



ACCESS AND RIGHTS TO GENETIC RESOURCES

A Nordic Approach (II)

**ACCESS AND RIGHTS TO
GENETIC RESOURCES:
A Nordic Approach (II)**

ISBN 978-91-986029-1-3 (Print)

ISBN 978-91-986029-2-0 (PDF)

© NordGen (2023)

Layout: Fia Djerf

Tryckeri: Exakta Print AB

Printed in Sweden



The Nordic Council of Ministers

The Nordic Council of Ministers is the official body for inter-governmental co-operation in the Nordic Region. It seeks Nordic solutions wherever and whenever the countries can achieve more together than by working on their own.

www.norden.org

The Nordic Genetic Resource Centre (NordGen)

NordGen is the Nordic countries' genebank and knowledge center for genetic resources. Its mission is to conserve and promote a sustainable use of genetic resources important for food and agriculture in the Nordic countries.

www.nordgen.org

ACCESS AND RIGHTS TO GENETIC RESOURCES

A Nordic Approach (II)

FOREWORD

Lise Lykke Steffensen

Chair of the Project Group

Executive Director, NordGen

This report is an update of the previous report from 2003 "Access and Rights to Genetic Resources: A Nordic Approach". It includes a set of new recommendations on access to and benefit sharing on the use of genetic resources for agricultural and horticultural plants, farm animals, domesticated and wild fish species, wild animals and plants, forest and microbials.

In 1397, the Kalmar Union was established. For more than 200 years, the union formed the largest gathered political domain in the history of the Nordic countries and constituted a joint Nordic view on many world matters. 480 years after the union's dissolution, in 2003, the historic Kalmar Castle was still proudly overlooking the signing of the Nordic Ministerial Declaration of Access and Rights to Genetic Resources. This declaration, more commonly called the Kalmar Declaration, was based on the predecessor to this report and a common view on access and rights to genetic resources in a Nordic perspective.

The Nordic countries today face entirely different challenges than the Kalmar Union did. The climate and biodiversity crises are currently some of the world's most pressing challenges and concrete threats to human life on earth. As biodiversity is lost at unprecedented speed, many genetic resources are also threatened – resources which are essential for human life on earth and provide us with food to eat, medicine when we are sick, clothes to keep us warm and building materials for protection. Genetic resources are valuable biological infrastructure. This is also the reason why facilitated access and rights to genetic material is not only a matter for the Nordic countries but for the whole world.

The Nordic countries have a very long history of collaboration and the collaboration on genetic resources is a remarkably good example of the value added when deciding on a common approach. The Kalmar Declaration of 2003 shared a unique, joint Nordic view on access to and sharing of genetic resources and how to manage access and benefit sharing at the common Nordic genebank.

The words in the Kalmar Declaration are now exactly 20 years old and we can see that the world has changed over these past decades. In this updated version of "Access and Rights to Genetic Resources: A Nordic Approach", several new issues are addressed such as for example the digitalization of genetic information and new international agreements such as the Nagoya Protocol and the implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture. This report also includes information on genetic resources of aquatic, wild and microorganisms in addition to genetic resources for agriculture, horticulture, and forestry.

I would like to thank the project group for its dedication to obtain the goals of the project. A special thanks to Christian Prip for accepting the challenge of being the Secretary of this project and for the great involvement in this report. It has been a pleasure to chair this Group. We have had fun, been challenged, and learned, and inspired each other over the past two years. As we worked through the different chapters, the commitment and the curiosity grew just larger.

I hope this report will enrich and inspire anyone with an interest into access and rights to genetic resources.

THE PROJECT REFERENCE GROUP

Consisting of national experts within different sectors:

Name	Country	Sector
Birgitte Lund	Denmark	Agriculture
Tuula Pehu (replaced during the project period by Kirsi Heinonen)	Finland	Agriculture
Svanhild-Isabelle Batta Torheim	Norway	Agriculture
Jens Weibull	Sweden	Agriculture
Eva Juul Jensen	Denmark	Environment
Agnes Stefánsdóttir	Iceland	Environment
Birthe Ivars	Norway	Environment
Mari Rusanen	Finland	Forestry
Helge Paulsen (replaced during the project period by Katrin Vilhelm Poulsen)	Denmark	Fisheries
Birgitte Jacobsen	Greenland	Fisheries
Lise Lykke Steffensen	NordGen	Chair
Christian Prip	The Fridtjof Nansen Institute	Secretary

CONTENTS

9	Summary and recommendations
15	1. Introduction
23	2. Specific features of genetic resources and their use
24	2.1. Plant genetic resources for food and agriculture
25	2.2. Animal genetic resources for food and agriculture
26	2.3. Forest genetic resources
26	2.4. Aquatic genetic resources
27	2.5. Wild genetic resources
29	3. Developments on access to genetic resources and benefit-sharing (ABS) from their use and related issues in international forums
29	3.1. The Convention on Biological Diversity and the Nagoya Protocol
35	3.2. The International Plant Treaty on Genetic Resources for Food and Agriculture (the International Plant Treaty)
39	3.3. FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)
39	3.4. New treaty on the way on the conservation and sustainable use of biodiversity in marine areas beyond national jurisdiction.
41	3.5. Intellectual property rights
44	3.6. Summing-up
47	4. Access and rights to genetic resources in the Nordic countries
47	4.1. Legal status of genetic resources in the Nordic countries
51	4.2. Legal or other measures to regulate access to genetic resources of users outside the country
51	4.3. Status on regulation of access
52	4.4. Registration of the collection of wild genetic resources
52	4.5. Legal or other measures to compel users of genetic resources to comply with the access and benefit-sharing regulations in the country providing the genetic resources
56	4.6. Legal or other measures to support that traditional knowledge associated with genetic resources held by indigenous peoples and local communities has been accessed with their approval and involvement

58	4.7. Legal or other measures to implement the International Treaty on Plant Genetic Resources for Food and Agriculture
60	4.8. Summing-up
63	5. Digital workshops on practices and experiences with the exchange of genetic resources
67	5.1. Summing-up
69	6. Access and rights to genetic resources held by the Nordic Genetic Resource Center (NordGen)
69	6.1. What is NordGen?
72	6.2. The Kalmar Declaration and NordGen
76	6.3. Material in transition
76	6.4. Faroe Islands and Greenland
76	6.5. NordGen and national access regulation
77	6.6. NordGen and a possible enhanced MLS of the International Plant Treaty
77	6.7. NordGen and Digital Sequence Information (DSI)
77	6.8. Summing-up

Plant Genetic Resources



Animal Genetic Resources



Forest Genetic Resources



Aquatic Genetic Resources



Wild Genetic Resources



International Forums



Access & Rights to Genetic Resources



SUMMARY & RECOMMENDATIONS

Genetic resources are essential for a significant part of the world's economic activity. They are the basis for agricultural and food production, including the improvement of agricultural crops, for bio-based solutions, and for the development of traditional medicines on which most of the world's population still depend. They are used for a very wide variety of purposes, ranging from basic research to the development of products in sectors such as the pharmaceutical industry, agriculture, horticulture, cosmetics, energy, and biotechnology. In order to utilise genetic resources, access to those resources is fundamental. Given the different opportunities to utilise genetic resources internationally, there is international agreements that the benefits resulting from the utilisation of genetic resources should be shared. Consequently, access and benefit-sharing have become an important part of the management of genetic resources.

Since the adoption of the Nordic Ministerial Declaration on Access and Rights to Genetic Resources (the Kalmar Declaration) in 2003 and the completion of the first Nordic project on this matter, several new and relevant international developments have occurred. This has created a need for renewed awareness and an update of the Nordic approach to access and rights to genetic resources. In 2010 the [Nagoya Protocol on Access and Benefit-sharing](#) (NP) was adopted under the Convention on Biological Diversity (CBD) and it entered into force in 2014. The Protocol reinforces the rights and obligations on access and benefit-sharing (ABS) under the CBD and expands on the legal requirements. Among other things, it establishes "user measures" – obligations for parties to take measures to ensure that genetic resources used within their jurisdiction have been accessed in accordance with the access requirements of the providing country. In addition, it includes obligations for

countries to ensure that traditional knowledge associated with genetic resources held by indigenous peoples and local communities has been accessed with their prior informed consent and on mutually agreed terms. In December 2022, the Contracting Parties of CBD adopted the Kunming-Montreal Global Biodiversity Framework, with new international goals and targets on biodiversity, including on access and benefit-sharing. Another international development was the entry into force of the [International Treaty for Plant Genetic Resources for Food and Agriculture](#) (the International Plant Treaty) and the development of the modalities of its Multilateral System for Access and Benefit-sharing (MLS). The International Plant Treaty was adopted prior to the Kalmar Declaration and so constituted one of the bases for the Kalmar Declaration even though the details of the MLS were not yet finalised at the time.

The Commission on Genetic Resources for Food and Agriculture in FAO has developed [Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture](#).

Moreover, access and rights to genetic resources is a determining element in the negotiations on an [international legally binding instrument under UNCLOS on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction](#) (BBNJ).

In recent years, it has been increasingly discussed whether the ABS legal framework in its current form is suited to delivering its objectives of facilitated access to genetic resources and the fair and equitable sharing of benefits from their use. The original ABS framework of the CBD presumes that providers and users negotiate agreements and exchange physical material with clear provenance, ownership, and

value, and that this material can be tracked through the research process, culminating in something of value. However, access to genetic resources is often not limited to one provider and one user but includes many steps and intermediaries in a value chain.

Reinforcing this discussion is the fact that genetic material can now be digitally sequenced and data exchanged rapidly between researchers, institutions, and countries. This has led to reduced demand for physical genetic material in some areas of use.¹ While it is generally acknowledged that the use of Digital Sequence Information (DSI)² is important for research and development, the question on how to address the sharing of benefits arising from the use of DSI has been the subject of difficult discussions up to COP15 of the CBD in December 2022. There it was agreed to establish a multilateral mechanism for benefit-sharing from the use of DSI on genetic resources, including a global fund, and a process to further develop and operationalize the mechanism to be finalized at COP 16 in 2024.³

Although the MLS for access and benefit-sharing under the International Plant Treaty has delivered major achievements in terms of facilitating the exchange of plant genetic resources of food and agriculture (PGRFA) and the implementation of four project cycles of the Benefit-sharing Fund, its impact in terms of generating monetary benefit-sharing has been more muted. The lengthy time-period required for research, development, and commercialisation and the fact that mandatory monetary benefits are only triggered by patents, partly explain the current low level of user-based monetary benefits generated by the standard Material Transfer Agreement (SMTA). Consequently, a subscription system linking payment obligations to access rather than commercialisation, and where users pay a fee for being granted access to all, or a select number of PGRFA within the MLS, has long been on the International Plant Treaty agenda. An agreement was almost reached in 2019, but negotiations failed. In September 2022, it was agreed to continue this process again.

The interrelation between the ABS regime and regimes on intellectual property rights (IPR) has been a complex and ongoing issue which was also addressed as part of the first Nordic project on access and rights. Many of the controversial issues still need to be addressed.

The Nordic countries have taken different approaches on the national regulation of access and benefit-sharing in line with the main rule of the international framework. The Kalmar Declaration therefore recommended initial steps to be taken as a basis for further consideration on the need for access regulation. These include determining the legal status of genetic resources (both wild and domestic) and the use of a simple system for registering collections of wild genetic resources. While Greenland and Norway have taken further steps toward ABS regulation, only Greenland has introduced access and benefit-sharing legislation with prior informed consent and mutually agreed terms. Norway's Nature Diversity Act states that such regulation could be introduced in respect of wild genetic resources, however this authorisation has yet to be used. Sweden and Denmark have officially declared that they do not intend to regulate access to domestic genetic resources.

The Kalmar Declaration recommended that the Nordic countries, as users of genetic resources, take measures in support of compliance with access legislation in providing countries. Such measures have been enacted by Norway and Denmark, as well as by the EU to which Finland, Sweden and Denmark are bound.

1. Scholz, A. H., Freitag, J., Lyal, C. H., Sara, R., Cepeda, M. L., Cancio, I., ... & Overmann, J. (2022). Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation. *Nature Communications*, 13 (1), 1–5.

2. "Digital Sequence Information" (DSI) is widely acknowledged as a placeholder term for which no consensus on a replacement or precise definition exists to-date. At the ninth meeting of its Governing Body in 2002, the International Treaty on Plant Genetic Resources for Food and Agriculture decided to use the term "Digital Sequence Information / Genetic Sequence Data" (DSI/ GSD) until new terminology is agreed. Resolution 16/2022 – Consideration of Digital Sequence Information / Genetic Sequence Data on Genetic Resources for the Objectives of the International Treaty.

3. CBD/COP/DEC/15/9. Digital sequence information on genetic resources

As regards access to and benefits arising from the use of genetic resources and associated traditional knowledge held by indigenous peoples and local communities (ILCs), Norway and Finland have enacted legislation that requires prior informed consent (PIC) from using traditional knowledge from ILCs.

On the implementation of the FAO International Plant Treaty, the Kalmar Declaration mainly addressed the role of the Nordic Gene Bank (now NordGen). Regarding the exchange of genetic resources, the Nordic countries have made no distinction between Annex 1 and non-Annex 1 taxa thereby following a Kalmar Declaration recommendation to facilitate access to PGRFA in general.

A series of thematic workshops on animal, plant, aquatic, forest, and wild genetic resources that took place in the first half of 2021 as part of this project, indicated that cross-border exchanges are widely taking place and is considered a benefit in itself. The flow of genetic resources is occurring mainly within the Nordic countries or between countries with similar climatic conditions. Furthermore, the workshops revealed that the level of knowledge of the ABS framework is generally low among practitioners, and that it has relatively little practical implication on exchanges of genetic resources involving the Nordic countries. This does not imply that cross-border exchanges of genetic resources are free from procedures and restrictions. However, these are mainly in the form of private legal contracts and import restrictions for the sake of human, plant, and animal health. These are often seen as bureaucratic and burdensome in themselves. Consequently, an additional layer of ABS regulation by many practitioners will be considered an additional burden.

The Kalmar Declaration devoted most attention to clarifying how NordGen should manage shared Nordic plant genetic resources when implementing the International Plant Treaty and its MLS. The Nordic countries, by signing up to the Kalmar Declaration, declared that they have exercised their sovereign rights in respect of the collected material by applying a joint approach and by entrusting the responsibility for the management and control of the material to NordGen. This has been achieved by placing the large NordGen collection of plant genetic resources – of Annex I as well as non-Annex 1 material – in the Nordic public domain, making it available through the International Plant Treaty's SMTA, and over the

years distributing an increasing amount of material to plant breeders, researchers, museums, botanical gardens, NGOs, and private users with a specific interest in saving old or rare varieties. From 2018 to 2020, NordGen witnessed a considerable increase (+89 %) in the number of requested seed samples. Seeds are primarily requested by Nordic and other European countries.

The distinction made by the Kalmar Declaration between plant genetic resources for food and agriculture and for other purposes has so far not been relevant for NordGen since, in practice, all its distributed accessions are used for food and agriculture.

Due to the special circumstances of the Faroe Islands and Greenland, being outside of both the International Plant Treaty and its MLS and the Nagoya Protocol, (but with Greenland having introduced access regulation) there is a need for agreements with the Faroe Islands and Greenland on the legal status and terms for access for NordGen accessions collected there. Preferably, their status should be the same as for other NordGen accessions.

By undertaking its many functions as the Nordic countries' joint gene bank and knowledge centre for genetic resources for food and agriculture, NordGen has played a crucial role in the follow-up of the Kalmar Declaration and international commitments.

Recommendations

THE NORDIC COUNTRIES SHOULD:

acknowledge the importance of the conservation and sustainable use of genetic resources and the fair and equitable sharing of benefits from their use in the implementation of the UN Sustainable Development Goals, in particular goals 2 and 15.

accommodate for the specific characteristics of genetic resources for food and agriculture when updating their national biodiversity strategies or action plans (NBSAPs) as part of implementing the Kunming-Montreal Global Biodiversity Framework

facilitate access to all genetic resources for food and agriculture and associated information.

support Nordic users of genetic resources from other countries in complying with the access regulations of these countries.

regularly review the experiences with domestic legal obligations on Nordic users of genetic resources from other countries.

raise awareness on the rights of indigenous peoples and local communities holding traditional knowledge associated with genetic resources.

encourage holders of private collections to include their material in the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

contribute to the Benefit-sharing Fund of the ITPGRFA through annual contributions based on seed sales and/or contributions through funds for development co-operation.

encourage the food processing industry to also contribute.

conduct a Nordic study on the status and possible trends of patenting of GRFA, plant and farm animal breeding, and related techniques of relevance for the Nordic countries.

engage actively in Nordic, European, and international collaboration on access and rights to genetic resources.

recognise that the Nordic countries have taken different approaches on the need to determine the legal status of wild genetic resources, register their collections, and regulate access.

recognise that the Nordic countries have taken different approaches to implementing farmers' rights as laid down in the ITPGRFA.

improve knowledge on the conservation and sustainable use of aquatic genetic resources and associated issues on access and rights to such genetic resources – this applies both to wild and domesticated aquatic genetic resources and their interrelationship.

improve knowledge on the conservation and sustainable use of genetic resources from invertebrates and micro-organisms and associated issues on access and rights to such genetic resources.

continue to collaborate at the Nordic level in exchanging experiences on access and rights to genetic resources and establish a permanent network for information sharing and/or joint Nordic projects.

NORDGEN SHOULD:

ensure that all seed accessions at NordGen, except for security collections held by NordGen for other gene banks, are under common Nordic management and in the public domain.

serve as an important Nordic institution for the implementation of the ITPGRFA – relevant material administered by NordGen shall be part of the MLS for plant genetic resources under the ITPGRFA.

continue to provide facilitated access to all its plant genetic accessions not only for food and agriculture but for all purposes and for all users.

make accessions available through one type of agreement, the SMTA of the International Plant Treaty, regardless of whether these are covered by the MLS of the treaty.

when handing over plant genetic material, require the recipient, in accordance with Article 12.3 (d) of the ITPGRFA, not to claim any intellectual property rights or other rights, which limit the simplified access to PGRFA, or to their genetic parts or components, and which pertain to the genetic material in the form in which it is received.

seek a formal agreement with the competent Faroese and Greenlandic authorities on how seed accessions from the Faroe Islands and Greenland are acquired, managed, and distributed by NordGen, and preferably under the same conditions that apply to NordGen's other accessions.

encourage the donors of "material in transition" to make this publicly available, as appropriate, and include it in the MLS of the ITPGRFA.

expand the documentation and use of genomic sequence information of plant genetic material in NordGen with free and open access.

support the granting of free and open access for crop wild relatives that are collected, donated to, and managed by NordGen, and continue to provide this plant genetic material in the public domain.

ensure that the legal ownership of farm animal genetic resources remains with the national owner in cases where NordGen conserves animal genetic resources at its premises – access shall be in agreement with the relevant national entity.

ensure that the legal ownership of forest tree genetic resources stored at NordGen remains with the national owner – if these resources shall be under the management of NordGen, it should preferably be under the same conditions that apply to NordGen's other seed accessions.

continue to facilitate Nordic collaboration on genetic resources within its given mandate.

improve communication and the raising of awareness on access and rights to genetic resources in the Nordic Region.

1. INTRODUCTION

1. INTRODUCTION

Genetic resources are one component of biodiversity. They provide essential ecosystem services, are a basis for all food production, and are crucial to research. The UN Convention on Biological Diversity (CBD), is the overarching legal framework for safeguarding genetic resources, supplemented by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA). The objectives of the legal framework are not only conservation and sustainable use, but also the equitable and fair sharing of the benefits resulting from the utilisation of genetic resources. It is stipulated that States have sovereign rights over their genetic resources and are entitled to a share of the benefits generated when citizens or companies of other States collect and exploit genetic resources within their jurisdiction for the research and development of, for example, pharmaceuticals, cosmetics, and plant and livestock breeding. Although establishing rules for a more just and equitable sharing of benefits was seen as an important aim in itself, it was also thought to create an additional incentive for the conservation and sustainable exploitation of biodiversity.

More than 50 years of Nordic co-operation on genetic resources and the comprehensive development of international law in relation to genetic resources served as the background to the Kalmar Declaration adopted in 2003 by the Nordic Council of Ministers for Fisheries, Aquaculture, Agriculture, Food and Forestry⁴ (Box 1). The Declaration built on the Nordic project *Access and Rights to Genetic Resources: A Nordic Approach*.⁵ The Kalmar Declaration established basic principles for the management of genetic resources in the Nordic countries and the Nordic Gene Bank (now NordGen), and provides recommendations on national and Nordic implementation of the international obligations.

The reasoning behind the Declaration is rapid developments in the field of international law and national regulations governing access and rights to genetic resources which do away with the principles of genetic resources as being part of human common heritage and being freely exploitable. This is combined with advances in modern biotechnology, which facilitate the dynamic development of crop, fish, and livestock breeding. The increased legal protection of biotechnological developments through various forms of intellectual property rights is also highlighted. It is claimed that there is a discrepancy between the active role and leading positions of the Nordic countries in terms of developing international law in this field and the low priority given to the issue of access and rights to genetic resources on a national level.

Moreover, the Declaration highlights that the Nordic countries need to introduce measures promoting the implementation of recent international regulations in the field, "above all, making it easier for the developing countries to implement the new conventions". It was envisaged that the Declaration would serve as inspiration for activities in other countries and regions regarding this issue.

4. [Nordic Council of Ministers' \(2003\) Ministerial Declaration on Access and Rights to Genetic Resources. \(Kalmar Declaration\) In Swedish.](#)

5. Nordic Council of Ministers' project report (2003). *Access and Rights to Genetic Resources: A Nordic Approach*.

In the introductory text, Norway is highlighted as being the only Nordic country to have started legal work on access and rights. This exposes an important divergence of opinions between the Nordic countries reflected in the Declaration – at an early stage, Norway saw a need for regulating access to wild genetic resources whereas other Nordic countries did not. For this reason, no clear recommendation in the Declaration could be made on this issue.

The Kalmar Declaration

The Nordic Council of Ministers responsible for fisheries, agriculture, forestry, food and environment have agreed upon the following declarations and recommendations, on the basis of their discussions at the ministers' meetings on 24–26 June and 28 October 2003.

The NORDIC COUNCIL OF MINISTERS

- 1.** notes with satisfaction the result of the Nordic Genetic Resources Council's project on rights to genetic resources, which is presented in the report Access and Rights to Genetic Resources – A Nordic Approach;
- 2.** refers to its conclusions from the ministers' meetings in August 2002, especially regarding the importance of fully implementing the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the follow-up of the "Strategy for sustainable development – new bearings for the Nordic countries" and the "Strategy for conservation of genetic resources in the Nordic Region 2001–2004";
- 3.** also refers to its conclusions from the same meeting, stating that genetic resources, with the exception of security collections held or administered by the Nordic Gene Bank (NGB), are to be regarded as a common Nordic resource, which is freely accessible, and which is subject to public administration and control, under the condition that no legal restraints exist;

4. underlines the importance of genetic resources for sustainable development, and that the efforts aimed at the conservation and sustainable utilization of genetic resources in the Nordic countries are given higher priority;

Plant genetic resources in the Nordic Gene Bank

The NORDIC COUNCIL OF MINISTERS

Declares that

5. all accessions of the Nordic Gene bank, except for security collections held by NGB for other gene banks, are under common Nordic management and in the public domain;

6. relevant material administered by the Nordic Gene Bank shall be part of the multilateral system for plant genetic resources under ITPGRFA following the agreement's ratification by all Nordic countries;

Emphasises that

7. the following recommendations shall be seen in relation to the negotiations on the implementation of ITPGRFA, especially the negotiations on a mutual standard agreement for the transfer of genetic material (Material Transfer Agreement – MTA). The results of the ITPGRFA negotiations can affect to what extent the recommendations of the Council of Ministers can be followed up. Recommends that

8. the respective Nordic governments should confirm the above-mentioned declarations by passing necessary resolutions or in other ways;

9. the Board of the Nordic Gene Bank should initiate the measures necessary for implementing the Nordic governments' confirmation of the above-mentioned declarations;

10. the Nordic Gene Bank should provide access to all its accessions on equal terms, regardless of whether they are covered by the scope of the multilateral system of the ITPGRFA or not. The terms should be set out in a standard Material Transfer Agreement (MTA);

11. the Board of the Nordic Gene Bank should consider the use of the provisional MTA, which now is used by international agricultural research centres, until the standard MTA for use in the multilateral system for simplified access and benefit-sharing is approved by IT-PGRFA's steering committee;

12. the Nordic Gene Bank should closely follow the negotiations on the above-mentioned standard MTA under ITPGRFA, and, if the need arises, approve a separate MTA in accordance with the current principles and terms for gaining access to the Nordic Gene Bank's genetic resources;

13. access should be facilitated to all its accessions for all purposes, not only for use in the fields of food and agriculture;

14. the Nordic Gene Bank requires, when handing over genetic material, that the recipient, in accordance with Article 12.3 (d) in ITPGRFA, should not have any intellectual property rights or other rights, which limit the simplified access to plant genetic resources for the food and agricultural sector, or to their genetic parts or components, and which pertain to the genetic material in the form in which it is received from the multilateral system;

15. the Nordic Gene Bank should not claim any monetary benefits in the case of commercialisation of the material withdrawn from NGB's accessions;

16. the Nordic Gene Bank should make it clear upon receiving genetic material that its inclusion in NGB's accessions entails that the material will be subject to common Nordic management and form part of the public domain;

Other domesticated plant genetic resources in the Nordic countries

The NORDIC COUNCIL OF MINISTERS

Recommends that

17. the Nordic countries determine the legal status of their plant genetic resources and their wild relatives, and thus consider the following options:

to declare that the rights to use genetic resources follow the rights to use the biological resources;

to specify that rights to use biological material include rights to restrict others from utilizing the genetic material except on terms mutually agreed upon in private contractual agreements;

to specify that rights to use genetic resources are separate from ownership over biological resources and that such rights can only be exercised through the use of intellectual property rights. This entails that in case access to genetic resources remains unregulated, the holders of biological resources cannot exercise any control over genetic resources.

18. the Nordic countries, as far as possible, handle the access to all domesticated plant genetic resources in the same manner, with the aim of facilitating free access to such genetic resources in the Nordic countries;

Farm animal genetic resources in the Nordic countries

The NORDIC COUNCIL OF MINISTERS

19. ascertains that farm animal genetic resources presently are regulated by private contractual agreements, and has therefore not identified any reasons to recommend any change of the present legal status or regulation of access;

Forest tree genetic resources

The NORDIC COUNCIL OF MINISTERS

Recommends that

20. the Nordic countries initiate a project with the aim of providing a basis for the Nordic countries' decision regarding the legal status of their forest

tree genetic resources, but has not identified any reasons to recommend regulation of access;

Wild genetic resources

The NORDIC COUNCIL OF MINISTERS

Recommends that

21. the Nordic countries establish the legal status of their wild genetic resources;

Ascertains that

22. the Nordic countries have divergent opinions regarding the need for regulating access to wild genetic resources and that the issue is under debate in some of the Nordic countries. For this reason, no recommendation can be made on this issue;

Recommends that

23. the Nordic countries consider the need to provide an overview of the benefits of wild genetic resources, e.g., in the form of a simple system for registering the collection of wild genetic resources in order to increase the knowledge and awareness of these genetic resources and their protection.

Measures for improved implementation of international agreements in the field of genetic resources

The NORDIC COUNCIL OF MINISTERS

Recommends that

24. the Nordic countries facilitate the implementation of international arrangements and agreements in the field of genetic resources by implementing the Bonn guidelines regarding access to genetic resources and benefit sharing adopted by the Conference of the Parties to the Convention on Biological Diversity, including that they as users of genetic resources take steps to help the providing countries comply with access legislation, as well as by designating a national coordinator for the exchange of information about genetic resources;

25. the Nordic Genetic Resources Council initiates appropriate measures for disseminating information and knowledge about the international agreements and arrangements in the field of genetic resources.

Since the adoption of the Kalmar Declaration in 2003, several new and relevant developments have occurred, including:

- The International Treaty on Plant Genetic Resources for Food and Agriculture (the International Plant Treaty or the ITPGRFA) entered into force in 2004 followed by the adoption of standard Material Transfer Agreement (SMTA) of the International Plant Treaty in 2006 as a global gene pool of plant genetic resources which can be shared equally on the terms of the SMTA.
- The Nordic Genetic Resource Center (NordGen) was established in 2008 as a merger between the Nordic Gene Bank, the Nordic Gene Bank for Farm Animals, and the Nordic Council for Forest Reproductive Material.
- The Nagoya Protocol was adopted in 2010 as a supplementary agreement under the Convention on Biological Diversity (CBD) with expanded and more detailed provisions to regulate access to genetic resources and benefit -sharing. The Protocol entered into force in 2014.
- CBD has adopted the Kunming-Montreal Global Biodiversity framework with goals and targets on access and benefit-sharing.
- FAO has developed guidance to countries on how to adapt the implementation of the Nagoya Protocol given the specific characteristics of genetic resources for food and agriculture.
- Negotiations for a global Treaty on Biodiversity in Marine Areas beyond National Jurisdiction under the Convention on the Law of the Sea were initiated in 2017 and are still ongoing at the time of writing. An important part of this Treaty will be the regulation of access to genetic resources in these areas and benefit -sharing from their use. Marine areas beyond national jurisdiction make up half of Earth's surface.

In recent years, there has been extensive technological and scientific development in relation to the extraction of the properties of genetic resources without having to retrieve them in the wild or from gene banks. Genes can be mapped, and the information stored digitally in data banks from where DNA sequences can be exploited. This technology, referred to as Digital Sequence Information (DSI) as a placeholder in the absence of an internationally agreed definition, has created a lack of clarity and disagreements as to whether the legal framework for access and benefit-sharing relating to genetic resources is applicable and, if so, how to apply it in relation to DSI. A major breakthrough for a common understanding on the issue was reached at COP15 of CBD in December 2022.

These and other developments since 2003 have created a need for an update of the Nordic approach to access and rights to genetic resources. Consequently, a new project, *Access and Rights to Genetic Resources: a Nordic Approach (II)* was approved by the relevant constellations of the Nordic Council of Ministers in 2019 and 2020. The project began in August 2020 with the following objectives:

- Assess and analyse the latest international events and processes in relation to plant, forest, animal, aquatic, and wild genetic resources and their possible implications for the management of the different types of genetic resources in the Nordic countries.

- Assess and analyse national regulations in the Nordic countries for access and rights to genetic resources 15 years after the conclusion of the Nordic project "Nordic Approach to Access and Rights to Genetic Resources".
- Discuss possible scenarios for changes to the multilateral system, the SMTA and access scenarios under the International Plant Treaty and their implications for NordGen.
- In light of the above, come up with recommendations for the Nordic countries and NordGen on approaches in international forums and on the future management and determination of rights and access to Nordic genetic resources.
- Raise awareness in the Nordic countries of the different types of genetic resources, access and rights to them, and their importance for society.
- Raise awareness of NordGen in the Nordic countries.

From the start, it was understood that the project should aim to improve visibility of a Nordic approach to genetic resources outside the Nordic Region by being present and organising side events at key international events. At the same time, relevant deliberations and results from the meetings could be fed into the project. However, because of the COVID-19 pandemic, the meetings were postponed several times.

The reference group met digitally during the project period roughly once every two months and had one hybrid meeting in August 2022.

Five thematic digital expert workshops were held between March and June 2021. Each discussed in turn a Nordic approach to access and rights to one of the five groups of genetic resources, namely animal, plant, aquatic, forest, and wild genetic resources. In May 2022 a sixth digital workshop was held on Digital Sequence Information in relation to access and rights to genetic resources.

The group has identified the following questions to be of particular relevance for the project:

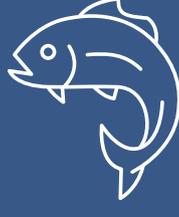
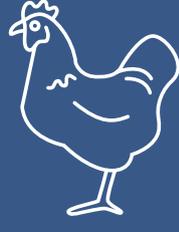
- What are key developments at the international level following the adoption of the Kalmar Declaration?
- What are the experiences in implementing the Kalmar Declaration by NordGen and by the different Nordic countries?

Based on the answers to these questions, the current relevance of the Kalmar Declaration is considered, and revised recommendations are made.

The project report will firstly provide a short description of genetic resources and their distinguishing features (Chapter 2). It will then give an account of developments in international forums relevant to the project (Chapter 3). The report will move on to discuss how the Nordic countries have addressed access and rights to genetic resources in light of the recommendations of the Kalmar Declaration (Chapter 4), followed by a short account of the series of digital workshops held as part of the project (Chapter 5). Finally, Chapter 6 will discuss how NordGen in the management of its plant/seed gene bank has responded to the recommendations of the Kalmar Declaration on this topic.

2. SPECIFIC FEATURES

of genetic resources and their use



2. SPECIFIC FEATURES

of genetic resources and their use

Genetic resources – defined as “biological materials of actual or potential value containing functional units of heredity”⁶ – are essential for a significant proportion of the world’s economic activity. They are the basis for agricultural and food production, including the improvement of agricultural crops, for bio-based solutions, and for the development of traditional medicines on which most of the world’s population still depend. They are used for a very wide variety of purposes, ranging from basic research to the development of products in sectors such as the pharmaceutical industry, agriculture, horticulture, cosmetics, energy, and biotechnology. Genetic resources are used both from wild species and from cultivated plants and domesticated animals in agriculture, aquaculture, forestry, and horticulture for further processing. The combined annual global market for products derived from genetic resources is estimated to be between USD 500 and 800 billion.⁷ Specific targets for genetic resources have been set under UN sustainable development goals 2 (zero hunger) and 15 (life on land).⁸

UN SUSTAINABLE DEVELOPMENT GOALS (SDGs)

And targets with specific reference to genetic resources.
UN sustainable development goals (SDGs) and targets with specific relevance and reference to genetic resources.

SDG 2

To end hunger, achieve food security and improved nutrition and promote sustainable agriculture.

Target 2.5: By 2020, maintain the genetic diversity of seeds, cultivated plants and farmed and domesticated animals and their related wild species, including through soundly managed and diversified seed and plant banks at the national, regional and international levels, and promote access to and fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge, as internationally agreed.

SDG 15

To sustainably manage forests, combat desertification, halt and reverse land degradation and halt biodiversity loss.

Target 15.6: Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed.

6. CBD definition of genetic resources

7. Kate, K., ten, and Laird, S. (1999). *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, Earthscan, Leiden.

8. SDG target 2.5: *By 2020, maintain the genetic diversity of seeds, cultivated plants and farmed and domesticated animals and their related wild species, including through soundly managed and diversified seed and plant banks at the national, regional and international levels, and promote access to and fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge, as internationally agreed.* SDG target 15.6: *Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed.*

The distinctive features of genetic resources for food and agriculture (GRFA) and the problems that need clear solutions is widely acknowledged. The Conference of the Parties to the CBD, at its fifth meeting in 2000, considered the distinctive features of agricultural biodiversity to include the following:

- Agricultural biodiversity is essential to satisfy basic human needs for food and livelihood security.
- Agricultural biodiversity is managed by farmers – many components of agricultural biodiversity depend on this human influence, while indigenous knowledge and culture are integral parts of the management of agricultural biodiversity.
- There is a great interdependence between countries in respect of genetic resources for food and agriculture.
- For crops and domestic animals, diversity within species is at least as important as diversity between species and has been greatly expanded through agriculture.
- Because of the degree of human management of agricultural biodiversity, its conservation in production systems is inherently linked to sustainable use.
- Nonetheless, much biological diversity is now conserved ex situ in gene banks or breeders' materials.
- The interaction between the environment, genetic resources, and management practices that occurs in situ within agro-ecosystems often contributes to maintaining a dynamic portfolio of agricultural biodiversity.

Some more sector-specific characteristics are presented below, based on the 2003 Nordic Approach project⁹.



2.1. Plant genetic resources for food and agriculture

Plant genetic resources for food and agriculture (PGRFA) are important for food security from both a short- and long-term perspective. To adapt to the environment and changing climate, soil, and water conditions, new genotypes of plants need to be developed in order to increase genetic variation. The use of this genetic variation is vital for the further development of new and improved varieties.

Throughout history, PGRFA have been widely exchanged throughout the world. Consequently, an important part of current crop production relies on the use of introduced genetic resources and all countries depend to some extent on genetic diversity that originated elsewhere.

Access to genetic diversity is, in most cases, a precondition for achieving enhancement within plant breeding programmes. The widespread use of plant varieties that share a similar genetic background may put crop production at risk. To this end, genetic diversity must be properly conserved as a means to safeguard plant breeding for sustainable food production.

9. FAO (2019). [ABS Elements: Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture with explanatory notes \(fao.org\)](#)

Plant genetic resources can be conserved in different ways:

In-situ conservation means the conservation of populations of wild or cultivated species in their natural surroundings or where they have developed their distinct properties. In this way, the ongoing evolutionary process is allowed to continue. *On-farm* conservation involves the maintenance of traditional varieties by farmers in agroecosystems. *Ex-situ* conservation involved the conservation of genetic resources outside their natural habitat, such as in seed or field gene banks. Since 1979, the Nordic countries have maintained a regional programme for the conservation and utilisation of plant genetic resources through the Nordic Genetic Resource Center (NordGen) and further described in Chapter 6. While NordGen manages the joint Nordic gene bank which conserves and facilitates the use of a common Nordic *ex-situ* conserved seed collection, including the common Nordic potato collection, the Nordic countries are responsible for conserving vegetatively propagated plants as well as *in-situ* and *on-farm* conservation.

2.2. Animal genetic resources for food and agriculture

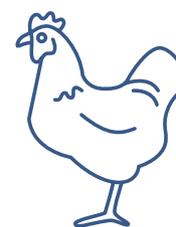
While the breeding of plants is focused on varieties, the breeding of animals is based on the use of propagation material from one individual to fertilise another individual.

Animal genetic resources contribute to human needs by providing meat, milk and dairy produce, eggs, fibre, clothes, resources for temporary and permanent shelter, manure for fertiliser and fuel, ecosystem services, draught power, hunting assistance, and marketable assets. Genetic diversity defines not only the production and functional traits of animal breeds, but also the ability to adapt to different environments, including food and water availability, climate, pests, and diseases.¹⁰

Only about 40 species are used in livestock production. The "big five" species – cattle, pig, sheep, goat and chicken – provide the majority of food products of animal origin. In the Nordic countries, approximately 146 farm animal species are endangered or close to extinction. The role of wild relatives of domesticated species in livestock breeding is very limited.

The development of modern reproductive technology (artificial insemination, deep-freezing of sperm, and multiple embryo transfer) has facilitated the exchange and increased international trade of breeding material from high-yielding populations and foreign breeds. Due to this and an increasing demand for profitability in agriculture, several local breeds have been reduced in size or are at risk of becoming endangered.

Between 1980 and 2014, global meat and milk production increased by 234 percent and 170 percent, respectively. This livestock revolution resulted in a significant shift of livestock production from temperate zones to the tropics and subtropics. The production increase was fostered by imports of carefully selected genetics, while in many cases native breeds were not improved through national breeding programmes.¹¹

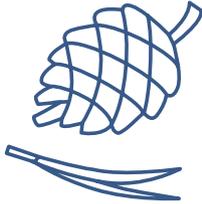


10. FAO (2007). [Global Plan of Action for Animal Genetic Resources and the Interlaken Declaration.](#)

11. Ibid.

Animal breeding is based on the exchange of propagation material regulated mainly by private law agreements and a common understanding among breeders of the rights associated with the material.

NordGen provides a farm animals service and knowledge centre that works to conserve and promote the sustainable management of animal genetic resources in the Nordic Region.¹²



2.3. Forest genetic resources

Forest genetic resources (FGR) and genetic diversity are crucial for the adaptation and continuous existence of trees in a changing climate. They provide society with multiple ecosystem services, such as by helping to mitigate climate change and providing a wide selection of wood-based products.

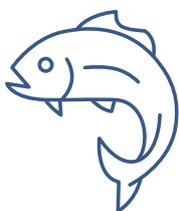
Trees are characterised by a long rotation period and exceptional reproductive capacity. Many tree species can be regarded wild or semi-domesticated and only a small proportion is subject to systematic breeding, although forest tree genetic resources have been transferred as seeds and plants between countries and continents for centuries. In breeding, although the selected trees are sometimes multiplied as clones, they are more commonly used for seed production through seed orchards where the trees are crossed with each other.

The ultimate goal of FGR conservation is to maintain the adaptive potential of forest tree species and populations, accommodating a wide ecological range and management options. This is of utmost importance in changing climatic conditions. Consequently, dynamic in-situ conservation through dedicated natural forest stands is the preferred method, complemented by ex-situ conservation.

It is essential that adaptation to local conditions is safeguarded for future use. This is achieved in gene conservation stands and areas. To improve survival, wood quality, and production, the seed is transferred both within the Nordic countries and imported from other countries. Numerous international provenance trials have been established for many tree species to test the performance of tree germplasm from different countries/regions.¹³

Breeding material has so far been exchanged completely freely between countries, also outside the Nordic countries.

Nordic co-operation on FGRs is organised through NordGen with an emphasis on improving methods of conservation and disseminating knowledge and experiences between the various stakeholders and to the public to develop better plant production and regeneration methods in forests.



2.4. Aquatic genetic resources

In this context, the category covers both wild and domesticated aquatic genetic resources (AGR).

While marine genetic diversity is greater than that of land, our present knowledge of many marine species is limited. Nevertheless, the search for new and useful genetic resources for the research and development of new commercial

products is increasingly conducted at sea. There are currently some 18,000 products with their origins in marine organisms belonging to 4,800 named species.¹⁴ This also applies to bioprospecting in some northern Nordic marine areas, which are some of the most productive in the northern hemisphere. The cold conditions of several marine biotypes make the genetic resources from these ecosystems especially interesting with their potentially unique properties related to their adaption to extreme temperatures.¹⁵

Aquaculture is a new industry developed within the last 60 years. The growth rate of aquaculture has been 8 to 10 percent per annum for the last 20 years, and today 50 percent of finfish consumed are farmed.¹⁶

Two parallel approaches are applied in aquaculture – the domestication of wild species, and the effective genetic management and improvement of species that are already produced commercially. Since aquaculture and the genetic improvement of AGRs is such a new undertaking, many farmed species are genetically very close to their wild relatives. Consequently, wild fish stocks may continue to play an important role in aquaculture production and breeding, including stocks with a poor conservation status. The reliance on wild types in aquaculture thereby provides an incentive to conserve these species and their habitats.¹⁷

Also in the Nordic Region, the aquaculture industry has undergone rapid growth in the last decades. It is estimated that Norway accounts for more than half of the global production of farmed salmon.¹⁸ Iceland ranks fourth among the main salmon producers in Europe and has the highest production of Arctic char.¹⁹

2.5. Wild genetic resources

Wild genetic resources (WGR) cover all wild organisms including wild-growing plants, trees, fish, wild animals, invertebrates, and micro-organisms. This also implies a wide range of uses.

In general, the genetic resources of wild organisms play a vital role in ecosystems and within the totality of renewable living resources. Consequently, those resources are also important in a long-term development perspective. Crop wild relatives of plants can continue to evolve in the wild and develop or adapt traits such as drought tolerance or pest resistance that breeders can use to produce new varieties of our domesticated crops. The designation of protected areas is an important means for the conservation of WGRs, including crop wild relatives.

12. [NordGen Farm Animals](#)

13. [FAO \(2019\) ABS Elements: Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture with explanatory notes](#)

14. Krabbe, N. (2021) *Bioprospecting and deep-sea genetic resources in a fragmenting international law*. University of Gothenburg School of Business, Economics and Law, Sweden. (Accessed 29 June 2021).

15. Rosendal, G. K., Myhr, A. I., & Tvedt, M. W. (2016). Access and benefit-sharing legislation for marine bioprospecting: lessons from Australia for the role of Marbank in Norway. *The Journal of World Intellectual Property*, 19(3–4), 86–98.

16. FAO (2019).

17. Ibid.

18. [Fauchald, O.K. \(2016\) Hvilke krav stiller Grunnloven § 112 til lakseoppdrettsnæringen?](#)

19. [Aquaculture in Iceland – Statistics Iceland](#)



3. DEVELOPMENTS ON ACCESS

to genetic resources and benefit-sharing (ABS) from their use and related issues in international forums



3. DEVELOPMENTS ON ACCESS

to genetic resources and benefit-sharing (ABS) from their use and related issues in international forums

Developing countries are those with the richest biodiversity, while the scientific and technological capacity to utilise genetic resources derived from biodiversity is found mainly in developed countries. Developing countries saw the Convention on Biological Diversity (CBD) as an opportunity to get the benefits derived from “their” genetic resources shared, and to rectify what was seen as an unjust situation dating back to colonial times where the colonial powers reaped huge profits by exploiting natural resources without returning the benefits.

The CBD regime and its principle of access to genetic resources and benefit sharing from their use (ABS) has since had a considerable impact for international law in such diverse areas as agriculture, intellectual property rights, health, and human rights.²⁰ This development will be the focus of this chapter with an emphasis on developments after the adoption of the Kalmar Declaration in 2003.



3.1. The Convention on Biological Diversity and the Nagoya Protocol

The third objective of the Convention on Biological Diversity (CBD) is the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. Based on the principle of national sovereignty and equity, the CBD establishes that benefits from using genetic resources shall be shared fairly and equitably with the provider of the resources, in return for providing access. Such access granted under the CBD is subject to prior informed consent (PIC) by the providing country, on mutually agreed terms (MAT) with the user.²¹

ABS was a controversial issue during the negotiations and remained so after the entry into force of the CBD in 1993. Developed countries generally were reluctant both to establish the ABS regime, in particular a legally binding regime, and to facilitate its implementation. The Nordic countries, however, took a more positive stance and acted as bridge-builders between developed and developing countries.

The focus of discussions on the implementation of ABS provisions was particularly on how to operationalise access. Little attention was paid on how to ensure benefit-sharing and compliance with provider-country access legislation. Developing countries reported many cases of alleged misappropriation (dubbed “biopiracy”), typically concerning inventions based on genetic resources and associated traditional knowledge that were patented without the PIC of the providing country and/or the community holding the knowledge. This maintained mistrust between developed and developing countries.²² The former was concerned about early examples of domestic access legislation in developing countries which they considered to be overly bureaucratic with a protectionist approach aimed at preventing biopiracy rather than incentivising bioprospecting.²³ The latter held

20. Glowka, L., and Normand, V., 2013. 'The Nagoya Protocol on Access and Benefit-sharing: Innovations in International Environmental Law' in: Morgera, E., Buck, M., and Tsioumani E., (eds), *The 2010 Nagoya Protocol on Access and Benefit Sharing in perspective: implications for international Law and implementation challenges*. Martinus Nijhoff, Leiden. Pp.21–51.

21. CBD Article. 15.

22. Oberthür, Sebastian and G. Kristin Rosendal (eds and introduction). 2014. *Global Governance of Genetic Resources. Access and Benefit Sharing after the Nagoya Protocol*. London: Routledge.

23. Smagadi, A. 2005. National measures on access to genetic resources and benefit sharing – The case of the Philippines, 1/1. *Law, Environment and Development Journal (LEAD Journal)* p. 50.

that developed countries, as hosts to most of the users of genetic resources, were obliged to take measures to prevent misappropriation and to ensure that benefits were actually shared, referring to the obligations outlined in CBD Art. 15.7.²⁴ While the level of national implementation of ABS remained generally low, it was particularly low in terms of "user measures".

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

A decade after the adoption of the CBD, a set of voluntary guidelines, "the Bonn Guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization" was adopted in 2002.²⁵ The Bonn guidelines never gained much importance and based on a recommendation of the World Summit on Sustainable Development (WSSD) in 2002, a negotiation process started under the CBD. In 2002, the WSSD "recommended developing an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources".²⁶ At CBD COP 10 in Nagoya in 2010, the Parties adopted the Nagoya Protocol (NP)²⁷ as part of a "Nagoya Package" which also included the CBD Strategic Plan 2011–2020 with the "Aichi Targets",²⁸ and a global strategy for resource mobilisation for biodiversity.²⁹ The Aichi Targets are 20 targets covering all three objectives of the CBD. According to target 16, the NP shall be in force and operational, consistent with national legislation, in 2015. The NP entered into force already in 2014 and to-date has been ratified by 138 Parties.

The NP is a legally binding instrument to operationalise and expand the third objective of the CBD by spelling out basic conditions for ABS including the key element of national measures in provider and user countries related to access, benefit-sharing, institutional responsibilities, and compliance. By creating a clear link between traditional knowledge and ABS, it breaks new legal ground as regards the rights of indigenous peoples and local communities.³⁰

The key elements of the NP, and points of contention about them, are examined in the following:

While the main approach of the ABS regime is to regulate access to the genetic resources, many benefits are generated from the use of derivatives of genetic resources. Consequently, how to relate derivatives to PIC and mutually agree terms was a controversial issue during the negotiation of the NP. Examples of derivatives are aromas, biochemicals in cells, and snake venom – compounds that are the basis of a wide range of medicinal, food, and cosmetic products and are often the real source of benefits. A compromise was reached (without any reference to the term "derivatives" in the legal provisions) on an interpretation of the NP, after which provider countries can regulate the utilisation of genetic resources on both the genes themselves and what could be derived from them.

Another question to discuss was the relationship of the NP with other instruments. Article 4 states that it will not create a hierarchy between the NP and other international instruments.³¹ It was also laid down that the NP shall be implemented in a mutually supportive manner with other instruments relevant to it.³²

24. Article 15.7: *Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.* The CBD includes a number of other obligations directed at users, including to provide the source country with access to technology and transfer such technology which makes use of its genetic resources (Art. 16.3), to enable *effective participation* in biotechnological research by (and where possible within) developing countries, especially the source country of genetic resources (Art 19.1) and to *promote and advance priority access on a fair and equitable basis* by source countries to the results and benefits arising from the biotechnologies based upon the source of country's genetic resources. (Art. 19.2). As noted by Tvedt and Young, 2007, CBD provisions on user obligations outnumber the requirements related to access.

25. [Bonn Guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization](#)

26. Johannesburg Plan of Implementation, para 44(o). Adopted at the World Summit on Sustainable Development (WSSD) in 2002.

27. UNEP/CBD/COP/DEC/X/1

28. UNEP/CBD/COP/DEC/X/2

29. UNEP/CBD/COP/DEC/X/3

30. Morgera, E., Buck, M., & Tsoumani, E. (Eds.). (2012). Introduction. *The 2010 Nagoya Protocol on access and benefit-sharing in perspective: Implications for international law and implementation challenges*. Martinus Nijhoff Publishers.

31. NP Article 4.1.

32. NP Article 4.3.

Developed countries demanded that the NP allow for the establishment of *sector-specific ABS regimes* (like the already established FAO International Treaty). This was accepted, with the qualification that such alternative ABS regimes are consistent with and do not run counter to the objectives of the NP and the CBD.³³ When a specialised ABS instrument is in place (like the IT-PRGFA with its multilateral ABS system) that instrument is to prevail over the NP.³⁴ Besides, the NP also encourages sectoral and cross-sectoral model contractual clauses for mutually agreed terms as well as voluntary codes of conduct, guidelines and best practices, and/or standards in relation to ABS.³⁵ In addition, the NP requires countries to consider the importance of genetic resources for food and agriculture and their special role for food security.³⁶

Developing countries attached particular importance to supporting compliance with domestic ABS legislation in order to prevent and react to future cases of the misappropriation of genetic resources and associated traditional knowledge. The NP includes an obligation for Parties to take measures, providing that genetic resources have been accessed in accordance with PIC and MAT if this is required by the providing country,³⁷ thereby expanding and reinforcing the requirements under the CBD. Parties are furthermore required to address non-compliance with these user measures.³⁸

To support compliance, countries shall designate one or more checkpoint(s) for collecting relevant information on PIC and MAT.³⁹ Further, the NP establishes an internationally recognised certificate of compliance to serve as evidence that genetic resources have been acquired legally.⁴⁰

Although the NP does not have a mandatory disclosure requirement regarding genetic resources in IPR application as a tool for enhancing compliance, IP Offices are considered a common checkpoint.

In return for accepting the obligations to support compliance, the developed countries insisted that provider countries should be obliged to ensure the legal certainty of their access legislation and procedures. A Party providing genetic resources must take various measures (access standards), as appropriate, to provide the user with clarity as to the requirements and the various steps involved in the process of obtaining access.⁴¹

Concerned that the NP could create burdens and obstacles to conducting research related to genetic resources, developed countries also achieved the inclusion of a provision for simplified measures on access for non-commercial research "taking into account the need to address a change of intent for such research".⁴²

In addition to user-country measures to support compliance, the provisions on traditional knowledge associated with genetic resources are probably the most innovative. The NP can be interpreted as enhancing the legal protection of the holders of traditional knowledge in international law.⁴³ Parties are required to take measures aimed at ensuring that traditional knowledge associated with genetic resources and held by indigenous peoples and local communities is accessed with their PIC and with MAT.⁴⁴ Parties are also obliged to consider the role of customary law and community protocol in their implementation of the NP,⁴⁵ and to take measures to enable the sharing of benefits from the use of traditional knowledge with the holders.⁴⁶ Finally, in parallel with user-country measures on compliance with national access legislation,



33. NP Article 4.2.

34. NP Article 4.4.

35. NP Article 19.1; 20.1.

36. NP Article.8c.

37. NP Article 15.1.

38. NP Article 15.2.

39. NP Article 17.1.

40. NP Articles 17.2 and 17.3.

41. NP Article 6.3. The NP Article 6(1) as well as the CBD Article 15(5) give Parties the option not to regulate access to domestic genetic resources.

42. NP Article 8a.

43. Buck, M. and Hamilton C. (2011) 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. Review of European Community & International Environmental Law, Volume 20, Issue 1.

44. NP Article 7.

45. NP Article 12.1.

46. NP Article 5.5.

Parties shall also take measures to support compliance with PIC and MAT from ILCs if this is required by domestic legislation.⁴⁷

Implementation and perceptions of the Nagoya Protocol

The Nagoya Protocol can only function if countries enact legal measures at national level to fulfil their International legal obligations and build capacity to manage these measures. Such measures need to address access as well as benefit-sharing and compliance. Users need legal certainty in provider countries when accessing genetic resources and provider countries need effective legal measures in user countries to ensure that they comply with benefit-sharing and otherwise do not misappropriate or misuse genetic resources or associated traditional knowledge. This has been the case ever since the CBD entered into force in 1993⁴⁸ and is unambiguously established by the NP.

The level of national implementation of the CBD provisions on ABS was generally low. The intention was to improve this, with the NP providing increased legal clarity and new momentum. However, national implementation of the NP is progressing slowly according to an assessment and review of the effectiveness of the NP presented at COP 14 in 2018. Besides reporting that legal and institutional measures are still in an early stage of development, it is worth noting that the assessment and review were unable to provide any conclusive data on the amount of monetary or non-monetary benefits triggered because of ABS transactions regulated by the NP.⁴⁹

A Compliance Committee has been established to oversee the implementation of the NP.⁵⁰ A report from April 2020 to this Committee shows moderate progress in domestic ABS measures. 95 country parties (77 percent) have now established some form of ABS measures of varying degrees of specificity and comprehensiveness (and of which a large part was adopted prior to the adoption of the NP). 59 countries are currently revising existing ABS measures or developing new ones to implement the NP.⁵¹

The NP is a success in terms of its relatively rapid entry into force. The fact, however, that a large number of countries still have not put in place laws and institutions to implement the NP, means that it can still not be considered to be fully operational.⁵² Moreover, while laws and institutions are prerequisites for the system to work, they do not necessarily imply substantive progress. Research has revealed that the benefits envisioned by the CBD and the NP have remained largely unfulfilled for states, indigenous peoples, and local communities – also in states with well-developed ABS measures in place. A telling symbol is the fact that an ABS icon, the National Institute of Biodiversity (IN-Bio) of Costa Rica, has now ceased to undertake bioprospecting due to limited successes. In 1991, a deal between INBio and the pharmaceutical giant Merck gained international fame for its apparent win-win-win for pharmacy, nature conservation, and income for Costa Rica. The deal was seen as a model case for the later ABS regime in the CBD.⁵³

While non-monetary benefits may be difficult to quantify, it is widely perceived that monetary benefit-sharing has so far been insignificant in an otherwise multibillion-dollar market. Benefits for the conservation of biodiversity seem even less apparent.⁵⁴ It should be noted, however, that research, development, and commercialisation processes in terms of genetic resources can be very lengthy.

47. NP Article 16.1.

48. According to CBD Article 15.7, Parties shall take legislative, administrative or policy measures, as appropriate, [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

49. [CBD/NP/MOP/DEC/3/1 \(2018\)](#)

50. [UNEP/CBD/NP/COP-MOP/DEC/1/4 \(2014\)](#)

51. [CBD/NP/CC/3/3 \(2020\)](#)

52. Smith, D., Hinz, H., Mulema, J., Weyl, P., Matthew, J. R. (2018) Biological control and the Nagoya Protocol on access and benefit sharing – a case of effective due diligence, *Biocontrol Science and Technology*, 28:10, 914–926.

53. [Fonseca Q., P. \(2015\). A Major Centre of Scientific Research Crumbles. Scientific American, 21 April 2015.](#)

An often-expressed view is that the ABS regime still creates obstacles to research since national legal frameworks often do not include a distinction between access to genetic resources for research and commercial use.

From the commercial side, it is often claimed that many companies have reduced or abandoned their interest in natural products, because of the legal uncertainty and other hurdles in accessing genetic resources.⁵⁵ At the same time, providing countries have been reluctant to work with multinational companies, because of suspicions of “biopiracy”. Consequently, the two parties to an ABS contract, who need to make the NP work, have to some extent both withdrawn from the opportunity. The result is that the countries of origin are not gaining a part of the possible benefits from their biodiversity, and a rich source of chemical diversity present in species from around the world, is being neglected.⁵⁶

Questions have been raised as to whether the legal ABS framework is compatible with the bioprospecting “value chain” from collection in nature to a manufactured product. Through this chain, the resources pass through many steps and intermediaries and thereby also many providers and users.⁵⁷

Digital Sequence Information (DSI)

The perception that developments have overtaken the current ABS regime of the CBD and the NP in providing fair and equitable benefit-sharing, has been further boosted in recent years through the rapid technological development of what has been dubbed Digital Sequence Information (DSI) as a placeholder in the absence of an internationally agreed definition. Although its meaning and scope continue to be disputed, essentially it refers to advances in bioinformatics, an interdisciplinary field of knowledge that develops and uses methods and software tools to extract knowledge from biological material.

ABS presumes that providers and users negotiate agreements and exchange physical material with clear provenance, ownership, and value, and that this material can be tracked through the research process, culminating in something of value. However, DSI turns most of this on its head.⁵⁸ Technological developments have significantly reduced demand for physical genetic material which can now be digitally sequenced relatively cheaply, and data can be exchanged rapidly between researchers, institutions, countries, and databases. Funders and publishers of scientific research demand that data be published and made openly available. Besides, the amount of DSI in publicly available databases is increasing exponentially, as is the exchange and use of such data. The use of DSI takes place without applying the concept of benefit sharing as per the ABS regime since it is extremely difficult to identify the original source of the sequences as well as to extract what are the “benefits” arising from its use. With “information” extracted, disembodied, or dematerialised from genetic resources, questions arise regarding the relevance of biological material in relation to ABS and as the vehicle for that disembodied information.⁵⁹

This has brought ABS into the spotlight again, with sharply divided views between north and south on how to deal with DSI. A core area of disagreement has concerned whether the use of DSI should be seen as the “utilisation” of genetic resources and thereby covered by the NP, or merely as descriptive information and thus out of regulatory scope. It has also been disputed whether the open access that DSI provides in itself can be regarded as a sufficient form of benefit-sharing.



54. [Muller, R.M. \(2018\). *Access to Genetic Resources and Benefit Sharing 25 Years on: Progress and Challenges*. Geneva: International Centre for Trade and Sustainable Development \(ICTSD\).](#)

55. Amirkia, V., Heinrich, M. (2015). Natural products and drug discovery: A survey of stakeholders in industry and academia. *Front. Pharmacol.* 2015, 6.

56. Heinrich, M. et al. (2020) Access and Benefit Sharing Under the Nagoya Protocol-Quo Vadis? Six Latin American Case Studies Assessing Opportunities and Risk. *Frontiers in Pharmacology*. [10.3389/fphar.2020.00765](#)

57. Prip, C., Rosendal, K. (2015). Access to genetic resources and benefit-sharing from their use (ABS) – state of implementation and research gaps.

58. [Laird, S., Wynberg, R., Rourke, M., Humphries, F., Muller, M.R., Lawson, C. \(2020\). Rethink the expansion of access and benefit sharing. *Science* 367 \(6483\), 1200–1202.](#)

59. Ruiz Muller, M. (2018). *Access to Genetic Resources and Benefit Sharing 25 Years on: Progress and Challenges*. Geneva: International Centre for Trade and Sustainable Development (ICTSD).

Many developing countries have feared that the free access to and exchange of DSI will undermine the third objective of the CBD and thereby also their incentives to protect biodiversity. By contrast, developed countries have seen DSI and its free accessibility as essential for all areas of the life sciences, including biodiversity research, food security, human health, and more. Establishing barriers to the already well-established free access and exchange would, in their view, undermine research and industrial development to the detriment of both the developed and the developing world.

Up to COP 15 in December 2022, developing countries had set resolving the question of benefit-sharing from the use of DSI on genetic resources as a key condition for their support to the overall Global Biodiversity Framework (GBF) with global targets for 2030 and goals for 2050. This question was therefore negotiated within the context of the GBF and DSI was included in the GBF in Goal C and Target 13, as well as in the resource mobilisation decision of COP15. At COP 15, it was agreed that the benefits from the use of DSI on genetic resources should be shared fairly and equitably. To this end, it was decided to establish a multilateral mechanism for benefit-sharing from the use of DSI, including a global fund as well as a time-bound process to further develop and operationalize the mechanism to be finalized at COP 16 in 2024.⁶⁰ There is still no official definition of DSI.⁶¹

All Contracting Parties to CBD are expected to show how they will contribute to the achievements of the global targets when updating their national biodiversity strategies and action plans (NBSAPs).

Genetic resources, and access and benefit-sharing, including DSI, in the Kunming-Montreal Global Biodiversity Framework

60. [CBD/COP/DEC/15/9. Digital sequence information on genetic resources](#)

61. Extract of decision CBD/COP/DEC/15/9: Recognizing the different understandings of the concept and scope of digital sequence information on genetic resources, and the range of views regarding the need to define such concept and scope.

Goal C

The monetary and non-monetary benefits from the utilization of genetic resources, and digital sequence information on genetic resources, and of traditional knowledge associated with genetic resources, as applicable, are shared fairly and equitably, including, as appropriate with indigenous peoples and local communities, and substantially increased by 2050, while ensuring traditional knowledge associated with genetic resources is appropriately protected, thereby contributing to the conservation and sustainable use of biodiversity, in accordance with internationally agreed access and benefit-sharing instruments.

TARGET 4

Ensure urgent management actions to halt human induced extinction of known threatened species and for the recovery and conservation of species, in particular threatened species, to significantly reduce extinction risk, as well as to maintain and restore the genetic diversity within and between populations of native, wild and domesticated species to maintain their adaptive potential, including through in situ and ex situ conservation and sustainable management practices, and effectively manage human-wildlife interactions to minimize human-wildlife conflict for coexistence.

TARGET 13

Take effective legal, policy, administrative and capacity-building measures at all levels, as appropriate, to ensure the fair and equitable sharing of benefits that arise from the utilization of genetic resources and from digital sequence information on genetic resources, as well as traditional knowledge associated with genetic resources, and facilitating appropriate access to genetic resources, and by 2030 facilitating a significant increase of the benefits shared, in accordance with applicable international access and benefit-sharing instruments.

Under the current project, a webinar titled "Digital Sequence Information (DSI) and Access and Rights to Genetic Resources" was held on 31 May 2022, with more than 40 participants representing both Nordic scientists/experts and representatives of the competent national authorities of the Nordic countries, among others.

The presentations at the webinar addressed:

- The increasing demand for and prevalence of DSI, using NordGen as an example.
- Challenges of adapting access to and benefit-sharing from DSI to the bilateral system using, for instance, the development of a COVID-19 vaccine using hundreds of sequences originating from a large number of countries as an example.
- The potential for a special multilateral system for DSI based on open licences using the Global Biodiversity Information Facility (GBIF) as inspiration.
- The status of the negotiations of DSI under the CBD prior to the upcoming COP 15 held in December 2022.



Subsequent discussions in digital break-out groups revealed broad support for:

- Access to DSI remaining open.
- Benefit-sharing from the use of DSI through a multilateral system.
- The solution to the DSI issue being international across the NP and the FAO International Plant Treaty, and possibly other international instruments.

3.2. The International Plant Treaty on Genetic Resources for Food and Agriculture (the International Plant Treaty)

There are no specific provisions on agricultural biodiversity and crop genetic resources in the CBD. During the negotiations, countries adopted the Nairobi Final Act recognising "the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: Access to ex-situ collections not acquired in accordance with this Convention; and (b) The question of farmers' rights."⁶²

Plant genetic resources for food and agriculture (PGRFA) are the necessary building blocks for crop improvement, and thus the world's agriculture and food production. To this end, a need was identified for a regime to promote the exchange of crops and their genes with as few restrictions as possible.

In 1994, negotiations commenced under the FAO Commission on Genetic Resources for Food and Agriculture on a legally binding instrument in harmony with the CBD and to replace the voluntary International Undertaking on Plant Genetic Resources.

The International Plant Treaty came into force in 2004 and, as of June 2022, has been ratified by 149 countries.

The International Plant Treaty was developed because of and with objectives mirroring the CBD – the conservation and sustainable use of PGRFA, and the fair

62. Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, Resolution 3: The Interrelationship Between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture 1992.

and equitable sharing of benefits derived from their use. However, the International Plant Treaty created an approach to access and benefit-sharing that differs from that of the CBD by establishing a Multilateral System of Access and Benefit-sharing (MLS).⁶³ Within this system, the Parties provide facilitated access to each other's genetic resources covered by the system for research, breeding, conservation, and training. The scope of the material to be included in the MLS was controversial. It was ultimately agreed to include 35 food crops and 29 forage crops which are listed in Annex 1 to the International Plant Treaty.

The intention of the International Plant Treaty is to facilitate benefit-sharing through information exchange, access to and transfers of technology, capacity building and monetary benefits – the latter either in the form of voluntary contributions to a benefit-sharing fund, or compulsory contributions in certain cases of the commercialisation of the use of a product derived from MLS material.⁶⁴ In respect of the latter, users commercialising a resulting product that “restrict” facilitated access to the product (understood to refer to patents) must make mandatory payments of 1.1% of product sales minus 30% to the MLS. Users commercialising products (understood to refer to Plant Breeders' Rights) are obliged to consider making voluntary payments.

The obligation to share benefits is not in direct favour of the provider, but of the MLS, and the free exchange of genetic resources is viewed as a benefit in itself. Monetary benefits are intended to primarily flow to farmers in developing countries through the Benefit-sharing Fund, established by the International Plant Treaty.

Collections of Annex I crops under the management and control of the Parties and in the public domain, as well as the collections of international institutions that have signed agreements with the International Plant Treaty's Governing Body, are included in the MLS and exchanged on the basis of a Standard Material Transfer Agreement (SMTA).⁶⁵ The MLS also includes PGRFA held in the *ex-situ* collections of the Consultative Group on International Agricultural Research (CGIAR) centres where they have signed agreements with the Governing Body. Other holders, including the private sector, are *encouraged* to include such material in the system to achieve larger coverage. While providers are usually public or international gene banks, users can be organisations, private entities, or individuals.

The ITPGRFA recognises farmers' rights, that is to say the invaluable contributions that farmers and their communities have made and continue to make in relation to the conservation and development of plant genetic resources. This includes provisions on rights to traditional knowledge relevant to PGRFA, participation in decision making in matters related to the conservation and sustainable use of PGRFA, and the use, retention, exchange, and sale of farm-saved seed/propagation materials.⁶⁶ However, the provisions on farmers' rights are legally subject to national legislation. Their application is highly dependent on the legal space provided by domestic legislation, which might also be influenced by other international legal instruments and in particular those addressing intellectual property rights and seed regulation.⁶⁷ The further conceptualisation of farmers' rights has benefited from several global consultations. The first in Zambia in 2007, another in Ethiopia in 2010, and the most recent in Indonesia in 2016. Norway has been actively involved in all of them. Based on the recommendation from the consultation in Indonesia, the seventh session of the Governing

63. ITPGRFA Part IV.

64. ITPGRFA article 13.2(d) and Standard Material Transfer Agreement.

65. ITPGRFA Articles 11(2) and (5).

66. ITPGRFA articles 9.2(a), (b), (c), 9.3.

67. Prip, C.; Fauchald, O.K. Securing Crop Genetic Diversity: Reconciling EU Seed Legislation and Biodiversity Treaties. *RECIEL* 2016, 25, 363–377.

Body in 2017 agreed for the very first time to an intersessional process on farmers' rights when it established the Ad Hoc Technical Expert Group (AHTEG) on farmers' rights. The AHTEG was mandated to (1) produce an inventory of national measures that may be adopted, best practices, and lessons learnt from the realisation of farmers' rights, and (2) based on the inventory, develop options for encouraging, guiding, and promoting the realisation of farmers' rights. The Governing Body welcomed the inventory at its eighth session in 2019, while it took note of the options, it is worth noting that options on legal measures were presented as co-chair proposals at its ninth session in 2022.⁶⁸

The MLS is generally considered to be functioning well in terms of facilitating access to and the exchange of PGRFA. As of mid-2019, more than 5.4 million samples of PGRFA had been transferred through the system.⁶⁹ Few mandatory payments have come about since the International Plant Treaty's entry into force. The Benefit-sharing Fund has primarily been operated on the basis of donor country voluntary contributions from governments and other donors such as the EU, Norway, Italy, Australia, the International Fund for Agricultural Development (IFAD), and recently also the seed sector. The lengthy time-period required for research, development, and commercialisation partly explains the low level of mandatory monetary benefits to date from the SMTA.⁷⁰ New plant varieties take 8 to 14 years to develop. There are some examples of voluntary monetary benefit sharing from the seed sector – some *ad hoc* – while the French seed sector has voluntarily committed to an annual contribution to the Benefit-sharing Fund that contributes predictable support to the fund.

Four project cycles have been supported by the Benefit-sharing Fund, while the fifth project cycle was launched in May 2022. In the current funding strategy, it has been agreed to develop a methodology to measure non-monetary benefit-sharing. Another explanation suggested by scholars is the inherent contradiction in the system that monetary benefit-sharing is triggered when material is taken out of the MLS (a system based on open access) and patented (a system based on restriction in use) contrary to the very essence of the MLS.⁷¹

Lastly, the limited coverage of the MLS could be a contributing cause of the limited amount of mandatory monetary benefits. During the International Plant Treaty negotiations some developing countries and China insisted that it should not cover such major crops as soybean, sugarcane, tomato, and coffee. These crops have attracted significant research efforts resulting in patented material, and their inclusion could result in mandatory benefit-sharing payments according to the SMTA obligations. However, precisely because of the high level of commercial interest, developing countries excluded these crops from the MLS, aiming for higher gains through bilateral transactions under the CBD terms.⁷²

However, there are some examples of voluntary monetary benefit-sharing from the seed sector both *ad hoc* and regular. Consequently, the French seed sector has voluntarily committed to an annual contribution to the Benefit-sharing Fund that provides predictable support for the fund.

Four project cycles have been supported by the Benefit-sharing Fund, while the fifth project cycle was launched in May 2022. In the current funding strategy, it has been agreed to develop a methodology to measure non-monetary benefit-sharing.



68. ITPGRFA GB 7. Resolution 7/2017. Implementation of Article 9, Farmers' Rights.

69. IIT/GB-8/19/8.1 Rev.1

70. Tsioumani, E. (2018). Beyond access and benefit-sharing: Lessons from the law and governance of agricultural biodiversity. The Journal of World Intellectual Property, 21(3-4), 106-122.

71. Frison C. (2016). *Towards redesigning the plant commons: A critical assessment of the multilateral system of access and benefit-sharing of the international treaty on plant genetic resources for food and agriculture*. PhD Thesis. Leuven: UCLouvain / KU Leuven.

72. Tsioumani, E. (2018).

As is the case with the ABS regime under the CBD/NP, there have been marked differences of opinion between developed and developing countries under the International Plant Treaty. Developed country stakeholders generally view the International Plant Treaty as a success and have been seeking to extend the scope of the MLS through an expansion of the Annex 1 list with more taxa. By contrast, several developing countries and NGOs are concerned about the few monetary benefits that have been generated through the MLS and consider the generation and sharing of tangible financial benefits on the basis of the present MLS coverage as a necessary prerequisite for expanding coverage. Furthermore, they consider "free" access to PGRFA to be rather illusive for as long as the system permits the private appropriation of resources through patents and plant breeders' rights. Compliance is feeble and many Parties have yet to place their PGRFA in the MLS.

The desire to improve the MLS led to a lengthy negotiation process under the International Plant Treaty from 2013 to 2019. The task of the Ad Hoc Open-ended Working Group to Enhance the Functioning of the MLS, was to develop measures to increase user-based payments and contributions to the Benefit-sharing Fund (BSF), as well as additional measures to enhance the functioning of the MLS.

Early on, the introduction of a subscription system, whereby users pay a fee for being granted access to all, or a select number of PGRFA within the scope of the MLS, was identified as a particularly important element for enhancing the functioning of the MLS, allowing access under one subscription instead of multiple SMTAs. Similarly, subscriptions were thought to also reduce compliance costs if subscribers do not need to track and trace the flow of individual PGRFA under SMTAs throughout their breeding programmes, and can instead use their subscriber status to demonstrate compliance. By linking payment obligations to access (rather than commercialisation, as under the current SMTA), a subscription model could also improve benefit-sharing in a more timely manner.⁷³ It was also widely viewed that a subscription system would indirectly ensure that benefits from DSI would be shared.

The task of the working group was, in essence, to address a package of two specifically important components that reflect the priorities of both developed and developing countries, namely an expanded list of crops in the MLS to equal the scope of the coverage of the International Plant Treaty (all PGRFA) in order to facilitate access to material for agricultural research and development, and a revised SMTA for transfers of PGRFA in the MLS in order to improve fair and equitable benefit-sharing. By the eighth meeting of the Governing Body (GB8) in November 2019, the working group had made decent progress on this package, with a tentative agreement reached on the expansion of the list of crops in the MLS, as well as significant progress on the revision of the SMTA, including details on the envisaged subscription system, which would have made the sharing of monetary benefits from all users compulsory, and the process of implementing it.

However, negotiations on the enhancement of the MLS collapsed at GB8 and, as is the case under the CBD and the Nagoya Protocol, the emerging use of DSI was again the critical element. Developing countries wanted to ensure that benefit-sharing obligations extended to DSI use in order to uphold the International Plant Treaty's integrity and relevance in light of the wave of technological

73. Rabitz, F. (2017)

74. Earth Negotiating Bulletin. Summary of the Eighth Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture 11–16 November 2019. <https://enb.iisd.org/vol09/enb09740e.html>

75. The GB10 is scheduled for 20–25 November 2023 in Rome and will decide on dates and place for the GB11.

76. FAO (2019) ABS Elements: Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture – with explanatory notes.

77. Report from Eighteenth Regular Session of the CGRFA, 27 September–1 October 2021.

developments. Developed countries, on the other hand, argued that, legally, DSI is beyond the scope of the International Plant Treaty.⁷⁴ GB8 encouraged informal consultations among the Contracting Parties and stakeholders to consider how the matter could be progressed. Switzerland took a lead in this, organising a couple of webinars. In July 2022, India and Switzerland organised a hybrid meeting in Geneva. The co-chair proposal on a possible way forwards formed the basis for further negotiation at GB9, which saw agreement on the recommencement of a formal negotiation process. GB9 elected two co-chairs to lead the work, with a stocktake expected to take place at GB10 in 2023 and finalisation of the process at GB11 in 2025.⁷⁵



3.3. FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)

The CGRFA is an intergovernmental body originally established by FAO in 1983 as only dealing with plant genetic resources. It was renamed in 1995 to reflect its broadened mandate to encompass all components of biodiversity for food and agriculture, including plant, animal, forest, aquatic, and micro-organism and invertebrate genetic resources. The CGRFA currently comprises 178 members. As guidance on how to adapt implementation of the NP to specific types of genetic resources, in 2015 the Commission issued a set of elements to facilitate the domestic implementation of ABS in the different subsectors of GRFA. These elements were complemented in 2019 with explanatory notes designed “to assist governments considering developing, adapting or implementing ABS measures to take into account the importance of GRFA, their special role for food security and the distinctive features of the different subsectors of GRFA, while complying, as applicable, with international ABS instruments”.⁷⁶ As elaborated on in Chapter 2, GRFA have widely recognised distinctive features, and thus, distinct considerations should be made when adopting ABS measures.

In addition, the CGRFA has addressed DSI. At its meeting in 2021, the Commission stressed the innovation opportunities DSI offers for research and development related to GRFA, as well as the challenges many countries face in developing the technical, institutional, and human capacity necessary to use DSI for research and development. The Commission will monitor relevant developments on DSI under the CBD and in other forums including ABS multilateral mechanisms for DSI.⁷⁷

In recent years, the CGRFA has worked more on micro-organisms and invertebrates in addition to GRFA for plants, animals, forests, and in the aquatic environment. The micro-organism and invertebrate sectors are not directly addressed in the Kalmar Declaration.

3.4. New treaty on the way on the conservation and sustainable use of biodiversity in marine areas beyond national jurisdiction

For 18 years, a process towards an international legally binding instrument (ILBI) under the Convention on the Law of the Sea (LOSC) on the conservation and sustainable use of marine biodiversity of areas beyond national jurisdiction (BBNJ) has been underway under various mandates of the UN General Assembly. Such marine areas cover nearly half of Earth’s surface and two-thirds of all

marine areas. The latest phase in this lengthy process was triggered by UN General Assembly (UNGA) resolution 72/249 in 2017, authorising an Intergovernmental Conference (IGC) to elaborate on the text of an international legally binding instrument. To date, five meetings of the IGC have been held without reaching a final agreement on the instrument.

The instrument is mandated to be a package deal addressing "the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas, environmental impact assessments and capacity-building and the transfer of marine technology".

As was the case for the CBD negotiations, the governance of marine genetic resources features in these negotiations as a prominent and polarising topic, the outcome of which may have an impact on the outcome of negotiations on the whole package, including provisions on conservation and sustainable use.

The exploitation of marine genetic resources is of growing interest for the pharmaceutical, food, and other industries. Research has revealed that ten developed countries account for 90% of patents related to marine genetic resources. Consequently, also here developing countries would like benefits to be shared more fairly and equitably.

What is or should be the legal status of marine genetic resources in areas beyond national jurisdiction?⁷⁸ With no sovereign rights for any state, there is no legally recognised provider entitled to prior informed consent (PIC) and a share of the benefits from the use of genetic resources under bilateral arrangements. Consequently, the issue is the establishment of an ABS system that is not dependent on this transactional approach, but which still creates incentives for governments and stakeholders to be transparent about the collection and use of genetic resources, and to share the benefits from their use. UNLOSC (and the CBD/NP) is silent, and countries have been clearly divided on this key issue.

Developing countries have argued that genetic resources should have a legal status similar to that of mineral resources of the deep seabed. The approach is such that the resources cannot be accessed exclusively by any State, but only for the benefit of humankind under the centralised control and administration of the International Seabed Authority.

Developed countries generally oppose a common heritage status for marine genetic resources.

In the later negotiations, the question of the common heritage of mankind as the legal status seems to have been downplayed by those that have previously supported it. A common understanding seems to emerge whereby access should rely on a notification rather than a permit system. With regard to benefit -sharing, there also seems to be less attention on commercial reward and more on non-monetary benefits, such as the sharing of research data, scientific co-operation, capacity building, and technology transfer. However, it is still disputed if and how monetary benefits should be covered. As for other ABS regimes, questions of if and how genetic resources accessed *ex situ* and whether DSI and derivatives should be covered, are also disputed here.

78. United Nations Convention on Law of the Sea (LOSC) distinguishes between two components of areas beyond national jurisdiction: "the Area" and the "High Seas". The Area is defined as "the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction" (LOSC, Art. 1). The Area and its mineral resources have a specific legal status as "common heritage of mankind" implying that states shall not claim or exercise sovereignty or sovereign rights over any part of the Area or its resources, and that activities in the Area must be conducted for the benefit of mankind as a whole (LOSC, Arts 136, 137 and 140). An International Seabed Authority (ISA) is established as an intergovernmental body to regulate and control all mineral-related activities in the Area. The High Seas encompass the water column beyond the 200 nautical miles Exclusive Economic Zones of coastal states and are governed by the traditional freedoms of the sea which include navigation, overflight, fishing, scientific research, laying of submarine cables and pipelines, and construction of artificial islands and other installations permitted under international law (LOSC, Arts 86 and 87).

3.5. Intellectual property rights

The connection between ABS regimes and intellectual property rights (IPR) regimes has always been a controversial issue. The reinforcement of national sovereignty over genetic resources as a backbone of the CBD ABS regime was largely to counterbalance the rapid evolution in modern biotechnology and, with that, the patenting of living material. By way of example, the number of patents originating from marine genetic resources has increased by an average 12 percent per year since 1999.⁷⁹ In general, developing countries viewed patents as enabling industry in developed countries to monopolise "their" genetic resources without compensation, while also imposing a high price for the "reintroduction" of the patented products based on the resources.

There are several links between IPR and ABS, in terms of both access and benefits. IPR could impact access by both contributing to the improvement of genetic resources, e.g. stimulating plant breeding of new varieties, while IPR can restrict access to protected material for other breeders, researchers, and farmers. Since IPR are rights to restrict the commercial use of protected material, they could contribute to the creation of benefits linked to the commercialisation of genetic resources, and thus obligations to share those benefits. Consequently, patent offices are considered as a suitable checkpoint in the Nagoya Protocol and several countries have included the provision of the disclosure of origin in their applications for IPRs.

Trade-Related Aspects of Intellectual Property Rights

The IPR development was enshrined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), one of the pillars of the World Trade Organization (WTO), which was negotiated in parallel with the CBD negotiations, but with no formal interconnections. TRIPS requires its member states to make patents available for inventions in any kind of technology, including technology on living organisms, cells, and genes. From this general point of departure, TRIPS allows member states certain exemptions: They may exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes". However, members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.⁸⁰

Leading developed countries were reluctant to address the interrelationship between the ABS regime and TRIPS both in the CBD and the NP negotiations and vice-versa in the TRIPS Council. Except for a very general and qualified stipulation in the CBD that IRPs should support and not run counter to the objectives of the CBD,⁸¹ there are no provisions in the CBD, NP, or TRIPS to the effect that patents or other IPRs shall respect prior informed consent and mutually agreed terms for access to genetic resources. However, the International Plant Treaty prohibits recipients of plant genetic resources from the MLS from acquiring IPR in the form received from the MLS.⁸²

Developing countries in the TRIPS Council have attempted to promote mutual support between the two regimes by introducing the obligation to disclose in patent applications the source and/or country of origin of biological resources, of associated traditional knowledge, and of the legal acquisition of such



79. Krabbe, N. (2021) *Bioprospecting and deep-sea genetic resources in a fragmenting international law*. University of Gothenburg School of Business, Economics and Law, Sweden. (Accessed 29 June 2021).

80. TRIPS, Article 27.3 (b).

81. CBD Article 16.5: "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

82. ITPGRFA Article 12.3 (d).

resources if such resources and/or traditional knowledge are contained in an invention for which an applicant is seeking a patent. The idea is to make transparent and subject to public scrutiny whether ABS obligations have been met, and to facilitate the identification of potential cases of misappropriation at the point in time when a patent application is made. Despite increasing support from developed countries, the US in particular has prevented the adoption of this proposal in the TRIPS Council.⁸³

This has not prevented several countries from introducing such disclosure requirements in their national legislation, including Belgium, Bolivia, Brazil, China, Colombia, Costa Rica, Denmark, Ecuador, Egypt, the EU, India, Norway, Peru, the Philippines, South Africa, and Switzerland. However, the provisions are different in terms of their binding nature, scope, and consequences in case of non-compliance. Some countries provide only a non-binding, voluntary disclosure requirement (e.g., the EU), while some provide mandatory disclosure requirements with links to criminal sanctions but with no effect on the validity of the patent in cases of non-compliance (e.g., Norway and Denmark), and others link the patentability, nullity, or revocation of patents with the disclosure of origin (e.g., India, Brazil, and South Africa). The provisions also differ as to whether they cover traditional knowledge.⁸⁴

The Union for the Protection of Plant Varieties

As described above, TRIPS allows for the protection of plant varieties either by patents or by an effective *sui generis* system. Many countries have opted for the latter in the form of the UPOV Convention. The Union for the Protection of Plant Varieties (UPOV) was established in 1961 with a Convention that created a new form of IPR, Plant Breeders' Rights (PBR), intended to provide breeders with exclusive rights to the propagation material, such as seeds, of new plant varieties.⁸⁵ PBR derive from the emergence of breeders as a profession distinct from farmers and the fact that plant material is self-replicating, making it easy to freely use breeder-innovated plant varieties. A breeder's exemption allows access to protected material for research, for further breeding. The 1991 Act of the UPOV Convention introduced the concept of Essentially Derived Varieties (EDV). The concept extends the right of the original rights holder vis-a-vis other breeders, and there is ongoing work to reach agreement on how to implement this provision. The breeder's exemption is considered key in plant variety protection, and the limitation of this exemption could adversely affect breeding.

Under the 1978 Act of the UPOV Convention, farmers could be allowed to retain propagation material for their own use and for non-commercial exchange (often known as farmers' privilege). However, the 1991 Act of the UPOV Convention limited this right for farmers and strengthened breeders' rights vis-a-vis other breeders and farmers. The possibilities of farmers to retain propagation material from protected varieties are limited to the use of farmers' own holdings and only under certain conditions.

Sui generis systems for the protection of plant varieties

Other *sui generis* systems for the protection of plant varieties have also emerged as alternatives to UPOV, including in India, Ethiopia, Thailand, and Malaysia. In India, the protection of plant varieties and farmers' rights are addressed in the same act.⁸⁶ Alternative systems may also include a requirement for the disclosure

83. See BIORES article "Disclosure of origin again on the TRIPS Council agenda" reporting from a TRIPS Council meeting in 2007. <http://www.ictsd.org/bridges-news/biores/news/disclosure-of-origin-again-on-the-trips-council-agenda-0>

84. [Prip, C., and van't Klooster, C. \(2016\) The Nagoya Protocol on access to genetic resources and benefit sharing: User-country measures and implementation in India. FNI Report 2/2016.](#)

85. [UPOV webpage.](#)

86. [Ramanna, A. \(2006\). Farmers' Rights in India: A Case Study. FNI report 6/2006.](#)

of information on the geographical origin of genetic resources as a way to fulfil policy objectives linked to monitoring the utilisation of genetic resources.⁸⁷

The UN World Intellectual Property Rights Organisation

The UN World Intellectual Property Rights Organisation (WIPO) is a third IPR forum relevant in this context. In 2000, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources (IGC).⁸⁸ For many years it was primarily a forum for policy dialogue, but in 2009 the IGC was mandated to begin formal negotiations aimed at reaching agreement on one or more international legal instruments to ensure the effective protection of genetic resources, traditional knowledge, and traditional cultural expressions. Such an instrument or instruments could range from a recommendation to WIPO members to a formal treaty that would bind the countries that ratified it. However, progress has been limited, due to the division of opinions between typical provider and user countries – as in the CBD/NP context.⁸⁹

The WIPO IGC's inability to find a consensus position has led the chair of the IGC to issue a chair's text of an international legal instrument which is now the basis for negotiations in the IGC.⁹⁰ The scope of the text has been narrowed down to address only disclosure requirements and only in relation to patents, not other types of IPR.

The European Patent Office

The European Patent Office (EPO) examines European patent applications and grants European patents under the European Patent Convention.⁹¹ In conformity with the TRIPS Agreement, this convention permits exceptions to patentability for "plant or animal varieties or essentially biological processes for the production of plants or animals" but excludes microbiological processes and their end products from this exception. (Article 53(b)).

An interpretation of the scope of this exception was made by the EPO by in 2015 by allowing patents for a tomato⁹² and a broccoli⁹³ obtained through conventional breeding techniques. The EPO claimed that although essentially biological processes for the production of plants, such as crossing, cannot be patented, this is not the case for the resulting plants or plant material, such as a vegetable or a fruit.

In 2015 and 2019, the European Parliament responded to these decisions through non-legislative resolutions that called for patents not to be granted for products obtained from essentially biological processes. It was argued that patent-free access to biological plant material is essential in order to boost the innovation and competitiveness of the European plant-breeding and farming sectors, to develop new varieties, to improve food security, and to tackle climate change and that access to genetic resources must not be restricted "as this could lead to a situation where a few multinational companies have a monopoly on plant breeding material, to the detriment of EU farmers and consumers".⁹⁴

In 2019, the Enlarged Board of Appeal of the EPO issued an opinion reversing the earlier EPO interpretation of Article 53(b). It now states that the non-patentability of essentially biological processes for the production of plants or animals also extends to plant or animal products that are exclusively obtained by means of an essentially biological process.⁹⁵



87. [OECD \(2021\), Making Better Policies for Food Systems](#), OECD Publishing, Paris.

88. [The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore \(IGC\)](#)

89. [Vivas-Eugui, D. \(2012\); Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee \(IGC\); ICTSD's Programme on Innovation, Technology and Intellectual Property; Issue Paper No. 34.](#)

90. [Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources.](#)

91. [EPO-Home](#)

92. [EPO case number G 0002/12.](#)

93. [EPO case number G 0002/13.](#)

94. [European Parliament press release 19 November 2019.](#)

95. [EPO Case G 0003/19](#)

Some countries have included a breeder's exemption in their domestic patent law. This reduces the potential negative impact of patents on breeding. The EU patent directive (directive on legal protection for biotech innovation) made it possible to patent plants and animals for the first time.

3.6 Summing-up

Since the adoption of the Kalmar Declaration in 2003 and the completion of the first Nordic project on access and rights to genetic resources, there has been extensive development in the international legal framework.

This applies not least to the adoption of the Nagoya Protocol in 2010 and its entry into force in 2014, which not only specified and reinforced CBD-established rights and obligations on access and benefit-sharing, but also expanded on legal requirements. The Protocol establishes "user measures" – obligations for parties to take measures to ensure that genetic resources used within their jurisdiction have been accessed in accordance with the access requirements of the providing country. Another legal expansion is the requirement for Parties to ensure that traditional knowledge associated with genetic resources held by indigenous peoples and local communities has been accessed with their prior informed consent and on mutually agreed terms. Higher ambitions for increased benefit-sharing from the use of genetic resources, including DSI are included in the recently adopted Kunming-Montreal Global Biodiversity Framework.

Experiences with ABS regulations and the so-far limited benefits that have been shared, as well as recent technological developments, have intensified the discussion about whether the bilateral ABS system is fit for purpose. Demand for physical genetic material which can now be digitally sequenced is falling, and data can be exchanged rapidly between researchers, institutions, countries, and databases (Digital Sequence Information, DSI). The DSI issue spills over to other international processes that address access and rights to genetic resources, such as the International Plant Treaty and the negotiations of an international treaty to protect BBNJ. The International Treaty on Plant Genetic Resources for Food and Agriculture came into force, and in the following years, the modalities of the Multilateral System for Access and Benefit-sharing were developed. This system has generally been considered a success in terms of facilitating the exchange of PGRFA, but not in terms of generating monetary benefit-sharing. To change this situation, an enhancement process was underway for years to enhance user-payment as well as to expand the scope of the MLS to include all PGRFA. The enhancement process failed to reach agreement at GB8, and after a period with only informal interactions among the Contracting Parties, GB9 agreed to recommence the process. Since the adoption of the Kalmar Declaration, there has also been significant progress in the International Plant Treaty on possible ways of encouraging, promoting, and supporting the realisation of farmers' rights.

The interrelation between the ABS regime and regimes on intellectual property rights (IPR) has been a controversial and ongoing issue with limited changes to the IPR regimes in the form of adaptations to the ABS regime. However, a tendency to interpret existing IPR rules in a more ABS-friendly direction may be seen by the European Patent Office in its interpretation of what type of living material is not patentable.



4. ACCESS AND RIGHTS

to genetic resources in the Nordic countries



4. ACCESS AND RIGHTS

to genetic resources in the Nordic countries

The 2003 Kalmar Declaration and the report of the first access and rights project established basic principles and understanding for the management of genetic resources in both the Nordic Gene Bank (the precursor to NordGen) and in the individual Nordic countries, considering the new international legal framework. The Declaration and the report contain several recommendations for the Nordic countries in respect of the determination of the legal status of genetic resources and ongoing follow-up of the international framework.

Since the Kalmar Declaration and the earlier project, the CBD legal framework has been expanded with the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, which entered into force in 2014. All of the Nordic countries apart from Iceland are parties to the Nagoya Protocol.

This chapter will first account for how the Nordic countries have individually followed up on the most relevant recommendations of the Kalmar Declaration. It will then address how the countries have followed up on the international legal framework on issues not directly covered by the Declaration. The collective response by the Nordic countries to the Kalmar Declaration through NordGen will be addressed in Chapter 6.

4.1. Legal status of genetic resources in the Nordic countries

In light of the new legal framework on access to genetic resources and sharing the benefits from their use, as well as the project report, the Kalmar Declaration recommended that the Nordic countries clarify the legal status of genetic resources. As it follows from the Kalmar Declaration recommendations below, the legal status differs from the different types of genetic resources:



17 The Nordic countries determine the legal status of their plant genetic resources and their wild relatives, and thus consider the following options:

- To declare that the rights to use genetic resources follow the rights to use the biological resources
- To specify that rights to use biological material include rights to restrict others from utilising the genetic material except on terms mutually agreed upon in private contractual agreements.
- To specify that rights to use genetic resources are separate from ownership over biological resources and that such rights can only be exercised through the use of intellectual property rights. This entails that in case access to genetic resources remains unregulated, the holders of biological resources cannot exercise any control over genetic resources.

None of the Nordic countries have followed any of these options.



18 The Nordic countries, as far as possible, handle the access to all domesticated plant genetic resources in the same manner, with the aim of facilitating free access to such genetic resources in the Nordic countries.

The Nordic countries have followed this recommendation. In the negotiations leading to the International Plant Treaty, the Nordic countries held that the MLS for facilitated access should not be restricted to certain species but should include all plant genetic resources for food and agriculture. The Nordic countries have followed this line by making no distinction between Annex 1 and non-Annex 1 taxa. This also follows from the fact that the Nordic countries are members of the European Cooperative Programme for Plant Genetic Resources (ECPGR) whereby access is granted on identical premises, using an SMTA.⁹⁶

In line with the division of responsibility between NordGen and the Nordic countries, the Nordic countries are obliged to facilitate access to vegetatively propagated material. Although this material is also formally included in the MLS, there remains practical and technical challenges in actually facilitating access to this material. For instance, there is a need for better information on the characteristics of the collections in field gene banks of vegetatively propagated material.

96. <https://www.ecpgr.cgiar.org/about/overview>The European Cooperative Programme for Plant Genetic Resources (ECPGR)

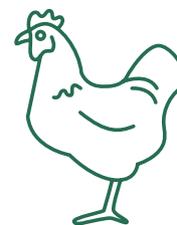
97. TemaNord 2008:588. Management and Exchange of Animal Genetic Resources – Nordic perspective

98. Ibid.

Domesticated animal genetic resources

19

Ascertains that farm animal genetic resources presently are regulated by private contractual agreements, and has therefore not identified any reasons to recommend any change of the present legal status or regulation of access.



The Nordic countries have followed this recommendation.

A follow-up project on the legal framework for the rights and exchange of animal genetic resources in the Nordic Region delivered a report in 2008 "Management and Exchange of Animal Genetic Resources – Nordic perspective". It addressed stakeholders' needs for a legal framework and offered possibilities for assessing the value of sales and exchange of genetic material from farm animals in the Nordic Region. In addition, the project analysed the possible need for framework and regulation related to animal breeding and genetic resources in a global context.⁹⁷

The report did not change the conclusion of the Kalmar Declaration on maintaining the legal status. However, it does conclude that "the Nordic countries either as a Nordic initiative or by individual countries could start analytical work and/or review the needs for regulatory framework in the sector...". It further concludes that "the current very active and beneficial exchange of animal genetic resources should not be constrained by stiff bureaucratic rules. On the other hand, code of conduct-related recommendations would be needed to guarantee sound schemes for gene-flow between widely deviating production environments." In respect of IPR, it is concluded that since animal breeds are very variable and under continuous development, they cannot be protected in the same manner as plant varieties, which are generally uniform, distinct, and stable. Nevertheless, so-called process patents linking data collection, analysis, and selection and management decisions together are relevant also for animal and plants. The report saw "an urgent need for a discussion about how the general principles [of process patents] apply to the area of animal breeding and the needs for implementing special rules in this field."⁹⁸

The Nordic countries have not acted upon the recommendations of this report.

Forest genetic resources

20

The Nordic countries initiate a project with the aim of providing a basis for the Nordic countries' decision regarding the legal status of their forest tree genetic resources, but has not identified any reasons to recommend regulation of access.



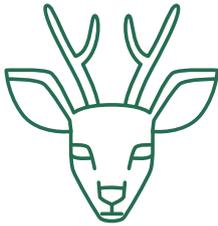
The Nordic countries have followed the recommendation both with regard to not introducing the regulation of access and to conduct a project on the legal status.

The 2012 project report concluded, among other things, that:

*All in all, given the practice in the Nordic countries, and the forthcoming and present international legislative regime, developments that could hinder access and exchange of FGR in the Nordic region could not be identified. Therefore, no specific legal steps seem necessary.*⁹⁹

When Norway decided to regulate the utilisation of genetic resources from abroad ("checkpoint regulation"), the use of OECD forest schemes is recognised as a certificate of compliance. Consequently, no additional bureaucracy has been introduced for FGR while compliance with NP is upheld and the international exchange of FGR can continue.

Wild genetic resources



21 The Nordic countries establish the legal status of their wild genetic resources.

Only Norway and Greenland have followed this recommendation.

The Nature Diversity Act of 2009 determines the legal status of wild genetic resources in Norway. Section 57 of the Act states that:

Genetic material obtained from the natural environment is a common resource belonging to Norwegian society as a whole and managed by the state. It shall be utilised to the greatest possible benefit of the environment and human beings in both a national and an international context, also attaching importance to appropriate measures for sharing the benefits arising out of the utilisation of genetic material and in such a way as to safeguard the interests of indigenous peoples and local communities.

Section 59 limits the possibilities to apply IPR to material in support of keeping material in the public domain:

*Any person that receives genetic material derived from a public collection shall refrain, in Norway or abroad, from claiming intellectual property rights or other rights to the material that would limit use of the material, such as use for food or agriculture, unless the material has been modified in a way that results in a substantial change.*¹⁰⁰

With regard to marine genetic resources, the Marine Resources Act (Section 2) determines that wild living marine resources belong to Norwegian society as a whole.¹⁰¹

Norway has not determined any explicit legal status of genetic resources from outside "the natural environment", a term that is not defined in Norwegian law. Collection for use in public collections and for use and further breeding or cultivation in agriculture or forestry does not require a permit.¹⁰²

Greenland in its act on the utilisation of genetic resources and related activities (No. 3 of 2016) states that the Greenland Government has a sovereign right to dispose of and utilise Greenland's genetic resources and to give others access to collect and utilise them. It also states that genetic resources of Greenland shall

99. [Myking T. et al. \(2012\). Access and rights to forest genetic resources in the Nordic region.](#)

100. [Norwegian Nature Diversity Act](#)

101. [Norwegian Marine Resources Act](#)

102. [Norwegian Nature Diversity Act, Section 57](#)

be managed in accordance with the Greenlandic people's rights as peoples and indigenous peoples under international law.¹⁰³ The law does not make a distinction between different types of genetic resources.

Other Nordic autonomous territories with responsibility for managing genetic resources within their territories are Åland (Finland) and the Faroe Islands (Denmark). Neither have introduced the regulation of access to genetic resources.

4.2. Legal or other measures to regulate access to genetic resources of users outside the country

22

The Nordic countries have divergent opinions regarding the need for regulating access to wild genetic resources and that the issue is under debate in some of the Nordic countries. For this reason, no recommendation can be made on this issue



4.3. Status on regulation of access

The different views referred to in the Kalmar Declaration are reflected in the different ways the Nordic countries have subsequently approached this issue.

The CBD specifies the sovereign rights to genetic resources as a right for countries to require prior informed consent (PIC) for access to their genetic resources unless otherwise determined by the country.¹⁰⁴ According to the 2003 project report on access and rights to genetic resources:

The Project Group does not, for the time being, find sufficiently convincing reasons to suggest regulating access to wild genetic resources. It does, however, recognise that national views on this matter may differ. Some members of the group, however, would not exclude future possibilities of regulating access to i.e. certain groups of genetic resources or to genetic resources located in specific areas. Circumstances in the future that may lead to a different conclusion should be based on better knowledge of the potential value of wild genetic resources, and further development of exclusive private rights to genetic resources through patents and other forms of intellectual property rights.

At present, only Greenland regulates access to its domestic genetic resources with no distinction between wild and domesticated genetic resources. Access to Greenlandic genetic resources is subject to PIC and a benefit-sharing agreement with the Government on the use of the resources.¹⁰⁵ This legislation was enacted in 2016 replacing legislation that covered not only access to genetic but also biological resources.

Norway has enacted an authorisation for regulation in the Nature Diversity Act according to which the King may determine that the collection of biological material from the natural environment for utilisation of such material, requires a permit from the Ministry. The authorisation provides different specifications on how it is to be implemented, including that the regulation of access does not limit any owner of biological material or land or other entitled person to deny access.¹⁰⁶ The Norwegian Marine Resources Act includes a similar authorisation for permits

103. [Inatsisartutlov nr. 3 af 3 juni 2016 om udnyttelse af genetiske ressourcer og aktiviteter i forbindelse dermed.](#) (Law on the utilisation of genetic resources and activities in connection with the same) § 2.

104. CBD Article 15, para. 5.

105. [Inatsisartutlov nr. 3 af 3 juni 2016 om udnyttelse af genetiske ressourcer og aktiviteter i forbindelse dermed.](#) (Law on the utilisation of genetic resources and activities in connection with the same) § 7.

106. Norwegian Nature Diversity Act. Act of 19 June 2009 No. 100 Relating to the Management of Biological, Geological and Landscape Diversity. Section 58. *The King may determine that the collection of biological material from the natural environment for the purpose of utilising the genetic material, or the utilisation of such material, requires a permit from the Ministry. If a collection permit has been granted, no new permit is required for subsequent utilisation, but the conditions for the permit apply correspondingly to any person that acquires the material or results arising from the collection. Collection for use in public collections and for use and further breeding or cultivation in agriculture or forestry does not require a permit. The first paragraph does not limit the right of any owner or other entitled person to deny access on other grounds) to the biological material, or b) to the land from which the genetic material is obtained.*

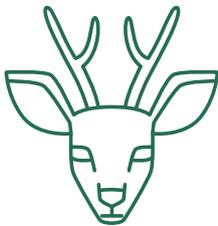
to marine bioprospecting. It includes a specification that a permit may lay down that a proportion of the benefits arising out of the use of Norwegian marine genetic material shall accrue to the state.¹⁰⁷

A process was initiated in 2013 to bring these authorisations in the Nature Diversity Act and Marine Resources Act into effect. This continues to be a work in progress. Meanwhile, the collection of biological material from the natural environment for the purpose of utilising the genetic material, or the utilisation of such material, currently requires no permit. The Act recognised the special nature of GRFA: "Collection for use in public collections and for use and further breeding or cultivation in agriculture or forestry does not require a permit."

Sweden, Denmark, and Finland have taken a different approach. When ratifying the CBD, Sweden and Denmark declared in accordance with CBD Article 15.5 that they, for the time being, would not regulate access to domestic genetic resources.^{108 109} This situation did not change when ratifying the Nagoya Protocol.

In connection with its implementation of the Nagoya Protocol, Finland opted not to regulate access to national genetic resources even if their value as northern adaptations was recognised during the preparatory work. For example, certain special forms of forest trees, seabed bacteria, and freshwater algae were identified as potentially valuable organisms, but it was also clear that few species are unique to Finland. It was considered that the administrative cost of regulating the genetic resources could easily exceed the potential revenues, whereas free access would support research and development and generate wider benefits.

4.4. Registration of the collection of wild genetic resources



23 The Nordic countries consider the need to provide an overview of the benefits of wild genetic resources, e.g., in the form of a simple system for registering the collection of wild genetic resources in order to increase the knowledge and awareness of these genetic resources and their protection.

None of the Nordic countries has introduced a registration system of this kind.

4.5. Legal or other measures to compel users of genetic resources to comply with the access and benefit-sharing regulations in the country providing the genetic resources



24 The Nordic countries facilitate the implementation of international arrangements and agreements in the field of genetic resources by implementing the Bonn guidelines regarding access to genetic resources and benefit sharing adopted by the Conference of the Parties to the Convention on Biological Diversity, including that they as users of genetic resources take steps to help the providing countries comply with access legislation, as well as by designating a national coordinator for the exchange of information about genetic resources.

The Kalmar Declaration and the former access and rights project were pioneers in highlighting the role of the Nordic countries and their citizens as users of genetic resources of other countries and on how the Nordic countries could support compliance with access regulations in providing countries. At that time, the issue of “user-country measures” was controversial among developed countries with no support from most of them. The project report offered a catalogue of different user country measures to be taken, and emphasised the importance of such measures both to support ABS as an incentive for protecting biodiversity and as a way to build trust with developing countries with high expectations for ABS.¹¹⁰

As referred to in Chapter 3, a primary rationale for the adoption of the Nagoya Protocol in 2010 was a demand by developing countries to complement the CBD framework for ABS with clear legal obligations for user countries in order to support compliance with provider-countries’ access regulations. This was generally supported by the Nordic countries being parties to the Protocol.

Norway was probably the first country in the world to introduce legislation of this kind through Section 60 of the Nature Diversity Act adopted in 2009.¹¹¹ The import into Norway of genetic material from a provider state that requires PIC may take place only in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent and the State may enforce the conditions by bringing legal action. The importer of genetic material is required to attach information regarding the country from which the genetic material has been received and, if PIC is required, proof of PIC.¹¹² If the provider country is not the country of origin, the country of origin shall also be stated.¹¹³

These provisions were enacted before the adoption of the Nagoya Protocol and consequently did not cover the new and more specific requirements for countries as user countries, for instance that they must designate checkpoints to receive and disseminate information on the exploitation of genetic material from other countries, and on an internationally recognised certificate of compliance. In addition, the Protocol introduced user measures regarding prior informed consent and mutually agreed terms for access to traditional knowledge from indigenous peoples and local communities. To fill these gaps, in 2021 Norway took steps to supplement its legislation by amending NDA Section 60 and issuing a new statutory order on checkpoints.¹¹⁴

In 2012, Denmark enacted the “Act on Benefit Sharing from the Utilization of Genetic Resources” as a basis for the ratification of the Nagoya Protocol. The Act prohibits the use of genetic resources acquired in violation of access legislation in the provider country. Such legislation shall fulfil the conditions for access regulation, including PIC. A similar requirement for users of genetic resources applies to the use of traditional knowledge associated with genetic resources in violation of the provider country’s legislation.¹¹⁵ The Act applies in parallel with EU Regulation 511/2014 discussed below, but in practice is considered to have been replaced by the EU Regulation. The Danish Environmental Protection Agency is the national competent authority for the Nagoya Protocol.

Finland has enacted the Act on Genetic Resources 394/2016 to supplement EU Regulation 511/2014 and appointed Natural Resources Institute Finland (Luke) and the Finnish Environment Institute (SYKE) as its national competent authorities. The Act also obliged users to notify the competent authorities within a month

107. Norwegian Marine Resources Act. Act of 6 June 2008 no. 37 relating to the management of wild living marine resources. Sections 9 and 10.

108. [Riksdagen \(1993\) Om godkännande av konventionen om biologisk mångfald Proposition 1992/93:227.](#)

109. [Folketinget \(1992\). Forslag til folketingsbeslutning om ratifikation af Konventionen om den biologiske mangfoldighed.](#)

110. Nordic Council of Ministers (2003) Access and Rights to Genetic Resources – A Nordic Approach. Nord 2003:16. Pp. 153-158.

111. [Nature Diversity Act, 2009. \(NDA\)](#)

112. NDA, Section 60.2.

113. NDA, Section 60.3.

114. [Høring – Endringer i naturmangfoldlovens § 60 og forslag til ny forskrift om kontroll med utnytting i Norge av genetisk materiale med opprinnelse i andre land og tradisjonell kunnskap knyttet til utnytting av slikt materiale.](#)

115. [Lov nr. 1375 af 23 december 2012 om udbyttedeling ved udnyttelse af genetiske ressourcer.](#)

116. [Förordning \(2016:858\) om användning av genetiska resurser och traditionell kunskap om sådana resurser. Miljötillsynsförordning \(2011:13\)](#)

117. [Inatsisartutlov nr. 3 af 3. juni 2016 om udnyttelse af genetiske ressourcer og aktiviteter i forbindelse dermed.](#) (Law on the utilisation of genetic resources and activities in connection with the same) § 8.

118. Regulation (EU) 511/2014 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 out of their Utilization in the Union. 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.

119. [Regulation 511/2014, Art. 4.1.](#) Although due diligence is not defined in the Regulation, [the Guidance document on the scope of application and core obligations of Regulation of 2020](#) identifies the following elements as common and are repeatedly cited:

Due diligence refers to the judgment and decisions that can reasonably be expected from a person or entity in a given situation. It is about gathering and using information in a systematic way. As such, it is not intended to guarantee a certain outcome or aiming at perfection, but it calls for thoroughness and best possible efforts.

Due diligence goes beyond the mere adoption of rules and measures; it also entails paying attention to their application and enforcement. Inexperience and lack of time have been held by the courts not to be adequate defences.

Due diligence should be adapted to the circumstances – e.g. greater care should be applied in riskier activities, and new knowledge or technologies may require the adaptation of previous practices.

120. Ibid. Art. 4.2.

121. Ibid. Art. 4.3(b).

122. Ibid. Art.5.

123. Ibid Art. 6.

124. Ibid. Art. 7.

125. Ibid. Art. 9.

126. Ibid. Art. 10.

127. Ibid. Art. 11.

after the import of material. Notification can be made electronically and must include the information defined in Article 4, paragraph 3 of the EU's Genetic Resource Decree.

Sweden has also supplemented the EU Regulation through the delegation of supervisory authority to the Swedish Environmental Protection Agency (Naturvårdsverket).¹¹⁶

Greenland prohibits the use of genetic resources and associated knowledge acquired in violation of access legislation in the providing country.¹¹⁷

EU Regulation on compliance measures for users of genetic resources

The user measure obligations of the Nagoya Protocol (NP) have been implemented by the EU through Regulation 511/2014 (ABS Regulation) and the Implementing Regulation 2015/1866, which are therefore applicable to the three Nordic EU member states, Denmark, Finland, and Sweden.¹¹⁸ The EU has, as such, not implemented other provisions of the NP. Consequently, it is left to the discretion of the member states to decide if and how they, as providers, wish to regulate access to their domestic genetic resources.

A key element of the ABS Regulation is that users of genetic resources are required to exercise due diligence:

*To ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilize 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.*¹¹⁹

Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms (MAT) if required by applicable legislation or regulatory requirements.¹²⁰ Users shall seek, keep, and transfer to subsequent users an internationally recognised certificate of compliance together with information on the content of the MAT. If this certificate is not available, other relevant information and documents about the transaction shall be kept and transferred to the users.¹²¹

The EU Commission shall establish a register of collections within the Union.¹²² Member states shall designate competent authorities and focal points,¹²³ and two checkpoints for monitoring compliance: when receiving research funding, and at the time of a final product developed.¹²⁴ Member states shall also conduct checks on user compliance with due diligence,¹²⁵ retain the records of these checks for at least five years,¹²⁶ and lay down rules on penalties.¹²⁷

The Commission Implementing Regulation lays down detailed rules for the implementation of Regulation 511/2014 regarding the registering of collections, the monitoring of user compliance, and best practices. In 2021, the EU Commission issued a guidance document on the provisions and implementation of the ABS Regulation.¹²⁸

An analysis of the consequences of applying the ABS Regulation for public research institutions and industry, based on interviews, was carried out in 2020.¹²⁹

The respondents express that the Regulation is creating a significant administrative burden for research and industry, primarily because users face difficulties in obtaining information about which obligations and procedures the providing countries need to be followed in a specific case. According to the respondents, users incur delays and additional costs. EU companies and researchers are seen as disadvantaged when compared to their counterparts in countries that lack similar compliance legislation. The analysis provides a number of recommendations to lessen the burden for research and industry ranging from increasing the level of information about the ABS Regulation to rethinking the whole NP approach of access to genetic resources and benefit-sharing on a country-to-country basis.

However, more criticism of the ABS Regulation has come from the opposite side, namely that the Regulation is too weak to meet its normative objectives. Its temporal scope has been criticised for applying to ABS transactions only after the entry into force of the NP, thereby not supporting compliance with access legislation enacted on the basis of the CBD. Moreover, for the transactions actually covered by the Regulation, the trigger is the time of *access*, not *utilisation*, thereby excluding large amounts of genetic resources and traditional knowledge acquired prior to the Nagoya Protocol, but which has still yet to be utilised.¹³⁰

It has also been criticised that the EU Regulation includes no means for structural monitoring and tracing compliance. User declarations will not be made public, and providers will depend on the accidental discovery of use and commercialisation.¹³¹

Measures to establish mutual supportiveness between ABS regulation (pursuant to the CBD/NP and the International Plant Treaty) and IPR regulation

One user measure with a particularly significant and controversial profile throughout the negotiations of ABS under the CBD and the Nagoya Protocol has been the disclosure of origin of genetic resources in patent and other IPR applications. As discussed in Chapter 3, a disclosure obligation has long been on the table in international IPR forums, although no agreement has been reached. Furthermore, the Nordic countries have different approaches on this issue.

Denmark was the first developed country to adopt legislation requiring the disclosure of origin in patent applications. According to the Danish provision from 2000, "if an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known." Failure to do so does not impede the granting of a patent or validity of the patent.¹³² Breach of this provision could imply a violation of the obligation in the Danish Penal Code to provide correct information to public authorities. The disclosure requirement does not include an obligation to disclose information on traditional knowledge.

In 2003, Norway amended its Patent Law to lay down that a patent application shall include information on the country from which the inventor collected or received the biological material (the providing country). If it follows from national law in the providing country that access to biological material shall be subject to PIC, the application shall provide information on whether such consent has been obtained. If the providing country is not the same as the country of origin of the biological material, the application shall also provide information on the

128. [Guidance document on the scope of application and core obligations of Regulation \(EU\) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. \(2021/C 13/01\).](#)

129. [Milieu Law & Policy Consulting, 2020. Analysis of implications of compliance with the EU ABS Regulation for research organisations and private sector companies.](#)

130. Natural Justice and Berne Declaration, 2013. [Will the European Union legalise biopiracy?](#) Rabitz, F. 2015. [Biopiracy after the Nagoya Protocol: Problem Structure, Regime Design and Implementation Challenges Brazilian Political Science Review.](#) The reason stated by the EU for the temporal scope of the ABS Regulation is the principle of non-retroactivity in legislation.

131. Godt, C., 2015. The multi-level implementation of the Nagoya Protocol in the European Union. In Coolsae, B. et al. 2015 (eds.) [Implementing the Nagoya Protocol. Comparing Access and Benefit-Sharing Regimes in Europe.](#) Brill Nijhoff.

132. Ministerial order. [Bekendtgørelse 1086 11/12 2000 om ændring af bekendtgørelse om patenter og supplerende beskyttelsescertifikater.](#)

133. [Norwegian Patents Act 2003, Section 8B](#).

134. (Plant Breeders' Rights Act, Section 4(3)).

135. [Norwegian Nature Diversity Act, Section 59](#).

136. [Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions](#)

country of origin and its legal requirements. Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code. Like in Denmark, the duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents.¹³³

Similar information requirements apply to applicants for plant variety protection.¹³⁴ Norway still adheres to the 1978 Act of UPOV rather than the 1991 Act given, in the view of Norway, its better balance between farmers' rights and breeders' rights.

In Norway, any person that receives genetic material from a public collection shall refrain, in Norway or abroad, from claiming IPR or any other rights to the material that would limit its use, such as for food or agriculture, unless the material has been modified in a way that results in a substantial change. If IPR over genetic material are established contrary to this, the competent authorities shall consider taking measures, including bringing legal action, to ensure the promotion of the genetic material as a common resource utilised to the greatest possible benefit of the environment and human beings.¹³⁵

The process recently initiated in Norway to amend its Nature Diversity Act (as described above), aimed at strengthening user measures in light of the Nagoya Protocol, also includes requirements on disclosure: It is envisaged that information in patent applications on the origin of genetic material and traditional knowledge and on consent requirements in the country of origin, must be entered in the patent register and disclosed in the announcement of a patent application. Corresponding requirements are introduced in relation to plant breeders' rights.

Finland, Sweden, and Denmark are covered by EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions which includes a preambular recital 27 (and thus non-binding) that if an invention is based on biological material, the patent application should, where appropriate, include information on the geographical origin of such material, if known.¹³⁶ Neither Finland or Sweden have introduced more specific national legislation on the disclosure of origin.

Breeders' exemption in patent law

The breeders' exemption is an important principle covered in laws on plant breeders, since all breeders need access to material to develop new, improved plant varieties. Although the EU patent directive does not have a breeders' exemption, some EU countries have opted to include this. Norway has considered including a breeders' exemption in a revision of the patent law in 2013, but these changes are yet to be made.



4.6. Legal or other measures to support that traditional knowledge associated with genetic resources held by indigenous peoples and local communities has been accessed with their approval and involvement

The topic of access and rights to traditional knowledge associated with genetic resources held by indigenous peoples and local communities was not covered by the Kalmar Declaration and the previous access and rights project. However, as discussed in Chapter 3, it was an important and legally innovative

topic for the Nagoya Protocol that was particularly relevant to Finland, Sweden, Norway, and Greenland with communities of indigenous peoples in those countries.

EU regulation No 511/2014 to which Finland, Sweden, and Denmark are bound determines that users shall exercise due diligence to ascertain that both genetic resources and associated traditional knowledge held by indigenous peoples and local communities have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements. Finland and Sweden have enacted supplementary legislation to the Regulation on this matter.¹³⁷

However, the point of departure of the EU Regulation with regard to traditional knowledge held by indigenous peoples and local communities is that applicable access and benefit-sharing legislation enacted by the State is already in place with which the user must comply. The Regulation does not prescribe that Member States introduce such legislation for indigenous peoples and local communities within the States.

In Finland, if the utilisation of the Sámi people's traditional knowledge is included in the use of genetic resources, PIC must be acquired. A competent authority (SYKE or Luke) may be consulted to establish whether it is necessary. A database, in which traditional knowledge of the Sámi people, related to genetic resources will be recorded, is under preparation. The right to access the information in this database shall be applied for via the competent authority (SYKE, Luke). The application must specify the genetic resources concerned, the intended use of the knowledge, and who the user is. The competent authority will inform the Finnish Sámi Parliament of the application.¹³⁸

In Sweden, a process is ongoing on legal provisions on consultation with the Sámi people in matters of Sámi concern,¹³⁹ including use of traditional knowledge. The new law is expected to enter into force on 1 March 2024.

An amendment to Norway's Nature Diversity Act provides that the interests of indigenous peoples and local communities shall be respected when traditional knowledge associated with genetic resources, held by such peoples and communities, is accessed and utilised.¹⁴⁰ A Regulation under the Nature Diversity Act was issued in 2017 stipulating that access to and utilisation of traditional knowledge requires PIC from the indigenous peoples or local communities holding the knowledge, as well as rules on sanctions against misappropriation. Furthermore, it stipulates that consent may be granted on specific conditions, for example that the indigenous peoples or local community shall receive a reasonable share of the benefits obtained by using the knowledge to which the consent applies.

Any person that uses traditional knowledge shall acknowledge and, to the extent reasonable, declare that the knowledge was developed, used, sustained, and passed on by the community in question.¹⁴¹

The ABS law of Greenland equates genetic resources and associated traditional knowledge implying that the provisions on access to genetic resources apply correspondingly to access to associated traditional knowledge. The law further lays down that a rights holder carrying out activities relating to the exploitation of genetic resources must examine and assess whether relevant

137. Sweden: Environmental Code, as amended through Law SFS 2016:783. Finland: Act on Genetic Resources 394/2016.

138. [Finnish legislation on access to genetic resources](#)

139. <https://www.regeringen.se/rattsliga-dokument/prop-osition/2021/10/prop.-20212219/> (in Swedish)

140. Norwegian Nature Diversity Act, Section 61(a).

141. [Forskrift om beskyttelse av tradisjonell kunnskap knyttet til genetisk materiale. \(Regulation on the protection of traditional knowledge associated with genetic material\).](#)

traditional knowledge exists and whether and how any traditional knowledge can be used in connection with the exploitation of the genetic resources.¹⁴² Notably, the permit to obtain access to traditional knowledge is also granted by the Greenlandic government, not by a community holding the knowledge as is the case in Norway.



4.7. Legal or other measures to implement the International Treaty on Plant Genetic Resources for Food and Agriculture

The Nordic Region is quite unique in terms of plant genetic resources for food and agriculture thanks to the application of a significant degree of joint governance through NordGen as discussed in Chapter 6. This may go some way to explaining why the individual Nordic countries have generally not found a need for substantial legislation to implement the International Plant Treaty.¹⁴³ Obligations in the International Plant Treaty directed at the Parties, such as those in Articles 5 and 6 on the conservation and sustainable use of PGRFA, have been addressed by national policies and programmes either broadly on genetic resources for food and agriculture or specifically on plant genetic resources.

Finland has two strategies in place: Genetic Resources Policy of the Ministry of Agriculture and Forestry from 2019 and "Finland's National Genetic Resources Programme for Agriculture, Forestry and Fishery" from 2020.¹⁴⁴ The National Genetic Resources Programme for Agriculture, Forestry and Fisheries revises and updates the earlier National Plant and Animal Genetic Resources Programmes (2001 and 2004). The programme covers the genetic resources of cultivated plants, domesticated animals, forest trees, and fish. It also provides the guidelines for the preservation, conservation, and sustainable use of genetic resources. The implementation of the programme is co-ordinated by Luke. Genetic resources are being conserved by several public and private operators, with Luke playing the most significant role.

In order to strengthen the strategic grip and consistency of genetic resources policy, the Finnish Ministry of Agriculture and Forestry has developed guidelines for genetic resources policy in its field. The key objectives of the guidelines are to integrate genetic resources into strategies for the protection and sustainable use of biological resources, to ensure the continuity of maintenance of genetic resources, and to promote the responsible use of genetic resources in a changing environment.

Denmark has issued the latest "Strategy for Plant Genetic Resources in Agriculture 2017–2020."¹⁴⁵ An updated five-year strategy for agricultural plant genetic resources is under development. The national programme for plant genetic resources for food and agriculture is co-ordinated by the Danish Agricultural Agency.

The latest strategy of Norway is a national strategy for the conservation and sustainable use of genetic resources for food and agriculture named "Storage of genes – opportunities and preparedness for future agriculture" from 2019.¹⁴⁶ Currently, an action plan that will operationalise the strategy is in its final stage of development.

142. [Inatsisartutlov nr. 3 af 3. juni 2016 om udnyttelse af genetiske ressourcer og aktiviteter i forbindelse dermed. § 5.](#)

143. Sweden has issued a one-paragraph regulation concerning facilitated access to plant genetic resources according to which a State administrative authority holding Annex 1 plant genetic resources may conclude an agreement with an individual on simplified access to the resources in accordance with Article 12 (4) of the Treaty. [Förordning om förenklat tillträde till växtgenetiska resurser.](#) Furthermore, decrees have been issued in Finland on the entry into force of the Treaty and the delegation of powers related to its provisions.

144. Pehu, T. (2019) [Genetic resources policy of the Ministry of Agriculture and Forestry](#) Pehu, T., Kiviharju, E., Rusanen, M., Kantanen, J., Heinimaa, J. (2020). [Finland's National Genetic Resources Programme for Agriculture, Forestry and Fishery](#)

145. [Strategi for jordbrugets plantegenetiske ressourcer 2017-2020.](#)

146. [Förråd av gener – muligheter og beredskap for framtidens landbruk. Nasjonal strategi for bevaring og bærekraftig bruk av genetiske ressurser for mat og landbruk.](#)

Another Norwegian contribution to the implementation of the International Plant Treaty is the establishment in 2006 of the Norwegian Genetic Resource Centre as an advisory and executive body for the Norwegian Ministry of Agriculture and Food. The role of the centre is to promote the conservation and use of Norwegian genetic resources in both livestock, plants, and forest trees.¹⁴⁷ A further contribution is the establishment of the Svalbard Global Seed Vault in 2008.¹⁴⁸ Furthermore, Norway is the only Nordic country to provide annual contributions to the International Plant Treaty Benefit-sharing Fund (equalling 0.1% of annual seed sales in Norway).

Sweden's "National programme for diversity of cultivated plants", established in 2000, recently launched its new five-year programme.¹⁴⁹

In terms of placing accession into the MLS and making plant genetic resources available for the MLS, the Nordic countries all assign a special role to Nord-Gen in this regard.¹⁵⁰ This role is further discussed in Chapter 6.

Iceland has issued a national strategy for the conservation of genetic resources in agriculture for 2019 to 2023. The programme covers the genetic resources of cultivated plants, domestic animals, forest, and freshwater fish. The programme is updated every five years and was first issued for the period 2009 to 2013. The programme is co-ordinated by the Icelandic Council for Genetic Resource in Agriculture (ICGRA) and the Genetic Resource Centre (GRC) at the Agricultural University of Iceland (Lbhl). The primary role of ICGRA and GRC is to distribute knowledge on genetic resources and their importance, advise stakeholders and government on the conservation and sustainable use of genetic resources in agriculture, and encourage research on genetic resources.

Interpretation of the International Plant Treaty requirement for plant genetic resources to be covered by the MLS that they are "under the management and control of the Contracting Parties and in the public domain"? (Article 11.2)

The 2003 report of the first project on access and rights discussed various interpretations of the notion under the management and control of the Contracting Parties and in the public domain. These include viewing the two elements as somehow overlapping, which implies that plant genetic resources in the public domain cover those that are publicly available, that is to say in public gene banks or on public land. Another interpretation put forwards is plant genetic resources not protected by IPR.¹⁵¹

In its preparatory work prior to acceding the International Plant Treaty, Sweden noted that the MLS covers all material in Annex 1 of the International Plant Treaty which is under the administration and control of the Parties and which is publicly available, that is to say all material which was not covered by special rights. It further noted that amendments to certain government instructions or other administrative regulations on the right of access to genetic resources under state administration might be considered, although any regulation should be postponed until a decision has been taken on how the SMTA was to be formulated.¹⁵²

In its proposition to ratify the International Plant Treaty, Norway clarifies that plant genetic resources listed in Annex I and managed by public administrative bodies and companies fall within the scope of the MLS.¹⁵³

147. [Norsk genressurscenter – Nibio.](#)

148. [Svalbard Global Seed Vault](#)

149. [Programmet för odlad mångfald 2021–2025 – samarbete för hållbarhet.](#)

150. [National Reports to the ITPGRFA.](#)

151. Nordic Council of Ministers. Access and Rights to Genetic Resources – A Nordic Approach. Pp. 68–69.

152. [Regeringens proposition 2002/03:52. Det internationella fördraget om växtgenetiska resurser för livsmedel och jordbruk.](#) No additional legal measures were taken as a result of the SMTA being adopted.

153. [St.prp. nr. 51 \(2003–2004\). Om samtykke til ratifikasjon av Den internasjonale traktat om plantegenetiske ressurser for mat og jordbruk.](#)

Measures taken to encourage private holders of plant genetic resources to include these under the International Plant Treaty's MLS (Article 11.3)

No systematic measures are known to have been taken by the Nordic country parties.

Options to realise farmers' rights

The International Plant Treaty has developed options to support, promote and enhance the realisation of farmers' rights. Farmers' rights support farmers' access to PGRFA, including from gene bank collections, as well as conditions for farmers in accessing and using different plant varieties. Options could be to realise farmers' rights by reviewing and adjusting seed regulation and IPR as necessary.

Only Norway and Sweden have shared experiences on the implementation of farmers' rights to the Inventory of the International Treaty.

Norway and Sweden have initiatives to support farmers' access to gene bank material through community seed banks.

Norway has decided to continue adhering to the 1978 Act of the UPOV Convention since it gives more flexibility to recognise farmers' rights to save and use farm-saved seeds. In 2010, Norway changed its seed regulation so as to better facilitate the use of traditional varieties.

4.8. Summing up

With regard to the regulation of access to domestic genetic resources in line with the CBD, the Kalmar Declaration did not produce direct recommendations to the Nordic countries, since there was no agreement to do so.

The Nordic countries continue to have different approaches to this matter. Sweden, Finland, Iceland, and Denmark have decided that there is no need for a permit to access domestic genetic resources. Even before the Kalmar Declaration, Sweden and Denmark officially declared that they did not intend to do so.

Greenland and Norway have taken steps toward regulating access. Both have determined a legal status of genetic resources different from the biological resources they are derived from, whereas for Norway this only applies to wild genetic resources.¹⁵⁴

Greenland is the only country to have gone further and introduce "classic" access and benefit-sharing legislation with requirements for PIC and MAT, while Norway has enacted an authorisation for such legislation concerning wild genetic resources. This authorisation has yet to be used.

The difference of the Greenlandic approach compared to the other countries may be seen in light of the country's isolated geographical location and thereby the uniqueness of its genetic resources.

The deliberate choice of not putting in place domestic ABS regulation in the Nordic countries (except Greenland) on genetic resources for food and agriculture (GRFA) could be considered to be in line with the advice of the FAO guidance since, according to this guidance, GRFA need to be accessed and sustainably used in order to be conserved.¹⁵⁵

154. The Greenlandic legislation does not distinguish between wild and domesticated genetic resources.

155. [FAO \(2019\) ABS Elements: Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture.](#)

The decision not to regulate access domestic resources does not mean a lack of respect of other countries choosing differently. The Kalmar Declaration was pioneering among developed countries in its recommendations to the Nordic countries as users of genetic resources to apply measures in support of compliance with access legislation in providing countries. This element was later strongly reflected in the NP. Such "user measures" were enacted by Norway already before the NP as probably the first country in the world, followed by Denmark after the adoption of the NP. The EU later adopted more detailed legislation on user-country obligations through Regulation 511/2014 to which Finland, Sweden, and Denmark are bound. In 2021, the checkpoint regulation entered into force in Norway.

Denmark was the first developed country to enact legislation on the disclosure of origin of genetic resources in patent applications, followed by Norway. Norway also requires the disclosure of origin in applications for plant breeders' rights. Norway considered including a breeders' exemption in a revision of the patent law of 2013.

As regards benefits arising from the use of genetic resources and associated traditional knowledge held by indigenous peoples and local communities (ILCs), Norway has enacted legislation that requires PIC for using traditional knowledge associated with genetic resources from ILCs. Finland has enacted a PIC requirement for using traditional knowledge held by the Sámi people, and Sweden is in the process of establishing formal consultation with the Sámi Parliament of Sweden on matters dealing with traditional knowledge. Greenland has similar provisions for access to genetic resources and access to associated traditional knowledge, with both requiring a permit from the government.

Regarding the implementation of the FAO International Plant Treaty, the Kalmar Declaration mainly addressed the role of the Nordic Gene Bank (now NordGen). Regarding the exchange of genetic resources, the Nordic countries have made no distinction between Annex 1 and non-Annex 1 taxa thereby following a Kalmar Declaration recommendation to facilitate free access to PGRFA in general.

5. DIGITAL WORKSHOPS

on practices and experiences with
the exchange of genetic resources

5. DIGITAL WORKSHOPS

on practices and experiences with the exchange of genetic resources

A series of digital expert workshops were held in the first part of 2021 to discuss in turn a Nordic approach to access and rights to one of the five groups of genetic resources, namely animal, plant, aquatic, forest, and wild genetic resources. Among other things, the workshops looked at practices and experiences with the exchange of genetic resources within the Nordic Region and between Nordic and other countries. The following information on the exchange of animal, aquatic and forest genetic resources has primarily been obtained through presentations and discussions at the expert workshops.

Wild genetic resources

The workshop discussed crop wild relatives (CWR) which contain genetic diversity that is likely to be of increased importance for breeding in the future in relation to climate change, food security, and environmentally friendly agriculture. 20% of NordGen's accessions are classified as wild representing around 6,500 accessions that are conserved and for which access is provided to researchers, plant breeders, botanical gardens, and museums.

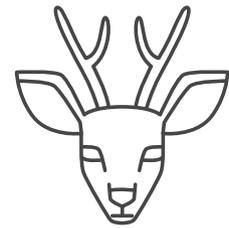
The workshop looked at the legislation on access and rights to genetic resources in Greenland, the only country that has enacted ABS regulation in accordance with the framework set up by the Convention on Biological Diversity (CBD) and the Nagoya Protocol. Users of genetic resources from Greenlandic territory are to obtain a permit from the Department of Business and Trade followed by negotiations of MAT. More than 300 permits have been granted between the introduction of the legislation in 2010 and 2020. These have mostly been for scientific purposes and, to a much lesser degree, for commercial purposes.

It was argued that, in an international perspective, Nordic wild genetic resources are probably most important for ecological and taxonomical research, except for some marine genetic resources where there is demand, and consequently ABS regulation may be relevant.

Examples were presented that the right of public access to nature in some of the Nordic countries may create conflicts with landowners due to increased commercial interest in wild berries.

With regard to access to traditional knowledge held by indigenous peoples and local communities, it was argued that experiences of the implementation of access regulation in Norway should be studied to assess the need for similar regulation in other Nordic countries. This could be the subject of a Nordic project.

The workshop revealed that there are still different approaches among the Nordic countries on the need of the Kalmar Declaration's recommendation to determine the legal status of wild genetic resources including CWR.



It was argued that the issue on how to deal with DSI should not hamper research, and that one option could be to set up a global mechanism with a subscription/payment system for using DSI like in university libraries and with the payments being used for nature conservation. Nordic countries act like bridge builders between developed and developing countries in establishing the ABS framework under the CBD. They should play a similar role in resolving the current obstacles to the framework.

Furthermore, it was argued that in the context of ABS, there is too much focus on monetary benefits and a lack of recognition of non-monetary benefits such as knowledge generation and capacity building, and that co-operation between the Nagoya Protocol and other instruments dealing with access to genetic resources (like the FAO Plant Treaty) should be strengthened.



Plant genetic resources for food and agriculture

The free exchange of plant genetic resources for research and development, breeding, and education within the Nordic Region and between Nordic and non-Nordic countries was considered very important. The main benefits are to create more genetic diversity and to discover and re-discover new genes and alleles to cope with upcoming challenges in agriculture such as disease resistance, abiotic and biotic stresses, and variation for yield components. Participants at the workshop expressed general satisfaction with exchanges taking place using the International Plant Treaty MLS approach (in contrast to a Nagoya Protocol bilateral approach) and with the way NordGen has applied this approach.

It was argued that the use of PGRFA is restricted by the lack of data on the characterisation of the plant genetic material and important information on traits, such as whether the material is affected by regional conditions and climatic changes. "PGRs need to be characterised to become usable".

It was also argued that even with the facilitated exchange of material under the International Plant Treaty, exchanges are complex because there are national regulations on top of the international regulations such as phytosanitary restrictions.

The workshop participants discussed a possible new subscription system for access to the MLS, including the payment of a fee for access to collections. Some feared that this would create an obstacle to free access to PGR, be bureaucratic, and limit the use of genetic resources, while others saw the subscription system as necessary for ensuring the sharing of benefits from the Benefit-sharing Fund.

The exchange of plant genetic resources for research and development, breeding, education, and the like between Nordic and non-Nordic countries was seen as very important. The primary benefits in this regard are the facilitation of diversity, and the discovery and re-discovery of new genes and alleles to cope with upcoming challenges in agriculture such as disease resistance, abiotic and biotic stresses, and variation for yield components.

Support was expressed for an expansion of the MLS Annex 1 list to include things like pears, berries, and vegetables.

Access to micro-organism and non-plant resources (e.g. plant pathogens) is expected to play an increasingly important role in the future.

It was suggested that ABS in relation to plant material could be seen as gaining access to improved genetic material via UPOV or could be in the form of technology sharing with the ability to develop breeding possibilities.

Some highlighted the importance of obtaining material from gene banks other than NordGen as new sources for various traits.

Also at this workshop, the emergence of DSI was seen in a positive light, and it was suggested that DSI will increase the willingness of users/breeders to pay, and with a reduction in the need of accession for testing.

Animal genetic resources

Animal genetic resources (AnGR) are perhaps the type of genetic resources with the lowest degree of cross-border exchange, although there is widespread exchange of both conservation breeds and commercial breeds within the Nordic Region. An example of a conservation breed presented at the workshop: When the Swedish cow breed, Rödkulla, was about to go extinct, it was saved by imports from Norway and Finland.

As there is no international legal framework for the exchange of AnGR, these are covered by the CBD and the Nagoya Protocol. However, the workshop participants found little relevance of the international ABS regime for AnGR partly because there are no typical provider and recipient countries of AnGR – countries are often both. Furthermore, AnGR are mostly privately and only to a very limited extent publicly owned, and exchanges take place based on private legal contracts. In line with the Kalmar Declaration, experts in this field therefore do not recommend any changes to the current legal status or the introduction of conditions of access.

Furthermore, it was argued that the utilisation of traditional knowledge of Sámi people related to AnGR could be considered in an ABS context.

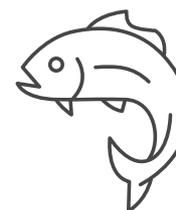
Further access to AnGR for the breeding industry was seen as important in order to maintain effectively sized populations and to avoid inbreeding in commercial breeds.

It was suggested to provide developing countries with access to Nordic animal genetic resources to help improve the production and economics of poor household farms.

Aquatic genetic resources

Aquatic genetic resources (AqGR) were not addressed as such by the Kalmar Declaration and the former access and rights project, but rather as a sub-component of wild genetic resources. Since then, the cultivation of AqGR has increased significantly both in the Nordic countries and worldwide.

In respect of the latter, there is a significant degree of cross-border exchange. Aquaculture production often takes place away from the native ranges of the species being used, and the industry is highly dependent on international flows of genetic resources both from the wild and from breeding centres. Since aquaculture is an expanding industry in both developing and developed



countries, genetic resources flow in all directions. Exchanges are regulated primarily by way of private legal commercial contracts that typically restrict the use of AqGR and prohibit their use for rival breeding programmes.

Shared benefits from the exchange of genetic resources for aquaculture have included co-operation on research and innovation, licencing for multiplier/broodstock producers, and strategic co-operation agreements and joint ventures. As was presented at the workshop, new genetic material is constantly needed in breeding to prevent inbreeding, to adapt to new pests and diseases, and to improve the disease resistance of farmed organisms. However, few exchanges are taking place between Nordic countries, mainly due to concerns about the health and protection of native wild populations.

It was revealed that the procedures applied for the exchange of genetic resources are mainly private legal contracts (MTAs) that restrict further breeding, and national restrictions due to health concerns and the risk of genetic interactions with native wild populations.

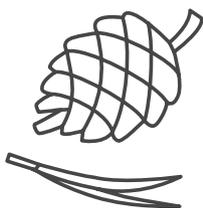
Some argued that the rapid improvement of growth and fish health when domesticating wild fish accords domestication with a large part of the value created by the breeder. This value needs protection in order to make breeding viable. It was also argued that there is limited knowledge about the effects of patenting (or other restrictions on access to AqGR) because most of the AqGR in aquaculture breeding programmes are privately owned.

With regard to wild aquatic genetic resources, there is growing international demand for genetic resources for marine bioprospecting also in Nordic and especially Arctic waters. This is the main reason why Norway has laid down authorisations for the King to prescribe that marine bioprospecting activities require a permit and that a proportion of the benefits arising out of the use of Norwegian marine genetic material for bioprospecting shall accrue to the state. As discussed above, these authorisations have yet to be utilised. The workshop discussions revealed that marine bioprospecting is perhaps the type of genetic resource use most relevant to "classic" ABS regulation as laid down in the CBD and the Nagoya Protocol. Iceland, with its well-developed bioindustry that uses material from the sea to produce high-value products, reported on preliminary considerations to introduce ABS regulation of marine bioprospecting.

A suggestion was made that Nordic countries could provide a legal model that does not restrict research while applying ABS for commercial activities, thereby continuing their bridge-building role vis-à-vis developing countries. It was argued that open access leaves all material open for patenting by big corporations. Others saw no need for a legal framework on ABS pointing to genetic resources already being restricted by other regimes, such as fishing laws CITES regulations and nature conservation laws.

Forest genetic resources

The thematic workshop revealed that cross-border exchanges of genetic resources primary take place within the same climate zone, and that, in practice, exchanges to and from Nordic countries take place with very few restrictions. The international ABS framework and the EU ABS Regulation appears to have very few implications for the users of forest genetic resources present at the workshop.



It was argued that smooth bureaucratic procedures for the exchange of forest genetic resources should be maintained. There are a number of inherent benefits in the import of access to forest genetic resources including increased productivity in forestry, climate change adaptation, and resistance improvement. Future climate change will probably require more materials from outside the Nordic countries. In addition, both basic research and breeding research are more efficient and can more easily produce novel information or solutions with broad access to forest genetic resources.

5.1. Summing up

An overall impression from the workshops was that cross-border exchanges within the Nordic Region and beyond are taking place widely, which is considered a benefit in itself. At the same time, the general level of knowledge of the international ABS legal framework is relatively limited among those involved in the exchange of genetic resources. From this follows that the international ABS legal framework has had relatively few practical implications for the exchange of genetic resources involving the Nordic countries. As providers of genetic resources, the Nordic countries (Greenland excluded) do not currently regulate access. As users of genetic resources from outside the Nordic Region, the imports that are taking place are largely from developed countries in the northern hemisphere, many of which have also opted not to regulate access to their domestic genetic resources. Consequently, the duties of users to comply with access regulation in providing countries, which is in place in four of the Nordic countries, are therefore less relevant.

This does not imply that cross-border exchanges of genetic resources are free from procedures and restrictions. However, these are mainly in the form of private legal contracts and import restrictions for the sake of human, plant, and animal health. These are often seen as bureaucratic and burdensome in themselves. Consequently, an additional layer of ABS regulation by many will be considered an additional burden.

6. ACCESS AND RIGHTS

to genetic resources held by the Nordic Genetic Resource Center (NordGen)

6. ACCESS AND RIGHTS

to Genetic Resources held by the Nordic Genetic Resource Center (NordGen)



6.1. What is NordGen?

The Nordic Genetic Resource Center (NordGen) is the Nordic knowledge centre for plant, animal, and forest genetic resources while also serving as the Nordic gene bank for seeds and plants. NordGen was established in 2008 as a merger between the Nordic Gene Bank (established 1979), the Nordic Gene Bank for Farm Animals (established 1983), and the Nordic Council for Forest Reproductive Material (NSFP) (established 1970). The institution falls under the umbrella of the Nordic Council of Ministers. Its plant genetic resources department (including the gene bank) is situated in Alnarp, Sweden, while the departments for animal and forest genetic resources are based in Aas, Norway. Additionally, NordGen has a security backup of in-vitro potatoes in Finland, and backups of the seed collection in Denmark and at the Svalbard Global Seed Vault.

As a knowledge centre and gene bank, NordGen's mission is to conserve Nordic genetic resources and facilitate their sustainable use for agriculture, horticulture, and forestry for current and future generations. Furthermore, NordGen shall promote the fair distribution of the sustainable use of genetic resources.¹⁵⁶

NordGen shares knowledge and genetic material to promote sustainable forestry, food and feed production, and other bio-based solutions in the Nordic Region's changing climate. It has a special responsibility for conserving and documenting genetic variation of Nordic material to ensure biodiversity and the sustainable use of genetic resources. It provides technical advice and information to decision-makers in the Nordic countries in international negotiations on genetic resources and aims to increase openness, co-operation, and the fair use of global genetic resources for the benefit of the Nordic countries through Nordic co-operation.¹⁵⁷ Furthermore, the cultural heritage that genetic resources for food and agriculture represents is important for NordGen's conservation practices.

Already in 1979, the Nordic countries established a Nordic Gene Bank for plants to conserve and facilitate the utilisation of their national plant genetic resources. The seed collection shall contribute to more resilience and new solutions to mitigate biodiversity loss and contributes to the increased use of genetic resources in order to achieve sustainable climate solutions, robust food and feed supply including new protein sources, sustainable plant choices in forests, better health, and sustainable ecosystem services.¹⁵⁸ At the same time, efforts are undergoing to improve documentation by characterising and evaluating the seed collection to make more data available to the Nordic community. All accessions in the gene bank, except for collections held for other gene banks, are under joint Nordic management and considered a shared asset.

156. [Statutes for NordGen \(in Swedish\)](#).

157. Ibid.

158. [NordGen Annual Review 2020](#)

Today, the gene bank contains a seed collection of approximately 34,000 seed samples (approximately 100 million seeds) from 530 species including crops and their wild relatives,¹⁵⁹ vegetables, forages, fibre and oil crops, industrial crops, medicinal plants, herbs, and ornamentals.¹⁶⁰ NordGen distributes seed material upon request to plant breeders, researchers, museums, botanical gardens, NGOs, and private users with a specific interest in saving old or rare varieties. From 2018 to 2020, NordGen witnessed a considerable increase (+89%) in the number of requested seed samples. Seeds are primarily requested by Nordic and European countries.¹⁶¹

NordGen manages the Nordic Partnership between Public and Private Actors (PPP), a collaboration aimed at strengthening work with plant breeding in the Nordic countries through collaboration between practical plant breeding and plant breeding research in pre-breeding.¹⁶²

NordGen is also responsible for operating the Svalbard Global Seed Vault in co-operation with the Norwegian Ministry of Food and Agriculture and the international organisation Crop Trust. The Seed Vault contains duplicates of seeds stored in gene banks for long-term storage to help safeguard the world's food supply in the face of famine, conflict, climate change, and the like.¹⁶³ The Svalbard Global Seed Vault offers free-of-charge, long-term storage of seed duplicates from international, national, and regional gene banks and institutions. The ownership of the seeds remains with the depositing gene bank.



Crop wild relatives

Crop wild relatives (CWR) are wild species that are closely related to cultivated crops. CWR are, in general, adapted to the local in their natural environment and climate.

CWR contain variations that are missing from modern cultivars. This include traits that are predicted to be of importance in future climate extremes, such as drought and heat tolerance, pest and disease resistance, and tolerance to water-logging. CWR are therefore one of the pieces needed for adapting Nordic agriculture to climate change and safeguarding future food security. CWR are of special interest to both researchers and plant breeders working on these issues. Targeted conservation activities are therefore needed to ensure CWR conservation.

The main approach for conserving CWR is to maintain them in their original environment through *in-situ* conservation. This is an efficient form of preservation since a large number of species can be conserved at the same time within protected habitats and there is a better potential to maintain large amounts of useful variation within species. Importantly, this increases the chances of long-term survival and creates opportunities for adaptation to ongoing climate change.

Ex-situ conservation at NordGen has an important role as a backup if *in-situ* conservation fails, and as a mechanism for facilitating access to CWR genetic resources. The two approaches should be co-ordinated in such a way that they support each other.

The implementation of *in-situ* conservation of CWR is a national issue. However, much can be gained by co-operation and the sharing of knowledge. In this way,

159. 20% (roughly 6,500) of NordGen's accessions are classified as wild.

160. Ibid.

161. [NordGen Annual Report \(2020\)](#)

162. [Nordic PPP co-operation – NordGen](#)

163. [Svalbard Global Seed Vault – NordGen](#)

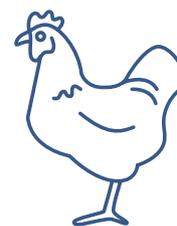
national efforts can be made more efficient and effective. In addition, tasks such as data handling, research projects, and communication have a lot to gain through Nordic co-operation.

For more than 40 years, NordGen has played an important role in the *ex-situ* conservation of CWR and has co-operated with Nordic national programmes and other stakeholders regarding *in-situ* (including on-farm) conservation.

There are large gaps in relation to the conservation of CWR. For instance, only about 20% of the species on the Nordic CWR priority list are conserved at NordGen with more than ten different accessions within the same species. No genetic reserves for the *in-situ* conservation of CWR are officially recognised in any of the Nordic countries (though Faerder National Park in Norway is expected to be recognised soon). Data on *in-situ/on-farm* conservation is not systematically registered in most Nordic countries, and only a limited number of the CWR accessions stored at NordGen have been evaluated for relevant traits. Consequently, there is a significant potential for strengthening the conservation of CWR by stepping up the focus on these topics at NordGen.

Farm animal genetic resources

The genetic diversity that our farm animals carry is invaluable. The landrace breeds originally used in Nordic agriculture have adapted to the Nordic climate and conditions over thousands of years. They have developed desirable qualities that make them tolerant. Landrace breeds often also have a broader genetic base than commercial breeds, giving them a better ability to adapt to changes. The animals usually also have good maternal characteristics, are kind, and are easy to handle.

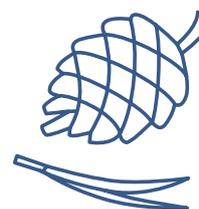


NordGen's farm animal activities are about providing tools and advice to preserve the genetic variation in living populations (*in-situ*) but also to advise on the establishment of cryo-storage of genetic material (*ex-situ*). NordGen works with a variety of projects with the aim of encouraging research and development projects related to categorisation, conservation, management, and sustainable use of animal genetic resources.

NordGen does not have any obligation to hold a common Nordic farm animal gene bank and does not conserve any farm animal breeds or breeding materials. For this reason there are no access provisions for farm animals for management at NordGen. However, there could possibly in the future be a national need for the emergency storage of cryo-preserved farm animal breeding materials.

Forest genetic resources

The focus of NordGen's forestry activities is on forest genetics and the conservation of forest genetic resources, seed and plant production, and the regeneration of forests. By disseminating knowledge and experiences between the various stakeholders and to the public, we help develop better plant production and regeneration methods in forests. We can also keep abreast of and initiate research and development in the field and conduct various projects and information activities.



Forests have always played an important role in the Nordic countries. Forests provide wood and bioenergy, protect against wind and erosion, promote biodiversity, and are a carbon dioxide sink which helps to mitigate climate change. In addition, timber can replace other materials that account for large volumes of emissions in their manufacture.

NordGen is currently involved in the conservation of forest tree seeds from private forest owners in the Nordic countries by way of a black box arrangement. The forest tree seeds are stored ex-situ at NordGen as a backup to the in-situ collection.

6.2 The Kalmar Declaration and NordGen

The precursor of NordGen, the Nordic Gene Bank (NGB), was the subject of much attention in the first Nordic project on access and rights to genetic resources and in the subsequent Kalmar Declaration. The sub-declarations and recommendations to the NGB are more numerous and detailed than on other topics. The Declaration remains a cornerstone for NordGen on how to manage the exchange of plant genetic resources.

NordGen was also the subject of a Nordic follow-up project, "Access and Acquisition Guidelines on Plant Material at NordGen" concluded in 2008 with a set of recommendations for NordGen's implementation of the Kalmar Declaration.¹⁶⁴

As referred to above, it was always a guiding principle for the NGB to promote free and open access to and transfer of plant genetic resources based on a standardised Material Transfer Agreement (SMTA). However, the legal status of the genetic material held was uncertain at that time, and the International Plant Treaty and its MLS (adopted but not in force at the time) would create a new legal situation for NordGen to navigate. The principles of the Kalmar Declaration related to NordGen served to provide legal clarity under which NordGen could fulfil its objectives in harmony with the International Plant Treaty. The following will elaborate more on these principles and how they have been followed up on in practice:

5

All accessions of the Nordic Gene Bank, except for security collections held by NGB for other gene banks, are under common Nordic management and in the public domain.

Relevant material administered by the Nordic Gene Bank shall be part of the multilateral system for plant genetic resources under IT-PGRFA following the agreement's ratification by all Nordic countries.

The International Plant Treaty established that plant genetic resources for food and agriculture shall be under the management and control of the Parties and in the public domain to be part of the MLS. Besides declaring officially that this is the case for NordGen's plant genetic resources, the Nordic countries, by signing up to the Kalmar Declaration, also declare that they have exercised their sovereign rights to the collected material by applying a joint approach and entrusting the responsibility for the management and control of the material to NordGen.

164. Project report (2008). [Access and Acquisition Guidelines on Plant Material at NordGen](#)

“Relevant material” refers to the 64 crop species that are covered by the MLS according to Annex 1 of the International Plant Treaty, the system under which its members provide free access to each other’s genetic resources for research breeding, conservation, and training. As contracting parties to the International Plant Treaty and having the accessions of NordGen under their joint management and control, the Nordic countries are obliged to include this material in the MLS (Article 11.2 of the International Plant Treaty). At the time of the first access and rights project, it was estimated that around 90% of NordGen’s material collection fell under this category.¹⁶⁵

165. Nordic Council of Ministers (2003) Access and Rights to Genetic Resources – A Nordic Approach.

166. FAO Treaty. [Standard Material Transfer Agreement](#)

10

The Nordic Gene Bank should provide access to all its accessions on equal terms, regardless of whether they are covered by the scope of the multilateral system of the IT-PGRFA or not. The terms should be set out in a standard Material Transfer Agreement (MTA).

During the negotiations of the International Plant Treaty, the Nordic countries did not favour limiting the MLS to a list of 64 crops and instead argued without success that the system should cover all crop species important for food and agriculture. Providing equal access to NordGen material, regardless of whether it is covered by Annex 1, is a logical consequence of this position and not legally prevented by the International Plant Treaty.

13

Access should be facilitated to all its accessions for all purposes, not only for use in the fields of food and agriculture.

The above principle even goes a step further by providing access to material for all purposes and not only for food and agriculture. Such accessions go beyond the scope of the International Plant Treaty and formally under the CBD with its main rule of subjecting access to genetic resources to the PIC of the providing country. The Kalmar Declaration establishes a deviation from this main rule regarding access to NordGen material. See below on how NordGen has handled this issue in practice.

11

The Board of the Nordic Gene Bank should consider the use of the provisional MTA, which now is used by international agricultural research centres, until the standard MTA for use in the multilateral system for simplified access and benefit-sharing is approved by IT-PGRFA’s steering committee.

12

The Nordic Gene Bank should closely follow the negotiations on the above-mentioned standard MTA under IT-PGRFA, and, if the need arises, approve a separate MTA in accordance with the current principles and terms for gaining access to the Nordic Gene Bank’s genetic resources.

A standard Material Transfer Agreement (SMTA) is a centrepiece in the operationalisation of the MLS. The terms of facilitated access are described in the SMTA adopted by the International Plant Treaty's Governing Body.¹⁶⁶ The SMTA must accompany all transfers of PGRFA in the MLS as a legally binding contract between the provider and the recipient of the PGRFA in question. The terms of the SMTA are not open for negotiation by the parties to the agreement.

At the time of the Kalmar Declaration, the SMTA had not yet been finally developed and adopted under the ITPGRFA. This happened in 2006, and from that point NordGen was obliged to use the SMTA for accessions covered by Annex 1 of the International Plant Treaty and thereby the MLS.

The question was then which SMTAs to apply for transfers of material not covered by Annex 1 and/or material for uses other than for food and agriculture. The 2008 Nordic project "Access and Acquisition Guidelines on Plant Material at NordGen" recommended that NordGen make use of three types of SMTAs: One for Annex 1 and non-Annex 1 material for the purposes of conservation and use for research, breeding, and training for food and agriculture; one for other purposes (except hobby uses); and one for hobby uses. Regarding the latter, the ITPGRFA SMTA was considered unsuitable. The project report proposed text for SMTAs for uses other than for food and agriculture and for hobby uses.¹⁶⁷

These recommendations were followed during the first years. Later, however, NordGen has made use of only one type of SMTA, namely the SMTA adopted by the ITPGRFA for material covered by the MLS and which through explanatory footnotes may also serve as an SMTA for non-Annex 1 material.

The receiver accepts the terms of the SMTA at the point of ordering the material and then receives the document together with the ordered material.

This SMTA explicitly states that it does not cover the use of the material other than for food and agriculture. It even specifies that "such purposes shall not include chemical, pharmaceutical and/or other non-food/feed industrial uses."¹⁶⁸ Still, NordGen no longer makes use of a special SMTA for "alternative" uses, a practice also followed by other European gene banks. The rationale is that NordGen does not, in practice, receive requests to provide genetic material for such other purposes. When a user orders material from NordGen through the electronic GENBIS system, this is done for research, education, home gardening, or "other" purposes. During the last five years, 62 requests have belonged to the "other" category. Often this is for purposes that could also fall under "education", such as the cultivation and display of varieties in botanical gardens or museums, or for use by seed conservation organisations. "Other" is also used for plant breeding since this purpose is not one of the options that can be chosen under GENBIS. Given the importance of plant breeding, NordGen acknowledges that this type of use should have its own category in the GENBIS system.

NordGen has not yet come across users intending to use the material for technical or pharmaceutical purposes. Regarding material for hobby uses, the above SMTA also applies. The SMTA in these cases is accompanied by an information letter to hobby users with a simplified text extracted from the SMTA to outline the conditions for transfer and use.

167. Project report (2008), Access and Acquisition Guidelines on Plant Material at NordGen, Appendices VII and X.

168. Article 6.1.

14

The Nordic Gene Bank requires, when handing over genetic material, that the recipient, in accordance with Article 12.3 (d) in IT-PGRFA, should not have any intellectual property rights or other rights, which limit the simplified access to plant genetic resources for the food and agricultural sector, or to their genetic parts or components, and which pertain to the genetic material in the form in which it is received from the multilateral system.

The SMTA used by NordGen provides for this. (Article 6.2).

15

The Nordic Gene Bank should not claim any monetary benefits in the case of commercialisation of the material withdrawn from NGB's accessions.

The single SMTA used by NordGen, adopted by the ITPGRFA and with mandatory text, does not allow NordGen as a provider to claim any monetary benefits in the case of the commercialisation of materials developed from plant genetic resources accessed from NordGen. The SMTA includes provisions for mandatory and voluntary payments to the MLS in case a product is not being commercialised with facilitated access as regulated by the International Plant Treaty¹⁶⁹ and described in Chapter 4. All recipients who are not obliged to share monetary benefits, are obliged to consider sharing monetary benefits on a voluntary basis.

16

The Nordic Gene Bank should make it clear upon receiving genetic material that its inclusion in NGB's accessions entails that the material will be subject to common Nordic management and form part of the public domain.

The 2008 Nordic project further elaborated on this principle and argued that, at the time of acquisition of the material to NordGen's collections, it was important to pass on clear and comprehensive information on the consequences of NordGen's acquisition to the providers of the material. It was recommended to achieve this through an Acquisition Information Letter explaining that the provider, by donating the material to NordGen, accepts that the material is made publicly available for plant breeding, research, and any other *bona fide* application.¹⁷⁰

NordGen has expanded on this recommendation by not only issuing an information letter to the donor of genetic material, but a formal agreement on the terms for donation to be signed both by NordGen and the donor. The donor is also required to describe the donated material in the agreement. The agreement specifies that NordGen only accepts material that has been legally acquired pursuant to national and international regulations and that the donor confirms that this is the case by signing the agreement.

169. Articles 6.7 and 6.8 and Annex 2 of the SMTA.

170. Project report (2008). [Access and Acquisition Guidelines on Plant Material at NordGen, Appendix VIII.](#)

6.3. Material in transition

The 2008 project report recommended that NordGen accept conservation material in transition (MIT), understood as material stored at NordGen for a given period, and subject to a given agreement. Consequently, NordGen stores MIT – at present around 600 accessions. During the transition period, this material and related information is owned by the provider and governed by a specific transition agreement under which the material is not in the public domain and NordGen cannot claim rights to it. The material will be included in the ordinary NordGen collection on standard terms and be freely distributed only after the expiry of the transition period.

6.4. Faroe Islands and Greenland

The Faroe Islands and Greenland, from which NordGen has stored genetic material for nearly 30 years, are autonomous territories of Denmark. When ratifying the ITPGRFA and the Nagoya Protocol, Denmark introduced a territorial exemption for the Faroe Islands and Greenland implying that these, in contrast to the rest of the Nordic Region, are not bound by the International Plant Treaty and the Protocol. Consequently, they are not required to include plant genetic resources in the MLS. Moreover, Greenland (but not the Faroe Islands) has introduced ABS legislation along the lines of the CBD and the Nagoya Protocol for access to Greenlandic genetic resources which does not exclude plant genetic resources for food and agriculture. This legislation is further described above in Chapter 4 of this report.

In 2006, NordGen collected 364 accessions in Greenland based on a permit from the Greenlandic Self-Government specifying that the plant material was collected for scientific purposes only and that any commercial use required a new application and permit from the Self-Government. The conditions of the Greenlandic access legislation were assumed to apply if anyone would seek access to the material from NordGen.¹⁷¹ When NordGen in 2007 collected 38 accessions from the Faroe Islands, the conditions of access to the material were not further clarified.¹⁷²

The 2008 project report discussed various options on how to address access to material from the Faroe Islands and Greenland held by NordGen considering the legal situation described above. These included tailormade SMTAs, the MIT status of the stored material, and agreements with the Greenlandic and Faroese authorities to grant access to NordGen material from there on the same terms as regular NordGen material from the other Nordic countries and in accordance with the Kalmar Declaration.¹⁷³

The latter has, in practice, become the case for accessions from the Faroe Islands though without a formal agreement with the Faroese authorities on the arrangement. For Greenlandic accessions, these currently have a MIT status pending negotiations with the Greenlandic authorities on their status and management.

6.5. NordGen and national access regulation

The CBD and the Nagoya Protocol (NP), with its procedures on Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), are relevant for NordGen in the case of acquisitions for the gene bank from countries that have introduced

171. Project report (2008).

172. Ibid.

173. Ibid.

such national regulations for access to their genetic resources. Of the Nordic countries, this is currently the case only for Greenland, as described above. NordGen does not collect genetic material outside of the Nordic Region.

6.6. NordGen and a possible enhanced MLS of the International Plant Treaty

As described in Chapter 3, a process for enhancing the MLS of the International Plant Treaty is underway. It is anticipated that all PGRFA will be included in the MLS, in accordance with Article 3 of the International Plant Treaty. This would be in line with current practices at NordGen. A subscription system is also expected to be introduced, whereby recipients of plant genetic resources covered by the MLS pay a fee to the International Plant Treaty's Benefit-sharing Fund for being granted access to gene bank collections. A new system is designed to enhance the functioning of the MLS, such as by linking payment obligations to access rather than to commercialisation, as is the case under the current system. The possible implications of a subscription system for gene banks such as NordGen that hold material under the MLS have so far attracted limited attention in the ITPGRFA negotiations. Although the details of such a subscription system remain to be ironed out, such a system may have an impact on the free and open access to the gene bank system that prevails today. A subscription system could have unwanted consequences, as it could encourage private companies and research projects not to share their germplasm and data within the public sphere. In addition, under such a system, gene banks such as NordGen could be assigned an additional function of controlling access terms and payments to the Benefit-sharing Fund when providing access to users of its material. Resources for a task of this kind are not currently available at NordGen. In future negotiations of the subscription system, it would therefore be relevant for the Nordic countries to strive to ensure that no additional administrative burdens are imposed upon NordGen and other gene banks.

6.7. NordGen and Digital Sequence Information (DSI)

DSI is a part of NordGen's current collections. NordGen holds nucleotide polymorphisms (SNPs) marker data on crops such as winter wheat, spring barley, and spring wheat. NordGen is currently also generating genomic sequence data for the analysis of its collections. This data will be freely available and distributed, just like other data relating to Nordic material at NordGen.

6.8 Summing up

By undertaking its many functions as the Nordic countries' joint gene bank and knowledge centre for genetic resources for food and agriculture, NordGen has played a crucial role in the follow-up of the Kalmar Declaration and international commitments.

The Nordic countries, by signing up to the Kalmar Declaration, declared that they have exercised their sovereign rights in respect of the collected material by applying a joint approach and by entrusting the responsibility for the management and control of the material to NordGen. This has been achieved by placing the large

NordGen collection of plant genetic resources – of Annex I as well as non-Annex 1 material – in the Nordic public domain, making it available through the International Plant Treaty's SMTA, and over the years distributing an increasing amount of material to plant breeders, researchers, museums, botanical gardens, NGOs, and private users with a specific interest in saving old or rare varieties.

From 2018 to 2020, NordGen witnessed a considerable increase (+89 %) in the number of requested seed samples. Seeds are primarily requested by Nordic and European countries.

The distinction made by the Kalmar Declaration between plant genetic resources for food and agriculture and for other purposes has so far not been relevant for NordGen since, in practice, all its distributed accessions are used for food and agriculture.

The CBD and the NP, with its procedures on PIC and MAT, are relevant for NordGen in the case of acquisitions for the gene bank from countries that have introduced such national regulations for access to their genetic resources. Of the Nordic countries, this is currently the case only for Greenland. NordGen does not collect genetic material outside of the Nordic Region.

Due to the special circumstances of the Faroe Islands and Greenland, being outside of both the International Plant Treaty and its MLS and the NP, (but with Greenland having introduced access regulation) there is a need for agreements with the Faroe Islands and Greenland on the legal status and terms for access for NordGen accessions collected there. Preferably, their status should be the same as for other NordGen accessions.

**ACCESS AND RIGHTS TO
GENETIC RESOURCES:
A Nordic Approach (II)**

ISBN 978-91-986029-1-3 (Print)
ISBN 978-91-986029-2-0 (PDF)