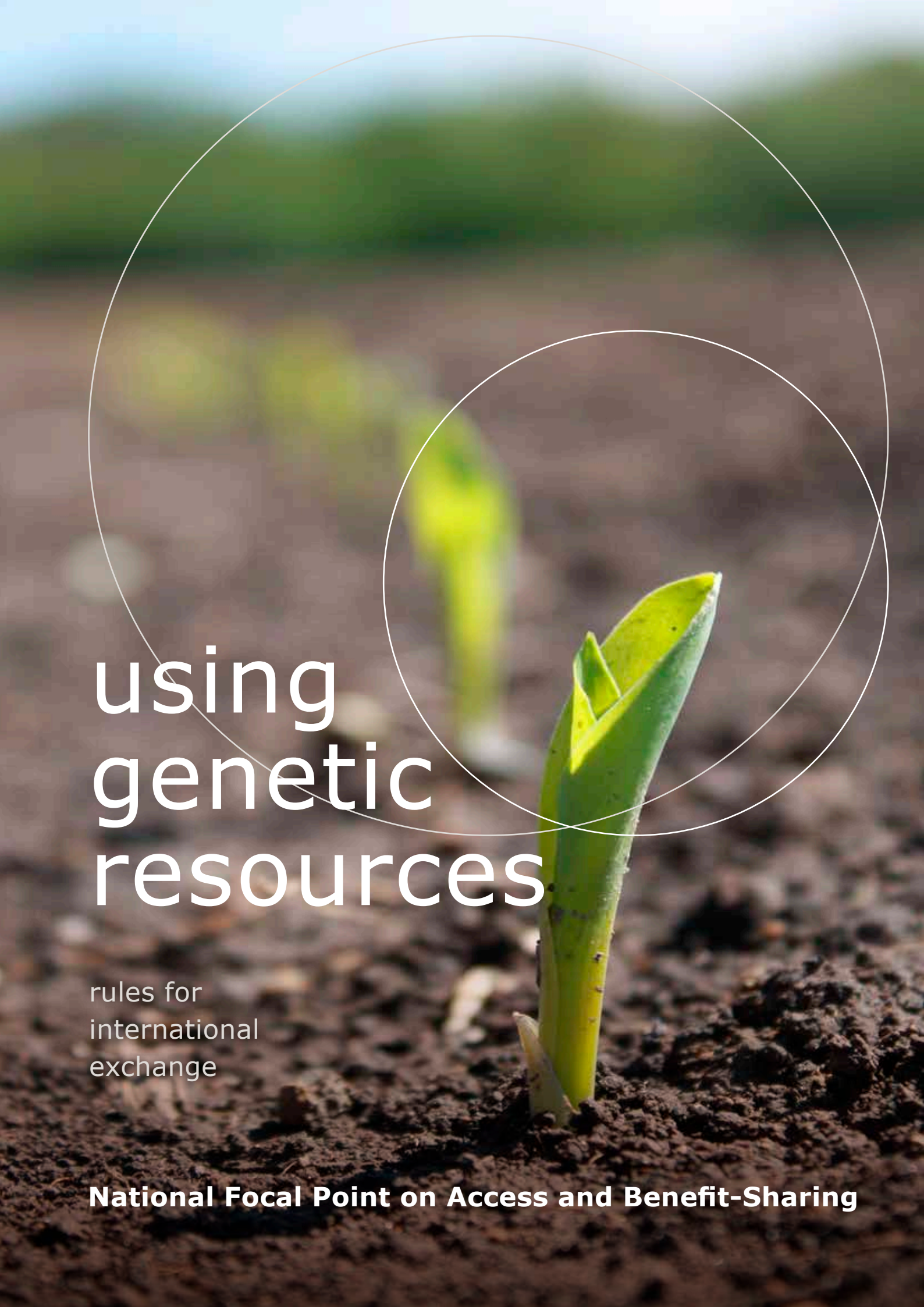
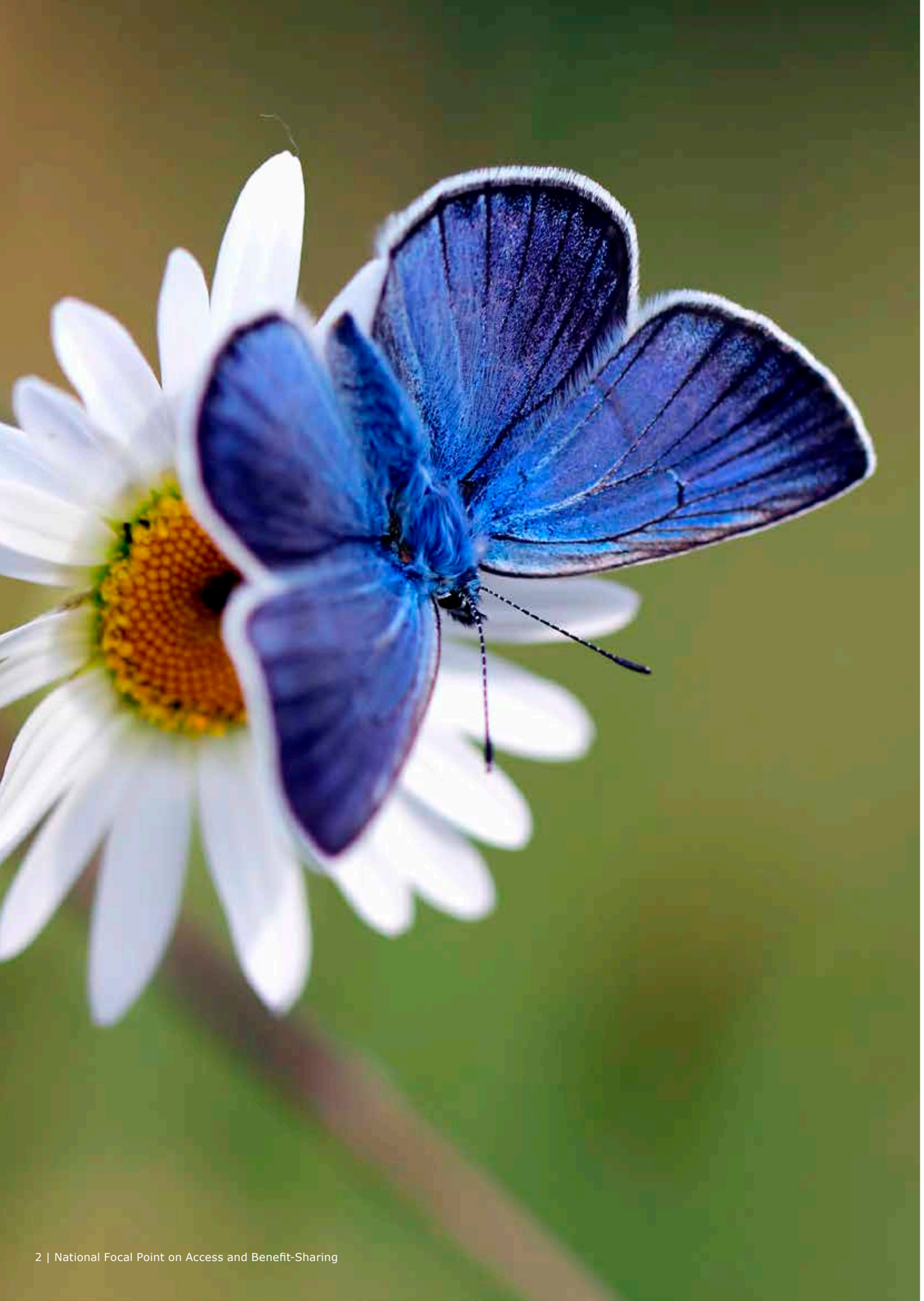


using genetic resources

rules for international exchange

National Focal Point on Access and Benefit-Sharing



access and benefit-sharing

International rules for the exchange and use of genetic resources have been agreed upon, and providers and users are obliged to follow these rules. This folder provides background information on the relevant international agreements, explains various terms that are often used, and provides basic guidance for users seeking access to genetic resources. This folder is relevant for all Dutch public institutes, companies and individuals using genetic resources for research and development.

Until some decades ago, collecting living organisms and taking these across national borders was normal practice and undertaken without any obligations. Seeds and plants were considered public property, and animals could be purchased from their owner for breeding purposes. No restrictions on the use of the genetic material incorporated in such organisms existed.

However, this practice has changed due to an increased awareness that genetic resources may have actual or potential value and the establishment of intellectual property rights on biological products. As a result, countries increasingly assert their rights over these resources.
In this context, the concept of Access and Benefit-Sharing (ABS) has been introduced. ABS refers to the regulation of access to and use of genetic resources and traditional knowledge, and the sharing of benefits stemming from this use between providers and users. It means that nowadays access to plants, animals and micro-organisms cannot be assumed as given, and may not be for free. Access and Benefit-Sharing are two sides of the same coin: benefit-sharing presumes access, and access is allowed under conditions securing benefit-sharing.

More detailed information on rules and practices can be found on the website of the Netherlands Focal Point on Access and Benefit-Sharing:
www.absfocalpoint.nl

international agreements

Access and Benefit-Sharing are regulated by the Convention on Biological Diversity, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, and the International Treaty on Plant Genetic Resources for Food and Agriculture.

The Convention on Biological Diversity (CBD) entered into force in 1993. Its objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The CBD covers all ecosystems, species, and genetic resources, except human genetic resources. The CBD sets general rules to regulate access to genetic resources and their use. It also sets rules for the sharing of benefits between providers and users, stemming from this use.

Article 15 of the CBD states that "… the authority to determine access to genetic resources rests with the national governments and is subject to national legislation …." and that "Access, where granted, shall be on mutually agreed terms" and "subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party." The Contracting Party is the government of the country where the genetic resources occur.

As a supplementary agreement to the CBD, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization was adopted in 2010. The Nagoya Protocol aims to provide a transparent legal framework for access to genetic resources and traditional knowledge, and the fair and equitable sharing of benefits arising out of their utilization.

The Nagoya Protocol rests on three main pillars: measures on access, benefit-sharing, and user compliance. The access pillar leaves it to countries that have adopted the Nagoya Protocol to regulate access or not. If countries decide to regulate access, certain criteria apply. Measures on benefit-sharing should be incorporated in Mutually Agreed Terms. The user compliance pillar obliges all Contracting Parties to the Protocol to ensure that only legally acquired genetic resources and associated traditional knowledge are utilized under their jurisdiction.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which entered into force in 2004, deals specifically with plant genetic resources for food and agriculture (PGRFA). It is a specialised instrument for ABS.
The core of the ITPGRFA is the Multilateral System (MLS), a defined shared pool of genetic resources of many important crops and forages. Genetic resources included in the MLS are available for research, breeding and training for food and agriculture purposes. The benefits arising from their use are to be shared through the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization. Access is provided on the basis of a Standard Material Transfer Agreement (SMTA) with fixed conditions.
If the ITPGRFA applies to a certain genetic resource, the provisions of the Nagoya Protocol are not applicable.

important terms used

Genetic resources and genetic material
'Genetic resources' means genetic material of actual or potential value; 'genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity.

Use/utilisation of genetic resources
'Utilisation of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

Prior Informed Consent (PIC)
The term 'Prior Informed Consent' (PIC) means approval, by the authorities of the country where access is sought, of access to and utilization of genetic resources. Users should always check if a country requires PIC. In the process of obtaining PIC, the Competent National Authority of the providing country must be informed of and approve the planned research. Depending on national legislation in the country concerned, it may also be necessary to involve other stakeholders (e.g. local communities managing farmers' varieties or sharing knowledge on plants with medicinal value) in the PIC process.

Traditional Knowledge
The term 'Traditional Knowledge' means the knowledge associated with genetic resources held or developed by indigenous and local communities (Article 8(j) of the CBD). Traditional knowledge does not have to be old to qualify as traditional. The term traditional refers to the context (society, culture) in which the knowledge was generated.

Mutually Agreed Terms (MAT)
Mutually Agreed Terms (MAT) are usually laid down in a contract between the users and providers of genetic resources. MAT define the conditions governing the use of genetic resources and benefit sharing. MAT are reached between two private parties under civil law contract (even if one of them is a government institution). The term 'Mutually Agreed Terms' indicates that the conditions upon which utilisation of genetic resources is based, should be the result of consensus. MAT may take the form of a Material Transfer Agreement.

Material Transfer Agreement (MTA)
A Material Transfer Agreement (MTA) is a contract between the provider and the recipient specifying the terms and conditions of the transfer. It covers rights and obligations of the provider and the recipient. It also covers how benefits are to be shared. The Standard Material Transfer Agreement of the ITPGRFA is a particular MTA, which is standard for every user.

Certificate of Compliance
An internationally recognized Certificate of Compliance provides legal certainty to the user of a genetic resource on its authorized use. Such a certificate represents a permit issued at the time of access in accordance with the provisions of the Nagoya Protocol. It provides evidence that Prior Informed Consent was granted and that Mutually Agreed Terms were reached.

Competent National Authority (CNA)
The Competent National Authority of a country is responsible for granting access, and advising on applicable procedures and requirements for obtaining Prior Informed Consent and entering into Mutually Agreed Terms.

implementation in the EU

In 2014 the European Union adopted Regulation 511/2014 for the purpose of implementation of the Nagoya Protocol in the EU, applying to all use of genetic resources in the EU. The Regulation includes obligations for users of genetic resources in the EU.

A broad range of actors in the European Union, including academic researchers and companies from different business sectors (for example, plant and animal breeding, bio-control, pharmaceutical, cosmetics, and food and beverage industries) use genetic resources for research and development purposes. Some also use traditional knowledge associated with genetic resources.

The EU Regulation on ABS includes the obligation for all users of genetic resources to exercise due diligence ("show that you did your utmost best to follow the law") to make sure that genetic resources and associated traditional knowledge were legally accessed, i.e. in line with applicable legal requirements, and that benefits are fairly and equitably shared on Mutually Agreed Terms. To that end, all users of a genetic resource will need to seek, keep, and transfer to subsequent users the information relevant for Access and Benefit-Sharing.

The EU Regulation obliges users to declare that they complied with their due diligence obligation. Member States are to check whether users comply with their obligations under this Regulation and to make sure that infringements of this Regulation by users are sanctioned.

Associations of users may apply for recognition of a combination of specific procedures, tools or mechanisms as a 'best practice', in order to achieve compliance with the Nagoya Protocol at an affordable cost and with a high level of legal certainty.

The EU Regulation applies directly to all member states of the EU, and as such to all institutes, companies and citizens. It will not apply to exchanges for which the terms and conditions of the SMTA of the ITPGRFA are utilised.

more information

More information can be found on the website of the Netherlands Focal Point on Access and Benefit-Sharing (www.absfocalpoint.nl). It provides the most recent developments in the field of ABS and the practical consequences for users of genetic resources.

On this website, you will find a list of frequently asked questions and their answers. Topics include:

- Status and scope of CBD, International Treaty and Nagoya Protocol
- Collecting genetic materials and related information abroad
- International transfer of genetic materials
- Access to *ex situ* collections of genetic resources held in the Netherlands
- Access to genetic resources occurring *in situ* in the Netherlands
- Obtaining information on the implementation of the CBD, the International Treaty and the Nagoya Protocol at the national level

basic guidance in seeking access

- **Genetic resources held *ex situ*.** In case of *ex situ* collections, it is important to find out if the collection holder has the right to provide access to the collection. If the authorized official to grant access to the collection is unknown or if you have any doubts, contact the National Focal Point or the Competent National Authority on Access and Benefit-Sharing of the country where the collection is held. The EU Regulation makes it possible to register collections. Users obtaining a genetic resource from a registered collection are considered to have exercised due diligence. Where genetic resources have been placed in the Multilateral System of the ITPGRFA, access is to be provided according to the provisions of the Standard Material Transfer Agreement (SMTA) of the ITPGRFA.

- **Genetic resources found *in situ*.** In case of access sought to materials *in situ*, contact the government (through the National Focal Point or the Competent National Authority on Access and Benefit-Sharing) who will inform you on procedures and conditions of access. If Prior Informed Consent is required, the Competent National Authority is the person to formally grant access, unless he/she has explicitly delegated this task. No legislation has been introduced regulating access to genetic resources occurring under *in situ* conditions in the Netherlands ('free access policy'), but permission for collecting may have to be obtained from the landowner.

- **Local purchases of genetic resources.** In case you acquire unpacked or brown-bagged (non-labelled) seeds, plants or other organisms in local markets, from farmers or from other individuals (including traders) and you intend to use that material for research or development, you should consider these as obtained from *in situ* conditions and check conditions for use with the government. In case you wish to access seeds from a breeding company or seed firm, you may directly contact this company for access conditions.

- **Private sector practices.** Across-border transfer of genetic resources between two locations of an international company or transfer between two subsidiaries of a company should be regarded as international exchange, unless agreed otherwise. If a cross-border transfer implies international exchange, national legislation regarding export of genetic resources might be applicable.

- **Domestic access.** Some countries have exempted national users from fulfilling any further access conditions for in-country use, i.e. in such cases use in the home country does not fall under Access and Benefit-Sharing regulations.

- **Intellectual property rights.** In particular patent rights and plant breeders' rights legislation may set restrictions to further use of certain acquired genetic resources. Please check this for your intended use.

- **Procedures and authorities.** Procedures for obtaining Prior Informed Consent are set by the authorities of the country providing the genetic resources. Enquire with the National Focal Point or the Competent National Authority on Access and Benefit-Sharing of the country for details. You may identify the National Focal Point or the Competent National Authority on Access and Benefit-Sharing of the country through the CBD website (www.cbd.int). It is advised to avoid access in the absence of such information.

national focal point and competent national authority

The role of the National Focal Point on Access and Benefit Sharing is to provide information to potential users and suppliers. The Competent National Authority is responsible for granting access.

In the Netherlands, the following two persons together form the CBD National Focal Point on Access and Benefit Sharing:

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Ms Léontine Crisson also is the Competent National Authority on Access and Benefit-Sharing in the Netherlands.
