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COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

INTERGOVERNMENTAL TECHNICAL WORKING GROUP ON ANIMAL GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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MODERN BIOTECHNOLOGY AND THE MANAGEMENT OF ANIMAL GENETIC RESOURCES: POLICY ISSUES

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MODERN BIOTECHNOLOGY AND THE MANAGEMENT OF ANIMAL GENETIC RESOURCES: POLICY ISSUES

I. INTRODUCTION

1. The Commission on Genetic Resources for Food and Agriculture (CGFRA), at its Eight Regular Session, agreed that FAO should continue to shape more clearly the framework of the Global Strategy for the Management of Farm Animal Genetic Resources, and develop its constituent elements, in consultation with countries. It agreed that the Intergovernmental Technical Working Group on Animal Genetic Resources should clarify the framework and better define and prioritize the constituent elements of the Global Strategy, at its current session. Noting that erosion of animal genetic resources was occurring, and was a threat to global food security, the Commission also agreed that the Working Group should investigate ways and means for increasing international co-operation and collaboration, to address the loss of animal genetic resources, and their better use and development.

2. The present document provides background information that the Working Group may wish to take into consideration in this task, in particular: the rapidly increasing world-wide demand for livestock products; the implications of modern biotechnologies for the conservation and sustainable use of animal genetic resources; and, in the light of Corporate Strategy B of the FAO Strategic Framework, *Promoting, developing and reinforcing policy and regulatory frameworks for food, agriculture, fisheries and forestry*, summary information is also provided on the relevant international policy and regulatory framework.

II. THE LIVESTOCK REVOLUTION

3. Human population growth, increasing urbanisation and rising incomes are fuelling a massive increase in demand for milk, meat and eggs in developing countries, where, for example, *per caput* meat consumption is expected to double between 1993 and 2020, when some 82 percent of all food and agriculture production will be in what are now developing countries. Global livestock production is growing faster than any other agricultural sector, which, it is predicted, will by 2020 be the most important sector, in terms of added value. This process has been referred to as the ‘livestock revolution’, and includes:

- A shift of livestock production from temperate and dry areas to warmer and more humid environments;
- A change in livestock keeping from a family-support activity to market-oriented, increasingly integrated production;
- Increasing pressure on grazing resources;
- More large-scale, industrial production units, located close to urban centres;
- Decreasing importance of ruminant *vis-à-vis* monogastric livestock species, both pigs and poultry; and
- A rapid rise in the use of cereal-based feeds.

Production and consumption

4. Increasing incomes and urbanization in developing countries are driving the demand for animal products and feed grains, especially in the case of poultry, pig and milk production, where

animal products currently provide about 20% of the metabolically available protein in the diet. High quality animal proteins also improve the nutritional value of dietary cereals by correcting amino acid deficiencies. This demand is met by both local production and imports. Developing countries are currently annual net importers of about 88 million tonnes of cereals, costing some US$15 thousand million, and are increasingly large net importers of milk and meat (with the exception of pig meat). Milk imports have about tripled since 1970.

5. Forecasts of future demand for plant and animal products in developing countries need to take into account changes in the consumption of both cereals and livestock products, the use of cereals as animal feed, and the balance between the production and the importation of plant and animal commodities.

Sustainable Economic Development

6. Livestock production contributes significantly to agricultural productivity, and hence economic growth. Primary livestock products (meat, milk, eggs, wool, hides, skins) account for approximately 22% of agricultural GDP in the developing regions of Asia, 25% in sub-Saharan Africa, 31 % in West Asia and North Africa, 38% in Latin America and 41 % in Central America. Livestock contributes on average 4-7% of developing countries' GDP, without considering the substantial value of draft power and manure, or indirect benefits of animal agriculture are not conventionally included in national income accounting, such as the role of livestock in transforming feeds and forage into marketable food products, adding value to farm enterprises, providing year-round employment, providing insurance against risk, and enhancing the biophysical and economic viability of agriculture as a whole.

7. There is scope for considerable improvement in animal production in developing countries, presenting a unique opportunity to increase economic growth and reduce poverty and malnutrition, often with significant benefits for marginal groups and women, who, for example, are estimated to own or manage half of sub-Saharan Africa's domestic livestock resources. Industrial countries have in recent years achieved significant increases in livestock production efficiency, primarily through the development and use of improved breeding, health, nutrition and management technologies, spurred both by high private sector investment, and, in the case of some commodities and regions, by excessive public production subsidies.

8. These technology-based advances in industrial countries have had little impact in developing countries, with the some notable exceptions in milk, poultry and pig-meat production, driven by increased demand for these products, and increased private and public sector investment. Higher efficiencies have also been achieved by the use of improved genotypes in higher input production systems, where environmental and dietary effects are reduced, and major diseases have been contained by prophylactic, chemotherapeutic and sanitary measures. Control of contagious, economically crippling livestock diseases, such as Newcastle disease and has also resulted in marked increases in animal agriculture. But, despite successes in increasing egg and milk production, in Africa annual egg production per chicken[1] and milk production per cow, is still only 10% and 43%, respectively, of the industrial world average; in Asia, 24% and 98%; and in Latin America, 28% and 51%.

Future Needs

9. The projected rapid increase in demand for livestock products in developing countries, especially meat and milk, will require greater production efficiency, in order to achieve sustained productivity increases, while minimizing adverse environmental effects. A diversity of technological improvements may be available for investment, but maximizing production while minimizing ecological risk will require balancing natural resource management and environmental considerations.

[1]Based only on commercial production as data is not available for village chicken production

10. Appropriately modern biotechnologies can provide developing countries with new tools for the better management of animal genetic resources, sustained production and productivity increases, on the basis of improved characterisation, conservation and utilisation of animal genetic resources, in sustainable production systems. The public sector will need to play a continued and increased role, to:

- increase the access of poorer sections of society to affordable animal protein and products;
- provide an enabling environment for sustainable production increases, especially by small-scale producers;
- identify the constraints to, and opportunities for, livestock production in particular environments, and particular species or breeds;
- invest in research and development for available and affordable public goods, particularly for small-scale livestock producers; and
- better manage animal genetic resources, through improved conservation, characterisation and utilisation, within sustainable production systems.

III. BIOTECHNOLOGIES IN ANIMAL GENETIC RESOURCES MANAGEMENT

Biotechnologies in animal agriculture in developing countries

11. This section discusses biotechnologies that are either currently applied or are likely soon to come on stream for use in animal agriculture, and considers how relevant and appropriate they are to enhance animal production and health in developing countries, and the factors determining their adoption, which Governments may wish to take into account in further developing the Global Strategy.

12. New molecular and *in vitro* culture technologies have been responsible for significant progress in research on livestock genetics, physiology and health, in the context of improved production efficiency. This results largely from large investments by both the public and private sector in basic biological research. Rapid advances in molecular biology and reproductive biology provide new powerful tools for further innovation, but are increasingly developed by large corporations, for developed country markets, rather than for the needs of small-scale farmers in tropical regions.

13. While developing countries contain an increasing majority of the world's people, farmers and animals, biotechnology research and development risks bypassing their requirements, and there has to date been little international support for applying modern biotechnologies to increase livestock productivity in developing countries. There has been little success in exploiting the genetic potential of indigenous breeds to resist disease and environmental stresses, and better utilise the available natural feed resources, or even in ensuring reliable long-term conservation of the many animal genetic resources at risk. The application of new genomics and new breeding strategies to the breeds of relevance to smallholder production in developing countries is presently unlikely, because of a lack of reliable longer term funding, inadequate technical and operational capacity, the low commercial value of the breeds, a lack of adequate conventional breeding structures, and the need to select in the relevant production environments.

14. This is also true for the development of improved sustainable control measures for tropical livestock diseases. Despite isolated successes, as in the case of rinderpest, the control of the major vector-borne pathogens still relies on chemotherapy, vector-control and the use of live vaccines.

15. A question the Working Group may wish to consider, in further developing the Global Strategy, is why the potential of the new biotechnologies is so under-utilised in developing countries. To what extent is technology transfer, adaptation and adoption, affected by, for example:

- a lack of clear national livestock development policies conducive to the introduction of new proven technologies;
- a failure to adapt technology to suit local and regional conditions;
- insufficient information for decision makers;
- cost factors, intellectual property rights, the presence or absence of backstopping after introduction, limiting farmer access to technology;
- an insufficient appreciation of the livestock owner or producer's decision-making process with regard to investment in animal production and health; and
- a weak expression of technology demand?

Reproductive Biotechnologies

16. Reproduction biotechnologies aim to increase reproductive efficiency, and rates of genetic improvement. They offer potential for greatly extending the multiplication and transport of genetic material, for conserving unique genetic resources in reasonably available forms for possible future use, and as the vector for the extended development and application of some molecular technologies. In the last 30-50 years, the development of artificial insemination (AI) and of embryo transfer (including oestrus synchronisation and multiple ovulation), have made the most impact.

Artificial Insemination (AI)

17. AI has already accelerated breeding progress in cattle, sheep, goat, pig, turkey and chicken improvement programmes in developed countries, primarily by increasing the intensity of selection of males, and by diffusing breeding progress, initially with fresh, and later with frozen semen, resulting in rapid world-wide transport of male genetic material. Globally, over 100 million cattle, 40 million pig, 3.3 million sheep, and 0.5 million goat artificial inseminations are performed annually. However, in only very few developing countries does AI impact substantially on livestock production. What are the reasons that such a powerful technology has not been more widely adopted in developing countries? What is required to use the technology with the same success as in developed countries?

Embryo transfer (ET)

18. ET, in mammalian species, enhanced by multiple ovulation and oestrus synchronisation (MOET), allows the acceleration of genetic progress, through increased selection intensity of females, while the freezing of embryos makes possible low cost transport of genetic material across continents, and also conservation of diploid genomes. MOET may also be used to produce crossbred replacement females, while maintaining only a small number of the straightbreds. Globally, in 1998 440,000 ETs were recorded in cattle, 17,000 in sheep, 1,200 in goats, and 2,500 in horses. About 80 % of the bulls used in AI are derived from ET. Despite the potential benefits of ET, its application is largely limited to developed countries. What are the required technical and policy factors that will enable developing countries to make use of these technologies on a greater scale?

19. ET is also one of the basic technologies for the application of more advanced reproductive biotechnologies such as ovum pick-up (OPU) and *in vitro* maturation and fertilisation (IVM/IVF), sexing of embryos, cloning, and transgenics.

OPU and IVM/IFM

20. OPU in mammals allows the repeated pick-up of immature ova, directly from the ovary, without any major impact on the donor female, and the use of these ova in IVM/IVF programmes. Making greater use of genetically valuable females at very early age may substantially increase genetic progress. These are advanced technologies, even in industrial agriculture, and the potential uses, and feasibility of use in developing countries needs to be carefully evaluated.

Sexing

21. Technologies for the rapid and reliable sexing of embryos allow the generation of the desired sex only, at specific points in a genetic improvement programme, markedly reducing the number of animals required, and enabling increased genetic progress. The sexing of semen, using flow-cytometric sorting, has decisively progressed in recent years, but still with limited sorting rates even for IVF. Sexed semen could markedly increase genetic improvement rates and have major implications for end-product commercial production. As an advanced technology, what is the scope for use in developing countries?

Cloning as an improvement technology

22. Cloning technologies offer potential as research tools, and in areas of very high potential return. IVM/IVF is a source of the large numbers of low-cost embryos required for fourth generation biotechnologies, such as cloning and transgenesis. Cloning will be used to multiply transgenic founder animals. There are three types of clones now being increasingly produced at the research level for the cattle, pig and sheep species, offering differing possibilities, the result of:

- limited splitting of an embryo (genetically identical);
- introduction of an embryonic cell into an enucleated zona (clones may differ in their cytoplasmic inheritance);
- introduction of the nucleus of a somatic cell (milk, blood, dermal cells) into an enucleated zona (clones may differ in their cytoplasmatic inheritance, and substantial knowledge of the phenotype of the parent providing the somatic cell is likely to already exist).

Cloning in the conservation of genetic diversity

23. Global surveys indicate that 40% of the 4183 remaining avian and mammalian livestock breeds with population data reported, are at risk of loss, and there is often little knowledge of these breeds, or of their potential. Most such breeds are found only in developing countries. Whilst animals cannot be reformed from DNA alone, the sampling of somatic tissue may make possible the low cost, rapid and low risk collection and transfer of breed samples from remote areas, for conservation purposes, with the development of practical field sampling protocols, and if the costs and technical challenges of re-establishing breeds from the stored cell lines can be overcome.

Molecular Biotechnologies

24. Various molecular biotechnology applications are available in animal production and health, for both on-farm production, and off-farm product-processing. With a focus on on-farm use, and on technologies based on DNA procedures, the potential applications include:

- production of monoclonal antibodies;
- production of DNA vaccines;
- production of enzymes to improve animal performance, through better nutrition;
- rendering animals resistant to or tolerant of specific diseases, or improving them for traits important for food and agriculture production, by marker-assisted selection, gene-introgression, and, in future, transgenesis;
- the development, through transgenesis, of better forages and improved rumen fermentation; and
- the use of molecular markers for pedigree identification; for characterising genetic distances amongst breeds; and for more effective and efficient research in understanding animal function both for production and adaptational characteristics, including at the gene level.

DNA technologies and animal health

25. Animal diseases are an increasingly important factor reducing developing country livestock productivity. Infectious diseases of livestock not present in the industrial world and for which there are as yet no sustainable means of control present a formidable barrier to increasing the efficiency of livestock productivity in the developing world. The use of DNA biotechnology may contribute significantly to improved disease control, facilitating breeding strategies that use the already existing domestic animal genepool.

26. Advanced biotechnology-based diagnostic tests make it possible to identify disease-causing agents, and to monitor the impact of disease control programmes, to a degree of diagnostic precision (at sub-species, strain or bio-type level) not previously possible. The relevance of such diagnostic tests to the livestock industry in developing countries, and their accessibility, may be key factors in permitting sustainable intensification of production.

DNA technologies in animal genetics and breeding

27. Most useful animal characteristics (including disease-resistance, intake, fibre and body growth, egg-production, fecundity and longevity) are determined by the combined interaction of many genes with the environment. The genetic improvement of locally adapted breeds will therefore be important in realising sustainable production systems, in the broad spectrum of developing country production environments, and will probably best be realised by the strategic use of both non-genetic and genetic interventions.

28. DNA technologies have promise for use in developing sustainable animal production systems of higher potential food output, through:

- characterising and better understanding the genetic variation coding directly for production of animals and breeds, and the variation that influences breed adaptive fitness;

- manipulating the variation within and between breeds, in order to realise more rapid and better-targeted gains in breeding value;
- conserving genetic material.

Characterising genetic variation

29. For genetic characterization at the molecular level, linkage maps of sufficient resolution for use in breeding improvement through marker-assisted selection are now available for cattle and pigs, and are rapidly being generated for other ruminants, poultry and fish. Such maps will be further refined in the near future, and the process of identifying molecular markers for important biological and commercial traits is underway. The physical location of individual genes on chromosome maps is also well advanced. The rapid development of both linkage and physical maps of the genomes of domestic livestock is a clear example of how the large investment in basic biology (particularly the construction of mouse and human genetic maps) can benefit domestic livestock research. A number of important research projects focussing on developed country breeds are well advanced and coordinated within and across countries, and ILRI has for several years been involved in a world-wide collaborative effort to create and improve bovine genetic maps, and is currently identifying markers associated with genetic resistance to trypanosomiasis. Such maps could lead to substantially improved decisions in the selection and mating processes of breeding programmes, and to significant reduction in the generation time of improved breeds, compared to conventional breeding, based solely on phenotype selection.

30. At the between-breed level, the use of microsatellites in genetic distancing of is gaining momentum, based upon the FAO/International Society for Animal Genetics protocol and standard marker sets. However, while most breeds are located only in the developing countries, the work to date has focused substantially on developed countries. A major challenge, with long-term implications for the development of the Global Strategy, will be to cover the developing country breeds of each farm animal species more extensively, and promote more comparable assaying, data storage and analytical protocols.

Genomics

31. Genomics (or functional genomics) focus on systematic data acquisition about the structure and the function of the genomes of individual livestock species, and of their pests and pathogens. Knowledge gained from sequencing the human, mouse, *Drosophila* and *Arabidopsis* genomes increases the understanding of the potential utilization of similar DNA sequences and genes, which are shared amongst species. Several technologies being developed for genome analysis will allow rapid genotyping and gene-expression studies, using micro-arrays. It should become possible rapidly to scan the genomes of different organisms, and to develop a systematic approach to mapping both multiple and single genes traits. Advances in bio-informatics may allow the prediction of gene-function from gene-sequence data: from a listing of an organism’s genes, it will become possible to build a theoretical framework of its biology. The comparison across organisms of physical and genetic maps and DNA sequences will significantly reduce the time needed for the identification and selection of potentially useful genes.

Speeding up locally adapted breed improvement

32. Rapid genetic progress depends on rapidly transmitting, from selected breeding parents to offspring, those alleles which contribute to the enhanced expression of the traits identified by farmers as valuable for their production environment. As almost all such traits are polygenic and indirectly expressed, accuracy in detecting superior parents is crucial. In developing countries, generation intervals in species of interest generally need to be much longer in the production herds and flocks: it remains to be seen if DNA technologies will make possible reliable, intense and accurate selection, and a shortening of generation intervals, in those herds and flocks used to

generate genetic gains of many locally adapted breeds that can contribute substantially to developing country livestock improvement. Possibilities include more reliable, lower-cost animal identification, at least in the breeding layer, which can disseminate superior stock to the food-production layer. Can the recent dense linkage maps facilitate the search for genetic traits of economic importance, in order to develop strategies of marker assisted selection (MAS) and marker assisted introgression (MAI), to meet developing country breeding goals? An important question is how best developing countries can strategically employ functional genomic information, given limited financial resources.

33. Developing countries will one day also need to evaluate the possible use of transgenic animals, which may offer opportunities for increased production, productivity, product quality and perhaps even adaptive fitness. However, the technology is currently very costly and inefficient, and applications in the near future seem limited to the production of transgenic animals for use in research, and as bio-reactors. The early difficulties with development of transgenic animals, such as perturbed physiology, physical weakness and impaired health and reproductive performance of the early transgenics with increased growth potential, are increasingly being overcome by research. Transgenic salmon, carp and tilapia carrying growth promoting genes (e.g. growth hormone or anti-freeze protein genes) may be the first genetically modified animals to enter food production on any scale. The potential significance of such technologies for developing countries will need to be kept under review, including technical, societal, political and ethical aspects.

DNA technologies in animal nutrition and growth

34. DNA technologies applied to animal nutrition and health can indirectly support genetic improvement programmes. Various as yet not very advanced applications aim at improving nutrition, through, for example, the use of enzymes to improve nutrient availability, lower feed costs, and reduce wastes in environment. Prebiotics and probiotics, or immune supplements, can inhibit pathogenic gut microorganisms, or make the animal more resistant to them. Recombinant somatotropin (ST) promotes accelerated growth, leaner carcasses, and increased milk production. Immunomodulation can enhance endogenous anabolic hormone activity. In poultry nutrition, possible applications include the use of feed enzymes, probiotics, single-cell protein, and antibiotic feed additives. Plant biotechnology may produce forages with improved nutritional value or incorporate vaccines or antibodies into feeds to protect animals against diseases.

35. The potential applications of biotechnology to rumen microorganisms are many, but technical difficulties are so far limiting its progress. Rumen biotechnology has the potential to improve the nutritive value of ruminant feedstuffs. Methods for improving rumen digestion include the use of probiotics, supplementation with chelated minerals, and the transfer of rumen microorganisms from other species.

IV. THE POLICY AND REGULATORY FRAMEWORK

36. As the FAO Strategic Framework states, policy and regulatory frameworks for food, agriculture, fisheries and forestry, at the international and national levels, are assuming ever more crucial importance in an increasingly interdependent and globalized world economy. In further developing the Global Strategy for the Management of Farm Animal Genetic Resources, and promoting the conservation and sustainable utilization of animal genetic resources, particularly in developing countries, the Working Group may wish to consider the policy and regulatory framework of relevance to animal production, including for animal biotechnology in relation to animal genetic resources, and in order to ensure synergy and co-operation between the various fora responsible for aspects of the policy and regulatory framework.

The Convention on Biological Diversity (CBD)

37. The CBD is a legally binding international instrument, applying to all biological diversity, including agricultural plant and animal biological diversity. It recognizes the sovereignty of nations over their genetic resources, including the capacity to establish conditions of access and benefit-sharing from the use of such resources.

38. FAO and the Conference of the Parties (COP) to the CBD are promoting the development of national plans and strategies for the conservation and sustainable use of agricultural biodiversity, including the integration of agricultural biodiversity sustainable use objectives in sectorial and cross-sectorial plans and programmes. The current and future use of modern agricultural biotechnologies should be considered in such national and international planning.

39. The Second COP, by decision II/15, recognized "the special nature of agricultural biodiversity, its distinctive features, and problems needing distinctive solutions". The Third COP, by decision III/11 established a multi-year work programme on agricultural biological diversity. The Fifth COP reviewed the first phase of this work programme, and, by decision V/5**,** endorsed it and its four elements: assessments, adaptive management, capacity-building and mainstreaming. Each element has operational objectives, a rationale and proposed activities, and identifies ways and means to achieve them, with timed and expected outputs. The decision specifies that the work programme is intended "to build upon existing international plans of action, programmes and strategies that have been agreed by countries, in particular, … the Global Strategy for the Management of Farm Animal Genetic Resources". It also expresses "support the ongoing or planned assessments of different components of agricultural biodiversity, for example, … the *Report on the State of the World's Animal Genetic Resources for Food and Agriculture*, …elaborated in a country-driven manner through consultative processes".

40. In relation to plant genetic resources for food and agriculture, FAO's Commission on Genetic Resources for Food and Agriculture is negotiating the revision of the International Undertaking on Plant Genetic Resources, in harmony with the CBD. The revised Undertaking is expected to become a binding, new international instrument, linked closely to both FAO and the CBD, which will regulate access and benefit-sharing with respect to plant genetic resources for food and agriculture. In this context, governments are negotiating a Multilateral System of Facilitated Access and Benefit-Sharing for Plant Genetic Resources for Food and Agriculture, covering the crops for which countries are inter-dependent and which are crucial for food security.

41. However, farm animal genetic resources have not been the object of much specific consideration within the CBD, and no consideration has been given to arrangements that meet the special nature and distinctive features of the sector.

The CBD Cartagena Protocol on Biosafety

42. The legally binding Cartagena Biosafety Protocol to the CBD was agreed by 130 governments in Montreal in January 2000, and will enter into force after 50 countries have ratified it. It aims at protecting the environment from risks posed by the transboundary transport of living modified organisms (LMOs) created by modern biotechnology. It specifies obligations for the international transfer of LMOs and sets out risk-assessment, risk-management, advance informed agreement, technology transfer, and capacity-building measures.

43. Under the Protocol, Governments will signal whether they are willing to accept imports of agricultural commodities that include LMOs through an Internet-based Biosafety Clearing House. Shipments of such commodities (including animal products) that may contain LMOs are to be labelled. Stricter advanced informed agreement (AIA) procedures will apply to seeds, live fish, attenuated vaccines and other LMOs that are to be intentionally introduced into the environment. In all cases, the exporter must provide detailed information to each importing country before the first shipment, and the importer must then authorize the shipment within a one-year period. While

human pharmaceuticals (including recombinant vaccines) are exempted from the Protocol, it is likely that veterinary pharmaceuticals will be covered. General procedures for risk-assessment are also outlined. Importing countries may require that exporters perform and pay for appropriate risk-assessment. Capacity-building is an important component of the agreement. The Protocol is not to affect the rights and obligations of Governments under any existing international agreements, and the Protocol and the World Trade Organization are intended to be mutually supportive.

Standard-setting under the WTO Sanitary and Phytosanitary Agreement (SPS)

44. The WTO SPS Agreement provides a framework for trade and regulatory measures specifically designed for the protection of human, animal or plant health. It does not apply to the environment *per se*. In as far as the SPS Agreement may apply to measures affecting the international movement of genetically modified organisms, or products, must be based on scientific principles or evidence, or international standards.

45. The Office International des Epizooties (OIE) is recognized as the standard-setting body for animal health. In particular, OIE guidance includes internationally agreed principles and methods for risk-analysis, with specific application in the evaluation of risk for animal diseases, and measures to be taken. The FAO/WHO *Codex Alimentarius Commission* is the standard-setting body for food, including for animal products. The International Plant Protection Convention (IPPC), for which FAO provide the Secretariat, is recognized as the standard-setting body for phytosanitary measures. The IPPC is currently considering how to address genetically modified organisms, and alien species, and *Codex* is considering food products involving genetically modified organisms.

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

46. Any country ratifying the Global Agreement on Trade and Tariffs (GATT) and becoming a member of the World Trade Organization (WTO) agreed to establish minimum intellectual property rights (IPR) standards.

47. Under TRIPS Article 27.3, members must provide various forms of intellectual property, many of which are relevant to animal genetic resources and animal products, including indications of geographical origins, trademark, trade secrets and patents. It provides that member countries must grant patents on all products and processes, except that they may exclude from patenting plants, animals and essentially biological processes, other than micro-biological ones. Provision is made for plant varietal protection under patents or a *sui generis* system, or a combination of these. There is no comparable system for animals. In the animal sector, contractual arrangements, trade secrets and trademarks are so far more important for animals than patenting. Animal-patenting, even in countries where it is permitted, is so far largely a phenomenon of medical and pharmaceutical research, rather than of agriculture, though this may change with the introduction of transgenic production animals.

48. Access by developing country public and private sectors to the IPR-protected enabling technologies used in modern biotechnology is as important as access to the final IPR-protected product, if they are to benefit from modern advances and potentials. Many of the enabling technologies are themselves proprietary, and, in recent years, developed in the private, rather than the public sector. This has changed the relationship of these sectors throughout the world.

V. CONCLUSIONS, AND ISSUES FOR CONSIDERATION BY THE WORKING GROUP

49. management of animal genetic resources, including for the conservation, evaluation, genetic improvement and sustainable use of locally adapted races in developing countries, the Working Group may wish to consider how biotechnology should be reflected in the further development of the Global Strategy, and in the preparation of the *Report on the State of the World's Animal Genetic Resources for Food and Agriculture*. It is clear that focused institutional development and capacity-building will be required, in light of the rapidly developing livestock revolution, and its potential as the vehicle of accelerating economic growth in developing countries, as well as the challenges this will put on Governments to develop and implement adequate policy and regulatory frameworks, where relevant in concordance with their international rights and obligations.

50. **In particular, the Working Group may** wish to consider the following policy issues, in relation to the role of governments in fostering the appropriate and safe application of new biotechnologies to the management of animal genetic resources.

The role of the public and private sectors

51. The new biotechnologies have to date primarily targeted efficiency improvement in livestock production in industrial countries, and have increasingly been developed in the private sector. Such research will necessarily concentrate on species and breeds that can generate a near-term profit, to the exclusion of research on less profitable species or traits.

52. At the same time, there has been limited public investment in animal biotechnology in most developing countries and only modest support for more conventional livestock research and development to improve productivity, nutrition and the health of farm animals. Few livestock breeding programmes exist in developing countries capable of applying molecular breeding and genomics, through marker-assisted selection and gene-assisted selection, as an aid in selection of improved livestock breeds. This situation is unlikely to change without significant investments in the public and private sectors. It should be noted that such programmes will need linkages to strong conventional animal breeding programs, since the interpretation of the genomics data requires information on observed production traits.

53. These factors point to the need for continued and additional public sector investments, especially in developing countries, in developing and applying biotechnologies strategically in the characterization, sustainable use and conservation of animal genetic resources, where local capital is unavailable and where private sector investment is unlikely to be commercially attractive in the short and medium term. Other key public sector research targets include improved diagnostics and therapeutics, particularly vaccines against the major livestock diseases, where information coming from the study of pathogen genomes can help develop more effect disease control. Public sector involvement in reproductive technologies may also have a pivotal role to play, because, in the same manner that crop seed is the delivery mechanism for genetically improved crops, it is likely that domestic animal semen-distribution channels will be the delivery mechanism for trait-enhanced animal genomes, at least where AI systems and markets exist.

54. Governments need to consider how best to support private-public sector collaborations in animal biotechnology research, especially for research oriented at non-commercial markets to generate public goods. It is important that such collaborations be transparent, and that the benefits accruing to both sectors be as equitable as possible. There may be scope for the development of incentive systems, analogous to "Orphan Drug Acts", to facilitate research on livestock research priorities important in the developing world. These applications are unlikely, if left solely to market mechanisms.

Regulatory Systems and Food Safety

55. A key role for governments is to ensure that an open, transparent and effective regulatory system in place, that permits the harmonious development of animal production, particularly in the light of the on-going livestock revolution, so as to maximize production while minimizing ecological risks. This will require balancing natural resource management and environmental considerations, and the use of a variety of policy and economic tools. Many of the factors that need to be addressed will arise from the sheer intensification of production. Others may arise with new products resulting from the use of modern biotechnologies.

56. In developing national frameworks and regulatory systems, governments need to consider how to harmonize these with their international rights and obligations, relevant international agreements to which they are parties, to be consistent with international norms, such as those proposed by FAO, OECD and OIE, and meet international obligations, including the Convention on Biological Diversity and the Cartegena Biosafety Protocol and WTO.

57. There is scope for regional co-operation in the harmonization of regulatory systems, and the development of regional capacities, legal instruments and regulatory procedures.

Intellectual Property Management

58. The use of new, and frequently proprietary, biotechnologies in the management of animal genetic resources will require developing countries more systematically to consider their relevant intellectual property policies and legislation, in order to provide enabling environments for the conservation and utilization of animal genetic resources and for associated public and private sector research and product development. This may be an important issue for member Governments of the WTO, in the review of the TRIPS Agreement. The following issues will be of importance for the future use of new biotechnologies in the management of animal genetic resources:

- harmonization of IP regimes;
- access by the public sector, and by the emerging private sector in developing countries to the enabling technologies required for biotechnological research and development;
- the nature of research exemption under patent regimes, especially for public goods-orientated research;
- the possible use of licensing and/or patent exemptions, for example, to develop generic veterinary products

Capacity-building

59. There is a serious need for capacity-building, especially in developing countries, if new biotechnologies are to be successfully applied to improve the management of animal genetic resources, for the benefit of farmers and consumers. This capacity building needs to be at all levels. There is a need to strengthen competence in the areas of science and technology, but also for regulatory issues and policy analysis.

60. With the rapid changes occurring through the livestock revolution, it is equally important to address the needs of the smallholder livestock owners, particularly women, who bear ultimate responsibility for the management of most of the world's animal genetic resources, and to improve their literacy, education, and access to technology, services and capital.

Communication and public awareness

61. Experience in developing countries has shown that there is a strong public interest in food and health questions arising from the use of modern biotechnologies, and that many groups in society perceive that there are important ethical issues that need to be addressed. This may be part of a broader public debate about the role of science and technology in society, the ethical issues associated with the use of particular technologies, and the risks and benefits associated with specific choices. There is a need for Governments to inform the public as to the benefits and risks of new biotechnologies and their potential role in the management of animal genetic resources. In building national development strategies, and the Global Strategy in general, it therefore appears crucial to address from the beginning the question of public awareness, education and information.