

# **Plenary session 1**

***Biotech in agriculture—challenges  
and opportunities***

# Biotechnology in animal agriculture and poverty alleviation: an NGO perspective

W. Bayer<sup>1</sup> and J. Wanyama<sup>2</sup>

<sup>1</sup>*Agrecol e.V., Rohnsweg 56, D-37085 Göttingen, Germany*

<sup>2</sup>*VetAid, Chokwe, Mozambique*

*E-mail: wb\_bayer@web.de; jacob\_wanyama@yahoo.com*

## Abstract

Biotechnology has only limited potential to alleviate poverty in rural Africa because it does not address the main reasons for poverty such as weak infrastructure, bad governance and unfavourable terms of trade. Looking at the main characteristics of the predominantly small-scale animal farming in Africa, the potentials and limitations for biotechnological applications in food processing, forage improvement, animal breeding and animal health are discussed. Indigenous biotechnology under the control of livestock farmers can be beneficial, whereas—with the exception of some animal health technologies—large-scale and ‘high-tech’ applications of biotechnology have shown little potential to alleviate poverty. Indeed, these applications can have the opposite effect. Rather than pouring an undue amount of human and financial resources into further refinement of advanced biotechnology, African livestock researchers should develop their own research agenda that addresses the real problems of small-scale livestock keepers and poverty alleviation.

**Key words:** livestock systems, indigenous knowledge, food processing, animal breeding, animal health, research prioritisation

## Introduction

In recent years, biotechnology—especially gene technology—has greatly altered agricultural production in industrialised countries. Some biotechnology advocates also claim that these new technologies have a great potential to alleviate hunger and poverty. This is open to debate. Here, we examine these claims with respect to animal agriculture in Africa. After outlining the main reasons for poverty, we broadly characterise smallholder and pastoral livestock keeping. We then consider which biotechnology options in animal agriculture can contribute to alleviating poverty and who controls them. Finally, we indicate alternative research priorities in animal agriculture to contribute to poverty alleviation.

## Reasons for poverty in Africa

Although statistics have their pitfalls, two things are clear: in Africa poverty is widespread and is largely rural. It is therefore understandable that many people think agricultural production must be increased to alleviate poverty. However, a closer look reveals that poverty and famine are rarely due to insufficient production but rather to:

- insufficient access to land and other productive resources
- unfavourable terms of trade for food products, especially for animal products
- remoteness and weak infrastructure (roads, markets, health services, schooling etc.)
- poor health of farmers (HIV/AIDS, malaria etc.)
- civil or international war or conflicts between groups
- external shocks, such as drought
- bad governance, including corruption
- disregard for indigenous knowledge (IK) and local agricultural resource management.

Moreover, female-headed households are much more likely to be poor than male-headed ones. Can biotechnology in animal agriculture help alleviate these reasons for poverty?

## **Crop and livestock farming in Africa: Main characteristics**

In contrast to industrialised countries where farmers are now a small minority—in the European Union 4.5% and in the USA a mere 0.7% (CIA 2005)—farmers make up the vast majority of the workforce in most African countries. For example, 80% in Tanzania, 75% in Kenya, 70% in Nigeria, and even in the industrial giant on the continent, South Africa, the livelihoods of 30% of the people depend on farming. African farmers are not only the majority of the labour force they are also the majority of consumers. They could be called ‘market-oriented subsistence’ farmers.

African farms are generally small labour-intensive operations in which animals serve multiple functions: providing food and raw materials (hides, skins, horns and wool), a savings account, an investment and a means to accumulate capital. If banks are few and far between how can money best be stored—under the bed where it may be eaten by rats or termites or as a productive investment, e.g. in livestock?

Most African farmers still depend primarily on their local knowledge, and this is dynamic. Within their economic possibilities, they are innovators. If they see opportunities they venture into new enterprises such as more intensive goat keeping in parts of Kenya or pig keeping in parts of southern Nigeria. They do this if the circumstances are right; but in many cases it makes economic sense to keep livestock more extensively. Whereas price ratios between meat (beef and mutton) and grain in the North are often more than 10:1, studies in sub-Saharan Africa indicate that the average price ratio of the cheapest grain to live weight is 1:5.6 (McIntyre et al. 1992). Today in parts of Ethiopia, the price of a kg live weight of sheep is almost at par with a kg of grain. Under these economic conditions, there are few ‘potentially profitable’ technical options to ‘improve’ in terms of intensifying husbandry—whether through biotechnological or other means. Additionally, external pressures such as drought or disease are common and are beyond the control of poor livestock keepers.

## **Biotechnology to alleviate poverty?**

Agricultural biotechnology is a loosely used term that includes a wide range of processes that change raw material into something edible or longer lasting. In a broad sense, the use of biotechnology in animal agriculture can be differentiated into four groups:

- food processing, such as fermenting milk and making cheese
- forage additives or fermentation (silage making)
- animal breeding, such as artificial insemination (AI) or embryo transfer (ET)
- improving animal health such as through the production of drugs and vaccines.

Many African societies have long used biotechnology in food processing, especially fermentation. As the souring process weakens pathogens of tuberculosis and brucellosis, drinking sour milk products is safer than drinking fresh non-pasteurised milk. Although men may often do the milking, women usually control milk processing and marketing. In Nigeria, Waters-Bayer (1988) found that particularly the poorer women (from households with few or no cattle) benefited from their application of biotechnology, as women from richer households sold unprocessed milk to poorer women who, in turn, fermented the milk and sold it at a profit in a popular mixture with cooked millet known as *fura da nono*.

Drying or smoking of meat and fish (which may or may not be called biotechnology) also contributes to household income. Meat processed in this way comes from not only domestic but also wild animals. As food processing—including meat processing—is often done by women, these practices can strengthen the position of women and projects building on these practices have indeed helped to alleviate poverty (see for example Lemunye 2002).

Larger-scale processing of milk using standardised cultures, e.g. to produce yoghurt or cheese, often relies on reconstituted milk and the products may compete with indigenous products. Large-scale drying and spicing of venison to make *biltong* as in southern Africa caters primarily for the urban and tourist markets. These larger enterprises create some employment but their contribution to poverty alleviation is minimal.

### **Biotechnology for forage treatment**

Forage conservation includes drying (hay-making), fermentation (silage-making) and feed additives, e.g. urea treatment of straw. In general, if forage can grow year-round it will be of better quality, making forage conservation superfluous. Where forage growth is highly seasonal, forage conservation can offer a way to balance forage supply to animal requirements but moderate weight losses during a dry season are quickly regained through compensatory growth in the next wet season. Hay can be useful for animal survival during a drought, as an extra ratio for sick animals and in urban farming when forage has to be transported to the animals. But in many other smallholder systems, forage conservation is simply not economic, so biotechnology to improve the processes will not benefit them.

Whereas haymaking can make sense for very small animal holdings, silage making and treatment with urea depends on scale. Wetter material is not easy to store; it needs to be covered and kept under anaerobic conditions. Larger units have less waste than smaller pits. Silage and urea-treated straw are better suited for medium-sized or large animal holdings. The biotechnology in these techniques will make little contribution to alleviating poverty among smallholders. Silage and urea-treated straw have a shorter storage life than hay and, because wet material cannot be transported as easily as can dry material, their use is also less flexible.

### **Biotechnology for animal breeding**

Biotechnology in animal breeding includes AI and ET in practical breeding and DNA-level analyses for breed characterisation. There are certainly merits for these techniques. AI was initially developed to reduce the incidence of reproductive disease in animals, but now allows the use of superior male animals on a larger scale than possible with natural service. If breeding or AI centres are available, smallholders, who often prefer keeping female animals, may no longer have to keep entire males. ET makes it easier to introduce exotic animals into countries that have strict quarantine requirements.

There are, however, a number of prerequisites for successful use of AI. Farmers need to recognise whether an animal is in heat; semen and insemination technicians must be within easy reach; liquid nitrogen has to be available etc. This infrastructure is lacking in large parts of Africa and experience with AI has often been disappointing. Even where it seems to work well, there are some dangers. In most cases, the semen is from animals of potentially high production in meat (rapid growth) or milk. Such high-yielding animals are less resistant to disease, more prone to heat stress, require more water than indigenous breeds and need good-quality feed to achieve their production potential. For a dairy cow that produces 6000 to 8000 litres of milk per lactation, straw with a digestibility of 50–55% is not good forage, whereas indigenous breeds that need only to survive as a savings account can manage on this kind of nutrition.

AI can also lead to loss in biodiversity. AI bulls can become semen millionaires, which may be good for the breeders and the AI businesses but has a disastrous impact on genetic variability in indigenous breeds. For example: Holstein Friesian (HF) is the most widely kept dairy cow in the world—currently at least 50 million cows. With current breeding practices, the HF population in the USA will consist of only 60 genotypes by the year 2015 (de Haan et al. 1997). There are currently about 8.5 million HF cows in the USA (WHFF 2005). The push for maximum production means that many bulls are closely related. This leads to an international uniformity among HF dairy cattle. ET will further accelerate this dangerous trend towards uniformity among dairy cattle.

These trends are occurring in the face of the need to conserve animal genetic diversity. The poorer livestock keepers in Africa have to cope with a great variability in ecological conditions and need animals adapted to the local environments. Uniform, high-producing animals cannot serve this purpose. Indigenous animal genetic resources are needed for that purpose (Vilakati et al. 2003)

Although predominantly used among specialised high-yielding breeds, there are exceptions. Nguni cattle semen and embryos are sold in South Africa. The Nguni are known to be well adapted to harsh environment, can cope with low-quality forage, are fairly tick resistant and tolerate a range of diseases (Bester et al. 2003). However, the number of donor animals does not reflect the variability of types found in the larger Nguni cattle population. And this use of biotechnology raises another difficult issue: the Nguni were originally selected by Zulu cattle breeders but the South African Government successfully discouraged the Zulu from keeping Nguni so white commercial farmers conserved Nguni cattle and brought them back to fame. If the Nguni continue to be commercially successful, who should benefit?

The importance of indigenous animals was also highlighted in research in Ethiopia in a study which assigned economic values to the multi-functionality of goats, including their insurance value. The findings suggest that indigenous goats under improved management practices give higher total benefits to the poorer livestock-keeping households than do crossbred goats, even though the crossbred goats produce more milk (Workneh Aleyew 2000).

Thus, it is unlikely that AI and ET can contribute greatly to poverty alleviation in Africa. Both techniques are presently used mainly for high-yielding animals with high demands with respect to feed quality, sanitation and hygiene. These high-input animals are kept on large farms which can out-compete small farms, e.g. in South Africa. If these large farms operate in a labour-intensive way, on-farm employment may contribute to poverty reduction, but this is not always the case. Another consideration is that breeding with the help of advanced biotechnology such as AI and ET takes the control of the breeding process out of the hands of smallholder livestock keepers and puts it into the hands of commercial breeders/firms and breed societies. These modern breeding institutions cater primarily for large farms and generally disregard the specific requirements of small-scale farmers and pastoralists.

A further application of biotechnology is the gene sequencing and modern genetic analysis of livestock genotypes such as recently done for African cattle by ILRI (Hanotte et al. 2002). Findings that prove the uniqueness and high value of indigenous breeds can be a source of pride for poor livestock farmers, but this still does not improve their economic situation. However, the information can help guide public spending on conservation and use programmes.

### **Biotechnology for animal health**

Modern biotechnology can be used for diagnosis (e.g. to differentiate closely related disease agents) and to develop veterinary medicines and vaccines. Ethno-biotechnology in veterinary medicine involves various types of preparations of leaves, bark, roots etc. The recipes for traditional medicines are often not in the public domain; they are the exclusive knowledge of traditional healers, who charge for their services. The process of developing and producing modern drugs and vaccines is not under the control of small-scale farmers or pastoralists—it is an external service, also provided at a price. Experience has shown that, if vaccination can prevent the loss of animals, using these external services is an investment which also small-scale livestock keepers and pastoralists are willing to make.

To control disease in many parts of Africa, however, the problem is not how to develop new, more effective diagnostic methods, vaccines or drugs. Rather, it is their availability at the local level. For this, more effective organisational structures for the delivery of veterinary services are more urgent than further refinement of diagnostic methods or the development of better vaccines. More effective services also include community-based animal health workers, who live within the livestock-keeping communities and provide the local animals with inexpensive ‘first aid’.

### **The way forward**

Biotechnology has only limited potential to alleviate poverty, because it cannot remove the main reasons for poverty which are: political instability, bad governance, insufficient infrastructure and services, disregard of indigenous knowledge, and insufficient recognition by government and researchers that smallholder and pastoral farming is a necessary and valuable part of animal agriculture. Research efforts therefore should be directed into: 1) better understanding the existing animal agriculture systems and IK; 2) developing necessary infrastructure; and 3) improving services, rather than into biotechnology developments that require a sophisticated infrastructure (Waters-Bayer and Bayer 2004). The challenge is to find better ways to address the problems of the vast majority of African livestock keepers and to help develop their potential to respond to opportunities and adapt to change. This is the real scientific revolution that African livestock keepers—and scientists—need. And this is the revolution that many NGOs working in Africa are seeking to bring about.

### **References**

- Bester, J., Matjuda, L.E., Rust, J.M. and Fourie, H.J. 2003. The Nguni: a case study. In: Vilakati, D., Morupisi, C., Setshwaelo, L., Wollny, C., von Lossau, A. and Drews, A. (eds), 2003. *Community-based management of animal genetic resources*. FAO (Food and Agriculture Organization of the United Nations), Rome, Italy. pp. 45–68.
- CIA (Central Intelligence Agency) 2005. *The world factbook*. <http://www.cia.gov/cia/publications/factbook>. CIA, USA.
- de Haan, C., Steinfeld, H. and Blackburn, H. 1997. *Livestock and the environment—finding a balance*. European Commission, Brussels, Belgium.
- Hanotte, O., Bradley, D.G., Ochieng, J.W., Verjee, Y., Hill, E.W. and Rege, J.E.O. 2002. African pastoralism: Genetic imprints of origins and migrations. *Science* 296:336–339.
- Lemunyete, L. 2002. Developing camel products. *LEISA Magazine* 18 (4):20–21.
- McIntyre, J., Bourzat, D. and Pingali, P. 1992. *Crop–livestock interaction in sub-Saharan Africa*. The World Bank, Washington, DC, USA.
- Vilakati, D., Vilakati, D., Morupisi, C., Setshwaelo, L., Wollny, C. von Lossau, A. and Drews, A. (eds). 2003. *Community-based management of animal genetic resources*. FAO (Food and Agriculture Organization of the United Nations), Rome, Italy.

- Waters-Bayer, A. 1988. *Dairying by settled Fulani agropastoralists in central Nigeria*. Wissenschaftsverlag Vauk, Kiel, Germany.
- Water-Bayer, A. and Bayer, W. 2004. Research to alleviate poverty in the face of industrialization of livestock production. In: Owen, E., Smith, T., Steele, M.A., Anderson, S., Duncan, A.J., Herrero, M., Leaver, J.D., Reynolds, C.K., Richards, J.I. and Ku-Vera, J.C. (eds), *Responding to the livestock revolution*. Nottingham University Press, UK. pp. 191–208.
- Workneh Ayelew. 2000. *Do smallholders benefit more from cross-bred (Somali × Anglo-Nubian) than from indigenous goats?* Cuvillier Verlag, Göttingen, Germany.

# **Agricultural biotechnology for poverty alleviation: One more arrow in the quiver!**

C. Seré and J.E.O. Rege  
*International Livestock Research Institute, P.O. Box 30709  
Nairobi 00100, Kenya*

## **Abstract**

Agriculture is the largest contributor to the economies of many African countries, generating more than half of the annual Gross Domestic Product (GDP) for many of these countries. The livelihoods of most rural and low-income communities in these countries are to a large extent based on agriculture. While global availability of food has increased, 35% of the 800 million poor of the world live in Africa, and face food insecurity. And yet agriculture constitutes, for the majority of these poor, the primary means of survival and livelihood sustenance. Agricultural biotechnology, which comprises a wide range of biological disciplines, offers enormous potential to speed up the development of plant varieties with pro-poor traits such as drought tolerance, pest resistance or tolerance, higher yields, increased nutritional value, among others. Similarly in animal production there is substantial opportunity for development of vaccines and diagnostics targeting diseases which constrain livestock production in developing regions of the world. In addition, genetic markers can aid breeding of livestock for important traits such as disease resistance, improved product quality as well as improved productivity. However, to date, the innovation essential to achieve these improvements has largely remained a technology of the North. While biotechnology does not provide the 'silver bullet' for poverty alleviation, it does enhance the effectiveness of other disciplines such as plant breeding, integrated pest and nutrient management, and livestock breeding, feeding and disease management. Importantly, because use of these technologies, as any other, is associated with risks, African scientists need to have access to the knowledge and scientific infrastructure to assess these risks and to contribute to better informed public discussions of the opportunities and challenges of these technologies. Should biotechnology be a preserve for the rich? Can developing nations afford to ignore the potential of biotechnology? Rather than debate on whether biotechnology can meet the needs of the poor, this paper argues that being just one aspect of a complex set of inter-related interventions required to enhance the contribution of agricultural development to poverty alleviation, discussions should be had on how best to take advantage of the opportunities and manage the risks associated with these technologies, for the benefit of the poor. There is need to explore new ways to build the capacity of the public sector - notably national governments in developing countries and development partners, as well as to tap into the resources of the private sector - to enable the continent come up with African solutions to the problem of poverty alleviation. This will require closer collaboration and transfer, between the North and the South, of appropriate biotechnology and the management of bio-safety issues. Thus, risk assessment has to be an integral part of biotechnology research and development. Africa missed out on the 'Green revolution', and should not miss out on the 'Gene revolution' as well.

## **Introduction**

Africa remains the world's poorest continent. Most African countries have economies characterized by slow and declining growth, low and declining per capita incomes, and declining participation in the global markets. The limited exports from Africa are predominantly low value commodities, while hunger, malnutrition and poverty remain widespread in the continent. An estimated 25 to 30 million children are malnourished and the World Health Organization estimates that 54% of child mortality in African countries is associated with malnutrition. About one-third of the children

in sub-Saharan Africa are stunted because of poor diet, while thousands of people die each day from hunger. Another one-third of the continent's adult population, about 200 million, are food insecure and are forced to live below their full potential because they lack the energy and full health to function at their best. If current trends continue, by 2010 Africa would account for nearly two-thirds of the undernourished people in the world. This vicious cycle of hunger and poverty needs to be broken.

Agriculture is the most important economic activity in Africa and offers the means to reverse these trends and to stimulate wider economic growth. This is because 70% of the people in sub-Saharan Africa live in rural areas and are dependent on agriculture for their livelihoods. However, African agriculture is performing dismally: crop production is the lowest in the world. Yields of basic food grains, for example, are one-fifth those of China. Fertiliser use in Africa is 8 kg per hectare; in Latin America, it is over 60 kg per hectare, and in Asia, over 100 kg per hectare. Only 4% of Africa's farmland is irrigated; in the Middle East and Asia, the figures are 29% and 34% respectively. The Green Revolution has had very little effect on the continent's agriculture in the last decade or so. In Asia and Latin America, between 60% and 80% of crop area is planted with modern varieties; in Africa, the figure is between 20% and 30%. As a result, Africa imports more than 25% of the grain it consumes. Ironically, up to 40% of the continent's harvest is lost to post-harvest damage. Moreover, due to rapid increase in human population, there is need to produce more food on less land, with less water, while conserving the environment.

Although the continent's GDP has improved over the years, the proportion of people living in absolute poverty is higher than it was in the 1980s and 1990s (UNDP 2005). While the economies expanded by 3% per annum between 1990 and 2004, the proportion of Africa's population classified as 'absolute poor' increased by 2 percentage points every year. It is estimated that it will take sub-Saharan Africa until 2012 just to restore average incomes to their 1980s levels (UNDP 2005). There is very limited opportunity for poor people to participate meaningfully in the economy as either producers of goods and services or as suppliers of labour.

## **Potential role of biotechnology**

Science and technology are recognized globally as drivers of increased wealth and continuously improving standards of living. The role of science and technological innovation in economic change and sustainable development is receiving attention at national, regional and international levels. There is ample evidence that economic advances in the developed and newly industrializing countries are results of technological and organizational innovations (Mokyr 2002). Scientifically and technologically advanced countries have become continuously wealthier, and their rates of growth have not slowed significantly over time (Pritchett 1995). These countries have succeeded by reinvesting a growing percentage of their gross domestic product (GDP) in further advancement of research. Translation of research into new, more efficient modes of production has brought dramatic benefits. Technological innovation is associated with turning scientific knowledge into products and processes: putting new technologies and their products on the market and incrementally modifying and adjusting them to respond to socio-economic conditions (Juma 2005). Some of the East Asian countries that capitalized on these opportunities have transformed themselves into middle- or high-income economies (Nankani 2005). The key to success has been to focus on improving skills in solving existing and new problems, putting a premium on continuous learning.

Application of knowledge through new technologies will provide opportunities for improving developing country economies and the well-being of the people, and offer a means for increasing agricultural production, improving human health, and addressing environmental degradation. In

this way it creates economic competitiveness and enhances industrialization. However, these benefits can only be achieved if countries formulate appropriate policies to facilitate the development and utilization of requisite human and financial resources and appropriate infrastructure and functioning support institutions.

In agriculture, advances in biotechnology have resulted in improved research leading to: drought resistant crop varieties; increased pest and disease resistance in crops and livestock; new, refined diagnostics and vaccines for livestock diseases (e.g. Foot-and-Mouth disease and East Coast fever); rapid propagation of clean planting material (e.g. flowers, vegetables, bananas etc.).

Current constraints to the research and application of biotechnology in developing countries include: lack of policies; lack of human and financial resources; lack of public and private investments at levels that can make a difference; absence of systems for the delivery of technologies to potential users; lack of awareness, leading to misconceptions about the potential of, and risks posed by, biotechnology.

## **What is the evidence that biotechnology can benefit developing countries?**

There is now ample evidence to demonstrate the opportunities offered by biotechnology in developing economies, and from which Africa should learn. Two examples are given here, from China and India.

### ***China***

In the early 1980s Chinese leaders decided that science and technology (S&T), especially biotechnology, would be one of the drivers to improve the agricultural sector, and committed substantial public investments in biotechnology, e.g. rice biotechnology (mapping rice genome) and rice breeding (to develop hybrid rice varieties), cotton biotechnology for insect resistance, production of value-added horticultural crops, and complimentary innovations such as use of nematodes for biological pest control leading to increased export markets. Currently, hybrid rice accounts for over 30% of rice in China and over 5 million small farmers are growing Bt-cotton on 1 million hectares of land. Use of biological control has reduced pesticide use on cotton by 30% nationally. Today, horticultural exports are expanding. Thus, through a deliberate effort to revolutionize agriculture, China is making quantum leaps in agricultural productivity and sustainability improvements. The country is now moving to the 'post-Green Revolution era' towards becoming an industrialised nation. As has been pointed out above, an efficient agricultural sector ensures food security and enables industrial development.

### ***India***

India's National Dairy Development Board (NDDB) oversees improved dairy production by millions of smallholder livestock producers, including many women. Success in using increased milk production to generate increased income on a daily basis is the result of investments in S&T targeting: improved feeding and nutrition of dairy cattle; vaccines to control endemic diseases; and improved animal genotypes and their delivery to farmers. The NDDB organizes delivery of services (including biotechnologies) at the points of milk collection. Payments for technical services are affordable and deducted from milk payments to smallholders. In the 1960s and 1970s India regularly had famines and was a net food importing country. The Green-Revolution in crops and the White Revolution in dairy production are the result of investments in S&T and infrastructure, especially irrigation and communications and the formulation and implementation of supportive public policies (prices, trade etc.) to encourage farmers to go into production. India is now using its productive agricultural sector to guarantee food security and is moving towards

industrialisation. Although there are still millions of people living in poverty in South Asia the trends in India and some of its neighbours are heading in the right direction, with millions moving out of poverty each year.

## **Livestock and poverty impacts: Role of science and technology**

Livestock products have for generations been known to be a pathway for income generation by the poor. There is also evidence that small-scale livestock income plays a disproportionately high role in the income sources of poor rural women and other disadvantaged groups in most parts of the developing world (von Braun and Pandya-Lorch 1991). Demand for food products of animal origin is expected to increase dramatically in developing countries (Delgado et al. 1999). The consumption of meat and milk, for example, is projected to grow at 2.9% and 2.7% per annum respectively, between the late 1990s to 2020. This 'livestock revolution' is also expected to result in increases in demand for pork (60%), poultry meat (80%) and red meat (50%) by 2020, with developing countries accounting for two-thirds of global meat consumption and more than half of global milk consumption. The trends in consumer demand for livestock products are driven primarily by growth in human population, increases in income and urbanization and associated changes in consumption patterns. In East Asia, even lower income rural households have begun to shift increasingly to food consumed outside the home, as they have elsewhere in urban areas of the developing world, which typically involves consuming larger amounts of higher quality animal products (Gale et al. 2005).

In Africa, livestock production remains largely in the hands of small-scale farmers who collectively keep approximately 70% of total livestock units. Given this concentration of livestock production, the potential for a viable industry built around these producers provides a significant opportunity for them to escape poverty while supplying the consumer demand. Diseases sharply reduce the productivity of livestock. Conservative estimates of annual losses of US\$ 4 billion in meat and milk production have been reported for sub-Saharan Africa—representing approximately one-fourth of the total value of livestock production. These losses have a significant impact both on food security and poverty. Apart from the zoonotic diseases (such as tuberculosis and Avian influenza) that also afflict poor people, who are in constant contact with different livestock species, there are also a number of other livestock diseases (such as Foot-and-Mouth disease, contagious bovine pleuropneumonia, Rift Valley fever and African Swine fever) which preclude livestock and livestock products of the poor from markets.

Concerns about animal disease transmission keep global livestock to less than 10% of the value of global production, whereas it is 40% for fish, a commodity with equally great food safety issues and where trade is overwhelmingly from the developing to the developed countries (Delgado et al. 2003). Implications of animal health issues on trade are, today, receiving increasingly high prominence at a time when developing country producers are recognizing expanded opportunities for international trade in livestock and livestock products. The stakes in effective disease control in developing countries and reliable 'point of transaction diagnostics for disease-free-status certification' have risen considerably as producers in many of these countries have become aware of the possibility of export as an addition to what had been relatively less attractive domestic markets. This is affecting not only those producers immediately capable of supplying export markets, but is also having an impact on all other producers in these regions. The negative impact of border closures in the Middle East due to an outbreak of Rift Valley fever (RVF) on the price of livestock in the remotest areas of East Africa (Nin-Pratt et al. 2005) is a case in point.

Technological change in animal disease control with associated policy reforms could bring about a major shift in the distribution of world livestock production in favour of developing countries with abundant labour and land resources (Rich 2005). Beyond the development and application of technologies (such as vaccines and diagnostics) to improve animal health and food safety for trade, there is also need for market and policy research to demonstrate the high costs of compliance with traditionally accepted norms and to evaluate the costs and benefits of alternative options for reducing risk of disease transmission, some of which may be more appropriate to particular developing country situations.

## **Livestock biotechnologies and poverty: Opportunities for Africa**

### ***Animal health***

Building on a good understanding (based on cumulative knowledge from within and without the continent) of the biology of livestock (hosts), disease vectors and pathogens, research on animal health in Africa should focus on the development of technologies to address the constraints posed by major livestock diseases in the continent to reduce losses (so as to secure the livestock assets), improve productivity and facilitate access to markets (domestic, regional and global).

As pointed out above, diseases such as contagious bovine pleuropneumonia (CBPP), rinderpest, Newcastle disease (ND), RVF, trypanosomosis, gastrointestinal nematodes, tick-borne diseases (such as East Coast fever (ECF), Heartwater and African Swine fever (ASF)), *inter alia*, continue to present significant challenges for livestock keepers particularly the poor small-scale farmers. These diseases affect intensification, productivity and trade. In terms of interventions, while regulatory measures and cost-effective technologies for disease control have been effective in developed countries, this has not happened in Africa.

Rapid advances in classical and molecular epidemiology, molecular biology, immunology and such new sciences as genomics, bio-informatics and proteomics are providing new technological options that can be applied for the control or eradication of animal diseases in Africa. Some of these technologies are on the threshold of being developed into effective new tools such as diagnostics and vaccines, and investment is required in applied research to facilitate this process. For some diseases, for instance, ND (vaccines), ASF (diagnostics) and ECF (vaccines) progress towards developing effective products is at stages where probability of success is high with only modest investments. Conversely, CBPP (vaccines and diagnostics) requires a two-pronged approach: a quick-win option to improve current vaccines and diagnostics and medium- to longer-term research to generate improved and more sustainable 'new generation' products.

Most, if not all, of the investment in research and development (R&D) relating to the above diseases has been obtained from public sources in developed countries with a fair amount of up-stream activities undertaken in the North. However, many of these diseases, e.g. ASF, ECF, CBPP, RFV, trypanosomosis, among others, have little relevance to the developed world and are unlikely to be of continuing interest to development partners in the North, except for scientific curiosity. In the case of ECF vaccine research, a substantial international effort has contributed to the progress toward proof-of-concept for a vaccine. Nonetheless, funding for completion of current and subsequent steps of R&D is not guaranteed. Similarly, research on short-term options for CBPP has benefited from some 'external' funding but there has not been adequate and sustained funding to increase the likelihood of success.

It is increasingly becoming imperative for Africa not only to define the continent's R&D agenda for livestock health but also to mobilize the required resources, including allocation of national resources, to implement the agenda. Recent technological advances, many already being successfully applied to address human and animal health problems in the North and, indeed in some developing countries in Asia and Latin America, provide opportunities which Africa needs to capture. The level of commitment will be needed both to support quick win options that will translate into products and strategies (such as the Pan-African Rinderpest Campaign initiative, improving the ND vaccine, developing ASF diagnostics, improving current CBPP vaccines and diagnostics) in the shorter term, but also to support medium- to longer-term R&D initiatives.

For some of the disease constraints, there are existing technologies previously developed and working for similar diseases or those developed for the same diseases but under different settings (e.g. pathogen strains, delivery infrastructure etc.) elsewhere. In these cases focus should be on the adaptation of these existing technologies to optimize their use or to enhance their strategic relevance to a wider range of users and production systems. In marginal areas, animal health constraints will need to be addressed through a strategy that combines disease control (through development of appropriate vaccines and diagnostics) and use of appropriate livestock genotypes (which combine productivity and adaptability to local environmental stresses). Conversely, in the rapidly changing sub-sectors, such as smallholder dairying in higher potential areas where exotic breeds and crossbred livestock are predominant, technological interventions need to focus on reducing disease risks and improving animal productivity taking advantage of the more benign environmental conditions.

### **Genetic improvement of livestock**

There is little known about the genetic diversity in indigenous livestock breeds and potential for genetic improvement in developing countries. To improve utilization of these resources, information is needed on: how much diversity exists in specific populations; uniqueness of populations; what breeds/populations to conserve; what conservation methods to apply; and how the genetic diversity in indigenous breeds can be utilised to generate greater benefits for the poor livestock keepers, without compromising the diversity. There are no working models for livestock genetic improvement in low input systems in developing countries, nor true equivalents of the seed systems that have been critical for the success in crop production. Furthermore, given the time required to effect genetic change in livestock, it is even more critical that development of breeding objectives take into account ongoing evolution in the production systems, hence there is need to understand the system changes and the key drivers. Indeed, it is now well accepted that, while *ex situ* approaches can support conservation of livestock diversity, a sustainable strategy has to be one in which the diversity is dynamically maintained as a functioning part of the production system. This underscores the need for strategies and breeding technologies that take the issues of systems changes and links to 'genotype-evolution' into account. Progress in livestock species genome sequencing is opening new ways for the identification and improved understanding of economically important traits and genes. These developments are catalysing the emergence of new tools (e.g. bioinformatics and gene expression units, such as micro-arrays) the applications of which represent new opportunities with significant potential for gene discovery research. These are common technologies for both vaccine research (e.g. antigen identification) and genetic improvement. These new technologies are providing newer, faster and possibly more efficient ways to achieving the same objectives (e.g. a specific breeding goal) and exemplify 'value addition' to, rather than replacement of, 'traditional technologies', by new technologies. There are many international efforts focusing on gene discovery for productivity traits in livestock. Efforts in Africa should focus on adaptive traits needed for the unique circumstances in the continent (e.g. disease resistance), adapting and applying methodologies developed in the North to speed the realization of desired outcomes and achievement of impact at local levels. For diseases such as

helminthosis, which affect livestock (especially small ruminants) across the world, there are good prospects for global partnerships.

### **Feeds and nutrition**

Most African livestock production is under traditional systems in which feeding and nutrition is dictated by climatic factors. Thus, there are large cyclical swings in feed availability and quality closely following the rainfall patterns. During a large part of the year, there is inadequate feed and the nutritive quality of whatever is available is generally too poor to support animal maintenance, much less production; a common problem is low protein and high fibre content. There are a number of biotechnologies which use micro-organisms to 'bio-process' feeds/foods with a view to improving nutritional quality, including digestibility. Important feed ingredients such as maize and soya which are commonly used in monogastric feeds can also be nutritionally enhanced through genetic manipulation. Specifically, marker-based technologies are increasingly used to understand the genetic diversity in forages and in food-feed crops; the technology also has potential use in food-feed crops in ways that ensure that food yields and qualities are preserved or enhanced while at the same time improving the feed attributes.

### **Institutional arrangements to develop and deliver technologies**

For both vaccine development and genetic improvement, lack of a working institutional arrangement to facilitate technology development and delivery can be a major impediment. The nature of these technologies requires the engagement of a large number of stakeholders, usually necessitating complex partnership arrangements, not made any easier by need for biosafety and intellectual property management. Consortia or networks of strategic international collaborators (including public research institutions in the North and the private sector) and national partners are almost invariably essential for success. Given the cost involved in putting together such consortia, it is advisable that, while the initial goal may be quite specific, their designs allow the flexibility to address other similar technological constraints. This is the basis of the concept of 'generic research platform' whose aim is to ensure that the best practices (at both technical and institutional levels) can be applied more broadly, for example, in the case of livestock, to multiple diseases, animal genetic resources and in other regions of the world under different settings. The nature of these platforms may vary considerably and will depend on the scope, focus on addressing a national or an international problem. An example of an innovative institutional arrangement of this type is a new initiative known as the Biosciences eastern and southern Africa (BecA).

BecA, an ILRI-NEPAD (New Partnership for Africa's Development) initiative, is a joint venture involving NEPAD, ILRI and stakeholders of countries in the sub-region. It is providing a platform of shared state-of-the-art research facilities and capacity for application of biosciences in agriculture. The generic nature of the technologies and the partnerships and institutional arrangements are allowing ILRI to expand the impact of its expertise—in such areas as immunology, molecular epidemiology and animal genetics—and research outputs focusing on what gets done rather than just what ILRI does, including availing research capacity beyond what is needed just for livestock research. The vision is to enable African scientists and institutions to become biotechnology innovators as well as technology users. This is to be accomplished through the conduct of biosciences research and innovation targeted at issues affecting Africa's development, while accessing and using the best of science available worldwide. The shared research platform hosted by ILRI is open to African scientists—including those from universities and national research institutes—and researchers from the broader international community willing to collaborate with African partners to address African agricultural constraints.

Another example is a recent initiative known as the Global Alliance for Livestock Vaccines and Diagnostics (GALV), the purpose of which is to establish and support public private partnerships

that will speed the development and delivery of vaccines and diagnostic products for use by poor livestock keepers in low income developing countries. It will do this by focusing on promising leads and aiming to develop these into useful pro-poor animal health products. The initiative is borne out of the recognition that academia and the donor community alone lack the expertise, experience and key technology required to turn promising leads, such as vaccine candidates, into new products for less developed countries through the complex and highly regulated development process. However, the private sector, whether big pharmaceutical companies or small biotechnology companies, usually do not have incentive to take on the expensive research and development programmes themselves for markets that are unlikely to provide a return on investment.

## Conclusion

Economic development in Africa will, of necessity, have to be initially linked to agriculture (broadly defined to include crop, livestock, forestry and fish). Staple crops and livestock are the most likely to promote economic growth in the continent. To date, public sector investment in biotechnology in Africa has led to few products. This has, in part, been due to lack of viable private sector partners who are able and willing to take new products to markets. There is also a critical need for innovative public/private sector partnerships which will help link public investments in R&D with private 'know-how' and technology for product development. However, similar to what is happening in Asia and Latin America, there is great opportunity for Africa to mobilize science to create wealth for its people and achieve higher economic growth. This requires: strategic investments in science and technology, with time scales in the range of 20 years (from discovery to delivery); investment in physical, human and financial resources to build indigenous science and technology capacity (human and infrastructure); political will to commit the required resources to develop the requisite capacity and to provide a supportive policy environment; vibrant private sector, including facilitating emergence of a critical mass of innovative and enterprising smallholder farmers. In the short-term, some benefits are possible in Africa from previous discoveries, when adapted and adopted in the African context (e.g. Bt cotton). In the longer-term, there will have to be local innovations that focus on critical constraints in Africa (e.g. endemic diseases of livestock).

For biotechnology to create wealth, at least the following must happen: there has to be a clear definition of priorities/targets (participatory research can assist in target identification); the best of *relevant* science regardless of where it comes from around the world must be mobilized and adapted to address the identified targets (a mechanism for proactive identification of new, relevant science must be put in place); and a critical mass of resources (human and financial) must be available for the targets to be met. In addition, the local private sector and communities need to be involved in product development and commercialization so that new technologies can be both affordable and accessible. Further, more delivery mechanisms have to be developed so that new (bio) technologies are accessible to those who need them. Lessons from the rapid uptake of mobile phone technology in developing countries are pertinent: if a new technology is useful and the price is right, the spread is almost unstoppable. Clearly, biotechnology is not a substitute for other technologies, but is an additional arsenal which should be used as and when appropriate to increase the pace of agricultural development. It is simply another arrow in the quiver!

## References

- von Braun, J. and Pandya-Lorch, R. 1991. Income sources of malnourished people in rural areas: A synthesis of case studies and implications for policy. In von Braun, J. and Pandya-Lorch, R. (eds), *Income sources of malnourished people in rural areas: Microlevel information and policy implications*. Working Papers on Commercialization of Agriculture and Nutrition 5. IFPRI (International Food Policy Research Institute), Washington, DC, USA.

- Delgado, C., Rosegrant, M., Steinfeld, H., Ehui, S. and Courbois, C. 1999. *Livestock to 2020: The next food revolution*. Food, Agriculture and the Environment Discussion Paper 28. IFPRI (International Food Policy Research Institute), Washington, DC, USA, FAO (Food and Agriculture Organization of the United Nations), Rome, Italy, and ILRI (International Livestock Research Institute), Nairobi, Kenya.
- Delgado, C., Wada, N., Rosegrant, M., Meijer, S. and Ahmed, M. 2003. *Fish to 2020: Supply and demand in a changing world*. IFPRI Book Series. IFPRI (International Food Policy Research Institute), Washington, DC USA. 226 pp.
- Gale, F., Tang, P., Bai, X. and Xu, H. 2005. *Commercialization of food consumption in rural China*. USDA Economic Research Report 8. USDA (United States Department of Agriculture), Washington, DC, USA. 37 pp.
- Juma, C. (ed). 2005. *Going for growth: Science, technology and innovation in Africa*. The Smith Institute, London, UK.
- Mokyr, J. 2002. *The gifts of Athena: Historical origins of the knowledge economy*. Princeton University Press, Princeton, New Jersey, USA.
- Nankani, G. 2005. Knowledge for productivity-led growth. In: Juma, C. (ed), *Going for growth: Science, technology and innovation in Africa*. The Smith Institute, London, UK. pp. 23-32.
- Nin-Pratt, A., Bonnet, P., Jabbar, M.A., Ehui, S. and de Haan, C. 2005. *Benefits and costs of compliance of sanitary regulations in livestock markets: The case of Rift Valley fever in the Somali Region of Ethiopia*. ILRI (International Livestock Research Institute), Nairobi, Kenya, and The World Bank, Washington, DC, USA.
- Pritchett, L. 1995. *Divergence, big time*. World Bank Policy Research Working Paper 1522. Background paper for World Bank Development Report 1995. The World Bank, Washington, DC, USA.
- Rich, K. 2005. *Spatial models of animal disease control in South America: The case of Foot-and-Mouth disease*. PhD dissertation, University of Illinois at Urbana-Champaign, Urbana, Illinois, USA.
- UNDP (United Nations Development Programme). 2005. *International cooperation at a crossroads: Aid, trade and security in an unequal world. UNDP Human Development Report 2005*. UNDP. New York, New York, USA.



# Applications of genetic engineering for livestock and biotechnology products<sup>1</sup>

A.A. MacKenzie

*Canadian Food Inspection Agency  
59 Camelot Drive, Ottawa, Ontario K1A 0Y9, Canada*

## Summary

The influence that biotechnology is having and will have in the future on animal health is now being realised well beyond the researchers' laboratories. An examination of the evolution of reproductive biotechnologies is presented. The latest techniques allow for the use of transgenic farm animals as sources of biologically activated proteins, bio-pharmaceuticals, as donors in xenotransplantations and for further research in gene therapy, all of which are important applications in human medicine. The beneficial applications of embryo transfer include disease control, transboundary movement of livestock and the provision of sexed sperm and sexed embryos. Although cloning of livestock is a multi-step complex process and the technology needs further evaluation, benefits such as the multiplication of desired traits and the conservation of animal germplasm clearly are substantial benefits. With the application of transgenesis in livestock, the benefits of disease resistance, improved meat, milk and wool quality and protein production in milk and meat (biofarm animals) are major benefits. It is predicted that biotechnology-derived vaccines will become common in animal health programmes where they can be shown to have improved efficacy and safety compared to conventional products.

When carrying out risk assessments for genetically engineered animals, conventional techniques and tools will be useful but it is important to be aware that because limited data are available, the actual hazard identification will be a considerable challenge. As the new technologies with their adherent applications evolve, standard setters and regulators will be faced with the challenge of moving in parallel with technological advances.

In response to a questionnaire sent to Delegates of OIE Member Countries, only 40% of respondents indicated that their animal health regulatory administrations have the capability of conducting risk assessments on biotechnology derived animals or products. Likewise, 20% of respondents do not consider the guidelines for risk analysis adequate to help carry out an import risk analysis on biotechnology-derived animals or products. Furthermore, 50% of respondents do not have a regulatory framework in place to govern cloning, transgenic production or products of biotechnology such as vaccines. Public perception in relation to cloning and biotechnology-derived animals will present considerable challenge to Member Countries with 79% reporting no public support for cloning and 52% reporting biotechnology-derived animals perceived as controversial.

There is considerable work that must be initiated by both Member Countries and the OIE to allow appropriate progression in the very important field of biotechnology and animal health.

---

<sup>1</sup>This paper was first presented as technical item II at the 73<sup>rd</sup> General Session of the International Committee of the World Organization for animal health (OIE) on 23 May 2005 in Paris, France. The PowerPoint presentation given during the 4<sup>th</sup> All Africa Conference on Animal Agriculture in Plenary Session 1: Biotech in Agriculture—Challenges and opportunities, held in Arusha, Tanzania, 21–24 September 2005 emphasised items, particularly in the questionnaire, which would be of special interest to the African region.

## Introduction

The continued challenge that OIE (World Organisation for Animal Health) member countries currently face with the globalisation of agriculture is not limited to the animal health issues arising from infectious and zoonotic diseases. The fact that reproductive biotechnologies combined with genetic manipulations have developed animals with varying traits poses a new and different kind of challenge to the OIE and the scientific community. We are entering an era which will see more widespread use of reproductive technologies combined with gene manipulations to develop livestock and aquatic animals that can propagate superior or desired traits. Central to the idea of genetic improvement of domestic animals by selective breeding or cross breeding, the world today is presented with the scientific opportunity through assisted reproductive technologies and genetic manipulations that could have a positive impact on public health and well being.

The techniques of molecular biology provide great potential for the production of important medical and agricultural products. The production of biotechnology-derived drugs and vaccines relies heavily on recombinant DNA technology for the design of useful products. The production of recombinant proteins in 'transgenic animal bioreactors' is another application of modern biotechnology in agriculture. Preceding the release of any biotechnology-derived animal into the environment, extensive safety evaluations are carried out to verify if it is safe according to currently available expertise. However, as the risk assessments rarely evaluate the risk as zero, biotechnology products in agriculture are regulated, and the purpose of the existing safety guidelines is to assure that these products pose a minimal risk to public health and the environment. The purpose of this OIE Technical Item II is to discuss the technology that is used to develop biotechnology-derived animals, the applications in the fields of animal health and diagnostics, the delicate balance between regulatory frameworks and the ethics of the science, sound risk assessments based on current science and to give member countries an overview of the applications of biotechnology in the global context.

## Techniques

The past four decades have witnessed the commercial adaptation of four generations of reproductive biotechnologies, particularly with cattle. It started with artificial insemination and moved to a second level when *in vivo*-derived embryos were harvested and transferred. The third generation consisted of the *in vitro* fertilised embryos, sex sorting sperm, ovum pick-up and cloning and finally we are at a stage when we are using functional deletion and addition of specific genes to the offspring's genome through transgenesis, combined with powerful molecular biology techniques of siRNA (small interfering RNAs) and the use of viral vectors. Recently there have been combinations of transgenics being propagated by somatic cell nuclear transfer techniques, thus taking reproductive biotechnologies a step further.

Embryo transfer of *in vivo*-derived embryos was a huge step to increase the propagation of germplasm of the desired trait. Compounded by the success of multiple ovulation and embryo transfer technology (MOET) there was an upsurge in the transfer of bovine embryos, especially in North America, where 35% of the 538, 312 embryos available worldwide were transferred in 2002 (Thibier 2003). The *in vitro* embryo production system was instrumental in bringing a spurt in embryo transfer activities across the globe. The data collected in 2002 showed that more than 80,000 *in vitro* produced (IVP) embryos were transferred. The IVP embryos provided a window of opportunity for 'invasiveness' in terms of techniques to assess the embryo characteristics. This included obtaining an embryo biopsy to determine prenatal sex. The use of biopsies for prenatal genetic diagnosis, blastomere assessment for cloning and for other purposes is still used in many settings.

Production of identical offspring with somatic cell nuclear transfer (cloning) was a big step forward, as earlier embryos were split before transfer to achieve the same result. As early as the 1980s Steve Willadsen showed that embryonic cells from 8–16 cell embryos could be used for embryonic cell cloning, but the birth of ‘Dolly’ in 1996 proved that it was possible to reprogramme adult differentiated cells. Nuclear cloning is, however, currently an inefficient process with a success rate of 6–10% of embryos transferred to the cattle resulting in a healthy offspring. There are concerns related to higher losses in pregnancy, placental dysfunctions, incorrect epigenetic reprogramming and post-natal complications. These abnormalities may be epigenetic errors that can be corrected during gametogenesis. While the technology is still not beyond the infancy stage, the confidence among the researchers that this could result in genetic preservation and disseminating genetic gains, begs attention both from the scientific point of view and other issues related to ethics, welfare and product safety. In contrast to the cloned animal in which some of the anomalies are viewed, the offspring of clones produced following sexual reproduction appear phenotypically normal. Because nuclear cloning can also result in physiologically normal animals, it is anticipated that the initial commercialisation of this technology will focus on producing small numbers of high value animals for breeding purposes, and possibly also transgenic dairy animals capable of producing valuable pharmaceuticals in their milk.

The first transgenic livestock were produced almost 20 years ago by micro-injection of DNA into the pronuclei of zygotes. Pronuclear micro-injection of DNA has been the standard method for producing transgenic animals. However, this is now being replaced by more efficient methods based on somatic nuclear transfer, which also permit targeted genetic modifications. Lentiviral vectors and siRNA technology are also being used for transgenesis. Research has been focussing on chimera generations via injection of pluripotent cells in early pre-implantation embryos or blastocysts. Transgenesis has also been achieved in livestock by the culture of spermatogonia and their transplantation into recipient males. A novel approach is the use of active siRNA; the simplicity of this has facilitated adoption of this method to generate permanent or transient knockouts for specific genes. The combination of siRNA and lentiviral vector technology may provide enhanced gene transfer efficiency and specificity in gene knockouts for cattle. Transgenic farm animals are important in human medicine as sources of biologically active proteins, biopharmaceuticals, as donors in xenotransplantation and for research in gene therapy.

## **Applications**

For ease of explanation, this part will deal with the applications of technologies in current use that have gained importance in the last three or four decades. The first consideration is the embryo transfer technology which is still the backbone of any assisted reproductive biotechnology. The embryo may be produced *in vitro* and may be manipulated or cloned, yet it still has to be transferred to a recipient to bear the offspring.

### **Embryo transfer: *in vivo* and *in vitro* embryos**

The embryo transfer industry grew rapidly in the late 1970s, both in terms of the number of practitioners and in the number of donors flushed. North America has continued to be the centre of commercial embryo transfer activity with more than 190,000 bovine embryos transferred annually. The importance of follicle wave dynamics and methods for the synchronisation of follicular wave emergence has simplified the means by which superovulation might be achieved, resulting in increased embryo production per unit time. Some of the applications that are of clear benefit to the embryo industry are:

### **Disease control**

Several large studies have now shown that the bovine embryo does not transmit infectious diseases, if recommended precautions such as those mentioned in the OIE *Terrestrial animal health code*

(the *Terrestrial code*) (OIE 2004a) are followed. In fact the International Embryo Transfer Society (IETS)—an international embryo biotechnologists association—has categorised disease agents based on the risk of transmission by a bovine embryo. None of the infectious diseases studied have been transmitted by *in vivo*-produced bovine embryos, provided embryo handling procedures were done correctly. Consequently, it has been suggested that embryo transfer could be used to salvage genetics in the face of a disease outbreak, which could also be a useful option in the establishment of disease free herds.

### **Transboundary movement of livestock**

The intercontinental transport of live animals costs a lot, whereas an entire herd can be transported, in the form of frozen embryos, for much less. Added benefits of frozen embryos over live animals include reduced risk of disease transmission, reduced quarantine costs, a wider genetic base, the retention of genetics within the exporting country, and adaptation. The procedures recommended by the IETS for embryo handling that have been endorsed by the OIE greatly reduce the possibility of infectious agents being transferred in *in vivo* derived embryos. However, there is still some risk of infectious agent transmission with *in vitro* derived, abattoir retrieved oocytes, and those with zona breaching.

The development of effective methods of freezing embryos has made embryo transfer a much more efficient technology that is no longer dependent on the immediate availability of suitable recipients. Researchers have directly addressed the question of using IVP as a substitute for *in vivo* production of embryos by conventional embryo transfer procedures. However, it is unclear whether IVP is a realistic alternative to conventional superovulation and embryo transfer for production of embryos from reproductively healthy cattle.

### **Sexed sperm and sexed embryos**

Determination of the sex of pre-implantation bovine embryos with the use of the polymerase chain reaction (PCR) is also commonly used in some situations. However, the removal of the biopsy from the embryo requires a high level of operator skill; embryo biopsy is an invasive technique that results in the invasion of the integrity of the zona pellucida and results in some reduction in the viability of the embryo. The flow cytometric technology used to separate X- and Y-bearing sperm into live fractions has been improved over the last 10 years. With a purity of 90%, about 10 million live sperm of each sex can be sorted per hour. In both cases there is a potential to establish embryo banks to obtain the progeny of choice in any setting. This can reduce the unnecessary cost of producing large number of embryos and transfers related to that.

The science and practice of artificial embryo production (*in vitro* produced and *in vivo* derived) has given us insight into the early embryonic period and the later foetal and neonatal development. By studying in greater detail the aberrant features of artificially produced embryos, one may find that these very same mechanisms lie behind the so-called 'normal' foetal and neonatal loss. This will not only help to improve the efficiency but also provide us with the possibility of critically analysing the more invasive procedures (like biopsy, pronuclear injections etc.) that precede the embryo transfer.

### **Nuclear transfer cloning**

Cloning livestock following somatic cell nuclear transfer involves multiple steps, each with potential for disturbing development of the embryo and foetus, and affecting health during adulthood. For these reasons, the technology needs to be thoroughly evaluated to fully appreciate the longer-term consequences on the animals produced. However the application of this technology, although limited at the present time, shows promise of increased benefits:

### **Multiplication of desired traits**

Cloning could enable the rapid dissemination of superior genotypes from nucleus breeding flocks and herds, directly to commercial farmers. Genotypes could be provided that are ideally suited for specific product characteristics, disease resistance or environmental conditions.

### **Conservation of animal germplasm**

Cloning technology can help salvage the germplasm of indigenous species that are near extinction, including intra-species nuclear transfer procedures which can be used to rescue genes from endangered species.

### **Research model**

Animals can be cloned for research to provide a basic research model of genetically identical individuals, reducing variability in the outcome of experiments.

### **In association with transgenic applications**

Cloning can provide a rapid way to increase the population or number of transgenic animals permitting the testing of genetic stability with reduced progeny intervals.

An increasing body of international data indicates that the major abnormalities in clones are probably epigenetic in nature and do not appear to be transmitted to offspring, even when male and female clones are mated. However, there is the need for molecular confirmation of this observation which will be important in providing confidence in large-scale breeding applications of genetically elite cloned livestock. Despite the current limitations in cloning, milk or meat from cloned livestock does not appear to be materially different from that of conventionally bred animals (FDA/CVM 2003). If the acceptability and utility of this emerging technology are to be improved, it is important to understand the biology behind nuclear cloning to improve the health and viability of the cloned animals produced and their surrogate mothers.

## **Transgenesis**

Application of transgenesis in livestock has been instrumental in the development of animals that are: resistant to diseases, have improved meat, milk or wool quality, can increase proteins in their milk or meat (biopharm animals), or which have characteristics which are environmentally friendly. The production of recombinant proteins is one of the major successes of biotechnology. Milk, egg white, blood, urine and seminal plasma can be sources of recombinant proteins. Numerous experiments have shown that the prediction of the expression of transgenic proteins is possible to a limited extent. The purification of proteins from milk or other body fluids is not too difficult except for those present in blood. The available techniques to produce pharmaceutical proteins can be used to add nutraceuticals to milk and to improve carcass quality or meat composition of livestock or farm animals. Antibodies seem to be the kind of proteins that will be most frequently used, as they could be a good alternative to antibiotics for some infectious diseases.

The application of techniques related to the production of recombinant proteins in milk has reached a certain degree of maturity but there is much to do yet. The combination of recent advancements in reproductive technologies with tools of molecular biology opens the horizon to a new era in transgenic biotechnology. The growing amount of data from the human genome project will certainly inspire intense genome sequencing in livestock and somatic cloning will pave the way for the introduction of novel transgenics in livestock.

## **Xenotransplantation**

The possibility that xenotransplantation may offer an opportunity to have an alternative to organ transplantation from human donors is very attractive to researchers. The application of transgenic

technologies can alter donor animals, so that the stimulus to induce immune rejection in recipient patients is much reduced. The research in this area is focussed on the pig genome, to make pig organs and tissues more compatible to humans. Disruption of the gene causing hyperacute rejection response (Galactose alpha 1, 3 galactose), by gene targeting in genetically modified (GM) pigs, has been achieved and further use of nuclear transfer for propagating them is in progress. This provides immense hope for patients awaiting transplantation and needing organs or tissues to fight major medical conditions such as heart disease and diabetes.

## **Vaccines**

There are three major considerations in the registration of vaccines for use in animals and biotechnology-derived vaccines have both advantages and disadvantages in each of these areas. The OIE *Manual of diagnostic tests and vaccines for terrestrial animals* (the *Terrestrial manual*) (OIE 2004b) and the *Terrestrial Code* (OIE 2004a) make mention of these conditions. However, considerations are described in different ways in different regulations, but the key elements that must be demonstrated in any vaccine are efficacy (not worthless, satisfactory potency), purity (not contaminated) and safety (not dangerous or harmful to the environment, humans or animals).

Efficacy is usually determined following a challenge of vaccinated and control animals using a specific disease model. The observed protection from clinical disease or death following a specific dose and route of vaccination is used to formulate a claim for the vaccine product. Subsequent batches or serials of vaccine are compared to the original batch used in this study, and a potency test is developed to enable the prediction that each serial with a satisfactory potency test will lead to the same level of protection observed in vaccinated animals in the study. Biotechnology-derived vaccines which incorporate antigens which are known to be targets of a protective immune response and which present those antigens in a manner to maximise the required type of immune protection may enhance efficacy. These vaccines may also have more thermostable antigens, perhaps plant-derived proteins, allowing this vaccine potency to be maintained in the absence of a cold chain in tropical countries. In many disease models though, the use of live attenuated disease organisms in vaccination leads to the highest level of immune protection, even if there are some residual safety concerns.

Purity is determined by ensuring that the organisms and ingredients used to make the vaccine are not contaminated with other micro-organisms, or toxins, or perhaps prions. With many biotechnology-derived vaccines, the platform expressing the antigens of interest is well characterised, and the vaccine can often be produced with a minimal risk of contamination. Growing more conventional pathogens for the production of killed vaccines often requires the use of materials of animal origin in order to maximise the expression of the antigens of interest, which increases risks of contamination of the vaccine. However, plant-made vaccines grown in open fields risk having undefined contamination such as weeds, fungus or insects, but this may not impact on the safety of the product if administered orally.

Safety is probably the most important potential advantage of biotechnology-derived vaccines. DNA vaccines which do not require oil-based adjuvants are safer to administer by humans and are also safer for animals including fish than some conventional vaccines. Vectors for recombinant vaccines can be selected to minimise any possibility of reversion to virulence which sometime occurs with live attenuated vaccines. Conventional vaccines may also contain toxic elements that are not completely inactivated or removed by the manufacturing process and which may not be necessary for stimulating immune protection in the animal. Removal of these toxins in biotechnology-derived vaccines improves product safety to both humans handling the vaccine or eating vaccinated animals and to the animals themselves. The use of genetically-modified vectors

or plants in the environment does raise some concerns of environmental safety which may be different than the use of conventional live attenuated vaccines. Steps must be taken in the approval process of these products to evaluate and to minimise all of the potential concerns which can be identified.

Ultimately, the usefulness of vaccines will be determined by their availability. This, in turn, is affected by elements such as cost of production and acceptance of a role of vaccination in disease control programmes. Biotechnology-derived vaccines will become common in animal health programmes in cases where they can be shown to have improved efficacy or safety when compared to conventional products, and if they are available.

## **Risk assessment considerations**

Advances in genetic engineering continue to emerge at an accelerating pace, enhancing the potential for its applications. It is anticipated that commercialisation of farm animals genetically engineered to produce unique traits will soon be a reality. Both transgenic and cloned animals raise potentially new concerns about food safety, human health, animal health (and welfare) and the environment. Therefore there is a pressing requirement to develop methodologies to adequately assess the safety of such animals.

To this end, there is a need to bring together scientists, regulators, international organisations, such as OIE, FAO and WHO and other stakeholders to identify and review the science-based data and concerns relevant to science-based risk assessment and management of genetically engineered animals released into the environment. These expert consultations could help design research to solve problems and to identify and develop appropriate management practices to minimise risks associated with genetically-engineered animals.

Risk assessment for genetically engineered animals is not much different than that for conventional animals but because of limited data, general uncertainties and unknowns, the paramount point of a risk assessment, hazard identification, remains an enormous challenge for the risk assessors.

The major difference resides in the identification of hazards from potential genetic abnormalities (phenotypically or genotypically) that can be of possible harm. Since animals exhibiting grossly undesirable effects are likely to be eliminated during commercial development, the areas of concern are those caused by subtle dysregulation of genes.

The following questions, arising from these subtle genetic abnormalities, will render risk assessment more complex and probably, in early stages, result in a high degree of uncertainty:

- How would one detect them?
- How would subtle genetic hazards from genetically-engineered animals differ from the gene dysregulation arising in conventional animals?
- How frequently do they occur compared to conventional animals?
- Would these genetic hazards pose a risk?
- Should they pose a risk, how to measure risks if they happen?

In addition to risk assessment, risk analyses pertaining to genetically-engineered animals involves risk communication (throughout the entire process) and risk management. These other components of the analysis must also take economic, ethical and societal as well as animal welfare factors into account.

At this early stage of the development of genetically-engineered animals, assessments will be based upon data extrapolated from related studies done with other genetic modifications or in other species, often utilising material supplied by the companies marketing the products. In this context, governments must maintain the public trust at a high level through impartiality, integrity and transparency of its decision making process with respect to genetically-engineered animals and their products.

It is perhaps reasonable to believe that in the coming years, the analysis of the risks associated with genetically-engineered animals will become routine, as it has for the import of conventional animals and animal products. Ongoing improvements in the techniques of genetically-engineered animal production will likely reduce the incidence of animal health problems now recognised, and the continued growth of the body of knowledge will reduce the uncertainties that now exist. In addition, new techniques and increased experience will also improve methods of risk management.

Conversely, future research and new techniques will perhaps identify hitherto unknown problems for the risk analyst to deal with—as old issues get resolved, new ones may emerge. It is safe to assume that the challenges presented by animal biotechnology for the risk analyst and other regulatory staff will continue for some time to come.

## **Regulatory framework**

New technologies need to be controlled by guidelines or regulations so as to maximise benefits and minimise risks to humans, animals and the environment. The acceptance of agricultural biotechnology will depend on whether consumers see an obvious personal and societal benefit in the new products. However, the role of the regulators is also to assist the public make an informed decision by critically evaluating the data related to the technology and determining the level of risk to the consumer, the animal population and the environment. Development of legislation and the regulatory provisions do not move as quickly as advances in science. In most cases the regulations are developed to address the concerns of the consumers and society and to provide a much needed level of protection.

Since transgenesis and cloning are relatively new scientific techniques, transgenic animals are new organisms for which there is limited information. The issues associated with the regulation and biosafety of transgenic animals pertain to environmental impact, food safety, animal health and welfare, trade and ethics. To regulate this new and powerful technology predicated on limited background information is a challenge not only for the regulators but also for the developers of such animals, who strive to prove that the animals are safe and merit bio-equivalency to their conventional counterparts. In principle, an effective regulatory sieve should permit safe products, while forming a formidable barrier for those assessed as posing an unacceptable risk.

The regulation of products derived from biotechnology can be based on the principles used for conventionally produced animals. Regulations and standards for determining a responsible use of animal biotechnology in food and agriculture are based on principles that take into account criteria such as benefits and risks, scientific basis of biotechnology and effects on the environment, and must also consider animal welfare and social acceptance (Howard et al. 2001). Transgenic animals may be viewed as most acceptable if the end result of the genetic manipulation applied is to provide better quality of life for humans, or to provide ‘environmentally friendly’ alternatives to ‘factory farms’. The regulations that each country uses to safeguard the public, the animal population and the environment from unintended effects of novel products or technologies are specific to the way the regulatory framework is established. For example, some countries may

have an approach to regulate the technology, while others may be regulating the products of biotechnology. Some of the salient considerations for sound regulation developments are:

- high standards for human and animal health and welfare
- development of clear standards and guidelines for assessments
- provision of sound scientific basis to evaluate associated risks
- consultation and involvement of stakeholders in the development of regulations
- maintenance of genetic diversity and conservation of environment
- building upon existing regulations.

The existing scenario allows us to extrapolate the standards and to develop regulations from the continued research and work being done by international organisations such as the OIE, FAO and IETS. IETS was founded in 1974 with 82 charter members representing researchers, academics and veterinary practitioners. A growing majority of the IETS membership is composed of basic researchers representing government, industrial or academic institutions, including human medicine. However, IETS has played a very important role in the dissemination of basic and applied information, allowing for the rapid growth of the embryo transfer industry in the 1980s and 1990s. In particular, the Import/Export Committee of IETS now referred to as the Health and Safety Advisory Committee (HASAC) has been instrumental in gathering and disseminating scientific information on the potential for disease control by the use of bovine embryo transfer. There was the round table meeting on sanitary issues related to embryo transfers between the IETS and OIE in 1985 (See reference ), resulting in the drafting of sanitary procedures for the international movement of embryos in the OIE *Terrestrial code*, and the International Embryo Movement Symposium, sponsored by IETS. These events along with continued close collaboration between IETS and OIE have made the international movement of cattle embryos possible. In this regard, the manual of the International Embryo Transfer Society (Thibier 1998) has become the reference source for sanitary procedures used in export protocols. Today most of the international movement of embryos is based on the recommendations of IETS many of which are endorsed by the OIE *Terrestrial code* and the procedures documented in the manual of IETS are the red book letters for the regulators.

International organisations such as FAO have conducted workshops as technology has progressed, including 'Gene-based technologies' (FAO/IAEA 2003), and the expert consultation on genetically modified animals held in Rome (FAO/WHO 2003). The recommendations of these consultations and workshops form a solid basis for development of regulations in general. The forums where the food safety of cloned animals and international movement, identification and traceability of the embryos is discussed and standards recommended, takes place under the auspices of different subcommittees of IETS.

In essence the regulatory framework may be very specific to the region and the country, yet the consideration is more towards harmonising the approach, so as to facilitate sharing of safety information and to help countries prevent the spread of disease or infections through germplasm. The OIE has therefore an important role to play as a standard-setting body in accordance with its mandate under the WTO-SPS Agreement.

## Questionnaire

The OIE sent a questionnaire to the delegates of all 167 OIE member countries to assemble baseline information on some questions relating to applications of biotechnology for livestock and animal health products. Responses were received from 91 countries, including a broad cross section of member countries from all regions. The results are presented as Appendices I and II and are summarised in this preliminary analysis. The questions and tabulated summary results

will be posted on the OIE website. This information will provide a useful baseline to identify topics for discussion in international reference groups and standard setting bodies such as the OIE, and international organisations such as Veterinary International Cooperation for Harmonisation (VICH), and IETS.

The responses to this survey have illustrated a number of common interests and concerns for animal health regulatory agencies and for livestock producers and consumers. There are many potential opportunities for international collaboration in establishing technical standards and risk assessment procedures for these technologies. It is clear that OIE and affiliated standard setting bodies will have a key role to play in facilitating the dissemination of information on development of appropriate risk-based regulatory standards, approval processes and certification procedures for biotechnology-derived livestock and animal health products.

The OIE formed a Biotechnology Working Group in 1989 that was active until November 2000. After the group stopped functioning it was decided that its work would be incorporated into other *ad hoc* groups which would be assigned to study specific topics. It is possible that this survey and the review papers in the Scientific and Technical Review will help to identify issues for further discussion, including some topics which might be referred to *ad hoc* groups for in depth analysis and recommendations.

The following 91 countries provided a response to the questionnaire: Algeria, Andorra, Angola, Argentina, Australia, Austria, Azerbaijan, Belgium, Benin, Bhutan, Bosnia and Herzegovina, Brazil, Brunei, Burkina Faso, Cambodia, Canada, Colombia, Congo (Dem. Rep.), Costa Rica, Cote d'Ivoire, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Eritrea, Estonia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Guinea Bissau, Hungary, Iceland, India, Japan, Kazakhstan, Kenya, Kuwait, Latvia, Lithuania, Luxemburg, Madagascar, Mali, Mauritania, Mauritius, Mexico, Moldavia, Morocco, Myanmar, Namibia, Nepal, Netherlands, New Caledonia, New Zealand, Nicaragua, Norway, Pakistan, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Serbia and Montenegro, Slovakia, Slovenia, Spain, Sudan, Swaziland, Sweden, Switzerland, Taipei China, Tanzania, Thailand, Togo, Trinidad and Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, United States of America, Uruguay, Venezuela and Zimbabwe.

### **Definitions**

Eighty-one of the ninety-one OIE member countries (89%) responding to question 1 agreed with the proposed definitions as applicable to livestock biotechnology. Agreement was consistently high across all geographical areas. Where respondents did not agree with the definitions, the most highly suggested sources for definitions were the Cartagena Protocol on Biosafety to the Convention on Biodiversity and Codex Alimentarius in its Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003).

### **Risk analysis**

Fifty-three of the eighty-nine (60%) member countries that responded to question 3 reported that the animal health authority in their country is not capable of conducting risk analysis on biotechnology-derived livestock and biotechnology products. The two main reasons reported for not performing risk analysis on these commodities are the absence of training (53%) and the lack of knowledge (26%).

Eighty-four per cent (75 of 89) of the respondents indicated that they do not have a dedicated unit conducting risk analyses pertaining to biotechnology commodities (question 4). Risk analyses are being conducted by the epidemiology and surveillance unit in 29% of cases, and 37% of

respondents answered that other units conduct these risk analyses. Only 9% use an external consultant to conduct a risk analysis on these commodities. Forty-five per cent of the Asian respondents indicated that risk analyses are conducted by the Import-Export unit.

In question 5, the major factors identified by the animal health authorities as being considered when determining the risk associated with these biotechnology commodities are respectively: food safety (26%), animal health (26%) and environmental impact (23%).

Only 25% of the member countries have conducted (or received a request to conduct) a risk analysis on biotechnology commodities, for a total of 33 requests (question 6). In 52% of the cases (17 cases out of 33), the risk analyses were conducted (or were requested to be conducted) on biotechnology products, whereas only 3 were requested on cloned animals and 7 were requested on transgenic animals. Most of the requests are from countries in the Americas (13 cases).

Only 29% (25 out of 89 respondents) of the member countries are willing to make their risk analysis document available for peer review or for public consultation, using official government publication as the main means of dissemination. Peer reviews are mainly conducted internally (45%) within the veterinary services. Only European member states reported having risk analyses peer reviewed internally (37%) or externally (36%) at approximately the same proportion.

Seventy-seven per cent of the respondents (63 of 81) to question 8 considered that the 'Guidelines for risk analysis' contained in the OIE *Terrestrial code* were adequate to carry out an import risk analysis on a biotechnology commodity. Forty-four per cent of the member countries (8 of 18 respondents) that considered that these guidelines were not adequate are from the Americas and these member countries also reported receiving most of the requests (39%) to conduct a risk analysis (question 6).

### **Regulatory framework**

Sixty-four per cent (58 of 91) OIE member countries responding to question 9 reported that they did not produce biotechnology-derived animals or biotechnology-derived products for use on animals. Out of the 31 countries responding 'yes' to this question (note that 2 did not answer), 14 countries (45%) are European Member States.

Respondents to question 10 reported having capabilities in the following fields: cloning (17%), transgenic production (20%) and products of biotechnology for use in animals such as vaccines and/or drugs (28%). Thirty-five per cent of respondents to the questionnaire did not provide an answer to this question.

Approximately half of the OIE member countries responding to question 11 reported having a regulatory framework in place to govern the use of a biotechnology commodity (44 reported having a framework out of 89 respondents). Sixty-two per cent of European members and fifty-three per cent of countries from the Americas responding to question 11 indicated that they have a framework in place to govern the use of such commodities

### **Research**

Slightly less than half (47%) of the 91 responding OIE countries to question 12 reported that there is research being conducted in their country into biotechnology-derived animals and products, including vaccines and drugs. At 64%, Asia had the highest percentage of responding countries engaged in animal biotechnology research activities, followed closely by Europe at 59%, the

Middle East at 50%, the Americas at 41%, and Africa at 25%. Although this question covers a wide variety of activities, the results indicate that this is an active area of research.

### **Animal vaccines**

Forty out of eighty-nine responding OIE Member countries (44%) to question 13 reported that they produced or used animal vaccines in their countries that are biotechnology-derived. This may include experimental products that are not currently licensed for general use, since the question did not ask that countries specify the licensing or marketing authorisation status of products.

Twenty-six of the forty countries who replied said that they produced or used viral vectored vaccines (29% of the responders to this question) which included antigen(s) from unrelated organisms. Sixteen countries (18%) reported using bacterial vectored vaccines which include antigen(s) from unrelated organisms. Twenty-two countries (25%) reported using vaccines which have deleted antigen(s) to differentiate infected animals from vaccinates (DIVA). Twenty-six (29%) of countries produced or used vaccines which included recombinant proteins, and six countries reported using DNA vaccines (7%). One other biotechnology-derived vaccine was reported but not described in the questionnaire.

Eighty-seven countries responded to question 14 which asked how biotechnology-derived vaccines and/or drugs are generally perceived by the public in their countries. Twelve countries (14% of responders) indicated they were perceived as safe, twenty-five (28%) said they were controversial, and thirty-nine countries (45%) said that the public was mostly unaware of biotechnology-derived vaccines. Eleven other countries (13%) made a variety of other comments in response to this question.

When examining public opinion research done in individual countries, it seems unlikely that approximately half of the population in the responding countries are truly 'aware' of biotechnology-derived veterinary vaccines and drugs. People can be unaware of products but, when asked, think the products are safe and well-regulated. They can also be aware and think the products are not safe and are not well-regulated. These questions are often separated in detailed polling for that reason.

### **Technologies**

Sixty-six per cent of the member countries that responded indicated that they do not have livestock cloning and/or transgenic animal production facilities in their country. However the European region indicated that 50% of the 34 countries that responded (69%) do have livestock cloning and/or transgenic animal production facilities in their country.

Out of the 91 countries that responded to the questionnaire, 64 (72%) indicated that biotechnology-derived animals or their products are not permitted in the food or feed supply in their country. In the Asian region 43% indicated that biotechnology-derived animals or their products are permitted in the food or feed supply in their country.

Eighty-three countries (83 of 91) responded to question 17; 79% of the responders indicated that there was no public support for cloning of animals. Of the 12% that indicated there was public support for cloning of animals the main purpose chosen was for the rescue of endangered species and generating stem cells (36% each).

When member countries were asked if there are transgenic animals present in their country, out of the 54% that replied to the question 79% indicated that there were no transgenic animals in their country. Of the 24% that indicated there were transgenic animals in that country, 45% reported that the animals were generated for biopharmaceuticals.

Of the 89 countries that responded to this question, 56% indicated that their country does not have the laboratory capacity to identify and detect transgenes in the food/feed supply. However, in the Asian region 50% and the European region 65% indicated that they do have the laboratory capacity to identify and detect transgenes in the food/feed supply.

### **Public perception**

Like question 14 above, this question asked people what they thought about the way other people think. Overall the evidence suggests that, as with most applications, people use the same case-by-case risk/benefit analysis when evaluating these new techniques. In public opinion research on biotechnology, there is a clear hierarchy of support for various applications, and often health applications are at the top of the list, and food applications are nearer to the bottom.

For questions 14 and 20 that asked about public perception, it is very difficult to meaningfully compare data from different public opinion questionnaires (i.e. different questions asked under different circumstances). These questions measure the perception of government workers about public opinion (as opposed to actually measuring public opinion). There are some efforts to create agreed-upon methodology and questions (e.g. by international groups of academics and researchers) and it could be useful if OIE could be informed of the expertise of these people.

### **Conclusion**

In conclusion the OIE may wish to consider further work as follows:

- 1) Development of a definition for biotechnology which can be agreed by OIE member countries.
- 2) Development of standards and guidelines for research on containment and environmental release of live attenuated vaccines in animal health.
- 3) Development of recommendations and guidelines for use of DNA vaccines in food animals.
- 4) Development of guidelines and recommendations for somatic cell nuclear transfer cloning—guidance for interspecies cloning, recognising that this process has the potential to increase the possibility for transmission of diseases between species.
- 5) Develop objective criteria for assessing the health of embryos and animals derived from cloning, and associated safety of cloned livestock and their products.
- 6) Develop policy guidelines for exclusion of unapproved animals and products from the livestock population, and segregation from the feed and food supply.
- 7) Develop identification, testing, and certification guidelines for international trade in livestock animals and their products for which biotechnology procedures have been used to confer disease resistance.
- 8) Incorporate standards into relevant OIE documentation such as the *Terrestrial manual* and the *Terrestrial code* and the companion standards for aquatic animals.
- 9) Development of guidelines relevant to the application of nanoscience/nanotechnology as it relates to animal health.

### **Acknowledgements**

I wish to express my sincere appreciation to Drs Gifford, Kochhar, Hutchings and Moreau for the technical expertise they provided in the preparation of the paper. I also wish to thank Mr Sacha Gagnon for the questionnaire layout, data entry and analysis.

## References

- USFDA/CVM (US Food and Drug Administration/Centre for Veterinary Medicine). 2003. *Executive summary of animal cloning: A risk assessment*. <http://www.fda.gov/cvm/Documents/CLRAES.pdf>. Accessed on 6 April 2005.
- FAO/IAEA (Food and Agriculture Organization of the United Nations/International Atomic Energy Agency). 2003. *Application of gene-based technologies for improving animal production and health in developing countries*. International symposium, 6–19 October 2003, Vienna, Austria. <http://www-pub.iaea.org/MTCD/Meetings/PDFplus/cn110frep.pdf>. Accessed on 15 May 2006.
- FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organisation). 2003. *Safety assessment of foods derived from genetically modified animals including fish*. Joint expert consultation, 1–21 November 2003, Rome, Italy.
- Howard, T.H., Homan, E.J. and Bremel, R.D. 2001. Transgenic livestock: Regulation and science in a changing environment. *Journal of Animal Science* 79(Supplement):1–11.
- OIE (World organisation for animal health). 2004a. *Terrestrial animal health code*. 13th edition. OIE, Paris, France.
- OIE (World organisation for animal health). 2004b. *Manual of diagnostic tests and vaccines for terrestrial animals*. 5th edition. OIE, Paris, France.
- Thibier, M. 1998. Introduction. The establishment and evolution of the International Embryo Transfer Society: Personal observations. In: Stringfellow, D.A. and Seidel, S.M. (eds), *Manual of the International Embryo Transfer Society*. 3rd edition. Savoy, Illinois, USA. pp. 1–6.
- Thibier, M. 2003. More than half a million bovine embryos transferred in 2002: A report of the IETS Data Retrieval Committee. *IETS Newsletter* 21(4):12–19.
- OIE (World organisation for animal health). 1985. Round Table meeting on sanitary problems related to embryo transfers, Paris, France, 9 December 1985. *Rev. Sci. Tech. Office International des Epizooties* 4(4):843–913.

## Appendix I. Regional membership of OIE member countries.

| Africa                   | Americas                 | Asia                              | Europe                 |
|--------------------------|--------------------------|-----------------------------------|------------------------|
| Algeria                  | Argentina                | Australia                         | Albania                |
| Angola                   | Barbados                 | Bangladesh                        | Andorra                |
| Benin                    | Belize                   | Bhutan                            | Armenia                |
| Botswana                 | Bolivia                  | Brunei                            | Austria                |
| Burkina Faso             | Brazil                   | Cambodia                          | Azerbaijan             |
| Burundi                  | Canada                   | China (People's Rep. of)          | Belarus                |
| Cameroon                 | Chile                    |                                   | Belgium                |
| Central African Rep.     | Colombia                 | India                             | Bosnia and Herzegovina |
| Chad                     | Costa Rica               | Indonesia                         | Bulgaria               |
| Comoros                  | Cuba                     | Japan                             | Croatia                |
| Congo                    | Dominican (Rep.)         | Korea (Republic of)               | Cyprus                 |
| Congo (Dem. Rep. of the) | Ecuador                  | Korea (Dem. People's Republic of) | Czech Republic         |
| Côte d'Ivoire            | El Salvador              |                                   | Denmark                |
| Djibouti                 | Guatemala                | Laos                              | Estonia                |
| Egypt                    | Guyana                   | Malaysia                          | Former Yugoslavia      |
| Equatorial Guinea        | Haiti                    | Mongolia                          | Rep. of Macedonia      |
| Eritrea                  | Honduras                 | Myanmar                           | Finland                |
| Ethiopia                 | Jamaica                  | Nepal                             | France                 |
| Gabon                    | Mexico                   | New Caledonia                     | Georgia                |
| Ghana                    | Nicaragua                | New Zealand                       | Germany                |
| Guinea                   | Panama                   | Pakistan                          | Greece                 |
| Guinea-Bissau            | Paraguay                 | Philippines                       | Hungary                |
| Kenya                    | Peru                     | Singapore                         | Iceland                |
| Lesotho                  | Surinam                  | Sri Lanka                         | Ireland                |
| Libya                    | Trinidad and Tobago      | Taipei China                      | Israel                 |
| Madagascar               | United States of America | Thailand                          | Italy                  |
| Malawi                   | Uruguay                  | Vanuatu                           | Kazakhstan             |
| Mali                     | Venezuela                | Vietnam                           | Kirghizistan           |

|                          |                      |                          |
|--------------------------|----------------------|--------------------------|
| Mali                     | Venezuela            | Kirghizistan             |
| Mauritania               |                      | Latvia                   |
| Mauritius                |                      | Lithuania                |
| Morocco                  | <b>Middle East</b>   | Luxembourg               |
| Mozambique               |                      | Malta                    |
| Namibia                  | Afghanistan          | Moldavia                 |
| Niger                    | Bahrain              | Norway                   |
| Nigeria                  | Iran                 | Poland                   |
| Rwanda                   | Iraq                 | Portugal                 |
| Sao Tomé and<br>Principe | Jordan               | Romania                  |
| Senegal                  | Kuwait               | Russia                   |
| Sierra Leone             | Lebanon              | Serbia and<br>Montenegro |
| Somalia                  | Oman                 | Slovakia                 |
| South Africa             | Qatar                | Slovenia                 |
| Sudan                    | Saudi Arabia         | Spain                    |
| Swaziland                | Syria                | Sweden                   |
| Tanzania                 | Turkey               | Switzerland              |
| Togo                     | United Arab Emirates | Tajikistan               |
| Tunisia                  | Yemen                | The Netherlands          |
| Uganda                   |                      | Turkmenistan             |
| Zambia Zimbabwe          |                      | Ukraine                  |

## APPENDIX II

### Results of responses to questionnaire on biotechnology

*Do you agree with these proposed definitions as applicable to livestock biotechnology?*

*Proposed Definitions:*

- A) “biotechnology” means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.
- 1 B) “living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of:
- in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or*
  - techniques involving the fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.*

|  | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|--|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes                                      | 81     | 89% | 23     | 96% | 15      | 88% | 12   | 86% | 29     | 85% | 2           | 100% |
| No                                       | 9      | 10% | 1      | 4%  | 2       | 12% | 2    | 14% | 4      | 12% | 0           | 0%   |
| Did Not Respond (DNR)                    | 1      | 1%  | 0      | 0   | 0       | 0   | 0    | 1   | 3%     | 0   | 0           | 0%   |
| If no – suggest an acceptable definition |        |     |        |     |         |     |      |     |        |     |             |      |
| Specify                                  | 10     |     | 1      |     | 3       |     | 3    |     | 3      |     | 0           |      |

*Key consideration<sup>2</sup>Please score the following considerations as they pertain to the application of genetic engineering to animals. For each topic listed below circle a score on a scale of 1 to 5, where 1 indicates unimportant considerations, and 5 indicates very important considerations.*

|                                   | Global |         | Africa |         | America |         | Asia  |         | Europe |         | Middle East |         |
|-----------------------------------|--------|---------|--------|---------|---------|---------|-------|---------|--------|---------|-------------|---------|
|                                   | Total  | Average | Total  | Average | Total   | Average | Total | Average | Total  | Average | Total       | Average |
| Animal welfare                    | 303    | 3,33    | 66     | 2,75    | 65      | 3,82    | 41    | 2,93    | 124    | 3,65    | 7           | 3,50    |
| Economic aspects                  | 334    | 3,67    | 99     | 4,13    | 68      | 4,00    | 51    | 3,64    | 109    | 3,21    | 7           | 3,50    |
| Food safety                       | 365    | 4,01    | 88     | 3,67    | 72      | 4,24    | 53    | 3,79    | 142    | 4,18    | 10          | 5,00    |
| Environmental impact              | 353    | 3,88    | 87     | 3,63    | 74      | 4,35    | 47    | 3,36    | 137    | 4,03    | 8           | 4,00    |
| Traceability                      | 348    | 3,82    | 91     | 3,79    | 73      | 4,29    | 49    | 3,50    | 125    | 3,68    | 10          | 5,00    |
| Nanotechnology                    | 248    | 2,73    | 60     | 2,50    | 55      | 3,24    | 34    | 2,43    | 90     | 2,65    | 9           | 4,50    |
| Human health<br>(other than food) | 362    | 3,98    | 98     | 4,08    | 72      | 4,24    | 46    | 3,29    | 136    | 4,00    | 10          | 5,00    |
| Animal health                     | 384    | 4,22    | 106    | 4,42    | 81      | 4,76    | 51    | 3,64    | 138    | 4,06    | 8           | 4,00    |
| Regulatory controls               | 351    | 3,86    | 92     | 3,83    | 74      | 4,35    | 52    | 3,71    | 127    | 3,74    | 6           | 3,00    |
| Xenotransplantation               | 308    | 3,38    | 66     | 2,75    | 69      | 4,06    | 43    | 3,07    | 123    | 3,62    | 7           | 3,50    |

3. Do the animal health regulatory administrations and/or agencies in your country have the capability to conduct risk analysis (risk assessment, risk communication, risk management) on biotechnology derived livestock and biotechnology products?

|   | Global |     | Africa |     | America |     | Asia |      | Europe |     | Middle East |      |
|---|--------|-----|--------|-----|---------|-----|------|------|--------|-----|-------------|------|
| Yes   | 36     | 40% | 4      | 17% | 6       | 35% | 5    | 36%  | 20     | 59% | 1           | 50%  |
| No  | 53     | 58% | 20     | 83% | 11      | 65% | 8    | 57%  | 13     | 38% | 1           | 50%  |
| DNR   | 2      | 2%  | 0      | 0%  | 0       | 0%  | 1    | 7%   | 1      | 3%  | 0           | 0%   |
| <i>If yes, has a National framework for conducting risk analysis on biotechnology derived livestock and biotechnology products been developed?</i>                        |        |     |        |     |         |     |      |      |        |     |             |      |
| Yes   | 23     | 64% | 1      | 25% | 4       | 66% | 5    | 100% | 13     | 65% | 0           | 0%   |
| No  | 12     | 33% | 3      | 75% | 1       | 17% | 0    | 0%   | 7      | 35% | 1           | 100% |
| DNR   | 1      | 3%  | 0      | 0%  | 1       | 17% | 0    | 0%   | 0      | 0%  | 0           | 0%   |
| <i>If no, what are the reasons for not performing risk analysis for decision-making process pertaining to biotechnology derived livestock and biotechnology products?</i> |        |     |        |     |         |     |      |      |        |     |             |      |
| Lack of knowledge   | 22     | 26% | 6      | 27% | 2       | 13% | 6    | 50%  | 6      | 27% | 2           | 50%  |
| Training  | 44     | 53% | 10     | 46% | 9       | 56% | 5    | 42%  | 10     | 46% | 2           | 50%  |
| Others (specify):   | 18     | 21% | 6      | 27% | 5       | 31% | 1    | 8%   | 6      | 27% | 0           | 0%   |

4. Do the animal health authorities in your country have a dedicated unit that conducts risk analysis pertaining to biotechnology derived livestock and biotechnology products?

|   | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|---|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes   | 14     | 15% | 2      | 8%  | 3       | 18% | 3    | 21% | 6      | 18% | 0           | 0%   |
| No  | 75     | 83% | 22     | 92% | 14      | 82% | 10   | 72% | 27     | 79% | 2           | 100% |
| DNR   | 2      | 2%  | 0      | 0%  | 0       | 0%  | 1    | 7%  | 1      | 3%  | 0           | 0%   |
| <i>If no, which unit is conducting risk analysis?</i> |        |     |        |     |         |     |      |     |        |     |             |      |
| Import-Export unit                                    | 19     | 23% | 6      | 26% | 3       | 20% | 4    | 45% | 5      | 15% | 1           | 50%  |
| Epidemiology and<br>Surveillance unit                 | 24     | 29% | 7      | 31% | 4       | 27% | 1    | 10% | 11     | 33% | 1           | 50%  |
| External consultant                                   | 9      | 11% | 3      | 13% | 1       | 7%  | 0    | 0%  | 5      | 15% | 0           | 0%   |
| Others (specify)                                      | 30     | 37% | 7      | 30% | 7       | 46% | 4    | 45% | 12     | 37% | 0           | 0%   |

5. What factors are taken into consideration when determining risk associated with biotechnology derived livestock and biotechnology products?

|                        | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|------------------------|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Animal Health          | 66     | 26% | 18     | 25% | 11      | 25% | 9    | 22% | 26     | 28% | 2           | 34% |
| Food Safety            | 69     | 26% | 20     | 29% | 10      | 23% | 10   | 24% | 27     | 29% | 2           | 33% |
| Environmental impact   | 58     | 23% | 15     | 21% | 8       | 19% | 9    | 22% | 24     | 25% | 2           | 33% |
| Economic consideration | 27     | 11% | 11     | 15% | 2       | 5%  | 6    | 15% | 8      | 8%  | 0           | 0%  |
| Others (specify)       | 24     | 9%  | 4      | 6%  | 10      | 23% | 5    | 12% | 5      | 5%  | 0           | 0%  |
| DNR                    | 12     | 5%  | 3      | 4%  | 2       | 5%  | 2    | 5%  | 5      | 5%  | 0           | 0%  |

6. Have the animal health authorities conducted (or received a request to conduct) a risk analysis on biotechnology derived livestock or biotechnology products?

|                                       | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|---------------------------------------|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes                                   | 23     | 25% | 3      | 13% | 7       | 41% | 4    | 29% | 9      | 26% | 0           | 0%   |
| No                                    | 66     | 73% | 20     | 83% | 10      | 59% | 10   | 71% | 24     | 71% | 2           | 100% |
| DNR                                   | 2      | 2%  | 1      | 4%  | 0       | 0%  | 0    | 0%  | 1      | 4%  | 0           | 0%   |
| <i>If yes, specify what commodity</i> |        |     |        |     |         |     |      |     |        |     |             |      |
| Not able to disclose                  | 3      | 9%  | 1      | 33% | 1       | 8%  | 1    | 20% | 0      | 0%  | 0           | 0%   |
| Cloned animal                         | 3      | 9%  | 0      | 0%  | 2       | 15% | 0    | 0%  | 1      | 20% | 0           | 0%   |
| Transgenic animal                     | 7      | 21% | 0      | 0%  | 3       | 23% | 1    | 20% | 3      | 60% | 0           | 0%   |
| Biotechnology products (specify)      | 17     | 52% | 2      | 67% | 6       | 46% | 2    | 40% | 0      | 0%  | 0           | 0%   |
| Others (specify)                      | 3      | 9%  | 0      | 0%  | 1       | 8%  | 1    | 20% | 1      | 20% | 0           | 0%   |

7. Do the animal health authorities in your country make their risk analysis document available for peer review or for public consultation?

|  | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|--|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Yes  | 25     | 27% | 6      | 25% | 7       | 41% | 4    | 29% | 8      | 24% | 0           | 0%  |
| No   | 60     | 66% | 16     | 67% | 10      | 59% | 10   | 71% | 23     | 67% | 1           | 50% |
| DNR  | 6      | 7%  | 2      | 8%  | 0       | 0%  | 0    | 0%  | 3      | 9%  | 1           | 50% |
| <i>If yes, what means of dissemination are used:</i> |        |     |        |     |         |     |      |     |        |     |             |     |
| Official government publication                      | 14     | 38% | 4      | 66% | 3       | 23% | 3    | 42% | 4      | 37% | 0           | 0%  |
| Electronic version                                   | 10     | 27% | 1      | 17% | 3       | 23% | 2    | 29% | 4      | 36% | 0           | 0%  |
| Others (specify)                                     | 13     | 35% | 1      | 17% | 7       | 54% | 2    | 29% | 3      | 27% | 0           | 0%  |
| <i>and who conducts the peer review:</i>             |        |     |        |     |         |     |      |     |        |     |             |     |
| Internally within the Veterinary Services            | 18     | 45% | 5      | 72% | 6       | 40% | 3    | 43% | 4      | 37% | 0           | 0%  |
| External reviewers                                   | 10     | 25% | 1      | 14% | 4       | 27% | 1    | 14% | 4      | 36% | 0           | 0%  |
| Others (specify)                                     | 12     | 30% | 1      | 14% | 5       | 33% | 3    | 43% | 3      | 27% | 0           | 0%  |

8. Do you consider the "Guidelines for risk analysis" contained in the OIE Terrestrial Animal Health Code, adequate to help carry out an import risk analysis on biotechnology-derived animals or biotechnology-derived products?

|                                       | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|---------------------------------------|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Yes                                   | 63     | 69% | 19     | 79% | 8       | 47% | 9    | 65% | 26     | 76% | 1           | 50% |
| No                                    | 18     | 20% | 3      | 13% | 8       | 47% | 3    | 21% | 4      | 12% | 0           | 0%  |
| DNR                                   | 10     | 11% | 2      | 8%  | 1       | 6%  | 2    | 14% | 4      | 12% | 1           | 50% |
| <i>If no, how can it be improved?</i> |        |     |        |     |         |     |      |     |        |     |             |     |
| Specify                               | 18     |     | 3      |     | 8       |     | 3    |     | 4      |     | 0           |     |

9. Has your country produced biotechnology-derived animals or biotechnology-derived products for use on animals?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes | 31     | 34% | 5      | 21% | 6       | 35% | 6    | 43% | 14     | 41% | 0           | 0%   |
| No  | 58     | 64% | 19     | 79% | 11      | 65% | 8    | 57% | 18     | 53% | 2           | 100% |
| DNR | 2      | 2%  | 0      | 0%  | 0       | 0%  | 0    | 0%  | 2      | 6%  | 0           | 0%   |

10. Do you have the following capabilities in your country?

|   | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|---|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Cloning   | 23     | 17% | 1      | 4%  | 6       | 23% | 6    | 23% | 10     | 18% | 0           | 0%   |
| Transgenic production   | 27     | 20% | 2      | 8%  | 4       | 15% | 6    | 23% | 15     | 26% | 0           | 0%   |
| Products of biotechnology for use in animals (e.g. vaccines and/or drugs) | 38     | 28% | 6      | 23% | 5       | 19% | 9    | 35% | 18     | 31% | 0           | 0%   |
| DNR   | 49     | 35% | 17     | 66% | 11      | 43% | 5    | 19% | 14     | 25% | 2           | 100% |

11. Do you have a regulatory framework in place to govern the use of the above?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes | 44     | 48% | 6      | 25% | 9       | 53% | 8    | 43% | 21     | 62% | 0           | 0%   |
| No  | 45     | 50% | 18     | 75% | 8       | 47% | 6    | 57% | 11     | 32% | 2           | 100% |
| DNR | 2      | 2%  | 0      | 0%  | 0       | 0%  | 0    | 0%  | 2      | 6%  | 0           | 0%   |

If yes, briefly please describe the framework and list the Administrations and/or Agencies and pertinent legislation(s) involved

| Specify | 39 | 5 | 8 | 7 | 19 | 0 |
|---------|----|---|---|---|----|---|
|---------|----|---|---|---|----|---|

12. Is research being conducted in your country into biotechnology-derived animals and products including vaccines and drugs?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Yes | 43     | 47% | 6      | 25% | 7       | 41% | 9    | 64% | 20     | 59% | 1           | 50% |
| No  | 46     | 51% | 17     | 71% | 10      | 59% | 5    | 36% | 13     | 38% | 1           | 50% |
| DNR | 2      | 2%  | 1      | 4%  | 0       | 0%  | 0    | 0%  | 1      | 3%  | 0           | 0%  |

13. Do you produce or use any animal vaccines in your country that are biotechnology-derived?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Yes | 40     | 44% | 4      | 17% | 7       | 41% | 7    | 50% | 21     | 62% | 1           | 50% |
| No  | 49     | 54% | 19     | 79% | 10      | 59% | 7    | 50% | 12     | 35% | 1           | 50% |
| DNR | 2      | 2%  | 1      | 4%  | 0       | 0%  | 0    | 0%  | 1      | 3%  | 0           | 0%  |

If yes, what types of biotechnology-derived animal vaccines are available?

|   |    |     |   |     |   |     |   |     |    |     |   |      |
|---|----|-----|---|-----|---|-----|---|-----|----|-----|---|------|
| Viral vectored vaccines which include antigen(s) from unrelated organisms                       | 26 | 27% | 2 | 50% | 5 | 28% | 4 | 19% | 15 | 29% | 0 | 0%   |
| Bacterial vectored vaccines which include antigen(s) from unrelated organisms                   | 16 | 16% | 1 | 25% | 2 | 11% | 5 | 24% | 8  | 15% | 0 | 0%   |
| Vaccines which have deleted antigen(s) to differentiate infected animals from vaccinates (DIVA) | 22 | 23% | 1 | 25% | 3 | 17% | 3 | 14% | 14 | 26% | 1 | 100% |
| Vaccines which include recombinant proteins   | 26 | 27% | 0 | 0%  | 6 | 33% | 6 | 28% | 14 | 26% | 0 | 0%   |
| DNA vaccines  | 6  | 6%  | 0 | 0%  | 2 | 11% | 2 | 10% | 2  | 4%  | 0 | 0%   |
| Other   | 1  | 1%  | 0 | 0%  | 0 | 0%  | 1 | 5%  | 0  | 0%  | 0 | 0%   |

14. How are biotechnology-derived vaccines and/or drugs generally perceived by the public in your country?

|                       | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|-----------------------|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Safe                  | 12     | 13% | 4      | 17% | 1       | 6%  | 3    | 21% | 4      | 11% | 0           | 0%  |
| Controversial         | 25     | 27% | 5      | 21% | 5       | 28% | 4    | 29% | 10     | 29% | 1           | 50% |
| Public mostly unaware | 39     | 41% | 11     | 46% | 7       | 38% | 6    | 43% | 15     | 43% | 0           | 0%  |
| Others (specify)      | 11     | 12% | 2      | 8%  | 5       | 28% | 0    | 0%  | 2      | 6%  | 1           | 50% |
| DNR                   | 7      | 7%  | 2      | 8%  | 0       | 0%  | 1    | 7%  | 4      | 11% | 0           | 0%  |

15. Do you have livestock cloning and/or transgenic animal production facilities in your country?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes | 28     | 31% | 0      | 0%  | 5       | 29% | 6    | 43% | 17     | 50% | 0           | 0%   |
| No  | 60     | 66% | 22     | 92% | 12      | 71% | 8    | 57% | 16     | 47% | 2           | 100% |
| DNR | 3      | 3%  | 2      | 8%  | 0       | 0%  | 0    | 0%  | 1      | 3%  | 0           | 0%   |

16. Are biotechnology-derived animals or their products permitted in the food or feed supply in your country?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes | 22     | 24% | 5      | 21% | 4       | 24% | 6    | 43% | 7      | 21% | 0           | 0%   |
| No  | 64     | 72% | 17     | 71% | 13      | 76% | 6    | 43% | 26     | 79% | 2           | 100% |
| DNR | 4      | 4%  | 2      | 8%  | 0       | 0%  | 2    | 14% | 0      | 0%  | 0           | 0%   |

Is there a public support for cloning of animals?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| Yes | 11     | 12% | 0      | 0%  | 2       | 12% | 4    | 29% | 5      | 15% | 0           | 0%   |
| No  | 72     | 79% | 22     | 92% | 13      | 76% | 7    | 50% | 28     | 82% | 2           | 100% |
| DNR | 8      | 9%  | 2      | 8%  | 2       | 12% | 3    | 21% | 1      | 3%  | 0           | 0%   |

If Yes, would there be a support for cloning for

|                              |   |     |   |    |   |     |   |     |   |     |   |    |
|------------------------------|---|-----|---|----|---|-----|---|-----|---|-----|---|----|
| Rescue of endangered species | 7 | 39% | 0 | 0% | 2 | 33% | 2 | 33% | 3 | 50% | 0 | 0% |
| Generating stem cells        | 7 | 39% | 0 | 0% | 2 | 33% | 2 | 33% | 3 | 50% | 0 | 0% |
| Pet cloning                  | 2 | 11% | 0 | 0% | 1 | 17% | 1 | 17% | 0 | 0%  | 0 | 0% |
| Food product homogeneity     | 2 | 11% | 0 | 0% | 1 | 17% | 1 | 17% | 0 | 0%  | 0 | 0% |

18. Are there transgenic animals present in your country?

|     | Global |     | Africa |      | America |     | Asia |     | Europe |     | Middle East |      |
|-----|--------|-----|--------|------|---------|-----|------|-----|--------|-----|-------------|------|
| Yes | 22     | 24% | 0      | 0%   | 3       | 18% | 4    | 29% | 15     | 44% | 0           | 0%   |
| No  | 67     | 74% | 24     | 100% | 14      | 82% | 10   | 71% | 17     | 50% | 2           | 100% |
| DNR | 2      | 2%  | 0      | 0%   | 0       | 0%  | 0    | 0%  | 2      | 6%  | 0           | 0%   |

If Yes, what purpose are they generated for

|                          |    |     |   |    |   |     |   |     |   |     |   |    |
|--------------------------|----|-----|---|----|---|-----|---|-----|---|-----|---|----|
| Altered Nutrient Content | 4  | 13% | 0 | 0% | 1 | 14% | 2 | 22% | 1 | 53% | 0 | 0% |
| Biopharmaceuticals       | 14 | 45% | 0 | 0% | 3 | 43% | 3 | 34% | 8 | 33% | 0 | 0% |
| Disease resistance       | 9  | 29% | 0 | 0% | 1 | 14% | 3 | 33% | 5 | 7%  | 0 | 0% |
| Environmental benefits   | 4  | 13% | 0 | 0% | 2 | 29% | 1 | 11% | 1 | 7%  | 0 | 0% |

19. Does your country have the laboratory capacity to identify and detect transgenes in the food/feed supply?

|     | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|-----|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Yes | 38     | 42% | 2      | 8%  | 6       | 35% | 7    | 50% | 22     | 65% | 1           | 50% |
| No  | 51     | 56% | 22     | 92% | 11      | 65% | 6    | 43% | 11     | 32% | 1           | 50% |
| DNR | 2      | 2%  | 0      | 0%  | 0       | 0%  | 1    | 7%  | 1      | 3%  | 0           | 0%  |

20. How are biotechnology-derived animals generally perceived by the public in your country?

|                          | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |     |
|--------------------------|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|-----|
| Safe                     | 2      | 2%  | 1      | 4%  | 0       | 0%  | 0    | 0%  | 1      | 2%  | 0           | 0%  |
| Controversial            | 53     | 52% | 10     | 41% | 10      | 50% | 8    | 53% | 24     | 59% | 1           | 50% |
| Public generally unaware | 30     | 29% | 9      | 38% | 5       | 25% | 5    | 33% | 11     | 27% | 0           | 0%  |
| Others (specify)         | 14     | 14% | 4      | 17% | 5       | 25% | 1    | 7%  | 3      | 7%  | 1           | 50% |
| DNR                      | 3      | 3%  | 0      | 0%  | 0       | 0%  | 1    | 7%  | 2      | 5%  | 0           | 0%  |

|         | Global |     | Africa |     | America |     | Asia |     | Europe |     | Middle East |      |
|---------|--------|-----|--------|-----|---------|-----|------|-----|--------|-----|-------------|------|
| English | 61     | 67% | 12     | 50% | 6       | 35% | 13   | 93% | 28     | 82% | 2           | 100% |
| French  | 18     | 20% | 12     | 50% | 0       | 0%  | 1    | 7%  | 5      | 15% | 0           | 0%   |
| Spanish | 11     | 12% | 0      | 0%  | 11      | 65% | 0    | 0%  | 0      | 0%  | 0           | 0%   |
| Other   | 1      | 1%  | 0      | 0%  | 0       | 0%  | 0    | 0%  | 1      | 3%  | 0           | 0%   |

|                                |     |     |    |     |    |     |    |     |    |     |    |     |
|--------------------------------|-----|-----|----|-----|----|-----|----|-----|----|-----|----|-----|
| Country Questionnaire Received | 91  | 54% | 24 | 49% | 17 | 61% | 14 | 54% | 34 | 69% | 2  | 15% |
| Member Countries               | 165 |     | 49 |     | 28 |     | 26 |     | 49 |     | 13 |     |

© World Organisation for Animal Health (OIE), 2005



# **Science and technology for our common future: Evolving programmatic initiatives of the New Partnership for Africa's Development**

J. Mugabe

*NEPAD, Science and Technology Commission, CSIR Building 43b, Rooms 219–226,  
Meiring Naude Road, Brummeria, Pretoria 0001, South Africa  
Email: john@nrf.co.za*

There is a relatively rich academic discourse on the role that science and technology play in economic change and sustainable development (for example Rosenberg 1982; Freeman 1992). This discourse has exposed the intimate and complex connections between science, technology and development. It has also demonstrated that science and technology are key factors in wealth creation and sustainable development. There is now enough empirical evidence that the gap between poor and rich countries in terms of real income is largely accounted for by differences in the accumulation and utilisation of science and technology. Closing this gap requires deliberate measures to build and/or strengthen capabilities of the poor countries and their people to harness, develop and use science and technology.

Science, especially basic research, and technological development have long been recognised as activities that, by their very nature, are not restrained within national boundaries. The flow of information is vital to the progress of science and technology. Economic globalisation and the rapid growth of information and communications technologies (ICTs) are changing the international context in which science is conducted.

The increasing costs of frontier research in many fields and the growth of the ICTs, including the Internet, have provided both the motivation and the means of intensifying regional and international collaboration in research, at the level of governments, institutions and individual scientists and engineers. At the same time, the increasingly blurred lines between basic research and application and the growing importance of science and technology to economic growth have made policy makers more aware of national interests in research and raised concerns about the risks of collaboration.

The academic discourse is to a large measure responsible for the increasing recognition among politicians and policy makers that science and technology are indeed engines of economic change and sustainable development. At the international level at least three cases demonstrate that political institutions and processes are increasingly recognising the roles of science and technology. These are the Plan of Implementation adopted at the World Summit on Sustainable Development (WSSD), the United Nations Millennium Development Goals (MDGs) and the Group of 8 Action Plan on Science and Technology.

At the WSSD the international community emphasised that development and application of science and technology enables humanity to address such problems as food insecurity, water scarcity, environmental degradation and deterioration in public health. Many of the WSSD recommended actions are about mobilising and directing science and technology for human development. The WSSD Plan of Implementation calls on the international community to '[p]romote technology development, transfer and diffusion to Africa and further develop technology and knowledge available in African centres of excellence; and [s]upport African countries to develop effective

science and technology institutions and research activities capable of developing and adapting to world class technologies” (UN 2002).

The MDGs also recognise that poverty reduction and sustainable development cannot be achieved without investments in science and technology. The UN established a special task force on science, technology and innovation under the Millennium Project to generate a report to inform the international community of strategic actions required to apply science and technology to meet the development goals. The task force is expected to generate recommendations on how best to achieve the goals through the development and application of science and technology. Of interest to African countries will be how the UN will translate the commitment to ‘take special measures to address the challenges of poverty eradication and sustainable development in Africa, including debt cancellation, improved market access, enhanced Official Development Assistance and increased flows of Foreign Direct Investment, as well as transfers of technology’ (UN 2001) into concrete actions. African countries require programmatic and organisational approaches that will enable them to invoke this commitment.

The meeting of the G8 group of countries added impetus to the political articulation of the role that science and technology play in sustainable development. G8 leaders meeting in Evian, France, 1–3 June 2003, adopted an action plan on science and technology for sustainable development. In the plan the leaders emphasise: ‘co-operative scientific research on transformational technologies offers potential to improve public health by cutting pollution and reducing greenhouse emissions to address the challenge of global climate change.’ In addition, they note that to meet the objectives of the WSSD, developing countries and countries with economies in transition need to build and strengthen their capacity to assimilate and generate knowledge for sustainable development. They reaffirm their commitment made at the WSSD to assist these countries to enhance their research capacities through international cooperation.

At the regional level, there are several policy and political pronouncements on science and technology. For example, Articles 103, 104 and 127 of the treaty establishing the Common Market for Eastern and Southern Africa (COMESA) are dedicated to issues of cooperation in the development of science and technology. Article 21 of the Southern Africa Development Community (SADC) Treaty recognises the importance of cooperation in areas of science and technology. SADC has also adopted a protocol with provisions aimed at promoting science and technology cooperation. The East African Community (EAC) Treaty devotes its Article 103 to issues of cooperation in science and technology. Similar provisions are found in the treaty of the Economic Commission of West African States (ECOWAS) and the Constitution of the African Union (AU).

Another important forum that has stressed the need to improve regional cooperation in science and technology is the Africa, Caribbean and Pacific (ACP) and the European Union Forum on Research for Sustainable Development held in Cape Town, South Africa, 29–30 July 2002. The Forum, attended by ministers responsible for science and technology, adopted the Cape Town Consensus stressing the importance of cooperation in science and technology. It called upon ‘the ACP States, EU Member States, European Commission and the ACP General Secretariat, to make appropriate and timely arrangements for the most effective utilisation of funding instruments in the 6<sup>th</sup> Framework Programme (FP6) and in the 9<sup>th</sup> European Development Fund (EDF9), in support of Science and Technology (S&T) Cooperation and research capacity building, respectively.’

The greatest challenge facing African countries now is how to translate the statements of intent and political recognition of the roles of science and technology into concrete activities, programmes and processes. Meeting this challenge requires policy guidance and the support of high-level political institutions. It demands that countries create platforms for political engagement and the formulation and implementation of strategic actions.

The New Partnership for Africa's Development (NEPAD) has been adopted by many African leaders, a growing constituency of civil and academic groups and the UN General Assembly as the framework for organising and promoting socio-economic development of the African continent. In NEPAD there is explicit recognition of science, technology and innovation as sources of social and economic transformation of Africa. Through the NEPAD framework and organisational context African countries aspire to individually and collectively harness, develop and apply scientific knowledge and associated technologies to improve human development and enhance their industrial competitiveness.

The formulation and adoption of the proposed NEPAD strategic framework and action plan on science and technology are knowledge and information intensive processes. Research on specific policy and institutional issues needs to be conducted to provide decisions makers with informed advice on what actions African countries should collectively take to stimulate and enhance the continent's scientific and technological development. A number of key issues that require research and/or additional information were identified by the first NEPAD workshop. These can be clustered into four categories: (a) improving policy development and implementation; (b) mobilising, networking, strengthening and efficiently utilising knowledge institutions or centres of excellence; (c) improving the quality of science and engineering education to build a critical mass of scientists in specific fields; and (d) ways of leveraging additional or increased financial expenditure on research and development (R&D).

## **Science and Technology in NEPAD**

NEPAD recognises that science and technology are central to its goals of promoting economic recovery, poverty reduction, better human health, good governance and environmental sustainability in Africa. One of its overall objectives is to bridge the technological divide between Africa and the rest of the world. It calls for the formulation and implementation of measures to: 'promote cross-border co-operation and connectivity by utilising knowledge currently available in existing centres of excellence in the continent'; and 'generate a critical mass of technology expertise in targeted areas that offer high growth potential, especially in biotechnology and geoscience' (NEPAD 2001).

There are seven main critical factors that currently constrain or undermine efforts to build and/or strengthen Africa's scientific and technological development. First, in most countries of the region there are weak links between scientific enterprise and political institutions. Political parties in the region have not accorded science and technology much attention in their manifestos and parliamentary activities. Technological change is a complex process that is influenced by many political factors. To engage in and manage this process, countries require the support of high-level political institutions. These institutions often determine the nature and levels of resources that go into public research and development activities and the overall governance of science and innovation. The workshop recommended that efforts be made to build strong political constituencies for science and technology development in Africa.

Second, most African countries formulated their science and technology policies in the 1970s and 1980s when development imperatives and technological opportunities were difficult. Many

of the policies are focused on organisational aspects and not on programmatic issues. Countries have for years been preoccupied with the creation of commissions or secretariats to promote science and technology. These institutions have given an administrative outlook to the role of science and technology in national affairs but they never really built the necessary programmes to anticipate and respond to long-term science and technology development issues. Some of these institutions have, over time, lost touch with the reality: it takes more than administrative oversight to promote science and technology development. Awareness of the importance of science and technology must be translated into concrete R&D activities to make a difference in a country's economic life.

Third, African countries have devoted considerably low, and in many cases declining, funding to R&D. Most of them spend less than 0.5% of their gross domestic product (GDP) on R&D. This so despite the declaration—in the Lagos Plan of Action and in national science and technology policies—that each country would allocate at least 1% of its GDP to R&D activities. In such economic areas as agriculture, funding to R&D has declined drastically in the last decade or so to the extent that the region's ability to acquire and sustain food security is being impaired. The low and declining expenditure on R&D is a manifestation of the low priority that countries have given to science and technology. The contribution of the private sector to public R&D is low or non-existent in many African countries. Most governments have not instituted specific policy and legal measures to attract private investment in R&D.

Fourth, associated with the above three factors, there is declining quality of science and engineering training at all levels of educational systems in Africa. Student numbers enrolling into science and engineering subjects at primary, secondary and tertiary levels are also falling. This undermines the continent's aspiration to build up its numbers of scientists, engineers and technicians.

Fifth, Africa is losing some of its best scientific and technical expertise to other regions of the world. Indeed the number of African scientists and technicians who are leaving the continent for employment abroad is growing. This 'brain drain' is caused by a variety of factors including poor research infrastructure and poor remuneration packages. While many Asian (e.g. India) countries have developed and adopted strategies to mobilise and utilise the expertise of their nationals living abroad, most African countries lack such measures. The region can no longer afford to ignore this capital—African scientists and technicians abroad. Indeed, it should tap the enormous scientific and technical talents of Africans abroad and use them for its own scientific and technological development. There is also need to put in place measures that will reduce the brain drain.

Sixth, another challenge faced by African countries relates to strengthening and/or building strong and 'smart' institutions dedicated to scientific and technological innovation for poverty reduction and sustainable development. As a result of the above factors, R&D institutions in many countries are getting weaker. Most countries have not organised and mobilised their institutions in such ways as to efficiently mobilise their scarce financial and human resources in specific fields of scientific and technological development. They tend to spread their resources thinly across the institutional terrain. The region as a whole has not been able to develop 'centres of excellence' in such areas as biotechnology, space science and ICTs.

Seventh, generally there are weak links between public R&D institutions and industry. Research results of public R&D activities are not often accessed and used by local industries. In many cases there is a mismatch between R&D activities and industrial development goals and strategies. For example, while industrialisation policies of most African countries have put emphasis on

building and strengthening small and medium-scale enterprises (SMEs), scientific R&D institutions have weak links to these enterprises.

Lastly, there are a number of other cross-cutting policy issues that impinge on the continent's scientific and technological development. These include such issues as intellectual property protection, biosafety, the role of women in R&D, the impact of new technologies on women, and ways and means of ensuring that foreign direct investment facilitates transfer of new technologies. These issues need to be addressed and where necessary new appropriate policies put in place.

## References

- Freeman, C. 1992. *The economics of hope*. Pinter Publishers, London, UK.
- NEPAD (New Partnership for Africa's Development). 2001. *New Partnership for Africa's Development*. Framework document adopted in Abuja, Nigeria, October 2001. pp. 36.
- Rosenberg, N. 1982. *Perspectives on technology*. Cambridge University Press.
- UN (United Nations). 2001. *The Millennium Declaration*. UN General Assembly, New York, USA.
- UN (United Nations). 2002. *Plan of Implementation of the World Summit on Sustainable Development (WSSD)*. Chapter 8; Sustainable Development in Africa. United Nations, New York, USA.