FACT SHEET
Nagoya Protocol and Public Health

Background
The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) is a treaty that supplements the Convention on Biological Diversity (CBD). It supports the implementation of one of the CBD’s three objectives: the fair and equitable sharing of benefits arising from the utilization of genetic resources. The Nagoya Protocol entered into force on 12 October 2014 and, as of January 2018, has 104 Parties. Parties to the CBD meet once every two years at the Conference of the Parties (COP) to the CBD. This meeting also serves as the Meeting of the Parties to the Nagoya Protocol (COP-MOP).

The Nagoya Protocol applies to genetic resources – and traditional knowledge associated with them – that are covered by the CBD. It also applies to the benefits arising from their utilization.

Nagoya Protocol principles and requirements
The Nagoya Protocol is based on the fundamental principles of access and benefit sharing established by the CBD:

- Access: Users who wish to access genetic resources must generally obtain the prior informed consent (PIC) of the provider country. A user and a provider country must agree to the terms and conditions of access and utilization of genetic resources through the establishment of mutually agreed terms (MAT).

- Benefit sharing: MAT also address the sharing of benefits that arise from the utilization of genetic resources. These benefits are to be shared in a fair and equitable way with the provider country. The benefits that are shared may be monetary or non-monetary. The Protocol contains an annex that lists some of these benefits.

Genetic sequence data under the Nagoya Protocol
In the context of the CBD and Nagoya Protocol, genetic sequences are referred to as “digital sequence information” (DSI); in the PIP Framework, the terms “genetic sequences” and “genetic sequence data” (GSD) are used. These terms have been used interchangeably.

Parties to the CBD and Nagoya Protocol discussed DSI during the December 2016 COP-MOP, noting that rapid advances in biotechnology have impacted the use of genetic resources. The Parties therefore decided to establish a process for the consideration of this issue.

Parties agreed to consider the implications that the use of DSI derived from genetic resources might have on the objectives of the CBD and Nagoya Protocol at the next COP-MOP, in November 2018.

Potential links to public health in the text of the Nagoya Protocol
Importance of the Nagoya Protocol to pathogen sharing
Rapid and comprehensive sharing of and access to pathogens and associated data are essential to protecting global human and animal health. They contribute to, among other things:

a. Ongoing surveillance, e.g., to detect emerging pathogens or pathogens with antimicrobial resistance;

b. Risk assessment to determine the level of risk posed by a pathogen and to identify public health interventions that will limit morbidity and mortality in human and animal populations;

c. Development of diagnostic tools to identify suspect cases, ensuring that patients are given appropriate medical care;

d. Implementation of evidence-based national and global public health strategies and measures to better control endemic diseases and prevent further spread of outbreaks;

e. Development of more-effective vaccines and therapeutics and more-accurate diagnostic tools.
Through these crucial activities, countries can prevent and respond to outbreaks.

**Article 4(4): Recognition of “specialized international access and benefit-sharing instruments”**

The Nagoya Protocol addresses its relationship to other international agreements and instruments, *inter alia*, as follows:

> ...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.²⁴

At their meeting in December 2016, the Parties to the Protocol requested that the CBD Secretariat conduct a study into criteria that could be used to define a specialized international access and benefit-sharing instrument and a possible process for recognizing such an instrument.³⁵ The results of this study will be released on 9 April 2018 and discussed by the Protocol’s Subsidiary Body on Implementation (SBI) in July 2018.¹⁶ Both the study and the SBI’s findings and conclusions will be submitted for consideration by the Parties at their next meeting, in November 2018.

At the 70th session of the World Health Assembly, WHO Member States reaffirm[ed] the importance of the PIP Framework in addressing present or imminent threats to human health from influenza viruses with pandemic potential, and emphasize[d] its critical function as a specialized international instrument that facilitates expeditious access to influenza viruses of human pandemic potential, risk analysis and the expeditious, fair and equitable sharing of vaccines and other benefits.¹⁸

**Health emergencies and the Nagoya Protocol**

The importance of pathogen sharing for public health is recognized in the preamble of the Nagoya Protocol, which states that Parties are “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”. Parties to the Protocol should therefore consider ways of implementing the Protocol in a manner that is supportive of human health.³⁹

Article 8(b) of the Protocol requires Parties to pay due regard to “present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally” when developing and implementing access and benefit-sharing (ABS) legislation. It states that

> In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall: (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.

Parties may implement Article 8(b) by, for example, developing special ABS measures for use during health emergencies to support timely and equitable public health responses, including access to affordable treatments by those in need, especially in developing countries. This could include putting in place rules and procedures to fast-track access to pathogens that threaten health in present or imminent emergency situations while ensuring equitable benefit sharing, for example, by making available to affected populations countermeasures developed using pathogen samples.

**Further information**

- See [Questions and Answers on Implementation of the Nagoya Protocol in the Context of Human, Animal and Plant Health: Access to Pathogens and Fair and Equitable Sharing of Benefits.](#)

- WHO [Report on the Public Health Implications of the implementation of the Nagoya Protocol](#), submitted to the 140th session of the Executive Board. A central conclusion of the study is that “(1) the Nagoya Protocol has implications for the public health response to infectious diseases, including influenza; and (2) these implications include opportunities to advance both public health and principles of fair and equitable sharing of benefits”.²⁰

**Abbreviations**

ABS – access and benefit-sharing  
CBD – Convention on Biological Diversity  
COP – Conference of the Parties to the Convention on Biological Diversity  
COP-MOP – Conference of the Parties to the
1 This Fact Sheet is adapted from Questions and Answers on Implementation of the Nagoya Protocol in the Context of Human, Animal and Plant Health: Access to Pathogens and Fair and Equitable Sharing of Benefits. It has been abridged and adapted to provide information relevant to the implementation of decision WHA70(10)(b). It is a living document and will be updated as new information arises. Readers may also wish to consult the study developed by WHO on the potential public health implications of implementation of the Nagoya Protocol for the 140th 2nd Executive Board (document EB140/15 and http://www.who.int/un-collaboration/partners/UNCBD/en/).
3 The list of Parties is available at https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml
4 The abbreviation COP-MOP stands for Conference of the Parties to the Nagoya Protocol serving as the Meeting of the Parties to the Nagoya Protocol.
5 Pathogens are not explicitly mentioned in the scope of the Protocol. Parties may therefore determine the legal status of pathogens in their implementing legislation. For example, the European Union Regulation 511/2014 on compliance measures for users from the Nagoya Protocol clearly states that pathogens fall within the scope of the Protocol. More information on access and benefit sharing and the Nagoya Protocol can be found in the fact sheets and information kits available at https://www.cbd.int/abs/resources/factsheets.shtml
6 See Article 15 of the CBD. Text available at https://www.cbd.int/convention/text/default.shtml
7 Unless otherwise determined by a Party to the Nagoya Protocol.
8 See Articles 15(4) and 15(5) of the CBD.
9 See Article 15(7) of the CBD.
10 See Annex of the Nagoya Protocol.
11 More specifically, at the 13th meeting of the COP to the CBD (COP 13) and the second meeting of the COP serving as the Meeting of the Parties to the Nagoya Protocol (COP-MOP 2).
12 See Annex for the statement by WHO.
15 See COP-MOP2 decision NP-2/15, Cooperation with Other International Organizations, Conventions and Initiatives. Text available at https://www.cbd.int/doc/cf6ce9878e/cff4-a887c2029963fe040a/sbi-02-02-en.pdf
18 See http://www.who.int/un-collaboration/partners/Nagoya_Full_Study_English.pdf?ua=1 at paragraph 21.