Ministry of the Environment of the Czech Republic

Implementation of the Nagoya Protocol and related legislation in the Czech Republic

15/09/2017

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Ministry of the Environment
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Convention on Biological Diversity(CBD)

- In force since 1993
- Objectives (**Art. 1**): 1. conservation of biological diversity, 2. sustainable use of its components, **3. fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources**
- **Art. 15:** recognises the **sovereign rights of States over their natural resources + access to genetic resources is subject to national legislation**

Nagoya Protocol (NP)

- **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
- Adopted 29/10/2010 in Nagoya (Japan)
- **Entry into force 12/10/2014 (also for EU and its MS)**
- CZ: also a Party to the Protocol (since 04/08/2016)
- 100 Parties (09/2017)

Nagoya Protocol (NP)

NP provides international legal framework for:

A. **Access to genetic resources** (and traditional knowledge associated with genetic resources): Countries have the right to regulate access to their genetic resources. → Access might be subject to **prior informed consent (PIC)** by the providing Country.
B. **Benefit sharing:** based on **mutually agreed terms** (**MAT**) between the provider and the user.
C. **Compliance by users:** Parties to the NP shall ensure that users of genetic resources within their jurisdiction comply with ABS legislation of the providing country.

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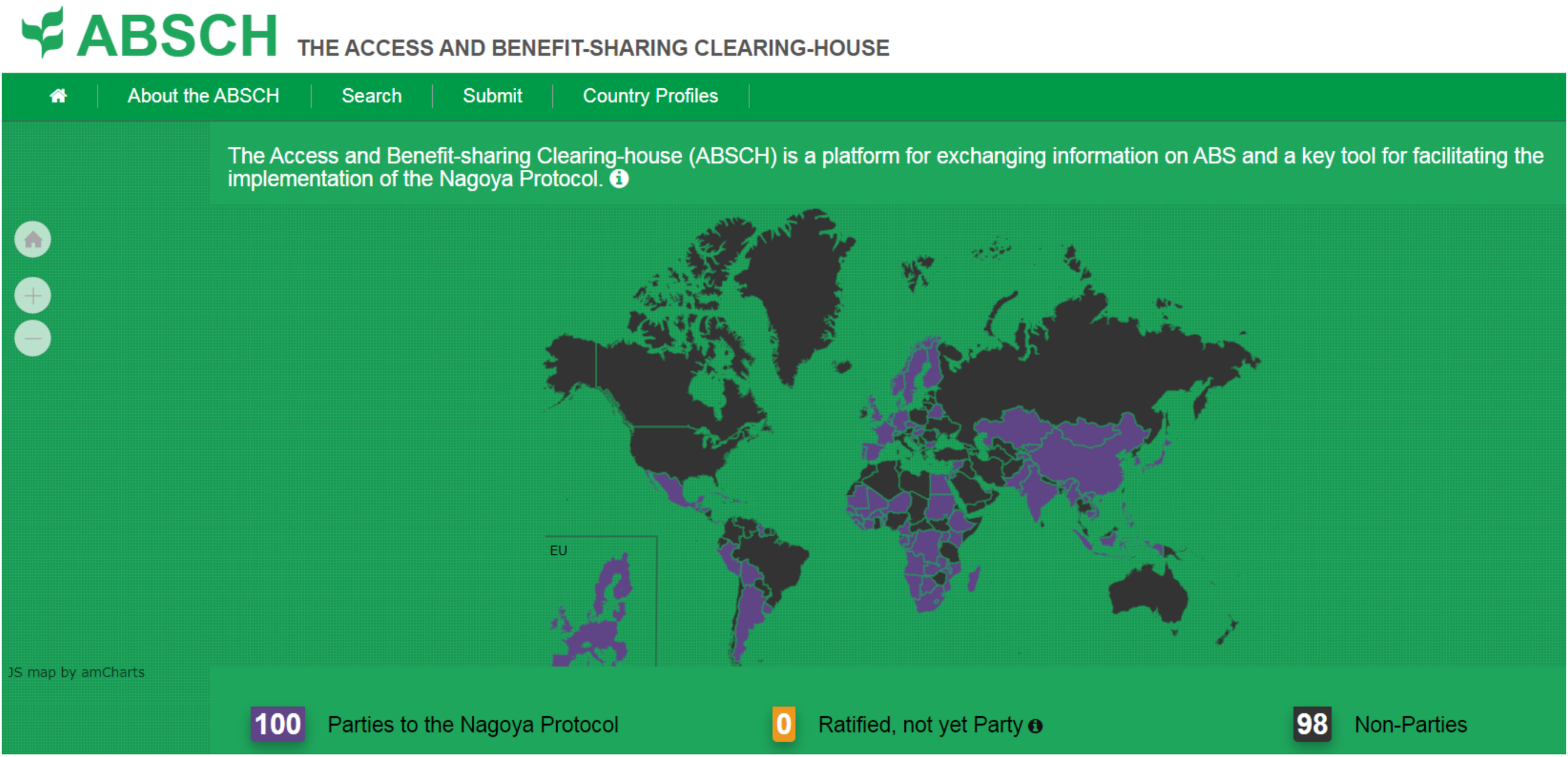
Access and Benefit-Sharing Clearing House: absch.cbd.int



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Terms and definitions

- **Genetic resource:** genetic material (any material of plant, animal, microbial or other origin containing functional units of heredity) of actual or potential value

- **Utilisation:** conducting **research and development** on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology

- **User:** a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources

- **Collection:** a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities

Nagoya protocol and the EU

- Implementation of **user compliance measures** (measures for access and benefit sharing up to MS)
- **Regulation (EU) No 511/2014** of the European Parliament and of the Council of 16 April 2014 on **compliance measures for users** from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union **= EU ABS Regulation**
- Entry into application **12/10/2014**
- Main obligations for users within the EU (due diligence), monitoring and checks on compliance, competent authorities, register of collections, best practices, etc.
- **Commission Implementing Regulation (EU) 2015/1866** of 13 October 2015 laying down **detailed rules for the implementation** of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices

Scope of applicability of the EU ABS Regulation

		Within scope (cumulative conditions*)	**Outside of scope**
Geographic scope (provenance of GR)**	***Access in …***	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	Provider country is …	Party to the Nagoya Protocol	Not a Party to the Protocol
	Provider country has …	Applicable access legislation	No applicable access legislation
Temporal scope	***Access …***	On or after 12 October 2014	Before 12 October 2014
Material scope	***Genetic resources***	Not covered by a specialised international ABS instrument	Covered by a specialised international ABS instrument
		Non-human	Human
		Obtained as commodities but subsequently subject to R&D	Used as commodities
	Utilisation	R&D on genetic and/or biochemical composition	No such R&D
Personal scope		Natural or legal persons utilising GR	Persons *only* transferring GR or commercialising products based on it
Geographic scope (utilisation)	***R&D …***	Within the EU	*Exclusively* outside of the EU

* To be within the scope, *all* conditions must be fulfilled.
** GR = genetic resource; to be read as also including "traditional knowledge associated with genetic resources", where appropriate.

ABS legislation and regulatory requirements in provider countries might go beyond the scope of the EU ABS Regulation. <u>Users in the EU are expected to respect such national legislation and requirements.</u>

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User obligations

- **Due diligence** (Art. 4): users shall seek, keep and transfer to subsequent users the internationally-recognised certificate of compliance (IRCC) or information and relevant documents on genetic resources (description, date and place of access, source, the presence or absence of ABS rights and obligations, PIC and MAT, where applicable)

- **Due diligence declaration** (Art. 7): at the stage of research funding and at the stage of final development of a product, through DECLARE web tool

Registered collections

- Establishment of a voluntary register of collections maintained by the Commission is foreseen
- Registered collections effectively apply measures in order to supply genetic resources and related information only with documentation providing evidence of legal access and ensuring the establishment of mutually agreed terms, where required
- Users obtaining a genetic resource from a registered collection considered to have exercised due diligence as regards the seeking of necessary information.

Obligations for registered collections

Registered collection or its part (Art. 5) has the capacity to:

(a) apply **standardised procedures for exchanging** samples of genetic resources and related information with other collections, and for **supplying samples** of genetic resources and related information to third persons for their utilisation in line with the Convention and the Nagoya Protocol;

(b) supply genetic resources and related information to third persons for their utilisation **only 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;

(c) **keep records** of all samples of genetic resources and related information supplied to third persons for their utilisation;

(d) establish or use **unique identifiers**, where possible, for samples of genetic resources supplied to third persons; and

(e) use **appropriate tracking**

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Users / Collections / Registered Collections

- **Users** (those who perform research or development): due diligence obligations (to seek, keep and transfer information + submit declarations)
- Holders of **registered collections**: to supply the material only with relevant information demonstrating compliance with ABS rules
- **Collections** (not registered, not performing R&D): EU ABS Regulation does not apply x due diligence as a good practice (reputation, credibility…)

Guidance documents

- Intended to further explain certain aspects of EU legislation + to assist users and national authorities in identifying and meeting due diligence obligations

- Not legally binding

- General **Guidance document on the scope of application and core obligations** of EU ABS Regulation (published 08/2016)

- Sector-specific guidance documents: Cosmetics, Animal Breeding, Plant Breeding, Biocontrol, Pharmaceuticals, Food and Feed, Biotechnologies, Public Research, **Collection Holders** (to be published in 2017/2018).

Implementation in EU MS

MS are obliged to:

- designate one or more competent authorities to be responsible for the application of the EU ABS Regulation;
- consider the inclusion of a collection (upon request), or a part of it, in the register;
- transmit relevant information from due diligence declarations to ABS CH;
- monitor user compliance: carry out checks (plan; risk-based approach);
- lay down rules on penalties and ensure that they are applied.

Implementation in the Czech Republic

- Draft legislation implementing relevant provisions of EU ABS Regulation (approved by Government in 2016, not yet by the Parliament)
- Awareness-raising activities
- CZ does not intend to regulate access to its genetic resources (**no PIC/MAT required**).

Thank you for your attention.

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