

# **Key Elements of ABS Frameworks: EU, France, Germany, Denmark**

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#### **Examples from the EU and its Member States**

- EU: Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol
- FR: Projet de loi relatif à la biodiversité
- DE: Bill on implementing the obligations arising from the Nagoya Protocol and implementing the Regulation EU 511/2014
- DK: Act on sharing benefits arising from the utilisation of genetic resources (pre-NP)



## Competent National Authority

#### EU

 each MS must designate at least one CNA



## Competent National Authority

France	Germany	Denmark
<ul> <li>Ministry of Agriculture, Agrifood and Forestry</li> <li>Ministry of Ecology, Sustainable Development and Energy</li> <li>Ministry of Social Services and Health</li> </ul>	<ul> <li>Federal Agency for Nature Protection</li> <li>on issues of agricultural and human GR the respective Federal institutions need to be involved</li> </ul>	• Ministry of Environment
<ul><li>uniform permit format</li></ul>		<ul> <li>will issue several regulations</li> </ul>



### **Access regulation**

#### EU

- access is not an issue for EU legislation
- determining on access is still under national souvereignty
- most EU member states will not require PIC
- mediterranean member states announced to introduce PIC



## **Access regulation**

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France	Germany	Denmark
<ul> <li>PIC required for access to GT and aTK</li> </ul>	• no PIC required	• no PIC required
<ul> <li>territorial scope:         <ul> <li>France,</li> <li>Martinique,</li> <li>Guadeloupe,</li> <li>French Guyana,</li> <li>Réunion and</li> <li>Mayotte</li> </ul> </li> </ul>		



### PIC procedure for GR

#### **France**

declarative procedure (no PIC) for

- · access for non-commercial research
- pathogens in emergency situation
- ex-situ collections

authorisation procedure (PIC) for GR in general



## **Benefit-sharing**

#### EU

#### **Principles**

- no specific provisions on benefit-sharing obligations
- benefit-sharing obligations only arise from MAT in ABS-contracts
- due diligence approach
  - users have to ensure their own compliance
  - minimal oversight by EU and MS institutions

#### Effects on provider countries

- user must comply with ABS regulation of the country of origin that is a Party to the NP
- no obligations for users utilising GR and aTK from counries that do not have ABS regulations



## **Benefit-sharing**

France	Germany	Denmark
<ul> <li>for national access</li> <li>model clauses in case of declaratory authorisation</li> <li>full MAT in case of authorisation procedure</li> </ul>	<ul> <li>no specific benefit-sharing clauses related to countries of origin</li> </ul>	<ul> <li>benefit-sharing         obligation for         utilisation in research         and for developing         and marketing of         products based on         GR</li> </ul>
<ul> <li>benefits go to French Agency for</li> <li>Biodiversity</li> <li>benefits may go to local community</li> </ul>		



### Compliance

#### EU

- all recipients of research funding must declare due diligence to the checkpoint; e.g. universities receiving project funding from national or EU research funding agencies
- excludes industry and budget-funded research institutes, e.g. all Federal German research institutions (Helmholtz-, Leipniz-, Fraunhofer-, Max-Planck-institutes)
- all user must declare due diligence in the final stage of product development
- compliance rules do not extent to "subsequent applications and commercialization", e.g. commercialisation of products based on GR and aTK is not covered by the EU ABS Regulation



## **Compliance**

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France	Germany	Denmark
<ul> <li>in addition:</li> <li>benefit-sharing obligations need to be passed to third party users</li> <li>information on PIC and MAT need to be passed to the French National Industrial Property Institute if a patent is applied for</li> </ul>	<ul> <li>in addition:</li> <li>German patent office needs to inform CNA if patent discloses the origin of GR</li> </ul>	<ul> <li>in addition:</li> <li>benefit-sharing obligation for utilisation for research and for developing and marketing of products based on GR</li> </ul>



## Illegal Utilisation and Commercialisation

#### EU

- adopted definition for illegal utilisation
- excluding illegal commercialisation
- no operational text on illegal utilisation or commercialisation



## Illegal Utilisation and Commercialisation

France	Germany	Denmark
<ul> <li>in addition:</li> <li>civil and criminal law sanctions possible</li> <li>up to 1 year prison and 150,00 EUR fine</li> <li>1 mill EUR fine in cases with commercial purpose</li> <li>denial of application for commercialisation</li> </ul>	<ul> <li>breach of compliance is an administrative offence</li> <li>50,000 EUR fine</li> <li>no prohibition of illegal utilisation and commercialisation</li> </ul>	in addition:  • prohibition of utilisation of illegally aquired GR and aTK



### Thank you very much!

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