

International agreements relating to plant genetic resources for food and agriculture and implications for Dutch policy

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Policy issues related to plant genetic resources are socially, technically and scientifically complex. This report summarises the international agreements and relevant bodies concerning plant genetic resources for food and agriculture, including the Convention on Biological Diversity (CBD), FAO Global Plan of Action on Plant Genetic Resources (GPA), the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA), the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the World Intellectual Property Organization (WIPO), and the International Convention for the Protection of New Varieties of Plants (UPOV). The various obligations arising from these conventions and treaties are reviewed. In so doing, this report concentrates exclusively on implications for plant genetic resources for food and agriculture while most of the agreements concern other resources and/or issues. The relationship between the agreements is analysed with reference to the evolution of policy priorities from promoting use of genetic resources to supporting conservation, in part through the sharing of benefits arising from use. In addition, the implications for genetic resources policy in the Netherlands are outlined and existing initiatives to fulfill these obligations are highlighted.

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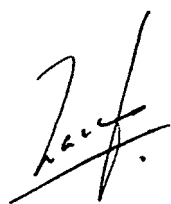
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Preface

This report was written within the framework of the research project, 'Organisation of the conservation of agricultural genetic resources', financed by the LNV/DLO research programme 'Integratie Mens- en Maatschappijwetenschappen (Gamma)'. Researchers from LEI (Derek Eaton and Jos Bijman) collaborated with CGN (Electra Kalaugher). The objective of this project was to analyse the institutional organisation of the conservation of agricultural genetic resources in the Netherlands.

This report provides detailed background material to a separate LEI report (No. 7.03.14), *Conservering van genetische bronnen voor de landbouw in Nederland; Organisatie en institutionele inbedding* (Conservation of agricultural genetic resources in the Netherlands; Organisation and institutional framework). That report describes the principal actors involved in the conservation and management of agricultural genetic resources in the Netherlands. Given the significant implications of international agreements and policies for the determination of Dutch policy, as well as their effects on various other actors, this current report was written and produced as a separate document given the considerable complexity of the issues involved.

A draft of this report was read and commented on by Rob van Raalte of the Department of International Affairs of the Dutch Ministry of Agriculture, Nature Management and Food Quality (LNV) and also by Chris van Winden of the Ministry's Department of Agriculture. The authors would like to thank these individuals for their detailed and constructive comments.



Prof. Dr. L.C. Zachariasse
Director General LEI B.V.

Summary

This report summarises the international agreements relating to plant genetic resources for food and agriculture. The various obligations arising from these conventions and treaties are reviewed with attention for potential interactions between such obligations. In addition, the implications for genetic resources policy in the Netherlands are outlined and existing initiatives to fulfill these obligations are highlighted.

Policy issues related to plant genetic resources are socially, technically and scientifically complex. They are also often highly controversial, particularly in light of recent developments in genetic research, which have led to an increase in the perceived commercial value of plant genetic resources. These developments, coupled with a longstanding mutual interdependence between countries for genetic resources, have reinforced the global nature of the topic and highlighted the range of different groups and individuals with vested interests in related issues, including breeders, agribusinesses, farmers, consumers, environmentalists, governments and international organisations.

A number of international instruments have been developed over the years in different fora to address these complex issues. The present array of international instruments can be considered in two main categories, according to their objectives:

- Those working towards the conservation and sustainable use of plant genetic resources and the equitable sharing of benefits arising from their use, such as the Convention on Biological Diversity (CBD), the FAO Global Plan of Action on Plant Genetic Resources (GPA), and more recently the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA); and
- Those aiming to protect intellectual property, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), (inter)national patent legislation, and *sui generis* systems of intellectual property protection such as the plant breeder's right under the International Convention for the Protection of New Varieties of Plants (the UPOV Convention).

Convention on Biological Diversity (CBD)

The CBD was signed by over 150 governments at the 1992 United Nations Conference on Environment and Development (UNCED) and came into force in 1993. The objectives of the CBD are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the use of genetic resources. The CBD recognises the national sovereignty of each country over genetic resources originating within its jurisdiction, and provides a framework of general principles for regulating the international exchange of genetic resources, referred to as 'mutually agreed terms' (MAT) and 'prior informed consent' (PIC). In 2002, the countries that have signed the CBD adopted the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization. These provide guidance for the development of national legislation and on contracts for benefit-sharing. The

Bonn Guidelines are voluntary and do not strictly entail legal obligations on parties involved in negotiating access and benefit-sharing. The Guidelines allow for such parties to take legal, administrative or policy measures to support compliance with PIC and MAT. Provisions are also suggested for access and benefit sharing in material transfer agreements (MTA), the name given to contracts governing the exchange of genetic resources.

While the CBD concerns all forms of biological diversity, domesticated and cultivated species of plants and animals have specific characteristics that complicate the implementation of the Convention. Most importantly, the widespread exchange and use of these species in the past makes the identification of a 'country of origin' quite difficult. The special nature of agricultural genetic resources has thus been recognised within the CBD.

Global System for Plant Genetic Resources

The Global System for Plant Genetic Resources refers to a collection of programs and plans overseen by the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the United Nations Food and Agriculture Organization (FAO). A key element is the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture (GPA), adopted in 1996. The GPA consists of a recommendations and activities that is intended to act as a framework and catalyst for initiatives at various levels to conserve and manage genetic resources.

International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA)

The IT-PGRFA was concluded in 2001 and will come into force once it has been ratified by forty countries. The IT-PGRFA complements the GPA, and can even be seen as part of the Global System. The new treaty is intended to resolve specific issues relating to agricultural biodiversity in the CBD.

The IT-PGRFA establishes a multilateral system (MS) for access and benefit-sharing. The MS applies to all plant genetic resources of a specified list of species and that are in the public domain. The list of species is referred to in Annex 1 of the IT-PGRFA and includes most major food crops and a list of important forages. The compiling of the list was a result of extensive negotiations and some notable crops, such as groundnut and tomato, was withheld.

Facilitated access to material held in the public domain of Annex 1 species is to be provided pursuant to a standard material transfer agreement (MTA). This will not entail any costs exceeding those required for handling and administration of the transfer. Furthermore, the MTA will require that recipients of material only have an obligation to share commercial benefits from the use of the material in breeding of new varieties if the availability of such new material is restricted, in particular through patent protection. Protection by means of plant breeders' rights will not automatically trigger any benefit-sharing provisions.

The IT-PGRFA also incorporates the important germplasm collections of the international agricultural research centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). The vast majority of the collections of the IARCs consist of Annex 1 species but current collections of other species held by IARCs will also be made available according to the same terms.

Material of non-Annex 1 species appearing in the public domain after the entry into force of the CBD will be subject to the terms of the CBD's Bonn Guidelines, and thus bilateral negotiation between the parties concerned. These terms will also apply to material of non-Annex 1 species acquired by IARCs after the entry into force of the IT-PGRFA. But the specific terms for material of non-Annex 1 species (not held by IARCs) collected before the entry into force of the CBD remain unclear and are not specified.

With the entry into force of the IT-PGRFA, there will thus be effectively three different groups of germplasm within the public domain: the MS, non-Annex 1 species subject to the CBD's Bonn Guidelines, and those with unclear status. The IT-PGRFA is thus an attempt to secure continued unencumbered exchange of plant genetic resources for breeding purposes. It is possible that further species may be added to the MS in the future.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The second grouping of international agreements concerns intellectual property rights (IPR). The most important is arguably TRIPS, which came into force in 1995 under the umbrella agreement establishing the World Trade Organization (WTO). The TRIPS Agreement applies thus to all WTO members. TRIPS establishes minimum standards for all forms of IPR protection.

TRIPS requires countries to offer patent protection for all inventions but allows an exclusion to be made for plants and animals (other than micro-organisms). Protection is however required for plant varieties, if not by patents, then at least by an effective *sui generis* system. Plant breeders' rights are considered to be the relevant option for such a system although TRIPS does not prescribe any particular variants.

Although TRIPS does allow members to preclude plants from patentability, the patent protection must be available for inventions pertaining to non-biological and microbiological processes for the production of plants and animals. This includes various applications developed in biotechnology, including genetic modification.

Within the European Union, national compliance with these provisions of TRIPS is meant to be ensured by EC Directive 98/44/EC on the legal protection of biotechnological inventions. Directive 98/44/EC states that plant and animal varieties are not patentable, but patents are to be made available for biotechnological inventions that are not confined to a single plant or animal variety. The Directive also clarifies the relationship between plant variety protection and patent protection where these two may overlap.

World Intellectual Property Organization (WIPO)

WIPO is a UN specialised agency that administers international treaties dealing with different aspects of intellectual property protection and promoting international harmonisation of IPR systems. In the area of PGRFA, WIPO is investigating, in collaboration with other international bodies, possibilities for the protection of the property rights of indigenous and traditional communities. WIPO is also collaborating with UPOV on the relationship between plant variety protection and patent protection for biotechnological inventions.

International Union for the Protection of New Varieties of Plants (UPOV)

UPOV is an international convention establishing agreement between its members on specific provisions of national plant variety protection legislation. Successive Acts of the

UPOV Convention in 1961, 1972, 1978 and 1991 have incrementally extended the scope of protection to be granted with a Plant Breeder's Right (PBR). Two major limitations to this protection were initially the breeders' exemption and the farmers' privilege. The breeders' exemption allows the use of a protected variety in further, commercial breeding activities. The farmers' privilege allows farmers to use harvested seed from cultivated protected varieties. The 1991 UPOV Act restricted the farmers' privilege to an optional exception. Partly for this reason, many developing countries have opted for the 1978 Act.

Relationship between the agreements

The international agreements relating to agricultural plant genetic resources were developed at different periods in time, and address an evolving policy agenda with respect to conservation, use and appropriation of benefits. In general, the agreements are complementary. The IT-PGRFA and the CBD recognise the common property nature, whether national or international, of existing plant varieties and establish conditions for their international exchange for use in breeding efforts. UPOV and TRIPS have allowed the creation of (intellectual) property rights, to be held by individual stakeholders such as companies, institutes and individuals, over newly created varieties. Uncertainties remain though as to the terms for access and exchange to some plant genetic resources which are not covered by the IT-PGRFA and also potentially not by the CBD.

The manner in which governments implement legislation to respect the conditions placed on the use of genetic resources by the IT-PGRFA and the CBD needs to take into account provisions of the TRIPS Agreements, and possibly UPOV. Under both the CBD and the IT-PGRFA, restrictions and conditions will be placed on the receiver of genetic material with respect to intellectual property protection that may subsequently be sought. Such restrictions can be incorporated into contractual agreements, such as Material Transfer Agreements. But the Bonn Guidelines for Access and Benefit-Sharing of the CBD also requires governments to take 'appropriate legal, administrative, or policy measures to support compliance with PIC and MAT. It has been suggested that governments should amend their IPR legislation for such purposes. Some amendments could be in conflict though with TRIPS and potentially with other IPR treaties. This would be the case, for example, for a requirement that patent applicants disclose the geographical origin or source of any biological material covered in a patent application, as a condition for granting patent protection. Because of conflicts with TRIPS, such a disclosure requirement has been proposed, for example in the EC Directive 98/44/EC, but in a such a way that it not be considered a formal condition for patent approval. Avoiding conflicts between these various agreements requires a proactive examination of the interaction of proposed national legislation.

Implications for the Netherlands

The Netherlands participates in all of the instruments described in this document and considers that 'international obligations regarding intellectual property, trade, agriculture and biodiversity are mutually reinforcing'. Government policy relating to agricultural genetic resources is presented in the document Sources of Our Existence, adopted in 2002. Dutch government policy documents on nature management and the environment, Nature for People, People for Nature and the 4th National Environmental Policy Plan are also relevant.

In addition, the International Policy Programme Biodiversity 2002-2006 indicates how a number of biodiversity-related policy commitments will be implemented, concentrating on international aspects.

Government policy is that the private sector, researchers and other organisations or stakeholders will be expected to assume most of the responsibility for implementing policy commitments. The government facilitates and supports this implementation, with an emphasis on national and international exchange of expertise and information. The government has thus concluded that additional legislation on the subject of genetic resources is not appropriate or necessary at this moment. This strategy depends on transparency over the management and use of genetic resources. In this regard, the Netherlands has supported at European level the requirement for disclosure of origin of biological material in patent applications.

To support the implementation of policy, the government has supported the establishment of a Genetic Resources Platform. This is to consist of representatives from the business sector, research organizations, social organizations and the government. The platform is to address, among other issues, the development and use of codes of conduct for various actors in order to support the implementation of government policy.

The Netherlands is thus an example of a country of the North trying to promote a solution with minimal adjustments to existing IPR agreements, which many developing countries would prefer to see. At this point, it is difficult to predict whether this approach will achieve the results desired by various stakeholders.

List of Acronyms

BBI	<i>Biodiversity International Policy Programme of the Netherlands 2002-2006 (Internationaal Beleidsprogramma Biodiversiteit 2002-2006)</i>
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (German Ministry for Economic Cooperation and Development)
CBD	Convention on Biological Diversity
CBS	Centraalbureau voor Schimmelcultures (Fungal Biodiversity Center)
CGIAR	Consultative Group on International Agricultural Research
CGN	Centre for Genetic Resources, the Netherlands (Centrum voor Genetische Bronnen Nederland)
CHM	Clearing-House Mechanism for Scientific and Technical Cooperation
CGRFA	Commission on Genetic Resources for Food and Agriculture
COP	Conference of the Parties
DLO	Dienst Landbouwkundig Onderzoek (Dutch Agricultural Research Service)
EC	European Commission
ECP/GR	European Cooperative Programme of Crop Genetic Resources Networks
EIARD	European Initiative for Agricultural Research for Development
EU	European Union
EURISCO	European Internet Search Catalogue
FAO	Food and Agriculture Organisation of the United Nations
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GPA	Global Plan of Action for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture
IARCs	International Agricultural Research Centers
IT-PGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IPR	Intellectual Property Right
IU	International Undertaking on Plant Genetic Resources
IUCN	World Conservation Union
LMOs	Living Modified Organisms
LNV	Ministerie van Landbouw, Natuurbeheer en Visserij (Dutch Ministry of Agriculture, Nature Management and Fisheries)
MAT	Mutually Agreed Terms
MS	Multilateral System
MTA	Material Transfer Agreement
NMP4	<i>4e Nationaal Milieubeleidsplan (Fourth National Environmental Policy Plan)</i>
NGO	Non-Governmental Organization
NIPS	Netherlands International Partnership for Sustainability

NvM	<i>Natuur voor Mensen, Mensen voor Natuur (Nature for People, People for Nature)</i>
NVZP	Nederlandse Vereniging voor Zaaizaad en Plantgoed (Dutch Seed Trade Association)
PADELIA	Partnership for Development of Environmental Law and Institutions in Africa
PGRFA	Plant genetic resources for food and agriculture
PIC	Prior Informed Consent
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SoE	<i>Sources of our Existence (Bronnen van ons Bestaan)</i>
SZH	Stichting Zeldzame Huisdierrassen (Dutch Rare Breeds Foundation)
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation
UNCED	United Nations Conference on Environment and Development
UNCTD	United Nations Centre for Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environmental Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPOV	International Union for the Protection of New Varieties of Plants

1. Introduction

Policy issues related to plant genetic resources are socially, technically and scientifically complex. They are also often highly controversial, particularly in light of recent developments in genetic research, which have led to an increase in the perceived commercial value of plant genetic resources. These developments, coupled with a longstanding mutual interdependence between countries for genetic resources, have reinforced the global nature of the topic and highlighted the range of different groups and individuals with vested interests in related issues, including breeders, agribusinesses, farmers, consumers, environmentalists, governments and international organizations.

A number of international instruments have been developed over the years in different fora to address these complex issues, often with potentially conflicting goals. The present array of international instruments can be considered in two main categories, according to their objectives:

- Those working towards the conservation and sustainable use of plant genetic resources and the equitable sharing of benefits arising from their use, such as the Convention on Biological Diversity (CBD), the FAO Global Plan of Action on Plant Genetic Resources (GPA), and more recently the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA); and
- Those aiming to protect intellectual property, such as the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), (inter)national patent legislation, and sui generis systems of intellectual property protection such as the plant breeder's right under the International Convention for the Protection of New Varieties of Plants (the UPOV Convention).

The diversity of interests in the issues at stake is reflected both in government representation in the negotiation of the instruments and in the international organisations that provide fora for negotiations. The first group of instruments was negotiated by ministries of environment and agriculture and is overseen and influenced by international organizations such as the United Nations Environmental Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO). The second group was predominantly negotiated by ministries of economic affairs, in association with the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).

In order to formulate sound national policy that fulfils international obligations under the different agreements, the relationships within and between these two categories of instruments must be clarified and reinterpreted at the national level. This report examines the array of obligations under the different instruments and what they mean for plant genetic resources policy in the Netherlands.

The first section of this report provides an overview of the international policy frameworks for the conservation of plant genetic resources, including their objectives, scope and means of implementation, as well as their relationship to each other and to the

international organizations that oversee their implementation. The second section examines the potential impact of these international treaties, agreements and organizations on Dutch government policy.

2. International Agreements

2.1 The Convention on Biological Diversity

Background and objectives

The Convention on Biological Diversity (CBD) was signed by over 150 governments at the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, and came into force in 1993. The CBD recognized for the first time that the conservation of biological diversity is 'a common concern of humankind'. The Convention is a legally binding agreement that applies to all ecosystems, species, and genetic resources. As of October 2002, the CBD has 186 Parties, including the Netherlands and the European Union.¹ Its objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.²

Implementation

The CBD is implemented through thematic work programs - at the national level by governments, and at the regional and international levels through regional and international agencies. A number of international structures support its implementation, including:

- the Conference of the Parties (COP), the governing body of the Convention, which advances implementation of the Convention through the decisions it takes at its periodic meetings (to date the Conference of the Parties has held 6 ordinary meetings, and one extraordinary meeting, resulting in a total of 146 procedural and substantive decisions);
- the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), which is composed of experts and provides advice to the COP;
- the Secretariat, which organizes meetings, facilitates international collaboration and responds to requests from the COP;
- the Clearing-House Mechanism for Scientific and Technical Cooperation (CHM); and
- a financial mechanism operated by the Global Environment Facility (GEF).

In addition to the thematic work programs of the CBD, there are a number of cross-cutting issues addressed by the CBD of relevance to all thematic areas, including biosafety; access to genetic resources; traditional knowledge, innovations and practices (Article 8(j)); intellectual property rights; public education and awareness; incentives; and others. Some

¹ See the website of the CBD at www.biodiv.org

² Convention on Biological Diversity, Article 1

cross cutting initiatives directly support work under thematic programs, while others can develop more independently - for example, the negotiations for a protocol on biosafety.

Relationships with other international agreements and organisations

One of the five thematic programs of the CBD is the program of work on agricultural biodiversity. The CBD Secretariat works closely with FAO on agricultural biodiversity-related issues, a relationship that has been formalized through a memorandum of understanding. The program of work encompasses agreed FAO plans and programs such as the Global Plan of Action for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture and the State of the World reports on plant and animal genetic resources. In particular, a close relationship has been maintained between the CBD and FAO in the context of the negotiations for the revision of the International Undertaking on Plant Genetic resources (IU) in harmony with the CBD. The revision of the IU was based on the Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity (1993), which recognized, the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular (a) access to ex-situ collections not acquired in accordance with this Convention; and (b) the question of Farmers' Rights.

At its second meeting in Jakarta, 1995, the COP took note of the Global System on Plant Genetic Resources for Food and Agriculture, recalled the Nairobi Final act and declared its support for the adaptation of the International Undertaking on Plant Genetic Resources.¹ Subsequent meetings have urged the completion of these negotiations, resulting in the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA; Section 2.3).

The CBD Secretariat has signed memoranda of understanding outlining areas for potential cooperation with a number of other international organizations and secretariats of international environmental agreements. For example, COP Decision VI/24 invites the World Intellectual Property Organization (WIPO) to prepare a technical study on methods, consistent with obligations in treaties it administers, for requiring the disclosure of information relating to genetic resources within patent applications, and to report its findings to the CBD's COP VII meeting (scheduled to take place in Kuala Lumpur in February 2004).

The relationship between the CBD Secretariat and the WTO is the subject of more tension than with other environmental organizations and agreements, in particular regarding the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). COP Decision VI/24 notes the interrelationship between the provisions of TRIPS and the CBD, and the fact that the relationship between the TRIPS agreement and the CBD is being examined by the TRIPS Council.²

Content of the CBD

In practice, the Convention establishes a range of general, flexible obligations that emphasize national action for conservation and sustainable use, while recognizing sovereign rights to set up environmental policy and exploit natural resources. It also provides a

¹ Decision II/15

² In conformity with Article 19 of the Doha WTO Ministerial Declaration, adopted in November 2001

framework of general principles for structuring the international exchange of genetic resources, based on the national sovereignty of each country over genetic resources originating within its jurisdiction (Bragdon and Downes 1998). It establishes that the right to determine access to genetic resources rests with national governments and is subject to national legislation.

National sovereignty over genetic resources is an important principle for developing countries, many of whom have expressed concern about the protection of their interests relative to bioprospecting from companies and research institutes from industrialised countries. Such organisations are more likely to have the technology for product development, and can obtain IPRs and patents on novel products to protect investments in research and development. However, the recognition of national sovereignty over genetic resources poses a number of problems when it comes to practical application. Plants do not stop growing at national boundaries and may therefore originate from more than one country, and in many cases it is hard to determine the 'original' origin of a plant variety, particularly domesticated plants that may have been considerably modified from their 'original' state. According to Fowler (2000):

Due to scientific and practical problems associated with the definition of Country of Origin in the Convention on Biological Diversity, it is unlikely that the CBD, as it now stands, could be easily, efficiently, or frequently followed in regards to domesticated and cultivated species.

The CBD (Article 15) establishes that exchange of genetic resources must be based on 'Mutually Agreed Terms (MAT)' and subject to 'Prior Informed Consent (PIC)'.¹ The interpretation of these concepts into national legislation, however, is the responsibility of national governments. Some 50 countries (mostly developing countries) have already developed, or are developing, laws and other policy measures to regulate access to genetic resources and benefit sharing. Existing national and regional regulations and draft regulations differ considerably in the extent to which they define PIC and MAT, and with whom PIC must be achieved and MAT be negotiated - national agency and/or local community or landowner. Benefit-sharing arrangements are also a matter to be defined on a case-by-case basis.

PIC can be organized at three levels of law, all enforcing the sovereign right of the countries over the genetic resources (Tvedt 2002):

1. individual agreements between the providing country and the entity using the genetic resources, depending on the access legislation of the providing country;
2. by bilateral agreements between one providing country and one user country. Bilateral agreement between one providing country and a group of user countries (for example the European Union). Bilateral agreements between a group of providing countries (for example a regional co-operation) and one or several user countries;
3. multilateral agreements where several countries are both user country and providing country (for example can the IT-PGRFA be seen as such a multilateral prior informed consent for a defined list of genetic resources). (Tvedt 2002, page 53).

¹ See annex 1 for a fuller description of these concepts

In Article 8 (j), the CBD obligates its member countries (as far as possible, as appropriate and subject to national legislation) to 'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles' that are relevant to biodiversity. This important goal presents a number of practical problems, for which the onus for resolution falls on national governments. The political and social structures of traditional communities may not be consistent with western legal conceptions and administrative regulations. Intellectual property of local and indigenous communities is difficult to protect under many existing regimes because the rights involved are collective and intergenerational in character. Also, such rights may not satisfy the criteria for IPR protection under current regimes such as novelty, inventiveness and capability of industrial application.¹ In a number of cases (e.g. the Executive Order No. 247 of the Philippines² and the Costa Rican Law on Biodiversity), Prior Informed Consent is required from indigenous or local communities involved as well as from the landowner and/or administration of the protected area, as the prerequisite for receiving state permission (BMZ 2001). This requires overcoming not only cultural and language barriers but also in many cases a lack of trust for any form of bioprospecting.

Conformation with national agreements that have been based on the CBD principles of PIC and MAT has generally been through bilateral agreements, often obtained after long and bureaucratic processes.

While the general principles of the CBD on access emphasize national action, they do not mandate bilateral transactions, nor do they preclude parties from establishing or entering into a multilateral system of regulating access. The new Multilateral System of the IT-PGRFA may greatly facilitate access and benefit sharing for its mandated crops (see section 2.3), in harmony with the CBD.

The Bonn Guidelines

To assist Parties in implementing the access and benefit-sharing provisions of the Convention, the Conference of the Parties recently adopted the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Decision VI/24, The Hague, April 2002). The guidelines, based on the recommendations of the first meeting of the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing (Bonn, Germany, in October 2001), provide guidance on the development of national legislation, and on contracts for benefit-sharing. They are meant to assist Parties, Governments and other stakeholders when establishing legislative, administrative or policy measures on access and benefit sharing and/or when negotiating contractual arrangements for access and benefit sharing.³

¹ Handbook on the Implementation of Conventions Related to Biological Diversity in Africa. (PADELIA)

² Executive Order No. 247 (Philippines) www.elaw.org/resources/text.asp?ID=257

³ CBD website on the Bonn guidelines at www.biodiv.org/programmes/socio-eco/benefit/bonn.asp

Box 1: Selected key elements of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization

- **Relationship with relevant international regimes:** The guidelines should be applied in a coherent manner 'mutually supportive' of the work of relevant international agreements and institutions (especially IT-PGRFA and taking into account the work of WIPO)... and take into account existing regional legislation and agreements.
- **National Focal Point:** Each Party should designate one national focal point for access and benefit sharing and make such information available through the clearing-house mechanism.
- **Competent national authority(ies):** Where established, competent national authorities may be responsible for granting access and advising on aspects such as the negotiating process, PIC and MAT requirements, mechanisms for participation of stakeholders, etc.
- **Responsibilities:** A number of responsibilities for Parties are outlined, including review of administrative and legal measures for compliance with Article 15, reporting on access applications e.g. through the CHM, and ensuring harmony with environmental objectives and the needs of local and traditional communities (including capacity building). In general, Parties should fulfil their role in a transparent and objective fashion, and establish mechanisms to ensure that decisions are made available.
- **Prior Informed Consent(PIC) and Mutually Agreed Terms (MAT):** Contracting parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures to support compliance with PIC and MAT. The Guidelines also provide an outline of steps in the access and benefit-sharing process, including principles and elements for a PIC system and MAT.
- **Participation of Stakeholders:** Relevant stakeholders should be consulted and their views taken into account in each step of the process, including in developing access and benefit-sharing arrangements and developing of national strategies; Appropriate consultative arrangements should be made such as national committees of representatives. The involvement of stakeholders should also be promoted through the provision of information and support for capacity building.
- **Material Transfer Agreements:** The guidelines provide suggested elements for Material Transfer Agreements, including access and benefit-sharing as well as legal provisions.

The voluntary Guidelines are viewed as a first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit sharing. They are to be kept under review by the COP and further refined as appropriate.

2.2 FAO and the global programs for genetic resource conservation and sustainable use, including the Global Plan of Action

The Global System on Plant Genetic Resources

The programs and plans monitored and coordinated by FAO on plant and animal genetic resources are considered vital elements that contribute to the CBD program of work on agricultural biodiversity. However, the development of the Global System on Plant Genetic Resources considerably predates the Convention - it began in 1983 with the establishment of the FAO Commission on Plant Genetic Resources (now the Commission on Genetic Resources for Food and Agriculture - CGRFA). The objectives of the Global System are to ensure the safe conservation, and promote the availability and sustainable use of plant genetic resources by providing a flexible framework for sharing benefits and burdens. The

CGRFA, with its Intergovernmental Technical Working Group on Plant Genetic Resources for Food and Agriculture, monitors and co-ordinates the development of the Global System.¹

The Global System comprises

- the International Undertaking on Plant Genetic Resources (which formed the basis for the development of the IT-PGRFA);
- the Global Plan of Action (GPA) for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture;
- the State of the World report on plant genetic resources;
- a variety of codes of conduct and scientific standards (the Code of Conduct for Germplasm Collecting and Transfer, Gene Bank Standards and Guidelines, and the Code of Conduct on Biotechnology), and;
- technical mechanisms (the crop and thematic networks, the International Network of Ex Situ Collections, and the World Information and Early Warning System).

The Global Plan of Action

A key element of the Global System is the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture (GPA), which was adopted by 150 countries at the Fourth International Technical Conference in Leipzig in 1996. The GPA is intended to provide a comprehensive global framework for action towards the conservation and sustainable utilization of Plant Genetic Resources for Food and Agriculture (PGRFA). The GPA was developed through a country-driven process that included 158 country reports, 12 sub-regional and regional meetings, and the preparation of the State of the World report on plant genetic resources.

The GPA is a set of recommendations and activities that follow on from the State of the World Report. It is intended as a framework, guide and catalyst for action at the community, national, regional and international level. It seeks to create an efficient system for the conservation and sustainable use of plant genetic resources, through better cooperation, co-ordination and planning and through the strengthening of capacities.²

The GPA describes 20 Priority Activities in four areas:

- in Situ Conservation and Development;
- ex Situ Conservation;
- utilization of Plant Genetic Resources; and
- institutions and Capacity Building.

Following the Plan's adoption at the Leipzig Conference, countries and institutions and organization concerned with Plant Genetic Resources have begun to use their own resources and existing capacity to implement the Plan. The Country Progress Report on the implementation of the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture (CGRFA-9/02/6, 2002), based on a survey of 177 National Focal Points, noted that national priorities continue to concentrate

¹ Source: FAO/CGRFA website at www.fao.org/ag/cgrfa

² Source: FAO/CGRFA website at www.fao.org/ag/cgrfa

on ex situ conservation activities (Activity areas 5 to 8), inventorying and surveying plant genetic resources (Activity area 1), and on building strong national programs (Activity area 15). According to the report, a significant number of activities are being undertaken to implement many activity areas of the Plan, however additional work is required at all levels to further implement all activity areas, particularly those related to Institutions and Capacity Building. The report notes the conclusions of the Inter-governmental Technical Working Group on Plant Genetic Resources (ITWG-PGR) that 'in many countries the lack of financial resources was constraining the full implementation of the Plan' and that there is a 'need for more coordination between stakeholders within countries and the need for more attention to the activities of stakeholders' (paragraph 3, page 1).

Relationship with other instruments

There are very close linkages between the GPA and the IT-PGRFA. Article 14 of the IT-PGRFA recommends that Contracting Parties 'should promote (the GPA's) effective implementation, including through national actions and, as appropriate, international cooperation to provide a coherent framework, for capacity-building, technology transfer and exchange of information, taking into account the provisions of Article 13', and in article 13.2, the Contracting Parties agree that 'benefits... 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, taking into account the priority activity areas in the rolling Global Plan of Action...'. The mutually supportive nature of these two agreements implies that activities under one will generally contribute to the implementation of the other - and thereby also to the implementation of the CBD.

2.3 The International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA)

The International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) concluded in 2001, is the result of negotiations to revise the previous International Undertaking (IU) on Plant Genetic Resources. Born in 1983, the non-binding IU was the first comprehensive international agreement dealing with plant genetic resources for food and agriculture. The IU recognized that 'plant genetic resources are a heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations' (preamble). The IU thus promoted the free international exchange of these resources. With the entry into force of the CBD in 1993, there was a need to revise the IU to bring it into harmony with this new agreement (FAO Commission on Genetic Resources for Food and Agriculture - CGRFA Resolution 7/93), resulting in the IT-PGRFA.

The objectives of the IT-PGRFA are the 'conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security' (Article 1).

Content

The IT-PGRFA itself applies to all plant genetic resources for food and agriculture, and a number of general provisions are laid out in the treaty to address the conservation and sustainable use of PGRFA (articles 5 and 6). The IT-PGRFA complements the existing Global Plan of Action, stating that 'Contracting Parties should promote...effective implementation (of the GPA)' (Article 14).

The centrepiece of the IT-PGRFA is a multilateral system (MS) for access and benefit sharing. The MS seeks to ensure that contracting parties have easier access to germplasm stocks for an agreed list of major crops and forages, contained in Annex 1 of the IT-PGRFA (see annex 4). The MS pertains to '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'¹ (article 11.2). Other holders of PGRFA included in annex 1 of the IT-PGRFA are invited to include such material in the MS.

Annex 1 of the IT-PGRFA comprises a fairly comprehensive list of most major food crops and a list of important forages. The list, based on 'criteria of food security and interdependence' (article 11), was the subject of extensive negotiations. A number of crops did not find place in the final list despite a relatively high contribution to global energy intake: Soybean, groundnuts, sugar cane, the wild relatives of cassava included in the genus *Manihot*, and tomato were controversial omissions (Cooper 2002).

For the MS, no distinction is made between material collected before and after the entry into force of either the treaty or the CBD.

The IT-PGRFA also addresses the important collections held 'in trust' by the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR).²

With the entry into force of the IT-PGRFA, there will effectively be three different groups of accessions or crop varieties within the public domain according to the terms of international access and exchange:

1. the MS (or available under effectively similar conditions):
 - varieties and ex situ accessions of crops included in the MS (annex 1 of the IT-PGRFA) and under the public domain (including IARC collections)
 - to this may be added ex situ accessions of crops not included in the MS, held by IARCs and received before the entry into force of the IT-PGRFA (essentially all of the relevant IARC collections)
2. subject to the CBD's Bonn Guidelines:
 - ex situ accessions of crops not included in the MS, collected after the entry into force of the CBD³ (or if held by an IARC, collected after entry into force of the IT-PGRFA)

¹ It should be noted that the treaty does not define the scope of the public domain. The simplest interpretation consists essentially of what is held in public, or publically-financed, genebanks. A more comprehensive definition of this term is to define all genetic resources that are not subject to intellectual property rights as under the public domain (Tvedt 2002). Distinctions can also be made between the physical resource and the genetic information embodied in that resource such as DNA, gene and genotype information (Correa 1994). Further precision of this term may be an issue to be resolved by the Governing Body of the IT-PGRFA.

² IARC refers here exclusively to research centres of the CGIAR.

³ 29 December 1993

3. those with unclear status concerning access/exchange:
 - ex situ accessions of varieties of crops not included in the MS, collected before the entry into force of the CBD (excluding such accessions held in an IARC)

Table 2.1 relates the status of germplasm in the public domain to the nature of the collection. As can be seen, the situation of the IARC collections introduces some complications into this typology. The vast majority of IARC collections consist of Annex 1 crops and these come under the MS. There are also collections held by IARCs of crops not listed in Annex 1, in particular soybeans, groundnuts and most species of tropical forages (Fowler et al 2003). According to the IT-PGRFA, these existing collections will be made available according to terms that will be similar to those for the MS. Thus such accessions, but not their respective species, can be seen as falling effectively under the MS. This provision reflects also the fact that IARC collections are held 'in trust' for the benefit of the international community according to a 1994 Agreement between the IARCs and the FAO, pending the conclusion of the negotiations for the IT-PGRFA. Fowler et al (2003) point out though that these collections risk being 'frozen in time' as provisions of the CBD will apply to any further accessions collected after the entry into force of the IT-PGRFA, potentially inhibiting further collection and research activities.

As noted above, the legal status of non-Annex 1 species and material collected pre-CBD that falls under public domain (and not held in an IARC) is still unclear in the sense that it is not covered by an international agreement. In principle, the relevant governmental authorities may determine themselves the conditions for access and benefit sharing. Countries whose governments negotiated in favour of a broad list of crops for the Multilateral System might be expected to maintain similar terms of access for such material.

Facilitated access to 'Annex 1' crops and forages is to be provided pursuant to a standard material transfer agreement (MTA), 'as well as the benefit-sharing provisions set forth in Article 13.2d(ii) and other relevant provisions of this Treaty' (article 12.4). In addition, the conditions of the original MTA should be applied to any subsequent transfers of the material. Material 'shall be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses...' (Article 12.3(a) of the IT-PGRFA).

Limitations are placed on claiming any new intellectual property rights on material received from the MS:

'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; (Article 12.3(d)).'

The term 'components' will still require further interpretation and definition. Fowler et al (2003) suggest that the interpretation of 'in the form received' involves equally controversial issues as some countries had contradictory opinions during the negotiations as to whether this precluded (utility) patenting of isolated, purified genes as is possible in the U.S. Note that recipients will be able to claim IPRs (patents and plant breeder's rights as

permitted by national legislation) on derivatives of the received material i.e. on new varieties or inventions which incorporate the received material.¹

Table 2.1: *International legal status of plant genetic resources in the public domain*

Legal Status ⁵	Crop species included in Multi-lateral System (Annex 1) ¹	Crop species not in Multilateral System (MS) ¹			
		Held in IARC ²		Not held in IARC ²	
		collected pre-IT-PGRFA ³	collected post-IT-PGRFA ³	collected pre-CBD ⁴	collected post-CBD ⁴
	Multilateral System MTA	Effectively Multi-lateral System ⁶	Bonn Guidelines	Not clear	Bonn Guide lines

Notes

1. Crops included in the MS are listed in Annex I of the IT-PGRFA.
2. International Agricultural Research Centre of the Consultative Group on International Agricultural Research (CGIAR).
3. The IT-PGRFA will come into force once 40 countries have ratified it.
4. The CBD came into force 29 December 1993. Note though that for public collections in countries that have not signed the CBD, all relevant material would not have any there is no distinction the U.S.A. is an example of a country that has not signed the CBD. This meaning that the international legal status of accessions held exclusively in public collections in the U.S. is also technically unclear. The U.S. has though signed the IT-PGRFA and it would therefore seem consistent for authorities responsible for public collections to follow a strategy of relatively easy access.
5. Refers to internationally agreed terms for international exchange (access and benefit-sharing).
6. Article 15.1(b) of the IT-PGRFA states that plant genetic resources 'other than those listed in Annex I...and collected before its entry into force that are held by the IARCs shall be made available in accordance with the provisions of the MTA currently in use.... This MTA shall be amended...in accordance with the relevant provisions of this Treaty, especially Articles 12 and 13....' This amounts to these resources effectively being included within the Multilateral System with respect to access and benefit-sharing provisions.

Farmers' Rights was another issue that resulted in a controversial compromise (Cooper 2002). The IT-PGRFA recognizes the basis for Farmers' Rights in

'...the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centers of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world (Article 9.1).'

¹ For a fuller description of key concepts and definitions see Annex 1

'...and agrees that 'in accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

- protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
- the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
- the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture' (Article 9.1).'

The responsibility for implementing Farmers' Rights, however, lies with national governments. The IT-PGRFA does not recognise any rights, for example, to save, use, exchange or sell farm-saved seed. Rather the basis for Farmers' Rights is reflected in the essentially international provisions for benefit sharing and finance. Article 13.3 of the IT-PGRFA notes that benefits 'should flow primarily, directly and indirectly, to farmers in all countries, especially in developing countries, and countries with economies in transition, who conserve and sustainable utilize plant genetic resources for food and agriculture.'

Benefit sharing under the IT-PGRFA

Benefit sharing in the MS is addressed in Article 13 of the IT-PGRFA. Benefits are to be shared at a general level through information exchange, access to and transfer of technology, capacity building and the sharing of monetary and other benefits of commercialisation. With respect to commercialisation, the IT-PGRFA states that

'the standard Material Transfer Agreement ... shall include a requirement that a recipient who commercializes a product ... that incorporates material accessed from the Multilateral System, shall pay to the (financial) mechanism ... 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 commercializes shall be encouraged to make such payment (Article 13.2 d (ii))'

This means that if the product is protected by a patent and thus restricted from further use in commercial breeding for example, then a payment to the financial mechanism is required. On the other hand, if the product consists of a plant variety that is protected only with a plant breeder's right, then such a payment will only be encouraged.¹

The financial mechanism referred to in the IT-PGRFA is to be established by the Governing Body (Article 19). The level, form and manner of the payment are to be determined by the Governing Body at its first meeting, 'in line with commercial practice' (Article 13.2 d (ii)). According to Article 13.2 d (ii), the Governing Body may also

¹ Provided the Breeder's Exemption applies; see Sections 2.6 and 2.8.

'decide to establish different levels of payment for various categories of recipients who commercialize 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. The Governing Body may, from time to time, review the levels of payment with a view to achieving fair and equitable sharing of benefits, and it may also assess, within a period of five years from the entry into force of this Treaty, whether the mandatory payment requirement in the MTA shall apply also in cases where such commercialized products are available without restriction to others for further research and breeding.'

Some observers expect that the number of instances of monetary benefit-sharing under the IT-PGRFA may initially be limited, given the time to develop new varieties as well as the fact that many potential users have their own PGRFA collections (Cooper 2002).

According to Article 15.1 (b) (iii), 'benefits arising under the...MTA that accrue to the mechanism shall be applied, in particular, to the conservation and sustainable use of the plant genetic resources for food and agriculture in question, particularly in national and regional programs in developing countries and countries with economies in transition, especially in centers of diversity and the least developed countries'. As mentioned in section 1.2, the closely linked objectives of the IT-PGRFA and the GPA mean that activities carried out in this context should also contribute to the implementation of the GPA.

Benefit sharing is a controversial issue. Identifying an appropriate level, manner and form of benefit sharing in the context of the IT-PGRFA will present one of the main challenges to the Governing Body at its first meeting.

Implementation

The IT-PGRFA will enter into force on the ninetieth day after the deposit of the fortieth instrument of ratification, acceptance, approval or accession. As of 10 December 2002, 78 states had signed (including the Netherlands and the European Community) and eleven had ratified, accepted, approved or acceded to the IT-PGRFA.¹ The CGRFA will act as the Interim Committee for the IT-PGRFA, until it enters into force.

As mentioned above, a Governing Body will promote the implementation of the IT-PGRFA (see box). The Governing Body will be composed of all Contracting Parties, who will each have one vote. All decisions of the Governing Body shall be taken by consensus 'unless by consensus another method of arriving at a decision on certain measures is reached'.

¹ Source: FAO legal website at www.fao.org/Legal/TREATIES/033s-e.htm

Box 2: The Governing Body of the IT-PGRFA

While the establishment of the International Treaty can be seen as a major achievement, many issues surrounding its implementation will still need to be resolved by the Governing Body. Article 19.3 notes that 'the functions of the Governing Body shall be to promote the full implementation of this Treaty, keeping in view its objectives'. Particular tasks of the Governing Body will include

- **Guiding implementation:** This will include providing policy direction and guidance and adopting plans and programmes for the implementation of the IT-PGRFA and the MS. The Governing body will also be responsible for establishing any necessary subsidiary bodies and adopting any required amendments to annexes to the IT-PGRFA
- **Establishing financial procedures:** The Governing Body will be responsible for adopting and periodically reviewing the funding strategy for the implementation of the IT-PGRFA, including the level, form and manner of payments to be made to the financial mechanism under the MS, and the budget for the IT-PGRFA. It may also need to establish an appropriate mechanism, such as a Trust Account, for receiving and utilizing financial resources.
- **Cooperating with relevant international organisations:** The Governing Body will be responsible for maintaining the relationship with the CBD, and other relevant international organizations and treaty bodies, and for approving the terms of agreements with the IARCs and other international institutions.
- **Adopting a Standard MTA:** Last but certainly not least, the Governing Body will be responsible for adopting a standard MTA for the MS.

2.4 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the agreements adopted in 1994 at the close of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade (GATT). It came into force in 1995 under the umbrella agreement establishing the WTO.

TRIPS and other WTO agreements are binding upon the 131 countries that are members of the WTO, with strong incentives for compliance including a dispute-settlement mechanism that provides for the imposition of trade sanctions (including sanctions on trade in unrelated products) against a Member found in violation of the Agreement.

Content

The TRIPS Agreement encompasses all forms of intellectual property and aims at harmonizing and strengthening standards of protection and providing for effective enforcement at both national and international levels. Important provisions include that of national treatment: property rights conferred at a national level must apply to nationals of all WTO member states. In addition, any advantage, privilege or immunity granted to a national of any other country must be accorded immediately and unconditionally to the nationals of all WTO members (most-favored-nation treatment).

Standards that are particularly important for PGRFA are found in Article 27 of TRIPS. Paragraph 1 requires that, subject to the provisions of paragraphs 2 and 3, 'patents shall be available for any inventions, whether products or processes, in all fields of tech-

nology, provided that they are new, involve an inventive step and are capable of industrial application'. Article 27.3(b) of the TRIPS agreement allows Members to exclude from patent ability '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 they are obliged to provide some form of intellectual property protection of plant varieties, 'either by patents or by an effective sui generis system or by any combination thereof'.¹

TRIPS currently allow considerable flexibility in the protection afforded to plant varieties. No specific requirements for a sui generis system are set down in the TRIPS Agreement other than that it be 'effective' (in protecting intellectual property). The International Union for the Protection of New Varieties of Plants (UPOV) is one existing international sui generis system that can fulfil this requirement, and a number of developing countries have reacted to these stipulations by signing one or other of the two valid versions of the UPOV Convention (UPOV 1978 and UPOV 1991; see Section 2.6 of this report). The UPOV Convention is designed to serve the needs of commercial seed breeders; however, for many developing countries, issues such as Farmers' Rights are insufficiently addressed by the UPOV convention and they have opted for the development of a national or regional sui generis system (e.g. the Indian Act No. 123 of 1999 for the protection of plant varieties and Farmers' Rights, which is enacted but not yet in force). On the other hand, in the United States, both (utility) patents and plant varietal protection are available for plant varieties.²

Implementation

The operation of the TRIPS Agreement and Members' compliance with its terms is monitored by the TRIPS Council, based in Geneva. The Council provides Members with a forum for consulting on TRIPS issues, and provides assistance to members as requested including assistance regarding dispute settlement. It is one of a number of institutions for monitoring implementation of WTO agreements, modifying or interpreting them if needed, negotiating new trade agreements and resolving disputes under existing ones. The Council generally meets formally four times a year, and also holds several informal sessions. Inter-governmental agencies may attend Council sessions, but NGOs may not (Bragdon and Downs 1998).

It was agreed that Article 27.3(b), was to be reviewed 'four years after the date of entry into force of the WTO Agreement.' The review of Article 27.3(b) began in 1999. At the Fourth World Trade Organization (WTO) Ministerial Conference held in Doha, Qatar in November 2001, the WTO Members agreed to launch a new round of multilateral trade negotiations that will have important implications for agriculture, fisheries and forestry. A substantial work program was agreed in the area of environment and trade, and the new round will also include a revision of TRIPS, in particular article 27.3 (b) on patentability of plant and animal inventions, and the protection of plant varieties.

The Doha Declaration also states that work in the TRIPS Council on these reviews or any other implementation issue should also look at: the relationship between the TRIPS

¹ See annex 1 on key terms

² Vegetatively-propagated plant species are eligible for a third category of protection, plant patents, in the United States.

Agreement and the UN Convention on Biological Diversity; the protection of traditional knowledge and folklore; and other relevant new developments that member governments raise in the review of the TRIPS Agreement. The deadline for negotiations specifically mandated in Doha Declaration is the 1 January 2005.

2.5 The World Intellectual Property Organization (WIPO)

WIPO is a UN specialized agency that administers 23 international treaties dealing with different aspects of intellectual property protection and reviews the suitability of existing instruments for the protection of property rights (i.e. patents, variety protection, copyrights, trade secrets etc.). In general, WIPO serves to promote international harmonisation of intellectual property systems, to facilitate information exchange and to support developing countries developing IP systems. WIPO currently has 179 member states¹.

With respect to PGRFA, WIPO is undertaking a number of activities with the International Union for the Protection of New Varieties of Plants (UPOV), aimed at clarifying the relationship between protection for plant varieties and patent protection for biotechnological inventions (see Sections 2.7 and 2.8).

WIPO is investigating, in collaboration with other international bodies, possibilities for the protection of the property rights of indigenous and traditional communities, when their knowledge and innovations are commercialized and marketed. This includes studying whether specific instruments of property rights protection (*sui generis*) need developing, if the indigenous peoples' requirements for protection cannot be met through the implementation of the established instruments. At WIPO's 26th General Assembly (September-October 2000), member states decided to establish a special body to discuss intellectual property issues related to genetic resources, traditional knowledge and folklore. This body, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held its first session in Geneva, April-May 2001.

The work of WIPO is in line with the work of the CBD on traditional knowledge. An echo is found in the CBD-COP decision V/16 on Article 8(j) and related provisions, which

'Recognizes the potential importance of *sui generis* and other appropriate systems for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use, to meet the provisions of the Convention on Biological Diversity, taking into account the ongoing work on Article 8(j) and related provisions, and transmits its findings to the World Trade Organization and the World Intellectual Property Organization'

In addition, as mentioned in section 1.1, The COP-CBD recently invited WIPO to prepare a technical study on the potential for disclosure of information relating to genetic resources within patent applications.

¹ Source: WIPO website at www.wipo.org

2.6 Plant Breeders' Rights and the UPOV Convention

The International Union for the Protection of New Varieties of Plants (UPOV) came into existence in 1961. Under the UPOV Convention, member states acknowledge the accomplishments of breeders of new plant varieties by making available to them exclusive rights of exploitation. The UPOV Convention was revised in 1972, 1978 and 1991. The 1961 Act of the Convention entered into force in 1968, the Additional Act of 1972 in 1977, the 1978 Act in 1981, and the 1991 Act on 24 April 1998. As of July 2003, UPOV comprised 53 members, mostly from industrialised countries.

UPOV provides for the granting of the Plant Breeder's Right (PBR) where 'the variety is new, distinct, uniform and stable', which in the 1991 Act mean that the following acts in respect of the propagating material of the protected variety require the authorization of the breeder (Article 14: Scope of the Breeder's Right):

- production or reproduction (multiplication);
- conditioning for the purpose of propagation;
- offering for sale;
- selling or other marketing;
- exporting;
- importing;
- stocking for any of the purposes mentioned in (i) to (vi), above.

The breeder may also make his authorization subject to conditions and limitations. In the 1978 Act, prior authorization of the breeder is required only for purposes of commercial marketing, offering for sale, or marketing of the reproductive or vegetative propagating material of the variety.

The 1978 Act allowed farmers to use protected varieties fairly freely for cultivation, known as the 'farmers' privilege'. The Act of 1991 restricted this privilege to an optional exception to the breeder's right that allows Contracting Parties to

'...within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right 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...'

Although the 1991 Act does not include the above 'farmers' privilege', it still maintains a restriction on PBRs: private, non-commercial and experimental acts are allowed, as well as for acts done for the purpose of breeding other varieties (known as the 'breeder's exemption'). Developing countries that have signed the UPOV Convention have generally opted for the less restrictive 1978 Act.

Like other forms of intellectual property rights, the breeder's right is granted for a limited period of time, at the end of which protected varieties pass into the public domain.

UPOV works in close contact with the World Intellectual Property Organization of the United Nations (WIPO), with which it has concluded a cooperation agreement. The Of-

Office of UPOV is under the direction of a Secretary-General who is, by agreement between UPOV and WIPO, is the Director-General of WIPO.

2.7 EU Directive on patenting of biotechnological inventions

The TRIPS Agreement requires that WTO member states offer patent protection for biotechnological inventions relating to other biological material and microbiological processes. In the European Union, EC Directive 98/44/EC, adopted in July 1998 obliges member states to offer such patent protection.

The Directive determines that plant and animal varieties are not patentable (as is allowable under TRIPS). To be eligible for protection, an invention, which concerns plants or animals, must not be technically confined to a single plant or animal variety.

According to the Directive, member states are required to offer patent protection for inventions that consist of 'biological material, which is isolated from its natural environment or produced by means of a technical process...' (Art 3, para 2). The Directive thus provides for the patenting of the isolation of (partial) sequences of genes contained in a plant variety provided the industrial application is disclosed and, as stated above, that this application is not confined to only that plant or animal variety.

Furthermore, Directive 98/44/EC indicates that a patent application for an invention that is based on plant or animal biological material should include information on the geographical origin of such material, if known, although this is without prejudice to the processing of patent applications. In 2002, the EC issued a communication to the TRIPS council in which it proposed that disclosure of origin was desirable but should not be formally required within patent law. This potentially avoids conflicts with TRIPS while ensuring that a means of monitoring compliance with the conditions on patentability stipulated for receivers of material from the Multilateral System of Facilitated Access and Benefit-Sharing (see section 1.6).

Regarding the relationship with TRIPS and the CBD, the Directive states (article 1 para 2) that 'this Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPS Agreement and the Convention on Biological Diversity'. It also notes that the European Community is party to the Convention on Biological Diversity and that '...Member States must give particular weight to Article 3 (on national sovereignty) and Article 8(j) (on traditional knowledge), the second sentence of Article 16(2)¹ and Article 16(5)² of the Convention when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive'. The Directive further notes the observation in CBD Decision III/17 that 'further work is required to help develop a common appreciation of the relationship between intel-

¹ 'In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights'(Article 16.2 of the CBD, second sentence)

² 'The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives' (Article 16.5 of the CBD)

lectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity'.

2.8 The relationship between the agreements

Historical developments

The international agreements relating to agricultural plant genetic resources were developed at different periods in time. The history of these agreements (represented in the timeline contained in Annex 2) reflects the evolution of various policy and management issues of major concern. These issues may be summarised as:

- Conserving plant genetic resources;
- Ensuring access to and use of plant genetic resources, particularly for breeding efforts (for all stakeholders, in the North and in the South);
- Distribution of the benefits arising from the use of plant genetic resources amongst a range of stakeholders (especially states, seed breeders, farmers, and rural communities).

The various international instruments have focused on different aspects of these issues. To address these issues, the various agreements have created or recognised certain property rights over agricultural genetic resources for different stakeholders.

The UPOV Convention (1961), which can be seen as an attempt to harmonise already existing national level PVP systems, addresses the use of plant genetic resources for commercial breeding purposes and the distribution of the resulting benefits. UPOV thus harmonised (intellectual) property rights granted (under national jurisdiction) to seed breeders for the development of new plant varieties. These exclusive exploitation rights were meant to ensure that the seed breeders would be allocated enough of the benefits from their varieties to make their activities commercially viable.

The non-binding FAO International Undertaking (1983), negotiated by ministries of agriculture, focused on both the conservation and use of existing genetic resources, such as landraces, for formal sector seed breeding. The IU promoted the perspective that these genetic resources be considered as a form of international common property. These were to be conserved (using public resources) and made available for both public and private sector stakeholders for the purposes of breeding new varieties. There is a clear parallel and consistency between the availability of these common property resources and the breeder's exemption provision of UPOV which ensures that new varieties are also freely available for yet further breeding efforts.

The CBD (1993) focuses on the conservation of genetic resources and the distribution of the benefits arising from their use. The management, including conservation, of genetic resources (particularly non-agricultural forms of biological diversity) has been largely a public task; the rationale of the CBD is thus to support that task by altering the distribution of benefits from the use of genetic resources. The CBD formally recognises all genetic resources as a form of national public property (national sovereignty). By regulating and controlling access to these resources, states are intended to be able to capture an 'equitable' share of the benefits from their use by stakeholders in other countries. But these

rights are not retroactive, applying only to the collection and exchange of resources after the entry into force of the CBD.¹ For agricultural plant genetic resources, the legal status of many (but not all) genetic resources collected and exchanged prior to the CBD has been clarified by the IT-PGRFA.

The IT-PGRFA (2001) is the outcome of a negotiation process to revise the IU and to bring it in line with the CBD. The IT-PGRFA thus also addresses the conservation and use of genetic resources. The IT-PGRFA, as a legally binding treaty, recognises a large group of these genetic resources (the Multilateral System for crops listed under its Annex 1) effectively as a form of international public common property.² In so doing, the IT-PGRFA can be seen as promoting the use of these genetic resources for further breeding efforts. The IT-PGRFA also addresses the distribution of the benefits arising from this use with its benefit-sharing provisions. As seen above, these place additional obligations for benefit-sharing on seed breeders who restrict the availability of their resulting innovations for further research with for example patent protection where possible. The IT-PGRFA also recognises another group of genetic resources as being national common property and thus falling under the CBD.

Parallel to the development of the CBD, the TRIPS Agreement was negotiated from a trade perspective within the framework of the GATT-WTO. Like UPOV, the TRIPS Agreement also addresses the use of genetic resources for developing new varieties and the distribution of the resulting benefits. In effect, the TRIPS Agreement ensures the establishment of (intellectual) property rights over new plant varieties in all WTO member countries. While UPOV is only one possible option for the creation of these rights, the type of property right to be established is similar in essence, if not necessarily in scope.³ Perhaps equally important, TRIPS also establishes intellectual property rights, in the form of patents, for all technological inventions. As a result, more and more countries are obliged to offer patent protection for biotechnological inventions, including those in the field of agriculture. While states may ensure that this excludes plants from patentability, overlapping rights may be introduced where patent protection is offered to biotechnological inventions that are then embodied in new plant varieties. This issue is addressed below.

Thus, in principle, the various agreements are largely complimentary. The IT-PGRFA and the CBD recognise the common property nature, whether national or international, of existing plant varieties and establish conditions for their international exchange for use in breeding efforts. UPOV and the TRIPS Agreement have allowed the creation of (intellectual) property rights, to be held by individual stakeholders such as companies, institutes and individuals, over newly created varieties. Uncertainties remain though as to the terms for access and exchange to some plant genetic resources, as reviewed in Section 2.3. Furthermore, the manner in which governments implement legislation to respect the conditions placed on the use of genetic resources by the IT-PGRFA and the CBD needs to take into account provisions of the TRIPS Agreement, and possibly UPOV. These areas are also discussed below.

¹ 29 December 1993.

² Although the principle of national sovereignty still holds.

³ The minimum form of intellectual property protection necessary under a *sui generis* system has yet to be defined or agreed upon within TRIPS.

Patents and Plant Variety Protection

The implementation of patents for biotechnological inventions and plant variety protection as required under TRIPs can lead to overlapping forms of protection. In particular, a new plant variety may also embody an invention, most likely in the form of a genetically engineered component (gene or genetic sequence) that is covered by patent protection. An important question is then whether the patent implies any restriction on the use of the variety for further commercial breeding purposes. Any such restriction would then not be consistent with the breeder's exemption provision of PVP (UPOV) legislation.

In general, the scope of either the patent or the plant breeder's right has to be limited if this issue is to be clarified. The patent can take precedence implying either a restriction of the breeder's exemption. Or, with appropriate legislation, the breeder's exemption could be given precedence implying a restriction on the normal scope of patents. Such a restriction may possibly be allowable under TRIPs by referring to Article 30 (Jordens 2002). A restriction to the breeder's exemption due to the scope of patents, on the other hand, is not likely to require any specific legislation.

The EC Directive 98/44/EC has addressed this issue (in Article 12) by obliging Member States to offer plant breeders the opportunity to apply for compulsory licences for use of the patented invention, including the payment of an 'appropriate royalty'. Applicants for such compulsory licences must demonstrate that they have not been able to negotiate a contractual licence and the plant variety under development 'constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent.' It can be argued that these conditions are not only vague but that the demands placed on plant breeders are rather onerous. Plant breeding typically involves many years before a potentially successful variety is developed. It is thus difficult to demonstrate the economic and technical value of the end product at the beginning of this period when a compulsory licence might be required (Jordens 2002).

WIPO and UPOV look for clarification on the interaction between patents and plant variety protection. The organisations therefore organised a joint symposium on this issue in October 2002.¹ UPOV in particular has recognised that the assured maintenance of the breeder's exemption is one of the defining characteristics of plant variety protection, as distinct from patents.

Protection and Benefit Sharing of Material falling under the CBD or the Multilateral System

Under both the CBD and the IT-PGRFA, restrictions and conditions will be placed on the receiver of genetic material with respect to intellectual property protection that may be sought by the receiver as well as ensuing financial obligations. Genetic resources that fall under the CBD are essentially national property and a foreign receiver of these resources

¹ This symposium also dealt with the issue of essentially derived varieties (EDV) which, under UPOV 1991 effectively extends the breeder's right to cover newly bred varieties that only differ from an existing protected variety by the insertion of a genetic element. Depending on national patent legislation, the new variety may effectively fall under the scope of patent protection afforded to the contained invention. UPOV 1991 ensures that the rights of the breeder of the first variety are still respected. For countries that adhere to the 1978 UPOV Act or other *sui generis* forms of protection, the issue of how to deal with EDVs still exist although it can be ignored.

may only apply for intellectual property protection on these resources or any derivative thereof provided that terms for so doing have been agreed with the originating country. Recipients of genetic resources from the Multilateral System are bound to refrain from claiming intellectual property rights on these resources, or their genetic parts or components.¹ Furthermore such recipients must also contractually require the same from any further parties to whom they make the same materials available. In addition, recipients of material from the Multilateral System who then incorporate this material into a commercialised product (e.g. a new plant variety) are obligated to pay a share of the resulting benefits to the financial mechanism to be established within the framework of the IT-PGRFA.

The issue is to what extent these conditions and provisions place obligations on governments. The Bonn Guidelines of the CBD requires countries to take 'appropriate legal, administrative, or policy measures to support compliance with PIC and MAT.' The range of available options is thus quite broad ranging from legislation to simple policies that lack effective implementation measures. With respect to the IT-PGRFA, it has been suggested that governments may be obliged to amend their IPR laws so as to deny the possibility of protection being sought and granted for material originating from the Multilateral System or for which PIC and MAT have not been obtained (Hefler 2002). But the IT-PGRFA states that obligations in the MTAs pertain to the parties to the MTAs and that governments are obliged to ensure that opportunities are available for these parties to seek judicial recourse. This can be seen as precluding the need for amendments to IPR legislation as long as providers of genetic material have the ability to enforce the terms of their MTAs (or eventually MAT) under contract law.

Avoiding any amendments to IPR legislation concerning fulfillment of conditions regarding MTAs or MATs is advantageous because of the possible conflicts between such amendments and TRIPS. Article 29 (Conditions on Patent Applications) of TRIPS restricts the imposition of additional conditions on the granting of protection.

Amendments relating to benefit sharing in IPR legislation, specifically in the case of patented products derived (in part) from material received from the Multilateral System, may be less problematic. Hefler (2002) indicates that TRIPS does not prohibit the imposition of fees and levies associated with the holding of patent rights, although it is not clear that allowing such fees to vary (i.e. to be higher for the types of patents in question) would be TRIPS compliant.

There is a logical precedent for not amending IPR legislation on these points and leaving enforcement of conditions contained in MTAs (and MAT) to the parties concerned. Current patent and plant variety protection systems must also deal with possibilities of wrongful applications to seek protection for material for which rights for exploitation are already defined (e.g. existing plant varieties), potentially under another form (e.g. public property). In some countries, the application review process is intended to eliminate some of these possibilities. Otherwise, the responsibility for contesting such claims essentially lies with the holder of any other conflicting rights that may be deemed to have precedence.

Placing the obligations of enforcing MTAs (MAT) on the providers of material raises however some practical problems. Most providers are stakeholders in developing countries

¹ The separate, but related, issue of defining what 'components' are has been addressed in Section 2.3.

such as public genebanks, or even governments in the case of MAT for material coming under the CBD. Such stakeholders are generally at a serious disadvantage in comparison to typical recipients of material in industrialised countries (e.g. corporations) in terms of resources and experience with IPR systems, including associated litigation.

The EC has proposed a measure that is intended to contribute to recipients of material respecting their contractual obligations with providers. EC Directive 98/44/EC states that a patent application for an invention based on biological material of plant or animal origin should include information on the geographical origin of such material. This is not proposed though as a formal condition on the granting of the patent.¹ The EC has made a similar recommendation to the TRIPS Council (EC 2002). This is thus one option for facilitating the use and enforcement of these agreements such as MTAs and MAT. A similar provision could be applied to PVP legislation but has received little attention presumably due to the fact that PVP, in contrast to patents, provides fewer restrictions on what may be done with the protected material.

In reaction, the International Seed Federation (an association representing commercial seed breeders and producers) has indicated that the industry could consider providing information in intellectual property rights applications as to the source of biological material (ISF 2003). This refers to where the material was obtained by the applicant, unless the source is no longer known (e.g. if the material has long been maintained in a breeder's own nursery) or if confidential contracts with the provider preclude such disclosure. The ISF position is that it is difficult in many cases, if not impossible, to indicate the origin of such biological material where the origin refers to the 'country of origin' as defined in the CBD.

Conclusions

In summary, the international agreements described above have been developed at different times and from different perspectives. As they currently stand, outright conflicts between the restrictions and conditions of the CBD and the IT-PGRFA, on the one hand, and the requirements of TRIPS and UPOV on the other, need not arise. Avoiding such conflicts will depend in part on negotiations in international arenas - such as the Doha negotiations and specific implications for TRIPS, as well as the work of the Governing Body of the IT-PGRFA. It should also be emphasised that specific conflicts will eventually materialise at the level of national implementation. Thus avoiding conflicting legislative frameworks requires a proactive examination of the interaction between existing and proposed implementing legislation at the national level. The approach of leaving enforcement of the CBD's and the IT-PGRFA's provisions on access and benefit-sharing to the realm of contract law will probably imply special challenges in the implementation of these agreements. The legitimacy of these frameworks among a variety of stakeholders could well depend, in part, on how such challenges are met.

¹ Pires de Carvalho (2000) has alternatively proposed that a disclosure requirement could be considered by the judiciary as a condition for enforcing protection, which would also not be in conflict with TRIPS.

3. Implications for Dutch genetic resources policy

3.1 Introduction

The Netherlands is actively involved in the development and implementation of the international instruments related to genetic resources. The Netherlands signed the Convention on Biological Diversity in 1992, and has adopted the CBD as a framework for national biodiversity policy. The Netherlands was one of the 150 countries to adopt the Leipzig Declaration and the FAO Global Plan of Action on Plant Genetic Resources for Food and Agriculture in 1996. The Netherlands is also a member of the WTO and thus a party to the TRIPS agreement, as well as being party to the 1991 Act of the UPOV Convention.

Government policy relating to agricultural genetic resources is presented in the policy document *Sources of Our Existence* (referred to hereafter as SoE¹), which was adopted in 2002. Dutch government policy documents on nature management and the environment, *Nature for People, People for Nature* (NvM)² and the 4th National Environmental Policy Plan (NMP4),³ are also relevant given the implications of environmental management for the use of genetic resources in agriculture. NvM takes the place of four previous nature management policy programmes including the Strategic Action Plan for Biodiversity, and also provides a framework for the conservation and sustainable use of biodiversity in various sectors, including agriculture.

Another important document is the International Policy Programme Biodiversity 2002-2006 (referred to hereafter as BBI)⁴ which indicates how a number of biodiversity-related policy commitments, contained in the various policy documents mentioned above, will be implemented, concentrating on international aspects. BBI notes that ultimate solutions to biodiversity loss are not clear. Policy in this evolving area is thus 'mainly concerned with establishing the right direction and identifying common ground.' (p. 9).

According to SoE, the Netherlands is committed to:

- Clarifying the specification of commitments under the Convention on Biological Diversity (CBD) and other conventions on genetic resources. This can be [formulated] in general CBD guidelines, which will contribute to an alignment of national policy and legislation;
- Implementing the International Treaty on Plant Genetic Resources for Food and Agriculture, focusing on management and utilization of the main crops in agriculture and food production;
- Specifying the cohesion between the CBD and international agreements on intellectual property rights, primarily as stated in WTO-TRIPS, UPOV and WIPO;

¹ Dutch title: *Bronnen van ons Bestaan*.

² Dutch title: *Natuur voor Mensen, Mensen voor Natuur*.

³ Dutch title: *Nationaal Milieubeleidsplan 4*.

⁴ Dutch title: *Internationaal Beleidsprogramma Biodiversiteit 2002-2006*.

- Implementing policy, regulations and legislation on modern biotechnology, in particular the Cartagena Protocol on Bio safety.

Both SoE and BBI indicate that the private sector, researchers and other organisations or stakeholders will be expected to assume most of the responsibility for implementing of policy commitments. The government assumes some but not all responsibility. The government states that it will facilitate or support implementation by others and emphasises the national and international exchange of expertise and information. Specific examples, such as the creation of an infrastructure for information exchange and the development of codes of conduct, are discussed below as well as with respect to the relevant articles of the CBD and the IT-PGRFA.

The government has thus concluded that additional legislation on the subject of genetic resources is not appropriate or necessary at this moment. Such legislation could conceivably entail the application of other types of policy measures, such as legal requirements or the use of financial mechanisms. BBI indicates at this point that the eventual need for such legislation will depend on progress in the application of policy and on developments in the context of international agreements such as the IT-PGRFA and the CBD, as well as on intellectual property issues. The development of common legislation and regulations within the European Union will also be considered.

SoE indicates that the possibilities for implementing the policy without resorting to additional legislation depend on the greatest possible transparency over the management and use of genetic resources, care in the transaction and exchange of genetic resources, and the assumption by all concerned of his/her own responsibility. While not specifically indicated, presumably the last of these conditions will be promoted through the development of codes of conduct.

To support the implementation of its genetic resources policy, the government is committed to establishing a Genetic Resources Platform, consisting of representatives from the business sector, research organizations, social organizations and the government. This platform, together with the National Information Centre for Genetic Resources (see Section 3.2), will form the institutional infrastructure for facilitating information exchange and presumably provide a means by which the government can encourage stakeholders to respect national policy in their actions. This stakeholders platform will address a number of specific issues relevant to Dutch genetic resources policy, including:

- Strengthening the economic position of The Netherlands concerning the use of genetic resources, with special attention to the role and input of the private industry in the agro-food sector and in biotechnology;
- Promoting the development and use of Codes of Conduct that contain the basic principles of this policy document;
- Promoting the development and use of Material Transfer Agreements, with which a prudent exchange of genetic resources can be set up;
- Improving the exchange of knowledge and information via the National Information Centre for Genetic Resources, among others;
- Reinforcing cooperation between The Netherlands and certain selected countries.

Table 3.1 provides an overview of selected obligations of the Dutch government under the international instruments discussed in Section 2 of this report. The following sections (3.2, 3.3 and 3.4) describe efforts of the Netherlands that contribute to the implementation of these international agreements, taking each one in turn. Section 3.5 provides some concluding remarks, including a summary of implications of international agreements that are still undergoing implementation.

Table 3.1 Summary of selected obligations under international agreements

Agreement [Article]	Obligation
CONVENTION ON BIOLOGICAL DIVERSITY	
CBD [6]	General Measures: Develop national strategies/plans/programs for biodiversity or adapt existing ones. Integrate biodiversity into (cross)sectoral strategies/plans/programs
CBD [8]	In situ conservation: protected areas; management of biodiversity in non-protected ecosystems; controlling LMOs & alien species risks; promoting compatibility between conservation & sustainable use & supporting developing countries
CBD [8 (j)]	Traditional Knowledge: Respect, preserve and maintain knowledge and practices of indigenous and local communities, equitable sharing of the benefits arising from the utilization of such knowledge and practices
CBD [9]	Ex Situ Conservation: Conserve biodiversity ex situ; rehabilitate and reintroduce threatened species as appropriate; Regulate and manage collection of biological resources so as not to threaten ecosystems or species; support developing countries
CBD [15]	Access and Benefit-sharing: Recognize national sovereignty. Facilitate access to genetic resources for environmentally sound uses by other Parties on mutually agreed terms (MAT) and subject to subject to prior informed consent (PIC)
CBD [16]	Technology Transfer: Provide/facilitate access for and transfer to other Parties of relevant technologies & take measures with the aim that Parties, especially developing countries, are provided access to and transfer of technology on mutually agreed terms including taking legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology for the benefit of both governmental institutions & private sector of developing countries; cooperate on IPRs.
CBD [17]	Exchange of Information: Facilitate exchange of information including exchange of research results, on training & surveying, specialized knowledge, indigenous & traditional knowledge & technologies.
CBD [18]	Technical and Scientific Co-operation: Promote international technical and scientific co-operation, including for indigenous and traditional technologies, for biodiversity, national policies, and capacity building. Promote cooperation in the training of personnel and exchange of experts, and joint research programs
CBD [19]	Biotechnology: Biotechnological research, promote priority access to Parties to biotech. benefits; consider the need for and modalities of a bio safety protocol; provide information on safety regulations required in handling LMOs, and information on impacts
INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (IT-PGRFA)	
IT-PGRFA [Part II]	General Provisions: Conservation, Exploration, Collection, Characterization, Evaluation & Documentation of PGRFA (art. 5); Sustainable use (art. 6) National Commitments & international collaboration (art.7) & technical assistance (art.8)
IT-PGRFA [Part III]	Farmers' Rights: Take measures to protect and promote Farmers' Rights, including protection of traditional knowledge, the right to equitably participate in sharing benefits & the right to participate in making decisions, at national level (art. 9)

IT-PGRFA [Part IV]	Multilateral System of Access and Benefit-Sharing: Place annex 1 PGR in the Multilateral System & encourage other holders; Facilitate access to MS PGR; Take necessary legal or other measures; Provide information on technology transfer & access; Contribute to capacity building for other countries
IT-PGRFA [Part V]	Supporting Components: Promote the implementation of the GPA (art. 14); Provide facilitated access to IARCs in the MS (art. 15); Encourage institutions to participate in networks (art. 16); Cooperate to develop and strengthen global information system (art. 17)
IT-PGRFA [Part VI]	Financial Provisions: Ensure resources for IT-PGRFA. Provide financial resources, including through the financial mechanism & for national PGRFA activities
AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)	
TRIPS [27(3)b]	IPR protection for plant varieties: Some form of intellectual property protection of plant varieties must be provided, 'by patents or by an effective sui generis system or by any combination thereof'
TRIPS [27(2)]	General exemption to patentability: Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment...
CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV) – 1991 ACT	
UPOV [2]	Basic Obligation: Grant and protect the breeder's right
UPOV [3(1)]	Genera & Species to be Protected: Apply the provisions of this Convention... at the latest by the expiration of a period of five years after the said date, to all plant genera and species (i.e., April 2003), and prior to this to all plants and species to which the previous version applies.
UPOV [5]	Requirements for Protection: Breeders rights shall be granted for varieties that are new, distinct, uniform and stable varieties, granting shall not be subject to any further or different conditions
UPOV [14(1)]	Scope of Breeders' Right: Authorization of the breeder required for: production or reproduction; conditioning for the purpose of propagation; offering for sale; selling or other marketing; exporting; importing; stocking for any of these purposes. Breeder may also make his authorization subject to conditions and limitations.
UPOV [15(1)]	Exemptions (research & breeding): Breeder's right shall not extend to private, non-commercial and experimental acts, or acts done for the purpose of breeding other varieties.
UPOV [15(2)]	Exemptions (farm-saved seed): Contracting parties may restrict breeder's right to permit farmers to use for propagating purposes, on their own holdings, the product of their own harvest.
EU DIRECTIVE 98/44/EC ON LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS	
[1]	Patentability biotechnological inventions: Protect biotechnological inventions under national patent law. Without prejudice to international agreements, especially TRIPS and CBD.
[11]	Farm-saved seed: Sale to a farmer of plant propagation material implies authorization for use of harvest product for propagation or multiplication on his own farm. Sale of breeding stock or animal reproductive material implies authorization to use it for agricultural purposes (but not sale).
[4(1)]	Exclusion from patentability: No patenting plant & animal varieties or essential biological processes for plant or animal production.

3.2 The Convention on Biological Diversity

The Netherlands signed the Convention on Biological Diversity (CBD) in 1992 and became a Party on the 12th July 1994. In 2002, the Netherlands hosted the 6th meeting of the Conference of the Parties (COP) to the Convention in The Hague.

Article 6. General Measures for Conservation and Sustainable Use

This article requires countries to develop national strategies, plans or programs for biological diversity or adapt existing ones, and to integrate biodiversity considerations into relevant sectoral or cross-sectoral efforts. NvM as well as the NMP4 form the national strategy and priority programmes in the area of biodiversity.

BBI states that an inventory and analysis of the Netherlands national status and trends of agro biodiversity will be prepared by 2004.

Article 8. In-situ Conservation

The relatively few remaining traditional crops and characteristic breeds in the Netherlands are generally no longer competitive from a productivity perspective. In situ management of genetic resources focuses on the conservation and management of a limited number of rare, characteristic plants and animals, primarily in nature areas and by hobby breeders and farmers. The government supports the use of specific instruments, including subsidies, to promote in situ conservation as an element of an integrated, region-oriented approach to multifunctional agriculture. SoE cites the example of the new *Subsidieregeling gebiedsgerichtbeleid*, which supports, among other activities, the development of regional specialty products, the maintenance of traditional regional specialty products, and the management, restoration and development of cultural-historical values.

SoE notes that local breeding and development of traditional crops and varieties in the context of in situ conservation can encounter problems with respect to existing legislation and regulations, in particular with respect to certification of planting seed for commercial sale (the *Zaaizaad- en Plantgoedwet*). SoE indicates that the need for possible amendment to the legislation will be studied, in an international context, noting that the European Commission has already initiated action in this area (Directive 98/95/EC treating 'conservation varieties').

Article 8 (j). Traditional knowledge

The Netherlands second report to the CBD notes that traditional knowledge is 'not relevant on the national level, but the Netherlands are addressing this issue at the international level'(p 28), and further notes that 'Dutch development cooperation policy gives priority to traditional communities and indigenous people'(p 31).

According to BBI, the Netherlands will contribute to the understanding of the potential commercial value of traditional knowledge, including through schools and training materials, and through the development of methods for the economic valuation of traditional knowledge. The Netherlands will also support studies and contribute to the work of WIPO on understanding the relationship between traditional knowledge and intellectual property rights. Particular attention will be given to capacity building for local groups, through bilateral cooperation (BBI).

Article 9. Ex-situ Conservation

The Centre implements the Dutch program for ex situ conservation and use of crop and farm animal genetic resources (DWK 366), with a budget of 1.275.000 Euro, for Genetic Resources, The Netherlands (CGN). The objectives of the program are the maintenance and documentation of collections and stimulating their use, as well as providing support for international collaboration on genetic resources. CGN's collections are much more extensive for plant species than for animals, for which genetic resources are maintained primarily by private sector breeders and the SZH.

The government has established the National Information Centre (see Article 17 below), which is intended in part to promote cooperation between the different institutions (botanical gardens, universities, etc.) managing ex situ microbial, plant and animal collections.

Article 15. Access and Benefit Sharing

As the country of origin to only a few varieties or species, and since it advocates free exchange of genetic resources, the Dutch government does not consider it necessary to secure its own national sovereignty regarding access and use of genetic resources in its legislation (SoE). The Netherlands does not find it necessary to establish a PIC system of its own but considers MTAs to be an appropriate instrument to obtain concurrence on terms of transaction of genetic resources, 'so long as they contain the right clauses, such as on the arbitration of disputes'(SoE). Examples of MTAs used by CGN are provided on the website of the National Information Centre (www.absfocalpoint.nl).¹ CGN does not claim ownership of its germplasm holdings, and requires the recipient, in the interest of continued free exchange, not to claim ownership over the material received or material that is essentially derived. The MTA used by CGN contains most of the elements suggested in the Bonn Guidelines, but no clauses on dispute settlement or on benefit sharing. The implementation of the IT-PGRFA and the development of a standard MTA will affect the use of MTAs in the Netherlands.²

The Netherlands has designated a National Focal Point (CGN, represented by Bert Visser) and a Competent National Authority (Marcel Vernooij).

The government considers that access, exchange and use of genetic resources by Dutch businesses, individuals or other organisations can probably be based on existing public law and regulations, supplemented by alternatives in the sphere of private law, such as MTAs (SoE). To promote the recognition of the principles of national sovereignty and prior-informed consent (as stipulated in Article 15 of the CBD) of genetic resources in other countries, the government calls on the private sector, individuals and other organisations to act carefully with respect to international and national regulations in other countries. The government has stimulated the development of codes of conduct, which is also to be one of the tasks of the national Genetic Resources Platform (SoE). A Code of Conduct for Botanical Gardens in The Netherlands: Compliance with the CBD has been formulated. Based on such a code, the botanical gardens will commit to the exchange of

¹ MTAs are also available on the website for the Fungal Biodiversity Centre (Centraal Bureau voor Schimmelfcultures, CBS). CBS prohibits distribution to third parties and use of the material for commercial purposes without permission of the legal owner.

² See section 2.3

material in accordance with the CBD (section 3.3. version). In addition, BBI indicates that a code of conduct for the use of genetic material originating from developing countries will be developed during the period 2002-2006, and applied on a trial basis, to those countries with which the Netherlands has signed a Sustainable Development Agreement (p. 44).

BBI states that the government is prepared to commit itself to more 'far-reaching measures' if the (voluntary) Bonn Guidelines do not lead to an effective sharing of the benefits arising from the use of genetic resources (BBI, p. 44). The example is given of a legally binding instrument, at least at the EU level. Such an instrument could include further detailed agreements on how to deal with genetic components and on mechanisms for establishing the origin of genetic resources when IPRs are requested.

In addition, BBI indicates the Netherlands will advocate (though not require) that the country of origin be stated on the claim to intellectual property of plants and animals (p. 44) which is also reflected in the EU Directive 98/44/EC. As discussed in Section 2.6, the formulation and force of such a requirement has been proposed by the EU in such a way as to avoid conflict with TRIPS and UPOV by not making it a condition for granting IPR protection. Although not yet implemented, such a policy stance can be seen as supporting implementation of the Bonn Guidelines and Article 15 of the CBD.

Article 17: Exchange of information

The National Information Centre for Genetic Resources (www.absfocalpoint.nl) has been established to support the national and international exchange of information on ex situ collections, contributing also to the implementation of Article 17 (see table 1).

Article 16. Technology Transfer & Article 18. Technical and Scientific Cooperation

The Netherlands collaborates internationally on issues related to biodiversity and genetic resources, contributing to Article 16 on Technology Transfer and Article 18 on Technical and Scientific Cooperation. SoE states that the Dutch government will, through bilateral and multilateral programs, 'facilitate an increase in the capacity of institutions in developing countries and central/eastern Europe with inadequate infrastructures and limited capacity for managing genetic resources'

On the international level, the Netherlands contributes to the implementation of the CBD through multilateral cooperation through:

- the FAO, including the FAO/NL partnership program, for which agricultural biodiversity is one of the three major areas of focus;
- financial support to the development of a global strategy on farm animal genetic resources, and advocates assisting developing countries in the use and further development of their breeds of farm animals, in coordination with the FAO;
- financial support to the international conservation and use of genetic resources by the CGIAR and its 16 Future Harvest Centres, including the International Plant Genetic Resources Institute (IPGRI).

On the European level, the government contributes to the development of a joint EU approach to genetic resources, including:

- Reinforcing coherence of policy and regulations within the EU and in EU efforts within multilateral forums;

- Integrating the sustainable use of genetic resources into the Common Agricultural Policy and Common Fisheries Policy, based on the Biodiversity Action Plan for Economic and Development Cooperation;
- Developing a joint approach to accessing genetic resources and a fair benefit-sharing, including a study of potential EU regulation;
- Maintaining and reinforcing alternatives for supporting research and measures for the conservation and sustainable use of genetic resources (SoE);
- Contributing financially to the establishment of a European Regional Focal Point, coordinating the conservation and sustainable use of animal genetic resources, and supporting the information exchange.

CGN is also involved in a number of international cooperation initiatives:

- active participation in the European Cooperative Programme of Crop Genetic Resources Networks (ECP/GR) and in corresponding efforts for the conservation of animal genetic resources, including support for the establishment of a European Regional Focal Point to co-ordinate the approach of individual countries and support the exchange of knowledge and information;
- coordination of the EU-funded project EPGRIS - the European Plant Genetic Resources Information Infra-Structure. This project will establish an infrastructure for information on plant genetic resources that are maintained *ex situ* in Europe, both through support for National PGR Inventories, and by creating a European PGR Search Catalogue with passport data on *ex situ* collections maintained in Europe (EURISCO).

With respect to bilateral cooperation, the government has stated that the Netherlands will work more intensively with a number of countries. At this point, LNV supports CGN in its collaboration on the development of a national program for genetic resources management in Bhutan. In general, the government considers that a joint effort towards further development of Codes of Conduct and Material Transfer Agreements is advisable.

The government also supports a number of international research collaboration initiatives, including:

- research on participatory enhancement of managing vegetable and poultry genetic resources by communities in Indonesia, Cambodia and the Philippines (PEDIGREA project; DLO/CGN with local civic society organisations);
- research on biotechnology, plant breeding and seed technology for Indonesian horticulture (BIOBREES and HORTIN projects);
- research and dissemination of information on useful plants in South East Asia (PROSEA) and also Tropical Africa (PROTA; Wageningen University).

Article 19. Biotechnology

The Netherlands became a Party to the Cartagena Protocol on Bio safety on the 8th January 2002.

The Netherlands is also guided by European Directive 98/95/EC, amending a number of previous Directives, which in its article 6 establishes that

'In the case of a genetically modified variety within the meaning of Article 2(1) and (2) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment' (Article 6, 1.4).'

The government indicated in an Integrated Policy Document on Biotechnology (September 2000) that the Netherlands encourages research on the alternatives provided by gene technology for food crops in developing countries.'

3.3 International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA)

The Netherlands promoted and was closely involved in the negotiations by which the International Undertaking evolved into the IT-PGRFA, signing this treaty on 6th June 2002¹. Implementation of the IT-PGRFA is a priority for the Dutch government, which 'will renew its efforts to achieve a speedy ratification and implementation' (SoE). For implementation of the treaty, The Netherlands will continue to advocate close collaboration between the FAO, the CBD and the CGIAR.

Part II: General Provisions

General obligations under Part II of the IT-PGRFA on conservation, exploration, collection, characterization, evaluation and documentation of PGRFA (article 5); sustainable use (article 6) national commitments and international collaboration (article 7) and technical assistance (article 8) overlap with obligations under the CBD. Many of the general activities described in sections 2.1 as well as the more specific ones mentioned in 2.2 thus contribute to their fulfillment. This work is also directly linked to and should facilitate the implementation of the Global Plan of Action.

Articles 5 and 6 of Part II of the IT-PGRFA allow a significant degree of flexibility in the interpretation of the specific obligations of contracting parties. Article 5 includes a long list of activities relating to both in situ and ex situ activities but Contracting Parties may determine which of these are deemed to be 'appropriate'. Article 6 includes a wide range of policy and legal measures that 'may' be promoted.

Part IV: The Multilateral System on Access and Benefit-Sharing (MS)

The Netherlands is obliged to place the genetic resources of crops and forages listed in annex 1 to the IT-PGRFA that it holds in the public domain at the disposal of the System, and encourage other holders in the Netherlands to do the same. The government is required to take the necessary legal or other appropriate measures to provide facilitated access to other Contracting Parties (and legal and natural persons under their jurisdiction) through the MS. According to SoE, the government is developing MTAs, with a distinction made between genetic material for which the government bears exceptional responsibility, and genetic

¹ Source: CGRFA website at www.fao.org/ag/cgrfa

material with primarily a commercial interest. Pending the ratification of the IT-PGRFA and the negotiation of a standard MTA for the MS, the Netherlands will then ensure that this is applicable for material held in the public domain in the Netherlands falling under the public domain (CGN). Recourse is already available under the Dutch legal system, consistent with applicable jurisdictional requirements, in case of contractual disputes arising under such MTAs.

It is important in the context of this policy and the IT-PGRFA to define clearly, which genetic resources available in the Netherlands fall in the public domain. This issue may be handled by the Genetic Resources Platform and may also be dealt with in a contract (covenant) between LNV and CGN.

In ratifying the IT-PGRFA, the Netherlands will agree to share fairly and equitably the benefits arising from the use of plant genetic resources for food and agriculture under the MS, including commercial benefits. This would be achieved through the exchange of information, access to and transfer of technology, capacity building, and the sharing of the benefits arising from commercialisation. As mentioned in section 1.3, this means that a recipient who commercializes a product incorporating material (including 'genetic parts and components') from the MS must pay an equitable share of the benefits arising from the commercialisation of that product, except when it is available without restriction to others for further research and breeding.

Considering that plant varieties are not patentable in the Netherlands, the strongest form of intellectual property rights to be applied to plant varieties are Plant Breeders Rights under the UPOV Convention (1991 Act). As mentioned in section 1.5, an exception to Plant Breeder's Rights is made for private, non-commercial and experimental acts, as well as for acts done for the purpose of breeding other varieties (i.e. the breeders exemption). Thus, any commercialized variety incorporating plant genetic resources accessed from the MS in the Netherlands will still be available for further research and breeding; sharing the benefits of commercialisation through a contribution to the financial mechanism will only need to be encouraged, not required by law. This issue is not mentioned explicitly in policy documents and the form by which such encouragement should take place has also not yet been defined.

SoE notes that the government seeks an integrated approach, 'generating as many agreements as possible on the level of organisms and their reproductive parts, instead of hereditary material.'

According to BBI, the Netherlands will advocate that the country of origin be stated on the claim to intellectual property of plants and animals (p. 44). This can be interpreted as a step to ensure implementation of Articles 12.3(d) and 13.2(d) of the IT-PGRFA.

Part V: Supporting Components

Other obligations include supporting international structures for the conservation and sustainable use of PGRFA such as the GPA and relevant networks such as ECP/GR, and providing financial resources for the implementation of the IT-PGRFA. The National Information Centre on Genetic Resources and the proposed Genetic Resources Platform can potentially contribute to meeting general obligations under the IT-PGRFA.

3.4 Intellectual Property Rights agreements

TRIPS and UPOV

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires in Article 27.3 (b) that some form of intellectual property protection of plant varieties be provided, either by patents or by an effective sui generis system or by any combination thereof. The TRIPS requirement for intellectual property protection of plant varieties is fulfilled by the Netherlands through its membership of UPOV (1991 Act), as an effective sui generis system of protection for plant varieties. The UPOV Convention in the Netherlands is implemented through the *Zaaizaad- en Plantgoedwet*.

Moreover, the Netherlands considers that the protection of breeders' rights is important to all countries, and endeavours to attain acknowledgement of UPOV as one of the effective sui generis systems for protection for plant varieties within the TRIPS Agreement. This position is based on the argument that discrepancies between a different sui generis system and the principles of the UPOV system can obstruct trade and the exchange of planting material (SoE, BBI).

EU Directive 98/44/EC

As a member of the European Union (EU), patent law on agricultural biological material in the Netherlands must conform with EU directive 98/44/EC, which provides for patent protection of biotechnological inventions, including biological material (such as gene sequences) which is isolated from its natural environment or produced by means of a technical process...even if it previously occurred in nature'. In 1998, The Netherlands supported by Italy and Norway, objected to this guideline, declaring that it should be declared invalid and that the right to patents in the field of biotechnology should be restricted to methods and not include products (Tvedt 2002). The European Court of Justice rejected the Dutch appeal for annulment, and the Netherlands remains obliged to implement the guideline.

In 1999, the Dutch government submitted proposed legislation to the Parliament, which approved the proposal in April 2003. However the Senate, given the controversial nature and simultaneous change in government, never approved the bill.¹ In July 2003, the EC declared that it would take the eight remaining member states, including the Netherlands, that had not implemented Directive 98/44, to court.²

3.5 Concluding remarks

The Netherlands participates in all of the instruments described in this document and considers that 'international obligations regarding intellectual property, trade, agriculture and biodiversity are mutually reinforcing'. The Dutch government contributes to the work of regional and international fora in this regard and also collaborates bilaterally.

¹ See Ministry of Economic Affairs (2003)

² European Commission Press Release IP/03/991, 10 July 2003.

- *Implementing the Multilateral System (MS)*: The implementation of the IT-PGRFA is a priority for the Dutch government and will require appropriate integration into national law. Many issues addressed by the IT-PGRFA, especially regarding benefit sharing, will be addressed by the Governing Body at its first meeting. A review of the status of ex situ plant collections in the Netherlands may be necessary in order to determine which collections will form a part of the MS. As indicated above, it is important to define clearly which genetic resources available in the Netherlands fall in the public domain. Furthermore, the position of the government on the patentability of genetic material still needs to be addressed with respect to fulfilling obligations under EU Directive 98/44/EC. This will also have to involve attention for ensuring that the implementation of eventual provisions on the patentability of material from the MS is compatible with various IPR agreements.
- *Role of government*: If the responsibility for policy implementation is to be left with the private and civil sector (SoE; see discussion under 2.1 above), the government will need to ensure a minimum level of infrastructure and public awareness on the issue, as well as monitoring:
 - *Infrastructure for genetic resources*: The Genetic Resources Platform and the National Information Centre described in SoE are important mechanisms for fulfilling national obligations under these agreements. The stakeholder platform, in particular, may provide a basis for building cohesion and consensus, and actively promoting much-needed linkages.
 - *Awareness-raising*: SoE notes 'an increasing social commitment to finding structural solutions to the loss of biodiversity and ways of achieving sustainable use of genetic resources'. But the extent to which the value of maintaining a variety of genetic resources on farm is recognized and promoted by government policy seems rather unclear. This may suggest a further need for raising awareness of the importance of in situ conservation.
 - *Monitoring implementation*: The government proposes to set goals for the conservation and sustainable use of genetic resources that are as concrete as possible, by specifying its policy in detail (SoE). In the process, it is intended that indicators will be developed to monitor and evaluate progress, linked to the development of indicators at an international level.

An open issue thus remains the extent to which encouragement and the facilitation of information exchange will ensure that policy is effectively implemented, as evidenced by the actions of the private sector, research organisations, civil society organisations and others. At some point, progress will have to be reviewed and assessed within the framework of monitoring activities.

4. Conclusions

The international agreements relating to agricultural plant genetic resources were developed at different periods in time, and address an evolving policy agenda. Policy issues concerned initially promoting use of agricultural genetic resources for breeding efforts, resulting in intellectual property protection systems. Relevant international agreements include the International Convention for the Protection of New Varieties of Plants (the UPOV Convention), the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Growing awareness of loss of agricultural genetic resources led to the FAO Global Plan of Action on Plant Genetic Resources (GPA), and more recently the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA). These instruments focus essentially on conservation concerns and are more closely related to the Convention on Biological Diversity (CBD). One of the strategic pillars of the CBD is the promotion of conservation through the sharing of economic benefits from using the genetic resources with those countries and communities responsible for the conservation. The IT-PGRFA recognises though the special circumstances of most agricultural genetic resources; they have long been exchanged locally and internationally (in some cases for centuries) meaning that the difficulty in designating providers of these resources should not restrict their further exchange.

In general, the agreements are complimentary. The IT-PGRFA and the CBD recognise the common property nature, whether national or international, of existing plant varieties and establish conditions for their international exchange for use in breeding efforts. UPOV and TRIPS have allowed the creation of (intellectual) property rights, to be held by individual stakeholders such as companies, institutes and individuals, over newly-created varieties. Uncertainties remain though as to the terms for access and exchange to some plant genetic resources which are not covered by the IT-PGRFA and also potentially not by the CBD.

The issue of primary attention concerning the relationship between the various agreements is that of ensuring that national/collective rights established by the IT-PGRFA and the CBD are respected by recipients of genetic resources. The current strategy, after much international debate, is to rely on contractual arrangements between providers and receivers of material, such as material transfer agreements (MTA) with as few changes to IPR systems as possible. Such changes would be admittedly complicated and would generally necessitate amendments to TRIPS and possibly other agreements. The example of the disclosure of origin 'requirement' proposed by the EC in its Directive 98/44/EC, as well as to the TRIPS Council, is thus an example of a legislative measure within the realm of intellectual property to support the IT-PGRFA and CBD, while carefully avoiding conflicts with TRIPS.

The Netherlands has played an active role in the development and implementation of these various international instruments. The government considers that the international obligations are 'mutually reinforcing'. At the same time, policy in the Netherlands has rec-

ognised the need for some kind of framework to ensure that private actors respect the provisions of the CBD and the IT-PGRFA as represented in terms of MTAs or other contracts. To this end, the government has supported the creation of a platform on genetic resources and the development by stakeholders of codes of conduct. The Netherlands has also supported at European level the requirement for disclosure of origin of biological material in patent applications.

The Netherlands is thus an example of a country of the North trying to promote a solution with minimal adjustments to existing IPR agreements which many developing countries would prefer to see. At this point, it is difficult to predict whether this approach will achieve the results desired by various stakeholders. Recipients of material certainly have an incentive to avoid new requirements. If this becomes apparent, pressure may increase for further adjustments to IPR regimes. But recipients of genetic resources can also be expected to consider this incentive against other concerns such as the increasing transaction costs for accessing genetic resources and alternatives. It is possible that many users will decide that the increasing costs of these resources are not worth the potential benefit. The resources in question might then be used less but their benefits shared more widely.

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Annex 1 Key concepts and definitions

Key concepts:

Mutually Agreed Terms: 'For access to be on 'mutually agreed terms' (MAT), both supplier and recipient must agree to the terms, thus providing an opportunity for the providing country to negotiate a share of the benefits derived from the use of the genetic resources. Usually this implies a contractual arrangement, executed on a bilateral basis. The contract often takes the form of a 'Material Transfer Agreement' (MTA) setting out the agreed terms on which the genetic material is transferred. The MTA may specify the permitted or prohibited uses of the genetic resources provided, including whether or not it may be commercialized; any rights which may or may not be taken out over the resource or its derivatives; and the benefits that are to be shared' (Cooper 2002).

Prior Informed Consent:

'...means that the responsible authority of the providing country can decide to grant or refuse access following a request from the applicant. In the application, the applicant may be required to provide information concerning the genetic resources required and the purpose for which they are required, as well as any proposal for benefit-sharing. As part of the PIC procedure, the responsible authority may consult with indigenous and local communities, or other stakeholders, concerned' (Cooper 2002).

Definitions:

Sui generis: from Latin, meaning literally, 'of its own kind'.

Sui generis systems: Latin for 'systems of their own kind'. This allows (WTO) members to be appropriately original and resourceful in designing these laws, no doubt so that the laws are effective in achieving desired objectives (Mangeni 2000).

Plant genetic resources for food and agriculture: any genetic material of plant origin of actual or potential value for food and agriculture. (Article 2 of the IT-PGRFA)

Genetic material: any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity. (Article 2 of the IT-PGRFA)

Variety: a plant grouping, within a single botanical taxon of the lowest known rank, defined by the reproducible expression of its distinguishing and other genetic characteristics. (Article 2 of the IT-PGRFA)

Variety: applies to any cultivar, clone, line, stock or hybrid which is capable of cultivation and which satisfies the provisions of subparagraphs (1)(c) and (d) of Article 6, i.e. to be sufficiently homogeneous, having regard to the particular features of its sexual reproduction or vegetative propagation, and to be stable in its essential characteristics, that is to say, it must remain true to its description after repeated reproduction or propagation or, where the breeder has defined a particular cycle of reproduction or multiplication, at the end of each cycle. (International Convention for the Protection of New Varieties of Plants, Act of 1961, Article 2)

Biotechnology: any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. (Article 2 of the CBD)

Country of origin of genetic resources: country that possesses those genetic resources in in-situ conditions. (Article 2 of the CBD)

Centre of origin: means a geographical area where a plant species, either domesticated or wild, first developed its distinctive properties. (IT-PGRFA Article 2)

Country providing genetic resources: 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. (Article 2 of the CBD)

Genetic material: any material of plant, animal, microbial or other origin containing functional units of heredity. (Article 2 of the CBD)

Genetic resources: means genetic material of actual or potential value. (Article 2 of the CBD)

Annex 2 Timeline

1961	Adoption of the UPOV Convention
1978	1978 Act of the UPOV Convention
1981	1978 Act of the UPOV Convention entered into force
1982	
1983	FAO Commission on PGR established & IU adopted
1989	Emergence of concept of 'Farmers' Rights' in IU negotiations (FAO Conf. Res. 5/89)
1990	
1991	1991 Act of the UPOV Convention
1992	UNCED – signing of CBD by 150+ states Entry into force of CBD (Nairobi final act) Decision to revise the IU in harmony with CBD
1994	Adoption of the TRIPS agreement Signing of agreements by CGIAR Centers creating the International Network of Ex Situ Collections under the Auspices of FAO
1995	Entry into force of TRIPS
1996	Leipzig Conference – adoption of the GPA
1997	
1998	1991 Act of the UPOV convention entered into force
1999	
2000	Bonn Guidelines on access and benefit-sharing developed
2001	Adoption of the IT-PGRFA
?	Entry into force of the IT-PGRFA

Annex 3 Legal Instruments relating to Plant Genetic Resources: Some relevant texts on internet

- Convention on Biological Diversity (1992) www.biodiv.org/convention/articles.asp
- Global System on Plant Genetic Resources www.fao.org/ag/cgrfa/PGR.htm
- International Treaty on Plant Genetic Resources for Food and Agriculture (2001) <ftp://ext-ftp.fao.org/waicent/pub/cgrfa8/iu/ITPGRe.pdf>
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- International Convention for the Protection of New Varieties of Plants, Act 1991, (UPOV 1991) www.upov.org/eng/convntns/1991/content.htm
- International Convention for the Protection of New Varieties of Plants, Act 1978, (UPOV 1978) www.upov.org/eng/convntns/1978/content.htm
- EU Directive 98/44/EC http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf

Annex 4 Crops included in the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA)¹

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 <i>Lepidium meyenii</i> (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 <i>Musa textilis</i> .
Rice	Oryza	
Pearl Millet	Pennisetum	
Beans	Phaseolus	Except <i>Phaseolus polyanthus</i> .
Pea	Pisum	
Rye	Secale	
Potato	Solanum	Section tuberosa included, except <i>Solanum phureja</i> .
Eggplant	Solanum	Section melongena included.
Sorghum	Sorghum	

¹ Source: Annex 1 of the IT

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	crisatum, 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