

Sectoral guidelines to implement EU ABS Regulation 511/2014

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Content

- European Commission guidance to implement EU ABS Regulation 511/2014
 - Horizontal guidance
 - Sectoral guidance documents

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- Guidance document for Collection Holders

- Guidance documents for Research

Horizontal guidance

- ❑ Published in 27th August 2016
- ❑ Establishes a scope of EU ABS Regulation 511/2014
- ❑ Developed by the COM in collaboration with Member states

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II
(Information)

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COMMISSION NOTICE

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)

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Scope of the EU ABS Regulation

- ❑ **Geographic scope — I:** the provenance of genetic resources
- ❑ **Temporal scope:** the genetic resource must be accessed and utilised as of 12 October 2014
- ❑ **Material scope**
- ❑ **Personal scope:** the regulation applies to all users
- ❑ **Geographic scope — II:** the regulation applies to utilisation in the EU

Sectoral guidance documents

Seven sectoral Guidance documents

- for animal breeding
- for cosmetic sector
- for plant breeding
- for pharmaceutical
- for biotechnology
- for food& feed
- for bio-control

Additional two imitated in 2017

- Guidance document for collection holders
- Guidance document for research

Sectoral guidance documents: process

- ❑ The work commissioned by the European Commission in December 2015
- ❑ The work conducted by the Consortium including two consulting companies and the Centre for Genetic Resources, the Netherlands
- ❑ Guidance Development Groups established by the Consortium in consultation with the European Commission to support this work

Guidance Document

Animal Breeding Sector: Process

- ❑ Establishment of the GDG (ERFP represented)
- ❑ Development of the draft
- ❑ Workshop with stakeholders: 1 July 2016
- ❑ Next round of comments from stakeholders and GDG
- ❑ Discussion at ABS Expert group (28 October 2016)
- ❑ Last available draft: 11th October 2016

Guidance Development Group

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Last available draft
October 11th 2016

17 cases: example of
activities

No unresolved issues

Draft 11

October 11, 2016

Guidance Document for the Animal Breeding sector

This revised draft has benefited from the suggestions made in the workshop, held in Brussels on July 1, 2016, and from written contributions received from the European Regional Focal Point for Animal Genetic Resources (ERFP), the League of European Research Universities (LERU), the Association of Manufacturers and Formulators of Enzyme Products (AMFEP), and from experts of Malta, the Netherlands, Slovakia, Spain, Sweden and the United Kingdom.

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Activities out of the scope of the EU ABS regulation

- ❑ acquisition of AnGR by genebanks to enhance their collection
- ❑ taxonomic characterization
- ❑ development and application of reproductive technologies (e.g. IVF, semen sexing) to increase reproduction efficiency
- ❑ trading genetic material
- ❑ buying semen for production purposes

Activities out of the scope of the EU ABS regulation

- ❑ exchange of genetic material of rare and traditional breeds between breeders within breed associations or networks
- ❑ exchange of genetic material within the same company
- ❑ using genetic resources as testing/reference tools
- ❑ using sequencing data from the public domain and import of commodities

Important

Even if activity is out of the scope
of the EU ABS Regulation

any acquisition of GR and associated TK

**should be done in line
with the ABS legislation**
and regulatory requirements
of the country of collection
(with PIC and MAT if access is regulated)

Activities in the scope of the EU ABS regulation

- genotypic and phenotypic characterization of breeds, breeding lines and individual animals
- basic scientific research on the genetic background of traits
- identification of causal mutations
- breeding activities using germplasm from external sources aimed at the genetic improvement of breeding material for the purpose of commercial sales

Activities in the scope of the EU ABS regulation

- ❑ breeding of genetic resources newly introduced from the wild for the purpose of aqua farming
- ❑ genome editing and use of molecular information for breeds/ animal traceability

The guidance document for breeding sector
has not been adopted yet
and interpretation of some activities may change

Guidance Document for Collection holders: Process

- ❑ Establishment of the GDG in March 2017 (ERFP represented)
- ❑ Development of the draft
- ❑ Workshop with stakeholders: 6 July 2017
- ❑ Next round of comments from stakeholders and GDG by 15th August (delivered)
- ❑ Next draft should be available end of September
- ❑ Discussion at the next ABS Expert group

Name	Institution	Country	Category
Michele Bozzano	European Forest Genetic Resources Programme (EUFORGEN)	Italy	European collaborative programme (FGR)
Catherine Cotton	Federation of European Microbiological Societies (FEMS)	Netherlands	Federation of microbiological societies
Philippe Desmeth	MIRRI/Uni Ghent	Belgium	Microbial collection holder
Matthew Jebb	National Botanic Gardens of Ireland, Glasnevin	Ireland	Botanical garden
Waltraud Kugler	SAVE	Germany	NGO
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Chris Lyal	Natural History Museum, London	UK	Natural History Museum
Ela Martyniuk	European Regional Focal Point for Animal Genetic Resources (ERFP) / Uni Warszawa	Poland	European collaborative programme (AnGR)
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Wieslaw Podyma	Botanical Gardens	Poland	Botanical garden
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Guidance Document for Research

- ❑ Establishment of the GDG in March 2017
- ❑ Development of the draft
- ❑ Workshop with stakeholders: 7 July 2017
- ❑ Next round of comments from stakeholders and GDG by 15th August (delivered)
- ❑ Next draft should be available end of September
- ❑ Discussion at the next ABS Expert group

Way forward:

All guidance documents

A number of „Unresolved issues“ identified in sectoral guidance documents, including:

- ❑ Human microbiome
- ❑ Commercial varieties
- ❑ Large scale screening
- ❑ Derivatives

These issues are being further analysed by ABS Expert Group.

Political decision to be taken by the Member States.

Thank you

