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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
MEETING OF THE PARTIES TO THE NAGOYA
PROTOCOL ON ACCESS TO GENETIC RESOURCES
AND THE FAIR AND EQUITABLE SHARING OF
BENEFITS ARISING FROM THEIR UTILIZATION

Third meeting

Sharm El-Sheikh, Egypt, 17-29 November 2018

Item 14 of the provisional agenda*

INFORMATION PROVIDED BY PARTIES TO THE NAGOYA PROTOCOL ON THE NATIONAL IMPLEMENTATION OF ARTICLE 8(B) AND OTHER RELEVANT PROVISIONS OF THE PROTOCOL

1. In decision NP-2/5 on cooperation with other international organizations, conventions and initiatives, the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol requested the Executive Secretary to share with the World Health Organization (WHO) relevant information provided by Parties in their interim national reports on the implementation of the Protocol, including its Article 8(b).¹
2. A note by the Executive Secretary with relevant information provided by Parties in their national reports on national implementation of the Nagoya Protocol, including its Article 8(b), was thus prepared and shared with WHO and published on their website.² This report is made available in the annex to the present document for the information of participants in the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol.

* CBD/NP/MOP/3/1.

¹ Decision NP-2/5, paragraph 2.

² <http://www.who.int/un-collaboration/partners/UNCBD/en/>.

*Annex***INFORMATION PROVIDED BY PARTIES TO THE NAGOYA PROTOCOL ON THE NATIONAL IMPLEMENTATION OF ARTICLE 8(B) AND OTHER RELEVANT PROVISIONS OF THE PROTOCOL****I. BACKGROUND**

1. The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity adopted in Nagoya, Japan, on 29 October 2010. Its objective is also one of the objectives of the Convention: the fair and equitable sharing of benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources. The Nagoya Protocol creates a global framework on access and benefit-sharing (ABS) for genetic resources and traditional knowledge associated with genetic resources, thereby contributing to the conservation of biological diversity and the sustainable use of its components³. The Nagoya Protocol entered into force on 12 October 2014. As of 31 May 2018, it has 105.
2. In accordance with Article 29 of the Nagoya Protocol, Parties to the Protocol are required to monitor the implementation of their obligations and to report to the governing body – the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol (COP-MOP) – on measures taken to implement the Protocol. In decision NP-1/3, the COP-MOP requested Parties to submit an interim national report on the implementation of the Nagoya Protocol. The interim national reports were to be submitted through the Access and Benefit-sharing Clearing-House⁴ and were due by 1 November 2017. Reports were also welcomed from non-Parties to the Protocol.
3. The preamble of the Nagoya Protocol notes the International Health Regulations (2005) of the World Health Organization (WHO) and the importance of ensuring access to human pathogens for public health preparedness and response purposes. Furthermore, Article 8(b) of the Nagoya Protocol provides that in the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall “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”.
4. Considering the linkages between the Nagoya Protocol and public health, the COP-MOP included, in its decision NP-2/5 on cooperation with other international organizations, conventions and initiatives, a request for the Executive Secretary of the Convention to share with the WHO relevant information provided by Parties in their interim national reports on the implementation of the Nagoya Protocol, including its Article 8(b)⁵.
5. This document has been prepared in response to this request. It is structured as follows: section II contains notes on the sources of information used for assessing national implementation of the Nagoya Protocol; section III contains a synthesis of relevant information provided by Parties and non-Parties in their interim national reports, including on the national implementation of Article 8(b) of the Nagoya Protocol; and section IV draws attention to key points from the analysis of interim national reports which may be of interest to the WHO and its Member States.

³ The text of the Nagoya Protocol is available at: <https://www.cbd.int/abs/text/>

⁴ The Access and Benefit-sharing Clearing-House (ABS Clearing-House) is a platform for exchanging information on access and benefit-sharing established by Article 14 of the Nagoya Protocol, as part of clearing-house mechanism under Article 18, paragraph 3 of the Convention. It is available at: <https://absch.cbd.int/>.

⁵ The text of decision NP-2/5 is available at: <https://www.cbd.int/doc/decisions/np-mop-02/np-mop-02-dec-05-en.pdf>

II. SOURCES OF INFORMATION

6. As of 31 May 2018, a total of 80 interim national reports have been submitted. However the analysis is based on the 75 interim national reports⁶ submitted as of 22 of February 2018.

7. All interim national reports received are available online on the ABS Clearing-House at the following link: <https://absch.cbd.int/reports> with the exception of two reports that were submitted offline. The ABS Clearing-House also hosts a report analyser tool that enables the analysis of information contained in the interim national report by question, country/ies or region.

8. The analysis provided in section III below is based on the information contained in the interim national reports and the ABS Clearing-House as of 22 February 2018. Relevant information provided through national biodiversity strategies and action plans (NBSAPs) and the fifth national reports on the implementation of the Convention was also considered to fill gaps in the case of those Parties that did not submit an interim national report.

III. ASSESSMENT OF PROGRESS IN IMPLEMENTING THE NAGOYA PROTOCOL

9. A number of steps are to be taken by Parties to the Nagoya Protocol to operationalize the Protocol. Specifically, Parties to the Protocol are to: (a) establish institutional structures; and (b) develop or revise legislative, administrative or policy measures on ABS to implement the Protocol. Furthermore, Parties to the Protocol are also required, via Article 14, to provide relevant information to the ABS Clearing-House.

A. Institutional structures

10. The Nagoya Protocol requires Parties to establish institutional structures to administer their ABS systems and support the implementation of the Protocol at the national level. These include:

(a) A national focal point, responsible for liaising with the Secretariat and making information available on procedures for accessing genetic resources and establishing mutually agreed terms, including information on competent national authorities, relevant indigenous and local communities and relevant stakeholders (Article 13(1));

(b) At least one competent national authority, responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms (Article 13(2));

(c) At least one checkpoint, responsible for monitoring by collecting or receiving relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms and/or to the utilization of genetic resources, as appropriate (Article 17(1)(a)).

11. As of 22 February 2018, information from the ABS Clearing-House and interim national reports indicate that:

(a) 170 have designated a national focal point on ABS: This is 103 Parties (98% of Parties) and 67 non-Parties;

(b) 65 countries (57 Parties and 8 non-Parties) have established one or more competent national authorities; and

(c) 30 countries (29 Parties and 1 non-Party) have designated at least one checkpoint.

12. Some of this information has not yet been made available to the ABS Clearing-House and the Secretariat is engaging with countries concerned to encourage the submission of information.

B. Legislative, administrative or policy measures on ABS (ABS measures)

⁶ 69 from Parties to the Protocol and 6 from non-Parties

13. The Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic resources, benefit-sharing and compliance.

14. According to information available, as of 22 February 2018, 75 Parties and 30 non-Parties had published measures in the ABS Clearing-House or reported having established some ABS measures. Out of these 75 Parties, 44 indicated that they are currently revising existing or developing new ABS measures to implement the Protocol and 10 Parties are planning to develop additional ABS measures.

15. A total of 25 Parties reported not having ABS measures in place and did not have measures published in the ABS Clearing-House. Based on the available information, two of these Parties are currently developing measures and 13 Parties are planning to develop such measures.

16. Interim national reports provide additional information on the implementation of ABS measures. In particular, it can be noted that:

(a) Under the Nagoya Protocol, access to genetic resources for their utilization⁷ is subject to the prior informed consent of the Party providing such resources, unless otherwise determined by that Party. According to the interim national reports, access to genetic resources is subject to prior informed consent in 37 Parties and two non-Parties (out of 75 countries that submitted their report)⁸. Additional countries reported that they are planning to establish procedures for prior informed consent as part of their national ABS framework. Other countries have taken a formal decision not to require prior informed consent for access.

(b) The Nagoya Protocol also provides that benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources. In their interim national reports, 46 Parties and four non-Parties out of a total of 75 countries reported having taken legislative, administrative or policy measures to ensure that benefits arising from the utilization of genetic resources are shared with the country Party providing such resources⁹. Several countries expressed that benefit-sharing provisions would be included in an ABS framework currently under development.

(c) The Nagoya Protocol also features compliance provisions, in order to ensure that ABS requirements are respected when genetic resources leave the Party providing such resources. With regards to compliance with domestic legislation or regulatory requirements on ABS, 36 Parties and four non-Parties out of 75 that submitted their report, indicated having taken measures to ensure that users of genetic resources in their jurisdiction comply with ABS requirements of other Parties¹⁰. Measures reported which address non-compliance include: fines, sanctions, notices, penalties and seizures, among others. Many countries expressed that compliance with ABS requirements of other Parties would be taken into account in the ABS framework currently under development.

17. Some of the ABS measures adopted by some countries have not yet been made available to the ABS Clearing-House and the Secretariat is engaging with the concerned countries to encourage the submission of this information.

C. SPECIAL CONSIDERATIONS (ARTICLE 8 (b) OF THE NAGOYA PROTOCOL)

18. With regards to Article 8, paragraph (b), which addresses health emergencies, the format of the interim national report (question 35) included two mandatory sub-questions. The following provides an overview of the responses to these questions.

⁷ Where “utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention. Nagoya Protocol, Article 2.

⁸ Answers to question 11 of the report.

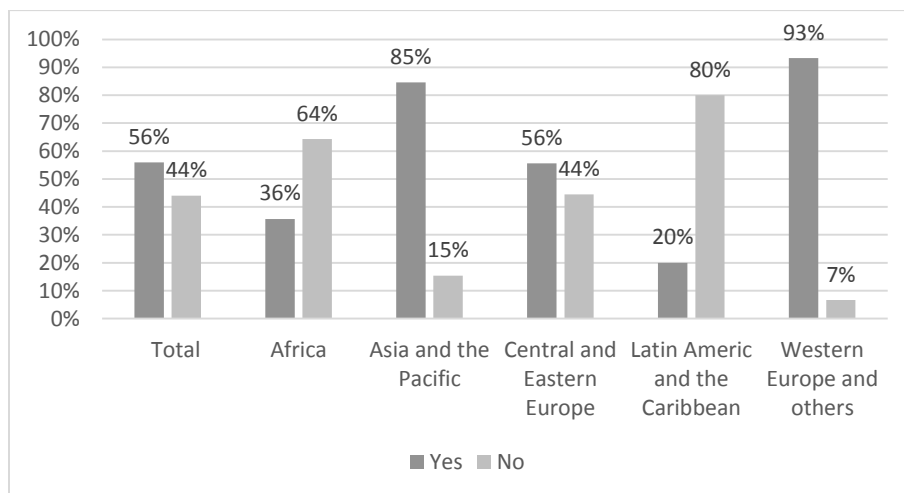
⁹ Answers to question 20 of the report.

¹⁰ Answers to question 24 of the report.

1. In the development and implementation of ABS legislation or regulatory requirements has your country paid due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health as provided in Article 8(b)

19. Out of the 75 countries that submitted a report, 39 Parties and 3 non-Parties reported having paid due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, while 30 Parties and 3 non-Parties reported not having done so.

Graph 1: Due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health (percentage of countries)



(a) Countries that answered “yes”

20. Some countries referred to existing ABS measures addressing this issue¹¹ or to draft measures under development or approval¹². Other countries indicated that they had some relevant mechanisms in place to address such emergencies¹³ and one Party stated that even though they had such mechanisms in place, Article 8(b) would be given due consideration in the development/review of their ABS measures¹⁴.

21. Several countries¹⁵ provided general information on measures taken and progress made to prevent threats to human health, as part of their efforts to implement the International Health Regulations (2005) and the Pandemic Influenza Preparedness (PIP) Framework of the World Health Organization.

22. The European Union explained that there is no access legislation at EU level hence there are also no measures on expeditious access to genetic resources for that purpose.¹⁶ Article 4(8) of Regulation 511/2014¹⁷ provides for a short temporal derogation from obligations contained in its Articles 4(3) and 4(5) for 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.

¹¹ E.g. Benin, Belgium, Bhutan, Czech Republic, Denmark, Finland, France, Germany, Hungary, India, Kenya, Malta, Mongolia, Netherlands, Slovakia, Spain, Sweden, United Kingdom of Great Britain and Northern Ireland, Viet Nam

¹² E.g. China, Norway, Morocco, Togo

¹³ E.g. Kenya, Niger, Peru, Senegal

¹⁴ E.g. Kenya

¹⁵ E.g. China, Lao People’s Democratic Republic, Mexico

¹⁶ The same information was provided by the EU Member States in their reports.

¹⁷ Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 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. Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-BG-201808>

23. In addition to Regulation (EU) No 511/2014, several Parties which are also Member States of the European Union reported on other measures taken at the national level to address cases of present or imminent health emergencies:

(a) Bulgaria reported that Article 66 (4) of the Biological Diversity Act¹⁸ provides for gratuitous provision of genetic resources if the resources are intended for non-commercial purposes, including scientific research, education, conservation of biological diversity, or public health;

(b) France indicated that the French law on biodiversity foresees a simplified procedure (declaration) for access to this type of genetic resources when the urgency of the situation is justified;

(c) Malta reported that Regulation 23 of S.L. 549.111 of the Laws of Malta¹⁹ enables the national competent authority to adopt interim measures in case of imminent threats to human, animal or plant health; and

(d) Spain reported that Article 8 of its ABS Decree²⁰ addresses access to genetic resources in emergency situations and provides that declaration of an emergency could justify an exceptional, provisional and immediate authorization for access to a genetic resource. Authorization is, however, granted on the condition that mutually agreed terms are established later on, and that a definitive authorization is granted within a period of six months.

24. Other countries reported on different approaches to access and benefit-sharing with regards to health emergencies:

(a) Article 16 of Benin's national ABS directives provides for simplified procedural documents for authorization requests made to the competent national authority for access to genetic resources and associated traditional knowledge in the case of emergencies pertaining to human, animal or plant health;

(b) The Biodiversity Bill of Bhutan, under Chapter 4 clause 30, provides for exemptions to be granted from procedural requirements or a fee waiver;

(c) Regulation 13 of India's Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014²¹, through Form B, facilitates the transfer of biological resources by governmental institutions in India to carry out urgent studies to avert emergencies like epidemics etc., through an expeditious and simplified process;

(d) Article 3, paragraph 4, of Switzerland's Nagoya Ordinance²² provides that, 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 utilization 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 utilized genetic resources.

25. Some countries provided further information on the content of their draft measures:

(a) China stated that procedures and measures will be simplified for access to genetic resources and benefit-sharing for emergency responses;

(b) Article 5 of Morocco's draft law 56-17 on ABS²³ states that the provisions of the law do not apply when genetic resources are collected according to special measures to protect animals and plants from health dangers. Furthermore, Article 15 contains a procedure for urgent requests to access genetic resources used to fight the spread of diseases or epidemics that constitute a real or imminent danger to

¹⁸ Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-BG-208570>

¹⁹ Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-MT-208508>

²⁰ Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-ES-208924>

²¹ Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-IN-208214>

²² Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-CH-207346>

²³ Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-MA-238754>

public health at the national or international level. The modalities of this emergency procedure will be established by regulation.

26. Peru provided information on the most relevant pathogens for their national context and indicated existing research groups working on pathogens in their country. They also emphasised the importance of strengthening the research and development capacities of those institutions through cooperation and collaboration among countries.

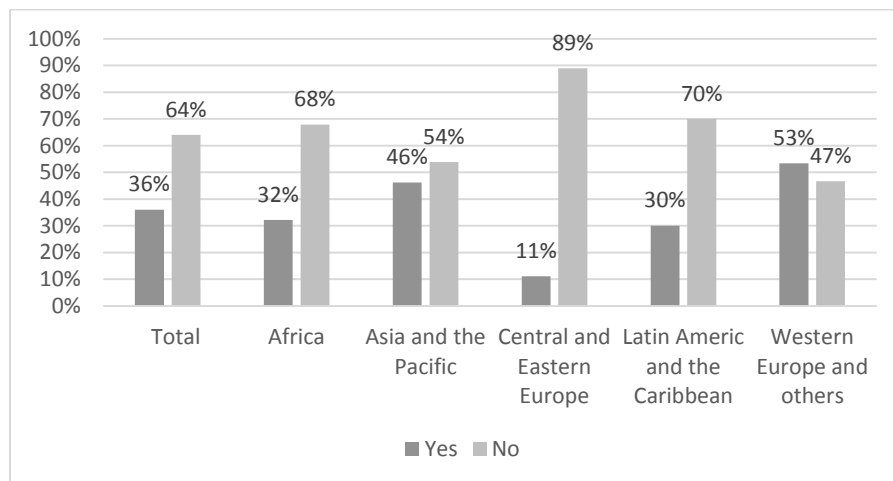
(b) Countries that answered “no”

27. Many countries²⁴ stated that due regard would be paid to cases of present or imminent emergencies that threaten or damage human, animal or plant health in future development or revision of ABS legislation or regulatory requirements. Two countries²⁵ explained that they have not yet done so due to the lack of ABS measures and another two countries²⁶ indicated that the question was not applicable as they did not have access requirements in place. Some countries also noted that there had not been any relevant cases so far.²⁷

2. In the development and implementation of ABS legislation or regulatory requirements has your country taken 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 as provided in Article 8(b)

28. Out of 75 countries, 26 Parties and one non-Party stated that they had taken into consideration the need for expeditious access and expeditious benefit-sharing in the development and implementation of ABS legislation or regulatory requirements, while 43 Parties and 5 non-Parties reported not having taken such a need into consideration.

Graph 1: Consideration of the need for expeditious access and expeditious benefit-sharing (percentage of countries)



(a) Countries that answered “yes”

²⁴ E.g. Antigua and Barbuda, Belarus, Botswana, Comoros, Côte d’Ivoire, Democratic Republic of Congo, Ethiopia, Madagascar, Malawi, Mexico, South Africa, Sudan, Uruguay

²⁵ Congo, Guinea Bissau

²⁶ Japan, Poland

²⁷ E.g. Cuba, Mexico

29. Some countries referred to existing ABS measures²⁸ addressing this issue or to draft measures under development or approval²⁹. Some countries³⁰ reported having relevant mechanisms in place to address expeditious access and expeditious benefit-sharing, including one Party³¹ who stated that even though they had such mechanisms in place, Article 8(b) would be given due consideration in the development/review of their ABS measures. A country³² answered “yes” to this question on the basis of not requiring access authorization in their country.

30. Answers provided were similar to those provided to the question above (due regard to cases of present or imminent emergencies). Additional information provided by countries include the following:

(a) China reported that in accordance with the International Health Regulations (2005) the country reports in a timely manner to the World Health Organization and the World Organisation for Animal Health about confirmed cases and publishes updated data on epidemics, shares relevant information with relevant organizations and their members, and reports on China’s progress in preventing and controlling epidemics. China explained that its draft ABS regulation will be consistent with and mutually supportive of those international treaties and conventions the country has ratified or acceded to, with adequate consideration given to existing mechanisms.

(b) Peru emphasised the importance of expeditious benefit-sharing in exchange for access to pathogens and in that regard they consider: (a) establishing expeditious procedures for access without undermining the need for PIC and MAT; (b) the confidential nature of information on pathogens accessed;

(c) (c) the interest of the country to benefit from access to vaccines and to freely distribute them among public entities and affected communities; and (d) the interest of the country to benefit from cooperation mechanisms with other countries to enhance the capacities and infrastructure of national research institutions.

(b) Countries that answered “no”

31. Many countries³³ stated that they will consider this issue in the future development or revision of ABS legislation or regulatory requirements. A number of countries indicated that there were no access rules, and hence no specific measures for expeditious access³⁴ and expeditious benefit-sharing³⁵. Two countries explained that they have not yet done so due to the lack of ABS measures³⁶ and one country³⁷ noted that there have not been any relevant cases so far.

32. Japan indicated that the Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization³⁸ specify that the procedural requirements in domestic measures based on Articles 15 and 16 of the Nagoya Protocol are relaxed in situations that are deemed emergencies, in accordance with the International Health Regulations of the World Health Organization, or domestic legislation (e.g. Infectious Disease Act) or regulatory requirements. In those cases, the acquirer is to submit a report to prove lawful access within six months of the date on which the terms for deeming that the emergency has been settled are fulfilled.

²⁸ E.g. Bhutan, Malta, Spain

²⁹ E.g. China, Mexico, Niger, Norway, Uganda

³⁰ E.g. Benin, Kenya,

³¹ Kenya

³² Netherlands

³³ E.g. Antigua and Barbuda, Botswana, Comoros, Côte d’Ivoire, Kenya, Malawi, Mongolia, South Africa, Sudan, Uruguay

³⁴ E.g. Belgium, Estonia, European Union, Finland, Germany, Japan, Poland, Slovakia, Sweden, United Kingdom of Great Britain and Northern Ireland

³⁵ E.g. Belgium, Estonia, European Union, Finland, Poland, Slovakia, Sweden, United Kingdom of Great Britain and Northern Ireland

³⁶ Congo, Guinea Bissau

³⁷ Antigua and Barbuda

³⁸ Available at: <https://absch.cbd.int/database/record/ABSCH-MSR-JP-238074>

D. KEY HIGHLIGHTS

20. The implementation of the Nagoya Protocol is at a relatively early stage. A number of Parties to the Convention are still ratifying or acceding to the Protocol.
21. The implementation and operationalization of ABS and the Nagoya Protocol at the national level requires several actions to be taken by Parties, including the establishment or designation of the appropriate institutional structures, and the development or revision of access and benefit-sharing legislative, administrative and policy measures aligned with the requirements of the Nagoya Protocol. For many Parties, this process takes long and can be challenging due to the cross-cutting nature of access and benefit-sharing which is relevant to various sectors and stakeholders.
22. Parties, as well as non-Parties, are making progress in implementing the Protocol. Most of the Parties (75 of them) have some measures in place. The information provided through the interim national reports indicate that a number of countries are also advancing towards implementing Article 8(b).
23. However, a number of Parties are still in the process of revising or developing their ABS frameworks. According to information available, 54 Parties are currently working on the adoption of ABS measures and another 23 Parties reported about their plans to develop ABS measures.³⁹ Many of those Parties have not yet addressed health emergencies in the context of the Nagoya Protocol.
24. Non-Parties are also working towards ratification and implementation of the Nagoya Protocol and taking the necessary steps to make it operational at the national level.
25. As countries are advancing with the implementation of the Nagoya Protocol, national coordination amongst ministries and institutions working on ABS-related issues and on issues related to human, animal and plant health can contribute to ensuring that ABS measures take into account public health considerations.

³⁹ Some of those Parties already have some ABS measures in place and are working on the development of additional ones.