

**Pandemic Influenza Preparedness Framework for the
sharing of influenza viruses and access to vaccines
and other benefits**

Decision WHA72(12) (2019), paragraph 1(b)

**Summary report on national legislation and regulatory
measures related to influenza¹**

Report by the Director-General

March 2020

¹ Data are valid up to 15 December 2019.

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INTRODUCTION

1. In May 2019, the Health Assembly requested the Director-General, inter alia:

(b) to prepare a report, with inputs from Member States and stakeholders, as appropriate, on the treatment of influenza virus sharing and the public health considerations thereof by existing relevant legislation and regulatory measures, including those implementing the Nagoya Protocol, in consultation with the Secretariat of the Convention on Biological Diversity as appropriate;

The present draft report addresses this request. In line with decision WHA72(12) it is submitted in order to garner relevant input from Member States and stakeholders, following which it will be finalized.

BACKGROUND

2. Further to the request in decision WHA72(12) (2019), paragraph 1(b), this summary report examines “the treatment of influenza virus sharing and the public health considerations thereof by existing relevant legislation and regulatory measures, including those implementing the Nagoya Protocol”. It summarizes the findings of the mapping review of law and policy documents (“instruments”) uploaded to the Access and Benefit-Sharing Clearing-House¹ by Parties to the Convention on Biological Diversity. The data (see Table 1) were analysed as at **15 December 2019**.

¹ <https://absch.cbd.int/> (accessed 15 April 2020).

Table 1. Overview of statistics**Project statistics**

197	Number of States/Parties reviewed
194	Number of WHO Member States reviewed
62	Number of WHO Member States who have uploaded a law or policy document (“instrument”) to the Access and Benefit-Sharing Clearing-House
206	Number of instruments assessed (i.e. including those for which a translation is currently unavailable)
146	Number of instruments reviewed for content (i.e. only those for which a translation is available)

Treaty statistics for WHO Member States

119	Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity
193	Parties to the Convention on Biological Diversity

WHO Member States with an instrument that includes a reference to:

	pathogens
4 (+EU ¹)	- expressly including pathogens
31 (+/ including EU)	- implicitly including pathogens in a broad definition of genetic resources (e.g. microbes and microorganisms)
1	- expressly excluding pathogens (NB: exclusion limited to specific circumstances)
2 (+EU)	the PIP Framework as a specialized instrument
1 (+EU)	influenza (seasonal/pandemic)
2 (+EU)	the International Health Regulations (2005)
4	genetic sequence data/digital sequence information

¹ EU: European Union.

Methodology

- For each WHO Member State, and the European Union, entries tagged in the Access and Benefit-Sharing Clearing-House of the Convention on Biological Diversity¹ as a “legislative, administrative, or policy measure” (instruments) were reviewed. Each instrument was then coded to identify if and how genetic resources were defined in the law or policy instrument. This analysis covered express consideration of pathogens, influenza viruses (both seasonal and those with human pandemic potential) and genetic sequence data. Each instrument was also coded to determine whether it made reference to instruments relevant to influenza virus sharing and public health, including the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits and the International Health Regulations (2005), as well as whether the instrument incorporated relevant provisions under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, including recognition of specialized international access and benefit-sharing instruments (pursuant to Article 4(4) of the Nagoya Protocol) and special considerations (Article 8(b)). The complete coding sheet is provided in Annex 1.

Limitations

- This report is based on an analysis of the law and policy instruments uploaded to the Access and Benefit-Sharing Clearing-House of the Convention on Biological Diversity. These instruments may not fully reflect a WHO Member State’s law or policies implementing the Nagoya Protocol, as there may be laws or policies that have not been uploaded to the Access and Benefit-Sharing Clearing-House or the Member State has more recently updated its uploaded laws and policies. Furthermore, the analysis may change as more instruments are reviewed. Finally, the content of some of the instruments could not be reviewed because of the language in which the documents were provided (see Appendix B).

SUMMARY ANALYSIS

Party status

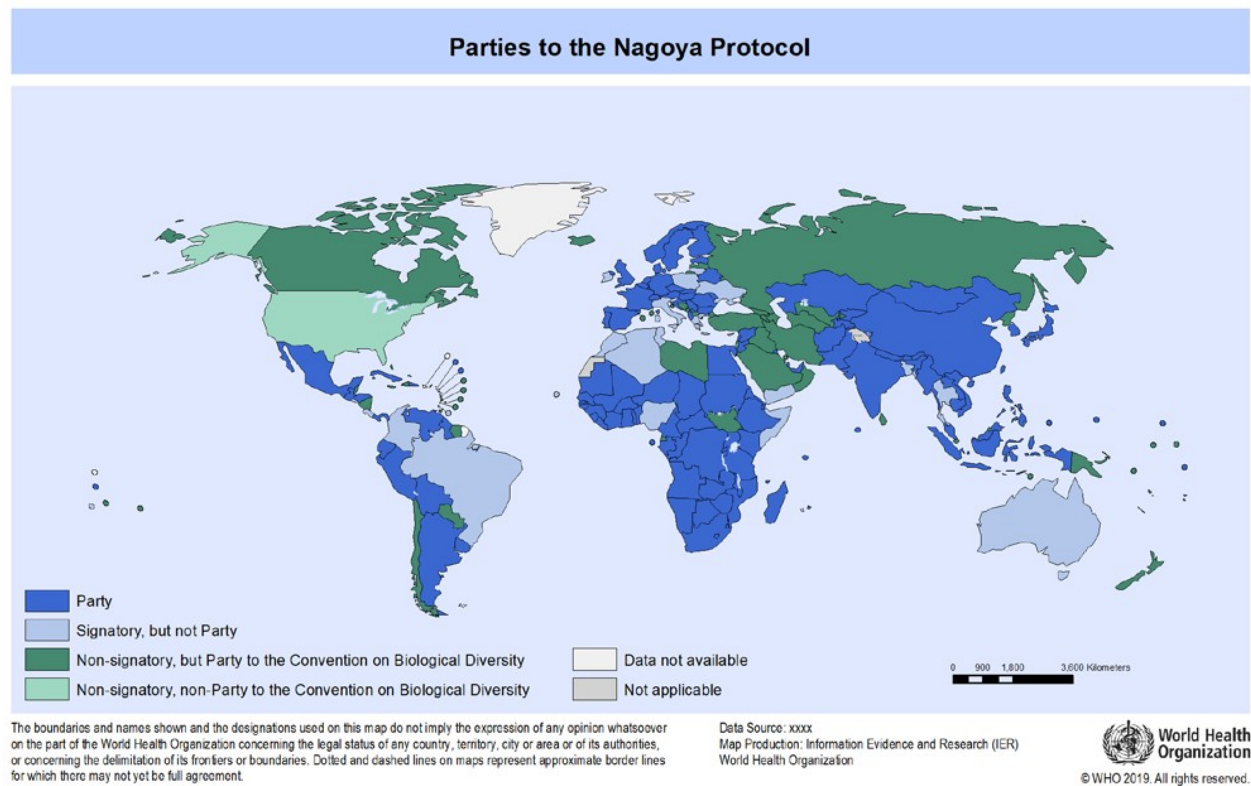
- Of the 120 Parties to the Nagoya Protocol, all but one (the European Union) are WHO Member States. Additionally, 23 WHO Member States are signatories to the Nagoya Protocol, meaning that they have indicated their intention to act in a manner that is consistent with the objectives of the Nagoya Protocol (see Table 2 and Fig. 1).

Table 2. WHO Member States and their Nagoya Protocol status

<i>Nagoya Protocol status</i>	<i>WHO Member States</i>
Party	119
Signatory	23
Non-Party	52
Total	194

¹ <https://absch.cbd.int/> (accessed 15 April 2020).

Fig. 1. WHO Member States and their Nagoya Protocol status (as at 15 December 2019)



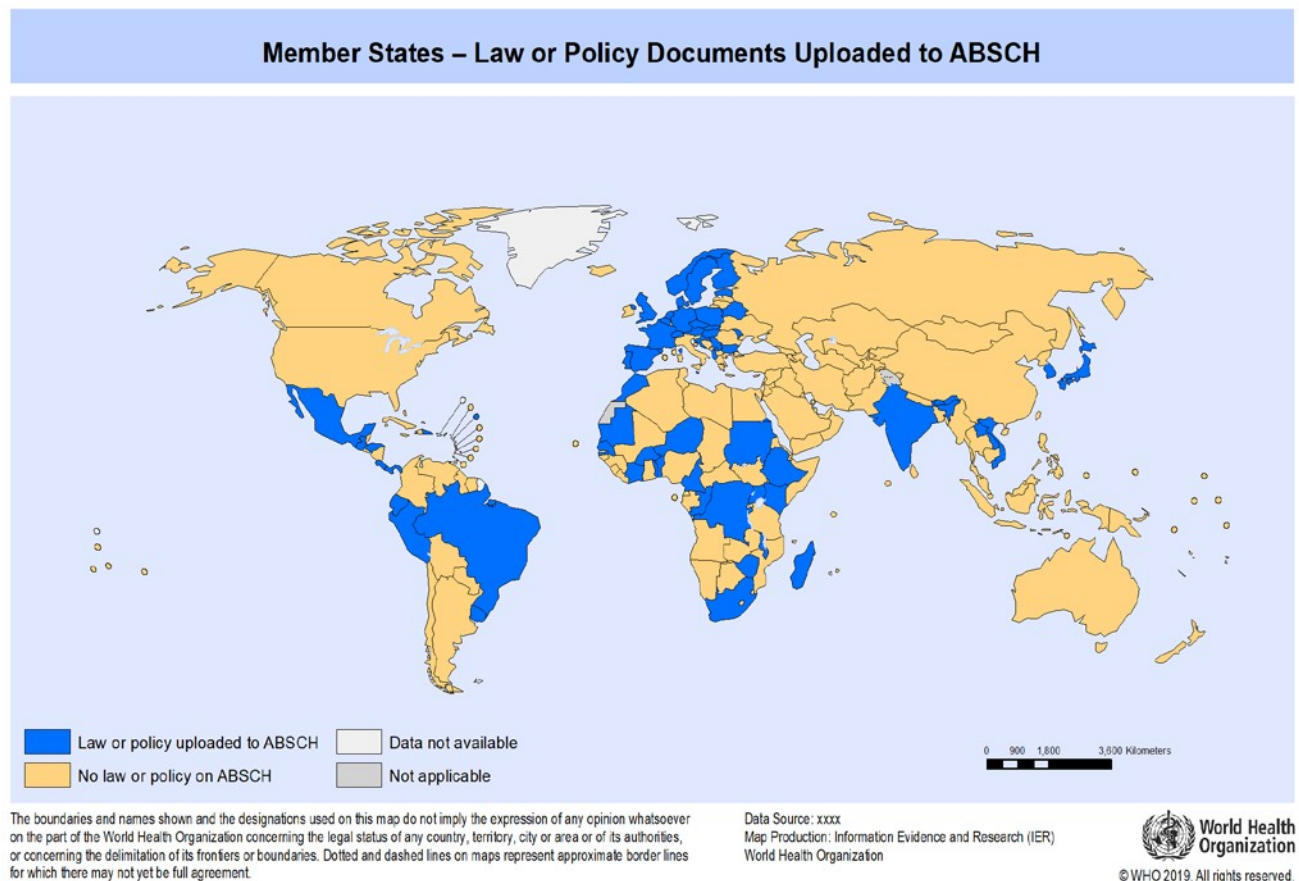
Status regarding the Access and Benefit-Sharing Clearing-House of the Convention on Biological Diversity

6. Of the 194 WHO Member States, 62 (32%) have uploaded at least one law or policy instrument to the Access and Benefit-Sharing Clearing-House and 132 (68%) have uploaded no such instrument (see Table 3 and Fig. 2).

Table 3. WHO Member States and their status regarding the Access and Benefit-Sharing Clearing-House

Status regarding the Access and Benefit-Sharing Clearing-House	WHO Member States
Law or policy instrument uploaded	62 (32%)
No law or policy instrument uploaded	132 (68%)
Total	194

Fig. 2. WHO Member States: law or policy instruments uploaded to the Access and Benefit-Sharing Clearing-House (ABSCH)



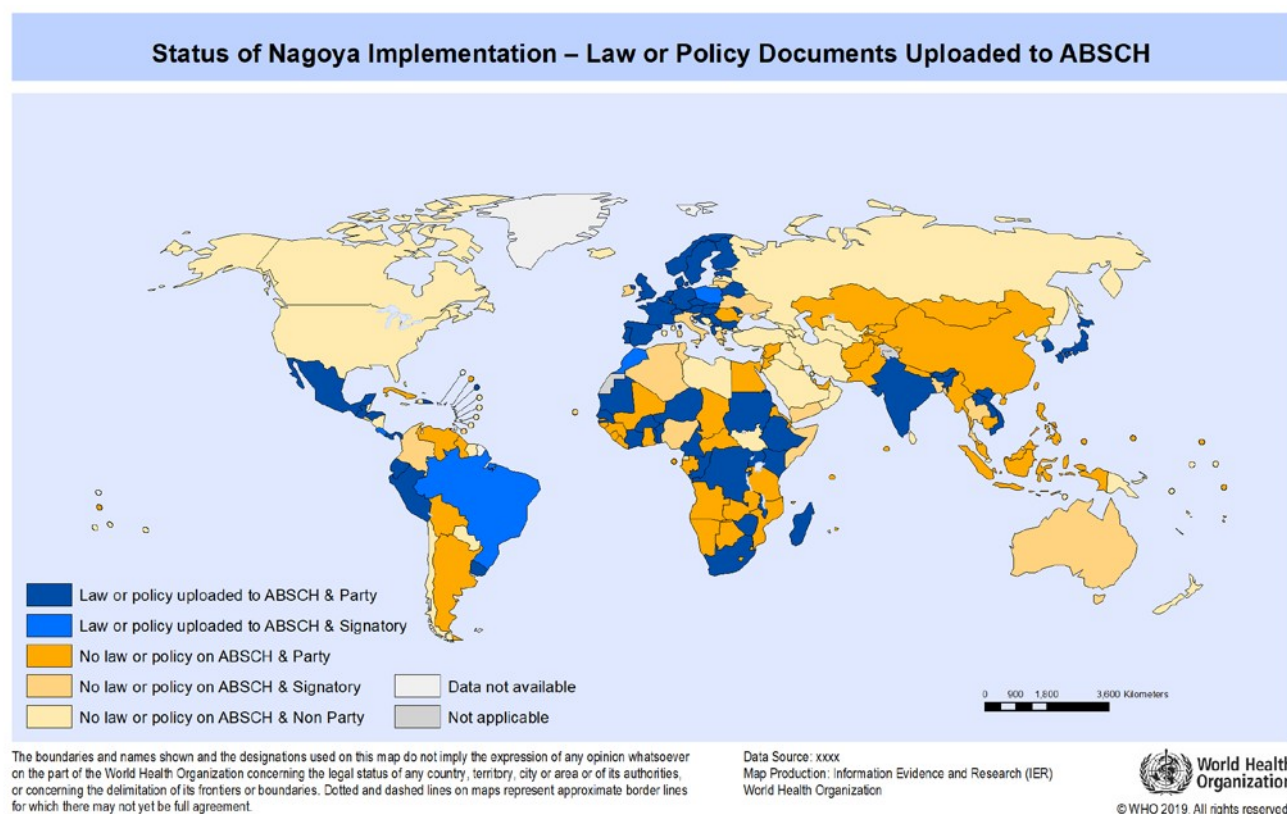
Scope of instruments in the Access and Benefit-Sharing Clearing-House

7. Just under half (49%) of all WHO Member States that are Parties to the Nagoya Protocol have uploaded instruments to the Access and Benefit-Sharing Clearing-House (see Table 4 and Fig. 3). Instruments uploaded include broad access and benefit-sharing legislation as well as those specific to biodiversity conservation, agriculture, plants, or other areas of legislative or national focus. Some instruments apply tangentially, without setting out access and benefit-sharing arrangements, and cover areas such as freedom of information or intellectual property instruments. Instruments include standard material transfer agreements and permits as well as instruments that do not specifically address the scope of implementation of the Nagoya Protocol or how it applies to health.
8. Some of the relevant instruments that WHO Member States have uploaded to the Access and Benefit-Sharing Clearing-House are policy documents, rather than legislation. These include strategy documents for implementation of the Nagoya Protocol adopted more recently than WHO Member States' biodiversity laws.

Table 4. WHO Member States, the Nagoya Protocol and their status regarding the Access and Benefit-Sharing Clearing-House

Status regarding the Access and Benefit-Sharing Clearing-House	Nagoya Protocol status	WHO Member States
Law or policy instrument uploaded	Party	58
No law or policy instrument uploaded	Party	61
Law or policy instrument uploaded	Signatory	4
No law or policy instrument uploaded	Signatory	19
Law or policy instrument uploaded	Non-Party	0
No law or policy instrument on uploaded	Non-Party	52
		194

Fig. 3. Status of Nagoya Protocol implementation and instruments uploaded to the Access and Benefit-Sharing Clearing-House



European Union Member States

1. The European Union is a Party to the Nagoya Protocol and has adopted implementing legislation examined in this analysis. Some European Union Member States have not uploaded national legislation or policy instruments to the Access and Benefit-Sharing Clearing-House, but are still covered by the operation of European Union implementing legislation.¹

¹ These Member States are Cyprus, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Romania and Slovenia.

Pathogens

9. Instruments were examined for their inclusion of pathogens in the definition of genetic resources and in the scope of instruments uploaded to the Access and Benefit-Sharing Clearing-House. As noted above, not all instruments established access and benefit-sharing regimes or contained provisions relevant for ascertaining the scope of implementing legislation.
10. Instruments were classified as:
 - (a) *expressly including pathogens*, that is, pathogens are expressly included in the definitions of genetic resources or expressly considered in the scope of the instrument;
 - (b) *implicitly including pathogens*, that is, pathogens are not expressly included or excluded in the definition of genetic resources or materials or in the scope of the instrument. However, the instrument potentially implies inclusion of pathogens through the use of terms such as “microbe” or “organism”, including the use of the definition under the Convention on Biological Diversity;² or
 - (c) *expressly excluding pathogens*.
11. For the purposes of this analysis, where an instrument used the definitions set out in the Convention of Biological Diversity for “genetic materials” or “genetic resources”, it was classified as (b) *implicitly including pathogens*. In practice, however, some WHO Member States may consider pathogens to be excluded from these definitions, for instance where the term “microbe” is considered to encompass only those microorganisms that do not pose a threat to human health. Furthermore, some WHO Member States may exclude viruses from the definition of microorganism. Further clarification on how WHO Member States interpret these definitions in practice would make it easier to assess the impact of implementation.
12. Four WHO Member States (and the European Union) expressly include pathogens within the scope of instruments, either directly in laws and regulations or indirectly through guidance documentation. Thirty-one WHO Member States (and the European Union, with partial overlap) do not expressly include or exclude pathogens, but implicitly include pathogens within the scope of instruments, either directly in laws and regulations or indirectly through strategy documents or guidance. These instances are summarized below in Table 5 and extracts reproduced in Table 6.
13. Only one WHO Member State expressly excludes pathogens from the operation of prior informed consent obligations in certain circumstances. Exceptions for human health or public health emergencies are explored in further detail below.

Table 5. Definitions of genetic resources in instruments uploaded to the Access and Benefit-Sharing Clearing-House

Pathogens included in the scope of instruments	WHO Member States
(a) pathogens expressly included	4 (+ European Union)
(b) pathogens not expressly included or excluded, potentially implied inclusion as “microbe” or similar term, including use of the definition set out in the Convention on Biological Diversity	31 (+ European Union)
(c) pathogens expressly excluded	1 (NB: exclusion limited to specific circumstances)

² Under the Convention on Biological Diversity, *genetic resources* are defined as “genetic material of actual or potential value”, whereas *genetic material* means “any material of plant, animal, microbial or other

origin containing functional units of heredity”.

Table 6. Pathogens explicitly or implicitly included in the definition of genetic resources

WHO Member State	Instrument title	Extract
(a) expressly including pathogens		
Bulgaria	Biological Diversity Act (2007)	SUPPLEMENTARY PROVISION No. 18a: "Natural genetic resources" shall be all genetic resources of the Republic of Bulgaria of its natural flora, fauna, micota and microorganisms, including pathogens.
Germany	Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014	Section 6.3: The competent authority shall make any determinations concerning the organization of enforcement with regard to human pathogens as a genetic resource and related decisions in agreement with the Robert Koch Institute. Details on the procedure for reaching agreement and, where necessary, other cooperation between the authorities, shall be regulated by means of an administrative arrangement.
Malta	Environment Protection Act (CAP. 549) Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations 2016	<i>NB: While expressly excluding pathogens from the scope of Art.4(3) obligations during an emergency, this includes pathogens within the scope of the provisions in non-emergency situations. Although this is an implied inclusion, it is express acknowledgement of pathogens within the scope of the legislation.</i> Article 14(2)(c): There is no failure to comply with Article 4(3) of Regulation (EU) No. 511/2014 of the European Parliament and of the Council if the competent authority is satisfied that: (c) the use is in accordance with Article 4(8) of the Council Regulation (use of pathogen for the purpose of public health emergency preparedness).
Mauritania	Loi No. 2000-042 Relatives à la protection des végétaux	Article 2: Organismes nuisibles : les ennemis des végétaux ou produits végétaux, appartenant au règne animal ou végétal, y compris les bactéries, virus, mycoplasmes ou autres agents pathogènes
European Union [not a WHO Member State]	Guidance document for Regulation (EU) No. 511/2014 (2016/C 313/01)	Section 1.2: 'Genetic resources' means genetic material of actual or potential value (Article 3(2) of the Regulation; Article 2 of the Convention on Biological Diversity). Section 2.3.3: Utilization excludes genetic resources when used as reference tools. Section 5.1: "Pathogenic organisms that pose a threat to human, animal or plant health are generally within the scope of the Regulation, given that they are covered by the Nagoya Protocol".
(b) pathogens not expressly included or excluded, potentially implied inclusion as a "microbe" or similar term, including use of the definition set out in the Convention on Biological Diversity		

Antigua and Barbuda	Environmental Protection and Management Act, 2015 (No. 11/2015)	Art. 2: “biological resource” means a genetic resource or organism or a part of such a resource or organism, a population, or any other biotic component of an ecosystem with actual or potential use or value for humanity
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WHO Member State	Instrument title	Extract
Antigua and Barbuda	Environmental Protection and Management Act 2019 (No. 10/2019)	Art. 2: “biological resource” includes genetic resources, organisms or parts of such resources or organisms, a population, digital sequence information of such resources or organisms, or any other biotic component of an ecosystem with actual or potential use or value for humanity
Brazil	Provisional Act No. 2.186-16 (August 23, 2001)	Art. 7 (I): Genetic heritage: information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from in situ conditions, including domesticated, or kept in ex situ collections, if collected from in situ conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone
Brazil	Law No. 13.123 (May 20, 2015)	Art. 2(I): Genetic heritage - genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms
Burkina Faso	Loi No. 20/2019 AN Portant Accès aux ressources phytogénétiques pour l'alimentation et l'agriculture et au partage des avantages résultant de leur utilisation	Art. 4: Ressources biologiques: ressources génétiques; organismes ou parties d'organismes, populations ou autres éléments biotiques des écosystèmes ayant une valeur effective ou potentielle pour l'humanité; ressources phytogénétiques: produit d'origine végétale, renfermant le matériel de reproduction et de multiplication végétative, contenant des unités fonctionnelles de l'hérédité et ayant une valeur effective ou potentielle pour l'humanité; ressources phytogénétiques pour l'alimentation et l'agriculture: matériel génétique d'origine végétale ayant une valeur effective ou potentielle pour l'alimentation et l'agriculture
Burkina Faso	Loi No. 070/2015 CNT Portant Loi d'Orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso	Art. 4: Ressources génétiques: matériel génétique ayant une valeur effective ou potentielle; ressources phytogénétiques pour l'alimentation et l'agriculture: matériel génétique d'origine végétale ayant une valeur effective ou potentielle pour l'alimentation et l'agriculture
Burundi	Plan stratégique de recherche sur les ressources génétiques médicinales au Burundi (October 12, 2014)	I.1.2: Types de ressources génétiques médicinales - Concernant les ressources génétiques médicinales, il existe des ressources génétiques médicinales végétales, des ressources génétiques médicinales mycologiques, des ressources génétiques médicinales animales, des ressources génétiques médicinales minérales et autres. Seront prises en comptes ici les ressources génétiques médicinales végétales et les ressources génétiques médicinales mycologiques.
Burundi	Projet de décret sur l'accès aux ressources génétiques et	Art. 3.6: «matériel génétique», tout matériel d'origine végétale, animale, microbienne ou autre, contenant

WHO Member State	Instrument title	Extract
	le partage juste et équitable des avantages qui en découlent	des unités fonctionnelles de l'hérédité; Art 3.7: «ressources génétiques», le matériel génétique ayant une valeur effective ou potentielle;
Cameroon	Stratégie nationale sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation	1.4: Ressources biologiques: ressources génétiques, organismes ou éléments de ceux-ci, populations, ou tout autre élément biotique des écosystèmes ayant une utilisation ou une valeur effective ou potentielle pour l'humanité. Ressources génétiques: matériel génétique ayant une valeur effective ou potentielle.
Congo	Stratégie nationale sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation	Annexe 1 - Glossaire: Matériel génétique d'origine végétale, animale, microbienne ou autre, contenant des unités fonctionnelles de l'hérédité et présentant une valeur réelle ou potentielle (CBD Art. 2). La valeur n'est pas forcément commerciale (c'est à dire monétaire), elle peut être de nature scientifique ou universitaire. L'information de valeur n'est pas forcément génétiques; elle peut consister, par exemple, dans l'information biochimique que contient le matériel. Comme le terme de "valeur", et plus particulièrement la valeur potentielle, n'a pas encore été défini, pratiquement toutes les ressources biologiques répondent à cette définition.
Côte d'Ivoire	Stratégie nationale sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (APA)	Ressource génétique : Matériel génétique ayant une valeur effective ou potentielle.
Czechia	Act No. 38 of 17 May 2018 on conditions of utilisation of genetic resources under the Nagoya Protocol	Section 1 refers to implementation of Regulation (EU) No. 511/2014.
Democratic Republic of the Congo	Loi No. 14/003 Relative à la Conservation de la Nature	Art. 2.40: ressources biologiques: ressources génétiques, organismes ou éléments de ceux-ci, populations ou tout autre élément biotique des écosystèmes ayant une utilisation ou une valeur effective ou potentielle pour l'humanité + Art. 2.41: matériel génétique ayant une valeur effective ou potentielle
Denmark	Act No. 1375 23/12/2012 on sharing benefits arising from the utilisation of genetic resources	Art 2.1: Genetic resources: The functional inherited properties of organisms and naturally occurring biochemical substances resulting from genetic expression or metabolism of the organisms.
Ethiopia	Proclamation No. 482/2006 To Provide for Access to Genetic Resources and Community Knowledge and Community Right	Art. 2.2: "biological resource" includes any genetic resources, organisms or parts thereof, populations or any other biotic component of ecosystem with actual or potential value for humanity. Art. 2.6: "genetic resource" means any genetic material of biological resource containing genetic information having actual or potential value for humanity and it including derivatives

WHO Member State	Instrument title	Extract
Ethiopia	Regulation No. 169/2009 To Provide for Access to Genetic Resources and Community Knowledge, and Community Rights	Art. 2.13: the terms "access", "genetic resource", "community knowledge", "local community", "person", "relevant institution" and "state" shall have the meaning given to them in the Proclamation
Finland	No. 394/2016 Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity	Section 4.1: genetic resources means the genetic resources as defined in Article 3, paragraph 2 of the EU Genetic Resources Regulation.
France	Law No. 108 2016 on Biodiversity	Art. 37 - Sous section 1.1: Utilisation de ressources génétiques : les activités de recherche et de développement sur la composition génétique ou biochimique de tout ou partie d'animaux, de végétaux, de micro-organismes ou autre matériel biologique contenant des unités de l'hérédité, notamment par l'application de la biotechnologie, ainsi que la valorisation de ces ressources génétiques, les applications et la commercialisation qui en découlent
Germany	National Strategy on Biological Diversity	Section A1: "biological diversity is not confined solely to the species of animals, higher plants, mosses, lichens, fungi and microorganisms. I2 Glossary: Genes: Genetic factors, genetic tendencies, genetic units for the inheritance of features, comprised of a defined sequence of nucleotides within the genetic information (DNA).
India	The Biological Diversity Act 2002_No. 18 2003	Section 2(c): means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value-added products) with actual or potential use or value, but does not include human genetic material
Japan	Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2017)	Chapter 1.2.1: "Genetic resources" means genetic material of actual or potential value, where genetic material is material of plant, animal, microbial or other origin containing functional units of heredity
Kenya	Protection of Traditional Knowledge and Cultural Expressions Act 2016	Part I (2): "genetic resources" means microorganisms, plant and animal material including indigenous seeds, genetic plant varieties and traditional animal breeds that contain functional hereditary units and whose management shall also be subject of other relevant legislations; "genetic material" means genetic material of plant, animal, microbial or other origin containing functional units of heredity

WHO State	Member	Instrument title	Extract
Kenya		Environmental Management and Coordination Act 2012 Revision	Part I (2): “biological resources” include genetic resources organisms or parts thereof, populations, or any other biotic component or ecosystems with actual or potential use or value for humanity; “genetic resources” means genetic material of actual or potential value;
Kenya		Wildlife Conservation and Management Act 2013 (EN)	Part I (3): "biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity;
Kenya		The Environmental Management and Coordination Act (No. 9 of 1999) 2006	Part I (1): “genetic material” means any genetic material of plant, animal, microbial or other origin containing functional units of heredity;
Kenya		Access and Benefit Sharing Toolkit	Section 1 (1.1): genetic resources refers to genetic material of actual or potential value whereby genetic material is understood to mean material of plant, animal or microbial or other origin containing functional units of heredity.
Lao People's Democratic Republic		Biotechnology Safety Law	Article 3: Genetic resource refers to biological resources which can transfer the genetic code that contains the basic characteristics of living organisms within a specific ecological area
Lao People's Democratic Republic		Lao National Framework on the Access to Genetic Resources and the Fair and Equitable Sharing of Benefit Arising from their Utilization	Chapter II - 2.2 - Part I - Article 3(9): “Genetic resources” means any material of plant, animal, microorganism and other origin of actual or potential value, that contain functional units of heredity.
Madagascar		Décret n°2017-066 du 31 janvier 2017 portant réglementation de l'accès et du partage des avantages découlant de l'utilisation des ressources génétiques	Included, not expressly excluded. Article 1: Matière génétique: toute matière extraite de plantes, d'animaux, de microbes ou d'autre origine biologique, contenant des unités fonctionnelles d'hérédité
Malawi		Environmental Management Act of 2017	Part I - Article 2: “genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity; “genetic resource” means any genetic material of actual or potential value;
Malawi		Environmental Management Act of 1996	Part I - Article 2: "genetic resource" means any genetic material of actual or potential value;
Malawi		Guidelines on Access to Biological Resources and the Fair and Equitable Sharing of Benefits Arising from their use	Glossary: Genetic material: means any material of plant, animal, microbial or other origin containing functional units of heredity.

WHO Member State	Instrument title	Extract
Morocco	Avant Projet de loi n° 56-17 sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation	Article 3.3: Matériel génétique : tout matériau d'origine végétale, animale, microbienne ou autre qui contient des unités fonctionnelles d'hérédité
Niger	Recueil des textes sur le code rural au Niger	Article 2: Ressources génétiques : les éléments des ressources biologiques d'origine végétale ou animale, microbienne ou autre contenant des unités fonctionnelles de l'hérédité et ayant une valeur effective ou potentielle pour l'humanité.
Niger	Loi No. 98-56 cadre relative à la gestion de l'environnement au Niger	Included. Article 2(r): Ressources génétiques : l'élément des ressources biologiques d'origine végétale, animale, microbienne ou autre, contenant des unités fonctionnelles de l'hérédité et ayant une valeur effective ou potentielle pour l'humanité
Niger	Loi No. 2004-048 du 30 juin 2004 portant loi cadre relative à l'élevage	Included. Article 2: Ressources génétiques: les éléments des ressources biologiques d'origine végétale ou animale, microbienne ou autre contenant des unités fonctionnelles de l'hérédité et ayant une valeur effective ou potentielle pour l'humanité.
Norway	Nature Diversity Act	Section 3(f): (f) genetic material: genes and other hereditary material in any biological material that can be transferred to other organisms with or without the help of technology, except for human genetic material.
Republic of Korea	Act on Access to and Utilization of Genetic Resources and Benefit Sharing	Article 2(1): The term “genetic resources” shall have the meaning ascribed thereto in subparagraph 4 of Article 2 of the Act on the Conservation and Use of Biological Diversity
Senegal	Stratégie et Plan National d'Action APA	Matériel génétique - Le matériel d'origine végétale, animale, microbienne ou autre, contenant des unités fonctionnelles de l'hérédité.
Serbia	The Law on Ratification of the Nagoya Protocol	Article 2(e): "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.
Switzerland	Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance)	Art. 2.a: genetic resources means genetic material of actual or potential value Art. 2.b: genetic material means any material of plant, animal, microbial or other origin that contains functional units of heredity.
Togo	Politique générale en matière d'APA	I. DEFINITIONS: Ressources génétiques : matériel génétique ayant une valeur effective ou potentielle, étant entendu que le «matériel génétique» signifie le matériel d'origine végétale, animale, microbienne ou autre, contenant des unités fonctionnelles de l'hérédité;

WHO Member State	Instrument title	Extract
		Matériel génétique : signifie le «matériel d'origine végétale, animale, microbienne ou autre, contenant des unités fonctionnelles de l'hérédité ».
Uganda	The National Environment (Access To Genetic Resources And Benefit Sharing) Regulations, 2005	Art. 2. "genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity; "genetic resources" means genetic material of actual or potential use or value, and includes their derivative products and intangible components;
United Kingdom of Great Britain and Northern Ireland	The Nagoya Protocol (Compliance) Regulations 2015	Article 2(3): "terms used in these Regulations that are used in the EU Regulation have the meaning they bear in that Regulation" - Art. 2 of Regulation (EU) 511/2014
Viet Nam	Biodiversity Law 2008	Art 3(21): 21. "Genetic specimen means any specimen of plant, animal, microorganism or fungus that possesses functional units of heredity which can regenerate." 22. "Genetic resource includes all species and genetic specimens in nature, conservation areas, biodiversity conservation facilities and scientific research and technological development institutions and in nature"
European Union [not a WHO Member State]	Regulation (EU) No 511/2014	Art. 3.1: 'genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity. Art. 3.2: 'genetic resources' means genetic material of actual or potential value
(c) pathogens expressly excluded		
Malta	Environment Protection Act (CAP. 549) Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations 2016	<i>NB: Pathogens are included consistent with EU Regulation 511/2014, however Malta's law expressly carves out pathogens from specific sub-parts.</i> Article 25: Part VIII (Access to Genetic Resources) of the Flora, Fauna and Natural Habitats Protection Regulations shall be substituted by the following: "PART VIII ACCESS TO GENETIC RESOURCES - 36. (1) Without prejudice to the Trade in Species of Fauna and Flora Regulations, and the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations, 2016 and the related regulations, access to wild fauna and flora to countries other than Malta shall be subject to prior informed consent of the competent authority, provided that wild birds and pathogens are excluded from this provision.

Influenza

14. Instruments were reviewed for their express inclusion of influenza in law or policy instruments uploaded to the Access and Benefit-Sharing Clearing-House. Only one WHO Member State (Malta) expressly includes influenza in its implementing legislation, although the legislation did not differentiate between seasonal and pandemic influenza. However, the European Union implementing law, which covered 28 WHO Member States, both includes express reference to influenza and differentiates between seasonal and pandemic influenza. Both extracts are included in Table 7 below.
15. Instruments were also reviewed for express reference to the PIP Framework and whether such reference expressly considered the PIP Framework a specialized international access and benefit-sharing instrument (“specialized instrument”) under Article 4(4) of the Nagoya Protocol. Only two WHO Member States (Japan and Malta) expressly included the PIP Framework in their implementing legislation, with recognition (express and implied) that it is a specialized instrument. In addition, the European Union implementing law and policy guidance document includes express reference to the PIP Framework as a specialized instrument. All related extracts are included in Table 8 below.

Table 7. Express inclusion of influenza and distinctions

WHO Member State	Instrument type	Instrument title	Influenza – extract	Seasonal/pandemic influenza differentiation — extract
Malta	Act	Environment Protection Act (CAP. 549) Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations 2016 (EN)	Article 2(3): The provisions of these regulations shall not prejudice specialised international access and benefit-sharing instruments which are consistent with the Nagoya Protocol, such as the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the ‘PIP’ Framework) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).	N/A

WHO Member State	Instrument type	Instrument title	Influenza – extract	Seasonal/pandemic influenza differentiation — extract
European Union [not a WHO Member State]	Regulation	Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union	Preamble Para. 16: On 24 May 2011, the Sixty-fourth World Health Assembly adopted the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the ‘PIP Framework’). The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not apply to seasonal influenza viruses.	Preamble Para. 16: The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not apply to seasonal influenza viruses.

Table 8. Express reference to the PIP Framework

WHO Member State	Instrument type	Instrument title	Extract
Malta	Act	Environment Protection Act (CAP. 549) Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations 2016	Article 2(3): The provisions of these regulations shall not prejudice specialised international access and benefit-sharing instruments which are consistent with the Nagoya Protocol, such as the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the ‘PIP’ Framework) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).
Japan	Administrative measure (Notification)	Notification of acquisition of the genetic resources in Japan	Condition of issuance No. 5: The genetic resource is NOT utilized under “The Pandemic Influenza Preparedness Framework” (PIPF).

WHO Member State	Instrument type	Instrument title	Extract
European Union [not a WHO Member State]	Regulation	Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union	Preamble Para. 16: On 24 May 2011, the Sixty-fourth World Health Assembly adopted the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the 'PIP Framework'). The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not apply to seasonal influenza viruses. The PIP Framework constitutes a specialised international access and benefit-sharing instrument that is consistent with the Nagoya Protocol and that should not be affected by the rules implementing the Nagoya Protocol.
European Union (not a WHO Member State)	Guidance Document	Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union	<p>Section 2.3.1: In accordance with Article 4(4) of the Nagoya Protocol, specialised ABS instruments prevail in respect of the specific genetic resource covered by the specialised instrument and for the purpose of that instrument, if it is consistent with and does not run counter to the objectives of the CBD and the Protocol. Accordingly, Article 2(2) of the EU ABS Regulation makes it clear that the Regulation does not apply to genetic resources for which access and benefit-sharing is governed by such specialised international instruments. This currently includes material covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (1) and the WHO's Pandemic Influenza Preparedness (PIP) Framework (2).; Section 5.1: Pathogenic organisms that pose a threat to human, animal or plant health are generally within the scope of the Regulation, given that they are covered by the Nagoya Protocol. However, specialised ABS instruments in the meaning of Article 4(4) of the Nagoya Protocol may also be applicable to certain pathogenic organisms.</p> <p>Material which is covered by specialised international instruments for access and benefit-sharing that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol, such as the WHO's Pandemic Influenza Preparedness (PIP) Framework, is outside of the scope of the Protocol and the Regulation (see Article 2(2) of the Regulation and above, p. 5).</p>

Specialized instruments – Article 4(4) of the Nagoya Protocol

16. Under Article 4(4) of the Nagoya Protocol:

“Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.”

17. Some WHO Member States have included express reference to Article 4(4) in instruments uploaded to the Access and Benefit-Sharing Clearing-House. These Member States are listed in Table 9 below.

Table 9. WHO Member State instruments with express reference to Article 4(4) of the Nagoya Protocol

WHO Member State	Instrument type	Instrument title	Extract
Benin	Strategy	Stratégie nationale sur l'accès et de partage des avantages issus de l'utilisation des ressources génétiques et des connaissances traditionnelles associées (FR)	2.2: Le TIRPAA (Article 1.1) et le PN/APA (les dispositions pertinentes du Préambule et l'article 4) affirment bien que ces deux traités doivent se mettre en œuvre en harmonie d'une façon mutuellement positive; Footnote 10: Le présent Protocole est l'instrument d'application des dispositions de la Convention relatives à l'accès et au partage des avantages. Lorsqu'un instrument international spécial sur l'accès et le partage des avantages s'applique, est conforme aux objectifs de la Convention et du présent Protocole et ne va pas à l'encontre de ces objectifs, le présent Protocole ne s'applique pas pour la ou les Partie(s) à cet instrument spécial en ce qui concerne la ressource génétique spécifique couverte par ledit instrument et pour les besoins de celui-ci.
Bhutan	Policy	འཛིན་སྲུང་གི་རྒྱུ་རྐྱེན་གྱི་ཐོན་སྐྱེད་ལ་བཟུངས་པའི་ལོ་རྒྱུས་ལྟར་བཞག་པའི་བཀའ་སློབ་ (BHU) Access and Benefit Sharing Policy of Bhutan 2015 (EN)	Art. 4.7: The access to duly registered ex situ collections of genetic resources for food and agriculture that fall under Annex-1 of the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) and are under the management and control of the government as well as in the public domain shall be in accordance with the terms and conditions of the Multilateral System of Access and Benefit Sharing, including the conclusion of a Standard Material Transfer Agreement (SMTA) while the access to other genetic resources in ex situ collections in the Actualization Phase shall be based on an ABS Agreement between the user of such resources and the National Focal Point

WHO Member State	Instrument type	Instrument title	Extract
Bhutan	Explanatory information	Access and Benefit Sharing Toolkit for the Management of Genetic Resources and Associated Traditional Knowledge in Bhutan (EN)	International Treaty on Plant Genetic Resources for Food and Agriculture: The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) popularly known as the International Treaty, is a legal instrument to ensure global food security through the conservation, exchange and sustainable use of the world's plant genetic resources for food and agriculture as well as the fair and equitable sharing of benefits arising from its use. The Treaty was opened for signature in 2001 and came into force in 2004 while Bhutan ratified the Treaty in 2003.
Bulgaria	Act	ЗАКОН за биологичното разнообразие (BUL) Biological Diversity Act (EN)	[...] published by the Secretariat of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), done at Washington on 3 March 1973 (ratified by a decision of the Great National Assembly, SG No.103/1990) (SG No. 6/1992), hereinafter referred to as "the Convention", [...]
Burundi	Draft law	Projet de décret No. 100/..... DU//...../2017 sur l'accès aux ressources génétiques et le partage juste et équitable des avantages qui en découlent (FR)	Art. 2: Il ne s'applique pas aux ressources génétiques pour lesquelles l'accès et le partage des avantages sont régis par des instruments internationaux spéciaux qui sont conformes aux objectifs de la convention et du Protocole de Nagoya et qui ne vont pas à l'encontre de ces objectifs.
Cameroon	Strategy (policy document)	Stratégie nationale sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (APA) (FR)	3.2. Outils de mise en œuvre: Des instruments juridiques contraignants (directives, codes de conduite, politiques et autres outils répondant à des besoins particuliers) ont été élaborés pour les différents types d'utilisateurs de ressources génétiques, afin d'aider à la mise en œuvre des dispositions de la CDB consacrées à l'APA. Ces outils devront être pris en considération dans la mise en œuvre de

WHO Member State	Instrument type	Instrument title	Extract
			la présente stratégie. On peut citer entre autres: a) Traité International sur les Ressources Phytogénétiques pour l'Alimentation et l'Agriculture (TIRPAA), b) Code International de Conduite pour la Collecte et le Transfert de Matériel Phytogénétique, c) Ressource en ligne pour l'accès et le partage des avantages entre les jardins botaniques autour du monde, d) Principes sur l'accès aux ressources génétiques et le partage des avantages, e) Réseau International d'Echange des Plantes (RIEP) et son Code de conduite pour les jardins botaniques régissant l'acquisition, le maintien et l'approvisionnement de matériel phytogénétique vivant, f) Code de conduite international et réglementation sur l'utilisation durable et l'accès aux microorganismes (MOSAICC)
Congo	Strategy (policy document)	Stratégie Nationale sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (FR)	IV-1: Ce sont des instruments juridiques existants qui participent à la mise en oeuvre des dispositions de la CDB consacrées à l'APA. Ces outils devront être pris en considération dans la mise en oeuvre de la présente stratégie. On peut citer entre autres: TIRPAA, Code International de Conduite pour la Collecte et le Transfert de Matériel Phytogénétique, etc.
France	Act	Law No. 108 2016 on Biodiversity	Art. 37 - Sous section 2.1 Art. L. 412-5. II.1(c): La présente section n'est pas applicable: 1. Aux activités mentionnées au I lorsqu'elles portent sur: c) Les ressources génétiques couvertes par des instruments internationaux spécialisés d'accès et de partage des avantages qui répondent aux objectifs de la convention sur la diversité biologique, adoptée à Nairobi le 22 mai 1992, et qui n'y portent pas atteinte
India	Administrative measure	Notification on exemption of crops listed in the Annex-I of the ITPGRFA from the purview of the Section 3 and 4 of the Biological Diversity Act 2002	Whereas, article 4 of the said Nagoya Protocol provides that the protocol does not apply for the party or parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument; Now, therefore, in exercise

WHO Member State	Instrument type	Instrument title	Extract
			<p>of the powers conferred by section 40 of the Biological Diversity Act, 2002 (hereinafter referred to as the said Act), and in fulfilment of the obligations of the Government of India to the ITPGRFA for providing facilitated access to the plant genetic resources for food and agriculture, the Central Government, in consultation with the National Biodiversity Authority, hereby declares that the Department of Agriculture and Cooperation may, from time to time specify such crops as it considers necessary from amongst the crops listed in the Annex I of the ITPGRFA, being food crops and forages covered under the Multilateral System thereof, and accordingly exempts them from Section 3 and 4 of the said Act, for the purpose of utilization and conservation for research, breeding and training for food and agriculture</p>
India	Guidelines	Guidelines for the Implementation of International Treaty on Plant Genetic Resources for Food and Agriculture for Facilitated Access under Multilateral System	<p>Section I - Introduction: Since, India has ratified Nagoya Protocol (NP), as per article 4.2 and 4.4 of the Protocol “nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol”. These guidelines are in harmony with the Convention and NP and do not run counter to the objectives of relevant international agreements and extant relevant national legislations. India signed and ratified ITPGRFA hereinafter referred to as the Treaty after approval from Cabinet, on 10th June, 2002. The objectives of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.</p>

WHO Member State	Instrument type	Instrument title	Extract
			As per Article 12 of the Treaty, all Contracting Parties (countries) are obliged to provide facilitated access to PGRFA that are under the management and control of Contracting Parties and in the public domain. Contracting Parties are also obliged to encourage natural and legal persons within their jurisdiction, who hold such PGRFA, to include these in the multilateral system (MLS) of the Treaty to facilitate their access. The list of 35 food crops and 29 forage crops as agreed by the Contracting Parties referred to as Annex 1 crops, is at Annexure II.
Japan	Guidelines	Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization	Chapter 1.3.2: These Guidelines do not apply to the utilization of genetic resources to which the International Treaty on Plant Genetic Resources for Food and Agriculture applies or to the utilization of other genetic resources to which the Protocol does not apply (meaning an act that does not constitute the utilization of genetic resources to which the Protocol applies).
Malta	Act	Environment protection act (CAP. 549) Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations 2016	Article 2(2)(d): These regulations shall not apply to: the genetic resources for which access and benefit sharing are governed by specialised international instruments that are consistent with, and do not run counter to, the objectives of the Convention and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union; Article 2(3): The provisions of these regulations shall not prejudice specialised international access and benefit-sharing instruments which are consistent with the Nagoya Protocol, such as the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the 'PIP' Framework) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

WHO Member State	Instrument type	Instrument title	Extract
Serbia	Act	The Law on Ratification of the Nagoya Protocol	Article 4.4: This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.
Switzerland	Act	Loi fédérale sur la protection de la nature et du paysage (LPN) (FR) Bundesgesetz über den Natur- und Heimatschutz (NHG) (GER) Legge federale sulla protezione della natura e del paesaggio (LPN) (IT) Federal Act on the Protection of Nature and Cultural Heritage (NCHA) (EN)	Art. 23n.2(d): Genetic resources are not subject to the due diligence requirement if they: (d) are covered for a specific use by a specialised international instrument under Article 4 of the Nagoya Protocol
United Kingdom of Great Britain and Northern Ireland	Regulation	The Nagoya Protocol (Compliance) Regulations 2015	Art. 8.3: There is no failure to comply with Article 4(3) of the EU Regulation if the Secretary of State is satisfied that— (a) the user is considered to have exercised due diligence under Article 4(4) of the EU Regulation (use of the Plant Treaty's Standard Material Transfer Agreement for material not listed in Annex 1 to that Treaty).
Viet Nam	Factsheet/ explanatory document	ABS Ở VIỆT NAM (VIET) ABS in Viet Nam (EN)	Viet Nam is Party to the following international treaties related to access to genetic resources and benefit sharing (ABS): • International Union for the Protection of New Varieties of Plants Convention (UPOV) — since 2006.
European Union [not a WHO Member State]	Regulation	Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union	Art. 2.2: This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by specialised international instruments that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol.

WHO Member State	Instrument type	Instrument title	Extract
European Union [not a WHO Member State]	Guidance document	Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union	<p>Section 2.3.1: In accordance with Article 4(4) of the Nagoya Protocol, specialised ABS instruments prevail in respect of the specific genetic resource covered by the specialised instrument and for the purpose of that instrument, if it is consistent with and does not run counter to the objectives of the CBD and the Protocol. Accordingly, Article 2(2) of the EU ABS Regulation makes it clear that the Regulation does not apply to genetic resources for which access and benefit-sharing is governed by such specialised international instruments. This currently includes material covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the WHO's Pandemic Influenza Preparedness (PIP) Framework.</p> <p>However, the EU ABS Regulation does apply to genetic resources covered by the ITPGRFA and the PIP Framework, if they are accessed in a country that is not a Party to those agreements but is a Party to the Nagoya Protocol. The Regulation also applies where resources covered by such specialised instruments are utilised for purposes other than those of the specialised instrument in question (e.g. if a food crop covered by the ITPGRFA is utilised for pharmaceutical purposes).;</p> <p>Section 5.1: Material which is covered by specialised international instruments for access and benefit- sharing that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol, such as the WHO's Pandemic Influenza Preparedness (PIP) Framework, is outside of the scope of the Protocol and the Regulation.; 5.2.1: PGRFA covered by Annex I of the ITPGRFA included into its multilateral system and obtained from ITPGRFA Parties. Such material is covered by a specialised international instrument for access and benefit-sharing that is consistent with, and does not run counter to, the objectives of the Convention and the Nagoya Protocol.</p>

WHO Member State	Instrument type	Instrument title	Extract
			<p>Any PGRFA received under a standard material transfer agreement (SMTA) from International Agricultural Research Centres such as those of the Consultative Group on International Agricultural Research or other international institutions that have signed agreements under Article 15 of the ITPGRFA. Such material is also covered by a specialised international instrument for access and benefit-sharing that is consistent with and does not run counter to, the objectives of the Convention and the Nagoya Protocol.</p>

Special considerations – Article 8(b) of the Nagoya Protocol and references to human health

18. Under Article 8(b) of the Nagoya Protocol, Parties shall:
 “[p]ay due regard to cases of present or imminent emergencies that threaten or damage human... health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources...”
19. Some Member States have expressly included Article 8(b) in their domestic implementing law. Extracts of these provisions are set out in Table 10 below.
20. As express reference to Article 8(b) is not a requisite for implementing the Nagoya Protocol, it is possible that Member States have satisfied the obligations under Article 8(b) without express reference to the provision. To seek to capture this, the instruments uploaded to the Access and Benefit-Sharing Clearing-House were also reviewed for more general references to human health. Extracts of these provisions are set out in Table 11 below.

Table 10. Member State law or policy with express reference to Article 8(b) of the Nagoya Protocol

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
Law			
Brazil	Act	Medida Provisoria No. 2.186-16 (PORT) Provisional Act No. 2.186-16 (EN)	Art. 5: Access to genetic heritage is hereby prohibited for practices that are harmful to the environment and to human health and for the development of biological and chemical weapons.
Bulgaria	Act	ЗАКОН за биологичното разнообразие (BUL) Biological Diversity Act (EN)	Art. 33(2): If the special area of conservation hosts a priority natural habitat type and/or a habitat of a priority species, the only considerations which may be raised for making the exception referred to in Paragraph (1) are those relating to human health or public safety [...]; Art. 48.2(3): Any exemption referred to in Paragraph (1) shall be granted in the following cases: 3. in the interests of public health and safety

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
Burkina Faso	Act	Loi No. 070/2015 CNT Portant Loi d'Orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso (FR)	Art. 78 par. 3: En cas de situation d'urgence, l'Etat prend, les mesures nécessaires pour faire cesser le danger et peut, à cet effet, suspendre la production ou la mise sur le marché de la denrée agro-sylvo- pastorale, halieutique et faunique considérée, faire procéder à son retrait en tous lieux où elle se trouve ou procéder ou faire procéder à sa destruction lorsque celle-ci est le moyen le plus approprié de faire cesser le danger; Art. 92 par. 3: Il organise, en cas de crise, les mesures d'urgence appropriées pour la prévention et la réponse rapide contre les maladies émergentes ou réémergentes.
Côte d'Ivoire	Act	Code de l'environnement Loi No. 96-766 du 3 octobre 1996 portant Code de l'Environnement (FR)	Art. 31:Lorsque l'urgence le justifie, l'autorité compétente peut prendre toutes mesures appropriées pour faire cesser immédiatement toute émission de bruits susceptibles de nuire à la santé des êtres vivants, de constituer une gêne excessive et insupportable pour le voisinage ou d'endommager les biens.; Art. 71: L'Etat, les régions, les départements et les Collectivités locales s'engagent à élaborer des programmes d'action et à organiser des plans d'urgence dans les domaines en vue de protéger l'Environnement.
Croatia	Decision	Odluku o Proglašenju Zakona o Zaštiti Prirode (CRO) Decision promulgating the Nature Protection Act (EN)	Art. 52(2): The Minister may in emergencies by an order set measures for the protection of strictly protected species and measures for the protection of their habitats.; Art. 37(3): If in the area of the ecological network is found a habitat type and/or species from the List of particularly threatened and significant habitat types and species, the overriding public interest may apply only to protection of human health, human safety and safety of property or to establishment of significantly more favourable conditions of primary importance for the environment.; Art. 155(2): in the interests of public health, public safety and safety of property, or for other imperative reasons of overriding public interest, including those of a social or economic nature and beneficial consequences of primary importance for the environment

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
Ethiopia	Proclamation	Proclamation No. 482/2006 To Provide for Access to Genetic Resources and Community Knowledge and Community Right (EN)	Art. 13.2: Conditions for Denial Access - The Institute may deny access to genetic resources, where: 2. the access may have adverse effects upon human health or the cultural values of the local community
France	Act	Loi No. 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages (FR) Law No. 108 2016 on Biodiversity (EN)	Art. 37 - Sous section 2.3.III: Est également soumis à déclaration à l'autorité administrative compétente l'accès aux ressources génétiques lorsque des situations d'urgence relatives à la santé humaine, à la santé animale ou à la santé végétale, autres que celles régies par l'article L. 1413- 8 du code de la santé publique, le justifient.
Malawi	Act	Environmental Management Act of 2017	Article 64(1): The Authority shall, in consultation with relevant lead agencies, prepare guidelines or plans for coordination, prevention, mitigation and management of environmental emergencies including [...]
Malawi	Act	Environmental Management Act of 1996	Article 37.3(c): The Minister may, on the recommendation of the Council: (c) monitor any waste disposal site and direct the control of any such site if its continued use as a waste disposal site constitutes or is likely to constitute a hazard to the health of the people living in the vicinity of, or to the environment adjacent to, the site.
Malta	Act	Att Dwar Il- Protezzjoni Tal- Ambjent (Kap. 549) Regolamenti tal-2016 dwar l-Aċċess għal Riżorsi Ġenetiċi u l- Qsim Ġust u Ekwu ta' Benefiċċji li Jirriżultaw mill-Użu tagħhom (MAL) ENVIRONMENT PROTECTION ACT (CAP. 549) Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations 2016 (EN)	Article 23: Without prejudice to the provisions of the Council Regulation, the competent authority and the assistant authorities may for reasons of imminent threats to human, animal or plant health adopt interim measures, as they deem fit in the circumstances; Article 24(c): The competent authority and the relevant assistant authorities may, as appropriate, promote additional measures and provisions which: (c) protect human and plant health.; Article 14(2)(c): There is no failure to comply with Article 4(3) of the Council Regulation if the competent authority is satisfied that: (c) the user is in accordance with Article 4(8) of the Council Regulation (use of pathogen for the purpose of public health emergency preparedness).; Article 16(2)(d): The requirement to serve a notice does not apply: (d) in an emergency situation

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
Morocco	Act (Draft)	Avant Projet de loi n° 56-17 sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (FR)	Article 15: une procédure d'urgence est appliquée sur les demandes d'accès aux ressources génétiques destinées à être utilisées pour faire face à la prolifération des maladies et épidémies constituant un danger imminent et réel sur la santé publique au niveau national ou international. Les modalités de cette procédure d'urgence sont fixées par voie réglementaire
Republic of Korea	Act	유전자원의 접근 · 이용 및 이익 공유에 관한 법률 (KOR) Act on Access to and Utilization of Genetic Resources and Benefit Sharing (EN)	Article 10(1): Article 10 (Exemptions from Reporting Access to Domestic Genetic Resource(s)) Notwithstanding Article 9 (1), the head of the Competent National Authority may, as prescribed by Presidential Decree, seek to simplify procedures for reporting access to genetic resource(s) or waive such reporting following consultation with the head of the relevant central administrative agency, in any of the following cases: 1. Where it is deemed that expedited access to or utilization of the genetic resource(s) is required for the development of therapeutic drugs and food security in the event there are threats to the life and health of humans, animals, and plants;
Serbia	Act	The Law on Ratification of the Nagoya Protocol (EN)	Article 8(b): Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
Switzerland	Ordinance	Ordonnance sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (Ordonnance de Nagoya) (FR) Verordnung über den Zugang zu genetischen Ressourcen und die ausgewogene und gerechte Aufteilung der sich aus ihrer Nutzung ergebenden Vorteile (Nagoya-Verordnung) (GER) Ordinanza sull'accesso alle risorse genetiche e la giusta ed equa condivisione dei benefici derivanti dalla loro utilizzazione (Ordinanza di Nagoya) (IT) Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance) (EN)	Art. 3.4: In an internationally or nationally recognised emergency that threatens the health of humans, animals or plants or the environment, it suffices if the due diligence requirement for the utilisation of genetic resources that are pathogenic or harmful organisms is fully met at the time of the commercialisation of products developed on the basis of the utilised genetic resources.
Switzerland	Act	Loi fédérale sur la protection de la nature et du paysage (LPN) (FR) Bundesgesetz über den Natur- und Heimatschutz (NHG) (GER) Legge federale sulla protezione della natura e del paesaggio (LPN) (IT) Federal Act on the Protection of Nature and Cultural Heritage (NCHA) (EN)	Art. 23n.5: If the requirements of paragraph 1 letters a and b are not met, users must ensure that they are met subsequently, or must refrain from utilising the genetic resources concerned or from benefiting directly from their utilisation. In emergencies, the Federal Council may provide for a delay in meeting the requirements for genetic resources that are pathogenic or harmful organisms.
United Kingdom of Great Britain and Northern Ireland	Regulation	The Nagoya Protocol (Compliance) Regulations 2015	Art. 8.3(c): "There is no failure to comply with Article 4(3) of the EU Regulation if the Secretary of State is satisfied that [...] the use is in accordance with Article 4(8) of the EU Regulation (use of pathogen for the purpose of public health emergency preparedness)"

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
European Union [not a WHO Member State]	Regulation	Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union	<p>Preamble Para. 16: The Nagoya Protocol requires each Party thereto to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally.; Art. 4.8: Users acquiring a genetic resource that is determined to be, or is determined as likely to be, the causing pathogen of a present or imminent public health emergency of international concern, within the meaning of the International Health Regulations (2005), or of a serious cross-border threat to health as defined in the Decision No 1082/2013/EU of the European Parliament and of the Council (9), for the purpose of public health emergency preparedness in not yet affected countries and response in affected countries, shall fulfil the obligations listed in paragraph 3 or 5 of this Article at the latest:</p> <p>(a) one month after the imminent or present threat to public health is terminated; or</p> <p>(b) three months after commencement of utilisation of the genetic resource; whichever is the earlier.</p>
Policy			
Benin	Strategy	Stratégie nationale sur l'accès et de partage des avantages issus de l'utilisation des ressources génétiques et des connaissances traditionnelles associées (FR)	Footnote 9: Reconnaissant l'importance des ressources génétiques pour la sécurité alimentaire, la santé publique
Benin	Directive (policy document)	Directives nationales pour l'accès et le partage des avantages Issus de l'utilisation des ressources génétiques et des connaissances traditionnelles associées (FR)	<p>Art. 16: Est également soumis à demande de permis d'accès auprès de l'Autorité Nationale</p> <p>Compétente, l'accès aux ressources génétiques et aux connaissances traditionnelles associées lorsque des situations d'urgence relatives à la santé humaine, à la santé animale ou à la santé végétale le justifient</p>

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
Côte d'Ivoire	Strategy	Stratégie Nationale sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (APA) (FR)	Art. 8: Indications spéciales : Le Protocole donne des indications à même d'aider les Parties à élaborer et à mettre en œuvre la législation ou les règlements en matière d'APA. En d'autres termes, les mesures que prennent les Parties au niveau local doivent permettre d'atteindre certains objectifs et résultats spécifiques. Ces indications données à l'Article 8 sont de trois ordres: - Prendre des mesures minimales permettant l'accès rapide aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation en tenant compte, le cas échéant, des situations d'urgence actuelles ou imminentes menaçant la santé de l'homme
India	Guidelines	Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014	Section 14.2: Provided that special consideration may be given to cases where technologies/products are developed for controlling epidemics/diseases and for mitigating environmental pollution affecting human/ animal/plant health; Section 13.2: Any Government Institution which intend to send biological resources to carry out certain urgent studies to avert emergencies like epidemics, etc., shall apply in Form 'B' annexed to these regulations.
Japan	Guidelines	Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization	Art 2.1.2: Human health emergencies The provisions of paragraph 1 do not apply to the access to genetic resources used for addressing situations that are deemed as emergencies as provided for under the International Health Regulations or human health emergencies. In this case, the acquirer is to submit a report using Form No. 1 along with a copy of the internationally recognized certificate of compliance to the Minister of the Environment within six months from the date on which the terms for deeming that the emergency has been settled are fulfilled. When it is difficult to determine the time of the occurrence and settlement of the emergency, the acquirer is to submit a report using Form No. 1 along with a copy of the internationally recognized certificate of compliance within one year from the date on which the genetic resources used for addressing the said emergency were accessed, regardless of the provision of (1) above.

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
Lao People's Democratic Republic	Policy	Lao National Framework on the Access to Genetic Resources and the Fair and Equitable Sharing of Benefit Arising from their Utilization	Article 11(2): Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Competent National Authorities on ABS may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in the Lao People's Democratic Republic and developing countries.
Malawi	Guidelines	Guidelines on Access to Biological Resources and the Fair and Equitable Sharing of Benefits Arising from their use	Where there are conditions requiring accessing biological resources for special uses including emergencies that threaten or damage human, animal or plant health the following procedure shall be undertaken (p. 14)
Togo	Policy/strategy/action plan	Politique générale en matière d'APA (FR)	III. Stratégie nationale: 3.2.1.: 3.2.1. Obligations en matière d'accès - Les dispositions à prendre en matière d'accès aux ressources génétiques en vue de leur utilisation doivent: tenir dûment compte des cas d'urgence actuels ou imminents qui menacent l'homme, la santé animale ou végétale ;

WHO Member State	Document type	Document title	Extract of provisions relating to Article 8(b)
European Union [not a WHO Member State]	Guidance document	Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union	<p>Section 5.1: 5.1. Health Pathogenic organisms that pose a threat to human, animal or plant health are generally within the scope of the Regulation, given that they are covered by the Nagoya Protocol.</p> <p>However, specialised ABS instruments in the meaning of Article 4(4) of the Nagoya Protocol may also be applicable to certain pathogenic organisms. Material which is covered by specialised international instruments for access and benefit-sharing that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol, such as the WHO's Pandemic Influenza Preparedness (PIP) Framework, is outside of the scope of the Protocol and the Regulation (see Article 2(2) of the Regulation and above, p. 5). More generally, the Protocol explicitly recognises the importance of genetic resources to public health. In the development and implementation of their access and benefit-sharing legislation or regulatory requirements, Parties are required to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health (Article 8(b) of the Protocol). Expeditious access and benefit sharing should therefore also be aimed at with regard to non- pathogenic genetic resources in emergency situations. The Regulation gives special status to a pathogenic organism that is determined to be (or is determined likely to be) the causing pathogen of a present or imminent public health emergency of international concern or a serious cross-border threat to health. To these genetic resources an extended deadline for compliance with the due diligence obligation applies (see Article 4(8) of the Regulation).</p>

Table 11. Member State law or policy with express reference to human health

WHO Member State	Instrument type	Instrument title	Extract
Antigua and Barbuda	Act	Environmental Protection and Management Act, 2015 (No. 11/2015)	Art. 4.1(c): The objects of this Act are to, within Antigua and Barbuda— (c) Provide for preventive and remedial measures for the control and mitigation of all forms of environmental degradation or pollution including the management of hazardous substances and wastes for the purposes of protecting human health and maintaining the quality of the environment; Art. 4.2(a): This Act shall regulate the social relations with regard to: (a) protection of the environment for the present and future generations and protection of human health; Art. 4.4(b): Environmental protection shall be based on the following principles: (b) prevention and reduction of risk to human health; Part VIII - Guidance for ABS/Art. 70.8(c): (8) The Department may, when it deems it necessary, establish restrictions or prohibitions on those activities which are directly or indirectly related to access to or introduction of biological resources, particularly in case of— (c) adverse effects upon human health or upon the quality of life or the cultural values of the local communities

WHO Member State	Instrument type	Instrument title	Extract
Antigua and Barbuda	Act	Environmental Protection and Management Act 2019 (No. 10/2019)	Art. 3.1(b): The object of this Act are to— (b) provide preventive and remedial measures for the control and mitigation of all forms of environmental degradation or pollution including the management of hazardous substances and wastes for the purposes of protecting human health and maintaining the quality of the environment; Art. 3.3(b): The implementation of the Act shall be based in the following principles: (b) prevention and reduction of risk to human health; Art. 82.7(): The Department may, when it deems it necessary, establish restrictions or prohibitions on those activities which are directly or indirectly related to access to or introduction of biological resources, particularly in case of: (c) adverse effects upon human health or upon the quality of life or the cultural values of the local communities
Benin	Strategy	Stratégie nationale sur l'accès et de partage des avantages issus de l'utilisation des ressources génétiques et des connaissances traditionnelles associées (FR)	3.3.1. Obligations en matière d'accès : Tenir dûment compte des cas d'urgence actuels ou imminents qui menacent l'homme, la santé animale ou végétale
Benin	Directive (policy document)	Directives nationales pour l'accès et le partage des avantages issus de l'utilisation des ressources génétiques et des connaissances traditionnelles associées (FR)	Art. 16: Est également soumis à demande de permis d'accès auprès de l'Autorité Nationale Compétente, l'accès aux ressources génétiques et aux connaissances traditionnelles associées lorsque des situations d'urgence relatives à la santé humaine, à la santé animale ou à la santé végétale le justifient.

WHO Member State	Instrument type	Instrument title	Extract
Brazil	Act	Medida Provisoria No. 2.186-16 (PORT) Provisional Act No. 2.186-16 (EN)	Art. 5: Access to genetic heritage is hereby prohibited for practices that are harmful to the environment and to human health and for the development of biological and chemical weapons.
Brazil	Act	Lei No. 13.123, de 20 de Maio de 2015 (PORT) Law No. 13.123, dated May 20, 2015 (EN)	Art. 5: Access to genetic heritage and to associated traditional knowledge is prohibited for practices that are harmful to the environment, to cultural reproduction and to human health, and for the development of biological and chemical weapons
Bulgaria	Act	ЗАКОН за биологичното разнообразие (BUL) Biological Diversity Act (EN)	Art. 33(2): If the special area of conservation hosts a priority natural habitat type and/or a habitat of a priority species, the only considerations which may be raised for making the exception referred to in Paragraph (1) are those relating to human health or public safety [...]; Art. 48.2(3): Any exemption referred to in Paragraph (1) shall be granted in the following cases: 3. in the interests of public health and safety
Burkina Faso	Act	Loi No. 070/2015 CNT Portant Loi d'Orientation agro-sylvo-pastorale, halieutique et Faunique au Burkina Faso (FR)	Art. 4: santé publique vétérinaire : activités de santé publique consacrée à la mise en application des techniques, du savoir et des ressources vétérinaires pour la protection et l'amélioration de la santé humaine; Art. 82 par. 3: Il garantit la biosécurité dans le cadre de la culture d'organismes génétiquement modifiés, en évaluant, de manière permanente, en concertation avec les autres acteurs, les effets et impacts de la culture d'organismes génétiquement modifiés sur les écosystèmes, la fertilité des sols ainsi que la santé humaine et animale; Art. 84: L'Etat assure la sécurité sanitaire des végétaux, des produits végétaux et des produits d'origine végétale à travers les mesures phytosanitaires et le contrôle phytosanitaire, en vue d'assurer la protection de la santé humaine, animale et de l'environnement; Art. 91: L'Etat assure la santé publique vétérinaire à travers la prévention et la riposte contre les maladies animales en vue de préserver la santé humaine; Art. 92: L'Etat assure la sécurité sanitaire des animaux et des produits animaux ou d'origine animale afin de protéger la santé humaine et animale et l'environnement.

WHO Member State	Instrument type	Instrument title	Extract
Burundi	Strategy (policy document)	Stratégie nationale et plan d'action en matière d'accès aux ressources génétiques et de partage des avantages découlant de leur utilisation au Burundi	I.5. CAPACITES EXISTANTES EN MATIERE D'ACCES ET DE PARTAGE, I.5.1. Capacités ou besoins pour établir les procédures d'accès et de partage: Tableau 1a: Prendre dument en considération les situations d'urgence actuelles ou imminentes qui menacent la santé humaine, animale ou végétale
Côte d'Ivoire	Act	Code de l'environnement Loi No. 96-766 du 3 octobre 1996 portant Code de l'Environnement (FR)	<p>Art. 1 : L'air est la couche atmosphérique dont la modification physique, chimique ou autre peut porter atteinte à la santé des êtres vivants, aux écosystèmes et à l'environnement en général; La pollution est la contamination ou la modification directe ou indirecte de l'environnement provoquée par tout acte susceptible:</p> <ul style="list-style-type: none"> - D'altérer le milieu de vie de l'homme et des autres espèces vivantes ; - De nuire à la santé, à la sécurité, au bien-être de l'homme, de la flore et de la faune ou aux biens collectifs et individuels; La pollution des eaux est l'introduction dans le milieu aquatique de toute substance susceptible de modifier les caractéristiques physiques, chimiques et/ou biologiques de l'eau et de créer des risques pour la santé de l'homme; La pollution atmosphérique ou pollution de l'air est l'émission volontaire ou accidentelle dans la couche atmosphérique de gaz, de fumée ou de substances de nature à créer des nuisances pour les êtres vivants, à compromettre leur santé ou la sécurité publique ou à nuire à la production agricole, à la conservation des édifices ou au caractère des sites et paysages; La nuisance est toute atteinte à la santé des êtres vivants, de leur fait ou non, par l'émission de bruits de lumière, d'odeurs, etc.; Les déchets dangereux sont des produits solides, liquides ou gazeux, qui présentent une menace sérieuse ou des risques particuliers, pour la santé, la sécurité des êtres vivants et la qualité de

WHO Member State	Instrument type	Instrument title	Extract
			<p>l'environnement ; Les risques naturels sont les catastrophes et calamités naturelles qui peuvent avoir des effets imprévisibles sur l'environnement et la santé ; Art. 3 : La Présente loi ne fait pas obstacle à l'application des dispositions législatives et réglementaires concernant l'urbanisme et les constructions, la santé, l'hygiène, la sécurité, et la tranquillité publique, la protection des écosystèmes et d'une manière générale à l'exercice des pouvoirs de Police ; Art. 5 : La présente loi s'applique à toutes les formes de pollution telles que définies à l'article premier du présent Code et susceptible de provoquer une altération de la composition et de la consistance de la couche atmosphérique avec des conséquences dommageables pour la santé des êtres vivants, la production, les biens et l'équilibre des écosystèmes ; Art. 6 : Les installations exploitées ou détenues par toute personne physique ou morale, publique ou privée qui peuvent présenter des dangers ou des inconvénients, soit pour la commodité, soit pour la santé, la sécurité et la salubrité publique; Art. 8 : Aux termes de la présente loi, sont visées les substances ou combinaisons de substances fabriquées ou à l'état naturel susceptibles, en raison de leur caractère toxique, radioactif, corrosif ou nocif de constituer un danger pour la santé des personnes, la conservation des sols et sous-sols, des eaux, de la faune et de la flore, de l'environnement en général, lorsqu'elles sont utilisées ou évacuées dans le milieu naturel.; Art. 26 : Tous les déchets, notamment les déchets hospitaliers et dangereux, doivent être collectés, traités et éliminés de manière écologiquement rationnelle afin de prévenir, supprimer ou réduire leurs effets nocifs sur la santé de l'homme, sur les ressources naturelles, sur la faune et la flore et sur la qualité de l'environnement.; Art. 31 : Lorsque l'urgence le justifie, l'autorité compétente peut prendre toutes mesures appropriées pour faire cesser immédiatement toute émission de bruits susceptibles de nuire à la santé des êtres vivants, de constituer une gêne excessive</p>

WHO Member State	Instrument type	Instrument title	Extract
			<p>et insupportable pour le voisinage ou d'endommager les biens.; Art. 76 : Il est interdit de rejeter dans les zones maritimes et lagunaires, toutes substances susceptibles de :</p> <p>: Constituer un danger pour la santé des êtres vivants; Art. 80 : Conformément aux dispositions spéciales des Conventions internationales ratifiées par la Côte d'Ivoire, sont interdits les déversements, les immersions et incinérations dans les eaux maritimes sous juridiction ivoirienne de substances de toutes natures susceptibles :</p> <ul style="list-style-type: none"> - De porter atteinte à la santé publique et aux ressources maritimes biologiques; Art. 98 : Est puni d'une amende de 100.000.000 de francs à 1.000.000.000 de francs et d'un emprisonnement de un à cinq ans ou de l'une de ces deux peines seulement sans préjudice des sanctions administratives en vigueur, quiconque, nonobstant les dispositions spéciales des Conventions internationales, procède à des déversements, immersion et incinération dans les eaux maritimes sous juridiction ivoirienne, des substances de toutes natures susceptibles: - De porter atteinte à la santé publique et aux ressources maritimes biologiques
Côte d'Ivoire	Strategy	Stratégie nationale sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation (APA) (FR)	<p>Art. 8 : Prendre des mesures minimales permettant l'accès rapide aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation en tenant compte, le cas échéant, des situations d'urgence actuelles ou imminentes menaçant la santé de l'homme; II.3.3 : Prendre des mesures minimales permettant l'accès rapide aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation en tenant compte, le cas échéant, des situations d'urgence actuelles ou imminentes menaçant la santé de l'homme;</p>
Côte d'Ivoire	Act	Loi No. 2014-390 du Juin 2014 d'Orientation sur le Développement durable (FR)	<p>Art. 23 : L'Etat met en place un cadre national de biosécurité permettant d'assurer un niveau adéquat de protection de la biodiversité, de la sante humaine et animale ainsi que de l'environnement contre les risques potentiels liés à l'utilisation des biotechnologies modernes et produits dérivés conformément aux impératifs du développement durable</p>

WHO Member State	Instrument type	Instrument title	Extract
Croatia	Decision	Decision promulgating the Nature Protection Act	<p>Art. 8: The provisions of this Act shall not apply in the case of deterring an immediate threat to human life or health or to property, of rescuing people and property or exercising activities in defence of the Republic of Croatia.; Art. 60 (5): Provisions of Article 59, paragraph 5 shall not apply to regular activities contained in plans for the management of natural resources for which the Ministry has issued nature protection requirements pursuant to Article 20 of this Act, and the emergency protection activities carried out in accordance with special regulations for the purpose of protecting human health, flora and fauna.; Art. 37(3): If in the area of the ecological network is found a habitat type and/or species from the List of particularly threatened and significant habitat types and species, the overriding public interest may apply only to protection of human health, human safety and safety of property or to establishment of significantly more favourable conditions of primary importance for the environment.; Art.</p> <p>155(2): Provided that there is no satisfactory alternative and the derogation is not detrimental to the maintenance of the populations of the strictly protected species at a favourable conservation status in their natural range, the Ministry may allow derogations from the provisions of Article 153 of this Act: in the interests of public health, public safety and safety of property, or for other imperative reasons of overriding public interest, including those of a social or economic nature and beneficial consequences of primary importance for the environment;</p>
Democratic Republic of the Congo	Act	Loi No. 14/003 Relative à la Conservation de la Nature	<p>Art. 20.2 : Sans préjudice des dispositions de l'article 19 de la présente loi, l'organisme public prévu à l'article 36 peut, à titre exceptionnel et dans les aires protégées qu'il gère, accorder des dérogations notamment :</p> <p>(2) dans l'intérêt de la santé et de la sécurité publique, ainsi que de la sécurité alimentaire des populations riveraines des aires protégées</p>

WHO Member State	Instrument type	Instrument title	Extract
Ethiopia	Proclamation	Proclamation No. 482/2006 To Provide for Access to Genetic Resources and Community Knowledge and Community Right (EN)	Art. 13.2: Conditions for Denial Access – The Institute may deny access to genetic resources, where: 2. The access may have adverse effects upon human health or the cultural values of the local community
France	Act	Loi No. 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages (FR) Law No. 108 2016 on Biodiversity (EN)	Art. 37 – Sous-section 2.1.III.5 : Les ressources génétiques collectées par les laboratoires au titre de la prévention et de la maîtrise des risques graves pour la santé humaine, régies par l'article L. 1413-8 du code de la santé publique. ; Sous-section 2.3.III : Est également soumis à déclaration à l'autorité administrative compétente l'accès aux ressources génétiques lorsque des situations d'urgence relatives à la santé humaine, à la santé animale ou à la santé végétale, autres que celles régies par l'article L. 1413-8 du code de la santé publique, le justifient.
Germany	Strategy/Action Plan (policy document)	Nationale Strategie zur biologischen Vielfalt (GER) National Strategy on Biological Diversity (EN)	Section A8: Above and beyond this, the Parties also receive support with implementing the Cartagena Protocol Biosafety to the Convention on Biological Diversity to limit the risks of modern biotechnology for biological diversity and human health
India	Guidelines	Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014	Section 14.2: Provided that special consideration may be given to cases where technologies/products are developed for controlling epidemics/diseases and for mitigating environmental pollution affecting human/ animal/plant health.
Japan	Guidelines	Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization	Chapter 2.1.2: Human health emergencies (1) The provisions of paragraph 1 do not apply to the access to genetic resources used for addressing situations that are deemed as emergencies as provided for under the International Health Regulations or human health emergencies. In this case, the acquirer is to submit a report using Form No. 1 along with a copy of the internationally recognized certificate of compliance to the Minister of the Environment within six months from the date on which the terms for deeming that the emergency has been settled are fulfilled.

WHO Member State	Instrument type	Instrument title	Extract
			(2) When it is difficult to determine the time of the occurrence and settlement of the emergency, the acquirer is to submit a report using Form No. 1 along with a copy of the internationally recognized certificate of compliance within one year from the date on which the genetic resources used for addressing the said emergency were accessed, regardless of the provision of (1) above.
Kenya	Act	Wildlife Conservation and Management Act 2013 (EN)	Section 34 (b)(a)(iv): Provided that there shall be no recommendation unless - (a) they are satisfied that such variation of boundary or cessation of national park proposed by the notice: (iv) does not prejudice biodiversity conservation, cultural site protection, or its use for educational, ecotourism, recreational, health and research purposes;
Lao People's Democratic Republic	Policy	Lao National Framework on the Access to Genetic Resources and the Fair and Equitable Sharing of Benefit Arising from their Utilization (EN)	1.2.3 (7): Establish or maintain the means to regulate, manage or control any risks associated with the use and release of living modified organisms resulting from modern biotechnology which are likely to have adverse environmental impacts that affecting the conservation and sustainable use of genetic resources, taking also into account any risks to human health.; 1.2.7: Recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the conservation and sustainable use of genetic resources that do not cause significant damage to the environment and human health.; Article 11(2): In the development and implementation of Lao People's Democratic Republic access and benefit-sharing legislation or regulatory requirements, Competent National Authorities on ABS shall: 2. Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally.

WHO Member State	Instrument type	Instrument title	Extract
			Competent National Authorities on ABS may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in the Lao People's Democratic Republic and developing countries
Malawi	Act	Environmental Management Act of 2017	Article 69(g): The Authority shall, in consultation with relevant lead agencies, prescribe measures and issue guidelines to promote the conservation of biological resources in situ in relation to: (g) safe handling, transfer, and use of living modified organisms resulting from modern biotechnology that may have adverse impact on biodiversity, human health, and the environment.
Malawi	Act	Environmental Management Act of 1996	Article 37.3(c): The Minister may, on the recommendation of the Council: (c) monitor any waste disposal site and direct the control of any such site if its continued use as a waste disposal site constitutes or is likely to constitute a hazard to the health of the people living in the vicinity of, or to the environment adjacent to, the site.
Malawi	Guidelines	Guidelines on Access to Biological Resources and the Fair and Equitable Sharing of Benefits Arising from their use	Where there are conditions requiring accessing biological resources for special uses including emergencies that threaten or damage human, animal or plant health the following procedure shall be undertaken (p. 14)
Malta	Act	Environment Protection Act (CAP. 549) Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations 2016	Article 23: Without prejudice to the provisions of the Council Regulation, the competent authority and the assistant authorities may for reasons of imminent threats to human, animal or plant health adopt interim measures, as they deem fit in the circumstances.
Mauritania	Act	Loi No. 2000-042 Relatives à la protection des végétaux (FR)	Article 12 : L'effet des interventions de ce dispositif sur la santé humaine ou animale, et sur l'environnement doit être tolérable.

WHO Member State	Instrument type	Instrument title	Extract
Niger	Act	Loi No. 2004-048 du 30 juin 2004 portant loi cadre relative à l'élevage (FR)	Article 53: Le ministre chargé de l'élevage, seul ou en accord avec les ministres concernés, prend toutes mesures destinées à prévenir l'apparition, à arrêter le développement et à poursuivre l'éradication des maladies animales dont l'existence est nuisible à la santé humaine ou à la rentabilité de l'élevage
Norway	Act	Lov om forvaltning av naturens mangfold (NOR) Nature Diversity Act (EN)	Section 18 (c): The King may make regulations or individual decisions permitting the removal of wildlife and salmonids and freshwater fish: (c) to safeguard general health and safety interests or other public interests of substantial importance
Republic of Korea	Act	Act on Access to and Utilization of Genetic Resources and Benefit Sharing	Article 10(1): Article 10 (Exemptions from Reporting Access to Domestic Genetic Resource(s)) Notwithstanding Article 9 (1), the head of the Competent National Authority may, as prescribed by Presidential Decree, seek to simplify procedures for reporting access to genetic resource(s) or waive such reporting following consultation with the head of the relevant central administrative agency, in any of the following cases: 1. Where it is deemed that expedited access to or utilization of the genetic resource(s) is required for the development of therapeutic drugs and food security in the event there are threats to the life and health of humans, animals, and plants;
Serbia	Act	The Law on Ratification of the Nagoya Protocol (EN)	Article 8(b): Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;
Switzerland	Ordinance	Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their	Art. 3.4: In an internationally or nationally recognised emergency that threatens the health of humans, animals or plants or the environment, it suffices if the due diligence requirement for the utilisation of genetic resources that are pathogenic or

WHO Member State	Instrument type	Instrument title	Extract
		Utilisation (Nagoya Ordinance)	harmful organisms is fully met at the time of the commercialisation of products developed on the basis of the utilised genetic resources.
Togo	Policy/strategy/action plan	Politique générale en matière d'APA (FR)	III. STRATEGIE NATIONALE: 3.2.1.: 3.2.1. Obligations en matière d'accès - Les dispositions à prendre en matière d'accès aux ressources génétiques en vue de leur utilisation doivent: tenir dûment compte des cas d'urgence actuels ou imminents qui menacent l'homme, la santé animale ou végétale ;
Zimbabwe	Regulation	Environmental Management (Access to Genetic Resources and Indigenous Genetic Resource- based Knowledge) Regulations, 2009	s3(c) The purposes of the regs are to "ensure the conservation and sustainable use of genetic resources in order to maintain and improve their diversity as a means of sustaining the life-support and health-care systems of the people of Zimbabwe"
European Union [not a WHO Member State]	Regulation	Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union	Preamble Par. 16: The Nagoya Protocol requires each Party thereto to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health
European Union [not a WHO Member State]	Guidance document	Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union	Section 5.1: Pathogenic organisms that pose a threat to human, animal or plant health are generally within the scope of the Regulation, given that they are covered by the Nagoya Protocol. However, specialised ABS instruments in the meaning of Article 4(4) of the Nagoya Protocol may also be applicable to certain pathogenic organisms. Material which is covered by specialised international instruments for access and benefit-sharing that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol, such as the WHO's Pandemic Influenza Preparedness (PIP) Framework, is outside of the scope of the Protocol and the Regulation (see Article 2(2) of the Regulation and above,

WHO Member State	Instrument type	Instrument title	Extract
			<p>p. 5).</p> <p>More generally, the Protocol explicitly recognises the importance of genetic resources to public health. In the development and implementation of their access and benefit-sharing legislation or regulatory requirements, Parties are required to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health (Article 8(b) of the Protocol). Expeditious access and benefit sharing should therefore also be aimed at with regard to non-pathogenic genetic resources in emergency situations.</p> <p>The Regulation gives special status to a pathogenic organism that is determined to be (or is determined likely to be) the causing pathogen of a present or imminent public health emergency of international concern or a serious cross- border threat to health. To these genetic resources an extended deadline for compliance with the due diligence obligation applies (see Article 4(8) of the Regulation).</p>

International Health Regulations (2005)

21. Two WHO Member States and the European Union included express consideration of and reference to the International Health Regulations (2005). Japan excludes resources that are required for emergencies as provided for under the Regulations. Similarly, the European Union provides for special considerations under Article 8(b) with reference to the Regulations. These provisions are indicated below in Table 12.

Table 12. Express reference to the International Health Regulations (2005) in law

WHO Member State	Extract
Japan	<p>Art 2.1.2: Human health emergencies</p> <p>(1) The provisions of paragraph 1 do not apply to the access to genetic resources used for addressing situations that are deemed as emergencies as provided for under the International Health Regulations or human health emergencies. In this case, the acquirer is to submit a report using Form No. 1 along with a copy of the internationally recognized certificate of compliance to the Minister of the Environment within six months from the date on which the terms for deeming that the emergency has been settled are fulfilled.</p> <p>(2) When it is difficult to determine the time of the occurrence and settlement of the emergency, the acquirer is to submit a report using Form No. 1 along with a copy of the internationally recognized certificate of compliance within one year from the date on which the genetic resources used for addressing the said emergency were accessed, regardless of the provision of (1) above.</p>
Serbia	<p>Preamble: Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,</p>
European Union [not a WHO Member State]	<p>Art. 4.8: [...] present or imminent public health emergency of international concern, within the meaning of the International Health Regulations (2005) [...]</p>

ANNEX 1

Coding

Table 13. Annotated coding sheet

Country Name	
ISO3	
Region	
EU Member State	For cross-checking implementation of EU Regulation 511/2014
Party to the Convention on Biological Diversity (CBD)	Yes/No
CBD Party	Date
CBD signed	If Yes, Date
CBD ratified	If Yes, Date
Nagoya Party	Yes/No
Nagoya Party	Date
Nagoya signed	If Yes, Date
Nagoya ratified	If Yes, Date
Review status	Complete Identification of translation issues No law or policy instrument found on the Access and Benefit-Sharing Clearing-House
Instrument type	Act/regulation (draft?)/policy/other (details)
Instrument title	In original language and English translation
Instrument date	Date of adoption, or for drafts, date of draft
Version	Official version/translation or unofficial version/translation
Language	Original and translation used
Source	Accessed via the Access and Benefit-Sharing Clearing-House/portal/website
Are genetic resources defined in the text?	Yes/No
Extract	If Yes, extract of provision.
Is the definition of genetic sources the same as in the CBD?	"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity. "Genetic resources" means genetic material of actual or potential value.
Express mention of pathogens in the definition of genetic resource or in text?	Yes/No
Extract	If Yes, extract of provision.
Express mention of genetic sequence data/digital sequence information in the definition of genetic resources?	Yes/No:
Influenza	Yes/No: express mention of influenza in instrument?
Extract	If Yes, extract of provision.
Seasonal/Pandemic	Yes/No: distinction made between seasonal and pandemic influenza?
Extract	If Yes, extract of provision.
Human health	Yes/No: express reference to human health, including as a consideration in applying the law or as an express exemption from access and benefit-sharing legislation
Extract	If Yes, extract of provision.
Pandemic Influenza Preparedness Framework	Yes/No: express reference to the PIP Framework? Is it expressly described as a "specialized instrument"?
Extract	If Yes, extract of provision.

Convention on Biological Diversity	Yes/No: express reference to the CBD, including that the law is implementing obligations under CBD or reference to Article 15 (genetic resources)?
Extract	If Yes, extract of provision.
Nagoya Protocol	Yes/No: express reference to the Nagoya Protocol, including that the law is implementing obligations under the Nagoya Protocol?
Extract	If Yes, extract of provision.
Specialized instruments (Article 4(4))	Yes/No: express reference to the ability to recognize specialized instruments or to Article 4(4)? Are any laws specifically defined as specialized instruments?
Extract	If Yes, extract of provision.
Special considerations (Article 8(b))	Yes/No: express reference to special considerations in implementing the Nagoya Protocol, including Article 8(b) or for human health/health emergencies/epidemics?
Extract	If Yes, extract of provision.
International Health Regulations (2005)	Yes/No: express reference to the International Health Regulations (2005)?
Extract	If Yes, extract of provision.
Genetic sequence data/digital sequence information	Is there any express reference to genetic sequence data/digital sequence information –generally or in reference to access and benefit sharing?
Additional factors	Any other relevant considerations, points of interest, areas of confusion or questions?

ANNEX 2

Translations required

22. To help to improve the accuracy of this review, Table 14 below identifies WHO Member States for which a translation (official or unofficial) was not provided in English or French. Table 15 identifies WHO Member States for which an unofficial/reference translation was uploaded.

Table 14. Member States for which a translation of the law or policy is still required

Albania	Translation required (from Albanian)
Austria	Translation required (from German)
Belarus	Translation required (from Russian)
Costa Rica	Translation required (from Spanish)
Dominican Republic	Translation required (from Spanish)
Ecuador	Translation required (from Spanish)
Guatemala	Translation required (from Spanish)
Honduras	Translation required (from Spanish)
Mexico	Translation required (from Spanish)
Panama	Translation required (from Spanish)
Peru	Translation required (from Spanish)
Portugal	Translation required (from Portuguese)
Republic of Moldova	Translation required (from Romanian)
Russian Federation	Translation required (from Russian) [NB: applies to one policy document; translations have been provided for other documents]
Slovakia	Translation required (from Slovak)
Spain	Translation required (from Spanish)
Sudan	Translation required (from Arabic)
Sweden	Translation required (from Swedish)
Uruguay	Translation required (from Spanish)

Table 15. Member States for which an unofficial/reference translation was provided to the Access and Benefit-Sharing Clearing-House and used for the review

Belarus	Complete – unofficial translation
Bhutan	Complete – unofficial translation
Brazil	Complete – unofficial translation
Bulgaria	Complete – unofficial translation
Croatia	Complete – unofficial translation
Czechia	Complete – unofficial translation
Estonia	Complete – unofficial translation
Finland	Complete – unofficial translation
Germany	Complete – unofficial translation
Hungary	Complete – unofficial translation
Japan	Complete – unofficial translation
Lao People's Democratic Republic	Complete – unofficial translation
Malta	Complete – unofficial translation
Republic of Korea	Complete – unofficial translation
Serbia	Complete – unofficial translation
Viet Nam	Complete – unofficial translation

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