



Nagoya Protocol and Public Health

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THE NAGOYA PROTOCOL

FROM THE PUBLIC HEALTH POINT OF VIEW

In this presentation:

- Why the NP is of interest to the health sector
- Equity between the NP, IHR(2005) and EU Decision 1082/2013
- Pandemic Influenza Preparedness Framework, PIPF
- Global Influenza Surveillance & Response System, GISRS
- WHO decisions in May 2019 on PIPF and Nagoya





Why the Nagoya Protocol is of interest to the health sector

- The Nagoya Protocol objective is the fair and equitable sharing of benefits arising from the *utilization of genetic resources*, including by appropriate *access to genetic resources*
- Genetic resources include *microbes* (in the scope of the CBD)
- *Sharing microbes continuously by public health authorities in a timely manner* is essential for global health safety and security



Why the Nagoya Protocol is of interest to the health sector

Sharing microbes – including pathogens - is *essential to public health and food security* for

- Conducting surveillance and risk assessment
- Development of diagnostic tools, vaccines and therapeutics
- Risk management and implementing of evidence-based public health strategies
- Conducting scientific research for human and animal health

Timely sharing of microbes and information related to them is needed for cross-border preparedness to detect, prevent and respond to public health events and emergencies



Points of concern for the health sector

Implementation of NP may result to *issues regarding sharing of microbes or samples and relevant information linked to them such as genetic sequence data* due to

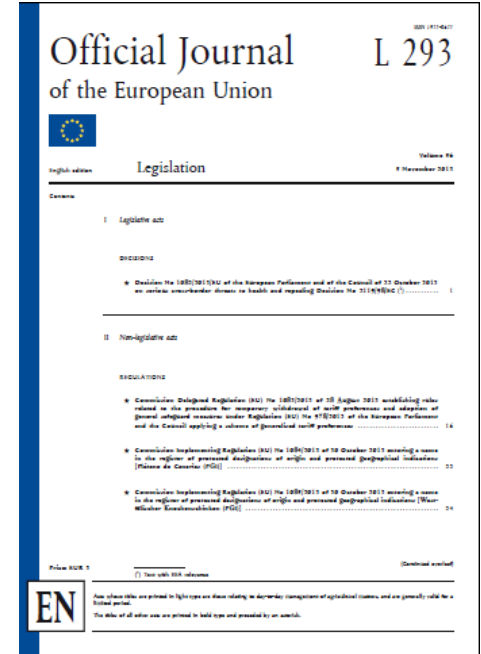
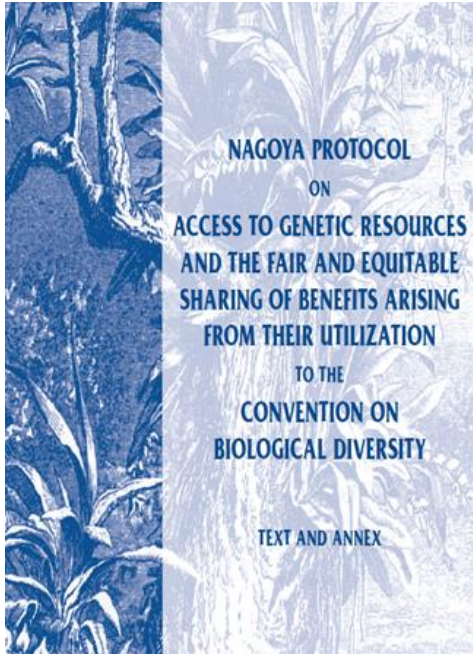
- Legal uncertainty at national level
- Delays in communication leading to delays in action
- International complexity of interpretation agreements

Anecdotal examples of seasonal and pandemic influenza viruses, Zika, Lassa fever, Ebola, malaria, cholera and other microbes

- *Recent studies* by the WHO and CBD
- *Current survey* by the WHO on WHO and CBD websites



Equity between the NP, IHR(2005) and EU Dec 1082/2013





Linkages between the NP, IHR(2005) and EU Dec 1082/2013

Preamble of the NP

- *Recognizing* the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change
- *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

Article 8(b) of the NP

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
- 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;



Linkages between the NP, **IHR(2005)** and **EU Dec 1082/2013**

International Health Regulations, IHR(2005)

- *Surveillance and timely response to epidemic threats is an obligation stated in the core capacities of the IHR(2005).*

EU Decision 1082/2013 on serious cross-border threats to health

Article 168 of the Treaty on the Functioning of the European Union (TFEU) states, inter alia, that a *high level of human health protection* is to be ensured in the definition and implementation of all Union policies and activities

- *Preparedness and response planning* is an essential element for effective monitoring, early warning of and combating serious cross-border threats to health
- *Surveillance and information exchange*



What is PIP, Pandemic Influenza Preparedness, Framework

- Access & benefit sharing instrument adopted by WHA65 (5/2011)
- Applies to H5N1 and other influenza viruses with human pandemic potential
- Does not apply to seasonal influenza viruses although relies on continuous sharing of all influenza viruses through GISRS, Global Influenza Surveillance and Response System
- Brings together Member States, industry, civil society organizations, other key stakeholders, and WHO – *recognized by EU as a specialized ABS international instrument for pandemic influenza*
- Guiding principles include transparency, equity & partnership



153 institutions in 115 countries in 2019



Several generations of scientists in developing and developed world since 1952



Decision WHA72/12 on PIP Framework

- *WHO to work with GISRS and relevant partners to collect, analyse and present **data on influenza virus sharing** to enable a deeper understanding of challenges, opportunities and implications for public health*
- *Identify specific **instances where virus sharing has been hindered** & how hindrances may be mitigated*
- *WHO to prepare a report, with input from MS and stakeholders, and in consultation with CBD Secretariat, as appropriate, on:*
 - *Treatment of **influenza virus sharing in existing relevant legislation and regulatory measures** – including those implementing Nagoya Protocol*



What has WHO been doing in relation to Nagoya

- Study requested by EB138 (1/2016)
- Study presented at EB140 (1/2017, **EB140/15**)
 - *The Nagoya Protocol has implications for the public health response to infectious diseases, including influenza*
 - *These implications include opportunities to advance both public health and principles of fair and equitable sharing of benefits*
- Internal WHO working group established in 2018
 - *composed of representatives from all relevant units under the direction of the DG and Chief Scientist*
- Discussion at WHA72 (5/2019) resulted in decision **WHA72/13**



Decision WHA72/13 on Nagoya

- In May 2019, the 72nd WHA requested the Director-General to broaden engagement with Member States, the Secretariat of the Convention on Biological Diversity, relevant international organizations and relevant stakeholders in order to:
 - *provide information on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications*
 - *provide a report to the 74th WHA (May 2021), through EB 148 (Jan 2021), as well as an interim report to EB 146 (Feb 2020)*

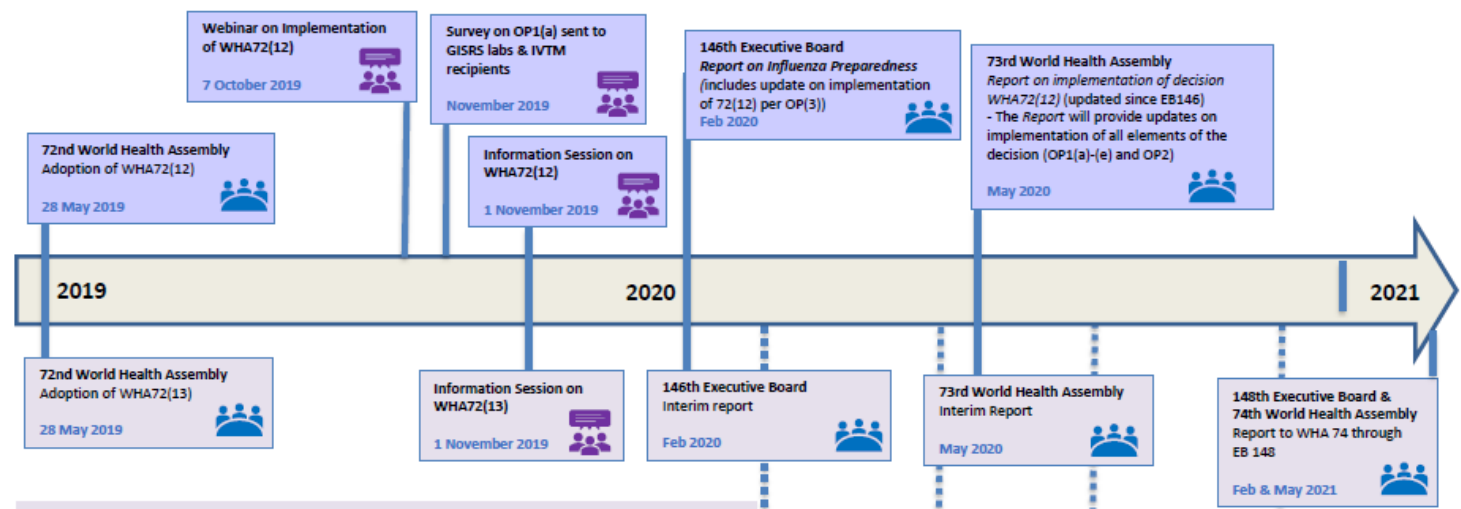
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Draft Notional Timeline (as of 30 October 2019)

Legend

- Governing body meetings
- Consultations / external inputs
- CBD/Nagoya events

PIP - WHA72(12) implementation milestones and events



NP & PH - WHA72(13) implementation milestones and events

Relevant CBD / Nagoya Protocol events





Key links

- PIP Framework webpage: <https://www.who.int/influenza/pip/en/>
- Analysis: Approaches to seasonal influenza and genetic sequence data under the PIP Framework: https://www.who.int/influenza/pip/Analysis_WHA70108b/en/
- Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications. Study by the Secretariat: https://www.who.int/influenza/Nagoya_Full_Study_English.pdf
- Decision WHA72(12): [http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72\(12\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(12)-en.pdf)
- Decision WHA72(13): [http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72\(13\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(13)-en.pdf)
- CBD Access & Benefit-sharing Clearinghouse: <https://absch.cbd.int/>



THANK YOU FOR YOUR ATTENTION

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