

Convention on Biological Diversity

Distr.
GENERAL

CBD/NP/MOP/3/INF/5
24 September 2018

ENGLISH ONLY

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*

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 BENEFIT: QUESTIONS AND ANSWERS

1. The secretariats of the World Health Organization (WHO) and the Convention on Biological Diversity, in consultation with the Food and Agriculture Organization of the United Nations and the World Organisation for Animal Health, collaborated on the development of a publication entitled *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: Questions and Answers*. This publication is made available in 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. The publication is also available on the Access and Benefit-Sharing Clearing House¹ and the website of WHO.²

2. The purpose of this publication is to answer questions received regarding the sharing of pathogens in the context of the implementation of the Nagoya Protocol. As each Organization drafted sections relevant to its work, all the views expressed in the document do not necessarily represent the views of each Organization.

* CBD/NP/MOP/3/1.

¹ https://absch.cbd.int/api/v2013/documents/612E94B5-D97A-0B5D-8E5A-40A991E29087/attachments/QA_NP_Public_Health.pdf

² http://www.who.int/influenza/pip/QA_NP_Public_Health.pdf?ua=1.



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

Questions and Answers

Version 1 - May 2018



Convention on
Biological Diversity



World Health
Organization

© Secretariat of the Convention on Biological Diversity and World Health Organization, 2018

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>). Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below.

This publication may be reproduced for educational or non-profit purposes without special permission from the copyright holders, provided acknowledgment of the source is made. The Secretariat of the Convention on Biological Diversity and WHO would appreciate receiving a copy of any publication that uses this document as source.

In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Secretariat of the Convention on Biological Diversity and World Health Organization. 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. Geneva; 2018. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing in Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Printed in Geneva, Switzerland.

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

Questions and Answers

Version 1 - May 2018



These Questions and Answers were developed by the secretariats of the Convention on Biological Diversity, the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE) and the World Health Organization (WHO). Their purpose is to answer questions received regarding the sharing of pathogens in the context of implementation of the Nagoya Protocol. As each Organization drafted sections relevant to its work, all the views expressed in the document do not necessarily represent the views of each Organization. **This document is deemed to be a “living document” and the Questions and Answers may be updated and expanded, as appropriate.** Further questions or feedback on the document should be sent to pipframework@who.int.



Convention on
Biological Diversity



World Health
Organization

Contents

Acronyms	2
Background on the Nagoya Protocol	
1. What are the Convention on Biological Diversity and the Nagoya Protocol?	3
2. What are genetic resources?	4
3. What are the ABS principles of the Convention on Biological Diversity?	4
4. What are the key requirements of the Nagoya Protocol?	4
5. How do I find more information on national ABS requirements?	5
6. How does the Nagoya Protocol address the sharing of digital sequence information / genetic sequence data?	6
Pathogen sharing in the context of human and animal health, and food safety	
7. What role does the sharing of pathogens play in human and animal health, and food safety	7
8. Why is rapid and timely sharing of pathogens crucial to responding to health emergencies?	8
9. How might implementation of the Nagoya Protocol impact the rapid and comprehensive sharing of pathogens ?	8
Supporting human and animal health, and food safety through the Nagoya Protocol	
10. Are there mechanisms under the Nagoya Protocol that specifically address human and animal health?	7
a. <i>Article 8(b)</i> - Special considerations related to health emergencies	8
11. Are there other mechanisms under the Nagoya Protocol that may also be relevant in addressing human and animal health?	8
a. <i>Article 4(4)</i> - Recognition of “specialized international access and benefit-sharing instruments”	10
b. <i>Articles 19 and 20</i> - Model contractual clauses, codes of conduct, guidelines, best practices and standards	10
12. How can Parties to the Nagoya Protocol implement the Protocol in ways that support pathogen sharing and promote human and animal health?	11
For further information	
13. Where can we find more information on the Nagoya Protocol?	12
14. Where can I find more information about the importance of access to pathogens?	12
Annex 1 - Pathogen sharing for human and animal health, and food safety	13
Annex 2 - International sharing of pathogens during health emergencies	16

Acronyms

ABS	Access and benefit-sharing
CBD	Convention on Biological Diversity
CC	WHO Collaborating Centres
FAO	Food and Agriculture Organization of the United Nations
GISRS	Global Influenza Surveillance and Response System
ICG	International Coordinating Group on Vaccine Supply
OIE	World Organisation for Animal Health
MAT	Mutually Agreed Terms
PIC	Prior Informed Consent
WGS	Whole genome sequencing
WHO	World Health Organization

Background on the Nagoya Protocol



1. What are the Convention on Biological Diversity and the Nagoya Protocol?

The Convention on Biological Diversity¹ (CBD) was adopted in May 1992 and entered into force in December 1993. It has near universal participation with 196 Parties. The objectives of the Convention are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. Article 15 of the Convention addresses ‘access to genetic resources’ and sets out the basis on which genetic resources are to be accessed and benefits shared.

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*² is a supplementary agreement to the CBD and supports the implementation of one of its three objectives: the fair and equitable sharing of benefits arising from the utilization of genetic resource.

The Nagoya Protocol was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014. As of January 2018, the Protocol has 104 Parties.³ Its objective is

the fair and equitable sharing of benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.⁴

The Nagoya Protocol applies to genetic resources, and traditional knowledge associated with genetic resources, that are covered by the CBD, and to the benefits arising from their utilization.⁵

¹ Text available at: <https://www.cbd.int/convention/text/>

² 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. Text available at: <https://www.cbd.int/abs/text/default.shtml>

³ List of Parties available at: <https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml>

⁴ Article 1 of the Nagoya Protocol.

⁵ More information on access and benefit-sharing and the Nagoya Protocol can be found in the factsheets and information kits available at <https://www.cbd.int/abs/resources/factsheets.shtml>

2. What are genetic resources?

'Genetic resources' are defined in the CBD to mean "genetic material of actual or potential value" while the term 'genetic material' is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity".⁶ The CBD and the Nagoya Protocol do not apply to human genetic resources.⁷

3. What are the access and benefit-sharing principles of the Convention on Biological Diversity?

The fundamental principles of access and benefit-sharing (ABS) are established by the CBD⁸. These principles are based on users of genetic resources obtaining the prior informed consent (PIC) of the country providing access to the genetic resource, and negotiating and agreeing on the terms and conditions of access and utilization of this resource through the establishment of mutually agreed terms (MAT). This agreement is also to address the sharing of benefits arising from the utilization of the resource. Furthermore, countries should endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses.

The Nagoya Protocol builds on these principles and aims to create greater legal certainty and transparency for both providers and users of genetic resources by establishing more predictable conditions for access to genetic resources and helping to ensure benefit-sharing when genetic resources leave the jurisdiction of the Party providing the genetic resources.

4. What are the key requirements of the Nagoya Protocol?

The Nagoya Protocol sets out core obligations for its Parties to take measures in relation to access to genetic resources, benefit-sharing and compliance. It also establishes an Access and Benefit-sharing Clearing-House to facilitate the exchange of information.

Access: Access to genetic resources is subject to the PIC of the provider country unless otherwise determined by that country. Parties that require PIC must establish clear and transparent procedures for accessing genetic resources and are to issue a permit when access is granted. The Protocol also specifies that it is access to genetic resources for their utilization that is regulated. The term 'utilization of genetic resources' is defined to mean "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".⁹

⁶ Convention on Biological Diversity, Article 2. The terms defined in Article 2 of the Convention also apply to the Nagoya Protocol, see Nagoya Protocol, Article 2.

⁷ See paragraph 5 of decision X/1 available at <https://www.cbd.int/decision/cop/?id=12267>.

⁸ See Article 15 of the Convention on Biological Diversity.

⁹ Article 2 (c) of the Nagoya Protocol.

Benefit-sharing: Under the Nagoya Protocol, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization are to be shared in a fair and equitable way with the provider country. This sharing is upon mutually agreed terms. The benefits to be shared may be monetary or non-monetary and the Protocol includes an annex with an indicative list of types of benefits that can be shared.

Compliance: With a view to support benefit-sharing once genetic resources have left the provider country and are being utilized in another country, the Protocol contains obligations to support compliance with the ABS requirements of the provider country and with the contractual obligations between users and providers of genetic resources reflected in mutually agreed terms.

In addition, the Protocol establishes a monitoring system regarding the utilization of genetic resources, based on internationally recognized certificates of compliance and the establishment of checkpoints. Parties are to establish at least one checkpoint in order to monitor the utilization of genetic resources.

ABS Clearing-House (<http://absch.cbd.int>): The Nagoya Protocol establishes the Access and Benefit-sharing Clearing-House as a platform for exchanging information on ABS and a key tool for facilitating implementation of the Protocol. Parties must publish information on their access and benefit-sharing procedures and the permits they issue in the ABS Clearing-House. Information on a permit published in the ABS Clearing-House constitutes an internationally recognized certificate of compliance, which provides evidence that the genetic resource was accessed with prior informed consent (PIC) and that mutually agreed terms (MAT) were established.

5. How do I find more information on national ABS requirements?

Users of genetic resources need to follow the ABS requirements of:

- the country providing the genetic resource; and
- the country where utilization of the genetic resource (i.e. research and development) takes place.

The most convenient way to find national information on those ABS requirements is through the country profiles on the ABS Clearing-House (<https://absch.cbd.int/countries/>).

The country profile contains all national information relevant to ABS made available by a country. This includes information on the national focal point, competent national authorities, checkpoints, measures on access and benefit-sharing, and internationally recognized certificates of compliance.

The national focal point is responsible for providing information on procedures for accessing genetic resources and establishing mutually agreed terms; whereas the competent national authority is responsible for granting access, or issuing written evidence that access requirements have been met. Consulting the relevant ABS measures can help users to understand how to comply with ABS requirements.

However, many countries are in various stages of developing their legal framework for ABS and making that information available on the ABS Clearing-House. In cases where information on ABS measures is not available in the ABS Clearing-House, the national focal point or the competent national authority will be able to provide further information.

6. How does the Nagoya Protocol address the sharing of digital sequence information / genetic sequence data?

The issue of digital sequence information on genetic resources was discussed during the UN Biodiversity Conference¹⁰ in December 2016. Noting rapid advances arising from research and development in biotechnology regarding the use of digital sequence information on genetic resources and therefore recognizing the importance of addressing digital sequence information on genetic resources in the framework of the Convention and the Nagoya Protocol in a timely manner, Parties decided to establish a process for the consideration of this issue.

Parties agreed¹¹ to consider at the next UN Biodiversity Conference, in November 2018, any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and the objective of the Nagoya Protocol.

¹⁰ More specifically at the thirteenth meeting of the Conference of Parties to the CBD (COP 13) and the second meeting of the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol (COP-MOP 2).

¹¹ See COP decision XIII/16 (available at <https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-16-en.pdf>) and COP-MOP decision NP-2/14 (available <https://www.cbd.int/doc/decisions/np-mop-02/np-mop-02-dec-14-en.pdf>)



Pathogen sharing in the context of human and animal health, and food safety

7. What role does the sharing of pathogens play in human and animal health, and food safety?

Rapid and comprehensive sharing of, and access to, pathogens and associated data as part of routine public health surveillance and during health emergencies is essential to protecting global human and animal health. It contributes to, *inter alia*:

- a. on-going surveillance to detect emerging pathogens or to inform disease control interventions;
- 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 or test for drug resistance, 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 to prevent further spread of outbreaks;
- e. development of more effective vaccines and therapeutics, and more accurate diagnostic tools;
- f. scientific research leading to a better understanding of diseases.

Each of these activities is crucial to prevent and respond to infectious diseases and requires at some point access to pathogens and their associated data.

For more information, examples of how pathogens are shared and used for routine public health surveillance and during outbreaks of infectious diseases are provided in Annex 1.

8. Why is rapid and timely sharing of pathogens crucial to responding to health emergencies?

A prompt and effective response to a public health emergency often depends on rapid access to and sharing of pathogens and associated data. Indeed, timely access is essential to detect new pathogens, diagnose cases, develop diagnostics to detect infection, conduct research on the pathogen and develop countermeasures. Delays in sharing can slow the international response to a health emergency, which can result in higher morbidity and mortality.


An infographic describing a potential scenario of international sharing of pathogens during a health emergency can be found in Annex 2.

9. How might implementation of the Nagoya Protocol impact the rapid and comprehensive sharing of pathogens ?

Implementation of the Nagoya Protocol may impact the sharing of pathogens if, for example, it entails multiple, complex and/or time-consuming processes. Some laboratories have expressed concerns about challenges they may face in complying with a variety of different national ABS processes and requirements in order to access pathogens.¹² This in turn could impact the comprehensiveness and speed of risk assessment as well as the timely development of effective vaccines, diagnostics and other medical countermeasures.

The importance of pathogen sharing for 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 Nagoya Protocol should therefore consider ways of implementing the Protocol in a manner that is supportive of human and animal health.

¹² World Health Organization, “Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications - Study by the Secretariat, p.12, available at http://www.who.int/un-collaboration/partners/Nagoya_Full_Study_English.pdf.



Supporting human and animal health, and food safety through the Nagoya Protocol

10. Are there mechanisms under the Nagoya Protocol that specifically address human and animal health?

a. Article 8(b)- *Special considerations related to health emergencies*

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 ABS legislation.

Article 8(b): 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.

Under this provision, Parties may, for example, develop special ABS measures for use during health emergencies in order to support timely and equitable public health responses, including access to affordable treatments to 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 the samples.

11. Are there other mechanisms under the Nagoya Protocol that may also be relevant in addressing human and animal health?

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

Article 4 of the Protocol addresses the relationship of the Nagoya Protocol with other international agreements and instruments. It provides that:

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. (paragraph 4)

It also provides that the Protocol is to be implemented in a mutually supportive manner with other international instruments relevant to this Protocol (paragraph 3).

At their last 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 in the context of Article 4(4) of the Nagoya Protocol and a possible process for recognizing such an instrument. The results of this study will be submitted for consideration by the Parties¹³ at their next meeting in November 2018.

At the 70th 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.¹⁴

b. Articles 19 and 20: Model contractual clauses, codes of conduct, guidelines, best practices and standards

Articles 19 and 20 of the Protocol require each Party to encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms, voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing. Model contractual clauses, codes of conduct, guidelines, best practices and standards are tools that can serve to promote consistency, legal certainty and transparency and reduce transaction costs.¹⁵

¹³ See COP-MOP 2 decision NP-2/5.

¹⁴ Decision WHA70(10) Review of the Pandemic Influenza Preparedness Framework. Text available at http://apps.who.int/gb/ebwha/pdf_files/WHA70-REC1/A70_2017_REC1-en.pdf#page=61

¹⁵ See the ABS Clearing-House for information on Article 19 and 20 tools developed. <https://absch.cbd.int/>

The development of such tools could contribute to raising the awareness of providers about the importance of facilitated access to pathogens for public health considerations, and assist users in fulfilling ABS requirements and providers' expectations.

For example, WHO is developing a Material transfer agreement capacity-building tool in the context of the Research and Development Blueprint to support the sharing of biological materials and information (such as epidemiological data or genetic sequence data) connected to severe emerging diseases with a potential to generate a public health emergency.¹⁶

12. How can Parties to the Nagoya Protocol implement the Protocol in ways that support pathogen sharing and promote human and animal health?

When implementing their obligations under the Protocol and putting in place ABS measures and authorities, Parties to the Nagoya Protocol may:

- a.** Include special measures for health emergencies consistent with Nagoya Protocol article 8(b), such as clear and expeditious processes for access to pathogens, and the sharing of benefits arising from their utilization (e.g. templates with pre-agreed benefit-sharing terms, expedited administrative processes or waivers for health emergencies);
- b.** Adopt a whole-of-government approach in developing ABS legislation and implementing the Nagoya Protocol, involving not only the Ministries of the Environment and Agriculture but also the Ministry of Health;
- c.** Support researchers and companies in complying with national ABS legislation.

Implementation of the Nagoya Protocol can support public health through clear and harmonized rules for rapid and systematic access to pathogens that affect human health, and through fair and equitable sharing of benefits arising from the utilization of those pathogens. Rapid access to pathogens would facilitate and speed up risk assessment as well as the development of vaccines and medicines while fair and equitable benefit-sharing can improve access to affordable treatments and help build capacities in such areas as disease surveillance and research and development.

Other benefits to be shared that can be supportive of public health include: research funding and joint publication; joint ownership of intellectual property rights; sharing of research and development results; collaboration, cooperation and contribution in scientific research and development programmes, particularly in biotechnological research activities; technology transfers; and capacity-building.

¹⁶ The draft tool is available at <http://apps.who.int/blueprint/mta-tool/>.



For further information

13. Where can we find more information on the Nagoya Protocol?

- The CBD website (<https://www.cbd.int/abs/>)
- The awareness-raising material developed by the Secretariat of the CBD (<https://www.cbd.int/abs/resources/factsheets.shtml>)
- The country profiles of the ABS Clearing-House contain information on implementation by Parties, including authorities, ABS measures and interim national reports. (<https://absch.cbd.int/countries>)
- Model contractual clauses, codes of conduct, guidelines, best practices and standards developed can also be found in the ABS Clearing-House (<https://absch.cbd.int/search>)
- The Virtual library of the ABS Clearing-House hosts resources and literature relevant to ABS (<https://absch.cbd.int/search>)

14. Where can I find more information about the importance of access to pathogens?

- WHO's PIP Framework: <http://www.who.int/influenza/pip/en/>
- WHO's Global Influenza Surveillance and Response System (GISRS) and FAO and OIE's OFFLU networks:
 - http://www.who.int/influenza/gisrs_laboratory/en/
 - <http://www.offlu.net/>
- WHO's Research and Development Blueprint:
 - http://www.who.int/medicines/ebola-treatment/blueprint_phe_data-share-results/en/
 - <http://www.who.int/blueprint/en/>
- Antimicrobial Resistance:
 - <http://www.fao.org/antimicrobial-resistance/en/>
 - <http://www.who.int/antimicrobial-resistance/en/>
 - <http://www.oie.int/our-scientific-expertise/veterinary-products/antimicrobials/>
- Food safety:
 - <http://www.who.int/foodsafety/en/>
 - <http://www.fao.org/food/food-safety-quality/home-page/en/>
- Malaria: <http://www.who.int/malaria/en/>
- WHO-CBD Collaboration: <http://www.who.int/un-collaboration/partners/UNCBD/en/>



Annex 1:

Pathogen sharing for human and animal health, and food safety

These examples have been included to illustrate how pathogens are shared and used for routine public health surveillance and during outbreaks of infectious diseases.

Antimalarial drug resistance and malaria diagnostics

Resistance to antimalarial medicines is a threat to global efforts to control and eliminate malaria. Improved access to effective malaria treatments has been a key contributing factor to the significant reduction in the malaria burden in recent years. Protecting the efficacy of the recommended malaria treatments is a top priority for malaria endemic countries and the global malaria community.¹⁷ Certain genetic change in malaria parasites can lead to diminished susceptibility or resistance to antimalarial medicines. Other mutations can lead to non-expression of genes which encode for proteins targeted by the majority of rapid diagnostic tests leading to false-negative test results.

Monitoring the prevalence of these genetic changes is becoming an increasingly important mechanism to inform malaria control and elimination activities. To do this, WHO facilitates the collection and sharing of parasite material, often in the form of dried blood spots, to accelerate the availability of high quality results. Testing for genetic changes is most often done in regional laboratories that have the experience, capacity and expertise to ensure that the results are consistently comparable and of high quality. Using this information, national malaria control programmes can then adapt their case management policy or develop and put in place appropriate prevention and containment strategies.

¹⁷ WHO, "Responding to antimalarial drug resistance" [website], http://www.who.int/malaria/areas/drug_resistance/overview/en/

Influenza

Monitoring evolution and spread of influenza is a continuous process, requiring constant access to samples of circulating influenza viruses. Every year, the 144 National Influenza Centres in the WHO Global Influenza Surveillance and Response System (“GISRS”) collect and process more than 2 million human clinical specimens from patients with influenza-like illness. Some of these samples are sent to WHO Collaborating Centres for influenza (“WHO CC”) located in Australia, China, Japan, the United Kingdom and the United States for further analysis. The WHO CCs conduct assays that provide essential information to assess the risk the virus represents to human health and to recommend public health control measures. With this information, WHO makes recommendations twice a year on the composition of influenza vaccines and monitors the risk of an influenza pandemic. In addition, WHO CCs use virus samples to develop candidate vaccine viruses used by manufacturers to make influenza vaccines.

To monitor influenza in animal populations, every year national reference centres send clinical samples for testing to the OIE Reference Laboratories and to the FAO Reference Centres for avian influenza, which are part of the OFFLU network. This allows them to carefully investigate the zoonotic potential of the viruses and to examine their pathogenicity and cross-reactivity with vaccines on the market and with reference materials used with diagnostic purposes. Results produced by the OFFLU network are disseminated across laboratories and used to outline effective control strategies and diagnostic procedures.

Yellow fever

The timely sharing of samples from suspected cases of yellow fever enables rapid confirmation of outbreaks, allowing risk assessment and implementation of control measures, as well as triggering the deployment of vaccines through the International Coordinating Group (ICG) on vaccine provision¹⁸. The ICG manages a stockpile of 6 million doses of yellow fever vaccines and approves their deployment. Based on laboratory results obtained from testing suspected yellow fever samples, the ICG makes a decision to release vaccines, which can be deployed in countries within 7 days.¹⁹ In 2016-2017, the ICG has been crucial in managing yellow fever outbreaks, releasing around 37 million vaccines to countries in need.

¹⁸ See ICG webpage at <http://www.who.int/csr/disease/icg/en/>.

¹⁹ See World Health Organization, Mapping of yellow fever vaccine supply in emergencies, <http://www.who.int/mediacentre/infographic/yellow-fever.pdf?ua=1>.

Food safety management

Countries increasingly rely on real-time Whole Genome Sequencing (WGS) to conduct routine food and environment testing of food production and processing or to track down sources of food contamination. Using samples from individuals sick with a foodborne illness, from food products or from production or processing facilities, laboratories can use WGS to determine the complete genome of a pathogen that has contaminated a food plant or that has caused an outbreak. By comparing pathogen genomes from these different samples, scientists can identify the source of contamination and prevent more people from becoming sick.²⁰ In many countries, WGS has enabled more robust outbreak detection and facilitated epidemiological investigations, allowing authorities, the food industry and partners to take steps to protect food safety.

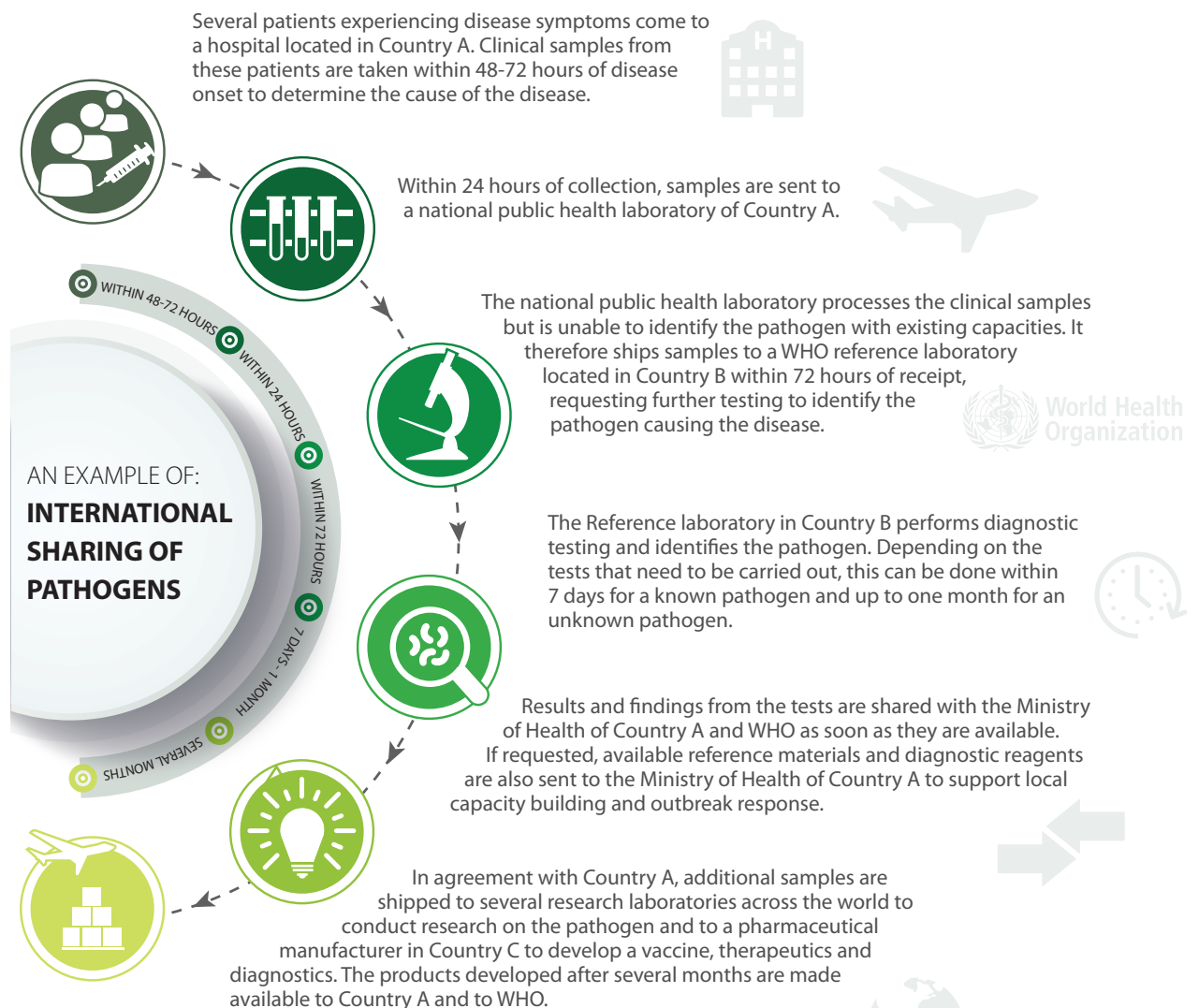
The food supply chain is increasingly global. Through global sharing of samples and data, and collaborative efforts between countries, technologies, such as WGS, can enable countries to better respond to foodborne outbreaks, protect food production and the food supply chain and protect public health.

²⁰ U.S. Food and Agriculture (FDA), Using Science to Find the Sources of Foodborne illness outbreaks, <https://www.fda.gov/downloads/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/UCM596438.pdf>

Annex 2:

International sharing of pathogens during health emergencies

This infographic presents one potential scenario of international sharing of pathogens during a health emergency. The timeline shows the timeframes within which the different steps of this process should occur to support an optimal emergency response. This process should take place with the full support of the providing country and in collaboration with international partners.



World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

