Management and Exchange of Animal Genetic Resources

– Nordic perspective

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Nordic co-operation

Management and Exchange of Animal Genetic ResourcesNordic cooperation is one of the world's most extensive forms of regional collaboration, involving Denmark, Finland, Iceland, Norway, Sweden, and three autonomous areas: the Faroe Islands, Greenland, and Åland.

Nordic cooperation has firm traditions in politics, the economy, and culture. It plays an important role in European and international collaboration, and aims at creating a strong Nordic community in a strong Europe.

Nordic cooperation seeks to safeguard Nordic and regional interests and principles in the global community. Common Nordic values help the region solidify its position as one of the world's most innovative and competitive.

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Preface

The new institution Nordgen or the Nordic Genetic Resource Center started operating at the beginning of 2008. NordGen is a Nordic centre of knowledge for conservation and sustainable use of genetic resources. It works towards ensuring the foundation and success of agriculture, horticulture, forestry and animal production now and for the future, and embraces the genetic diversity work on plants, forest and animals in one institution. NordGen is promoting high profile and efficient Nordic collaboration in these sectors. The institution is actively promoting the cultural and historical values of genetic resources. NordGen aims to be among the forefront international service and knowledge centres for maintaining plant, animal and forest genetic resources and contributes through the Nordic member countries to develop policies and measures for open and equitable utilisation of global genetic resources. In the animal sector, NordGen aims to develop knowledge of sound management of genetic variation both in the preservation of local rare breeds and in the implementation of sustainable breeding operations. The animal sector is a direct continuation of the work carried out by Nordic Gene Bank for Farm Animals (NGH) since early 1980's.

This report is based on a project ‘Legal framework for the rights and exchange of animal genetic resources in the Nordic region’ that was funded by the Nordic Council of Ministers, Norwegian Genetic Resource Centre and Nordic Gene Bank for Farm Animals. The authors would like to thank the funding bodies for providing the opportunity to carry out the work.

Many persons contributed to this report by giving information. The views expressed in this report are solely the responsibility of the authors.

On behalf of the authors

Jokioinen, April 2008

Asko Mäki-Tanila
Project leader

Foreword from NordGen

The International Technical Conference on Animal Genetic Resources for Food and Agriculture, which took place in Interlaken, Switzerland, from 3. to 7. September 2007, was attended by delegations from 109 countries and 42 intergovernmental and non-governmental organizations. The Conference welcomed the report of the Food and Agriculture Organizations (FAO) on The State of the World's Animal Genetic Resources for Food and Agriculture, and formally adopted the Global Plan of Action for Animal Genetic Resources through the Interlaken Declaration on Animal Genetic Resources.

The Editors of FAO's report on Animal Genetic Resources urges the nations to follow up stating: Governments must demonstrate the sustained political will to implement the Global Plan of Action, and resources will have to be found nationally and internationally. Success will depend on farsighted cooperation among many stakeholders. Governments, international organizations, the scientific community, donors, civil society organizations and private sector all have important roles to play.

NordGen intents to follow up this recommendation in order to enable the ministers for food and agriculture in the Nordic countries and the Nordic Council of Ministers to take a political leadership in a process that can fulfill the Interlaken Declaration in an efficient, rational and beneficiary way for all the responsible parties of Animal Genetic Resources management.

Jessica Kathle
Director

Executive summary

This report is based on a project ‘Legal framework for the rights and exchange of animal genetic resources in the Nordic region’ which was funded by the Nordic Council of Ministers and Norwegian Genetic Resource Center and Nordic Gene Bank for Farm Animals (now part of NordGen). The project delivers a report concerning the stakeholders’ needs for legal framework and possibilities to assess the value of sales and exchange of genetic material of farm animals in the Nordic region. The project also analysed possible needs for framework and regulations related to animal breeding and animal genetic resources in a global context.

The first chapter presents the main challenges and opportunities which the utilisation and conservation of animal genetic resources are facing today. There are major changes influencing the animal production sector: 'livestock revolution' seen as increased global consumption of animal products, intensive and industrialized production systems, major environmental impacts, global warming, increased risks for pandemic diseases (even zoonoses), international trade of high-output breeds, narrow selection goals and loss of variation in breeding programmes, niche production with local breeds and growing interest in patenting.

The importance of genetic diversity is widely acknowledged and the Convention of Biological Diversity forms the base for international regulation and legislation on this. The chapter reviews the Convention and other *international regulatory framework*. The emphasis is on the processes related to development of regulations covering farm animal diversity.

The second chapter looks at the issues from the *Nordic perspective* and raises and prioritises the questions from this standpoint. The breeding programmes are typically run by co-operatives and are based on extensive on-farm recording which includes many longevity traits. The Nordic countries have joint breeding schemes in dairy cattle and in pigs. The

interest in local breeds has generated active national and Nordic operations since early 1980's. The recognition of sustainability of breeding programmes and sound international exchange are the most important objectives from the Nordic perspective. The Nordic experts are eager to contribute to the international work on finding guide lines and regulations along these objectives.

FAO coordinates the work on guidelines and agreements on genetic resources of plants and animals related to food and agriculture. Chapter three covers the *differences between the plant and animal* genetic resources and the implications from these.

Whereas plant genetic resources are held in public gene banks, the genetic resources in animals lies in the variability of dynamically developing breeding stocks. Therefore the viability stemming from sound selection goals, cost-efficient operations and proper management of genetic variation, all important to the proper management of breeding programmes, is crucial for individual breeds and for the joint total diversity over breeds. The main requirements for a *sustainable breeding programme* are described in the fourth chapter. The next step is to consider how these are implemented in breeding programmes and if there is a need to facilitate a light appraisal and monitoring system within countries.

Chapter five discusses the international *exchange of animal genetic resources*. The current very active and beneficial exchange should not be constrained by stiff bureaucratic rules. On the other hand code of conduct related recommendations would be needed to guarantee soundness for gene-flow between widely deviating production environments. There is much variation between countries in how cryo preservation work is organised. In many cases the deposition and maintenance of *ex situ* banks resort to the expertise and facilities in artificial insemination co-operatives. There is still a need to clarify the management of gene banks. If local breeds are moved from the country, the transfer should be accompanied by a detailed bilateral agreement, following the Bonn Guidelines. Other questions related to ownership and free choice are livestock keepers’ rights to land and producers' choice for genetic stock in the vertically integrated production.

Chapter six describes the current state of *patenting in animal breeding*. While plant varieties are uniform, distinct and stable, animal breeds are very variable and under continuous development. Therefore the animal breed concept cannot be a target for patent like systems. Molecular genetics has been able to surface genes which have a major influence on the differences between breeds or animals, and in few cases their use in selection programmes has been subject for patenting. As genomic research is expanding at a fast rate, the number of such findings is growing. The patenting in this context is straightforward and has received popularity. Soon there may also be applications related to special diets meeting the requirements of a known genotype. The knowledge about gene regulation in animals is still inadequate and the successful production of transgenic animals remains unattractive, although progress is steadily made also in this area. There is a new trend also to patent typical animal breeding operations which are step-by-step processes linking data collection, analysis and selection and management decisions together. These *process patents* are obvious in a business world because inventions, whether products or processes, in all fields of technology are subject to a patent. There are possible exemptions related natural biological processes for the production of animals, while animal breeding operations involve enough human interaction to make them eligible for patent protection. The applications for process patents are clearly testing the limits for an awardable patent in animal breeding. There is an urgent need for a discussion about how the general principles apply to the area of animal breeding and the needs for implementing special rules in this field. The dismissal of test-day model patent in Europe shows that it is possible to mitigate unfavourable developments in process patent applications by publishing actively all the methods in animal breeding.

Project description

The Nordic Ministers' declaration (2003) and the background study report for this declaration regarding access and rights to genetic resources outlines the need to clarify the legal issues of Nordic farm animal genetic resources. The Nordic Council of Ministers notifies that animal genetic resources are regulated by laws on civil rights possession and states that there should be no reason to change the present situation regarding legal rights or access. There are a number of international, European and national changes and a need continuously to review the situation; and to clarify whether changes such as the patenting systems and patent practice and subsequently research on biological material generate needs for reviewing the regulatory situation.

In animal production, including aquaculture, new international markets are readily developed for exporting genetic stock, semen and embryos from the Nordic countries. These export markets can represent high economic values. Previously the legal conditions and regulation for the genetic resources, after leaving the exporting country, have not been specified by the receiving country's law. Consequently, there is a need to understand the requirements and regulations for securing position and framework in international competition.

These issues were also discussed more actively during the preparation of the Global Plan of Action for animal genetic resources under the coordination of FAO, which was finalised in Interlaken in September 2007. The intention of this project is to contribute to the common Nordic grounds early in the process subsequent to this meeting.

The project delivers a report concerning the stakeholders' needs for legal framework and possibilities of assessing the value of sales and exchange of genetic material of farm animals in the Nordic region. The project also analysed possible needs for framework and regulations related to animal breeding and animal genetic resources in global context.

Project funding

The project was financed by funds submitted by the Nordic Council of Ministers (NMR), originating from two separate funds ("agriculture" EK-FJLS and "sustainable development" EK-M). Additional support was obtained from the Norwegian Genetic Resource Centre (Norsk genressurssenter) and Nordic Gene Bank for Farm Animals (NGH).

Project steering group

The intention of the project was to produce a background document from which conclusions could be drawn. The expert group carrying out the task was therefore composed of delegates from breeders´ organisations, national gene resource committees, research institutes and national authorities. Thereby the expert group connected the most important stakeholders to the project. This, in addition to seminars and other open discussions ensured that the most important actors were involved in formulating Nordic views on the issues.

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	Morten Walløe Tvedt, Senior Research Fellow at the Fridtjof Nansen Institute has been responsible for the legal analysis in this report and contributed to the editing of the whole report. He has in recent years published extensively in the field of genetic resources and law from various angels. His latest book, *Beyond Access – Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, is an analysis of the needs for legislation in developed countries to meet the benefit sharing obligations in the CBD.
	Lars Landbo from the Danish Plant Directorate took part in the project work by presenting the content of the International Treaty on Plant Genetic Resources for Food and Agriculture.
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persons have given information and contributions to the text:	.
	The results have been presented in the Nordic Side Event at the Intergovernmental Technical Workshop in Rome on 14 Dec 2006, in the seminar 'International policy framework for conservation and breeding' at Foulum on 30 May 2007, in the Nordic Side Event at the meeting of the Commission on Genetic Resources for Food and Agriculture (CGRFA) at FAO in June 2007, at the NGH seminar 'After Interlaken' at Höör (Sweden) in December 2007 and at the final workshop in Copenhagen on 14 April 2008.

I. Background for discussing regulatory options

The regulatory framework relevant for sustainable use, exchange of and access to animal genetic resources (AnGR) is changing both at the international and at the national level. Several of these changes are not responses to the particular needs of the animal sector, but rather expanders and changes in general law which are being applied also to the animal sector. This raises unforeseen consequences for the animal sector. This report is an attempt to shed light on the most relevant general legal frameworks and outline some particular consequences for sustainable breeding in the future.

In September 2007 the Food and Agriculture Organisation (FAO) launched the International Technical Conference on Animal Genetic Resources at Interlaken in Switzerland. During the process towards the Interlaken meeting the FAO commissioned an interdisciplinary study in economics, breeding, policy and law which resulted e.g. in the report *Exchange, Use and Conservation of Animal Genetic Resources: Identification of policy and regulatory options* (Hiemstra et al. 2006). The scope of this report is broad, covering conservation, sustainable use and exclusive rights with a global perspective.

The present Report is a Nordic contribution to the ongoing global discussion of regulatory options for exchange, sustainable use and exclusive rights in the field of animal breeding, looking at the issue with a Nordic perspective. Animal breeding in the Nordic countries balances upon cooperatives and private ownership, with relevant differences between animal species. The area at large balances on sustainable breeding and a sustainable trade in breeding material and animal genetic resources. These traditions influence the needs of the animal breeders and farmers of the

Nordic countries for future international regulation. The Report is the first contribution with a Nordic approach and perspective on the issues of animal genetic resources. The aim is to capture some of these Nordic particularities and to make these views available to the global discussion.

Objectives and regulations for activities on genetic resources have been developed during the last decades. The regulations fall into two main categories: 1) applying existing legal rules and regulations to new fields; and 2) trying to establish new legal tools to cope with the rapid technological development. The main challenge in the first category is that the general principles of law have not been adequately adapted to suit the particular needs of the animal breeding sector. One example on this is how intellectual property rights are applied to the field of genetic resources. The challenge of using traditional legal tools for such animal genetic innovation does not necessarily support the objectives of the CBD (1992, Convention on Biological Diversity). The system for Access and Benefit Sharing under the CBD is an example on this. The recently accomplished Global Plan of Action for Farm Animal Genetic Resources (see section D of this chapter) encourages starting review work on these questions.

Prospects of genetic diversity and breeding programmes in farm animals

Major changes in animal sector

The global consumption of animal products is fast increasing. The consumption of meat and milk worldwide has been rapidly growing since the early 1980s. This increase is accounted for mainly by developing countries. Increasing demand strongly stimulates production. The change is so dramatic that the term ‘livestock revolution’ has been used. Intensive and industrialized production systems contribute to meeting most of the growing demand for livestock-derived food. The intensification of production has major influences on environment if left without mitigation. Also the risks for pandemic animal diseases are increased, among which the most serious ones are zoonoses threatening also human health.

The consumption of meat and milk products in Europe is rather stable compared to that in developing countries. Consumers are increasingly concerned about issues of product quality and safety, production ethics, environmental impact and local culture. The changes are mainly characterised by fragmentation with scope for niche production with a local breed. Therefore, in Europe many local breeds are experiencing a renaissance as their milk or meat is used for preparing gourmet dishes or for branding products with geographical distinction. The maintenance of culturally tied landrace breeds has improved the image of the animal production sector and therefore the activities need further support and encouragement.

The climate change is affecting many aspects of animal production. It opens up new possibilities for feed production in the north or restricts the use of the existing ones in areas suffering more extensively from droughts. Along with the warming climate, some animal parasites and insects that are disease vectors are able to spread further up in the north.

Animal breeding is part of national food security. The objectives include development of animals suitable for local consumption and available feed resources. In many countries there are national breeding programmes which are run and coordinated by farmer-owned co-operatives or farmer-driven societies. The EU legislation (also adopted in EEA countries in Europe) specifies the requirements for animal breeding organisations. Country-specific successful breeding work also provides less dependence on importation and contacts with other production regions, thereby lowering the risk for animal diseases. Many of the before mentioned developments in the animal sector coincide with the changes in the coordination, ownership and marketing area of the breeding programmes. The farmer-owned co-operative schemes with long-term national goals are taken over by international companies with high expectations on quickly made profits.

Outline of developments in animal breeding industry

- Animal breeding has proven to be a very *cost-efficient* tool in developing animal production. In most species of livestock, vast changes in performance have occurred over recent decades. A major part of this change is genetic, produced by selection between and within populations. With moderate operative costs, selection yields permanent changes which are disseminated without any extra cost throughout the whole population within few generations. In animal breeding, the ratio between cost and benefit is very impressive as Smith (1984) and Mitchell et al. (1982) have shown that the overall returns from one round of selection can be up to 50 times the amount of costs.

- The success of an animal breeding scheme depends on few key factors. These are thoroughly described by Woolliams et al. (2006). The first vital one is *genetic variation.* Animal breeders know that the risks and opportunities of a selection scheme are linked to genetic variation. With regard to the depletion of genetic variation, in large breeding populations there is no evidence that selection limits have been reached for production traits and it is likely that continued rapid improvements can and will be accomplished. If progress is continued in selection, or if there is need to reconsider the direction in the improvement or respond to environmental or production constraints, genetic variability is essential. There are now tools to check unwanted developments in genetic variation. The key factor is to keep the genetically relevant population size (technically termed effective populations size) sufficiently large. This is achieved by a balanced use of families and ancestral lineages in the population. These considerations affect the genetic progress, however the compromises are minor and are paid back by long-term sustained improvement.
- Management of a breeding programme aims at efficient utilisation of existing genetic variation. On the other hand the genetic improvement scheme may fail because of improper use of *information and infrastructure*. In the competitive market, such an operator is removed very quickly. For any breeding operation, it is now a norm to have a department for quality control and proactive marketing. The marketing needs product branding, expert advice and eager salespersons. The Nordic breeding scheme may have the best animals in the continent, whilst others have achieved the best profits by selling more and at a better price.
- A selection scheme is profitable, if it is capable of offering a satisfactory breeding stock for the market. The focus in selection should be on production traits. Selection on the most important traits will affect the current variation in both the selected and other traits which may in due course also grow in importance, or need attention. We may see undesirable side effects in fitness traits, such as impaired conformation, fertility or health (cf. van Noordwijk and de Jong 1986, Rauw et al.

2002). Information is needed on genetic variances in these traits, in order to picture the overall outcome of selection. The harmful co-responses come as a surprise if the genetic relationships between the traits have not been studied. As a rule, animal breeders have observed that if counteractive selection is practiced, then considerable improvement can be made in reducing the incidence of defects. In other words, there is much genetic variation in all the traits. Once recognised, making appropriate changes to the *selection profile* will avoid undesirable trends becoming established and a satisfactory compromise between production and animals' robustness can be achieved. From a genetic point of view, there is a need for quantitative information on the genetic covariation between production and fitness-related traits. Since many fitness traits are difficult to measure on large numbers of animals, such information is scarce and costly. In practice, the main task for breeders is to implement a sufficiently sophisticated data collection scheme.

- Producers' awareness of the possibilities of genetic improvement is usually initiated by an outstanding breed. Whereas this should encourage establishing an efficient selection scheme, a more common consequence is the *replacement of local breed* with a new promising and well-marketed breed. Such a transition can be done smoothly if the imported breed is expected to perform well also in the new production environment. This is not necessarily so if a breed with a good performance record in a high input environment is taken to less suitable conditions. This is not necessarily an issue within the Nordic region, but very important in the international breeding trade. There may cases when a breed from a country with high-input production environment is sold to a region where the feeding and management are more extensive. When the production environments are widely deviating, the breed change should be accompanied by an extensive testing of the exotic breed in the local production circumstances.
- All the existing breeds originate from several populations, although in the last few decades many intensively selected programmes have been closed for any external breeding stock. Global production of meat, milk and eggs is increasingly based on a limited number of *high-output breeds* – those that are most profitably utilised in industrial production systems. In the present breeding world there is extensive ge-

netic exchange between the countries. A foreign population is used to upgrade the domestic population. Gradually such a gene-flow may become unilateral. For example, the Holstein dairy cattle is almost uniform everywhere in the advanced milk producing world, with development work relying on the same few elite animals within the breed. In a more extreme situation, such a development may bear a risk for narrowed genetic basis (smaller effective population size). Wickham and Banos (1998) found that 50% of almost 5000 dairy bulls born in 1990, evaluated by the Interbull Center, were sons of only five sires.

- The commercialisation and international trade have brought along *business practices* which were less exploited in the past, such as patenting. An animal breed itself is far from being uniform and therefore fails to be patentable under a product patent. The outcome from a pair of selected parents is a group of offspring distributed widely with an average moderate deviation from the mean of the parent generation. However, there is a considerable amount of variation around the mean. Molecular genetics is offering new kind of methodology and there are now powerful tools to dissect the observed variation into better defined and transmitted parts. Some of the variation can be traced back to few recognisable genes with substantial effect on an economically important trait. The utilisation of such findings in selection programmes can be a subject for patenting. There are now some genes for which a patent has been issued for use in selecting better producing animals. The economically most important applications are mutants causing genetic defects whereas the genes with positive effects on production traits are less common and still often lack general validation.
- There is a new trend to patent also typical animal breeding operations which are step-by-step processes linking data collection, analysis and selection and management decisions together. The applications for *process patents* are clearly testing the limits for an issuable patent in animal breeding and indirectly granting an exclusive right to the offspring from applying such a method. There is an urgent need for a discussion on general principles in the area.

In conclusion, genetic diversity provides unlimited potential for developing animal production and therefore a proper management of the variation also is needed. Profitable breeding programmes form the most cost-efficient strategy to maintain diversity. The profitability of a breeding programme is mainly determined by the competitiveness of the genetic stock it is producing and selling. Geneticists are concerned about how rapid genetic change in efficiency can be made without being harmful or perceived to be so. The animal breeding sector must be both economically sound and attuned to public needs and demands. The selection objective has to cover both production and fitness traits, and the practical operations should therefore contain a collection of information on disease resistance and other fitness related traits. As animal breeding is part of food security, it is important that the breeding organisations and their selection schemes have sound objectives and efficient operations.

Animal breeding is relying on a growing international collaboration, and it is important to review the state and challenges in exchange of breeding stock and in business practices between the countries. Modern animal breeding is operated by both farmers-owned national co-operatives and international companies. At the same time the production structure is dominated by very large industrial units which are closely integrated with the other partners in the production and food chain. This kind of challenging issues should be solved to continue benefiting from international collaboration and in strengthening the role of the national operators and individual farmers in breeding business.

The genetic diversity of farm animals is possibly underutilised and there is a need to set guidelines for conserving and utilising the local breeds which otherwise become replaced by international well marketed breeds.

The regulatory framework relevant for sustainable use, exchange of and access to animal genetic resources is changing both at the international and at the national level. Several of these changes are not responses to the particular needs of the animal sector, but rather expanders and changes in general law which is being applied also to the animal sector. This raises unforeseen consequences for the animal sector. This report sheds light on the most relevant general legal frameworks and outlines some particular consequences for sustainable breeding in the future. There are a number of legal and regulatory documents that are of relevance for the farm animal sector without having been developed specifically for this sector.

Convention on Biological Diversity

The Convention on Biological Diversity (CBD) from 1992 is general in scope and covers all biological diversity encompassing genetic resources from wild species to the highly domesticated ones. It rests on an assumption of the importance of genetic diversity in both wild and domesticated plants and animals. The three main objectives of the CBD are

- conservation of biological diversity
- sustainable use of the component of biological diversity
- fair and equitable sharing of the benefits arising out of the utilisation of genetic resources

The obligations of the Convention and the work to implement and develop the Convention covers both wild biological diversity and agriculture genetic resources.

Beyond addressing a number of topics relevant for biological diversity the CBD establishes a number of core principles for the access and benefit sharing related to genetic resources in general. CBD article 15.1 establishes the principle that each country has the sovereign right to regulate several aspects of genetic resources. The wording is general in scope and covers in principle also animal genetic resources. Parties shall endeavour to facilitate access to genetic resources and access to genetic resources shall be subject to prior informed consent (PIC) of the provider and when granted, shall be on mutually agreed terms (MAT). One element which shall be included in the PIC and MAT is the conditions for the sharing of the benefits from the utilisation of the genetic resources. CBD aims at establishing an international system for access and benefit sharing partly based on the assumption that exchange of genetic resources takes place in a bilateral relationship. The implementation of these general norms into practical feasible national rules is, however, lagging behind (see Tvedt and Young 2007).

The implementation of the convention is based on the combined action of the CBD bodies SBSTTA and COP. The permanent secretariat is in Montreal. SBSTTA is a scientific body (Subsidiary Body on Scientific, Technical and Technological Advice), which coordinates the generation of recommendations. The Conference of Parties (COP) is the decision making body. COP has agreed to the non-binding guidelines (Bonn Guidelines, 2002) on access and benefit sharing of genetic resources. The World Summit on Sustainable Development in Johannesburg recognised that the system for access and benefit sharing (ABS) is not yet functional and urged the CBD to develop an International System for ABS. The work of the open-ended Ad Hoc Working Group on Access and Benefit sharing started in 2005 with the aim to make ABS function. This work is rather general in scope and has not yet addressed the particular needs of the animal sector. Also the potential consequences from these negotiations for the animal sector need to be brought to attention. Until recently the main aim and focus of the CBD and under the implementation of article 15, has been on the implementation of access legislation in developing countries, but this is changing now towards recognising the need for user countries also to implement legislation (Tvedt and Young 2007). Possibly the second aspect of ABS is entering the stage of negotiation in the CBD. The benefit sharing requirements of the CBD needs to be developed as incentives for users to share a part of the benefits arising from the utilisation of genetic resources with their provider, in particular when there is no private law contract governing the transaction. This requires measures to be taken in the providing or source countries, but equally important there is a need for corresponding legal, administrative and policy measures in the countries where the benefits from the utilisation of genetic resources are arising, to make a functional balance in such a system.

The discussions in the COP and the Ad Hoc Working Group are broad and general in scope. This implies that for the farm animal breeding sector the rules will apply as they are general in scope and a low level of attention is given to the particular needs and characteristics of this sector. Thus, there is a chance that rules, guidelines and regulations are formulated in a manner not adequately adapted to the farm animal breeding sector.

Intellectual Property Rights

One increasingly important area is Intellectual Property Rights (IPR). Various types of IPR are important for the animal breeding sector, e.g. geographical indications, trademarks and patents. Whereas the two first grant protection of a brand or reputation in the market, the latter grants exclusive rights to inventions relevant to utilisation of genetic resources. They are thought to create economic incentives to increase research and development by ensuring returns to inventors and researchers. The patent system is often said to promote early publishing and thereby enhancing scientific progress due to the requirement to disclose the invention.

There is a long tradition of international harmonisation of IPR. The most extensive one is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which was signed as part of the establishment of the World Trade Organisation (WTO). The TRIPS Agreement takes harmonisation both broader in a geographical and thematic sense, as it addresses a number of IPRs (i.e. geographical indication, trademarks and trade secrets) and is binding for all 146 country-members of the WTO. Patent protection for products and processes shall be made available in almost all fields of technology, when they meet the three criteria: novelty, inventive step and industrial application (more about patent law in chapter IV below). The discussions in the TRIPS Council of the WTO have made little progress. There are substantial differences among countries: developing countries mainly want to make the obligations more optional and weaker and better adapted to the national circumstances for innovation and use of already existing technologies. Developed countries mainly defend the need for predictability and maintaining the obligations at the current level (subject to some modifications in the field of medicines). On this background one cannot expect that the special needs of the farm animal sector will be addressed in the TRIPS Council, although patents are currently applied for in a large quantity relevant for the breeding sector.

The World Intellectual Property Organisation (WIPO), as the UN organisation with responsibility for IPR, has a longer record of striving towards global harmonisation. For example, until 2006 all countries negotiated a new international treaty for the harmonisation of the so-called substantial patent law issues (draft Substantial Patent Law Treaty). These negotiations broke down due to disagreement on the underlying rational for further harmonisation which became manifest in an irresolvable disagreement on the future agenda for the work of the Standing Committee on Patent Law (Tvedt 2007, Tvedt 2005). IPR have not been a major issue in animal production – so far; and little has been done to foresee the potential consequences of increasing the number of patents in this field. The WIPO provides for technical assistance in the prior art search for patent applications. Currently, the WIPO databases therefore are an important source for knowledge about patent application in the farm animal breeding sector.

Geographical indications and trademarks are more directed towards the market than towards the innovative or breeding process. Therefore, these legal mechanisms are highly important for the farm animal breeding sector, but cannot be expected to interfere with the activity at the breeding level to a similar degree as patents to the processes themselves.

Coordination by FAO

Food and agriculture issues are addressed by the United Nations Organisation for Food and Agriculture (FAO). The guidelines and agreements related to cultivated plants and domesticated animals are prepared and decided by the member countries of the FAO. The FAO body for addressing issues related to animal genetic resources is the Commission on Genetic Resources for Food and Agriculture (CGRFA). In chapter III we seek to learn from the breeding, conservation and regulatory options chosen in the plant sector and discuss the differences between plant and animal sector.

FAO has just completed the process for the Global Plan of Action (GPA) for animal genetic resources (AnGR) at the International Technical Conference on AnGR at Interlaken in Switzerland in September 2007. The first step in the process was the preparation of the country reports on the status and development of animal genetic resources and animal production. Also international organisations working in the field of AnGR were asked to submit a report on their activities. FAO has also had several working groups which prepared reports on different themes: diseases, molecular genetics, economics, conservation strategies, legal framework, environmental effects, traditional animal keepers, biotechnology, exchange of AnGR, and various aspects of emergency situations. These elements serve as background material in of the report on the State of the World's Animal Genetic Resources for Food and Agriculture (SoW-AnGR).

The documents on SoW-AnGR, Global Plan of Action and Interlaken Declaration are all available on http://www.fao.org/ag/againfo/programmes/en/genetics/ITC_docs.html

In the Global Plan of Action the priorities for the implementation are derived from the proposals made by the countries. The priorities are discussed and presented in four areas: 1 Characterization, inventory and monitoring of trends and risks, 2 Sustainable use, 3 Conservation, 4 Policies, institutions and capacity building. The document on priority areas was prepared for and discussed at ITWG-AnGR (International Technical Working Group) in December 2006 in Rome and at the meeting of the Commission on Genetic Resources for Food and Agriculture (CGRFA) at FAO in June 2007. This Global Plan of Action is the first step in the FAO process on farm animal genetic resources. In particular the fourth area of priorities gives the FAO mandate to continue the work on regulatory and legal options. This future process will, however, necessarily be partly member-country driven, which implies that the country or countries providing information and suggesting options at an early stage might have substantial impact on the future work of the FAO in this area as agenda setter.

Europe and EU

The implementation of CBD is carried out by individual countries. The treaties, obligations, standards and recommendations accepted at an international level are developed within the countries by adjusting and completing the respective national strategies and policies, laws and statutes. Each country has typical networks for the management of genetic resources, including administration, breeding organisations, research and public societies.

European Regional Focal Point for FAO programme

Europe plays an important role in the global programme for AnGR. Until 2007 it was the only region which has a common secretariat working towards a coordinated programme. It is called ERFP – European Regional Focal Point for AnGR. Now a regional focal point has been established also in South-America. In comparison to AnGR, the European regional work is much more coherent for the plant sector (ECP/GR – European Cooperative Programme for Crop Genetic Resources Network) and also for forestry (Euforgen – European Forest Genetic Resources Programme) sector. Within the FAO programme, there is clearly a need to strengthen the European regional coordination on animal genetic resources.

Common EU policies

Over the years, EU has shown much interest in incorporating the issues on genetic resources in the policy making. The Member States coordinate their common position at Council level and the Member State holding the presidency expresses the EU position at FAO level. So far, the AnGR issues are dealt by several DGs (Directorate-General): SANCO (Health and Consumer Affairs – zootechnics, animal health), AGRI (Agriculture and Rural Development – CAP Common Agricultural Policy), ENV (Environment – follow-up of CBD), RTD (research) and DEV (Development - FAO-issues). Currently, the European Commission is, however, lacking experts devoted to AnGR issues. The work on animal genetic resources would benefit from a single body dealing with the animal breeding and conservation issues within EU, as is the case for plants. There is a substantial amount of EU legislation on animal breeding and conservation. This has harmonized the national legislation in EU countries and raised the awareness of the importance of sustainable conservation and utilization of AnGR. EU is emphasizing the need for achieving profitable production for all farm animal breeds. With respect to IPR, patent rights are defined in Europe by the European Patent Convention and EU has adopted a Directive for biotechnological patents which sets special rules for the grant of and scope of the protection for this type of patents (98/44/EC). This is fairly unique in a global scale as patent law is mostly general in scope and expression. This Directive has rules targeting patents on both plant and animal related inventions. It is, however, left to be seen how the national courts will apply these rules in concrete single-cases (see Tvedt 2008, Tvedt and Finckenhagen 2008). So far, no national courts in Europe have ruled on the scope of patent protection in animal breeding for food and agricultural purposes, but they have been presented cases regarding the grant of patents.

II. Nordic issues on animal genetic resources

The Nordic countries are actively networking in the area of animal genetic resources. This includes collaboration between research, breeding organisations and the joint work within Nordic Gene Bank for Farm Animals (NGH), now within NordGen (The Nordic Genetic Resource Center). Such a close sub-regional collaboration is unique within Europe and even globally. It stems from common values, needs and goals and brings benefits in cost-efficiency and increased critical mass.

When individual countries delivered reports on animal genetic resources to FAO, there was a summary compilation prepared by NGH (2004) for the Nordic region.

Species and breeds

In the Nordic region, the most important farm animal species are cattle, pigs, poultry species, sheep, horse and farmed fish species. There are some species that are important in the Nordic region, but less common elsewhere, such as reindeer and fur animal species – mainly mink and fox. In all these species, except poultry, there are local active breeding programmes. The commercial poultry production is totally based on hybrids of imported parent or grandparent lines.

There is much variation in the use of breed concept in the world. In North-America some groups are following very stringent breed definitions. Compared to the rest of the world, Europe has the largest number of farm animal populations for which the term breed is appropriate. This is very much due to culture and tradition, as there is much less interest outside Europe in paying attention to the typical characteristics defining a breed, such as the exterior traits differentiating populations from each other. The breeding organisations stem from activities devoted to a breed or a cluster of breeds and e.g. the EU legislation strictly ties the organisations and herdbook-keeping to respective breeds. In comparison to other European regions, the number of breeds is relatively low in the Nordic region. On the other hand, Iceland is an exception in a sense that a uniform outlook has never been a target in cattle, sheep or horse, vice versa variation in colour has been much appreciated (Adalsteinsson 1981). Therefore the present Icelandic animal populations exhibit a wide range of colour in a way not usually found elsewhere in Europe. In some breeds, the fanatic emphasis of exterior breed characteristics may hamper the breed development.

Breeding co-operatives

The Nordic breeding organisations are mainly co-operatives owned by the farmers. The national breeding schemes are typically run with open transparent operations. Farmer involvement is the core of the operations. Farmers are actively recording performance in production and reproduction traits and thereby forming the base in data collection schemes. The breed societies within species are closely collaborating and the breeding programmes are jointly run for breeds within cattle, pigs, sheep and horse.

Health status and sound objectives

The health status of production animals is very good in the Nordic countries. Most of the serious animal diseases are non-existing in these countries. Also veterinary care is very well organised. In Europe, Finland, Iceland, Norway and Sweden are salmonella free and they have an exemption within EU and EAA from examining feed and animal products for possible salmonella contamination.

The drive towards high health status is reflected in the breeding programmes and in setting the goals in genetic improvement programmes.

The resistance to production diseases has a high emphasis in the breeding profile of dairy cattle. The genetic ranking of the artificial insemination (AI) bulls is based on a wide body of information collected from the farms. The health recording scheme is carried out in collaboration with veterinarians. The Nordic recording schemes for disease data is still unique in the world.

As the health status deviates substantially from that in neighbouring countries, importation of breeding animals from countries outside the Nordic area is always a health hazard. It is in the interest of the Nordic countries to observe the health regulations in international trade and also ask for information on health and fertility traits for imported breeding animals.

Nordic collaboration in breeding operations

National programmes in dairy cattle breeding are collaborating across borders. The collaboration consists of joint genetic comparison, exchange of genetic material and joint MOET schemes. In the case of loss of all the breeding animals and semen storage due to disease outbreak or catastrophic events, the neighbouring countries are prepared to help in replenishing the breeding stock and re-establishing the breeding programme. In pigs the variation of health status between the countries prevents an active exchange programme between the countries, and in exchanging breeding stocks, strict hygienic measures have to be followed. In the pig sector, there is variation between the countries in the way how the slaughter industry is supporting the breeding activities.

The Future of Nordic Red Dairy Cattle

In advanced milk producing countries production is almost entirely based on the Holstein breed. The red dairy breed is very important in the Nordic region and is dominant in Finland and in Norway. The Holstein breed is suffering from lowered performance in reproduction and health traits (e.g. Begley et al. 2007; Heins et al. 2006 a, b, c), possibly due to long-lasted emphasis solely on production yield. As the breeding operations in the

Holstein breed are highly concentrated, there is a risk for a narrowing breeding base. Genetic improvement schemes in Ireland and in US are carrying out crossbreeding trials with Nordic red breeds. The results are encouraging and the red Nordic breeds are predicted to have a growing demand for crossbreeding purposes. The crossbred animals are produced to make use of heterosis to improve longevity traits and partly to combine different characteristics for which the breeds have been previously selected. Heterosis is restoring the performance lost on inbreeding (see Mäki-Tanila, 2007). Heterosis is fully expressed in the first generation cross while the benefits are quickly diluted in subsequent generations without proper coordination and planning. The Nordic Reds are a choice in such improvement schemes. Therefore the continuation of smoothly running international trade on animal genetic stock would interest also the Nordic breeding organisations.

Nordic joint work on animal genetic resources

The Nordic Gene Bank for Farm Animals (NGH) has served as an umbrella organisation for the Nordic activities on animal genetic resources since 1984. NGH has increased the awareness of the importance of genetic variation and sustainable breeding programmes and conservation activities through different means of communication and by organising workshops and seminars. NGH facilitates cooperation between the parties in the field of genetic resource management, know-how development and policy making. NGH interacts actively with the national coordinators and committees. Now the animal sector activities are part of NordGen.

III. What lessons can be learnt from the regulation of plant breeding?

The plant genetic resources have specific features to be considered. Distribution patterns of genetic resources are heavily influenced by man. "Country of origin" kind concepts are difficult to apply, as specimens are stored in genebanks and in several localities (users can get the same material from different sources). Countries are highly dependent on GR of other countries and continued exchange of material is necessary. There are crucial differences between plant genetic resources and animal genetic resources (see Hiemstra et al. 2006). This chapter looks at the plant sector and contrasts it with the animal sector for the purpose of identifying what can be learnt from the existing regulations.

Outline of the International Treaty on Plant Genetic Resources for Food and Agriculture

In 2001 the member countries of the FAO agreed to an International Treaty for Plant Genetic Resources for Food and Agriculture (IT-PGRFA) after more than seven years of negotiations, which entered into force in 2004. Altogether 106 parties have signed it, including all the Nordic countries.

The main elements of the treaty are:

- conservation, exploration, collection, characterization, evaluation and documentation of GR including promotion of in situ conservation of wild crop relatives and wild plants and an efficient system of ex situ conservation

- sustainable use of genetic resources
- technical assistance to developing countries or countries with economies in transition
- multilateral system of access and benefit sharing
- acknowledgement of farmers' rights

The active exchange among public gene banks made the bilateral contracting stated by CBD too complex to follow. One major achievement by the IT-PGRFA is the establishment of a Multilateral System (MS) for access and benefit sharing. The open system for exchange is considered as a benefit to the parties in itself. Subject to more specific detailed rule, benefits arising from the use of plant genetic resources from the Multilateral System are to be shared to others. Specific commercial uses will under certain conditions trigger economic benefit sharing. The payments resulting from economic benefit sharing will go to a fund controlled by the treaty's governing body.

The plant genetic resources covered by the multilateral system are delimited in two ways: a) by the list of species which are covered; and b) plant genetic resources in the *public domain* are subject to the access rules in the system.

The species list which determines the scope of the MS is a result of political rather than scientific decisions. It includes several globally important crops like wheat, rice, maize, potato, rye, barley, oats etc.; some regionally important crops: yams, coconut etc. and a number of forages, mainly from the temperate region. It excludes, however, important species like soybean, groundnut, sugarcane, cotton and tomato, and certain wild relatives (e.g. of maize). It is the plant genetic resources in the *public domain* that are covered by the System. This implies that countries are not obliged to impose an obligation upon private parties to open their private collections of plant genetic resources for exchange in the system. Although, in many countries ownership to PGR is not regulated, the IT-PGRFA does not further define the *public domain* or set any rules for how this shall be delimited. Parties are obliged to encourage other holders of plant genetic resources to include these in the multilateral system. Access under the system is provided for research, breeding and training for food and agriculture, not for e.g. industrial or pharmaceutical uses.

The further details for access under the multilateral system are specified in a standard Material Transfer Agreement (sMTA). The sMTA of the International Treaty was adopted in Madrid in June 2006. It specifies the rights and obligations of the provider and the recipient. For the provider these are, briefly: access shall be accorded expeditiously and free of charge, passport data and other non-confidential information shall be made available, access to GR under development shall be at the discretion of its developer and access to protected material shall be consistent with relevant laws; and for the recipient: material shall be used or conserved only for research, breeding and training for food and agriculture and the recipient shall claim no intellectual property rights to the material or its genetic parts and components "in the form received" that limit the facilitated access. A recipient, who commercializes a product, shall pay a fixed percentage of the sales of the product if the product is not available without restrictions.

One crucial benefit is the facilitated access to the plant genetic resources itself. Other benefits from the system are the exchange of information between all parties through the global information system (catalogues, results of research etc.), access to and transfer of technology relating to conservation and use of GR, capacity building (education, development) and monetary and other benefits of commercialisation.

Plant Breeder's Right – UPOV

The plant breeders' right follows the UPOV (International Union for the Protection of New Varieties) system and is granted under the national plant breeders' rights legislation. UPOV shares secretariat with WIPO (World Intellectual Property Organization) in Geneva, but is a standalone organisation. This is one example of a *sui generis* intellectual property right, which means a system for intellectual property right which is adapted to one particular area of innovation. It offers a system for registration of an intellectual property right to *plant varieties*. This system shares some resembling features with the patent system, but is distinct as it is assumed to take into account the particular needs of the plant breeding sector. The four criteria for being granted a plant breeders' right are novelty, distinctiveness, uniformity and stability. The scope of the right is more adapted to the needs of the plant breeding sector, by establishing two modifications to the exclusive right: For a new plant variety which is protected by such a right, others have the possibility of using protected varieties for the purpose of breeding new varieties. In some relations the UPOV system recognises a farmer's rights. Farmer's rights allow 'farmers to use, for propagation purposes on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety'. The principle of farmers' rights is continued in the IT-PGRFA under the FAO, but is not made mandatory and will be depending upon the implementation in national legislation in each country (IT-PGRFA Art. 9).

The farm animal gene banks are within the breeding programmes

Plant breeders release a finished uniform variety to the market. Plant Breeder's Right is a special system of intellectual property rights for plant varieties and it resembles patenting. Animal breeds are, however, completely different and the patent like concept does not fit into them as they are far from uniform when looking at individuals within a breed. Actually a major part of genetic diversity of animals is within the breeds, whilst in plants the diversity lies among varieties. Animal breeds are under continuous improvement and in most of the animal breeding operations, the breeder and farmer are jointly taking breeds further without explicit intellectual property issues.

The genetic resources in plants are kept in public genebanks. The public gene banks are accessible via the multilateral exchange system which includes fund collection. The breeding animals are owned by farmers and the breeding organisation, and the ownership and exchange are smoothly handled under the private law, even between countries (e.g. Hiemstra 2006). It is probably not an exaggeration to say that 99% of farm animal genetic resources are privately owned, while in plants most (at least 50%) of the genetic resources are public. When the variation is in the production animals and in the co-operative breeding programmes, a critical factor in the maintenance of diversity is to coordinate the collaboration with farms and breeding schemes, so that the management of genetic variation is well integrated in the activities. The viability of breeding programmes and long-term policies on variation management and ultimately their profitability,, are the key factors in maintaining diversity. Hence it is no exaggeration to say that breeding programmes are the farm animal gene banks. Therefore the following chapter is entirely devoted to the discussion of the factors enhancing sustainability of animal breeding programmes.

IV. Criteria for sustainable use of animal genetic resources

The chapter presents the main elements for sustainable animal breeding schemes. The topic is thoroughly discussed and presented by Woolliams et al. (2006).

Collaboration over production chain

A feasible outcome for a sustainable use of AnGR would require that the objectives in the operations are shared by all the stakeholders in the production chain. The stakeholders include the primary production partners (producers, animal breeding organisations, animal health experts and animal feed producers), the processing industry and manufacturers, the retail groups and finally consumers and the society.

The development of animal production should address food security (quantity, quality, biological/technological safety), socio-economic impact (rural economy, national economy, subsidies, export / import), public perception on breeding technology, environmental impact (quality of environment, landscape management), animal health and welfare and production ethics.

Analysis for breeding goals

Sustainable breeding schemes have several properties. The starting point is analysis of demand and market. The analysis should take into account political and economic global and national trends, the preference by the consumers and the society. Fragmentation in consumption habits and marketing is an important factor in modern societies. The results of the analysis are used in determining the breeding objectives and the selection criteria are then formulated from recorded traits and the genetic relationships among the traits. The functionality – such as normal reproduction, disease resistance, conformation - of animals is a key objective in breed development work.

Recording schemes

A common missing factor in breeding operations is information, as the recording schemes are vital for decision making. The schemes can be an integrated part of production in farms. The more expensive schemes involve test stations and data collection on slaughter, health and welfare traits and molecular genetic typing of animals.

Avoiding genetic risks

The design of a breeding programme should be established with the avoidance of genetic risks as a guideline. The risks may stem from a low number of selected (tested) animals. This is reflected in genetic drift or even as inbreeding depression. Both are causing the realised response to deviate from the predicted one. Sometimes the genetic parameters are estimated with improper methods which would result in wrong parameters. The use of wrong parameters would affect several factors in the breeding scheme, such as the chosen volume of information and testing and selection weighting. Molecular genetics is now used to detect genes or chromosomal segments with large effects on the variation in the traits. Such information can be used to improve the efficiency of selection, especially in traits with much non-genetic variation. If the findings in genomics are over-optimistic, their use will not give predicted increase in the efficiency, rather the opposite. The long-term results in breeding programme may deviate from the desired ones due to ignorance of unfavourable side-effects due to narrowly focussed selection.

The genetic variation is maintained if the number of top breeding animals is large enough and the use of family lineages is balanced. There are now efficient tools for selecting the breeding animals when the pedigree information is available. They are used to minimise the kinship of parents and to consider the allocations of mating between the selected males and females (Meuwissen 1997, Sonesson and Meuwissen 2000, Sørensen et al. 2005). A breeding programme needs a back-up storage of genetic material in frozen semen and embryos to replenish the genetic variation in the future – in case there has been a considerable reduction in family lineages or accidental loss of breeding animals.

Planned importation

If the domestic population of the breed is too small, the genetic improvement is often based on continuous importation of semen from elite foreign sires. If the domestic breeding population is large enough for import-free selection, recording and operations should be continuously revised and made cost-efficient. This is especially true if the selection profile differs from the fashionable ones. For example, in dairy cattle the imported bulls are often lacking information on fitness traits for which in the Nordic countries the domestic bulls would have records available.

Importation planning should also take into account the possible risks for diseases. Avoiding continued dependence on importation is in this sense very wise.

Operative risks

There are organisational risks related to competitiveness of the breeding schemes. The best possible experts should be used in development, planning and operative work. The major costs in breeding schemes are the testing of selection candidates and the maintenance and use of the top breeding animals. The costs are manifold if there are several breeds/lines and production animals are crosses. An often neglected task is continuous monitoring of the realised results and co-response (fitness traits), market share, need for several breeds/lines and cost-efficiency of the breeding programme and the need for adjustments in the selection scheme. The programme is not successful if the decision making is sub-optimal and lacks commitment. Also if the marketing is not done professionally, domestic or international operations may fail in gaining new market ground or in maintaining the existing one.

Checklist for sustainable breeding schemes

The breeding organisation should carry out regular self-appraisals for sustainability. When genetic improvement is based on open national breeding programmes, the organisation may give annual reports to appropriate authorities. The self-appraisal and evaluation should be based on criteria that are easy to report and compare. The most important features of a sustainable breeding programme can be summarised as a list of questions. The list is adopted from the book *Sustainable Management of Animal Genetic Resources* by Woolliams et al. (2006). The list covers the most important issued and can be used in assessing the long-term sustainability of a breeding programme.

- Is the market and product well defined (including factors related to consumption, production system, crossbreeding, social changes, agricultural policies)
- Is the breeding goal well defined (feed, prod environment, health, welfare)
- Is sensitivity to external factors addressed (market, food safety, G x E, public perception)
- Are sufficient economic, infrastructure (R&D) and human resources available
- Is the genetic basis in the population wide enough (effective population size, are different breeds necessary and wide enough)
- Is recording sufficient (selection goal deduced also from the functionality of animals, changes in welfare)
- Are the expected effects of selection predicted (goal and other traits)
- Is the value of importation properly assessed (poor information vs own recording scheme for fitness traits, disease risks)
- Is genetic progress monitored and evaluated

- Are time horizons and milestones defined (predicted vs realised changes, market review)
- Is the profitability of the breeding scheme evaluated

Some of these objectives are now included in the Global Plan of Action for AnGR. For example, the rationale text states: ‘The five main livestock species: cattle, sheep, goats, pigs and chickens, provide the majority of food production, and among these, a small number of international trans boundary breeds account for an ever-increasing share of total production. This process leads to a narrowing genetic base, as breeds, and indeed species, are discarded in response to market forces. In commercial breeds, high selection pressure leads to a narrowing genetic base, with the potential risk for present and future food security. Breeding programmes and policies should include consideration of broad genetic variability within populations and breeds, which is essential for the development of livestock production to meet the future challenges. Long-term sustainability of selection programmes requires regular assessment of genetic changes and adjustments in selection goals.’

Further in the Global Plan, among the strategic priorities the area 2 ‘Sustainable use and development’ contains the following priorities:

- Establish and strengthen national sustainable use policies
- Establish national species and breed development strategies and programmes, with the actions
    - assess environmental and socio-economic trends
    - develop realistic scenarios for long-term planning and strategic breeding programmes
    - strengthen breed development programmes towards need of markets and consumption
    - develop organisational structures of breeding programmes
    - implement elements for the maintenance of genetic variation within breeds
    - collect information on other than production traits (health, welfare) to monitor the changes
    - include back-up storage of frozen semen or embryos
    - promote agro-ecosystems approaches to the management of animal genetic resources

The next step is to consider how these are implemented in breeding programmes and if there is a need to establish a light appraisal and monitoring system within countries (see Box 1).

BOX 1:

Swedish law on sustainable use of animal genetic resources in breeding populations

In 2006 the Swedish parliament changed and added new rules into the law (2006:807) concerning the control and supervision of farm animals. It is now required that breeding organisations take active measures to promote sustainable use of animal genetic resources through their breeding programmes. Further and detailed legislative steps, like monitoring and supervision from authorities, still remain to be definitely set and adapted in regular application.

In their own "Plans and guidelines" (approved by the national authorities) breeding organisations have to describe, what kind of measures are taken within their breeding programme to support genetic diversity in the breed they are working with. Monitoring and, if possible, measuring, ongoing trends, like effective population size, should be included.

These "Plans and guidelines" form the basis for the decision of the Swedish Board of Agriculture to recognize an official breeding organisation. The guidelines have to be renewed every third year, so each organisation is thoroughly screened regularly. The intensions of the organisation regarding genetic diversity should also appear from the annual reports and rules of each organisation.

Additionally, the monitoring done by the authorities will be included in the regular check–ups (no stipulated time). Contacts with major cattle and pig breeding organisations are frequent and the Board of Agriculture receives up-dates of the situation easily. There are several such breeding organisations approved, many of them small, especially those dealing with horses. It is expected to take time before all the breeding manuals are ready.

V. Exchange of animal genetic resources

Active exchange

There is very active exchange of breeding animals and frozen embryos and especially of frozen semen between countries. Elite genetic material is imported to upgrade the domestic breeds. In some cases 'new blood' from unrelated animals may upgrade the performance and widen the genetic basis of the selection candidates and thereby may have a long-term effect on the efficiency of domestic breeding operations. Many Nordic breeding programmes are also selling products from own breeding programmes to other countries. The sales income can contribute significantly towards funding the domestic operations.

In dairy cattle the freezing techniques for semen are very advanced and make it possible to distribute and deliver large amounts of semen doses all over the world. The export and import market of dairy bull semen have a very high volume. The Nordic countries have an active exchange programme between themselves and with other countries. For example, in 2006 Sweden exported some 500 000 bull semen doses outside the Nordic countries and another 77 000 to the other Nordic countries. The Swedish import figures in the same year were 113 000 and 31 000, respectively. Finland exported 44 000 semen doses in 2006 and the number of imported doses was 130 000. The data has been provided by Swedish Dairy Association (Svensk Mjölk) and Faba Breeding.

Crossbreeding is used to bring new features to production animals, such as meatiness or meat quality in pork production. When unrelated breeds are crossed, the hybrids are usually better than the cross average due to heterosis. Heterosis is more pronounced in fitness related traits, such as fertility and health traits. Maintenance of several breeds can be expensive and the costs can be drastically reduced if the costs related to breed maintenance and development are shared between the countries.

Gene flow from North to the South:

Purchasing a cow can mean a lot of different things depending where we are. A farmer in a developing country can buy a cow that is perfectly adapted to the needs of the farm – an animal that can be used as a draught animal while producing milk, meat, a hide and manure that can be used as fuel and building material; an animal that often is the farmer's only form of financial investment. The local breed usually has genes that are adapted to the local environment – genes that give such valuable traits as climate tolerance, disease resistance and the ability to utilise a broad range of local feedstuffs. Under such relatively harsh and changing environments, the imported "super cows" often fail to achieve the expected production levels. But by the time the farmer has realised this, the original local breed has perhaps vanished. In such cases, what was thought to be a huge step forward (import of a "better" breed) quickly turns into a catastrophe.

In any case, animals – and therewith their genes – are being traded on a grand scale. The ratifying states are committed to adapting their legislation, administration and policies to comply with the intentions of the CBD. The adaptation of national regulations has taken much longer than expected, or in some cases, has not even been initiated. This means that a simple basic agreement should be developed as a guideline for the trade with farm animal genetic resources – an agreement that combines the Rio Convention's intentions with existing private-law regulations. The objective should be that animals with traits that either are useful now or could be beneficial in the future are not totally replaced by breeds that give the highest profits in the short term. In such a process, individual countries, companies or research environments enrich themselves at the expense of poor countries by utilising their resources without fairly sharing the benefits. Most farm animals in the world are privately owned, and thus private-law procedures apply. So farm animal genes are usually traded between two legal persons, a buyer and a seller, and since the utility value is converted to a price which is in proportion to the utility, the transaction benefits both parties. However, we are increasingly witnessing stakeholders who wish to secure markets, without respecting the intentions of the CBD. This could negatively affect our common goal of safeguarding the sustainable use of farm animal genetic resources.

The gene flow from north to south need special attention, because the production environment and disease pressure are most likely very different and genotype-environment interaction is bound to occur. The buyer should have a chance to test how the imported breed would perform in the new conditions. It is important that these issues are openly discussed and some international recommendations for code of conduct are prepared.

It is arguable to support the development of a global set of simple, basic guidelines. This would enable the sustainable breeding and trade with farm animal genetic resources. This would also ensure correct information about and appropriate appraisal of the animals' actual and potential benefits. Accordingly it is desirable to have trade with farm animals conducted under consideration of the actual value of the animals with regard to ethics, animal welfare, cultural and historical aspects, the natural environment, animal and human health, and the effects on landscapes and different human populations.

Animal health

The international exchange is regulated by veterinarian regulations. The founding of WTO in 1994 included also an agreement on sanitary and phytosanitary (SPS Agreement, 1995) measures. The health related regulations have so far the greatest influence on the international exchange. Because animals in the Nordic countries have a very good health status, it is in the Nordic interest to pay full attention to the regulations and not to take any risks in animal trade.

Open comparison and good practices

Globally, most of the exchange of AnGR is among the developed countries where animal production is industrialised. In these countries the feed and other production input factors are very similar and therefore the production following exported and imported animals does not meet any surprises. Therefore animals which have a high genetic expectation in the selling country, can be assumed to perform well also in the buying country (or genotype-environment interaction can be neglected, mainly because the range of the environments is very similar). The importations can be a major investment and therefore the buyer would like to have a full and accurate picture of the genetic quality of the imported animals. This could be only achieved if the selling breeding company has a reliable genetic evaluation done for all the interesting traits, including the non-production traits.

The Nordic cattle breeder is always making a compromise when buying a dairy bull from outside the region, as the quality of information on fertility and production disease resistance is poorer than what is available at home. The Interbull conversion of breeding values between the countries gives some guideline for genetic ranking between countries, but is obviously restricted to the traits that are recorded.

Avoiding the risk of being accused of biopiracy

Very widely different breeds are good candidates for investigating the genetic factors for physiological differences. This kind of research may pave a way for new selection tools or novel nutritional factors in animal production or even in human medicine. This is similar to collecting information for the use of plant material in disease curing and in rituals. The uncertainties in guaranteeing the rights of local peoples and the countries of origin, have brought the sharing of information and plant material, into halt in some countries. Similarly we need firm guidelines on how to proceed with exotic rare breeds in case they attract foreign research groups. It would be most unfortunate to start preparing the regulations after the first case on the biopiracy in farm animals enters the news.

Ownership of animal genetic resources

There are several areas where the ownership questions are rising also for animal genetic resources. The exchange of breeding animals in main stream breeds is extremely common both within and between countries. The ownership is smoothly transferred in purchasing breeding males, semen doses or embryos. The present private law practices are favoured by breeding companies. In some cases the selling party may want to put restrictions to the use by a third party in the bilateral contract.

The conservation programmes are mainly based on keeping animals in production herds (in situ). In order to have possibilities for replenishment after a major pandemic disease or other catastrophe seriously reducing the number of animals, there is a need to have cryo-storage of semen doses or embryos. It is usually the national conservation programme which owns the material in the cryo-bank (ex situ). The principles for this kind of ownership have to be clear when the donor animals for the ex situ conservation are collected or purchased.

BOX 2:

The Danish contract on delivering semen and embryos of endangered breeds to gene bank

The rare local breeds have small populations and are therefore all the time under a high risk of extinction, especially due to increased threat of infectious diseases. Therefore it is important to establish and maintain storages of frozen semen and embryos which can be used to re-establish the breed or replenish the genetic variation. The gene back collection should make contracts with the owners of animals that are donating material into the bank.

The contract is made between the owner of the donor animal and the gene bank. The contract document contains information on the donor animal (species, breed, sex, id code and date of birth). In case of embryos, similar details should be given also for the male parent. The veterinary status of the herd and condition of the donors must be checked and recorded. All the semen doses and embryos should have the date and place of collection and the persons who have carried out the operations.

The contract should also include assessment of quantity and quality of the collected material and actions taken, and necessary terms if the collection fails to meet the expectations.

In Denmark, the rare breed owners are granted incentive payments and in return they are obliged to deliver donors. The duration of that obligation is the year, in which the incentive payment has been granted. If the owner is expected to assist at blood sampling, semen / embryo collection on the farm, or transport of donors or alike, this is specified in the contract. If the donors are moved to a collection site outside the farm, an insurance coverage may be purchased. To compensate the owner for the additional work that follows delivering donors to the gene bank, a premium is granted for each donor. The premium is 5.000 DKK for stallions and bulls, and 3.000 DKK for all other donor animals. The Genetic Resource Committee covers all costs that are directly related to the deliverance of genetic material to the Gene Bank. The payment is not conditioned by the outcome of the operation.

The genetic material is stored in the Gene Bank for AnGR. The content of the bank belongs to the Danish state, and is administrated by the National Committee for AnGR.

In a wider international context, the livestock keepers’ rights are often raised. They are somewhat related to farmers' rights in the plant breeding context. The most active groups seeking for the acknowledgement of livestock keepers' rights are the pastoralist groups. The main concern is about the animals' access to the pasturing areas and close-by sites providing drinking water for the animals. For many indigenous breeds such traditional privileges are vital for survival.

The intensive systems in industrialised production are very much directed by the end-user. Such a vertical integration may also restrict the producers' possibilities in choosing and maintaining the animal breed. This is also a factor increasing the risk of loosing local breeds.

In conclusion, there are many practices in animal production, breeding and conservation work which have become a norm or tradition, where undesired development could be prevented by harmonising their existence with some kind of regulation.

Possible model agreement for exchange

The current practices in animal breeding follow private law and work well within and between private parties, including in different countries. The process could be described and formulated in simple recommendations (code of conduct).

The basic guidelines stem from the principle of bilateral exchange formulated in CBD. The principles are very general and obviously the animal sector needs guidelines which acknowledge the current practices and needs. One of the three main goals of CBD is "the fair and equitable sharing of the benefits from the use of genetic resources". In Article 15 of the CBD parties agree to: "take legislative, administrative or policy measures, as appropriate...with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources." There is a need for adapting these general principles to the animal sector.

The Bonn Guidelines aim to help countries achieve this objective. The Bonn Guidelines are non-binding and do not alter the obligations embedded in the CBD. The Guidelines aim at assisting governments in the structuring of national and regional legislation and mechanisms to ensure fair access to genetic resources, and sharing of benefits from these resources. The Bonn Guidelines, however, focus mainly on the legislation in the providing countries, and there is a lack of guidance for the implementation of the CBD in user countries of genetic resources. There is flexibility built into the guidelines to allow revision as experience is gained.

Access to genetic resources is seen as important to sustainable development and the preservation of biodiversity, but only when there is fair distribution of benefits: both short-term and long-term; financial or technological; and with the preservation of traditional/ indigenous knowledge. The Guidelines ask for transparency in policy and procedure in this area and suggest that prior informed consent procedures are used. They also suggest that voluntary verification mechanisms are initiated.

Material Transfer Agreements (MTA) presented in the Bonn Guidelines can serve as background for any contract or code of conduct for regulating access to genetic resources and possible descriptions of benefits arising from the use of the material. A model MTA could address the following elements:

i. Property rights cover three types of property rights:
   - Contractual based restrictions
   - Physical property rights
   - Intellectual property rights

Most of the animal genetic material is privately owned. Property rights of material need to be in balance between the rights of the owner and the rights of the person/organisation who pays for the operations. Also the use of a third party should be considered here.

ii. The MTA might want to address to what extent the receiver shall have property right of offspring and to what extent the user shall have the right to claim any intellectual property rights.
iii. Confirmation of veterinary status of the material.
iv. Data protection
v. Benefit sharing arrangement (including a possible third party)

There is, however, a need for looking deeper into existing contractual practices to gain experience about solutions and approaches that will be conducive for the animal sector. Such a study could be a good knowledge-base for further development of standards.

VI. Patenting in animal breeding sector

The expansion of the scope of patent law to the animal sector has been the subject of very little discussion, and the probable consequences for the livestock sector have not been analysed. Rothschild & Newman (2002) and Rothschild et al. (2004) are singular examples of attempts to identify patents in the animal sector. For an analysis of exchange and property rights in the field of fish breeding and fish farming, see Rosendal et al. (2006). For a profound analysis of patent law applied to the animal breeding sector, see Tvedt (2008), for process patents in animal breeding, see Finckenhagen (2008) and Tvedt and Finckenhagen (2008). The general justification for patents that they lead to increased innovation is merely repeated for the livestock sector, without looking into the structure of the sector to see whether the existing incentives for research and development are sufficient, or how the introduction of patent law may alter them.

Description of the tendencies in applying patents to the animal sector

In the Nordic countries patents have not been much used in the animal breeding sector. In a global context patents have been applied to the plant breeding sector for a longer period of time than is the case for animals. There is a commencing trend of multinational companies applying for patents also in the animal sector. In the plant sector patents have played the major role for transgenic plants and in genetic modification foremost when a new gene has been modified into the cells of a plant. This makes a product patent to that gene and the plant cell where the gene has been introduced a highly relevant manner for establishing an exclusive right to those genetically modified (GM) plants. GM animals are still not technologically viable or accepted in food production by consumers. The cases on transgenic animals for production traits are still far away. In all the farm animal species there are now findings on genes affecting the economically relevant traits (Dekkers, 2004) and a few patents have been issued (Box 3). Animals are physiologically more complex than plants and dissection of genetic variation into specific genes is very demanding and costly research. These are probably some of the reasons why patenting of genes and cells as products is relatively more limited in the animal sector compared to for plants. However, animal genomics is likely to benefit from the flourishing human medical genomics receiving good supplies of funding. The case-law on patents applied to animals is the classic one from laboratory animals, with the famous Harvard 'oncomouse' as the prime example, since it triggered a Supreme Court decision in Canada, a court decision in the USA and a Board of Appeal decision in the European Patent Organisation. This could be taken as an example that patents in the animal field are uneasy. Even despite the substantial differences between farm animal breeding and laboratory animals, one can expect these decisions to be relevant in the farm animal sector as well, due to the principles of law.

BOX 3:

Patented use of individual genes in farm animals

Considerable progress has been in the last 10-15 years through application of genomics in the identification of chromosomal regions and even loci that affect the variation in the economically important traits of farm animals (Andersson and Georges, 2004). The chromosomal regions are usually called quantitative trait loci (QTL). The applicability of the findings depends on the cost and reliability of typing animals for the specific loci. Two types of useful loci can be distinguished: loci that code for the actual gene causing variation and loci (or markers) that are closely linked to the functional gene. Because such cheaply applied and well-specified findings may have substantial economic expectations, they are now a common subject for patent claims and several patents have been issued. Selection could be applied among the variants of the gene itself or of the linked marker. Markers can be used within the population (marker assisted selection) or in enhancing crossing programmes (marker assisted introgression). Let us consider three examples.

Many genome scans done in dairy cattle have found a QTL for milk traits on chromosome 14 and fine mapping studies have shown the main responsible gene be a locus coding an enzyme DGAT1 (e.g. Coppietiers et al. 1998). More specifically, the presence of the K232A mutation in the gene results in a decrease in milk fat percentage, milk fat yield, solid fat content and milk protein percentage, while increasing milk volume and milk protein yield. The finding has been granted a patent EP 2001992795 on 24 Jan 2007.

While the previous is bearing prospects of elevating the current production, there are also cases on gene causing quality defects and the molecular genotyping would then provide an efficient tool for a quick eradication of the undesired production. Lunden et al. (2002) showed that a fishy off-flavour in milk from cows under rape seed feeding is caused by a functionally altered enzyme FMO3. The US patent 7273703 for the result was issued on 25 Sep 2007. Closely related finding in egg-layers (Honkatukia et al. 2005) has been awarded the patent EP 1518936B1 on 22 Aug 2007.

BOX 4:

European dismissal of the Patent for test-day model

A case on patents of processes is the genetic and management evaluation of dairy cattle using test-day model. The invention was done at Cornell University in early 1990’s. Background information on the Cornell patent can be found on the PSAS website, at: www.psas-web.net/specific_cases-.htm#The Cornell_patenting_case. On 19 June 2007, the Board of Appeal of the European Patent Office has dismissed the appeal T0365/05 of Cornell Research Foundation in the matter of patent 0637200 with the title “Method of bovine herd management”. The board found that the patent did not contain an inventive step. With the support of several countries it was possible to find relevant publications from the 1970's and 1980's, to demonstrate that the problem was not new and innovative. The joint approach, initiated by the German Cattle Breeders Organisations and supported by all European ICAR (International Committee for Animal Recording) member states, was therefore very successful. The result means that the matter is settled once and for all and European computing centres are free to use test-day models in genetic evaluation and for other purposes. However, import of products using this process patent to countries where this patent has not been revoked will fall under the indirect product patent protection (TRIPS Agreement Article 28).

The tendency in patent application since 2003 (when Monsanto delivered one early patent application to animal breeding method) is that patents are applied for processes relevant to breeding (Tvedt 2008). A patent can target an invention which is either described as a product or a process. All inventions can either be described as a product or a process. ‘Product’ in the patent law language is not limited to daily linguistic use as for example a ‘product in the market’. It rather means any invention which targets a thing or an object. A ‘process’ targets an exclusive right to an invention in a more dynamic manner, as the invention in this case is rather a method than a result. Since animal breeding currently is not based on genetically modification, the new invention in animal breeding is typically rather new manners to breed a better next generation of individuals, new methods for handling the animals or for detecting e.g. diseases. ‘Better’ in this context means the selection towards relevant breeding goals that are desired to be improved. New breeding methods or using technological insight and knowledge about the genes and the animals is one core area of potential to achieve the most rapid advancements in breeding. Such methods are most open for patenting (if they are found to be new and inventive by the Patent Office). One cannot, however, exclude the possibility of products patents being applied more frequently in the animal breeding sector in the future, but today this seems further ahead than the application of process patents. The focus here is therefore on processes as product patents lie more in the future. To get a broad overview over the picture, it is interesting to look at a selection of filed patent applications that have been published (the international patent search system operates with a delay for the publication of applications) (Accessed June 2007, see also Fitzgerald, 2005) Here are the results from the WIPO databases for patent applications handled by the international searching authority:

- (WO/2006/134579) Methods for preventing the inactivation, due to specific bacteriophages, of probiotic strain mixtures used in cattle-breeding;
- (WO/2006/108255) A system and method of individualization of animals and herd management;
- (WO/2006/103905) Feed composition and method of breeding animal;
- (WO/2006/101623) CSTF1 AND C20ORF43 Markers for meat quality and growth rate in animals;
- (WO/2006/073447) Enriched Pag-55 fraction and methods for early detection of pregnancy in ungulate animals;
- (WO/2006/052994) Systems and methods for improving efficiencies in avian species;
- (WO/2006/042885) System for breeding, restocking and maintaining red-legged patridge and other animals with similar biological characteristics in the natural environment;
- (WO/2006/035513) Amphiploid aquatic animal and method of breeding the same;
- (WO/2005/120219) Facilities and methods for breeding animal or plant, animal or plant bred by the facilities and methods and apparatus for generating activated gas;

- (WO/2005/101230) Systems and methods or improving livestock production;
- WO/2005/095590 “Sperm suspensions for sorting into X or Y chromosome-bearing enriched populations” (not confined to one particular species);
- WO/2005/094852 “Sperm suspensions for use in insemination” (not confined to one particular species);
- WO/2005/017204 “Use single nucleotide polymorphism in the coding region of the porcine leptin receptor gene to enhance pork production”;
- WO/2005/015989 “Method for genetic improvement of terminal boars” (these patent claims will be examined in a short case study in the next subsection);
- WO/2004/088283 “Apparatus and methods for providing sex-sorted animal sperm” (not confined to one particular species);
- WO/2004/087177 “Process for the staining of sperm” (not confined to one particular species);
- WO/2004/059282 “Method and means for early detection of pregnancy in animals by combination testing” (not confined to one particular species);
- WO/2004/003697 “Swine genetics business system”;
- WO/2003/096799 “Multiple cloned nucleus breeding for swine production”;
- WO/2003/043524 “Compositions and methods for accurate early pregnancy diagnosis” (not confined to one particular species).

Some of these patents are not confined to any particular animal species. Thus, they will apply to all animal species. Others of these methods are targeting single species only e.g. swine breeding. One particularly relevant observation is that when a breeding method or process for breeding is patented, the offspring produced by applying this method might become subject to the exclusive right (the principle is embedded in the TRIPS Agreement Article 28). We will come back to this later, but this is partly what makes process patents applied to the breeding sector a powerful tool. In the utmost consequence a breeder might end up infringing a patent by applying a method, which probably would leave the patentee with some kind of an exclusive right reaching through to the offspring from the application of the patented process. Let us assume that a fairly basic method becomes patented, then the use of that process applies also to the animal flock owned by someone else than the patentee (the owner of the patent) (Tvedt and Finckenhagen 2008). This raises difficult challenges from applying patents to breeding methods.

Patentability for animal breeding techniques

The first interesting question is whether there are any standard exemptions in the type of breeding methods that can be subject for a process patent.

The Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement) which is one of the agreements under the World Trade Organisation (WTO) requires all member countries to provide for patent protection to "any inventions, whether products or processes, in all fields of technology". The point of departure is that countries are obliged to grant process patents also in the field of animal breeding. TRIPS Agreement Article 27, paragraph 3, allows countries to exempt "…essentially biological processes for the production of […] animals", but requires countries to delimit such an exemption and provide for patents to "other than non-biological and microbiological processes". But what then is an "essentially biological process"? And what is "other than non-biological process". The scope of this discretion for countries turns on the interpretation of the term 'non-biological process'.

De Carvalho, who is a WIPO official, argues that "[…] it follows that patentability should provide as wide a coverage as possible" when he talks about how the exemptions to patent protection should be interpreted and applied (de Carvalho 2005: 171). In relation to the process patent protection he argues: "Being an exception, exclusion from patentability for essentially-biological processes should be read in a restrictive manner." (de Carvalho 2005:. 218). Further "…jurisprudence of the EPO may be of relevance…" since that language of the TRIPS Agreement was inspired by the EPC (de Carvalho 2005: 217). Cases from EPO have applied such a principle of narrow interpretation of the exemptions from eligibility for patent protection according to the European Patent Convention, but the principle of interpretation in the EPO is not applicable for the

TRIPS Agreement as the members to the two treaties are not the same. The Argentinean professor Correa, on the hand takes the opposite view and states that: "[…] the exclusion is to be interpreted in broad terms, inclusive of animals and plants as such, plant varieties, as well as animal races and plant species." (Correa 2007, at p. 293).

These two statements about the interpretation of the exemptions are contradictory. The Vienna Convention Law of the Treaties (which is recognised to express international customary law at this point) refers the interpretation of treaties to "be interpreted in good faith in accordance with the ordinary meaning to be give to the terms of the treaty in their context and in the light of its objective and purpose". It does not establish any general principle for the interpretation of exemptions in international law to be narrower or wider interpreted. Also, there is not any support for such a view in the Statues to the International Court of Justice. Such a principle has been applied by the boards of appeal in the European Patent Organisation. It is also (probably) this practice de Carvalho refers to when referring to the jurisprudence of the EPO (see above). Despite the fact that the EPC does not specify such a principle, the boards of appeal have applied such a principle of narrow interpretation of the exemptions. The reference by de Carvalho to EPO-practice has very limited value as methodology when interpreting the TRIPS Agreement, as the EPC and EPO-practice are only applicable to a small number of WTO-members (Vienna Convention Law of the Treaties Article 31.3 (c)). Both the reference to the EPO-practice and to the norm developed there can therefore not be applicable to the interpretation of the TRIPS Agreement. There are also no positive sources under the TRIPS Agreement indicating that such a principle should be applied. The principle of sovereignty is a strong normative argument in favour of not interpreting exemptions from a treaty-obligation narrower than follows from the general principle and the *ordinary meaning*; the countries relay on the wording when they ratify the obligations, narrowing the exemptions later would not be well in line with this. For a politically controversial provision as TRIPS Agreement Article 27.3(b), the need for all countries to be relaying on the wording, also for the exemption, finds strong support in the principle of sovereignty.

To illustrate with one example on how this discretion of implementation has been done: in the EU Patent Directive, Article 4 uses the same terms as the TRIPS Agreement and exempts "1. (b) essentially biological processes for the production of plants or animals" from patent protection. The EU has gone one step further in specifying what this implies in greater detail: "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection." (EU Patent Directive 98/44/EC, Article 2, para 2) The seemingly broad term "essentially biological processes" is thus defined more narrowly than required under the TRIPS Agreement, and refers only to those processes that are entirely natural phenomena. The term "entirely natural phenomena" excludes any interactions by humans. This leaves the scope of patentability broad, and the exemption is very narrowly defined.

From a practical perspective, this narrow exemption would make it impossible to patent processes such as the principle of an animal feeding and thus growing, or the principle of one animal meeting another and mating (Tvedt 2008). These two examples would obviously consist entirely of natural phenomena (and anyway, they would not have been patented, because they would probably not have been considered as inventions). Elsewhere, however, it becomes harder to produce examples that would fall under the exemption. For example, the act of feeding an animal would involve a certain level of human interaction, and thus a feeding method could be eligible for patent protection (subject to the patent criteria). Breeding techniques will also be eligible for patent protection, because breeding involves some step of human innovative action. A technique for using artificial insemination or principles for selection would both clearly be processes beyond an entirely natural phenomenon and consequently outside the exemption, according to the EU Directive. In order for a patent to be granted, the patent criteria must of course be met, but the conclusion is that the exemption from eligibility in the EU is extremely narrow and will probably not have any practical effects.

Also "microbiological processes" should be patentable subject matter for patent law. The EU has defined "microbiological process", as to mean "any process involving or performed upon or resulting in microbiological material." (EU Patent Directive 98/44/EC, Article 2, para 1b) A process involving or performed upon or resulting in microbiological material shall be patentable. Thus, according to the EU Patent Directive, the animal sector is allowed almost all types of process patents. The exemption from eligibility is probably without any practical significance. This is an important observation as it increases the probable significance of patents in this field. To be awarded a patent the method or process must be regarded as an invention and it must be regarded novel, inventive and have industrial application.

Prior art for animal breeding methods

The basis for judging whether an invention is novel and involves a sufficient level of inventiveness is the prior art. Ideally, the body of prior art should have been equal to all knowledge and insights made available to the public; in our field it should reflect all breeding methods used in a manner made available to the public. This is however only the theoretical utopian ideal. The practical search carried out by the patent offices is much narrower. The narrower the base of sources searched as the prior art is, the easier it is for a patent to be granted to something which in fact was not novel or inventive. This would expose already known techniques to being patented, despite the fact that they already are in use, although not published in a manner that is disclosed or found as part of the technical prior art search. (For a more profound analysis of this issue and a look at the literature available, see Tvedt 2008)

Novelty and inventiveness in animal breeding

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 and factual 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.

The scope for exclusive right

After a patent is granted, the next task is to determine the scope of the exclusive right that the claims would confer to the patentee. According to the TRIPS Agreement, Article 28.1.b, the scope of a process patent protection is:

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

The product patent covers an exclusive right to the use or application of the described method. But the scope of protection also covers at least the product obtained directly by that process. This means that the scope of process patent protection in the TRIPS Agreement requires countries to provide a protection for indirect product patent a protection that covers at least the outcome from the use of a patented method. Using a patented process might therefore give the patentee a legal position in relation to the offspring from the application of the process.

One problem with indirect patent protection from breeding methods is that it might create a situation with complex rights concerning the offspring, as the owner of the animals already has a right to his animals and the patent-holder has the right to prevent "using, offering for sale, selling" the product from the application of the process. The scope of protection in the TRIPS Agreement was not particularly designed for the field of animal breeding, so these consequences have probably not been foreseen by the WTO. Indirect protection for products from processes is confirmed by EU Patent Directive:

The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. (EU Patent Directive 98/44/EC, Article 8, para 2)

This indicates that the offspring or next generation of animals can be covered by the exclusive right of the patentee to the breeding method.

The wording of the Directive implies that this protection is to extend not only to the first generation but to all subsequent generations of individuals. Thus, a linguistic interpretation indicates that all future generations of offspring from the herd improved by the use of that method will also be covered by the exclusive right. (This interpretation would also find support in the statement from Attorney-General Jacobs in the preparatory work in the case between the Netherlands and the Commission) The wording does not specify a number of generations to which the exclusive right will continue, but after the expiry of the patent (normally 20 years), the patent-holder will not have a claim to the said animals. The question will be whether the next generations will be in an identical or in an divergent form, which is sufficiently stable in respect to the characteristics.

Indirect product protection has the potential to establish a completely new property right structure in farm animal breeding. The patentee might become entitled to exclude the original owner of the animals from the offspring if these have been produced by means of a patented process. This conflict of rights will have to be dealt with by the courts, and the solution is hard to predict and will probably vary among countries. On the one hand, it seems clear that a patent cannot delimit the already existing rights held by the farmer. But on the other hand, if patent law is to allow for an exemption for the cases of indirect product patent protection in the animal sector, then a process patent to breeding techniques would not be worth much. This difficult question seems likely to trigger a number of court cases that will probably be solved differently among countries.

In addition to these concerns, in applying the patent law, the doctrine 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 also to 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 of closing another’s possibilities to breed and/or to do research. Little attention has been given to this doctrine applied to the animal sector. 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 is hardly 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.

Exemptions from the scope of patent protection

Attention should be given to the possibility in the TRIPS Agreement Article 30 to allow for exemption in the exclusive right granted by the patent. It could be useful to consider exemptions that would lead to more balanced application of patent law vis-à-vis the livestock sector. According to Article 30 of the TRIPS Agreement “countries have discretion to implement exemptions to 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 opens for implementation of 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. This is, however, made optional for member countries. Nevertheless, surprisingly few developing countries have implemented such legitimate exemptions in their patent legislation.

General observation on patent law applied to the animal sector

There are no studies analysing whether patent protection is needed in the farm animal sector to increase or maintain the current level of investments in breeding. The justification of patenting is that it promotes research and development. There are no studies or knowledge about whether this is the case for the animal sector – or whether applying patents to this field mostly will increase transaction costs (applying for patent, using lawyers or going to court) and only have a limited effect on the investments in breeding. Since patent law historically was developed for industrial technical inventions, there might be a need for special adoption of patent law to this sector.

VII. Conclusions

As the FAO agenda is a smorgasbord of possible tasks to undertake in the future, the Nordic countries either as a Nordic initiative or by individual countries could start analytical work and/or review the needs for regulatory framework in the sector to contribute to the work by FAO. By starting to provide such analysis now, the Nordic countries have an historical opportunity to influence the agenda in the FAO and to lead the way for how these difficult issues can be dealt with.

There are major changes influencing the animal production sector: 'livestock revolution' seen as increased global consumption of animal products, intensive and industrialized production systems, major environmental impacts, global warming, increased risks for pandemic diseases (even zoonoses), international trade of high-output breeds, narrow selection goals and loss of variation in breeding programmes, niche production with local breeds, growing interest in patenting.

Many of these changes are also challenging the animal genetic resources and the operations devoted to conservation and breeding. The regulatory issues should be discussed with respect to the Convention of Biological Diversity forming the base for international regulation and legislation on this.

In the Nordic countries the breeding programmes are typically run by co-operatives and are based on extensive on-farm recording which includes many longevity traits. The Nordic countries have joint breeding schemes in dairy cattle and in pigs. The interest in local breeds has generated active national and Nordic operations since early 1980's. The recognition of sustainability of breeding programmes and sound international exchange are the most important objectives from the Nordic perspective. The Nordic experts are eager to contribute to the international work on finding guidelines and regulations along these objectives.

The plant genetic resources are held in public gene banks, whereas in animals the genetic resources are in the variability of dynamically changing breeding stocks. Therefore the viability stemming from sound selection goals, cost-efficient operations and proper management of genetic variation, all important in the proper management of breeding programmes, is crucial for individual breeds and for the joint total diversity over breeds. The main requirements for a sustainable breeding programme are described in the fourth chapter. The next step is to consider how these are implemented in breeding programmes and if there is a need to establish a light appraisal and monitoring system within countries, and to develop further the regulatory framework to support these goals.

The current very active and beneficial exchange of animal genetic resources should not be constrained by stiff bureaucratic rules. On the other hand, code of conduct-related recommendations would be needed to guarantee sound schemes for gene-flow between widely deviating production environments. There is much variation between countries in how cryopreservation work is organised. In many cases the deposition and maintenance of *ex situ* banks resort to the expertise and facilities in artificial insemination co-operatives. There is still a need to clarify the management of gene banks. If animals of a local breed are moved from the country, the transfer should be accompanied by a detailed bilateral agreement, following the Bonn Guidelines. Other questions related to ownership and free choice are livestock keepers' rights to land and producers' choice for genetic stock in the vertically integrated production.

While plant varieties are uniform, distinct and stable, animal breeds are very variable and under continuous development. Therefore animal breeds cannot be protected under a plant breeders' rights system. Molecular genetics has been able to surface genes which have a major influence on the differences between breeds or animals, and in few cases their use in selection programmes have been subject to patenting. As genomic research is expanding at a fast rate, the number of such findings is increasing. The knowledge about gene regulation in animals is still inadequate and the successful production of transgenic animals remains unattractive, although progress is steadily made also in this area. There is a new trend to patent also typical animal breeding operations which are step-by-step processes linking data collection, analysis and selection and management decisions together. The *process patents* are obvious in a business world because inventions, whether products or processes, in all fields of technology are subject to a patent. There are possible exemptions related to natural biological processes for the production of animals, while animal breeding operations involve enough human interaction to make them eligible for patent protection. The applications for process patents are clearly testing the limits for an awardable patent in animal breeding. There is an urgent need for a discussion about how the general principles apply to the area of animal breeding and the needs for implementing special rules in this field. The dismissal of test-day model patent in Europe shows that it is possible to mitigate unfavourable developments in process patent applications by publishing actively all the methods in animal breeding.

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Sammendrag

Anbefalinger og retningslinjer for forvaltning og utveksling av husdyrgenetiske ressurser – Et nordisk perspektiv

Denne rapporten er basert på prosjektet 'Rettslige rammer for rettigheter til og utveksling av dyregenetiske ressurser fra Norden'. Prosjektet ble finansiert av Nordisk Ministerråd, Norsk genressurssenter og Nordisk Genbank Husdyr (som nå er en del av NordGen). Prosjektrapporten tar opp aktørenes behov for rettslige rammer og mulighetene for å fastsette verdien av salg og utveksling av husdyrgenetisk materiale i Norden. Prosjektet utredet også mulige behov for rammer og retningslinjer i forhold til dyreavl og dyregenetiske ressurser i global sammenheng.

Rapportens første kapittel presenterer hovedutfordringene og mulighetene som utnyttelsen og bevaring av husdyrgenetiske ressurser står overfor i dag. Husdyrsektoren er for tiden påvirket av store endringer: 'husdyrrevolusjonen', i betydning av økende globalt forbruk av husdyrprodukter, intensive og industrialiserte produksjonssystemer, store miljøeffekter, global oppvarming, økt risiko for pandemier (t.o.m. zoonoser), internasjonal handel med høytytende raser, smale avlsmål og tap av variasjon i avlsprogrammene, nisjeproduksjon basert på lokale raser og økende interesse i patentering.

Betydningen av genetisk mangfold er allment anerkjent, og Konvensjonen om biologisk mangfold utgjør grunnlaget for internasjonale regler og lover på dette området. Kapittelet gir et overblikk over Konvensjonen og andre *internasjonale rammeregler*. Det legges vekt på prosessene i forbindelse med utvikling av retningslinjer for husdyrmangfold.

Kapittel to ser på disse temaene i et *nordisk perspektiv*, og løfter frem og prioriterer spørsmål fra dette ståsted. Typiske nordiske avlsprogrammer er drevet etter samvirkeprinsippet, og er basert på omfattende husdyrkontroll, som blant annet omfatter mange funksjonelle egenskaper. De nordiske landene har felles avlsopplegg for melkefe og gris. Interessen i lokale raser har ført til nasjonale og nordiske aktiviteter siden tidlig på 1980-tallet. Ut fra et nordisk perspektiv, er de viktigste målene anerkjennelsen av avlsprogrammenes bærekraft og forsvarlig internasjonal utveksling. Nordiske eksperter er ivrig etter å bidra til det internasjonale arbeidet med å utvikle retningslinjer og regler i forhold til disse målene.

FAO koordinerer arbeidet med utvikling av retningslinjer og avtaler for plante- og dyregenetiske ressurser for mat og landbruk. Rapportens kapittel tre beskriver *forskjellene mellom plante- og dyregenetiske ressurser*, og hvilken betydning disse forskjellene har.

Mens plantegenetiske ressurser oppbevares i statlige genbanker, ligger de genetiske ressursene hos dyr i variasjonen som oppstår i den dynamiske utvikling av avlsmaterialet. Derfor er levedyktigheten som stammer fra fornuftige avlsmål, kostnadseffektiv drift og riktig forvaltning av genetisk variasjon - alt sammen viktig for fornuftig forvaltning av avlsprogrammene - avgjørende for mangfoldet både innen enkelte raser og for det samlede mangfold mellom raser. De viktigste kravene til et *bærekraftig avlsprogram* er beskrevet i rapportens fjerde kapittel. Det neste skrittet er å vurdere hvordan disse blir realisert i avlsprogrammer, og utrede behovet for enkle nasjonale evaluerings- og overvåkingssystemer.

Kapittel fem diskuterer internasjonal *utveksling av husdyrgenetiske ressurser*. Den nåværende svært aktive og nyttige utvekslingen må ikke bli begrenset av et stivbent byråkrati. På den andre siden, ville anbefalinger i form av etiske retningslinjer være nødvendig for å sikre bærekraftige genstrømmer mellom svært ulike produksjonsmiljøer. Organiseringen av kryokonserveringsarbeidet varierer betydelig mellom land. Ved deponering i og vedlikehold av *ex situ* genbanker, tyr man i mange tilfeller til avlssamvirkeorganisasjonenes kompetanse, anlegg og utstyr. Det er fremdeles nødvendig å avklare forvaltningen av genbankene. Hvis lokale raser skal flyttes fra et land, bør overføringen også omfatte en detaljert bilateral avtale, i henhold til "Bonn-retningslinjene". Andre spørsmål i forbindelse med eierskap og valgfrihet er husdyrbøndenes rettigheter til jord og produsentenes valg av genetisk materiale i vertikalt integrert produksjon.

Kapittel seks beskriver dagens situasjon i forhold til *patentering i dyreavl*. Mens plantesorter er ensartede, lett å skille fra hverandre og stabile, er dyreraser svært variable og under konstant utvikling. Av den grunn kan ikke dyrerase-konseptet være gjenstand for patentlignende systemer. Molekylærgenetikken har kunnet påvise gener med stor innflytelse på forskjellen mellom raser eller dyr, og i enkelte tilfeller har deres bruk i avlsprogrammer blitt patentert. Siden omfanget av genomforskning øker med stor fart, vokser antallet av slike funn. Patentering i denne sammenhengen er ukomplisert og har blitt populær. Snart kan det muligens utvikles applikasjoner i forhold til spesielle fôrplaner som oppfyller kravene til en kjent genotype. Kunnskapen om genregulering hos dyr er fremdeles utilstrekkelig, og vellykket produksjon av transgene dyr er fortsatt ikke interessant, selv om fremskritt gjøres kontinuerlig også på dette område. En ny trend er å patentere typiske husdyravlsvirksomheter, som er trinn-for-trinn prosesser som kobler sammen datainnsamling, analyse, seleksjon og forvaltningsbeslutninger. Slike *prosesspatenter* er selvsagte i forretningslivet siden oppfinnelser, enten som produkt eller prosess, på alle teknologiområder kan patenteres. Det finnes mulige unntak i forhold til naturlige biologiske prosesser for produksjon av dyr. Derimot omfatter husdyravlsvirksomheter nok samspill med mennesker til at de er berettiget til patentvern. Anvendelsen av prosesspatenter presser tydeligvis grensene for hva som kan patenteres i husdyravl. Det er et akutt behov for å diskutere hvordan de generelle prinsippene skal anvendes på dyreavlsområdet og nødvendigheten av å innføre spesielle regler på dette området. Avslaget på "test-dag modell" patentet i Europa viser at det er mulig å dempe en uheldig utvikling i prosesspatentanvendelser ved aktiv publisering av alle husdyravlsmetoder.