautaire de biosécurité de l’UEMOA qui a fait l’objet d’un examen en février 2015 (à Ougadougou), par les experts des Etats parties de l’UEMOA et d’une approbation par les Ministres sectoriels (concernés par la biosécurité). Toutefois, en l’absence d’adoption (par le Conseil des Ministres) et de l’entrée en vigueur du Règlement communautaire (qui est en cours d’adoption), l’information n’a pas été publiée au BCH. |
| 26 | Slovenia | YES | YES  EC Treaty |
| 27 | Swaziland | NO | NO  The country has no bi-lateral agreement at the moment. However it has endorsed both the Southern African Development (SADC) and COMESA Guidelines on Biotechnology and Biosafety. Both guidelines cover the handling of LMO food aid, policy and regulations, public awareness and participation and capacity building. |
| 28 | Sweden | YES | NO  Sweden is a Member State of the European Union. In the European Union the main part of issues covered by the Cartagena Protocol is totally harmonised legislation |
| 29 | Tonga | NO | NO  Bilaterals are with regional organisation (SPREP) for Technical assistance. |
| 30 | United Rep. of Tanzania | NO | NO  Tanzania is a party to East African Community (EAC) and signatory to the Protocol on Environment and Natural management that governs the Partner States in their cooperation in management of environment and natural resources. Together with other areas, the Protocol applies to Biosafety and Biotechnology.  Tanzania is also a member to SADC and is participating in the development of Regional Guidelines for Food Safety Management that provide a framework to assist member state in development and operation of regional and national food safety management system. |
| 21 | Viet Nam | NO | NO  In implementation of the WTO, Vietnam has been established the focal point, including: Office of Vietnam Technical Barriers to Trade Notification Authority and Enquiry Point (TBT Vietnam) and Office of Vietnam Sanitary and Phytosaniary Notification Authority and Enquiry Point (Vietnam SPS). Details of these two offices are found on the websites.  Viet Nam became the World Trade Organization's (WTO) 150th member on 11 January 2007. The WTO is the international organization whose primary purpose is to open trade for the benefit of all. |
| 32 | Zambia | NO | NO  The country has signed and ratified about 25 International Environmental Agreements, however, specific bilateral or agreements on LMOs or FFPs are few. |
| 33 | Zimbabwe | NO | NO  Zimbabwe is a member of COMESA and has signed the COMESA Policy on Biotechnology and Biosafety. The policy seeks to provide a mechanism for harmonising matters to do with emergency food aid, commercial planting and trade of GMOs. Zimbabwe is a member of SADC. An Advisory Committee for Biotechnology and Biosafety exists within SADC. The Committee's recommendations guiding the region on handling of food aid, policy regulations, capacity building and public awareness and participation were approved by SADC in 2003. These were approved as interim measures aimed at guiding the region on issues relating to biotechnology and biosafety. SADC has recommended the region to develop a harmonised policy and regulatory system based on the African Biosafety Model law, the Cartagena Protocol on Biosafety and other relevant international processes. |
| **Parties that reported that they have not entered into bilateral, regional or multilateral agreements or arrangements (Question 72 of third national report), but nevertheless submitted such agreements or arrangements under this category to the BCH.** | | | |
|  | **Party** | **Document available in the BCH** | |
| 1 | Croatia | Announcement on the Entry into Force of the Cartagena Protocol on Biosafety for the Republic of Croatia (Official Gazette No. 13/2003)  Uploaded: 2011-10-05 | |
| 2 | Finland | Tasavallan presidentin asetus biologista monimuotoisuutta koskevaan yleissopimukseen liittyvän Cartagenan bioturvallisuuspöytäkirjan voimaansaattamisesta ja pöytäkirjan lainsäädännön alaan kuuluvien määräysten voimaansaattamisesta annetun lain voimaantulosta (130/2004)  (This Decree of the President of the Republic of Finland concerns accession and implementation of the provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity)  Uploaded: 2014-08-01 | |
| 3 | Grenada | Signed MOU Agreement Between Designated Biosafety Laboratory & University of the West Indies  Uploaded: 2017-10-05 | |
| 4 | Mexico | Canada; Mexico; United States of America - Document of Understanding Regarding Documentation Requirements for Living Modified Organisms for Food or Feed; or for Processing (LMO/FFPs)  Uploaded: 2005-05-05 | |
| 5 | Nicaragua | Arreglo Relativo al Articulo 24 Entre La Republica de Nicaragua y Los Estados Sobre Los Requisitos de Documentación para los Organismos Vivos Modificados Destinados a Alimento Humano o Animal o al Procesamiento  Uploaded: 2006-03-13 | |

**Table 4. Notifications concerning unintentional transboundary movements (Article 17(1))**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Party** | **Question 101: In the current reporting period, how many times has your country received information concerning occurrences that led, or may have led, to unintentional transboundary movement(s) of one or more LMOs to or from territories under its jurisdiction?** | **Question 102: Has your country notified affected or potentially affected States, the BCH and, where appropriate, relevant international organizations, of the above release?** | **Question 103:**  **Who did you notify?** | **BCH records**  **(Figures in red font indicate inconsistency of information)** | **Relevant text/comments from third national report** |
| 1 | Cameroon | Less than 5 | No | -- | 0 | During the reporting period, there is an article published online under the Food and Nutrition Sciences website (Vol.5 No.10(2014), Article ID:45604,7 pages DOI:10.4236/fns.2014.510102) by Djoulde D. R and Sobda Gone titled "Evidence of the Presence of Genetically Modified Foods in the Sudano-Sahelian Zones of Cameroon". This article claims that there is an illegal and perhaps an unintentional transboundary movement of five (05) GMOs in the Northern Regions of Cameroon.  A Masters' Degree Thesis in Biochemistry by Ghepdeu Gisele in 2009 titled "Detection of Foreign Genes in Food Products in Cameroon: Case of Cereals and Cereal-based Products" also indicates that GMOs can be found in the commercial sector in Cameroon. |
| 2 | Germany | More than 10 | Yes, for some occurrences | The affected or potentially affected State | 0 | See report of the EC comment to question 103: information generally generated i.e.by inspection or control activities of competent national institutions. Since no adverse effect to the biological diversity of the receiving environments could be verified neither in the exporting nor the importing country, occurrences were not notified to the BCH. |
| 3 | Hungary | More than 10 | Yes, for every occurrence | Relevant international organizations | 0 | -- |
| 4 | Norway | Less than 5 | No | Relevant international organizations | 0 | For more information, please see Q191.  With regard to Q102-104; we have had no incidents of unintentional movements from Norway and thus we recognise these questions as not applicable  Text of Q191: Each year the Norwegian Food Safety Authority takes 100-150 samples of products consisting of, containing or produced from soy beans, maize, rape seeds, rice and papaya in their annually based monitoring and surveillance program ‘Monitoring of genetically modified material’. The samples are taken from shipments, production sites and shops and are analysed for GMO, and documentation controls are performed. So far the sampling and testing have in most cases revealed low levels (mostly below 0.9 %) of unintentional or technically unavoidable GMO presence in conventional soybeans, maize, rape seeds and rice. The papaya products were processed and, hence not considered LMO. |
| 5 | Zambia | Less than 5 | No | The affected or potentially affected State | 0 | All these occurrences referred to above are with respect to processed foods and not LMOs. |

**Table 5. Illegal transboundary movements (Article 25(3))**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Party** | **Question 186**  **In the current reporting period, how many times has your country received information concerning cases of illegal transboundary movements of an LMO to or from territories under its jurisdiction?** | **Question 187**  **If your country received information concerning cases of illegal transboundary movements of an LMO in the current reporting period, has your country informed the BCH and the other Party(ies) involved?** | **BCH records**  **(Figures in red font indicate inconsistency of information)** | **Relevant text/comments from third national report** |
| 1 | Austria | ***More than 10*** | Only the other Party(ies) involved | 0 | For further information regarding measures concerning illegal transboundary movement of LMOs see the respective submission of the European Commission. |
| 2 | Belgium | ***More than 10*** | Only in some cases | 1 |  |
| 3 | China | ***More than 10*** | No | 0 | SAQSIQ has established a system to track and oversee the risks related to the import and export of agricultural GM products, by sample screening and testing GM products, and tracking the unintentional transboundary movement. In doing so, a number of cases of illegal transboundary transfer of GMOs and their products have been obtained, including afew below: In September 2011, Shenzhen Luohu AQSIQ checkpoint intercepted maize seeds (a total of 25 bags weighing 250 kg) carried by "tour smugglers" going through the Hong Kong-Macao channel. It was found out that the maize seed belongs to the super sweet maize variety and named "CUPOLA", a kind of GM hybrid variety, which was developed by Synthega in its Idaho base. The checkpoint personnel confiscated and destroyed maize seeds because these "tour smugglers" did not show the approval document issued by the competent authorities of China and the certificate of plant quarantine officially issued by the USA. In May 2013, Harbin AQSIQ intercepted 21 bags of maize seeds mailed from the USA, totaling 115 kg. The seeds were found to be GM after testing, and have been destroyed. From October 2013 to December 2014, the inspection and quarantine administrations across the country tested a total of 2.863 million tons of maize imported from the USA. Among them, 924,600 tons of maize were found containing GM elements MIR162, which were not approved by China. Relevant SAQSIQ bodies have returned all of them to the exporter in accordance with relevant laws. SAQSIQ has informed relevant US authorities, and requested them to require the exporters to strengthen their pre-shipment checking to ensure that the imported maize will meet the relevant legal requirements and quality and safety standards of China. An application for safety certificate was submitted for anti-insect maize MIR 162 for the first time in February 2010. An import safety certificate was issued in December 2014 following the review and examination of the Committee of Biosafety of Agricultural GMOs. |
| 4 | Denmark | ***Less than 5*** | Only the other Party(ies) involved | 0 | There has only been one occurrence of tranboundary unintentional presence of GMO. The matter was handled by the EU Commission and the involved member states according to procedure Reference is made to the third national report from the European Union |
| 5 | Egypt | ***Less than 5*** | Only the BCH | 0 | *(in Arabic)* |
| 6 | EU | ***More than 10*** | Only the other Party(ies) involved | 2 |  |
| 7 | France | ***Less than 10*** | Only the other Party(ies) involved | 0 | Cf réponses relatives à l'article 17 |
| 8 | Germany | ***More than 10*** | Only the other Party(ies) involved | 0 | See report of the EC |
| 9 | Hungary | ***More than 10*** | Only the other Party(ies) involved | 0 | During the reported period all LMO's detected in conventional seed lots and field trial materials. In all cases the imports were illegal but unintentional. In all cases the contaminated seed lots as well the plants were destroyed. |
| 10 | |  | | --- | | Japan | | ***Less than 5*** | Yes | 1 | In the current reporting period, Japanese government received information about one case of illegal import of LMO (papaya). This case happened because the importer had not recognized that it was genetically modified. To prevent adverse effect on biological diversity, Japanese government took measures such as recall or disposal of the LMOs and required importers to take preventive steps. |
| 11 | Latvia | ***More than 10*** | Only the other Party(ies) involved | 0 | For details please refer to the EU report. |
| 12 | Mali | ***Less than 5*** | No | 0 | Il a été signalé un mouvement transfrontalier du Coton Bt à la frontière entre le Burkina Faso et le Mali. Dans le cadre des activités retenues par la convention de l'UEMOA et les Gouvernements des pays membres, il est prévu une étude sur l'état des lieux de la présence des OVM dans les différents pays de l'espace. |
| 13 | Netherlands | ***Less than 5*** | Yes | 1 |  |
| 14 | Norway | ***Less than 5*** | Only the other Party(ies) involved | 1 | Each Year the Norwegian Food Safety Authority takes 100-150 samples of products consisting of, containing or produced from soy beans, maize, rape seeds, rice and papaya in their annually based monitoring and surveillance program ‘Monitoring of genetically modified material’. The samples are taken from shipments, production sites and shops and are analysed for GMO, and documentation controls are performed. So far the sampling and testing have in most cases revealed low levels (mostly below 0.9 %) of unintentional or technically unavoidable GMO presence in conventional soybeans, maize, rape seeds and rice. The papaya products were processed and, hence not considered LMO. However, one sample of maize from Argentina contained the illegal event Bt 176. Due to the low level presence of GMO, documentation provided by the responsible persons/companies on the measures taken to avoid such GMO presence, the fact that the GMO present have been authorized in the European Union and an assessments of environmental and health risks related to the presence, it has been concluded that the presence did not contravene the Gene Technology Act. However, during the current reporting period we have had one incidence of illegal genetically modified Zebra fish, as notified at BCH. For emergency measures regarding specific non-authorized LMOs, please refer to the EU report. |
| 15 | Tonga | ***Less than 5*** | Yes | 0 |  |
| 16 | United Kingdom | ***Less than 10*** | Only the other Party(ies) involved | 0 | The UK has experienced a limited number of cases where GM fish have been exported to the UK which are not authorized for marketing or release in the EU. These cases have been dealt with in conformity with EU regulations. These cases have not posed any harm to human health or the environment. |
| 17 | Zambia | ***Less than 5*** | No | 0 |  |

**Table 6 Relevant laws, regulations and guidelines to implement the Protocol (Article 20(3)(a))**

*Note: The responses to Question 20 are colour coded for ease of reference as follows: Yes / Partially / No*

*Information submitted that was missing the corresponding document or functional link is colour coded as follows: N*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Country | Has your country’s biosafety framework / laws / regulations / guidelines been submitted to the Biosafety Clearing-House (BCH)? (Question 20) (Y/N/Partially) | Free text submissions | Information submitted to the BCH | | | | | | | | |  |
| LAWS  Law name/title/ designation | Document in the BCH? (Y/N) | Date verified | REGULATIONS  Regulation name/title/ designation | Document in the BCH? (Y/N) | Date verified | OTHER REGULATORY INSTRUMENTS   Instrument name/title/ designation | Document in the BCH? (Y/N) | Date verified | Comments |
| Albania | Partially |  | Law on Environmental Impact Assessment | Y | 15-Jun-17 | -- | -- | -- | Draft National Biosafety Framework | Y | 15-Jun-17 |  |
| Law on Environment Protection | Y | 15-Jun-17 | -- | -- | -- | -- | -- | -- |
| **Draft** Law on Biosafety | Y | 15-Jun-17 | -- | -- | -- | -- | -- | -- |
| Law on BIO products | Y | 15-Jun-17 | -- | -- | -- | -- | -- | -- |
| Law on Consumer Protection | Y | 15-Jun-17 | -- | -- | -- | -- | -- | -- |
| Law on food | Y | 15-Jun-17 | -- | -- | -- | -- | -- | -- |
| Algeria | Yes | Concernant les lois nationales, un seul texte promulgué concerne les organismes génétiquement modifiés sous forme d'arrêté du Ministère de l'Agriculture et du Développement Rural. Cet arrêté ministériel n°910 du 24 décembre 2000 interdit l'importation, la production, la distribution, la commercialisation et l'utilisation du matériel végétal génétiquement modifié. Ce texte stipule que "l'importation, la distribution, la commercialisation et l'utilisation de matériel végétal ayant fait l'objet d'un transfert artificiel de gène en provenance d'un autre individu appartenant à une espèce différente, voire d'un gène bactérien est interdite". Il est entendu par matériel végétal "les plantes vivantes ou parties vivantes de plantes y compris les yeux, greffes, greffons, tubercules, rhizones, boutures, pousses et semences, destinés à la multiplication ou à la reproduction". | -- | -- | 15-Jun-17 | Arrêté du 24 décembre 2000 interdisant l'importation, la production, la distribution, la commercialisation et l'utilisation du matériel végétal génétiquement modifié | Y | 15-Jun-17 | Draft National Biosafety Framework | Y | 15-Jun-17 |  |
| -- | -- | -- | -- | -- | -- | Cadre National de Biosécurité | Y | 15-Jun-17 |
| Antigua and Barbuda | Partially | The Environment Protection and Management Act (EPMA) was passed into law in 2015. The EPMA has [pollution control] provisions that directly apply to biosafety and provides a domestic legal framework that formerly regulates national biosafety. The Act further bolsters existing laws related to trade management, phytosanitary control, pest and chemical management and pharmaceutical control, forestry and watershed management are the primary means of legal control and enforcement.  The Plant Protection Act No. 18 of 2012 has some provisions related to Biosafety [namely import restrictions and permits (section 15 and 16) and containment and eradication of pests(Part 5)].   The government has established a Technical Advisory Committee comprised of representatives from various public sector and private sector agencies and civil society, which provides technical advice upon request for all matters regarding the implementation of Multilateral Environmental Agreements. This body stands as a resource available to the management framework for Biosafety.  Significant administrative systems have been put in place to ensure that the administrative work continues, but is expected to change when the legal framework in in place. To date, some genetically modified (GM) seeds have been confiscated by the Plant Protection agency. Through funding provided by the UNEP-GEF Regional National Biosafety Frameworks Implementation Project for the Caribbean, a draft biosafety policy as well as a draft Biosafety bill and draft regulations have been developed and are currently in the consultative phase prior to submission to Parliament for approval. | -- | -- | -- | -- | -- | -- | Draft National Biosafety Framework | Y | 15-Jun-17 | Draft  law awaiting approval  (see free text)   Instruments missing  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Austria | Yes | The EU biosafety framework as reported by the European Commission (EC) is directly or indirectly applicable to Austria. The EU-Regulations as referenced by the EC are directly applicable, the relevant EU-Directives have been transposed into Austrian legislation.  The Austrian Gene Technology Act regulates the application of GMOs in agriculture and medicine in a general way. It is in force since 1995 and was amended several times. The Act transposes the European Directive for the deliberate release and the placing on the market of GMO products, as well as the EU Directive concerning contained use of GMOs. Implementation of the Austrian Gene Technology Act is supported by a number of ordinances established at the federal level.  To implement measures for Co-existence of GM crops and non-modified crops the 9 federal provinces ("Bundesländer") introduced specific regulations, which apply within their territories.  An overview on the Austrian legal framework is provided at http://www.biosafety.at/ms/biosafety/en/enbiosafety\_law/ ; a brief description of the framework is available at: http://bmg.gv.at/home/Schwerpunkte/Gentechnik/Fachinformation\_Allgemeines/ , Section Behördeninformationen: "Description of Austrian Regulations on Genetic Engineering" | Austrian GMO-Act (Gentechnikgesetz) | N | 15-Jun-17 | Ordinance on Public Hearings for GMO notifications (Anhörungsverordnung BGBl.Nr. 61/1997, i.d.F. BGBl. II Nr. 164/1998) | Y | 15-Jun-17 | -- | -- | 07-Oct-16 | Some links missing / incorrect |
| Ratification of the Cartagena Protocol on Biosafety by the Austrian Parliament | Y | 15-Jun-17 | Ordinance on Arable Land for the Production of Seed (Saatgut-Anbaugebiete-Verordnung BGBl. II Nr. 128/2005) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Co-existence Act, Salzburg (Salzburger Gentechnik-Vorsorgegesetz, LGBl. Nr. 75/2004) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Ordinance on Work with GMOs in Contained Use (Systemverordnung 2002, BGBl. Nr. 431/2002) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Ordinance on GMO-Registers (Gentechnik-Registerverordnung, BGBl. II Nr. 141/2006) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Ordinance on Genetically Modified Seed (Saatgut-Gentechnik-Verordnung, BGBl. II Nr. 478/2001) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Ordinance on labelling of products that contain GMOs (Gentechnik-Kennzeichnungsverordnung, BGBl. II Nr. 5/2006) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Protection of Employees against Hazards caused by Biological Agents (Verordnung biologische Arbeitsstoffe -VbA BGBl. II Nr. 237/1998) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Ordinance on sewage emissions from GMO-facilities (AEV Gentechnik, BGBl. II Nr. 350/1997) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Ordinance on Deliberate Release of GMOs into the Environment (Freisetzungsverordnung 2005, BGBl. II Nr. 260/2005) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Nature Conservation and Landscape Development Act, Vorarlberg (Vorarlberger Gesetz über Naturschutz und Landschaftsentwicklung, LGBl. Nr 22/1997 i.d.F. LGBl. Nr. 1/2008) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Tyrolean Co-existence Act (Tiroler Gentechnik-Vorsorgegesetz, LGBl. Nr. 36/2005) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Viennese Co-existence Act (Wiener Gentechnik-Vorsorgegesetz, LGBl. Nr. 53/2005) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Lower Austrian Co-existence Act (NÖ Gentechnik-Vorsorgegesetz, 6180-0 Stammgesetz 81/05 2005-08-31) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Upper Austrian Co-existence Act (OÖ Gentechnik-Vorsorgegesetz, LGBl. Nr. 79/2006) | N | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Co-existence act, Burgenland (Burgenländisches Gentechnik-Vorsorgegesetz, LBGL. Nr. 64/2005) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Styrian Co-existence Act (Steiermärkisches Gentechnik-Vorsorgegesetz, LGBl. Nr. 97/2006) | Y | 15-Jun-17 | -- | -- | -- |
| -- | -- | -- | Carinthian Co-existence Act (Kärntner Gentechnik-Vorsorgegesetz, LGBl. Nr. 5/2005) | Y | 15-Jun-17 | -- | -- | -- |
| Bahamas | Partially | None | -- | -- | 16-Jun-17 | -- | -- | 16-Jun-17 | Draft National Biosafety Framework | Y | 16-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Bahrain | No | A domestic law aligned with the Gulf Countries Council Arab States was issued in 2012 (Law No. 34-2012) regulating the handling of GM seeds, tuber and seedlings. The law on Specification and Standards (Law No. 9 - 2016) make indirect provision for the handling and intentional release of LMO in the environment. The plant quarantine law (Law No. 5 - 2003) can support the implementation of the CPB. It is worth noting that in parallel with the development of the present report, Bahrain is formulating a series of guidelines including administrative and regulatory frameworks on the implementation of the CPB. Those are based on the national biosafety assessment and consultation meetings undertaken in the context of the development of the present report. They will pave the way for the implementation of the CPB. | -- | -- | 16-Jun-17 | -- | -- | 16-Jun-17 | -- | -- | 16-Jun-17 | No instruments uploaded to the BCH |
| Bangladesh | Yes | The Biosafety Guidelines of Bangladesh has been gazetted by the Ministry of Environment and Forests (MOEF) in 2008. National Biosafety Framework (NBF) has also been developed in 2007. The Guidelines for the Assessment of Foods Derived from GE Plants has been Gazetted by the MOEF in 2012. Bangladesh Biosafety Rules, 2012 has been enacted in 2012. Biosafety Guidelines of Bangladesh appended as part of the rules. | -- | -- | 16-Jun-17 | -- | -- | 16-Jun-17 | Draft National Biosafety Framework | Y | 16-Jun-17 | Instruments missing  (see free text) |
| -- | -- | -- | -- | -- | -- | Biosafety Guidelines of Bangladesh | Y | 16-Jun-17 |
| Barbados | Partially | The draft biosafety framework was developed, but it has not been operationalized. | -- | -- | 16-Jun-17 | -- | -- | 16-Jun-17 | Draft National Biosafety Framework | Y | 16-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Belarus | Yes | By 2006 the National Biosafety Framework had been developed and established in the Republic of Belarus. The most important result of its establishment was the adoption of the Law on “Safety in Genetic Engineering Activities”, №96 dated January 9, 2006. The National legislation of the Republic of Belarus (laws, regulations, guidelines) can be entirely found on the Biosafety Clearing-House website (http://bch.cbd.int/database/results?searchid=642147) in "Belarus" profile. Accession of the Republic of Belarus to the Customs Union of the Eurasian Economic Community (EurAsEC) resulted in the adoption of Technical Regulations of the Customs Union of the EurAsEC (Customs Union Commission Decision № 880 "On Food Safety" and № 881 " Food Products in Terms of their Labeling" of December 9, 2011), setting a threshold of 0.9% instead of 0% for the labeling of products containing genetically modified ingredients and establising the need to quantify GM components. | The Law of the Republic of Belarus "On Safety in Genetic Engineering Activities" | N | 16-Jun-17 | The Resolution of Council of Ministers of the Republic of Belarus "On Establishment of the National Co-ordination Biosafety Centre" | Y | 16-Jun-17 | ТR СU 021/2011 "On Food Safety" (Multilateral Agreement or Arrangement) | Y | 16-Jun-17 | Some links missing / incorrect |
| The Law of the Republic of Belarus "On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity" | Y | 16-Jun-17 | The Resolution of the Council of Ministers of the Republic of Belarus "On Measures for Implementation of the Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity" | Y | 16-Jun-17 | "On Supervision over the Circulation of Food Products Containing GMO" | Y | 16-Jun-17 |
| On Quality and Safety of the Food Raw Materials and Foodstuffs for Human Life and Health | N | 16-Jun-17 | The Resolution of the Council of Ministers of the Republic of Belarus "On Approval of the Provision on Order and Condition of Providing Information from Information Data Bank of Genetically Engineered Organisms" | Y | 16-Jun-17 | ТR СU 022/2011 "Food products in terms of their labeling" (Multilateral Agreement or Arrangement) | Y | 16-Jun-17 |
| Law of the Republic of Belarus "On Protection of Customers Rights" | N | 16-Jun-17 | On the Procedure of Registration of Nonpathogenic, Genetically Engineered Organisms Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed as Transit Goods through its Territory by Legal Entities and Individual Entrepreneurs | N | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On the Procedure of Information Submission to the State Scientific Institution "Institute of Genetics and Cytology at the National Academy of Sciences of Belarus" | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Providing Information to the Databank of Genetically Engineered Organisms | N | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Some Issues of Providing Information for Consumers about Food Raw Materials and Foodstuffs | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Safety Requirements for Trial Fields and Other Objects Provided for Testing Nonpathogenic Genetically Engineered Organisms under their First Release into the Environment | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Approval of Instruction on Procedures of Testing Non-pathogenic Genetically Engineered Organisms under their Release into the Environment | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On the Order of Notification of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the Carrier when Transit Through the Territory of the Republic of Belarus of Nonpathogenic, Genetically Engineered Organisms | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Safety Requirements for Trial Fields and Other Objects Provided for Testing Nonpathogenic Genetically Engineered Organisms under their First Release into the Environment | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Approval of Instruction on Procedures of Testing Non-pathogenic Genetically Engineered Organisms under their Release into the Environment | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Safety Requirements for Contained Use Systems During Performing Works of the First Risk Level of Genetic Engineering Activities | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Approval of Instructions on the Procedure of Risk Assessment of Possible Adverse Effects of Genetically Engineered Organisms on the Environment | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Approval of Instructions on the Procedure of Issuing Permits to Seed Import to the Republic of Belarus and Seed Export from It | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On approval of Regulations on the procedure for State Safety Examination of genetically engineered organisms and of approximate terms of contracts concluded for its carrying out, and issuing permits to release of non-pathogenic, genetically engineered organisms into the environment for testing | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Approval of the Statute of the Expert Council for Safety of Genetically Engineered Organisms at the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Approval of Application Forms | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Approval of Regulations for State Registration Order of Genetically Engineered Plant Cultivars, Genetically Engineered Agricultural Breeds and Non-Pathogenic Genetically Engineered Microorganisms | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Some Problems of Certain Commodity Transfer Across the Customs Border of the Republic of Belarus | Y | 16-Jun-17 | -- | -- | -- |
| -- | -- | -- | On Some Issues of State Control Over Seed-Growing and Variety-Testing | Y | 16-Jun-17 | -- | -- | -- |
| Belgium | Yes | The implementation of the Cartagena Protocol in Belgium is ensured through a set of regulatory instruments, most of which corresponding to the direct application or the transposition in Belgian law of EU legal provisions. Many of these legal instruments were also in place largely before the adoption of the Cartagena Protocol. These regulatory instruments cover in particular the contained use of GMOs, their environmental release (for R&D and for commercialization), their use as food or feed, their transboundary movements, and their coexistence with non-GM and organic agricultural products. Since competencies on GMO matters are shared between the Federal State and the three Regions, a cooperation agreement between all the competent entities has been established since 1997 to manage in an harmonized way the administrative and scientific implementation of the Belgian GMO regulatory framework. As a result, decisions by different administrative bodies representing different institutional levels are based on a single science-based biosafety advisory system, composed of the Belgian Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health. In this system, all regulatory-related aspects of the uses of GMOs and pathogens are assessed altogether in a coordinated way, independently of the specific regulation(s) involved. Competent Authorities (supported by permanent and temporary experienced staff) have been appointed for all regulatory matters related to the implementation (including control) of the Cartagena Protocol. This implementation is also supported by guidelines developed at Belgian or EU level. National focal points for the Protocol and for the BCH have also been designated. For more information about the Belgian biosafety framework, please refer to the BCH. | Arrêté du Gouvernement wallon du 4 juillet 2002 déterminant les conditions sectorielles relatives aux utilisations confinées d'organismes génétiquement modifiés ou pathogènes | Y | 16-Jun-17 | -- | -- | 16-Jun-17 | -- | -- | 16-Jun-17 |  |
| Besluit van de Vlaamse regering van 6 februari 2004 tot wijziging van het besluit van de Vlaamse regering van 6 februari 1991 houdende vaststelling van het Vlaams reglement betreffende de milieuvergunning, en van het besluit van de Vlaamse regering van 1 juni 1995 houdende algemene en sectorale bepalingen inzake milieuhygiëne | Y | 16-Jun-17 | -- | -- | -- | -- | -- | -- |
| Arrêté du Gouvernement de la Région de Bruxelles-Capitale du 8 novembre 2001 relatif à l'utilisation confinée d'organismes génétiquement modifiés et/ou pathogènes et au classement des installations concernéess | Y | 16-Jun-17 | -- | -- | -- | -- | -- | -- |
| Royal Decree of 21 February 2005 on the deliberate release into the environment and the placing on the market of GMOs or GMO-containing products | Y | 16-Jun-17 | -- | -- | -- | -- | -- | -- |
| Benin | No answer provided | No answer provided | National Focal Points for International Protocol and agreements | Y | 19-Jun-17 | Relevé des décisions administratives n°10/SGG/REL du 06 mars 2002 portant texte du Moratoire sur les OGM | Y | 19-Jun-17 | National Biosafety Framework | Y | 19-Jun-17 | Some links missing / incorrect |
| Loi des finance exercice 2017 (Loi N°2016-33 du 26 Décembre 2016 Portant Loi des finances pour la gestion 2017 de la République du Bénin) | Y | 19-Jun-17 | Décret n°2004-293 du 20 mai 2004 portant création, attributions et fonctionnement du comité national de biosécurité (CNBS) | Y | 19-Jun-17 | Avant-projet de loi relative à la sécurité de la biotechnologie moderne | Y | 19-Jun-17 |
| -- | -- | -- | Relevé des décisions administratives adoptées par le Conseil des Ministres en sa séance du mercredi 12 mars 2008, tenue sous la présidence de Monsieur Pascal I KOUPAKI, Ministre d'Etat Chargé de la Prospective, du Développement et de l'Evaluation de l'Action Publique | Y | 19-Jun-17 | REGLEMENT N°007/2007/CM/UEMOA RELATIF A LA SECURITE SANITAIRE DES VEGETAUX, DES ANIMAUX ET DES ALIMENTS DANS L'UEMOA (Regional Agreement or Arrangement) | Y | 19-Jun-17 |
| -- | -- | -- | Arrêté Année 2009 N°0037/MEPN/DC/SGM/SA du 08 juin 2009 portant nomination du Point Focal National du Protocole de Cartagena sur la prévention des risques biotechnologiques et du Centre d'échange pour la prévention des risques biotechnologiques | Y | 19-Jun-17 | Loi 2012-29 du 10 Juillet 2012 portant ratification de la convention africaine sur la conservation de la nature et des ressources naturelles | Y | 19-Jun-17 |
| -- | -- | -- | Arrêté Année 2009 N° 0038/MEPN/DC/SGM/SA du 08 juin 2009 portant nomination du Coordonnateur National du Programme Régional de Biosécurité de l'UEMOA (PRB-UEMOA) | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Décret n° 2010-639 du 31 décembre 2010 portant création, attributions, organisation et fonctionnement du Centre d'Etudes, de Recherches et de Formation Forestières (CERF) | N | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | TITRES D'AFFECTATION DES PERSONNELS DES EAUX-FORETS ET CHASSE DU BENIN 2013 | Y | 19-Jun-17 | -- | -- | -- |
| Bhutan | Partially | Bhutan has enacted the Biosafety Act of Bhutan in 2015. This Act applies to all genetically modified organisms, products derived from genetically modified organisms, and all stages of import, export, and direct use of products that have genetically modified content within Bhutan. | Sales Tax, Customs and Excise Act of the Kingdom of Bhutan 2000 | N | 19-Jun-17 | RULES AND PROCEDURES FOR IMPORTS FROM THIRD COUNTRIES | Y | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | Some links missing / incorrect |
| Forest and Nature Conservation Act of Bhutan 1995 | Y | 19-Jun-17 | Rules on Sales Tax, Customs and Excise Act of the Kingdom of Bhutan 2000 | N | 19-Jun-17 | National Biosafety Framework for Bhutan 2006 | Y | 19-Jun-17 |
| Bio Diversity Act of Bhutan | Y | 19-Jun-17 | Cordyceps Rules and Regulation 2011 | Y | 19-Jun-17 | Guideline on Environmental Risk Assessment of Genetically Modified Plants | Y | 19-Jun-17 |
| THE PLANT QUARANTINE ACT OF BHUTAN, 1993 | Y | 19-Jun-17 | -- | -- | -- | Guidelines for Handling Applications for GMOs/LMOs and Their Products | Y | 19-Jun-17 |
| THE FOOD ACT OF BHUTAN, 2005 | Y | 19-Jun-17 | -- | -- | -- | Guidelines for Inspection and Monitoring of GMOs/LMOs | Y | 19-Jun-17 |
| Environmental Assessment Act, 2000 | Y | 19-Jun-17 | -- | -- | -- | Manual for Training Workshop on GMO/LMO | Y | 19-Jun-17 |
| THE SEEDS ACT OF BHUTAN, 2000 | Y | 19-Jun-17 | -- | -- | -- | Risk Assessment of Food and Feed Products Derived from Genetically Modified Plants 2014 | Y | 19-Jun-17 |
| THE LIVESTOCK ACT OF BHUTAN, 2000 | Y | 19-Jun-17 | -- | -- | -- | Fourth National Report on the UN Convention on Biological Diversity (categorised as 'National Law' on BCH) | Y | 19-Jun-17 |
| Biosafety Act of Bhutan | Y | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Bhutan Forest Act 1969 | Y | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Bolivia (Plurinational State of) | Partially | None | RESOLUCIÓN ADMINISTRATIVA N° 044/2005 | Y | 16-Jun-17 | Reglamento de la Decision 391 del Acuerdo de Cartagena y de Bioseguridad | Y | 16-Jun-17 | -- | -- | 16-Jun-17 |  |
| Resolucion Multiministerial No 1 | Y | 16-Jun-17 | -- | .-- |  | -- | -- | -- |
| Resolucion Administrativa VRNMA No 135/05 | Y | 16-Jun-17 | -- | -- | -- | -- | -- | -- |
| Resolucion administrativa No 016/2005 | Y | 16-Jun-17 | -- | -- | -- | -- | -- | -- |
| Bosnia and Herzegovina | Partially | Law on food partially addresses GMOs and is reported to the BCH. Adopted Law on GMO and 5 appropriate regulations are still not reported ] | Law on Food | Y | 16-Jun-17 | -- | -- | -- | -- | -- | -- | Instruments missing  (see free text) |
| Botswana | Partially | The framework has been developed and currently undergoing legal processes to be adopted by the country. | -- | -- | 16-Jun-17 | -- | -- | 16-Jun-17 | Draft National Biosafety Framework | Y | 16-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Brazil | Yes | None | National Biosafety Law (Law 11.105/2005) | Y | 19-Jun-17 | Decree 5.591/2005, which regulates Law 11.105/2005 | Y | 19-Jun-17 | Communication no. 7 - conditions of isolation and disposal to grant planned authorisation release into the environment of genetically modified sugar cane | N | 19-Jun-17 | Some links missing / incorrect |
| Communication No. 03 - approval procedure for research in contained use of GMOs containing herbicide tolerance and insect resistance | N | 19-Jun-17 | Normative Resolution No. 01 - National Technical Biosafety Comission | N | 19-Jun-17 | Communication no. 6 - ISOLATION OF PLANNED RELEASES IN THE ENVIRONMENT FOR GENETICALLY MODIFIED SOYBEAN | N | 19-Jun-17 |
| -- | -- | -- | Normative Resolution No. 02 - National Technical Biosafety Comission | N | 19-Jun-17 | Communication no. 5 - authorize activities of import, export and transportation of class 1 risk GMO derivatives for the sole use in research under a regime of restraint; | N | 19-Jun-17 |
| -- | -- | -- | Normative Resolution No. 03 - National Technical Biosafety Comission   (N.B. this Resolution was cancelled by Normative Resolution No. 09, see BCH entry) | N | 19-Jun-17 | Communication no. 4 - isolation conditions to enable authorization of planned release to the environment of genetically modified cotton plant | N | 19-Jun-17 |
| -- | -- | -- | Normative Resolution No. 04 - National Technical Biosafety Comission | N | 19-Jun-17 | Normative Resolution no. 8 - simplified rules of Planned Release into the environment mentioned in this Ruling Resolution are applicable to the Risk Class I Genetically Modified Organisms and their derivatives that have previously being passed by CTNBio for the purpose of experimental assessment | Y | 19-Jun-17 |
| -- | -- | -- | Communication No. 01 - National Technical Biosafety Comission | N | 19-Jun-17 | Normative Resolution no. 07 - release into the environment of Risk Class I Genetically Modified Microorganisms and Genetically Modified Animals and their derivatives. | Y | 19-Jun-17 |
| -- | -- | -- | Communication No. 02 - National Technical Biosafety Comission | N | 19-Jun-17 | Normative Resolution no. 9 - Makes provisions on rules for genetically modified organisms postcommercial release monitoring | Y | 19-Jun-17 |
| -- | -- | -- | Normative Resolution no. 05 - Commercial release of GMOs and their derivatives (including risk assessment) | N | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Normative Resolution No. 06 - planned release to the environment of Genetically Modified Organisms (GMO) of plant origin and their derivatives | N | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | DECREE No.6,925, OF AUGUST 6. 2009. | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | RULING INSTRUCTION 10 - Sets isolation conditions for Planned Release into the Environment of genetically modified sweet orange (Citrus sinensis (L.) Osbeck). | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | RULING INSTRUCTION No. 13 - Establishes post-harvesting isolation and monitoring conditions for planned release actions related to genetically modified sorghum into the environment. | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | RULING INSTRUCTION No. 11 Amends Article 16(V) and Article 16(V)(a) to 16(V)(c) of Ruling Resolution no. 01 | Y | 19-Jun-17 | -- | -- | -- |
| Bulgaria | Yes | As a member state of European Union, Bulgaria applies the relevant EU legislation. - European Regulations are directly applicable at national level. Directives 2001/18/EC and 2009/41/EC are transposed in national legislation by Bulgarian Law on GMO, Bulgarian Regulation on the contained use of GMOs and Regulation on the deliberate release and placing on the market of GMOs.  LMOs intended for direct use as food or for processing are regulated by Bulgarian Food Law and those for feed by the Bulgarian Feed Law on Feeds. | Genetically Modified Organisms Act | Y | 19-Jun-17 | Ordinance for the requirements for the labeling and the presenting of the foods | Y | 19-Jun-17 | -- | -- | 12-Sep-16 |  |
| Bulgarian Law on Foodstuffs | Y | 19-Jun-17 | Regulation on the contained use of GMOs | Y | 19-Jun-17 | -- | -- | -- |
| Medicinal Products in Human Medicine Act | Y | 19-Jun-17 | Regulation on the deliberate release into the environment and placing on the market of GMOs | Y ( | 19-Jun-17 | -- | -- | -- |
| Domestic regulations that apply with respect to transit | N | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Veterinary Practice Act | Y | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Burkina Faso | Partially | Mesures administratives : cadre national de biosécurité en 2004; autorité nationale compétente: Agence nationale de biosécurité (ANB) en 2005; acquisition d'une autonomie administrative et de gestion en 2015; Comité scientifique national de biosécurité (CSNB) en 2006; Observatoire national de biosécurité (ONB) en 2008.Mesures juridiques : règles nationales en matière de sécurité en biotechnologies en 2004; loi n°005-2006/AN portant régime de sécurité en matière de biotechnologie au Burkina Faso; loi n°064-2012/AN portant régime de sécurité en matière de biotechnologie Décret n°254-2015/PRES-TRANS/PM/MRSI/MEFdu 17/3/2015 portant fixation des modalités financières pour l'évaluation des demandes d'utilisation et les inspections des organismes génétiquement modifiés; Décret n°219-2015/PRES-TRANS/PM/MRSI/MERH/MESS/MARHSA/MICA, du 5/3/2015 portant conditions de transport et d’exportation / importation des organismes génétiquement modifiés; Décret n°253-2015/PRES-TRANS/PM/MRSI/MEF du 7/3/2015 portant attributions, composition, organisation et fonctionnement du Comité Scientifique National de Biosécurité (CSNB); Décret n°225-2015/PRES-TRANS/PM/ MRSI/MERH/MARHASA/MS/MICA du 5/3/2015 portant conditions de dissémination ou de mise sur le marché des organismes génétiquement modifiés. Décret n°2015/PRES-TRANS/PM/MRSI/MESS/MERH portant évaluation des risques biotechnologiques Décret n°216-2015/PRES-TRANS/PM/MRSI/MARHASA/MRA/MS du 5/3/2015 portant procédures d’essai des organismes génétiquement modifiés en milieu ouvert. Décret n°217-2015/PRES-TRANS/PM/MRSI/MERH/MS/MESS/MARHASA/MRA/MICA du 5/3/2015 portant conditions de destruction des organismes génétiquement modifiés présentant des risques avérés pour la santé humaine, animale et/ou l’environnement; Décret n°215-2015/PRES-TRANS/PM/MRSI/MERH/MRA/MESS/MS du 5/3/2015 portant détermination des risques et modalités de confinement des travaux de biotechnologie ;Décret n°444-2015/PRES-TRANS/PM/MEF/MRSI portant attributions, composition, organisation et fonctionnement de l'Observatoire national de biosécurité; Décret n°2015/PRES/PM/MEF/MRSI portant érection de l’Agence Nationale de Biosécurité (ANB) en établissement public de l’Etat à caractère scientifique, culturel et techniqueLoi 003-2011/AN du 5/01/2011 portant code forestier au Burkina Faso;Loi n°06-2013/AN du portant code de l'environnement au Burkina FasoLoi 008-2014/AN du 8/04/2014 portant loi d'orientation sur le développement durable. | Loi no. 005-2006/AN portant régime de sécurité en matière de biotechnologie au Burkina Faso (LOI DU BURKINA) | Y | 19-Jun-17 | Regulation- Règles Nationales en Matière de Sécurité en Biotechnologie au Burkina | Y | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | Instruments missing (see free text) |
| Loi N°064-2012/AN du 20 décembre 2012 | Y | 19-Jun-17 | Décret sur le comité scientifique national de biosécurité | N | 19-Jun-17 | Ministerial order- Arrêté Experimentation coton transgenique tolerant au glyphosate | Y | 19-Jun-17 |
| -- | -- | -- | Décret portant détermination des risques | Y | 19-Jun-17 | Ministerial order- Arrêté Expérimentation Niébé Bt | Y | 19-Jun-17 |
| -- | -- | -- | Décret portant organisation de l'observatoire national de biosécurité | Y | 19-Jun-17 | Ministerial order- Arrêté Expérimentation Sorgho transgenique | Y | 19-Jun-17 |
| -- | -- | -- | Décret portant condition de destruction des OGM | Y | 19-Jun-17 | Ministerial order- Arrêté Importation semence coton transgenique tolerant au glyphosate | Y | 19-Jun-17 |
| -- | -- | -- | Décret portant évaluation des risques biotechnologiques | Y | 19-Jun-17 | Ministerial order- Arrêté Importation semence Niébé Bt | Y | 19-Jun-17 |
| -- | -- | -- | -- | -- | -- | Ministerial order- Arrêté Importation semence Sorgho transgenique | Y | 19-Jun-17 |
| Burundi | Yes | Le Burundi a déjà mis en place un Cadre National de Biosécurité et un projet de loi sur la biosécurité se trouve à la table du gouvernement. Le Cadre National de Biosécurité donne toutes les mesures et les organes nécessaires pour la mise en œuvre le Protocole de Cartagena sur la Prévention des Risques Biotechnologiques. Les organes actuellement fonctionnels sont l'Autorité Nationale Compétente, le Point Focal du Protocole et celui du Biosafety Clearing House (BCH). D'autres organes prévus par le Cadre National de Biosécurité notamment le Comité National Consultatif, le Comité National d'Experts et le Comité National Public ne sont pas encore mis en place du fait que la loi n'est pas encore adoptée. | Loi n°1/010 portant Code de l'Environnement de la République du Burundi | Y | 19-Jun-17 | -- | -- | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | Draft law awaiting approval  (see free text) |
| Cambodia | Yes | Article 13, 15 and 29 of the Law on Biosafety required all decisions approved to be placed in the BCH. | National Law on Biosafety | Y | 19-Jun-17 | Sub-Decree on Mechanisms and Procedures for Implementing the Law on Biosafety | Y | 19-Jun-17 | Cambodia National Biosafety Framework | Y | 19-Jun-17 |  |
| Cameroon | Partially | Within the reporting period, the following regulatory framework have been put in place: - Decree N°2012/431 of 1st of October 2012 organizing the Ministry of Environment, Protection of Nature and Sustainable Development, - Order N° 039/CAB/PM of 30th of January 2012 carrying the creation, organization and functioning of the National Biosafety Committee, - Decision N° 00334/D/MINEPDED/CAB of 9th of September 2014 constituting the National Biosafety Committee. - An interinstitutional and trans-sectoral coordination mechanism is under piloting within the Cameroon Biosecurity Project especially with respect to the functioning of its Project Advisory Committee. - Setting up of mixed control posts in charge of surveillance at entry points. | Law laying down safety regulations governing modern biotechnology in Cameroon | Y | 19-Jun-17 | Décret No 0737 PM du 31 Mai 2007 d'Application de la loi 2003/006 du 21 Avril 2003 portant régime de sécurité en matière de Biotechnologie Moderne au Cameroun | Y | 19-Jun-17 | -- | -- | 13-Sep-16 | Instruments missing  (see free text) |
| Central African Republic | Partially | D’autres lois, réglementations ou lignes directrices qui s’appliquent indirectement à la prévention des risques biotechnologiques. (La République Centrafricaine a adopté une loi portant réglementation des semences végétales et animales. Cela devra être pris en compte dans cette question) Le fonds National de l’Environnement s’occupe de l’environnement, mais aussi prend en compte les questions liées à la biosécurité et à la mise en œuvre du Protocole | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | Instruments missing  (see free text)   No instruments uploaded to the BCH |
| Chad | Yes | None | -- | -- | 13-Sep-16 | -- | -- | 13-Sep-16 | Cadre national de biosécurité au Tchad | Y | 19-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| China | Partially | The regulations and sectoral bulletins related to biosafety issued in China since 2011 include: In December 2013, the State Forestry Administration issued "Rules for Monitoring of Biosafety of GM Trees" (SFAST No. 215, 2013). The rules were effective from 1 February 2014, and will be valid till 31 January 2019. In August 2014, MOA issued its Bulletin No. 2147, concerning "On-Line Application for Administrative Approval of Agricultural GMOs". The national health sector standard (WS/T 442-2014) effective from 15 December 2014, that contains biosafety guidelines for clinical labs regulates the biosafety management of clinical labs. The revised Food Safety Law of the People's Republic of China adopted in April 2015 by the fourteenth meeting of the Standing Committee of the National People's Congress includes additional provisions concerning GM food labeling and related rules for penalties. The law was effective from 1 October 2015. In addition, the MOA, SAQSIQ and MEP have issued a series of national and sectoral standards for testing GM composition and the environmental safety of GMOs. SAQSIQ and its local administrations have issued local standards for screening GM composition, determination of tolerance traits of GM crops, and safe operations in labs and in the environmental release, thus contributing significantly to improving the legal system for biosafety management of GMOs. | NY/T672-2003 Detection of Genetically Modified Plant Organisms and Derived Products: General Requirements | Y | 13-Sep-16 | Regulations on Safety of Agricultural Genetically Modified Organisms | Y | 13-Sep-16 | Agri. Bul.869-1-2007 Labeling of agricultural genetically modified organisms with label | Y | 13-Sep-16 | Some Links missing / incorrect   Instruments missing  (see free text) |
| NY/T673-2003 Detection of Genetically Modified Plant Organisms and Derived Products:Sampling | Y | 13-Sep-16 | Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms | Y | 13-Sep-16 | Agri.Bul.869-2-2007 Food safety detection of genetically modified organisms and derived products: Method of target protein digestive stability in simulative gastric and intestinal fluid | Y | 13-Sep-16 |
| NY/T674-2003 Detection of Genetically Modified Plant Organisms and Derived Products:DNA Extraction and Purification | Y | 13-Sep-16 | Implementation Regulations on the Safety of Import of Agricultural Genetically Modified Organisms | Y | 13-Sep-16 | Agri.Bul. 869-3-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for insect-resistant and herbicide-tolerant maize Bt11 and its derivates | Y | 13-Sep-16 |
| NY/T1101-2006 Guideline for safety assessment of food from Genetically Modified Plant and derived Products | Y | 07-Oct-16 | Implementation Regulations on Labeling of Agricultural Genetically Modified Organisms | Y | 13-Sep-16 | Agri.Bul. 869-4-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant rapeseed MS1,RF1 and their derivates | Y | 07-Oct-16 |
| NY/T 1102-2006 Safety assessment of genetically modified plant and derived products-90-day feeding test in rats | Y | 07-Oct-16 | Regulation on Inspection and Quarantine of Import and Export Genetically Modified Commodities | Y | 13-Sep-16 | Agri. 869-5-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant rapeseed MS8,RF3 and their derivates | Y | 07-Oct-16 |
| NY/T 1103.1-2006Safety assessment of genetically modified plant and derived products Part 1: assay of anti-nutrients phytate, gossypol and erucic acids | Y | 07-Oct-16 | Regulations on Approval of Agricultural LMOs for Processing | N | 13-Sep-16 | Agri.Bul. 869-6-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant rapeseed MS1,RF2 and their derivates | Y | 07-Oct-16 |
| NY/T 1103.2-2006Safety assessment of genetically modified plant and derived products Part 2: assay of anti-nutrients pancreatic typs in inhibiter | Y | 07-Oct-16 | Regulations on Examination and Approval of Forest Genetic Engineering Activities | N | 13-Sep-16 | Agri.Bul. 869-7-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for insect-resistant and herbicide-tolerant maize TC1507 and its derivates | Y | 07-Oct-16 |
| NY/T 1103.3-2006 Safety assessment of genetically modified plant and derived products | Y | 07-Oct-16 | -- | -- | -- | Agri.Bul. 869-8-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for insect-resistant and herbicide-tolerant maize Bt176 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.869-9-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for insect-resistant maize MON810 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul. 869-10-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for insect-resistant maize MON863 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul. 869-11-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant canola GT73 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.869-12-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant maize GA21 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.869-13-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant maize NK603 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.869-14-2007 Detection of Genetically Modified Plant and Derived Products: Qualitative PCR Method for Herbicide-tolerant Maize T25 and Its Derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri. Bul. 953-1-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for insect-resistant maize Bt10 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-2-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for insect-resistant maize CBH351 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-3-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant canola T45 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-4-2007 Detection of genetically modified plants and derived products: Qualitative PCR method for herbicide-tolerant canola Oxy-235 and its derivates | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.953-5-2007 Detection of genetically modified animals and derived products: Qualitative PCR method for growth promoting ScGH transgenic common carp | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-6-2007 Detection of genetically modified plants and their derived products: Qualitative PCR methods for Bt rice to control insect pests | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-7-2007 Evaluation of environmental impact of genetically modified plants and its derived products: Fertility-altered rapeseed | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-8-2007 Evaluation of environmental impact of genetically modified plants and its derived products: Insect-resistant rice | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-9-2007 Evaluation of environmental impact of genetically modified plants and its derived products: Disease-resistant rice | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-10-2007 Evaluation of environmental impact of genetically modified plants and its derived products: Insect-resistant maize | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-11-2007 Evaluation of environmental impact of genetically modified plants and its derived products: Herbicide-tolerant maize | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Bul.953-12-2007 Evaluation of environmental impact of genetically modified plants and it's derived products: Insect-resistant cotton | Y | 07-Oct-16 |
| -- | -- | -- | -- | -- | -- | Agri.Sci.Letter[2006]55 Guideline for safety administration on field test of genetically modified plants | N | 07-Oct-16 |
| Colombia | Yes | None | DECRETO 3075 DE 1997 Por el cual se reglamenta parcialmente la Ley 09 de 1979 y se dictan otras disposiciones. | Y | 19-Jun-17 | Resolución 3492: Por la cual se reglamenta y se establece el procedimiento para la introducción, producción, liberación y comercialización de Organismos Modificados Genéticamente (OMG) y se dictan otras disposiciones. | Y | 19-Jun-17 | -- | -- | 19-Jun-17 |  |
| Plan de manejo, bioseguridad y seguimiento para siembras comerciales en el país | Y | 19-Jun-17 | Acuerdo 00013: Por el cual se crea el Consejo Técnico Nacional (CTN) para introducción, producción, liberación y comercialización de Organismos Modificados Genéticamente (OMG) de uso agrícola. | Y | 19-Jun-17 | -- | -- | -- |
| DECRETO 1840 DE 1994 (agosto 3) Diario Oficial No 41.473, del 4 de agosto de 1994 | Y | 19-Jun-17 | Resolución 2935: Por la cual se reglamenta y establece el procedimiento de bioseguridad para la introducción, producción, liberación, comercialización, investigación, desarrollo biológico y control de calidad de Organismos Modificados Genéticamente, OMG, de interés en salud y producción pecuaria, sus derivados y productos que los contengan. | Y | 19-Jun-17 | -- | -- | -- |
| Ley 740 de 2002: Por medio de la cual se aprueba el "Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica", hecho en Montreal, el veintinueve (29) de enero de dos mil (2000). | Y | 19-Jun-17 | Acuerdo No. 00002: Por el cual se modifica el Consejo Técnico Nacional (CTN) para introducción, producción, liberación y comercialización de Organismos Modificados Genéticamente (OMG) de uso agrícola, creado por el Acuerdo 00013 del 22 de diciembre de 1998. | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Acuerdo No. 00004: Por el cual se crea el Consejo Técnico Nacional de Bioseguridad Pecuario (CTN Pecuario). | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Decreto 4525: Por el cual se reglamenta la Ley 740 de 2002. | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución 958: Por la cual se regula el funcionamiento del Comité Técnico Nacional de Bioseguridad para Organismos Vivos Modificados -OVM con fines exclusivamente ambientales que puedan tener efectos sobre el medio ambiente y la biodiversidad | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución 957: Por la cual se establece el procedimiento para la autorización de actividades con Organismos Vivos Modificados -OVM- con fines exclusivamente ambientales, y se adoptan otras determinaciones | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución 946: Por la cual se establece el procedimiento para el trámite ante el ICA de solicitudes de Organismos Vivos Modificados, OVM; se aprueba el Reglamento Interno del Comité Técnico Nacional de Bioseguridad, CTNBio para OVM con fines exclusivamente agrícolas, pecuarios, pesqueros, plantaciones forestales comerciales y agroindustria, y se dictan otras disposiciones | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución 0227: Disposiciones sobre la convocatoria, funciones y sesiones del Comité Técnico Nacional de Bioseguridad para Organismos Vivos Modificados OVM (Salud). | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución ICA 001063: Por la cual se expiden normas para el registro de personas que realicen actividades de importación, comercialización, investigación, desarrollo biológico y control de calidad de Organismos Modificados Genéticamente (OMG) de interés en salud y producción pecuaria, sus derivados y productos que los contengan . | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolucion 4254 de 2011 Por la cual se expide el reglamento tecnico que establece las disposiciones relacionadas con el rotulado o etiquetado de alimentos derivados de OGM para el consumo humano y con la identificacion de materias primas para consumo humano que los contengan | Y | 19-Jun-17 | -- | -- | -- |
| Congo | No | L'avant projet de loi sur la biosécurité a été réactualisé pour être soumis à l'approbation par le Gouvernement et l'adoption par le parlement après plusieurs sensibilisations aux parlementaires et parties prenantes. | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | Draft law awaiting approval  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Costa Rica | Yes | Se ejecutó exitosamente un proyecto UNEP-GEF de Implementación de un Marco Nacional sobre Seguridad de la Biotecnología GLF/2328-2716-4B61 (Duración 36 meses, Octubre 2010 a marzo 2014), así como el Proyecto LAC Biosafety: América Latina: Construcción de Capacidad multipaís para el cumplimiento del Protocolo de Cartagena en Bioseguridad. En cumplimiento con los instrumentos jurídicos establecidos hay un conjunto de leyes, las cuáles son: Ley de Protección Fitosanitaria N° 7664 y su reglamento N° 26921-MAG, Ley de Biodiversidad N°7788, Ley SENASA N°8495, Reglamento de Auditores en Bioseguridad N. °32486-MAG, el Protocolo de Cartagena, Ley No. 8537 y el decreto ejecutivo 36801-MAG sobre el uso del sistema digital: www.ovm.go.cr, publicado en la Gaceta 113 del 2013.En recurso humano disponible y permanente, en el país existe una participación Interministerial, por medio de la integración de la Comisión Técnica Nacional de Bioseguridad, creada por ley y ratificada su constitución y funciones por la Ley de Servicio Nacional de Salud Animal (SENASA) y la Ley de Biodiversidad, además de Organizaciones N° Gubernamentales y de empresa privada en las actividades relacionadas en materia de OVM´s, por tanto se contabilizan mas de 10 personas en funciones relacionadas con la materia La Ley de Protección Fitosanitaria Nº 7664 y sus posteriores modificaciones, en su articulo 40 crea la Comisión Técnica Nacional de Bioseguridad y en su Reglamento Nº26921 articulo 112 indica su conformación de la siguiente manera: 1. Un representante del Ministerio de Ciencia y Tecnología. 2. un representantes del Servicio Fitosanitario del Estado y un representante del Servicio Nacional de Salud Animal 3. Dos representantes del Ministerio del Ambiente y Energía. 4. Un representante de la Oficina Nacional de Semillas. 5. Dos representantes designados por la Academia Nacional de Ciencias. 6. Dos representantes de la Sociedad Civil. 7. Dos representantes del Ministerio de Salud | Ley de Protección Fitosanitaria Nº 7664 | Y | 19-Jun-17 | Normas Generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad | Y | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 |  |
| Ley de Biodiversidad N°7788 | Y | 19-Jun-17 | Reglamento N°26921-MAG; Reglamento a la Ley de Protección Fitosanitaria N°7664 | Y | 19-Jun-17 | -- | -- | -- |
| Ley General de Salud, Cap.III. Secc.III De los Alimentos | Y | 19-Jun-17 | Reglamento para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad en condiciones ex situ | Y | 19-Jun-17 | -- | -- | -- |
| Ley Nacional N°8537 Protocolo de Cartagena sobre Seguridad de la Biotecnología | Y | 19-Jun-17 | decreto Ejecutivo Nº 35242-MAG-H-MEIC Reglamento para el Desarrollo, Promoción y Fomentode la Actividad Agropecuaria Orgánica. | Y (in Additional info) | 19-Jun-17 | -- | -- | -- |
| General Law on The National Service of Animal Health | Y | 19-Jun-17 | Reglamento de Auditoria en Bioseguridad Agricola del Ministerio de Agricultura y Ganadería en Bioseguridad Agricola Nº 32486 | Y | 19-Jun-17 | -- | -- | -- |
| Côte d'Ivoire | Yes | -- | Law n° 64-490, December 21st 1964 regarding plants protection. | Y | 19-Jun-17 | CONDITIONS D'ENTREE EN CÔTE D'IVOIRE D'EXPORTATION ET DE REEXPORTATION | Y | 19-Jun-17 | Decree n° 63-457, November 7th 1963 establishing the importation and exportation conditions of plants and others materials which are liable to carry dangerous organisms regarding the cultivations. | Y | 19-Jun-17 |  |
| Law n° 96-766, October 3 rd 1996 relating to Environment Code | Y | 19-Jun-17 | DECRET N° 2014-822 DU 16 DECEMBRE 2014 PORTANT ADHESION DE LA REPUBLIQUE DE COTE D'IVOIRE AU PROTOCOLE DE CARTAGENA SUR LA PREVENTION DES RISQUES BIOTECHNOLOGIQUES RELATIF A LA CONVENTION SUR LA DIVERSITE BIOLOGIQUE ADOPTE LE 29 JANVIER 2000 A CARTAGENA (COLOMBIE) | Y | 19-Jun-17 | Draft National Biosafety Framework ( Developed under the UNEP-GEF Biosafety Project) | Y | 19-Jun-17 |
| Decree n° 96-894, November 8th 1996, establishing the rules and procedures regarding the environmental impact studies of development projects. | Y | 19-Jun-17 | -- | -- | -- | Biosafety National Framework | Y | 19-Jun-17 |
| LOI N° 2014-821 DU 16 DECEMBRE 2014 MODIFIANT LA LOI N° 2007-496 DU 31 MAI 2007 AUTORISANT LE PRESIDENT DE LA REPUBLIQUE A FAIRE ADHERER L'ETAT DE COTE D'IVOIRE AU PROTOCOLE DE | Y | 19-Jun-17 |  |  |  |  |  |  |
| LAW N° 2016-553 OF BIOSAFETY OF JULY 26TH, 2016 | Y | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Croatia | Yes | National biosafety framework became operational in 2008 when both the Council for GMOs and two Committees (Committee for contained use of GMOs, Committee for intentional/deliberate release of GMOs into the environment) have been established and started to work. In the period covering the Second National Report (September 2007 - September 2011) and until 1 July 2013 when Republic of Croatia became the 28th Member State of the EU, all national legislation (biosafety laws and regulations, other laws, regulations indirectly applicable to biosafety) had been already in line with the comprehensive EU legal framework for ensuring safety in the development, use and transfer of GMOs. It means that provisions of the Directive 2001/18/EC, Regulations (EC) No 1829/2003, Regulation (EC) No 1830/2003, Regulation (EC) No 1946/2003, Regulation (EC) No 641/2004, Directive 2009/41/EC, Commission Regulation 619/2011, and of the Commission Implementing Regulation (EU) No 503/2013 have been transposed into the national legislation and all national legislation was in line with the EU framework. Republic of Croatia had been actively involved in the preparation of the Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory. | Act on Genetically Modified Organisms (Official Gazette No. 70/2005) | Y | 13-Sep-16 | Regulation on the Minimum Threshold for Genetically Modified Organisms in Products below which the Products placed on the Market do not have to be labelled as Products containing Genetically Modified Organisms (Official Gazette No. 92/2008, 36/2009, 33/2010, 88/2011) | Y | 13-Sep-16 | Draft National Biosafety Framework | Y | 13-Sep-16 | See EU's laws, regulations and guidelines for more. |
| Food Act (Official Gazette No. 81/2013) | Y | 13-Sep-16 | Ordinance on the Conditions of Monitoring the Impact of Genetically Modified Organisms or Products containing and/or consisting of or originating from Genetically Modified Organisms and their Use (Official Gazette No. 110/2008 and No. 41/2010) | Y | 13-Sep-16 | Announcement on the Entry into Force of the Cartagena Protocol on Biosafety for the Republic of Croatia (Official Gazette No. 13/2003) (Multilateral Agreement or Arrangement) | Y | 05-Oct-16 |
| Law on Ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Official Gazette No. 7/2002) | Y  (in Croatian only) | 05-Oct-16 | Ordinance on the Content and Method of Implementing the Plan of Measures for Removing the Uncontrolled Spread of Genetically Modified Organisms into the Environment (Official Gazette No. 5/2007) | Y  (in Croatian only) | 13-Sep-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Content and the Method for submitting the Notification for Deliberate Release of Genetically Modified Organisms into the Environment (Official Gazette No. 64/2007) | Y (in Croatian only) | 13-Sep-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Risk Assessment of the Deliberate Release of Genetically Modified Organisms into the Environment (Official Gazette No. 136/2006) | Y (in Croatian only) | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Regulation on Transboundary Movements of Genetically Modified Organisms (Official Gazette No. 89/2010) | Y (in Croatian only) | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Form and Manner of Keeping the Unique Register of Genetically Modified Organisms and the Manner of Establishing Printout Costs (Official Gazette No. 125/2007) | Y | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the content and scope of risk assessment in relation to placing on the market of genetically modified organisms or products which contain and/or consist of or derive from genetically modified organisms, methodology for the preparation of assessment and requirements that have to be fulfilled by a legal person for the preparation of risk assessment (Official Gazette No. 39/2008) | Y | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Content of the Notification and Technical Dossier for the Placing on the Market of Genetically Modified Organisms or Products containing and/or consisting of or deriving from GMOs and on the Requirements for Labelling and Packaging of GMOs or Products containing and/or consisting of or deriving from GMOs (Official Gazette No. 106/2008) | Y | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Conditions and the Procedure for Obtaining the Authorization for the First Placement of Genetically Modified Food and Genetically Modified Feed on the Market of the Republic of Croatia and the Requirements relating to the Traceability, and Specific Labelling of Genetically Modified Food and Genetically Modified Feed (Official Gazette No. 110/2008) | Y | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Scope and Content of the Assessment Report on the Adequacy of Placing on the Market GMOs or Products containing and/or consisting of or originating from GMOs (Official Gazette No. 93/2008) | Y | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Decision on the Establishment of the Council for Genetically Modified Organisms (Official Gazette No. 156/2008) | Y | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Content of the Notification for the Closed System (Official Gazette No. 84/2006) | Y (in Croatian only) | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Safety Measures and Standards for Facilities in Closed System for Contained Use of Genetically Modified Organism (Official Gazette No. 84/2006) | Y (in Croatian only) | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Content of the Notification for Contained Use of Genetically Modified Organisms classified within the second, third or fourth level of hazard (Official Gazette No. 84/2006) | Y (in Croatian only) | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on the Content, Scope and Methodology for the Preparation of Risk Assessment in relation to the Contained Use of Genetically Modified Organisms (Official Gazette Nol. 84/2006) | Y (in Croatian only) | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | Ordinance on conditions to be complied with by laboratories for testing, control and monitoring of GMOs and products containing and/or consisting of or originating from GMOs (Official Gazette No. 26/2010) | Y | 5-Oct-16 | -- | -- | -- |
| -- | -- | -- | List of legal entities that are authorized to perform technical tasks of risk assessment for the purpose of introducing genetically modified organisms into the environment (Official Gazette No. 133/2010) | Y (in Croatian only) | 5-Oct-16 | -- | -- | -- |
| Cuba | Partially | En el período que se reporta se encuentran en proceso de aprobación, las modificaciones realizadas al Reglamento que aborda el uso confinado de OVMs y en fase de modificación el Reglamento que regula el proceso de toma de decisiones para OVMs.  En materia de salud humana, el Ministerio de la Salud Pública es el Organismo de la Administración Central del Estado que traza las pautas fundamentales para la preservación de la Salud Humana: Específicamente para los OVMs está en fase de aprobación un Reglamento que regula el proceso de toma de decisiones para los productos alimenticios obtenidos por medios biotecnológicos, en el cual se establece que para el otorgamiento del Registro Sanitario, la autorización de seguridad biológica tiene un carácter vinculante. Con esta institución, el Centro Nacional de Seguridad Biológica mantiene estrechas relaciones de coordinación en función de la toma de decisiones en materia de OVMs importados para uso directo como alimento humano.  La legislación cubana de Bioseguridad, está colocada íntegramente en el Centro de Intercambio de Información del Protocolo. No obstante, nos encontramos en una fase superior en la que se hace necesario mostrar otras normas jurídicas igualmente relevantes que inciden en el tema de los OVMs. | Decreto-Ley No.190 De la Seguridad Biológica | Y | 19-Jun-17 | Resolución No.103 Reglamento para el Establecimiento de los Requisitos y Procedimientos de Seguridad Biológica para las Instalaciones en las que se hace uso de agentes biológicos, organismos y fragmentos de éstos con información genética | Y | 19-Jun-17 | -- | -- | 19-Jun-17 |  |
| Decreto Ley No. 153 de la Sanidad Vegetal | Y | 19-Jun-17 | Resolución No.8 Reglamento General de Seguridad Biológica para las Instalaciones en las que se manipulan agentes biológicos, organismos y fragmentos de éstos con información genética | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución No.112 Resolución para el establecimiento de los requisitos y procedimientos de Seguridad Biológica en las instalaciones en las que se hace uso de animales y plantas con riesgo biológico | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución No.67 Creación del Centro Nacional de Seguridad Biológica | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución No.2 Reglamento para la Contabilidad y el Control de materiales biológicos, equipos y tecnología aplicada a éstos | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución No. 180/2007 Reglamento para el otorgamiento de la Autorización de Seguridad Biológica | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución No. 38/2006 Lista oficial de agentes biológicos que afectan al hombre, los animales y las plantas | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Resolución No. 103/2008 Reglamento de la Inspección Estatal de la Actividad reguladora Ambiental | Y | 19-Jun-17 | -- | -- | -- |
| Cyprus | Partially | Cyprus as a member of the EU adopts the EU legislation on genetically modified organisms (GMOs). The main legal instruments of the EU include the following directives and regulations on which Cyprus bases its national legal framework: Directive 2009/41/EC on the contained use of genetically modified microorganisms Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, covering the field testing of GMOs and the placing on the market of GMOs as well as products containing or consisting of GMOs. Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms. Regulation (EC) No 1829/2003 on genetically modified food and feed. Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. | Law on the Protection and Management of Nature and Wildlife (153(I)) | N | 19-Jun-17 | -- | -- | -- | -- | -- | -- | Links missing / incorrect  See EU's laws, regulations and guidelines for more |
| Law on the Protection and Management of Game and Wild Birds (152(I)) | N | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Czech Republic | Yes | The Czech Republic is a member state of the European Union, therefore the Czech legislative framework has been harmonized with the European Union legislation. The EU legislation is listed and described in the parallel 3rd National Report of the European Union. In the Czech Republic, the first basic national legal instrument regarding the use of GMOs was adopted already in 2000. Since February 2004, the Act 78/2004, on the Use of Genetically Modified Organisms and Genetic Products, as amended, with an implementing Decree 209/2004 have been in force. The Act transposes EU Directives 2001/18/EC and 2009/41/EC, therefore it covers the contained use, deliberate release of GMOs into the environment (e. g. field trials) and placing on the market of GMOs as or in products. It has been in force since February 2004.  General rules on the co-existence of genetically modified crops with conventional and organic farming are set by the Act 252/1997, on Agriculture, as amended, and specified by the Decree 89/2006, on detailed conditions for growing a genetically modified variety, as amended. Re Q16: Amendments of some Acts and corresponding Decrees related to biosafety are under way, on the basis of recent developments and knowledge and in compliance with the new EU legislation. More information is available through the Czech national node of the BCH at http:www.mzp.cz/biosafety The EC Regulations 1829/2003 and 503/2013 concerning the authorization of GM food and feed, Regulation 1830/2003 on traceability and labelling of GMOs and GM food and feed, Regulation 1946/2003 implementing the Cartagena Protocol and relevant implementing decisions have been directly applicable in the Czech Republic since its accession to the EU in May 2004. For more information on EU legislation, please refer to the EU report. | Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products, as amended | Y | 19-Jun-17 | Decree of the Ministry of Environment on detailed conditions for the use of genetically modified organisms and genetic products | Y | 19-Jun-17 | Decree 89/2006 on more detailed requirements for cultivation of genetically modified variety | Y | 19-Jun-17 |  |
| Democratic Republic of the Congo | Yes | Les commentaires suivants concernent les dispositions légales et règlementaires qui peuvent s'appliquer pour la biosécurité ainsi que le nombre d'employés affectés à la gestion de la prévention des risques biotechnologiques. En ses articles 53 et 202 point 36.m, la Constitution de la RD Congo du 16 février 2006 tout comme la Loi du 09 juillet portant principes fondamentaux relatifs à la protection de l'environnement, en ses articles 62 et 63 jettent d'ores et déjà les bases d'une législation sur la gestion des risques biotechnologiques ainsi que sur l'utilisation de la biotechnologie. D'autres textes juridiques de portée générale réglementent indirectement les organismes vivants modifiés. Il s'agit notamment de: - la législation sur l'exercice du commerce (loi n°73-009 du 05 janvier 1973 telle que modifiée et complétée à ce jour; - la législation sur la forêt (Code forestier). La Loi n°14/003 du 11 février 2014 relative à la conservation de la nature contient aussi des dispositions susceptibles d’être capitalisées dans le cadre de la biosécurité notamment les dispositions relatives à l’étude d’impact environnemental et social. La Loi n°11/022 du 24 décembre 2011 portant principes fondamentaux relatifs à l’agriculture stipule à son article 71 que le Gouvernement veille à ce que la mise au point, l’utilisation, le transfert et la libération dans l’agriculture des organismes génétiquement modifiés et des pesticides se fassent de manière à éviter ou à réduire les risques pour l’environnement et la santé. Il veille également à ce que certaines pratiques agricoles n’aient pas d’impact négatif sur l’environnement et la santé. | LOI N° 11/009 DU 09 JUILLET 2011 PORTANT PRINCIPES FONDAMENTAUX RELATIFS A LA PROTECTION DE L'ENVIRONNEMENT | Y | 19-Jun-17 | -- | -- | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | Instruments missing  (see free text) |
| Denmark | Yes | Reference is made to the third national report of the European Union which outlines the legislative framework applying to the use of GMO's within the European Union, including imports. As a member of the European Union Denmark has implemented the directives and ensured the enforcement of the EU regulations. Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of Genetically Modified Micro-Organisms is implemented through 3 different Statutory Orders:  1) Statutory Order No. 225 of March 19, 2009 on Approval of Production with Genetically Modified Organisms 2) Statutory Order No. 226 of 19 March 2009 on Transport and Notification when marketing Genetically Modified Organisms 3) Statutory Order No. 910 of September 11 2008 on Genetic Engineering and Working Environment.   Directive 2001/18/EC is implemented in Danish legislation by Act No 840 of 7 July 2015 on Environment and Genetic Engineering and by Statutory Order No. 37 of 19 January, 2012 on deliberate release into the environment of genetically modified organisms.  Directive 2015/412 is in the process of being implemented through a change of the Act on Environment and Genetic Engineering and the Act on Coexistence No . It is expected to enter into force in the spring of 2016.  Regulation (EC) No. 1946/2003, No. 1829/2003, No. 1830/2003 and No. 641/2004 applies directly. | Consolidated Environment and Genetic Engineering Act No 869 of 26 June 2010 | Y | 19-Jun-17 | Statutory Order No. 35 of 19 January, 2012 on Approval of Production with Genetically Modified Plants and Animals | Y | 19-Jun-17 | -- | -- | 19-Jun-17 |  |
| Statutory Order no 88 concerning the Fee for Processing and Inspections under the Environment and Genetic Engineering Act No 869 of 26 June 2010 | Y | 19-Jun-17 | Statutory Order No. 225 of 19 March, 2009 on Approval of Production With Genetically Modified Microorganisms | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Statutory Order No. 36 of 19 January, 2012 on Approval of Exhibition of GMO's and Information Sharing | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Statutory Order on the Working Environment and the Environment | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Statutory Order on Transport of LMOs and the Information Procedure when transporting LMO's Approved for Marketing in the EU | Y | 19-Jun-17 | -- | -- | -- |
| -- | -- | -- | Statutory Order on conditions concerning the environment, nature and human health in approvals following Environment and Genetic Engineering Act No 869 of 26 June 2010 | Y | 19-Jun-17 | -- | -- | -- |
| Dominica | Yes | Same as reported in previous report.   (From **Second National Report:**"There is a draft CARICOM harmonizing Plant Protection Act which has some provision related to Biosafety. However, there is much work still to be done to implement the National Biosafety Framework (NBF).") | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 |  |
| Dominican Republic | Partially | el proyecto de Ley sobre la Seguridad de la Biotecnologia en cual fue formulado dentro las disposiciones del Protocolo de Cartagena fue aprobado por el Congreso Nacional en fecha julio del 2015. Se espera que el mismo sea promulgado por el Poder Ejecutivo. | PROYECTO DE LEY SOBRE LA SEGURIDAD DE LA BIOTECNOLOGIA | Y | 19-Jun-17 | -- | -- | 15-Sep-16 | MARCO NACIONAL DE BIOSEGURIDAD | Y | 19-Jun-17 | Draft law awaiting approval  (see free text) |
| LEY GENERAL DE PROTECCIÓN DE LOS DERECHOS AL CONSUMIDOR (385-05) | Y | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Ley sobre la Seguridad de la Biotecnología (219-15) | Y | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| LEY 6400 (Ley General sobre Medio Ambiente y Recursos Naturales) | Y | 19-Jun-17 | -- | -- | -- | -- | -- | -- |
| Ecuador | Yes | La Constitución Ecuatoriana aprobada en el año 2008 contiene estipulaciones específicas sobre organismos genéticamente modificados (organismos vivos modificados) en los Artículos 15, 73, 401, aunque estos artículos no están vinculados a la aplicación del PCB.  Las siguientes leyes también tienen consideraciones sobre los OVMs y Bioseguridad: Ley de Gestión Ambiental; Ley Orgánica de Defensa del Consumidor; Ley Orgánica de Salud; Ley Orgánica del Régimen de Soberanía Alimentaria; Texto Unificado de Legislación Ambiental Secundaria del MAE (TULAS); Acuerdo Ministerial No. 013, publicado en el Registro Oficial No. 425 del 27 de enero del 2015, mediante el cual se actualiza la estructura, funcionamiento y atribuciones de la Comisión Nacional de Bioseguridad; Política Nacional de Bioseguridad establecida en el Plan Nacional del Buen Vivir 2013-2017. | Constitución de la República del Ecuador | Y | 20-Jun-17 | Texto Unificado de Legislación Ambiental Secundaria | Y | 20-Jun-17 | Norma INEN 1334 (Etiquetado de OGMs) | Y | 20-Jun-17 | Instruments missing  (see free text) |
| Ley Orgánica del Régimen de Soberanía Alimentaria | Y | 20-Jun-17 | ROTULADO DE PRODUCTOS ALIMENTICIOS PARA CONSUMO HUMANO ( (\*amended by *Norma INEN 1334*) | Y | 20-Jun-17 | Norma Técnica para el Etiquetado de OVM | Y | 20-Jun-17 |
| Ley Orgánica de Defensa al Consumidor | Y | 20-Jun-17 | Reglamento Sanitario de Etiquetado de Alimentos Procesados para el Consumo Humano (\*amended by *ROTULADO DE PRODUCTOS ALIMENTICIOS PARA CONSUMO HUMANO*) | Y | 20-Jun-17 | Modificatoria a la Reglamentación Técnica del Rotulado de Alimentos Genéticamente Modificados (\*amended by *ROTULADO DE PRODUCTOS ALIMENTICIOS PARA CONSUMO HUMANO*) | Y | 20-Jun-17 |
| Ley de Gestión Ambiental | Y | 20-Jun-17 | Comisión Nacional de Bioseguridad | Y | 20-Jun-17 | -- | -- | -- |
| Ley Orgánica de Salud | Y | 20-Jun-17 | -- | -- | -- | -- | -- | -- |
| Egypt | Partially | GOOGLE TRANSLATE, original in Arabic: Egypt still apply the provisions of the Protocol which has not yet issued a national law regard to this matter, which may pose difficulties in interpretation - but that, based on national laws and the Constitution, the provisions of the Protocol, which was ratified become binding and should be in contradiction with the texts of other national laws and the concerned authorities the obligation to do so without objection from any of the state institutions concerned - note that the Council of Ministers approved the issuance of national law in effect in 2011. | Biosafety Law for Release of Genetically Modified Products | N | 20-Jun-17 | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Some links missing / incorrect   Draft law awaiting approval |
| El Salvador | Yes | En El Salvador el Reglamento Especial para el Manejo Seguro de los Organismos Modificados Geneticamente, emitido en el año 2008, establece las normas de seguridad a las que habrá de sujetarse las variedades resultantes de la acción humana mediante la biotecnología moderna, supervisando su empleo, a fin de minimizar el impacto adverso sobre la diversidad biológica nativa, tomando en cuenta la salud humana. Este Reglamento tiene como marco y base jurídica el Protocolo de Cartagena sobre Seguridad de la Biotecnología y la Ley del Medio Ambiente - Capítulo IV sobre Evaluación Ambiental, Articulos 16, 21, 22 y 68. | -- | -- | 20-Jun-17 | Reglamento Especial para el Manejo Seguro de OMG | Y | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 |  |
| Eritrea | Yes | The Department of Environment (DoE)which is the focal point for Biotechnology/Biosafety in Eritrea has developed the following documents on Biosafety . 1.Biotechnology/Biosafety Assessment Report for Eritrea(in 2007) 2.National Biosafety Framework for Eritrea(in 2007) 3.National Biosafety policy for Eritrea(in 2007) 4.National Biosafety Legislation for Eritrea(in 2007) 5.National Biosafety Guideline(2007)  6.Strategy and Action Plan for the Implementation of the Cartagena Protocol on Biosafety (in 2012) but not submitted. | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Instruments missing  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Estonia | Partially | As an EU Member State, Estonia complies with European Community law. For the description of the EU framework, please see the report of EC.  Estonia has adopted the Act on the Release into the Environment of Genetically Modified Organisms, valid since 01.05.2004, which provides regulations in accordance with Directive 2001/18 of the European Council. The act was amended and provisions about co-existence of GMOs and conventional crops were added in 2011.  Additionally, there are several sectoral legal acts connected to biosafety, based on EU legal acts: The Act on Contained Use of Genetically Modified Microorganisms (01.08.2002); The Food Act (last redaction since 11.06.2015); The Act on Seeds and Plant Propagation Material; The Feed Act (11.06.2015). | Release into the Environment of Genetically Modified Organisms Act | Y | 20-Jun-17 | Assessment methods of the conformity of novel foods to requirements and the procedure of application for and issuing of novel food handling permits   (\*\*\*In "additional information" section: "Amendments:expired 01.05 2004") | Y | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Instruments missing  (see free text) |
| Contained Use of Genetically Modified Micro-organisms Act | Y | 20-Jun-17 | Requirements for the contents of the environment monitoring report associated with marketing of genetically modified organisms and products and the procedure of submitting the report | Y | 20-Jun-17 | -- | -- | -- |
| The Food Act | Y | 20-Jun-17 | -- | -- | -- | -- | -- | -- |
| The Feed Act | Y | 20-Jun-17 | -- | -- | -- | -- | -- | -- |
| Medicinal ProductsAct | Y | 20-Jun-17 | -- | -- | -- | -- | -- | -- |
| Ethiopia | Partially | Ethiopia amended its Biosafety Law in 2015. The Law had been amended with full participation of different stakeholders and endorsed by the Counsel Ministers as Biosafety Law No. 896/2015 for enactment. 7 Implementing guidelines have been prepared and also revised according to the revised Biosafety amended Law. | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Instruments missing  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| European Union | Yes | EU legislation on genetically modified organisms (GMOs) has been in place since the early 1990s. The EU introduced specific legislation on GMOs to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology products. The EU has created a comprehensive legal framework for ensuring safety in the development, use and transfer of GMOs. The main pieces of legislation are:- Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, covering the field testing of GMOs and the placing on the market of GMOs as well as products containing or consisting of GMOs, e.g. for cultivation, import or processing into industrial products.- Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed, covering the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs. - Regulation (EC) No 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.- Regulation (EC) No 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms covers exports of GMOs to third countries and unintentional movements of GMOs.- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms.- Commission Regulation 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorization procedure is pending or the authorization of which has expired.- Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorization of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006.- Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.More information on the content of these legislative acts is available at: http://ec.europa.eu/food/plant/gmo/new/legislation/index\_en.htmIn the case of Directives 2001/18/EC and (EU) 2015/412, and of Regulations (EC) No 1829/2003, 1830/2003 and 1946/2003, Member States have introduced domestic provisions to ensure enforcement and/or transposition of this legislation within their territories. For implementing legislation at EU Member States level, please refer to the Member States national reports. | Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC | Y | 20-Jun-17 |  |  |  | Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 | Y | 20-Jun-17 | Instruments missing (see free text) |
| Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation | Y | 20-Jun-17 |  |  |  | Commission Decision 2009/770/EC establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms | Y | 20-Jun-17 |
| Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products | Y | 20-Jun-17 |  |  |  | Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council | Y | 20-Jun-17 |
| Commission Regulation (EU) No 619/2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorization procedure is pending or the authorization of which has expired | Y | 20-Jun-17 |  |  |  | European Commission Recommendation 2010/C200/01 of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops | Y | 20-Jun-17 |
| Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms | Y | 20-Jun-17 | -- | -- | -- | 2002/811/EC: Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC | Y | 20-Jun-17 |
| Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms | Y | 20-Jun-17 | -- | -- | -- | 2002/813/EC: Council Decision of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market | Y | 20-Jun-17 |
| Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed | Y | 20-Jun-17 | -- | -- | -- | 2002/812/EC: Council Decision of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products | Y | 20-Jun-17 |
| Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC | Y | 20-Jun-17 | -- | -- | -- | 2002/623/EC: Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (Text with EEA relevance) (notified under document number C(2002) 2715) | Y | 20-Jun-17 |
| Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms | Y | 20-Jun-17 | -- | -- | -- | Council Decision 2002/628/EC of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety | Y | 20-Jun-17 |
| DIRECTIVE 2009/41/EC ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS | Y | 20-Jun-17 | -- | -- | -- | -- | -- | -- |
| Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules | Y | 20-Jun-17 | -- | -- | -- | -- | -- | -- |
| Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use | Y | 20-Jun-17 | -- | -- | -- | -- | -- | -- |
| Finland | Yes | See the EU Commission's (EU CION) report.The Gene Technology Act (377/1995) regulates the use of GMOs in Finland. The aim of the Act is to promote the safe use and development of gene technology in accordance with the precautionary principle and in an ethically acceptable way, and to protect human and animal health and the environment when contained use or deliberate release into the environment of GMOs is carried out. The organisms referred to in the Gene Technology Act do not include human beings.The Gene Technology Act is based on the EU Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and on the Directive 2009/41/EC on the contained use of genetically modified micro-organisms (the former Directive 90/219/EEC). The Gene Technology Act pertains also to the contained use of GM plants and animals, thus differing from the latter Directive.The Gene Technology Act is supplemented by Government Decrees and Decrees of the Ministry of Social Affairs and Health. The statutes have been amended several times after the year 1995. The list below contains the unofficial translations of the statutes in force at present.Gene Technology Act (377/1995) Government Decree on Gene Technology ( 928/2004)  Decree of the Ministry of Social Affairs and Health on the deliberate release of genetically modified organisms ( 110/2005)Decree of the Ministry of Social Affairs and Health on the differentiated procedure relating to the deliberate release of genetically modified organisms (90/2005)Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified micro-organisms, on classification of the contained use, and on containment and other protective measures ( 1053/2005)Decree of the Ministry of Social Affairs and Health on notifications and applications relating to the contained use of modified organisms, on keeping a record of the contained use and on an emergency plan ( 272/2006)Decree of the Ministry of Social Affairs and Health on Inspection Procedures under the Gene Technology Act ( 198/2007)Government Decree on Chargeable Performances under the Gene Technology Act ( 1158/2009)Decree of the Ministry of Social Affairs and Healthon principles of risk assessment of the contained use of genetically modified animals, on classification of the contained use, and on containment and other protective measures (771/2014)Finnish legislation includes also other statutes pertaining to GMOs. | Gene Technology Act | Y | 20-Jun-17 | Government Decree on Gene Technology | Y | 20-Jun-17 | -- | -- | 15-Sep-16 | Instruments missing (see free text)  Quite a few documents in the BCH are only available in Finnish. |
| Medicines Act (395/1987) | Y (NB link under "unofficial documents" does not work) | 20-Jun-17 | Decree of the Ministry of Social Affairs and Health on the deliberate release of genetically modified organisms ( 110/2005) | Y | 20-Jun-17 | -- | -- | -- |
| Seed Trade Act (728/2000) | Y | 20-Jun-17 | Decree of the Ministry of Social Affairs and Health on the differentiated procedure relating to the deliberate release of genetically modified organisms (90/2005) | Y | 20-Jun-17 | -- | -- | -- |
| Government Decree on Chargeable Performances under the Gene Technology Act (1539/2015) | Y | 20-Jun-17 | Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified micro-organisms, on classification of the contained use, and on containment and other protective measures (1053/2005) | Y | 20-Jun-17 | -- | -- | -- |
| Decree of the Ministry of Social Affairs and Health on principles of risk assessment of the contained use of genetically modified animals, on classification of the contained use, and on containment and other protective measures | Y | 20-Jun-17 | Decree of the Ministry of Social Affairs and Health on notifications and applications relating to the contained use of genetically modified organisms, on keeping a record of the contained use and on an emergency plan ( 272/2006) | Y | 20-Jun-17 | -- | -- | -- |
| -- | -- | -- | Decree of the Ministry of Social Affairs and Health on Inspection Procedures under the Gene Technology Act ( 198/2007) | Y | 20-Jun-17 | -- | -- | -- |
| -- | -- | -- | Tasavallan presidentin asetus biologista monimuotoisuutta koskevaan yleissopimukseen liittyvän Cartagenan bioturvallisuuspöytäkirjan voimaansaattamisesta ja pöytäkirjan lainsäädännön alaan kuuluvien määräysten voimaansaattamisesta annetun lain voimaantulosta (130/2004) (This Decree of the President of the Republic of Finland concerns accession and implementation of the provisions of the Cartagena Protocol) | Y | 20-Jun-17 | -- | -- | -- |
| -- | -- | -- | Valtioneuvoston asetus muuntogeenisistä elintarvikkeista ja rehuista annetun Euroopan parlamentin ja neuvoston asetuksen (EY) N:o 1829/2003 voimaantulon edellyttämistä kansallisista järjestelyistä (910/2004) (Decree laying out the national arrangements for implementing the EU Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed). | Y | 20-Jun-17 | -- | -- | -- |
| -- | -- | -- | Valtioneuvoston päätös työntekijöiden suojelemisesta työhön liittyvältä biologisten tekijöiden aiheuttamalta vaaralta ( 1155/1993) (Decision of the Council of State lays out the requirements for the protection of workers from risks related to exposure to biological agents at work, including GMOs.) | Y | 20-Jun-17 | -- | -- | -- |
| France | Partially | Comme il est indiqué en réponse à cette question dans le rapport de l'Union européenne (UE), cette dernière a mis en place depuis les début des années 90 un cadre réglementaire complet visant à assurer la sécurité liée à l'utilisation des organismes génétiquement modifiés. L'ensemble des textes cités dans le rapport de l'UE s'applique donc à la France qui en fait partie. Si les règlements européens sont d'application directe dans les États membres, les directives nécessitent une transposition dans le droit national.  La France a adopté de nombreuses dispositions législatives et réglementaires visant à encadrer l'utilisation des organismes génétiquement modifiés (OGM) sur son territoire. Ces dispositions se trouvent dans le Code de l'environnement et couvrent aussi bien l'utilisation confinée que la dissémination volontaire de ces organismes.  Les installations souhaitant utiliser des OGM à des fins de production industrielle sont soumises à la réglementation des installations classées pour la protection de l'environnement. A ce titre elles doivent répondre aux dispositions du Titre Ier du Livre V du code de l'environnement.  Les dispositions relatives à l'autorisation et aux obligations afférentes à l'utilisation d'OGM constituent le Titre III du livre V de ce même code.  Des dispositions relatives aux conditions de mise en place des cultures, à l'information du public, au contrôle et à la surveillance des OGM sont également prévues dans le Code rural et de la pêche maritime (Livres II et VI)  Les modifications les plus récentes réalisées sur ces parties du Code de l'environnement [et du Code rural et de la pêche maritime] ont été engendrées par l'adoption de la loi 2008-595 relative aux organismes génétiquement modifiés du 25 juin 2008. | Code de l'Environnement L511-1 à L517-2 | Y\* | 20-Jun-17 | Décret 77-1133 modifié par le décret 94-484 | Y\* | 4-Oct-16 | -- | -- | 04-Oct-16 | Some links are incorrect   Instruments missing  (see free text)  \*Most links provided are to Legifrance only, with instructions on how to search for the specific instrument in the "Additional Information" section. |
| Code de l'environnement art L531-1 à L537-1 | Y\* | 20-Jun-17 | Décret 93-773 | Y\* | 4-Oct-16 | -- | -- | -- |
| Arrêté du 19 mars 2007 relatif à la collecte d'informations sur la mise en culture de végétaux génétiquement modifiés | N | 20-Jun-17 | Décret 93-774 modifié par les décrets 94-527, 98-18 et 2007-357 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 93-1177 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 94-46 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 94-359 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 95-487 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 95-1172 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 95-1173 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 96-850 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 97-685 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 98-318 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 27 juillet 1994 portant autorisation et à des fins de mise sur le marché de semences de la variété de tabac ITB 1000 0X résistant aux herbicides | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 21 septembre 1994 relatif au dossier de demande de dissémination volontaire dans l'environnement à toute autre fin que la mise sur le marché et au dossier de mise sur le marché de plants, semences ou plantes génétiquement modifiés | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 27 décembre 1994 relatif au dossier de demande d'agrément prévu au titre Ier du décret no 93-773 du 27 mars 1993 | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 18 juillet 1995 fixant le contenu des dossiers de demande d'autorisation de dissémination volontaire, à des fins de mise sur le marché ou non, des organismes génétiquement modifiés destinés à l'alimentation humaine autres que les plantes, les semences, les plants et les animaux, ou entrant dans la composition des produits de nettoyage des matériaux et objets destinés à entrer en contact avec des denrées, produits ou boissons destinés à l'alimentation de l'homme ou des animaux | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 28 août 1996 relatif à la composition du dossier d'agrément prévu à l'article 43-1 du décret no 77-1133 du 21 septembre 1977 modifié | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 4 février 1997 portant autorisation de mise sur le marché de lignées de maïs (Zea mays L.) génétiquement modifiées protégées contre la pyrale et présentant une tolérance accrue aux herbicides de la famille du glufosinate-ammonium | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 5 février 1998 portant modification du Catalogue officiel des espèces et variétés de plantes cultivées en France (semences de maïs) | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 2 juin 1998 relatif aux prescriptions générales applicables aux installations classées pour la protection de l'environnement soumises à déclaration sous la rubrique no 2680-1 Organismes génétiquement modifiés (installations où sont mis en oeuvre dans un processus de production industrielle ou commerciale des) | Y\* | 4-Oct-16 | -- | -- | -- |
|  |  |  | Arrêté du 2 juin 1998 relatif aux règles techniques auxquelles doivent satisfaire les installations soumises à autorisation au titre de la rubrique 2680-2 de la Nomenclature des installations classées pour la protection de l'environnement | Y\* | 4-Oct-16 |  |  |  |
| -- | -- | -- | Arrêté du 3 juin 1998 portant habilitation des agents à rechercher et constater les infractions aux dispositions relatives à la dissémination volontaire dans l'environnement de produits phytopharmaceutiques, de plantes, semences et plants composés en tout ou partie d'organismes génétiquement modifiés | Y\* | 4-Oct-16 | -- | -- | -- |
|  |  |  | Arrêté du 3 août 1998 portant consentement écrit, au titre de l'article 13, paragraphe 4, de la directive 90/220/CEE du 23 avril 1990, des décisions 98/293/CE et 98/294/CE du 22 avril 1998 concernant la mise sur le marché de maïs génétiquement modifiés (Zea mays L. T 25 et MON 810) | Y\* | 4-Oct-16 |  |  |  |
| -- | -- | -- | Arrêté du 3 août 1998 portant modification du Catalogue officiel des espèces et variétés de plantes cultivées en France (semences de maïs) | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 23 décembre 1999 fixant le contenu du dossier technique accompagnant la demande d'autorisation de dissémination volontaire d'organismes génétiquement modifiés dans le cadre d'expérimentations portant sur des médicaments vétérinaires | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 18 octobre 2000 fixant le contenu du dossier technique accompagnant la demande d'autorisation de dissémination volontaire d'organismes génétiquement modifiés dans le cadre de recherches biomédicales portant sur des médicaments à usage humain ou des produits mentionnés aux 8o, 9o et 10o de l'article L. 5121-1 du code de la santé publique | Y\* | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret n°2007-358 du 19 mars 2007 relatif à la dissémination volontaire à toute autre fin que la mise sur le marché de produits composés en tout ou partie d'organismes génétiquement modifiés | N | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Décret 2007-359 du 19 mars 2007 relatif à la procédure d'autorisation de mise sur le marché de produits non destinés à l'alimentation composés en tout ou partie d'organismes génétiquement modifiés | N | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Arrêté du 19 mars 2007 relatif à la dissémination volontaire dans l'environnement et à la mise sur le marché de certains produits composés en tout ou partie d'organismes génétiquement modifiés | N | 4-Oct-16 | -- | -- | -- |
| Gabon | No | Texte de Loi qui s'applique indirectement sur la prévention des risques, la Loi n° 007/2014 du 1er Aout 2014 section 4. Toute fois le projet de Loi sur la biosécurité n'a pas abouti. | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Gambia (the) | Yes | Plant importation and regulation act, Volume 9, Cap. 58:01, 1963, Section 3 & 4: The establishment of The Board and functions National Agricultural Research Institute, Volume 9, Cap. 59:04, 1993, Section 3 & 4: The establishment of The Board and functions Hazardous Chemicals and Pesticides Control and Management Act, Volume 9, Cap. 60:01, 2004 in Section 3. Control & management mechanism (Board Biodiversity and Wildlife Act, Volume 9, Cap. 62:01, 2003. The act is main legal instruments which have a definitive impact on biological diversity. Both the act and policy and legislation provide for the protection, conservation and sustainable use of wildlife and encourage the maintenance of minimum stock of vulnerable species through protection. It further stipulates that optimum returns of ecological, cultural, aesthetic, scientific and economic gains are fundamental aspects to proper biodiversity management. Part XII, Section 89. (1)There is hereby established an inter-sectoral Committee on Biodiversity and Wildlife (in this part referred to as the Biodiversity and wildlife Committee) as an appendage of the Agriculture and Natural Resources Working Group, which shall consist of at least twelve members] Fisheries Act, and Subsidiary legislation., Volume 9, Cap. 63:01, 2008, Section 4 – 6: Establishment and functions of the committee National Environment Management Act, Volume 12 Cap. 72:01-02, 2008 in sections 6 through to section 19 establishing the Council, the Agency, the various committees and working groups. The Gambia Environmental Action Plan (GEAP) provide the government’s medium term operational guidelines for the protection, management, exploitation and utilization of environmental resources.  National Disaster Management Act, 2008, Chapter II deals with the establishment of the national coordination and Chapters III and IV regulates the decentralized coordination Food Safety Act, Cap. 40:07, 2005. | - | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Instruments missing  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Georgia | Partially | None | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Instruments missing   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Germany | Yes | As a member of the EU the European legislation on genetically modified organisms (GMOs), which has been in place since the early 1990s, is either directly applicable in Germany or has been implemented into German law. The EC has created a comprehensive legal framework and introduced specific legislation on GMOs. Therefore the comprehensive information given in the report of the EU also partly covers the situation in Germany.  Germany has fully implemented existing EC-legislation into national law through the German Gentechnikgesetz [Gene Technology Act] and the EG-Gentechnikdurchführungs-gesetz [German law regulating the implementation of the European provisions in the field of GMO]. These legal measures are publicly available on the homepage of the German CompetentNational Authority (BVL) which also hosts the German BCH-homepage (currently under development): http://www.bvl.bund.de/cln\_027/nn\_491818/DE/06\_Gentechnik/09\_BiosafetyClearingHouse/05\_\_RechtlicheGrundlagen/rechtGrundlagen\_\_node.html\_\_nnn=true and http://www.biosafety-bch.de/ In addition to European legislation German law foresees administrative fines and penalties to ensure compliance with relevant provisions.   The Articles 38 and 39 of the German Gentechnikgesetz [Gene Technology Act] as well as the §§ 6 and 7 of the German EG-Gentechnik-Durchführungsgesetz [German Law regulating the implementation of the European provisions in the field of GMOs] include penal provisions that serve to enforce the aims and provisions of the Cartagena Protocol. These provisions penalize behaviours that can contravene the goals of the Cartagena Protocol, for example the deliberate release of a GMO into the environment or the placing on the market of a GMO without the necessary authorization by the competent authority. Moreover, § 6, 2nd paragraph of the German EG-Gentechnik-Durchführungsgesetz [German Law regulating the implementation of the European provisions in the field of GMOs] penalizes the transboundary movement of living modified organisms carried out in contravention of the relevant German and European laws. Further details see report of the EC | German Gene Technology Act | Y | 20-Jun-17 | German Regulation on costs for notification procedures of GMO for deliberate releases and placing on the market | Y | 20-Jun-17 | Harmonized experimental monitoring of the GMO content in seeds | Y | 20-Jun-17 | Most documents are only available in German |
| German Act on the implementation of EU-Regulations regarding Gene Technology and on the labelling of food produced without the application of methods of genetic engineering | Y | 20-Jun-17 | German Regulation on safety classification and safety measurements regarding contained use of GMO | Y | 20-Jun-17 | Concept for seed analysis for genetically modified plant content | Y | 20-Jun-17 |
| -- | -- | -- | German Regulation on documents required for applications and notifications and on procedures of application and notification with respect of the German Gene Technology Act | Y | 20-Jun-17 | General Position statement of the ZKBS on frequently carried out genetic engineering operations based on the criteria of comparability: Gene transfer using Adenovirus type 5 | Y | 20-Jun-17 |
| -- | -- | -- | German Regulation on records regarding the contained use and the deliberate release of GMO | Y | 20-Jun-17 | Position statement of the ZKBS on criteria for assessing and categorizing plant viruses, phytopathogenic fungi and phytopathogenic bacteria as donor and recipient organisms in genetic engineering operations | Y | 20-Jun-17 |
| -- | -- | -- | German Regulation on public awareness and participation regarding decision making processes for contained use and for deliberate releases of GMO | Y | 20-Jun-17 | Position statement of the Central Biosafety Commission (ZKBS) on the risk assessment of laboratory strains of the lymphocytic choriomeningitis virus as donor or recipient organisms in genetic engineering operations according to § 5 paragraph 1 of the Genetic Engineering Safety Regulations | Y | 20-Jun-17 |
| -- | -- | -- | German Regulation on the involvement of EU Council, EU Commission and Competent Authorities of the EU Member States and of Countries of the European Economic Area regarding notification procedures of deliberate releases, placing on the market of GMO and in case of retroactive measures according to the German Gene Technology Act | Y | 20-Jun-17 | General position statement of the ZKBS on frequently carried out genetic engineering operations based on the criteria of com-parability: Gene transfer using retroviral vectors | Y | 20-Jun-17 |
| -- | -- | -- | German Regulation on external emergency plans and on the necessity of information | Y | 20-Jun-17 | Position statement of the Central Biosafety Commission on the risk assessment of influenza viruses | Y | 20-Jun-17 |
| -- | -- | -- | German Regulation on the Central Commission of Biological Safety | Y | 20-Jun-17 | Position statement of the Central Biosafety Commission (ZKBS) on the risk assessment of simian immunodeficiency viruses as donor or recipient organisms in genetic engineering operations according to § 5 paragraph 1 of the Genetic Engineering Safety Regulations | Y | 20-Jun-17 |
| -- | -- | -- | Regulation on good agricultural practice of the production of genetically modified plants | Y | 20-Jun-17 | Opinion of the Central Committee on Biosafety (ZKBS) on the safety assessment of antibiotic resistance genes in the genome of genetically modified plants | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | General position statement of the ZKBS on frequently carried out genetic engineering operations based on the criteria of comparability: Genetic engineering operations with Sindbis virus and Semliki Forest virus expression systems | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of the ZKBS on classifying genetic engineering operations with primary cells from vertebrates | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | General position statement of the ZKBS on the risk assessment of E. coli K12 containing the cDNA of a complete retrovirus genome | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of Central Biosafety Commission (ZKBS) on the risk assessment of human hepatitis D virus (HDV) as a donor or recipient organism in genetic engineering operations according to § 5 paragraph 1 of the Genetic Engineering Safety Regulations (GenTSV) | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of the Central Biosafety Commission (ZKBS) on the risk assessment of human hepatitis B virus (HBV) as a donor or recipient organism in genetic engineering operations according to § 5 paragraph 1 of the Genetic Engineering Safety Regulations | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of the Central Biosafety Commission (ZKBS) on the risk assessment of GB virus C / hepatitis G virus (GBV-C/HGV) as a donor or recipient organism in genetic engineering operations according to § 5 paragraph 1 of the Genetic Engineering Safety Regulations | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | General position statement of the ZKBS on the classification of genetic engineering operations with highly pathogenic avian influenza A viruses (HPAIV) which possess the potential for efficient airborne transmission between mammals | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of the ZKBS on new plant breeding techniques | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of the ZKBS on the present state of scientific knowledge concerning the effect of Bt toxins in mammals | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of the ZKBS on the classification of genetic engineering operations for the production and use of higher organisms using recombinant gene drive systems | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | General position statement of the ZKBS on the use of zinc finger nuclease-1 technique (ZFN-1) | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Monitoring of Synthetic Biology in Germany 1st Interim report of the Central Committee on Biological Safety | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Opinion on the legal classification of new plant breeding techniques, in particular ODM and CRISPR-Cas9 | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Position statement of the ZKBS on the risk assessment of Highly pathogenic avian Influenza virus A strains of the subtypes H5 and H7 and derived laboratory strains according to Sec. 5 (1) GenTSV | Y | 20-Jun-17 |
| Ghana | Yes | Recruitment of staff is on-going. Regulations for the full implementation of the Law are being prepared. | Biosafety Act , 2011- Act 831 | Y | 20-Jun-17 | BIOSAFETY (MANAGEMENT OF BIOTECHNOLOGY) REGULATIONS, 2007: LEGISLATIVE INSTRUMENT 1887 | Y | 20-Jun-17 | Guidelines for Risk Assessment of Genetically Modified Organisms in Ghana | Y | 20-Jun-17 |  |
| -- | -- | -- | -- | -- | -- | National Biosafety Framework for Ghana - Administrative Guidelines | Y | 20-Jun-17 |
| -- | -- | -- | -- | -- | -- | Public Participation Guidelines (with Respect to Genetically Modified Organisms) | Y | 20-Jun-17 |
| Grenada | Partially | A draft Biosafety bill has been prepared and is now at the Ministry of Legal Affairs awaiting submission to Cabinet for endorsement following which the bill would be passed into law in Parliament. The biosafety regulations are now being drafted. | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft bill on biosafety (NB title of entry is "Draft National Biosafety Framework | Y | 20-Jun-17 | Draft law awaiting approval  (see free text) |
| Guatemala | Yes | En Guatemala no se dispone aun de una ley específica sobre la aplicación del Protocolo de Cartagena. Dentro del marco jurídico del país figuran algunas leyes con las que se puede relacionar la aplicación del Protocolo de Cartagena; en primer lugar, la Ley del Organismo Ejecutivo (Decreto 114-97) delega las funciones y atribuciones de las entidades estatales, pudiéndose identificar aquellas que podrían tener relación con el tema de la bioseguridad de la biotecnología. En segundo lugar, la Política Nacional sobre Bioseguridad de los Organismos Vivos Modificados 2013-2023 (Acuerdo Gubernativo 207-2014) determina al Ministerio de Agricultura, Ganadería y Alimentación (MAGA); al Ministerio de Ambiente y Recursos Naturales (MARN); y al Ministerio de Salud Pública y Asistencia Social (MSPAS) como Autoridades Nacionales Competentes. Y, por aparte en dicha Política, se reconoce al Consejo Nacional de Áreas Protegidas (CONAP) como Centro Focal para Guatemala y la Secretaría del Protocolo de Cartagena sobre la Seguridad en el Uso de la Biotecnología del Convenio de la Diversidad Biológica. Dentro del marco normativo que refiere a los OVMs se han impulsado diferentes leyes y acuerdos: 1) Acuerdo Ministerial 386-2006; 2) la Ley de Protección y Mejoramiento del Medio Ambiente (D.L. 68-86) y el nuevo Listado Taxativo (A.G 61-2015); 3) Ley de Sanidad Vegetal y Animal (D.L. 36-98); 4) Política Nacional de Bioseguridad de los Organismos Vivos Modificados 2013-2023 (A.G. 207-2014); 5) Maíz Patrimonio Cultural e Intangible de la Nación (D.L. 13-2014); y, 6) propuesta de Reglamento de Bioseguridad de los Organismos Vivos Modificados. El Acuerdo Ministerial 386-2006 (del 16 de junio de 2006), es el instrumento legal del MAGA, vigente y aplicable para semillas, que establece los requisitos para importación, transporte y manejo dentro del país, establecimiento de experimentos de campo y producción de OVMs dentro del país con fines de exportación pero con prohibición para el consumo interno. Dicho Acuerdo no satisface en todo al Protocolo de Cartagena, y a falta de una Ley específica aplicada a la bioseguridad de los organismos vivos modificados, el Proyecto “Desarrollo de Mecanismos para la Implementación del Protocolo de Cartagena en Guatemala" ejecutado en CONAP, planteó una propuesta de Reglamento de Bioseguridad para OVM, aún pendiente de aprobación por las tres Autoridades Nacionales Competentes; dicho reglamento contiene la normativa fundamental de aplicación de los preceptos de Protocolo de Cartagena. En el marco de las leyes existentes, el MSPAS se rige en base al Código de Salud (D.L. 90-97); dicho código no refiere los OVMs, por lo que es necesario que emita disposiciones ministeriales en las que se incluya el aspecto de la bioseguridad, de conformidad con su competencia. Acerca del personal permanente asignado al marco nacional de trabajo de bioseguridad, se diría que éste es escaso en las tres Autoridades Nacionales Competentes. El MAGA, el MARN y el MSPAS cuentan, cada uno, con dos personas a cargo; y, luego, el CONAP como Centro Focal posee directamente asignadas 3 personas para atender los asuntos de bioseguridad, según su competencia. | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Instruments missing  (see free text) |
| -- | -- |  | -- | -- | -- | POLITICA NACIONAL DE BIOSEGURIDAD DE LOS ORGANISMOS VIVOS MODIFICADOS 2013-2023 | Y | 20-Jun-17 |
| Guinea | No | None | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Guinea-Bissau | Partially | Le cadre réglementaire national de Biosecurité a été élaboré et approuvé par le Gouvernement et adopté par le Parlement. | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Instruments missing  (see free text)   No instruments uploaded to the BCH |
| Guyana | Partially | Guyana has made efforts in relation to the implementation of Article 2 under the Protocol. The National Biosafety Framework (NBF) was prepared and approved in 2008 under the "Development of the National Biosafety Framework Project".  Other national legal instruments which directly relate to biosafety include: Environmental Protection Act Cap 20:05; Biosafety Bill [Drafted]; Biosafety (Placing on the Market) Regulations [Drafted]; The Use of GMOs or their derivatives as Food - Biosafety (Labelling) Regulations [Drafted]; Biosafety (Environmental Release) Regulations [Drafted]; Biosafety (Contained Use) Regulations [Drafted]; Food and Drugs Act Cap 34:01; Pesticides and Toxic Chemicals Control Cap 68:09; Customs Act Cap 82:01; Seeds Act No. 8 of 2011; Competition and Fair Trading Act Cap 90:07; Consumer Affairs Act No.13 of 2011; Crops and Livestock Registration Act Cap 68:04; Plant Protection Act Cap 68:03; Fisheries Act Cap 71:08; Guyana National Bureau of Standards Act Cap 90:16; Animal Health Act No. 7 of 2011; Animals (Control of Experiments) Act Cap 71:03; Occupational Health and Safety Act Cap 99:10; National Agricultural Research and Extension Institute Cap 68:02;  University of Guyana Act Cap 39:02 and Caribbean Agricultural Research and Development Institute Act Cap 18:04 | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Draft National Biosafety Framework | Y | 20-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Honduras | Yes | None | Ley Fito Zoosanitaria Decretos 157-94 y 344-2005 | Y | 20-Jun-17 | Reglamento de Bioseguridad con énfasis en plantas transgenicas | Y | 20-Jun-17 | -- | -- | 20-Jun-17 |  |
| Hungary | Partially | New legislations - related to Article C - entered into force since the 2nd National Report in Hungary: Act C of 2012 on the Criminal Code of the Republic of Hungary (Violation of Legal Liabilities Relating to Genetically Modified Plant Varieties 362. §) Act on the publication of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Act No. CLXXI of 2013) Decree 53/2013. (VI. 17.) of the Ministry of Rural Development on the safeguard clause on the seeds of stems and hybrids of maize MON810 | Act No. XXVII of 1998 on gene technology activities | Y | 20-Jun-17 | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | Instruments missing  (see free text) |
| India | Yes | The Government of India has created a comprehensive framework for ensuring safety while dealing with transboundary movements of GMOs/LMOs.  The Ministry of Environment, Forest and Climiate Change (MoEFCC) has notified the "Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells through Notification No. 621 in Official Gazette of Govt. of India on December 5, 1989 under the provisions of the Environment Protection Act,1986 (EPA) with a view to ensure sound application of biotechnology making it possible to accrue benefits arising from modern biotechnology while minimizing the risks to environment and human health. These rules and regulations commonly referred as 'Rules 1989' cover areas of research as well as production,manufacture, storage, export and import of genetically engineered cells or organisms and products thereof including drugs, pharmaceuticals and food stuffs. The other relevant regulations and guidelines involving the manufacture, use, export, import and storage of LMOs include the following: REGULATIONS: i. Protection of Plant Varieties and Farmers Rights Act,2001 ii. Biological Diversity Act, 2002  iii.Plant Quarantine (Regulation of Imports into India) - Order, 2003  iv.Food Safety & Standards Act, 2006  v.Notification relating to Inclusion of GM Policy in the Foreign Trade Policy (2006-09) by Directorate General of Foreign Trade vi.The Export (Quality Control & Inspection) Act 1963 and Scheme for Non GMO Certification (Doc No. EIC/NON GMO Cert Scheme/ Aug 2006/Issue II) & it related Amendment No. 1, Amendment No.2 GUIDELINES: viii. Recombinant DNA Safety Guidelines, 1990 ix. Revised guidelines for research in transgenic plants, 1998 x. Guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other biologicals, 1999  xi. Guidelines & SOPs for conduct of confined field trials of regulated, GE Plants, 2008 xii. Guidelines & Protocols for the safety assessment of foods derived from GE Plants, 2008  xiii. Guidelines for Institutional Biosafety Committees (IBSCs), 2011 xiv. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2012 | -- | -- | 20-Sep-16 | Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989. | N | 20-Sep-16 | Recombinant DNA safety guidelines, 1990 | Y | 20-Sep-16 | Some links missing / incorrect   Instruments missing  (see free text) |
| -- | -- | -- | -- | -- | -- | Protocols for food and feed safety assessment of GE crops, 2008 | Y | 20-Sep-16 |
| -- | -- | -- | -- | -- | -- | Revised Guidelines for Research in Transgenic Plants, 1998 | Y | 20-Sep-16 |
| -- | -- | -- | -- | -- | -- | Guidelines for generating preclinical and clinical data for rDNA Vaccines, Diagnostics and other Biologicals, 1999. | Y | 27-Oct-16 |
| -- | -- | -- | -- | -- | -- | Guidelines for the safety assessment of foods derived from genetically engineered plants, 2008 | Y | 20-Sep-16 |
| -- | -- | -- | -- | -- | -- | Director General of Foreign Trade (DGFT) notification No. 2(RE-2006) / 2004-2009, regarding import policy, 2006. | Y | 20-Sep-16 |
| -- | -- | -- | -- | -- | -- | Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008. | Y | 20-Sep-16 |
| Indonesia | Partially | None | Law Number 31 year 2004 concerning Fishery | N | 20-Jun-17 | Regulation of The Government of Republic Indonesia No 21 year 2005 on Biosafety of Genetically Engineered Product | Y (both versions) | 20-Jun-17 | -- | -- | 20-Sep-16 | Some inks missing / incorrect |
| -- | -- | -- | GOVERNMENT REGULATION OF THE REPUBLIC OF INDONESIA NUMBER 28/2004 CONCERNING SAFETY, QUALITY AND NUTRITION OF FOOD | N | 20-Jun-17 | -- | -- | -- |
| Iran (Islamic Republic of) | Yes | Iran Biosafety Law has been approved in July 2009. Executive regulations of required conditions for the packaging and labeling, transport and transboundary movement of LMOs has been prepared by National Biosafety Coordinating Committee and approved by National Biosafety Council in 19 April 2015. Moreover Ministry of Health and Ministry of Agriculture Jihad (Competent National Authorities) have provided executive ministerial guidelines to implement Iran Biosafety Law. | Islamic Republic of Iran Biosafety Act | Y | 20-Sep-16 | Executive regulation of Article 7-II of Islamic Republic of Iran Biosafety Law | N | 20-Sep-16 | Iran National Biosafety Framework | Y | 20-Sep-16 | Some links missing / incorrect |
| The act of accession of Islamic Republic of Iran to Cartagena protocol on Biosafety | N | 20-Sep-16 | -- | -- | -- | Guideline of the Ministry of Health, Treatment and Medical Education on living modified organism and food-related products | Y (in English only) | 20-Sep-16 |
| -- | -- | -- | -- | -- | -- | Guideline for Registration and import of Biological Products | N | 20-Sep-16 |
| Iraq | No | The Council of Ministers approved the issuance of biosafety legislation Authority System Resolution No.(2) for the year 2015 according to the report published by the Iraqi newspaper facts with number 4357 in 23/3/2015 | -- | - | 20-Jun-17 | -- | -- | 20-Jun-17 | -- | -- | 20-Jun-17 | No instruments uploaded to the BCH |
| Ireland | Yes | EU legislation on genetically modified organisms (GMOs) has been in place since the early 1990s. The EU introduced specific legislation on GMOs to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology products. The EU has created a comprehensive legal framework for ensuring safety in the development, use and transfer of GMOs.  - Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (transposed in Irish domestic law as the Genetically Modified Organisms (Deliberate Release) Regulations 2003).  More information on the content of these legislative acts is available at: http://ec.europa.eu/food/plant/gmo/new/legislation/index\_en.htm In the case of Directives 2001/18/EC and (EU) 2015/412, and of Regulations (EC) No 1829/2003, 1830/2003 and 1946/2003, domestic provisions to ensure enforcement and transposition of this legislation within Ireland is available here http://www.epa.ie/licensing/gmo/legislation/#.Vh5c8\_lVhBc and here http://www.irishstatutebook.ie/eli/home.html. | Section 111 of the Environmental Protection Agency Act 1992, as amended by section 17 of the Protection of the Environment Act 2003 | N | 20-Sep-16 | Genetically Modified Organisms (Contained Use) Regulations 2001 | N | 20-Sep-16 | -- | -- | -- | Some links missing / incorrect |
| -- | -- | -- | Genetically Modified Organisms (Deliberate Release) Regulations, 2003 | Y | 20-Sep-16 | -- | -- | -- |
| -- | -- | -- | Genetically Modified Organisms (Transboundary Movement) Regulations, 2004 | Y | 20-Sep-16 | -- | -- | -- |
| -- | -- | -- | European Communities (Feedingstuffs) (Genetically Modified Feed) Regulations 2004. S.I. No. 424 of 2004. | Y | 20-Sep-16 | -- | -- | -- |
| Italy | Yes | None | National Law No. 27 of January 15 2004 - Ratification and Implementation of the Cartagena Protocol on Biosafety | Y | 20-Sep-16 | -- | -- | 20-Sep-16 | -- | -- | 20-Sep-16 |  |
| Legislative Decree N. 224 of 8 July 2003: Implementation of Directive 2001/18/CE on the deliberate release into the environment of genetically modified organisms | Y | 20-Sep-16 | -- | -- | -- | -- | -- | -- |
| Legislative Decree No. 70 of 21 March 2005: Available sanctions for violations to EC Regulations No.1829/2003 and No. 1830/2003 | Y | 20-Sep-16 | -- | -- | -- | -- | -- | -- |
| Legislative Decree 12 April 2001 n. 206: implementation of Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms. | Y | 20-Sep-16 | -- | -- | -- | -- | -- | -- |
| Jamaica | No | None | -- | -- | 19-Jun-17 | The Plants (Importation) Control Regulations (1997) | N | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | Some links missing / incorrect |
| Japan | Yes | Japanese seven government ministries responsible for the implementation of the Cartagena Protocol on Biosafety are full-time staffed and secure a budget to operate the domestic law for the implementation of the Protocol. | Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003) | N | 20-Sep-16 | Regulations related to the Enforcement of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms | N | 20-Sep-16 | -- | -- | 20-Sep-16 | Links missing / incorrect |
| Kazakhstan | Partially | \*\* List of instruments provided (sometimes followed by short explanations). Most of these instruments have an entry in the BCH. | Закон Республики Казахстан от 21 июля 2007 года №301 " О безопасности пищевой продукции" (Law on food safety) | N | 20-Sep-16 | Technical regulation on the safety requirements for food products derived from genetically modified plants and animals) | N | 20-Sep-16 | Draft National Biosafety Framework | Y | 20-Sep-16 | Links missing / incorrect   Draft law awaiting approval (see free text)   Instruments missing  (see free text) |
| Закон РК «О ратификации Картахенского протокола по биобезопасности к Конвенции о биологическом разнообразии» (Law on the ratification of the Cartagena Protocol) | N | 20-Sep-16 | (Technical regulation on the safety requirements for food products destined for consumption by children and adolescents") | N | 20-Sep-16 | ТР ТС 015/2011 (Technical regulation of the Eurasion Customs Union on the safety of grains) | N | 20-Sep-16 |
| Закон Республики Казахстан «О семеноводстве» (Law on seed production) | Y | 20-Sep-16 | Method of identification of GMOs of plant origin using a biological microchip | N | 20-Sep-16 | ТР ТС 022/2011 (Technical regulation of the Eurasion Customs Union on the labelling of food products) | N | 20-Sep-16 |
| Закон РК "О защите прав потребителей" (Law on the protection of consumer rights) | Y | 04-Oct-16 | (Method of identification of GMOs of plant origin) | N | 4-Oct-16 | ТР ТС 021/2011 (Technical regulation of the Eurasion Customs Union on the safety of food products) | N | 20-Sep-16 |
| Экологический кодекс Республики Казахстан (Environmental code of the Republic of Kazakstan) | Y | 04-Oct-16 | -- | -- | -- | (Nomenclature (list of) products that are subject to border control in Kazahstan) | N | 20-Sep-16 |
| Кодекс Республики Казахстан "О здоровье народа и системе здравоохранения" (Code on people's health and the health care system) | -- | -- | -- | -- | -- | (Rules on the methods for scientifically-based confirmation of the safety of GMOs) | N | 04-Oct-16 |
| -- | -- | -- | -- | -- | -- | Правила оборота генетически модифицированных объектов (Rules on the circulation of GMOs) | N | 04-Oct-16 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Kenya | Yes | Kenya signed the Cartagena Protocol in 2000 and ratified in 2003. Kenya approved the National Biotechnology Policy in 2006, enacted the Biosafety Act in 2009, established the National Biosafety Authority in 2010. Regulations have been developed and published for contained use (2011), environmental release (2011), imports, exports and transit (2011) as well as labelling (2012). Regulations for handling, packaging, transporting and storage of GMOs are at an advanced stage of development. | The Biosafety Act No.2 of 2009 | Y | 20-Sep-16 | The Biosafety (Contained Use) Regulations, 2011 | Y | 20-Sep-16 | -- | -- | 20-Sep-16 | Instruments missing  (see free text) |
| -- | -- | -- | The Biosafety (Import, Export and Transit) Regulations, 2011 | Y | 20-Sep-16 | -- | -- | -- |
| -- | -- | -- | The Biosafety (Environmental Release) Regulations, 2011 | Y | 20-Sep-16 | -- | -- | -- |
| -- | -- | -- | The Biosafety (Labelling) Regulations, 2012 | Y | 20-Sep-16 | -- | -- | -- |
| Kiribati | Yes | Kiribati's National Biosafety Framework has been endorsed by Cabinet years back. However to fully implement this framework, the national biosafety regulation is needed but it is yet to be endorsed. | Environment Act 1999 - as ammended | Y | 20-Sep-16 | DRAFT BIOSAFETY (LIVING MODIFIED ORGANISMS) REGULATIONS 2005 | Y | 20-Sep-16 | National Biosafety Framework | Y | 20-Sep-16 |  |
| Kyrgyzstan | Partially | В целях осуществления положений Картахенского протокола проделана определенная работа, в частности приняты ряд постановлений, национальных программ и стратегий приведенные ниже: постановление Правительства Кыргызской Республики от 2 апреля 2014 года № 197 «Об утверждении Национального контрольного списка Кыргызской Республики контролируемой продукции», в которой утверждается Список подлежащих экспортному контролю возбудителей заболеваний (патогенов) человека, животных и растений, генетически измененных микроорганизмов, токсинов, оборудования и технологий; Технический Регламент «О безопасности кормов и кормовых добавок», утвержденный постановлением Правительства Кыргызской Республики от 22 мая 2014 года N 268, разработанный в соответствии с Законом Кыргызской Республики "Об основах технического регулирования в Кыргызской Республике"; постановление Правительства Кыргызской Республики от 5 марта 2013 года № 113 “Об утверждении Технического регламента "О безопасности медицинских имплантатов"; постановление Правительства Кыргызской Республики от 5 августа 2013 года №444 «Об утверждении Технического регламента "О безопасности ветеринарных лекарственных средств», которое определяет обязательные требования ко всем производимым (изготавливаемым) и ввозимым (импортируемым) на территорию Кыргызской Республики ветеринарным лекарственным средствам, процессам их производства, хранения, транспортировки, реализации, применения и утилизации (уничтожения); национальная Стратегия развития племенного животноводства в Кыргызской Республике на 2011-2015 годы, утвержденная постановлением Правительства КР от 5 июля 2011 года № 367, целями которой являются развитие и сохранение генетического потенциала племенного животноводства в республике для обеспечения продовольственной безопасности страны; технический Регламент «О безопасности продуктов детского питания», утвержденный постановлением Правительства Кыргызской Республики от 23 ноября 2012 года N 792, целью которого является обеспечение защиты жизни и здоровья детей от воздействия опасных и вредных факторов в пищевых продуктах; Технический Регламент «О безопасности хлеба, хлебобулочных и макаронных изделий»,утвержденный постановлением Правительства Кыргызской Республики от 17 июля 2012 года N 502; Технический Регламент «О безопасности лекарственных средств для медицинского применения», утвержденный постановлением Правительства Кыргызской Республики от 6 апреля 2011 года N 137. Кроме этого разработан проект Закона Кыргызской Республики «О биологической безопасности». | -- | -- | 20-Sep-16 | -- | -- | 20-Sep-16 | Draft National Biosafety Framework | Y | 20-Sep-16 | Instruments missing  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Lao People's Democratic Republic | Partially | Since Lao PDR has become a party of the Convention on Biological Diversity on September 20, 1996 and the Cartagena Protocol on Biosafety on November 1, 2004. The Lao government is obliged to develop its national regulatory framework in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology for reducing potential consequences that may have an adverse effect biological diversity and human health. Laos has participated in a UNEF/GEF funded project to develop National Biosafety Framework (NBF). The NBF has been developed since 2002 and was adopted by the government on December 25, 2004. It consists of a combination of policy, legal, administrative and technical instruments that are set in place to address safety contains of six components including the government policy on Biosafety, the regulatory regime for Biosafety, administrative systems for Biosafety, mechanism for public education awareness and participation, capacity building programs to implement CPB and project priorities to implement the NBF. This NBF was also used to prepare a Biosafety Law Draft which was introduced initially at the Lao Government Meeting on August 30, 2005 based on the comments from Ministry of Justice on 18 July 2005. The Law then adopted by the National Assembly on 18 December 2013, ref No. 017/NA and promulgated by the president of Lao PDR, Ref No. 058/PO, dated 28 January 2014. The law defines the principles, regulations and measures on management and monitoring of biotechnology safety to ensure safety in research, development, handling, movement, and the use of Genetic Modified Organisms (GMOs) resulting from the use of biotechnology, which may result in having negative impacts on conservation and sustainable use of biodiversity, with a focus on the limitation and reduction of risks to the life and health of human beings, animals, plants and the environment that can be linked at the regional and international levels, and which contribute to national socio-economic development. The law is a significant indication which illustrates the country efforts on its commitment on the Cartagena Protocol. Since new decisions have been agreed by the Parties at the COP/MOP meetings of 2006 and 2008, the Biosafety regulations need to revise to be in-line with these COP/MOP decisions and also to be supported by drafting appropriate secondary and tertiary instruments. During this reporting period, contained use, food and feed and environmental release regulations are in the process of reviewing from the Ministry of Justice before sending the draft regulations to the National Biosafety Committee for adoption based on the Biosafety Law (2014). In addition, Biosafety Guideline, Administrative Task and Handling Application are drafted in order to support the law implementation and Biosafety in the nation. | Biotechnology Safety Law | Y | 20-Sep-16 | -- | -- | 20-Sep-16 | Lao National Biosafety Framework | Y | 20-Sep-16 |  |
| Latvia | Yes | For details please refer to the EU report. | Law on Circulation of Genetically Modified Organisms | Y | 20-Sep-16 | Procedures for the contained use of genetically modified micoorganisms and issuance of a permit | Y | 20-Sep-16 | Draft National Biosafety Framework | Y | 20-Sep-16 |  |
| -- | -- | -- | By-law of the Monitoring Council of Genetically Modified Organisms | Y | 20-Sep-16 | The composition of the Supervisiory Council's personnel for Genetically Modified Organisms (Order of the Ministry of Agriculture) | Y | 20-Sep-16 |
| -- | -- | -- | Amount of the State fee to be paid for preparation of the risk assessment's opinion of genetically modified organisms | Y | 20-Sep-16 | -- | -- | -- |
| -- | -- | -- | Regulations on deliberate release of Genetically Modified Organisms | Y | 20-Sep-16 | -- | -- | -- |
| -- | -- | -- | Methodology for the Risk Assessment of Genetically Modified Organisms | Y | 20-Sep-16 | -- | -- | -- |
| Lebanon | No | Under UNEP-GEF Project Number GF/2716-01-4319 that was executed by the Lebanese Ministry of Environment in 2004 and 2005, the National Biosafety Framework of Lebanon was developed in 2005 in collaboration with a wide range of stakeholders. The “Plant Quarantine and Phytosanitary Measures” Law # 778 dated 28/11/2006 states in its Article 14 that the plants or its derivatives are forbidden from entering the country "if it was genetically modified and if the aforementioned modification would create a risk or damage to humans or animals", while in its Article 16, the Law states that "Subject to the provisions of Articles 6, 8 and 9 of this Law, the Ministry of Agriculture shall issue instructions regulating plant quarantine procedures, including…prohibiting the import of Living Modified Organisms".  This Law should be amended and updated, especially that the Government of Lebanon has ratified the Cartagena Protocol on Biosafety (CPB) through law # 31 dated 16/10/2008, and accessed the Protocol in 2013, and the provisions of the CPB are predominant and shall apply at national level. On the other hand, and while awaiting the issuance of a specific national legislation on Biosafety, the Minister of Agriculture has established a “National Committee on Biotechnology and Biosafety” through the Decision # 612/1 dated 11/10/2010, which includes 13 members representing concerned ministries, research and academic institutions and independent experts. The Committee’s mandate is to follow up and discuss all matters of relevance to the use of biotechnology in agricultural production and their potential impact on the environment and human health, in order to submit scientific suggestion and appropriate recommendations needed for the issuance of suitable decisions in this field, and to suggest national policies related to the use of biotechnology in the programmes of improvement of agricultural production. Once the National Decree on Biosafety which was approved recently (mentioned in the last paragraph below in this box), will be issued and become operational, this committee will be replaced with that one proposed by the recently approved National Decree.  The Food Safety Law # 35 dated 26/11/2015 established a "Food Safety Lebanese Commission" (FSLC) to be the designated body responsible for the enforcement of this law, and states in its Article (19) that the Ministry of Agriculture in coordination with the "Food Safety Lebanese Commission” sets the criteria and standards that should be met by the genetically modified food. In order to put national legal measures for the implementation of the Cartagena Protocol on Biosafety at national level, the Ministry of Environment (MoE) has developed and submitted to the Cabinet of Ministers (CoM) a draft decree on national measures regarding Biosafety which was approved by the CoM through its decision No. 53 dated 27/11/2014, the decree is currently in process of issuance. This approved Decree establishes a National Council on Biosafety of 18 members (including representatives from: MoE; MoA; MoE&T; MoPH; MoF/Customs; NCSR; LARI; IRI; Academic Institutions; Union of the Chambers of Commerce, Trade and Agriculture; Syndicate of Lebanese Agro-food Industries; Consumers Lebanon Association; Non-Governmental Organization (dealing with Biosafety issues) to manage the issue of LMOs in the country. | -- | -- | 20-Sep-16 | -- | -- | 20-Sep-16 | Draft National Biosafety Framework | Y | 20-Sep-16 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Lesotho | Yes | Lesotho is implementing the provisions of the protocol through biosafety Policy | -- | -- | 20-Sep-16 | -- | -- | 20-Sep-16 | National Biosafety Policy | Y | 20-Sep-16 |  |
| -- | -- | -- | -- | -- | -- | Draft National Biosafety Framework | Y | 20-Sep-16 |
| Liberia | Yes | Liberia's Plant and Animal Quarantine Law has provisions that can be applied in implementation of Article 2. This law was adopted in 1973. Basically, it regulates the importation of exotic living plants and animals or parts thereof. The main thrust of the law is prevention and control of harmful plants and animals or harmful substances from such organisms, into Liberia.  Additionally with support from GEF for implementation of its NBF, Liberia revised its draft Biosafety Act in 2012. It has been reviewed by the Law Reform Commission and will now be sent to the Legislature for enactment. The draft Biosafety Policy has been revised and five implementing regulations have been prepared. These instruments are awaiting endorsement by the Policy Council, the highest decision-making body of the Environmental Protection Agency of Liberia to come into effect. | -- | -- | -- | -- | -- | -- | General Guidelines on Biosafety | Y | 20-Sep-16 | Draft law awaiting approval  (see free text)    Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Lithuania | Yes | A Framework Law on Genetically Modified Organisms has been adopted on 12 June 2001 and has entered into force on 31 December 2002 (amendments in 2003, 2006). The Law on Genetically Modified Organisms regulates the state management of GMOs in a broad sense while other domestic orders fully implement the EU-Directives. The EU-Regulations are directly applicable in Lithuanian legislation. The list of legal measures pertaining to GMOs has been submitted to the Biosafety Clearing-House. An overview on the Lithuanian legal framework is provided at http://gmo.am.lt Further information is provided in the EU 3rd National Report. | Law on Genetically Modified Organisms | Y | 21-Sep-16 | Order on Genetically Modified Organisms Deliberate Release into Environment and Placing on the Market | N | 21-Sep-16 | -- | -- | 21-Sep-16 | Some links missing / incorrect |
| Code on Administrative Right's Violation | N | 21-Sep-16 | Order on Contained Use of Genetically Modified Micro-organisms | Y | 21-Sep-16 | -- | -- | -- |
| Civil Code of the Republic of Lithuania | Y | 21-Sep-16 | Establishment of Genetically Modified Organisms Experts Committee | N | 21-Sep-16 | -- | -- | -- |
| Law on Environmental Protection | Y | 21-Sep-16 | Establishment of Genetically Modified Organisms Steering Committee | Y | 21-Sep-16 | -- | -- | -- |
| Ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity | Y | 21-Sep-16 | Order on Regulation of Genetically Modified Microorganisms Classification | Y | 21-Sep-16 | -- | -- | -- |
| Ratification of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety | N | 21-Sep-16 | Regulation on Arrangement of Monitoring Plan of Genetically Modified Organisms or their Products after the Placing on the Market | Y | 21-Sep-16 | -- | -- | -- |
| -- | -- | -- | Order on Genetically Modified Organisms Information System | Y | 21-Sep-16 | -- | -- | -- |
| -- | -- | -- | Order on Risk Assessment on Genetically Modified Organisms to Human Health and Environment | Y | 21-Sep-16 | -- | -- | -- |
| -- | -- | -- | Order on Regulation on Public Information and Participation in Issuing of Permits for the Use of GMOs | Y | 21-Sep-16 | -- | -- | -- |
| -- | -- | -- | Order on Coexistence of Genetically Modified Crops with Conventional and Organic Farming | Y | 21-Sep-16 | -- | -- | -- |
| -- | -- | -- | Order on Approval of the Regulations for Inspection of Genetically Modified Plants and Plant Products not Intended for Human Consumption and Animal Feed and their Propagating Material Imported to Lithuania and European Community and Carried as Transit | Y | 21-Sep-16 | -- | -- | -- |
| Luxembourg | No | La mise en œuvre du Protcole de Cartagena au Grand-Duché du Luxembourg est assurée par un cadre règlementaire, dont la loi modifiée du 13 janvier 1997 et des règlements d'application, notamment le Règlement grand-ducal du 17 février 1997. La plupart des dispositions proviennent du droit communutaire, donc de l'application directe ou de la transpoisition en droit luxembourgeois des dispositions juridiques de l'Union Européenne.  Plus particulièrement, ces instruments couvrent l'utilisation en milieux confinés des OGM, tout comme leur dissémination dans l'environnement, leur utilisation comme alimentation humaine et animale et leurs mouvements (intentionnels et non intentionnels) transfrontières.  Le ministère de la Santé a été désigné comme compétent en ce qui concerne le contrôle de l'utilisation et de la dissémination des OGM, tandis que le ministère de l'agriculture est compétent en matière de commercialisation et de coexistence des cultures génétiquement modifiées.  Un comité interministériel fût mis en place et est responsable du contrôle de l'utilisation et de la dissémination des organismes génétiquement modifiés, et conseille les ministères pour les prises de décision en la matière.  Finalement il est renvoyé au rapport de la Commission européenne [ci-apèrs "le Rapport de l'UE") quant aux différentes directives et règlement européens, ainsi que pour les décisions prises au niveau de la Commission européenne. | -- | -- | 21-Sep-16 | -- | -- | 21-Sep-16 | -- | -- | 21-Sep-16 | No instruments uploaded to the BCH |
| Madagascar | Yes | -Notre pays a élaboré un Guide pour la participation du public - Coordonnateur National du Projet et Assistant technique | Projet de loi relative au régime de la biosécurité | N | 21-Sep-16 | DECRET N° 99-954 DU 15 DECEMBRE 1999 modifié par le décret n° 2004-167 du 03 février 2004 relatif à la mise en compatibilité des investissements avec l'environnement (MECIE) | Y | 21-Sep-16 | Draft National Biosafety Framework | Y | 21-Sep-16 | Links missing / incorrect   Draft law awaiting approval   Instruments missing  (see free text) |
| Décret n°2012- 833 portant attributions des organes de la biosécurité à Madagascar | Y | 21-Sep-16 | LOI n°2011-002 portant Code de la Santé | Y | 21-Sep-16 | PROJET DE LOI N°028/2008 du 29 Octobre 2008 portant refonte du Code de Gestion des Aires protégées. | Y | 21-Sep-16 |
| -- | -- | -- | -- | -- | -- | Politique nationale de biosécurité à Madagascar | Y | 21-Sep-16 |
| Malawi | Partially | The National Biotechnology and Biosafety Policy of 2008, Science and Technology Act, 2003 and Consumer Protection Act, 2003 and Pharmacy, Medicines and Poisons Act of 1988 all have provisions of biosafety in some form. | Biosafety Act | Y | 21-Sep-16 | -- | -- | -- | -- | -- | -- | Instruments missing  (see free text) |
| Malaysia | Yes | Malaysian Biosafety Act entered into force on 1 December 2009. The Biosafety (Approval and Notification) Regulations 2010 was enforced on 1 November 2010. This Act complements the National Policy on Biological Diversity (1998) and the National Biotechnology Policy (2005) and covers only modern biotechnology activities. The objective of the Act is to protect the health and safety of people, animals, plants, the environment and biological diversity by regulating the release, importation and contained use of Living Modified Organisms (LMOs) and/or the release of products of such organisms. The Ministry of Natural Resources and Environment is the National Focal Point for the Cartagena Protocol on Biosafety. The National Biosafety Board (NBB) makes decisions on LMOs activities in Malaysia. A committee called the Genetic Modification Advisory Committee (GMAC) was established in May 2010 to provide scientific, technical and other relevant advice to the NBB. The Department of Biosafety which was set up to be the focal point of all biosafety related activities in Malaysia carries out such duties as envisaged by the NBB. | Biosafety Act 2007 (Act 678) | Y | 21-Sep-16 | Biosafety (Approval and Notification) Regulations 2010 | Y | 21-Sep-16 | Institutional Biosafety Committee (IBC) Guidelines | Y | 21-Sep-16 | Instruments missing  (see free text) |
| Animals Act 1953 | Y | 21-Sep-16 | Exemption under S68 of Biosafety Act | Y | 21-Sep-16 | Guidelines for Contained Use Activity of Living Modified Organism | Y | 21-Sep-16 |
| -- | -- | -- | Control of Drugs and Cosmetics Regulations 1984 (Amendment 2009) | Y | 21-Sep-16 | User's Guide to the Malaysian Biosafety Act and Regulations | Y | 21-Sep-16 |
| -- | -- | -- | Regulations for food safety and food labelling including genetically modified food (GMF) | Y | 21-Sep-16 | Biosafety Guidelines: Confined Field Trial of Living Modified Plants in Malaysia | Y | 21-Sep-16 |
| -- | -- | -- | -- | -- | -- | Biosafety Guidelines: Environmental Risk Assessment of Genetically Modified Plants in Malaysia | Y | 21-Sep-16 |
| -- | -- | -- | -- | -- | -- | Biosafety Guidelines: Risk Assessment of Genetically Modified Microorganisms | Y | 21-Sep-16 |
| Maldives | Partially | In 2006 the National Biosafety Framework of Maldives was formulated. At that time a draft regulation on National Biosafety was prepared. This regulation has not come to force due to the technological constraints regarding the implementation of the Cartagena Protocol on Biosafety in Maldives. However, there are legal instruments in place that indirectly apply to biosafety. These include the Environmental Protection and Preservation Act, Fisheries Law, Maldives Customs Law, Regulations for Import and Sale of Drugs in Maldives, Consumer Protection Act, Law on Protection of Plants, Import and Export Law. In addition to this a draft food act, draft food import regulation, and a draft food safety policy has been formulated which will address LMOs to some extent. Maldives is developing a Good Agricultural Practices Certification Scheme expected to start certification next year. Also, a National Standard for Labelling Packaged Foods exists in Maldives which currently does not include labelling for GM foods. Maldives has plans to change the draft biosafety regulation to a biosafety law, to pave way for effective implementation of Cartagena Protocol on Biosafety. The implementation of the biosafety framework and the enforcement of the biosafety regulation would require certain scientific and technical capacity which is not present. Therefore, strong technological foundation with supporting institutional capacity, along with the required procedures in place are needed for the effective implementation of the protocol. | -- | -- | -- | -- | -- | -- | Draft  National Biosafety Framework | Y | 21-Sep-16 | Instruments missing  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Mali | Yes | Le Chapitre I: Des Dispositions Générales de la loi n°08-042/AN-RM du 1er Décembre 2008, relative à la sécurité en Biotechnologie en République du Mali dans sa Section I: Du Champ d'Application dans son Article 1 cite:  Article 1 : La présente loi s’applique à l’importation, l'exportation, le transit, l’utilisation confinée, la libération ou la mise sur le marché de tout Organisme Génétiquement Modifié (OGM) qu'il soit destiné à être libéré dans l'environnement ou utilisé comme denrée alimentaire, aliment pour bétail ou produit de transformation, ou d'un produit dérivé d'organisme génétiquement modifié. Elle s’applique également aux OGM à double fonction pharmaceutique et alimentaire d’intérêt agricole. | La Loi Relative à la sécurité en Biotechnologie en République du Mali | Y | 21-Sep-16 | -- | -- | 21-Sep-16 | Draft National Biosafety Framework | Y | 21-Sep-16 |  |
| -- | -- | -- | -- | -- | -- | Cadre National de Biosecurite du Mali- Rapport Final | Y | 21-Sep-16 |
| -- | -- | -- | -- | -- | -- | Le décret portant sur la composition, les attributions et les modalités de fonctionnement du Comité National de Biosécurité | Y | 21-Sep-16 |
| -- | -- | -- | -- | -- | -- | Le décret fixant les modalités d'expérimentation des OGM par le recherche au Mali | Y | 21-Sep-16 |
| Malta | Yes | Reference is made to the third national report on the implementation of the Cartagena Protocol on Biosafety as submitted by the European Union | Maltese Environment and Development Planning Act, 2010 | Y | 19-Jun-17 | Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2010 (L.N. 485 of 2010 repealing L.N. 170 of 2002) | Y | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | EU laws and regulations also available |
| The Contained Use of Genetically Modified Micro-organisms Regulations, 2010, (L.N. 265 of 2010) amending L.N. 127 of 2008 | Y | 19-Jun-17 | Contained Use of Genetically Modified Micro-Organisms Regulations, 2008 (L.N. 127 of 2008 as amended by L.N. 265 of 2010 and repealing L.N. 169 of 2002)) | Y | 19-Jun-17 | EC accession treaty | Y | 19-Jun-17 |
| -- | -- | -- | Biosafety Co-ordinating Committee Regulations, 2002 (L.N. 290 of 2002 ) | Y | 19-Jun-17 | Guidance Document - Contained Use Genetically Modified Organisms | Y | 19-Jun-17 |
| -- | -- | -- | -- | -- | -- | Guidance Document - Release in the Environment Genetically Modified Organisms | Y | 19-Jun-17 |
| Mauritania | Partially | La Mauritanie ne dispose pas de cadre réglementaire spécifique à la biosécurité, cependant des lois existent sur l'environnement, sur les semences, la protection du matériel végétal et les pesticides, sur la protection des végétaux et s'appliquent indirectement à la prévention des risques.  Un projet de cadre juridique de Biosécurité proposé par la coordination nationale a été élaboré mais pas encore entré en vigueur | Loi N°2000-042 relative à la protection des végétaux | Y | 22-Sep-16 | -- | -- | 22-Sep-16 | Document-Cadre du Sous-Programme Biosécurité de la Mauritanie | Y | 22-Sep-16 | Instruments missing  (see free text)   Draft law awaiting approval  (see free text) |
| Mauritius | No | Draft regulations and guidelines are available and will be finalised | The Genetically Modified Organisms Act 2004 - Mauritius | Y | 22-Sep-16 | -- | -- | 22-Sep-16 | -- | -- | 22-Sep-16 | Instruments missing  (see free text) |
| The Plant Protection Bill 2006 | Y | 22-Sep-16 | -- | -- | -- | -- | -- | -- |
| Mexico | Yes | En la pregunta 15 se marca como año de inicio del marco nacional de seguridad de la biotecnología el año 2005, año en el que se publica la Ley de Bioseguridad de Organismos Genéticamente Modificados (LBOGM). Previo a la publicación de la Ley de Bioseguridad se contaba con una Norma Oficial Mexicana para la regulación de las pruebas de campo de organismos vivos modificados (NOM 056-FITO-1995), así como con provisiones que contribuían a su regulación en diversos ordenamientos normativos. Se han publicado en el Diario Oficial de la Federación a partir de la entrada en vigor de la Ley de Bioseguridad de Organismos Genéticamente Modificados, los siguientes instrumentos normativos: en 2006, el Reglamento de la Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM); en 2007, las Reglas de Operación de la CIBIOGEM; en 2008, el Reglamento de la LBOGM; en 2009, el Decreto por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la LBOGM, para instrumentar el Régimen de Protección Especial del Maíz; en 2011, se publicó el Acuerdo por el que se determina la información y documentación que debe presentarse en el caso de realizar actividades de utilización confinada y se da a conocer el formato único de avisos de utilización confinada de organismos genéticamente modificados (OGMs); en 2012, el Acuerdo por el que se determinan Centros de Origen y Centros de Diversidad Genética del Maíz; en 2014, la Norma Oficial Mexicana NOM-164-SEMARNAT/SAGARPA-2013, que establece las características y contenido del reporte de resultados de la o las liberaciones realizadas de organismos genéticamente modificados, en relación con los posibles riesgos para el medio ambiente y la diversidad biológica, adicionalmente, a la sanidad animal, vegetal y acuícola, y finalmente la Norma Oficial Mexicana NOM-001-SAG/BIO-2014, que dispone las especificaciones generales de etiquetado de OGMs que sean semillas o material vegetativo destinados a siembra, cultivo y producción agrícola. También se han hecho públicos en la página del Sistema Nacional de Información sobre Bioseguridad los siguientes instrumentos: las Reglas de Operación del Fondo para el Fomento y Apoyo a la Investigación Ciencia y Tecnología en Bioseguridad y Biotecnología, y las Reglas de Operación y Funcionamiento de la Red Mexicana de Monitoreo de OGMs. Adicionalmente las autoridades competentes han desarrollado guías, procedimientos y lineamientos internos para atender diferentes procesos relativos al uso seguro de la biotecnología, que se encuentran disponibles en sus respectivas páginas electrónicas.  Con fundamento en el artículo 31 de la Ley de Bioseguridad de Organismos Genéticamente Modificados se constituyó el Fondo para el Fomento y Apoyo a la Investigación Científica y Tecnológica en Bioseguridad y Biotecnología (FONDO CIBIOGEM). Las Secretarías que conforman la CIBIOGEM deben considerar en su presupuesto los recursos necesarios para hacer la aportación anual el fideicomiso. | Ley General de Salud | Y | 22-Sep-16 | Reglamento de la Ley General de Salud en materia de Publicidad | Y | 22-Sep-16 | Document of Understanding Regarding Documentation Requirements for Living Modified Organisms for Food or Feed, or for Processing (LMO/FFPs) (Multilateral Agreement or Arrangement) | Y | 22-Sep-16 | Some links missing / incorrect   Instruments missing  (see free text) |
| Ley Federal de Producción, Certificación y Comercio de Semillas | Y | 22-Sep-16 | Reglamento de la Ley General del Equilibrio Ecológico y la Protección al Ambiente en Materia de Evaluación del Impacto Ambiental | Y | 22-Sep-16 | Acuerdo por el que se determinan Centros de Origen y Centros de Diversidad Genética del Maíz (Acuerdo Nacional) | Y | 22-Sep-16 |
| Código Penal Federal | Y | 22-Sep-16 | Reglamento de Control Sanitario de Productos y Servicios | Y | 22-Sep-16 | Norma Oficial Mexicana NOM-001-SAG/BIO-2014, Especificaciones generales de etiquetado de organismos genéticamente modificados que sean semillas o material vegetativo destinados a siembra, cultivo y producción agrícola | Y | 04-Oct-16 |
| Ley General de Desarrollo Forestal Sustentable | Y | 22-Sep-16 | Official Mexican Standard 002-SCT2/1994, list of the hazardous substances and materials frequently transported | N | 22-Sep-16 | NORMA Oficial Mexicana NOM-164-SEMARNAT/SAGARPA-2013, Que establece las características y contenido del reporte de resultados de la o las liberaciones realizadas de organismos genéticamente modificados, en relación con los posibles riesgos para el medio ambiente y la diversidad biológica, y adicionalmente, a la sanidad animal, vegetal y acuícola. | Y | 04-Oct-16 |
| Ley de Desarrollo Rural Sustentable | Y | 22-Sep-16 | Reglamento de Insumos para la Salud | Y | 22-Sep-16 | Reglas de Operación de la Comisión Intersecretarial de Bioseguridad de Organismos Genéticamente Modificados | Y | 04-Oct-16 |
| Ley Federal de Sanidad Vegetal | Y | 22-Sep-16 | Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados | Y | 22-Sep-16 | -- | -- | -- |
| Ley General del Equilibrio Ecológico y la Protección al Ambiente | Y | 22-Sep-16 | Acuerdo por el que se determina la información y documentación que debe presentarse en caso de realizar actividades de utilización confinada y se da a conocer el formato único de avisos de utilización confinada de organismos genéticamente modificados | Y | 22-Sep-16 | -- | -- | -- |
| Ley Federal de Sanidad Animal | Y | 22-Sep-16 | -- | -- | -- | -- | -- | -- |
| Utilización Confinada y Avisos | Y | 22-Sep-16 | -- | -- | -- | -- | -- | -- |
| Ley de Bioseguridad de Organismos Genéticamente Modificados | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Comunicaciones relacionadas a las decisiones sobre tránsito y uso confinado de OVM (artículo 6) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Mongolia | Partially | Some PAEP activities will be implemented by relevant NGOs such as Biosafety Research Institute and Biotechnology Association on the basis of Cooperation Agreement. | Law on LMOs | N | 22-Sep-16 | Registering, monitoring and evaluation of the LMOs | N | 22-Sep-16 | Draft National Biosafety Framework | Y | 22-Sep-16 | Links missing / incorrect |
| Morocco | No | En ce qui concerne le cadre réglementaire de biosécurité, il n’existe pas encore de texte législatif relatif aux OVM au Maroc. Seule une circulaire du Département de l'Agriculture émise le 11 août 1999 interdisant l'introduction des produits issus d’OVM est en vigueur. Dans ce cadre, l’importation de semences d’OVM est interdite, à l’exception de celles destinées pour l’alimentation du bétail avec certaines restrictions. Les cultures expérimentales au champ et les cultures dont les produits sont destinés à la commercialisation ainsi que la recherche scientifique en matière d’OVM et les essais en milieu confiné ne sont pas encore autorisés.  En revanche, il existe de nombreux textes législatifs et réglementaires touchant indirectement aux biotechnologies modernes, notamment ceux qui réglementent le contrôle sanitaire et phytosanitaire, la protection et la mise en valeur de l'environnement, ceux relatifs aux études d’impact sur l’environnement, etc. Par ailleurs, le Département de l'Agriculture a déjà préparé un projet de loi relative aux OVM et qui a été soumis pour avis aux différents départements ministériels (Santé, Environnement, Enseignement supérieur et recherche, etc.). Ce projet de loi est en cours d'actualisation et de finalisation en vue de le soumettre pour approbation. | -- | -- | 22-Sep-16 | -- | -- | 22-Sep-16 | Cadre National de Biosécurité | Y | 22-Sep-16 | Instruments missing  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Mozambique | Yes | Q15: 2006 correspond to 2007 | -- | -- | 22-Sep-16 | -- | -- | 22-Sep-16 | Draft National Biosafety Framework | Y | 22-Sep-16 |  |
| -- | -- | - | -- | -- | - | Decreto no. 6/2007- Regulamento sobre Bio-Segurança Relativa à Gestão de Organismos Geneticamente Modificados | Y | 22-Sep-16 |
| Namibia | Yes | The Biosafety Act of 2006 is enforced, regulation are still to be finalized. | Biosafety Act | Y | 22-Sep-16 | -- | -- | 22-Sep-16 | -- | -- | 22-Sep-16 |  |
| Netherlands | Yes | Most of the legislation for LMOs as applicable in the Netherlands is based on EU legislation. The most important legislative instruments for LMOs are directives 2001/18/EC and 2009/41/EC and regulations EC/1829/2003, EC/1830/2003 and EC/1946/2003. For details on the EU legislation on LMOs, please see the report of the European Union.  EU regulations are directly applicable in all Member States. However, Member States are responsible for the penalization of infringements of the regulations. In the Netherlands, infringement of the EU regulations has been included in the Law on Economic Offenses, with penalties ranging from fines to imprisonment.  EU directives are implemented in the national legislation of Member States. In the Netherlands, the EU directives on LMOs have been implemented in the Genetically Modified Organisms Act (GMO Act). This Act contains rules for contained use, introduction into the environment of LMOs and introduction into the environment of LMO-FFP’s. A courtesy translation of this Act is available through the BCH. | -- | -- | 22-Sep-16 | GMO Decree, Chemical Substances Act (Bulletin of Acts and Decrees, 1993, 435) | Y | 22-Sep-16 | -- | -- | 22-Sep-16 | Instruments missing  (see free text) |
| -- | -- | -- | Ministerial Regulation (concerning GMOs) | Y | 22-Sep-16 | -- | -- | -- |
| New Zealand | Yes | None | Biosecurity Act | N | 22-Sep-16 | Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003 | N | 22-Sep-16 | MAF/ERMA Containment Standards | N | 22-Sep-16 | Some links missing / incorrect |
| Agricultural Compounds and Veterinary Medicines Act | N | 22-Sep-16 | Hazardous Substances and New Organisms (Methodology) Order 1998 | N | 22-Sep-16 | -- | -- | -- |
| Hazardous Substances and New Organisms Act 1996 | N | 22-Sep-16 | Import and Exports (living modified organisms) Prohibition Regulations 2005 | N | 22-Sep-16 | -- | -- | -- |
| Medicines Act | N | 22-Sep-16 | Hazardous Substances and New Organisms (organisms not genetically modified) regulations 1998 | N | 22-Sep-16 | -- | -- | -- |
| Food Standards Australia New Zealand Act 1991 | Y | 22-Sep-16 | -- | -- | -- | -- | -- | -- |
| Nicaragua | Partially | Decreto No. 59-2003: REFORMAS Y ADICIONES AL DECRETO No. 2-99, REGLAMENTO DE LA LEY No. 291, LEY BASICA DE SALUD ANIMAL Y SANIDAD VEGETAL.  Arreglo Relativo al Articulo 24 Entre La Republica de Nicaragua y Los Estados Sobre Los Requisitos de Documentación para los Organismos Vivos Modificados Destinados a Alimento Humano o Animal o al Procesamiento.  Plan Nacional de Biotecnologia 2013-2020  Ley Nº 705 - Ley sobre prevención de riesgos provenientes de organismos vivos modificados por medio de biotecnología molecular.  Ley 807, LEY DE CONSERVACIÓN Y UTILIZACIÓN SOSTENIBLE DE LA DIVERSIDAD BIOLÓGICA. | -- | -- | 22-Sep-16 | Decreto No. 59-2003: REFORMAS Y ADICIONES AL DECRETO No. 2-99, REGLAMENTO DE LA LEY No. 291, LEY BASICA DE SALUD ANIMAL Y SANIDAD VEGETAL | Y | 22-Sep-16 | Arreglo Relativo al Articulo 24 Entre La Republica de Nicaragua y Los Estados Sobre Los Requisitos de Documentación para los Organismos Vivos Modificados Destinados a Alimento Humano o Animal o al Procesamiento | Y | 22-Sep-16 | Instruments missing  (see free text) |
| Niger | Yes | EXISTING NATIONAL BIOSAFETY PROJET LAW AND REGIONALWEST AFRICAN BIOSAFETY GUIDELINES WHICH WILL BE ADOPTED IN 2016 | Loi n° 2004-040 du 8 juin 2000, portant régime forestier au Niger | N | 22-Sep-16 | Niger Access to Public Information Law | Y | 4-Oct-16 | Draft National Biosafety Framework | Y | 22-Sep-16 | Links missing / incorrect   Draft law awaiting approval |
| Loi 98-07 du 29 avril 1998 et son décret d'application fixant le régime de la Faune et de la Protection de la Faune sauvage | N | 22-Sep-16 | -- | -- | -- | cadre réglementaire de biosécurité | N | 04-Oct-16 |
| National Biosafety law Project of Niger Republic | Y | 04-Oct-16 | -- | -- | -- | Cadre National de Biosécurité | N | 04-Oct-16 |
| Law project related to vegetal seeds | Y | 04-Oct-16 | -- | -- | -- | UEMOA GUIDELINE (Regional Agreement or Arrangement) | Y | 04-Oct-16 |
| -- | -- | -- | -- | -- | -- | INITIATIVE <3N> FOR FOOD AND NUTRITIONAL SECURITY AND AGRICULTURAL SUSTAINABLE DEVELOPMENT | N | 04-Oct-16 |
| -- | -- | -- | -- | -- | -- | ANALYSE DU CADRE JURIDIQUE ET INSTITUTIONNEL DU NIGER SUR L' APA. | Y | 04-Oct-16 |
| -- | -- | -- | -- | -- | -- | REGULATION PROJECT RELATING TO BIOSAFETY IN WEST AFRICA (Regional Agreement or Arrangement) | Y | 04-Oct-16 |
| -- | -- | -- | -- | -- | -- | REGULATION C/REG.4/06/2008 ON HARMONISATION OF THE RULES GOVERNING QUALITY CONTROL, CERTIFICATION AND MARKETING OF SEEDS (Regional Agreement or Arrangement) | Y | 04-Oct-16 |
| Nigeria | Yes | None | NATIONAL BIOSAFETY MANAGEMENT AGENCY ACT 2015 | Y | 23-Sep-16 | -- | -- | 23-Sep-16 | Nigeria Biosafety Guidelines | Y | 23-Sep-16 |  |
| -- | -- | -- | -- | -- | -- | Draft National Biosafety Framework | Y | 23-Sep-16 |
| -- | -- | -- | -- | -- | -- | Nigeria National Biosafety Containment Facility Guidelines | Y | 23-Sep-16 |
| -- | -- | -- | -- | -- | -- | NATIONAL GUIDELINES FOR BIOSAFETY ADMINISTRATION IN NIGERIA | Y | 23-Sep-16 |
| Niue | Yes | Biosecurity Bill awaiting enactment by June 2016 | -- | -- | 23-Sep-16 | -- | -- | 23-Sep-16 | Draft National Biosafety Framework | Y | 23-Sep-16 | Draft law awaiting approval  (see free text)   Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Norway | Yes | None | Act relating to the production and use of genetically modified organisms, etc (Gene Technology Act) / Lov om framstilling og bruk av genmodifiserte organismer m.m. (genteknologiloven). | Y | 23-Sep-16 | Regulations relating to the labelling, transport, import and export of genetically modified organisms / Forskrift om merking, transport, import og eksport av genmodifiserte organismer | Y | 23-Sep-16 | Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) | N | 23-Sep-16 |  |
| -- | -- | -- | Regulations relating to impact assessment pursuant to the Gene Technology Act / Forskrift om konsekvensutredning etter genteknologiloven | Y | 23-Sep-16 | EEA agreement, Annex XX, Part IV, para 24-25 (Bilateral Agreement or Arrangement) | Y | 23-Sep-16 |
| -- | -- | -- | Regulation on contained use of genetically modified micro-organisms / Forskrift om innesluttet bruk av genmodifiserte mikroorganismer. | Y | 23-Sep-16 | -- | -- | -- |
| -- | -- | -- | Regulation on contained use of genetically modified animals / Forskrift om innesluttet bruk av genmodifiserte dyr | Y | 23-Sep-16 | -- | -- | -- |
| -- | -- | -- | Regulation on contained use of genetically modified plants/Forskrift om innesluttet bruk av genmodifiserte planter | Y | 23-Sep-16 | -- | -- | - |
| Oman | No | -- | -- | -- | 23-Sep-16 | -- | -- | 23-Sep-16 | -- | -- | 23-Sep-16 | No instruments uploaded to the BCH |
| Pakistan | Yes | The Establishment of National Biosafety Centre Project was approved by the defunct Ministry of Environment (now renamed as Ministry of Climate Change) and National Biosafety Centre was established in Pakistan Environmental Protection Agency (Pak-EPA) since April, 2006. In exercise of the powers conferred by section 31 of Pakistan Environmental Protection Act (PEPA) 1997, the Federal Government notified Pakistan Biosafety Rules Vide S.R.O.336(1)/2005 on 21st April, 2005. National Biosafety Guidelines were notified in October, 2005 which provides the procedure for the implementation of Pakistan Biosafety Rules, 2005. Biosafety Guidelines provides procedures for the research and development on LMOs/GMOs and their products, release of LMOs/GMOs and their products for field trials and release of LMOs/GMOs for commercial purpose.  Pak EPA is working to regulate GMOs/LMOs and their products related activities in the country which includes secretarial services to three committees' i.e., National Biosafety Committee (NBC), Technical Advisory Committee (TAC) and Institutional Biosafety Committees (IBCs) essential for the implementation of the entire regulatory framework. Pak EPA is entrusted for the regulatory functions by the Government of Pakistan essential to regulate GMOs/LMOs and their products in the country. A number of TAC subcommittees had been assigned different tasks of monitoring and evaluation of Research and development, Field trials and commercialization of GMOs/LMOs and their products in the country. These subcommittees had been functioning as per the directions of TAC and submit their reports to TAC for furnishing recommendations to NBC for decision making. | Pakistan Biosafety Rules, 2005 (S.R.O. (I) 336(I)/2005) | Y | 23-Sep-16 | -- | -- | 23-Sep-16 | National Biosafety Guidelines - Notification No. F.2(7)95-Bio | Y | 23-Sep-16 |  |
| Palau | No | None | -- | -- | 19-Jun-17 | Republic of Palau National Biosafety Framework | N | 19-Jun-17 | -- | -- | 19-Jun-17 | Links missing / incorrect |
| Panama | Partially | None | Law 48 [courtesy translation] | Y | 23-Sep-16 | -- | -- | 23-Sep-16 | Resolución 046 Comité Sectorial de Bioseguridad de Salud para Organismos Geneticamente Modificados | Y | 23-Sep-16 | Some links missing / incorrect |
| Law 72 [courtesy translation] | Y | 23-Sep-16 | -- | -- | -- | -- | -- | -- |
| Law Decree No. 11 of February 22, 2006. Creates the Panamanian Food Safety Authority, as the Autonomy Authority of the Panamanian Government who authorizes the imports and transit of food, animal feed and food for processing | Y | 23-Sep-16 | -- | -- | -- | -- | -- | -- |
| Ley 47 (de 9 de julio de 1996) "Por la cual se dictan medidas de protección fitosanitaria y se adoptan otras disposiciones" | N | 23-Sep-16 | -- | -- | -- | -- | -- | -- |
| Paraguay | Partially | None | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Peru | Yes | P16.- A la fecha existen dos Leyes Nacionales que regulan a los OVM: Ley de prevención de riesgos derivados del uso de la biotecnología (Ley n°. 27104) y la Ley de moratoria al ingreso y producción de OVM en el territorio nacional por un periodo de 10 años (Ley n°. 29811). Ambas leyes cuentan con sus respectivos reglamentos. El Protocolo de Cartagena sobre Seguridad de la Biotecnología también constituye una Ley Nacional. Actualmente se viene trabajando en reglamentaciones sobre seguridad de la biotecnología para el sector agrícola, pesquero y salud. | Ley 27104, Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología | Y | 23-Sep-16 | Reglamento de la Ley de Prevención de Riesgos Derivados del uso de la Biotecnología - DS No. 108-2002-PCM | Y | 23-Sep-16 | Draft National Biosafety Framework | Y | 23-Sep-16 |  |
| Ley N° 29811 que establece la moratoria al ingreso y producción de OVM en el territorio nacional por un periodo de 10 años | Y | 23-Sep-16 | DEROGADO por la Ley N°29811. Decreto Supremo 003-2011-AG que aprueba el Reglamento Interno Sectorial sobre Seguridad de la Biotecnología en el Desarrollo de Actividades con Organismos Vivos Modificados Agropecuarios o Forestales y sus Productos Derivados | Y | 23-Sep-16 | -- | -- | -- |
| -- | -- | -- | Reglamento de la Ley 29811, Ley que establece la Moratoria al Ingreso y Producción de Organismos Vivos Modificados al Territorio Nacional por un período de 10 años | Y | 23-Sep-16 | -- | -- | -- |
| -- | -- | -- | Procedimiento de control de ingreso OVM al territorio nacional en el marco de la Ley de Moratoria | Y | 23-Sep-16 | -- | -- | -- |
| Philippines | Yes | QUESTION 15 The Philippines has a National Biosafety Framework as per Executive Order 514 (E.O. 514) issued on 17 March 2006. Guidelines are in place for risk assessment of agricultural plants and plant products by way of a Department of Agriculture Administrative Order No. 08, series of 2002. The Department of Environment and Natural Resource is formulating regulations for GM forest and wildlife resources. Guidelines are also in place for Contained Use of LMOs, including Transgenic Arthropods, which is being implemented by the Department of Science and Technology. QUESTION 16 National Biosafety Framework- E.O. 514, issued on 17 March 2006 Regulations: DA AO No 8s. 2002 is based on Presidential Decree 1433, known as the Plant Quarantine Act, The Consumer Code, our commitments to WTO-SPS (World Trade Organization-Sanitary and Phytosanitary Measures), Adoption of Codex and IPPC (International Plant Protection Convention) standards. Biosafety Guidelines - Executive Order 430, issued on 16 October 1991, creating the National Committee on Biosafety of the Philippines; Philippine Biosafety Guidelines series of 1991; Guidelines on the Planned Release of GMOs and PHES (Potentially Harmful Exotic Species) issued on 8 September 1998; DA Administrative Order No. 8: Guidelines on Risk Assessment for Field Trials, Propagation and Direct Use for food, feed or processing, The Philippines Revised Guidelines on Contained use of GMOs (2014); The Philippines Guidelines on Containment of Transgenic Arthropods (2014). Other laws, regulations that indirectly apply to GMOs : Wildlife Resources Conservation and Protection, Plant Variety Protection Act, Network of Integrated Protected Areas, etc. QUESTION 17 EO 514 mandates the DOST, DENR, DA and DOH to allocate from their existing budgets such amount as may be necessary to implement the NBF, including to support the operations of the NCBP and its secretariat.  QUESTIONS 18 and 19 Permanent staff per concerned agency and on top of their regular workload | -- | -- | 26-Sep-16 | Department of Agriculture Memorandum Circular No. 8 series of 2004 : Risk Assessment for Stacked Gene Products Imported for Direct Use as Food and Feed or Processing | N | 26-Sep-16 | Department of Agriculture Memorandum Circular No. 8 series of 2005: Strengthening the DA's Science-Based Insect Resistance Management for Bt Corn and Amending Section III.a.(ii) of Memorandum Circular No. 17, Series of 2003 | Y | 26-Sep-16 | Links missing / incorrect   Instruments missing  (see free text) |
| -- | -- | -- | Department of Agriculture Memorandum Circular No. 2 series of 2006 : Guidelines for the Conduct of Field Test for Plants Derived from Modern Biotechnology | Y | 26-Sep-16 | Executive Order 430: Philippine Biosafety Guidelines, series 1990 | Y | 26-Sep-16 |
| -- | -- | -- | Department of Agriculture Memorandum Circular No. 6 series of 2004 : Risk Assessment of Plants Carrying Stacked Genes For Release Into the Environment | Y | 26-Sep-16 | Department of Agriculture Administrative Order No. 8, series of 2002 | Y | 26-Sep-16 |
| -- | -- | -- | Department of Agriculture Memorandum Circular No. 8 series of 2003: Guidelines for the Phytosanitary Inspection of Regulated Articles for Food, Feed and Processing | Y | 26-Sep-16 | Executive Order 514: Establishing the National Biosafety Framework | Y | 26-Sep-16 |
| -- | -- | -- | Department of Agriculture Memorandum Circular No. 12 series of 2003:Annexes I, II and III Pursuant to Memorandum Circular No. 8 s.2003 and DA AO No. 8, s. 2002 | Y | 26-Sep-16 | Department of Agriculture Memorandum Circular No. 11 s2003: Additional Signatories to the declaration of GMO content pursuant to DA Memorandum Circular No. 8 s. 2003 | Y | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | Department of Agriculture Administrative Order No. 22, series of 2007 | Y | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | Department of Agriculture Administrative Order No. 31, series of 2008 | Y | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | Department of Agriculture Administrative Order No. 01, series of 2009 | Y | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | Department of Agriculture Memorandum Circular No. 6 series of 2007, Guidelines for the Renewal of Permit of Regulated Articles for Direct Use as Food and Feed, or for Processing | Y | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | Department of Agriculture Memorandum Circular No. 6 series of 2007 : Guidelines for the Safety Evaluation of Plants Derived from Modern Biotechnology Prior to Propagation | Y) | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | Department of Agriculture Memorandum Circular No. 2 series of 2007: Guidelines for the Renewal of Permit of Regulated Articles for Propagation | Y | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | The Philippines Biosafety Guidelines for Contained Use of Genetically Modified Organisms, Revised edition, September 2014 | Y | 26-Sep-16 |
| -- | -- | -- | -- | -- | -- | The Philippines Biosafety Guidelines for Containment of Transgenic Arthropods | Y | 26-Sep-16 |
| Poland | Yes | The New GMM and GMO Law has been submitted to the BCH in April 2015. There are some changes related to contained use of GMM and GMOs in it. | The act of 22 June 2001 on Genetically Modified Mikroorganisms and Organisms (GMM and GMO) (Journal of Laws of 2015, 2015 r. poz. 277) | Y | 23-Sep-16 | -- | -- | 23-Sep-16 | -- | -- | 23-Sep-16 |  |
| Portugal | Yes | The EU biosafety framework as reported by the European Commission (EC) is directly or indirectly applicable to Portugal. The EU-Regulations as referenced by the EC are directly applicable, the relevant EU-Directives have been transposed into Portuguese legislation.  The Portuguese Decree-law no. 72/2003, of 10th April, transposes the European Directive 2001/18/EC on the deliberate release into the environment of GMO, covering the field trials of GMOs as the placing on the market of GMOs as well as products containing or consisting of GMOs, e.g. for cultivation, import or processing into industrial products.  Decree-law no. 7/2004, of 17th April, that approves the Protocol on Biosafety of the Convention on Biological Diversity. Decree-law no. 164/2004, of 3th July, that modifies the Decree-law no. 72/2003, of 10th April in accordance with Regulation no. 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed and Regulation no. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.  Decree-law no. 168/2004, of 7th July, that executes Regulation no. 1830/2003 of the European Parliament and the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC  Notice no. 205/2004, of 21st December, where the Ministry of Foreign Affairs makes public that the Government of the Portuguese Republic has deposited, in 30 of September of 2004, its instrument of relative adhesion to the Cartagena Protocol on Biosafety of the Convention on Biological Diversity.  Decree-law no. 36/2006, of 20th February, It assures the execution and it guarantees the fulfilment, in the national jurisprudence, of the decurrent obligations for the Portuguese State of the Regulation No 1946/2003 of the European Parliament and of the Council, of 15 July 2003, on transboundary movements of genetically modified organisms  Decree-law no. 55/2015, of 17th April, concerning the contained use of genetically modified microorganisms and genetically modified organisms, with a view to protecting human health and the environment, transposing Directive No. 2009/41/EC of the European Parliament and of the Council, of 6 May 2009 | Decree-law no. 72/2003, of 10th April, concerning the deliberate release into the environment of genetically modified organisms and the placing on the market of GMOs as or in products, transposing into internal jurisprudence the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC | N | 26-Sep-16 | -- | -- | 26-Sep-16 | -- | -- | 26-Sep-16 | Links missing / incorrect   Instruments missing  (see free text) |
| Decree-law no. 2/2001, of 4th January, concerning the contained use of genetically modified micro-organisms transposing into internal jurisprudence the Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC. | N | 26-Sep-16 | -- | -- | -- | -- | -- | -- |
| Decree-law no. 7/2004, of 17th April, that approves the Protocol on Biosafety of the Convention on Biological Diversity. | N | 26-Sep-16 | -- | -- | -- | -- | -- | -- |
| Decree-law no. 164/2004, of 3th July, that modifies the Decree-law no. 72/2003, of 10th April | N | 26-Sep-16 | -- | -- | -- | -- | -- | -- |
| Decree-law no. 168/2004, of 7th July, that executes Regulation no. 1830/2003 of the European Parliament and the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC | N | 26-Sep-16 | -- | -- | -- | -- | -- | -- |
| Notice no. 205/2004, of 21st December, where the Ministry of Foreign Affairs makes public that the Government of the Portuguese Republic has deposited, in 30 of September of 2004, its instrument of relative adhesion to the Cartagena Protocol on Biosafety of the Convention on Biological Diversity. | N | 26-Sep-16 | -- | -- | -- | -- | -- | -- |
| Decree-law no. 36/2006, of 20th February, It assures the execution and it guarantees the fulfilment, in the national jurisprudence, of the decurrent obligations for the Portuguese State of the Regulation No 1946/2003 of the European Parliament and of the Council, of 15 July 2003, on transboundary movements of genetically modified organisms | N | 26-Sep-16 | -- | -- | -- | -- | -- | -- |
| Republic of Korea | Yes | None | THE ACT ON TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS, ETC.(Law No. 6448) | Y | 26-Sep-16 | The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms | N | 26-Sep-16 | Draft National Biosafety Framework | Y | 26-Sep-16 | Some links missing / incorrect |
| PHARMACEUTICAL AFFAIRS ACT | N | 26-Sep-16 | -- | -- | -- | The Enforcement Guideline of the Act on Transboundary Movements of Living Modified Organisms | N | 26-Sep-16 |
| Republic of Moldova | Yes | There are total 24 records published to the BCH, including: Laws, Regulation or Guideline - 5 | Law on Biosafety | Y | 27-Sep-16 | The Decision of the Government Nr. 603 from 20.05.2003 regarding the National Committee for Biosafety. | Y | 27-Sep-16 | Draft National Biosafety Framework | Y | 27-Sep-16 |  |
| -- | -- | -- | The Decision of the Government Nr. 1153 from 25.09.2003 on approvement of Regulation concerning the authorization of activities dealing with the acquirement, testing, usage and marketing of GMOs. | Y | 27-Sep-16 | Biosafety Action Plan for the period 2009-2015 | Y | 27-Sep-16 |
| -- | -- | -- | -- | -- | -- | ASSOCIATION AGREEMENT between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part, 30.08.2014 (Multilateral Agreement or Arrangement) | Y | 27-Sep-16 |
| Romania | Partially | As EU member since 2007, Romania has transposed the EU legislation on GMOs, which is consistent with the provisions of the Protocol, aiming at ensuring safety in the development, use and transfer of GMOs. The main legal measures include: - The EGO No 43/2007 on the deliberate release of the genetically modified organisms, approved by the Law No 247/2009 (transposing 2001/18/EC Directive)  -The EGO No 44/2007 on the contained use of genetically modified micro organisms, approved by the Law No 3/2008 (transposing 2009/41/EC Directive) -Governmental Decision No 497/2007 on establishing measures for the implementation of the Regulation of the European Parliament and of the Council No 1946/2003 on transboundary movements of LMOs  Romania also created the institutional framework to ensure the enforcement of the EU Regulations: - 1829/2003 on genetically modified food and feed, covering the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs.  -1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. - 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. Also general provisions are introduced in the frame law for environmental protection of Romania : EGO no. 195/2005 on the environmental protection with further amendments. Related legislation: - Order No 61/2012 regarding the authorization and control of the genetically modified plant growers and for ensuring the coexistence of genetically modified crops with conventional and organic. -Order No 34/2011 approving the Regulation on organization and plant quality control on the import and export of seeds and planting material. -Order No 1573/2014 of Ministry of Agriculture, Forests and rural Development on official control of seed quality by testing non GM varieties in regard with contamination with GMO. - Common Order No 1160/2902/2010 regarding the approval of the control procedure regarding the import, export and transit of the GMOs A list of all legal measures related to genetically modified organisms is available at: http://www.mmediu.ro/legislatie/biosecuritate.htm  Please also see the EU report. | Law no. 59/11.03.2003 for the ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity | No | 27-Sep-16 | -- | -- | 27-Sep-16 | Draft National Biosafety Framework | Y | 27-Sep-16 | Links missing / incorrect   Instruments missing  (see free text) |
| Emergency Governmental Ordinance No 43/2007 on the deliberate release and placing on the market of genetically modified organisms | No | 27-Sep-16 | -- | -- | -- | -- | -- | -- |
| Rwanda | No | Rwanda has National Biosafety Framework with Biosafety regulations, Policy and Law. The Biosafety Policy and Law are reviewed and in process to be submitted to the Parliament for approval. It is being processed to pass through the Rwanda Law Reform Commission. | -- | -- | 27-Sep-16 | -- | -- | 27-Sep-16 | Draft GMO Regulatory Framework | N | 27-Sep-16 | Links missing / incorrect   Draft law awaiting approval |
| -- | -- | -- | -- | -- | -- | Draft National Biosafety Framework | Y | 27-Sep-16 |
| Saint Kitts and Nevis | Yes | None | Biosafety Act, 2012 | Y | 27-Sep-16 | -- | -- | 27-Sep-16 | Draft National Biosafety Framework | Y | 27-Sep-16 |  |
| Saint Lucia | Yes | Legislation has been drafted and reviewed to be compliant with local laws and other treaties/conventions. Consideration of the legislation by Parliament is beyond the control of the Biodiversity Unit. Biosafety has been placed on the agenda and the legislation will be reviewed in the upcoming months. | -- | -- | 27-Sep-16 | -- | -- | 27-Sep-16 | Draft law and regulations on biosafety (Title of BCH entry is "Second Draft National Biosafety Framework | Y | 27-Sep-16 | Draft law awaiting approval  (see free text) |
| Saint Vincent and the Grenadines | Yes | While we have not yet implemented the framework, there is advancement on the legislative work. improvement have been made on the legislation from the last reporting period. The final draft of this piece of legislation will be submitted in September with the anticipation of forwarding to the Cabinet | BILL: Biosafety Act 2007 (Title of BCH entry is "Draft National Biosafety Framework (Developed under the UNEP-GEF Biosafety Project)") | Y | 19-Jun-17 | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 |  |
| Samoa | No | A draft Biodiversity Bill, Biosafety (LMOs) Regulations (draft) and National Biodiversity Policy (draft) have been prepared following an inclusive process and is with the Attorney General's Office for final drafting and subsequent submission to Parliament for enactment. In the meantime, the Biosecurity Act 2005 regulates all movement of live animals and plants including cultures, in and out of the country and has guidelines in place for screening and risk assessment.  For Q 19, In the absence of the functioning national biodiversity framework, MAF-Quarantine effectively perform the functions directly related to the national biosafety framework in so far as regulating the entry of all living organisms including cultured germplasm into the country. One exception is pharmaceutical LMOs, which falls under the responsibility of the Ministry of Health. MAF-Quarantine collaborates with other agencies and institutions notably, MAF-Fisheries, MAF-Livestock, MAF Crops Division, the National University of Samoa and the Scientific Research Organization of Samoa (SROS) on matters related to risk assessments where required expertise is not available within Quarantine. | -- | -- | 27-Sep-16 | -- | -- | 27-Sep-16 | Draft National Biosafety Framework | Y | 27-Sep-16 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Senegal | Yes | Le Sénégal a adopté la loi 2009 - 27 portant sur la biosécurité. Cette loi consacre en son article 5 la création d'une Autorité Nationale de Biosécurité (ANB) et d'un Comité National de Biosécurité (CNB). En 2009, deux décrets portant sur les missions, l'organisation et le fonctionnement de l’ANB et du CNB, ont été signé. L'ANB est une structure administrative composée de représentants des différents ministères concernés par la problématique de la biosécurité. Elle est chargée de faire des propositions en matière de décision sur la base du rapport scientifique d'évaluation des risques élaboré par le Comité National de Biosécurité. Ce Comité qui regroupe entre autres quinze personnalités scientifiques choisies en raison de leurs compétences est chargé de l'évaluation des risques liés à tout organisme vivant modifié ou produit dérivé pour lequel une demande d'autorisation d'activité est soumise au Ministre en charge de l'environnement. L’arrêté portant composition du Comité National de Biosécurité a été signé en mars 2012.Le Directeur Exécutif de l’Autorité National de Biosécurité a été nommé en février 2014 ; toutefois, la signature du Décret portant composition de l’ANB n’est pas encore effective. En perspective de l’intégration des dispositions du Protocole additionnel de Nagoya Kuala Lumpur et du règlement communaire de l’Union Economique et Monaitéaire de l’Afrique de l’Ouest (UEMOA), la loi nécessite une révision. En outre, dans la même dynamique, une dizaine d’arrêtés seront rédigés pour compléter la loi sur la biosécurité. Il s’agit de : - l’arrêté fixant les conditions de transport d’OGM ou de produits dérivés ;- l’arrêté fixant les modalités de confinement des OGM ;- l’arrêté fixant les modalités de dissémination volontaire des OGM dans l’environnement ;- l’arrêté fixant les conditions, principes et méthodes d’évaluation des risques liés aux OGM ;- l’arrêté fixant les modalités de nomination et d’intervention des agents chargés du suivi et du contrôle ;- l’arrêté fixant les conditions de destruction des OGM ou produits dérivés qui présentent des risques avérés pour la santé humaine ou animale, de même que pour la diversité biologique et l’environnement ; - l’arrêté fixant les modalités d’étiquetage des emballages et produits commerciaux contenant des OGM ;- l’arrêté fixant la période d’observation des OGM ou produits dérivés importés ou de production locale. | Loi sur la Biosécurité au Sénégal - LOI n° 2009-27 du 8 juillet 2009 portant sur la Biosécurité | Y | 28-Sep-16 | Décret n° 2009-1409 du 23 décembre 2009 portant missions, organisation et fonctionnement de l'Autorité Nationale de Biosécurité (ANB). | Y | 28-Sep-16 | -- | -- | 28-Sep-16 |  |
| -- | -- | -- | Décret n° 2009-1408 du 23 décembre 2009 portant missions, organisation et fonctionnement du Comité National de Biosécurité (CNB). | Y | 28-Sep-16 | -- | -- | -- |
| Slovakia | Yes | The Act on the use of genetic technologies and genetically modified organisms No. 151/2002 Coll., as amended, became effective on 1st April 2002. The Decree No. 399/2005 Coll. of the Ministry of Environment of the Slovak Republic implements the Act. These legal measures are based on the Directive 2009/41/EC on the contained use of genetically modified micro-organisms and Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. All approval procedures for import of GMOs are common for all Member States of the European Union.  For more information see the 3rd national report of the European Union. | The Act No. 184/2006 on cultivation of genetically modified plants in agricultural production - (coexistence) | Y | 29-Sep-16 | Regulation No. 399/2005 Coll. as amended by the Regulation No. 312/2008 Coll. and Regulation No. 86/2013 Coll. implementing the Act on use of genetic technologies and GMOs | Y | 29-Sep-16 | Draft National Biosafety Framework | Y | 29-Sep-16 |  |
| Act No. 151/2002 Coll. as last amended by the Act No. 448/2012 Coll. | Y | 29-Sep-16 | -- | -- | -- | NATIONAL BIOSAFETY POLICY FOR SLOVAKIA | Y | 29-Sep-16 |
| Slovenia | Yes | None | Health and Hygiene Safety of Foods, and of Materials and Articles Intended to Come into Contact with Foods Act | Y | 29-Sep-16 | -- | -- | 29-Sep-16 | EC Treaty (Regional Agreement or Arrangement) | N | 29-Sep-16 |  |
| Management of Genetically Modified Organisms Act | Y | 29-Sep-16 | -- | -- | -- | Draft National Biosafety Framework | Y | 29-Sep-16 |
| Medicinal Products and Medical Devices Act | Y | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Somalia | No | None | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | No instruments uploaded to the BCH |
| South Africa | Yes | South Africa regulates all activities relating to genetically modified organisms (GMOs) in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) which is administered by the Department of Agriculture, Forestry and Fisheries (DAFF). Section 3 of the GMO Act makes provision for the establishment of an Executive Council, an intergovernmental body which includes representation from the departments of Agriculture, Forestry and Fisheries, Arts and Culture (DAC), Science and Technology (DST), Environmental Affairs (DEA), Trade and Industry (the dti), Labour (DoL) and Health (DoH). The Executive council is the decision making body. In addition to the GMO Act, South Africa also has the following pieces of legislation that considers biosafety issues: 1) National Enviromental Management Act 107 of 1998 (provides for environmental impact assessment of selected categories of LMOs) 2) National Environmental Management Biodiversity Act 10 of 2004 (provides for long term monitoring of potential impacts of LMOs) 3) Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (deals with safety standards as well as labelling of certain class of foodstuffs derived from LMOs) | Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) | Y | 29-Sep-16 | Environment Conservation Act, 1989, Regulations: The Identification under Section 21 of activities which may have a substantial detrimental effect on the environment. | N | 29-Sep-16 | -- | -- | 29-Sep-16 | Links missing / incorrect   Instruments missing  (see free text) |
| Genetically Modified Organisms Act,1997 Regulations | Y | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Spain | Yes | España es un Estado Miembro de la Unión Europea y ha traspuesto a su legislación la normativa sobre organismos vivos modificados elaborada por la Unión Europea y el resto de directa aplicación, destacando la directiva 2001/18/CE y los reglamentos 1829/2003 y 1830/2003. Adicionalmente, durante el periodo que comprende el informe, se han aprobado el Reglamento de Ejecución (UE) no 503/2013 de 3 de abril de 2013 sobre las solicitudes de autorización de alimentos y piensos modificados genéticamente de conformidad con el Reglamento (CE) nº 1829/2003 del Parlamento Europeo y del Consejo y por el que se modifican los Reglamentos (CE) nº 641/2004 y (CE) nº 1981/2006, y la Directiva (UE) 2015/412 del Parlamento Europeo y del Consejo, de 11 de marzo 2015, por la que se modifica la Directiva 2001/18 /CE en lo que respecta a la posibilidad de que los Estados miembros restrinjan o prohíban el cultivo de OMG en su territorio (véase el informe nacional realizado por la Unión Europea). El marco legislativo actual se regula a través de la Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente y el Real Decreto 178/2004, de 30 de enero, por el que se aprueba el Reglamento general para el desarrollo y ejecución de la Ley 9/2003, el cual ha sido modificado posteriormente por el Real Decreto 191/2013, de 15 de marzo.Adicionalmente, varios instrumentos, reales decretos, órdenes y reglamentos internos se han aprobado con el objeto de desarrollar la Ley 9/2003 y adaptarse a la realidad cambiante de la biotecnología y dar mayor visibilidad en materia de bioseguridad a la sociedad, destacando entre ellos:- Instrumento de Ratificación del Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica, hecho en Montreal el 29 de enero de 2000.- Real Decreto 367/2010, de 26 de marzo, de modificación de diversos reglamentos en el área de medio ambiente para su adaptación a la Ley 17/2009, de 23 de noviembre, sobre libre acceso a las actividades de servicios y su ejercicio, y a la Ley 25/2009, de 22 de diciembre, de modificación de diversas leyes para su adaptación a la Ley de libre acceso a actividades de servicios y su ejercicio. (El Capítulo V modifica parcialmente el Real Decreto 178/2004). - Orden ARM/2616/2010, por la que se establece la composición y funcionamiento del Comité de Participación en el marco del Consejo Interministerial de Organismos Modificados Genéticamente. - Reglamentos internos de la Comisión Nacional de Bioseguridad, del Comité de Participación y del Consejo Interministerial de Organismos Modificados Genéticamente.Por otro lado, las Comunidades Autónomas han desarrollado igualmente las competencias que les atribuye la Ley 9/2003 y han elaborado normas que complementan a las mencionadas anteriormente. Esta normativa se puede encontrar en la página Web del Ministerio de Agricultura, Alimentación y Medio Ambiente: <http://www.magrama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/legislacion-general/Legislacion_espaniola.aspx>. Finalmente, existe normativa horizontal que no es específica de la seguridad de la biotecnología pero que hay que tener en cuenta a la hora de la comercialización y liberación de organismos modificados genéticamente. ocasionar los Organismos Vivos Modificados. Dentro de esta normativa se encuentra:- Ley 26/2007, de 23 de octubre, de Responsabilidad Medioambiental.- Ley 27/2006, de 18 de julio, por la que se regulan los derechos de acceso a la información, de participación pública y de acceso a la justicia en materia de medio ambiente.- Orden ARM/1783/2011, de 22 de junio, por la que se establece el orden de prioridad y el calendario para la aprobación de las órdenes ministeriales a partir de las cuales será exigible la constitución de la garantía financiera obligatoria, previstas en la disposición final cuarta de la Ley 26/2007, de 23 de octubre, de Responsabilidad Medioambiental. Además en España, como Estado Miembro de la Unión Europea, es de aplicación la normativa comunitaria, la cual ha sido recogida en el Informe Nacional de la Unión Europea. | Ley 9/2003, Organismos Modificados Genéticamente | Y | 29-Sep-16 | Real Decreto 367/2010 de modificación de diversos reglamentos del área de medio ambiente | Y | 29-Sep-16 | INSTRUMENTO de Ratificación del Protocolo de Cartagena | Y | 29-Sep-16 |  |
| Real Decreto 178/2004 OMGs | Y | 29-Sep-16 | Corrección de errores del Real Decreto 367/2010 | Y | 29-Sep-16 | Orden ARM/2616/2010 por la que se establece la composición y funcionamiento del Comité de Participación | Y | 29-Sep-16 |
| Ley 26/2007 de Responsabilidad Medioambiental | Y | 29-Sep-16 | Orden ARM/1783/2011, sobre calendario para constitución de garantía financiera obligatoria, prevista en la Ley 26/2007, de Responsabilidad Medioambiental. | Y | 29-Sep-16 | -- | -- | -- |
| Ley 27/2006, sobre información, participación pública y acceso a la justicia en materia de medio ambiente. | Y | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Sri Lanka | Partially | Sri Lanka developed its national Biosafety framework including National Biosafety Policy under the UNEP-GEF Project on Development of National Biosafety Frameworks. National Biosafety Framework includes five sections, namely: Governement policy on Biosafety regime, system to handle notifications or requests for authorizations, mechanisms for public awareness, education and participation, system of monitoring and enforcement. National Biosafety Policy got Cabinet approved in year 2005. Regulatory regime has identified some provision of certain Genetically Modified Organisms (GMOs). It suggests drafting and enacting new biosafety law considering all the weaknesses in existing legal framework complying with biosafety policy and regulatory framework. The only piece of legislation directly related to biosafey at present is Food Regulations 2006. The Ministry of Healthcare and Nutrition developed regulations under the Food Act of 1980, Food (Control of Import, Labelling and Sale of Genetically Modified Foods) Regulations 2006 which has come into effect from January 2007. Food which contains or has genetically modified organisms less than nought decimal five per cent (0.5%) are exempted from the provisions of these regulations.  The Country has drafted a new Biosafety Act, which is at Legal Draftsman at present. "Guidelines for the Safe Use of Recombinant DNA Technology in the Laboratory " was first published in 2003 and secondly in 2005 by the National Science Foundation.  Laboratory manual on Detection of Genetically Modified Organisms, Food, Feed and Processed Products was published in 2005. | Fauna and Flora Protection Ordinance, No. 2 of 1937 | N | 29-Sep-16 | -- | -- | -- | National Guidelines for Import and Planned release of Genetically Modified Organisms and Products thereof (Draft), Ministry of Environment and Natural Resources | N | 29-Sep-16 | Links missing / incorrect   Draft law awaiting approval (see free text)   Instruments missing  (see free text) |
| Fisheries and Aquatic Resources, Act No. 2 of 1996 | N | 29-Sep-16 | -- | -- | -- | Guidelines for the Safe Use of Recombinant DNA Technology in the Laboratory, National Science Foundation | N | 29-Sep-16 |
| Animals Act, No. 29 of 1958 | N | 29-Sep-16 | -- | -- | -- | Laboratory Manual on Detection of Genetically Modified Organisms, Food, Feed and Processed Products, 2005, Agricultural Biotechnology Center, University of Peradeniya | N | 29-Sep-16 |
| Animal Diseases Act, No. 59 of 1992 | N | 29-Sep-16 | -- | -- | -- | Draft National Biosafety Framework | Y | 29-Sep-16 |
| Animal Feed Act |  | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Plant Protection Act, No 35 of 1999 | N | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Water Hyacinth Ordinance, No. 09 of 1909 | N | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Control of Pesticides Act, No. 33 of 1980 | N | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Food Act, No.26 1980 | N | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Consumer Affairs Authority Act | N | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Intellectual Property Act, No. 36 of 2003 | N | 29-Sep-16 | -- | -- | -- | -- | -- | -- |
| Sudan | Yes | The National Biosafety Council was constituted in June 2012 to include 24 members representing the biosafety stakeholders. In June 2012 also the Biosafety Technical Committee was established of 10 members representing the Biotechnology research scientists, the regulatory partners in the biosafety and the civil societies. | National Biosafety Law 2010 | N | 29-Sep-16 | -- | -- | 29-Sep-16 | Draft National Biosafety Framework | Y | 29-Sep-16 | Links missing / incorrect |
| Suriname | No | Suriname has produced a National Biosafety Framework in 2004. In addition, a first draft of biosafety legislation has to be revised. A National Biosafety Committee was established which convened on a regular basis. A first draft of an implementation plan for the National Biosafety Framework in Suriname (2011-2016) was prepared: this plan elaborates on the establishment of a detailed implementation strategy; an effective coordination mechanism and the development and approval of a biosafety Framework Law. | -- | -- | 29-Sep-16 | -- | -- | 29-Sep-16 | Draft National Biosafety Framework | Y | 29-Sep-16 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Swaziland | Partially | Q16 - Draft Regulation in place but in the process of being approved by Parliament.  - Q18 & Q19 - The Competent Authority now has the Biosafety Registrar - Q20 - The Biosafety Act 2012 has been submitted to the BCH. The Regulations and Guidelines are yet to be submitted. | Biosafety Act of 2012 | Y | 29-Sep-16 | -- | -- | 29-Sep-16 | Draft National Biosafety Framework | Y | 29-Sep-16 |  |
| Sweden | Yes | EU legislation on genetically modified organisms (GMOs) has been in place since the early 1990s. The EU introduced specific legislation on GMOs to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology products. The EU has created a comprehensive legal framework for ensuring safety in the development, use and transfer of GMOs. The main pieces of legislation are:- Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, covering the field testing of GMOs and the placing on the market of GMOs as well as products containing or consisting of GMOs, e.g. for cultivation, import or processing into industrial products.- Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed, covering the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs. - Regulation (EC) No 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.- Regulation (EC) No 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms covers exports of GMOs to third countries and unintentional movements of GMOs.- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms.- Commission Regulation 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorization procedure is pending or the authorization of which has expired.- Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorization of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006.- Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.More information on the content of these legislative acts is available at: http://ec.europa.eu/food/plant/gmo/new/legislation/index\_en.htmIn the case of Directives 2001/18/EC and (EU) 2015/412, and of Regulations (EC) No 1829/2003, 1830/2003 and 1946/2003, Member States have introduced domestic provisions to ensure enforcement and/or transposition of this legislation within their territories. For implementing legislation at EU Member States level, please refer to the Member States national reports. | Swedish Environmental Code (SFS 1998:808) | N | 29-Sep-16 | The Swedish Board of Agriculture's Regulations on the Deliberate Release of Genetically Modified Plants | Y | 29-Sep-16 | -- | -- | 29-Sep-16 | Some links missing / incorrect |
| The Genetically Modified Organisms (Deliberate Release) Ordinance (SFS 2002:1086) | Y | 29-Sep-16 | The Swedish Board of Agriculture's Regulations on the Use of Genetically Modified Animals | Y | 29-Sep-16 | -- | -- | -- |
| -- | -- | -- | The Swedish Agency for Marine and Water Management's Regulations on Genetically Modified Aquatic Organisms | Y | 29-Sep-16 | -- | -- | -- |
| -- | -- | -- | The National Board of Forestry's Regulations on the Deliberate Release and Placing on the Market of Genetically Modified Forest Trees. | Y | 29-Sep-16 | -- | -- | -- |
| Switzerland | Yes | Switzerland implemented the Cartagena Protocol with the Ordinance on Transboundary Movements of Genetically Modified Organisms), also referred to as the CartO (Cartagena Ordinance). The CartO aims to fill gaps in the legislation concerning transboundary movements of GMOs in addition to referring to other laws and 'ordinances that regulate the use of GMOs. CartO went into effect on 1 January 2005.References to the Ordinance on the Handling of Organisms in the Environment (CartO articles 2, 5 and 8) were updated in 2008, those to the Ordinance on Handling Organisms in Contained Systems (CartO articles 2 and 5) in 2012,The responsibility for implementing the Cartagena Protocol in Switzerland lies with the Swiss Federal Office for the Environment, FOEN. However, other offices are also implicated (Federal Food Safety and Veterinary Office FSVO; Swiss Federal Office for Agriculture FOAG; and the Swiss Agency for Therapeutic Products, Swissmedic).There are essentially no activities relating to transboundary movements of LMO in Switzerland, due to a gene technology moratorium on deliberate release of LMO and the unwillingness of the Swiss population to buy LMO containing products. In 2005, Swiss voters accepted a five-year moratorium on the commercial use ofGM plants, which lasted until 2010 and has been prolonged twice by the Federal Council, first until 2013 and then until 2017. The moratorium does not concern the deliberate release of LMOs for research purposes, which is allowed after approval of the application from the competent authorities (FOEN). At this moment, two field trials of LMOs were accepted in 2013 and 2014 (cisgenic potato resistant to late blight and transgenic wheat resistant to mildew) and are conducted for research purposes. Furthermore, no import of LMO derived products for feed, food or processing (LMO-FFP) have been conducted during the period of the report, although four LMO are authorized for import as LMO-FFP. | Ordinance on the GM Livestock Feed Catalogue | Y | 29-Sep-16 | -- | -- | 3-Oct-16 | -- | -- | 03-Oct-16 |  |
| Ordinance on the circulation of phytosanitary products | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on the Production and Placing on the Market of Feedstuffs (Animal Feed Ordinance) | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on Production and Marketing of Plant Propagation Material | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on Foodstuffs and Utility Articles | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on the Handling of Organisms in the Environment (Release Ordinance, RO) | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on the contained use of organisms | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Federal Law relating to Non-human Gene Technology | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Federal Law on Epizootic Diseases | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Federal Act on the Protection of the Environment (Environmental Protection Act, EPA) | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Federal Act on fight to diseases transmissible of humans (Federal Act on Epidemics) | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on the Placing on the Market of Phytosanitary Products | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on the Transboundary Movements of Genetically Modified Organisms (Cartagena Ordinance, CartO) | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Ordinance on genetically modified food | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Federal Constitution of the Swiss Confederation; Art. 120: Gene Technology in the Non-Human Field | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Federal Act on animal protection | Y | 03-Oct-16 | -- | -- | -- | -- | -- | -- |
| Tajikistan | Yes | The Republic of Tajikistan ratified the Cartagena Protocol, which is confirmed by the Decree of Majlisi Namoyandagon Majlisi Oli (Lower Parliament) of the Republic of Tajikistan "On ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity» № 932 dated 22.10.2003.  In April 2004, at national workshop with stakeholders responsible authorities developed and approved Biosafety Framework, which included the National Biosafety Framework.  Policy and legislative frameworks for the implementation of the Cartagena Protocol was adopted in February 2005 of the Law "On Biosafety" (Resolution by the Majlisi Milli Majlisi Oli (Higher Parliament) of the Republic of Tajikistan on the adoption of the Law "On biological safety», № 602 dated 11.02.2005 ).  National Biodiversity and Biosafety Center (NBBC), created by the Government of the Republic of Tajikistan in 2003 was a key agency for the implementation of obligations under the Cartagena Protocol and the establishment of coordination structures on Biosafety. NBBC responsible for liaison with the Secretariat of the Convention on Biological Diversity (CBD) and is working as the focal point for the formation of the Biosafety Clearing House Mechanism (BCH).  Despite the existence of legal means of implementation of laws in Tajikistan (Law on Biosafety), the institutional framework has not been created, but operates a diversified structure of preventive measures (various inspection services: pest control, variety testing, etc.). The NBBC in consultation with UNEP prepares and implements an appropriate project for the establishment of a national biosafety system in Tajikistan through the establishment and building of capacity, with the approval of the GEF. | Law on Biological Safety | Y | 03-Oct-16 | -- | -- | 3-Oct-16 | National Biosafety Framework | Y | 03-Oct-16 |  |
| Thailand | Yes | None | Plant Quarantine Act B.E. 2507 Amended by Plant Quarantine Act (No.2) B.E. 2542 and Plant Quarantine Act (No.3) B.E. 2551 | N | 03-Oct-16 | Manual for GM plant import and confined experiment permission request | N | 3-Oct-16 | Biosafety guideline for work related to modern biotechnology and genetic engineering | N | 03-Oct-16 | Links missing / incorrect |
| Agricultural Standards Act, B.E. 2551 (2008) | N | 03-Oct-16 | Notification of the National Committee on Agricultural Commodity and Food Standards, Subject: Thai Agricultural Commodity and Food, Standard: Principles for the Risk Analysis of Foods Derived from Modern Biotechnology B.E.2549 (2006) (TAS 9010-2006) | Y | 3-Oct-16 | Importation of Aquatic Animals into Thailand | Y | 03-Oct-16 |
| -- | -- | -- | Notification of the Ministry of Public Health (No. 251), B.E. 2545 (2002) entitled "Labelling of Food Obtained Through Certain Techniques of Genetic Modification/ Genetic Engineering" | N | 3-Oct-16 | Biosafety guidelines for contained use of genetically modified microorganisms at pilot and industrail scales | N | 03-Oct-16 |
| -- | -- | -- | -- | -- | -- | Notification of the Ministry of Public Health (No.215), B.E.2544 (2001) entitled "Prescribed prohibited foods to be produced, imported or sold Cry9C Corn" and additional amendments (Notification of the Ministry of Public Health No.217, B.E. 2544 (2001) and No.246, B.E. 2544 (2001) | N | 03-Oct-16 |
| -- | -- | -- | -- | -- | -- | Notification of the National Committee on Agricultural Commodity and Food Standards, Subject: Thai Agricultural Commodity and Food Standard: Assessment of Possible Allergenicity B.E.2549 (2006) (TAS 9011-2006) | Y | 03-Oct-16 |
| -- | -- | -- | -- | -- | -- | Notification of the National Committee on Agricultural Commodity and Food Standards, Subject: Thai Agricultural Commodity and Food Standard: Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants B.E.2549 (2006) (TAS 9012-2006) | Y | 03-Oct-16 |
| -- | -- | -- | -- | -- | -- | Notification of the National Committee on Agricultural Commodity and Food Standards, Subject: Thai Agricultural Commodity and Food Standard: Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms B.E.2549 (2006) (TAS 9013-2006) | Y | 03-Oct-16 |
| Togo | Yes | 1- National Biosafety Framework is adopted on December 6th , 2004; Further to the ratification of the Cartagena Protocol on July 2nd, 2004, Togo has adopted on December 6 of that same year, its National Biosafety Framework. This framework provides guidance for the establishment of:  - Institutional and legal framework for Biosafety management,  - Biotechnology risks assessment and management mechanisms,  - Public awareness and participation system. Togo adopted its Law on Biosafety on the 6th January, 2009 by the Act No.2009-001. The Law on Biosafety in Togo was promulgated but it will not enter into force unless its regulations are adopted and implemented and also unless technical capacity building is made before. The legal and institutional frameworks related to plant protection, food and human health, animals quarantine, intellectual property rights and the environmental impact assessment study are, inter alia, related frameworks to that of biosafety. 2- The Act No. 2009-001 of 6th January 2009 on biosafety. | Loi sur la prévention des risques biotechnologiques | Y | 03-Oct-16 | -- | -- | 3-Oct-16 | Draft National Biosafety Framework | Y | 03-Oct-16 |  |
| Tonga | Yes | -- | Biosafety Act 2009 | Y | 03-Oct-16 | -- | -- | 3-Oct-16 | Draft National Biosafety Framework | Y | 03-Oct-16 |  |
| Trinidad and Tobago | No | Due to a recent change in government in 2015, the Ministry responsible for Biosafety is yet to be confirmed. However, a national biosafety policy has been approved (April 2014) and the framework document will be finalized once the relevant Ministry has been identified. These documents make provisions for the hiring of permanent staff and guidelines on administrative procedures. Also, after a review of current legislation, new legislation is being drafted to implement the Cartagena Protocol | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | -- | -- | 19-Jun-17 | No instruments uploaded to the BCH |
| Tunisia | Partially | La Tunisie a pris des mesures juridiques, administratives et autres nécessaires à la mise en œuvre du Protocole à savoir : - La mise en place d'une commission nationale technique consultative sur la biosécurité (CTB) et trois sous commissions : 1/ Aspects institutionnels et réglementaires; 2/ Réseau national des laboratoires; 3/ Education, sensibilisation et communication du public. - Elaboration des guides techniques (Analyse des risques biologiques , détection et quantification des OGM, guide introductif sur les biotechnologies et la biosécurité) (publié en juin 2015); - Elaboration d’un projet de loi sur la biosécurité : OGM, Agents Pathogènes et Espèces Exotiques Envahissantes ( phase finale); - Création d’un réseau de laboratoires de contrôles officiels (détection, identification et quantification) des Organismes Génétiquement Modifiés et produits dérivés et son intégration dans la région Mena (Banque Nationale des Génes "BNG", Laboratoire Central d'Analyses et d'Essaies "LCAE", Centre Technique Agro-alimentaire "CTAA", Laboratoire de Contrôle des Semences et Plants "LCSP") (2013 / Signature de la convention en cours); - Elaboration d’un plan national de communication et de sensibilisation du public (juin 2015); - La mise en œuvre d’un programme de renforcement des capacités nationales « formations & sensibilisation »(2009 – 2015)  Actions projetées (2016 – 2020) - Création de la Haute Instance Nationale de Biosécurité et la promulgation de la loi; - Accréditation des laboratoires de contrôles officiels des OGM; - Renforcement des capacités nationales en matière d’évaluation et de gestion des risques biologiques; - Initier le même processus pour l’utilisation des agents pathogènes et les espèces exotiques envahissantes (réseau laboratoire , plan de surveillance et de communications, mise en place des mesures de biosécurité et de biosûreté , ect…) | Projet de la loi sur la biosécurité en Tunisie | Y | 03-Oct-16 | -- | -- | 3-Oct-16 | -- | -- | 03-Oct-16 | Instruments missing  (see free text) |
| Turkey | Yes | None | Biosafety Law | Y | 03-Oct-16 | The Regulation on Genetically Modified Organisms and Products | Y | 3-Oct-16 | Draft National Biosafety Framework | Y | 03-Oct-16 |  |
| -- | -- | -- | The Regulation Connected with Working Procedure and Principles of Biosafety Board and Committees | Y | 3-Oct-16 | -- | -- | -- |
| Uganda | Partially | A NATIONAL BIOTECHNOLOGY AND BIOSAFETY POLICY WAS PASSED IN 2008. THE BIOSAFETY LAW IS STILL IN DRAFT FORM BEING SUBJECTED TO THE DUE PROCESS OF PARLIAMENT. A NATIONAL BIOSAFETY COMMITTEE WAS ESTABLISHED IN 1996 (IN ACCORDANCE WITH THE NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY ACT, 2000) TO ADVISE THE CNA ON ALL MATTERS OF RELEVANCE TO BIOSAFETY AND IT IS DOING ITS WORK, PENDING THE COMPLETION OF THE LAW. THE NATIONAL BIOSAFETY FRAMEWORK WAS COMPLETED AND SUBMITTED TO THE BCH | -- | -- | 03-Oct-16 | -- | -- | 3-Oct-16 | -- | -- | 03-Oct-16 | Draft law awaiting approval (see free text)   Instruments missing  (see free text)   No instruments uploaded to the BCH |
| Ukraine | Yes | During the reporting period the following legislative acts were adopted: Law of Ukraine of 23.02.2012 № 4441-VI “On amending the Law of Ukraine “On the State Biosafety System in Creating, Testing, Transporting, and Using Genetically Modified Organisms” The amendments introduce the provisions on: regulation of some issues regarding placing into market of GMOs and products containing GMOs or produced with their use; establishing requirements that business entities, during first placing into market of product containing GMOs or produced with their use, should prepare a written declaration, in which is necessarily indicated that product contains GMOs or produced with their use, as well as the registration number of such products in the State Register of GMOs; necessity to establish the Scientific and methodological centre on the identification of genetically modified organisms for the purpose of scientific and methodological coordination of testing laboratories to determine the content of GMOs in products; establishing a network of testing laboratories to determine GMO content in products to the state control over the placing in the market of GMOs and products containing GMOs or produced with their use. Law of Ukraine of 16.10.2012 № 5456-VI “On amending the some laws of Ukraine on authority optimization of executive bodies in the field of ecology and natural resources, Including at the local level” The amendments clarify the competence of central executive bodies, in particular by the separation of their functions on the formation or implementation of state policy in relevant areas. Law of Ukraine of 27.03.2014 № 1170-VII “On amending the some laws of Ukraine in connection with the adoption of the Law of Ukraine "On information" and the Law of Ukraine "On access to public Information”” The amendments clarify access to information on use of GMOs – the information on the potential impact of GMOs on human health and the environment cannot be attributed to information with limited access. Law of Ukraine of 09.04.2014 № 1193-VII “On amending the some laws of Ukraine on reducing the number of permits” The amendments cancel the provisions on the need to obtain permission to import GMOs intended for research purposes or state field trials.Law of Ukraine of 22.07.2014 № 1602-VII “On amending the some laws of Ukraine on food products” The amendments cancel the provisions on: state registration of products containing GMOs or produced with their use (the object for registration is the GMOs used for the production of such products only); regulation of the import of feed and food produced from GMOs; carrying out of sanitary and epidemiological expertise of products produced with using GMOs to substantiate its conclusion on the safety of the products for human health and life; approval of the list of feed, feed additives and veterinary drugs, in which the content of GMOs should be under control. Law of Ukraine of 02.03.2015 № 222-VIII “On licensing of economic activities”  The cancellation of the provisions regarding licensing of organizations and enterprises that are engaged in genetic engineering activities in closed systems. Resolution of the Cabinet of Ministers of Ukraine of 10 October 2012 № 761-p "On appointment of the scientific institution, authorized to perform functions of the Scientific and methodological centre for the determination of GMOs” The State Institution "Institute of Food Biotechnology and Genomics of the National Academy of Sciences of Ukraine" is authorized to perform the functions of Scientific and methodological centre for the determination of genetically modified organisms. The purpose of the Centre activity is to carry referent functions, ensuring the implementation of modern methods of detection of genetically modified organisms, the implementation of scientific and methodological coordination of testing laboratories to determine the content of genetically modified organisms in products. Act of Cabinet of Ministers of Ukraine of 11.07.2013 № 700 “On approval of the regulation on network of testing laboratories to determine the content of genetically modified organisms in products” The Act lays down the general principles and main tasks for operating network testing laboratories to determine the content of genetically modified organisms in products. Act of Cabinet of Ministers of Ukraine of 11.07.2013 № 701 “On approval of the regulation on scientific and methodological centre for the determination of genetically modified organisms” The Act regulates activity of scientific and methodological centre on the identification of genetically modified organisms. The purpose of the centre activity is to carry referent functions, ensuring the implementation of modern methods of detection of genetically modified organisms, the implementation of scientific and methodological coordination of testing laboratories to determine the content of genetically modified organisms in products. Act of Cabinet of Ministers of Ukraine of 28.08.2013 № 808 “On approval of list of activities and objects of high environmental hazard” The Act approves the list of activities and objects of high environmental hazard.  Genetically engineering activity (in open and closed systems), placing on the market of genetically modified organisms and products obtained with their use are included into the list of activities and objects of high environmental hazard. Order of the Ministry of Health of Ukraine of 04.01.2013 № 3 “On Amendments to the Order of the Ministry of Health of Ukraine of 26.08.2005 № 426 and the annulment of some orders of the Ministry of Health on the registration of medicinal products” (order is registered by Ministry of Justice of Ukraine 15.03.2013 № 425/22957) The order specifies that an application for state registration of medicinal products, if needed, should contain a resume of the risk assessment, in accordance with the Law of Ukraine “On the State Biosafety System in Creating, Testing, Transporting, and Using Genetically Modified Organisms”, including: a copy of the written authorization for deliberate release of GMOs into the environment for research purposes, issued by the competent authority of the country of origin, data, including detection and identification methods, as well as unique code of the GMO and any additional information on the GMO or substance that is important for environmental risk assessments; a report on environmental risk assessments. Order of the Ministry of Health of Ukraine of 28.12.2011 № 986 “On approval of standards for the provision of administrative services (registered by the Ministry of Justice of Ukraine 16.03.2012 № 404/20717)” The Order approves, inter alia, the Standard for the provision of administrative services by the Ministry of Health of Ukraine on the state registration of genetically modified organisms as sources of food, as well as food products, cosmetics and pharmaceuticals that contain GMOs or produced with their use. Standard registered by the Ministry of Justice of Ukraine on March 16 2012 r. № 407/20720. The Standard requires that the application for state registration of genetically modified organisms as sources of food, as well as food products, cosmetics and pharmaceuticals that contain GMOs or produced with their use should be accompanied by: Conclusion of the State sanitary-epidemiological service; Conclusion of the state ecological expertise (if products contain genetically modified organisms or their parts, which are able to reproduce itself or transfer hereditary factors). | Law of Ukraine "On the State Biosafety System in Creating, Testing, Transporting, and Using Genetically Modified Organisms" | Y | 04-Oct-16 | Act of Cabinet of Ministers of Ukraine On Approval of the Permit Issuance Order for State Field Trial (Testing) of Genetically Modified Organisms in an Open System of April 2, 2009 №308 | Y | 4-Oct-16 | -- | -- | 04-Oct-16 | Instruments missing  (see free text) |
| -- | -- | -- | Order of the Ministry of Ecology and Natural Resources of Ukraine of February 7, 2011 № 36 "On Approval of Criteria for Risk Assessment of the Potential Impact of Genetically Modified Organisms on the Natural Environment" | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine On Approval of the Permit Issuance Order for Transit of Unregistered in Ukraine Genetically Modified Organisms | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine On Approval of the State Registration Order of Genetically Modified Organisms as Sources for Food, as well as Food, Cosmetics and Pharmaceuticals that Contain, Derived from GMOs or Obtained from Their Use | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine On Some Issues of Carrying out the State Field Trials and the Registration of Genetically Modified Organisms of Agricultural Plant Varieties of July 23, 2009, №808. | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine On the Implementation of Article 7 of the Law of Ukraine "On the State Biosafety System in Creating, Testing, Transporting, and Using Genetically Modified Organisms" of October 12, 2010, № 919. | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine On Approval of the Interim Safety Criteria for the use of Genetically Modified Organisms and Genetic Engineering Activity in a Closed System of October 16, 2008, №922 | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine of 11.07.2013 № 700 "On approval of the regulation on network of testing laboratories to determine the content of genetically modified organisms in products" | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine of 11.07.2013 № 701 On approval of the regulation on scientific and methodological centre for the determination of genetically modified organisms | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine of 28.08.2013 № 808 On approval of list of activities and objects of high environmental hazard | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Act of Cabinet of Ministers of Ukraine of May 13, 2009 № 468 "On approval of the labeling of food products containing genetically modified organisms or produced with their use and are placed on the market" | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Order of the Ministry of Health Protection of Ukraine of 09.11.2010 № 971 "On approval of the list of food products in respect of which the content of genetically modified organisms is controlled" (order is registered by Ministry of Justice of Ukraine of 13.12.2010 № 1248/18543) | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Order of the Ministry of Health of Ukraine from 04.01.2013 № 3 On Amendments to the Order of the Ministry of Health of Ukraine dated August 26, 2005 № 426 and the annulment of some orders of the Ministry of Health on the registration of medicinal products (order is registered by Ministry of Justice of Ukraine від 15.03.2013 № 425/22957) | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Standard for the provision of administrative services by the Ministry of Health of Ukraine on the state registration of genetically modified organisms as sources of food, as well as food products, cosmetics and pharmaceuticals that contain GMOs or produced with their use. | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Resolution of the Cabinet of Ministers of Ukraine of 10 October 2012 № 761-p "On appointment of the scientific institution, authorized to perform functions of the Scientific and methodological centre for the determination of GMOs. | Y | 4-Oct-16 | -- | -- | -- |
| United Arab Emirates | No | (Unofficial translation): The Emirates Authority for Standardization and Metrology issuing the following technical regulations and standards:  • GSO CAC / GL 45: 2009: Guidelines for assessing the safety of foods derived from genetically modified plants and (DNO A) • GSO CAC / GL 46: 2009:: toolkit to assess the safety of foods produced using genetically modified organisms (GMOs) the (DNA) (Standard Specification) • GSO ISO TS 21098: 2009: Food-based methods of DNA analysis of living genetically modified organisms and products derived from them - • information to be disclosed and add product to methods of ISO --21 569 or 21570 or 21571 specification (Standard) • GSO ISO 21570: 2009: food analysis methods for the detection of living modified organisms (GMOs) and derived products based methods of quantitative DNA (Standard). • GSO 2142: 2011: General requirements for food and feed manufacturers of genetically modified (technical regulations).  There are some domestic legislation runs organisms and genetically modified products in the UAE, such as: - [B] Local Order No. (11) for the year 2003, on public health and safety of the community in the Emirate of Dubai and its implementing regulations. [/ B] The state in the process of preparing a federal law regarding the biosafety of genetically modified organisms and their products,  - [B] as well as the process of preparing a national biosafety framework. In addition to the Law on Biosafety [/ b] | -- | -- | 04-Oct-16 | -- | -- | 4-Oct-16 | -- | -- | 04-Oct-16 | No instruments uploaded to the BCH |
| United Kingdom of Great Britain and Northern Ireland | Yes | See the EU report for applicable Regulations and Directives. The UK has introduced domestic legislation to implement EU legislation relating to GMOs as follows: Part VI of the Environmental Protection Act 1990 (EPA) is the primary legislation giving general powers and responsibilities to control the deliberate release of GMOs in Britain. - The Genetically Modified Organisms (Deliberate Release) Regulations 2002 (SI 2443/2002, as amended by SI 2411/2002); The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (SSI 541/2002, as amended by SSI 439/2004); The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (SI 3188/2002, as amended by SI 1913/2005); The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003 (SI 167/2003, as amended by SI 206/2003 and SI 272/2005) - The Genetically Modified Animal Feed (England) Regulations 2004 (SI 2334/2004); The Genetically Modified Animal Feed (Scotland) Regulations 2004 (SSI 433/2004); The Genetically Modified Animal Feed (Wales) Regulations 2004 (SI 3221/2004); The Genetically Modified Animal Feed Regulations (Northern Ireland) 2004 (SI 386/2004) - The Genetically Modified Food (England) Regulations 2004 (SI 2335/2004); The Genetically Modified Food (Scotland) Regulations 2004 (SSI 432/2004); The Genetically Modified Food (Wales) Regulations 2004 (SI 3220/2004); The Genetically Modified Food Regulations (Northern Ireland) 2004 (SI 385/2004) - The Genetically Modified Organisms (Transboundary Movement) (England) Regulations 2004 (SI 2692/2004); The Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005 (SSI 316/2005); The Genetically Modified Organisms (Transboundary Movement) (Wales) Regulations 2005 (SI 1912/2005); The Genetically Modified Organisms (Transboundary Movements) Regulations (Northern Ireland) 2005 (SI 209/2005) - The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004 (SI 2412/2004); The Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004 (SSI 438/2004); The Genetically Modified Organisms (Traceability and Labelling) (Wales) Regulations 2005 (SI 1914/2005); The Genetically Modified Organisms (Traceability and Labelling) Regulations (Northern Ireland) 2005 (SI 271/2005)  - The Genetically Modified Organisms (Containded Use) Regulations 2014 (SI 2014/1663) | The Environmental Protection Act | Y | 04-Oct-16 | -- | -- | 4-Oct-16 | -- | -- | 04-Oct-16 | Instruments missing  (see free text) |
| Genetically Modified Organisms (Deliberate Release) (Wales) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Deliberate Release) (Scotland) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Deliberate Release) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Animal Feed (Northern Ireland)  \*\* NB this instrument has two entries in the BCH | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Deliberate Release) (Northern Ireland) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Animal Feed (Scotland) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Animal Feed (Wales) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Animal Feed (England) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Animal Feed (Scotland) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Transboundary Movements) (England) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Transboundary Movement) Scotland | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organism (Transboundary Movements) Wales | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Transboundary Movements) Northern Ireland | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Food (England) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Food (Wales) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Food (Northern Ireland) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Traceability and Labelling) England | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Traceability and Labelling) Scotland | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Traceability and Labelling) Wales | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Organisms (Traceability and Labelling) Northern Ireland | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| Genetically Modified Food (Scotland) | Y | 04-Oct-16 | -- | -- | -- | -- | -- | -- |
| United Republic of Tanzania | Partially | None | -- | -- | 29-Sep-16 | -- | -- | 29-Sep-16 | Draft National Biosafety Framework | Y | 29-Sep-16 | Only instrument uploaded to the BCH is the Draft National Biosafety Framework |
| Uruguay | Yes | Antecedentes: Comisión Asesora de Análisis de Riesgo en la Dirección General de Servicios Agrícolas del MGAP para analizar autorización soja 40-3-2 (año 1996); Comisión de Evaluación de Riesgo de Vegetales Genéticamente Modificados (CERV), creada por Decreto 249/2000 como organismo asesor del poder Ejecutivo, para analizar autorización maíces MON810 (año 2003) y BT11 (año 2004).  El Decreto 353/008 (y textos modificativos Decs.535/008 y 280/009) es la norma vigente actualmente en materia de bioseguridad de vegetales genéticamente modificados a través de la cual se materializa la salida de la etapa de moratoria establecida previamente (Decreto 037/007), definiéndose la actual estructura institucional para vegetales y sus partes genéticamente modificados (VGMs). Estructura institucional creada por Decreto 353/008: - Gabinete Nacional de Bioseguridad (GNBio), integrado por los Ministros de Ganadería, Agricultura y Pesca (ejerce la presidencia); Salud Pública; Economía y Finanzas; Vivienda, Ordenamiento Territorial y Medio Ambiente; Relaciones Exteriores; Industria, Energía y Minería. El GNBio autoriza, previo trámite correspondiente, las solicitudes de VGMs que ingresan al país; define lineamientos de la política nacional de bioseguridad de VGMs.  - Comisión para la Gestión del Riesgo (CGR); integrada por un delegado de cada uno de los Ministerios del GNBio. Lleva a cabo las actividades para la ejecución del sistema; entre otras funciones, elabora los Términos de Referencia que orientan la Evaluación de Riesgo de cada caso analizado, así como la formalización de la comunicación pública.  - Evaluación del Riesgo en Bioseguridad (ERB); es la instancia técnico-científica de la Evaluación de Riesgo. Entre sus funciones, está la de asegurar el análisis caso a caso de la Evaluación de Riesgo sobre bases científicas objetivas, promoviendo el trabajo en red entre evaluadores. Para llevarlo a cabo, se vincula con el Comité de Articulación Institucional.  - Comité de Articulación Institucional (CAI); es la instancia auxiliar básica del proceso de Evaluación de Riesgo integrada por delegados de diferentes organismos públicos, de investigación y la Academia, quienes elaboran las evaluaciones de riesgo respectivas. Además, la Ley Nº 17.283 de Protección del Medio Ambiente (año 2000), establece en materia de bioseguridad (art.23) que el Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente dicte las providencias y aplique las medidas necesarias para prevenir y controlar los riesgos ambientales derivados de la creación, manipulación, utilización o liberación de OGMs en cuanto pudieran afectar la conservación y utilización sostenible de la diversidad biológica y el ambiente.  Se está trabajando actualmente en la elaboración de un proyecto de Ley Nacional de Bioseguridad para todos los organismos genéticamente modificados a ser enviado al Parlamento Nacional. | Ley 18792 mediante la cual se aprueba el Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica | N | 04-Oct-16 | Decreto 353/008. Bioseguridad de vegetales y sus partes genéticamente modificadas | N | 4-Oct-16 | Draft National Biosafety Framework | Y | 04-Oct-16 | Links missing / incorrect |
|
| Venezuela (Bolivarian Republic of) | Yes | None | Ley de gestion de la diversidad biologica | Y | 19-Jun-17 | Decreto N° 4.334. Creacion Comisión Nacional de Bioseguridad | Y | 19-Jun-17 | NORMAS PARA REGULAR LA INTRODUCIÓN Y PROPAGACIÓN DE ESPECIES EXOTICAS DE LA FLORA Y FAUNA SILVESTRES Y ACUATICAS | Y | 19-Jun-17 | Some links missing / incorrect |
| Resolucion conjunta sobre organizacion y funcionamiento de la Comision Nacional de Bioseguridad | N | 19-Jun-17 | NORMAS SOBRE EVALUACION AMBIENTAL DE ACTIVIDADES SUSUCEPTIBLES DE DEGRADAR EL AMBIENTE | Y | 19-Jun-17 | Draft National Biosafety Framework | Y | 19-Jun-17 |
| -- | -- | -- | -- | -- | -- | Estrategia Nacional para la Conservación de la Diversidad Biológica | Y | 19-Jun-17 |
| -- | -- | -- | -- | -- | -- | National Strategy for the Conservation of Biological Diversity | Y | 19-Jun-17 |
| -- | -- | -- | -- | -- | -- | ESTRATEGIA NACIONAL PARA LA CONSERVACIÓN DE LA DIVERSIDAD BIOLÓGICA 2010-2020 y su Plan de Acción Nacional | Y | 19-Jun-17 |
| Viet Nam | Yes | Vietnam has established the regulation regarding biosafety of GMOs:\*) The Laws:- The Law on Biodiversity No. 20/2008/QH12 dated 13 November, 2008 of The National Assembly: Article 65 to 69.- The Law on Food Safety No. 55/2010/QH12 dated 17 June, 2010 of The National Assembly.\*) The Decrees: - Decree number 69/2010/ND-CP dated 21 June, 2010 of Government on Biosafety of GMOs, Genetic specimen and Products Derived from GMOs.- Decree number 108/2011/ND-CP dated 30 November, 2011 of Government to amending some articles of the Decree No. 69/2010/ND-CP dated June 6th, 2010 of the Government on Biosafety of GMOs, Genetic specimen and Products Derived from GMOs.- Decree number 38/2012/ND-CP dated 25 April, 2012 of Government detailed regulations for implementation some articles of Law on Food safety.- Decree number 179/2013/ND-CP dated 14 November, 2013 of Government on the sanction of administrative violations in the domain of environmental protection.\* ) The Decisions:- Decision number 79/2007/QD-TTg dated 31 May, 2007; Decision number 102/2007/QD-TTg dated 10 July, 2007 of Prime Minister promulgating comprehensive plan to strengthen management capacity in Biosafety of GMOs, goods and products originating from GMOs until 2010, as well as implementation of Cartagena Protocol on Biosafety.- \* The Circulars: Circular number 69/2009/TT-BNNPTNT dated 27 October, 2009 of Minister of Agriculture and Rural development  Circular number 72/2009/TT-BNNPTNT dated 17 November, 2009 of Minister of Agriculture and Rural development; Circular number 23/2010/TT-BNNPTNT dated 7 April 2010 of Minister of Agriculture and Rural development; Circular number 09/2012/TT-BTNMT dated 22 August, 2012 of Minister of Natural Resources and Environment; Circular number 20/2012/TT-BKHCN dated 20 November, 2012 of Minister of Science and Technology; Circular number 21/2012/TT-BKHCN dated 20 November, 2012 of Minister of Science and Technology; Circular number 08/2013/TT-BTNMT dated 16 May, 2013 of Minister of Natural Resources and Environment; Circular number 13/2013/TT-BTNMT dated 21 June, 2013 of Minister of Natural Resources and Environment; Circular number 02/2014/TT-BNNPTNT dated 24 January, 2014 of Minister of Agriculture and Rural development; Circular number 36/2014/TT-BTC dated 24 March, 2014 of Minister of Finance; Circular number 106/2014/TT-BTC dated 08 August, 2014 of Minister of Finance; Circular number 29/2014/TT-BNNPTNT dated 5 September, 2014 of the Minister of Agriculture and Rural Development; Joint Circular No. 160/2014/TTLT-BTC-BTNMT dated 29 October, 2014 of Minister of Finance and Minister of Natural Resources and Environment The regulations are constantly updated via Vietnam BCH Portal: [www.antoansinhhoc.vn](http://www.antoansinhhoc.vn). | -- | -- | 04-Oct-16 | Decision 102/2007/QD-TTg July 10th 2007 of Prime Minister on the approval of the "Master Scheme of strengthening capacities on biosafety management over genetically modified organisms and products and goods originating from genetically modified organisms until 2010 in order to implement Catargena Protocol on Biosafety" | Y | 4-Oct-16 | Draft National Biosafety Framework | Y | 04-Oct-16 | Instruments missing (see free text) |
| -- | -- | -- | Decree 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Circular 69/2009/TT-BNNPTNT on risk assessment of genetically modified crops to biodiversity and environment | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | No. 108/2011/ND-CP | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Circular stipulated the order and procedure for granting and provoking biosafety certificate for GM crops  \*\* N.B. this instrument has two entries in the BCH, the second one being under "Circular 08/2013/TT-BTNMT" | Y | 4-Oct-16 | -- | -- | -- |
| -- | -- | -- | Circular 02/2014/TT-BNNPTNT | Y | 4-Oct-16 | -- | -- | -- |
| Yemen | Partially | (GOOGLE TRANSLATE, original in Arabic: "The completion of the national framework of Islam biogenic was adopted by the Council of Ministers. There have been some observations on the frame of some of the relevant authorities and have been absorbed but due to emergency conditions experienced by Yemen since 2011 have not been so far the framework approved by the Board of Representatives for not held") | -- | -- | 29-Sep-16 | -- | -- | 29-Sep-16 | National Biosafety Framework | Y | 29-Sep-16 | Links missing / incorrect |
| -- | -- | -- | -- | -- | -- | National Biosafety Framework | N | 29-Sep-16 |
| Zambia | Partially | The National Biosafety Authority (NBA) has a Board which was constituted in July 2013. In addition the following Committees of the Board were appointed:  i) Scientific Advisory Committee; and ii) Finance and Administration Committee. The NBA has since employed seven (7) permanent staff. | THE BIOSAFETY ACT, 2007 | Y | 29-Sep-16 | -- | -- | 29-Sep-16 | NATIONAL BIOTECHNOLOGY AND BIOSAFETY POLICY | Y | 29-Sep-16 |  |
| Zimbabwe | Yes | A provisional biosafety framework was put in place in 1998. In 1998, The Research Act was amended to provide for the management of potentially harmful technologies and undertakings. In 2000, the Research (Biosafety) Regulations were developed and gazetted. A national policy on biotechnology and its safe use was developed in 2005. In 2005, the Government through the National Biotechnology Policy agreed to allocate 0.5% of GDP towards biotechnology research, development, application and regulation. To reinforce the policy framework, a new law establishing the National Biotechnology Authority into place - the National Biotechnology Authority Act [Chap.14.31] of 2006 was gazetted.  There are challenges in accessing biosafety funds which are channelled through the GEF star allocations.] | National Biotechnology Authority Act of 2006 [Cap14:31] | N | 29-Sep-16 | -- | -- | 29-Sep-16 | Biosafety Guidelines | N | 29-Sep-16 | Links missing / incorrect   Instruments missing  (see free text) |

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1. \* The Secretariat encourages members of the Committee to use of the electronic version of this large document in order to avoid printing it. [↑](#footnote-ref-1)
2. As referred to in document CBD/CP/CC/15/2. [↑](#footnote-ref-2)