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Legal Aspects of Exchange, Use and Conservation of Farm Animal Genetic Resources

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Abstract

This report forms a background study and the material contained in this document served as input for the FAO commissioned study 'Exchange, Use and Conservation of Animal Genetic Resources: Policy and Regulatory Options' (CGN 2006/6) (Hiemstra et alia 2006). The two main topics that are dealt with are: first, a look through the existing legal regulations that apply to Animal Genetic Resources (AnGR); and second, an analysis of the options for how the challenges in exchange, conservation and sustainable use of AnGR can be dealt with by the use of regulatory means. One of the main challenges for regulating AnGR is to have a clear picture of the differences to the areas where the law is already developed, notably the plant sector. All the current legal regulations of genetic resources target either genetic resources in general or they target plant genetic resources specifically. This study analyses the options for breeding laws, import and export regulations, model/standard material transfer agreements, bilateral ex¬change agreements, patent law, sui generis intellectual property rights to AnGR and livestock keepers' rights. The report aims to provide points of departure for further detailed studies and work.

Key Words

Animal genetic resources, conservation, sustainable use, exchange, access, intellectual property rights, breeding laws, sui generis systems, livestock keepers' rights

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1 Background

Genetic resources law and policy at the international level, has mostly been focused at plant genetic resources for food and agriculture[1] and on genetic resources and biological diversity in general.[2] A literature review disclosed that Farm Animal Genetic Resources (AnGR) is only very scarcely addressed compared to plant genetic resources (PGR). This does not mean that AnGR are less important for food security and nutrition since, for example, 30% of total nutrition is covered by food from animals. In rural and marginalised areas, livestock contributes 70% of the livelihood.[3] There is a growing interest among the member countries to the FAO for the need to address AnGR at the international level. When the topic policy and regulatory options for AnGR now comes into attention, there is a danger that experiences from the plant sector may be directly applied to farm animals.[4] Policy and regulatory options should, however, be adapted to the special circumstances for the animal sector and avoid a 'copy-paste approach' from the plant sector, if those solutions are not found adequate for the animal sector.

2 The Subject Matter – Farm Animal Genetic Resources

2.1 Differences between Plants and Animals

A point of departure for a policy and regulator analysis is to develop a clear understanding of the subject matter that is up for discussion. Since the body of policies and regulations mainly have been developed in the plant sector, it is interesting to compare these two sectors to identify similarities and differences relevant for policy making and regulation. At first sight plant breeding does not differ much from animal breeding. Plant and animal breeding are similar in that they need genetic diversity in order to advance, and that the genetics determine adaptation to particular agro-ecological and product qualities to a large extent.

However, marked differences do exist. While plant breeders aim at development of new varieties to replace old varieties and that may be protected by plant breeders' rights, farm animal breeding is largely based on selection of individuals within populations based on a continuum of genetic material rather than complete shifts to a new breed. The farm animal breeders are interested in individual animals and populations,

[1] The Food and Agriculture Organisation, Commission on Genetic Resources for Food and Agriculture and the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA), and the CGIAR; there is also a substantial body of literature relevant for plant genetic resources.
[2] Convention on Biological Diversity (CBD); the World Intellectual Property Rights Organisation (WIPO), in particular the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) and the WTO-TRIPS.
[3] FAO, 1999 LID, 1999.
[4] For a comparison of plant and farm animal genetic resources, see below.

while a plant *variety* is the main focus of plant breeders. Maintaining genetic variation within populations and minimizing inbreeding is much more relevant in farm animals than for plants.

Although an individual animal might carry unique gene combinations or new mutations, in contrast to the situation with many plant species, exploiting the unique genetic characteristics of an individual animal is currently extremely difficult due to long generation intervals, low reproduction rates, high cost of evaluating the genetic characteristics of a single animal and the absence of effective use of recombinant gene technology in the animal sector. The unit of diversity in AnGR is, therefore, generally considered to be a population of animals, often referred to as a breed.[5] The animal breeding sector largely concentrates on the diversity within populations; the costs are often too high to introduce exotic materials into a genetic background required for modern farming due to long generation intervals and small numbers of offspring. This marks a difference, as for plants the introduction of a new gene may be less costly.

Biological differences clearly require different approaches to conservation, breeding and use. Compared to plants, fecundity and reproductive capacity is extremely low in farm animals, although there are substantial differences between species. Also, collection, storage and distribution of seeds are easier for plants. Due to the differences in creating genetic progress and its dissemination, the management of genetic resources is more complicated for animals than for plants.[6]

In plants, intensification of crop production has generally been accompanied by emergence of a strongly institutionalized and centralized genetic resources sector dominated by publicly funded national and international centres in addition to collections held by private firms. Institutional capacity for AnGR conservation is limited, with only a few existing public sector national *ex situ* collections and none under the auspices of FAO. These are not involved in large-scale exchange or breeding programs. Ownership of AnGR is perceived to almost exclusively reside in the private sector.

Costs to collect, cryopreserve and subsequently reconstitute AnGR germplasm are many times greater per preserved genome than costs to collect, store and subsequently utilise seeds. This is one important reason why AnGR conservation has much more heavily emphasized *in situ* conservation. One advantage for conservation of AnGR is that cryoconserved gametes will remain viable in perpetuity and do not require viability tests or replanting and harvesting programs, and thus the costs of maintenance of cryoconserved stock are low.

[5] Gibson and Pullin 2005.
[6] Notter 2004.

Table 1 Biological, Technical and Institutional Differences between Plant and Farm Animal Genetic Resources

Factor	*Plant genetic resources*	*Farm animal genetic resources*
Mendelian segregation	Yes	Yes
Self pollination	Yes	No
Asexual reproduction / clonal propagation	Yes	No, only artificial
Crossbreeding	Yes, between inbred lines	Yes, between selected lines
Inbreeding	Yes	No, not desirable
Genetic modifications	Possible and efficient	Possible, hardly accepted
Generation interval	Low < 1 year	High 1 up to 8 years
Number of offspring	High	Small number up to high number
Economic value individual or germplasm	Low	Moderate to high
Phenotyping costs production (individual/family)	Very low to low	High to very high
Phenotyping costs adaptation, resistance (individual/family)	Very low to moderate	Very high
Cost of breed/variety testing	Inexpensive	Expensive
Status of in situ genetic conservation	Promoted	Promoted
Status of in vivo ex situ conservation	Minor role	Major component
Status of gene banks	Extensive collections (important role of CGIAR*)	Semen collections in developed countries (no involvement of CGIAR*)
Technical feasibility of ex situ (in vitro) conservation	For majority of species	Semen ok for majority of species
Conditions for storage	In cool conditions	Only liquid nitrogen
Ease and costs of extracting/testing accessions from gene banks	Generally easy and relatively low cost	Difficult, costly and/or time consuming (often several generations backcrossing)
Ongoing collection of indigenous/wild germplasm	Still significant	Very little activity
Costs of collection	Low	High to very high
State of global databases	Relatively advanced databases	Country controlled data in FAO database

** Consultative Group on International Agricultural Research*

Source: Adapted from Gibson and Pullin (2005)

The organisation of the animal breeding sector differs significantly among animal species. The commercial breeding industry for poultry, pig and dairy cattle is as concentrated as in major crops, whereas commercial large scale interest in other species is minimal and left to livestock keepers themselves. In developing countries animal breeding programmes are often less developed than those for plants.

Finally, the centres of diversity for AnGR are not as clearly defined as for plants. South-North exchange is very limited; North-South exchange is high and South-South exchange is becoming more important. It seems that the entering into force of the CBD has hardly influenced the exchange of AnGR so far. In plants, implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) relies heavily on the institutions of the seed sector that were already heavily involved in the international movements of germplasm. In contrast, the global movement of AnGR is already limited by strict sanitary regulations designed to protect health of national herds, and by high costs of movement, testing and development. Collection and testing of AnGR from the developing world is therefore less frequent.

Even if there are some similar features between plants and animals, the differences are substantial and require caution when drawing a parallel between them for regulatory purposes. These differences need to be reflected in the policy and regulatory options for AnGR.

2.2 The Term 'Animal Genetic Resources'

The term 'Animal Genetic Resources' (later referred to as AnGR) is used to describe the subject matter. The term is used in a very practical manner and applied scope referring to all uses of animals for breeding purposes. The term 'breeding purposes' is also used in a broad sense, covering a number of different methods applied in the livestock sector. The main element of AnGR is the genetic material of animals used in further breeding and in the production of food and industrial products. This covers semen and eggs, embryos and live animals when they are being used for breeding purposes. Genetic material also refers to DNA molecules, RNA, proteins and other micro-physical genetic material. The term AnGR is used in a practical manner and does not focus on the informational elements of 'genetic resources'.

The differences between farm animals and plants, identified above, need to be reflected in the legal analysis. In the farm animal sector there is yet another important component, the techniques and methods for breeding and husbandry. This does not fall under the term 'genetic resources' as such but is important to have in mind when discussing law and AnGR.

2.3 The Concept 'Genetic Resources' in the CBD

The Convention on Biological Diversity (CBD) uses the term 'genetic resources' in a rather specific meaning.[7] The definition of the term is derived from two definitions specifically included in the Convention:

> *'Genetic resources' means genetic material of actual or potential value.*[8]
>
> *'Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity.*[9]

Read together 'genetic resources' include any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value. This indicates that all biological material is source or origin for 'genetic resources'.[10] A necessary condition is that the origin is biological. The term 'any material of … animal' is broad and covers animals, even though regulating animal breeding is not the main aim of the CBD. This is however only the first delimiting criterion for determining when the obligations and rights apply according to the CBD. The term 'genetic resources' is used in the CBD to establish a new category of resources: When value and benefits are drawn from biological material in particular manners, these manners are defined by the two criteria:

- containing functional units of heredity
- actual or potential value

The term 'containing functional units of heredity' is the first delimiting criterion for determining whether one is under the scope of the obligations in CBD Article 15. The term *functional units of heredity* is not defined in the convention, but is generally thought to refer to DNA, RNA and proteins derived therefrom. This formulation points towards parts (units) of the material that are related to the hereditability of the organisms. It is important to note that the definition is not linked to the units of heredity as sciences described them in 1992 or even today; the wording does not use the term *gene* or DNA-molecule. It has been formulated in a technology-neutral manner making the scope of the obligations according to CBD Article 15 flexible, covering the use also when technologies shift and develop in the future, so other as-yet-unknown components will be embraced by the definition. In recombinant gene technology all these parts of biological material are of direct interest. Although technological difficulties and consumer opinion do not allow as yet for commercial development of Genetically Modified-animals (GM-animals) this might become the reality in the near future, so the regulatory and policy options must take them into account. Some species, e.g. farmed fish are near such developments, which emphasises the need for law to be robust. Thus, *genetic material* as a legal concept is linked to the part of the biological material which is subject to any heritable interest beyond the biological

[7] For a through discussion of the term, see Tvedt 2006, at p. 194–197.
[8] CBD Article 2, section 10.
[9] CBD Article 2, section 9.
[10] CBD Article 2 tenth section read in conjunction with ninth section.

properties of the organisms where it once was found. From a practical perspective the obvious example in animal breeding is that semen, eggs, fertilised eggs and embryos are expressions of and contain genetic material.

One difficult question arises when for example a calf is sold. It could be sold as a breeding male and it could be sold to be fed and slaughtered (or a combination of these), and it may also be used to extract DNA for industrial or agricultural inventions. The young calf is surely carrying *functional units of heredity* and consequently genetic material. Farm animal breeding is characterised by such multiple purpose use. Sales of an individual, e.g. a calf could entail both sales for the purpose of feeding and slaughtering as well as the intention of using it as a breeding animal (either in pure breed or in cross-breeding aiming at introducing certain characteristics into the other breed).

The next delimiting criterion in the CBD is that the *genetic material* must have 'actual or potential value'. The focus of this criterion and thus the definition of genetic resources is at the value that arises from uses capturing the value of the genes.[11] This includes breeding seeking to improve the properties of the next generation of animals, for example disease resistance, higher lactation or better meat quality. The CBD establishes a special concept of resources, the use of genetic material for taking advantage of the genes as a resource. The concept 'genetic resources' in the CBD is closely related to the benefit-sharing obligations of the CBD. The benefit-sharing obligation according to the CBD is focused on sharing 'the benefits arising out of the **utilization** of genetic resources'[12] and 'the results of **research and development** and the benefits arising from the **commercial and other utilization** of genetic resources'.[13]

Common for these formulations is that they are geared towards the *utilisation* rather than the access to or export of biological material, seeking to capture a part of the value created by the use of the genetic material to be shared back to providers and conservers of biological diversity. The legal concept 'genetic resources' according to the CBD could therefore be understood as including all activities that **result in capturing** the 'actual or potential value' of genetic material by taking advantage of the 'functional units of heredity'.

It is suggested by Tvedt and Young that in the process of making the term 'genetic resources' operational in a legal system based on the CBD, three elements of resources should be included:

1. The micro-physical genetic material, when the user is aiming at drawing benefits from the genetic material and not from the bulk value of biological material;
2. The intangible genetic information;

[11] Tvedt 2006 and Tvedt and Young 2007 forthcoming.
[12] CBD Article 1 (emphasised here).
[13] CBD Article 15.7 (emphasised here).

3. Any combination of the micro-physical/tangible genetic material and the genetic information.

This dual understanding of genetic resources is an important step for the successful implementation of the objectives of the CBD. For the animal sector the informational elements are also extremely important. Knowledge about the breeding value of an animal, or specific traits that it carries, is of crucial value for breeders. Knowledge takes various forms, from systematic archives on pedigree (herdbooks), performance data and medical history to more dispersed informal or traditional expressions of knowledge. We, however, concentrate on AnGR in a narrower sense, focusing mainly on the physical elements of 'genetic resources', not on the related knowledge.

2.4 Available Legal Tools Relevant for AnGR

In the area of AnGR international, regional, and national law along with customary law are relevant. Animal breeding happens within the territory of one country. Therefore, the point of departure for breeders, farmers and livestock keepers is the national legislation of their country. Multinational breeding companies relate to the national laws in all the countries where they conduct business. Since food production is increasingly an international area and market, there is also a web of relevant regional and global agreements. In the field of genetic resources a substantial amount of law-making goes on at the international arena and at a regional level. International and regional law may be totally new (e.g. CBD) or target harmonisation of national laws (e.g. veterinary regulations). This leaves legal analyses in a schizophrenic situation of whether to focus on national or international law. For AnGR, elements from both are particularly interesting, so the focus of the analyses shifts – we need to keep an eye on both the national and international level.

There are no comprehensive international regulations or policies that specifically address the management, sovereignty, ownership and benefit sharing for AnGR.[14] It has been noted that 'AnGR lag behind plant genetic resources at the international level' and there are also very few countries that have policy frameworks explicitly for managing AnGR among other genetic resources.[15] There are, however, several international treaties with a general scope applying to AnGR.[16] The Convention on Biological Diversity (CBD) establishes sovereign rights over 'genetic resources', which implies that a country has the right to regulate various aspects regarding the resource, inter alia property rights to it. The sovereign rights do, however, not automatically include a property right for the state or government, and they go together with the obligations of signatory countries to conserve and promote sustainable use.

[14] Gibson and Pullin, 2005.
[15] FAO, 2005.
[16] The Convention on Biological Diversity, the Agreement on Trade-Related Intellectual Property Rights under the World Trade Organisation and the patent system as maintained by a number of agreements under the World Intellectual Property Organisation, the WIPO.

Four different areas/angles are interesting to discuss under the current regulatory framework regarding the effect on exchange, use and conservation:

- Ownership and exclusive rights to AnGR (section 3);
- Exchange, access and benefit sharing related to AnGR (section 4);
- Sanitary issues related to exchange of AnGR (section 5).

The overall objective of this analysis is to contribute to the development of options for international law to respond to current needs and future developments in AnGR (section 6).

3 Ownership and Exclusive Rights in Animal Breeding

One topic which is increasingly relevant is that of exclusive rights or property rights to genetic material, even though the literature discussing AnGR is still scarce.[17] Several types of law are relevant for exercising exclusive rights pertaining to AnGR:

1. Property rights to or ownership of individual animals or populations of animals;
2. Contracts for transferring property rights or ownership;
3. Intellectual property rights created to protect novel developments or inventions (non-physical or intangible values).

3.1 Property Rights – Ownership of the Individual Animal

For farm animals and thus also AnGR, private ownership is the rule and the public domain the exception. The point of departure and main rule is that the owner of the individual animal has the right to use the genetic resources in further breeding. This ownership to AnGR is seldom specified in legislation and is most often based upon customary law. For farm animals there are strong biological and physical means of protection available:[18] The owner of the animal can more easily than the plant breeder have an overview and control over who is receiving genetic material from his animals or his population. This physical control, however, diminishes for secondary use and subsequent generations. The case is different for poultry and pig breeding where farmers often buy hybrids whose genetics are more difficult to reproduce. The sale of hybrids is thus an important strategy for maintaining physical control over the genetic material by physical control over the material. For other breeds, in particular cattle, the physical ownership is often combined with a register, a herd book that maintains a protocol for the generations of animals fulfilling the criteria for registration.

[17] See for example the Nordic Council of Ministers 2003:19.

[18] For a discussion of the parallel situation for fish, see Rosendal 2006, at p. 398 sig.

Property right or *ownership* is often understood as a bundle of rights – a set of actions which the 'owner' has the exclusive right to exercise. Ownership of one single animal or a population covers *inter alia* the right to:

- breed the next generation of individuals (use of genetic material);
- sell the animal (can be exchange of genetic material);
- sell its products (if semen is sold for artificial insemination (a.i.) it will be exchange of genetic resources), or;
- slaughter it and use or sell the products (which would be equal to destructing genetic material).

Ownership of an animal includes, as a point of departure, all these types of use of the animal. This is considered to be fairly obvious by farmers and breeders as well as policy makers. It becomes more complex when the concept 'genetic resources' is taken into account including different levels of rights, as some of these actions draw benefits from the genetic material of the individual rather than the biological material.

Animal keepers and breeders continuously upgrade their breeding stock, sell animals or genetic material or disseminate genetic progress within a company. Improved traits are passed to further generations by various breeding techniques. This may imply that extra cash flow from the improved genetic material flows back to the subsequent genetic improvement programmes or to the owners of the breeding animals.

These property rights are seldom explicitly regulated in an act. There are no international agreements specifying anything about property rights. It is the national level that is the source of law for property rights, as it is the nation state which has the power to safeguard and maintain the property rights within its borders. As ownership is seldom regulated in an act, this issue is solved by various forms of customary rights. It is widely recognised that for a norm to be regarded as international customary law, three conditions must be fulfilled:

1. To become customary law there must be a continuing practice over a certain period of time;
2. The practice must be fairly consistent by the relevant entities (states for international customary law and persons within each legal system);
3. It must have been followed as it was a binding norm, so-called *opinion juris*.

The fact that the ownership of the individual animal and the right to use it in breeding has been the practice in the complete history of animal husbandry and breeding; this practice has also probably been consistent in the sense that no comprehensive legal systems/general legal regulations have been departing from the right of the owner of the animal to use its genetic material. It can be expected that farmers have followed this practice as a legally binding norm (*opinion juris*) to the extent that this issue has been thought of in legal terms over a long period. This might be

considered as obvious by the majority of farmers or policy makers. The fact that this legal point of departure is viewed as fairly obvious to all relevant stakeholders strongly indicates that this is a well established customary law.

When a norm is recognised as customary law, delimitations in the right must be justified. If any limitations exist, they need to be based either on the consent by the owner (contract) or by legislation (by parliaments) altering the *customary law*. The holder of the right to animals can, inter alia, be a private person, a cooperative or it can be a group of persons or a community of livestock keepers. The general principle applies that there are no legitimate or legal limitations in the property right over the genetic material from the animals under the 'ownership' by a community. To fully conclude on the issue of ownership one must analyse the legal sources of each country.

3.2 Contractual Agreements: Contracts – Transferring an Existing Right to Another Person

The right to use the animal in breeding is often specified in a (formal or informal) contract between the seller and the buyer of an animal. The main rule that ownership can be transferred also applies to animals. The contract or informal agreement determines the scope of what is transferred and which rights still belong to the seller (if any). As a contract is individually agreed, the seller may keep or reserve himself certain rights to the offspring of the animals. The contract then determines which rights are transferred to the contracting party. If no reservation is included in the terms for the sales, the assumption is that the buyer of the animal receives all the rights that the seller had, including taking advantage of the genetic resources. If an animal is sold to the slaughter house for the meat value, the interpretation of that contract will likely be that the buyer does not have a right to use the genetic resources, but only a right to use the meat and other products.

Contracts imply a dynamic element in establishing (or transferring) rights from one owner to the other. The point of departure is that the owner can transfer what he has the right to, but he cannot transfer more than already is covered by his legal right. The contract determines the scope of what is transferred and which rights still belong to the seller. A contract is individually agreed, and is thus more specific than the general rules of ownership. The owner decides whether he or she wants to sell the animal or give access to the genetic material by selling e.g. semen, eggs or embryos. Thus, the exchange of genetic material is subject to a contract between the provider (seller) and the user (buyer), also if the transaction is between persons in different countries.

The value of a contract is closely related to the compliance by others to its terms and conditions. Therefore, the potential to use contracts must be seen in the perspective of the possibility to enforce others to comply with the content of the contract. In a transparent market, where the seller has good control over the further use of what he sells, the use of contracts will probably be effective. This is for example the case where one needs to register the animal in a herdbook for the next generation of animals to

become valuable, and the register depends upon the documentation of the parents of the young animal.

The seller of semen could for instance reserve for himself the right to sell semen, or reserve for himself a right to the off-spring of the next generation of calves, to ensure a right to the genetic resources coming out of the breeding with his individual. This agreement or contract could be more or less formal and more or less standardised. A comprehensive study of contractual practice regarding transfer of AnGR has not been undertaken yet, and is difficult because such contracts are commonly kept secret.

An obvious advantage to using contracts is that industry is accustomed to this legal tool. Effective contract law including systems for enforcement are in place in the majority of countries, increasing the chance for achieving the content of the agreement. The most important limitation of the use of a contact is that it only applies between two parties, and has no legally binding effects for third parties. Thus a contract can hardly be binding for the next rounds of transfer of the AnGR. A contract may include clauses which seek to regulate the subsequent transfer of the genetic material, the enforcement of which may only be possible in a highly regulated or transparent market, or if an effective tracing system is in place.

3.3 Introduction to Intellectual Property Rights

Ownership and contracts are two dimensions of property rights relevant to the animal sector. The limitation of these legal tools is the effect in relation to third parties. Here various forms of intellectual property rights become relevant as these general rights are enforceable upon third parties (within the same jurisdiction). By the Agreement on Trade-Related aspects of Intellectual Property Rights (The TRIPS) as a part of the World Trade Organisation (WTO) in 1994, international harmonisation of intellectual property rights were sought by laying down minimum requirements for all types of IPRs. Before the TRIPS Agreement the scope and extension of intellectual property rights were mostly a national issue.

Four types of intellectual property rights are relevant in the field of AnGR: 'geographical indications, trademarks, trade secrets and patents'.[19] Intellectual property rights are developed to capture revenues from intangible resources, for example from knowledge, a brand or an invention. Intellectual property rights create a (commonly temporary) exclusive right, granted by the government, based on national legislation which may be subject to regional or international harmonisation.

There are two international organisations working in the field of harmonisation of intellectual property rights on a global level: The World Trade Organisation and its Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and the World Intellectual Property Organization (WIPO), which administers a number of treaties. Whereas the TRIPS Agreement implied the largest single change in international

[19] FAO, 2005: 28.

IPR law, the WIPO represents more of a continuous process on international cooperation and harmonisation of intellectual property rights. In addition there is a growing number of regional and bilateral agreements dealing with IPR.

Intellectual property rights are not a 'breeding tool' or a technique for improving the breed. They pertain to the value of a product or a process in a market. By introducing a legal tool like intellectual property rights into a new sector, the climate for competition and for production may be altered. Thus, there is a need for analysing the consequences that this introduction has already had and the probable consequences it will bring in the future. This has not yet been done for the animal sector.

The interesting main question for our purpose is what kind of intellectual property rights are available for the animal sector? This can be separated into three more detailed questions:

1. Who is the holder of the right (entitled)?
2. What is the subject matter that is protected by the right?
3. What is the scope of the right? Or which acts are under the exclusive right of the holder of the intellectual property rights?

3.4 Trademarks

A trademarks is a 'sign, or any combination of signs, capable of distinguishing the goods or services' that may add value to a product by distinguishing the product from other similar products in the market.[20] Trademarks offer legal protection of a brand or signs illustrating a brand. The TRIPS Article 15 to 21 regulates a minimum level of recognition of trademarks required upon all WTO members. Even if the TRIPS obliges a large number of countries to provide a high level of minimum protection, the cooperation in the WIPO is more detailed and plays an important law-making role.

Trademarks are being used to add value to a product by including certain intangible elements into a product, for example a famous label that is linked to a history of tradition or special methods to bring this specific product to a market. The owner of a trademark is the register or the one who has created it. The main idea of trademarks is to protect a distinction between one product and all other products in the market – for the purpose of charging a higher price than competing products. Thus, genetic material *per se* cannot be protected or covered by a trademark. A trademark can, however, be a useful tool in the animal sector as the value-adding elements created in breeding can be protected. A trademark can improve the value of a product.

[20] TRIPS Article 15.

3.5 Geographical Indications

Geographical indications can protect 'indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin'. (TRIPS Article 22, paragraph 1). Similar to trademarks, geographical indications do not protect the breed or genetic material *per se*, but may add commercial value to the animals of breed produced in a particular region. Geographical indications prevent all others than the producers from that original location from using that particular geographical indication incorrectly as a trademark for other products than those from that area. The essence of this intellectual property right is the protection of the combination of a territorial name (geographical origin) and 'a given quality, reputation or other characteristic of the good'. Geographical indications do not protect or establish any exclusive rights to the genes *per se*. They may be interesting as a value-adding legal mechanism in the animal sector, if the quality or reputation of a product is linked to a certain geographical area, and commonly linked to the use of particular breeds. Typically, this applies to agriculture, i.e. Champagne and Parma. Geographical indications are closely interlinked with the protection of trademarks, as a trademark should be not be granted if it is based upon a geographical indication 'other than the true place of origin in a manner which misleads the public as to the geographical origin of the good' (TRIPS Article 22, paragraph 2a).

Box 1 Example of Protected Designation of Origin

The French production of chicken meat is differentiated as standard broiler (SB), label chicken (LB), certified chicken (CF), organic chicken and Protected Designation of Origin. At the moment the latter category is reserved for the Bresse breed only. These chickens, 1.4 million raised per year, are produced in the Bresse geographical area only, as defined by law. The production is characterized by natural conditions and a production system unique for that area. For the Bresse, the district was defined in 1936 and the name 'Volaille de Bresse' was protected by law in 1957. The breed has unique phenotypic characteristics. After an initial starting period of 5 weeks a fixed set of specific growing conditions (diet, housing) must be applied for at least 9 weeks. Specific regulations also apply to slaughtering conditions and processing of carcasses. Since 1995, the selection procedure is regulated and the final product is a cross of three sub lines obtained after mild selection. The price for the chicken is 50-60% higher than for standard or label chicken. Starting as a threatened breed kept by fancy breeders, the Bresse breed became locally a very popular breed yielding high profits.

Reference: Verrier et al., 2005

3.6 Trade Secrets

Trade secrets or 'Protection of Undisclosed Information' are regulated in TRIPS Agreement Article 39. This can hardly be categorised as an intellectual property right as it does not establish an exclusive right over a specific subject matter. The character of these obligations is rather related

to the protection against unfair competition according to the Paris Convention 10*bis*. The scope of this legal measure is rather narrow and it does not provide for exclusive commercial rights to the one seeking to hold information secret. Protection of undisclosed information is relevant in animal breeding, where commercial breeders want to keep their nucleus stock and the pedigree and value information away from competitors. However, protection by trade secret is more difficult to enforce than the other rights discussed here.

3.7 Patents

A patent grants an exclusive right to the commercial use of a new invention either described as a *product* or a *process*. Patenting of living matter is fairly new in a global context and in the large majority of countries, and patenting in the field of animal breeding is a very recent phenomenon.[21] The watershed court case is the often quoted Diamond vs. Chakrabarty from the US Supreme Court in 1980. The question in this case was whether one particular genetically engineered bacterium could be patented; where the Court formulated the all-sweeping general statement that: 'anything under the sun that is made by man' is patentable.[22] This court case has had major impact on the legal situation throughout the world as it prepared the ground for altering the basic principle that patent protection was not available for life forms.[23] The effect of patents on research and development in animal breeding is yet insufficiently explored. The degree to which such protection should extend to plants and animals is contentious among countries and there are potential areas of incompatibility or overlap with the aims of the Convention on Biological Diversity.[24] An overall challenge is that patent law operates with general concepts originally chosen for promoting technical industrial inventions, whereas now the same legal concepts are applied to new fields of technology which were not thought of being relevant for patent protection.[25] The patent criteria are, according to TRIPS Agreement Article 27, paragraph 1 that an invention shall be patented if i) it is novel, ii) involves an inventive step and iii) have an industrial application (the footnote to the paragraph states that the terms 'non-obvious' and 'useful' can be used synonymously). The TRIPSAgreement prescribes that all areas of innovation must be open for patent protection, except some particular types of

[21] In the US, where the expansion of application of patent law is going most rapidly, there were according to Lesser a total number of 45 animal patents from 1995 to 2001 (Lesser 2002, at p. 9).

[22] Diamond v. Chakrabarty, 447 U.S. 303 (1980) Decided June 16, 1980.

[23] The Diamond v. Chakrabarty was referred to by the Canadian Supreme Court in Harvard College v. Canada (Commissioner of Patents), the Canadian Onco Mouse Case, Neutral citation: 2002 SCC 76.File No.: 28155.

[24] See for example this issue in the TRIPS Council under the WTO, IP/C/W/368, IP/C/W/369, IP/C/W/467–IP/C/W/475.

[25] For example Westerlund 2001 discusses profoundly the concepts of *invention or discovery*, *enabling disclosure* and *the doctrines of equivalence* for biotech patents (however focused on plants); and Bostyn 2002 who discusses the requirement for *enabling disclosure* in depth. See also the report from the Nuffield Council which expresses several concerns.

subject matters, defined in Article 27. The more detailed interpretation and application of these criteria is left to be determined by national practice for each area of innovation.

A patent is granted by the Patent Office of one country and is valid in the territory of that country.[26] Patents are territorial, but developments aimed at harmonising these national laws are ongoing in the World Intellectual Property Organisation. This illustrates that the legal analysis in the field of animal breeding needs to reflect the international, regional and national level. The focus here is patent law at international level. A multilateral forum for discussing topics related to *genetic resources* and intellectual property rights is the Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore which was established in 2000.[27] The work of the IGC is general in scope and does not address AnGR in particular. The outcome from these discussions is however going to apply equally to AnGR. Even though the IGC has met ten times, it is far from reaching a legally binding treaty on these questions.

Another process of harmonisation of patent law that may have a large effect on the animal sector was led by the Standing Committee on the Law of Patents (SCP). In the Standing Committee the work aims at establishing complete harmonisation of the patent criteria (invention, novelty, inventiveness and industrial application) and a number of other crucial patent concepts. The general scope of these draft texts is general and will apply to the animal breeding sector. The effects from the general law on this particular area of innovation are however not at all in focus.[28] In April 2006 the Standing Committee failed to agree upon a future working plan for further harmonisation of patent law global in scope. The countries in the so called B-Group of the WIPO, mainly the OECD countries and a small number of developing countries have decided to continue the harmonisation of patent law outside the general fora of the WIPO. As the degree of consensus among these countries is higher, they are probably going to reach harmonisation of those issues that the Standing Committee did not achieve. These harmonised rules will apply to the animal sector even if they are not built upon any analysis of how these rules are going to affect the sector.

3.7.1 Patentability According to the TRIPS Agreement

The question the types of inventions that are eligible for patent protection was previously left to the discretion of each country. This was radically altered by the TRIPS Agreement, which establishes a comprehensive scope of patentability by requiring all member countries to provide for

[26] For the member countries of the European Patent Organisation, a patent can be granted for several countries at the same time. There is a similar system administered by the OAPI, the African Organisation for Intellectual Property, which grants patents that are valid in 16 mainly francophone West African countries.

[27] www.wipo.int/tk/en/igc/

[28] For an analysis of the effect from this draft for genetic resources in general, see Tvedt 2005.

patent protection in all fields of invention, save some narrow exemptions: Countries are allowed to exempt patent protection of *animals other than micro-organisms*; and for *essentially biological processes*.[29]

The TRIPS Agreement opens for exempting *animals* other than *micro-organisms* from **product** patent protection in national patent law. The practical implications of this exemption depend upon the interpretation of the legal concept '*other than micro-organisms*'. There is no definition or any agreed understanding of the term *micro-organisms* among the parties to the TRIPS Agreement. Thus, countries have significant discretion as to whether to include or exclude animal, animal- proteins, genes and cells under patent protection in their national patent system, which may have a significant impact on biotechnology. One linguistically possible interpretation of this term is that countries have the freedom to exempt product patent protection regarding every category of animal-related biological invention except those being clearly recognised as micro-organisms in a biological sense.

The TRIPS agreement obliges all member countries to provide for **process** patent protection to 'any inventions, whether products or processses, in all fields of technology'. The point of departure is that countries are bound to grant process patents also in the field of animal breeding. The TRIPS article 27 paragraph 3 opens for countries to exempt '…essentially biological processes for the production of […] animals', but obliges countries to delimit such an exemption and provide for patents to 'other than non-biological and microbiological processes'. The essential question is what is an 'essentially biological process'? A WIPO official, de Carvalho, argues that this wording should '… be read in a restrictive manner…' since it is an exclusion and maintains that: '…there are processes which are biological, to the extent they comprise some phase in which biological reproduction is employed, yet their most important steps consist of acts of human direct interference. These processes, in essence, are not biological' and must therefore, according to him, be patentable according to his understanding of the TRIPS Agreement.[30] However, the TRIPS agreement does not specify the legal concept further, and countries have a wide discretion to implement a broad or narrow definition of *essentially biological processes for the production of […] animals*. As the wording here is not clear, the TRIPS Agreement encompasses a level of discretion for countries in their implementation and practice based on this provision. When having determined that countries have a significant discretion for specifying and establishing exemptions in the eligibility from patent protection, the next step is to look at the criteria for the patent to be granted:

3.7.2 Definition of Prior Art – *Criteria for Granting the Patent*

The concept of *prior art* defines what the patent system regards as previously known and thereby not open to be included under patent protection. The main principle is that what is not novel or does not involve a sufficient level of inventiveness cannot be covered by a new patent. In

[29] TRIPS Agreement 27, paragraph 3.
[30] de Carvalho 2005, at p. 217–218.

principle, nothing that already is provided to the public shall be patentable; it is included under the *prior art*. This general principle is however narrowed down by technical definitions of what the patent system considers to be *prior art*; and by a technical procedure for searching the existing information to determine what is *prior art*, to find out what was already known before a new patent application. The TRIPS Agreement does not specify what is included under the *prior art*. The technical definition of *prior art* was suggestion to be harmonised globally in the draft SPLT as:

> *The prior art with respect to a claimed invention shall consist of all information which has been made available to the public anywhere in the world in any form [as prescribed in the Regulations,] before the priority date of the claimed invention.*[31]

A first look at the wording gives the impression that the definition is broad. It includes 'all information', 'available to the public anywhere in the world' and 'in any form'. This gives an impression of a worldwide concept of prior art that in principle excludes everything available to the public from patent eligibility. However, to be included under prior art it must be conceived as 'information' according to the draft Treaty, it must be 'available to the public' in the manner prescribed by patent law and it must be presented 'in any form' accepted by the patent system. Hence, what appears to be a worldwide, comprehensive definition will be delimitted when made operational in the patent systems. These seemingly broad terms are narrowed down in the draft Regulation that goes into more detail and specifies the obligations according to the draft Treaty.[32] One challenge regarding the *prior art* in the field of AnGR is that a lot of the best practices are poorly documented. The practice of the definition of *prior art* might thus allow for patents that include some already known techniques, but whether this becomes a problem rests in the practice of the patent offices. The *prior art* is used as a basic for the assessment of whether the invention is regarded as novel and implies a sufficient level of inventiveness. Also these considerations are general ones, but will have particular effects in the field of animal breeding.

3.7.3 Scope of Protection

The acts covered by a patent are harmonised at the global level for all fields of technology by the TRIPS Agreement Article 28:

> *A patent shall confer on its owner the following exclusive rights:*
>
> *(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of:* ***making, using, offering for sale, selling, or importing*** *for these purposes that product;*
>
> *(b) where the subject matter of a patent is a process, [it confers a right] to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering*

[31] Article 8 (1) Draft SPLT, SCP/10/4, at p. 15.

[32] For a more detailed discussion see Tvedt 2005, at p. 327–329.

> *for sale, selling, or importing for these purposes at least the product obtained directly by that process.*

These acts are formulated in a wide and general manner. To answer the question of how patent law will apply to the animal sector, these general acts of infringement must be coupled with the typical manners to formulate a patent claim. How the scope of patent protection will adhere to the field of animal breeding is yet to be observed, as this has not been affirmatively determined by any courts yet. Therefore, at the international level it is not certain what the legal situation is when it comes to the protection conferred by a patent in this field of animal breeding.[33]

One fundamental difference between regular industrial inventions and those based on naturally occurring biological material is that the industrial invention is likely to be man-made from scratch; whereas for example a gene is already there in nature, in most cases only in a slightly different form. This implies that a product patent relates to something already existing in nature. This has a potential to raise difficulties in the animal field both in terms of prior art and scope of protection, specifically because AnGR is mainly already in private or communal ownership. Therefore, there is a latent conflict between the owner of the animal genes in the animals and a subsequent patentee.[34]

The product patent covers an exclusive right to the use or application of the described method. But the scope of protection extends also to cover *at least the product obtained directly by that process*. This means that the scope of process patent protection in the TRIPS Agreement indirectly requires product patent protection to be covering the outcome from the use of a patented method. Using a patented process might therefore give the patentee rights to the off-spring from the application of the process. The scope of protection in the TRIPS Agreement is not adapted to the field of animal breeding – so these consequences are probably not foreseen in the WTO.

3.7.4 Limited Exclusion

The TRIPS Article 30 opens for members to:

> *[…] provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*

This option to provide for limited exemptions in the scope of protection has not yet been thoroughly examined in the patent literature. Also the limits of which exemptions that are sufficiently 'limited' and when they do not imply an 'unreasonable prejudice' and what is 'legitimate interests' of the patentee are not clarified by any court or board of appeal.

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[33] For an analysis of the legal situation in Europe based on the EU Patent Directive EC/98/44, see Tvedt 2007.

[34] See Tvedt 2007 for a more profound analysis of this issue.

Also not many countries have developed specific exemptions for the field of animal breeding or biological patents in general. The EU has implemented a system for exemptions according to this article in the TRIPS.[35] When developing countries call for flexibility in the TRIPS Agreement and for their national implementation, one first step could be to explore whether the already existing exemptions could be used.

4 Access and Benefit Sharing Related to AnGR — The Convention on Biological Diversity

The Convention on Biological Diversity (CBD) is broad in scope and applies to biological diversity, which is defined as:

> *the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.*[36]

This includes by principle also farm animals. The definition of 'genetic resources' in the CBD is, as discussed above, a rather specific one. According to the CBD all genetic resources are under the sovereign rights of the states as part of their sovereign right over natural resources.[37] Sovereign rights include the right to regulate various aspects including access to the resources and property rights to them. The general rules as explained in the previous section regarding property rights, contracts and intellectual property rights are all regulated at the country level, although not necessarily explicitly and in detail.

Beyond the obligations to take a number of conservation measures, the CBD establishes the right of countries to develop procedures and conditions for access and benefit sharing, often referred to as ABS. Thus, access to AnGR from another country could be dependent upon the regulations in the country where access is sought. There are however not many countries with an effective access legislation in place. The CBD prescribes that access could be made subject to *prior informed consent* from the providing country (or parties in the country) before genetic

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[35] The EU has for example enacted this exemption in the EU Directive on Biotechnological Patents Article 11: '… 2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.
….3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.'

[36] CBD Article 2, first subsection.

[37] CBD Article 15, paragraph 1 reads: 'Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation'.

resources legally can be accessed. It also specifies that access should be on *mutually agreed terms*. The further details as to how these two legal instruments could be applied are not specified in the CBD. The regulation of access is primary dependent upon the regulation in each country. In (April) 2002, the Conference of the Parties to the CBD adopted the Bonn Guidelines (CBD, 2002), a voluntary set of suggestions to assist governments and regional bodies to develop policies, legislation and administrative practices to develop access legislation. The main focus in the Bonn Guidelines is almost exclusively on measures to be taken in the provider country.[38] Despite these efforts, there are not many countries claiming to have a well-functioning system for access in place. Access is often referred to as a contract between the provider country and the user of genetic resources. The contractual approach has been used since the CBD entered into force in 1993, but there are still not many documented examples of contracts. The CBD does not differentiate among the various types of organisms, even though the use of genetic resources differs among types of species. The little focus on farm animals in the CBD could expose the access rules under the CBD to having an undesired effect for access to and exchange of AnGR.

The other side of ABS is a wide set of benefit sharing obligations upon users and user countries of genetic resources in the CBD. The more detailed implementation of benefit sharing legislation has so far been referred to the national level without good guidance from the international level, and effective results are still to be seen. Until now there has been only a limited focus on how to implement the obligation in CBD Article 15, paragraph 7:

> *7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.*

Despite the clear wording obliging countries to take legislative, administrative or policy measures aiming at sharing benefits in a fair and equitable way, user countries have been very reluctant to take any such steps. The question of how these obligations can be implemented at the national level is now being raised in the Conference of the Parties to the CBD. The construction of an international architecture for ABS was given further endorsement and impetus by the Plan of Implementation adopted at Johannesburg World Summit on Sustainable Development in (September) 2002. The CBD COP 7 negotiated a mandate for the so-called Ad Hoc Working Group on ABS to negotiate an International System for ABS. The Ad Hoc Working Group has met twice before the COP-8 in 2006, and will meet before the next CBD-COP with the aim of presenting concrete results.

[38] Bonn Guidelines Article 7, 16 and 42 c.

The CBD recognises that agricultural genetic resources need to be treated differently than other forms of biodiversity, but the CBD has not taken any initiatives to support a specific focus on AnGR.

The Commission on Genetic Resources for Food and Agriculture under the UN FAO is a forum through which governments can discuss and negotiate matters related to genetic resources for food and agriculture. The agricultural sector (under the FAO Commission) has sought to promote access and benefit sharing to plant genetic resources by concluding the International Treaty on Plant Genetic Resources for Food and Agriculture. The focus of the Commission to date has been on plant genetic resources, but it is now moving to address AnGR more systematically.

5 Sanitary and Veterinary Regulation of AnGR

Exchange of AnGR is dependent upon regulations of import and export. Many countries have developed legislation on the importation of animals or breeding stock, setting out detailed and specific requirements on animal identification and breeding documentation, as well as on the health status of imported stock (FAO, 2005). In countries that consider export of breeding stock as a commercial enterprise, no export regulations are provided by the state. There appears to be an assumption that quality and health standards should be laid down by the importing party. On the other hand, countries may want to regulate export of breeds or breeding stock as a protection measure for their genetic resources.

Regulation of sanitary issues for AnGR is foremost a topic that is regulated in national legislation. The objective of this type of legislation is to protect animal health to prevent the spread of diseases and not to regulate exchange of genetic resources. Liberalisation of trade in goods (commodities) is identified as an important goal inter alia under the WTO. Import restrictions based on animal health can easily imply a hidden barrier to trade. The indirect effect of this might be that the national food production is guarded from effective competition from foreign producers. The WTO Agreement on the Application of Sanitary and Phytosanitary measures (SPS) deals with sanitary (human and animal health) and phytosanitary measures (plant health) that can be applied in the international trade in, among others, plant and animal products. The SPS Agreement aims at restricting the use of unjustified sanitary and phytosanitary measures for the purpose of promoting trade. The SPS Agreement encourages governments to establish national SPS measures consistent with international standards, guidelines and recommendations. This process is often referred to as ‘harmonization’. The Office International des Epizooties (OIE) is recognized as the standard-setting body for animal health. OIE standards are relevant to the management of AnGR in the import-export context.

Legal frameworks are frequently negotiated in political and regional groups of countries to improve cooperation, coordinate activities and minimise duplication of work. For example, EU sanitary legislation is made up of Directives and Regulations which must be implemented at the Member State level. Sanitary regulations are currently the most relevant (and often restrictive) regulation for exchange between countries within

EU and exchange between EU countries and countries outside Europe. In many countries there are specific and very strict regulations regarding the exchange of live animals in order to protect against the introduction of animal diseases in livestock trade (FAO, 2005), while regulations on exchange of semen, ova and embryos are usually sufficiently addressed in Animal Breeding Law and Veterinary Law.

6 Current Debate on Regulatory Issues

In the following sections, potential regulatory measures to address the access, exchange, conservation and sustainable use of AnGR are discussed. There is a considerable amount of overlap between measures under the three different areas of challenges, conservation, exchange and use of AnGR. In this section the various regulatory approach areas are examined in further detail.

6.1 Increased Breeding Capacity and the Development of Breeding Laws

There are few well organized selection programs based on local/ indigenous breeds and it is crucial for the survival of local/indigenous breeds for on-going breed improvement to be taking place. Local/indigenous breed improvement may also be accompanied by the development of controlled cross-breeding programs, depending on specific production circumstances and markets.

Breeding laws serve different purposes. A general objective is to improve the quality of breeds or breeding populations and to contribute to the conservation of breeds. It is generally accepted that breed associations or herd books play a prominent role in breed development and breed conservation, as they will promote maintenance and improvement of quality of pure breeds. Breed associations should spearhead the official performance and pedigree recording of the animals belonging to the respective breeds. Use of *trademarks* or *geographical indications* could also protect registered breeds. Many countries have breeding laws and regions might also aim at harmonization of national regulations (e.g. the cross border recognition of breed associations/herd books in the EU). Further harmonization of breeding laws would facilitate exchange and could contribute to livestock sector development and possibly also to breed conservation.

Potential disadvantages that would have to be overcome include the fact that the establishment of herd books or recognized breed associations could result in trade barriers, as they could be used to block the import of non-registered breeds and breeds from countries where the particular regulations do not apply.

6.2 Regulation of Import

Exchange of AnGR between countries has contributed positively to breed and livestock sector development in the past. However, there have also been direct or indirect negative effects on farm animal genetic diversity. Intensification of production systems and the importation of high output,

commercial breeds can constitute threats to other (local) breeds in the importing countries. Countries should consider implementing genetic impact assessments before importing AnGR. Impact (both positive and negative) assessments could also be extended to include economic and livelihood impacts, as well as other developmental and/or environmental impacts. Potential risks of Living Modified Organisms (LMOs), as well as food safety issues, are likely to become a major issue if and when genetic modification becomes widespread in the livestock sector.

The advantage of implementing impact assessments is the expected reduction of unwanted introgression or breed replacement. It creates stronger responsibilities for both exporters and importing countries and it has a direct effect on the conservation of local resources.

Potential disadvantages that would have to be overcome include the fact that the impact assessment requirements of importing countries may result in more bureaucracy, thereby blocking imports and reducing livestock sector development opportunities. From a regulatory perspective it would be necessary to ensure that impact assessments do not unduly constitute a barrier to trade. There are also additional costs involved in the realization of impact assessments, including for monitoring and mitigation activities. Institutional and technical capacity would also have to be strengthened. Although the development of genetic impact assessments have been discussed in the literature for a number of years, to the authors' knowledge no actual methodological development has yet taken place. Drawing heavily on the genetics and environmental impact assessment literatures, a methodology that assessed introgression and breed substitution risks based on, *inter alia,* a range of crossbreeding scenarios (from controlled to uncontrolled) and differentiated by production systems and socio-economic factors, would first have to be developed and tested.

Although the obligation to carry out a (genetic) impact assessment could be regulated at national or international levels, such an activity would clearly benefit from support from the international community. This would help ensure that a widely applicable model/standard impact assessment instrument could be developed.

Exporter/importer impact assessment responsibilities could be phrased either in terms of binding (national or international) regulations or by the development and implementation of a '*code of good practice'*. Where voluntary approaches might be expected to function well, these might be preferred. For both voluntary and binding approaches, the quality of the assessment would have to be assessed by an appropriate institution (e.g. in the importing countries or in conjunction with an independent institution).

6.3 Regulation of Export

The CBD presupposes the right of a country to exercise sovereign control over its AnGR (accompanied by a number of responsibilities). From the perspective of an exporting country, one of its main concerns is to maintain any property rights it may wish to retain over the AnGR after the

resources have left the country. Similarly, it may wish to ensure that the rights of the exporter are respected by the buyer/importer of the AnGR. The most prominent rationale for a country to regulate export of AnGR would be to secure a right over that particular material in the future, including preventing that countries or companies gain control over these resources (e.g. through patenting or other forms of intellectual property rights), which might reduce the value of it in the exporting country.

A second rationale for regulating the export of genetic resources has been the expectations of benefit sharing arising out of the use of genetic resources. However, it is a difficult task to determine any exact future economic value and potential monetary benefits may be substantially lower for AnGR than for plant genetic resources in general (see Table 1 for key differences between AnGR and PGR). Nevertheless, one should keep in mind the fact that current international AnGR research already involves considerable non-monetary benefit sharing with national institutions and livestock keepers, in terms of information exchange, technology transfer, training, joint research and development, and institutional capacity building.

Furthermore, it can be argued that private parties agree on benefit sharing elements when farm animal genetic material is being transferred by a private law agreement. Particularly in the commercial breeding sector, private law contracts often include payment not only for the purchase of the animal but also for any subsequent use of the genetic resource for breeding purposes. The level of payment for breeding material will typically be determined by the market positions of the buyer and the seller. In well functioning markets one can expect that a 'fair' price is reached. However, where negotiation capacities and market position are inequitable, intervention may be required to ensure that a fair price is actually agreed upon. In such a context, an *export regulation* could provide a useful supplementary tool for private law agreements. Such a regulation would set rules or a minimum standard for the content of a private law agreement to be considered legal or valid, thereby regulating the sale of AnGR/breeding material to another country/private entity.

From the perspective of the CBD, an interesting question is whether it is relevant for a country to require its *prior informed consent* for each cross-border transaction of AnGR. Access laws are often accused of being too bureaucratic and to block the exchange of genetic resources rather than promoting their access, although there is little documented evidence of this. A general observation is that if there is a need for authorizing the export of AnGR, the particular country should have a clear objective in mind. A system for *prior informed consent* does not necessarily need to be a bureaucratic one. It can be as simple as conferring a duty to register transactions so that the exporting country collects better information about its gene flow or to distribute certain benefits back to the provider of the genetic material. Such systems might facilitate access in international trade in AnGR rather than restricting it. A register could also contribute to increasing traceability later, in particular for the purpose of detecting diseases, or in determining sources of origin for any future property claims. Where a system of *prior informed consent* is connected to a bene-

fit sharing obligation (monetary or otherwise) then it could also generate support for conservation, use and livelihoods.

6.4 Model or Standard Material Transfer Agreements

Currently, questions arise under the CBD regarding access to genetic resources and the fair and equitable sharing of the benefits arising from the use of these new types of resources. Those questions also apply to AnGR, although the discussion itself has been mainly dominated by wild biodiversity and plant genetic resources. Stakeholders are in general happy with current exchange practices, although some notable exceptions exist and it is also clear that uncontrolled exchange can sometimes negatively affect farm animal genetic diversity. At the same time, future scenarios suggest that an increasing number of problems may arise in the future and therefore it is important to develop specific (voluntary or binding) policies or regulations, which best deal with the risks and problems currently or likely to be in the future associated with AnGR exchange.

As noted in previous sections, cross-border transfer of AnGR is often protected through the use of private law agreements. From a regulatory or policy point of view such private law guided exchange could be supplemented by a *standard or model Material Transfer Agreement (MTA)* which would supplement or replace the fragmented use of contracts today. The use of a standard MTA could supplement or replace the existing private law MTA and could be a response to unequal negotiating capacity and the market dominance of larger entities in the commercial livestock sector, helping to level the playing field. One alternative is therefore to develop an international standard MTA that regulates the desired aspects of the transfer of AnGR. A number of different formats may be useful:

- Legally binding multilateral agreement aiming at governing all transactions;
- Standard or model MTA;
- MTA guidelines or check list;
- Code of conduct.

All these formal expressions of a common level for the regulation of exchange of AnGR could be developed both at a multilateral and at a regional level. A binding agreement under international law would be the most onerous for countries; it would probably guarantee the highest level of harmonisation among countries, but would also be the hardest to reach consensus about. Other alternatives have in common that they are less onerous in a purely legal sense and might end up in being more effective given the additional flexibility that could be built in. Although non-binding alternatives are just that, i.e. non-binding, when private parties use such standards within a private law agreement they become legally binding *inter parties*. Similarly, non-binding alternatives at the international level could be implemented, if so desired, within national policies or law in a more binding manner. This could be achieved, for example, if countries chose to impose an obligation upon importers and/or exporters

of AnGR to use a specific standard MTA or a contract similar to a model MTA.

A further issue relates to which topics/issues such a standard MTA should address and how difficult issues could be solved by the use of an international standard or model. A general observation is that such a standard needs to include perspectives of both the exporters and importers. The content of such a standard could cover*, inter alia*, the following:

- Characteristics of AnGR
- Transfer prices
- Transfer conditions
- Use restrictions
- Supplementary benefit sharing agreement

The main advantage of a standard MTA is that it could reduce the transaction costs and time needed for negotiating every transfer individually and may also support the establishment of a more balanced legal relationship between two unequal parties. Development of a standard tool would need to start with a detailed review of existing contractual practises. The standard MTA could be evaluated regularly based on experiences with this tool.

6.5 Bilateral Exchange Agreements

The common contractual private law practice (i.e. regulating relationships between individual private parties) for AnGR operates in a context of public law (i.e. regulating relationships between individual private parties and the state). Countries could therefore decide to develop a *bilateral framework agreement* aiming at facilitated exchange of AnGR, following a pre-negotiated set of rules. The bilateral framework agreement could cover national policies related to the export and import of AnGR including sanitary standards; and countries could adapt the agreement to specific conditions (‘*mutually agreed terms*‘). A standard bilateral agreement would fit very well into the system under the CBD, whereby countries are given the authority to grant *prior informed consent* for access to genetic resources. It could also regulate the responsibilities of both exporting and importing parties, taking on board elements of genetic impact assessments. A bilateral approach could be developed in conjunction with a standard MTA. Similar advantages may also be achieved by stimulating stakeholders to discuss a *code of conduct* for AnGR exchange.

Discussions on voluntary guidelines for Access and Benefit Sharing have resulted in the Bonn Guidelines (CBD, 2002). If countries are to enter into bilateral agreements, it is important to analyse which elements from the CBD and the Bonn Guidelines are relevant for AnGR and adapt them to this particular context. A legally binding international regime for ABS is currently under discussion under the auspices of the CBD. The outcome from this process could affect AnGR, and thus it is important to have the specific needs and challenges of AnGR in mind when developing general law under the CBD. A particularly adapted bilateral exchange

agreement for AnGR could also contribute to the general CBD discussion and minimize any negative effects from newly developed general rules.

6.6 Measures in Patent Law

Patent law is general in scope, applying to all fields of technology and innovation. Consequently, it does not necessarily take into account the specific needs and challenges of AnGR or the breeding sector. The main legitimacy of this existing legal framework rests in its contribution to innovation, research and development. If the intellectual property right is not contributing to increased research and development, time-limited monopolies can hardly be justified. The concern for AnGR is that a high number of claims, as is common for patent applications, may lead to the establishment of a significant body of exclusive rights with substantial impact upon the use of AnGR by researchers, breeders and farmers. The potential consequences are yet to be seen.

In the plant breeding sector, the main rule is that PGR are in a *public domain* open to use by everyone. This is different for AnGR which are often in individual or communal private ownership. It may well be that the need for maintaining a viable *public domain* for AnGR is not as important as for plants. However, if patent protection is granted with a low requirement of *inventiveness* and *novelty* (potential examples are in fact in the process of being granted), and if granted broadly in terms of scope, research and breeding activities which were previously widely possible might become more restricted. In some cases this could even impact traditional uses in the country of origin. Due to the short history of applying patents to AnGR, there is an absence of case law and scholars commenting on how these general principles of law will be applied in this particular area. In this context, this study has identified four questions that may raise particular problems in the future.

6.6.1 Prior Art

The concept of *prior art* relates to what is considered as the body of information which cannot be patented. In principle, everything already known should be considered part of *prior art* and thus ineligible to meet the patent criteria. However, this is only a formal point of departure as the Patent Office must put this principle into practice. For an activity where the current practices or *prior art* are not necessarily published in a sufficiently formal manner, there is a concern that common knowledge could conceivably become patent protected. To avoid such occurrences, measures could be taken to ensure that all relevant sources be covered during the *prior art* search process. Such a measure could be implemented by expanding the check-list for Patent Offices when they search for *prior art*.

Although preventive publishing is often put forward as a strategy to ensure that common knowledge will be considered *prior art*, it should be taken into consideration that such publishing only prevents patents from being granted in relation to that specific and particular form of published information. This means that preventive publishing may prove to be less

effective in protecting against small adaptations to what was originally published.

6.6.2 Novelty and Inventiveness

The *novelty* of an invention is considered by comparing the *prior art* with the invention described in the patent claims. If these two textual sources are identical the *novelty* criterion is not met and the patent should not be granted. In technical areas where extensive publication is not the norm, the chance for meeting the novelty criterion is higher than for areas where there is an extensive body of publications. The livestock sector might thus be exposed to many patent applications meeting the patent criterion even if they are not particularly novel in a practical sense. The same elements of *prior art* are used to assess *inventiveness*. If a low level of *inventiveness* is required, a granted patent may include what was de facto already known or in practice. Practical measures to deal with these problems include the development of *specific guidelines* for Patent Offices relating to how such assessments should be conducted. Such *specific guidelines* would of course have to comply with the requirement in the TRIPS Agreement, which states that patent protection is granted without discrimination among the various technological fields. Specific regulation of aspects for biotechnology patents is already accepted by the EU Directive on Biotechnological Patents (EC/98/44).

6.6.3 Scope of the Granted Right

In addition to concerns regarding the above principles and the granting of patents, the application of the principal of *equivalence* may create further difficulties when applied to livestock sector issues. While interpreting the written source of the patent claim, in some countries the scope of patent protection is made even broader than it appears from a reading of the patent claims. The invention as described in the patent claims might be interpreted to become wider to also cover inventions that are so-called 'equivalent' to the invention described in the patent claims. If such an expansive 'doctrine of equivalence' is applied, there is a chance for closing another's possibilities to breed and/or to do research. Little attention has been given to this principle in patent law. It is nevertheless important, as it might become a significant factor in establishing broad exclusive rights. This will have unforeseeable consequences for AnGR. Since there hardly is any case-law dealing with these questions in the livestock sector, there is a need for a thorough, systematic legal analysis related to assessing how general patent law rules will apply to AnGR and breeding.

6.6.4 Exemptions to the Patent Protection

An additional measure for supporting the adaptation of patent law could involve the identification of useful exemptions that would lead to more balanced application of patent law vis-à-vis the livestock sector. In this context, it is important to note that although a patent grants the exclusive right to use an invention as it is described in the patent claim, Article 30 of the TRIPS Agreement specifies that 'countries have discretion to implement exemptions in the right conferred by the patent on a general level in the patent act'. One example of such an exemption applies to

plants in Europe, where the EU Patent Directive Article 11 implements a version of the 'farmers' privilege' – i.e. the right of the farmer to reuse his harvest as seeds under certain specific conditions even if containing a patented gene. There is a similar opening for EU countries to implement an exemption in the animal sector. Nevertheless, surprisingly few developing countries have implemented such legitimate exemptions.

Finally, it is also worth considering the degree to which patent protection is needed in practise to promote breeding, research and development in this sector. While the issue of increased bureaucracy is often raised as a counter argument to the implementation of CBD-based access legislation, it should also be taken into consideration that the patent application process and subsequent enforcement are also time consuming and expensive. It would therefore be useful to assess what the potential benefits of patent protection might be for breeding, research and development in this sector. This should be compared to any potential costs, e.g. increased costs of breeding material and reduced exchange and use of AnGR.

6.7 A *Sui Generis* System

The term '*sui generis*' is not a clearly defined legal term and concept in international intellectual property law. The TRIPS Agreement talks about '*an effective sui generis system*' for the protection of plant varieties as an alternative to providing patent protection to the same subject matter. But the TRIPS Agreement does not itself define such a system '*of its own kind*' – a *sui generis* model for plant variety protection. One example of such a *sui generis* system for the protection of plant varieties are the *plant breeders' rights* under the different versions of the UPOV Convention. *Sui generis* systems for *traditional knowledge* have also been on the agenda in WIPO for some years, but agreement on such an international system is still far off. If a *sui generis* system for AnGR shall be developed, it is crucial that the differences between plants and animals are carefully taken into account.

For AnGR it is not immediately apparent which *subject matter* requires further intellectual property protection. Where such a *subject matter* is found and could be protected within the context of a *sui generis* system, then there is still a need to clarify *inter alia* i) who needs protection, ii) which entity should be the holder beneficiary to the right, iii) what should be the criteria for achieving protection, and iv) what should be included under the exclusive right. In the following section a number of options for *sui generis* protection are discussed.

6.7.1 Animal Variety or Breed Protection

In considering the application of an intellectual property right such as a *sui generis* system for AnGR or the breeding sector, defining the precise subject matter that should be protected by the right is clearly important. Compared to *plant variety* protection, providing intellectual property protection for 'animal varieties/breeds' would not make much sense. The variety/breed is probably not the most relevant entity in animal breeding, but rather the individual breeding animal or its germplasm. Furthermore,

the concept of an animal variety/breed is not easily defined. Such considerations mean that in terms of development of a *sui generis* system for the livestock sector, it would be difficult to identify characteristics that could serve as a standard description of the '*subject matter'*. Further work is required to clarify the relevant subject matter for protection.

6.7.2 Establishment of Breed Associations

A *sui generis* system could be linked to eligibility for *being registered in a particular register or herd book* (managed by a *breed association*). Under such a *sui generis* protection system, registration would lead to the establishment of a right and the criteria for being granted that right are those required for being registered. The difficult question here is what the rights (and legal consequences) conferred by such a registration should entail. For example, should such a registration give any exclusive rights to the genetic material? One alternative could be that registration gives rights to the individual animal. However, such a registration would not add much in addition to the already held physical property right over the animal plus the complete genome of the particular animal in question. A second alternative could be that registration of individual animals also confers an exclusive right to single genes or alleles in the registered animals. This alternative is however problematic, as single genes or alleles often occur in a similar form in different individual animals and there is a need to avoid creating competing exclusive rights to the same gene. A third alternative could be that only those farmers and breeders with animals registered by the breed association have the right to use the name or brand of the breed. Such a '*sui generis* protection' would be more similar to a regular *Trademark approach.* Establishment of breed associations or herd book registration (governed by breeding laws) combined with Trademark protection would be a good alternative for breed conservation and property right protection.

6.7.3 Rights to Genetic Material of Individual Animals

One might also think about establishment of a *sui generis* right to the *genetic material of the individual animal*. With reference to the second alternative in the preceding paragraph, the first problem of such a right is the parallel occurrence of similar or identical genes and alleles in other animals. This would either undermine the exclusivity of such a right or result in competing property right claims. Establishing a general *sui generis* right to the genes of the individual animal would probably not bring much new compared to ownership of the animals.

6.7.4 Geographical Related Properties

A *sui generis* protection could also be linked to *special geographical related properties* and characteristics of the animals or their products (geographical indications). A final alternative for a *sui generis* system would be to *leave it to the breeder to characterise* in a sufficiently precise manner as to what s/he claims as an exclusive right. This could then be used to establish a system for securing rights to technological developments and provide, for example, protection for a single gene when iso-

lated and described. Such protection is however covered by the existing patent system.

To sum up, there are a number of relevant *subject matters* for intellectual property protection:

- at the level of the individual animal – protection is conferred by physical ownership of that animal and/or its offspring. Rights transferred during the purchase/sale of individual animals can be protected through the use of contracts.
- at the breed level – protection through the establishment of breed associations and the use of trademarks may be appropriate;
- at the allelic, gene or protein level – protection would be covered by patent law;
- regarding technical inventions relevant for breeding – protection would be covered by current patent law.

6.8 Livestock Keepers' Rights or Farmers' Rights

One approach in the further development of policies or regulations is to address the issue of whether particular groupings of stakeholders are in need of an improved legal or regulatory environment. In the plant sector the assignment of property rights (Plant Breeders' Rights - PBRs) at the retail end of the pharmaceutical and plant breeding industries have tended to create incentives to invest at that end of the industry but not in the earlier parts (i.e. the genetic resource providers sector). This has had an impact on both efficiency and equity within the plant sector. 'Farmers' Rights' (see the comprehensive study summarized by Andersen, 2006) have been proposed as a form of counterbalance to PBRs, leading to the protection of traditional knowledge and equitable participation in benefit sharing. For the livestock sector the concepts of *farmers' rights* or *livestock keepers' rights* are worth analysing in more depth.

Livestock keepers' rights or *farmers' rights* are unexplored legal or political concepts in the livestock sector. The term 'farmers' rights' is mentioned in Article 9 of the ITPGRFA (FAO International Treaty on Plant Genetic Resources for Food and Agriculture). *Farmers' rights* 'recognize the enormous contribution' farmers have made regarding plant genetic resources (PGR). Responsibility for realizing such rights rests with the national governments and there is a clause specifying that article 9 shall not limit any already existing '*rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law'*. From a legal point of view, these '*rights*' are not formulated in a legally binding sense, which raises issues about their enforcement in practice.

Implementing a version of farmers' rights *for* livestock keepers (e.g. as formulated in such documentation as the 'Karen Declaration', which includes support for indigenous knowledge remaining in the public domain and that AnGR be excluded from IPR claims) would first require similar international recognition of their crucial role and contribution to AnGR.

Different strategies have been suggested for securing livestock keepers' rights, and these include codifying the customary laws that relate to the management of AnGR. A first step in this direction would be to review relevant customary law in order to identify which principles need to be included. Given that *grazing rights* are crucial to maintaining pastoral societies and are thus closely linked to conservation both at a breed level and at an allelic level, *livestock keepers' rights* could include production and *grazing rights*, as well as the protection of traditional knowledge. Mechanisms to strengthen livestock keepers' understanding of AnGR issues, their negotiation capacity and access to legal support would also necessarily be a crucial element of a strategy for developing *livestock keepers' rights*.

Obstacles to the implementation of *livestock keepers' rights* are that they could conflict with other intellectual property rights. For example, if a patent on a particular gene existed, the consent of the patent holder could be required when animals that express that gene were used for further breeding. Addressing this potential conflict is not however an insurmountable problem. For example, India has developed a Farmers' Rights law which carefully balances these rights for crop seeds. Similarly, where *livestock keepers' rights* could potentially conflict with other intellectual property rights, there would be a need to have rules for how these interests should be taken into account within the highly specified and enforceable body of patent law. One approach would be that *livestock keepers' rights* could *inter alia* be relevant for inclusion both when assessment of the patent criteria is carried out, as well as during enforcement. Livestock keeper practises are typically not published in a manner qualifying as *prior* art according to the patent system. Two alternative approaches also might be considered: i) either single countries could implement exemptions to intellectual property rights for livestock keepers, or ii) standard exemptions could be developed at a regional or multilateral level.

It is also possible to imagine some form of a *sui generis* protection system for *livestock keepers' rights*. This concept would have to be developed further on a theoretical level, as suggested elsewhere in this study, but could include a model for benefit sharing or could combine individual and community rights over AnGR. A crucial issue in the development of such a concept would be whether a *sui generis* system should include a positive right to exclude others or whether it should be geared towards being a negative right aiming at preventing misappropriation of what is in use by livestock keepers.

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