

## **The Nagoya Protocol:**

- **Brief background**
- **Specialized International Access and Benefit Sharing Instruments (SIIs)**
- **Examples of benefits**

**INB5 (Resumed)**

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# 1: Brief background on the Nagoya Protocol (NP)

# Background on the NP

- **“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** is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. It entered into force on 12 October 2014.”

(NP website: <https://www.cbd.int/abs/>)

- 196 Parties to the Convention on Biological Diversity (CBD)

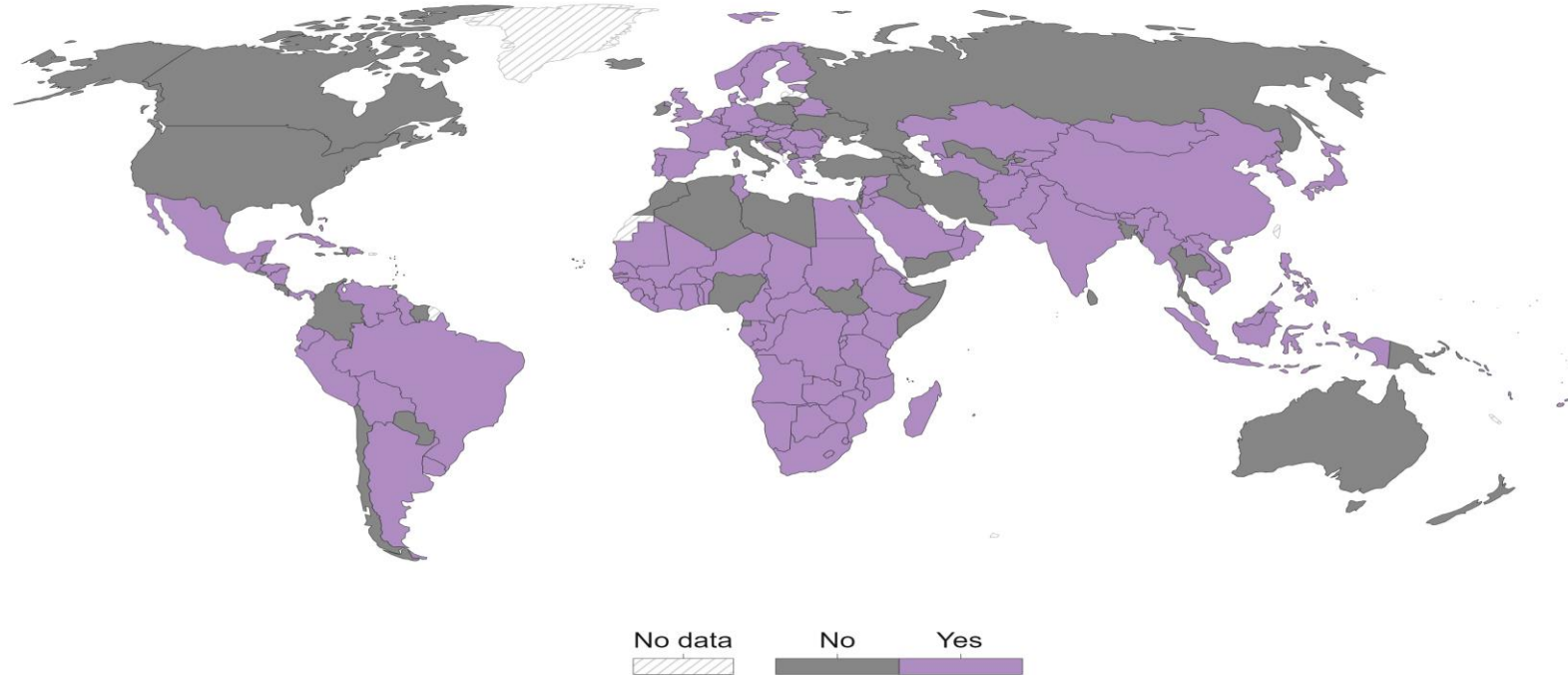
(CBD website: <https://www.cbd.int/information/parties.shtml>)

- 139 Parties to the NP (map visual on next slide)

(NP website: <https://www.cbd.int/abs/nagoya-protocol/signatories/>)

# Countries that are party to the Nagoya Protocol, 2021

Being party to the Nagoya Protocol<sup>1</sup> means agreeing to follow the rules and guidelines set forth in the agreement, which aim to ensure that the benefits of genetic resources are shared fairly and equitably, and that traditional knowledge is protected and respected.



Source: Data from multiple sources compiled by the UN

OurWorldInData.org/biodiversity • CC BY

**1. Nagoya Protocol:** The Nagoya Protocol is an international agreement that was adopted in 2010 under the UN Convention on Biological Diversity. It aims to ensure that the benefits of genetic resources are shared fairly and equitably between countries and the people who provide them. The Protocol also sets out rules for accessing genetic resources and sharing the benefits that arise from their use. It applies to both traditional knowledge and modern genetic resources, and is intended to protect the rights of indigenous and local communities that are often associated with these resources.

<https://ourworldindata.org/grapher/countries-that-are-parties-to-the-nagoya-protocol>

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## 2: The NP and specialized international access and benefit sharing instruments (SIIs)

## SIIs: addressed in Article 4(4) of the NP

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“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 [on Biological Diversity] 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.”

## What this means . . .

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- In effect, it means that certain requirements of the NP do not apply to whatever the agreed genetic resource is.
- Those requirements would not apply because countries agree a special, formal arrangement that “is consistent with, and does not run counter to” the objectives of the Protocol and the CBD.
- In other words, Article 4(4) offers an option: Parties may establish an international instrument on a specific genetic resource, e.g., a pathogen/s, and agree that the NP will not apply to that GR... provided that there is, in essence, "fair and equitable sharing of the benefits arising from the utilization" of that genetic resource.

# How is an SII defined /determined?: NP Governance

- “SII” not defined in the text of the NP.
- March 2022: NP Subsidiary Body on Implementation (SBI) took note of a list of “indicative criteria” for an SII (see next slide)
- December 2022: NP Meeting of the Parties (MOP) took note of March 2022 SBI report, decided to further review at its next meeting (2024)

(NP MOP decision: <https://www.cbd.int/doc/decisions/np-mop-04/np-mop-04-dec-11-en.pdf>)

*\*NB SIIs also discussed in earlier NP Governance meetings, incl. in 2018*



**INDICATIVE CRITERIA FOR SPECIALIZED INTERNATIONAL ACCESS AND  
BENEFIT-SHARING INSTRUMENTS IN THE CONTEXT OF ARTICLE 4, PARAGRAPH 4,  
OF THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR  
AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION**

NP SBI report:

<https://www.cbd.int/doc/recommendations/sbi-03/sbi-03-rec-16-en.pdf>

1. These indicative criteria are reference points or elements to consider as guidance when developing or implementing specialized international access and benefit-sharing instruments. They are intended to contribute to strengthening coordination and mutual supportiveness between the Nagoya Protocol and other international access and benefit-sharing instruments, without creating a hierarchy among them.
2. **Intergovernmentally or internationally agreed** — The instrument is agreed [or adopted] through an intergovernmental process and/or is [explicitly] endorsed by States [and/or Governments][through a decision of a governing body of an international organization]. [The instrument may be binding or non-binding.]
3. **Specialized** — The instrument:
  - (a) Applies to a specific set of genetic resources and/or traditional knowledge associated with genetic resources which would otherwise fall under the scope of the Nagoya Protocol;
  - (b) Applies to specific uses of genetic resources and/or traditional knowledge associated with genetic resources, or to specific purposes, which require a differentiated and hence specialized approach.
4. **Mutually supportive** — The instrument is consistent with and supportive of, and does not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol, including with respect to:
  - (a) Consistency with biodiversity conservation and sustainable use objectives;
  - (b) Fairness and equity in the sharing of benefits;
  - (c) Legal certainty with respect to access to genetic resources or traditional knowledge associated with genetic resources, including [as appropriate] the application of prior informed consent, and to [the fair and equitable sharing of benefits][benefit-sharing];
  - (d) Full and effective participation of indigenous peoples and local communities concerned;
  - (e) Contribution to sustainable development, as reflected in internationally agreed goals;
  - (f) Other general principles of law, including good faith, effectiveness and legitimate expectations.]

# How is an SII defined /determined?: Practice

Text

20.5.2014 EN Official Journal of the European Union L 150/59

**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**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

## How is an SII defined /determined?: Practice (cont.)

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“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.”

*EU REGULATION (EU) No 511/2014 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, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0511>*

# Additional info on the NP and health

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- **Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications: Study by the Secretariat. WHO, 2016**

[https://www.who.int/docs/default-source/documents/nagoya-protocol/nagoya-full-study-english.pdf?sfvrsn=ec2ab49d\\_12&download=true](https://www.who.int/docs/default-source/documents/nagoya-protocol/nagoya-full-study-english.pdf?sfvrsn=ec2ab49d_12&download=true)

- **Key Finding:** 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.

# Additional info on the NP and health (cont)

- “The public health implications of implementation of the Nagoya Protocol”: decision WHA72(13), and Report by the Director-General, document A72/32 (2019)

[https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\(13\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(13)-en.pdf) and

[https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_32-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_32-en.pdf)

**Key Finding:** The principles of global public health, including those enshrined in the Constitution of the World Health Organization, and the critical importance of timely access and fair and equitable benefit sharing can serve as a reference for future steps in developing collaborative arrangements to promote: both access and benefits; surveillance of pathogens; effective international response to outbreaks; and appropriate collective use of benefits and their distribution based on global public health needs.

# Additional info on the NP and health

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- **“Questions and Answers: Implementation of the Nagoya Protocol in the context of human and animal health, and food safety: Access to pathogens and fair and equitable sharing of benefits” CBD and WHO (2018)**

[https://cdn.who.int/media/docs/default-source/documents/nagoya-protocol/qa\\_np\\_public\\_health-2018.pdf?sfvrsn=3d2d10f0\\_1&download=true](https://cdn.who.int/media/docs/default-source/documents/nagoya-protocol/qa_np_public_health-2018.pdf?sfvrsn=3d2d10f0_1&download=true)

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## 3: Benefits - in the NP, and other arrangements

# Examples of benefits under the NP

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- The NP includes a list of benefits, divided into two categories: monetary and non-monetary.
- Each category provides examples of benefits that may be included, presented in the following slides.



# Examples of monetary benefits under the NP

## Nagoya Protocol Annex - Monetary benefits

- a) Access fees/fee per sample collected or otherwise acquired
- b) Up-front payments
- c) Milestone payments
- d) Payment of royalties
- e) Licence fees in case of commercialization
- f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity
- g) Salaries and preferential terms where mutually agreed;
- h) Research funding
- i) Joint ventures
- j) Joint ownership of relevant intellectual property rights.

# Examples of non-monetary benefits under the NP

## Nagoya Protocol Annex - Non-Monetary benefits

(a) Sharing of research and development results;	(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;	(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies
(c) Participation in product development	(l) Contributions to the local economy;
(d) Collaboration, cooperation and contribution in education and training	(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
(e) Admittance to ex situ facilities of genetic resources and to databases;	(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity	(o) Food and livelihood security benefits;
(g) Strengthening capacities for technology transfer;	(p) Social recognition;
(h) Institutional capacity-building;	(q) Joint ownership of relevant intellectual property rights.
(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;	

# Other examples of benefits

- The PIP Framework and the Global Influenza Surveillance and Response System (GISRS) both provide public health benefits

## PIP Framework Benefit Sharing System and Mechanisms

1) WHO Coordination of pandemic influenza preparedness and response	9) Pandemic influenza preparedness vaccine stockpile
2) Pandemic risk assessment and risk response	10) Access to vaccines in the inter-pandemic period for developing countries
3) Provision of PIP candidate vaccines	11) Access to pandemic influenza vaccines
4) Provision of diagnostic reagents and test kits	12) Tiered pricing
5) Provision of reference reagents for potency determination of vaccines	13) Technology transfer
6) Laboratory and influenza surveillance capacity building	14) Sustainable and innovative financing mechanisms – <b>Partnership Contribution</b> (currently US\$ 28 M/yr from manufactures to WHO for preparedness and response)
7) Regulatory capacity building	15) <b>Standard Material Transfer Agreements 2 (SMTA2)</b> – Advance supply agreement for future access to pandemic vaccine (and other products) in real-time
8) Antivirals stockpiles	16) Acknowledgement of contributions of collaborators, including laboratories/countries providing clinical specimens or IVPPs or reagents

Legal certainty regarding use of influenza viruses with pandemic potential

# Other examples of benefits (cont'd)

- Members of GISRS receive a range of public health benefits that arise from the sharing of viruses and the collective work of the laboratories. Benefits include, but are not limited to, the following:

## GISRS Material and Non-Material benefits

<p>1. Reagents and viruses including:</p> <p>a) Annually updated laboratory reagent kits for influenza viruses; b) molecular primers/probes; c) Updated reference viruses; d) Tissue culture media for influenza virus growth; f) Updated vaccine viruses and prototype candidate vaccine viruses (CVVs); g) Vaccine potency reagents; j) Annual proficiency panels for participation in the WHO Global External Quality Assessment Programme (EQAP); h) Use of the WHO Shipping Fund to share influenza viruses with WHO CCs and ERLs; i) Access to genomic sequencing at WHO CCs for countries without established sequencing capacities</p>	<p>2. Public health information and tools, including:</p> <p>a) Analyses &amp; reports detailing the genetic, antigenic and antiviral susceptibility characterization of viruses; b) Updated lab protocols for detection and characterization of emerging influenza viruses and non-influenza respiratory viruses of public health significance; c) Tools to aid countries in monitoring influenza and performing risk assessments</p>
	<p>3. Training, mentoring and capacity strengthening</p>
	<p>4. Regular and timely surveillance updates and situation reports for influenza</p>
	<p>5. Rapid access and technical support to genetic sequence data (GSD)</p>

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Thank you.