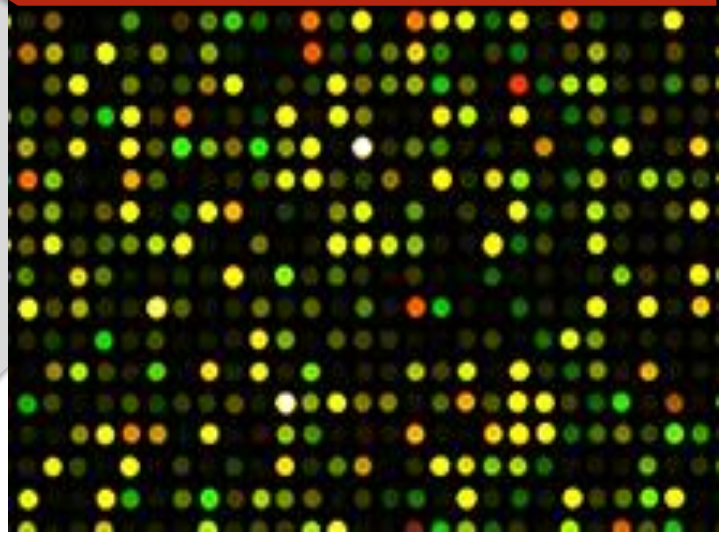
Status update ABS - VLIR

Unlocking genetic resources

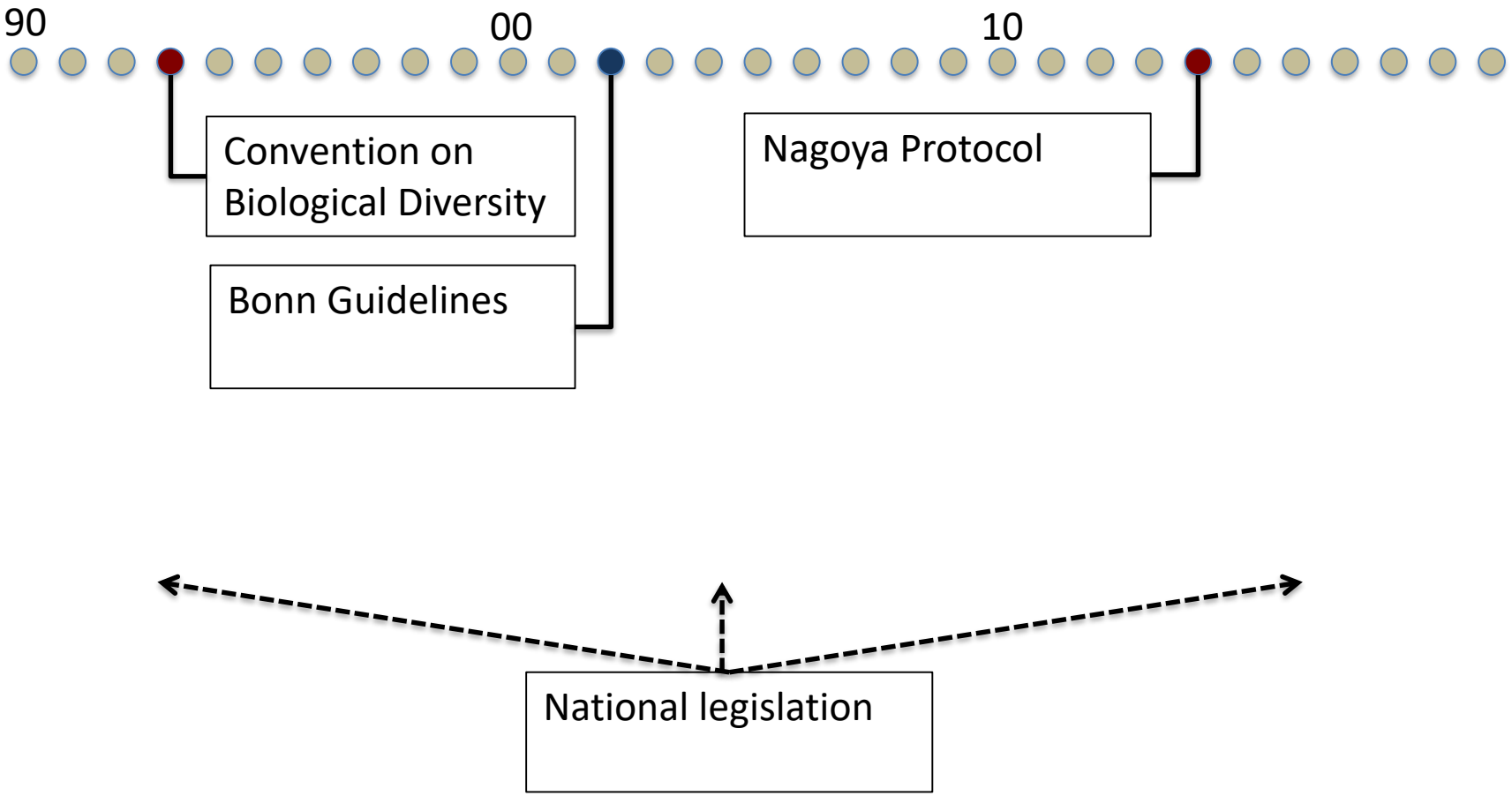


Selected topics:

Status update DSI;
Update scope EU ABS Regulation;
ABS & Covid-19

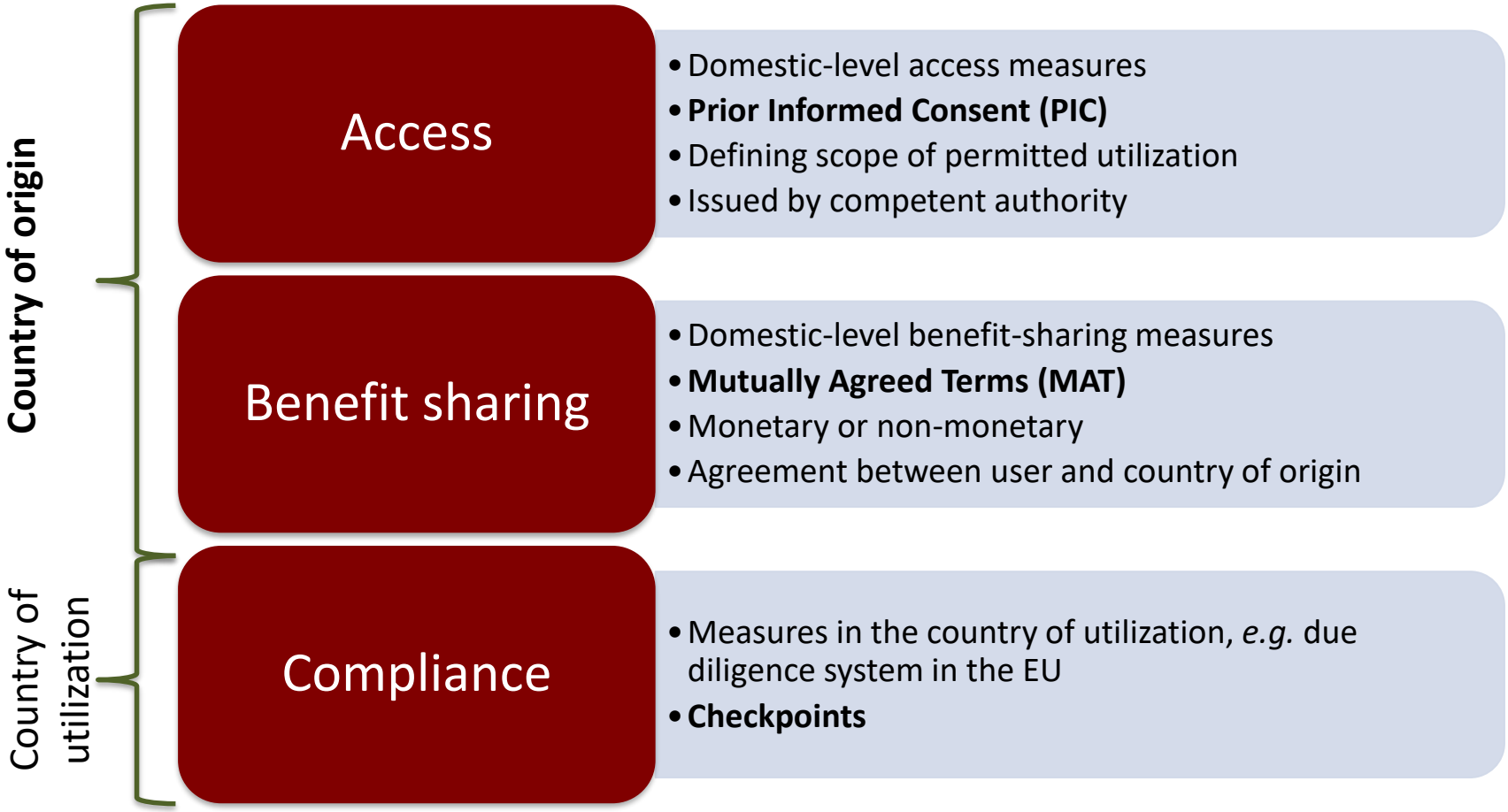
Dominic Muyldermans

ABS Legal framework



Nagoya Protocol

ABC of ABS



ABS legal framework

Material scope: **genetic resources and associated traditional knowledge**

Genetic resources over which states exercise sovereign rights

Traditional knowledge associated with genetic resources

Status update DSI

ABS legal framework

Material scope - **Information?**

- **Digital Sequence Information (DSI):**
  - "DSI" not clearly defined – GRSD/GSD/NSD;
  - Some push for inclusion of DSI in the scope of (benefit sharing obligations under) the Nagoya Protocol;
  - Ongoing International discussions in the context of CBD and Nagoya Protocol – key topic in discussion up to COP-MOP;
  - Common concerns by all academic and non-academic stakeholders:
    - Safeguard open access and exchange of DSI
    - Important to unlock potential of genetic resources;
    - Impact in existing databases (cfr INSDC);
    - Direct and non-monetary benefit sharing.
  - How to address request for monetary benefit sharing?
  - "DSI" addressed in other instruments: ITPGRFA and PIP;
  - Some national laws already include DSI (*e.g.* Brazil).

ABS legal framework

DSI

COP 14 decision – intersessional process:

- "Science and policy-based" process for information gathering is established consisting of the following:
  - **Submission** of Parties, Observers and stakeholders of views and information on concept and benefit sharing:
  - Commissioning of four science-based peer reviewed fact finding **studies**, drawing from relevant views and information submitted, by the CDB Secretariat:
    - On concept and scope of digital sequence information on genetic resources and how DSI on genetic resources is currently used;
    - On ongoing developments in the field of traceability+ study on public and, to the extent possible, private databases of DSI;
    - On domestic measures.

ABS legal framework

DSI

COP 14 decision – intersessional process:

- Establishment of an extended[3] **Ad Hoc Technical Expert Group** which will meet to:
    - consider the CBD secretariat's compilation and synthesis of views and information and the peer-reviewed **studies**;
    - develop options for **operational terms** and **their implications** to provide **conceptual clarity** on DSI on GRs;
    - identify key areas for **capacity-building**;
- The open-ended working group established by COP-14 on the post-2020 global biodiversity framework will consider the AHTEG's outcomes and make recommendations to COP-15 on how to address digital sequence information on genetic resources.

ABS legal framework

DSI

Up to COP 15 – intersessional period – status (1)

- Submissions on concept + benefit sharing done (infra);
- Four fact-finding studies have been issued:
  - Study on INSDC stresses the importance of open access + explains roles of databases to ensure interconnectivity in scientific research;
  - Study on scope and terminology provides a frame with options.
- (virtual) second AHTEG 17-20 March:
  - Focus on scope and terminology:
    - Group 1 – DNA & RNA – NSD;
    - Associated information is not DSI;
    - More qualifying elements recognized, i.a. degree of biological processing and proximity to the underlying genetic resource;
  - Value of open access reiterated;
  - Only preliminary observations re impact on research (private + public);
  - Importance of (well-defined) capacity building endorsed

ABS legal framework

DSI

Up to COP 15 – intersessional period – status (2)

- Post-2020 global biodiversity framework discussions ongoing:
  - Second meeting of Working Group took place in Rome end of February;
  - Multi-layered discussion re biodiversity (goals-targets);
  - ABS part of the goals and targets;
  - DSI (not yet) at the center of the debate – open access to DSI is key to reach the goals re biodiversity;
  - “nature based solutions”, importance of innovation;
  - DSI to be looked at in the broader policy discussion of resource mobilization for biodiversity;
  - Innovative funding mechanisms

ABS legal framework

DSI

Up to COP 15 – intersessional period – status (3)

- Developments under national law:
  - Certain countries have it included in national law (cfr Brazil as driver for international inclusion);
  - Often included in national laws under development
- CBD & NP decisions: assess the impact of DSI in the context of the 3 objectives of CBD;
- COP meeting: clear indications that China will push for a "successful" outcome; put pressure on a "solution"; national law incl 'DSI' is being finalized;
- BUT: due to corona, timeline of CBD process revised:
  - SBSTTA meeting: 2-7 November (tentative)
  - COP-MOP: likely Q2 or Q3 2021.

ABS legal framework

DSI

Up to COP 15 – country positions (1)

- Demandeurs (megadiverse countries/developing countries – **Brazil** (Grulac) – Africa (i.a. South Africa) – Asia (i.a. **India**, Malaysia): DSI explicitly included – monetary benefit sharing re commercial use;
- Non-demandeurs (i.a. **Japan**, Korea): DSI outside of scope – only physical genetic resources (*but Japan might shift to middle group*);
- 'Middle' group (i.a. **EU**, Canada): DSI is not a GR – safeguard open access – address (monetary) benefit sharing re commercial use; **UK:** strong proponent of open access, *stronger position independent from EU contemplated*; **Switzerland** very strong proponent of open access.
- **US:** (not a party to CBD): strong proponent of open access – proposed terminology: GSD

ABS legal framework

DSI

Up to COP 15 – country positions - issues (2)

- Acknowledgment of open access?
- Focus on monetary benefit sharing re commercial use:
  - Recognition and valuation of non-monetary (direct) benefits;
  - Qualification of "commercial" use (cut-off criteria)?
- Element of 'control':
  - Bilateral system;
  - Multilateral system(s) – link with art 10 – scope of CBD/NP
- International database system:
  - Basis for value creation;
  - INSDC;
  - Public and private scientists

ABS legal framework

DSI

General observations

- Focus on (monetary) “green gold” might undermine real (non-monetary) benefits/value resulting from open exchange of data;
- Need for a well-defined **term**: “GRSD”; “NSD”, “GSD”
- Need for a better understanding and quantification of non-monetary **benefits** re open exchange of data;
- Need for a better understanding of terms and conditions of data access and sharing under existing databases;
- Need for capacity building to ensure better access and use in developing countries.

ABS legal framework

DSI

Key elements advocacy position

- DSI cannot be equal to physical genetic resource;
- Imposing ABS obligations will seriously impede R&D and advancement of science;
- Use of DSI to advance conservation and sustainable use makes a significant contribution to CBD, NP and Sustainable Development Goals (link between open access – scientific progress – societal benefits);
- Clarify the concept of DSI based on scientific definitions and expertise;
- Recognise the unencumbered access to DSI held in public databases, which are an effective and inclusive system for sharing DSI globally, as a form of (non-monetary) benefit sharing;
- Benefits from use of "DSI" can already be covered by MAT;
- Priority should be given to an effective implementation of the NP, putting in place national rules and infrastructure to safeguard sustainable use of genetic resources and safeguard legal certainty.

ABS legal framework

DSI

Joint stakeholder declaration:

- Signed by a wide variety of stakeholders, including companies, public institutions, universities, including from US (US Culture Collection Network, American Society for Microbiology, American Institute of Biological Science), and developing countries;
- Clear evidence of common concerns among all users;
- Global reach;
- Growing concerns and involvement of public sector research community
- Growing support to make potential adverse impact on research more visible
- Efforts, but continuing difficulties in engaging research community in developing countries;

ABS legal framework

DSI

CBD & "DSI" – terminology - other terms

- A more scientifically precise term;
- Alternative term of scientific community: "Nucleotide Sequence Data" or "NSD" (cfr AHTEG)
- Alternative term of certain countries: "Genetic Sequence Data" or "GSD":
  - More precise than "DSI";
  - Already in use in other fora (p.e. WHO PIP)
- "GRSD" proposed by private sector;
- BUT: Inclusive, open term proposed by developing countries which is very open-ended and unworkable, with no cut-off point (cfr first AHTEG + ongoing discussions re "natural information" at second AHTEG);

ABS legal framework

DSI

Benefit sharing (1)

- Imposing additional ABS obligations will have a significant impact on current benefits:
  - Exchange of data (unlocking value of GR) leads to societal benefits, contributing to objectives of CBD and NP;
  - Well established and functioning international (scientific) framework ensuring open exchange of data;
  - Considerable non-monetary benefits are derived from open exchange by all countries (INSDC-172 countries).
- Existing benefit generation and sharing to be shown in detailed **use cases** + complexity of use cases explained in detail;
- Public scientists more and more vocal on benefits in all applications - reinforced in advocacy;
- Ongoing discussions about possible options;
- Policy position on value – direct benefits – non-monetary – monetary benefits.

ABS legal framework

DSI

Benefit sharing (2)

- How to safeguard value creation and sharing re "DSI";
- Overarching policy frame re biodiversity – link with SDGs – integration of (physical) GR;
- Expectations:
  - Benefit sharing expectations:
    - Monetary benefit sharing re commercial use;
    - BUT: direct benefits + non-monetary benefit sharing
  - Sustainable use as basis for value creation
- Optimising value creation and sharing:
  - Safeguard and reinforce value creation:
    - Open access;
    - Integrity of open database system;
    - Targeted capacity building
  - Safeguard benefit sharing:
    - Direct benefits (examples) – societal benefits;
    - Additional benefit sharing:
      - Non-monetary (examples)
      - Monetary?

ABS legal framework

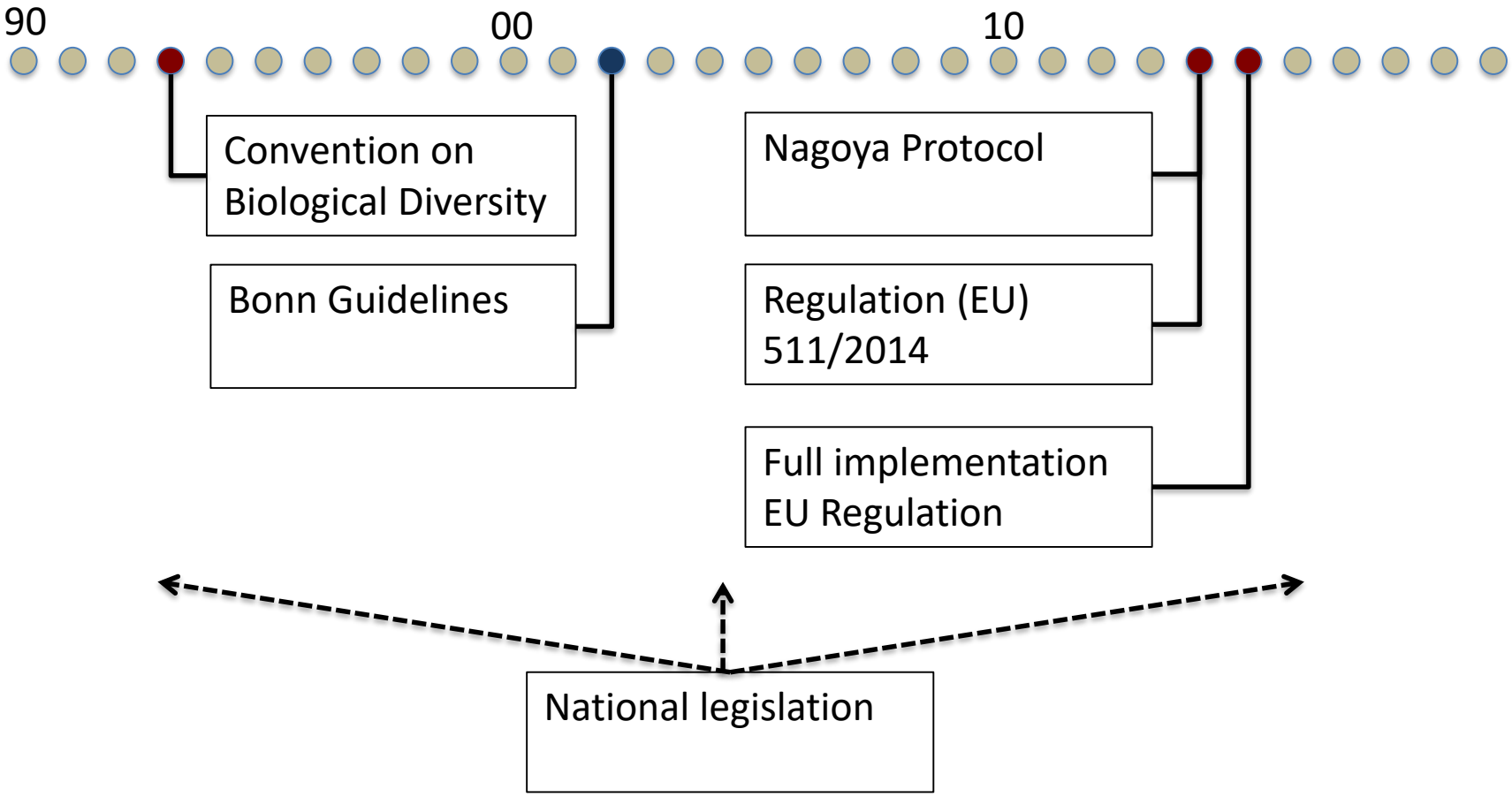
DSI

Potential impact of regulating "DSI"

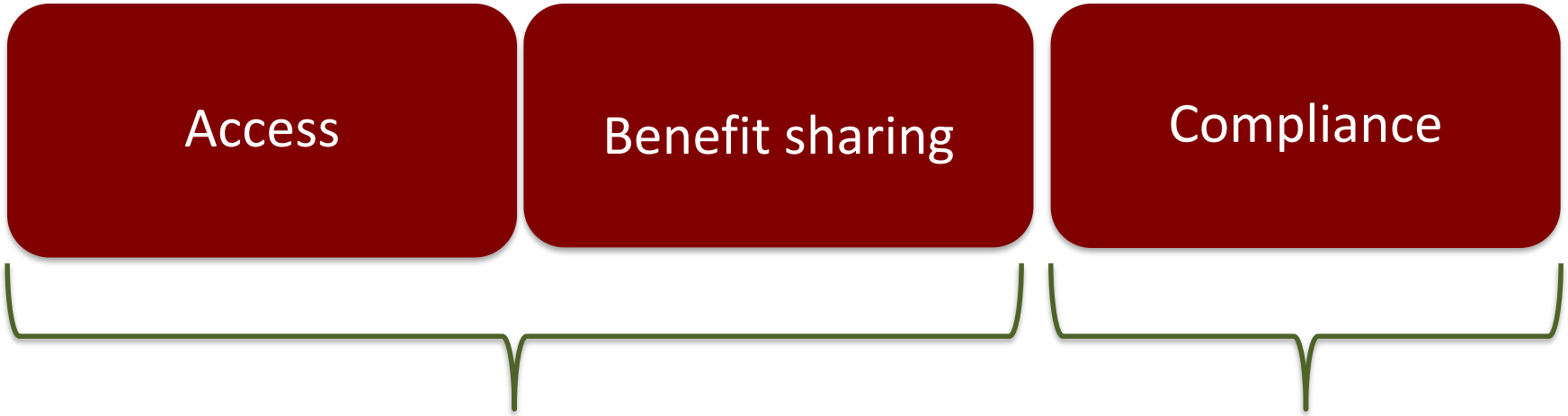
- Restricting access undermines (biodiversity/data) basis for research (including private-public sector cooperations) - negative impact on value creation;
- Possible impact of (broad) obligations:
  - Legal uncertainty;
  - High transaction costs (cfr track and trace);
  - Probability of innovation undermined (scope of 'usable' biodiversity reduced)
- The research ecosystem is impacted
- COVID-19 as a prime example of the need for continued open access and exchange.

Update scope EU ABS Regulation

ABS legal framework



ABS legal framework in EU



Regulation (EU) No 511/2014

Facts

Title

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

Dates

12/10/2014 Entry into force

12/10/2015 Entry into force Art. 4, 5, 7 and 9

More

- Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.
- Horizontal Guidance Document on the scope of application and core obligations or Regulation (EU) No 511/2014, published on 27 August 2016.
- A revised Horizontal Guidance Document and a Vertical Guidance Document are being finalised and likely published in 2020.

Regulation (EU) No 511/2014

Scope - **Geographical**

- The provider country is a party to the Nagoya Protocol;
- The provider country exercises sovereign rights over the genetic resources – has established access measures;
- These ABS measures apply to the specific genetic resources at the time of access
- Indirect acquisition via an ex situ collection: the original access by the collection defines potential ABS obligations;
- Specific case of alien and invasive alien species.

Regulation (EU) No 511/2014

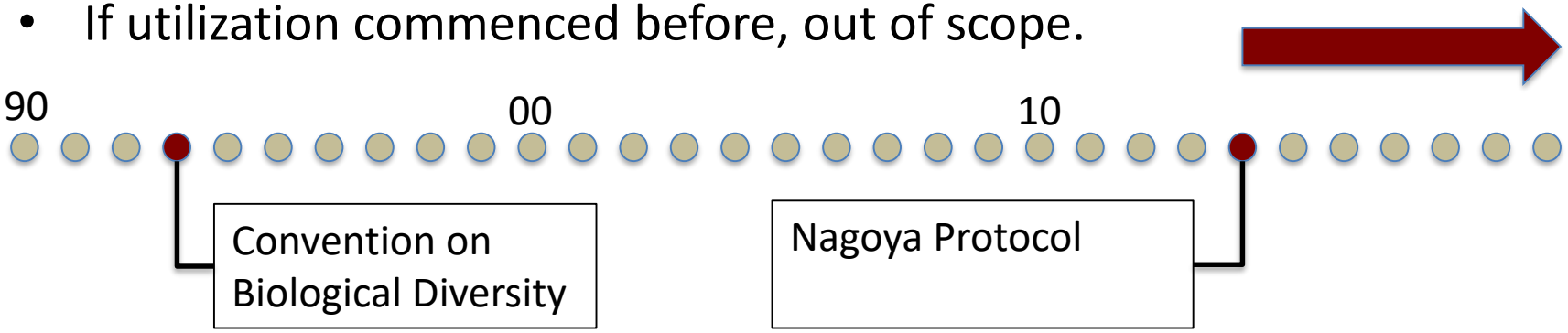
Scope - **Geographical**

- **Alien species:**
  - Not relevant whether alien species are invasive or not;
  - Not relevant whether alien species are introduced intentionally or unintentionally (except specimens intentionally introduced for R&D prior to establishment) ;
  - When do countries qualify 'alien species' as in situ?
  - Application of ABS obligations:
    - CBD defines 'in situ' as "where the species has developed its distinctive properties";
    - EU ABS Regulation: "alien species once established, i.e. having at least one self-sustaining population in the wild, can be seen as occurring in in situ conditions in the country where they are alien".
    - The situation is different when the species have been introduced intentionally.

Regulation (EU) No 511/2014

Scope - **Temporal**

- Genetic resources over which states exercise sovereign rights and traditional knowledge associated with genetic resources that are **accessed after the entry into force of the Nagoya Protocol** for the Union;
- If utilization commenced before, out of scope.



Compliance under national law might go further than EU Regulation, *e.g.* some national laws use utilisation as a trigger point.

Regulation (EU) No 511/2014

Scope - **Material**

Genetic resources over which states exercise sovereign rights

Traditional knowledge associated with genetic resources

Regulation (EU) No 511/2014

Scope - **Material**

- **Pathogenic organisms**
  - Within scope;
  - Extended deadline for compliance with the due diligence obligations in case a genetic resource is determined to be (or as likely to be) the causing pathogen of a present or imminent public health emergency of international concern, or of a serious cross border threat to health;
  - “no exclusive rights of any kind will be claimed”
  - Pandemic Influenza Preparedness (PIP) Framework
  - Limits of bilateral approach re pathogens – ongoing discussion.

Regulation (EU) No 511/2014

Scope - **Material**

- **Unintentional introduction of pathogens and pests:**
  - Pathogens and pests often spread in an uncontrolled manner;
  - Pests can be introduced unintentionally together with commodities;
  - Difficult or impossible to define the country of origin;
  - EU ABS Regulation does not apply to “pathogenic organisms or pests present on (…), and animal, plant (…) or any other material, which as such are introduced unintentionally to a place in the EU”
  - Examples: isolation of a corona virus from a sample taken from a patient.

Regulation (EU) No 511/2014

Scope - **Material**

- **Associated organisms:**
  - organisms associated with other biological specimens, i.a. parasites, pests, symbionts or its microbiota;
  - “Any organism residing in or on another one”;
  - Application of ABS obligations:
    - EU ABS Regulation: “when an associated organism is brought in the EU together with a genetic resource falling in scope, and the association was established in the provider country”;
    - Country of origin of underlying genetic resource;
    - Conditions of access and use should cover associated organisms

Regulation (EU) No 511/2014

Scope - **Material**

- **Derivatives:**
  - EU ABS Regulation: “when access to a derivative is combined with access to a genetic resource from which that derivative was obtained or when R&D on such a derivative is addressed in the MAT”
  - Ascertainable level of continuity between a derivative and the genetic resource:
    - R&D using a derivative forms part of a research project covering the genetic resource and including the derivative;
    - A user has obtained the derivative or commissioned a third party to obtain the derivative from a genetic resources in a research collaboration or as a specific service;
    - The derivative is acquired from a third party and is transferred with PIC and MAT conditions that cover the respective R&D using the derivative

Regulation (EU) No 511/2014

Scope - **Material**

- **Derivatives:**
  - No continuity:
    - Derivative is acquired from a third party as a product available on the market; and
    - Is transferred without PIC and MAT that cover R&D on the derivative
  - Any use of a derivative that is traded or obtained as a commodity without PIC and MAT, or without access to a specific genetic resource is not within scope;
  - Definition of "naturally occurring"; reference to definition in REACH re "not chemically modified", i.e. a substance whose chemical structure remains unchanged, even if it has undergone a chemical treatment.

Regulation (EU) No 511/2014

Scope – **Material**

- **Human Microbiome**
  - Human microbiome: the collective genomes of all microorganisms residing on or in the human body;
  - 'While associated with human beings and essential for the well-being and the survival of human individuals, the human microbiome represents genetic resources of non-human nature';
  - Separate from human genetic resources – distinct and different organisms;
  - Application of ABS rules in addition to ethical codes of conduct (right of individual to grant personal consent for sampling);
  - Study of microbiota as such is out of scope, but individual taxa isolated from a sample are potentially in scope.
  - Sovereign rights of the country where the microbiota were sampled

Regulation (EU) No 511/2014

Material scope- **Utilisation**

- Conducting R&D on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology

Any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use

  - Only R&D *on*, not *with* a genetic resource:
    - Use as a testing tool (to be construed restrictively);
    - BUT R&D on the tool is included.
  - Only R&D activities, pre- and post-R&D activities are excluded:
    - Storage;
    - Identification and characterisation - taxonomy;
    - Large scale screening
    - Rearing and multiplication;
    - (pre)commercial, regulatory activities.

Regulation (EU) No 511/2014

Material scope - **Utilisation**

- **Activities preceding the R&D process:**
  - Taxonomic identification:
    - Morphological or molecular analysis, incl through the use of DNA sequencing;
    - Out of scope of EU ABS obligation since it does not involve " the discovery of specific genetic and/or biochemical properties";
    - Identification of the derivative is equivalent to taxonomic identification of an organism.
  - Characterisation:
    - Part of identification (examination of morphological characteristics) and quality control, as standard practice in collections;
    - Out of scope of EU ABS Regulation if it does not involve the discovery of specific genetic and/or biochemical functions;
    - In scope in case it is combined with research on the specific genetic or biochemical composition.

Regulation (EU) No 511/2014

Material scope - **Utilisation**

- **Activities preceding the R&D process:**
  - Large scale screening:
    - An activity which involves the analysis of usually large number of genetic resource samples to evaluate them against specific criterion;
    - Process is frequently automated;
    - Binary questions;
    - Objectives: to screen out the vast majority of samples not or interest of (and not used in) the R&D project (negative) and to identify the few samples that may have potential (positive);
    - Out of scope: aim is description and hence does not qualify as “utilization”.
    - As soon as activity focuses on identifying the qualities and functions of genetic resources, within scope;
    - National laws of country of origin?

Regulation (EU) No 511/2014

Material scope - **Utilisation**

- **Genetic resources as tools**
  - Testing or reference tools
    - Use of laboratory animals;
    - Pathogens used for testing the resistance of plant varieties;
    - Rats used in toxicological studies;
    - Bacteria used to test the effectiveness of an antibiotic;
    - BUT development of the tool itself is in scope.
  - Vector or host
    - BUT optimizing the host is in scope.
  - Biofactory
  - Laboratory strains
    - When the strain becomes a new laboratory strain shared by laboratories, its further use is out of scope;
    - Contractual benefit sharing obligations might apply.

Regulation (EU) No 511/2014

Material scope - **Utilisation**

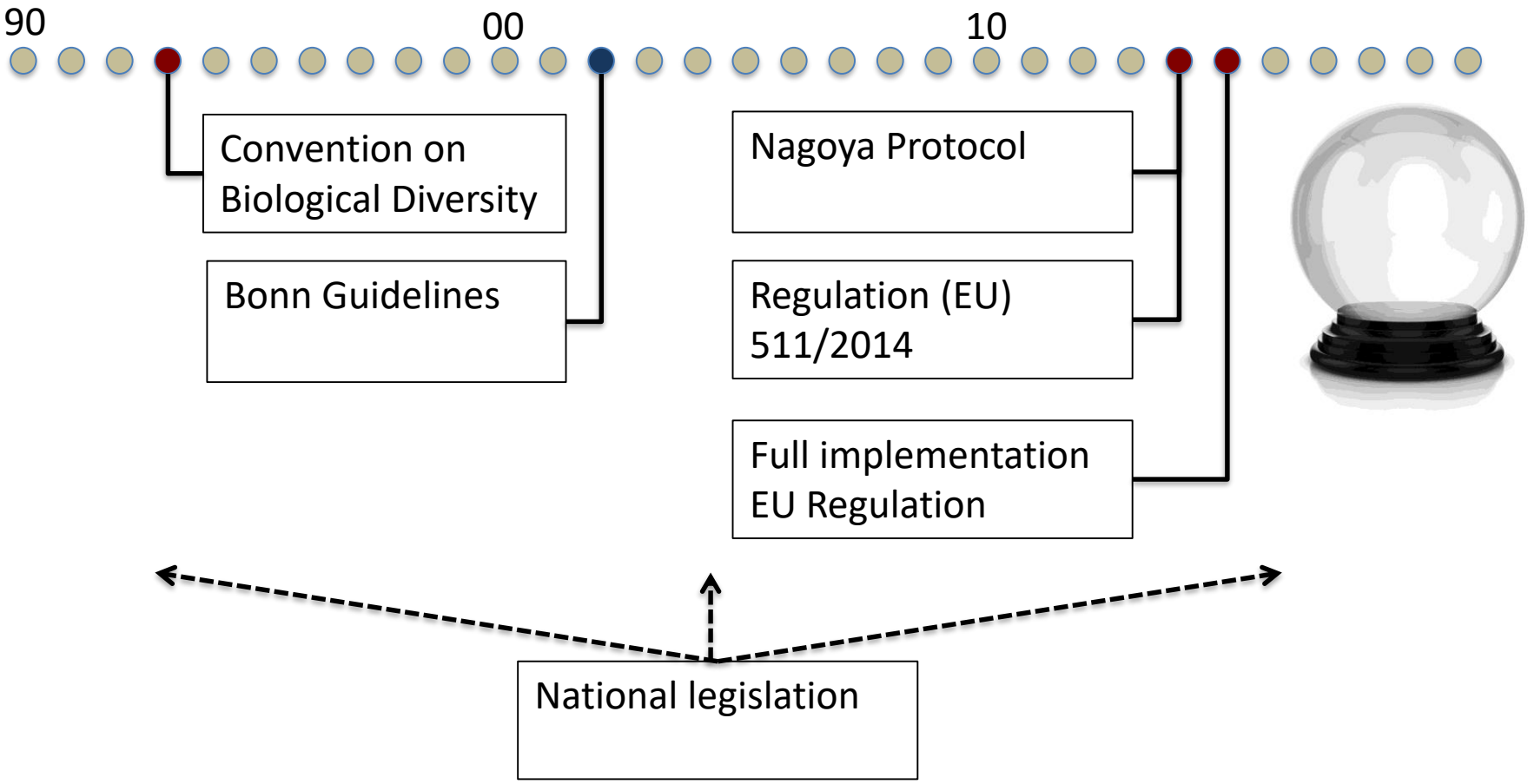
- **Processing, formulation, product testing & trials**
  - Processing
    - The mere processing for subsequent incorporation of a genetic resource or compound in a product in case the function of the genetic resource or compound is already known or not relevant, is out of scope.
  - Product formulation
    - Mixing ingredients or adding compounds as such is out of scope.
  - Product testing
    - Testing as an essential element of the R&D process is in scope
    - Tests on the final product, in case these do not result in further R&D are out of scope
  - Phase III and IV clinical trials aim at confirming existing understanding and are out of scope, unless further R&D is taking place.

Regulation (EU) No 511/2014

Material scope - **Utilisation**

- **Subcontracting:**
  - Service provider not to be qualified as user if certain conditions are complied with (made explicit in contract), i.a.:
    - Obligation to return or destroy the material;
    - No IP rights granted on the results;
    - No right to transfer
  - The sub-contracting entity is considered to be the user responsible for compliance with ABS obligations;
  - Provides more clarity and legal certainty;
  - Ensures protection of confidential data.

ABS Legal framework



Covid 19 & ABS

ABS legal framework

Pathogens

Contentious issue

- Not considered in CBD negotiations;
- Exclusion advocated for since many years;
- Conservation of biodiversity/benefit sharing & pathogens?;
- Issue surfaced in NP negotiations in 2009:
  - following developments in the WHO re influenza;
  - Indonesia's claims based on the alleged right to refuse to share samples because "it controls access to samples collected in its territory";
- Developed countries advocating for an explicit exclusion and developing countries for an explicit inclusion.
- Final decision not to explicitly include, nor exclude in NP;
- Sovereignty (global spread) & timely sharing of pathogens;
- Ongoing WHO discussion

ABS legal framework

Pathogens – health related emergencies

Referred to in legislative texts:

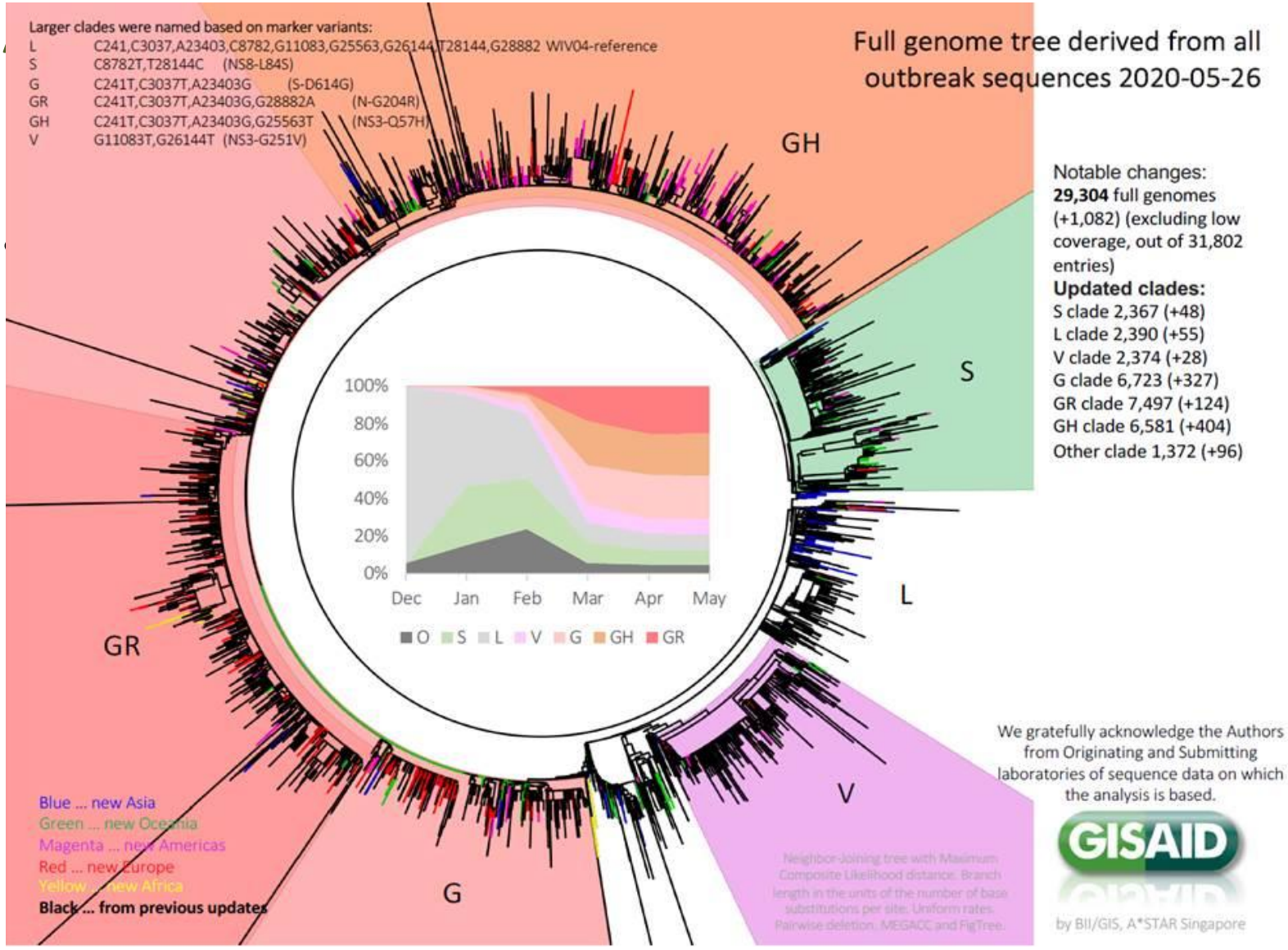
- Preamble 17 Nagoya Protocol:
  - "Mindful of the International Health Regulations (2005) of the WHO and the importance of ensuring access to human pathogens for public health preparedness and response purposes"
- Art 8, b) Nagoya Protocol:
  - "in the development and implementation of its ABS legislation, 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. 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"
- Article 4.8 EU ABS Regulation – delay in obtaining an access permit

ABS legal framework

Pathogens – COVID-19 (1)

Possible ABS restrictions highly relevant in R&D re COVID- 19:

- Sovereign rights exist and ABS restrictions might apply;
- Dangerous to assume Access and Benefit Sharing obligations are waived because of a pandemic:
  - Art 8, b) provides a right not an obligation for expeditious access (+ does not assume no conditions apply);
  - Countries might use ABS as bargaining chip to get favourable access to treatments or vaccines (reference to “affordable treatments to those in need”)
- Term for delay under EU ABS Regulation has ended;
- How will users manage this – health authorities, universities?
- Governments and EU Commission have been made aware?
- Common EU position / country position?
- Paramount that license to operate for health authorities and research community is safeguarded!
- Cfr annual sharing of 40,000 influenza pathogens in GISRS



Notable changes:
29,304 full genomes (+1,082) (excluding low coverage, out of 31,802 entries)

Updated clades:
S clade 2,367 (+48)
L clade 2,390 (+55)
V clade 2,374 (+28)
G clade 6,723 (+327)
GR clade 7,497 (+124)
GH clade 6,581 (+404)
Other clade 1,372 (+96)

We gratefully acknowledge the Authors from Originating and Submitting laboratories of sequence data on which the analysis is based.

GISAID

by BII/GIS, A*STAR Singapore

ABS legal framework

Pathogens – COVID-19 (2)

DSI as a key tool to manage COVID-19

- 'Management' of COVID-19 relies upon global collaboration;
- Requirement of quick and easy access and exchange of DSI – real value emerges from wealth of data from different geographies;
- Importance of DSI for 1) reporting characterization and 2) development of diagnostics, vaccines and treatments;
- From full genome sequencing by Chinese public health laboratories to full genome data sharing on GISAID EpiCoV database in less than 24h! (SARS: more than 2 months);
- Sharing of more than 32,000 sequences on a global scale;
- Importance of DSI recognized by WHO;
- Continued open access and exchange of DSI is key to develop vaccines and treatment and manage the pandemic going forward (still growing and becoming more global);
- **Essential to manage track and trace – second wave;**
- Nature 27 May "how countries are using genomics to help avoid a second coronavirus wave".

ABS legal framework

Pathogens – COVID-19 (3)

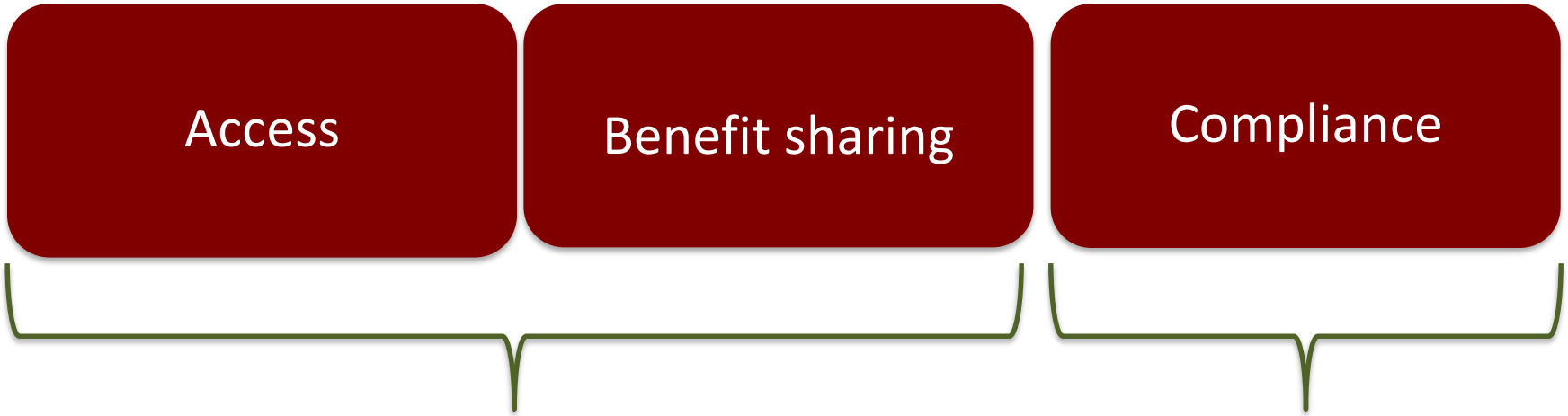
Proposed way forward:

- Map the situation re genetic resources for the relevant institutions and universities (i.a. the ones that are cooperating with companies);
- Make a risk based ABS assessment;
- Inform the relevant authorities (health, ABS, research) and make them aware of the potential issues and need for policy support – explain it is key enable track and trace to manage second wave (enabling precision interventions) - DSI is key to re-open an economy and avoid total lockdown;
- Define a common plan of action / code of conduct;
- Coordinate with European counterparts and monitor EU discussions;
- Continue to stress the importance of open access and exchange;
- Continue to use COVID-19 as a case to showcase the importance of open access and exchange;
- Use the COVID-19 example to prepare guidance for ABS issues re other pathogens and human health issues.

Back-up slides:
ABS obligations & compliance

ABS obligations

Two sets of obligations



National Laws in country of origin

Regulation (EU) N° 511/2014, applied by national/regional authorities

ABS obligations under national law: Access

Prior Informed Consent (PIC)

- A **permit** issued by the competent national authority of the country of origin defining the conditions of use;
- Requirement and conditions specified in national (or regional) ABS laws of country of origin;
- Country of origin can be *each* country which possesses the GR in *in situ* conditions (jurisdiction shopping);
- Requiring PIC is a right of the country of origin, not an obligation;
- PIC is not a sample permit or export permit;
- Role of indigenous people *re* traditional knowledge?
- Does (intended) scope of utilisation require PIC (as stipulated by ABS laws of country of origin)?

ABS obligations under national law: Benefit sharing

Mutually Agreed Terms (MAT)

- **Written agreement** between country of origin and user defining the benefit-sharing terms;
- Monetary and non-monetary benefit sharing (open list in Nagoya Protocol):
  - Monetary: access fee, upfront payment, license fee, royalty;
  - Non-monetary: sharing of results, tech transfer, co-ownership of IP.
- Terms on change of intent;
- Complicated and time consuming (bilateral) negotiation;
- Some countries have a predefined terms & conditions, such as a predefined royalty rate (p.e. Brazil)

ABS obligations: Compliance in country of use

- Obligation of every **country of use** to establish a compliance system to monitor utilisation of genetic resources through designated checkpoints;
- Obligation of every user to comply with obligations in country of origin and country of use;
- EU has established a harmonised compliance system; i.e. an information (and material) management system with due diligence obligations and designated checkpoints.;
- Many EU countries have operationalised the compliance system and are monitoring

Regulation (EU) No 511/2014

Obligations – Due diligence

Obligation of conduct or result?

1) Obtain PIC and settle MAT, if required;
2) Use and transfer material in accordance with MAT;
3) Substantiate due diligence, obligation by seeking, keeping and transferring information to subsequent users;
4) Notify authorities at checkpoints by Due Diligence Declaration.

In case of **insufficient information or uncertainties** about legality of access and use:

- Obtain PIC and establish MAT; or
- Discontinue utilisation.

ABS obligations: EU compliance

EU due diligence system: (information) management obligations

1. **Seek**
2. **Analyse**
3. **Declare**
4. **Transfer**
5. **Keep**

ABS obligations: EU compliance

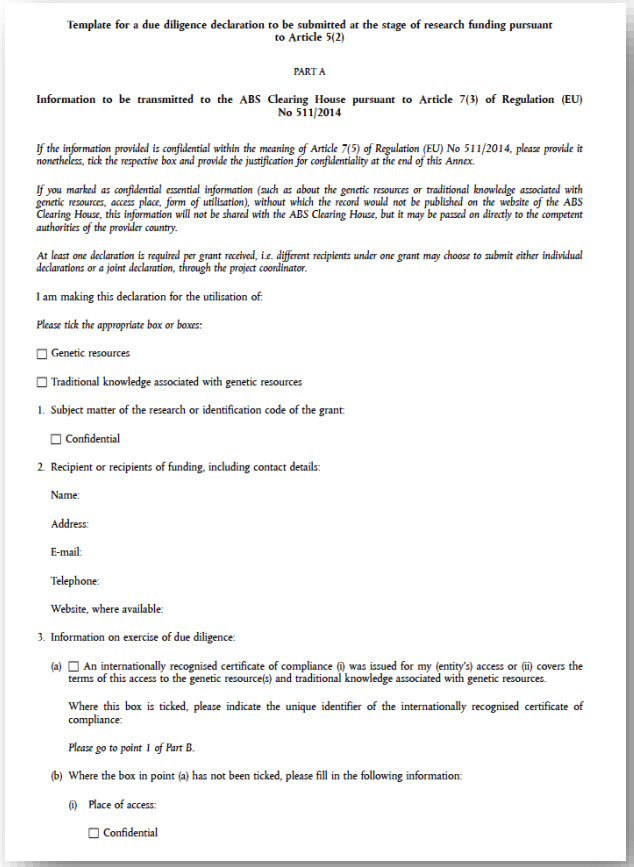
Seek & analyse

- Due diligence starts *before* actual access;
- Obtain the necessary ABS information & documentation:
  - PIC and/or MAT from competent national authority;
  - Information from third party (ex situ) provider;
  - Information from local partner;
  - Internationally recognised certificate of compliance.
- Evaluate whether ABS documentation is complete, correct and up-to-date;
- Evaluate whether scope of ABS permit (PIC) and agreement (MAT) is adequate for intended utilisation;
- Document assessment re absence of ABS obligations
- In case of insufficient information or uncertainties about legality of access and use:
  - Obtain a PIC and establish MAT as required; or
  - Discontinue utilisation.
- When it is not possible to identify the provider country?

ABS obligations: EU compliance

Declare

- Inform authorities at checkpoints via a <u>Due Diligence Declaration:</u>
  - Monitor when a “checkpoint” is reached:
    - Research Funding;
    - Final Stage of Development
  - Submit to national competent authority, transmitted to international ABS Clearing House and to the country or origin;
  - Use of pre-defined format - “Declare” tool;
  - Part of submitted information can be qualified as confidential.



Template for a due diligence declaration to be submitted at the stage of research funding pursuant to Article 5(2)

PART A

Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilisation), without which the record would not be published on the website of the ABS Clearing House, this information will not be shared with the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

At least one declaration is required per grant received, i.e. different recipients under one grant may choose to submit either individual declarations or a joint declaration, through the project coordinator.

I am making this declaration for the utilisation of:

Please tick the appropriate box or boxes:

☐ Genetic resources

☐ Traditional knowledge associated with genetic resources

1. Subject matter of the research or identification code of the grant:

   ☐ Confidential

2. Recipient or recipients of funding, including contact details:

   Name:

   Address:

   E-mail:

   Telephone:

   Website, where available:

3. Information on exercise of due diligence:

   (a) ☐ An internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources.

   Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate of compliance:

   Please go to point 1 of Part B.

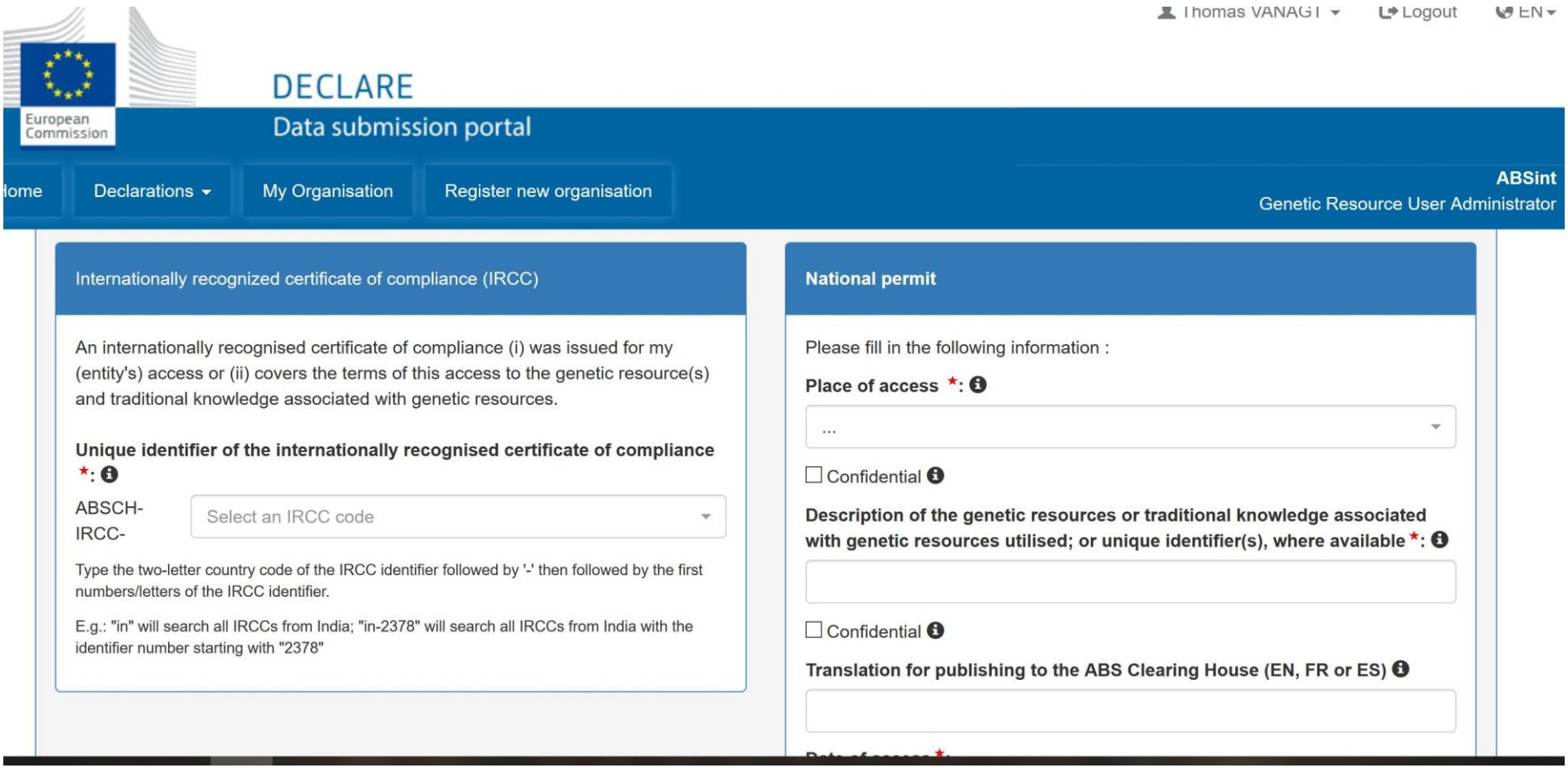
   (b) Where the box in point (a) has not been ticked, please fill in the following information:

   (i) Place of access:

   ☐ Confidential

Using the DECLARE tool

Using the DECLARE tool



Using the DECLARE tool

Part B - Information not to be transmitted to the ABS Clearing House

Direct source of the genetic resource and the traditional knowledge associated with genetic resources *:

Are there any restrictions in the mutually agreed terms limiting the possible utilisation of the genetic resource(s) or the traditional knowledge associated with genetic resources, e.g. allowing for non-commercial utilisation only? *:

- ○ Yes
- ○ No
- ○ Not applicable

Have there been rights and obligations agreed regarding subsequent applications and commercialisation in the mutually agreed terms? *:

- ○ Yes
- ○ No
- ○ Not applicable

Using the DECLARE tool

Where the genetic resource(s) was(were) obtained from a registered collection, please provide the registration code of the collection:

If you are implementing a best practice recognised under Article 8 of Regulation (EU) No 511/2014, please provide the registration number:

Which category best describes your product?:

- ○ Cosmetics
- ○ Medical products
- ○ Food and beverage
- ○ Biological control
- ○ Plant breeding
- ○ Animal breeding
- ○ Other, please specify

Member State(s) in which the utilisation of genetic resources and traditional knowledge associated with genetic resources has taken place *:

ABS obligations: EU compliance

Declare

- Due Diligence Declaration Checkpoint: **Research funding**
  - What
    - Any financial contribution, by means of a grant to carry out research, commercial or non-commercial;
    - NOT internal budgetary resources.
  - Who
    - Recipients of research funding carrying out research in the EU;
    - Research funding obtained from inside or outside the EU;
    - Possibly by the project coordinator (e.g. for a consortium).
  - When
    - After the first instalment of research funding has been received **AND** all GR and TK have been obtained;
    - Not later than at the final report **OR** the project end;
    - Time of submission may be further specified by national authorities (cfr this is not further specific under national German law).

ABS obligations: EU compliance

Declare

- Due Diligence Declaration Checkpoint: **Final stage of development**
  - What
    - In principle: "final stage of development" = end of utilisation;
  - When
    - Four different situations which constitute "final stage of development":
      a. A regulated product: prior to submission of an authorisation or notification;
      b. A non-regulated product: prior to placing on the Union market for the first time;
      c. Sale or transfer of result of the utilisation to a third party in the Union who will commercialise in the Union;
      d. Sale or transfer of outcome of the utilisation outside of the Union.
    - a), b) and c) are linked to commercialisation, *d) not necessarily*.
    - In Germany, the DDD needs to be filed 4 weeks before the end of utilisation.

ABS obligations: EU compliance

Transfer

- Verify if and ensure that conditions allow transfer to third party;
- Provide subsequent user with relevant ABS information;
- Obligation to provide information is not upon request;
- Important role for Material Transfer Agreement (MTA);
- Importance of track and trace system.

ABS obligations: EU compliance

Transfer

As a sender:

- Never send material without copies of all the necessary paperwork;
- Never send material if you do not have permission to do so;
- Define in the MTA that you transfer the responsibilities (scope of use, benefit sharing) to the recipient.

As a receiver:

- Never accept material without copies of all the paperwork;
- Stick to the permitted use;
- Comply with contractual arrangements (benefit sharing, end of use, data, material);
- Re-negotiate terms (with country of origin) if your (intended) use falls outside the granted permit/ contractual terms.

ABS obligations: EU compliance

Keep

- Records must be kept up to 20 years after end of utilisation of the genetic resource;
- The obligation to keep information is related to the aim to ensure that "*the necessary information related to the genetic resource is available all throughout the value chain in the EU*";
- Maintain a searchable (digital) archive.

ABS obligations: EU compliance

Formal compliance

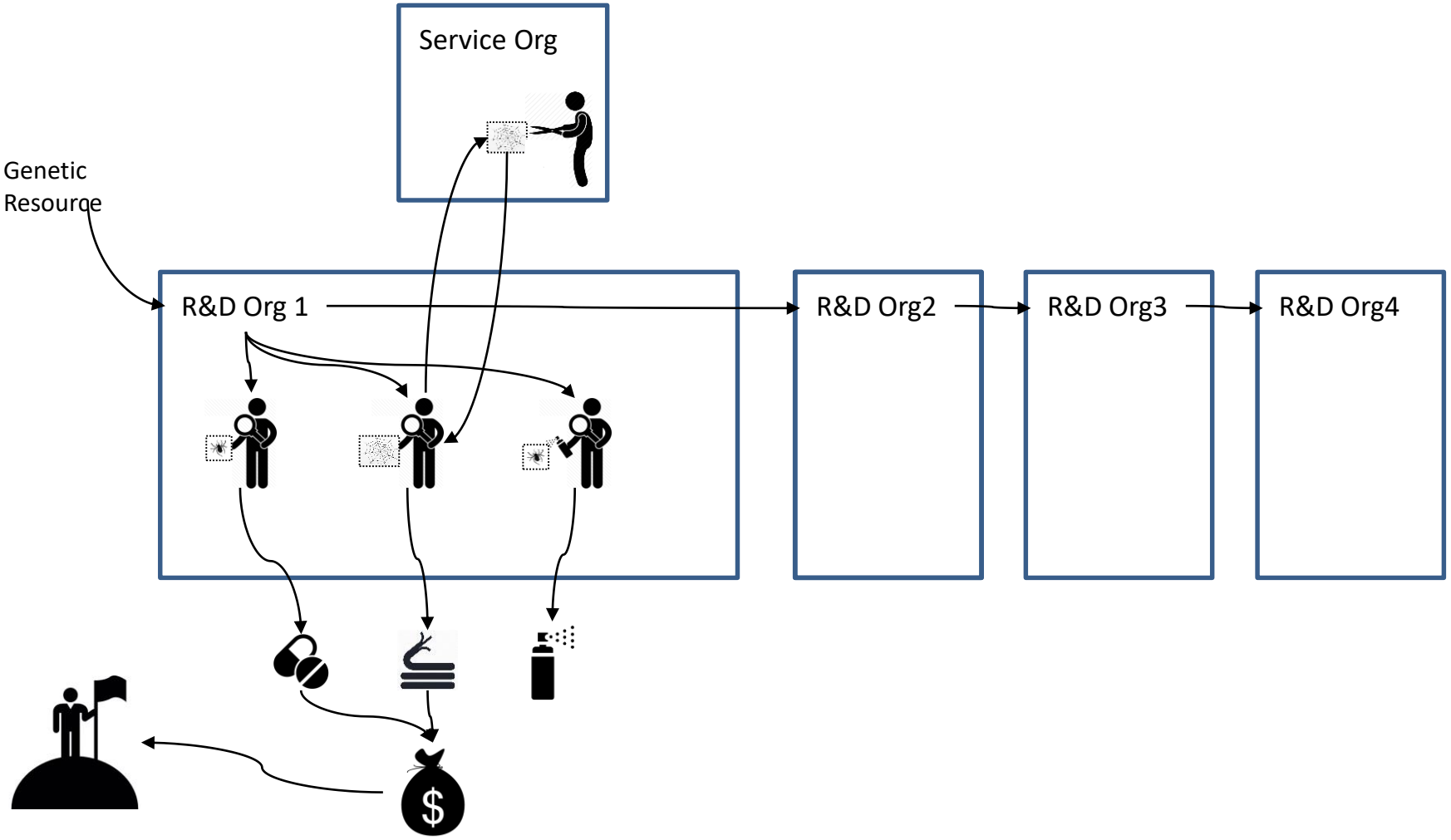
- Utilisation within the scope of the permit and agreed contractual framework;
- Document compliance;
- Support authorities in case of an inspection/investigation
- EU due diligence is limited to **‘formal’ compliance:**
  - Intended to assist the country of origin, not to replace it;
  - Compliance with PIC conditions are checked;
  - Compliance with contractual arrangements (MAT) may be checked for obvious discrepancies/non-compliance.

Regulation (EU) No 511/2014

Compliance checks

- **Effective, proportionate and dissuasive checks**
  - Following a risk based approach;
  - Based on relevant information, including substantiated concerns provided by a third party;
  - Best practices may reduce risk of non-compliance.
- **What is checked?**
  - Measures taken by user;
  - Documentation and records that demonstrate due diligence;
  - Instances where a declaration was due.
- **Measures**
  - (notice of) remedial action or measures;
  - Immediate interim measures.
- **Penalties**
  - Defined by Member States.
  - Administrative fees and criminal sanctions

ABS obligations in an R&D process



ABS obligations in an R&D process

- Define which genetic resource is required;
- Identify the (recommended) country of origin by assessing national ABS laws:
  - Check ABS Clearing House;
  - Contact Competent National Authority or National Focal Point
- Check ABS status:
  - For in situ material: obtain PIC and enter into MAT if and as required;
  - For ex situ material: assess provided information and documents;
  - Document assessment in case of no ABS obligations.
- This information will need to be kept, assessed and transferred throughout the R&D process;
- Due Diligence Declarations required at defined checkpoints;
- Prior to the start of *each* specific R&D activity the ABS status needs to be checked:
  - Assess whether this activity qualifies as “utilisation” under relevant laws;
  - Assess whether this is covered in the scope of the existing PIC and MAT. If not, the scope needs to be adapted or the research cannot proceed;
- Ensure compliance with benefit sharing obligations, also after utilisation.

ABS compliance system

Components

Corporate ABS
Policy, management system & procedures

Staff
Training & awareness

Staff
ABS Roles & responsibilities

Biological Material
Access procedures (+ historical update)

Biological Material
(Change of) Use as specified in permits and ABS agreements

Biological Material
Transfer procedures

Documentation
Permits, ABS agreements & Material Transfer Agree-ments with 3rd parties

Documentation
Track & trace of material

Documentation
Due diligence declarations

ABS compliance system

How to get ready

ABS compliance system

Obligations to ensure compliance

- Essential for Access & Benefit Sharing:
  - Acquire material in accordance with all applicable laws;
  - Obtain PIC if required
  - Enter into relevant agreements;
  - Comply with terms of permits and agreements;
  - Renegotiate conditions in case of change of use, if needed.
- Essential for due diligence:
  - Manage and keep track of information;
  - Transfer all relevant information down the value chain;
  - Submit due diligence declarations as required.

ABS compliance system

Recommendations for supporting compliance

- Understanding the relevance of ABS obligations – ensure management buy-in;
- Identifying the scope of ABS obligations:
  - Assessment of utilisation of genetic resources;
    - Typical cases of utilisation in the organisation;
    - Involve all relevant departments.
  - Audit
- Informing the organisation:
  - Awareness raising;
  - Staff training;
  - Toolkit/best practices.

ABS compliance system

Recommendations for supporting compliance

- Implementation:
  - Development of internal protocols & procedures:
    - Define roles and responsibilities;
    - Designate ABS responsible(s);
    - Flow charts.
  - Establish material and information management system (track & trace):
    - In and out;
    - Sufficient features (date and place of access, description, pictures, codes, intended use, ABS documents).
- Checking implementation:
  - Auditing and management of inspections;
  - Prepare for compliance checks;
  - Defence in case of legal or public challenge.

Any questions?

Audit & inspection

Awareness raising

Contract drafting & Negotiation

Legal & scientific advice

Track & trace

Training

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