



Breeding – Are you using genetic resources?

REMEMBER to use the Nagoya Protocol!



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The exchange of the genetic material of plants is subject to international rules. Users of these resources must comply with the Nagoya Protocol. What does the protocol involve? And how can you ensure you meet all requirements?

There used to be no limitations on the use of genetic material of plants. Until the international awareness rose that such resources could generate knowledge or profits, started to increase. Consequently, more and more countries wanted to assert their rights to genetic resources, the concept of Access and Benefit Sharing (ABS) was introduced. The ABS agreement aims to regulate access and usage of genetic resources (and traditional knowledge) and the sharing of the benefits arising from this utilisation between providers and users.

European regulation

The Nagoya Protocol entered into force on 12 October 2014. The aim of the Nagoya Protocol is to provide a legal framework for access to genetic resources and the sharing of the benefits. All member countries (including the Netherlands) must ensure that in their country, only legally obtained genetic resources (and any associated traditional knowledge) are used.

The European Union adopted an ABS Regulation (Regulation 511/2014) for the implementation of the Nagoya Protocol. This regulation applies to all use of genetic resources within the EU. It includes the obligation for the users of genetic resources to perform due diligence or exercise of care to ensure that the genetic resources (and associated traditional knowledge) were obtained in a legal way.

The EU ABS Regulation applies to all institutions, companies and citizens within the EU. All member states are obliged to check if users comply with the obligations and they must penalise non-compliance.

For the implementation of the European ABS Regulation the Nagoya Protocol Implementation Law was enacted. This law provides further details regarding the implementation, sanctions and designation of competent authorities. The Netherlands Food and Consumer Product Safety Authority (NVWA) is responsible for the supervision of compliance with the law. The law does not contain any rules regarding access to genetic resources from the Netherlands, though.

When do these rules apply to your business?

The rules apply, if all the following conditions are met:

- the genetic resources are accessed on or after 12 October 2014;
- the genetic resources originate from countries that are parties to the Nagoya Protocol and have established ABS legislation or regulatory requirements;
- access and benefit-sharing of the genetic resources are not governed by any other, specialised international instrument;
- the genetic resources are used for research and development on their genetic and/or biochemical composition;
- the utilisation is within the EU.

What does 'utilisation' mean?

The utilisation of genetic resources means: research and development on the genetic and/or biochemical composition of the genetic resources. However, the precise interpretation of the concept of 'utilisation' is still under discussion within the EU. The EU did publish a guidance document, which outlines in more detail what should be considered 'utilisation' or not.

If you collect, propagate and sell seed or other plant materials without doing any further selection and/or breeding, you are in principle not subject to the European ABS Regulation. However, if you do select on a specific property and/or use the material in a breeding programme, you are subject to the regulation. It is still unclear to what extent the use of commercial plant varieties are subject to the Nagoya Protocol.

Besides, it should be noted that the interpretation in a supplying country might be different from the EU's. Even if your activities are not subject to the EU ABS Regulation, you are expected to adhere to the laws and regulations of the country of origin.

What must you do, if your activities are subject to the Nagoya Protocol?

- Check the access rules of the country you obtained the genetic resources from (for example via the ABS Clearing House website <https://absch.cbd.int/>) or the National Focal Point of the supplying country);
- If necessary: obtain permission (Prior Informed Consent; PIC) of the Competent National Authority (CNA) of the supplying country;
- Negotiate the terms and conditions with your supplier and record them in a contract (Mutually Agreed Terms; MAT).
- Use the genetic resources only in accordance with the terms and conditions agreed with the supplier;
- Document your usage carefully;
- Keep all documentation up to 20 years after you have ended the usage;
- If you receive research funding or if you launch a product on the market, submit a declaration of due diligence (via webgate.ec.europa.eu/declare/);
- Transfer information to any subsequent users of the genetic material.

Increased awareness of value genetic resources

Some plants, animals, bacteria and fungi have interesting properties, which can be used for medicines, cosmetics and in agriculture, for example. Research and development of these so-called genetic resources (defined as 'any material of plants, animals, microbial or other origins containing functional units of heredity and of actual or potential value') can generate knowledge or profit. For example, when a plant becomes the basis for a successful drug.

Until a few decades ago, collecting genetic resources and taking them across the



border was completely normal and not subject to any obligations at all. There were no limitations on the use of the genetic properties of such organisms. However, when people became more aware of the actual or potential value of genetic resources, this all changed.



Would you like more information?

Are you a user of genetic materials subject to the obligations of the EU ABS Regulation, or do you think you might be? Please find more information on the website of the Dutch ABS Focal Point: absfocalpoint.nl/nl. Or contact the Focal Point via email: NagoyaNL@wur.nl. The Focal Point is hosted by the Centre for Genetic Resources the Netherlands (CGN), which is part of Wageningen University & Research.

The ABS Clearing House site: absch.cbd.int provides information on which countries that are parties to the Nagoya Protocol and the rules and regulations of these countries. Contact details of the authorities for each country can also be found on this site.



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