



New Access & Benefit Sharing (ABS) Regulations: *Implications for the Biocontrol Industry*

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ABIM 21 October 2014

12 October 2014

Nagoya protocol on ABS came into force
EU regulation 511 on ABS came into force



COP12 / MOP7 / MOP1
PYEONGCHANG KOREA 2014

ties to the Convention on Bio-
the Cartagena Protocol on Biosafety (COP-
Nagoya Protocol on Access and Benefit Sharing

29 September to 17 October 2014 | Pyeongchang, Republic of Korea



CBD COP 12, Cartagena Protocol COP-MOP 7 & Nagoya Protocol COP-MOP 1
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Convention on Biodiversity (1993)



Objectives

1. The conservation of biological diversity
2. The sustainable use of the components of biological diversity
- 3. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources**

194 parties (USA has not signed)



Fair and equitable Sharing of Benefits...

Background:

- *It is unfair that biodiversity is explored and big money is made out of it, without giving countries of origin anything in return*

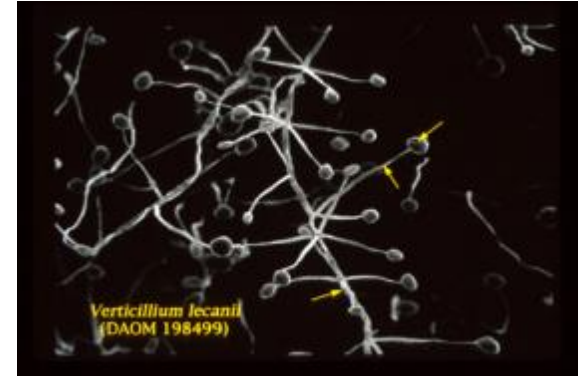
Idea:

- *Benefit sharing:* Money flows back to (developing) countries to be used for conservation and sustainable use

High expectations by developing countries:
Genetic Resources will become the **GREEN GOLD** of the South



genetic resources...



- Genetic material with actual or potential value
 - *Any material of plant, animal, microbial origin (except human origin)*
- All biocontrol products, incl. semiochemicals
 - Also if genetic resources are used for development of product

Access & Benefit Sharing: What is arranged in the CBD?



- Countries have the sovereign rights over their natural resources
- Access to Genetic Resources is subject of national regulation
- Minimum requirements for use of Genetic Resources:
 - Permission to collect and export
 - Contract with agreements on use
 - Certificate of Origin
- Bilateral agreements / International regime on ABS



Access...



biopiracy....



What is the 'Nagoya protocol'



- International Regime on Access and Benefit Sharing
- Legal **framework** for effective implementation of Access and Benefit Sharing regulations on national level
- Adopted October 2010, Nagoya, Japan
- Came into force 12 October 2014, Korea (50 ratifications)



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Biocontrol development under the Nagoya Protocol

1. Facilitated access for research
2. Plant health and Food Security
3. Benefit Sharing: Monetary or non-monetary

1. Facilitated access for research

art. 8a of Nagoya protocol

Create conditions to promote and encourage *research which contributes to the conservation and sustainable use of biological diversity*, particularly in developing countries, including through *simplified measures on access for non-commercial research purposes*, taking into account the need to address a change of intent for such research;

- Non-commercial research contributing to biodiversity should be facilitated
- Agreement includes only use for research
- New agreement required for commercialization: new negotiations
- What is non-commercial research ?

2. Food Security: role of FAO

art. 8c of Nagoya protocol:

*Consider the importance of genetic resources for food and agriculture and their **special role for food security**.*

- Biocontrol is crucial in food security
- ‘consider’...
- FAO Commission on Genetic Resources for Food and Agriculture
- Multilateral agreement/ Treaty (example: Seed Treaty)
- **Option for IBMA: long term!**

3. *Benefit Sharing: monetary*

Art. 5.4 of Nagoya Protocol

Benefits may include monetary and non monetary benefits, including but not limited to those listed in the Annex.

Monetary Benefit Sharing:

- access fees, milestone payments, royalties, joint ventures, fees to trust funds, research funds
- Relatively little money to share in Biocontrol
- Administrative costs high

3. Benefit Sharing: non monetary

Art. 5.4 of Nagoya Protocol

Benefits may include monetary and non monetary benefits, including but not limited to those listed in the Annex.

Non Monetary Benefit Sharing:

- Sharing of research results, collaboration in research, training
- Exchange in research takes place anyhow
- In Biocontrol there is a benefit for all
- Biocontrol products are public goods (esp. classical biocontrol)
- *Will this be accepted on national level?*

EU regulation 511/2014 :

- On **compliance** measures for users from the Nagoya Protocol on ABS in the European Union
- Came into force 12 October 2014

Main issues:

- Due Diligence
- Best Practices
- Compliance checks



EU regulation 511/2014: Due diligence

*(Art.4) Users shall exercise **due diligence** to ascertain that Genetic resources and traditional knowledge were accessed in accordance with applicable ABS legislation and that benefits are fairly and equitably shared*

- Users have to prove that they acquired Genetic Resources legally
- Users need to collect and keep the following info:
 - Where and when accessed
 - Description of genetic resource (incl. ID)
 - Presence/ absence of rights
 - Access decisions and agreements

EU regulation 511/2014: Best practices

*(Art. 8) Associations of users or other interested parties may submit an application to have a combination of procedures, tools or mechanisms recognised as **best practice***

- User associations can develop a Best Practice
 - Should be supported by evidence and information
 - All users are committed to comply
 - Users of a Best Practice are considered to have a lower risk of non-compliance – could result in less checks
- **Important option for IBMA**

The EU and the Nagoya protocol: Compliance

Compliance will be **monitored** (art. 7):

- When applying for public research funding
- When requesting market approval / commercialisation

Compliance will be **checked** (art. 9):

- By competent authorities of member states
- Following a risk-based approach
- On request of third countries when they provide substantiated concerns about non-compliance
- Start October 2015

EU regulation 511/2014: national regulation

- Ownership of Genetic Resources is up to member states
- If countries claim their Genetic Resources, then national regulation applies also for users from other member states

- Right now: Denmark, Hungary?
- Netherlands: no rights claimed

What are the consequences?

- Access to Genetic resources becomes limited
 - Especially when directly collected from nature (Invertebrates)
 - Negotiation time long (uncertainties, unknown sector)
- Increased costs:
 - Access
 - Administration
 - Benefit sharing



➤ Product development is slowed down

Your obligations under ABS

For Genetic resources already in your possession:

- Take record of all Genetic Resources and their source
- Check existing ABS legislation in source countries
- If necessary make agreements before commercialisation

For collection of Genetic Resources from now onwards:

- All new accessions have to be justified under bilateral agreement, Nagoya Protocol or treaty

The IBMA and ABS

- Involved since 2008
- Focus on invertebrates
- **CBD**: working groups, side events (together with **ICC**)
- **CGRFA/ FAO**: preparation of advice for FAO, together with
- **IOBC** global commission on biocontrol and ABS: Background Study paper 47 FAO
- **EU**: input on draft regulation
- **Working group ABS: all professional groups**
 - Best practice document (with help from lawyers)
 - Multilateral agreement/ Treaty FAO
 - Share experiences



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WORKING OUT ABS

Preparing to comply with the new
EU Rules on Access and Benefit-sharing



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