Implementation of the Regulation 511/2014 in Animal Breeding and Research Sector

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Content

- State of implementation of the Nagoya Protocol
- Key elements of the EU ABS Legislation
- Guidance documents development process
- Guidance for livestock sector
  - ✓ Out of the scope cases
  - ✓ In the scope cases
- Unresolved issues

State of Ratification: 6th December 2017

101 + 3

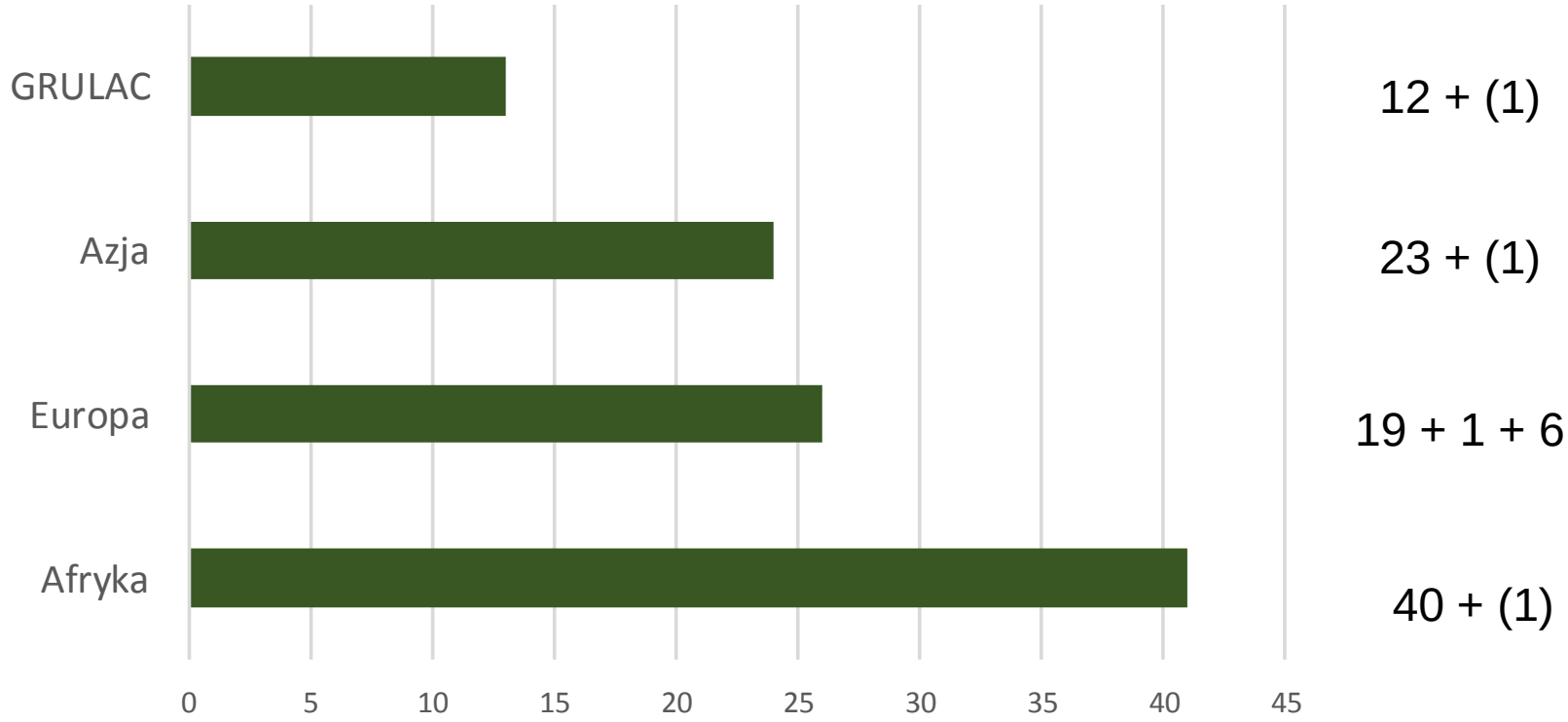
White = Non CBD Parties
Beige = CBD Parties
Lime green = NP Signatories
Dark green = NP ratified/acceded

Albania, Angola, Antigua and Barbuda, Argentina, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Chad, China, Comoros, Congo, Côte D'Ivoire, Croatia, Cuba, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominican Republic, Ecuador, Egypt, Ethiopia, European Union, Fiji, Finland, France, Gabon, Gambia, Germany, Guatemala, Guinea, Guinea Bissau, Guyana, Honduras, Hungary, India, Indonesia, Japan, Jordan, Kazakhstan, Kenya, Kuwait, Kyrgyzstan, Lao PDR, Lebanon, Lesotho, Liberia, Luxembourg, Madagascar, Malawi, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, the Federated States of Micronesia, Mongolia, Mozambique, Myanmar, Namibia, Netherlands, Niger, Norway, Pakistan, Panama, Peru, Philippines, Portugal, Qatar, Republic of Korea, Republic of Moldova, Rwanda, Samoa, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Slovakia, South Africa, Spain, Sudan, Swaziland, Sweden, Switzerland, the Syrian Arab Republic, Tajikistan, Togo, Uganda, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, Uruguay, Vanuatu, Viet Nam, Zambia and Zimbabwe

State of ratification in regions

6th December 2017

101 + (3)



Developing countries: 75 + (3)

CEEC: 6

Developed countries: 19+1

ABS Clearing House

6th December 2017

Access and Benefit-Sha

Bezpieczna | https://absch.cbd.int

National records

RECORD TYPES	NUMBER OF RECORDS PUBLISHED	NUMBER OF GOVERNMENTS WHO HAVE PUBLISHED
ABS National Focal Points	177	171
Competent National Authorities	67	51
Legislative, Administrative or Policy Measures	200	50
National Websites and Databases	35	28
Internationally Recognized Certificates of Compliance	116	10
Checkpoints	45	21
Checkpoint Communiqués	0	0
Interim National Reports on Implementation	51	51

Reference records

Virtual Library Records

24 NOV 2017
Balanites aegyptiaca: First Record for the Flora in Qatar

24 NOV 2017
Effective Methods to Improvement Capparis Spinosa L. (Caper) Seeds Germination by Breaking Seed Dormancy in Qatar Gene B...

24 NOV 2017
Les détenteurs des connaissances traditionnelles à l'école du protocole de Nagoya

Capacity-building Initiatives

05 DEC 2017
SCBD-IDLO Capacity Building Programme 2015-2016: Establishing Legal Frameworks to Implement the Nagoya Protocol

07 NOV 2017
Ratification and Implementation of the Nagoya Protocol in the countries of the Pacific Region

13 OCT 2017
Strengthening of National Capacities for the implementation of the "Nagoya Protocol on Access to Genetic resources and t...

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

14 NOV 2017
Utilization of genetic resources and associated traditional knowledge in academic research – A good practice guide for a...

14 NOV 2017
Agreement on Access and Benefit-sharing for Academic Research – A toolbox for drafting Mutually Agreed Terms for access ...

26 SEP 2017

Community protocols and procedures and customary laws

11 AUG 2016
Biocultural Community Protocol for Cerrado Raizeiras

27 JUN 2016
Ogiek Bio Cultural Community Protocals (BCP)

2 RECORDS

22:53
06.12.2017

IRCC: 116

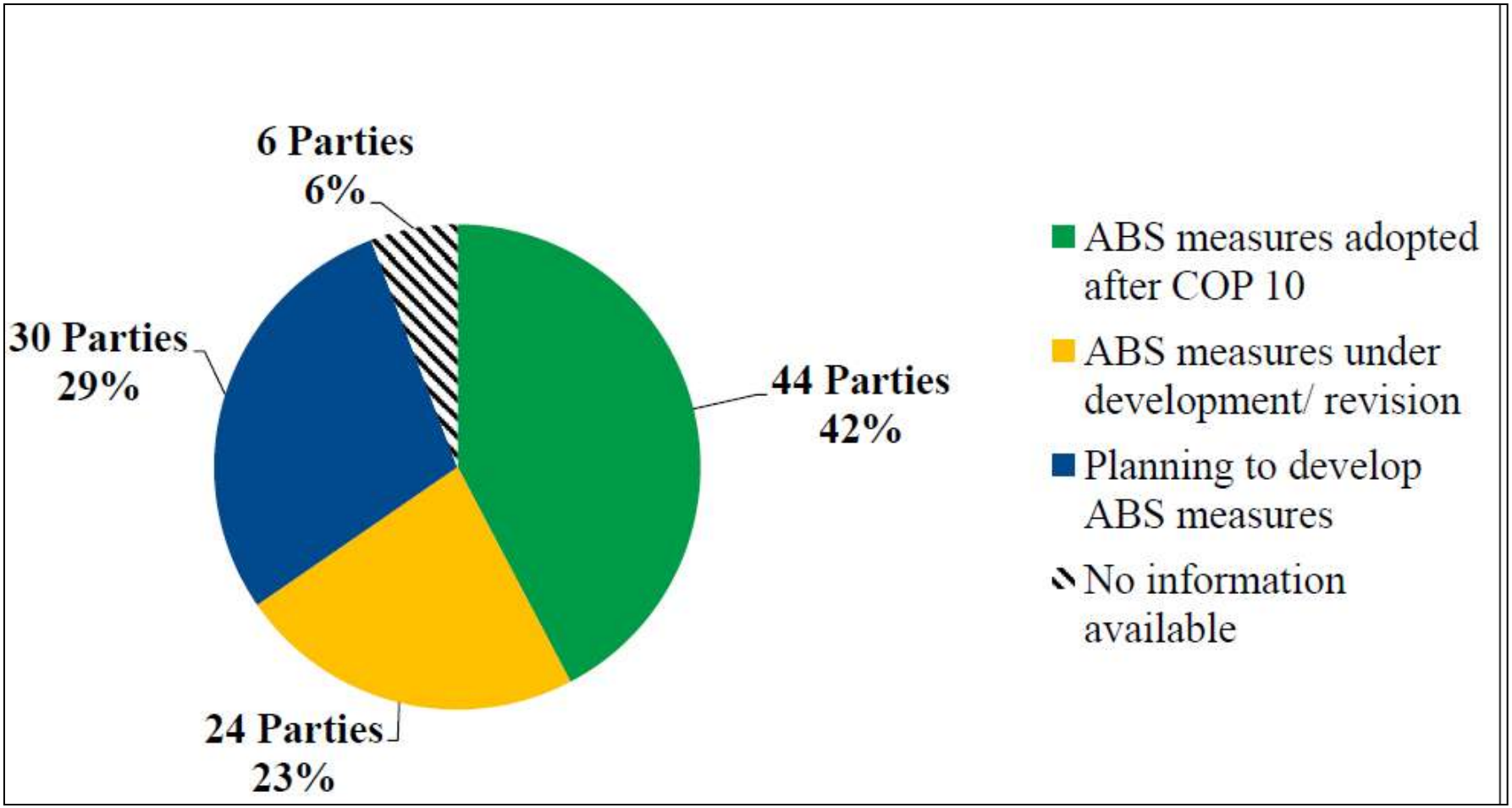
30 November 2017

Country	IRCC
India	86
South Africa	9
Kenia	5
Spain	5
Mexico	3
Bulgaria	3
Guatemala	2
Dominican Rep.	1
Malta	1
Panama	1

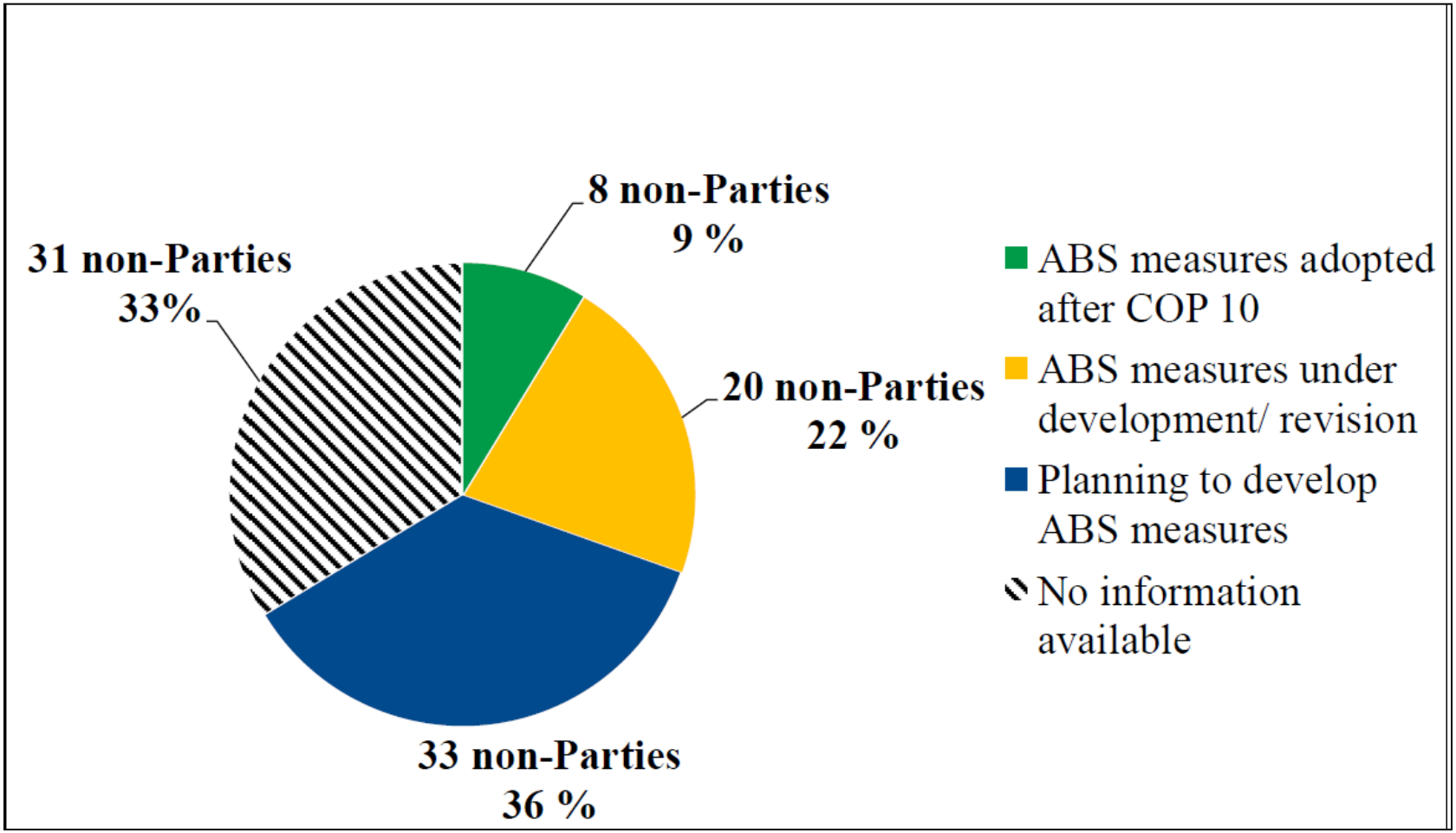
First IRCC
from developed country
Spain, 21 April, 2017

file:///C:/Users/EM/Downloads/absch-ircc-es-237603-2.pdf

Progress by Parties in establishing ABS measures



Progress by non-Parties in establishing ABS measures



Interim National Report:
deadline 1st November (Parties and non-Parties)

INRs received by Region - Parties

	Parties per region	Reports received	Reporting Rate
Africa	39	17	44%
Asia-Pacific	26	7	27%
CEE	8	7	88%
GRULAC	12	7	58%
WEOG	15	11	73%
TOTAL	**100**	**49**	49%

ABC of the Protocol and 511/2014

Access

Sovereign rights of Member state to decide on access

Benefit sharing

Bilateral transaction

conditions in MAT

Compliance

EU ABS Regulation 511/2014

Obligation of users based on *due dilligence*

EU ABS Regulation

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,

Key provisions of the EU ABS Regulation

User's *due diligence* obligation

Monitoring = checkpoints

Receiving funding

Best practices

Register of collections

Compliance checks

Penalties

Final stage of development

Implementing Regulation 2015/1866

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

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 (1), and in particular Article 5(5), Article 7(6) and Article 8(7) thereof,

Process to develop guidance documents

- **Horizontal (scope + core obligations of users)**
  - Draft: European Commission and MS
  - ABS Expert Group:
  - ABS Consultation Forum
  - Adopted on 22 August 2016

Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union
(2016/C 313/01)


Official Journal C 313
of the European Union
Information and Notices
EN

Adopted as Commission Notice 22/08/2016
Published in OJ 27/08/2016

ANIMAL BIOTECHNOLOGY 2017

NITRA, 7 December 2017

Horizontal Guidance Document

- Geographical scope I – provenance of GR
- Temporal scope
- Material scope
- Personal scope
- Geographical scope II – utilisation in the EU

BUT
user has also respect
legislation of provider country

Horizontal Guidance Document

- Obligations on the user from 511/2014
  - ✓Due diligence obligation
  - ✓Establishing whether the Regulation is applicable
  - ✓Demonstrating due diligence when it has been established that the Regulation is applicable
  - ✓TK of ILCs
  - ✓Registered collections
- Different events triggering due diligence declarations
- Selected sector specific issues

Process to develop guidance documents

- **Sectoral guidance documents (7)**
  - Consulting consortium supervised by the EC
  - ***Guidance Development Group***: experts from MS representing professional organizations
  - Workshops with stakeholders separately for each sector
  - Many opportunities to provide comments

- **Additional two documents**
  - The same process as above

Guidance documents: work in progress

- **Sectoral guidance documents (7)**
  - Animal breeding
  - Plant breeding
  - Food and Feed
  - Biocontrol and biostymulants
  - Pharmaceutical
  - Cosmetics
  - Biotechnology
- **Additional guidance documents (2)**
  - Research
  - Collection holders

Sectorial guidance documents

ABS case studies

Animal breeding

Out of the scope: animal breeding

1. Use of sequencing data from the public domain

2. Taxonomic identification

11. Application of reproductive technologies (e.g. In Vitro Fertilisation (IVF), semen sexing) to increase reproduction efficiency

12. Trading genetic material

13. Farmers buying animals, semen or embryos for production purposes

Out of the scope: animal breeding other issues

14. Exchange of genetic material of rare and traditional breeds between breeders, within breed associations or networks

15. Within-company across-country exchange

17. Genetic resources as testing/reference tools

18. Import of commodities

In the scope: animal breeding

3. Genotypic and phenotypic characterisation of animal genetic resources

4. Basic scientific research on the genetic background of traits

5. Identification of causal mutations

6. Breeding activities using germplasm from external sources aimed at the genetic improvement of breeding material for the purpose of commercial sales

7. Breeding of genetic resources newly introduced from the wild for the purpose of aqua farming

In the scope: animal breeding

8. Breeding of genetic resources newly introduced from the wild for the purpose of novel companion animals.

9. Breeding of companion animals using newly introduced genetic resources

10. Genome editing

16. Use of molecular information for breeds/animal traceability

No	Description	Documents
3.	Unresolved issues under sectorial guidance documents: **large scale screening** – feedback from the small drafting group	Document prepared by Germany & further developed by small drafting group (tbc)
4.	Unresolved issues: **commercial varieties**	Document by the Commission on 2 October 2017
5.	Unresolved issues: **threshold** in animal breeding	Draft sectorial guidance document for **animal breeding sector, chapter 3.1**
6.	Unresolved issues under sectorial guidance documents: **derivatives ("continuum")**	Document sent by the Commission on 20 September 2017
7.	Unresolved issues: **routine modifications & tests**	Draft sectorial guidance document for **pharmaceutical sector, chapter 3.1**
8.	Unresolved issues: **phase III and IV clinical trials**	Draft sectorial guidance document for **pharmaceutical sector, chapter 3.5**
9.	Unresolved issues: **zoonotic diseases induced by human-originating viruses**	Draft sectorial guidance document for **pharmaceutical sector, chapter 3.2**
10.	Unresolved issues under sectorial guidance documents: **end of utilisation**	Draft sectorial guidance document for **biochemical sector, chapter 3.2**
11.	Emerging unresolved issues: **laboratory strains, TKaGR, intentionality of access**	Draft guidance document for **research;** draft guidance document for **collection holders (chapters 3)**
12.	Guidance documents: **status of taxonomy**	Draft guidance documents for **research & collection holders**

Animal breeding

- Cut-off point for obligations

F1- 50 % ; F2 - 25%; F3 - 12,5%

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 into the breeding programme in which the used genetic resources was included.

- Can we establish such a point at the EU level?
- MAT conditions?
- Proposal: New genetic resource with first commercialisation

Clinical tests

Some hold that Studies in Phase III and IV are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population e.g. through monitoring side effects, comparison with commonly used treatments, collecting more information. They argue that these **studies are intended to provide an adequate basis for marketing approval**, and that they normally only aim at confirming preliminary results rather than generating new evidence. For these reasons **Phase III and Phase IV studies would normally not constitute utilisation** under the Regulation.

However, other stakeholders argue that phase III and IV studies regularly **provide new scientific insights related to side effects, comparison with other medicines** etc. They therefore take the view that **Phase III and IV clinical trials should be regarded as utilisation** in the meaning of the EU ABS Regulation.

Zoonosis caused by human-borne viruses

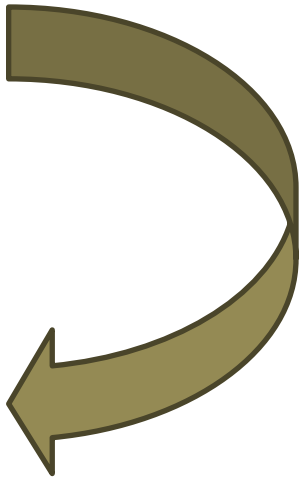
It may be possible to obtain the same virus from two different source materials, one of human origin and the other from an animal. How should this situation be treated?

One view is that viral material obtained from human cells, which has replicated and multiplied in the human cells (and may well have acquired genetic changes as result) **should be regarded as of human origin, and therefore exempt**.

An alternative view is that **pathogens causing zoonotic diseases are by definition not strictly human pathogens**, and **should not be excluded** from the scope of the EU ABS Regulation.

Other issues:

- Large scale screening
- Intentionality of access
- Laboratory strains
- TKaGR



to be discussed
during Consultation Forum,
18th December 2017

Summing up

- Guidance documents at the last stage of preparation
- Continuous collaboration of the CNA in EU MS

- A lot of efforts to develop mutual understanding between EU and provider countries
  - ✓ Initiative of German CNA -Vilm workshop, August 2017
  - ✓ EC workshop on advancing implementation, Brussels, Nov 2017

- Little understanding on obstacles related to regulation access to AnGR within developing regions

Biodiversity is life
Biodiversity is our life

United Nations Decade on Biodiversity

Thank you for listening