

THE ABS
CAPACITY
DEVELOPMENT
INITIATIVE



L'INITIATIVE DE
RENFORCEMENT
DES CAPACITES
POUR L'APA

ABS and national law

EU ABS Compliance Regulation 511/2014

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ABS Capacity Development Initiative

30.11.2015, Paramaribo, Suriname

funded by

BMZ



Federal Ministry
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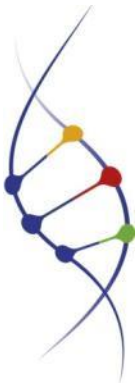


implemented by

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Programme implementing
The Biodiversity Convention

Political statements on ABS / NP



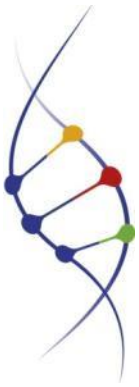
Commission Proposal COM(2012) 576 final (04.10.2012)

- "The Protocol rests on two main pillars: measures on access, and measures on user compliance."
- "Union implementation and ratification of the Protocol will create new opportunities for nature-based research, and contribute to the development of a bio-based economy."

EU Council Note on Art. 7 during EU Trialogue (Nov. 2013)

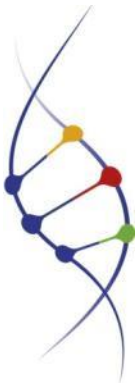
- Restricting checkpoints to the phase of utilisation "Using the principle of: 'nothing more, nothing less, than the Nagoya Protocol.' "

Art. 1 - Subject matter



This Regulation establishes **rules governing compliance with access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources** in accordance with the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the 'Nagoya Protocol').

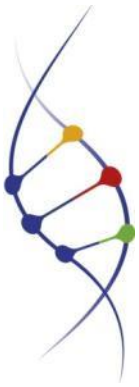
Art. 2 - Scope



Art. 2.1 This Regulation applies to **genetic resources over which States exercise sovereign rights** and to **traditional knowledge associated with genetic resources** that are **accessed after the entry into force of the Nagoya Protocol for the Union**. It also applies to the benefits arising from the utilisation of such genetic resources and traditional knowledge associated with genetic resources.

Art. 2.4 This Regulation applies to genetic resources and traditional knowledge associated with genetic resources **to which access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol are applicable**.

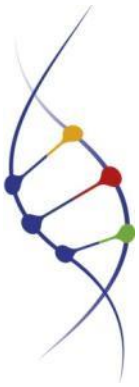
Art. 2 – Scope & Art. 3 - Definitions



EU ABS compliance rules only apply when these four conditions are met:

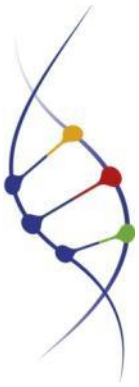
1. Access to genetic resource or associated traditional knowledge took part after Oct 2014
2. Aquisition of genetic resource or associated traditional knowledge occurs in a Party to the Nagoya Protocol
3. Genetic resources accessed is under sovereignty of a State
4. ABS legislation of a Party to the Nagoya Protocol needs to be applicable to genetic resource of associated traditional knowledge accessed

Art. 4 – User compliance



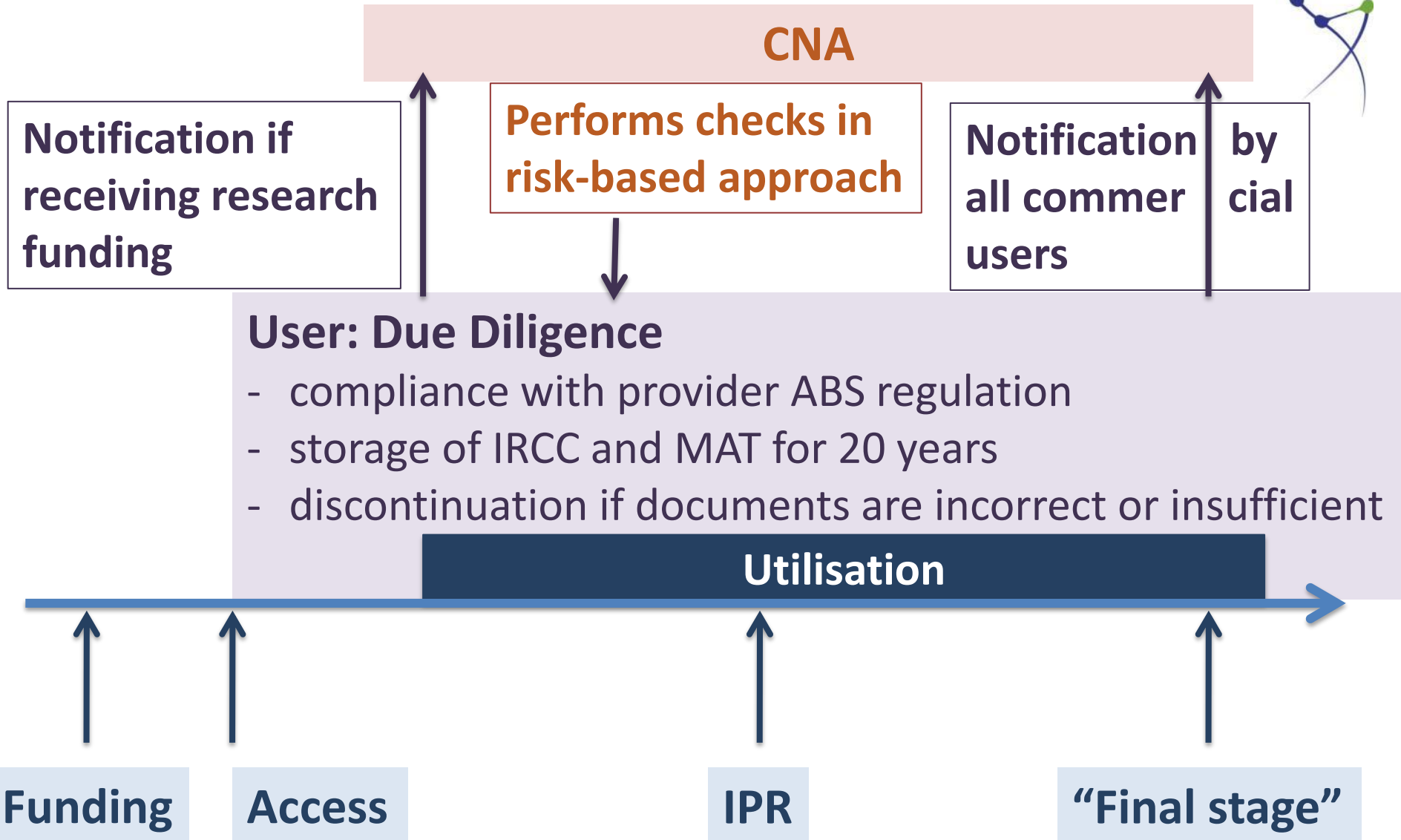
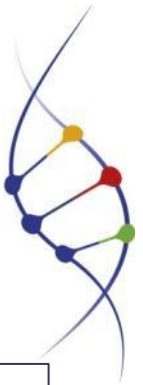
Art. 4.1 Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

Art. 7 – Monitoring user compliance

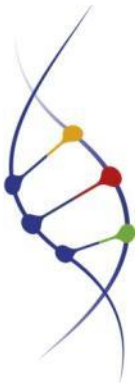


- Recipients of research funding involving the utilisation of GR and aTK shall notify the CA at the beginning of utilisation
- Research funding means third party grants from public or private funders
- Utilisation financed through institutional budgets does not need to be notified at its beginning
- At the stage of final development of a product, all users shall notify the CA and submit the relevant ABS documents
- Market approval, ...
- Member States shall transmit this information to the ABSCH, the European Commission and the CA of the provider country

Compliance during utilisation



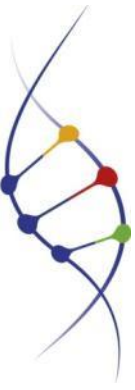
Art. 5 – Register of collections



The Commission shall establish and maintain a register of collections under the condition that

- genetic resources and related information are only supplied to third persons for their utilisation with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with mutually agreed terms
- records on transfers and users are kept
- unique identifiers are established

Users of such GR have exercised due diligence



Art. 6 – CAs and FPs

Art. 9 – Checks on user compliance

Each Member States shall designate one or more CAs

- CAs shall carry out checks to verify whether users comply with their obligations under Articles 4 and 7
- in accordance with a periodically reviewed plan developed using a risk-based approach
- based on relevant information, including on the basis of substantiated concerns provided by third parties, regarding a user's non-compliance, special consideration shall be given to such concerns raised by provider countries

Art. 11 – Penalties



Art. 11.1 Member States shall lay down the rules on penalties applicable to infringements of Articles 4 and 7 and shall take all the measures necessary to ensure that they are applied.

Art. 11.2 The penalties provided for shall be effective, proportionate and dissuasive.

„nothing more than the NP“ can pose problems



The EU ABS Compliance Regulation does not cover commercialisation

- If illegal utilisation is detected at second check point, illegal commercialisation could not be prevented if, e.g.:
 - the final steps of development of a drug are based on meanwhile chemically synthesised compounds and do not any longer rely on the genetic resource itself
 - the production of cosmetics is based on extracts from genetic resources which can be purchased outside of the scope of the EU ABS and does not any longer rely on the genetic resource accessed for utilisation

„The Nagoya Protocol rests on two main pillars“: access and compliance

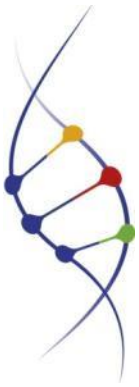


The EU ABS Regulation does not implement benefit sharing obligations of its Parties under NP Art. 5

NP Art. 5.1 ... benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources Such sharing shall be upon mutually agreed terms.

NP Art. 5.3 To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

„The Nagoya Protocol rests on two main pillars“: access and compliance

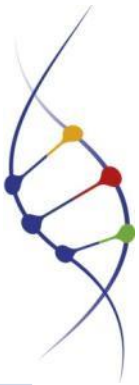


The EU ABS Regulation does not implement benefit sharing obligations of its Parties under NP Art. 5

NP Art. 5.3 Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

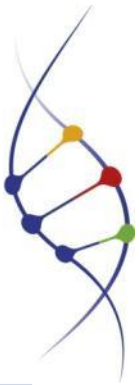
NP Art. 5.2 contains comparable, slightly less obligatory, language on GR held by ILCs

Patent office as check point



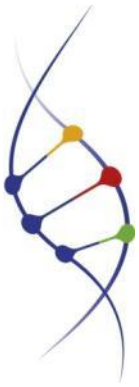
France (draft)	<ul style="list-style-type: none">• If patent applications is based on GR, PIC and MAT need to be disclosed, CA has to be informed• <i>(Non-compliance effect on granting patent unclear)</i>
German (adopted)	<ul style="list-style-type: none">• If patent application based on plant or animal GR discloses geographic origin, CA has to be informed• Disclosure of origin is voluntary, no requirement to disclose PIC and MAT at patent office
Spain (in force)	<ul style="list-style-type: none">• If patent applications is based on GR, PIC and MAT need to be disclosed, CA has to be informed• Non-compliance has effect on granting the patent
UK (draft)	<ul style="list-style-type: none">• No provisions on patent office as check point

Penalties for illegal utilisation (and commercialisation?)



France (draft)	<ul style="list-style-type: none">• Civil: Withdrawal of permit• Criminal: 150,000 €, 1y prison• Illegal commercial use: up to 1,000,000 €
German (adopted)	<ul style="list-style-type: none">• Civil: Confiscation of GR, up to 50,000 €• Illegal commercial use: profits could be skimmed
Spain (in force)	<ul style="list-style-type: none">• Civil: Confiscation of GR, up to 2.000,000 €• Illegal commercial use: can be stopped
UK (draft)	<ul style="list-style-type: none">• Civil: Stop notice, monetary penalties• Criminal: If notices of CA are not followed• Illegal commercial use: Stop notice can be issued

Thank you for your attention !



Contact

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