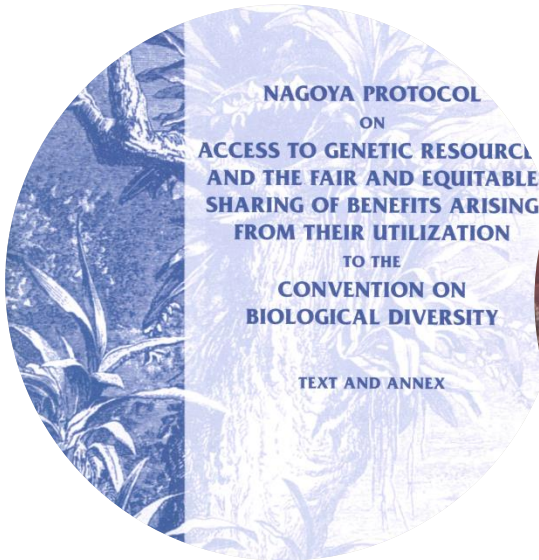


ABS and Animal Breeding legislation → relationships and interactions

Elzbieta Martyniuk and Sipke Joost Hiemstra

SANCO, 7 February 2017



This presentation

- ABC of the Nagoya Protocol
- Regulation 511/2014 and Implementing act 2015/1866
- General scope
- Obligations of users
- Development of (sector-specific) guidelines for implementation of EU Regulation 511/2014
- Relevance of ABS for the animal breeding sector

Convention on Biological Diversity (29 Dec 1993)

■ Objectives:

- conservation of biological diversity;
- sustainable use of its components;
- fair and equitable sharing of the benefits.

■ New principle and concept:

- genetic resources no longer 'heritage of mankind'; instead, states have sovereign rights over genetic resources;
- access and benefit-sharing (ABS), through bilateral contracts on a case-by-case basis.

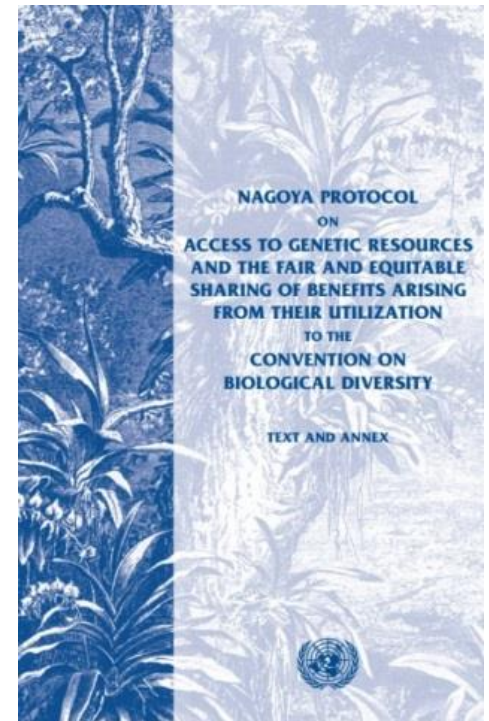
Nagoya Protocol: 12 October 2014

■ Objective:

- further advance the implementation of the third objective of the CBD:
fair and equitable sharing of benefits arising from the utilisation of genetic resources

■ Important elements:

- Bilateral contracts: PIC and MAT on GR and associated TK
- Facilitating access: simple and transparent procedures
- Compliance of users
- Compliance of Parties



Important terms: CBD

- **Prior Informed Consent (PIC):** approval, by the authorities of the country where access is sought, of access to and utilization of genetic resources; involvement of IPLC in case of TK associated with GR
- **Mutually Agreed Terms (MAT)** contract between two parties under a civil law including benefit sharing provisions



Important terms: Nagoya Protocol

- **Utilisation of genetic resources:**
to conduct **research and development** on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

as defined in the CBD



- **Genetic resources:**
genetic material of actual or potential value
- **Genetic material**
any plant, animal, microbial or other origin containing functional units of heredity

Summary: ABC of the Protocol

■ Access

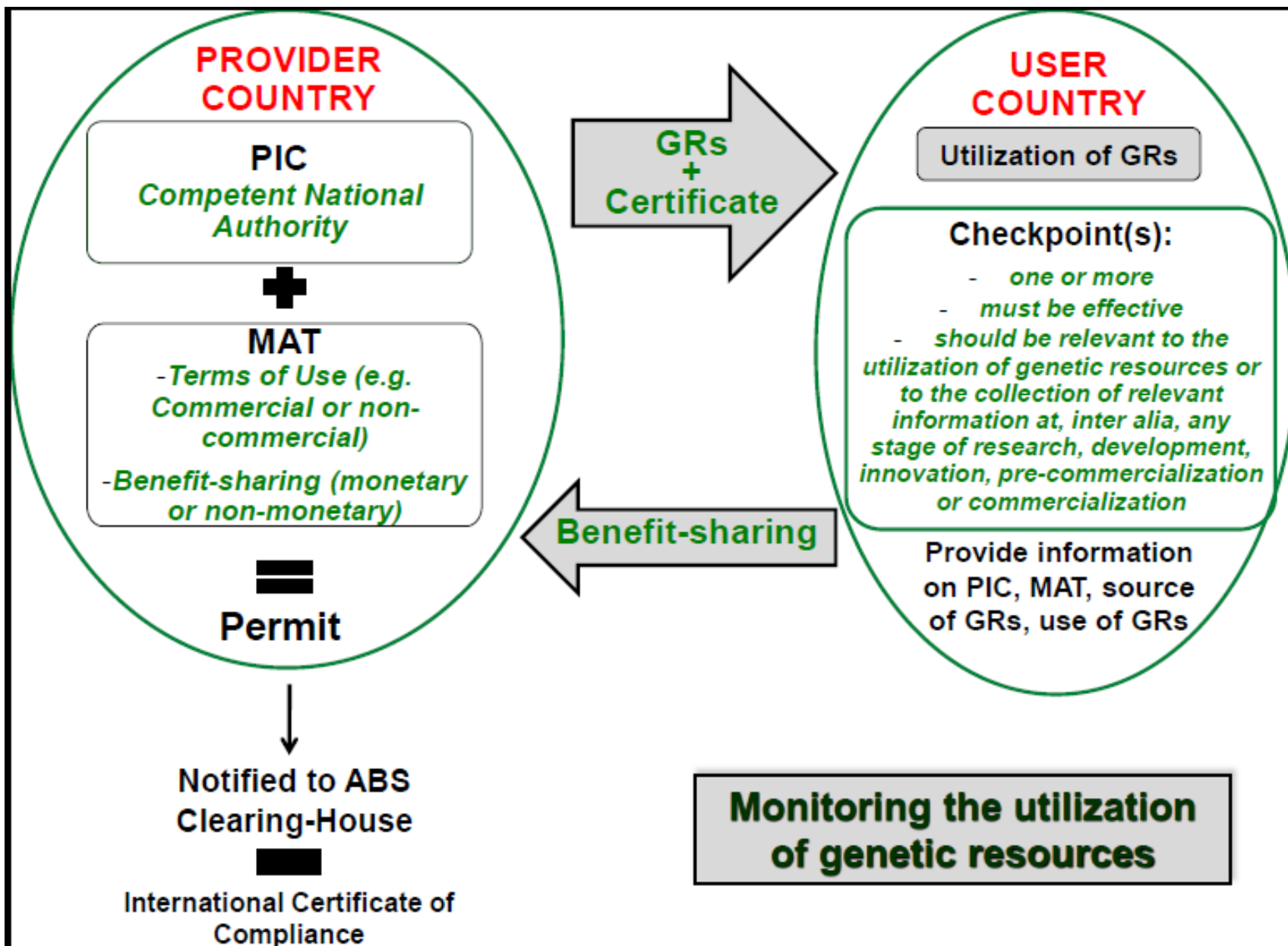
- to GR and TK (PIC)
- (or no access regulations)

■ Benefit Sharing

- bilaterally: according to MAT
- the GMBSM?
- monetary/non-monetary

■ Compliance

- national legislation
- IRCC/checkpoints
- monitoring users



State of ratification, 5th February 2017

Access and Benefit-Shari x

→ ↻ <https://absch.cbd.int>



89

Parties to the Nagoya Protocol

6

Ratified, not yet Party ⓘ

109

Non-Parties

?

ABS Clearing House

Access and Benefit-Shari x

https://absch.cbd.int

National records


170 Countries

- have published 177 -

ABS National Focal Points 


38 Countries

- have published 50 -

Competent National Authorities 

31 Countries

- have published 86 -

Legislative, Administrative or Policy Measures 

20 Countries

- have published 24 -

National Websites and Databases 

4 Countries

- have published 50 -

Internationally Recognized Certificates of Compliance 

13 Countries

- have published 30 -

Checkpoints 


0 Countries

- have published 0 -

Checkpoint Communiqués 

0 Countries

- have published 0 -

Interim National Reports on Implementation 

Reference records

93 Virtual Library Records 

30 JAN 2017

The Nagoya Protocol on Access and Benefit Sharing - Dialogue between Brazil and the European Union

23 JAN 2017

El patentamiento de genes a cambio de la formación de un cartel de países proveedores de información genética ¿una retór...

19 JAN 2017

Access and Benefit Sharing - Key Points for Policy Makers - Agriculture

22 DEC 2016

The Interface between access and benefit-sharing rules and BioTrade

22 DEC 2016

The two worlds of Nagoya – ABS legislation in the

43 Capacity-building Initiatives 

03 JAN 2017

Explorando la relación entre la implementación del Protocolo de Nagoya, el Acceso y Participación de Beneficios y el Bio...

03 JAN 2017

Addressing the intersection between the Nagoya Protocol, access and benefit sharing rules, and BioTrade


21 NOV 2016

Survey, Collection and conservation of plant genetic resources of the State of Qatar

07 NOV 2016

Taller de Capacitación en Manejo del Centro de Intercambio de Información en Acceso y Participación en los Beneficios (C...

12 OCT 2016

17 Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards 

01 FEB 2017

Global Genome Biodiversity Network Guidance: Material Transfer Agreements

01 FEB 2017

Global Genome Biodiversity Network Guidance: Code of Conduct

01 FEB 2017


Global Genome Biodiversity Network Guidance: Best Practice

21 NOV 2016

Utilization of genetic resources and associated traditional knowledge in academic research - A good practice guide for a...

03 NOV 2016

MPRI Best Practice Manual on Access and

2 Community protocols and procedures and customary laws 

11 AUG 2016

Biocultural Community Protocol for Cerrado Raizeiras

27 JUN 2016

Ogiek Bio Cultural Community Protocols (BCP)



IRCC: 50

India: 46

Mexico: 1

South Africa: 2

Guatemala: 1

Access and Benefit-Shari x

https://absch.cbd.int/search/nationalRecords?schema=absPermit

Home | About the ABSCH | Search | Submit | Country Profiles

CBD > ABSCH > SEARCH > SEARCH

Internationally Recognized Certificate of Compliance x CLEAR

Search the ABSCH

SEARCH FILTERS National records Reference records SCBD records Keywords Country Regions Date Saved searches SAVE SEARCH

National records 50 Reference records 155 SCBD records 1084

EXPORT

Guatemala PARTY TO THE NAGOYA PROTOCOL SIGNATORY ENTRY INTO FORCE: 12 OCT 2014 1

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC)

Contract of access to genetic resources for research purposes on Mahogany (*Swietenia macrophylla* King) and Cedar (*Cedrella odorata* L)

INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE | GUATEMALA | ABSCH-IRCC-GT-206790-1 | NON-COMMERCIAL | 30 MAR 2016

India PARTY TO THE NAGOYA PROTOCOL SIGNATORY ENTRY INTO FORCE: 12 OCT 2014 46

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC)

India/NBA/App1/9/701

INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE | INDIA | ABSCH-IRCC-IN-207621-2 | UPDATE | 22 NOV 2016

India/NBA/App1/592

11:33 02.02.2017



ABSCH-IRCC-IN-204353-1

Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

General Information

Issuing country

INDIA

Verification link (view latest version)

<http://absch.cbd.int/database/ABSCH-IRCC-IN-204353>

ABS-CH Unique Identifier (UID)

ABSCH-IRCC-IN-204353-1

Issuing Authority

Competent National Authority

National Biodiversity Authority (NBA)

5th Floor, TICEL Biopark, CSIR Road, Taramani
Chennai, Tamilnadu
600 113, India

Phone: +91 44 2254 2777

Fax: +91 44 2254 1200

Email: secretary@nbaindia.org, chairman@nba.nic.in, secretary@nba.nic.in

Website: <http://www.nbaindia.org>

Details of the permit or its equivalent

Reference number of the permit or its equivalent

India/NBA/Api/9/684

Additional national references or identifiers

Application in Form-I for accessing ethno-medicinal knowledge of the Siddi community from Gujarat for research

Date of issuance of the permit or its equivalent

27 Mar 2015

Date of expiry of the permit or its equivalent

26 Mar 2018

Prior Informed Consent (PIC) Information

Confirmation that prior informed consent (PIC) obtained or granted

YES

Provider The person or entity that holds the right to grant access to the genetic resources in accordance with domestic legislation.

CONFIDENTIAL INFORMATION

Entity to whom PIC was granted

Ms Seema Solanki

Medical Anthropology and Ethno biology,
Research Scholar (-)
University of Kent
Canterbury
United Kingdom of Great Britain and Northern Ireland
Phone: +91 9717032453
Email: seemasolanki.du@gmail.com, ss830@kent.ac.uk

Mutually Agreed Terms (MAT) Information

Confirmation that mutually agreed terms (MAT) have been established

YES

Additional information about the mutually agreed terms

1. The user shall not obtain any form of IPR based on the biological resources and/or associated knowledge accessed under this agreement in any manner without obtaining the prior approval of NBA under provisions of the Biological Diversity Act, 2002.
2. The applicant shall submit a report to NBA on the outcome of the research work.

Subject-matter

Subject-matter or genetic resources covered:

Accessing ethno-medicinal knowledge of the Siddi community from Gujarat for research

Information on the utilization of the genetic resource(s)

Type of use allowed by the permit or its equivalent

CONFIDENTIAL INFORMATION

Conditions for third party transfer:

The user shall not transfer or part with the biological resources and/or associated knowledge accessed under this agreement in any manner without obtaining the prior approval of NBA under provisions of the Biological Diversity Act, 2002.

Certificate History

Date	Action	Author	Comment
01 OCT 2015 11:52 AM	PUBLISHED	Hem Pande (hempande@nic.in)	Permit information published to the ABS clearing-house and certificate generated.

Further Information

Questions about the permit or its equivalent constituting an internationally recognized certificate of compliance should be addressed to the competent national authority issuing the permit or its equivalent. Additional information about the permit or its equivalent may be available in the Access and Benefit-Sharing Clearing House (<http://absch.cbd.int/>).

Questions about the Nagoya Protocol on Access and Benefit-sharing or the operation of the Access and Benefit-sharing Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity

Secretariat of the Convention on Biological Diversity

413 rue Saint-Jacques, suite 800
Montreal, Québec, H2Y 1N9

Canada
Fax: +1 514 288-6588
Email: secretariat@cbd.int

First IRCC

UN Biodiversity Conference, Cancun, 2016



Important decisions on:

Synthetic biology

Digital sequence information

Article 10


COP/MOP 2 Cancun, 2016



NP-MOP Decisions x

→ ↻ 🔒 Bezpieczna | https://www.cbd.int/decisions/np-mop/?m=np-mop-02

English | Español | Français Sign up for an account |

 Convention on Biological Diversity

Search

The Convention Cartagena Protocol Nagoya Protocol Programmes **Information** Secretariat

Information








News & Communications


- Web Announcements
- Statements
- Notifications
- News Headlines on Biodiversity
- Press Releases
- RSS Feeds
- Twitter
- Facebook
- Discussion Forums

National Information

> Information > NP-MOP Decisions

Decisions

- Decision 2/1**
Review of progress towards Aichi Biodiversity Target 16 on the Nagoya Protocol
 [English](#)
 [English](#)
- Decision 2/2**
The Access and Benefit-sharing Clearing-House and information-sharing (Article 14)
 [English](#)
 [English](#)
- Decision 2/3**
Report of the Compliance Committee (Article 30)
 [English](#)
 [English](#)
- Decision 2/4**
Assessment and review of the effectiveness of the Protocol (Article 31)
 [English](#)

 **Search**
Decisions and Recommendations

Decisions

- COP
- Biosafety COP-MOP
- ABS COP-MOP

Recommendations

- SBSTTA
- SBI
- WGRI
- WG8J
- ABS ICNP
- Biosafety ICCP

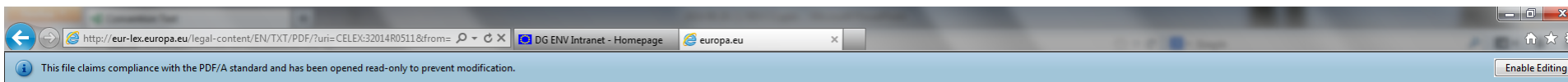


FAO Commission on Genetic Resources for Food and Agriculture

A strong interest in ABS issues in relation to GRFA

- to contribute to negotiations under the CBD
- to consider impact of the Nagoya Protocol on GRFA
- to facilitate development of national ABS legislation
(ABS Elements adopted by CGRFA in 2015)
- to develop explanatory notes for subsectors of GRFA
- to consider use of digital sequence information on GRFA for conservation and sustainable use and its implications for ABS

EU ABS law



5.2014

EN

Official Journal of the European Union

L 1

REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014

**on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and
the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,



ABC of the Protocol and 511/2014

■ Access

- Sovereign rights of MS over GR
- Not implemented at EU level

■ Benefit Sharing

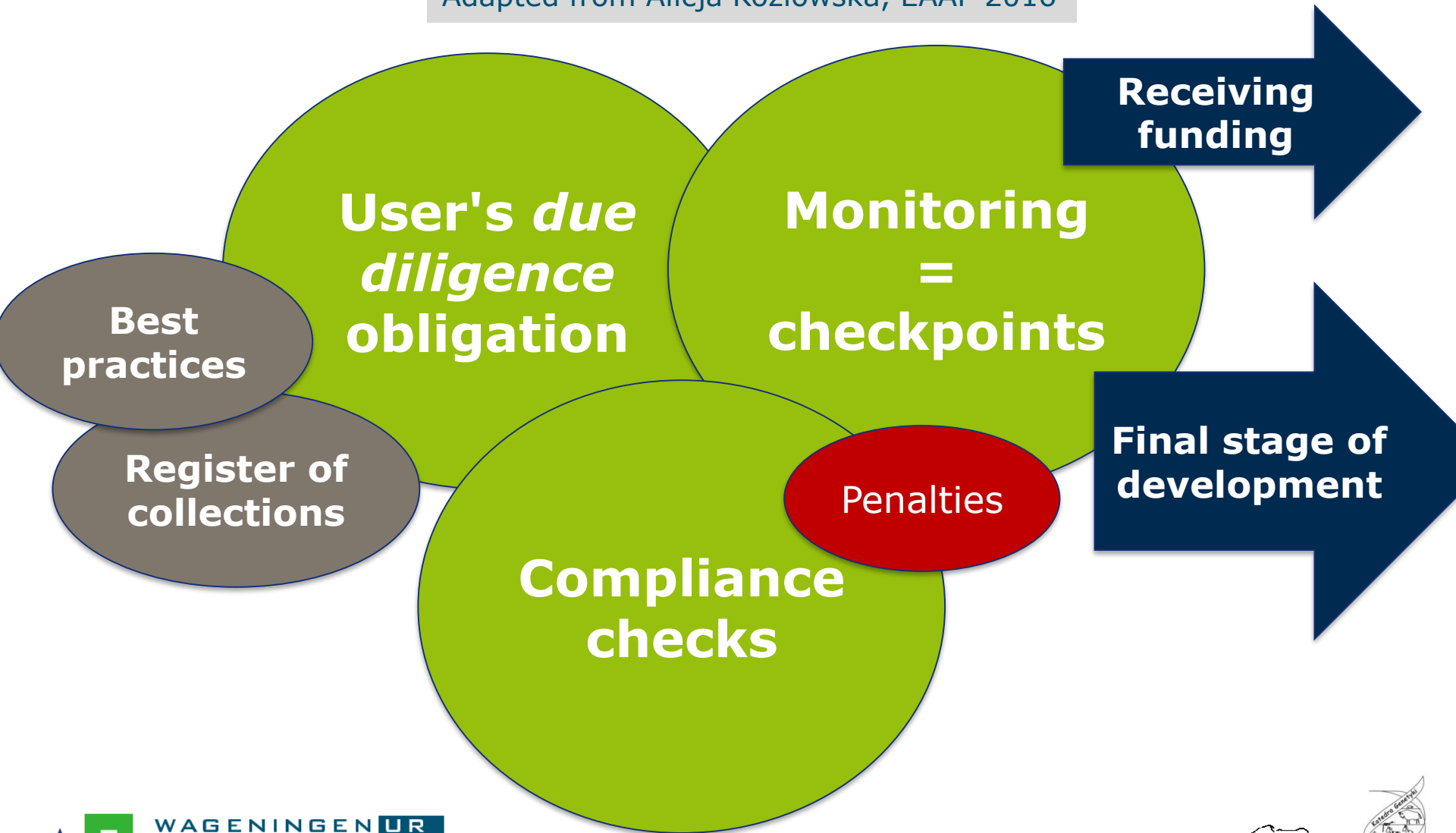
- Subject to contractual agreement (MAT) between user and provider
- Not implemented at EU level

■ Compliance

- **EU ABS Regulation 511/2014:**
- The same /requirements for users of GR and associated TK within the Union

Key provisions of the EU ABS regulation

Adapted from Alicja Kozłowska, EAAP 2016



Art. 4: Obligations of Users



- **Due diligence** a key concept in defining obligations of users
- **Obligation to Seek, keep and transfer to subsequent users:**
 - the IRCC
 - relevant information:
 - GR/TK associated with GR, date/place of access, source, any rights & obligations, PIC & MAT

Art. 7: Checkpoints

Two checkpoints:

- at the stage of **research funding** where research involves utilisation of GR and associated TK
- at the stage of **pre-commercialisation** (final stage of development of the product)

IT tool being developed by the COM to facilitate exchange of information (MS – EC – ABS CH)

Art. 9: Compliance checks:

- Carried out by Member States
- Based on risk-assessment plans (periodically reviewed)
- Based on information received (substantiated complaints from the provider countries)
- Checks take into account implementation by the users of best practices

EU Implementing Act 2015/1866

- Providing detailed rules on the implementation of Articles 5, 7 and 8 of the Regulation 511/2014
 - Register of collections
 - Check points: due diligence declarations in the case of research grants and product marketing
 - Application of best practices

Scope of the EU ABS Regulation:

Guidance document on the scope of application

- **Material scope:** GR and associated TK
- **Temporal scope:** applicable from 12 October 2014
(GR and associated TK must be accessed and utilised after this date)
- **Geographical scope:** applicable to GR and associated TK to be accessed in countries which have:
 - ratified the Nagoya Protocol
 - have adopted national ABS legislation (access measures)

(BUT users of GR and TK from Non-Parties should comply with national legislation or regulatory requirements of such a country and respect any MAT

Application of 511/2014



- EU Regulation applies directly to
 - all EU MS
 - all users of all EU Member states

- National legislation needed to clarify issues like:
 - access measures
 - implementation framework (NCA)
 - monitoring system to check compliance of users
 - penalties

Elements of 511/2014 & 1012/2016

	511/2014	2016/1012
Scope of the regulation	all livestock and all animal species	bovine, porcine, ovine, caprine and equine species
Conditions of entry into the Union of breeding animals	PIC and MAT and/ or IRCC issued by the CNA of the provider's country	under conditions that the rules applicable to trade in third countries are closely comparable to those the Union
Purpose of entry	utilisation: potentially in the future, single GR for R&D	placing on the internal market: breeding animals and their germinal products, a substantial volume
Post entry requirements for progeny	cutting point for benefit sharing, depends on MAT	only zootechnical, no further financial obligations

EU Guidance document for Animal Breeding sector **DRAFT**



- Draft V2.0 of January 2017 under final discussion
- Content
 - Focus on classification of activities in relations to utilisation
 - Many examples listed to consider as cases within/outside the scope of the 511/2014
 - Background information on the sector (description, economic importance, organization, exchange practices... in Annex)
- Other sector-specific guidance documents under development since 2016

DRAFT EU Guidance – Case 1: OUT



- Use of sequencing data from the public domain
- Use of DNA sequence data of animals of various species and breeds that have been made available in public databases (in association with scientific publications) in order to identify interesting traits and underlying sequences in the genetic resources studied. Such use is likely to increase with the availability of new technologies allowing fine-tuned changes in the genome (genome editing).
- The use of digital sequencing data often stored in publicly available databases may be considered to be out of scope of the ABS Regulation.

DRAFT EU Guidance – Case 2: OUT



- Taxonomic identification
- Describing and documenting the basic characteristics of an acquired GR at the species level (i.e. to answer the question to which species the acquired genetic resource belongs to) may form a basic and early step preceding breeding efforts, for example in the case of newly introduced wild fish species for the purpose of aqua farming, and in the case of rare companion animals. Such activity could be undertaken by any public or private actor, and is more likely to involve fish and companion animals than livestock.
- Taxonomic identification of genetic material, in the form of verification of received material and morphological analysis is not considered to constitute R&D.

DRAFT EU Guidance – Cases 3-5: IN



- Genotypic and phenotypic characterisation for the purpose of understanding genetic variation within and between breeds and breeding lines.
- Scientific research specifically performed on the genetic background of traits of interest, to analyse which genes, gene complexes or regulatory sequences and mechanisms governing their expression are involved.
- Scientific research on genetic abnormality, resulting from a causal mutation that may lead to a diagnostic test that may be commercialised.
- These activities are considered to be R&D and hence to fall within the scope of the EU ABS Regulation.

DRAFT EU Guidance – Cases 6-10



- Breeding activities using germplasm from external sources aimed at the genetic improvement of breeding material for the purpose of commercial sales.
- Breeding of genetic resources newly introduced from the wild for the purpose of aqua farming.
- Breeding of genetic resources newly introduced from the wild for the purpose of novel companion animals.
- Breeding of companion animals using newly introduced genetic resources.
- Genome editing at the single nucleotide level, directed at the introduction of one or more specific mutations for the purpose of improving traits of interest or to ‘repair’ genetic abnormalities.

DRAFT EU Guidance – Cases 6-10: IN



- Breed improvement or creating new breeds or lines in livestock and in companion animals are considered R&D and hence to fall within the scope of the Regulation.
- The fact that such activity is considered as a standard activity does not warrant the conclusion that such activity does not qualify as research and development.
- Breeding of less studied aqua species/ novel companion animals lead to increased knowledge and create added value and potential benefits for the breeder.
- Improvement of animals or animal populations by genome editing is considered R&D and to fall within the scope of the Regulation.
Whether such activity triggers any BS obligations depends on the status of the data used. Providing countries may have set conditions to the publication and use of DNA sequence data.

DRAFT EU Guidance – Case 11: OUT



- Development and application of reproductive technologies (e.g. In Vitro Fertilization (IVF), semen sexing) to increase reproduction efficiency
- The development and application of reproduction technologies do not address the genetic resources contained in specimens. Results are normally species-specific but independent of the intra-specific diversity in a species. Therefore, the development and application of reproductive technologies do normally not constitute R&D on the animal genetic resources and hence are not in scope of the EU ABS Regulation.

DRAFT EU Guidance – Cases 12-13: OUT



- Selling or trading breeding animals or other types of genetic material (semen) to customers in their own and other countries.
- Trading does not constitute R&D, and hence does not fall within the scope of the EU ABS Regulation
- Buying animals, semen or embryo's from commercial providers, including importers, to improve the genetic potential of their own farm herd and thereby to improve the value of their stock.
- As long as animals and/or their products are only sold as a commodity, this is normally considered to fall outside the scope of the EU ABS Regulation
- When farmers sell progeny as breeding animals for further use in breeding, case 6 would apply.

DRAFT EU Guidance – Cases 14-15: OUT



- Exchange of genetic material of rare and traditional breeds between breeders, within breed associations or networks
- Trade or exchange between farmers and breeders within an association/network for the purpose of conservation of rare or traditional breeds is considered out of scope of the EU ABS Regulation
- Within-company across-country exchange
- This type of exchange may be characterised by dissemination of genetic progress rather than by marketing of the results of R&D, and the activity of the distributing entity would normally be considered to fall outside the scope of the EU ABS Regulation

DRAFT EU Guidance – Case 16: IN



- Use of molecular information for breeds/animal traceability
- The use of molecular information derived from relevant animal genetic resources to develop methods for the purpose of traceability of a genetic resource and its products involves detailed study of the genome of individual animals for traits identified in the breeding objectives.
- Such activities lead to increased knowledge and create added value and potential benefits for the breeder. Such activities are considered R&D and to fall within the scope of the EU ABS Regulation.

DRAFT EU Guidance – Cases 17-18: OUT

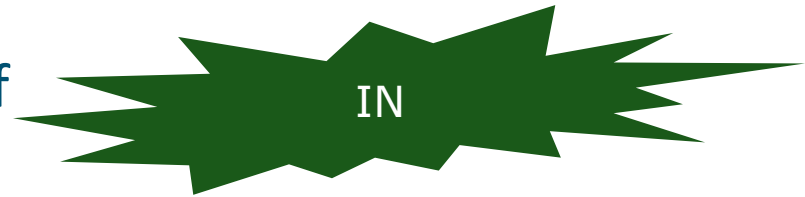


- Genetic resources as testing/reference tools
- Since the animal genetic resources is not the subject of research and development when it is used as a testing/reference tool, in such activity the animal genetic resource is considered to fall outside the scope of the Regulation
- Import of commodities
- Commodities are out of scope of the Regulation, whereas further R&D on such commodities would imply a change of intent in the use and qualify that activity as to be within scope of the EU Regulation, if the further use would involve R&D.

Which activities are considered utilization/R&D ?

General picture:

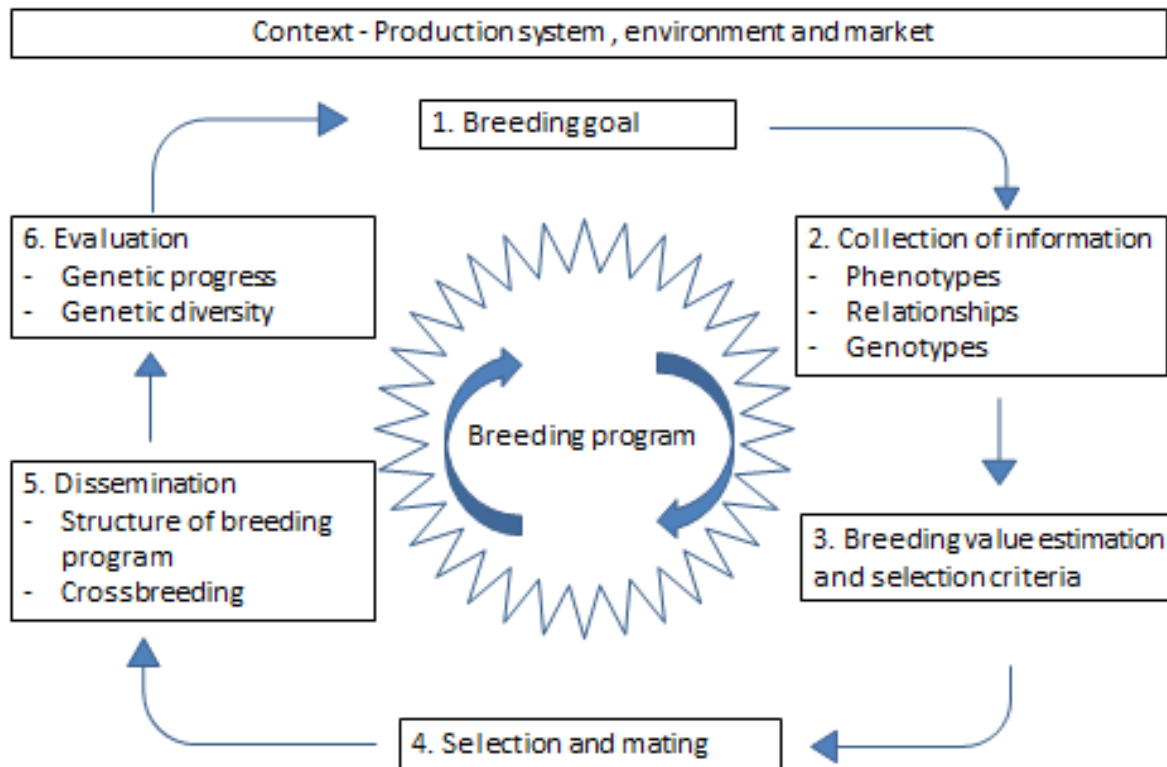
- Breeding activities, selection, mating aimed at the genetic improvement of populations and to generate better offspring



- Activities when AnGR are not the subject of Research and Development



When ABS legislation becomes relevant...



Introduction of :

- New breeds/lines
- Individual breeding animals
- Any type of genetic material



Is ABS legislation relevant for animal breeding sector in the EU?

- YES
- BUT - short term impact limited
 - Introduction of breeding material, from countries that have or are developing ABS access legislation, has been limited
 - Rare examples of commercially successful introgression of exotic genotypes to mainstream breeds (e.g. Meishan pig) + negligible use of wild relatives



Is ABS legislation relevant for animal breeding sector in the EU?

- Gene flows may change in the future
 - Driven by technology → genomic research, genome editing
 - Driven by climate change → adaptive traits

MOREOVER

- Difficulties to establish ownership of a breed: cumulative genetic progress
- A frequent exchange of genetic material for scientific research collaboration (public /public-private)



Izrael ARO, Volcani Center

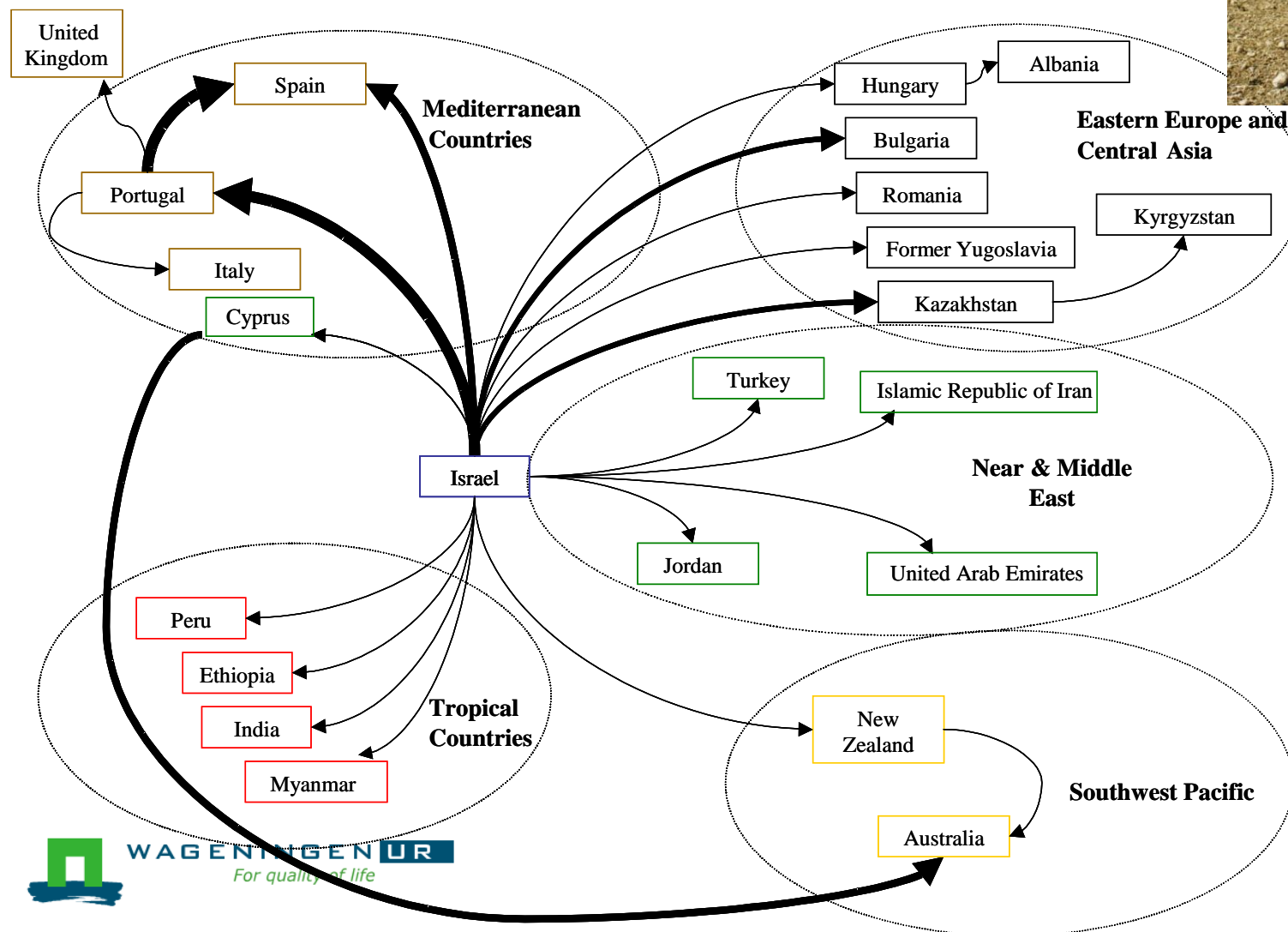


Assaf:5/8 Awassi 3/8 East Friesian



Awassi & Assaf

Zarate i wsp., 2006



Issues to consider

At present: no interest within a breeding industry to use exotic genetic resources in commercial breeding programmes

Gene flow North-North and North-South

- Potential access legislation to livestock genetic resources in MS (not the case so far but cannot be excluded)
- Import of individuals/ germinal material of native breeds from third countries that have no rules applicable to trade that are comparable to those the Union (derogation?)
- Use of digital genetic sequence data on livestock GR

(a process set under the CBD COP 13 and the FAO CGRFA to better understand the scope of use and ABS implications)



DRAFT EU Guidance – Unresolved issues

Cut-off point for applying DD [Benefit Sharing]

- F1: 50%
- F2: 25%
- F3: 12.5%
- F4: 6.25%

of the genome of the genetic resource
accessed from a provider country



One possible interpretation: Due diligence obligations under the EU ABS Regulations only extend to genetic resources resulting from breeding activities wherein a genetic resource accessed from a provider country is represented with a minimum of 6.25% or wherein a trait of market value has been incorporated.

All obligations on the use of certain genetic resources exhaust 20 years after the first introduction of a progenitor genetic resource.

Summary and conclusions

- Generally animal breeding should be considered as utilization/R&D
- In case of importing GR for R&D, after 12 October 2014 from countries being Parties to the Nagoya Protocol and having access legislation – PIC and MAT are required
- Recommendation to negotiate broad ABS arrangements between provider and the first user
- Transactions to subsequent users (next generations) may trigger obligations of the purchaser towards the original providing country
- Low/no demand in EU for GR from the South - impact of ABS on animal breeding currently limited, but exchange patterns may change

Thank you for your attention!

