Genetics for Africa – Strategies & Opportunities

Mzima Cow Strategy & Theory of Change – Translating from Genetic Research in Africa to Adoption and Social Value: Workshop Report

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Cover photo: "Tumaini", ILRI's cloned bull, Hannah Walker

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Executive Summary

The workshop was held in Nairobi from 18-19 January 2017 with the aim of exploring the strategic elements of a Theory of Change to support ILRI's Mzima Cow project and, by extension, possible strategies and considerations for other similar research initiatives in developing countries, characterised by both the potential for great benefit in terms of expected impact but also the potential for great controversy, which risks affecting the uptake. Theory of Change is a "critical, multi-stakeholder exploration of intentions, interests, power and gender relations, in order to contribute to social justice, equality and sustainable development". It sets out to answer the following questions: "What change, for whom, why – and who says so?" The workshop additionally set out to explore in greater depth some of the challenges projects like the Mzima Cow might face in regulatory understanding and clearance, and particular challenges in communicating the research and its outputs to encourage uptake.

Although the research is still at an earlier stage, it was assumed for the discussions at the workshop that the product (the trypanosomiasis or sleeping sickness resistant cow) was ready for deployment, and participants were encouraged to reflect how to best optimise reach and impact on target beneficiaries.

The first part of the meeting discussed the scientific and social burden of trypanosomiasis. Two forms of African trypanosomiasis affect humans, both caused by sub-species of *Trypanosoma brucei*. *T.b. gambiense* causes chronic sleeping sickness, while infection with *T.b. rhodesiense* results in acute sleeping sickness. The World Health Organisation (WHO) has targeted Human African Trypanosomiasis for eradication, and significant progress has been made towards achieving this goal. However, a significant and overlooked obstacle is that domestic (mostly cattle) and wild animals provide the reservoir for *T.b. rhodesiense* parasites, and therefore targeting human infection alone is not enough for effective suppression of the disease.

In addition to its impact on human health, trypanosomiasis is also a huge economic burden to Africa, in particular for resource-poor smallholder farmers and pastoralists, who are often not able to afford medication to treat infected animals. Livestock is a key livelihood in the continent; animals and animal products are a very important source of income and also deliver a wide range of other benefits. These include a direct contribution of proteins and high quality nutrients to households; the provision of animal labour and manure for agricultural production (and hence the possibility of keeping cattle correlates with increases in crop productivity); and livestock can act as economic buffer in periods of financial need. Critically, livestock is central to many African cultures, with animals being important for social status and key in many social interactions (for example, as part of wedding dowries). In addition, animal source products (in particular milk) are among some of the few economic assets women are able to control, and therefore trypanosomiasis disproportionately impacts the wellbeing of this group.

There have been a number of initiatives focussing on trypanosomiasis control, such as the Pan-African Tsetse and Trypanosomiasis Eradication Campaign (PATTEC), established in 2000 to eradicate tsetse flies (which transmit the disease) in Zimbabwe, Zambia, Senegal, Ethiopia, Nigeria, Ghana, Kenya and Burkina Faso. Challenges faced include how to ensure sustainability, since successful eradication requires long-term commitment and funding from national governments. In addition, extensive use of insecticides has serious environmental and human health implications, in addition to the risk of development of resistance in vector populations.

A more sustainable approach to controlling trypanosomiasis would be to develop cattle breeds able to resist infection. A limitation of using conventional breeding methods is that there are no livestock breeds which are fully resistant to trypanosomes. There is one breed – N'Dama cattle – which is able to tolerate infection, but animals of this breed are small and not suitable as draught animals. Tolerance to the disease is controlled by a number of genes, each with a relatively low effect on variation, and therefore the development of tolerant breeds by crossing is an expensive, long-term endeavour likely to result in an imperfect solution. Controlling the disease through the development of a vaccine is also not possible because trypanosomes are able to evade attack by the immune system of susceptible hosts due to their ability to continuously change their surface antigens.

However, some primate hosts (including humans) have resistance to trypanosomes, provided by a protein – **ApoL1** – which is found in a complex called the Trypanosome Lytic Factor (TLF) and which circulates in the blood as part of "good" cholesterol. Therefore, an alternative strategy, to be deployed ultimately as part of a set of integrated solutions, is to develop a GM cow (Mzima Cow) with a synthetic ApoL1 transgene. This technology has been proven to result in full resistance to trypanosomes in transgenic mice.

A key challenge for the deployment of new agricultural technologies, which include genetic modification (GM), gene editing and gene drive technologies, is the lack of appropriate regulatory frameworks in African countries. The New Partnership for Africa's Development (NEPAD) African Biosafety Network of Expertise (ABNE) and National Biosafety Authorities have the mandate to assist in the development of regulations that allow harnessing technological advances while minimising potential risks to the environment and human health.

Workshop participants were asked to reflect on and discuss the key stakeholders affected by African trypanosomiasis; on the potential impacts of deploying the Mzima Cow, including unintended effects; and develop a Theory of Change to maximise the beneficial impacts of the technology. Two key challenges were identified as important for the entire timescale and success of the project:

1. Build trust and public acceptance of Mzima Cow by all stakeholders concerned. Specific actions and target groups vary according to the stage of the project and geographical location.
2. Develop high quality studies and data for the scientific, economic and social impact

of the technology, before and after deployment.

A further key challenge, which will need to be addressed once a proof of concept is available, will be to:

3. Devise a detailed plan for technology deployment ensuring that targeted beneficiaries have access to Mzima cow, and are prepared for scale-up.

More generally, it was felt there an opportunity for more engagement and awareness raising with stakeholder groups who were unaware of some of the nuances and paradigms of animal genetic research, but for whom such knowledge would be critical in playing their part in facilitating the effective uptake of the outputs of such research (regulators, for example.

Until they had more knowledge, it is difficult for such stakeholder groups to know how existing procedures need to evolve in order to be applicable to animal research. But participants did feel there was merit in trying to coordinate between the regulatory and other authorities of countries across Africa in order to achieve a harmonised regulatory environment.

In general, the approach recommended by the workshop was endorsed by pan-African agencies present, and was felt to fit will with the AU's 2063 Agenda and strategy.

The unique approach of inviting such a diverse group of stakeholders to engage with research projects early was greatly appreciated, and participants felt there was a strong case for a series of such workshops to be held as the research progresses.

Session 1: Introduction and Welcome

Introduction to the Workshop

Nick Manson, Interim Programme Director, Mzima Cow Project

The purpose of the Mzima Cow workshop is to develop the strategic elements of a Theory of Change to support this project as well as other similar research initiatives in Africa which may be potentially beneficial for the continent. The Theory of Change is a comprehensive exercise which aims to determine how specific programme activities and interventions may lead to the desired project goals, and to identify the conditions that must be in place for this to happen.

Mzima is a Swahili word meaning well, able-bodied, or healthy – hence its use for this project to describe cattle who are resistant to trypanosomiasis.

This project is in the vanguard for a number of reasons: the Mzima Cow is the first non-commercial programme for developing a transgenic animal for use in the public domain, and this may also be the first time the Theory of Change approach has been applied in such a context. The outcome of this workshop is likely to set precedents for future interventions and provide insights and guidance for other, similar research initiatives.

To develop the Mzima Cow Theory of Change, several key assumptions have been made: the product development pipeline is nearly complete, and the trypanosomiasis-resistant GM cow is ready for deployment. The workshop also assumes that the new technology is a "force for good", although it considers the GM cow as only part of the solution to a complex problem. However, it is not assumed that the GM cow is desirable, and participants are encouraged to reflect on the impact that the technology may have on different stakeholders, society as a whole, agricultural production, markets, and animal and human health. The workshop is also not intended to provide a space for debating the specific merits of the technology, nor to develop a detailed implementation plan (which will be the topic of subsequent workshops).

Introduction to the International Livestock Research Institute

Steve Kemp, Program Leader Animal Biosciences, ILRI

The International Livestock Research Institute (ILRI) is a member of the Consultative Group for International Agricultural Research (CGIAR), a global research partnership for a food-secure future. ILRI has the mandate to carry out research for a better and more sustainable use of livestock, with a specific focus on poor nations and households. ILRI's main campuses are in Nairobi and Addis Ababa, and the institute has offices in another fourteen developing countries.

Animal sourced products are critically important from several perspectives. Livestock products now comprise 4 of the 5 highest value traded agricultural commodities, and demand is expected to rise sharply in the coming decades, especially in developing countries where increases in meat consumption are outpacing those of developed nations. It is estimated that the amounts of dairy products and meat required will have to nearly double by 2050 compared to 2005 levels in order to meet demand.

In addition, livestock plays a central role in the life of resource-poor, small scale farmers. Most animal products in developing countries are produced by smallholders and are consumed in the same country or region, and over 70% of livestock products are sold ‘informally’ in markets. Livestock production is also very important for women’s livelihoods and for the nutritional status of their households in resource-poor communities.

Developing sustainable food systems is an imperative research goal. Productivity and efficiency need to improve in order to produce sufficient food with a lower environmental footprint, while there is also a need to promote the consumption of animal source foods in appropriate quantities (curbing over-consumption) and reducing waste. Livestock investments can deliver significant socio-economic, health and environmental gains to both poor nations and households. However, the current research funding scenario does not reflect the importance of this field. Emerging key challenges are zoonotic diseases and the increase in levels of antimicrobial resistance due to their overuse in food animals. About 75% of emerging diseases come from animals with an estimated annual impact on society of up to US$ 6 billion. Costs of SARS (Severe Acute Respiratory Syndrome), a viral respiratory disease of zoonotic origin, alone have been estimated at over US$40 billion in the 2-year period between 2002 and 2004.

Livestock research is also critical from an environmental perspective, as nearly half of the agricultural greenhouse gas (GHG) emissions are produced by animals. Since the amount of GHG per kg of animal protein produced has a very large geographical variation, with highest emissions found in developing countries, there are big opportunities for mitigation. Reducing the incidence of disease in livestock populations also has a positive impact on the environmental impact of animal rearing. The removal of trypanosomiasis would lead to significant increases in both productivity and in GHG emissions across all productions system. However, the increases in production are greater than increases in emissions, especially in dairy systems, which is related therefore translates into a reduced environmental impact per kg of animal product.

In summary, the best approach to increase livestock productivity minimising the effect on the environment is therefore to target animal genetics and health.

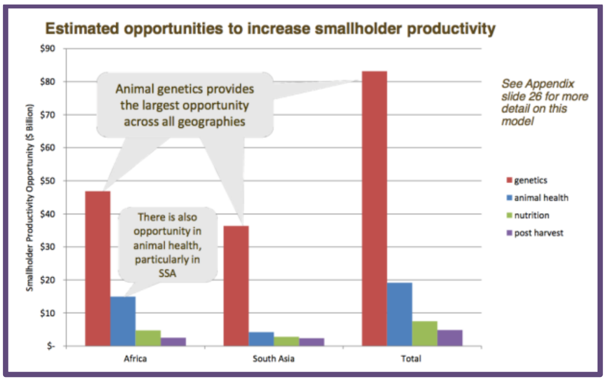

Figure 1: Estimated opportunities to increase livestock productivity in smallholder farming settings in Africa and South Asia and relative contribution of animal genetic improvement; animal health; nutrition and reducing post-harvest loses. Source: ILRI

Welcome from Genetics for Africa Strategies & Opportunities (G4ASO)

Bernie Jones, Project Co-Leader, G4ASO

The G4ASO project has been working in Africa over 3 years to examine the breadth of genetic research (in plants, animals and

humans) across the continent, and how well understood and communicated that research is to regulators, decision-makers, the media and the general public – and the challenges that are faced in outreach, understanding, and therefore ultimately adoption of the outputs of such research.

Broadly, the findings have shown that outreach, public understanding and misinformation are challenges across the whole of genetic research in Africa – however, the challenges for animal research seem particularly challenging, in that this area is generally even less-well funding than plant and human research, and regulators are – in general – not sensitised to it. Even more challenging potentially is the sense that regulatory frameworks have been developed largely with crops in mind, and therefore their ability to deal sensibly with animal research and its outputs is untested, and will at worst result in an inability to regulate such research and may therefore prevent its uptake.

This workshop is therefore an opportunity not only to explore potential regulatory and communications hurdles ahead for the Mzima Cow project, but also to seek to learn from that project in considering how animal genetic research and biotechnology might more generally face particular regulatory and communications challenges in Africa, and more widely.

This is an aspect which is of particular interest to G4ASO and its funders, the John Templeton Foundation and the Cambridge Malaysian Education and Development Trust.

The Cornell Alliance for Science

Hannah Walker, Digital Manager and Multimedia Producer

The Cornell Alliance for Science seeks to promote access to scientific innovation as a means of enhancing food security, increasing environmental sustainability and improving the quality of life globally. Funded by the Bill and Melinda Gates Foundation, the initiative aims to increase access to agricultural innovations through collaboration and innovative communication strategies. It does so by establishing a network of partners around the world and delivering training to develop the tools and skills needed to communicate about science and to promote evidence-based decision making. Training is provided not only to scientists but also to other key stakeholders, who are encouraged to train in turn other stakeholders, to foster science-based conversations and a climate for positive change.

A number of programmes tackle related problems. The "Climate for Change" initiative explores problems in agriculture associated to climate change and considers how these may be addressed, through a change in socio-political climate and the empowerment of "global champions". Another initiative aims to showcase the role and importance of women scientists and farmers in agriculture. Finally, farming stories are shared with the general public to highlight the human perspective of agricultural production.

Session 2: Social and Scientific Perspectives on the Burden of Trypanosomiasis

Disease elimination, animal reservoirs & other considerations: a public health perspective

Eric Fèvre, Chair of Veterinary Infectious Diseases Institute of Infection and Global Health, University of Liverpool & ILRI

Trypanosomes are unicellular parasitic organisms responsible for a number of diseases transmitted by tsetse flies where the parasite has an obligate life stage (*ie* it relies on its host to complete its life cycle). *Trypanosoma congolense* and *T. vivax* affect livestock only, however subspecies of *T. brucei* are also important human pathogens.

There are two forms of human African trypanosomiasis (HAT) or sleeping sickness, depending on the parasite involved. *T.b. gambiense* causes chronic sleeping sickness, which is most common in West and Central Africa, while *T.b. rhodesiense* is responsible for acute sleeping sickness, prevalent in East Africa with Uganda as the hotspot of currently diagnosed human cases. The two diseases are very different also from a human clinical perspective: untreated infection with *T. b. gambiense* leads to death of the patient in 140 to 160 months, while *T.b. rhodesiense* infection results in an acute disease and untreated people die much earlier.

Defining reservoirs of HAT is an important priority for eradicating the disease. A reservoir host is one that, either alone or in concert with other species, plays a significant role in sustaining a pathogen (tolerating infection) and allowing it to be transmitted. Humans are the main reservoir of *T. b. gambiense* parasites, while animal hosts provide the reservoir for *T.b. rhodesiense*. Eradicating HAT by treating human cases alone is only possible in the absence of an animal reservoir, (e.g. for *T.b. gambiense*) and therefore it is critical to determine which of the components of animal reservoirs is most important for eradicating the Rhodesian form of HAT. Wildlife is an important element of the zoonotic disease in locations with high numbers of wildlife habitats and animal populations, where it remains the principal reservoir of the parasite. Surveying wildlife is however technically challenging, expensive and strictly regulated by legislation. By contrast, in largely agricultural areas domestic animals are taking over the role of the reservoir, with cattle being most important hosts, although the number of infected pigs is increasing in affected areas.

HAT can be contained by controlling tsetse vector populations, a measure which is equally effective for both forms of the disease as it reduces transmission regardless of the duration of infection. However, there are important issues of cost and sustainability with this approach. Infected cattle can also be treated with chemoprophylaxis, which are the most effective control measure for *T.b. rhodesiense*. Disadvantages of this control method include the fact that it is too expensive for many smallholder farmers; there is not always an adequate distribution network for genuine veterinary inputs in rural areas; and that the use of drugs can lead to the development of resistance.

Significant efforts for eliminating HAT have resulted in a dramatic reduction in the

incidence of infection in the last 15 years, although the disease has not yet disappeared. The World Health Organisation (WHO) has developed a set of primary and secondary indicators for enumerating cases of infection in a Road Map for eradicating HAT. Primary indicators are updated annually and include the number of cases and the number of foci reported. Secondary indicators, updated biennially, include the geographical distribution of the disease; the population at risk, by levels; and the coverage of the exposed population by control and surveillance activities. The traditional definition of a focus is a “zone of transmission”, which in practice is not possible to measure. However, this concept needs to be replaced with a measurable, standardised definition of an “area of risk”, based on actual observation of human cases, which recognises the dynamic nature of the spread of infection.

Despite the progress, the WHO Road Map largely ignores the importance of animal reservoirs. Zoonotic HAT remains a neglected issue in the continent, even though Rhodesian sleeping sickness is estimated to threaten a total of 12.3 million people in Eastern and Southern Africa.

In summary, there are three key challenges for the elimination of African sleeping sickness:

1. Integrate HAT control into the health system. This requires shifting to passive case detection in areas of low HAT prevalence through the development of diagnostic tests and algorithms to replace costly and time consuming active case finding and parasitological examinations.
2. Avoid the re-emergence of the disease. Epidemiological pattern will be determined by distributions of reservoirs, of people and other components of the transmission systems (such as environmental variables, and distribution of tsetse vectors). It is critical to develop a comprehensive clinical oversight of HAT, which requires improving coverage; detecting asymptomatic carriers; and developing effective post-elimination monitoring to detect outbreaks early.
3. Develop new safe drugs for oral use, including an accurate and early and non-invasive test of cure.

Furthermore, in areas where livestock are the principal reservoir of HAT, it is important to quantify the role of different species in all risk areas, including their role in transmission. A detailed understanding of the livestock trading systems is also essential with respect to the livestock reservoir.

Perspectives on the Burden of Trypanosomiasis on society and gender issues

Isabelle Baltenweck, ILRI

Almost a billion people rely on livestock for their livelihood, and over 100 million landless people keep livestock. Livestock and animal-sourced products provide a large number of benefits. Direct consumption of animal foods has a very positive benefit on the level of nutrition of resource-poor households, while their sale is an important source of revenue. Livestock also improves farm productivity through the provision of manure (which comprises over 70% of soil fertility amendments in the poorest countries) and of

farm labour. In areas where agriculture and trypanosomiasis coincide, livestock production is reduced by 20–40%, depending on the degree of agricultural activity and rainfall. Critically, the ownership of livestock also has many intangible benefits: it increases the resilience of resource-poor communities towards adversity. This is very important since resource-poor farmers often do not have a bank account and lack access to conventional insurance and financing mechanisms. The inability to keep cattle therefore translates to a reduced buffer against economic shocks and periods of adversity. Livestock is important for social standing in the community, and is an intrinsic part of many social and cultural practices (for example, as a component of wedding dowries). Livestock is also an important provider of employment, with many people engaged in local informal livestock product markets and inputs and service delivery.

In areas where the disease challenge prevents livestock rearing, the burden of trypanosomiasis manifests itself as reduced opportunities for improving household nutrition from animal sourced products, and a loss of revenue. In addition, since livestock and livestock products (especially milk) are some of the few assets women may own, trypanosomiasis has an important impact on women's revenue and on the overall household's welfare, since there is a much more direct correlation between women's income and money spent directly on the household and children's education.

In view of the complexity of causes, it is important to develop and adopt a quantitative system or integrated approach to determine the burden of trypanosomiasis in a community.

Reducing the Burden of Trypanosomiasis – Successes and Challenges

Gift Wiseman Wanda, Principal Policy Officer, PATTEC

The Heads of States and Governments made the decision in 2000 to eradicate tsetse and trypanosomiasis in Africa[1]. This decision culminated in the formation of the Pan-African Tsetse and Trypanosomiasis Eradication Campaign (PATTEC) in Burkina Faso in October 2001, and the subsequent establishment of a coordination unit at the commission of African Union (AU) in Addis Ababa to implement the Plan of Action.

PATTEC was established in response of the urgent need to eliminate severe animal and public health and rural development problems resulting from tsetse and tsetse transmitted trypanosomiasis. This situation is aggravated by the increasing rates of tsetse infestation and prevalence of trypanosomiasis and the reduced effectiveness and availability of trypanocides for treating disease animals. Further challenges include the differing levels of programme identification, formulation and management and of resource availability in countries affected by trypanosomiasis.

PATTEC'S overall strategy is to advocate for vector eradication through a phased-conditional, area-wide and sustained approach, through coordinated action between affected countries and joint planning and programming at national, regional and sub regional levels. The campaign also promotes the integration of

[1] Decision AHG/156 (XXXVI) of the 36th Assembly of Heads of State and Government, Togo

appropriate technologies based on sound policy and strategy development and high quality baseline data, and advocates for a participatory approach and for comprehensive monitoring and evaluation.

Countries currently engaged in active programmes include Zimbabwe, Zambia, Senegal, Ethiopia, Nigeria, Ghana, Kenya and Burkina Faso. Progress has been made in all participating countries, including the eradication of tsetse flies in part of the national territories.

Challenges encountered include unclear long-term political commitment and funding; weak regional mechanisms for joint planning and programming; weak monitoring and evaluation systems; limited number of management structures with dedicated full-time staff across in affected areas; inconsistent implementation of critical programme components at national level; and inadequate peer review mechanisms for national programmes. From a strategic point of view, there is limited international consensus on appropriate control strategies and a debate on the relative merits of eradication vs. suppression, containment or prevention of the disease, and a lack of internationally recognized standards. A further important challenge is that tsetse and trypanosomiasis are an African problem with no threat to other continents, which means that although it is recognized as a problem, it is not considered a priority for international organisations.

In the Q&A session the environmental impact of the large-scale application of insecticides on non-target species, which is not fully understood and quantified, was raised by a participant. Another impact is the effect of the disease on tourism - an important generator of revenue in several affected countries -, which represents a significant economic burden for many communities, and remains largely an unrecognised problem. The disease can also lead to potentially explosive social conflicts, especially between pastoralist and settled communities, due to the spread of infection and its consequences on farming areas.

Table Exercise 1: Burden of Trypanosomiasis – Different perspectives

The purpose of the exercise was to capture the scope, and instances, of the burden of bovine trypanosomiasis, providing insights and stories of different stakeholder groups: pastoralists, smallholder farmers, and large livestock and dairy farmers.

Nomadic pastoralism, developed originally as a successful adaptation to arid and semi-arid conditions, is central to the economy and culture of many African societies, and is characterised by spatial mobility and a subsistence economy mainly dependent on livestock. Husbandry of livestock occurs in ‘natural’ pasture lands (although pastoralism has had a big impact shaping the continent’s ecosystems), and domestic animals are not only of great economic importance but also play an important role in social exchanges and rituals. Livestock is also central for many smallholder non-nomadic farmers, and critical for good farm productivity.

From an economic perspective, trypanosomiasis reduces the trading value of livestock and the productivity of dairy animals, especially since the most productive breeds are also the most susceptible to the disease. Therefore, **farmers** tend to select

less productive but more tolerant breeds. And since the milk is often the property of women, they lose one of the few economic assets they are entitled to control, which also has direct implications on the nutritional status of the household nutritional and health status, especially those of children. The economic burden of disease is furthermore transgenerational, since livestock not only plays a key role as a financial buffer in moments of need for a household, but is also central to many social interactions, such as an important part of dowries. The family heritage is often affected, and the implications can be fundamental: for example, children of families with diseased cattle may not be able to get married. Trypanosomiasis affects tourism as well, an important economic activity for many parts of Africa, not only directly since tourists tend to avoid infected areas, but potentially also indirectly due to the effect of the disease on wild animal populations.

The eradication of trypanosomiasis will also result in improved animal welfare, since available drugs have important side effects and currently many infected animals are either not treated or treated ineffectively.

Trypanosomiasis exacerbates social conflicts between pastoralists and farmers. These are sometimes of violent nature, and are due to competition for land use, disruption of agricultural land, and increasing urbanization. These problems are exacerbated when nomadic livestock are infected with trypanosomes and hence sources of infection to farm animals.

Challenges in controlling trypanosomiasis include poor access to extension services for pastoralists communities, and the fact that the drugs to treat the disease are beyond the economic reach of many pastoralist households. This problem is aggravated by the high incidence of poor quality, ineffective and fake drugs in the market. Control methods relying on the use of insecticides to reduce tsetse populations rely on the long-term commitment and provision of funds by governments.

The ecological and health impact of insecticide use is poorly characterised at many levels. These include development of resistance in flies, adverse effects on target species and on water and soil quality, and threats to human health since treated animals and their products (especially milk) are consumed by humans. In addition, trypanosomiasis also negatively affects patterns of land use, leading to overgrazing of disease-free pastures and to active avoidance of areas known to hold diseased animals.

In situations where tsetse populations have been eradicated from an area, very large increases in farming productivity have been recorded. Since farmers are constantly trying to use animals, the moment an area is freed from trypanosomiasis the effect on the economy is transformative. It is important to address different options for eradication, their relative costs and merits, and consider cultural factors that may shape the acceptance or rejection of specific interventions. The risk of disease re-emergence and how it would be handled also needs to be considered.

Session 3: Mzima Cow Project, the Science and Alternate Approaches

Mzima Cow project background

Steve Kemp, Program Leader Animal Biosciences, ILRI

Trypanosomiasis is one of the most significant constraints to cattle production in Africa. The disease directly affects livestock productivity (meat and milk production), and indirectly lowers crop productivity as cattle play a crucial role as farm labour, which means that in the absence of livestock resource-poor farmers are dependent on the heavy work of hand tillage. Cattle also contribute manure to agricultural land, important since the levels of use of chemical fertilisers in Africa are the lowest in the world.

A study mapping the benefits of eradicating trypanosomiasis in the Horn of Africa estimated that benefits per square km would be up to US$ 12,500 over a 20-year period in high potential areas where the disease's impact and costs are highest[2]. These areas include mixed farming, high-oxen-use agricultural zones; fertile agricultural land; and dairy production zones. In addition, benefits would spill out the trypanosomiasis affected zones due to movement of cattle outside tsetse areas.

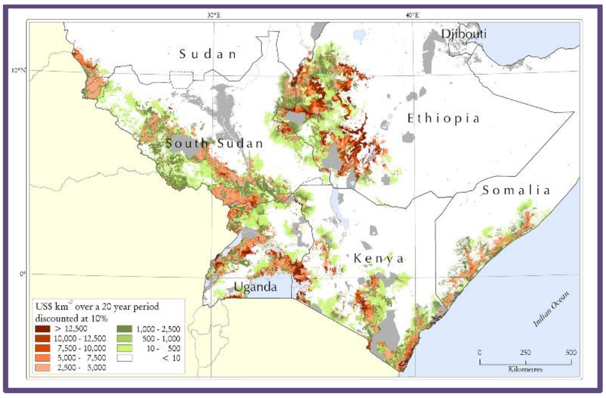

Figure 2. The mapped benefits from the removal of African Animal Trypanosomiasis (AAT) in the Horn of Africa. Source: Adapted from Shaw et al., 2016[3].

Existing measures for controlling trypanosomiasis include the use of insecticides to control tsetse populations, a measure that is expensive; has important environmental effects which are not fully quantified; and requires sustained interventions over time to be effective, (so they rely on long-term political commitment and allocation of funding). Efforts to develop a vaccine against the parasites have so far yielded no positive outcomes due to the mutability of the pathogen; and drugs to treat the disease are expensive; not always available to farmers; and have important side effects.

The African N'Dama cattle breed, native to West Africa, is tolerant of infection with *T. congolense*, remaining healthy and productive despite harbouring parasites. However, their small size and temperament make them unsuited for draught purposes.

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[2] From: Yaro, M., Munyard, K.A., Stear, M.J. and Groth, D.M., 2016. Combatting African Animal Trypanosomiasis (AAT) in livestock: The potential role of trypanotolerance. Veterinary Parasitology, 225, pp.43-52.

[3] Shaw, A.P.M., Wint, G.R.W., Cecchi, G., Torr, S.J., Mattioli, R.C. and Robinson, T.P., 2015. Mapping the benefit-cost ratios of interventions against bovine trypanosomiasis in Eastern Africa. Preventive Veterinary Medicine, 122(4), pp.406-416.

Development of trypanotolerant breeds that are better adapted to the diverse needs of African farmers would substantially improve productivity in the whole agricultural system.

A study to determine the genetic determinants of trypanotolerance in N'Dama cattle was carried out with the aim of introgressing[4] this characteristic into Boran breeds. Ten major candidate quantitative trait loci (QTLs[5]) involved in trypanotolerance in cattle were genetically mapped on the progeny of a cross between Boran and N'Dama cattle. However, each locus is responsible only for a small proportion of the total variance. Comparative gene network analysis is ongoing to identify the role individual genes in the pathway, and to determine how they interact for controlling tolerance.

The fact that trypanosome tolerance is not controlled by a single or few major genes makes it very difficult to improve target breeds by conventional breeding. Not only it is necessary to select for the presence of all the key loci in the progeny of breeding crosses, but also to remove undesirable genes and characteristics from the N'Dama breed, such as low milk production. This would require a very large number of backcrosses to the Boran parent. This would be a time-consuming approach, very demanding on resources, and likely to result only in an imperfect solution, namely incomplete disease tolerance.

[4] In genetics, introgression is the movement of a gene from one species into the gene pool of another by the repeated crossing of an interspecific hybrid with one of its parent species (this is also known as backcrossing).

[5] A quantitative trait locus (QTL) is a section of DNA (the locus) that correlates with variation in a phenotype (the quantitative trait), because it contains or is linked to the gene/s that control a proportion of the variance of the phenotype.

Introduction to Transgenics

Joseph Verdi, New York University School of Medicine

Transgenesis (also known as genetic modification or GM) refers to the process of introducing a gene or genes into the genome of an organism with the purpose of enabling it to acquire (or 'express') a new characteristic or trait. An important tool in the study of basic biological processes, for example, is to visualize in live tissues the activity of specific genes and proteins by tagging them with a fluorescent protein derived from jellyfish. This allows us to determine 'normal' activity during growth and development, and also to identify how deviation from this pattern may be associated with disease.

In addition to being a very important research tool, transgenesis has many practical applications. In agriculture, it can be used to develop plant and crop varieties with improved resistance to pests and diseases; enhanced tolerance to adverse environmental conditions such as drought, salinity and heat (which are increasingly important constraints to production); increased nutritional content; and ability to tolerate herbicides. Transgenesis is also being used for developing animal breeds with improved disease resistance and enhanced growth rates. And in a non-controversial application of the technology, transgenesis is used for the development of cheap, high-quality human medications, mostly in

bacterial cells. Over 100 drugs are produced via genetic modification, including insulin.

Success stories of transgenesis in agriculture include the development of insect-resistance Bt crop varieties: maize and cotton have been grown commercially now for about two decades, while cowpea and aubergine are in the last stages of regulatory approval for commercial release. Bt crops derive their name from the soil bacterium *Bacillus thuringiensis*, which produces proteins toxic only to the target pest insects but not to mammals, birds and other insect species. Rainbow papaya, another success story, was engineered to resist the Papaya ringspot virus (PRSV), and has been successfully released in Hawaii. It is also grown in China, and exported to Japan.

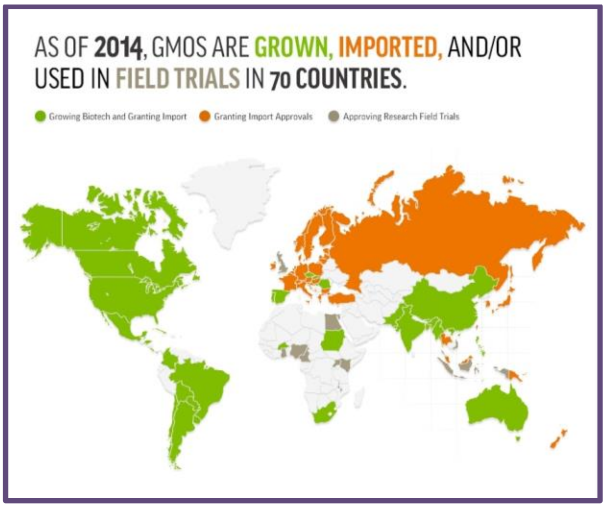


Figure 3. World map showing countries that planted (green); imported (orange) and/or used transgenic crops in field trials in 2014. Source: GMOanswers.com

As of 2014, transgenic crops were grown, imported or tested in field trials in 70 countries. And it is estimated that 179.7 million hectares of GM crops were planted in 2015[6], a testimony of the importance of the technology in the agricultural sector.

The use of transgenesis is however not limited to crops: the first GM animal, AquaBounty Salmon, was approved for release in the USA in 2015, although ongoing debate over labelling requirements is impeding commercialization.

The genetic modification of animals for the production of medicinal drugs is less controversial. The first drug produced by GM animals is ATryn, the commercial name of an anticoagulant medicine manufactured in the USA. It is made from the milk of goats that have been genetically modified to produce human antithrombin, a plasma protein used to treat a hereditary disease. One GM goat can produce as much high quality protein in a year as the quantity yielded by 90,000 blood donations.

Figure 4. ATryn GM goats. Source: Revo Biologics.

[6] James, C. 2015. 20th Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015. ISAAA Brief No. 51. ISAAA: Ithaca, NY.

In summary, transgenesis has been used effectively for decades. And although many people have benefitted from the available technologies, many more have not. Marketable transgenic organisms are no longer limited to plants and bacteria, with animals in effective and approved use today.

Trypanosome Resistance and Transgenesis

Jayne Raper, Principal Investigator Mzima Cow Project, New York University School of Medicine

Domestic animal trypanosomes are mainly confined to the African continent and to South America, and they are transmitted to humans by biting insects, tsetse flies and through sexual intercourse. Virulent trypanosomes evade the response of the mammalian host system by rapidly changing their surface proteins, a property called antigenic variation.

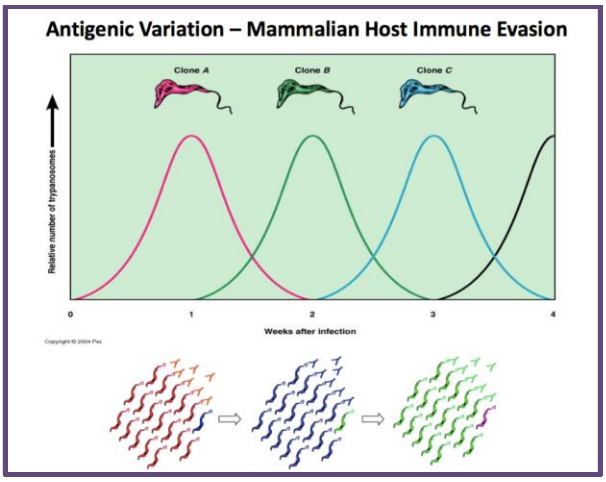


Figure 5. Graph showing the antigenic variation of trypanosomes that enables them to evade the immune response of susceptible mammalian hosts. The parasites completely change their surface antigens in 2 hours. Source: Jayne Raper.

However, some primates have innate immunity to African trypanosomes, including humans, although not to all species or subspecies of the parasite. For example, although humans are resistant to infection by *Trypanosoma brucei brucei* parasites, they succumb to *Trypanosoma brucei rhodesiense* and *T. b. gambiense* which cause sleeping sickness. Humans also display innate resistance to *T. congolense* parasites, although this parasite severely limits livestock productivity in the African continent. Critically, baboons are resistant to all trypanosome species.

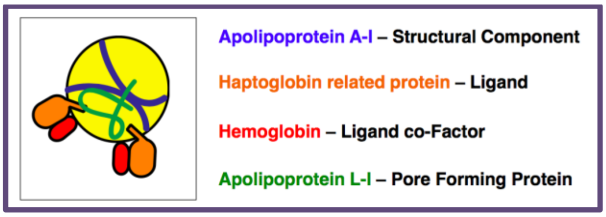


Figure 6. Schematic representation of the Trypanosome Lytic Factor (TLF) and its components. Source: Jayne Raper.

Immunity to trypanosomes is conferred by a protein complex termed the Trypanosome Lytic Factor (TLF), which contains the Apolipoprotein L-I (APOLI), a pore forming protein specific to primates. APOLI circulates in the blood serum as part of High-Density Lipoprotein (HDL) complexes called Trypanosome Lytic Factors: the "good" cholesterol of blood.

The TLF is ingested by trypanosomes, and the parasite is killed as the result of the pores that APOLI generates in its membranes. APOLI proteins from different primate species differ in their sequence and in their resistance to different trypanosomes parasites, and only the baboon form of the

protein is able to confer complete immunity to all parasites.

Although mice lack innate immunity to trypanosomes, transgenic mice for a synthetic form of TLF are fully resistant to the parasites.

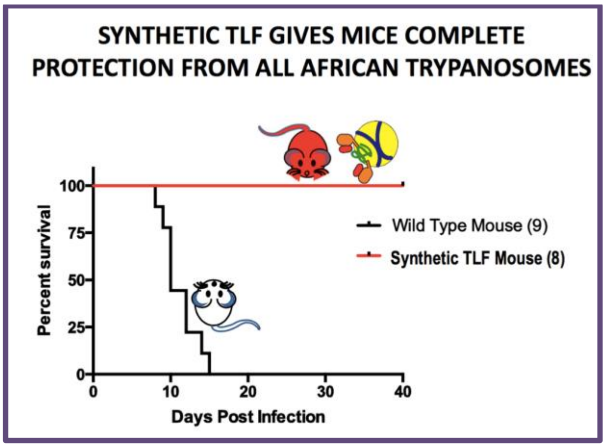


Figure 7. Graph showing the protection provided by a synthetic TLF transgene to mice: all the GM animal infected with trypanosomes are able to resist infection and survive. By contrast, unmodified animals die within two weeks of infection. Source: Jayne Raper.

Cattle species also have genes similar to *APOLI*, but do not produce the 'good cholesterol'. Efforts are now underway to establishing whether the presence of synthetic TFL in cows would also confer innate immunity to trypanosomes. The first step was to develop a cloned bull, named Tumaini, a healthy and fertile animal. Subsequent steps will require the development of transgenic animals and studies to ascertain the impact on immunity of the synthetic APOLI protein. If successful, this approach may significantly reduce the impact of the disease in the continent to both humans and livestock, and remove human infective parasite reservoirs, a step which is essential for eradicating the disease.

Figure 8. Tumaini, the cloned bull, and his progeny. Source: ILRI.

In the Q&A session it was explained that the technology used to generate trypanosome resistant cows will be GM and not gene editing, since the differences between the native cow *APOLI* gene and the synthetic version conferring resistance are too numerous for targeted modifications. Once a 'GM cow' (which really will be a bull) is developed and the technology proven to work, the trait will be disseminated by artificial insemination. Since the gene is dominant, the presence of a single copy will be enough to confer immunity in GM animals. It will then become very important to develop other transgenic breeds to produce founder animals to cater for the variety of livestock needed in different African cattle producing areas, and to prevent a loss of genetic diversity in the sector.

Participants agreed that it is difficult to predict how regulatory approaches and public opinion to GM may change in coming years. While GM salmon has been granted approval for commercialisation, the technology may not be adopted for other reasons. These include increased public resistance to the technology because an animal is concerned as opposed to a crop, and market considerations and competing economic agendas by stakeholders. On the

other hand, the pressing needs of African livestock holders, and the key impact that the technology may have on the development of the continent may provide an impetus to leapfrog current regulatory burdens to GM technology. Other factors that may cause a shift in opinion towards GM are the spread of Africa swine fever, which threatens production in Eastern European countries, and the spread of vector borne diseases, for example, the Zika virus.

In terms of communication priorities, it will be very important for the project to convey early on the fact that the gene used to develop transgenic cows is a synthetic copy, partly generated using sequence information from baboons, but is not a baboon gene.

Building Regulatory Capacity in Africa on Gene Drive Technology

Silas Obukosia, Business Manager of NEPAD ABNE

The New Partnership for Africa's Development (NEPAD) African Biosafety Network of Expertise (ABNE) is a biosafety resource network for African regulators and policy makers. Its overall goal is to enhance the capacity of African countries to build functional biosafety regulatory systems to harness modern agricultural biotechnology while minimising potential risks to the environment and human health.

The Africa 2063 Agenda recognizes science, technology and Innovation (STI) as key drivers for achieving Africa's sustained growth, competitiveness and economic transformation. Genetic engineering is currently the flagship tool in the area of biotechnology, but gene editing and gene drive technologies are emerging as potentially transformative technologies. Genome editing is the deliberate alteration of a selected DNA sequence in a cell using site-specific DNA nucleases, a technology described as revolutionary in both medicine and agriculture. In gene editing, site-specific double stranded breaks are generated by engineered nucleases[7], which activates the cell's own repair system resulting in small deletions or insertions, due to imperfections in repair. When exogenous DNA is simultaneously introduced in cells, it can support the repair process at the target site and enable a predetermined exchange of single or multiple nucleotides, in a process called targeted mutagenesis.

Gene drive, on the other hand, is a process of biased inheritance that allows a gene to be transmitted from parent to offspring increasing in frequency in a population over multiple generations. This technology can be used, for example, to spread a gene in mosquito populations that confers resistance to infection by the malaria parasite *Plasmodium falciparum*. The technology could be an important tool for the eradication of malaria, a disease transmitted by mosquitoes endemic in more that 100 countries and which affects about half of the world's population. Despite ongoing control efforts, malaria is still the most important parasitic infectious disease globally. According to the World Health Organisation (WHO), in 2015 there were about 212 million malaria cases and an estimated 429,000

[7] A nuclease is an enzyme (a protein that catalyses a chemical reaction) that cuts the strands of DNA or RNA. Sometimes nucleases are referred to as 'molecular scissors'.

malaria deaths. While there is a pledge to eradicate the disease, it is also acknowledged that this goal is unattainable with current control tools. Gene drive technology has potential for the control of other important insect borne diseases, such as dengue, Zika virus and chikungunya.

Progress to date in the development of GM mosquitoes includes the sequencing of the genomes of two species, and the identification of sex, tissue and developmental stage specific DNA control sequences. In addition, genetic modification protocols have been developed for all the major mosquito genera.

A number of regulatory frameworks for testing genetically modified mosquitoes have been developed, including a Guideline Framework by the WHO and the Foundation for National Institute of Health; and a protocol for the environmental assessments of all genetically modified organisms by the European Safety Authority. However, a weak regulatory framework in Africa risks impeding the use of this technology in the continent.

To strengthen the regulatory capacity of African countries, in particular Burkina Faso, Mali and Uganda, NEPAD is engaged in the three-year *Target Malaria* intervention with the following objectives:

- Assess the capacity and readiness of Sub-Sahara African countries to use gene drive technology in fighting malaria
- Assist to develop adequate policy at the national, regional and continental levels that will support the adoption of the technology
- Build the required regulatory capacity at national, regional and continental levels
- Leverage the political will in Africa to embrace the technology
- Raise public awareness about the potential benefits of gene drive

Following the approval granted early in 2016 by the Burkina Faso Biosafety Agency to start contained experiments with transgenic mosquitoes, the Target Malaria project is close to submitting an application for contained use of transgenic mosquitoes in Mali.

Session 4: The Theory of Change

Theory of Change

Nick Manson, Interim Programme Director, Mzima Cow Project

Theory of Change is a 'critical, multi-stakeholder exploration of intentions, interests, power and gender relations, in order to contribute to social justice, equality and sustainable development'. The key questions are: 'What change, for whom, why – and who says so?'. This analysis helps to identify opportunities to optimise the positive impact of a project or initiative.

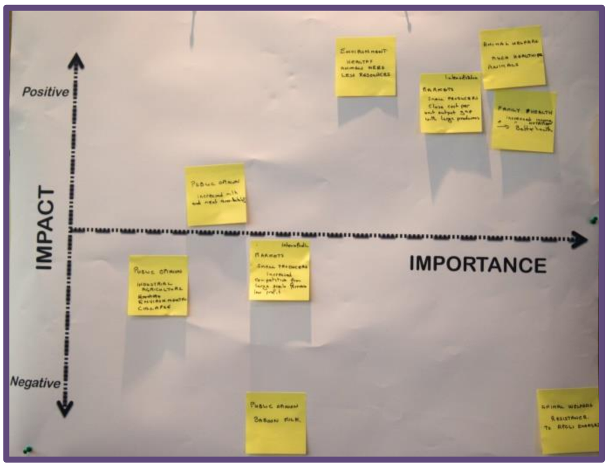
Theory of Change is an appropriate methodology to apply to the Mzima Cow project for a number of reasons:

1. It is an established standard for projects of the CGIAR system (including ILRI), as well as for other international agencies and funders
2. Establish an implementation programme supporting the Mzima Cow initiative
3. Inform funding bids
4. Inform a stakeholder engagement strategy
5. Provide the basis for the programme monitoring, evaluation and learning
6. Help inform and assist regulatory authorities

Table Exercise 2: Contexts and Stakeholders

The exercise aimed to address the following question: 'Who do we want to benefit?', and to identify key stakeholders in different contexts: pastoralists; smallholder farmers and large commercial livestock and dairy producers. Participants were instructed to rank stakeholders according to their 'proximity' to the beneficiaries; attribute a score according to their perceived importance in terms of risk, value and dependence (3 for very important, to 1 to less important); and reflect whether on balance their status or influence would be 'negative' or 'positive' with respect to Mzima Cow. The intended output of the discussions is to identify and map stakeholders and to identify common actors across contexts, who therefore need to be considered as key stakeholders.

Critical stakeholders in pastoralists and farming communities identified during the discussions include village leaders and traditional chiefs, because of the respect they command and because of their role in advising on extension. For smallholder farmers and pastoralists, other members of the community, in particular respected individuals with high social standing, were identified as important stakeholders, setting example for either adoption or rejection of new technologies or solutions. Local cooperatives, responsible for buying and distributing milk and meat products, are also critical gatekeepers, and their positive attitude towards Mzima Cow will be defining for the successful deployment of the technology.



One of the group outputs of Table Exercise 2

Animal health professionals (veterinary doctors and inputs dealers) were also considered important stakeholders, and ones likely to have a negative attitude to the technology due to loss of revenue for treating sick animals. However, it was also pointed out that demand for other veterinary services may increase, such as the artificial insemination of cows (with transgenic sperm) and assisting with animal births.

Stakeholders further removed from the key beneficiaries include politicians, important because they may either accept or reject the technology depending on how they perceive their chances of become elected. The degree of their influence is likely to be dependent on the local political context, for example, elected leaders tend to be more active and play a more important role before, rather than after, national elections. Another key stakeholder group, and also one that could play either a positive or negative role, is the media.

In terms of industry, pharmaceutical companies producing trypanosome drugs are unlikely to oppose the new technology. However, since those drugs are low-volume, low profit margin products, the risk is that producers may cease production altogether if revenues drop even further because of reduced need for treatment. Biotech companies are likely to support the new technology. Animal research initiatives for developing countries and scientists working in these projects are expected to be positive towards this technology, as the project would raise awareness of the importance of livestock in developing countries, and potentially result in increased funding for the sector.

NGOs were identified as important stakeholders in all contexts, and participants agreed their likely attitude to the Mzima Cow would depend on whether the NGO in question is an African organisation or from the USA or Europe. African NGOs, while having a focus on environmental considerations, are in general also mindful of how people may be socially and economically affected by a specific problem (and for example, they also promote access to healthcare). Foreign environmental NGOs from industrialised countries, on the other hand, are less familiar with the human impact of animal and crop diseases in developing countries, and therefore likely to disregard social and economic considerations of possible course of actions and focus solely on the environment (minus the people in the environment).

Participants agreed it is important to develop a communication strategy with clear messages on the expected benefits and possible risks of the project. How these messages are delivered is likely to influence whether ‘middle ground’ NGOs; politicians and media professionals develops a positive or a negative attitude towards Mzima Cow, and therefore these groups are all key stakeholder for the project. However, it was also agreed that negative activism from some groups is to be expected, and hence it is important to prepare for this. For example, NGOs identified to be completely negative towards all the applications of GM may not be a suitable target for communication efforts.

The impact of the project time scale on the development of a stakeholder engagement plan was also discussed. It is estimated that a GM calf will be available, at the earliest, in

two years. Commercial deployment of trypanosome resistant cows, of different breeds, is therefore at least 10-15 years away, and it will require overcoming a series of scientific and regulatory hurdles. However, it was agreed that it is important to engage with stakeholders at very early stages of the project, to inform and guide the development of a regulatory framework that both safeguards human health and the environment, while allowing the deployment of the technology in such a way that maximises positive impacts.

In summary, it is critical to develop very early on a communication strategy that balances the need for caution related to the long project timeline with the requirement to be open and transparent to all stakeholders, while also allaying unfounded fears and misconceptions. It is also important for this strategy to be flexible and dynamic, since both the regulatory and the disease environments may change during the duration of the project.

Session 5: Cross-Cutting Issues – Communication and Regulation

Genetics for Africa Strategies and Opportunities, (G4ASO)

Bernie Jones, Project Co-Leader, G4ASO

The Genetics for Africa – Strategies & Opportunities (G4ASO) planning grant was developed in in response to the feedback received to a three-year project that focused on communication and dialog activities crop genetic improvement to improve the uptake of indigenous research for increased agricultural productivity: Biosciences for Farming in Africa (B4FA). B4FA trained 160 journalists from four Sub-Saharan African countries: Ghana, Nigeria, Tanzania and Uganda, and established a lively network of media and research professionals which led to the publication of over 1800 media pieces. B4FA also drew attention to the fact that despite the richness in indigenous research projects addressing important national priorities, little of this research is generally known to the general public or even to members of the scientific community working in other fields or outside the country.

B4FA highlighted the importance of genetics research for achieving key developmental goals in African countries. However, participants remarked that keeping the focus solely on plant genetics was artificial, since genetic research on animal and insects is also critical for increasing the productivity and profitability of agricultural systems. In addition, human genetics research is very important not only for addressing major health challenges specific to Africa, but also for deepening understanding of the evolution

of mankind, since the human species originated in this continent. Increasing the visibility of the range of research activities in the continent would facilitate streamlining of priorities, reduce duplication of efforts, encourage collaborations and help to prioritise national and international funding for increased impact. Demand for increased communication of genetics research should furthermore not be limited to the original four target countries.

A follow-on initiative on communication and outreach activities focused on genetics in Sub-Sahara Africa would therefore have three main objectives: 1) Cover genetic research more widely, including in animals and humans; 2) Promote public outreach in more African countries; 3) Uncover and celebrate African research and researchers.

G4ASO aimed to answer three key questions:

1. *Where* – which African countries should be the focus of future genetics communication?
2. *Who* is active in genetics research in the continent? And what are motivations?
3. *Which* areas of genetics should be showcased?

Three focused two-day planning workshops were organised for each topic. The first, held in July 2015 in Cambridge, United Kingdom, reviewed recent advances and applications of the new plant breeding technologies (NPBTs) and epigenetics. The second workshop was held in Nairobi, Kenya, in September 2015, and reviewed existing initiatives in animal, fish and insect genetics. The third and final event in the series was a workshop on human genetics, held in South Africa in January 2016.

Some of the lessons derived from the three workshops are applicable to all forms of genetics research in Africa. Firstly, genetics research is key for improving nutrition, health and livelihoods in the continent, and it is therefore important to increase the visibility and awareness of indigenous programmes and initiatives, a requisite to attract more funding and increased political support. There is also a requirement to improve public understanding of genetics by promoting the subject at school level; and by actively engaging in the public communication of science. Over-regulation risk making new technologies inaccessible: the regulatory approach needs to become more sophisticated and responsive to the needs of African countries while ensuring the safe and responsible deployment of technology. To achieve this aim, there is a need to improve the skills of regulators, practitioners and other stakeholder groups. Genetics research in the continent also requires improving training of African researchers; developing higher capacity for national and international collaboration and networking; develop African-appropriate research tools and methods; and encouraging African leadership in the sector.

In terms of animal genetic research, this field is particularly key in Africa for enhancing nutrition, health and livelihoods, and the continent is an invaluable “world resource” for animal genetic diversity. In addition, there is an important interplay with plant genetics and human genetics/health. Regulatory schemes are however untested and designed for plants rather than animals. Public engagement and communication are critical since some areas of research are potentially very beneficial but also require assessing

ethical considerations and fears. Therefore, develop public trust in animal biotechnology should be a key objective.

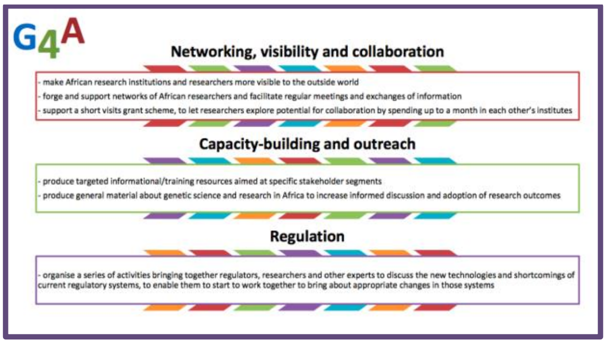


Figure 9. Overview of key activities needed to promote African genetics research and maximise its potential development impact. Source: Genetics for Africa, G4A.

From the point of view of G4ASO, the additional potential of the Mzima Cow workshop is to address the following questions:

- Is the attitude towards crop biotech going to be repeated for animals?
- How will people react/respond to biotech animals?
- Will the same degree of activism (as in crops) be present?
- How will regulators see the issue?
- Are current regulations and frameworks sufficient and/or appropriate?
- Are there differences between attitudes to GM cattle vs eg GM mosquitos or chicken?
- What will be the differences in attitudes across different countries, religions, social groups etc?

NEPAD Agency and the Development of Biosafety Regulatory Frameworks in Africa

Diran Makinde, Senior Advisor, NEPAD Industrialization, Science, Technology and Innovation Hub

The Africa Union Agenda 2063 is a strategic framework for the socio-economic transformation of the continent over the next 50 years. It builds on, and seeks to accelerate the implementation of past and existing continental initiatives for growth and sustainable development. It has been developed through a consultative process with the African Citizenry. The choice of a 50-year timeframe has a symbolic significance as it marks the 50th Anniversary of the Organisation of African Unity. It responds to the need to take stock of its achievements and set its long-term vision and goals. In operational terms, the Agenda 2063 is a rolling plan with short (10 years), medium (10-25 years) and long-term (25-50 years) timeframes.

Africa 2063 sets seven aspirations:

1. A prosperous Africa based on inclusive growth and sustainable development
2. An integrated continent, politically united and based on the ideals of Pan- Africanism and the vision of Africa's Renaissance
3. An Africa of good governance, democracy, respect for human rights, justice and the rule of law
4. A peaceful and secure Africa
5. An Africa with a strong cultural identity, common heritage, shared values and ethics
6. An Africa where whose development is people-driven, relying on the potential of African people, especially its women and youth, and caring for children
7. Africa as a strong, united, resilient and influential global player

The Aspirations translate into 20 Goals and Priority Areas. There are significant parallels between these aspirations and the United Nations Sustainable Development Goals (SDGs). Both agendas underscore the importance of partnerships and synergies at

all levels and across all sectors for the realization of all aspirations, goals, priority actions and targets. The 2063 Agenda also signals the willingness of Africa countries to take control over their own development goals, and to take full responsibility for financing development.

The AU Science, Technology and Innovation Strategy for Africa 2024 (STISA-2024) was developed in parallel to the AU Agenda 2063. The STISA-2024 is the first of the ten-year incremental phasing strategies to respond to the demand for science, technology and innovation to impact across critical sectors including agriculture, energy, environment, health, water and infrastructure development. The strategy is firmly anchored on six distinct priority areas: Eradication of Hunger and Achieving Food Security; Prevention and Control of Diseases; Communication (Physical and Intellectual Mobility); Protection of our Space; Live Together- Build the Society; and Wealth Creation.

The New Partnership for Africa's Development (NEPAD) has established two platforms as models for regulation for the safe and responsible deployment of new technologies: the African Biosafety Network of Expertise (ABNE); and the African Medicines Regulatory Harmonization (AMRH). The AMRH program is implemented within the framework of the Pharmaceutical Manufacturing Plan for Africa (PMPA), the AU Roadmap on Shared Responsibility and Global Solidarity on AIDS, TB and Malaria Response in Africa (2015-2030).

ABNE and AMRH complement each other and both agencies aim to facilitate information sharing between health regulators and agricultural/environmental regulators across countries and regions. Work to date includes the development of policies and regulations to promote safe development, dissemination, and adoption of agricultural biotechnology tools, and risk assessment techniques and their application to inform decision-making. Delivering training to improve critical mass of regulators with enhanced competencies in biosafety regulation is also a key activity.

Crop Improvement Projects using GM in Africa comprise the development of insect resistant maize and cowpea varieties: improvement of nitrogen use efficiency and salt tolerance in rice; development of virus resistant cassava, and of nutritionally enhanced crops (cassava, banana, sorghum). GM technologies (transgenic mosquitoes) are also being deployed to combat malaria; and to develop a GM entomopathogenic fungus[8].

In terms of the current burden of trypanosomiasis, a priority should be to map countries with greatest burden of disease, and determine whether they appropriate regulatory frameworks are in place or being developed.

Communications Practices for Livestock Genetic Research in Africa

Susan MacMillan, Team Leader, Communications, Awareness and Advocacy, ILRI

Communicating scientific advances to the wider community is critically important for maximising the benefits of science and

[8] An entomopathogenic fungus is a fungus that can act as a parasite of insects and kills or seriously disables them.

research, especially for research projects with potential to be controversial or to generate public concerns.

There are three key principles for communicating controversial topics:

1. *Build bridges*: Listen to people's concerns; non-specialists have a right to be worried, especially concerning new advances that could significantly alter the status quo. Promote thoughtful conversations and responses to advances in animal genetics.
2. *Build trust*: Share your values and concerns, and provide information that is clear and helpful. Underscore that the values of the project are aligned with those of your audience.
3. *Build a vision*: Be bold. Africa is a big continent with big energy, resources and potential as well as challenges.

Projects should map, and regularly update, their 'boundary partners' to determine which partners could be most helpful and which most damaging to the project. Develop different communication formats to suit different audiences. Avoid jargon. Establish a consistent coherent communications record. Marry facts and figures with stories and anecdotes.

Keep your audience focused on the size of the problem that the research is addressing. Emphasise that the data and results obtained from the research will be open to all. Establish that safety is a top priority of your project and describe the measures in place to ensure that safety. Emphasize that your project is profoundly international and long-term in nature.

THE "TEN COMMANDMENTS"

1. Tell the truth
2. Paint a picture
3. Keep it simple
4. Make it dramatic
5. Be real
6. Be accessible
7. Be vulnerable
8. Speak from the heart
9. Make it personal
10. Make it new

Figure 10. The "Ten Commandments" for the successful communication of potentially controversial science topics. Source: Susan MacMillan

Session 6: Theory of Change

Table Exercise 3: Potential Impact of Mzima Cattle

The purpose of the exercise was to begin to understand the potential impact of trypanosome resistant cattle in different contexts: pastoralists, smallholder farmers and intensive production systems. Participants were requested to also consider related impacts, which in turn may generate other consequences or ripple effects that may not be initially apparent, and to discuss whom or what may be affected.

It was agreed that a likely consequence of the dissemination of trypanosome resistant cows for smallholder farmers and pastoralists would be an increase in livestock productivity, although it was also emphasised that the exact effect of the transgene on milk and meat production is currently not known and must be carefully assessed in impact and safety studies. For smallholder farmers, an increase in livestock productivity would also lead to an overall enhancement of farm productivity due to the availability of animal labour and improved soil fertility from manure.

Increases in productivity would likely translate into improved nutrition and health of household, and - provided the enabling infrastructure is in place (such as access to markets, financial services, etc.)-, also into a higher household income level. This will depend of course depend on whether consumers are happy to buy and consume the milk and meat of GM cows. Nevertheless, participants remarked that increased household income does not necessarily correlate with increased family wellbeing. Improvement in available resources, for example, may result in people having more children, and therefore individuals in the household would not be better off than before. This may be a like outcome especially in rural areas in Africa where having more children is perceived to be beneficial for the family, and where politicians often encourage big families.

It was also agreed that women would stand to benefit significantly from the technology because of the reduced required for human farm labour and the increased milk productivity in the absence of trypanosomiasis. Milk is traditionally one of the few assets controlled by women. However, it was remarked that existing social and cultural norms and household dynamics may be an obstacle for the realisation of these benefits. For example, there are many documented examples of women losing control of their traditional economic assets once these become more productive and profitable, because men take over. Increased earning capacity by women in the household also sometimes results in family conflicts and instability (the woman may become “too independent”), and in men relinquishing some of their financial responsibilities, such as the education of children. So, while women may have a higher purchasing power, this may not translate into a personal benefit. In addition, increased household income sometimes results in men acquiring new wives, resulting in loss of status of the first wife. Increased alcohol consumption by male adults of the household is also another possible negative outcome of increased family income. In pastoralist communities, the technology may also negatively affect the education of boys, since additional family

members would be required to look after larger livestock herds.

Cultural settings and beliefs usually alter very slowly, and generally this process starts from “the inside” under the influence of prominent members of the community championing change, rather than as response to outside pressures.

Religious leaders and members of the community were identified as potentially in conflict with new technologies, since they may believe scientists are “playing God”. However, since sacred texts promote the wellbeing of the community and the sharing of benefits among people, they may support Mzima Cow.

Veterinary doctors would constitute a stakeholder group potentially negatively affected by the deployment of trypanosome resistant cows, due to a loss of income from selling drugs. They would also need to acquire a new knowledge base to deal and treat the new animals. On the other hand, there would also be a requirement for increased monitoring and for specific veterinary services, such as the artificial insemination of cows with transgenic semen.

It will be important to marry the dissemination of the new technology with effective agricultural extension services to ensure proper breeding of the animals so as to maintain resistance to the disease in livestock populations. All stakeholders will require education in the new technology, including community members, vets, politicians and scientists.

The environmental impacts of Mzima Cow were also discussed. It was agreed that the overall levels of GHG emissions (methane) would rise as (and if) the number of livestock increases, although emissions per kg of animal product (milk and meat) would decrease. Since healthy animals also require smaller levels of resources, this would constitute a beneficial environmental impact. However, larger livestock populations may have detrimental effects on the level of biodiversity of natural habitats pastures because of the effects of over-grazing. An increase number of livestock due to the removal of disease may also result in heightened conflicts for available resources, especially water, which is required for many other uses, such as crop production and household needs.

In terms of the level of genetic diversity in cattle breeds, a transgenic approach could be more beneficial that conventional breeding techniques, since it relies on introducing a single, known gene into the genome of a target breed as opposed to the mixing of two different genomes by crossing two breeds. However, it will be very important to establish a large number of founder animals to maintain genetic diversity, to cater for the diverse conditions of the African continent and to prevent just one breed dominating the sector. This will be a challenging endeavour that will require careful planning and consideration.

In terms of market impacts, the effects of the new technology will depend on a number of factors. Large-scale producers may be able to increase the efficiency of production faster, potentially driving prices down to the detriment of small scale-producers. However, this may not be the case if both types of producers cater for different markets: the large producers targeting national and international markets and small producers mostly selling their products in informal, local

markets. How the process of change takes place will also be influential. Large-scale producers are generally better connected and more open to new technologies, and therefore also likely to be early adopters of the technology and benefit sooner. Small-scale producers on the contrary tend to live in more remote areas, be less aware of new technologies, and therefore likely to be late adopters, which means that the technology will initially be detrimental to them. However, since small-scale and resource-poor farmers are also less able to treat sick animals, once they adopt the technology they stand to accrue the largest percentage benefits in terms of gain, and to benefit the most.

The new technology is also likely to become very divisive topic in communities, with some individuals being very for and others totally against it.

With respect to communicating the technology, on one hand there is a large, positive public relations story to be told, related to the elimination of the tsetse belt which would enable an agro-industrial revolution across a huge expanse of land. It is important however that this story is told properly. On the other hand, it is critical to prepare for worst-case scenarios, because they will happen, and to be aware that a single misplaced message may destroy the accumulated benefits long-term communication efforts. In particular, there is a significant risk of Mzima Cow being branded the "baboon cow" even if the gene introduced is synthetic. In the discussion on how to deal with this issue, it was suggested that it is very important to emphasise that the sequence of the synthetic gene was designed only with guidance from the sequence of the baboon gene, and to be fully transparent and truthful about the technology. Failure to do so will most certainly backfire. Addressing the situation proactively was also suggested as a possible course of action. Insulin to treat human diabetes, produced in GM pigs, is after all never called "pig juice".

In summary, it was agreed it is important to be cautious into assuming too much about the impact of the technology. It will not provide a panacea, and there are a large number of complexities, cultural issues and hurdles associated with its deployment.

In terms of the process of change, there are two different possible levels of engagement. While governments usually opt for national campaigns, which are outside-in and top-down interventions, change usually happens from the inside, starting from the activity of key influencers and gate-keepers, at the level of individual communities. These individuals must first buy into a new technology or idea before encouraging other members of the community to follow suit.

The discussion also highlighted high level of complexity of all the topics discussed. It will be very important to carry out detailed baseline studies to collect data in different sectors, and to monitor how these change over the years. This data should be used to develop models and projections, which will be very important for the project and very valuable tools for communication and fundraising.

Biosafety, Public Acceptance of Modern Biotechnology; and the role of Communication

Eric Okoree, CEO National Biosafety Authority, Ghana

A competent, transparent and trusted biosafety system is an effective tool for the acceptance of modern biotechnology and new technologies. Trust is achieved by fostering public participation in decision making, which in turn relies on successful communication and active engagement of stakeholders. A number of African countries have established Biosafety Frameworks, such as South Africa, Kenya, Nigeria, Burkina Faso and Ghana, but most African countries lack appropriate regulations.

In Ghana, the National Biosafety Authority (NBA) is has established the provision for the public to contribute to biosafety decision. The NBA is committed to publish in the Gazette a notice concerning an application for release into the environment for the general information of the public, within fourteen days of the submission of the application. On request, the Authority may avail to a person/s portions of an application which do not qualify as confidential information. And finally, the public is to be notified of all decisions made. In reaching a final decision on an application, the NBA takes into account the following: 1) information submitted by the applicant; the risk assessment report; relevant comments submitted by the public; and socio- economic considerations arising from the impact of a proposed activity and of the genetically modified organism on the environment.

A problem in Ghana, as in other African countries engaged in biotechnology research or seeking to commercialise GM crops, is the influence of NGOs seeking to halt the research, production and sale of GM crops. As a result of pressure from (mostly international) NGOs, an Accra Fast Track High Court Order has halted the production and sale of Genetically Modified cowpeas and rice in Ghana. A civil society group has also sued the National Biosafety Committee in a bid to prevent the commercialisation of GM crops.

Public engagement is a key part of the solution to the problem. Scientists need to communicate actively, improving their capacity to do so at all levels, and present their case and the importance of their research clearly and in a language accessible to all. Engaging the public at the conceptual stage of research is very important. Only if scientists communicate effectively, will modern biotechnology gain acceptance through transparent biosafety.

African Parks – a Wildlife Perspective

Sam Kamoto, African Parks Environmental Education and Extension Manager

African Parks is a non-profit conservation organisation that takes the complete responsibility for the rehabilitation and long-term management of national parks and protected areas, in partnership with governments and local communities. It manages 10 national parks and protected areas in seven countries covering six million hectares: Malawi, Zambia, Central African Republic, the Democratic Republic of Congo, the Republic of Congo, Rwanda and Chad. It employs the largest counter-poaching force in Africa, with a workforce of over 600 rangers. It aims to be the leading player in

African conservation in terms of size and number of areas managed, and with respect to the diversity of ecosystems and species. It also seeks to improve the impact of conservation on local communities, and the level of governance of protected areas.

Engaging communities is essential to counterbalance the negative economic impact of setting land aside and to build a constituency for conservation. A central belief of the organization is that the ecosystem services that natural parks generate and the biodiversity that they conserve are necessary for the wellbeing of humanity and therefore worth conserving. Since conservation is a choice of land use, and a choice that needs to be made by people living locally, it is critical to build a constituency at the level of communities for conservation, where people understand and are enabled to value and protect the benefits that can be provided by these parks through good management. In so doing, conservation is more likely to remain the land-use of choice.

Each Park develops its own community engagement strategy, which is tailored to the individual needs of the park, with three key engagement objectives:

1. Create emotional ownership of the park by local communities, by establishing collaborative duties and by sharing responsibilities and benefits
2. Mitigate the negative impact of setting aside protected areas aside, ensuring that the parks contribute positively to the livelihoods of local communities and to poverty alleviation
3. Reduce human population pressures on the park and the surrounding resources that people depend on. The pressure on resources has become unsustainable due to poverty levels, poor job and career prospects, and high population growth

Trypanosomiasis is a problem in the parks. Staff are tested for the disease every 6 months, and treatment is immediately provided to individuals who are infected. Nkhotakota Wildlife Reserve in Malawi has also established a tsetse fly control programme. Future plans include placing monitoring traps throughout the project area in order to monitor tsetse population fluctuations and occurrence.

The deployment of GM trypanosomiasis resistant cows may increase the productivity and wealth of local communities, and in this way and reduce the negative economic impact of setting aside land for conservation.

On the other hand, without proper herd management and land conservation strategies, a cheap and effective trypanosomiasis solution – such as the Mzima cow – may result in increases in herd sizes and pressure on parks from livestock holders for grazing purposes.

Animal Biotechnologies and the Foreign Agricultural Service

Diane Wray-Cahen, Senior Science Advisor USDA Foreign Agricultural Service

The first transgenic organisms were developed in the 1980s: mouse in 1982, followed by tobacco (1983), fish (1983) and pig (1985). It was also during this decade that the need for the establishment of regulatory oversight of this technology was expressed.

GM crops were first approved for and commercial release in the 1990, and in the following 20 years these have been planted

in a cumulative area of 2 billion hectares (and 179.7 million hectares just in 2015). These figures make the technology very successful for agriculture.

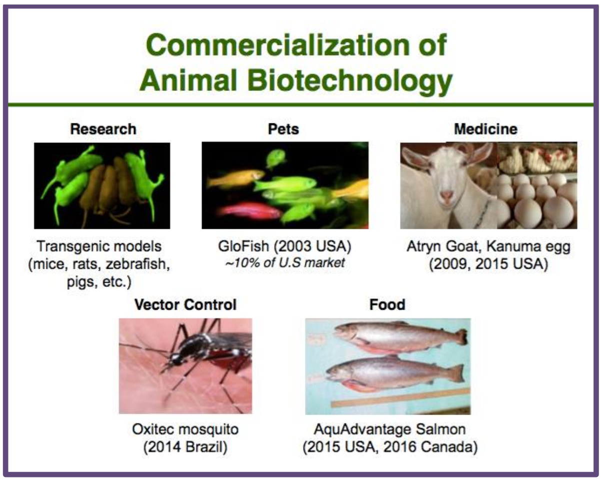


Figure 11. GM animals approved for research; the pet industry; drug production; disease control; and for food (yet to be commercialised). Source: Diane Wray-Cahen.

While the development of transgenic animal models has been crucially important for research and in the study of diseases, the commercialization of animal biotechnology products has lagged behind. GloFish (pet fishes that glow in the dark) have been in the market in the USA since 2000, and command a non-negligible share of the market. GM animals approved in the USA for the production of medicines include Atryn goat (approved in 2009) and Kamuna chickens (approved in 2015). Kamuna eggs contain lysosomal acid lipase, used to treat patients with Wolman disease, a rare condition but potentially lethal that affects 200,000 people in the USA alone. GM mosquitos for the control of malaria were release in Brazil in 2014, and the list is completed with the approval of AquAdvantage Salmon, in 2015 in the USA and 2016 in Canada, although commercialisation is still pending.

However, the sector has also experienced lost opportunities. For livestock, efforts to improve disease resistance in animals and reduce the environmental footprint of agriculture have failed. Mastitis Resistant Cows, developed in 2000 to resist attack by one of the pathogens that causes infection of the cow's milk glands, has yet to be deployed, despite the fact that the disease causes a loss of USD 1.7 billion per year. EnviroPigs (made in Canada in 1999), are genetically modified with the capability to digest plant phosphorus more efficiently than conventional pigs. The technology is beneficial because it reduces the cost of feeding animals (it removes the need to supplement feed with phosphorous) and lowers the level of phosphorous in manure, which is a potential source of environmental pollution.

Why use GM or genome editing techniques instead of developing new crop and animal varieties by conventional breeding? These technologies offer the possibility of introducing new characteristics or traits in target species which cannot be achieved through conventional breeding. In addition, they increase the precision and efficiency of introducing desirable traits; overcome low heritability of some traits; and eliminate problems due to linked traits[9]. The also

[9] Genetic linkage refers to the tendency of genes or DNA segments that are physically close on the same chromosome to be inherited together because they are less likely to recombine during sexual reproduction. A consequence of linkage is that non-desirable genes 'linked' to the gene/s (or characteristic) of interest are also introduced in the progeny of breeding crosses. Removing them is difficult, sometimes not possible, and takes a long time. It relies on crossing the

reduce the time necessary for genetic advancement of a breed, which with conventional methods takes many generations of back crossing. Developing a new breed, such as the Brangus -a cross between Angus and Brahman cows-, takes between 30 and 40 years.

The USA Foreign Agricultural Service (FAS) leads the efforts of the US Department for Agriculture (USDA) to help developing countries improve their agricultural systems and build their trade capacity. It also supports agricultural development and education through training programmes. These include the Cochran Program, a short course to improve agricultural systems for the production of domestic food and fibres; and the Borlaug Fellowship Program (with a duration of 6-12 weeks) which provides training and collaborative research opportunities. Faculty Exchange Programmes provide training for agricultural educators from institutions of higher learning, and last between 4 and 5 months. Workshops, including a periodic international workshop on the regulation of animal biotechnologies, aim to provide science communication training; support the development of science-based regulations; and promote data transparency.

An effective regulatory system must have the following characteristics:

- Effective – i.e., protect public safety
- Science-based, risk-based and defensible
- Timely and predictable (important for innovation)
- Credible to the public – whose concerns may reflect non-scientific, values-based issues
- Transparent to all
- Allow production and trade of safe products

Meeting the challenges of the future sustainably will require optimising the selection of the most appropriate and targeted tools. It is important to ensure that future generation have more options and not fewer to address global problems.

It is critical to remember that developing and deploying a biotech animal is much more complex than delivering a new product, and that success relies on social transformation.

Communicating about GMOs and Modern Agriculture

Jon Entine, Executive Director, Genetic Literacy Project

Plant, animal and human genetics are central to agriculture and food production, medicine and to our understanding of human evolution. Research in these areas can improve food security, help preserve finite natural resources, reduce environmental footprints and dramatically revolutionise medicine. For this reason, innovation can also generate public concern and raise ethical considerations.

There are many challenges in communicating to the general public issues associated with genetics and genetics research, although these are mostly non-scientific. They include scepticism towards government and government institutions; anti-corporation attitudes in members of the public; lack of scientific training amongst media professionals; a polarised political

progeny to one of the parent breeds for several generations, a process called backcrossing.

environment; and the social media "echo chamber", which leads to the polarisation of views and opinions and the active self-segregation of users in entrenched ideological groups.

The Genetic Literacy Project (GLP) explores the intersection of DNA research and real world applications of genetics with the media and policy worlds in order to disentangle science from ideology. The commitment of the GLP is to promote public awareness and constructive discussion of genetics, biotechnology, evolution and science literacy. GLP is a non-profit initiative funded by grants from independent foundations and charities. It employs a core team of number of communication specialists and also draws work from contributing columnists.

The GLP website provides information on human and agricultural genetic topics, and its resources include a weekly newsletter.

"If you try to outlaw the future, it will just happen somewhere else."

– Paul Graham

Session 7: Theory of Change – Moving Forward

Table Exercise 4: Building a Roadmap/Recommendations

The aim of the exercise is to identify key challenges and priorities for action, and to determine when in the product development pipeline these actions should take place (and by whom). The timescale considered is five years before product development; deployment of the new technology; and five years after the release of Mzima Cow.

Two key challenges were identified as important for the entire timescale:

1. The need to build trust and public acceptance of Mzima Cow by all stakeholders concerned. Actions and target groups would however vary according to the stage of the project and geographical location.
2. The requirement of high quality studies and data on the scientific, economic and social impact of the technology, before and after deployment.

A further key challenge, which will need to be addressed once a proof of concept is available, will be to:

3. Devise a detailed plan for technology deployment ensuring that targeted beneficiaries have access to Mzima cow, and prepare for scale-up.

These will be discussed in more detail below.

1. Develop a Public Engagement and Communication Strategy

From the very beginning of a project…

Negative feedback from anti-GM modification is to be expected from the onset of the project, and the project needs to prepare to counteract it. A specific challenge of Mzima Cow will be that the transgene is designed based on information derived from the sequence of a primate gene. It is important that messages are carefully developed and managed, underlying potential benefits while also being open and transparent about the technology. Improved sustainability of livestock production and improved animal welfare should be emphasized as key objectives of the project, since these will be critical for gaining public acceptance.

Communication targets need to be identified at all levels: small-scale and large-scale farmers; farming cooperatives; policy makers; government representatives; civil society and consumer groups. Engagement with groups hostile to the technology should also be considered. A stakeholder group specific to Africa are consumer groups who in addition to representing consumers also promote the wellbeing of resource-poor smallholder farmers and pastoralists, who often have no voice and limited possibilities for protecting their interests. It is very important that the debate does not create a sense of conflict between the interests of smallholder farmers and pastoralists and the interests of large-scale, industrial producers. Engaging smallholder groups, their cooperatives, and grass root organisations from the beginning is essential.

Agricultural extension professionals are a key target group and should be engaged from the beginning and during all subsequent stages of the project. In addition to the fact that their buy-in of the technology is critical, members of this group will be able to advise on the current set-up and status of existing technology dissemination avenues; their likely pitfalls; and social and cultural sensitivity issues that may arise (such as sentimental attachment to local breeds). Their input is hence very important in formulating a deployment strategy.

The media is also a crucial target group, and campaigns should encourage constructive dialogue, with focus on the potential benefits technology but also acknowledging likely risks and uncertainties.

Effective communication is also central ensure the project is able to attract sufficient resources to proceed. It is important to reflect on the public acceptability of project partners, and be selective in establishing associations.

Last but not least, regulators need to be an early focus of communication and engagement to ensure that target areas for the release of the technology have the regulatory framework in place to allow deployment. Since asynchronous approval in a region will generate many managerial problems due to the movement of livestock and animal products across national borders, the importance of the harmonisation of regulation should be a key message.

Closer to the time of deployment…

Champion farmers and trailblazer individuals and communities are key communication targets at this stage of the project, and should become partners in pilot studies set to assess the economic and social impacts of Mzima Cow. Provided the potential benefits of the technology are proven and evident to them, members of this group will be the most powerful witnesses and supporters of the project because they will be talking from experience.

Farming communities in countries where consumption of primates and bush meat is acceptable, such as West Africa, should also be targeted for pilot studies and or initial deployment. This will require early engagement with regulators and relevant ministries of the countries concerned.

Agricultural extension agents should be engaged to determine the most suitable locations for pilot studies and the modality of initial deployment, which are likely to have a very significant impact on success.

A communication tool that has been successful in increasing acceptance of controversial topics are 'town councils'. These are organised at the level of communities, and everybody is invited to apply for a ticket to participate and talk for a defined, short amount of time (usually 10-15 minutes) to expose their view to the rest of the participants. The condition for taking part is that nobody is allowed to interrupt anyone else, nor talk outside of their allocated slot. In addition, everybody needs to commit to attend the entire event, which generally lasts a few hours. This forum allows people with opposed views, and who may be affected by the technology in different ways, to share their viewpoint, current plights, and fears and/or hopes for the technology. This exchange may facilitate bridging gaps and opening opportunities for constructive dialogue in later on.

At the time of deployment of Mzima Cow and afterwards…

It will be critical to establish and effective communication and training programme targeting agricultural extension agents, vets, farmers and pastoralists on how to deal with the new technology, to ensure sustainability on the ground. In particular, training on required breeding protocols (relying on artificial insemination) will be essential, to ensure the transgene is maintained in livestock populations. It will be important to make available a simple diagnostic kit to test for the presence of the transgene in cattle that can be used in the field with no requirements for specialised equipment, similar to the strip pregnancy test. A challenge will be to develop a test that can differentiate between animals homozygous for the transgene and heterozygous individuals.

A serious risk to the project, especially in the early stages after deployment, is to prevent problems unrelated to the technology being attributed it, for example, the death of animals as a result of a different disease. Managing this risk will require close monitoring on the ground, and effective communication and information channels between different stakeholder groups.

2. Plan and Perform Scientific, Environmental and Socio-economic Impact Studies

Scientific and socio-economic impact studies are important at all stages of the project, and should underpin communication and engagement communities in addition to guide product development and deployment. The most critical group that needs to be clearly convinced of the benefits of the technology are the members of the Mzima Cow research team. The efficacy of the transgene in providing long term resistance to trypanosomes to cattle needs to be studied and monitored over a number of years (and over a number of generations of cattle). The development of resistance to the transgene also needs to be carefully assessed. Monitoring and evaluation studies of the socio-economic and environmental impact of the technology will also be required, and it is important that these are long-term endeavours as opposed to short studies immediately after deployment.

It is also essential to plan for increasing genetic diversity of Mzima Cow, as a small number of founder animals will result in a narrow gene pool that can then lead to health and productivity problems unrelated to the presence of the transgene or the disease. This will be a great challenge for the project, and one that will require many careful planning and significant level of resources.

3. Devise a Plan for Technology Deployment and Scale-up

The challenges of scaling up deployment of Mzima Cow should not be underestimated. Overcoming them will require developing a comprehensive deployment plan; establishing key partnerships (e.g. with biotech companies to disseminate GM semen and government institutions); and sustained political will and support.

The three broad key actions support and complement each other rather than parallel strands of work, and are all integral for the success of the project.

4. Other Recommendations

In addition to recommending early dialogue with regulators on specific projects, it was felt that there was an opportunity for general awareness-building among the regulatory community of animal genetic research and its paradigms.

Without knowing more about the general principles of animal genetic research (for example, timescales and costs of breeding and research, key differences between plant and animal genetics, risk scenarios) it was difficult for members of the regulatory community present to engage with the specifics of whether their own regulatory regime would be appropriate for animal regulation. However, based on some of the scientific presentations at the workshop, they felt that it was possible that they would face challenges in applying existing regulations to the products of animal biotechnology research.

In addition to general awareness raising, participants felt there was a particular opportunity for regulators to work together to try to produce a harmonised, common approach, and that by starting soon they would have the opportunity to have an appropriate framework in place by the time applications began to be made in the future.

It was also felt that the general approach discussed and recommended by the workshop was fully in keeping with the strategies of AU-NEPAD, the AU 2063 Agenda and other pan-African networks such as ABNE, and that they would endorse the approach.

The workshop was felt to be uniquely valuable by participants, not just for the very unusual opportunity to engage with public genetic research early in its cycle, to build a community of awareness and interest around it that would ease its ultimate translation and uptake, but also for bringing together – for the first time – such a diverse range of stakeholders, from regulators to NGO's and research scientists, to share their experiences, insights and their own particular requirements and contributions in supporting the eventual successful release of the research outputs.

With this in mind, and to begin to implement the recommendations, participants felt there was a need to repeat similar stakeholder engagement workshops regularly as the research project unfolded, possibly with an "evolving" panel of participants – beginning with a greater number of regulators and other who needed to be aware of the research early, and who wanted to coordinate their activities, and – as the research got closer to the release stage – a greater number of stakeholders from the general public and beneficiary side. ILRI for its part undertook to engage and cooperate with such stakeholder workshops in the future, if relevant support could be found.

Appendix 1: List of Participants

Wednesday 18th January 2017

Day 1 AM	**Introduction**	
09:00	Welcome & Introductions	ILRI, Bernie Jones, Nick Manson
	Social/Scientific Perspectives	
10:00	**Some Perspectives on the Burden of Trypanosomiasis** 1. Burden on human health/zoonosis 2. Burden on Society, gender issues 3. Current state of interventions - successes and challenges	Eric Fevre Isabelle Baltenweck Gift Wiseman Wanda
10:45	**Table Exercise 1:** Burden of Trypanosomiasis – Your perspectives	All
11:15	BREAK: Tea & Coffee	
	Mzima Cow Project , the Science & Alternate Approaches	
11:30	4. History of the Project & Current Position 5. Tryp. resistance & transgenesis – Overview 6. An alternate means of combatting Trypanosomiasis	Steve Kemp & Jayne Raper Joseph Verdi Dr Silas Obukosia
12:20	Review of Morning, Questions, What's coming up	Bernie Jones & Nick Manson
12:45-13:30	LUNCH	
DAY 1 PM	**Theory of Change**	
13:30	About Theory of Change	Nick Manson
13:45	**Table Exercise 2:** Contexts & Stakeholders a) Into which 'contexts' will these cattle be introduced? b) Who are the stakeholders in these contexts? c) Who are the stakeholders in common across contexts? d) Who do we want to benefit?	All
15:15	BREAK: Coffee & Tea	
	Cross-cutting issues – Communications & Regulation	
15:30	1. Learning from G4FA & G4A 2. Biosafety in Africa: NEPAD-ABNE 3. Good practice in communications	Bernie Jones Diran Makinde Susan Macmillan
16:30	Review & Discussion	Discussant
17:00	**End of Session**	
18:00	Drinks & Workshop Dinner	ILRI
	After Dinner talk	Jon Entine

Thursday 19th January 2017

Day 2 AM	**Theory of Change**	
08:00	ILRI Tour	
09:00	Recap Day 1 & Questions	Bernie Jones
09:15	**Table Exercise 3:** Potential impact of these cattle	All
10:45	Break: Tea & Coffee	
11:15	A Series of Short Talks on Related Topics	Eric Okoree Sam Kamoto Diane Wray-Cahen
12:45	Lunch	
Day 2 PM	Theory of Change - Implementation	
13:30	**Table Exercise 4:** Moving forward	All
14:30	Coalesce Ideas and Discussion	Discussants
14: 45	What now?	Bernie Jones
15:00	**Close**	

Appendix 2: List of Participants

1. Isabelle Baltenweck, Interim Program Leader, Livelihoods, Gender, Impact and Innovation, ILRI, Kenya
2. Martin Bundi, Biosafety Officer, Kenyan National Biosafety Authority, Kenya
3. Claudia Canales Holzeis, G4A Project Co-Leader, United Kingdom
4. Jon Entine, Founder and Executive Director Genetic Literacy Project, United States
5. Eric Fevre, Chair of Veterinary Infectious Diseases, Epidemiology and Population Health,ILRI and Liverpool University, Kenya and United Kingdom
6. Brian Heap, Scientific Advisor at the Smart Villages Initiative
7. Bernie Jones, G4A Project Co-Leader, United Kingdom
8. Hellen Kajuju, Kenyan National Biosafety Authority, Kenya
9. John Kamanga, Director, South Rift Association of Land Owners (SORALO), Kenya
10. Carol Kamau, Agricultural Marketing Specialist, USDA FAS (Nairobi), Kenya
11. Sam Kamoto, Park Manager African Parks, Malawi
12. Margaret Karembu, Director, International Service for the Acquisition of Agri-biotech Applications (ISAAA), Kenya
13. Steve Kemp, Program Leader for Animal Biosciences and Professor in Tropical Genetics, ILRI and University of Edinburgh, Kenya and United Kingdom
14. Michael Kidoido, Economist, ILRI, Kenya
15. Martin Kiogora, Research Scientist, Kenya Agricultural and Livestock Research Organisation (KALRO) Biotechnology Research Institute, Kenya
16. Susan MacMillan, Team Leader, Communications, Awareness and Advocacy, ILRI, Kenya
17. Diran Makinde, Senior Advisor at NEPAD Agency, AU NEPAD, South Africa
18. Nick Manson, Interim Programme Director, Mzima Cow Project, United Kingdom
19. Emma Naluyima, Veterinary doctor and farmer, Uganda
20. Nehemiah Ngetich, Biosafety Officer, Kenyan National Biosafety Authority, Kenya
21. Julia Njagi, Biosafety Officer, Kenyan National Biosafety Authority, Kenya
22. Harry Noyes, Programme Scientific Adviser, United Kingdom
23. Silas Obukosia, Operations Manager, NEPAD - African Biosafety Network of Expertise, Burkina Faso
24. Eric Amaning Okoree, Chief Executive Officer, Ghana National Biosafety Authority (NBA), Ghana
25. Jayne Raper, Professor of Biological Sciences, Hunter College, City University NY, United States
26. Stanley Kimaren Riamit, Executive Director, Indigenous Livelihoods Enhancement Partners (ILEPA), Keny

27. Kevin Sage-EL, Agricultural Counselor, USDA-FAS, Kenya
28. Hannah Smith Walker, Digital Manager and Multimedia Specialist Cornell Alliance for Science, United States
29. Neil Stahl, Executive Vice President, Research and Development, Regeneron, United States
30. Joey Verdi, PhD Student, Hunter College, City University NY, United States
31. Gift Wiseman Wanda, Senior Policy Officer, Pan African Tsetse and Trypanosomiasis Eradication Campaign (PATTEC), Addis Ababa, Ethiopia
32. Nabulindo Nakami Wilkister, Veterinarian, Nairobi, Kenya
33. Diane Wray-Cahen, Senior Science Advisor, Foreign Agricultural Service, USDA, United States

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