Access and Rights to Genetic Resources

A Nordic Approach

Nordic Council of Ministers

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Nordic Environmental Co-operation
Environmental co-operation is aimed at contributing to the improvement of the environment and forestall problems in the Nordic countries as well as on the international scene. The co-operation is conducted by the Nordic Committee of Senior Officials for Environmental Affairs. The co-operation endeavours to advance joint aims for Action Plans and joint projects, exchange of information and assistance, *e.g.* to Eastern Europe, through the Nordic Environmental Finance Corporation (NEFCO).

Nordic Co-operation in Agriculture and Forestry
Agriculture and forestry in the Nordic countries are based on similar natural pre-requisites, and often face common challenges. This has resulted in a long-established tradition of Nordic co-operation in agriculture and forestry. Within the framework of the Plan of Action 1996–2000, the Nordic Council of Ministers (ministers of agriculture and forestry) has given priority to co-operation on quality agricultural production emphazising environmental aspects, the management of genetic resources, the development of regions depending on agriculture and forestry and sustainable forestry.

The Nordic Council of Ministers
was established in 1971. It submits proposals on cooperation between the governments of the five Nordic countries to the Nordic Council, implements the Council's recommendations and reports on results, while directing the work carried out in the targeted areas. The Prime Ministers of the five Nordic countries assume overall responsibility for the cooperation measures, which are co-ordinated by the ministers for cooperation and the Nordic Cooperation committee. The composition of the Council of Ministers varies, depending on the nature of the issue to be treated.

The Nordic Council
was formed in 1952 to promote cooperation between the parliaments and governments of Denmark, Iceland, Norway and Sweden. Finland joined in 1955. At the sessions held by the Council, representatives from the Faroe Islands and Greenland form part of the Danish delegation, while Åland is represented on the Finnish delegation. The Council consists of 87 elected members – all of whom are members of parliament. The Nordic Council takes initiatives, acts in a consultative capacity and monitors cooperation measures. The Council operates via its institutions: the Plenary Assembly, the Presidium and standing committees.

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Preface

The conservation and utilisation of genetic resources is an integrated and important part of the Strategy for a Sustainable Nordic Region.

As a follow-up to this overarching, crosscutting strategy, the Strategy for Conservation of Genetic Resources in the Nordic Region 2001–2004 elaborates and specifies the goals and measures in the field of genetic resources.

It recognises a need for development at Nordic level of a common attitude as to how the Convention on Biological Diversity is to be interpreted in relation to the resources stored in the joint gene bank and networks. It also makes reference to the issue of patent rights.

The Strategy puts forward the establishment of an ad hoc working group instructed to submit proposals on how the Nordic region is to interpret the provisions in international legal instruments within the framework of co-operation on genetic resources. The group report to the Nordic Genetic Resources Council.

As a follow-up to the Strategy's provisions, the Project Group on rights and access to genetic resources was established in the beginning of 2002.

The group comprised the following members: *Director Erling Fimland* (Nordic Gene Bank Farm Animals), *Director Hannu Kukkonen* (Plant Production Inspection Centre, Finland), *Head of Division Sigridur Nordmann* (Ministry of Agriculture, Iceland), *Senior Administrative Officer Lennart Pettersson* (Ministry of Agriculture, Sweden), *Senior Advisor Christian Prip* (Danish Forest and Nature Agency), *Director Eva Thörn* (Nordic Gene Bank) *Research Station Manager Martin Werner* (Nordic Council for Forest Reproductive Material) and *Senior Adviser Grethe Evjen*, chair (Ministry of Agri-

culture, Norway). *Research Fellow Morten Walløe Tvedt* from the Fridtjof Nansen Institute in Norway acted as secretary for the group.

The Group, jointly with the Nordic Genetic Resources Council and the Norwegian Agriculture Ministry, organised a seminar in Hamar, Norway 19–20 September with a view to open up for broad discussion among stakeholders, receive feed back on a draft of its report as well as share information on the issues involved.

The issue is of great political interest to the Nordic countries. The Nordic Council of Ministers with responsibility for fisheries, agriculture, forestry and food issues, as well as for environmental questions, respectively, have emphasised their support for the work on conservation and sustainable use of genetic resources. The ministers will by summer 2003 discuss the issue of rights to genetic resources based on the recommendations by the Nordic Genetic Resources Council and the Project Group's report.

The group hereby submits its report and proposals for further action. The questions raised, the choice of solutions and recommendations presented will hopefully facilitate further consideration when addressing these issues the in the sectors, the Nordic institutions and countries.

The task given to the Project Group has been interesting and challenging. The understanding of the issues, which integrate legal, biological and political aspects, has required the outmost of our skills and effort. The work of the Project Group has been based on a good co-operative and constructive attitude and we believe that the participation of the Nordic countries and sectors in the group has been an effective way of cooperation and contributed to the common understanding of the issues.

On behalf of the Project Group
15 February 2003
Grethe Evjen

The Project Group for Genetic Resources
Grethe Helene Evjen, Ministry of Agriculture, Norway, chair
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Eva Thörn, Nordic Gene Bank
Martin Werner, Nordic Council for Forest Reproductive Material
Morten Walløe Tvedt, the Fridtjof Nansen Institute, secretary

Summary

The conservation and utilisation of genetic resources is an integrated and important part of the Strategy for a Sustainable Nordic Region. As a follow-up to this overarching, crosscutting strategy, the Strategy for Conservation of Genetic Resources in the Nordic Region 2001–2004 elaborates and specifies the goals and measures in the field of genetic resources. It recognises a need for development of a common attitude at Nordic level regarding how the Convention on Biological Diversity is to be interpreted in relation to the resources stored in the joint gene bank and networks. The strategy suggests an ad hoc working group instructed to submit proposals on how the Nordic region is to interpret the provisions in international legal instruments within the framework of co-operation on genetic resources. On this background, the ad hoc working group has delivered this Report to the Nordic Genetic Resources Council.

The Report addresses various aspects related to rights and access to genetic resources in the Nordic countries. The report examines all genetic resources, while pointing out relevant differences between types of resources. The report studies the rights and access to the genetic resources managed by the Nordic Gene Bank. It also provides recommendations and alternatives for rights and access to genetic resources within the Nordic countries. It gives an overview of the need for and means of implementing the provisions of the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) and other international agreements in the Nordic countries. The report further analyses how rights and access to genetic resources relate to international law on intellectual property rights applied to genes and living organisms.

The development of modern gene- and biotechnology has introduced new tools for an effective improvement of plants, animals and forest trees to meet the needs of mankind. These techniques have also opened up for the use of genetic resources for biotechnology industry and other non-traditional purposes. Consequently, interest in genetic material of living organisms for commercial purposes has increased, and questions concerning access and the rights to genetic resources have become more important.

Genetic resources are valuable not only for supporting mankind with food, medicines and other products, but also due to their cultural and historical value and the intrinsic value of nature itself. The value of genetic resources lies to a great extent in the diversity or variation *per se*, among individuals or specimens, within populations and among populations or species. Thus, a rich genetic diversity is invaluable for all who use genetic resources for any purpose. The topic for the Report is *genetic resources*. In short, biological resources are genetic resources when they are used for the purpose of exploiting genes or other functional units of heredity – not for their physical properties. The definition of *genetic resources* excludes the use of biological material when not used for the purpose of its genes. The same biological material can be used as both a genetic resource and a biological resource, dependent on the purpose of the use. This implies a conceptual challenge when discussing access and rights to this particular natural resource.

The Report provides and discusses different policy options for the management of access and rights to five categories of genetic resources as a basis for the recommendations. These are:

- Plant Genetic Resources in the Nordic Gene Bank (Chapter 4.2).
- Domesticated Plant Genetic Resources in the Nordic Countries (Chapter 4.3).
- Access to Animal Genetic Resources for Food and Agriculture (Chapter 4.4).
- Access to Genetic Resources of Forest Trees (Chapter 4.5);
- Access to Wild Genetic Resources (Chapter 4.6).

The Report also takes another perspective by addressing the challenges for the Nordic countries in dealing with access legislation of other countries (Chapter 4.7).

The Nordic Gene Bank

The International Treaty on Plant Genetic Resources for Food and Agriculture represents the most important future legal framework for the Nordic Gene Bank. The Project Group acknowledges that a major aim for the Nordic Gene Bank is to ensure facilitated access and exchange of all its plant genetic resources for conservation, research and development purposes. The Project Group recognises a need to clarify the legal status of the plant genetic resources in the Nordic Gene Bank. The Project Group believes that an ambiguous legal status may cause uncertainty for the recipients of the material and will not facilitate the use of these plant genetic resources. The Project Group recommends that:

- The Nordic Council of Ministers should be invited to declare that all the accessions of the Nordic Gene Bank, except for security collections held by the NGB of other gene banks, are under common Nordic management and control and in the public domain.
- The respective Nordic governments should confirm this decision nationally and declare that the accessions of the Nordic Gene Bank are in the public domain and under common Nordic management and control.
- The board of the Nordic Gene Bank should thereafter implement the decision.

The material of the Nordic Gene Bank is available according to the terms set out in the Material Transfer Agreement (MTA) of the Nordic Gene Bank. This agreement will soon need to be revised. About 90% of the accessions of the Gene Bank will fall under the scope of the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture. The facilitated

access to these accessions will be according to the terms of access and benefit sharing of the International Treaty, upon its entry into force and subsequent implementation. The Project Group emphasises the need for a simple and non-bureaucratic system that ensures facilitated access to all plant genetic resources in the Nordic Gene Bank and for all *bona fide* purposes.

Domesticated Plant Genetic Resources in the Nordic Countries

The domesticated plant genetic resources in the Nordic countries include those that are covered by the scope of the Multilateral System of the International Treaty and those mandate species of the Nordic Gene Bank that may not be included in the Multilateral System. The Project Group emphasizes the need to ensure that all these plant genetic resources are made available for conservation purposes *e.g.* in NGB, and for information, research, breeding, and development purposes.

Plant genetic resources which are privately owned or subject to intellectual property rights will not be automatically included in the Multilateral System, even when these resources are covered by its scope. The Report does not investigate relevant national law in the Nordic countries in this respect but stresses the importance of determining the legal status of the plant genetic resources. In order to ensure sustainable utilization of genetic resources, there is a need to establish transparent and predictable conditions both for the users and providers of such resources. The Project Group underlines the importance of such a clarification as a prerequisite for possible future regulations of access to such resources, even in countries that currently have no plans for such regulations.

The implementation of a standard MTA for access to the species covered by the Multilateral System of the International Treaty will ensure a smooth exchange of the plant material between the Nordic countries, as well as between the Nordic countries and the Nordic Gene Bank. It would be practical if the same terms for

facilitated access were also applied to the other mandated species of the NGB. This argument can also be put forward as a reason for not imposing any restrictions on the access at all, or at least not impose more severe restrictions on the access than the NGB does for the same material. Using the same MTA will also create a transparent Nordic system, and the transaction costs may well be lower. However, if one or more of the Nordic countries were to decide to implement more restricted access regimes to such plant genetic resources, difficulties may arise for the Nordic cooperation on these crops, both for collection activities as well as for the utilization of the genetic resources. The Nordic countries were strong advocates for the Multilateral System to cover all crops, and it would therefore be natural to follow this up at the national level.

Animal Genetic Resources for Food and Agriculture

It is important to take into account the different breeding methods for plants and animals when addressing policy and legislative measures for these two categories. The breeding of animals for production is also for the purpose of genetic improvement, *i.e.* constitutes a step in a breeding programme. Variation within the productive population is therefore of crucial importance for the progress that may be achieved. In plants, exchange of genetic resources is valued as important for increasing the genetic variation. In animals, however, introduction of high-yielding homogenous breeds, at the expense of lower yielding breeds with higher genetic variation, will in the end represent a threat to the overall genetic variation. Exchange of animal genetic resources is usually regulated by private contractual agreements. Such contracts may also include limitations on the use of the off-spring. This is, however, a very regulated area, and currently there seems to be no need for further clarification of the legal status. There is no internationally negotiated standard MTA for access to animal genetic resources. The MTAs that are used are private contractual agreements, which seem to function well.

Forest Tree Genetic Resources

Forest trees are characterised by a long rotation period and exceptional reproductive capacity. The trees might be regarded as semi-cultivated and only a few species have high commercial value. In forest tree breeding it is common to make a selection among individual trees. Selected trees are then used for seed production or multiplied as clones.

In most of the Nordic countries the forest tree genetic resources are mainly found on private property, while the breeding and cultivation activities are conducted by governmental or non-commercial organisations. In Finland, Norway and Sweden the public has a right to access to private land. Such rights do to some extent also include rights to collect cones and other plant material that could be suitable for breeding and multiplication of trees. There seems to be, however, a trend towards the forest owners claiming commercial rights from trees on their properties that have been successful in a breeding programme and that subsequently result in forest trees with improved productivity. Such claims, however, may form obstacles to the breeding activities and create uncertainty and low predictability for the breeders, a situation which in the long run might be a drawback for the forest owners. The Project Group recognises the need to determine the rights of breeders regarding access to forest tree genetic resources.

The Project Group identifies a need to ensure free and open exchange of forest tree genetic resources in the future. Increased use of various contractual agreements would increase bureaucracy and may create an obstacle to the future development of forest tree genetic resources. The long rotation period of trees and the low commercial profit from the sale of seeds also indicate that it currently may be difficult to introduce regulations of access and benefit sharing to forest tree genetic resources.

Wild Genetic Resources

Wild genetic resources include wild-growing plants, except the wild relatives of the species covered by the IT-PGRFA Annex I, wild animals, most marine species and micro-organisms. The legal status of wild genetic resources has not been determined in any of the Nordic countries. The Convention on Biological Diversity specifies the sovereign rights to genetic resources as a right for the countries to require giving their *prior informed consent* (pic) before giving access to genetic resources. The CBD specifies that this is an optional right of the countries, *"unless otherwise determined"*. The Nordic countries have not implemented any relevant domestic legislation regulating access to genetic resources. Denmark and Sweden have officially determined that for the time being, they do not intend to require a *Prior Informed Consent*. The Project Group recognises the need for a predictable legal situation in order to promote sustainable use of wild genetic resources. A predictable legal status could also facilitate any future need to regulate access to such resources.

The Project Group believes that the Nordic countries should also facilitate access to wild genetic resources to the extent possible in accordance with article 15 paragraph 2 of the CBD. Free access to genetic resources may facilitate any inventions and development made on the basis of such resources. With regard to a *prior informed consent* procedure to control access to genetic resources and trigger benefit sharing from the use, the Project Group holds the view that the potential benefits can hardly make up for the administrative burden of creating such a regulatory system, although future benefits are difficult to predict and the situation may differ for different types of genetic resources. Therefore 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, do not

wish to exclude future possibilities for 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.

The Access Legislation of Other Parties

Discussions on access legislation have mainly focused on regulations in the providing countries. Developing countries increasingly insist that the issue of how user countries (typically developed countries) ensure compliance with access regulation in the providing countries should be on the CBD agenda, and the newly adopted Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilisation also include this aspect.

Regardless of whether or not measures in user countries are required in strict legal terms according to the CBD, the Project group considers the application of measures with the aim of assisting the enforcement of access regulation in the providing countries as an act of good faith, trust building and support for the CBD objectives. The Project Group therefore suggests that the Nordic countries follow up on the Bonn Guidelines and take action in this field. The Project Group has discussed the following not mutually exclusive measures:

- Regulation of import of genetic resources.
- Regulation and record keeping on the use of genetic resources.
- Requirement for disclosure of origin of genetic resources in IPR applications as a condition for IPR.

- Requirement for disclosure of origin of genetic resources in IPR applications but not as a condition for granting IPR (as already enacted by Denmark and under consideration in Sweden and Norway).
- Certification.
- Possibility of Enforcement.
- Access to courts and administrative dispute resolution mechanisms.
- Information to potential users of genetic resources on the CBD access and benefit sharing requirements.

The Project Group believes that there is lack of knowledge and consciousness among users of genetic resources regarding their obligations to comply with access and benefit sharing requirements. This latter measure is believed to be an important first step for generating compliance with the access legislation of other CBD Parties. The development of relevant information strategy could be a common Nordic Project initiated by the Nordic Genetic Resource Council.

Sammendrag

Bevaring og bruk av genetiske ressurser er en integrert og viktig del av Strategien for en bærekraftig nordisk region. Strategien for bevaring og bruk av genetiske ressurser i den nordiske regionen 2001–2004 følger opp den brede strategien, og utvikler mer spesifikke mål innenfor feltet genetiske ressurser. Den anerkjenner et behov for en fellesnordisk tilnærming til gjennomføringen av Konvensjonen om biologisk mangfold, spesielt for de genetiske ressursene som oppbevares i fellesnordiske genbanker og nettverk. I strategien foreslås det at det opprettes en midlertidig arbeidsgruppe som skal komme med forslag om hvordan Norden kan fortolke og anvende bestemmelsene i de relevante internasjonale avtalene. Med denne bakgrunnen har arbeidsgruppen for tilgang og rettigheter til genetiske ressurser levert rapporten *En nordisk tilnærming til rettigheter og tilgang til genetiske ressurser* til Nordisk genressursråd.

Rapporten tar opp et bredt spekter av problemstillinger som knytter seg til rettigheter og tilgang til genetiske ressurser i de nordiske landene. Rapporten undersøker alle typer av organismer, og søker å få frem de relevante forskjellene mellom de ulike typene av ressurser. Rapporten fokuserer særlig på rettigheter og tilgang til genetiske ressurser som er administrert av Nordisk genbank. Den foreslår videre tiltak for rettigheter og tilgang til genetiske ressurser i de nordiske landene. Den gir en oversikt over behov for og virkemidler for å implementere bestemmelsene i Konvensjonen om biologisk mangfold (CBD) og Den internasjonale traktaten om plantegenetiske ressurser for matvare- og landbruksproduksjon (IT-PGRFA). Rapporten tar også opp forholdet til andre internasjonale avtaler. Den går særlig inn på hvordan spørsmål knyttet til

rettigheter og tilgang til genetiske ressurser forholder seg til immaterielle rettigheter til levende organismer.

Utviklingen av moderne gen- og bioteknologi har introdusert nye metoder for effektiv forbedring av planter, dyr og skogstrær, slik at de blir bedre tilpasset menneskets behov. Slike teknikker har åpnet for bruk av genetiske ressurser i bioteknologisk industri og andre ikke-tradisjonelle former for bruk. Følgelig har den kommersielle interessen for genetisk materiale i levende organismer økt. Spørsmål om rettigheter og tilgang til genetiske ressurser har derfor blitt mer viktige.

Genetiske ressurser er verdifulle for å forsyne menneskeheten med mat, medisiner og andre produkter; men har også en selvstendig, iboende verdi som følge av deres kulturelle og historiske verdi. En stor del av verdien av genetisk materiale ligger nettopp i genetisk variasjon, mellom individer innen en art, innenfor populasjoner og mellom populasjoner eller arter. Derfor er et rikt mangfold svært verdifult for alle som bruker genetisk materiale for noe formål. Objektet som denne rapporten fokuserer på er *genetiske ressurser*. Kort sagt kan man i si at biologiske ressurser er genetiske ressurser når de benyttes med det formål å ta direkte nytte av genene eller andre funksjonelle arveenheter i dem; og ikke for deres biologiske egenskaper. Definisjonen av genetiske ressurser omfatter ikke bruk av biologisk materiale når bruken ikke fokuserer på dets funksjonelle arveenheter. Det samme biologiske materialet kan altså bli brukt både som genetiske ressurser og som biologiske ressurser avhengig av formålet med bruken. Dette innebærer en konseptuell utfordring for diskusjoner av rettigheter og tilgang til genetiske ressurser

Rapporten diskuterer og foreslår ulike alternativer for forvaltning og organisering av rettigheter og tilgang til genetiske ressurser for fem hovedkategorier av organismer:

- Plantegenetiske ressurser i Nordiske genbanken (kapittel 4.2).
- Plantegenetiske ressurser i domestiserte arter i de nordiske landene (kapittel 4.3).

- Dyregenetiske ressurser i matproduksjon og i landbruket (kapittel 4.4).
- Skogstræs genetiske ressurser (kapittel 4.5).
- Genetiske ressurser i ville organismer (kapittel 4.6).

Rapporten diskuterer også hvordan de nordiske landene skal forholde seg for å overholde relevant lovgivning i andre land (kapittel 4.7).

Nordisk genbank

Den mest relevante internasjonale folkerettslige rammeverket for Nordisk genbank er Den internasjonale traktaten om plantegenetiske ressurser for matvare- og landbruksproduksjon (IT-PGRFA). Prosjektgruppen legger stor vekt på at et hovedformål med Nordisk genbank er å promotere tilgang til og utveksling av plantegenetiske ressurser for bevaringsformål, for forskning og utvikling. Prosjektgruppen legger til grunn at det er et behov for å klargjøre den rettslige statusen for det plantegenetiske materialet i genbanken. Prosjektgruppen antar at en utydelig og uklar rettslig status for materialet kan lede til usikkerhet for mottagere av materialet og vil ikke gjøre tilgang og bruk av det enklere. Prosjektgruppen foreslår derfor at:

- Nordisk ministerråd bør bli invitert til å erklære at alle prøvene i Nordisk genbank, unntatt sikkerhetskolleksjonene som genbanken bevarer for andre, er under fellesnordisk forvaltning og kontroll og er en fellesnordisk ressurs i det offentlige domenet.
- De respektive nordiske regjeringene bør bekrefte denne beslutningen på nasjonalt nivå og erklære at prøvene i Nordisk genbank er under fellesnordisk forvaltning og kontroll og er en fellesnordisk ressurs i det offentlige domenet.
- Styret i Nordisk genbank bør deretter implementere disse beslutningene.

Materialet i Nordisk genbank er tilgjengelig på de vilkår som fremgår av den standarde utvekslingsavtalen, den såkalte *Material Transfer Agreement* (MTA). Denne standardavtalen bør snart revideres i tråd med endringer i internasjonale reguleringsregimer. Den internasjonale traktaten om plantegenetiske ressurser for matvare- og landbruksproduksjon (IT-PGRFA) innebærer at 90% av prøvene i Nordisk genbank vil omfattes av det multilaterale systemet for fri utveksling av genetisk materiale.

Den tilrettelagte tilgangen til disse prøvene vil være i overensstemmelse med vilkårene for tilgang og fordeling angitt i den internasjonale traktaten. Dette forutsetter imidlertid at traktaten trer i kraft og blir effektivt gjennomført. Prosjektgruppen fremholder behovet for et enkelt og ubyråkratisk system som sikrer tilgang til alle plantegenetiske ressurser i den nordiske genbanken og for alle *bona fide* formål.

Domestiserte plantegenetiske ressurser i de nordiske landene

De domestiserte plantegenetiske ressursene i de nordiske landene inkluderer ressurser som er omfattet av det multilaterale systemet i den internasjonale traktaten samt mandatarter i den nordiske genbanken som ikke er omfattet av det multilaterale systemet. Prosjektgruppen fremhever behovet for å sikre at alle plantegenetiske ressurser blir gjort tilgjenglige for konserverings-, informasjons-, forsknings-, foredlings- og utviklingsformål, for eksempel i NGB. Plantegenetiske ressurser i privat eie eller som er gjenstand for intellektuelle rettigheter vil ikke automatisk bli inkludert i det multilaterale systemet, selv om disse ressursene faller innenfor dets virkeområde. Rapporten har ikke gått inn på relevant nasjonal lovgivning i de nordiske landene i denne sammenheng, men fremholder viktigheten av å fastlegge den rettslige statusen til plantegenetiske ressurser. For å sikre bærekraftig bruk av genetiske ressurser, er det behov for å etablere gjennomsiktige og forutsigbare vilkår både for brukere og givere av slike ressurser. Selv om

landene på det nåværende tidspunkt ikke har planer om slike reguleringer, understreker prosjektgruppen betydningen av en klarlegging som en nødvendig betingelse for mulige fremtidige reguleringer av tilgang til plantegenetiske ressurser.

Implementeringen av en standard MTA for tilgang til arter omfattet av det multilaterale systemet i den internasjonale traktaten vil sikre en smidig utveksling av plantemateriale mellom de nordiske landene samt mellom de nordiske landene og den nordiske genbanken. Det ville være praktisk om de samme vilkårene for tilgang kunne anvendes også for andre arter i NGB. Dette argumentet kan også trekkes frem som en begrunnelse for å ikke innføre restriksjoner på tilgangen i det hele tatt, eller i det minste ikke mer omfattende restriksjoner enn NGB gjør. Å benytte samme MTA vil skape et gjennomsiktig nordisk system. Videre vil transaksjonskostnadene trolig bli lavere. Det vil dessuten kunne oppstå vanskeligheter for det nordiske samarbeidet hvis ett eller flere av de nordiske landene skulle innføre strengere tilgangsordning for plantegenetiske ressurser. Dette vil kunne gjelde både aktiviteter i forbindelse med innsamling og utnyttelse av ressursene. Endelig peker prosjektgruppen på at de nordiske landene var sterke forkjempere for et system hvor det multilaterale systemet skulle omfatte hele samlingen, og det er derfor nærliggende å følge dette opp på nasjonalt plan.

Dyregenetiske ressurser for mat og landbruk

Når de legislative tiltakene for dyregenetiske ressurser skal vurderes, er det viktig å være klar over forskjellene i foredlingsmetoder mellom planter og dyr. Avl av dyr for produksjon har også genetisk foredling som mål. For eksempel vil dette være tilfellet når foredlingen utgjør et ledd i et avlsprogram. Variasjon innen den produktive populasjonen er derfor av avgjørende betydning for den fremgangen som kan oppnås. Utveksling av genetiske ressurser er viktig for å øke den genetiske variasjonen. For dyr vil imidlertid introduksjon av en homogen besetning med potensial for høy

avkastning på bekostning av en populasjon med større genetisk variasjon, men mindre mulighet for profitt, på lang sikt kunne utgjøre en trussel for det generelle genetiske mangfoldet. Utveksling av dyregenetiske ressurser er vanligvis regulert av privatrettslige kontrakter. Slike kontrakter kan også inkludere begrensninger av anvendelsen av avkommet og dermed også en begrensning på bruken av det som genetiske ressurser. Dette systemet fungerer godt, og på dette tidspunkt anses det ikke nødvendig med en ytterligere klarlegging av rettstilstanden. Det finnes ingen velfungerende internasjonalt fremforhandlet standard MTA for tilgang til dyregenetiske ressurser.

Genetiske ressurser for skogtrær

Skogtrær er karakterisert ved en lang rotasjonsperiode og en spesielt velutviklet reproduktiv kapasitet. Trærne kan bli betraktet som delvis kultivert og bare enkelte arter har stor kommersiell verdi. I skogtreforedling er det vanlig å gjøre et utvalg blant enkelt trær. Utvalgte trær blir så brukt til frøproduksjon eller mangfoldiggjort som kloner. I de fleste nordiske land finnes de genetiske ressursene i skogtrærne hovedsakelig på privat grunn mens foredling og kultivering blir utført av offentlige- eller ikke-kommersielle organisasjoner. Befolkningen har i Finland, Norge og Sverige en rett til å ferdes på privat eiendom. Slike rettigheter inkluderer også i noen grad retten til å samle kongler eller annen materie som er egnet for foredling og mangfoldiggjørelse av trær. Det er en tendens til at skogeiere krever økonomiske rettigheter for trær på deres eiendom som har vært en suksess i foredlingsprogrammer, og som dermed fører til trær med økt produktivitet. Slike krav kan legge hindringer i veien for foredling, og skape usikkerhet og liten forutsigbarhet for foredlerne. En slik situasjon vil i det lange løp kunne være uønsket for skogeierne. Prosjektgruppen anerkjenner behovet for å fastlegge foredlernes rettigheter til tilgang til de genetiske ressursene i skogtrær.

Prosjektgruppen anerkjenner også behovet for å sikre fri og åpen utveksling av genetiske ressurser i skogtrær. Økt bruk av ulike kontrakter vil øke byråkratiet og kan innebære en hindring for fremtidig utvikling av genetiske ressurser i skogtrær. Den lange rotasjonstiden for trær og den begrensede økonomiske profitten ved salg av frø indikerer også at det på det nåværende tidspunkt vil være vanskelig å introdusere reguleringer for tilgang og profittdeling for genetiske ressurser for skogtrær.

Ville genetiske ressurser

Ville genetiske ressurser innbefatter viltvoksende planter, med unntak av ville slektninger av arter omfattet av IT-PGRFA Annex I; ville dyr, de fleste marine arter og mikroorganismer. Rettstilstanden når det gjelder ville genetiske ressurser har ikke blitt fastlagt i noen av de nordiske landene. Konvensjonen om biologisk mangfold (CBD) spesifiserer suverene rettigheter til genetiske ressurser som en rett for stater til å kreve at forhåndssamtykke (*Prior Informed Consent,* PIC) fra staten innhentes før tilgang til genetiske ressurser gis. CBD presiserer at dette er en valgfri rett for statene, hvis ikke annet er bestemt. De nordiske landene har ikke innført noen relevant nasjonal lovgivning som regulerer tilgangen til genetiske ressurser. Danmark og Sverige har offisielt meddelt at i dagens situasjon ønsker de ikke å kreve forhåndssamtykke. For å fremme bærekraftig utnyttelse av de ville genetiske ressursene, erkjenner prosjektgruppen behovet for en forutsigbar rettstilstand. En forutsigbar rettstilstand vil også kunne legge til rette for et fremtidig behov for å regulere tilgangen til slike ressurser.

Prosjektgruppen mener at de nordiske landene bør legge til rette for tilgang også til ville genetiske ressurser i den utstrekning det er mulig i overensstemmelse med artikkel 15 andre ledd i CBD. Fri tilgang til genetiske ressurser kan føre til oppfinnelser og utvikling. Prosjektgruppen tviler på at en prosedyre for forhåndssamtykke som kontrollerer tilgangen til genetiske ressurser, og utløser en profittfordeling fra bruken, kan veie opp for den administrative

byrden knyttet til opprettelsen av et slikt reguleringssystem. Dette til tross for at fremtidig profitt er vanskelig å forutse og at situasjonen kan være ulik for ulike typer av genetiske ressurser. Prosjektgruppen finner ikke, på det nåværende tidspunkt, tilstrekkelig tungtveiende argumenter for å foreslå innføringen av regulering av tilgang til ville genetiske ressurser. Den anerkjenner imidlertid at nasjonenes syn på dette spørsmålet kan være ulike. Enkelte medlemmer av gruppen ville ikke utelukke muligheten av fremtidig regulering av tilgang til for eksempel spesielle grupper av genetiske ressurser, eller til genetiske ressurser lokalisert i bestemte områder. Omstendigheter i fremtiden kan føre til en annen konklusjon basert på bedre kunnskap om den potensielle verdien av ville genetiske ressurser. Det er derfor viktig å holde muligheten åpen for en fremtidig regulering av spørsmålet. Dette gjelder særlig hvis utviklingen av eksklusive private rettigheter til genetiske ressurser i form av patenter og andre former for immaterielle rettigheter vil kreve en regulering.

Tilgangsreguleringen hos andre parter

Diskusjoner om tilgangsregulering har hovedsakelig vært rettet mot regulering i det landet hvor den genetiske ressursen finnes. Utviklingsland har tatt til orde for rettslig reguleringer i brukerland (typisk industriland) som sikrer samsvar med tilgangsreguleringen i opphavslandene. Utviklingslandene er av den oppfatning at problemstillingen burde være på CBDs agenda. Bonn Guidlines, som gjelder genetiske ressurser og den rimelige og rettferdige deling av profitten skapt fra brukerlandets anvendelse, fokuserer på dette aspektet.

Prosjektgruppen har vurdert det slik at uavhengig av om tiltak i brukerland rettslig sett er nødvendig for å være i overensstemmelse med CBD, så bør de nordiske landene gjennomføre slik lovgivning. En viktig begrunnelse for det er å bidra til håndhevelsen av tilgangsregulering i opphavsland, noe som er en viktig for å bygge tillit og fremme formålene med CBD. Prosjektgruppen foreslår

derfor at de nordiske landene følger opp Bonn Guidelines og inntar en aktiv rolle på dette feltet. Prosjektgruppen har diskutert følgende ikke gjensidig utelukkende tiltak:

- Regulering av import av genetiske ressurser.
- Regulering og arkivering av bruken av genetiske ressurser.
- Krav til å oppgi opprinnelsen til de genetiske ressursene i søknader om immaterielle rettigheter som et vilkår for å oppnå immaterielle rettigheter.
- Krav til å oppgi opprinnelsen til de genetiske ressursene i søknader om immaterielle rettigheter, men ikke som et krav for å oppnå immaterielle rettigheter (Dette er rettstilstanden i Danmark. Modellen vurderes også i Sverige og Norge).
- Sertifisering.
- Håndhevelsesmuligheter.
- Tilgang til domstoler og administrative tvisteløsningsmekanismer.
- Informasjon om potensielle brukere av genetiske ressurser på grunnlag av kravene til tilgang og profittdeling i CBD.

Prosjektgruppen er av den oppfatning at det er mangel på kunnskap og bevissthet om forpliktelser til å etterkomme kravene til tilgang og profittdeling blant brukere av genetiske ressurser. Dette siste tiltaket er ment å være et første viktig steg for å skape samsvar i tilgangsreguleringen hos de kontraherende parter til CBD. Utviklingen av relevante informasjonsstrategier kan være et felles nordisk prosjekt initiert av Nordisk genressursråd.

1 Introduction

1.1 Introduction to the Report

This report from the Project group on access and rights to genetic resources mandated by the Nordic Genetic Resources Council addresses various aspects related to rights and access to genetic resources in the Nordic countries. The report examines all genetic resources, whilst pointing out relevant differences between types of resources. The report studies the rights and access to the genetic resources managed by the Nordic Gene Bank. It also provides recommendations and alternatives for rights and access to genetic resources within the Nordic countries. It gives an overview of needs for and means of implementing the provisions of the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) and other international agreements in the Nordic countries. The report further analyses how rights and access to genetic resources relate to international law on intellectual property rights applied to genes and living organisms.

1.2 Background to the Issues Addressed in the Report

Throughout time, organisms have been developed by means of natural selection where the driving force is the interplay between the environment and the genetic material of the organisms. For cultivated species man has been a major factor in the development of animals and crops for agriculture purposes and over the years traditional breeding methods have resulted in crops and animals

that are better adapted to the needs of man. When the work of the monk Gregor Mendel, who discovered the fundamental laws of heredity, were rediscovered in 1900, plant- and animal breeding received a scientific basis and since then the development of new and better varieties has accelerated considerably compared to before. The current crop varieties, farm animal breeds and even forest seedlings have been highly improved in the context of high-yield and climatic adaptation and quality as a result of extensive exchange and free access to the genetic material between regions and countries during centuries. In this context, the access to and exchange of genetic resources has been of invaluable importance for the development in agriculture production.

The development of modern gene- and biotechnology has introduced new tools for an effective improvement of plants, animals and forest trees to the needs of mankind. These techniques have also opened up for uses of genetic resources for biotechnology industry and other non-traditional purposes. Consequently the commercial interest for genetic material of living organisms has increased and questions concerning access and the rights to genetic resources have become more important.

Genetic resources are valuable in supporting mankind with food, medicines and other products but also because of their cultural and historical value and the intrinsic value of nature itself. To a great extent the value of genetic resources lays in the diversity or variation *per se*, among individuals or specimens, within populations and among populations or species. Thus, a rich genetic diversity is invaluable for all who use genetic resources for any purpose.

Biological diversity, defined as the variation within species, among species and among ecosystems, has been and still is decreasing rapidly. Since genetic resources are found in the biological material, a decrease in biological diversity leads to a subsequent loss of genetic variation. Agricultural genetic resources are to a certain extent conserved in gene banks or by other arrangements to counter this trend. The decrease in genetic resources is a parallel feature for both cultivated and wild biological material,

however, due to different reasons. Genetic erosion in cultivated genetic diversity is caused partly because modern plant breeding has been very efficient and farmers tend to use the best and most profitable crops. This implies that in many countries the use of locally adapted landraces has diminished. Loss of wild biological diversity finds habitat loss, as for example deforestation, as its major cause.

In a historical context, access to genetic resources has not been subject to international regulation. When the former colonies gained their independence, the sovereign right over natural resources became an important issue for the new governments. At about the same time the need for protection of the investments connected to the development of new and commercially interesting crop varieties led to the development of international co-operation for the protection of plant varieties through the UPOV conventions. Later on patents were applied to living organisms and genes for the same reason. *Inter alia* these developments led to the recognition of national sovereign rights over genetic resources under the Convention on Biological Diversity. The application of intellectual property rights to living organisms in some countries has later been embedded worldwide by the agreement on Trade-Related Intellectual Property Rights (TRIPS-agreement) under the World Trade Organisation (WTO).

The application of intellectual property right law to living organisms and to genes has improved the conditions for innovations based on genetic resources. In the international discussion, it has also been argued that application of intellectual property rights to genetic resources leads to individualisation and monopolisation of these resources; and therefore being an obstacle to access to genetic resources and connected information for research and development and to the fair and equitable sharing of benefits arising from the use. Enforcement of the sovereign rights and strict regulation of access to genetic resources can also prevent the identification, collection and use of potentially valuable genetic resources. In the last decade there has been a decline in the rate of exchanges of genetic resources between researches. To

encourage research and development and avoid further erosion of genetic resources, any regulations in this field must build on co-operation and compromise between the collective and individualised rights in developed and developing countries.

The focus of the international debate has, beside research and development on genetic resources, been on ecology conservation and economic development. The challenge will be to conserve genetic variation in both wild and cultivated living organisms for the future. At the same time there is a need to ensure that genetic resources are made available for research and development on fair and equitable terms. One aim of this report is to discuss needs and options for the implementation of relevant international agreements in Nordic domestic legislation.

1.3 Distinct Challenges for the Various Organisms

1.3.1 Plant Genetic Resources for Food and Agriculture

Plant genetic resources for food and agriculture are important for food security both in a short-term and in a long-term perspective. In order to adapt to the environment, climate conditions, soil and water conditions new genotypes of plants are developed which increase the genetic variation. Throughout time there has been a large worldwide exchange of plant genetic resources. It is therefore not very easy, if at all possible, to determine the historical *country of origin*: *the country that possesses, or possessed those genetic resources in in-situ conditions*,[1] of the genetic material of plants used for food and agriculture. What has been possible is to suggest historical main centres of origin for various crops, from where these have spread to other areas and continents where they have adapted and developed new properties. The use of this genetic variation is of crucial importance for the further development of new and improved varieties. The genetic variation and thereby the

1. CBD article 2 fourth subsection.

genetic resources may be threatened due to several reasons. *Inter alia*, deforestation, cultivation, soil-sealing, overgrowing, intensification of agricultural production, reduced number of marketed or used crop varieties, may have effects on plant genetic diversity. Access to genetic diversity is in many cases a precondition for achieving enhancement within plant breeding programmes. The use of uniformly bred plant varieties might lead to reduction of genetic diversity within the variety unless the diversity is conserved in gene banks.

Plant genetic resources can be conserved in different ways. *In-situ conservation* means conservation of populations of wild or cultivated species in their natural surroundings or where they have developed their distinct properties. The term o*n farm conservation* is often used for domesticated material conserved by active use of the material. This does not interrupt the ongoing evolutionary process. *Ex-situ conservation* means conservation of genetic resources outside their natural habitat, for example in seed or field gene banks *ex-situ* conservation is a cost efficient method and a reasonably static way of conserving genotypes.

Since 1979 the Nordic countries have maintained a regional programme for the conservation and utilisation of plant genetic resources (PGR). This programme, realised by the Nordic Gene Bank (NGB), has as its main objective to conserve Nordic genetic material from species of value to agriculture and horticulture and to co-ordinate and support the utilisation of plant genetic resources in the Nordic countries. The mandate of the NGB covers in total 236 species of cultivated crops and wild relatives. Approximately 31,000 accessions are stored in the central seed storage. The collection consists of local and modern varieties, landraces, collected material and genetic stocks. The ordinary collection consists of almost 12,000 accessions representing 126 mandate species. The remaining part of the collection consists of special collections of mostly cereal and *Pisum* material. Conservation of vegetative propagated crops such as fruits and berries and some vegetables is carried out nationally in collaboration with research institutes and botanical gardens, *inter alia* the clone archives for fruits and berries

on the domestic level, whereas the NGB assumes a responsibility for information and documentation. For potato the NGB assumes full responsibility for the conservation of this material, which is stored *in vitro*. Botanical gardens, open air museums, and various private and public breeding and research institutes are further examples of organisations holding *ex-situ* collections of plant genetic resources in the Nordic countries.

1.3.2 Genetic Resources for Animal Breeding

The methods for reproduction of animals used in food production differ from those of forest tree and plant genetic resources for food and agriculture. Reproduction of animals is based on the use of the propagating material from one particular individual to fertilise another individual. Traditional livestock breeding is based on breeding populations, from which the following generation's parents are selected. One important property of a breeding population or breed is that the genetic diversity should be as large as possible. The process of selection has led to the development of various breeds, which *de facto* have been the different breeding populations. The present breeds are mainly the result of: 1) the selection of parents, 2) the trait(s) on which this selection is based, and 3) the reliability of this selection. The registration of traits associated with individual animals has thus traditionally been an important foundation for livestock breeding, and it represents a vital tool for targeted breeding efforts. The breeds can develop certain properties over generations if selection criterions remain the same. Within a species, it is presumed that variation between breeds accounts for 50% of the total genetic variation, whereas within-breed variation accounts for the rest. Traditionally, the development of breeds occurred locally, implying that the breeds were adapted to the local environmental and production conditions. This development generated the total farm animal genetic diversity, which thus represents the existing genetic resource for farm animals.

Originally, the farmers' organisations were usually responsible for running the breeding scheme for all farm animal species in the Nordic countries. These schemes were often simple selection programmes, but within the most reproductive species such as pigs and poultry, breeding lines and breeds were sometimes used in cross-breeding. Lately, within all species (above all for poultry), there is a trend that the breeding programmes are run by specific breeding companies managed by foreign owners. An increasing number of breeding associations have been shut down in recent years. In the Nordic countries, there are presently no breeding programmes for poultry, and poultry production in the region is therefore dependent on the supply of production stock from international breeding companies. The same trend can also be observed in swine production. For example, a discontinuation of the Swedish national pig-breeding programme has been discussed. This may, however, provide an opportunity to further closer Nordic co-operation, which seems to be the case for the swine breeding work. In dairy cattle breeding, an initiative has been taken to collaborate among the breeding associations in Denmark, Finland, Norway and Sweden. Regarding the situation of Iceland, the border has been closed for import of breeding material to this country, especial for dairy cattle and sheep.

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 become reduced in size or are at risk of becoming endangered.

The relevant breeding material in animal breeding is the individual of a breed or semen from particular individuals or, less frequently, embryos. Therefore, the origin of the genetic material is easily traceable. Since it is possible to determine from which individual the propagating material is derived, the exchange of such and the genetic resources of animals is individualised. Animal breeding is based on the exchange of propagating material regu-

lated by private law agreements and a common understanding among breeders of the rights associated with the material.

The Nordic countries were among the first to initiate efforts aimed at the conservation of breeds at risk. This commitment was primarily based on historical and cultural aspects. Pioneers, often with public support, as well as a few organizations in the 1970s and 80s initiated national measures. The Nordic Council of Ministers established the Nordic Gene Bank for Farm Animals in 1984 as a permanent agency, with the goal of promoting the conservation of breeds at risk in the Nordic countries. Conservation measures for breeds at risk in the Nordic region are developed at a national level. National committees for animal genetic resources are developing or implementing national programmes for these resources in many of the Nordic countries. This work has given important results, such as maintenance of living populations and deep-freezing of sperm and embryos.

By the Convention on Biological Diversity (CBD) the focus of the activities was directed at both the short-term and long-term use and conservation of the genetic resources. The principles for the sustainable management of genetic diversity were developed in line with the CBD and a sustainable utilization and food supply for the world's rapidly growing population. Since, there are no specific international agreements besides the CBD, regarding access to genetic resources for animal breeding, the need for national measures on access and rights must be taken by implementing the principles of the CBD at the national level.

In 1993, the FAO was given the mandate to carry out the "Global Strategy for the Management of Farm Animal Genetic Resources". The strategy's mission is to:

- Document existing animal genetic resources.
- Develop and improve their sustainable use.
- Maintain breeds of actual or potential value.
- Facilitate access to animal resources for food and agriculture.

FAO's commitment has resulted in a global process in which the national farm animal genetic resources are to be reported as a

strategic document describing the status, objectives and strategies necessary in order to achieve the specified goals. These country reports were to be submitted in autumn 2002.

Since it has taken a long time to formulate the international agreement on plant genetic resources, the initiation of the equivalent process for farm animals has been postponed.

Nordic Gene Bank for Farm Animals

There is a considerable difference between the activities of the Nordic Gene Bank (NGB) and the Nordic Gene Bank for Farm Animals (NGH), due to biological differences and the practical implication of the work. A short presentation of the activities of NGH is thus necessary.

The activities of NGH have undergone a transition from conservation to developing a strategy for the sustainable utilization and conservation of farm animal genetic resources in the Nordic countries. The main reasoning for this is that the total genetic diversity is the basis for the genetic resources available in the future. Conservation and utilization must therefore be seen as a whole when developing policies and instruments for the maintenance of genetic diversity.

The Nordic countries have followed up the Convention on Biodiversity by designating national responsibility for the conservation of breeds at risk to specific agencies (*e.g.*, the Gene Resource Committee in Norway) or within the existing public administrative structures. "Gene banking", in the form of stored semen and embryos is conducted at a national level. NGH thus has no control over genes, in the way the NGB does via its stores of seed and other genetic material. However, as a result of NGH's research activities, blood- and DNA-samples from different breeds of cattle and pigs from the Nordic countries have been stored by NGH.

For breeds of farm animal, there are no international regulations for specific rights comparable to the plant rights regulated by the UPOV Convention. This is a major difference, which has had a significant effect on the development so far.

When considering genetic diversity as a resource for the future, issues related to value appraisal will play a major role. The values of genetic diversity are either real values or potential values. The challenge is to apply policy-making, expertise and technological development to the creation of added value based on farm animal genetic resources in agreement with the principles of the Convention on Biodiversity.

Mission and Areas of Priority for NGH
Based on the political context and the Nordic mode of national breed conservation, NGH has formulated strategies and activities. The main objective is to create values through the conservation and sustainable utilization of genetic resources of Nordic farm animals. Based on the organization's objectives and strategies, NGH has defined the following areas of priority:

- Knowledge transfer and information.
- Networking.
- Research and technology development.
- Supportive information technology.
- Administration and internal professional development.

NGH's activities shall contribute to the sustainable management of farm animal genetic resources. The achievement of this goal is dependent on the development of policies that stimulate, and of technologies that facilitate the practical conservation and breeding work. The main activities of the NGH are thus information, networking and research and development projects.[2]

1.3.3 Genetic Resources of Forest Trees

Forest tree genetic resources have been transferred between countries and continents as seeds and plants for centuries, and long before anyone understood the importance of planting materials well adapted to the new location. Especially in northern Scandi-

2. See also www.nordgen.org.

navia, forest tree populations are showing a continuous variation from south to north in adaptation to climatic conditions, and a substantial variation within populations. It is essential that adaptation to local conditions will be secured for future use. This is achieved in gene conservation stands and areas. In Finland the total gene conservation area comprises 5,000 hectares and in Sweden 3,700 hectares. National parks and other protected areas are not included in the areas above, but are also genetic resources that can be used in this connection, especially for preserving marginal populations and rare species. In addition, materials with characterised genetic variability are conserved in breeding and research populations.

In Finland, the research organisation METLA has the practical responsibility for gene conservation. In Sweden the National Board of Forestry has a special responsible department *"Skogliga Genbanken"*. In both countries the main resources have been invested in the main species, *Scots pine* and *Norway spruce*. In Norway, genetic resources of non-commercial tree species are conserved mainly *in-situ* in nature conservation areas, while the commercial species also are conserved in breeding populations. A separate committee provides advice to the Ministry of Agriculture, and the Norwegian Forest Research Institute is responsible for forest gene resource management. In Denmark t he National Forest and Nature Agency (department Tree Improvement Station: *"Statsskovenes Planteavlsstation"*) has the practical responsibility for gene conservation. The Danish programme includes, besides forest trees, also non-timber trees and major bush species of the forest ecosystem. In Iceland planning of gene conservation has just started. Besides the traditional gene conservation material, the Nordic breeding organisations have records of a large number of field trials and also detailed knowledge of material in different breeding populations.

Nordic cooperation is organized through the Nordic Council for Forest Reproductive Material (NSFP), a network between the Nordic countries for improving methods of conservation, exchange of information, and for information to the society. This network

is cooperating with the "Nordic group for management of genetic resources of trees" within Nordic Forest Research Co-operation Committee (*SamNordisk Skogforskning,* SNS). The cooperation within Europe is organized in EUFORGEN, which is a collaborative programme among more than 30 countries aiming at ensuring the effective conservation and sustainable use of forest genetic resources in Europe. Activities are carried out in networks, in which scientists and forest officials, working with the same species, agree on strategies and methods and exchange information that can be beneficial for national programmes. This organization is not intended to be a permanent one. On the worldwide level gene conservation aspects are covered by the Union of Forest Research Organisations (IUFRO), within its different research groups and by FAO.

The use of forest reproductive material is still, to a certain extent, depending on stand seed, *i.e.* seeds harvested in appointed stands. To improve survival, wood quality and production, this seed is transferred within Nordic countries but also imported from other countries. For example Norway spruce is mainly imported from East Europe.

Forest tree breeding started in the late 1930. In all Nordic countries, organisations responsible for forest tree breeding are supported by the state. Breeding comprises selection of superior trees (plus-trees) in forests. The selected trees are propagated vegetatively for future use in breeding and for seed production. Seeds from the selected trees are used for the establishment of trials for progeny testing. After progeny testing the genetically best plus-trees are cloned by vegetative propagation and planted out in random mixtures in seed orchards to produce a superior seed. An increasing part of Nordic forest reproductive material originates from seed orchards. Breeding material has so far been exchanged completely freely between countries, also outside the Nordic countries. Breeders are members of the research groups mentioned above. Common international projects have promoted establishment of series of trials with different origins of forest

reproductive material, and also exchange of material between countries. Decades of research in field trials have increased the knowledge from where the best material can be taken for different regions. It is therefore essential to be able to get material from appointed areas also in the future.

1.3.4 Fish and Marine Genetic Resources

Most fish and other marine organisms are wild, not domesticated. A growing tendency is, however, extensive breeding of fish lines for fish farming. This underscores the importance and value of the genetic diversity among fish and other marine species. The recent incidents of German research submarines searching the coral-reeves of the Norwegian coast illustrate the potential of marine and aquatic genetic resources. There are, however, no ongoing Nordic incentives for a common conservation and use of these genetic resources.

1.3.5 Wild Organisms

Beside the above-discussed distinct groupings of genetic resources, the scope of this report is to address the genetic resources of other groups of biological material. These are in particular wild living animals and wild growing plants. The scope also covers the genetic resources of maritime or aquatic organisms. Wild growing plants are of potential interest to the pharmaceutical industry. In general, the genetic resources of wild organisms play a vital role in ecosystems and within the totality of the renewable living resources. Thus, those resources are also important in a long-term development perspective. Wild-growing relatives of plants used in agriculture can be of interest in the breeding of commercially interesting varieties.

1.4 Strategy for Discussing Access and Rights to Genetic Resources

Pursuant to Nordic guidelines and strategies for cooperation in this field, especially the Strategy for Conservation of Genetic Resources in the Nordic Region 2001–2004 and the decisions from the Nordic ministerial meetings in summer 2002, the Project Group has identified the following objectives for the management of genetic resources in the Nordic countries:

- To encourage conservation of the resources.
- To encourage an efficient and sustainable use of the resources.
- To facilitate access to and exchange of genetic resources.
- To promote a fair and equitable sharing of benefits arising from the use of genetic resources.
- To contribute to the international development of the area.

2 Regulations of Genetic Resources in International Law

2.1 Regulations at a Global Level

2.1.1 "Genetic Resources" in International Law

The point of departure for a Nordic implementation of obligations under international law is the definition of *genetic resources* in the relevant treaties. The Convention on Biological Diversity article 2 tenth subsection defines *genetic resources* as *"… genetic material of actual or potential value"*. *Genetic material* is defined as *"… any material of plant, animal, microbial or other origin containing functional units of heredity"*.[3] In the following sections, the CBD definition will be discussed in light of these three elements: (1) any material of plant, animal, microbial or other origin, (2) functional units of heredity, and (3) of actual or potential value.

(1) Any Material of Plant, Animal, Microbial or Other Origin
According to the definition, *"… any material of plant, animal, microbial or other origin …"* can be the source of genetic material and thereby a genetic resource. This definition is rather comprehensive covering all living organisms. *Genetic resources* are inherent in biological material, and are thereby one category of *biological resources*.[4]

3. CBD article 2 ninth subsection.

4. CBD article 2 second subsection.

Biological material is used or taken advantage of in numbers of different manners. For the understanding and interpretation of the term *genetic resources* in international law it is of interest to have a look at examples of such uses. For example: trees can be used as timber, plants can be harvested and used for food or feed, animals can be hunted and used for food and certain medicinal plants can be used to heal a wound or to relieve pain. Common for these examples is that the organisms are used for their physical properties and not because of their *genetic resources*. Hence, the term *genetic resources* in the CBD does not address rights and access to biological resources for such purposes.

Material of plant, animal, microbial or other origin can, however, be used for other purposes than those mentioned above. Biotechnology can be explained as *"any technological application that uses biological systems, living organisms, or derivates thereof, to make or modify products or processes for specific use."*[5] The term any technological application is a very broad definition, covering for example traditional fermentation techniques and procedures for purification of water, soil and air. The use of biological material for such technologies does not imply a direct use of their inherent genes, and is therefore not covered by the definition of genetic resources. In modern breeding, biotechnology and in particular in gene-technology, genetic resources within the biological material are explored in a more direct manner. Gene-technology can be explained as a set of technologies to handle genetic material including the technology to transfer genes from one species to another (recombinant-DNA technology). Gene technology thus makes it possible to combine traits or properties from different species, for example may the genes coding for the ability of a fish to live in low temperatures be transferred into plants and thereby make them more resistant to frost.

5. CBD article 2, third subsection.

(2) Functional Units of Heredity

Genes and promoters are such *units of heredity*. A promoter is a control sequence, which can activate a gene and regulate its expression. A gene can be explained as a molecular structure in a chromosome that codes for a specific protein, for example an enzyme, a hormone or a receptor. Different genes may code for one protein. The proteins, in turn, influence the properties of cells, and thereby the organism. Different organisms, varieties and species have different sets of genes and this genetic variation is the basis for plant and animal breeding including breeding methods based on gene technology. All cells and thereby all biological material contains *units of heredity*. When technology identifies other hereditary elements in the cells than those presently known, the wording *functional units of heredity* will cover them.

(3) Actual or Potential Value

The difference between *genetic resources* and *genetic material* is that genetic resources are genetic material of *actual or potential value*. As it is difficult to predict the characteristics and properties of value in the future what follows is a scenario whereby in principle all genetic material could be regarded as a genetic resource. "Value" as a term is not defined in the CBD. The genetic material could represent different types of value as food, as feed, as propagating material in agricultural production, value as input in biotechnology research and development, in breeding activities, it could represent historic or cultural value, ecological value or the value of the genetic material for itself, its intrinsic value.

As genetic material is included in the definition of a *genetic resource*, the term *"actual and potential value"* in the definition could be understood to be referring to the value of the functional units of heredity. Thereby, the definition of a *genetic resource* does not encompass genetic material as a value for their biological properties, as food, feed and seeds, but in activities where the use of the functional units of heredity play a vital role. Therefore, the definition of *genetic resources* does not cover for example agricultural product imported in bulk, for the use as food or feed.

The Essence of the Definition

The core of the definition is that *genetic resources* must be understood in the context of use of biological material. In short, biological resources are genetic resources when they are used for the purpose of exploiting genes or other functional units of heredity – not for their physical properties. The definition of *genetic resources* excludes the use of biological material when not used for the purpose of its genes.[6] The following examples can illustrate the relationship between biological resources and genetic resources:

- A seed is a genetic resource when used for the purpose of developing a new plant variety, but a biological resource when used for production of food or when used as a commodity. One particular issue that arises is whether seeds are genetic resources according to the definition? This must depend on the purpose of the use. If the seed is going to be sown for the purpose of being harvested and used as a commodity, the seed cannot be regarded a genetic resource according to the definition, since it is not used for its genetic code *per se*. If the seed is used for the purpose of cross-breeding or in developing a new strain or variety, it is covered by the definition of genetic resources.
- A bull is used as genetic resources when used in fertilising cows, but a biological resource when slaughtered for the use of the beef.

These examples illustrate how the same biological material can be used both as *genetic resources* and *biological resources* dependent on the purpose of the use. It also shows that it may be very difficult to distinguish *genetic resources* from biological resources as legal

6. ten Kate and Laird 1999 page 17. The Central-American Agreement on Access to Genetic Resources and Biochemicals and to Traditional Knowledge is an interesting example, whereas it excludes from its scope: "Access to and use of biological resources different from the use of them as a source of genetic resources and biochemicals." Translated from Spanish here. Even though this implies a double negation it defines genetic resources rather precisely.

terms. It might, however, be important to establish such a distinction to enable the implementation of international agreements on this matter in domestic legislation. This legal distinction is, however, fundamental to understand the discussions of the legal status for *genetic resources* in Chapter 4. These discussions do not at all address legal rights to the biological resources, but rights to *genetic resources* as suggested as a legal term in this chapter.

2.1.2 The Convention on Biological Diversity

The United Nation Convention on Biological Diversity (CBD) was negotiated within the framework of the UN Environment Program (UNEP), and was opened for signature at the Earth Summit in Rio de Janeiro on 22 May 1992. The Convention entered into force on 29 November 1993 after the ratification of 30 countries. The Convention has to date been ratified by more than 180 States including all the Nordic countries. Thailand and the USA are signatories to the CBD.

The CBD can be seen as a result of an increasing international attention being paid to the risk of extinction of a large number of species. This international attention on biological erosion had also before the CBD led to the conclusion of several international conventions addressing particular problems.[7] Despite of these treaties, there were still estimates suggesting that a high number of species will become extinct during the next 25 years. The CBD applies an ecosystem approach to conservation of biological diversity rather than addressing these challenges one by one. The CBD defines biological diversity as: *"the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this*

7. Examples are the 1971 Convention on Wetlands of International Importance, Especially as Waterfowl Habitat, the 1972 Convention Concerning the Protection of the World Cultural and Natural Heritage, the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora, the 1979 Convention on Preservation of Migratory Species of Wild Animals and the 1982 Law of the Sea (10. December 1982) articles 61–65.

includes diversity within species, between species and of ecosystems".[8] One of the core words in the definition is *variability*. Biological diversity is defined as the variation *per se "…within species, between species and of ecosystems"*. The term *living organisms* is yet a broader concept; it includes all forms of living biological material from micro-organisms to humans. The definition of biodiversity does not make any distinction between wild, semi-domesticated and domesticated species.

The CBD emphasises the interrelation between ecology and development purposes (sustainable use and fair and equitable benefit sharing arising from the use of genetic resources). The ecological concern is *inter alia* reflected in one of the objectives: conservation of biological diversity, whereas monetary interests and technological development are foremost reflected by the terms *"fair and equitable sharing of the benefits arising out of the utilisation of genetic resources"*. The third objective of the CBD, the *"sustainable use of its components"* comprises both these dimensions. Before the CBD the World Commission on Environment and Development urged industrialised nations: *"seeking to reap some of the economic benefits of genetic resources (…) to support the efforts of the Third World nations to conserve species"* and *"developing countries must be ensured an equitable share of the economic profit from the use of genes for commercial purposes"*.[9] The CBD follows this recommendation by turning this recommendation into legally binding obligations in international law. The obligations of the CBD must, however, be implemented at the national level. As follows from the general principles in international law, each Party to a convention must take efficient legislation, administrative or policy measures to fulfil its objectives and obligations. The CBD article 23 establishes the Conference of the Parties, which has as one of its purposes to develop further the principles of the Convention at the international level. The sixth Conference of the Parties (COP 6) adopted the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Benefit Sharing Arising from their Utilization.[10]

8. CBD article 2, first subsection.
9. Our Common Future 1987.
10. UNEP/CBD/COP/6/6.

The Scope of Article 15 – Sovereign Rights to Genetic Resources

The Convention on Biological Diversity specifies the legal regime regarding genetic resources. Originally, exchange of plant genetic resources was based on a principle of *common heritage of mankind*. This principle was to some extent undermined as patent legislation was interpreted to cover innovations in the field of biotechnology and biological material. According to the FAO Undertaking of 1983, all categories of plant genetic resources were regarded as a *common heritage of mankind*. This, however, changed by the 1989 amendment of the Undertaking when it was recognised that plant breeders' rights, as provided for by the International Union for the Protection of New Varieties of Plants (UPOV) were not inconsistent with the Undertaking. This reopened issues on rights to genetic resources in international law. The South abandoned the *common heritage*-strategy and successfully demanded reconfirmation of *national sovereign rights* over genetic resources in the CBD negotiations.[11] This lead to the adoption of CBD article 3:

> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.[12]

CBD article 15, paragraph 1 specifies the right of the countries to genetic resources further by stating:

> Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

Hence, genetic resources are under the sovereign rights of each Nordic country. However, countries in one region share, to a large extent, the same biological diversity. Consequently, issues like conservation of and access to genetic resources are topics that might very well be addressed at the regional level. One example of such

11. Rosendal 2003.

12. CBD article 3.

regional cooperation is the Andean Pact Countries that have adopted common legislation on access to genetic resources and benefit sharing. In the Nordic area the Nordic Gene Bank conserves, characterizes and documents genetic resources donated and collected from all the Nordic countries. However, the CBD does not grant any formal rights at the regional level.

Even though the point of departure of article 15 is national sovereign rights over the genetic resources, "each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources … by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."[13] The wording "endeavour to create" implies a soft obligation according to international law. This emphasises, however, that the sovereign rights as embedded in the CBD are not meant to impose undue restrictions or reduce the exchange of genetic resources from one country to another.

CBD article 15 specifies the scope of regulation of access to genetic resources. Article 15 paragraph 3 expresses that:

> for the purpose of this Convention, the genetic resources being provided by Contracting Party … are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have a[c]quired the genetic resources in accordance with this Convention.

CBD article 15 does not cover genetic resources that were collected before the Convention entered into force and are held under *ex-situ* conditions, as for example in botanic gardens or gene banks. A provision that exempts genetic resources acquired before the entry into force of the CBD is a natural consequence of the principle of law that acts cannot be retroactive. Since, the International Undertaking was not legally binding, it is not clear what followed from international customary law: It is possible that also before the CBD the legally binding international situation was that the genetic resources was under the sovereignty of the Parties, and that the International Undertaking sought to facilitate access to plant genetic resources.

13. CBD article 15 paragraph 2.

The wording used in the preamble of the CBD whereas: *"The Contracting Parties, Reaffirming that States have sovereign rights over their own biological resources"*, indicates that the CBD did not alter the formal legal situation. It is probably not possible for states to retroactively regulate access to genetic resources that were collected before the CBD.

The country providing genetic resources is "the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country".[14] According to CBD article 15 it is the providing country that is entitled to give its prior informed consent to access to the genetic resources. The term countries of origin of genetic resources is, however, defined in CBD as: "the country which possesses those genetic resources in *in-situ* conditions".[15] For species that are not domesticated or cultivated, the term *in-situ* conditions means "conditions where genetic resources exist within ecosystems and natural habitats…"[16] For these species the country of origin is where they are naturally occurring within an ecosystem or in natural habitats. In general terms this implies that the country where these genetic resources are found will also be the country of origin. For domesticated or cultivated species *in-situ* conditions is defined as: "…the surroundings where they have developed their distinctive properties".[17] It is not very easy to determine, if at all possible, where domesticated or cultivated species have developed their distinctive properties.[18] For these genetic resources it has been and still is an extensive cross border exchange, which implies that several of the properties of one variety typically have been developed in a number of regions and countries.

Exercising the Sovereign Rights over Genetic Resources

According to CBD article 15 paragraph 5: *"Access to genetic resources shall be subject to prior informed consent of the Contracting Party pro-*

14. CBD article 2 fifth subsection
15. CBD article 2 fourth subsection.
16. CBD article 2 twelfth subsection.
17. CBD article 2 twelfth subsection.
18. Andersen, 2001.

viding such resources, unless otherwise determined by that Party". Hence, the sovereign rights over genetic resources can be exercised either by requiring a prior informed consent before bioprospecting activities take place or by the country stating that access to genetic resources within its territory does not require any permission. CBD article 15 paragraph 4 reads: *"Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article"*. Where access to genetic resources is granted according to a prior informed consent, such access shall be mutually negotiated, taking into account the other provisions of article 15.

How to organise such permissions and to impose terms for granting access to genetic resources, or whether to leave access to genetic resources open is to a large extent left to the discretion of each Party. The Conference of the Parties under the CBD has, through the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing, developed Guidelines (that are voluntary) for the purpose of facilitating the work of the Parties to implement access legislation. The Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising from their Utilization, stress the importance for the Parties to establish a national focal point responsible for handling applications on access to genetic resources.[19] In the case of access to *ex-situ* collections of genetic resources, the Guidelines suggest the body governing the collection as an appropriate focal point.[20] The Guidelines emphasise *"legal certainty and clarity"*, facilitation of access at a minimum cost, transparency for the restrictions and that consent must be sought from all relevant stakeholders as basic principles for the implementation of a system for requiring *prior informed consent*.[21] The Guidelines outline comprehensively the procedures for *prior informed consent* and *mutually agreed terms* in paragraphs 22–44.

19. Bonn Guidelines II. A–C, paragraph 13–16.
20. Bonn Guidelines IV. C, paragraphs 32.
21. Bonn Guidelines IV. C, paragraphs 26.

Rather than referring to all these provisions, this report draws upon these suggestions when discussing potential means of implementation in Chapter 4.

Environmentally Sound Use

Article 15 paragraph 2 emphasises that access to genetic resources shall be facilitated for *"environmentally sound uses"*. This term reflects the environmental dimension of the CBD in terms of access to genetic resources. The meaning of "environmentally sound uses" in this context has, however, not been subject to any detailed discussions in international law. Even the Bonn Guidelines only address the environmental aspects of access legislation in a few paragraphs.[22] The core of this term is to develop mechanisms to include considerations of the ecological impacts from the bioprospecting when determining whether to grant access to genetic resources. The CBD article 14 outlines a system for Impact Assessments for "*…proposed projects that are likely to have significant effects on biological diversity with a view to avoid or minimizing such effects…*". Environmental Impact Assessments (EIA) are not specifically mentioned in relation to access to genetic resources. However, being a general measure in the CBD, it is of relevance for the Parties to consider whether to adopt a requirement of a cost-effective EIA in the access legislation. The challenge for implementing the term *"environmentally sound uses"* as a legal concept is how to combine an efficient legal system, where the transaction costs are low, with an efficient assessment of the environmental effects or consequences from the bioprospecting from an ecological or biological point of view. At this point legal or policy measures meet biology – which imposes specific challenges in the implementation of the principles of the CBD.

22. *Inter alia* Bonn Guidelines II, paragraphs 14(f), 16(a)(v), 36(b), (e), (f), (g) and 44(a).

Fair and Equitable Benefit Sharing

CBD article 15 paragraph 7 provides for the *"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"*. Potential measures by which benefit sharing can take place have been developed in the international debate. The most comprehensive work on this issue is Annex I to the Bonn Guidelines, enclosed as appendix I to this Report.

The concept *"Fair and Equitable"* has not been developed in any detail as a legal concept in international law.[23] The Bonn Guidelines focus on other aspects than the level of benefit sharing. The Guidelines emphasise that the level of benefit sharing should be flexible and *"... will vary on a case-by-case basis"*.[24] The challenges related to this concept lie in developing mechanisms – legally binding or in other manners, providing for or enforcing the bioprospector to be morally or legally bound to share a *fair and equitable* bulk of the *research results*, *development*, *technological* and *economic benefits* arising from commercial and other utilisation of genetic resources with the provider of them.[25] Both the word *fair* and the word *equitable* imply references to ethical norms. What level of benefit sharing that is regarded as *fair* will probably vary among stakeholders. One example can be a pharmaceutical company from a Nordic country that establishes contact with a local indigenous community in a developing country. The indigenous community has used an herb as a medicine for generations. The company buys one sample of the herb and conducts a long-term and expensive research and development leading to a new medicine. On the one hand, the local indigenous community will probably tend to be in favour of claiming a large part of the profit, due to the fact that they provided the genetic resource along with their related traditional knowledge. On the other hand, the pharmaceutical company has invested technology, time and money in the

23. Bonn Guidelines IV, D, paragraph 45–50.

24. Bonn Guidelines IV, D, paragraph 49.

25. CBD article 15 paragraph 7.

research and development, facing the risk of not developing a successful medicine. To determine what is *fair and equitable* in such a context is a difficult question. In order to eliminate the individuality of this consideration, access legislation can establish an objective mechanism to reflect the interests of the both parties. In terms of the CBD one of the objectives is conservation of biological diversity. One possibility is that *fair and equitable* can be understood as to require the user of genetic resources to contribute substantially to conservation efforts taken in the providing country. The background of the provisions in CBD regarding access to genetic resources was a compromise between the interests of developed and developing countries. The claim for benefit sharing was mainly a claim from the South in achieving benefits in return from the use of their natural resources. In this context and for achieving poverty reduction it is possible to argue that the level of benefit sharing should be generous. Another view is that what is *fair and equitable* must be determined in each individual case based on the negotiation between the user and the provider of the genetic resources, and that the conclusion of agreed terms as such is *fair and equitable*. This point of view does, however, not reflect differences in negotiating capacity between the participants.

The Bonn Guidelines paragraph 51 points out three very relevant measures in the implementation of access legislation:

a) …
b) The use of well-designed economic and regulatory instruments, directly or indirectly related to access and benefit-sharing, should be considered to foster equitable and efficient allocation of benefits;
c) The use of valuation methods should be considered as a tool to inform users and providers involved in access and benefit-sharing;
d) The creation and use of markets should be considered as a way of efficient achieving conservation and sustainable use of biological diversity.

These are all very interesting as to establish mechanisms that can standardise the level for benefit sharing. However as it follows from the wording of paragraph 51 these are *"incentives"* and are listed under *"V. Other Provisions"* in the Guidelines. Hence, it could be discussed if there is a need for developing them as legal mechanisms also at the international level. The Johannesburg Declaration paragraph 42 (o) recommends the international community to:

> (o) Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;

This provision might lead to a negotiation of an international mechanism for benefit-sharing.

The Scope of Article 16

CBD article 16 has been given less attention than article 15 in the international debate. The article emphasises that access to and transfer of technology *are essential* to attain the objectives of the CBD. *Technology* in this context refers to gene- and biotechnology. According to article 16 paragraph 2 access to and transfer of technology shall be on *"… fair and favourable terms …"*. The article uses the term *fair*, which might be considered as an obligation upon the Parties describing the terms for transfer of technology.

Technology transfer shall, however, be as follows:

> In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights.[26]

According to article 16 paragraph 5:

> The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this

26. CBD article 16 paragraph 2.

> 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.

The wording is vague in a legal sense and the legally binding obligation according to the article is therefore not very favourable for the countries in need of technology transfer. The obligations according to paragraph 5 are general but imply a legal obligation upon the member countries that cannot be overseen. Products based on gene- and biotechnologies are typically the results of research and development, and often protected by intellectual property rights. Transfer of technology consistent with intellectual property rights implies that such transfer must respect these rights. The relevant manner to comply with intellectual property rights is to enter into a licence agreement regulating the terms for the transfer, including paying a licence fee to the holder of the patent. The reference to the effective property right might undermine the chance for a developing country to succeed in receiving the newly developed technology that could be used in commercial activities. However, it should be kept in mind that to a large extent the knowledge coming out of gene- or biotech research is published in scientific papers or made available free of cost in databases.

2.1.3 The International Treaty on Plant Genetic Resources for Food and Agriculture

Background for and Scope of IT-PGRFA

The exchange of seeds and plants over short and long distances has been crucial for the development of agriculture and socio-economy throughout the past 10,000 years. The importance of this open exchange was recognised and embedded in the non-binding International Undertaking under the UN Food and Agriculture Organisation (FAO IU) of 1983, where:

> The objective of this Undertaking is to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes. This Undertaking is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction.

However, the FAO IU was only one of several parallel contemporary features: From the 1970s intellectual property rights were applied to genes and living organisms. This was, besides promoting invention, also leading to privatisation and individualisation of the plant genetic resources in the world, creating a need for a legally binding instrument of international law to ensure free and open exchange of plant genetic resources for food and agriculture purposes. Also, after the entry into force of the CBD, some countries started exercising their sovereign rights to genetic resources in such a manner that the access to the resources was restricted. This created a need for a legally binding instrument to promote a free and open exchange of plant genetic resources for food and agriculture. There was also an additional formal reason: Under the final negotiations of the CBD in Nairobi, there were several outstanding issues that the negotiators did not agree upon. FAO was encouraged to bring forward these topics in the renegotiation of its International Undertaking, when harmonising it with the principles of the CBD.

In this context, the International Treaty on Plant Genetic Resources for Food- and Agriculture (later referred to as the IT-PGRFA) was negotiated because of *"the special nature of plant genetic resources for food and agriculture, their distinctive features and problems needing distinctive solutions"*.[27] The IT-PGRFA addresses *plant genetic resources for food and agriculture*. The term *for food and agriculture* has two implications: first plant genetic resources that are interesting for food- and agricultural production are covered by

27. IT-PGRFA preamble first subsection. The need for renegotiating the FAO IU was also expressed during the negotiations of the CBD.

the Treaty; and second only access to plant genetic resources are regulated by the Treaty when the purpose is to use them in food and agriculture.[28] Also wild relatives are covered when they have actual or potential value for food and agriculture. Besides these general rules the IT-PGRFA, in Parts IV, VI and VII provides for a Multilateral System of Access and Benefit-Sharing, which applies to a selection of crops listed in its Annex I. The Treaty was adopted 3 of November 2001 at the FAO conference. According to IT-PGRFA article 4, *"Each Contracting Party shall ensure the conformity of its laws, regulations and procedures with its obligations as provided in this Treaty."* Hence, the Treaty implies an obligation upon the Parties to harmonise their legislation.

The Multilateral System for Access and Benefit Sharing

The two main purposes of the Multilateral System are to *facilitate access* and the *fair and equitable benefit sharing* arising from the use of the genetic resources made available under the System. The core of the System is to make genetic resources available for certain purposes without bilateral negotiations. The Contracting Parties to the IT-PGRFA recognise that:

> in the exercise of their sovereign rights over their plant genetic resources for food and agriculture, states may mutually benefit from the creation of an efficient multilateral system for facilitated access to a negotiated selection of these resources … [29]

The Treaty establishes a Governing Body, which shall carry out a number of functions according to *inter alia* article 19.3. By the IT-PGRFA, the Parties accept to exercise their sovereign rights over genetic resources by establishing the Multilateral System provided for by the International Treaty.[30] In the terms of the CBD, one can say that the parties to the IT-PGRFA, by ratifying the Treaty, give their *prior informed consent* to access to certain genetic resources.

28. IT-PGRFA article 1.1, article 2 third subsection, article 3

29. IT-PGRFA preamble fourteenth subsection.

30. IT-PGRFA article 10.

The provisions in the IT-PGRFA specify the conditions for granting such standardised *prior informed consent*. In addition, the Governing Body under the Multilateral System shall adopt a standard Material Transfer Agreement (MTA). In terms of the CBD, one can say that the standard MTA will fulfil the role of establishing a framework for the *mutually agreed terms*, and that each of the Parties has forfeited the right to require additional mutual negotiations of the terms for the individual access. Access shall be carried out *"expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved"*.[31] Provided that a large number of states become parties to IT-PGRFA, it will promote deregulation and facilitation of access to plant genetic resources for food and agriculture. In addition, the IT-PGRFA provides for the fair and equitable benefits sharing arising from use of these resources.

Coverage

The point of departure is that the Multilateral System shall include "all plant genetic resources for food and agriculture listed in Annex I that are under the management and control of the Contracting Parties and in the public domain".[32] One way of looking at the expression "under the management and control of the Contracting Parties and in the public domain" is to see it as an entity, meaning that the material has to be under the ownership of the Party. This was used in the negotiations proceeding to the adoption of the IT-PGRFA. Another way is to analyse its components separately. Thus, according to the latter view, the definition of the scope can be analysed as a term that comprises three components:

31. IT-PGRFA article 12.3.b.

32. IT-PGRFA article 11.2.

… listed in Annex I …	*… under the management and control of the Contracting Parties …*	*… in the public domain*
This refers to the **selection of species** covered by the Multilateral System	This part implies a delimitation of **which physical/biological material** (**the physical accessions**) that are under the scope of the MS.	The **legal status of the genetic resources** ***per se***, that appear in the biological material of the relevant species
Determined in the IT-PGRFA annex I.	The biological material that is covered by the Multilateral System depends on domestic property rights to biological material.	The exclusive right to genetic resources will also be regulated by domestic legislation. (The term genetic resource is discussed above in Chapter 2.1.1.)

To be included under the Multilateral System, all these three conditions must be fulfilled: The biological material must be of certain species; the biological material must be publicly accessible and the genetic resources must be in the public domain.

The Species Listed in Annex I

The IT-PGRFA delimits the scope of the Multilateral System to certain species listed in Annex I to the Treaty. In the negotiations the countries belonging to the European region wanted the multilateral system to cover all crops for food and agriculture. This was, however, rejected by a number of developing countries with references *inter alia* to the patent practice in developed countries. For example, soybeans, peanut and oil palm are not included on the list, whereas important vegetables, fruit and berries are only partly included. The position of the Nordic countries during the negotiations was that the Multilateral System should not be limited to such a list, but to cover all plant genetic resources for food and agriculture, to ensure the most facilitated exchange of genetic resources.

ANNEX I

List of Crops Covered under the Multilateral System

FOOD CROPS

Crop	Genus	Observations
Breadfruit	*Artocarpus*	Breadfruit only.
Asparagus	*Asparagus*	
Oat	*Avena*	
Beet	*Beta*	
Brassica complex	*Brassica* et al.	Genera included are: *Brassica, Armoracia, Barbarea, Camelina, Crambe, Diplotaxis, Eruca, Isatis, Lepidium,Raphanobrassica, Raphanus, Rorippa*, and *Sinapis*. This comprises oilseed and vegetable crops such as cabbage, rapeseed, mustard, cress, rocket, radish, and turnip. The species *Lepidium meyenii* (maca) is excluded.
Pigeon Pea	*Cajanus*	
Chickpea	*Cicer*	
Citrus	*Citrus*	Genera *Poncirus* and *Fortunella* are included as root stock.
Coconut	*Cocos*	
Major aroids	*Colocasia,* Xanthosoma	Major aroids include taro, cocoyam, dasheen and tannia.
Carrot	Daucus	
Yams	Dioscorea	
Finger Millet	Eleusine	
Strawberry	Fragaria	
Sunflower	Helianthus	
Barley	Hordeum	
Sweet Potato	Ipomoea	
Grass pea	Lathyrus	
Lentil	Lens	
Apple	Malus	
Cassava	Manihot	Manihot esculenta only.
Banana / Plantain	Musa	Except Musa textilis
Rice	Oryza	
Pearl Millet	Pennisetum	
Beans	Phaseolus	Except Phaseolus polyanthus.
Pea	Pisum	
Rye	Secale	
Potato	Solanum	Section tuberosa included, except Solanum phureja.
Eggplant	Solanum	Section melongena included
Sorghum	Sorghum	
Triticale	Triticosecale	
Wheat	Triticum *et al.*	Including Agropyron, Elymus, and Secale.
Faba Bean / Vetch	Vicia	
Cowpea *et al.*	Vigna	
Maize	Zea	Excluding Zea perennis, Zea diploperennis, and Zea luxurians.

FORAGES

Genera	Species
LEGUME FORAGES	
Astragalus	Chinensis, cicer, arenarius
Canavalia	Ensiformis
Coronilla	Varia
Hedysarum	Coronarium
Lathyrus	Cicera, ciliolatus, hirsutus, ochrus, odoratus, sativus
Lespedeza	Cuneata, striata, stipulacea
Lotus	Corniculatus, subbiflorus, uliginosus
Lupinus	Albus, angustifolius, luteus
Medicago	Arborea, falcata, sativa, scutellata, rigidula, truncatula
Melilotus	Albus, officinalis
Onobrychis	Viciifolia
Ornithopus	Sativus
Prosopis	Affinis, alba, chilensis, nigra, pallida
Pueraria	Phaseoloides
Trifolium	Alexandrinum, alpestre, ambiguum, angustifolium, arvense, agrocicerum, hybridum, incarnatum, pratense, repens, resupinatum, rueppellianum, semipilosum, subterraneum, vesiculosum
GRASS FORAGES	
Andropogon	Gayanus
Agropyron	Cristatum, desertorum
Agrostis	Stolonifera, tenuis
Alopecurus	Pratensis
Arrhenatherum	Elatius
Dactylis	Glomerata
Festuca	Arundinacea, gigantea, heterophylla, ovina, pratensis, rubra
Lolium	Hybridum, multiflorum, perenne, rigidum, temulentum
Phalaris	Aquatica, arundinacea
Phleum	Pratense
Poa	Alpina, annua, pratensis
Tripsacum	Laxum
OTHER FORAGES	
Atriplex	Halimus, nummularia
Salsola	Vermiculata

Under the Management and Control of the Contracting Parties

The term *the management and control of the Contracting Parties* refers to the biological material in which the genetic resources are inherent and could be understood as all the genetic resources within the country's border. Such an interpretation presupposes that governments will adjust the existing law accordingly. The text elsewhere in the Treaty does not, however, support such an interpretation since it states that the rights of private and other holders of genetic material should be respected. Thus, the term could be interpreted to cover only plant genetic resources on land and in institutions under state possession and that these should be included under the scope of the Multilateral System. The first grouping of biological material can easily be described: that is the plant genetic resources under the management and control of the Contracting Parties. This will typically cover publicly owned and administered gene collections, including for example all public institutions. Whether the genetic resources are under the *management and control of the parties* will probably depend on the rules of each of the institutions. For research institutions there may be little interest in defining research material under development or research material received on specific terms from other breeders or institutions, as being under the management and control of the Governments. The obligation of the parties to include material in the Multilateral System seems in any case to be limited. In many countries only very few collections will automatically be included in the Multilateral System.

Genetic resources in privately owned biological material is, according to national property law, generally not managed and controlled by the public. Most property laws in the Nordic countries cover ownership to the biological material. Therefore, the Multilateral System does not automatically cover biological material under the ownership of for example private persons, enterprises and indigenous people. The principle of common public access to nature in Finland, Norway and Sweden, entails limited legal access to biological material. Whether biological material that is accessible under these common legal principles also must

be seen as to be *under management and control* of the Contracting Party is an open question.

As to promote a development towards a broader scope for the Multilateral System, the IT-PGRFA provides means for the Parties to increase the accessibility to the biological material. This is addressed in IT-PGRFA article 11.2-second sentence, 11.3 (including the follow-up mechanism in article 11.4) and 11.5 for various types of holders of biological material.

IT-PGRFA article 11.2: "invites all other holders of the plant genetic resources for food and agriculture listed in Annex I to include these plant genetic resources for food and agriculture in the Multilateral System". These non-public holders of plant genetic resources can choose to facilitate access to their resources by including them in the System. This refers to private holders of biological material interesting as plant genetic resources, such as plant breeders, private gene banks and private botanical gardens. Thus, member countries can invite these holders of biological material to include it under the Multilateral System.

Countries shall take appropriate measures to "encourage natural and legal persons within their jurisdiction who hold plant genetic resources for food and agriculture listed in Annex I," to join the Multilateral System.[33] The Contracting Parties to the IT-PGRFA have agreed to take appropriate measures to achieve this objective. The wording indicates that this is a vague obligation under international law. What kind of means that the countries must or can use to promote this does not follow from the wording of IT-PGRFA. Article 11.4 provides for a follow-up after two years to assess to what extent the member countries have succeed in including interesting biological material of natural and legal persons under the Multilateral System. This provision puts pressure on these holders by opening up for taking measures against such persons that have not included these PGRFA in the Multilateral System. It seems appropriate that the Parties while implementing the Treaty also should address how such voluntary inclusion could be facilitated; *i.e.* by determining what constitutes "appropriate measures".

33. IT-PGRFA article 11.3 and 11.4.

Public Domain

The scope is also qualified by the next term: *in the public domain*. This term could be interpreted as covering genetic material that is publicly available, *e.g.* in public gene banks or on public land. The term will then have an overlapping meaning of the previous term *(under management and control)*. Such an interpretation of the term *in the public domain* will, however, make the use of the term redundant, since the Treaty specifies that the material covered should be both *under the management and control of governments* as well as *in the public domain*. Another way to understand the term *in the public domain* is that genetic resources in the public domain refers to resources that are not protected by intellectual property rights. Such an understanding will exclude plant genetic resources covered by private intellectual property rights, such as patents, from automatically being covered by the scope of the Multilateral System. The choice of interpretation here will not only have an effect on the coverage of the Multilateral System but also on the need for and how access to the genetic resources should be regulated in national legislation.

The term *public domain* may also be interpreted as referring to the particular legal status of genetic resources. Most property laws in the Nordic countries cover ownership to the biological material, but do not specify the right to the genes specifically. It is clear that the owner of the biological material has the right to dispose over the inherent genes in several manners. It is, however, not necessary that the holder of the genetic resources can exclude others from using the genes, if the other has a legal title to the biological material. So even if the plant material, *e.g.* found within private property is covered by existing property laws, it may be questionable whether the right to the plant material that represents a genetic resource also hold the right to exclude others from exploiting this resource if the plant material is legally acquired. This question has until lately not been actualised in the Nordic countries. However, prospecting for biological material for further development in *e.g.* pharmacy, food and agriculture production has been

carried out in the Nordic countries. Such increased activity indicates that there exists a need for clarification of the ownership to genetic resources and that such an issue could be addressed in connection to the implementation of the IT-PGRFA (This issue is further dealt with in Chapter 4.3.2).

In legal systems influenced by Code Civil, *e.g.* Latin American countries, genetic resources are often considered *dominio publico*, which can mean the property of the nation – administered by the government.[34]

To clarify whether plant genetic resources are in the public domain is left to the discretion of the Parties. This report outlines scenarios and their consequences by declaring genetic resources in public domain for each group in Chapter 4. To declare that the genetic resources are in the public domain will not alter the possibility to apply for and be issued intellectual property rights.

Since the term *under the management and control of the Contracting Parties and in the public domain* must be understood as a whole, to be covered by the Multilateral System the physical material must be publicly available and its inherent genetic resources must not be subject to private exclusive rights.

The Terms for Being Granted Access

The objective of the facilitated access under the Multilateral System is to ensure uses of plant genetic resources for particular purposes, namely: *"solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture"*.[35] The Multilateral System does not apply when the purpose of the access includes *"chemical, pharmaceutical and/or other non food/feed industrial uses"*. Two issues arise: When imposing two legal categories like those, there will typically be a grey-zone – in this case *"multi-*

34. See Perez 1997 pp. 219–232 and for example The Costa Rican Biodiversity Act article 6, which reads: *"Dominio Público*. All biochemicals and genetic properties found in the biodiversity, both the wild grown and domesticated species are *dominio público*." (translated from Spanish).

35. IT-PGRFA article 12.3.a.

ple-use crops" – and the question of how to deal with these crops. By its terms these categories seem to be clear, but they imply a challenge to the legal system when it comes to enforcing compliance: How will the authority of the System know for which purpose the genetic resources are being used? According to article 12.3, in the case of multiple-use, their importance for food security should be the determinant for their inclusion in the Multilateral System.

The terms for facilitated access are partly determined by the wording of the Treaty:[36]

- Access under the Multilateral System only applies to plant genetic resources for the purpose of utilization and conservation for research, breeding and training for food and agriculture.
- Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved.
- The recipient shall not "claim any intellectual property or other rights that limit the facilitate access to the PGRFA … or their genetic parts or components, in the form received from the Multilateral System".
- The recipient shall keep the material under the Multilateral System.
- There shall be sharing of benefits resulting from the use of the material according to article 13.

For the purpose of facilitating access according to these provisions, the Governing Body of the Treaty shall adopt a standard *Material Transfer Agreement* (MTA) containing more detailed provisions. The MTA shall be linked to the material received also for subsequent transfers.

36. IT-PGRFA article 12.3.a, b, d and g and article 13.2.d (ii).

The IT-PGRFA recognises, and addresses the issue of interaction between access to genetic resources and applying intellectual property rights to them. According to IT-PGRFA article 12.3.d, the receiver of the genetic resources undertakes an obligation, according to the *Material Transfer Agreement*, not to apply for, or register, any intellectual property rights on the *parts and components* of material in the form it was received in a manner that limits future access to that material.[37]

The provision does not prevent the receiver from applying for a patent to an invention containing the received material provided that the patent criteria are met. To what extent this material can be protected by a patent is depending upon the patent law of each country, on the patentability under European Patent Convention (EPC) and other relevant international agreements.

The text is, however, not totally clear on how *in the form received* should be interpreted and raises some very complicated legal and biological issues. As this article is based on a compromise the different parties will also probably interpret it differently. The European Union expressed its view by making a formal declaration when the Treaty was adopted. In its declaration the EU concluded that the European Community and its member states interpret the text to say that plant genetic resources for food and agriculture or genetic parts and components thereof, that have been subject to innovation, may be object of intellectual property rights, provided that the criteria for such rights are met. The article states, however, that the obligation of not claiming rights is an obligation on the recipients who, when receiving material from the Multilateral System, and would not in any case oblige the Contracting Parties to adjust their patent laws. When the text is unclear the wording normally is to be viewed in the context of the objectives of the Treaty: To ensure facilitated access to the material covered by the Multilateral System in a way that encourage both providers and users of the PGRFA to exchange material within this system.

37. IT-PGRFA article 12.3.d.

Fair and Equitable Sharing of Benefits

The Parties to IT-PGRFA recognize that facilitated access to plant genetic resources constitutes itself a major benefit, and that the accruing benefits shall be shared fairly and equitably.[38] According to article 13.2.d (ii):

> The Contracting Parties agree that benefits arising from the use, including commercial, of plant genetic resources for food and agriculture under the Multilateral System shall be shared fairly and equitably through the following mechanisms: the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialisation.

Article 13.2 (d) specifies the terms for the benefit sharing:

> a recipient who commercialises a product which is a plant genetic resources for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay an equitable share of the benefits arising from the commercialisation of that product, except whenever such a product is available for others for further research and breeding, in which case the recipient should be encouraged to make such payment.

The distribution of benefits shall be conducted through a Trust Account to be managed under the agreement and not to the country providing the genetic resources.[39] The obligation of payment to the Trust Account does not apply when the genetic resource is kept available to others for research or breeding. The Parties to the IT-PGRFA shall, however, encourage distribution of benefits in all cases. According to the plant breeders' rights the owner of the variety cannot prevent further use of the protected variety for breeding. Since this is the dominating way of protection of plant varieties in the Nordic countries, this obligation of payment will have limited significance to Nordic plant breeders.

38. IT-PGRFA article 13.1.

39. IT-PGRFA article 19.3(f) provides for establishing a Trust Account according to the agreement.

Development of the Concept Farmers' Rights in International Law
The current legal situation under international law establishes, on the one hand, specific rights for the patentee and the plant breeder. On the other hand, the rights of a farmer as the user of plant varieties are not as precisely developed under international law. Article 9 of the IT-PGRFA recognises *Farmers' Rights*. According to Article 9, paragraph3, *"nothing in this Article shall be interpreted to limit any rights that farmers have to save, use and sell farm-saved seed/propagating material"*. This formulation presupposes and therefore refers to any already existing right to save, use and sell farm-saved seed/propagating material.

2.1.4 The Agreement on Trade-Related Intellectual Property Rights

The Agreement on Trade-Related Intellectual Property Rights (TRIPS) under the World Trade Organisation (WTO) is a comprehensive agreement in international law, since it covers a variety of intellectual property rights. It can be described as a minimum convention, since its obligations are prescribing the level of intellectual property protection that the members at least must comply with. It is not formulated as an attempt to harmonise patent laws in the member states. It requires that all its members shall make patents available for inventions in any fields of technology.[40] All the Nordic countries are members to the WTO, and bound by the TRIPS-agreement. Since patents shall be made available for all inventions, the point of departure is that patents also shall be made available for living organisms, cells and genes. From this general point of departure TRIPS article 27.3 (b) makes certain exemptions:

> Members may also exclude from patentability: … (b) 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 …

40. TRIPS-agreement article 27.1.

According to the term *may*, it is optional for the member countries to exclude certain objects from patentability. TRIPS article 27.3 (b) opens up for excluding *plants and animals* that are not micro-organisms, from the scope of patentability. The members to the WTO shall, however, provide protection of *plant varieties*. For *plant varieties*, the article names three alternative manners for protection: *patents* or *effective sui generis system* or *by any combination thereof*. The concept *"effective sui generis system"* is not authoritatively defined by the TRIPS-agreement, and the member countries have according to the wording in the article a certain freedom when implementing it. The 1991 UPOV-convention has been suggested as to be the *effective sui generis system*. The wording of the TRIPS-agreement does, however, not refer to the UPOV-agreements. Thus, this form of protection is clearly not the only manner to fulfil this obligation. The fact that far from all the members to the WTO are signatories to the UPOV supports this interpretation.

The exemption in TRIPS article 27.3 (b) does no specify whether it opens up for members to exclude genes or cells, from the scope of patentability. Since the point of departure is that patents shall be made available, TRIPS can probably not be interpreted as opening up for such an exemption. For the Nordic countries this discussion can be said to be rather theoretical since the EU Directive 98/44 provides for patent protection of genes and cells where they are coded and the organisms. Compared to the CBD and the IT-PGRFA, the TRIPS agreement uses the terms *"plants and animals"* and *"plant varieties"* rather than *genetic resources*. The scope of patent protection is thereby different than of the CBD and the IT-PGRFA.

According to TRIPS patents shall be made available on micro-organisms. *Micro-organisms* is not defined as a legal term under the TRIPS-agreement.

"Essentially biological processes for the production of plants or animals" can also be exempted from the scope of patentability under the TRIPS-agreement. However, *"non-biological and microbiological processes"* shall be eligible for patent. This provision raises a question of interpretation what is required for a process for production of plants and animals to be *essentially biological*.

There is also an exemption of a more general character. Inventions that are contrary to the *ordre public* of the country can also be rejected from being granted a patent. It must be determined individually for each application whether the invention is contrary to the *ordre public* of the country. According to the wording, it is not sufficient to reject a patent *merely because law prohibits the exploitation*.

The TRIPS-agreement articles 30 and 31 (a) to (l) impose several requirements upon the domestic procedure for exemptions from conferred rights. These refer to the position of the holder of the patent. TRIPS-agreement article 34 requires that the legal order of the member countries in certain cases refer the burden of proof upon the person accused of infringement to prove that he did not use the patented process.

Since there are differences between the members of the WTO, and because the Least Developed Counties have had problems with implementing the obligations according to international agreements, the TRIPS-council has decided that they shall be granted a grace period in their implementation of these obligations.

According to the wording of the TRIPS-agreement disclosure of origin of the genetic material is not imposed as a condition for granting patent protection. Also, there is no requirement that the patent applicant document that the genetic resources have been obtained legally according to the legislation of the source country. In the international debate this has been considered as an obstacle for the efficient implementation of access legislation according to the CBD or the limitation in patentability for IT-PGRFA Annex I species.

2.1.5 International Union for the Protection of New Varieties of Plants

Two conventions under the International Union for the Protection of New Varieties of Plants (UPOV) are relevant for the discussion of individualised rights to *plant varieties*: the 1978 and 1991 UPOV-conventions. Denmark, Finland and Sweden are members

to UPOV 1991, Iceland is not member at all and Norway has ratified UPOV 1978. The scope of the UPOV is the protection of new *varieties of plants*; hence animal varieties are not covered. Since also the TRIPS-agreement provides for patent protection of plant varieties, as one of three alternative protections, there might be overlap between the intellectual property protections provided.

In biology, organisms are classified in *divisio, classis, ordo, familia, genus, species*. The species is the core of the classification. The species is referred to either by the name of the species or to its common name, for instance as *wheat* or *rose*. These categories are, however, not used as legal terms in the UPOV-conventions. Their scope is to provide for rights to a *plant variety*. For a breeder and farmer it is of interest to categorise the specimens with similar properties within one species as a variety. In UPOV 1991, plant *variety* is defined as:

> Plant grouping within a single botanical taxon of lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeders' right are fully met, can be
> - defined by the expression of the characteristics resulting from a given genotype or combination of genotypes
> - distinguished from any other plant grouping by the expression of at least one of the said characteristics and
> - considered as a unit with regard to its suitability for being propagated unchanged.[41]

The scope of the protection in UPOV is the *variety*, not the genetic structure *per se* or single genes. However, the plant variety is defined by the expression of the genetic structure or a set of genes. Thereby, the use of terms in the UPOV-convention is similar to that of the TRIPS-agreement, although not focusing on single genes and cells. Compared to the CBD and the IT-PGRFA, the UPOVconvention does not provide for protection of *genetic resources*, genes or cells. A plant variety will typically have a bulk share of common genetic material.

The use of the term *genotype* in the definition of *plant varieties* is fairly new. Traditionally, plant breeders have turned their atten-

41. UPOV-91 article 1 (vi).

tion towards the *phenotype* expression of the *variety. Genotype* and *phenotype* can be explained as:

> Because of dominance and recessiveness, an organism's appearance does not always reveal its genetic composition. Therefore, we have to distinguish between an organism's appearance, called its phenotype, and its genetic makeup, its genotype.[42]

Due to the technology used in plant breeding, the plant variety's appearance and active characteristics have been important to obtain plant variety protection. The definition of *plant variety,* above, indicates a new approach to the question of what a *plant variety* is. Now, it is emphasised that the relevant expression of the *variety* is its genetic composition rather than its active properties.

The terms for plant variety protection, according to article 6 of the 1978-Convention and article 5 in the 1991-Convention are:

- The plant variety must be found new or novel. This implies that it cannot be offered for sale or have been in commercial sale under specified periods of time before the application. Non-commercialised varieties developed a long time ago and presently in use can be regarded as novel, and therefore be the object of a plant breeders' right.
- The variety must be distinct or clearly distinguishable from the other varieties known at the time of application.
- It must be *uniform*.
- It must be *stable*, meaning that it must have the capacity of reproducing the properties in generations, while *its relevant characteristics* remains *unchanged*.

The practice of how the requirements are interpreted and determined are likely to develop differently in the member countries of the conventions. UPOV-91 article 5(2) also expresses that the granting of breeders' rights *shall not be subject to any further or different conditions*. Hence the obligation under UPOV-91 is to harmonise the regulations rather than provide for a minimum level of protection.

42. Campell, Reede and Mitchell 1999, page 243.

The scope of the breeders' rights according to the UPOV-91 is listed in article 14, whereas the exemptions from the scope of the protection are listed in article 15. According to article 14 (1), the following acts in respect of the propagating material shall require the authorisation of the breeder: *"production and reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, stocking for any purposes mentioned in (i) to (vi) above."* These acts refer to the propagating material *per se*. According to article 14 (4), the parties to the convention may provide that *"acts other than those referred to in items (i) to (vii) … shall also require the authorization of the breeder"*. Hence, whereas the parties cannot impose additional terms for the protection, they have the right under UPOV-91 to implement a scope of protection, for the benefit of the breeder, that is more comprehensive than the level prescribed. At this point the UPOV-91 is a minimum convention rather than a convention of harmonisation. According to article 14 (5), the protection also covers *essentially derived and certain other varieties*. These regulations are rather complicated and cannot be dealt with within the scope of this report.

Article 14 (2) broadens the scope of the positive rights of the breeder also to cover *"harvested material, including entire plants and parts of plants, obtained through unauthorized use of propagating material"* unless the breeder has had the possibility to exercise his rights to the propagating material. Hence, the right of the breeder to the harvested material only applies when his rights according to article 14 (1) is infringed. Also in the case when propagating material is used in an unauthorized manner, the right of the breeder can cover "products made directly from the harvested material of the protected variety".[43]

The scope of the breeders' rights is also determined by specifying certain exemptions. UPOV-91 comprises both compulsory exceptions and optional exceptions. The compulsory exceptions are:

43. UPOV-91 article 14 (3).

That the breeders' right shall not extend to
- acts done privately and for non-commercial purposes,
- acts done for experimental purposes and
- acts done for the purpose of breeding other varieties, and, except where … other provisions of art. 14 apply.[44]

The optional exemption is that the parties may "within reasonable limits and subject to the safeguard of the legitimate interests of the breeder, restrict the breeders' rights in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety …".[45] The core of this provision is that parties may grant the farmers the right to use their harvest as the seeds for the next harvest. This provision is interesting in an historical context: Seed-saving, the very basic technique for agriculture where farmers save the best part of the harvest for the next year, has been conducted throughout time; has in the UPOV-91 become an optional exemption. The provision also raises another issue: Does the use of the term on their own holdings delimit the scope of the optional exemption in relation to farmers who do not *own* their land. For several developing countries as well as for many developed countries this could pose a problem since there are a lot of farmers who do not own the land they cultivate.

UPOV-91 article 17 (1) reads: "Except where expressly provided in this Convention, no Contracting Party may restrict the free exercise of a breeders' rights for reasons other than of public interest".

The time period for protection shall be not shorter than 20 years and at least 25 years for trees and vines.[46] Also at this point the UPOV-91 is a minimum condition convention.

The Office of the Union has compared the acts that constitutes infringements of the intellectual property rights according to TRIPS-agreement article 28 and UPOV article 14:[47]

44. UPOV-91article 15 (1).
45. UPOV-91 article 15 (2).
46. UPOV-91 article 19.
47. UPOV, Administrative and Legal Committee, *Specific issues concerning the interface between patents and plant breeders' rights*, CAJ/45/3.

TRIPS article 28	**UPOV-91 article 14**	**UPOV-78 article 5**[48]
1. A patent shall confer in its owner the following exclusive rights:	1. [Acts in respect of the propagating material]	1. The effect of the right granted to the breeder
a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of:	a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:	is that his prior author isation shall be required for:
Making, using,	i) production or repro duction (multiplication) ii) conditioning for the purpose of propagation,	•the production for purposes of commercial marketing
Offering for sale,	iii) offering for sale,	•the offering for sale
Selling, or	iv) selling or other marketing,	•the marketing
importing	v) exporting, vi) importing,	
For these purposes that product;	vii) stocking for any of the purposes mentioned in (i) to (vi) above.	
		…of the reproductive or vegetative propagating material, as such, of the variety.

From this table we see that the scope of protection provided by the UPOV-91 and the TRIPS-agreement article 28 is not very different. The UPOV-91 provides for stronger plant breeders' rights than those provided by the UPOV-78.

2.1.6 The World Intellectual Property Organisation

The World Intellectual Property Right Organisation (WIPO) under the United Nations is the secretariat for several conventions, among them the UPOV-conventions. WIPO has addressed intellectual property rights in the context of genetic resources and tradi-

48. The comparison with UPOV-78 is made for this report.

tional knowledge. This has resulted in the establishment of the *WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*. The Committee had its first two meetings in 2001, and addressed the relationship between the CBD and the intellectual property regimes, as TRIPS and UPOV, as well as regional obligations. One of the objectives of the Intergovernmental Committee is to discuss intellectual property protection for traditional knowledge. The ongoing discussions are at an early stage, and at the fourth meeting in December 2002, several countries deemed it too early, some characterised it as *premature*, to outline such an intellectual property protection.

In WIPO there are also other ongoing negotiations on how to harmonise the terms for being granted patents. These negotiations have as its objective to as further harmonise patent law internationally.

2.2 The European Level

2.2.1 The European Union

Background

The background of the EU Directive 98/44 on Biotechnological Patents (later referred to as the Directive or the Patent Directive) is the growing importance of biotechnology for the development of the industry and the need to eliminate differences in the legislation of the member states, which might be an obstacle to trade and the function of the inner market. The Directive also aims at bringing the scope of patentability under the European laws in harmony with the patentability regimes in Japan and the USA. Harmonisation of the patent laws of the European countries is intended to create a predictable, uniform and stable legal situation regarding the patentability of biotechnological inventions. The Directive aims at promoting investments in biotechnological activities. It implies an obligation upon the member countries to the European Union to bring the subject matter for patentability and

the practice for the patent terms in harmony. This Directive is also relevant legislation for the European Economic Area agreement and will therefore be legally binding for all the Nordic countries.[49] It was adopted 6 July 1998.

The Directive has been controversial in the EU. The Netherlands, supported by Italy and Norway, claimed that the Directive should be declared invalid, that it was not in consistency with the principle of subsidiarity and that the right to patents in the field of biotechnology should be restricted to methods and not include products. The issue was brought before the Court of the European Union, which rejected the claims.[50]

Patentability

The point of departure is that biotechnological inventions shall be eligible for patents on the same conditions as inventions in other technological fields. The Directive, however, specifies certain exemptions from the scope of patentability. These exemptions are partly done due to ethical reasons.

The Directive requires that animals and plants, however, not plant varieties and animal varieties, shall be subject matter to patents. This exemption has been made to prevent such inventions from being protected both by the plant breeder protection and by patents. To determine the scope of patentability it is a need for clarifying the distinction between *plants* and *plant variety* as well as between *animal* and *animal varieties*, as legal or juridical concepts. The term *plant variety* is defined in article 2 by a reference to the definition in the Regulation (EC) No. 2100/94 article 5, whereas *plant variety* is defined as in the UPOV-conventions. The term *plant* can be conceived as "a single specimen" or as one plant. Such understanding of the term does, however, not make good sense. A holder of a patent will typically not be interested in patent to one spec-

49. For Norway, this depends on whether the *Storting* will accept this as an obligation under international law. For Iceland this depends on whether Althingi, the Parliament of Iceland will accept this as a part of Icelandic legislation. Both Iceland and Norway are now preparing appropriate amendments of the legislation.

50. Case C-377/98R.

imen, but to a line or variation of specimen. The term *plant* cannot be conceived as that a *species* is eligible for patent, since a patent right to a *species* would imply an indeed a broad patent. The preamble paragraph 32 addresses this by stating that if the invention is one genetic change in one plant variety, and the result is a new variety, the new variety will be excluded from the scope of patentability regardless of whether the new variety is the result of biotechnological techniques or biological processes.

The Directive provides for registering patents to naturally occurring genes by isolating and describing them. According to the preamble, a simple sequence of DNA, without a technological description, cannot be characterised as a eligible for patent invention and can therefore not be patented.

Patent shall not be granted for "essentially biological processes for the production of plants or animals". This opens up an issue of interpretation: When is a *process essentially biological*? This is defined in article 2 paragraph 2, as "a process for the production of plants or animals is essential biological if it consists entirely of natural phenomena such as crossing or selection".

Inventions *"where their commercial exploitation would be contrary to ordre public"* are also exempted from the scope of patent protection.[51] In this context, processes that will alter the genome of an animal, and which are likely to cause suffering for the animal shall only be eligible for patent when such is reasoned in "substantial medical benefit to man or animal".[52]

Patent Terms

The preamble emphasises that when granting a patent to biotechnological inventions the same criteria as applied in other areas shall be used.[53] Several of the paragraphs in the preamble address patent practice on the patent conditions. The Directive aims at clarifying the distinction between invention and discovery in the field of biotechnology.

51. EU Patent Directive article 6.
52. EU Patent Directive article 6.
53. EU Patent Directive preamble paragraph 22.

The preamble prescribes for a disclosure of the geographic origin, where it is known, of the biological material used in the invention. The lack of such disclosure shall, however, not be used as a ground for rejecting a patent claim or as a reason to counter the validity of the patent. In the international debate this has been regarded as an important measure to ensure that companies are working in consistency with the legislation of the country providing genetic resources. NGOs have argued that this should rather be a condition for patents than optional.

The Scope of the Patent Protection

In order to determine the object of protection for a granted patent two sources are of particular interest: The scope of patent legislation, as for example the EU Patent Directive; and the individual patent claims. The patent claim is the description of the invention given by the applicant at the application time. To determine the extent of what the patent protects, the point of departure is an interpretation of the patent claims.

The Patent Directive Chapter II regulates the scope of protection of the patent. According to the Patent Directive the patent covers all propagation or multiplication of the patented material, as long as the biological material has the same properties as described in the patent claims.[54] This right applies unconditional of the form in which the reproduction has taken place. This implies that also the next generation of individuals, and every descendent reproduced from the patented plant or animal is covered by the protected right of the patent. Preparing the case before the Court the EU General Attorney gave the following consideration:

> 121. A patent for a product normally gives the holder the exclusive right to manufacture that product (subject to compliance with applicable laws and regulations). In the case of patented material that is capable of reproducing itself, the value of the patent would clearly be eroded if it did not extent to future generation of such material. For example, if the

54. EU Patent Directive article 8 and 9.

> purchaser of patented seeds were able to use the seeds produced by the crop grown from the purchased seeds, the value of that patent would be much reduced. …[55]

This implies an extensive right for the patent holder. The Patent Directive, however, provides for the possibility of compulsory cross-licensing.

2.2.2 The European Patent Organisation

Whereas all the above mentioned international agreements imply obligations of implementation in the various domestic legislations,[56] the European Patent Organisation provides for patent protection in its member states autonomously, in addition to the domestic patent legislation. The European Patent Convention (EPC) regulates the scope of patentability, the conditions for granting a patent and the scope of the protected invention. This short introduction to the European Patent Convention and its practice, is based upon an EPO-paper.[57] The point of departure according to EPC article 23c that:

> Biotechnological inventions shall also be patentable if they concern: (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.

From this point of departure EPC article 53 makes the following exemptions:

a) inventions the publication or exploitation of which would be contrary to ordre public or morality, provides that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
b) plant or animal varieties or essential biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

55. Opinion of the General Attorney in case C-377/98R, paragraph 121.

56. Paterson 1992, page 7.

57. Galligani 2000.

Hence, the exemptions according to the EU Directive are identical to those of the EPC. These terms are interpreted in practice under the EPO.[58]

2.3 The Patent System in Short

2.3.1 An Overview of the Patent System

The essence of a patent is that it grants an exclusive right to prohibit others from using an *invention* for commercial purposes. The invention must fulfil the following criteria: it must be new (or novel) compared with what was previously known (prior art), it must involve an inventive step (am: non-obvious) and must be capable of industrial application.

The objective of the patent system is to promote inventive contribution and disclosure of inventions. To achieve these goals, the inventor is given an advantage in form of an exclusive right to commercially exploit the invention for a limited period of time.

By definition patents and plant breeders' rights follow a principle of territoriality: the granted right is valid for the countries or areas where granted. The point of departure is that each country issues exclusive intellectual property rights for the use of the invention within their territory. In this regard the European Patent Organisation makes an exemption: Under this legal regime it is possible to apply for a patent in all or in a selection of its member countries. The EPO is based on the principle of territoriality, the territory is, however, several countries. The EPO grants patents with direct effect for the countries chosen. In this respect EPO has character of being a supra-national organisation. On the other hand, EPO has features that emphasises that the organisation in other respects is not supra-national. Civil actions concerning alleged void patents and infringement have to be dealt with by

58. Galligani 2000 gives a brief overview of this practice.

national courts. Furthermore, judgements on void patents are only valid in the country where the judgement is pronounced.

The patent system can be explained by the legal acts or actions:

1.

A first issue is whether the said invention is *subject matter* to patentability; is it at all possible to apply for a patent for such inventions. The TRIPS-agreement article 27.1 obliges the member countries to grant patents to:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[59]

Article 27.3 specifies this general obligation by recognising that the member countries may exempt certain inventions from the scope of patentability. In this respect the TRIPS-agreement is a minimum obligation, since it leaves discretion to the parties whether to adapt these exemptions from the scope of patentability. Thus the member countries may choose to grant patents to all inventions. The EU-Directive on the other hand obliges the member countries to standardise the patentable subject matter. The practices from the EPO investigators and from the boards of appeal have specified this scope of protection under this legal regime. (Since the EPO grants patents with a direct effect for its member countries, this practice is of importance for the patentability in all the member countries.)

2.

The second consideration is whether the patent terms describe an *invention*. This is a basic requirement for being granted patent pro-

59. The TRIPS-agreement article 27.1 specify in a footnote that: *"For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively."*

tection.[60] The content of the term is not clearly identified in relevant national or international legislation. *Invention* can be described by three sub-terms: *Technical character, technical effect* and *reproduction.*[61] An invention can thus be defined as a practical solution to a problem, where the solution has technical character, technical effect and is reproducible.

Technical character is described as when the product or the process makes use of the material and/or energy in nature in order to solve the problem at hand. Patent legislation often negatively defines the term *technical character* by formulating some aspects that are not conceived as an *invention.*[62]

Technical effect implies that the product or process has to function. Consequently, patents claims with no known application can, as a point of departure, not be granted.[63] It has, however, been argued that it is sufficient that the product or process in a candidate for research and development. The question of *technical effect* is often debated in relation to the field of biotechnology.

The term *reproducible* implies that a generally skilled professional on the relevant field can be able to produce the product or bring the process to effect. This can be derived from the demands to the description that has to be attached to the patent claims.[64] It is not demanded that the professional actually has to reproduce the claimed invention; only that it is possible to reproduce it.

3.

A third legal action is the investigation of whether the invention fulfils the patent three terms:

a) Novelty.
b) Involve an inventive step or not be obviousness to a person skilled in the technology.
c) Capable of technical application.

60. See for example Article 52 (1) EPC.
61. See for example Bently and Sherman, page 371.
62. See for example Article 52 (2) EPC.
63. See for example Article 5 (3) 98/44/EC and the preamble point 22–24 in the same document.
64. See for example Article 83 EPC, cf. EPC Guidelines C-II, 4.9.

A main principle of these considerations is that the applied patent must not already be in the public domain – it must add something new to the *prior art*. To fulfil this objective or terms the patent examiner must have a sufficient overview over the existing *prior art*. Since it is close to impossible to have a complete overview over the worldwide *prior art*, the search is standardised. An argument often put forward in the international debate is that the procedures for investigation has not been able to prevent genes and related knowledge in the *prior art* from being patented. (There are no legally binding definitions regarding practice for the patent terms, or of the *prior art* in international law. Thus this will be determined by the patent office in each country. However, in the WIPO there are negotiations for a Treaty going on that has as objective to standardise these considerations. From the European point of view, the EPO examines and grants patents, and thus develops practice for these considerations.)

4.

A subsequent question is what the granted patent gives an exclusive right to. This is determined by three legal sources: the granted patent claim, the principle of equivalence and the patent legislation. At this point the TRIPS-agreement article 28 imposes minimum requirements to the domestic legislation on what a patent right ought to cover. This is described in the table above. To determine the scope of protection is crucial when considering another product is infringing the grated patent. It is important for other inventors, companies and breeders to know what is patented to predict their freedom to operate, without infringing a patent or licensing the patented invention from the patent holder. It either the patent claims themselves or by an interpretation by equivalence are interpreted in a broad manner, the patent can become to cover more than the "new" and "innovative step" that it is meant.

2.3.2 The Relationship to the IT-PGRFA

The obligation under the IT-PGRFA article 12.3 (d) is as follows:

> Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic part or components, in the form received from the Multilateral System;

This can be seen considered in at least four manners:

1. As an contractual obligation upon the receiver of the genetic material not to claim such intellectual property rights.
2. As an obligation related to the scope of the patentability: That the said material shall not be subject to patent protection in the form received.
3. As an imperative to the practice of the patent terms. That the material in the form received from the Multilateral System does not fulfil the terms for a patentable invention.
4. As a principle to the interpretation of the scope of the patent protection: a granted patent shall not be interpreted as to cover or restrict the use of the genetic resources under the Multilateral System.

These alternatives are not mutually exclusive. Thus the relationship between the IT-PGRFA and the intellectual property regimes can be described as to follow all these four interpretations. The European Community and its member states have at the time when the Treaty was adopted made the statement that plant genetic resources for food and agriculture or genetic components thereof, which have been subject to innovation, may be object to intellectual property rights, provided that the criteria for such rights are met.

2.3.3 The Relationship to the CBD

The relationship between the CBD and the patent regimes is a very debated issue internationally. Lately the Conference of the Parties of the CBD referred the issue to the Intergovernmental Committee (IGC) of the WIPO, for their view upon this issue. A preliminary study has been conducted and was presented at the fourth meeting of the IGC in December 2002.[65]

65. WIPO/GRTKF/IC/4/11.

3 Initiatives on Access to Genetic Resources in the Nordic Countries

3.1 Nordic Gene Bank

The present legal regulation of the Nordic Gene Bank is that the legal status of the genetic resources in its possession is uncertain. There does not exist any written agreement specifying the terms for the establishing of the NGB. The authority of the NGB is its Board, where the Nordic countries are represented. According to the statutes the NGB is a common Nordic institution, with the objective and purpose to conserve and to document the variations of the Nordic plant genetic resources for species of value for agriculture and horticulture. The collections of the NGB shall be made available for plant breeding – both for research and for development and other *bona fide* uses. A guiding principle for the management of the Nordic Gene Bank has been to promote the free and open access to and transfer of plant genetic resources. There is, however, an urgent need to clarify the legal status of the material. When access is provided the user of the genetic resources and Nordic Gene Bank conclude a Material Transfer Agreement (later referred to as a MTA). The MTA is standardised *inter alia* with the aim of facilitating access to the genetic resources of the NGB. By signing the MTA, the recipient of the genetic resources undertakes only to use the material for plant breeding, research and educational purposes. From a legal point of view, the MTA must be seen as a private law agreement, between the Nordic Gene Bank and

the user. There is an ongoing review of the MTA. The current MTA is enclosed as appendix II to the Report.

Approximately 90% of the material is included under the Multilateral System according to Annex I of the IT-PGRFA. Passport data including country of origin, donor country and donor institute is available for the greater part of the accessions in the ordinary collection. Approximately 20% of the accessions have no donor country information and 10% no information on country of origin. All material in the special collection has information about donor country, however, the information about country of origin varies. An estimate is that 90% of the samples in the Nordic Gene Bank is from the time before the CBD and therefore not regulated by for the access legislation of article 15.

3.2 Denmark

Denmark, at the time of the ratification of the CBD, determined that access to genetic resources should not require a prior informed consent. Denmark has not yet decided upon whether to regulate access to genetic resources in the longer term. Greenland is in the process of developing legislation on access to genetic resources. There exist several acts on rights to, use of and access to biological material that might have implications for access to genetic resources.

Denmark has been focusing on the interrelation between regulation of access to genetic resources and intellectual property rights applied to genes and living organisms emphasising, however, that these are two separate issues. Denmark has emphasised that one practical manner to ensure that intellectual property right laws do not undermine access legislation is to require disclosure of the origin of genetic resources in the application for the intellectual property right. With reference to recital 27 of the EC Directive 98/44, Denmark has inserted the following provision in a regulation (in Danish language: bekendtgørelse):

> 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. If the applicant does not know the geographical origin of the material, this shall be indicated in the application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent.[66]

Breach of this provision could imply violation in the Danish Penal Code to provide correct information to a public authority, but will not have any consequences for the validity of the patent.

3.3 Finland

In Finland there is no regulation of access to genetic resources. Finland ratified the CBD 25 October 1994. In 2003, an advisory board on genetic resources will be established. Among the most important issues to be discussed and further elaborated by this board will be the implementation of international agreements regarding genetic resources, in particular the CBD and the IT-PGRFA. Finland implemented the Patent Directive in national legislation in June 2000.

3.4 Iceland

Iceland has ratified the CBD, is a member to WTO (and is thereby bound by the TRIPS-agreement) and WIPO and has the intention to ratify the IT-PGRFA. The conventions are not implemented in national legislation. There are no particular acts in Iceland regulating access to, rights to or ownership to genetic resources. There is no general requirement for seeking permission to have access

66. Bekendtgørelse om ændring af bekendtgørelse om patenter og supplerende beskyttelsescertificater BEK number 1086 af 11/12/2000.

to genetic resources. It is not clear from Icelandic legislation which ministry should handle these issues. Various acts addresses issues related to genetic resources:

- Act number 58/2000 regulates the protection of new plant varieties. The act fulfils the requirements of the UPOV-conventions even though Iceland has not ratified the conventions.
- Act number 70/1998 on Agriculture has as its main objective to protect genetic resources in Icelandic agriculture.
- Act number 57/1998 about research and use of resources in the soil paragraph 34 requires a permission from the Ministry of Industry before research or use of micro-organisms (in Icelandic: mikroørverur) in geothermal areas can be conducted. According to paragraph 36 of the Act, paragraph 34 should be reviewed before 1 January 2001. The draft act on biotechnology was presented for Althingi, the Parliament of Iceland, in the period 2001–2002, but was not adopted.
- According to act number 17/1991 about intellectual property rights can a patent be issued for substances and compositions of substances and the act does not prohibit that a patent can be issued for inventions as a result of biotechnology. According to this act plant and animal varieties and procedures for production of plants or animals that mainly are biological are not subject matter to patents. Methods and procedures in microbiology and products of such methods are subject matters to patents according to the act. The EU directive number 98/44 has not yet been implemented.

3.5 Norway

The issue of access or rights to genetic resources is not regulated comprehensively in Norwegian legislation at the present. There exist several acts on rights to, use of and access to biological material that might have implications for access to genetic resources. There have been several cases of search for genetic resources in

the exclusive economic cone: the area beyond and adjacent to the territorial sea. In these cases the Act on the Exclusive Economic Zone (Act of 17 December, no. 90 1976) has been used as a legal framework.

The public committee on biological diversity the *"Biomangfold-lovutvalget"* began its work in October 2001, and is expected to give its recommendations during the fall of 2003. One of its core projects is to develop and suggest regulation of access to genetic resources found within the territory of Norway; and guidelines for the use of genetic resources from other countries when used in Norway. The Committee will probably also address the relationship between access to and rights over genetic resources in the context of patents to living organisms and plant variety protection.

Norway is Party to the UPOV Convention (1978), which is implemented in the Plant Variety Act (Act of 12 March, 1993 no. 32).

Norway is member to the WTO and is therefore bound by the TRIPS-agreement. So far the EU Directive 98/44 has not been implemented in the Patent Act. Patent practice indicates that patents are granted to both modified and naturally occurring genes of plants, animals and micro-organisms. A governmental working-group has discussed several aspects on the implementation of EU Directive 98/44. Among the subject discussed is how to implement the Directive ensuring compliance with access legislation of other countries.

3.6 Sweden

Sweden is Party to the Convention on Biological Diversity but has so far not taken any initiatives to regulate the access to genetic resources. The Swedish position is that plant and other genetic resources should be available with a minimum of bureaucracy and restrictions. Sweden is currently (February 2003) on its way to implement Directive 98/44/EG on legal protection of biotech inventions. Sweden is also member of the UPOV 1991 Convention, the European Patent Convention and WIPO. Sweden holds the

position that intellectual property rights are important incitements for research and development of innovations. Sweden will ratify the International Treaty on Plant Genetic Resources for Food and Agriculture. The Swedish position is that there is no need for new or amended legislation to ratify the Treaty. From the Swedish point of view the ideal situation is that all crops should be included in the Multilateral System for facilitated access and benefit sharing, and there are for the time being no plans to in any way restrict the access to any genetic resources in Sweden.

3.7 Membership to the Relevant Agreements of International Law

	Denmark	**Finland**	**Iceland**	**Norway**	**Sweden**
CBD	21/12/1993	27/7/1994	12/09/1994	9/7/1993	5?/4/1995
IT-PGRFA	6/6/2002 (signature)	6/6/2002 (signature)		12/06/2002 (signature)	6/6/2002 (signature)
UPOV	6/10/1968 (1991 act)	16/4/2002 (1991 act)	Not member	13/09/2002 (1978 act)	17/12/1971 (1991 act)
WTO/TRIPS	1/1/1995	1/1/1995	1/1/1995	1/1/1995	1/1/1995
WIPO	All Nordic countries are members to WIPO				
EU Directive	The directive, to which Iceland and Norway are bound through the EEA-agreement, binds all the Nordic countries.				

4 Management of Genetic Resources in the Nordic Countries

4.1 Methodological Approach to Discuss Policies and Legislation

4.1.1 Overview over Chapter 4

In this chapter different policy options for the management of access and rights to genetic resources will be discussed as a basis for the recommendations. The chapter draws upon the discussions of the relevant international treaties in Chapter 2 and the overview of related Nordic domestic initiatives in Chapter 3. The text is structured in scenarios for different categories of genetic resources. The categories are as follows:

- Plant Genetic Resources in the Nordic Gene Bank (Chapter 4.2).
- Domesticated Plant Genetic Resources in the Nordic Countries (Chapter 4.3).
- Access to Animal Genetic Resources for Food and Agriculture (Chapter 4.4).
- Access to Genetic Resources of Forest Trees (Chapter 4.5).
- Access to Wild Genetic Resources (Chapter 4.6).

The discussion under each of these categories is structured as follows: First, the framework conditions for the management of genetic resources are presented. Secondly, based on these condi-

tions different options to approach the issues are discussed. Finally, conclusions and recommendations are offered.

The discussion of the options comprise the following topics:
1. Description of the specific problems or challenges for the particular category of genetic resources.
2. Identification of typical stakeholders.
3. Relevant international agreements.
4. Relevant domestic legislation.
5. Identification of objectives for the management of the genetic resource.

The Project Group has identified three main topics for consideration:
- Rights to genetic resources as a consequence of property rights to the organism where they are found.
- Access to and exchange of genetic resources.
- Intellectual Property Rights covering living organisms that are related to the transfer of genetic resources.

Chapter 4.7 addresses challenges for the Nordic countries in dealing with access legislation of other countries. Thus it addresses various means to promote compliance with the legislation of other countries.

4.2 Plant Genetic Resources in the Nordic Gene Bank

4.2.1 Framework Conditions

Problems and Challenges

The following discussions are focused on the accessions of germplasm from all kinds of species that are held in the collections of the Nordic Gene Bank (NGB). The material comprises germplasm that is physically stored within the facilities of the NGB (incl. security collections); and accessions held by national clone-archives in

the Nordic countries that are under the administration of the NGB in accordance with special agreements. Plant genetic resources outside the mandate of the NGB, which are conserved domestically either *in-situ* or *ex-situ* are discussed in Chapter 4.3.

All mandate species of the NGB are described in its databases. All available data, information and knowledge related to the characteristics of the germplasm will be of value in utilizing these plant genetic resources. Analytically, it might be possible to distinguish between the genetic resources *per se* and the related knowledge. However, in practice the close relation between the physical material and the knowledge justifies addressing them simultaneously. The IT-PGRFA also implies that related information shall be made available on the same terms as the related germplasm.

The present system for access to and exchange of plant genetic resources of the NGB is functioning well. The need for a revision of the Material Transfer Agreement (MTA) currently in use by the NGB must, however, be addressed due to the international development. For example, the European network for plant genetic resources has started a process to draft a model MTA adapted to European gene banks. Upon the entry into force of the IT-PGRFA a new legal situation will emerge. In particular, the Parties to the Treaty will be developing a standard MTA with terms for access and benefit sharing. One particular challenge is therefore to analyse how a standard MTA can be implemented for the plant genetic resources in the NGB. One issue in this context is to clarify the legal status of the plant genetic resources in the NGB (see Chapter 4.2.2). Since the IT-PGRFA establishes a distinct legal system for a specific list of the most important species for food and agriculture, it is necessary to determine whether access to the genetic resources of all mandate species of the NGB and not only those listed in the IT-PGRFA shall be regulated by the same terms.

Identification of Stakeholders

Apart from the Nordic Governments and the Nordic Gene Bank itself, the following categories of stakeholders can be identified:

- Plant breeders.
- Researchers.
- Other gene banks.
- Farmers.
- Indigenous peoples: the Saamí people and the Inuit people.
- Open air museums, arboreta and botanical gardens.
- Non-governmental organisations.
- Private persons.

All stakeholders might be providers as well as users of the material in the NGB.

Relevant International Agreements

The IT-PGRFA covers plant genetic resources generally, and is thereby the most relevant agreement. It establishes a Multilateral System for facilitated access and benefit sharing for a number of species that are important for food and agriculture, the so-called Annex I-species.[67] In the negotiations the Nordic countries argued, without success, that the Multilateral System should cover all species important for food and agriculture. By ratifying the IT-PGRFA, a country, exercising its sovereign right to determine access to genetic resources in accordance with Article 15 of the CBD, gives its general *prior informed consent* to access to the species listed in Annex I of the IT-PGRFA. The mutually *agreed terms* of such access are those that will be specified in the standard MTA to be developed by the Parties.[68] For plant genetic resources outside the scope of the Multilateral System, the CBD is the relevant international agreement. The CBD leaves it at the discretion of the Party to determine whether to regulate access to such genetic resources or not.

67. IT-PGRFA Annex I is referred in subsection 2.1.3.

68. This is discussed in depth in subsection 2.1.3, see also the discussions of the CBD in subsection 2.1.2.

The TRIPS-agreement, the EU Patent Directive, the UPOV, the EPO and the EU plant breeder rights regulation, as referred to in Chapter 2, require respective Parties to grant exclusive rights to plants and its parts and components. These international regulations thus influence how material accessed from the NGB can be used.

Relevant Domestic Legislation
There is no legislation in the Nordic countries specifically regulating access to the genetic resources held by the NGB.

Objectives
It is the opinion of the Project Group that a main objective for the Nordic countries is to establish a legal framework in which the NGB can operate to fulfil its objectives in harmony with the IT-PGRFA. The Nordic countries have so far not required monetary benefits from exchange of genetic resources held by the NGB. The Project Group considers that facilitated access is a major benefit *per se*. It is therefore crucial to ensure facilitated access and exchange of all plant genetic resources for research and development purposes.

The NGB takes active part in capacity building and conservation programmes in Southern Africa, Russia and the Baltic countries. The Project Group believes that implementing the IT-PGRFA also will support these activities, as the benefit sharing mechanisms of the Multilateral System will be directed to conservation activities in developing countries and countries with economies in transition.

4.2.2 Clarifying the Legal Status for the Material in the NGB

Presentation of the Issue
The Convention on Biological Diversity recognises the sovereign rights of states to determine access to genetic resources. The Conference of the Parties (COP) to the CBD has adopted voluntary guidelines on access and benefit sharing of genetic resources. In the international debate, it has been regarded particularly impor-

tant to clarify the legal status of genetic resources. An unclear situation with lack of transparency has a potential to cause uncertainty for recipients of the material, and their legal responsibilities may be unpredictable. An unclear legal situation will not facilitate access to the genetic resources.

A practical approach to this is that institutions holding genetic resources should seek to clarify the legal status of their material. The Nordic Council of Ministers representing the Nordic countries should express their view as regards the legal status of the material that is under the management and control of the NGB. Since genetic resources are under the sovereign rights of the countries, continued management by the NGB of the material held by it, requires that the Nordic countries declare that they exercise these rights by bestowing the responsibility for the management and control of this material to the NGB.

The legal status of the material refers to the terms on which the provider makes the plant genetic resources available for the NGB. This is a two-fold question: What was the agreement or the understanding between the NGB and the provider at the time when the material was deposited at the NGB; and what shall be the legal status of the accessions that will be deposited at the NGB in the future? Most of the accessions in the NGB were collected and provided for without written agreements, but with the common understanding that the gene bank would provide for facilitated access, free of charge, to such material to anyone. To ensure that the legal status of the accessions in the NGB is clear in the future, the NGB should formally notify the receiver of material of the conditions under which the accessions are received.

In the Public Domain of the Nordic Countries

The Multilateral System of the IT-PGRFA only covers material that is *in the public* domain and *under the management and control of* Governments. The Project Group therefore recommends that the Nordic countries declare the genetic resources in the NGB as being in the public domain and under the management and control of the Nordic Governments. This recommendation requires:

- A declaration from the countries and from the NGB stating that all the accessions, except for security collections held by the NGB for other gene banks, are under common Nordic management and control and in the public domain.
- The Nordic Gene Bank should upon receiving the material ensure that its providers are notified that the material will be under the management and control of the Nordic Gene Bank and made available to third parties under the terms set by the NGB.
- The NGB should consider including as a condition for access in a revised MTA that the genetic resources should not be given to third parties unless under the same terms as in the MTA of the NGB is applied.

The above recommendations will have the following consequences:

- The plant genetic resources in the NGB will automatically be covered by the Multilateral System of the IT-PGRFA.
- The Nordic cooperation on genetic resources will be provided for.
- The benefits from the cost effective Nordic cooperation on conservation and use of plant genetic resources for food and agriculture will be promoted.
- Access to the genetic resources of the NGB will be on the conditions stated in IT-PGRFA, Article 12.3. The user of the genetic resources will, according to the IT-PGRFA, Article 12.4, be required to accept access on the terms of the standard material transfer agreement (MTA) to be developed by the Parties to the IT-PGRFA.
- Facilitated access to all the genetic resources of the NGB will be maintained.
- The bureaucratic procedures can be kept at a minimum.

The Project Group believes that the suggested approach will express the collective intention of the Nordic Governments to implementing the principles and the obligations of the IT-PGRFA

even before it enters into force, thereby giving an important signal to other countries. A rapid ratification and implementation of the Treaty by the Nordic countries might also create an incentive for other countries to ratify the IT-PGRFA. In the process of assessing alternative solutions, the Project Group also considered three other alternatives that were rejected:

- Repatriation of the plant genetic resources in the NGB to the Nordic country from which it was received. The main reasons for not pursuing this alternative are that it is not cost-effective, it is time-consuming, it requires comprehensive work, it will be bureaucratic and it will not promote Nordic co-operation.
- Giving an exclusive individual right to each private or public donor who provided the material to the NGB, to determine the conditions for access. This alternative will run counter to the objectives of the international agreements. This would also not be cost-effective, it would be time-consuming and it would require comprehensive work.
- No action taken. The legal situation would remain unchanged. This alternative does not provide for a solution to the problem that the Project Group has been asked to consider and solve.

Conclusions

The Project Group recommends that:

- The Nordic Council of Ministers be invited to declare that the genetic resources held by the Nordic Gene Bank, except for security collections held by the NGB for other gene banks, are under the management and control of the Nordic Governments and in the public domain.
- The respective Nordic governments should confirm this declaration through an appropriate national decision.
- The board of the Nordic Gene Bank should finally implement the decisions.

The Nordic Gene Bank should make it clear upon receiving plant genetic resources in the future, that these will be included in the Multilateral System of the IT-PGRFA and be made available to third parties on facilitated access under the conditions of the Multilateral System.

The NGB should consider imposing as a condition for access to material in the NGB that the genetic resources received shall be kept in the public domain by the receiver.

4.2.3 Implementation of the IT-PGRFA: Terms for Access and Benefit Sharing for Plant Genetic Resources in the NGB

Presentation of the Issue

The Project Group does not suggest the wording for a new Material Transfer Agreement (MTA). The standard MTA that eventually will be adopted by the Governing Body of the IT-PGRFA will apply to the Annex 1 species, which represent more than 90% of the material in the NGB. The core purpose of the MTA in the Treaty is to create a balance between the rights of the provider of the genetic resources, the receiver of the genetic resources and other potential future users of the same genetic resources. The project group underlines the need to create a system for access to material in the NGB that is non-bureaucratic and simple in order to *facilitate* access. It must be recognized that all countries are both providers and receivers of genetic resources and will, in the long run, benefit from an international regime that truly facilitates access to plant genetic resources for food and agriculture.

Scope for Access

According to IT-PGRFA article 12.3 a, access to plant genetic resources that are covered by the scope of the Multilateral System

> … shall be provided solely for the purpose of utilization and conservation for (…) food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

This implies that the MTA used by the NGB may regulate access to plant genetic resources differently depending upon the purpose of the use.

Two main scenarios can be put forward:

SCENARIO A: Adopt the scope of the IT-PGRFA, and thus grant facilitated access to the NGB material for conservation and utilization for food and agriculture uses only.
SCENARIO B: Provide facilitated access to the NGB material regardless of the purpose.

Scenario A – Facilitated Access to NGB Material for Utilization and Conservation for Food and Agriculture Uses Only
To grant access for the purpose of utilization and conservation for food and agricultural uses only will have the following consequences:

- It promotes similar or identical regulation of access to genetic resources if all countries being Party to the IT-PGRFA follow the same approach.
- It will discourage research on genetic resources for other purposes, and thereby delay or hinder useful discoveries and development.

Scenario B – Facilitated Access to the NGB Material for All Purposes
To grant access regardless of purpose will probably have the following consequences:

- It requires less administration from the NGB.
- It is cost-effective and reduces bureaucracy.
- It promotes the objectives of the NGB in a good manner.
- If the NGB receives genetic resources from gene banks or countries that only provide the material for the purposes of utilization and conservation for food and agriculture, the NGB must treat that material under separate conditions. The NGB may also decide not to accept such material. There is a risk that these providers can be reluctant to exchange material with the NGB for this reason.

It is the opinion of the Project Group that the objective of the IT-PGRFA primarily is to ensure facilitated access and exchange for food and agriculture, not to restrict access for other uses. Thus, to provide access without restrictions as to the use of the material is not in disharmony with the spirit of the IT-PGRFA.

Restricting access to genetic resources for other purposes than for food and agriculture uses can reduce scientific research, prevent important discoveries from being done and hinder commercialisation of products. At present the NGB does not differentiate between purposes of use. There seem to be many good arguments for the NGB to provide access on the same terms, regardless of the purpose of use.

Conclusion The Project Group recommends that the NGB grants facilitated access to its material regardless of the purpose of use.

The Provisional MTA for the CGIAR

The specific conditions for access to genetic resources for food and agriculture uses follows from IT-PGRFA Articles 10 to 14, in particular Articles 12.3 (a), (d) and (g) as well as Article 13.2 (d) (ii). These provisions in the international Treaty are discussed in Chapter 2.1.3. The standard MTA shall according to the IT-PGRFA be negotiated among the parties and adopted by its Governing Body. In the time before these negotiations are concluded there may be a need for a provisional MTA. At its 9th regular session in October 2002 the Commission on Genetic Resources under the FAO adopted a provisional MTA for the *ex-situ* collections held by the International Agricultural Research Centres within the Consultative Group on International Agricultural Research (CGIAR). This provisional MTA is in harmony with the provisions of the IT-PGRFA. The provision for commercial benefit sharing is pending specifications that will have to be adopted by the Governing Body of the Treaty. This provisional MTA is enclosed as appendix III to this Report.

Conclusion The Project Group recommends that the Board of the NGB considers using the provisional MTA of the International Agricultural Research Centers adopted by the Commission on Genetic Resources of the FAO until a standard MTA has been adopted by the Governing Body of the Treaty.

Distribution of Benefits Arising from the Use of the Genetic Resources for Food and Agricultural Uses

One other issue that is of general interest and importance for the management of the NGB is to what extent the MTA shall provide for benefit sharing from the recipients of the material that falls outside the scope of the Multilateral System. According to IT-PGRFA Article 13.2 (d) (ii):

> The Contracting Parties agree that the standard Material Transfer Agreement referred to in Article 12.4 shall include a requirement that a recipient who commercialises a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to the mechanism referred to in Article 19.3 (f), an equitable share of the benefits arising from the commercialisation of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercialises shall be encouraged to make such payment.
>
> The Governing Body shall, at its first meeting, determine the level, form and manner of the payment, in line with commercial practice. The Governing Body may decide to establish different levels of payment for various categories of recipients who commercialise such products; it may also decide on the need to exempt from such payments small farmers in developing countries and in countries with economies in transition.

As follows from this article, the standard MTA will determine the level of the monetary benefit sharing. The obligation does not mean that each institution providing genetic material from the Multilateral System, *e.g.* the NGB, shall require monetary benefit sharing for their own ends, but whether commercialisation of the plant genetic resources received from the NGB, shall trigger bene-

fit sharing to be paid to the financial mechanism of the Treaty. It is the understanding of the Project Group that the NGB is primarily interested in feedback and sharing of research results from the exchanged material. This is regarded by the NGB as a benefit sharing *per se*.

Conclusion The Project Group suggests that the NGB shall not claim any monetary benefits as a condition for access. The Project Group suggests that the NGB promotes benefit sharing within the Multilateral System by sharing research results emanating from research on material accessed from the bank.

Intellectual Property Rights to
Plant Genetic Resources under the Multilateral System

Presentation of the Issue

One issue of special interest for the relationship between users of genetic resources is the issue of granting intellectual property rights, patents and plant breeders' rights, for inventions and varieties based on material received from the NGB. The IT-PGRFA, Article 12.3 (d) specifies that:

> Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System;

Since the Project Group recommends that the NGB shall use the standard MTA, the obligation in Article 12.3 (d) will be applicable to genetic resources under the Multilateral System accessed from the NGB. The NGB could consider to make the information about the accessions under its management and thus under the Multilateral System easily available for the patent examiners. The purpose of this would be to make the investigation of *prior art* and *non-obviousness* easier. The standard MTA has character of being a private law agreement, and applying for intellectual property rights to NGB material *in the form received* will imply a breach of contract.

Conclusion The Project Group recommends that the MTAs of the NGB shall specify, in accordance with IT-PGRFA article 12.3 (d), that the recipient shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received.

Access to Non-Annex I Species from the NGB

The issue at stake is whether the NGB shall grant facilitated access to plant genetic resources not covered by the IT-PGRFA Annex I. There are no obligations in international law requiring that these resources may not be made available on the same terms. The Project Group has considered whether the NGB should apply the same MTA or apply different terms for non-annex I species. The unequivocal recommendation is that the same MTA is used. This is supported by the following arguments:

- The objectives of the NGB are the same regardless of whether the species are listed in Annex I or not.
- Access to genetic resources will become equally facilitated for the benefit of research and development.
- It will lower transaction costs for the recipient as well as the donor of genetic resources.
- The Nordic countries argued for a widest possible scope of the Multilateral System. Based on the needs of the breeders and the agricultural sector. To apply the same conditions regardless of whether the plant species and genera are listed in the Annex 1 or not, will give a signal to the international society that the Nordic countries still considers that exchange of all genetic resources for the purpose of food and agriculture should be facilitated and that Annex 1 of the Treaty shall include all relevant species and varieties.
- The Nordic countries have argued in the international debate that the CGIAR centres should apply common rules to genetic resources held in trust. By applying the standard MTA, the Nordic countries would facilitate the work of these gene banks.

- About 10% of the accessions in the NGB are estimated to represent non-annex I material. The Project Group has not identified any reasons for implementing different conditions for these species than IT-PGRFA Annex I species. From the perspective of the NGB, there are no reasons for regulating these genetic resources differently than those listed in IT-PGRFA Annex I.
- However, since the standard MTA under the Multilateral System is not yet negotiated, it is difficult to predict how strict regulations such an MTA eventually will represent. If the final MTA would result in severe restrictions on access, the NGB might ensure for more facilitated exchange of its genetic resources by applying a different MTA for non-Annex I material.

Conclusion The Project Group recommends that the NGB applies the same MTA and principles of the Multilateral System to all accessions and all mandate species, regardless of whether they are listed in Annex I or not.

The Project Group suggests that if the standard MTA under the Multilateral System proves to be too restrictive, the NGB should consider applying an MTA for non-annex I species which is less restrictive.

4.3 Domesticated Plant Genetic Resources in the Nordic Countries Outside the NGB

4.3.1 Framework Conditions

Problems and Challenges

This Chapter addresses all domesticated plants of interest for food and agriculture and their wild relatives save forest trees that are addressed in Chapter 4.5 below. From a perspective of international law, these genetic resources can be divided in two group-

ings: those species listed in Annex I and thus covered by the Multilateral System and those that are not. The Nordic countries were, as mentioned above, in favour of the Multilateral System to cover all plant genetic resources for food and agriculture, and not establishing such a legal distinction. The IT-PGRFA provides for a legal framework that will regulate exchange of plant genetic resources of the species listed in Annex I. Its legally binding obligations are in some cases unclear and open for interpretation, the Multilateral System should cover including to what extent plant genetic resources in the Nordic countries. The Report focuses on these unclear issues with a view to suggest recommendations for how Nordic domestic legislation can promote the objectives of the IT-PGRFA.

Identification of Stakeholders

In addition to the Nordic Governments the following categories of stakeholders can be identified:

- Plant breeders.
- Researchers.
- Gene banks.
- Farmers.
- Indigenous peoples: the Saamí people and the Inuit people.
- Open air museums, arboreta and botanical gardens.
- Non-governmental organisations.
- Private persons.
- Local and regional authorities.
- Public common land (*e.g.* Statsalmenninger).

Relevant International Agreements

The international agreements that apply to the collections of the NGB are also relevant to other plant genetic resources in the Nordic countries. The legal starting point according to Article 15 of the CBD is that the *"authority to determine access to genetic resources rests with the national governments and is subject to national legislation"*.[69]

69. CBD article 15 paragraph 1.

The Parties' sovereign rights imply a right for each country to provide access to its genetic resources subject to prior *informed consent, unless otherwise determined*.[70] Hence, there are two main alternatives: Each country can choose not to regulate access to its genetic resources; or it can choose to require *prior informed consent* for access. In the international debate both the countries requiring a *prior informed consent* and those that decided not to regulate access to genetic resources are encouraged to clarify the legal status of their genetic resources by formally declaring the conditions for access.

By ratifying the IT-PGRFA the Nordic countries exercise their sovereign right to determine access to genetic resources, if they give their general *prior informed consent* to access to those genetic resources, according to the provisions of the International Treaty and the standard Material Transfer Agreement to be developed by the Governing Body of the Treaty. This report presupposes that the Nordic countries will become Parties to the IT-PGRFA and consequently intend to regulate access to plant genetic resources covered by Annex I accordingly. Because the standard MTA is not yet finalised, the Project Group has decided not to go into detail in discussing terms for such a MTA.

The scope of the Multilateral System covers plant genetic resources for food and agriculture listed in Annex I of the IT-PGRFA when they *"are under the management and control of the Contracting Parties and in the public domain"*[71]. The implementation of the term *management and control of the Contracting Parties and in the public domain* will determine the scope of the genetic resources covered by the Multilateral System for facilitated access and benefits sharing; and thus the genetic resources that can be accessed from the NGB.[72] Therefore, it is of a general Nordic interest how the Nordic countries implement these terms in their domestic legislation.

70. CBD article 15 paragraph 5.

71. IT-PGRFA Article 11.2

72. See subsection 2.1.3 for an analysis of this term.

Relevant Domestic Legislation

This Report does not investigate the current legal situation in each Nordic country regarding rights to genetic resources. This is a matter that needs to be explored domestically before clarifying the legal status of the genetic resources. The question to be answered can be formulated as: Are there any property rights to genetic resources?

Not only ownership to physical biological resources is of interest. Also patent law and plant breeder's rights apply. When a gene is patented, the holder of the patent has exclusive right to commercially exploit the *invention* for a specified time. Also, a patented gene will be a part of *prior art* when a new patent application is examined, since it will no longer be novel in a patent law sense. For plant breeders' rights this issue is different. The scope of this type of protection is not the individual genes but the plant variety as such.

Objectives

One objective for the discussion of *access to the plant genetic resources for food and agriculture* is to ensure that genetic resources will to the largest extent possible, taking all relevant legislation into account, be made available for all purposes. Plant genetic resources may contribute to food security and may represent value for conservation, research development etc. regardless of whether they are listed in Annex I of the IT-PGRFA or not. Therefore, to promote facilitated access and free exchange are recognised as important objectives for the discussions on rights and access to plant genetic resources in the Nordic countries.

4.3.2 The Legal Status of Plant Genetic Resources

Presentation of the Issue

One issue of particular importance is to determine the legal status of the plant genetic resources. In order to ensure sustainable utilization of plant genetic resources there is a need to establish transparent and predictable conditions both for the users and the

providers of such resources. The plant breeders need to carry out their work under predictable terms. An ambiguous legal situation can be regarded as an obstacle for both plant breeders and other users of plant genetic resources. A company that invests time and money in plant breeding needs to know if other persons have any rights to the genetic resources used in their research and breeding programmes.

The Multilateral System for facilitated access applies to plant genetic resources that *are under the management and control of the Contracting Parties and in the public domain*. Therefore, plant genetic resources that are privately owned or subject to intellectual property rights are not included in the Multilateral System, even if these resources are covered by Annex 1 of the IT-PGRFA .[73]

The current property legislation in the Nordic countries addresses ownership to biological material. The question is to what extent such legislation also regulates the rights to genetic resources. The project group has not been able to investigate in detail national legislation in the Nordic countries in this respect but stresses the need to investigate further these issues. According to proprietary rights, the owner of plant material will have the right to use it for food- and feed production and for direct consumption. A first question is if such rights also include the right to use the plant genetic resources and/or sell it, for breeding and other development purposes? If so, could the owner of the plants also claim rights to any future generations of such material, also when such plant genetic resources no longer are under the owner's physical control?

One way to look at these issues is that the proprietary rights of biological material only implies a non-exclusive right to use the genetic resources. Intellectual property rights on the other hand implies a right to exclude others from using that plant, even if the rights to use the physical plant are held by others than the patent-holder. When the CBD recognises the sovereign rights to genetic

73. IT-PGRFA article 11.2. This article is profoundly discussed in subsection 2.1.3 and 4.3.3.

resources, and the right for Parties to require prior informed consent before giving access to their genetic resources it implies that there may be additional rights attached to the biological material than intellectual property rights or property rights to physical material.

Thus, another manner to look at the issue is that proprietary rights to biological material only implies non-exclusive rights to such material: The difference between the two different kinds of property rights, *e.g.* physical and intellectual are, however, not totally clear. Furthermore, the future development of the way in which holders of these rights will exercise their ownership can cause serious impediments to research and development in food and agriculture. The right-holders to biological material may wish to benefit from their use in *i.e.* plant breeding by requiring contractual agreements for access. Such agreements may introduce exclusive rights to the use of the biological material for research and development in plant breeding or for industrial applications. This type of development is likely to result in a need for tracking the exchange of the genetic resources and may cause difficulties for breeders, developers and others who use genetic resources for conservation, information, breeding or other development purposes. No such cases have yet been reported in the Nordic countries, but some developing countries have introduced very strict access legislation covering all genetic resources.

A third way to address this issue is to specify that rights to genetic resources are separate from ownership over biological resources and that such rights can only be exercised through the use of intellectual property rights. The private property rights to the biological material will still be respected, but granting of rights to the *genetic resources* is left to national regulations. This entails that in case access to genetic resources remains unregulated, the holders of biological resources can not exercise any control over genetic resources. This alternative does not entail that the countries will regulate access to genetic resources. By this alternative the countries will, however, reserve the right to introduce such regulations at a later point in time, if deemed necessary.

According to the CBD, states have sovereign rights to determine access to their genetic resources and could thereby use these rights to create a predictable legal situation. A prerequisite for introducing regulation on access is to clarify the legal status of the genetic resources. The countries can choose between several alternative options when determining the legal status:

- To declare that the rights to use genetic resources follow the rights to access the biological material. (This alternative can be characterised as a non-exclusive right to use the genetic resources.)
- To specify that rights to biological resources include rights to restrict others from utilizing their genetic resources except on terms mutually agreed upon in private contractual agreements.
- To specify that rights to 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 can not exercise any control over genetic resources.

Conclusion The project group emphasises the importance of clarifying the legal status of plant genetic resources even in countries that currently have no plans for such regulations. The project group therefore recommends that the Nordic countries investigate the need for determining the legal status of their plant genetic resources.

4.3.3 Terms for Access and Benefit Sharing

Implementing the IT-PGRFA

Since the Project Group presupposes that the Nordic countries will become Parties to the IT-PGRFA, access and benefit sharing for the species covered by the scope of the Multilateral System will be regulated by the standard MTA to be developed by the Governing Body of the Treaty. The Project Group does not identify a sim-

ilar need for the Nordic countries to implement a provisional MTA for access to the genetic resources outside those managed by the NGB. When the Governing Body of the Multilateral System has adopted the standard MTA, the Nordic countries will be required to give access to Annex I species on these terms.

The Scope of the Multilateral System

The scope of the material under the Multilateral System will be determined by the legal situation in each country.

Material under the Management and Control of the Parties

It follows directly from the wording of the Treaty that the Multilateral System provides facilitated access to plant genetic resources that *are under the management and control of the Contracting Parties and in the public domain*.[74] From the perspective of the users of plant genetic resources it is important that countries establish a clear legal situation regarding which material that is under the facilitated access regime. The Project Group recommends that the Nordic countries specify this when ratifying the IT-PGRFA.

Other Holders of Plant Genetic Resources

The IT-PGRFA recognises private rights to biological material, and establishes mechanisms for including such material under the Multilateral System.[75] The IT-PGRFA leaves it to domestic legislation to implement means to establish a framework for other holders of plant genetic resources to include their material under the Multilateral System. The Parties are, however, obliged to *encourage natural and legal persons within their jurisdiction who hold plant genetic resources for food and agriculture*.[76] This will to a large extent depend upon means taken in each country. The Project Group has

74. For an interpretation of this terms, see subsection 2.1.3.

75. See IT-PGRFA 11.2 second sentence: *"invites all other holders of the plant genetic resources for food and agriculture listed in Annex I to include these plant genetic resources for food and agriculture in the Multilateral System"*.

76. IT-PGRFA article 11.3 and 11.4.

not looked into the specific mechanisms that the countries can apply to encourage this.

Promotion of facilitated access to plant genetic resources – the resources that *"are under the management and control of the Contracting Parties and in the public domain"* – should be defined as broadly as possible, taking relevant legal and practical factors into account. Such an approach will promote open access, and hence exchange of genetic resources for the benefit of research and development of new crop varieties. To define the scope of the Multilateral System narrowly can undermine facilitated exchange and therefore also plant breeding and development in a long-term perspective.

The Nordic countries approach could therefore be to include a wide range of plant genetic resources in the Multilateral System at an early stage may influence other countries' efforts to implement a broad definition of the concept *"management and control of the Contracting Parties and in the public domain"*. If the first ratifying countries implement narrow definitions of the scope of the Multilateral System, this might cause others to follow the same pattern. The consequence of this might be that the efficiency of the Multilateral System is reduced. On the other hand, private ownership has to be respected. Otherwise it might send negative signals to investors and private companies. This is an argument in favour of a solution whereby every inclusion of privately owned material in the Multilateral System must be voluntary, but that such inclusions are strongly advocated.

Conclusion

The Project Group recommends that the Nordic countries interpret the expression under the management and control of the Contracting Parties and in the public domain as broadly as possible when implementing the IT-PGRFA. The Project Group recognises that private property rights must be respected. The Project Group recommends that the Nordic countries take measures to encourage private holders of plant genetic resources to include these under the Multilateral System.

4.3.4 Regulation of Access to Plant Genetic Resources not Covered by the Scope of the Multilateral System

Presentation of the Issue

For plant genetic resources not covered by the scope of the Multilateral System, the specific international legal regime for access and benefit sharing is the CBD and the Bonn Guidelines. As previously explained these regulations leave it up to each country to determine whether to regulate access or not. Again, two main alternatives exist: either to leave access to plant genetic resources not covered by the Multilateral System unregulated; or to regulate them on the same conditions as the standard MTA. The Project Group has also considered the possibility of regulating access to plant genetic resources on different terms. The group has concluded that there are no convincing reasons for choosing this alternative.

The Nordic countries argued against the idea of establishing a distinction between different species of plant genetic resources in the negotiations of the International Treaty. This is an argument in favour of granting access to these genetic resources on the same terms, regardless of whether they are listed in Annex I of the ITPGRFA or not.

To leave access to plant genetic resources unregulated will not require any specific procedures, and can therefore be seen as an important measure for facilitating access to such resources. If access is regulated and the same standard MTA is applied for access to all plant genetic resources, the benefits provided could be distributed through the financial mechanism of the International Treaty. If the standard MTA adopted by the Governing Body proves to be too comprehensive and bureaucratic it will not facilitate access, which in the opinion of the Project Group is an important objective. In that case other measures should be considered to deal with conditions for access.

Another argument in favour of implementing the same MTA as for the material under the Multilateral System is to promote the

open exchange of plant genetic resources between the Nordic countries and the NGB. This argument can also be put forward as a reason for not imposing any restrictions on the access at all, or at least not to impose more severe restrictions on the access than for the same material. Using the same MTA will also create a transparent Nordic system and the transaction costs may well be lower.

Conclusion The Project Group recognises that the Nordic countries may wish to regulate this topic in different manners. The Project Group recommends that Annex I and non-annex I material are handled in a similar manner.

4.4 Access to Animal Genetic Resources for Food and Agriculture

4.4.1 Framework Conditions

Problems and Challenges

This chapter deals with animal genetic resources for food and agriculture. Breeding in animals is focused on individuals and breeds, whereas breeding of plants is focused on varieties. Thus, in animal breeding the individuals of the breed are the biological expression of the genetic resources. It is important to take the different breeding methods into account when addressing policy and legislative issues. For example, this difference is reflected in the use of private law agreements for exchange of animals and propagating material. This contractual practice ensures exchange of animal genetic resources.

For productive breeding with genetic improvement one important factor is the documentation and information regarding the pedigree table of individuals, including their recorded performance data. Examples of such recorded information are milk yield (per lactation), slaughter or live weight per fixed age, growth rate

within fixed time intervals or egg weight per time unit. These traits may also be connected to quality, like fat- and protein contents, cell counts for milk or meat fat contents. The variation in the production environments may for example be identified by herd, age at calving and season of calving. A detailed knowledge of recorded environmental factors makes the phenotypic performance data of the individuals more useful as information for breeding purposes. Other important recorded information may be health standards, treatment of different diseases and reproduction- and mortality data. Such information can be used for selection of genetic improvements in animal health, reproductive capacity and morality. One important part of the value of animal genetic resources is thus knowledge about the inherent material of the individuals.

Variation within the population is of crucial importance for the rate of progress obtainable by selective breeding. Immigration of genes from a breed with better performance through crossing is a way of improving the efficiency of the home breed. These types of improvements arise either from the need to counteract inbreeding or the need for upgrading the genetic performance of the breed. Thus, availability of different breeds with good performance for the purpose of immigrating plus-genes become less available as breeds are gradually disappearing because of absence of effort of conservation.

If the genetic diversity within one breed becomes homogeneous, further improvement by selection is not attainable. (For example, one breed in the UK is calculated to be 96% homozygotic, *i.e.* almost no variations because of all genes are fixed.) The breeding objectives in the Nordic countries are aiming more at maintaining the genetic diversity by taking health, reproduction and longevity aspects into account within the commercially interesting breeds. Most other countries have maximal increase of production as the only and narrowing breeding objective. This might imply deterioration of traits negative correlated to yield, like health and reproduction. The long-term consequences of negative response of those important traits ought to imply high risk of danger to a

sustainable production system. Foreign breeding company increase their sale of semen or other breeding materials to the Nordic countries. In the long run, increasing part of the import of breeding material might lead to reduced ability to respond to changing demands from the production system and the consumers.

Identification of Stakeholders

The most relevant stakeholders can be described as:

- Farmers with livestock.
- Breeding companies.
- Breeders' organisations.
- Indigenous peoples: the Saamí people and the Inuit people.
- Genetic resources councils (Denmark, Finland, Norway and Sweden), the boards of agriculture.
- Buyers and users of genetic material.
- Universities.
- Research Institutions.
- Gene banks.

Relevant International Agreements – A Nordic Approach

The scope of the CBD is biological diversity, and covers thereby animal genetic resources. The principle of sovereign rights of countries over genetic resources and the authority to determine access applies to animal genetic resources. Access to animal genetic resources is not subject to any other legally binding multilateral agreements. According to the relevant intellectual property right agreements the point of departure is that all inventions are patentable. The TRIPS-agreement leaves it to the discretion of the member countries to decide whether to exempt animals (and animal varieties) from the scope of patentability. The EU Patent Directive uses this discretion to exempt animal varieties from the scope of patentability. However, animals are patentable under the Directive provided there is an *invention* and that it fulfils the patent terms. The term *animal variety* is not clearly defined in law, as plant variety is in the UPOV-conventions. As reflected previously

the *breed* or the breeding population and the *individuals* are the relevant expressions of genetic resources for animals.

Relevant Domestic Legislation

At the present, exchange of animal genetic resources is not specifically regulated by domestic legislation in the Nordic countries. However, the health status of the herd of the country of export is an example of cause that can stop export of biological material. Exchange of animal genetic resources is to a large extent based on private law agreements. By using the terms from the plant-breeding sector, a private law agreement can be seen as a Material Transfer Agreement. Also, there might exist customary law regulating rights to animal genetic resources, like a contract of selling genetic material might have requirement that the production individuals of the transfer should not be used as breeding individuals.

Objectives

Two objectives can be put forward as the most important:

1. To facilitate exchange of animal genetic resources.
2. To promote conservation of diversity among breeds and within breeds. This implies two main challenges: firstly, to conserve the diversity within the commercially interesting breeds, and thereby avoiding inbreeding; and secondly, to prevent extinction of the non-commercial breeds. The latter is more of a political issue due to the lack of direct economic benefits form such activities. The conservation of the diversity is closely related to the agriculture politics, as for example national and EU subsidy to farmers keeping endangered breeds. The policy for conservation of endangered breeds varies among countries, but they all try to promote the productive use of breeds classified as non-commercial. Another objective of these breeds may be the possibility to use animals for the purpose of maintaining cultural landscape. Nevertheless, it might also be of importance as insurance for long-term breeding purposes.

4.4.2 Exclusive Rights to Animal Genetic Resources

This section addresses the topic exclusive rights to animal genetic resources. A point of departure for this topic is that private persons, *e.g.* farmers and breeders, own the individual animals. This property right implies a right to the physical material, as for example the right to use and sell it for propagation purposes. The owner of an animal probably has the right to the specimens and thus the DNA-molecules of each individual.

A large part of the genome of each individual is common within the breed and within the species. Since property rights to animals cover a right to the individuals, the owner of an animal cannot prevent others from using the same genetic parts and components if they are found in their individuals. Thus, the holder of the individual can only enforce his right to the very specific combination of genes that is inherent in his animals.

The right to the animal genetic resources is closely related to the control of the individuals. Therefore, one issue arises: Does the owner of the individuals have an exclusive right to the genetic resources if they spread out of his control? Since the relevant expression of the genetic resources is the individual, its owner will typically have a practical possibility to exclude others from using the inherent DNA-molecule. Thus, the owner of an animal has good control of the genetic resources of his animals. Therefore, this issue might not be problematic.

Transfer of animal genetic resources is typically regulated by a private law agreement. The contractual terms are binding for the parties to the contract. If the contract specifies that the buyer does not have the right to use the production animals for selling offspring as breeding materials, but breaches these terms it is doubtful whether the first seller of the genetic resources have any rights to the genes of the animals of the third Party. This situation will be regulated by the general principles of contract law.

Conclusion The Project Group has not identified any current needs for countries to change the present legal status of animal genetic resources.

4.4.3 Transfer Agreement for Animal Genetic Resources

The Project Group bases its conclusion on the assumption that the system for exchange of animal genetic resources based on private law agreements functions well. Due to the fact that the relevant biological expression for animal genetic resources is the particular individual, private law agreements determining the conditions for exchange and sales of animal propagating material, appear to be the relevant legal means for regulating this topic. When importing or exporting new breeds of animals to an existing population, the purpose of such trade of animal genetic resources is to make improvements but it can not be ruled out that it in certain cases might cause negative effects.

There is no internationally negotiated standard MTA for transfer and exchange of animal genetic resources. Since the MTA is a private law agreement, the parties can impose and undertake obligations regarding the use of the transferred material. Therefore, one relevant term in the MTA is to determine the scope of uses of the propagating material. One issue that the provider of the animal genetic resources might want to regulate is the possibility to register intellectual property rights to the transferred material. Non-compliance with such an obligation will probably not have consequences for a patent application; but will be a breach of a contractual obligation, and thus be followed by adequate legal actions.

Conclusion The Project Group has not found convincing reasons to suggest regulations of exchange of animal genetic resources, and supports the present legal situation for exchange of animal genetic resources and related information. The Project Group recommends the Nordic countries to take appropriate measures to stimulate sustainable management of animal genetic resources.

4.4.4 Applying Patent Law to Animal Genetic Resources

Patent protection can be granted in all fields of technology that are not excluded from patentability. The EU Patent Directive makes an exemption from patentability for animal varieties. However, the notion of *animal variety* is still to be defined. An *invention* that consists of an animal and that fulfils the patent terms is according to the EU Patent Directive and patent practice, patentable. The same applies to an inventive technique that is not linked to one particular animal breed, even if the patent thereby *de facto* grants an exclusive right to prevent everyone from using one or several of the said varieties can be patented.

Conclusion The Project Group recommends that incentives other than access regulations be used to stimulate sustainable management of animal genetic resources.

4.5 Access to Genetic Resources of Forest Trees

4.5.1 Framework Conditions

Problems and Challenges

Genetic resources of forest trees have similarities both to plant genetic resources for food and agriculture and to animal genetic resources. In forest tree breeding it is common to select individual trees, which are multiplied as clones by different methods of vegetative propagation. Cloned individuals from a number of selected clones are planted in so called seed orchards to mass-produce improved seed. For some tree species, selected individuals can be multiplied as clones, *e.g.* by cutting propagation, and used to replace seedlings for reforestation purposes. In this respect the individual tree is the relevant biological unit. There is seldom use of pure lines as in plant breeding.

Forest tree genetic resources are quite distinct from other plant genetic resources and also from animal genetic resources. In particular because of the following reasons:

1. Forestry uses both natural regeneration and planting.
2. Many tree species are not utilised commercially, at least in some parts of their natural range, and should be considered as wild species. However, their genetic resources have potential value.
3. The rotation age is high for many species, up to more than 100 years (which is the patent protection period times five).
4. Trees have exceptional reproduction capacity. A single tree can produce hundreds and thousands of seeds during a rotation period.
5. There is an increasing tendency in national forestry policies and legislation to emphasise conservation of biological diversity at the expense of wood and pulp production (in Swedish legislation these are emphasised equally). The aim to conserve and sustainably use forest biodiversity is increasing in all countries.
6. Environmental certification systems, as Forest Stewardship Council (FSC) and Pan European Forest Certification (PEFC) for ecologically sound forests will have an impact on the genetic resources in the sector. The public influences, through the use of market mechanisms, management of the forest. The issue of public participation and the right of common access to private land (*allemannsretten,* everyman's right) are other features important for public opinion on the use of forest genetic resources.
7. In the Nordic countries, the non-commercially oriented breeding dominates. It is related to voluntary work and activities partly financed by the governments, non-commercial organisations and partly by the commercial forestry.
8. The physical genetic material for breeding purposes and gene conservation is mostly grown on private property, and only to a minor extent grown on properties owned by the state or breeding organisations. Thus, the breeder will typically not have the right to the biological material.

These following features must be reflected in policies and legislation regarding the genetic resources:

- Forests have a multipurpose function by providing wood, recreational opportunities and habitats for important species.
- Forest trees species are domesticated at very different levels. Some should be considered as wild species, others as semi-domesticated.
- Most trees cross-pollinate and are wind-pollinated, implying an extensive gene-flow.
- Measures for vegetative propagation leads to the use of clones.
- The climatic adaptation of forest trees is very important – often linked to the latitude.
- Transfer of forest tree genetic resources (reproductive material), within countries and among countries is important to achieve better production.
- Forest tree breeding can provide considerable genetic gain.
- There is research going on to develop GMO-trees, but there is so far no approved material for use.
- Tendency of increasing use of patents to forest trees.

For forest tree breeding the researchers have benefited from free access and open exchange of forest tree genetic resources within and among countries on a purely voluntary basis. Since participants in breeding of plant genetic resources for food and agriculture are leading the legal development in the field of intellectual property right, the research institutions for forest trees are likely to be following their path of individualisation and privatisation of forest tree genetic resources.

The situation is that Nordic producers of forest plants to some extent buy seeds in other countries and produce plants that are used for reforestation purposes, but also in breeding and development. The result from these imports of seeds and breeding activities is considered to be for the benefit of society. Forest tree genetic resources can be considered to be of some private commercial interest, but most of all of a strong national economic impor-

tance. The forests are a combination of national public economy and private economic incentives. Thus the society has a share of the interests. The long-term perspective is stronger for forest trees, since, the harvest is long time in the future.

Identification of Stakeholders

The following is a selection of the most relevant stakeholders to forest genetic resources:

- Forest- and landowners.
- The public.
- Indigenous peoples: the Saamí people and the Inuit people.
- Breeding organisations.
- Research institutions.
- The Nordic countries.
- Other countries.

Relevant International Agreements

Exchange of forest tree genetic resources has not been subject to specific international negotiations. The general obligations of the CBD apply. There have been initiatives for the UPOV to apply plant breeders' rights more extensively for forest trees. The patent law treaties apply: Forest trees are plants, thus the exemptions to plant varieties from the scope of patentability apply for forest tree varieties.

The OECD scheme for the Control of Forest Reproductive Material Moving in International Trade is a certification system that provides information about reproductive materials traded across borders. Denmark, Finland, Norway and Sweden participate in this system.

According to the EU Forest Tree Directive of 22. December 1999, cross-border exchange of forest tree genetic resources must be notified to the right authority. This is an example illustrating that there is an existing non-bureaucratic access regulation in place in this field.

Relevant Domestic Legislation

The fact that forest trees are used for many different purposes is reflected in the domestic legislation in this field. The landowners must adhere to a broad set of regulations. These are, to some extent, infringing on the rights of landowners where trees are grown. A selection of landowners has agreements with gene banks undertaking obligations to rejuvenate their forest with seeds of the same genetic material. Due to principles of private contractual law and the fact that such agreements cannot be registered in the land-register, it is rather doubtful whether these agreements can be enforced upon the next landowner. Thus, this manner to ensure the conservation of genetic resources has an insecure legal position in domestic legislation.

Objectives

There is a strong wish to leave the prevailing situation as it is when it comes to access to genetic resources – within and between the Nordic countries, and other countries. The system of easy access is well functioning, thus an important objective is to ensure a legal regime that will not further restrict access in the future. The relationship between the private owner of the land and the public interest of forests as for recreation can create tension. Thus, it is a challenge to ensure a proper balance between interests.

4.5.2 Legal Status of Forest Tree Genetic Resources

Presentation of the Issue

Property rights to forest tree genetic resources have not been debated as intensively as plant genetic resources. The long rotation period for trees implies a challenge for the countries to look at this issue from a long-term perspective. Therefore, an unclear legal situation for forest tree genetic resources will be an obstacle for forest tree breeding.

Breeding of forest trees is often conducted on the land of private persons. Therefore, it is particularly important for the breeders that the legal status of the forest tree genetic resources is pre-

dictable. A private breeding company that invests time and money in tree breeding has a need for a clear legal relationship with the landowner. One tentative problem is the following: The present systems for *register of land* does not open for registering ongoing forest tree breeding on the land of one particular landowner. Thus the terms for such long-term breeding and conservation depend upon a contract between the landowner and the breeder. If the land is sold, it is doubtful whether the agreement can be enforced towards the new landowner.

It can be discussed if there is a need for investigating domestic legislation to determine to what extent the landowner can exercise an exclusive right to the forest tree genetic resources. The Project Group has not conducted such a domestic study of the existing legislation in each country. Thus, the following discussion of this topic is not based on detailed knowledge about the existing domestic legislation. The Project Group provides a general analysis of the topic.

General Approach

Property legislation is typically focused on trees as wood, *i.e.* the biological resource, and typically does not address property rights to forest tree *genetic resources*. A reason for this might be that exclusive private property rights to genetic resources are a new legal concept. Forest tree genetic resources can be said to have a non-exclusive character: All individuals of one species have, to a large extent, a similar combination of genes. Thus a similar combination of genetic resources exists on different lands, in different parts of a country, in different countries and in different regions of the world. Thus, it is difficult to talk about exclusive individual property rights to forest tree genetic resources. Also, the wind- and cross-pollination strategies of forest trees undermine the possibility to recognise such an exclusive right.

The scope of this subsection of the Report deals with other property rights than intellectual property rights. The scope of property protection is that the landowner has an exclusive right to the timber on his land. The landowner will typically also have the

right to collect seed, use them as seeds for breeding purposes and use the timber or wood.

The public has, in Finland, Norway and Sweden, a right to *public access to private land*. These rights may also include rights for the public to collect cones and branches from the trees that are found on the ground. Thus the landowners do not have factual control over all the biological material on their land. This question is mostly regulated under the current legal situation, in the penalty acts and wildlife legislation.

Scenarios for the Legal Status of Forest Tree Genetic Resources

Three alternatives regarding the legal status of the genetic resources in forest trees can be put forward:

SCENARIO A: Exclusive rights of the owner of the biological material to genetic resources in forest trees.
SCENARIO B: Consider the genetic resources in forest trees as in the *public domain*.
SCENARIO C: Unclear legal status.

Scenario A – Exclusive Rights

Whether this scenario requires any new or altered legislation will depend on the interpretation of the present legal situation in the country. This scenario may have the following consequences:

- It might be difficult for the landowner to exercise his/her rights in all situations. From a practical point of view it is hardly possible to prevent others from using the inherent genetic resources of his forest. If one person finds a cone on the ground in the forest, and has the right to pick it up, it is very difficult for the landowner to prevent the finder if he/she wishes to use these seeds to grow new trees; Exclusive private rights can, however, be enforceable if methods of tracing genetic material are utilized. That possibility may be complicated by the fact that similar genetic resources may be found in the trees owned by landowners in many countries.

- To recognise individual exclusive rights to the forest tree genetic resources will give a false impression of each sample having a commercial value. One consequence might be that each landowner claims monetary compensation when genetic resources from his/her land are used. The fact that the forest tree breeding only to a limited extent is carried out as a commercial activity, implies that such compensation will prevent useful publicly financed breeding activities.
- Recognition of exclusive rights may create restricted access; thereby distorting the Nordic co-operation and the open exchange of the resources among the Nordic countries and other countries.

Scenario B – Public Domain

An alternative to the recognition of exclusive private rights to forest genetic resources is to state that the forest genetic resources are in the public domain as long as the biological material is legally obtained.

- This scenario does not alter the right of the landowners to regulate access to the biological material on their land.
- It implies that use of biological material from forest trees for conservation, research, information and breeding purposes can not be prevented as long as the material is legally accessed.
- To claim that the forest tree genetic resources should be in the public domain will ensure free exchange and further development of the material.
- Free exchange of forest tree genetic resources will increase the benefits from the Nordic cooperation on conservation and sustainable utilization of these resources.
- This scenario will allow countries the possibility to regulate access to these genetic resources, if regarded as a suitable means to achieve the objectives above.

Scenario C – Unclear legal status
This scenario requires no changes in the existing legal situation, and could have these following consequences:

- By choosing not to address the topic, the legal situation remains unclear. Thus, governments will have little influence on the future development.
- The situation for forest trees as concerns intellectual property rights can be expected to follow the development for plants. This can easily lead to the development of private contractual agreements. The ramifications for issues of public interest in forests are unclear but need to be monitored carefully.

Conclusion The Project Group recommends that the Nordic countries determine the legal status of their forest tree genetic resources.

4.5.3 Access to Forest Tree Genetic Resources

The present system for exchange of and access to forest tree genetic resources is well functioning, and the Project Group does not see a need for introducing new regulations. The Project Group emphasises the need for a system of access with as few regulations as possible. The exchange of genetic resources of forest trees has been dominated by free and open exchange, generosity and simple procedures. The Project Group strongly favours a legal situation that ensures a similar situation in the future.

Problems might occur in the future. When landowners realise that forest genetic resources have a potential value this might lead to expectations of monetary benefits, which will be difficult to meet because the development of forest propagation material normally is not commercially oriented. This will probably lead to an increased use of written agreements specifying the conditions for access, *i.e.* to an increased bureaucracy. Another problem is that the rotation time of forest trees is so long that the land on which a research or seed production activity takes place might be sold to other owners with other priorities before the activity is finished.

This can put seed plantations and valuable genetic resources in danger. It can be necessary in the future to specify the terms for access in a standardized Material Transfer Agreement (MTA) that could be similar to the standard MTA of the IT-PGRFA.

Conclusion The Project Group recommends that the present legal situation with simple and non-bureaucratic access to forest tree genetic resources should be maintained. If future development results in complications due to a proliferation of exclusive private rights, the Nordic countries should consider the need to introduce measures to promote access. As pointed out in the discussions on the international legal situation above, there is already a system in place for notification of access. If it proves necessary to regulate these issues the procedures can be based upon this existing mechanism.

4.5.4 Applying Patent Law to Forest Tree Genetic Resources

The Project Group recognises that applying patents to forest tree genetic resources can lead to less generosity when it comes to the open and free exchange. This might also lead to an increased focus on exclusive property rights and to increased expectations of monetary benefits arising from the genetic resources.

Forest tree breeding is to a large extent based upon public funding. The use of patents might lead to development of the new and profitable ways of exploiting forest tree genetic resources. At the same time the costs of the society for breeding of forest propagation material might increase. The Project Group does, however, not see convincing reasons to suggest limitations to the possibilities to apply patents to forest trees.

Conclusion The Project Group concludes that forest genetic tree resources should be kept available as freely as possible and recommends that the Nordic countries only consider changes in their relevant regulations in order to ensure access also for the future.

4.6 Access to Wild Genetic Resources

4.6.1 Framework Conditions

Problems and Challenges

The scope of this chapter is rights and access to genetic resources of wild living organisms. This includes wild growing plants, except the wild relatives of the species covered by the IT-PGRFA Annex I that are addressed in Chapter 4.3, wild animals, most marine species and micro-organisms.

One aspect that implies a particular challenge for these groups of organisms is the lack of knowledge of and control over the species at stake. It is not easy to estimate the commercial and other value of the wild genetic resources, and their role in the eco-system. Also, these resources can be found in areas under different land ownership. As for forest tree genetic resources, wild genetic resources are typically not found in only one locality. The only exceptions are some endangered species that can be found at only one or few locations. Conservation and management of endangered species and their habitats are a public interest and is often regulated nationally. All these features have implications for how to address the related legislative issues.

Identification of Stakeholders

- Biotechnological Research and Development Companies.
- Botanical Museums.
- Arboreta.
- Universities.
- Private landowners.
- Indigenous peoples: the Saamí people and the Inuit people.
- Local, regional and central authorities.
- State owned land.

Relevant International Agreements

- The Convention on Biological Diversity, including the Bonn Guidelines on access to genetic resources and the fair and equitable benefits sharing arising from their utilisation.
- International Patent Agreements.

The Convention on Biological Diversity (CBD) specifies the sovereign rights to genetic resources as a right for the countries to require *prior informed consent* (PIC) for access to their genetic resources. The CBD specifies that this right of the countries follow from ratifying the Convention, *unless otherwise determined by the Party*.[77]

The sixth Conference of the Parties (COP-6) to the CBD adopted the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilisation (Decision 6/24). These voluntary guidelines aim to assist Parties, Governments and other stakeholders in developing an overall access and benefit-sharing strategy, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing. The guidelines are meant to assist when establishing legislative, administrative or policy measures on access and benefit sharing and/or when negotiating contractual arrangements for access and benefit sharing.

The Johannesburg Plan of Implementation adopted at the World Summit for Sustainable Development (WSSD) in September 2002 called for the wide implementation of the Bonn Guidelines.[78] The Johannesburg decision related to genetic resources states the following (para. 44 n and o of the Plan of Implementation):

- Promote the wide implementation of and continued work by the Parties to the CBD on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization, as an input to the Parties when developing and drafting legislative, administrative or policy

77. CBD article 15 paragraph 5.

78. WSSD Plan of Implementaion paragraph 44(o).

measures on access and benefit-sharing as well as contract and other arrangements under mutually agreed terms for access and benefit-sharing.
- The negotiation within the framework of the CBD, bearing in mind the Bonn Guidelines, of an international regime to promote and safeguard the fair and equitable sharing of benefits arising out from the utilization of genetic resources.[79]

The Ad Hoc Open-ended Working Group on Access and Benefit-sharing under the CBD will hold its second meeting in December 2003. It will mainly deal with the follow-up to the Bonn Guidelines, including the question of how to support compliance with the requirements for prior informed consent and the mutually agreed terms for access to the genetic resources. It will also address the question on how to deal with the WSSD decisions to start negotiations on an international regime on benefit sharing. The meeting will report to the CBD COP-7 in 2004.

The COP-6 addressed the role of intellectual property rights in access and benefit-sharing arrangements. It invited Parties and Governments to encourage the disclosure of the country of origin of genetic resources and of related traditional knowledge, innovations and practices relevant to the conservation and sustainable use of biological diversity in applications for intellectual property rights. This also applies when the subject matter of the application concerns or makes use of genetic resources and/or traditional knowledge in its development. It was also recognised that further work is needed to assess the implications and efficacy of such measures. WIPO and other relevant international organisations have been invited to assist in this work.

The TRIPS-agreement and the EU Patent Directive specifies that the main rule under intellectual property regimes is that patents are applicable for all fields of innovation.

79. WSSD Plan of Implementaion paragraph 44(n).

Relevant Domestic Legislation

The Nordic countries have not implemented any relevant domestic legislation regulating access to genetic resources. Denmark and Sweden have officially declared that for the time being, they do not intend to require *prior informed consent* for access to genetic resources.

Objectives

The Nordic countries have traditionally been strong proponents of the access and benefit sharing of the CBD, and should actively work towards its implementation. The two components are important in different ways. To facilitate access to wild genetic resources is important for further use of the potential of genetic resources in research, breeding, pharmaceutical and biotechnological industry as well as other commercial activities. Benefit sharing resulting from the use of genetic resources is important to create incentives for the conservation and sustainable use of biological diversity.

4.6.2 Legal Status of the Genetic Resources of Wild Organisms

Genetic resources of wild-living organisms are a rather diverse group. Therefore, it is necessary to approach this issue by dealing with different groups of organisms separately. A general feature is the need for a predictable legal situation. This has been emphasised as important to promote facilitated access to genetic resources. The legal status of wild genetic resources has not been determined in any of the Nordic countries. The Nordic countries need to further investigate this topic. The Project Group recognises the need for a predictable legal situation in order to promote sustainable use of wild genetic resources. A predictable legal status could also facilitate any future needs to regulate access to such resources.

Conclusion The Project Group recommends the Nordic countries to determine the legal status of the wild genetic resources and by this establish a legal basis for possible regulation of access to wild genetic resources in the future.

4.6.3 Access and Benefit Sharing

Presentation of the Issue

The access and benefit-sharing regime of the CBD will only function after being implemented at the national level through legislation and setting up of institutions. A large number of countries, especially developing countries, have already taken such steps and others are in the process of doing so. Many more are likely to follow as a consequence of the newly adopted Bonn guidelines. The first generation of access and benefit sharing legislation has given rise to debate. From the perspective of the users the following concerns have been raised:

- Lack of information on conditions for access and which institution is responsible for granting access.
- Too extensive processes, among both various official authorities and among civil society.
- Lack of overview of the relevant stakeholders for concluding agreements on transfer of genetic resources.
- Problems of keeping information confidential.
- Negotiations with particular local interests may be time consuming.[80]

From the providing countries the concerns have included:

- Lack of institutional capacity.
- Lack of negotiating and contractual skills.
- Lack of information on the market structure for and values of the genetic resources.
- Unapproved use of genetic resources in academia and *ex-situ* collections.
- Lack of confidence in existing intellectual property rights regimes to support the implementation of the CBD objectives.

80. ten Kate and Laird 1999, page 30.

These concerns must be taken into account when discussing whether to regulate access to genetic resources. Many developed countries are not likely to regulate access to genetic resources of their countries, but the picture is unclear since only a few have so far made official declarations of this intent. Such declarations should be done to create legal clarity for users of genetic resources.

Options for Prior Informed Consent

If a country is discussing whether to regulate access to genetic resources, it can take into account that prior *informed consent* can be organised at three levels of law:

ALTERNATIVE A: Through individual agreements between the providing country and the entity using the genetic resources, depending on the access legislation of the providing country.

ALTERNATIVE B: Through bilateral agreements between one providing country and one user country; through bilateral agreement between one providing country and a group of user countries (for example the European Union); and through bilateral agreements between a group of providing countries (for example a regional co-operation) and one or several user countries. This approach can be highly relevant where the authorities of one country know that there will be a lot of bioprospecting activities from several different universities and companies in one particular country, it might be cost-effective for both sides to negotiate and conclude a bilateral *prior informed consent*.

ALTERNATIVE C: Through a multilateral agreement where several countries are both user country and providing country (for example the IT-PGRFA be seen as such a multilateral prior informed consent for a defined list of genetic resources).

Information about Use of Genetic Resources

A non-bureaucratic manner to oversee transfer of genetic resources can be to require registration of export and import of wild genetic resources. Such a registration system can be set up to achieve and accumulate information about the magnitude of transfers and

what kind of genetic resources that are exchanged. Such information can also be useful as a tool for ensuring conservation and sustainable use of biological diversity. It might also promote use of genetic resources rather than functioning as a tool of control and thus restrict access. The EU already requires registration of the cross-border exchange of forest tree genetic resources. Therefore, it can be useful to look into whether this form for registration can be used in respect of transfer of genetic resources in wild living organisms form one country to another. Such registration can be done at a focal point for genetic resources. The focal point can function as a service entity, providing information relevant for the users of genetic resources and thereby promoting access to genetic resources.

Discussion of Access Legislation

In this section, the Project Group discusses reasons for regulating access to genetic resources and requiring benefit sharing resulting from the use of them. The following viewpoints have been discussed in the Project Group:

- To leave access to genetic resources unregulated promotes free and open access, since everyone can search for and use interesting and useful material.
- The implementation of access legislation will typically require administration and financing. Given that the interest in looking for genetic resources in the Nordic countries may be rather limited, the costs for setting up such a system may not be worthwhile.
- All potential access legislation might lead to the development of bureaucratic procedures. Such procedures may hinder not only prospecting for commercial purposes but also hinder academic research.
- An argument in favour of regulating access to genetic resources is that the country can obtain a fair and equitable share of the commercial benefits that may arise from utilization of their genetic resources.

- On the other hand, the potential for substantial monetary benefits to be shared might be marginal.
- To establish a focal point can promote cooperation with other countries and thus provide for worldwide contacts for Nordic users of genetic resources.
- Establishing legislation and a common right of access to genetic resources can ensure access to the genetic resources for commercial as well as non-commercial research in the future, and thereby creating both public and private profit.
- By requiring prior informed consent, the providing country can establish a legal framework for the purpose of ensuring that the uses of genetic resources are environmentally sound, and thereby promote conservation of genetic diversity.
- To establish a counterpart in relation to the individualisation of rights over genetic resources (as for example to control that patents are not interfering with state of the art and to ensure that the patent claims do not cover more than the protected inventive step).

The Nordic countries are committed to the successful implementation of the CBD access and benefit-sharing regime. Thus, one element is to facilitate access to wild genetic resources. As Parties to the CBD the Nordic countries are obliged to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties in accordance with Article 15, paragraph 2. This, however, does not imply an obligation to establish a *prior informed consent*-procedure.

If the Nordic countries would require benefit sharing, this would have required a regulatory system in the Nordic countries, enabling them to control access to the resources.

The Project Group has in its discussions emphasised probable financial and administrative consequences from a regulatory system. This should be balanced against the possibilities of receiving sufficient benefits from such access legislation. Although the potential value of genetic resources in the Nordic countries is difficult to predict, and the need for regulation may differ for differ-

ent types of genetic resources, the Project Group believes that the potential benefits is not likely to make up for the administrative burden. In certain areas of some of the countries this might be different. Thus, the countries might consider this issue differently. The main conclusion from the Project Group is, however, that, for the time being, it has not found sufficiently convincing reasons to suggest regulating access to wild genetic resources. A less burdensome approach is to establish some kind of a register for access to genetic resources to acquire information about access to genetic resources.

Conclusion The Project Group does not, for the time being, find sufficiently convincing reasons to suggest regulating access to wild genetic resources, but recognises that there might be domestic variations in the view on this issue.

The Project Group recommends the Nordic countries to consider establishing a simple system of registering the collection of genetic resources in order gain better knowledge of the demand and value of genetic resources.

4.7 The Access Legislation of Other Parties

4.7.1 Framework Conditions

Presenting the Issue

All countries are both providers and users of genetic resources. The Project Group has so far focused on the Nordic countries as providers of genetic resources. In this chapter the scope changes so as to treat the Nordic countries as users of genetic resources from other countries.

Discussions on access legislation deal mainly with regulation of access to genetic resources in the providing countries. Developing countries have insisted that compliance with the regulation of access to genetic resources in the providing countries is an issue

that should be addressed by the COP of the CBD. From the view of all donor countries, and for developing countries in particular, it is of crucial interest that other Parties to the CBD ensure that their entities comply with access legislation.

From a user country perspective genetic resources from outside its borders will typically come from one of four main sources:

- Genetic resources under the jurisdiction of another country, and possibly subject to prior informed consent according to CBD article 15.
- Genetic resources covered by the scope of the Multilateral System of the IT-PGRFA.
- The genetic resources found in *ex-situ* collections from the time before the CBD entered into force.
- Genetic resources found outside the sovereign rights of other countries, for example in oceans beyond the territorial waters. CBD will in the near future deal with the issue of genetic resources in the deep sea-bed.

These four groups of genetic resources raise particular issues. A providing country has a legitimate right to enforce its access policies. It is in the interest of a gene bank or *ex-situ* collection that the user of the genetic resources complies with the terms of their MTA.

Problems and Challenges

From a donor country perspective there are two distinct situations: (1) where the genetic resources and associated knowledge are collected illegally;[81] and (2) where there exists an agreement with or permission from the right holder or relevant authority in the source country.

81. The term "biopiracy" is defined as a legal term in the Mesoamerican Agreement on Access to Genetic Resources, Biochemicals and Traditional Knowledge article 2 subsection 5, and is defined as "Extracción y/o uso de material bioógico con fines de acceso a los recursos genéticos o bioquímicos que contiene, realizada sin la obtención de la autorización de acceso correspondiente otorgada por la autoridad competente."

In the second case, non-compliance with the terms is a breach of contract. In international private law there exists international mechanisms for enforcing a private law agreement under the jurisdiction of another country. In the first situation, the bio-piracy will probably be regarded as a criminal offence. The international mechanisms for investigating and prosecuting such a criminal act are less developed than those of private law measures. Therefore, it will not be an easy task for the providing country to exercise its rights based on a criminal charge. The burden of proof is also different in the two situations: To be found guilty in a criminal charge the court has to find it proved *beyond reasonable doubt* that the crime was committed; whereas a breach of contract requires that it is proved to be more likely than the other alternative. Thus, to pursue bio-piracy as a criminal offence will probably not be efficient from the perspective of the providing country.

Several developing countries also mistrust the practice of certain patent offices and their practice regarding patent terms. This mistrust, true or false, is based on granted patents that are said to have appropriated genes or biological resources that have previously been well known and used. Those resources should according to the patent terms have been considered as prior art or as the property of the previous users. Therefore, one objective of this chapter is to discuss how a legal system enforcing compliance with the access legislation of the providing country is important to prevent misappropriation and the following mistrust.

Several developing countries lack the technical and legal capacity to apply suitable legal regimes and to enforce their rights. Also, developing countries will typically not have the resources to monitor all relevant granted patents to prevent their *prior art* to be included under a patent claim.

Bio-piracy can thus be a problem for user countries since it might build mistrust and may lead to restricted access to genetic resources. Consequently, research possibilities may be reduced. One inherent problem of regulating access is to identify the right "country of origin" as is the term used in the CBD.[82] The main rea-

82. CBD article 15. See the discussion of this in Chapter 2.1.2 above.

son for this is the historically extensive exchange of genetic resources throughout the world.

The main challenge of this chapter of the Report can be formulated as: Whether or not, and if so, how the Nordic countries should implement legal and other means to ensure that entities under their jurisdiction behave according to the legal provisions for access to these genetic resources.

Objectives

The specific objectives can be described as:

- To promote the short- and long-term access to and use of genetic resources from other countries.
- To contribute to the conservation of genetic resources.
- To promote a fair and equitable benefit sharing and sustainable use of genetic resources in accordance with the CBD and IT-PGRFA.
- To establish a legal framework for the use of genetic resources that builds trust and reduces the potential for misuse and misappropriation of genetic resources.

Identification of Stakeholders

The counterpart in the providing country can be for example: the government, a local representative, institutions, indigenous peoples and local groups, private persons and enterprises or an *ex-situ* collection and stakeholders in user countries.

Relevant International Agreements

According to CBD article 15 paragraph 2, the Parties commit themselves *"…not to impose restrictions that run counter to the objectives of this Convention."* The wording does not by its terms require a country to implement such legislation. According to CBD article 15 paragraph 7 the Parties:

> … shall take legislative, administrative or policy measures, as appropriate, and in accordance with Article 16 and 19 and, where necessary,

> through the financial mechanisms established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the benefits arising from the commercial and other utilisation of genetic resources.

According to this obligation countries shall *"take legislative, administrative or policy measures, as appropriate"* to ensure compliance with access legislation of other countries. This was further emphasised by the COP 5 in Nairobi that recommended:

> Countries that are receivers of genetic resources are encouraged to establish legal and other measures that are supporting countries providing genetic resources, for the purpose of ensuring that the management of them is accordance with cbd article 15 and 16.

Even though this recommendation is not legally binding according to the principles of international law, it emphasises the need for countries to take *legislative, administrative or policy measures* to ensure compliance. The wording is using the terms *"as appropriate"*, implies that the legally binding obligation is not very severe.

In spite of the uncertainty in strict legal terms, it cannot be denied that it would be an act of good faith and in support of implementing the CBD to apply measures with the aim to assist the enforcement of access regulation in countries providing genetic resources.

The Bonn Guidelines were developed and negotiated partly following an initiative of developing countries. Chapter *V. Other Provisions* addresses issues related to enforcement of access legislation of another country:

> **B. Accountability in implementing access and benefit-sharing arrangements**
>
> 52. Parties should endeavour to establish mechanisms to promote accountability by all stakeholders involved in access and benefit-sharing arrangements.
>
> 53. To promote accountability, Parties may consider establishing requirements regarding: Reporting; and Disclosure of information.

54. The individual collector or institution on whose behalf the collector is operating should, where appropriate, be responsible and accountable for the compliance of the collector.

C. National monitoring and reporting

55. Depending on the terms of access and benefit-sharing, national monitoring may include: Whether the use of genetic resources is in compliance with the terms of access and benefit-sharing; Research and development process; Applications for intellectual property rights relating to the material supplied.
56. The involvement of relevant stakeholders, in particular, indigenous and local communities, in the various stages of development and implementation of access and benefit-sharing arrangements can play an important role in facilitating the monitoring of compliance.

D. Means for verification

57. Voluntary verification mechanisms could be developed at the national level to ensure compliance with the access and benefit-sharing provisions of the Convention on Biological Diversity and national legal instruments of the country of origin providing the genetic resources.
58. A system of voluntary certification could serve as a means to verify the transparency of the process of access and benefit-sharing. Such a system could certify that the access and benefit-sharing provisions of the Convention on Biological Diversity have been complied with.

E. Settlement of disputes

59. As most obligations arising under mutually agreed arrangements will be between providers and users, disputes arising in these arrangements should be solved in accordance with the relevant contractual arrangements on access and benefit-sharing and the applicable law and practices.
60. In cases where the access and benefit-sharing agreements consistent with the Convention on Biological Diversity and national legal instruments of the country of origin of genetic resources have not been complied with, the use of sanctions could be considered, such as penalty fees set out in contractual agreements.

A decision by the sixth COP of the CBD has referred the further development of these issues to the next meeting of the Open-Ended Working Group on Access and Benefit Sharing.

The Intergovernmental Committee (IGC) under WIPO discusses this issue in their paper WIPO/GRTKF/IC/4/11, and will continue to discuss this topic at its next meeting.

The IT-PGRFA article 12.5 provides that:

> Contracting Parties shall ensure that an opportunity to seek resources is available, consistent with applicable jurisdictional requirements, under their legal systems, in case of contractual disputes arising under such MTAs, recognizing that obligations arising under such MTAs rest exclusively with the parties to those MTAs.

This is an obligation to establish legal mechanisms for dispute resolution that are available for the parties to the MTAs in all member countries to the Treaty.

The EU Directive, preamble subsection 27 expresses that:

> Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;

The disclosure of origin is only addressed in the preambular text and not in the legally binding text of the Directive. Thus, the EU Patent Directive does not require Member States to impose such requirements as a condition for granting a patent. The EU has in the TRIPS-Council expressed willingness to discuss the inclusion of similar text in the context of the TRIPS-Agreement.[83]

83. Communication by the European Communities and their Member States to the TRIPS-Council on the Review of the Article 27.3 (b) of the TRIPS-agreement and the relationship between the TRIPS-agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore.

Relevant Domestic Legislation

Denmark has, as mentioned under 3.2, implemented the EU Patent Directive by a Statutory Order to the Patent Act. The text of this Statutory Order is quoted above in 3.2.

In Norway a Governmental Working-Group that has considered the implementation of the EU Patent Directive, has come up with suggested recommendations on mechanisms for compliance with access legislation of other countries.[84] The Parliament Bill regarding the implementation of the EU Patent Directive addresses this topic, without any specific suggestions.[85] The ongoing working group, the so-called *Biomangfoldlovutvalget*, which has as one of its main tasks to provide suggestions for the implementation of the CBD in domestic legislation, can be expected to address this topic.

Sweden considers to implement a new § 5 a in a Statutory Order.

> If an invention concerns biological material from plants or animals, or if such material is part of the invention, the patent application shall provide information on the geographical origin, if this is known. The lack of information about the geographical origin or the lack of knowledge about it, shall not have any legal effects on the validity of the patent application or the rights that follows from a granted patent.[86]

In Finland and Iceland there is no relevant legislation.

4.7.2 Measures for the Regulation of Ensuring Compliance with Access Legislation

The following section outlines some suggestions for measures discussed by the Project Group. The suggestions are not exhaustive and not mutually exclusive.

84. The Report of the Governmental Working-Group.

85. Proposition to the Storting nr. 43 (2002–2003).

86. Unauthorised translation from Swedish for the purpose of this Report.

MEASURE A: Regulation of Import of Genetic Resources.
MEASURE B: Registration of the Use of Genetic Resources.
MEASURE C: A Condition for Being Granted Intellectual Property Rights.
MEASURE D: Not Conditional for Being Granted Intellectual Property Rights.
MEASURE E: Certification.
MEASURE F: No Regulation of the Issue.
MEASURE G: Possibility of Enforcement.
MEASURE H: Access to courts and administrative dispute resolution mechanisms.
MEASURE I: Information.

Measure A – Regulation of Import of Genetic Resources
One measure that has been suggested to enforce access legislation has been to control the *prior informed consent* or the *material transfer agreement* at the border of either the providing or user country. Because of the character of genetic resources, the fact that only very small quantities of biological material is needed to explore and exploit the resource, makes such enforcement of the legislation unrealistic. Therefore, this approach to control access is not practical.

Measure B – Registration of the Use of Genetic Resources
There is a possibility to require registration for all uses of genetic resources, as a measure to control that the user complies with the regulation of the source country. Registration of all use of genetic resources is, however, not practically feasible due to the large volume of genetic material being used.

Measure C – A Condition for Being Granted Intellectual Property Rights
In principle one could impose as a requirement for being granted an intellectual property right that the biological material has been acquired legally, *e.g.* that the patentee provides documentation of

the legality of the acquisition of the biological material. To add such an additional condition for being granted intellectual property protection is generally being perceived as not being in conformity with the TRIPS-agreement, the UPOV 91 Convention and the EU Patent Directive. Therefore, to impose such a condition is rather a theoretical option in the light of the current legal situation. Several NGOs along with certain developing countries emphasises that this alternative would ensure access legislation for all cases where IPR protection is sought.

Measure D – Not Conditional for Being Granted Intellectual Property Rights

A country can follow the example of the Danish decree and the Swedish proposal, by requiring disclosure of origin of genetic resources in the application for intellectual property rights. The absence of information can be followed by other sanctions, such as a penalty or requiring a higher patent fee. Such a requirement can be imposed without making it a condition for granting the patent. This alternative will give a clear indication that the country supports the principles embedded in the CBD: the sovereign rights to genetic resources and the right of a country to regulate access to the resources. It will probably also build trust among countries and therefore promote facilitated access to genetic resources in the future. This also will provide for a legal basis to balance the rights of the providing and the user of the genetic resources. This alternative can be a useful means to trace compliance with the access legislation of the providing countries and the conditions for prior informed consent.

The Project Group therefore supports this approach.

Measure E – Certification

Switzerland has launched the idea of a certification system for biosprospecting activities in which compliance with user country legislation will be a parameter for a certificate. For an in-depth analysis of this issue, see *Towards a Certification System for Bio-*

prospecting Activities.[87] The Swiss proposal first discusses potential ways to organise a Certification System. The proposal entails that certificates can be issued at three levels: local, national and at regional level based on cooperation between neighbouring states. It draws upon the experiences from other certification systems, and discusses how elements from these systems can be used for classifying exchange of genetic resources. It recommends that if a global system is envisaged, it should be set up in cooperation with the CBD.

The idea of a certification system is very much based on using market-mechanisms. Thus, this approach presupposes that there exists a commercial market for genetic resources. The total value of such a market is, however, uncertain.[88]

The Swiss proposal assesses the feasibility of a system of certifying bioprospecting activities.[89] It first points at the variety of types of transactions involving genetic resources, and that this will imply a challenge to a system. The proposal points at four major factors that must be taken into account:

1. The possible scale of the system.
2. The costs and the supporting funds.
3. The stakeholders that would participate in the system.
4. The relationship to other certification systems.

The proposal does not conclude by recommending or rejecting the idea of a certification system, but points to the need for further studies before conclusions of the feasibility of a certification system can be drawn. The Project Group supports further work to develop the idea.

Measure F: No Regulation of the Issue

One alternative is that the Nordic countries do not address this topic at all. However, the international pressure and the legitimate interest that access legislation should be complied with are strong

87. Glowka 2001.

88. For a profound analysis of this topic, see ten Kate and Laird 1999.

89. Glowka 2001 pp. 41–62.

arguments against this approach. Also, this would increase the international distrust regarding access and rights to genetic resources that would lead in the wrong direction. The Project Group therefore warns against such an approach to the issue.

Measure G: Possibility of Enforcement

The parties to an agreement on access have a reciprocal need for mechanisms to enforce the agreement. A means to enforce such agreements is to provide for efficient possibilities for the parties to use the legal system of the other country for these purposes. The Project Group consider this as a necessary approach and suggests that the countries further investigate how this can be achieved in their domestic legislation.

Measure H: Access to Courts and Administrative Dispute Resolution Mechanisms

To provide for access to courts and to administrative dispute resolution mechanisms can be a means to promote the access legislation of the provider country. This is closely related to measure G, and the Project Group therefore suggests that countries look into these topics in relation.

Measure I: Information

Sufficient information for all stakeholders and participants is a basic requirement of a well-functioning market. Information is a tool to achieve a well-functioning market. Thus, there is a need for proper information to all relevant users and providers of genetic resources on existing international legal frameworks as well as domestic legislation in this field; and that each participant must adhere to them. The Project Group recognises that there is a lack of such information in the Nordic countries, and therefore suggests that the Nordic countries take appropriate action to make relevant information available by the relevant authorities. The Project Group suggests that this might be a task for the Nordic Genetic Resource Council.

Suggestions from the Project Group

One reason for regulating this topic might be to emphasize conservation of biological diversity, fair and equitable benefit sharing and sustainable use of genetic resources in accordance with the CBD. Biotopes have typically economic value when used in commercial activities, for example forests can be exploited for timber, soil for agriculture, land for prospecting for oil or minerals. Even if the economic value of genetic resources *per se* cannot finance all conservation efforts, one reason behind the CBD was to establish an understanding of the value – also the economic value – of the biological diversity in *i.e.* non-timber use. Enforcing compliance with access legislation in other countries promotes this incentive.

The alternatives spelled out above are not mutually exclusive and one country might therefore choose to implement one or several of them.

Conclusion

The Project Group emphasises the need for building trust. The Project Group suggests that the Nordic countries implement and follow-up the Bonn guidelines to promote mutual trust. The Project Group presupposes that the CBD will follow up this issue. The Project Group emphasises that the relevant actors must take this issue seriously. The Project Group emphasises the need for information to users, both academic and commercial actors, about these regulations. Information can be a common Nordic project initiated by the Nordic Genetic Resources Council.

5 Conclusions and Recommendations

This chapter reflects the recommendations of Chapter 4. The discussions in Chapters 1–3 form the basis for these recommendations and will only be referred to when necessary.

5.1 The Nordic Gene Bank

The International Treaty on Plant Genetic Resources for Food and Agriculture represents the most important future legal framework for the Nordic Gene Bank. The Project Group acknowledges that a major aim for the Nordic Gene Bank is to ensure facilitated access and exchange of all its plant genetic resources for conservation, research and development purposes.

5.1.1 Clarifying the Legal Status

The Project Group recognises a need for clarifying the legal status of the plant genetic resources in the Nordic Gene Bank. The Project Group believes that an ambiguous legal status may cause uncertainty for the recipients of the material and will not facilitate the use of these plant genetic resources.

The Project Group recommends that:

- The Nordic Council of Ministers should be invited to declare that all the accessions of the Nordic Gene Bank, except for security collections held by the NGB of other gene banks, are under common Nordic management and control and in the public domain.

- The respective Nordic governments should confirm this decision nationally and declare that the accessions of the Nordic Gene Bank are in the public domain and under the common Nordic management and control.
- The Board of the Nordic Gene Bank should thereafter implement the decision.

5.1.2 Terms for Access and Benefit Sharing

The material of the Nordic Gene Bank is available according to the terms set out in the Material Transfer Agreement (MTA) of the Nordic Gene Bank. This agreement will soon have to be revised. About 90% of the accessions of the Gene Bank will fall under the scope of the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture. The facilitated access to these accessions will be according to the terms of access and benefit sharing of the International Treaty, upon its entry into force and subsequent implementation.

The Project Group emphasises the need for a simple and non-bureaucratic system that ensures facilitated access to all plant genetic resources in the Nordic Gene Bank and for all *bona fide* purposes.

The Project Group therefore recommends that:

- The Nordic Gene Bank should provide access to all its accessions according to the terms of the same MTA, regardless of whether they are covered by the scope of Multilateral System of the International Treaty or not.
- Access should be facilitated to all its accessions for all purposes, not only for use in the field of food and agriculture.
- The Nordic Gene Bank should not claim any monetary benefits, but promote benefit sharing within the Multilateral System. The Nordic Gene Bank should make it clear upon receiving the plant genetic resources that these will form part of the common public domain, and made available under the Multilateral System.

- The Board of the Nordic Gene Bank should consider the use of the provisional MTA of the International Agricultural Research Centres until the standard MTA enters into force.

5.2 Domesticated Plant Genetic Resources in the Nordic Countries

These resources include plant genetic resources in the Nordic countries of the same plant species as the mandate species of the Nordic Gene Bank. The Project Group emphasizes the need to ensure that all these plant genetic resources are made available for conservation purposes *e.g.* in NGB, and for information, research, breeding, and development purposes.

5.2.1 Legal Status

Plant genetic resources which are privately owned or subject to intellectual property rights will not be automatically included in the Multilateral System, even when these resources are covered by its scope. The Project Group has not been able to investigate relevant national law in the Nordic countries to this respect but stresses the importance of determining the legal status of the plant genetic resources. In order to ensure sustainable utilization of genetic resources there is a need to establish transparent and predictable conditions both for the users and providers of such resources.

The Project Group underlines the importance of such a clarification as a prerequisite for possible future regulations of access to such resources, even in countries that currently have no plans for such regulations.

The Project Group therefore recommends that the Nordic countries:
Investigate the need for determining the legal status of their plant genetic resources and consider the following possible options:

- To declare that the rights to use genetic resources follows the rights to access the biological material. (This alternative can be characterised as a non-exclusive right to use the genetic resources.)
- To specify that rights to biological resources include rights to restrict others from utilizing their genetic resources except on terms mutually agreed upon in private contractual agreements.
- To specify that rights to 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 can not exercise any control over genetic resources.

5.2.2 Terms for Access and Benefit Sharing

The implementation of a standard MTA for access to the species covered by the Multilateral System of the International Treaty will ensure a smooth exchange of the plant material between the Nordic countries, as well as between the Nordic countries and the Nordic Gene Bank. It would be practical if the same terms for facilitated access were applied also to the other mandate species of the NGB. This argument can also be put forward as a reason for not imposing any restrictions on the access at all, or at least not to impose more severe restrictions on the access than the NGB does for the same material. Using the same MTA will also create a transparent Nordic system and the transaction costs may well be lower. However, if one or more of the Nordic countries were to decide to implement more restricted access regimes to such plant genetic resources difficulties for the Nordic cooperation on these crops, both for collection activities as well as for the utilization of the genetic resources, may arise.

Also, bearing in mind that the Nordic countries were strong advocates for a system whereby the Multilateral System would cover all the crops, *the Project Group recommends that the Nordic countries:*

- Ensure that the coverage of the Multilateral System be as broad as possible, while respecting private property rights;
- Handle access to all plant genetic resources in the same manner.

5.3 Animal Genetic Resources for Food and Agriculture

It is important to take into account the different breeding methods for plants and animals when addressing policy and legislative measures for these two categories. The breeding of animals for production also has the purpose of genetic improvement, *i.e.* constitutes a step in a breeding programme. Variation within the productive population is therefore of crucial importance for the progress that may be achieved. Exchange of genetic resources is valued as important for increasing the genetic variation in plants. In animals, however, introduction of high yielding homogenous breeds, at the expense of lower yielding breeds of higher genetic variations, will in the end represent a threat to the overall genetic variation.

5.3.1 Legal Status

Exchange of animal genetic resources is usually regulated by private contractual agreements. Such contracts may also include limitation for the use of the off-spring. This is, however, a very regulated area, and currently there seem to be no need for further clarification of the legal status.

The Project Group has:

- Not identified any current needs for countries to change the present legal status of animal genetic resources.

5.3.2 Access and Benefit Sharing

There is no internationally negotiated standard MTA for access to animal genetic resources. The MTAs that are used are private contractual agreements, which seem to function well.

The Project Group:

- Has not found convincing reasons to suggest regulations regarding the exchange of animal genetic resources.
- Recommends that the Nordic countries take appropriate measures to stimulate sustainable management of animal genetic resources.

5.4 Forest Tree Genetic Resources

Forest trees are characterised by a long rotation period and exceptional reproductive capacity. The trees might be regarded as semi-cultivated and only a few species have high commercial value. In forest tree breeding it is common to make a selection amongst individual trees. Selected trees are then used for seed production or multiplied as clones.

5.4.1 Legal Status

In most of the Nordic countries the forest tree genetic resources are mainly found on private property while the breeding and cultivation activities are conducted by governmental or non-commercial organisations. The public has, in Finland, Norway and Sweden a right to public access to private land. Such rights do also to some extent include rights to collect cones and other plant material that could be suitable for breeding and multiplication of trees. There seems to be, however, a trend towards the forest own-

ers claiming commercial benefits from trees on their properties that have been successful in a breeding programme and subsequently gives rise to forest trees of improved productivity. Such claims, however, may form obstacles to the breeding activities and create uncertainty and low predictability for the breeders, a situation which in the long run might be a drawback for the forest owners. The Project Groups recognises the need to determine the rights of breeders of access to forest tree genetic resources.

The Project Group recommends that the Nordic countries:

- Determine the legal status of their forest tree genetic resources.

5.4.2 Access and Benefit Sharing

The Project Group identifies the need to ensure free and open exchange of forest tree genetic resources in the future. Increased use of different contractual agreements would increase bureaucracy and may create an obstacle to the future development of forest tree genetic resources. The long rotation period of trees and the low commercial profit from the sale of seeds also indicate that it currently may be difficult to introduce regulations of access and benefit sharing to forest tree genetic resources.

The Project Group concludes that:

- There are no convincing reasons to suggest regulations regarding the exchange of forest tree genetic resources.

5.5 Wild Genetic Resources

Wild genetic resources include wild growing plants, except the wild relatives of the species covered by the IT-PGRFA Annex I, wild animals, most marine species and micro-organisms.

5.5.1 Legal Status

The legal status of wild genetic resources has not been determined in any of the Nordic countries.

The Convention on Biological Diversity specifies the sovereign rights to genetic resources as a right for the countries to require giving their *Prior Informed Consent* (PIC) before having access to genetic resources. The CBD specifies that this is an optional right of the countries, *"unless otherwise determined"*. The Nordic countries have not implemented any relevant domestic legislation regulating access to genetic resources. Denmark and Sweden have officially determined that for the time being, they do not intend to require a *prior informed consent*.

The Project Group recognises the need for a predictable legal situation in order to promote sustainable use of wild genetic resources. A predictable legal status could also facilitate any future needs to regulate access to such resources.

The Project Group recommends that the Nordic countries:

- Determine the legal status of the wild genetic resources and by this establish the legal basis for possible regulation of access to wild genetic resources in the future.

5.5.2 Access and Benefit Sharing

The Project Group believes that the Nordic countries should facilitate access also to wild genetic resources to the extent possible in accordance with article 15 paragraph 2 of the CBD. Free access to genetic resources may facilitate any inventions and development made on the basis of such resources.

With regard to a *prior informed consent* procedure to control access to genetic resources and trigger benefit sharing from the use, the Project Group holds the view that the potential benefits can hardly make up for the administrative burden of creating such a regulatory system, although future benefits are difficult to pre-

dict and the situation may differ for different types of genetic resources.

Therefore 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.

The Project Group recommends that the Nordic countries:

- Consider the establishment of a simple system of reporting to the competent authority on the collection of wild genetic resources. This kind of information would lead to a better understanding of the demand and value of wild genetic resources.

5.6 The Access Legislation of Other Parties

Discussions on access legislation have mainly focused on regulations in the providing countries. Developing countries are increasingly insistent that the issue of how user countries (typically developed countries) ensure compliance with access regulation in the providing countries should be on the CBD agenda, and the newly adopted Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilisation also include this aspect.

Regardless of whether measures in user countries are required in strict legal terms according to the CBD, the Project group considers the application of measures with the aim of assisting the

enforcement of access regulation in the providing countries as an act of good faith, trust building and support for the CBD objectives. The Project Group therefore suggests that the Nordic countries follow up on the Bonn Guidelines and take action in this field. The Project Group has discussed the following not mutually exclusive measures:

- Regulation of import of genetic resources.
- Regulation and record keeping on the use of genetic resources.
- Requirement for disclosure of origin of genetic resources in Intellectual Property Rights applications as a condition for Intellectual Property Rights.
- Requirement for disclosure of origin of genetic resources in Intellectual Property Rights applications but not as a condition for granting Intellectual Property Rights (as already enacted by Denmark and under consideration in Sweden and Norway).
- Certification.
- Possibility of enforcement.
- Access to courts and administrative dispute resolution mechanisms.
- Information to potential users of genetic resources on the CBD access and benefit sharing requirements.

The Project Group believes that there is lack of knowledge and consciousness among users of genetic resources on their obligations to comply with access and benefit sharing requirements. This latter measure is believed to be an important first step for complying with the access legislation of other Parties. The development of a relevant information strategy could be a common Nordic Project initiated by the Nordic Genetic Resource Council.

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Appendices

Appendix I:
Annex I to the Bonn Guidelines.
Appendix II:
The current MTA of the NGB.
Appendix III:
The provisional MTA of the CGIAR-FAO.

APPENDIX I

Decision VI/24
Access and benefit-sharing as related to genetic resources

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization

SUGGESTED ELEMENTS FOR MATERIAL TRANSFER AGREEMENTS

Material transfer agreements may contain wording on the following elements:

A. Introductory provisions

1. Preambular reference to the Convention on Biological Diversity
2. Legal status of the provider and user of genetic resources
3. Mandate and/or general objectives of provider and, where appropriate, user of genetic resources

B. Access and benefit-sharing provisions

1. Description of genetic resources covered by the material transfer agreements, including accompanying information
2. Permitted uses, bearing in mind the potential uses, of the genetic resources, their products or derivatives under the material transfer agreement (e.g. research, breeding, commercialization)
3. Statement that any change of use would require new prior informed consent and material transfer agreement
4. Whether intellectual property rights may be sought and if so under what conditions
5. Terms of benefit-sharing arrangements, including commitment to share monetary and non-monetary benefits
6. No warranties guaranteed by provider on identity and/or quality of the provided material
7. Whether the genetic resources and/or accompanying information may be transferred to third parties and if so conditions that should apply
8. Definitions
9. Duty to minimize environmental impacts of collecting activities

C. Legal provisions

1. Obligation to comply with the material transfer agreement
2. Duration of agreement
3. Notice to terminate the agreement
4. Fact that the obligations in certain clauses survive the termination of the agreement
5. Independent enforceability of individual clauses in the agreement
6. Events limiting the liability of either Party (such as act of God, fire, flood, etc.)
7. Dispute settlement arrangements
8. Assignment or transfer of rights
9. Assignment, transfer or exclusion of the right to claim any property rights, including intellectual property rights, over the genetic resources received through the material transfer agreement
10. Choice of law
11. Confidentiality clause
12. Guarantee

APPENDIX II

Monetary and non-monetary Benefits

1. Monetary benefits may include, but not be limited to:

a. Access fees/fee per sample collected or otherwise acquired;
b. Up-front payments;
c. Milestone payments;
d. Payment of royalties;
e. Licence fees in case of commercialization;
f. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
g. Salaries and preferential terms where mutually agreed;
h. Research funding;
i. Joint ventures;
j. Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

a. Sharing of research and development results;
b. Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;
c. Participation in product development;
d. Collaboration, cooperation and contribution in education and training;
e. Admittance to *ex situ* facilities of genetic resources and to databases;
f. Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
g. Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
h. Institutional capacity-building;
i. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
j. Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
k. Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
l. Contributions to the local economy;
m. Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
n. Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
o. Food and livelihood security benefits;
p. Social recognition;
q. Joint ownership of relevant intellectual property rights.

APPENDIX II

Agreement

This Agreement, made and entered into on 22 October 2003 between the Nordic Gene Bank, (hereinafter denoted "NGB"), P.O. Box 41, SE-230 53 Alnarp, Sweden, and

(hereinafter denoted "the Recipient", acknowledges that NGB and the Recipient, relating to seed sample of .....
(crop or species)

with the quantity of .....
(grams or distribution bags)

hereinafter called "the Material",

hereby agree that the Material shall only be used for

.....

research / trial / plant breeding / training / demonstration
(please exclude what does not apply), in accordance with the conditions below.

- NGB shall make available to the Recipient, the quantities of the Material specified above.
- the Recipient shall only use the Material for the purposes stated above.
- the Recipient shall *not* distribute the Material to third Party.
- the Recipient shall provide to NGB any information and results relating to trials assessments and experiments carried out by the Recipient on the Material for inclusion in the NGB's genetic resources database and thereby be available to other users.
- the Recipient shall send copies of publications or patent reference number citing use of the Material to NGB.
- the Recipient shall indemnify NGB against any claims arising out of the use of the Material.
- the Recipient shall defray the expenses for phytosanitary declaration, if requested.

This agreement has been issued in duplicate of which each Party has one copy.

....

Recipient's signature NGB's signature

APPENDIX III

Draft revised material transfer agreement for plant genetic resources held in trust by the [centre]*

The plant genetic resources (hereinafter referred to as the "material") contained herein are being furnished by the [Centre] under the following conditions:

The [Centre] is making the material described in the attached list available as part of its policy ofmaximizing the utilization of material for research, breeding and training. The material was eitherdeveloped by the [Centre]; or was acquired prior to the entry into force of the Convention on Biological Diversity; or if it was acquired after the entering into force of the Convention on Biological Diversity, it was obtained with the understanding that it could be made available for any agricultural research, breeding and training purposes under the terms and conditions set out in the agreement between the [Centre] and FAO dated 26 October 1994.

The material is held in trust under the terms of this agreement, and the recipient has no rights to obtain Intellectual Property Rights (IPRs) on the material or related information.

The recipient may utilize and conserve the material for research, breeding and training and maydistribute it to other parties provided such other parties accept the terms and conditions of this agreement.[91]

The recipient, therefore, hereby agrees not to claim ownership over the material, nor to seek IPRs over that material, or its genetic parts or components, in the form received. The recipient also agrees not to seek IPRs over related information received.

The recipient further agrees to ensure that any subsequent person or institution to whom he/she may make samples of the material available, is bound by the same provisions and undertakes to pass on the same obligations to future recipients of the material.

* The attention of the recipient is drawn to the fact that the details of the MTA, including the identity of the recipient, will be made publicly available.
** This does not prevent the recipients from releasing the material for purposes of making it directly available to farmers or consumers for cultivation, provided that the other conditions set out in this MTA are complied with.

The [Centre] makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the material being furnished. The phytosanitary condition of the material is warranted only as described in the attached phytosanitary certificate. The recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material.

Upon request, the [Centre] will furnish information that may be available in addition to whatever is furnished with the material. Recipients are requested to furnish the [Centre] with related data and information collected during evaluation and utilization.

The recipient of material provided under this MTA is encouraged to share the benefits accruing from its use, including commercial use, through the mechanisms of exchange of information, access to and transfer of technology, capacity building and sharing of benefits arising from commercialization. The [Centre] is prepared to facilitate the sharing of such benefits by directing them to the conservation and sustainable use of the plant genetic resources in question, particularly in national and regional programmes in developing countries and countries with economies in transition, especially in centres of diversity and the least developed countries.

The material is supplied expressly conditional on acceptance of the terms of this Agreement. The recipient's acceptance of the material constitutes acceptance of the terms of this Agreement.

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Access and Rights to Genetic Resources
A Nordic Approach

This report from the Nordic project group on rights and access to genetic resources mandated by the Nordic Genetic Resources Council addresses various aspects related to rights and access to genetic resources in the Nordic countries.

The report examines all genetic resources, whilst pointing out relevant differences between types of resources. The report studies the rights and access to the genetic resources managed by the Nordic Gene Bank.

It also provides recommendations and alternatives for rights and access to genetic resources within the Nordic countries. It gives an overview of needs for and means of implementing the provisions of the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) and other international agreements in the Nordic countries.

The report further analyses how rights and access to genetic resources relate to international law on intellectual property rights applied to genes and living organisms.

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