

November 2004

E



منظمة الأغذية  
والزراعة  
للأمم المتحدة

联合国  
粮食及  
农业组织

Food  
and  
Agriculture  
Organization  
of  
the  
United  
Nations

Organisation  
des  
Nations  
Unies  
pour  
l'alimentation  
et  
l'agriculture

Organización  
de las  
Naciones  
Unidas  
para la  
Agricultura  
y la  
Alimentación

## COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

### THE LEGAL FRAMEWORK FOR THE MANAGEMENT OF ANIMAL GENETIC RESOURCES

This paper has been prepared jointly by the Legal Office of FAO (in particular by Marta Pardo Leal and Daniele Manzella from the Development Law Service, with the assistance of Antonella Ingrassia, FAO Consultant) and the Animal Production and Health Division (in particular by Irene Hoffmann from the Animal Production Service, with the assistance of Elzbieta Martyniuk, FAO Consultant), at the request of the CGRFA Secretariat and in order to contribute to the first *Report on the State of the World's Animal Genetic Resources* and the further development of the Global Strategy for the Management of Farm Animal Genetic Resources.

## THE LEGAL FRAMEWORK FOR THE MANAGEMENT OF ANIMAL GENETIC RESOURCES

### Table of Contents

	<i>Page</i>
1. Introduction	1
2. National Legal Framework: Main Features	1
2.1 <i>Institutional arrangements</i>	1
2.2 <i>Improvement</i>	2
2.3 <i>Conservation</i>	3
2.4 <i>Animal Health</i>	4
2.5 <i>Food Safety and Food Quality</i>	5
2.6 <i>Land and Farm Management</i>	6
2.7 <i>Animal welfare</i>	7
2.8 <i>Marketing of animal products</i>	8
2.9. <i>National policies and strategies</i>	8
2.10. <i>Customary law</i>	10
2.11. <i>The adequacy of existing national legal frameworks</i>	11
3. The International Framework: Major Instruments	13
3.1 <i>Legally Binding Instruments</i>	13
3.2 <i>Soft Law</i>	18
4. Material Transfer Agreements in the context of international research cooperation related to AnGR	20
5. Conclusions	21

## THE LEGAL FRAMEWORK FOR THE MANAGEMENT OF ANIMAL GENETIC RESOURCES

### 1. Introduction

This paper reports the findings of a study of the international and national legal framework applicable to the conservation and sustainable use of farm animal genetic resources (AnGR). The study is based on responses to a questionnaire completed by 55 countries as well as additional research. The study describes the state of the development of relevant international law, reviews the approaches taken and problems identified in national legislation, as well as national implementation of the relevant international law. The paper is intended to contribute to the setting of the international agenda in legislation and regulation of farm AnGR management, and to support the work of the members of the Commission in improving national legislation.

### 2. National Legal Framework: Main Features

A review of national legislation dealing with AnGR issues indicates that national legislation on AnGR issues is divided into four principal categories (institutions, improvement, conservation and health) and four ancillary ones (food, land and farm management, animal welfare and marketing of agricultural products) for comparative purposes. Therefore, the results of the questionnaire responses and other research are summarized below according to this scheme.

#### 2.1 *Institutional arrangements*

A distinctive institution in AnGR management is the breeders' society, which plays a crucial role in the breeding process. Breeders' societies are responsible for various elements of the breeding process, including implementation of improvement programmes. Some societies embrace entire species but most often deal with individual breeds. Activities of breeders' societies vary, and include basic activities like: herdbook keeping; organization of sales and shows, implementation of the breeding programme and associated activities, support in managing reproduction (especially in case of rare breeds where a semen bank may be run by the society), training and extension, and organization of competitions. Some breeders' societies also run performance recording schemes and support marketing of special products.

Farmers' organizations are another key player in the AnGR scenario, since they are involved in the organization of production, supplies and marketing. Hence, the establishment and functioning of breeders' societies and farmers' organizations need a legal basis to clarify their roles and responsibilities in the livestock sector.

However, institutional arrangements for the management of AnGR are not as frequently found in legislation as other matters reported in the study. According to the responses to the questionnaire, 41 countries (75%) reported having legislation that lays out the requirements for the establishment of stakeholder organizations in animal breeding and production. Such legislation is implemented in 31 countries.

Results of the questionnaire clearly show that there is no single pattern regarding distribution of responsibilities among stakeholders involved in animal breeding and production. Moreover, no distinctive trends or differences were observed between regions. The institutional frameworks in place reflect the specific situations, needs and conditions of particular countries, including infrastructure development, the state and importance of animal production and the status of breeders' organizations. Countries with a long tradition of breeders' involvement in decision making and implementation of breeding activities have developed systems where breeders'

societies play an instrumental role in carrying out various elements of breeding work. In countries where intensive production systems have a substantial share in the livestock sector, roles and services provided by commercial companies are gradually increasing, particularly in poultry and pigs. In the absence of breeders' organizations responsibilities for organization of the breeding sector are still with the government or specially established organizations acting on behalf of the government, including research and educational institutions.

Specific activities related to animal breeding and production may involve a single stakeholder or, as was frequently indicated, several stakeholders. The majority of countries reported that animal identification was an area of significant governmental involvement, often implemented by specially established organizations and supported by breeders' societies. Respondents indicated that responsibilities for performance recording were shared between breeders' societies, research/educational institutions and sometimes specially established organizations. A few countries reported that performance recording was species-specific and involved different organizations. Several stakeholders were identified as involved in animal reproduction and artificial insemination, in particular government, breeders' societies and farmers' organizations, as well as local communities and commercial companies. Evaluation of breeding value was reported as a responsibility of research or educational organizations, special institutions and breeders' societies. Breeders' societies, farmers' organizations and commercial companies were most often identified as responsible for the exchange of breeding stock. Most of the countries reported that production services such as feed supply and marketing of animal products are provided by commercial companies or farmers' organizations, but in several countries such activities are also implemented by government and specially established organizations, especially in the case of marketing. Extension services were reported to be provided by almost all stakeholders, while training was identified as a domain of research and educational institutions as well as government.

## **2.2 Improvement**

Legislation on improvement addresses all elements of the breeding process, from animal identification and herd book-keeping through performance recording to breeding value evaluation and dissemination of genetic progress. Improvement-specific legislation is relatively well-developed throughout the world, but much of it is quite recently enacted or currently under amendment. In 38 of the responding countries (69%), animal breeding laws have been developed and six countries indicated that they were under preparation.

Animal reproduction, including natural service and artificial insemination, is usually addressed in animal breeding acts with details on implementation being provided in separate regulations. One aim of this legislation is to ensure the dissemination of genetic progress through males coming from improvement breeding schemes. The second purpose is to prevent the spread of sexually transmitted diseases and these issues are usually covered in veterinary laws. Thirty-five countries reported having animal reproduction legislation, and most of them implemented (31) and monitored (32).

The enhancement of genetic progress can be facilitated by subsidies for importation of high quality genetic stock or through support for the national pedigree sector. While subsidies for importation are usually granted on a case-by-case basis, and on special conditions, support for the pedigree sector, such as subsidies for raising breeding stock and for carrying out breeding activities (e.g. performance recording) is usually provided on a long-term basis. About half of the responding countries (26) reported having legislation that facilitates such subsidies. Twenty-one countries indicated that such incentive measures are not implemented. The lack of legislation to enhance genetic progress in the livestock sector was reported both in countries where most aspects of animal production are regarded as purely commercial and in others that are financially unable to provide subsidies to breeders.

Legislation providing rules for the exchange of breeding stock and breeding material within country was reported by 30 respondents. Exchange of livestock is not regulated in 17 countries. While the exchange of semen, ova and embryos are usually sufficiently addressed in animal breeding and veterinary laws, in many countries there are specific and very strict regulations regarding the exchange of live animals in order to protect against the introduction of animal diseases through livestock trade. In countries where seasonal outbreaks of such diseases as Food and Mouth Disease (FMD) are observed, emergency measures, including prohibition of trade of live animals, are implemented.

The majority of responding countries (47) have developed legislation on the importation of breeding stock, setting out detailed and specific requirements on animal identification and breeding documentation, as well as on health status for imported stock. Such legislation may introduce obligatory health examinations and rules regarding quarantine. Thirty-seven countries reported implementation of legislation addressing import of animals.

In some countries, the export of breeding stock is regarded as a commercial enterprise, so export regulations are not provided by the state. There appears to be an assumption that quality and health standards have to be imposed by the importing party. In total, 17 countries reported that they do not have legislation covering the export of breeding stock. In 36 countries, such legislation has been developed in order to ensure quality standards in international trade. While export of commercial breeds is generally not limited, there might be certain restrictions imposed on the export of indigenous species or breeds that are regarded as “national genetic reserve”, for example requiring permission from the Ministry of Agriculture.

Thirty-two of the responding countries reported legislation that sets out the requirements for organizations that are involved in activities related to animal breeding and improvement, such as herdbook-keeping, performance recording and implementation of genetic improvement programs. Usually these specific regulations are under the animal breeding laws and are in harmony with legislation on civil society organizations.

Thirty-two countries indicated that they have legislation supporting agricultural research; six reported such legislation was currently being developed, while 14 reported the absence of such legislation. In some instances, legislation specifically addresses characterization and valuation of AnGR as priority research areas, as it is in the case of the EU legislation. Special provisions on AnGR characterization and valuation were reported by countries where the research component consists of an integral part of the AnGR conservation programme. Even in countries where legislation does not specifically address characterization and valuation of AnGR, such research can be supported by bodies such as national scientific or research agencies within the scope of agricultural research programmes.

Concerning biotechnology-based improvement, the results of the questionnaire indicate that significant efforts are still required to advance legislation on biotechnology. Only 23 countries reported having such legislation, although 15 indicated that legislation is currently being discussed. Many countries reported that their biotechnology legislation is purely GMO-oriented. Developing countries identified a lack of capacity to develop biotechnology legislation. Respondents indicated that where legislation for biotechnology has been developed, implementation and monitoring rapidly follow.

### **2.3 Conservation**

In the present paper, the conservation section covers only legislation related to the conservation of AnGR for food and agriculture. Existing legislation may address in-situ and ex-situ conservation measures separately.

Provisions for the in-situ conservation of AnGR were reported in the legislation of 31 countries. In several countries, animal breeding laws contain separate chapters on conservation and sustainable use of AnGR, and provide detailed descriptions of the scope and measures for

conservation. In other countries, there are no specific laws but there are national conservation programmes in place that were endorsed and are financially supported by the Ministry of Agriculture. Implementation and monitoring of in-situ conservation legislation was reported by 28 countries.

Only 20 countries indicated that they have legislation that supports ex-situ conservation of AnGR, namely establishment and management of gene banks, or cyro-conserved genetic material. Seven countries reported the preparation of such legislation. As in the case of in-situ conservation, substantial efforts and activities on collection and storage of genetic material are carried out within national AnGR conservation programmes.

## **2.4 Animal Health**

Animal health status has enormous impact on individual performance, production output and efficiency of the livestock sector, as well as affects trade of animal-origin products. Animal health may also affect human health, and therefore is considered an important issue that requires state regulation. In general, animal health regulations are among the first aspects of agriculture legislation developed. The results of the questionnaire indicate that significant efforts have been made worldwide in developing legislation to control and protect animal health. The number of countries that have such legislation is greater than in any other area.

In general terms, according to the questionnaire responses, legislation on prevention and control of animal diseases has been adopted by 52 countries. The majority of countries reported having a Veterinary Law supplemented by more detailed regulations. In many instances, separate instruments address prevention and control of specific infectious diseases or regulate management activities that may pose risks for animal health. Implementation of veterinary laws is well advanced and was reported by 44 countries. A few countries indicated that implementation is not complete, or that the legislation is currently being amended.

Legislation on animal health encompasses a very broad area, including issues of animal health and prevention of animal diseases, as well as legislation related to food of animal origin and biotechnology. Animal health legislation generally applies to reproduction, trade and movement of livestock, emergency response in disease outbreaks and animal welfare. Food safety and food quality legislation include quality standards, traceability of animal origin products, quality assurance schemes and other measures for product identification (e.g. labeling and geographical identification).

Stock movement is one of the specific issues usually regulated within veterinary law. In countries where hazards of outbreaks and transmission of infectious animal diseases are high, there are separate laws setting out strict rules on stock movement within countries, and measures to enforce their observation. According to the responses, 48 countries have legislation on stock movement, with full implementation in 39, and monitoring in 41.

Regulations on quarantine are necessary both in the case of the importation of live animals and when disease outbreaks occur. Fifty-one countries have developed legislation setting out quarantine standards for various farm animal species. Implementation of quarantine regulation was indicated by 42 countries. A few countries reported that emergency enforcement of quarantine measures involves compensation.

Stock disease regulations often refer to semen or to poultry and state the need for a permit for introducing, disposing, and using (for AI) semen in the country (e.g. Botswana Stock Diseases–Semen-Regulations, where a written permit issued by Chief Veterinary Officer is also needed for introducing any poultry into the country, but the permit is not needed where a certificate has been issued by a veterinarian authorized by the Government of the country of origin). Even if not explicitly aimed at reproductive material, health regulations easily affect the import and export of AnGR. If on one hand health requirements help modern breeding by giving assured sources of genetic material, on the other they may hinder the exchange of AnGR between countries.

Following the outbreak of Bovine Spongiform Encephalopathy (BSE), also known as mad cow disease, many countries were forced to develop or strengthen legislation in the area of animal health, including stricter rules on traceability of animal-by-products. The outbreak of BSE resulted in a ban on imports of animals for human consumption.

The very favourable health status enjoyed by Argentina for BSE and Scrapie has enabled the country to maintain an excellent position in international trade and to be considered a reliable exporter of animal products. Preventive measures to avoid the importation of BSE and Scrapie were adopted in Argentina in 1990 with the enactment of Resolution 429. The rule established a ban on all imports from the UK of live animals, genetic material (semen/ova and embryos) and by-products of bovines, sheep and goats, and implemented the necessary measures to ensure compliance. The restrictions were enforced, and in 1995, as a result of the concern caused by the greater knowledge about the diseases and their consequences, new rules were established requiring animal feed and import controls, in addition to an epidemiological surveillance programme. These rules established a ban on the use of bovine and/or sheep meat and bone meal as ruminant feed, as stated in the OIE Recommendations. Although the causal agent was not present in the country, the ban ensured no possibility of the agent entering the feed chain of ruminants and provided additional guarantees to buyers. Subsequent Resolutions restricted imports of live animals, semen, embryos, meat and meat by-products and milk and dairy products from countries with a different health status for BSE. In 1995 Law N° 270 on Animal Health (Sanidad Animal) was adopted, stating that sanitary norms for animals will be applied to all animal species, domestic or wild, susceptible to contract and to spread infected-contagious, parasitic or other animal diseases that can injure economic interests.

Concerns have been expressed for the consequences of FMD legislation and cull programmes aimed at creating “firewalls” to end the spread of the disease irrespective of breed, risk status, etc. There appears to be a real risk of rare breeds of traditional livestock being threatened because of measures against FMD. Culling (stamping out) continue to be the favoured way to try and contain FMD in the EU which has authorized limited vaccination programmes in the Netherlands and the United Kingdom, but is wary of allowing wider inoculations largely because it means loss of disease-free status in world trade markets and a block for two years on export of products from vaccinated animals.

## ***2.5 Food Safety and Food Quality***

The main objectives of food safety and food quality legislation are to ensure food safety and to address food-related aspects of human health through setting minimum quality standards for various animal products. Another objective is to provide a legal framework for identification of high quality products of animal origin. Such identification enables marketing and promotion and leads to enhancement of profitability.

According to the questionnaire responses, 39 countries have developed legislation that introduces national level quality standards for animal products, and seven countries are working on such legislation. Implementation closely follows development and was reported by 37 countries. The legislation is usually sector specific, addressing the meat and dairy industries and setting out both quality standards and control measures. Some EU countries that have not developed food safety legislation indicated that commercial processing companies are responsible for ensuring quality standards, following good manufacturing practices and complying with recommendations of European bodies providing quality standards.

Introduction of traceability of animal origin products has resulted from the 1996 BSE crisis. Legislation has been developed world-wide to ensure identification and registration of bovine animals and labeling of beef and beef products. Thirty-two countries have adopted legislation that enforces traceability of animal products (especially beef) and in 13 countries such legislation is under development. Implementation and monitoring was reported by 27 and 29 countries respectively. The rapid development of traceability legislation has been observed in those

countries that are beef exporters and were forced to comply with international market requirements.

Quality assurance schemes have been introduced in order to build consumer confidence in safety and quality of animal products and to satisfy consumer concerns regarding production conditions, including observation of animal welfare. Quality assurance schemes are mainly applied in organic agriculture and grazing/range-land production systems. Twenty-seven countries (16 European) have developed legislation that enables identification of production chains and introduces quality assurance schemes. Fourteen countries reported on preparation of such legislation and implementation was achieved in 21 countries. Some developing countries indicated that such schemes have been introduced but operate on a voluntary basis.

There are various ways and means to enable identification of animal-origin products on the market, in order to provide for their protection, to enhance recognition by consumers and to facilitate promotion. Legislation in this area encompasses geographical identification<sup>1</sup>, identification of traditional processing procedures and origin of raw material (breed-identified products), as well as identification of production systems (e.g. organic produce). Legislation introducing various labeling systems was reported by 20 countries (16 European) and in 10 countries it is being developed. Twenty countries, mainly from developing regions, reported the absence of product identification legislation and indicated that they considered this a gap in their legal frameworks.

Consumer involvement is increasingly important, as consumer concerns and preferences have to be both better expressed and better addressed by producers and the market. In some countries, there is legislation in place that enables consumer organizations to play a role in the food market, evaluating quality of products, lobbying for certain developments in the food chain, including introduction of changes in production systems. Twenty-four countries indicated the presence of such legislation, while eight countries indicated that legislation is being prepared. Implementation and monitoring was reported by 21 countries. It is clear that this area of legislation is still at the initial stage of development.

## **2.6 Land and Farm Management**

Land and farm management have a substantial impact on AnGR. In extensive production systems, especially in case of pastoralism, access to land is crucial to sustain such systems and maintain and conserve AnGR used by pastoralists. On the other hand, utilization of grazing animals enables management of the ecosystem and provides for vegetation control.

Legislation on land use and farm management regulates various aspects of farm establishment and management, including establishment and operation of industrial enterprises and setting rules on agricultural practices in order to prevent negative effects of agriculture on the environment. Such laws generally reflect policies on environmental protection and nature protection, and are focused on agriculture as a main land user and a potential polluter or degrader. There are also laws implementing state policies on agricultural development that provide incentive measures to

---

<sup>1</sup> In terms of article 22(2) of the TRIPs Agreement in respect of geographical indications

“Members shall provide the legal means for interested parties to prevent:

- (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;
- (b) any use which constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention (1967).”



support desirable changes in agriculture (promotion of specific production or agricultural practices) or to ensure the maintenance of agricultural activities in difficult production systems.

According to the questionnaire responses, 44 countries have developed legislation setting out rules on access to agricultural land and land ownership, establishment of farms and requirements to conduct agricultural activities. In some countries, such legislation is connected with land reform (commercial and communal land acts). Legislation in this area is currently under preparation in five countries. The implementation and monitoring ratio is high, being reported by 38 and 37 countries respectively.

Respondents indicated that many laws and regulations have been established that set out rules on agricultural practices in respect to use of fertilizers, pest control agents, and the management of manure and waste products. There are laws aimed at all economic sectors to prevent soil, water and air pollution which also affect agricultural enterprises. Forty countries indicated that they have developed legislation on agricultural practices to prevent negative impacts on the environment, and three others have legislation under preparation. Several countries reported implementation of codes of conduct and principles on best agricultural practices.

Specific legislation on intensive animal production systems was reported by respondents from 32 countries. This legislation focuses either on environmental protection and human health issues in relation to the operation of industrial farms or on the welfare of animals that are used in such systems. In many countries, specific animal protection and welfare laws cover industrial production systems and are supported by specific regulations, setting out for example requirements on housing facilities and management practices. Implementation was limited to 24 countries, while thirteen indicated they had not yet developed legislation addressing industrial livestock production systems.

Twenty-five countries (15 European) have established legislation to provide support for farmers operating in difficult production systems, which in EU legislation are referred to as Less Favoured Areas. This legislation enables maintaining farming activities in low productive areas through support programs on non-productive functions of agriculture and to achieve landscape management objectives.

Thirty-nine countries reported legislation implementing agricultural and livestock policies, which establishes incentive measures to support and encourage desirable developments in agricultural production. Regulations provide for preferential credit access and subsidies for farm modernization and infrastructure development, e.g. water supply or manure tanks installations. Respondents indicated that such regulations may be temporary and routinely changed in accordance with national financial conditions.

## **2.7 *Animal welfare***

The moral and political importance of animal welfare is increasingly recognised by governments. Animal welfare is a complex, multi-faceted public policy issue that includes important scientific, ethical, economic and political dimensions. The terms “health” and “welfare” overlap in that health is an important part of welfare. The welfare of an animal is its state as regards its attempts to cope with its environment (Broom, 1986). Health is that part of welfare which concerns coping with pathogens and pathology. Both poor health and other aspects of poor welfare can have economic consequences. Farm animal disease can cause great economic problems as well as pose risks for human health. Poor welfare can result in reduced survival of young animals, failure to conceive or successfully give birth, impaired growth or impaired production of milk or eggs.

It is felt that, because of its growing importance in society, animal welfare must be addressed in a scientifically credible manner. Thirty-six countries responding to the questionnaire reported on specific legislation on animal welfare, and seven countries on preparation of such legislation. There were two approaches being adopted in the development of animal welfare legislation. In some countries, legislation focused on the prevention of cruelty to animals and on the use of farm

animals as well as on the utilization of animals in research, entertainment and for other non-production purposes. In other countries, welfare legislation mainly sets standards for keeping and handling farm animals, especially during fattening, transportation and slaughter.

The actual effect of legislation on the welfare of animals depends upon the responses of those owning and managing the animals. This response, in turn, depends upon the nature of any enforcement. Some systems for farm animal production will not continue if they are made illegal because they depend upon large manufacturers who are more easily forced to comply with legal changes. Other aspects of legislation can be enforced only by checks on farm, transport vehicles, markets, slaughterhouses, etc., and the extent of law-breaking will be significantly affected by the frequency and quality of the checks. For many transgressions, unannounced inspections are necessary if transgressors are to be discovered. Implementation and monitoring were reported by most countries that had welfare legislation.

An interesting outcome of the research carried out is the fact that GM animals are covered by some agriculture and welfare legislation. One example is the UK where GM animals fall within the definition of livestock covered by the Agriculture (Miscellaneous Provisions) Act 1968 and the Northern Ireland Welfare of Animals Act 1972, under which it is an offence to cause unnecessary pain or distress to any livestock kept on agricultural land. There are also provisions in the Welfare of Farmed Animals (England) Regulations 2000 and in the Northern Ireland Welfare of Farmed Animals Regulations 2000 to address the welfare concerns arising from both natural and artificial breeding procedures.

The Office International des Epizooties (OIE) has established a working group to develop standards on animal welfare related to five areas which were entrusted to five ad-hoc groups (slaughter; killing of animals during disease outbreaks; animal transport on land; animal transport on sea; aquaculture).

## **2.8 Marketing of animal products**

Another issue considered is the marketing of animal product which, according to responses, is regulated in 44 countries. Only nine reported no legislation in this area. Legislation sets standards for animal products and for product handling. In many instances, legislation is product specific (for example the Meat Industry Act or the Karakul Pelt and Wool Act of Namibia). Implementation of legislation on marketing of animal products has been reported in 36 countries and is being monitored in 38 countries.

## **2.9 National policies and strategies**

National policies, even though not legally binding, have relevance in the context of national legal frameworks because they express national interests and could set the basis for legislation. There are several policy areas that may have a direct or indirect impact on management of AnGR, and provide a basis for setting developmental goals and objectives that influence the livestock sector as a whole, including the management of AnGR.

Land use policies usually provide general goals for agriculture development, agrarian structure and conditions for establishment of farms. In many cases, land use issues are included in policies aimed at development of rural areas. The results of the questionnaire indicate that land use policies are well developed at the national level. Forty-seven countries indicated that they have adopted such policies, and such policies are currently under development in the other reporting countries. Implementation and monitoring of land use policy are well advanced and were reported by 43 and 40 countries respectively.

Policies for agriculture and rural areas are usually intended to establish a long-term vision of the development of agriculture and its role in contributing to the national economy, in terms of contribution to both the gross national product and employment. Policies may support a number of specific objectives, including improvement of the agrarian structure, creation of instruments to

encourage certain production directions or farm modernization, and ways and means to strengthen farmers' position in the market, as well as to encourage and support implementation of biological improvement measures. Agricultural policies also often contain goals for the sustainable development of rural areas, protection of the natural environment and cultural heritage.

Livestock development policy/strategy may constitute an integral part of agricultural policy, or it may be adopted as a separate policy document establishing developmental goals for the livestock sector.

National agricultural policies have been adopted by 44 of responding countries. Eight others are presently being prepared. In the majority of countries, agricultural policies are monitored. Separate strategies for livestock sector development were reported by 35 countries and are being currently prepared in nine other countries. Such strategies may address livestock production as a whole, or focus on specific aspects, for example, dairy production or pig production. Seven countries reported that they did not have livestock development strategies.

The National Development Plan 9 (NDP9) of Botswana (covering the period 2003-2009) is a good example of a national policy prepared with the aim of guiding the development of the economy and drawing up programmes of public expenditure on recurrent and development projects. Adherence to effective planning has contributed to Botswana's transformation from one of the poorest countries at independence to a middle income country, changing the country from being essentially a cattle-rearing and rural based economy to a fast growing economy. In the NDP9 it is highlighted that one of the major concerns in the agriculture sector has been low productivity of the sector and its relatively declining contribution to GDP.

The review of agricultural subsidy schemes, such as the Arable Land Development Programme and Services to Livestock Owners in Communal Areas is foreseen to be completed during NDP9 to determine their impact and to retarget them better. The strategy for development of arable, irrigated agriculture and dairy production is expected to help the sector to improve diversification, create more employment opportunities, boost productivity and increase agricultural output. Another initiative is provision of agricultural insurance and credit to minimize farmer risks resulting from annual and seasonal climatic variability and natural disasters, which will also facilitate investments in agriculture.

Specific livestock policies are in place in a number of countries. The Tanzania Livestock Policy was drawn up in June 1993, to guide the development of the livestock industry in consonance with broader social objectives and the need to have policies which are both clear in their objectives and feasible to implement. The main broad policy goals are to increase national income, increase the per capita income of rural people, attain self sufficiency in food production, increase net foreign earnings and consolidate the policy of socialism and self-reliance.

More specifically, the policy endeavoured to increase the production of meat, milk and eggs to satisfy the domestic market and the surplus for the export market to earn foreign exchange, improve the incomes/earnings of the livestock peasants in the rural areas, whose livelihood and welfare is very much dependant on livestock, and direct small-holders and pastoralists to proper and optimal utilization of pasture and rangelands for sustainable livestock productions.

Improved livestock production is a very important component in Uganda's plan for modernisation of agriculture. In an effort to streamline breeding activities, Uganda has put in place the National Animal Breeding Policy which is backed by an institutional and legal framework in the form of the Animal Breeding Act.

A national policy specifically dealing with AnGR is the Netherlands policy on "Sources of Existence: Conservation and Sustainable Use of Genetic Diversity", which recognizes that genetic resources are part of the entire biological diversity and that they concern all material containing the hereditary building blocks for animals, plants and micro-organisms, with an actual

or potential value to humanity. This policy highlights that governments have an essential task in creating frameworks and legislation to guide the management of genetic resources.

The Netherlands AnGR policy deals with, *inter alia*, farm animals and focuses on the role of farm animals in multi-functional agriculture and the relationship between genetic erosion and animal diseases (in section 4.2.3). The policy also considers the development of the Global Strategy for Farm Animal Genetic Resources, under FAO coordination, with the objective of obtaining a global overview and inciting the conservation and management of diversity in farm animals. The Netherlands will continue to contribute to this effort in various ways, such as international cooperation and adopting a strategic national approach.

The policy also specifies that a gene bank for farm animals is under development. AnGR are mainly collected within the private sector. Consequently, conservation and management of farm animals can only succeed if the agriculture and food production sector assumes its responsibilities. As in the case of microbial and plant genetic resources, the government exhorts the sector to apply the basic principles of this document in the form of Codes of Conduct and MTAs. Conservation of animals *in-situ* is preferred, particularly in cases where specific breeds are threatened. Animals are easier to manage in their natural habitat and the breed can continue to develop. In the case of small populations, intervention is necessary to avoid inbreeding.

When conservation of the agricultural situation is no longer feasible, the possibility of *ex-situ* conservation elsewhere must be examined. The method of preference is *ex-situ* management in the field. The Netherlands will continue to promote the use of rare breeds of domestic animals in nature management. Hobby breeders and urban farms also contribute to the conservation of many rare farm animals and their activities are highly significant in a cultural-historical and educational context.

Other examples of national policy relevant for AnGR management are the Rural Development Programmes developed by all EU countries according to Regulation (EC) n° 1257/1999. Article 41 of the EC Regulation states that rural development plans shall be drawn up at the geographical level deemed to be the most appropriate. They shall be prepared by the competent authorities designated by the Member State and submitted by the Member State to the EC after competent authorities and organizations have been consulted at the appropriate territorial level. Rural development plans shall cover a period of seven years from 1 January 2000, and shall include, *inter alia*, a quantified description of the current situation showing disparities, gaps and potential for development, the financial resources deployed and the main results of operations undertaken in the previous programming period with regard to the evaluation results available.

Human health protection policies might also impact on AnGR management. In fact, respondents to the questionnaire indicated that human health is one of the major concerns with respect to animal production. Forty-nine countries reported existence of policies that provide directions for national health care, and also address issue of zoonosis related to the prevention of diseases and safety of animal products. Forty-five respondents indicated that such policies are being actively implemented and 44 indicated that the results are being monitored.

Policies related to civil society may contain provisions on establishment and activities of self-governing and vocational organizations, which provide an important framework for the development of farmers' organizations and breeders' societies. In most of the responding countries, policies have been developed that regulate and encourage participation of self-governing organizations and strengthen their position. Such policies were reported by 44 countries, while seven countries indicated they were being developed. Implementation and monitoring of policy on civil society organizations has been indicated by 35 countries.

### **2.10. Customary law**

The theory of customary law defines custom as a practice that emerges outside of legal constraints, and which individuals and organizations spontaneously follow in the course of their

interactions out of a sense of legal obligation. Gradually, individual actors embrace norms that they view as requisite to their collective wellbeing and customary practices, for instance in respect to land use, gradually expand their force to become a source of law.

In responding to the questionnaire, only a few countries, mainly from the African region, gave examples of customary law having an impact on AnGR management. These include utilization of certain indigenous breeds (e.g. the West African Shorthorn cattle) as marriage payments or for other social ceremonies, also as gifts for chiefs, etc. The social and cultural importance of indigenous breeds provides incentives for their conservation. Other examples of customary laws are related to livestock management, and include such procedures as castration of undesired males, exchange of sires, or loans between families or herders and community support for restocking in cases where a family has lost their livestock. In some cases, customary laws may have a negative impact on AnGR management. An example refers to the destruction in Bolivia of the collective property of the rangelands associated with the destruction of the centres of management of llama and alpaca (*Lama lama* and *lama paco*) males. In absence of these centres, the reproduction rate of this species was negatively affected.

### ***2.11. The adequacy of existing national legal frameworks***

The analysis indicates that there are significant area-related differences in the state of legal and regulatory frameworks. This impairs an integrated approach in the development and implementation of an adequate legislative framework which is needed if management of AnGR is to be successfully addressed. The most extensive legislation world-wide has been developed in the area of animal health and prevention of animal borne diseases. The unintended negative impact of such legislation on import/export and market access has been greatest for those countries, especially developing ones, whose infrastructure and legislative framework was not sufficiently developed to face the challenge. Many developing countries have also suffered from rapid changes in the legislative framework of trading partners (mainly the EU).

Legislation is relatively well developed to address specific aspects of animal breeding strategies and production and certain aspects of land and farm management. Institutional arrangements are not sufficiently addressed by national legislation, therefore not supportive of an effective implementation of the overall legislative framework.

Growing recognition of the roles and values of AnGR over the past decades has led to the initiation of conservation efforts. Many countries have attempted, or are attempting, to conserve some of their most important breeds using both in-situ and ex-situ conservation measures. Nevertheless, conservation efforts for AnGR lag far behind conservation efforts for plant genetic resources.

The national legislative framework in place does not properly address all the requirements for the effective management of farm animal use, development and conservation needs at the country level. Based on the gaps emerged from the analysis, the following list, far from being exhaustive, sets out some of the requirements and objectives countries may wish to consider in developing enabling regulatory frameworks for:

- Identification and listing of breeds; their description and characterization, in order to understand their unique qualities and potential contributions, and to identify those breeds that have the greatest potential to contribute to necessary variety in the future;
- Monitoring of the population statistics for each breed and regular reporting to the world of those breed populations currently at risk of extinction;
- Facilitating the current use of as many breeds as possible – the wise use of a breed is likely to be the most cost-effective way of conserving its gene pool for the future;
- Promoting and supporting farmers and indigenous communities' efforts to manage and conserve their AnGR;
- Supporting acknowledgement and documentation of community-based conservation systems and breeding strategies;
- Supporting awareness-raising and information exchange, especially for farmers and local communities;
- Providing incentives for breeding and raising local traditional livestock;
- Ensuring the necessary infrastructure supportive to local livestock production;
- Defining breeding objectives;
- Enhancing productivity and maintaining of local adaptation;
- Supporting the marketing of products from local traditional livestock production;
- Promoting in-situ conservation;
- Supporting the active participation of individual farming and breed societies in conservation efforts;
- Preserving adequate samples of as many of the unique breeds as possible, in the form of live animals if feasible, preferably supplemented by managed banks of frozen semen, ova and embryos, to enable the future regeneration of a lost population of animals;
- Implementing education and training programmes in conservation genetics and effective field techniques, especially for farmers and indigenous communities;
- Cooperating to promote the development of an efficient and sustainable system of ex-situ conservation, taking into account the need for adequate documentation and characterization;
- Maximizing involvement of all stakeholders that are necessary to implement the legislation, such as, inter alia, farmers, indigenous community, breeding associations and other stakeholders, and government policy makers.

What should be emphasized in outlining the elements of an enabling legal framework for conservation of AnGR is that conservation is not simply preserving or storing samples of semen and/or embryos. This should be taken into account when developing effective national legislation and programmes for maintaining and making the best use of animal genetic diversity. Whilst the basic operations of identification and characterization of genetic resources are universally required and an information system and management entity are essential for the facilitation and co-ordination of the conservation effort, a variety of activities and technologies is needed in order to include all the processes required to best conserve a particular breed. Factors such as the breed's current use, the climatic, social and political stability of the area in which it is located, the

number of animals in the existing breed population and the extent and type of performance recording and cross-breeding employed should all be considered. National policies and local attitudes, culture, and of course, available financial resources, are also important factors. The conservation means is also dependent upon the species involved, the financial and human resource capacity, the establishment of policy concerning incentives for conserving breeds at risk and availability of reliable long-term cryo-preservation storage.

Finally, an essential element for the successful development of a legislative framework for AnGR management is intensive cooperation between lawyers and technicians. The lack of such cooperation has been reported by many countries as hindering the development of adequate legislation. This, in turn, calls for a multidisciplinary approach to legislation, requiring cooperation among the different Ministries.

### **3. The International Framework: Major Instruments**

Concerns over the risk of extinction of about 32% of livestock breeds worldwide as well as concerns over the continuously accelerating rate of extinction have not yet prompted the development and adoption of either legally binding or “soft law” (non-binding) AnGR-specific international instruments. However, the management of AnGR at an international level must take into account a variety of hard law and soft law agreements, some of which are directly related to animals and others not. International zoosanitary agreements, for example, are directly relevant to the movement and use of AnGR. A number of relevant existing international instruments, and some others that have the potential to become relevant in the future, are described in this section. These include both legally binding and non-binding instruments.

#### **3.1 Legally Binding Instruments**

##### **3.1.1 The Convention on Biological Diversity (CBD)**

The Convention on Biological Diversity (CBD), though not focusing on AnGR as such, does cover all kinds of genetic resources. Article 2 of the CBD defines genetic resources as “genetic material of actual or potential value” and further defines genetic material as “any material of plant, animal, microbial or other origin containing functional units of heredity.”

The three objectives of the CBD, as set out in Art. 1, are: the conservation of biological diversity, the sustainable use of components of biological diversity, and the fair and equitable sharing of the benefits arising from the utilization of genetic resources.

Although not directly stated in the CBD, conservation of biological diversity necessarily includes conservation of animal and plant genetic resources, which are the prerequisites for food security and the improvement of agricultural productivity. The CBD states that, while nations have the sovereign right to exploit their own resources (Art. 3), they also have the duty to conserve them. The need for policy development and integration is acknowledged in the CBD, and governments are requested to develop national strategies on biodiversity (Art. 6a), and to integrate “the conservation and sustainable use of biological diversity into relevant sectoral and cross-sectoral plans, programmes and policies” (Art. 6b).

The benefit-sharing dimension of the third objective of the CBD, which is “the fair and equitable sharing of the benefits arising out of the utilization of genetic resources” as stated above, includes appropriate access to genetic resources and appropriate transfer of relevant technologies, taking into account all rights to those resources and technologies, as well as funding.

With regard to access to genetic resources, Art. 15 of the CBD recognizes the sovereign rights of States over their natural resources, and states that access is subject to national legislation (Art. 15.1). Access is to be granted on mutually agreed terms (Art. 15.4), therefore through bilateral agreements. This implies that both supplier and recipient of genetic material must agree on the terms and conditions of the transfer, and that, unless otherwise determined by that Party, prior

informed consent of the Contracting Party providing the genetic resources applies (Art. 15.5). The legal provisions in such a bilateral agreement can be taken to mean that the provider of genetic resources must be fully informed in advance by the access-seeking party about the objectives, as well as the economic and environmental implications of such access.

The CBD foresees the necessity of legislative, administrative or policy measures to provide for fair and equitable sharing of the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources (Art. 15.7).

A benefit-sharing component is also found in Art. 8(j), which contains provisions to encourage the equitable sharing of the benefits arising from the utilization of knowledge, innovations and practices of indigenous and local communities, embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity.

The special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions have been consistently recognized by the Conference of the Parties (COP) to the CBD. Much of the work on agricultural biological diversity under the CBD to date has been undertaken in cooperation with FAO. The fifth COP to the CBD in 2000, by decision V/5, endorsed a multi-year work programme on agricultural biodiversity which includes four programme elements: assessments, adaptive management, capacity building and mainstreaming. The multi-year work programme also contains a specific set of decisions related to FAO's work on AnGR. In these decisions the COP "welcomes the process initiated by the FAO for the preparation of the first Report on the State of World's Animal Genetic Resources, and encourages Parties to participate in this process". Moreover, the COP invited Parties, other Governments, the financial mechanism and funding organizations to provide adequate and timely support to enable countries to participate fully in the preparatory process and implement follow-up actions. In 2002, in decision VI/5, the COP recognized that the process "will contribute to conservation sustainable use, access and benefit-sharing of animal genetic resources for food and agriculture.

### ***3.1.2 The Biosafety Protocol to the CBD***

The Cartagena Protocol on Biosafety was adopted in January 2000 by the COP to the CBD as a supplementary agreement to the CBD, and entered into force on 11 September 2003. The Cartagena Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms (LMOs) resulting from modern biotechnology. The Cartagena Protocol applies to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, as well as risks to human health. However, LMOs that are pharmaceuticals for human consumption are excluded from the scope of the Cartagena Protocol if they are covered by another international agreement or arrangement.

The Cartagena Protocol establishes an advanced informed agreement (AIA) procedure in order to ensure that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory (Art. 7). However, a number of LMOs are excluded from the AIA procedure because of the specific activity or the intended use of the LMO. The LMOs that may be excluded from the AIA procedure are: LMOs in transit, LMOs destined for contained use, and LMOs intended for direct use as food or feed or for processing.

The Cartagena Protocol reserves the right of Parties to take decisions on imports on the basis of the precautionary principle in relation to both LMOs to be introduced into the environment and LMOs to be used for food, feed or processing. The Cartagena Protocol states that lack of



scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of an LMO shall not prevent an importing Party from taking a decision with regard to the import of that LMO in order to avoid or minimize such potential adverse effects (Art. 11.8). Socio-economic considerations arising from the impact of LMOs on biodiversity may also be taken into account in import decisions.

The Cartagena Protocol is likely to become relevant to AnGR management in the future. While there is no specific reference to AnGR in the Cartagena Protocol, the use of biotechnology in breed improvement and conservation is not a new phenomenon. By creating transgenic animals with genes from another species, or by removing or “turning off” genes, animals can grow bigger and more rapidly, or possess traits beneficial to humans, such as meat with higher protein and lower fat content. As is the case with any new technology, it is almost impossible to state that there is no concern. Some concern, for example, has been expressed over the ability of certain genetically engineered organisms to escape and reproduce in the natural environment. Genetically engineered insects, shellfish, fish and other animals that can easily escape, are highly mobile and become feral easily are of particular concern, especially if they are more successful at reproduction than their natural counterparts.

### **3.1.3 The World Trade Organization (WTO) - Basic Principles**

An analysis of the WTO Agreements relevant to AnGR management must first take account of some of the basic WTO principles, as follows:

- a. Trade without discrimination – This principle was one of the foundations of the General Agreement on Tariffs and Trade (GATT). In the WTO Agreement, this principle is effected through the operation of various clauses included in the multilateral agreements on trade in goods, the General Agreement on Trade in Services (GATS), and the Trade-Related Intellectual Property Rights Agreement (TRIPs), such as:
  - i. Most-favoured-nation (MFN) clause - The MFN clause requires WTO Members to grant to the products of other contracting parties treatment no less favourable than that accorded to products of any other country.
  - ii. National treatment - The national treatment principle condemns discrimination between foreign and national goods or services and service suppliers or between foreign and national holders of intellectual property rights.
- b. Transparency - Provisions on notification requirements and the Trade Policy Review Mechanism are set out in the WTO Agreement and its Annexes, with the objective of guaranteeing the fullest transparency possible in the trade policies of its Members in goods, services and the protection of intellectual property rights.

### **3.1.4 The WTO Agreement on Agriculture**

The WTO Agreement on Agriculture (AoA), adopted in 1994, governs world trade in agricultural products, including livestock products. The AoA sets out commitments which countries were required to apply over a six-year implementation period (1995 - 2000), but which will remain in force until a successor agreement, currently under negotiation, is made. These commitments are: to reduce domestic support, to improve market access, and to cut export subsidies.

A wide range of domestic government support was however exempted from the measure of support to be reduced, on the grounds that the government support is production limiting (‘blue box’ exemptions), or minimally market distorting (‘green box’ exemptions). In practice, developing countries do not use production limiting exemptions, as the limitation of domestic production is hardly a priority, and because of the high budget costs of such measures. In addition, developing countries often do not have the resources to apply ‘green box’ measures, such as investment in research and extension.

Developing countries are in any case more interested in improved market access, and this is generally governed by preferential access regimes in the most important markets. Such access regimes are permitted, but not required, to be granted to developing countries.

An example of this trend is the new Cotonou Agreement between the African-Caribbean-Pacific (ACP) states and the European Community (EC) and its member states, which provides a framework for supporting the mutually reinforcing effects of trade cooperation and development aid. The EC and the ACP States have agreed on a process to establish new trading arrangements to promote trade liberalisation between the parties and formulate provisions in trade-related matters. The objectives of economic and trade cooperation **are** to promote integration of ACP economies into the world economy through enhancement of production, supply and trading capacities and full conformity with WTO provisions.

### **3.1.5 The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)**

Sanitary (human and animal health) and phytosanitary (plant health) measures apply to domestically produced food or local animal and plant diseases, as well as to products coming from other countries.

The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) encourages governments to establish national SPS measures consistent with international standards, guidelines and recommendations. As far as animals are concerned, the relevant international standards under the SPS Agreement are those set by the *Office International des Epizooties* (OIE) and the Codex Alimentarius Commission (Codex).

International standards are often higher than the national requirements of many countries, including developed countries, but the SPS Agreement explicitly permits governments to choose not to use the international standards. However, if the national requirement which differs from the international standards results in a greater restriction of trade, the country imposing the different standard may be asked to provide scientific justification, demonstrating that the relevant international standard would not result in the level of health protection the country considered appropriate.

Countries must establish SPS measures on the basis of an appropriate assessment of the actual risks involved, and if requested, make known what factors were taken into consideration, the assessment procedures used and the level of risk which was determined to be acceptable.

Governments are required to notify other countries of any new or changed SPS requirements which affect trade, and to set up offices (called “Enquiry Points”) to respond to requests for more information on new or existing SPS measures. Governments must also open to scrutiny their methods of applying food safety and animal and plant health regulations. The systematic information exchange among the WTO’s member governments provides a better basis for development of national standards.

The increasing importance of zoosanitary standards under the SPS agreement, and of zoosanitary regulations resulting from recent episodes of zoonotic and animal-specific disease (such as avian flu, and foot and mouth disease) make it increasingly difficult for developing countries to trade in animals and animal products, and can be an effective barrier in the movement of animals—including for research and breeding purposes.

### **3.1.6 *The Office International des Epizooties (OIE) and the Codex Alimentarius Commission (Codex) - Standard setting instruments under the SPS Agreement***

The OIE is recognized as the standard-setting body for animal health. Health measures contained in the Terrestrial Animal Health Code (in the form of standards, guidelines and recommendations) have been formally adopted by the OIE International Committee. The Terrestrial Animal Health Code is a reference document for use by veterinary authorities, import/export services, epidemiologists and all those involved in international trade.

Due to the relationship between animal health and animal welfare, the representatives of the OIE's 164 member countries asked the OIE to take the lead role in animal welfare as well. The areas of OIE's initial work on animal welfare standards will be land and sea transport, slaughtering for human consumption and depopulation for disease control. A Permanent Working Group on Animal Welfare was established and had its first meeting in October 2002.

The Codex Alimentarius Commission (Codex) is the standard setting body for food, including animal products. One of its projects is the preparation of a Code of Practice for Good Animal Feeding, undertaken in response to food trade and health problems arising from animal feed. The Code applies to feed manufacturing and to the use of all feeds, other than those taken while grazing free-range. The primary objective of the Code is to encourage adherence to Good Manufacturing Practices during the production, harvesting, handling, storage, processing (however minimal) and distribution of feed for food-producing animals. A further objective is to encourage good feeding practices on the farm.

An Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology to consider the health and nutritional implications of such foods was also established by Codex in 1999. In particular, the Task Force will develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices. The Task Force submitted a preliminary report to Codex in 2001, a mid-term report to the Executive Committee in 2002, and a full report was expected to be provided to Codex in late 2003.

An expert consultation on the "Safety Assessment of Foods Derived from Genetically Modified Animals including Fish" was held in November 2003, continuing the work of FAO and the World Health Organization (WHO) on the safety assessment of genetically modified (GM) foods and focuses on GM animals, including fish, and the foods derived therefrom. The main purpose of this expert consultation was to discuss and describe ways to assess the safety and risk of GM animals, including fish. This was done through the review and analysis of data on the current situation. One of the topics of the working papers of the expert consultation was an overview of the state of the art related to GM animals. Environmental and ethical issues related to the production of GM animals/fish were discussed as additional issues.

### **3.1.7 *The WTO Trade-Related Intellectual Property Rights Agreement (TRIPs)***

TRIPs, which has been in force since January 1995, is the broadest multilateral agreement on intellectual property in that it applies to: copyright and related rights, trademarks, including service marks, geographical indications, including appellations of origin, industrial design, patents, including the protection of new varieties of plants, the layout designs of integrated circuits, and undisclosed information, including trade secrets and test data.

Under Art. 27.3 of TRIPs, WTO Members must protect various forms of intellectual property, some of which are relevant to AnGR, including indications of geographical origins, trademark, trade secrets and patents. TRIPs requires Members to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability.

There are three permissible exceptions to the basic rule on patentability. The exception relevant to AnGR is contained in Art. 27.3 (b), stating that Members may exclude “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”.

Most countries worldwide have explicitly excluded patents for animals. It will be many years at least before animals are treated equally with other applications in the patent system. Animal patenting may become an issue with the introduction of transgenic production animals.

Even where animals or parts thereof are deemed, in principle, patentable, a patent application may be rejected on moral or public order grounds, in accordance with Art. 27.2 of TRIPs. Nevertheless, the notions of morality and public order are quite vague and changing, and their content will depend on national perceptions by patent offices and judges. In fact, the determination of whether certain conduct may be contrary to fundamental values of a society is a matter of national public policy.

### **3.1.8 *The World Intellectual Property Organization (WIPO)***

The World Intellectual Property Organization (WIPO) is an international organization whose mandate is to ensure that the rights of creators and owners of intellectual property are protected worldwide and that inventors and authors are thus recognized and rewarded for their creativity.

**WIPO's** Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was established in 2000. The committee provides ‘a forum for international policy debate about the interplay between intellectual property and traditional knowledge, genetic resources and traditional cultural expressions (folklore)’.<sup>2</sup> The committee has met five times in 2003 and 2004. The current key questions are a possible International Instrument on Intellectual Property in Relation to Genetic Resources and on the Protection of Traditional Knowledge and Folklore, and a possible requirement that patent applications include a mandatory disclosure of the source of genetic material used.

## **3.2 *Soft Law***

Soft law refers to non-binding legal instruments that are utilized for a variety of reasons, including strengthening member commitment to agreements at the policy level, reaffirming international norms, and establishing an informal precedent for subsequent treaties.

### **3.2.1 *FAO Global Strategy for the Management of Farm Animal Genetic Resources***

The FAO Global Strategy for the Management of Farm Animal Genetic Resources consists of several inter-related components and elements. The major components are: the intergovernmental mechanisms to ensure direct government involvement and continuity of policy advice and support; the planning and implementation structure, providing the enabling framework for country action and regional and global support; the technical programme of work, aimed at supporting the effective management of AnGR at the country level; and the reporting and evaluation component to provide the critical data and information required for guidance, cost-effective planning and action; and to report on the state of diversity, the state of country capacity and the state of the art, to ensure that development and implementation of the Global Strategy are successful. The Global Strategy is being developed under guidance of the Commission on Genetic Resources for Food and Agriculture. Since 2001, FAO is coordinating the development of a country-driven Report on the State of the World's Animal Genetic Resources, which will provide an internationally agreed framework for the development of the sector, including agreed strategic priorities for action.

---

<sup>2</sup> <http://www.wipo.int/tk/en/>

### 3.2.2 *Agenda 21*

Chapter 14 of Agenda 21 on Promoting Sustainable Agriculture and Rural Development (SARD) states as the major objective of SARD increasing food production in a sustainable way and enhancing food security. Among the programme areas included in Chapter 14, of particular relevance is programme area (h) on the conservation and sustainable utilization of AnGR for sustainable agriculture. According to the management-related activities specified in this programme, Governments should: a) draw up breed preservation plans for endangered populations, including semen/embryo collection and storage, farm-based conservation of indigenous stock and in-situ preservation, b) plan and initiate breed development strategies, and c) select indigenous populations on the basis of regional importance and genetic uniqueness, for a 10-year programme, followed by selection of an additional cohort of indigenous breeds for development.

At the World Summit on Sustainable Development held in Johannesburg in 2002, sustainable agriculture and rural development was one of the issues considered in the Plan of Implementation. Paragraphs 6(i) and 38 of the Final Declaration stress the importance of sustainable agriculture and rural development as essential to the implementation of an integrated approach to increasing food production and enhancing food security and food safety in an environmentally sustainable way.

### 3.2.3 *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising from their Utilization*

The Bonn Guidelines have been developed by the CBD and were adopted under [Decision VI/24](#). They provide for a set of voluntary rules that will assist Parties, Governments and other stakeholders when establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing.

The Bonn Guidelines state that before collecting any genetic resources, a collector should have a written agreement that includes certain key provisions: prior informed consent of the national government of the country of origin; access to genetic resources or the “traditional knowledge” of an indigenous community or communities will normally require obtaining the prior informed consent of that community; the non-monetary and/or monetary benefits the collector will provide; and whether, and under what conditions, the collector may transfer the collected genetic resources to another party.

The development of mutually agreed terms should be based on the principles of legal certainty and minimization of costs. The Bonn Guidelines enumerate a detailed description of the type of provisions that could form part of a contractual arrangement. Some of the proposed provisions are quite innovative and include the specification of uses, the regulation of those uses in light of ethical concerns, the continuation of customary uses over genetic resources, the possibility of joint ownership of IPRs according to contributions, and the existence of confidentiality clauses and sharing of benefits from commercial and other utilization of genetic resources including derivatives (paras 41-44).

#### 4. Material Transfer Agreements in the context of international research cooperation related to AnGR

Material transfer agreements (MTAs) are contractual arrangements that set the agreed conditions and terms under which genetic material is to be transferred. MTAs are widely used in the private seed sector, but also by public research organizations.

Following a Pig Biodiversity research project funded by the European Union (EU), an agreement for the long-term conservation and use of genetic resources was developed and initially signed by 13 contracting parties including FAO. The initial agreement had as its objective the protection of the ownership and property rights of the blood and DNA samples transferred among participants to the project. Written permission from both the individual provider and the country of origin was an obligatory requirement for using the material which remains the property of the individual providers.

A second long-term agreement, to be applied in a manner consistent with the provisions of the CBD, has as its objectives: the facilitation of the conservation of the genetic material collected under the project, to be used for international R&D, to clarify property rights in all genetic material sampled in the project, and to establish a structure for the management and use of the stored DNA and project data. According to the agreement, a Management Group representing the interests of all parties is responsible for the governance of the agreement and for taking decisions on control of access to the stored DNA and project data, taking into account the provisions of the CBD and FAO's Global Strategy for the Management of Farm Animal Genetic Resources.

Under this agreement, stored DNA will be maintained for each breed and animal using internationally accepted methods. The original material providers own the IPRs related to the genetic material. Control and access to this DNA for further research and any other use resides with the original material provider. The project DNA remaining with the typing laboratories can be retained by the laboratory or returned to the material providers, as specified by the material provider.

A example from the plant sector is the MTA for the transfer of plant genetic resources held in trust by the International Agricultural Research Centres (IARCs), under agreements signed in 1994 with FAO, through which the IARCs agree not to seek legal ownership of these materials, and recognize the intergovernmental authority of FAO and its Commission on Genetic Resources for Food and Agriculture in setting the relevant policies.<sup>3</sup> In accordance with the current MTA,<sup>4</sup> the recipient "agrees not to claim ownership over the material, nor to seek IPRs over that material, or its genetic parts or components, in the form received. The recipient also agrees not to seek IPRs over related information received. The recipient further agrees to ensure that any subsequent person or institution to whom he/she may make samples of the material available, is bound by the same provisions and undertakes to pass on the same obligations to future recipients of the material".

The ITPGRFA invites the IARCs and other international institutions holding *ex situ* collections of plant genetic resources for food and agriculture to sign agreements with the Governing Body of the Treaty with regard to such *ex situ* collections.<sup>5</sup> These materials will form part of the ITPGRFA's Multilateral System of Access and Benefit-sharing and will be made available for research and plant breeding under standard MTAs that conform to the provisions of the

---

<sup>3</sup> Agreement Between [name of centre] and the Food and Agricultural Organization of the United Nations (FAO) Placing Collections of Plant Germplasm Under the Auspices of FAO, Oct. 1994, available at <ftp://ext-ftp.fao.org/ag/cgrfa/GS/cgtexte.pdf>.

<sup>4</sup> Available in Appendix E of CGRFA-9/02/Rep, Report of the Ninth Regular Session of the Commission on Genetic Resources for Food and Agriculture, at <ftp://ext-ftp.fao.org/ag/cgrfa/cgrfa9/r9repe.pdf>.

<sup>5</sup> By Article 15 of the ITPGRFA.

ITPGRFA, including for mandatory sharing of the monetary benefits of commercializing a product that incorporates material accessed for the Multilateral System, which is not available without restriction to others for further research and breeding.

These standard MTAs embody internationally agreed arrangements for multilateral access and multilateral benefit-sharing, to obviate the need for bilateral negotiations on a case-by-case basis, and to reduce transaction costs to a minimum.

## 5. Conclusions

AnGR plays an important role in contributing to food and agricultural production globally for the present and the future and in sustaining most production systems and community livelihoods. Their value encompasses social, cultural and economic aspects. Better management of these resources is crucial for the demand for food and agriculture to be met and for enabling future generations to respond to the challenges of disease, climatic changes, and other threats.

There is hardly an ideal way of managing genetic resources, but it is certainly appropriate to point out that genetic resources are not only plants but also animals and that there are some intrinsic differences between plant and animal resources and the way they can be managed: differences in reproduction, storage and transport, ownership, costs (for animal improvement the cost is much higher than for crop improvement, and it takes much longer), long-term commitment of donors and funding institutions, etc. The importance of the management of AnGR has so far been neglected; AnGR lag behind plant genetic resources at the international level. Conservation of animal genetic germplasm has not received as much attention in recent years as crop germplasm conservation. The same is true for utilization and breed improvement, particularly in low-input systems. Even though the majority of farm animals are located in developing countries, the majority of breeds undergoing active genetic improvement reside in developed countries.

The fact is that problems of productivity as well as diversity in the livestock sector are no less complex than in the crop sector. If anything, these are more challenging. Unlike crops in which germplasm diversity can generally be captured in a few kilograms of seeds, in animals one has to maintain a very large gene pool to manage and maintain diversity of a reasonable order. Further, the adaptation of animals to their habitat may be far stronger than in the case of seeds. In addition, animals, unlike plants, have feelings, moods and preferences. The relationship between animal keepers – men, women, children and their communities – and animals is somehow different from the relationship between farmers and crops or soil. Also, livestock provide farmers with a wide range of different benefits, including food (meat, milk, eggs), fibers (wool, hides and skins), draught power, manure and fuel. Since animals are an integral part of farming systems in most regions, the conservation of animal germplasm is not totally independent of the conservation of habitat, socio cultural and ecological knowledge systems and interaction between different species and even ecosystems in the case of transhumant livestock.

In addition, with regard to AnGR there is not the huge investment in the public sector that exists for plants. Gene banks are considered useful tools for ex-situ conservation of plants, but less of animals. There is no equivalent of a global genetic repository system for AnGR such as the Consultative Group on International Agricultural Research nor is there any indication that such an ex-situ global conservation effort will be implemented in the near future. These differences mean that action to support the maintenance of farm animal and farm plant biodiversity will differ, but this should not undermine the need for legislation in both fields.

At the national level, the development of adequate AnGR-legislation is not an easy task, especially for developing countries, in that it should ideally strike a balance between conservation and sustainable use on one hand, and maximization of the national export potential on the other.

Moreover, development of legislation involves the active participation of all stakeholders. The gap analysis above has highlighted how the participatory approach to AnGR management, vital

to identify and evaluate various aspect of traditional breeding strategies and to achieve active involvement of the livestock keeping communities, is not always reflected in national legislation.

Differences in the state of legal and regulatory frameworks on AnGR management between developed and developing countries are quite substantial. Developing countries often identify a lack of capacity as a major obstacle in the development of legislation and regulatory frameworks. With the absence of adequate human and financial resources and weak institutional and infrastructure development they need to develop legislation based squarely on their needs and possibilities.

The analysis has also indicated significant subject matter differences in the state of national legislation, identifying animal health legislation as the most developed world-wide, animal breeding as relatively well developed, and with conservation and institutional arrangements legislation as not sufficiently developed to face the various challenges involved. Adequate legislation for AnGR management for use and conservation should address all issues involved and achieve a better balance of development in the different areas to respond to countries needs.

Internationally, although domestic animal diversity was recognized as an important component of global biodiversity by the United Nations Conference on Environment and Development (UNCED, 1992), by the CBD and Agenda 21, formal international activities on the sustainable use and conservation of AnGR for food and agriculture are still very scarce compared with those on plant genetic resources. The recent adoption of the ITPGRFA is a self-explanatory example of international debate and interests focusing mainly on plant genetic resources, It is an important example of how governments can address and resolve complex issues that require synergy across sectors—in this case, the agriculture, environment and trade sectors—in building a coherent international policy and regulatory framework for food and agriculture. Through the ITPGRFA, countries have found specific solutions for the specific problems and needs of the sector, in particular arrangements for multilateral access and benefit-sharing, that take into account the fact that all countries are inter-dependent in relation to plant genetic resources for food and agriculture, and that these are crucial of food security, now and in the future.

The international legal framework does not fully make up for the lack of adequate legislation at national level. The WTO SPS Agreement is the only agreement whose implementation at national level seems to be covered by the extended zoosanitary legislation responding to the SPS Agreement's requirement to establish national SPS measures consistent with international standards, guidelines and recommendations, bearing in mind that if the national requirement results in a greater restriction of trade, a country may be asked to provide scientific justification demonstrating that the relevant international standard would not result in the level of health protection the country considered appropriate.

With the exception of the CBD, which refers to animal genetic material in its definitions of genetic resources, most international agreements deal with genetic resources with no specific reference to AnGR. Conservation, sustainable use, access and equitable sharing are among the concepts developed under the CBD which recognizes the sovereign rights of states over their natural resources and their authority to determine access conditions to such resources. It is then responsibility of states to develop general regulations with regard to the requirements of the Convention, which also requests the development of national strategies and development plans. Such regulations and plans should not only focus on plants but also consider the peculiarities of AnGR in regard to both conservation and utilization purposes as well as to access and benefit sharing. In the animal sector to date, technological resources and contractual practices, rather than formal IPRs strategies, have been the norm.

The discussion on access and benefit sharing is quite intense between the providers and the users of plant genetic resources. Access and benefit-sharing is not yet a major issue in the discussion of farm AnGR, but it is likely to become so in the future not least because conservation incorporates all operations involved in the management of genetic resources, including the establishment of



better access to a wider variety of these resources, particularly for research and development.<sup>6</sup> Countries possess different subsets of the total breeds found throughout the world, forming each domestic animal species. Additionally, countries are likely to become increasingly interdependent in seeking access to unique AnGR from elsewhere. In this case, it may be worth considering the need to have facilitated multilateral access regulations, as are provided by ITPGRFA.

The Biosafety Protocol to the CBD is being rapidly implemented through national legislation. While most attention has focused on GM crops, biotechnology is also relevant to both livestock breeding and feed. The peculiarities of livestock will require greater specific attention as the regulatory framework for biotechnology develops.

TRIPs and IPR are, at present, not a major concern in maintaining farm animal genetic diversity. The majority, but not the entirety, of countries worldwide have explicitly excluded patents for animals. It will be at best many years before animals are treated equally with other applications before the patent system. In the future, it will be interesting to see whether IPR protection will nevertheless be sought and obtained in countries excluding patents for animals in terms of article 27(3)(b) of TRIPs ('Members may exclude plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes').

Following the recognition by the international community of the special nature of agricultural biodiversity, and the increasing recognition of the special characteristics of AnGR and the challenges the international community faces in halting the increasing erosion of AnGR, an appropriate regulatory system for successful management of AnGR needs to be discussed. FAO is the obvious forum, in co-operation with the CBD and with the involvement of different stakeholders, including governments and non-governmental organizations; the private sector, which owns most of the animals; intergovernmental and other research and development agencies; as well as local training, research and animal production groups, particularly animal geneticists and veterinarians, who commonly provide much advice to industry and government. Farmers and their communities, as the custodians of the genetic resources also have to play an important role in the development of policies and legislative frameworks.

---

<sup>6</sup> There are currently only two legally binding international agreements on access and benefit-sharing in relation to genetic resources, the CBD and then ITPGRFA, which are in harmony. In decision VI/5, the COP/CBD recognized that the process for the preparation of the *State of the World's AnGR* "will contribute to ... access and benefit-sharing of animal genetic resources for food and agriculture".