

# NAGOYA PROTOCOL ON ABS: THE CHALLENGE OF THE PRACTICAL IMPLEMENTATION OF ITS COMPLIANCE MEASURES

ABS SEMINAR  
A SEED JAPAN  
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# PRACTICAL IMPLEMENTATION OF THE COMPLIANCE MEASURES OF THE NP-ABS

The objective of this meeting is to start the debate on the practical implementation of the Nagoya Protocol, in particular its compliance measures and introduce the process that Spain is following.

Nagoya Protocol

Compliance Measures

- Obligations arts. 15 and 16
- Checkpoints (art. 17)

Spanish Approach



# NAGOYA PROTOCOL

# Nagoya Protocol

- Adopted in Nagoya (Japan) 29th October 2010
- Objective: the fair and equitable sharing of the benefits arising from the utilization of genetic resources (Third objective of the CBD in connection with the other two) (article 1)
- 36 Articles + 1 Annex
- Open for signature since 2nd February 2011 (65 signatories, including Japan, EU and Spain)
- Entry into force: 90 days after 50 ratifications (possible entry into force for COP-11?)

# Nagoya Protocol

- **SCOPE:** genetic resources under article 15 of the CBD + traditional knowledge associated with the genetic resources (article 3)
- Regulates access to genetic resources (national sovereignty) and benefit sharing (PIC +MAT)
- **MAJOR INNOVATIONS:** Introduces legal obligations on:
  - Access to traditional knowledge associated with genetic resources held by ILCs (arts. 7 and 12);
  - Compliance with national access legislation in user countries [genetic resources (art. 15) and TK (art. 16); and
  - National permit (art.6e) – internationally recognised certificate of compliance (art. 17.2-4); and
  - Monitoring the utilization of genetic resources (art. 17 checkpoints)
- **Other measures:**
  - simplified measures on access for non-commercial research purposes (art. 8.a); and
  - Possible establishment of a global multilateral benefit-sharing mechanism (art. 10)



# COMPLIANCE MEASURES



# COMPLIANCE IN THE NAGOYA PROTOCOL

Different compliance measures:

1. Compliance with domestic legislation on ABS and TK associated with genetic resources (arts. 15 and 16)
2. Monitoring the utilization of genetic resources (art. 17) [checkpoints]
3. Compliance with MATs (art. 18)
4. Institutional mechanisms to promote compliance with the Protocol (art. 30)

# COMPLIANCE WITH NATIONAL LEGISLATION ON ABS (ART. 15)

1. Each Party shall take appropriate, effective and proportionate measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with domestic law of the provider Party
2. Parties shall take measures to address situations of non compliance with para 1
3. Parties shall cooperate in cases of alleged violation of ABS national legislation



# COMPLIANCE WITH NATIONAL LEGISLATION ON ABS (ART. 15)

## Significance of article 15.1:

- Establishes legal certainty at intal level: biopiracy is the breach of ABS national legislation;
- Unusual obligation at intal level: Parties are almost oblige to observe and apply the access legislation of the provider country (without any harmonization apart from the general one of article 6)

# COMPLIANCE WITH NATIONAL LEGISLATION ON TK (ART. 16)

Same structure as art. 15.

1. Each Party shall take appropriate, effective and proportionate measures to provide that TK associated with genetic resources utilized within its jurisdiction have been accessed with PIC and MAT of the ILCs, as required by the domestic law of the provider Party
2. Sanctions
3. Cooperation with other Parties

# COMPLIANCE WITH NATIONAL LEGISLATION ON TK (ART. 16)

- definition of TK?

Subject to the different national legislations  
(further work from other processes).

- No law, no misappropriation of TK

# COMPLIANCE WITH NATIONAL LEGISLATION (ARTS 15 AND 16)


Can a Party know and apply the different national legislations of 193 CBD Parties?

- Connection and relevance of the national permit (art. 6.3.e) and initially recognized certificate of compliance (art. 17.2-4): further harmonization and inclusion of TK



# MONITORING THE UTILIZATION OF GENETIC RESOURCES (ART. 17)

Two parts :

1. Checkpoints (art. 17.1)
  2. Internationally recognized certificate of compliance (art. 17.2-4)
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# CHECKPOINTS (ART. 17)

Main obligation: designation of one checkpoint that shall:

- Require users of genetic resources to provide information related to the PIC, the source of the GR, the establishment of MAT and the utilization of the genetic resources (including from the intally recognized certificate of compliance)
- Communicate that information to the relevant national authorities, the provider Party and to the ABS-CH



# CHECKPOINTS (ART. 17)

Checkpoints discussed during the negotiations:

- Competent national authority (CNA) in the user country;
- Research institutions subject to public funding;
- Entities publishing research results relating to the utilization of genetic resources;
- Intellectual property examination offices;
- Authorities providing regulatory or marketing approval of products derived from genetic resources.

# CHECKPOINTS (ART. 17)

Relevant information at the relevant moment



CNA (user & provider countries) [+ ABS-CH]



Active the procedures under arts. 15 and 16





# SPANISH APPROACH

# EUROPEAN POLICY ON ABS

- **No formal EU policy on ABS**
- States maintain their sovereignty over GR
- The view of most of the Member States is that in Europe access to genetic resources should continue being free

FREE ACCESS


MORE RESEARCH  
AND LESS  
BARRIERS

MULTIPLIER EFFECT  
IN RESEARCH

IMPULSE THE  
BIOTECH SECTOR



# EU APPROACH TO THE IMPLEMENTATION OF THE NAGOYA PROTOCOL

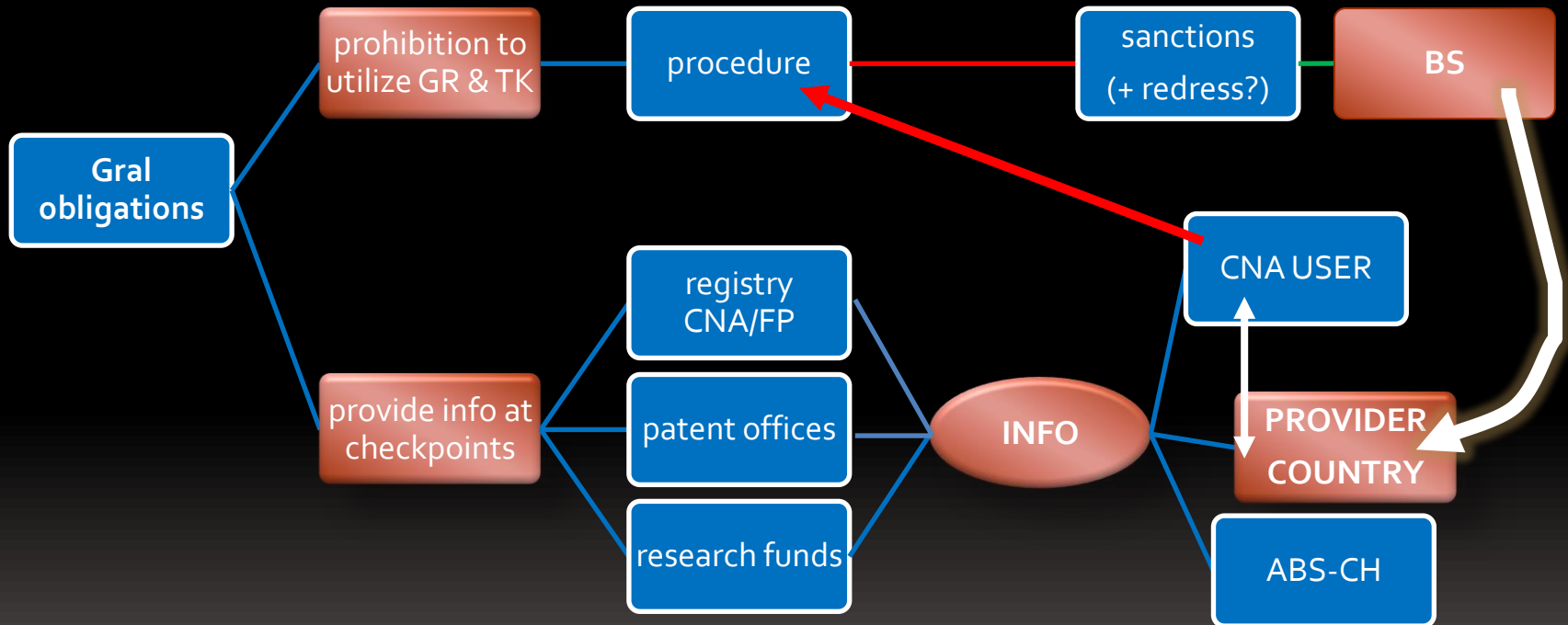
- Mixed competence: EU and Member States
  - Some Member States are preparing the internal ratification process- others will wait to the EU
  - Extra of complexity for the correct implementation of the Nagoya Protocol
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# SPANISH APPROACH TO THE IMPLEMENTATION OF THE NAGOYA PROTOCOL

- Ratification process: well advanced pending the political decision of its debate and approval by Parliament
- Draft legislation to regulate access to spanish genetic resources and to establish compliance procedures and measures. Major challenges:
  - Checkpoints
  - TK
  - Sanctions and redress

# IMPLEMENTATION IDEAS FOR DISCUSSION





**THANKYOU FORYOUR KIND  
ATTENTION**

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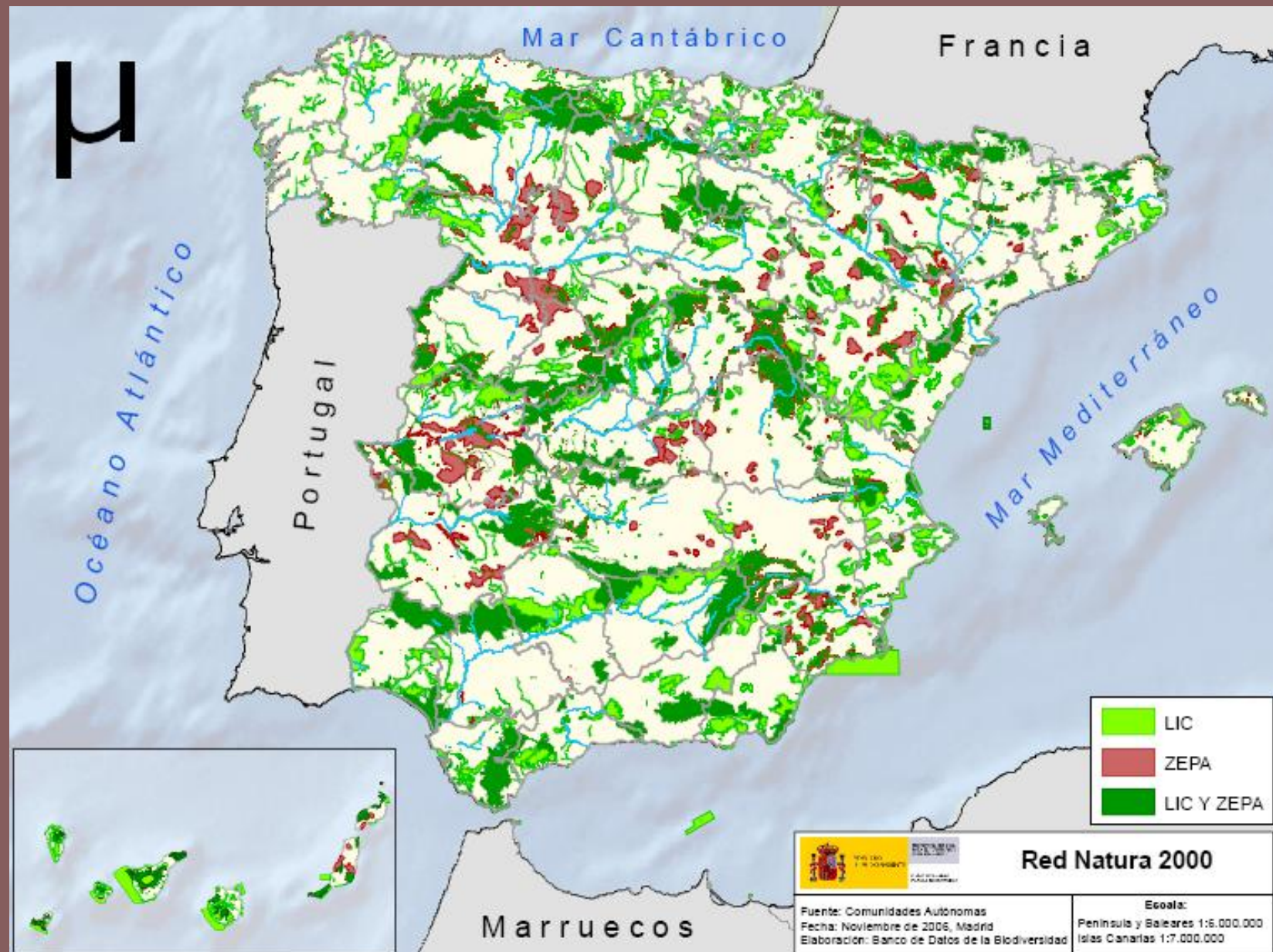
# AT NATIONAL LEVEL

## Some special features and figures:

- The most biodiverse country in Europe.- Natura 2000 (Almost 25% of the entire network is in SPAIN (23,6 %))
- User and provider country
- Some european (and international) research campaigns

	<b>MS Area (km<sup>2</sup>)</b>	<b>Total Num</b>	<b>Total Area (km<sup>2</sup>)</b>	<b>Terrestrial Area (km<sup>2</sup>)</b>	<b>% Terre strial</b>
<b>SPAIN</b>	504.782	1380	119.112	113.921	22,6
<b>EU</b>	3.940.746	20.862	560.445	482.638,59	12,2

# NATURA 2000 in SPAIN





# AT NATIONAL LEVEL

## OTHER FEATURES:

- **Cuasi-federal State:** 17 Autonomous Communities (regions)
- **Environment shared competence:** Central State.- basic legislation; Autonomous Communities: management
- **Highly controversial:** 75% Environment legislation ends up in the Constitutional Court

# Administrative Division



# AT NATIONAL LEVEL

**Law 30/2006 seeds and greenhouse plants**

**Law 42/2007 (Natural Heritage and Biodiversity Act) Art. 68:**

- The government can regulate the access to GR through a Regulation, in accordance with the CBD and ITPGRFA
- Autonomous Communities would be in charge of PIC and MAT
- No ABS regulation at the moment: Free access (subject to private property rights).- exceptions for protected areas and species