Understanding the Business Implications of Global Access and Benefit Sharing Policies

Wednesday September 13, 12:00 PM – 1:00 PM ET

Bio Biotechnology Innovation Organization

Webinar Objective:

Through interactive discussions we will explore the intricate relationship between national and global concerns for **Access and Benefit Sharing (ABS)**, while uncovering the potential implications for industry

Presenters

Host and Moderator:
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SVP for Infectious Disease & Emerging Science Policy, BIO

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Bayer

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BIO

Access to Biological Resources and Sharing Benefits from their Utilization

An ever-expanding challenge for life sciences companies

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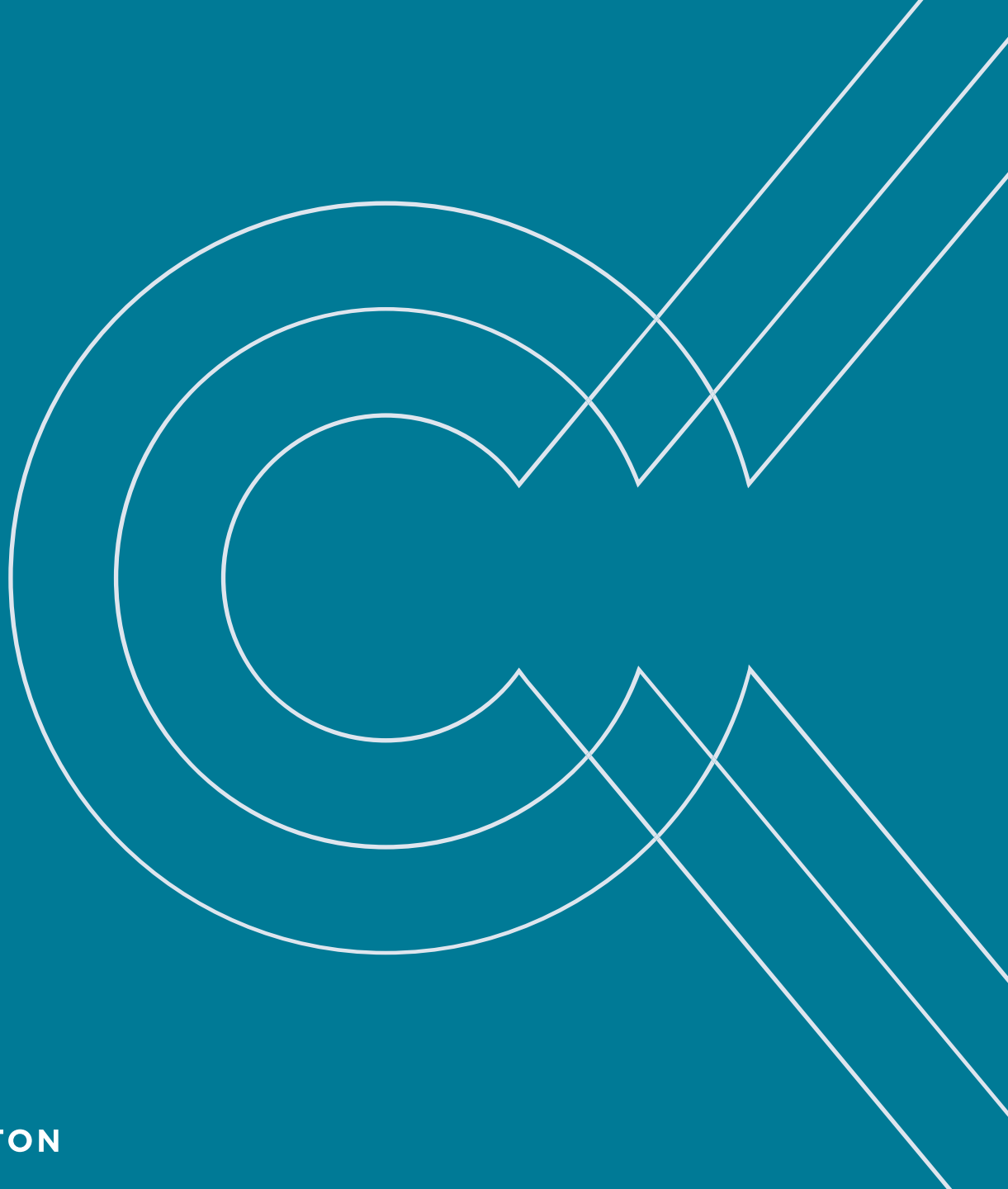
Structure of Presentation

1. The Origins of ABS: Biodiversity Convention and the Nagoya Protocol
2. An extraordinary Compliance Challenge
3. A hypothetical example using SARS-CoV-2
   - Obligations in Provider Countries: Switzerland, South Africa, Brazil, India
   - Obligations in User Countries: EU, UK, Switzerland
4. The Future of ABS
5. Contact Information

The Convention on Biological Diversity and its Nagoya Protocol

The Origin of Access and Benefit-Sharing



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Access and Benefit-Sharing: Monetization of Biological Resources

UNITED NATIONS
1992

CONVENTION ON BIOLOGICAL DIVERSITY

Affirming that the conservation of biological diversity is a common concern of humankind,

Reaffirming that States have sovereign rights over their own biological resources,

Acknowledging that substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits from those investments,

Have agreed as follows:

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, 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, 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.

UNITED NATIONS
2010

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

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

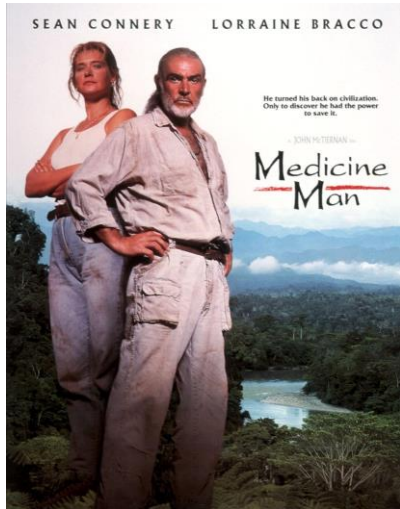
ARTICLE 6

ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

The Convention has 196 Parties, Nagoya Protocol has 140 Parties, who legally agreed hat:

- Countries own their biodiversity, and biodiversity requires monetary and non-monetary resources
- Therefore, “users” of a country’s biodiversity should share the “benefits”
- So that countries are (1) incentivized and (2) have the resources to protect their biodiversity.

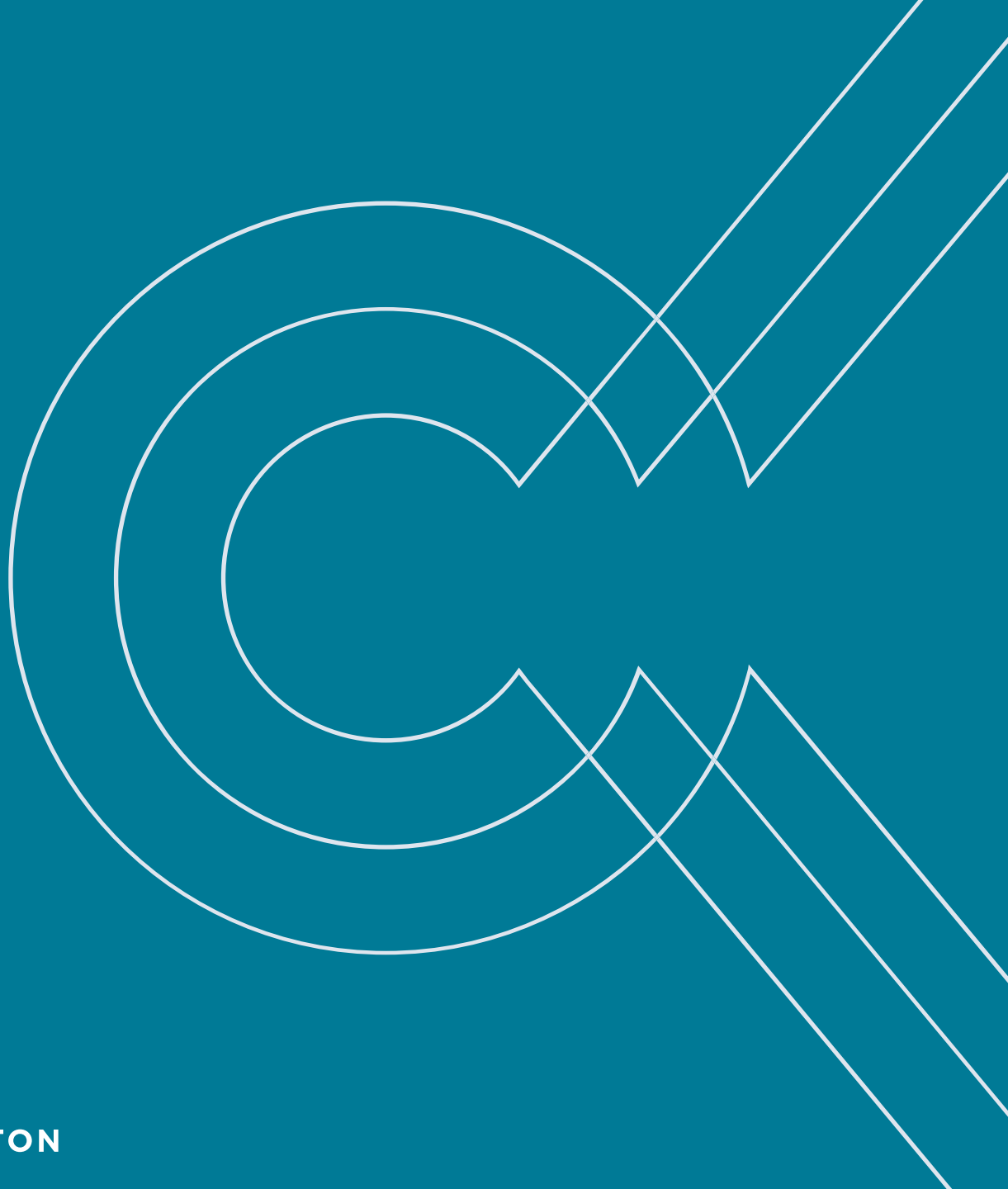


Source: imdb.com

Access and **B**enefit-**S**haring: Legal obligations for countries and companies

Legal Implementation of the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Benefit-Sharing from their Utilization		
Access	Benefit-Sharing	Compliance
What **may or must** a **Country** do?		
A country **may** require a permit in order to acquire a pathogen sample from their territory.	A party **may** require that the user agree to "share benefits" from R&D on the biological material	All countries **must** check compliance with ABS laws of **another party** and address non-compliance.
What **must** a **Company** do?		
In the Provider Country: **Request a permit** from the national authority	In the Provider country: Under the permit, **share monetary and/or non-monetary "benefits"** from the result of your R&D	In the User Country: **Confirm your compliance** with ABS laws of provider country

An extraordinary compliance challenge



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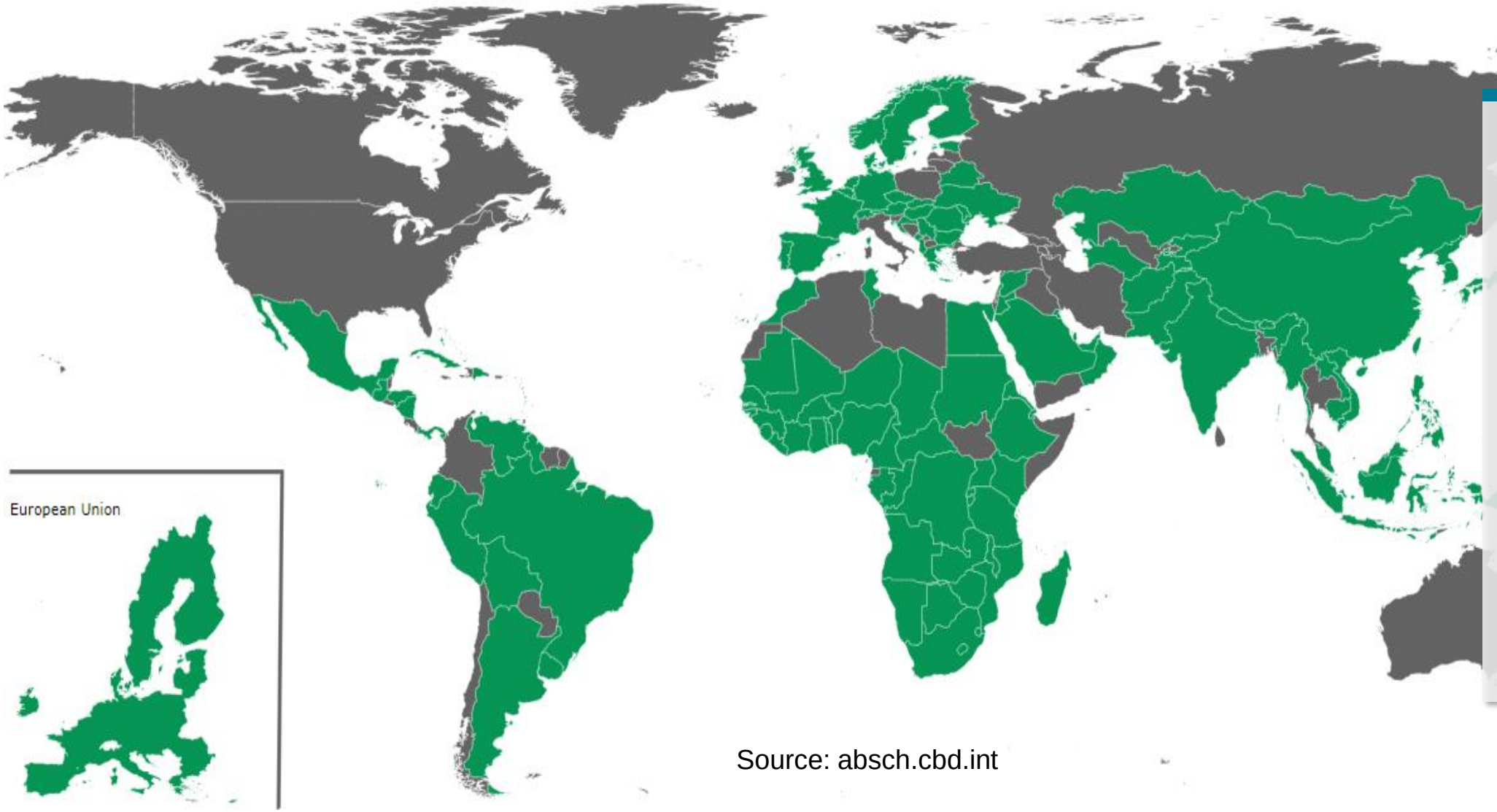
An extraordinary compliance challenge…



140

Are **Party** to the **Nagoya Protocol**

~100

Provider country **ABS regimes** at country level, with **sanctions**

~40

User country compliance obligations

Source: absch.cbd.int

What are the Risks? How is ABS enforced?

NGOs: Reputational

- Third Wold Network: Ebola
- Public Eye: Stevia
- “Biopiracy”

Authorities

- **Enforcement in Provider countries:** e.g. India, Peru, South Africa, Brazil
- **Inspections in User countries** e.g. Germany, UK, Switzerland

Business to Business

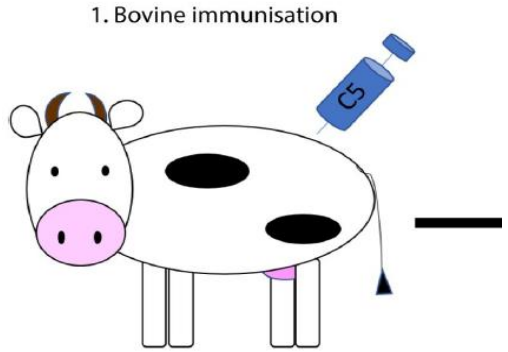
- Compliance with law during transactions, e.g. M&A, R&D, licenses
- Supplier due diligence

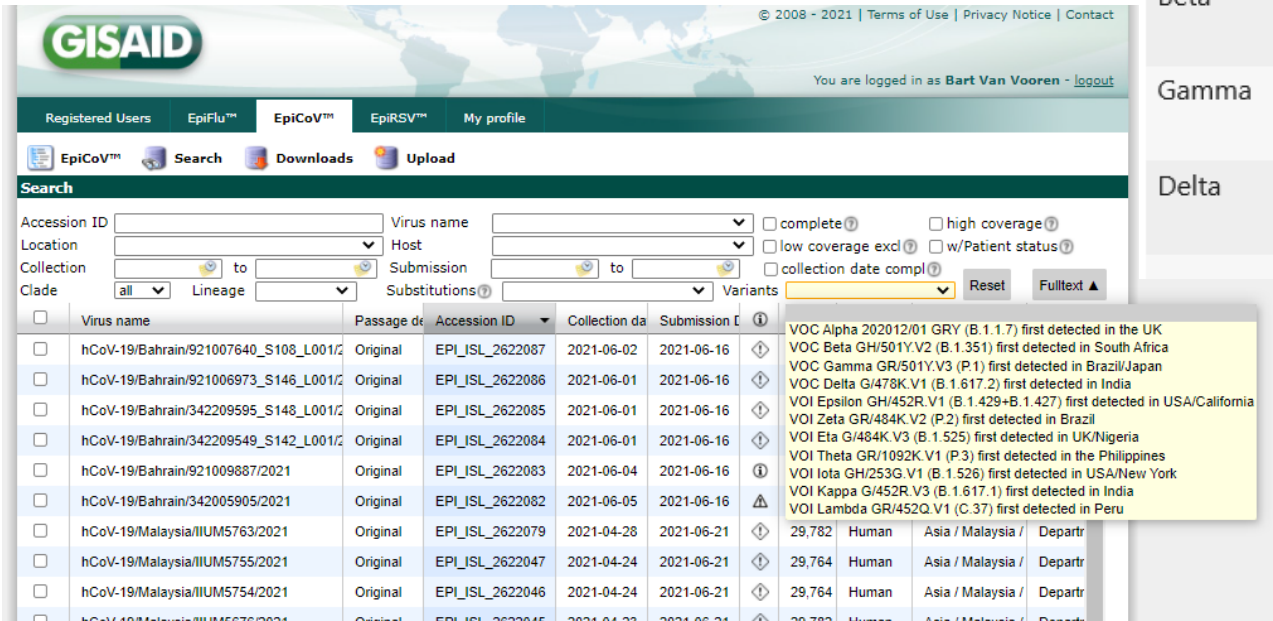
ESG Agenda

- Corporate Sustainability Reporting
- Corporate Sustainability Due Diligence

A hypothetical

- Macpherson et al. (2020) Isolation of antigen-specific, disulphide-rich knob domain peptides from bovine antibodies. PLoS Biol 18(9)
- For my lawyerly brain: cows are injected with SARS-CoV-2 spike protein





VARIANTS OF CONCERN

WHO label	Pango lineage	GISAID clade	Nextstrain clade	Earliest documented samples	Date of designation
Alpha	B.1.1.7	GRY	20I/S:501Y.V1	UK, Sept 2020	Dec 2020
Beta	B.1.351	GH/501Y.V2	20H/S:501Y.V2	South Africa, May 2020	Dec 2020
Gamma	P.1	GR/501Y.V3	20J/S:501Y.V3	Brazil, Nov 2020	Jan 2021
Delta	B.1.617.2	G/452R.V3	21A/S:478K	India, Oct 2020	May 2021

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Obligations in ‘Provider’ Countries

ABS if the biological material originated from Switzerland, South Africa, Brazil, India and France

ABS in Switzerland

Art. 8 Nagoya Ordinance

1 On **accessing** genetic resources in Switzerland, the **user must record and retain** following information and pass it on to **subsequent users**:

- a. the name and address of the user;
- b. description of the genetic resource or subject matter and its utilisation;
- c. date on which and location where the genetic resource was accessed;
- d. in the case of direct acquisition of the genetic resource from a third party: the name and address of this person and the date of acquisition;
- e. in the case of the transfer of genetic resources: the name and address of the subsequent user and the date of the transfer.

…

3 The **user must notify** the FOEN of the information specified in paragraph 1 **before market approval** or, if such approval is not required, before the commercialisation of **products developed on the basis of utilised genetic resources.**

…

5 The user **receives a register number** as evidence of the **notification** and, on request, an **attestation** to the effect **that the Swiss provisions** on access and sharing of benefits have been **complied with.**

Key issues

- Trigger = access
- User = who?
- No benefit-sharing obligation, but 'recommended'
- Proof of compliant access in Switzerland

= From a compliance perspective, this is okay

ABS in Brazil

Registration upon Access	**What?**	• R&D on genetic heritage and associated traditional knowledge; or, • Shipping samples outside of Brazil
	When?	Prior to: (1) shipping abroad, (2) seek IP right, (3) commercialization of finished product or reproductive material, or (4) disclosure of results of R&D
	How?	SisGen Platform (requires Brazilian partner)
Notification to trigger Benefit Sharing	**What?**	Benefit-Sharing from finished product for commercialization: 1% annual global net revenue
	When?	Prior to commercialization
	How?	SisGen (requires Brazilian partner)

ABS in South Africa

2004 National Environmental Management: Biodiversity Act (NEMBA)

Applies to "*indigenous species*"
= "*a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the Republic, but excludes a species that has been introduced in the Republic as a result of human activity.*"

Two steps:

- Discovery phase on potential commercial product = notification + export permit;
- Commercialization (e.g. clinical trials, seeking market approval) of product = export and bioprospecting permit

Key issues

- When is a resource indigenous?
- Negotiate benefit-sharing with the "provider" of the indigenous resource?
- A foreign legal entity cannot apply, it must be with and through a South African legal entity
- Criminal penalties

ABS in India

- Trigger: "obtaining" a resource (also metabolites) from India, including if held in a collection abroad (2023 amendment).
- For "Commercial utilization" = *"end uses of biological resources for* ***commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics,*** *emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention"*
- There is a **strong legal** case to be made that India's ABS rules, including the discrimination between Indian and foreign entities, apply them **likely violate** India's obligations under **WTO law**
- **If only someone would convince the US Trade Representative to take this up with India and go to WTO**

Impact on U.S. companies is real.

2. On perusal of the application, it is observed that the following information/details/clarification is required for further processing the application

a. Exact Quantity accessed for research (mg, gm, Kg, etc.)
b. Exact Date of access of biological resources (Proof the be enclosed)
c. Exact dates of commencement and completion of the research
d. Details of the research activities carried out after accessing the biological resource in this instant application, not exceeding 250 words.

e. Current status of the research.

f. Details of the patent filed in outside India and their current status.

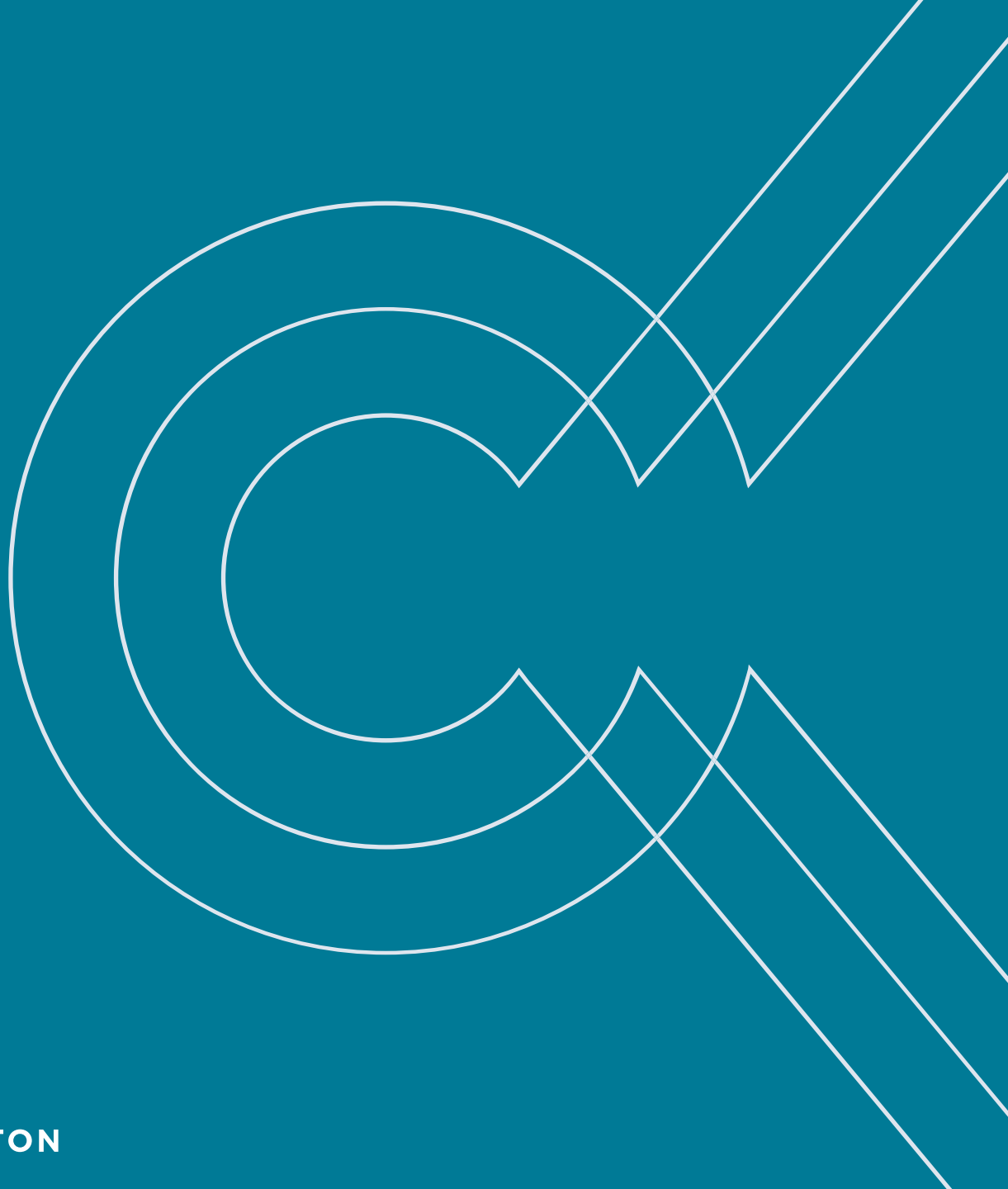
g. Details of commercial activities so far. If any product developed on the accessed biological resources, with product - year-wise sales figures, etc.

h. Is there any prior approval has been obtained for the access of biological resources from India as per section 3 of the Biological Diversity Act 2002, if YES, the copy for the same, if NOT the reason for the same.

3. Please send your reply within 15 days of receipt of this communication.

Compliance in ‘User’ Countries

Demonstrating compliance with ABS in jurisdictions where the biological material is ‘used’: EU, Germany, Switzerland, UK …



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European Union (EU) Rules Enforcing Compliance with the Nagoya Protocol

Companies doing R&D in any EU country must, under Regulation 511/2014:

Art. 4(1) exercise due diligence that access was in accordance with ABS rules;

Art. 4(2) transfer and utilize Genetic Resources only in accordance with MAT;

Art. 4(3) seek, keep and transfer to subsequent users:
date, place, description, source, users, obligations; PIC; MAT;

Art. 4(6) keep that information for 20 years after R&D ends;

Art (4(5) if the information is insufficient, or uncertainties about the legality of access and utilization persist: obtain PIC/MAT or discontinue utilization;

Art. 7 submit a compliance declaration when receiving research funding or prior to commercialization.

Similar rules in …

Switzerland

Federal Act
on the Protection of Nature and Cultural Heritage

Art. 23*o*[78]

[1] Notification of compliance with the due diligence requirement must be given to the FOEN before market authorisation has been obtained or, if such authorisation is not required, before the commercialisation of products developed on the basis of utilised genetic resources.

Art. 24*a*[87]

[2] Any person who wilfully fails to provide information or provides false information under Article 23*o* shall be liable to a fine not exceeding 100,000 Swiss francs; in cases of negligence, the penalty shall be a fine not exceeding 40,000 Swiss francs. The court may order the publication of the judgment.[89]

UK

Due diligence obligations of the EU Regulation which are subject to civil sanctions

8.—(1) Subject to paragraphs (2) and (3), civil sanctions may be imposed in relation to a failure to comply with any of the following provisions—

(a) Article 4(1) of the EU Regulation (obligation to exercise due diligence);

(b) Article 4(3) of the EU Regulation (obligation to seek, keep and transfer information and documentation to subsequent users);

(c) Article 7(2) of the EU Regulation (obligation to make a declaration of due diligence).

(2) There is no failure to comply with the provisions referred to in paragraph (1) if the Secretary of State is satisfied that the user has shown that they have effectively implemented best practice recognised under Article 8(2) of the EU Regulation.

(3) There is no failure to comply with Article 4(3) of the EU Regulation if the Secretary of State is satisfied that—

(a) the user is considered to have exercised due diligence under Article 4(4) of the EU Regulation (use of the Plant Treaty's Standard Material Transfer Agreement for material not listed in Annex 1 to that Treaty);

(b) the user is considered to have exercised due diligence under Article 4(7) of the EU Regulation (users obtaining material from a registered collection); or

(c) the use is in accordance with Article 4(8) of the EU Regulation (use of pathogen for the purpose of public health emergency preparedness).

Korea

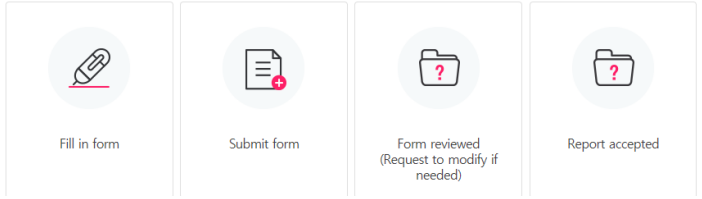
National Institute of Biological Resources
ABSCH Genetic Resources Information Center

Report compliance

Integrated Reporting Service › Guide › Report compliance

How to report procedural compliance for foreign genetic resources

˙ How to report procedural compliance for foreign genetic resources



Japan

Chapter 2 Measures for promoting compliance with legislation in provider countries

No. 1 Report concerning the lawful access to genetic resources

1. Report by acquirers

If a person has obtained access to genetic resources to which legislation in the provider country applies (excluding genetic resources, etc. to which the Protocol does not apply; the same applies hereinafter) and imported them into Japan (hereinafter referred to as an "acquirer") and an internationally recognized certificate of compliance concerning the said

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The future

Other ABS instruments are under way

The Future: ABS on "Digital Sequence Information"

UN environment programme

CBD

Convention on Biological Diversity

Distr.
LIMITED

CBD/COP/15/L.30
18 December 2022

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
Fifteenth meeting – Part II
Montreal, Canada, 7-19 December 2022
Agenda item 11

Digital sequence information on genetic resources

16. *Decides* to establish, as part of the post-2020 global biodiversity framework, a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund;[9]

17. *Also decides* to establish a fair, transparent, inclusive, participatory and time-bound process to further develop and operationalize the mechanism, as outlined in paragraphs 18 and 20 to 22 below, to be finalized at the sixteenth meeting of the Conference of the Parties;

18. *Establishes* an ad hoc open-ended working group on benefit-sharing from the use of digital sequence information on genetic resources to undertake further development of the multilateral mechanism, including the elements identified in the annex, and to make recommendations to the Conference of the Parties at its sixteenth meeting;

Let's create it, and then figure out how to make it work

The Future: Pathogens, Marine, and IP Disclosure

Diplomatic Conference on Intellectual Property and Genetic Resources

On July 21, 2022, the WIPO General Assembly decided to convene a Diplomatic Conference to conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources no later than 2024.

ARTICLE 3
DISCLOSURE REQUIREMENT

3.1 Where the claimed invention in a patent application is [*materially*/*directly*] based on GRs, each Contracting Party shall require applicants to disclose:

(a) the country of origin of the GRs, or,

(b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the GRs.

Intergovernmental conference on an international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction
Resumed fifth session
New York, 20 February–3 March 2023

MARINE GENETIC RESOURCES, INCLUDING QUESTIONS ON THE SHARING OF BENEFITS

Article 7
Objectives

The objectives of this Part are:

(a) The fair and equitable sharing of benefits arising from marine genetic resources of areas beyond national jurisdiction for the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction;

World Health Organization

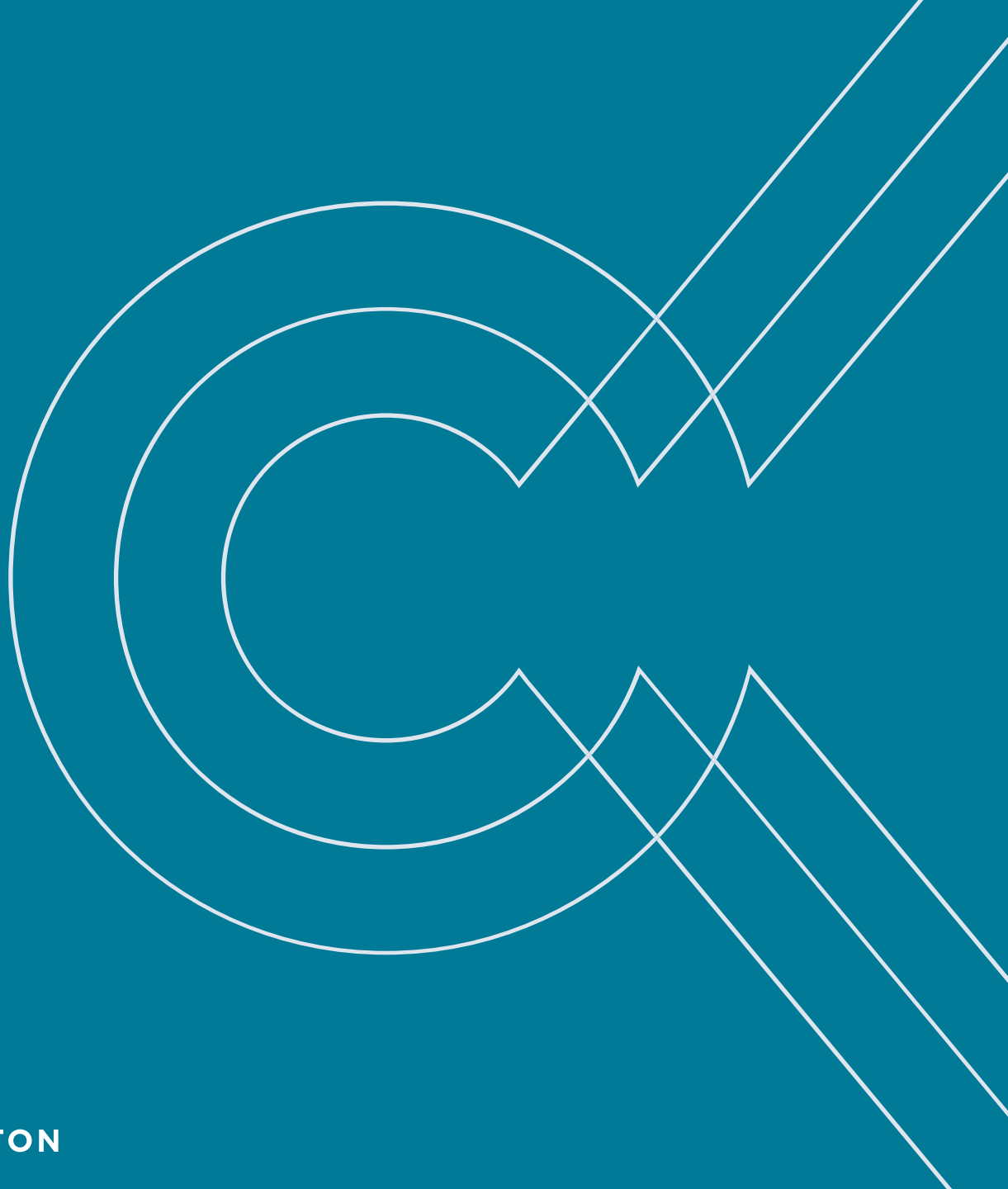
THIRD MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE

Article 9. Fair, equitable and timely access and benefit-sharing

1. The Parties [shall]/[should] develop provisions on access and benefit-sharing to promote rapid and transparent sharing, in a safe and secure manner, of pathogens with pandemic potential and genetic sequence data on the one hand, and fair and equitable access to benefits arising from such sharing on the other, by establishing a comprehensive system for access and benefit-sharing, taking into account relevant elements of the Convention on Biological Diversity and its Nagoya Protocol, including by building upon or adapting mechanisms and/or principles contained in existing or previous instruments, such as, but not limited to, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the WHO Pandemic Influenza Preparedness Framework.

Thank you

Contact me at
Bvanvooren@cov.com



About me & ABS

Bart (*first name)* **Van Vooren** *(last name)* =

- A life sciences regulatory lawyer (i.e. deep life sciences industry knowledge);
- Who has worked on ABS / Nagoya for 10 years;
- For food, pharma, cosmetics, biotech and agricultural clients;
- On a breadth of ABS-related assignments, including:
  - ABS public policy support at national, EU and international level
  - Trainings and organize compliance programs for startups and multinationals
  - ABS due diligence of specific biological assets, R&D projects and during M&A
  - In-depth advice on key ABS laws, including permit negotiations in *e.g*. France, South Africa, Viet Nam
  - Drafting ABS clauses in a range of contracts, e.g. material transfer, R&D collaboration
  - Engage during enforcement actions in provider and user countries
  - Litigation

Email: bvanvooren@cov.com

Panel Discussion

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Biotechnology Innovation Organization

Q&A

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