THE FUTURE OF THE WESTERN CAPE AGRICULTURAL SECTOR IN THE CONTEXT OF THE 4TH INDUSTRIAL REVOLUTION

Review: Genetics

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1. Technology Overview and Detailed Description

Genetic engineering, also called genetic modification, is the direct manipulation of an organism's genome using biotechnology. It is a set of technologies used to change the genetic make-up of cells, including the transfer of genes within and across species boundaries to produce improved or novel organisms. New deoxyribonucleic acid (DNA) is obtained by either isolating and copying the genetic material of interest using molecular cloning methods (DNA or RNA techniques) or by artificially synthesizing the DNA either randomly, or targeted to a specific part of the genome. A construct is usually created and used to insert this DNA into the host organism, or directly through micro-injection, macro-injection and micro-encapsulation techniques. As well as inserting genes, the process can also be used to remove, or "knock out", genes.

An organism that is generated through genetic engineering is genetically modified (GM) and the resulting entity is a genetically modified organism (GMO). Genetic engineering therefore alters the genetic make-up of an organism. The resulting organism is called transgenic. If genetic material from the same species or a species that can naturally breed with the host is used the resulting organism is called cis-genic.[1]

Agricultural genetics is the applied study of the effects of genetic variation and selection used to propagate desired and useful traits in animals and crops. These traits can be inherited by subsequent generations of crops and animals, to ensure continued benefit. The discipline of agricultural genetics uses genetic markers to guide this breeding.

For the purposes of this report, the creation of GMOs within the discipline of agriculture, will be referred to as **agricultural biotechnology.**

The primary tools used in agricultural biotechnology

More fundamental concepts of genes such as the Genetic Code, Initiation and Termination signals, the definition of a Cistron, Open Reading Frames (ORFs) and the identification of genes in DNA sequences may be found in other literature[2]. However, the main tools used in agricultural biotechnology will be described briefly[3,4]

- **Genetic engineering** inserts fragments of DNA into chromosomes of cells and then uses tissue culture to regenerate the cells into a whole organism with a different genetic composition from the original cells. This is also known as rDNA technology; it produces transgenic organisms. Tissue culture manipulates cells, anthers, pollen grains, or other tissues so that they live for extended periods under laboratory conditions or become whole, living, growing organisms.

- **Embryo rescue** places embryos containing transferred genes into tissue culture to complete their development into whole organisms. Embryo rescue is often used to facilitate "wide crossing" by producing whole plants from embryos that are the result of crossing two plants that would not normally produce offspring.
- **Somatic hybridization** removes the cell walls of cells from different organisms and induces the direct mixing of DNA from the treated cells, which are then regenerated into whole organisms through tissue culture.
- **Marker-aided genetic analysis** studies DNA sequences to identify genes, QTLs (quantitative trait loci), and other molecular markers and to associate them with organismal functions, i.e. gene identification.
- **Marker-aided selection** is the identification and inheritance tracing of previously identified DNA fragments through a series of generations.
- **Genomics** analyses whole genomes of species together with other biological data about the species to understand what DNA confers what traits in the organisms. Similarly, proteomics analyses the proteins in a tissue to identify the gene expression in that tissue to understand the specific function of proteins encoded by specific genes. Both, along with metabolomics (metabolites) and phenomics (phenotypes), are subcategories of bioinformatics.
- **Gene inactivation** is the direct genetic modification to render a gene of an organism inactive.
- **Epigenetic**s studies the influence of reversible hereditary changes in the gene function that occur without changes in the DNA sequence in the nucleus. Epigenetics also researches the processes influencing the development of an organism.
- **Cis-genesis** is the direct genetic modification which only uses the genes of the species itself.
- **Trans-genesis** is the direct genetic modification which uses the genes of other species. In the case of transgenic animals, the technologies used include micro-injection, retrovirus-mediated gene transfer, somatic cell nuclear transfer, sperm-mediated gene transfer, liposome's mediated technology, the linker (receptor) based method, and Restriction Enzyme-Mediated Integration (REMI)[5]

2. Application Examples and Case Studies

Applications of agricultural biotechnology

The first crops to be realised commercially on a large scale provided protection from insect pests or tolerance to herbicides. Fungal and virus resistant crops have also been developed or are in development[6]. This makes the insect and weed management of crops easier and can indirectly increase crop yield[7].GM crops that directly improve yield by accelerating growth or making the plant hardier (by improving salt, cold or drought tolerance) have been developed.

Crops that have been genetically modified for increased production, increased tolerance to abiotic stresses, alter the composition of the food, or have been used to produce novel products.[8]

GMOs have been developed that modify the quality of produce by increasing the nutritional value or providing more industrially useful qualities or quantities. The Amflora potato, for example, produces a more industrially useful blend of starches. Cows have been engineered to produce more protein in their milk to facilitate cheese production. Soybeans and canola have been genetically modified to produce more healthy oils. The first commercialised GM food was a tomato that had delayed ripening, increasing its shelf life[9,10,11,12].

Plants and animals have been engineered to produce materials they do not normally make. Pharming uses crops as bioreactors to produce vaccines, drug intermediates, or the drugs themselves; the useful product is purified from the harvest and then used in the standard pharmaceutical production process. Cows and goats have been engineered to express drugs and other proteins in their milk, and in 2009 the FDA approved a drug produced in goat milk[13,14,15].

More directed examples of examples of agricultural biotechnology are described below.

Insect resistance

In the last few years, several crops have been genetically-engineered to produce their own Bt proteins, making them resistant to specific groups of insects. "Bt" is short for *Bacillus thuringiensis*, a soil bacterium that contains a protein that is toxic to a narrow range of insects, but not harmful to animals or humans. Varieties of Bt insect-resistant corn and cotton are now in commercial production. Other crops being investigated include cow peas, sunflower, soybeans, tomatoes, tobacco, walnut, sugar cane, and rice.

Herbicide tolerance

Chemical herbicides are frequently used to control weeds. Weeds growing in the same field with crop plants can significantly reduce crop yields because the weeds compete for soil nutrients, water, and sun light. Many farmers now control weeds by spraying herbicides directly onto the crop plants.

Researchers realized that if a crop plant is genetically engineered to be resistant to a broad-spectrum herbicide, weed management could be simplified and safer chemicals could be used.

A decrease of pesticide and herbicide use when farmers adopted GM seeds was noted, and was found to be significant[16].

Resistance to synthetic herbicides has been genetically engineered into corn, soybeans, cotton, canola, sugar beets, rice, and flax. Some of these varieties are commercialized in several countries. Research is on-going on many other crops. One application of this technology is that herbicide could be coated on seed from an herbicide resistant variety (for example, maize) and while the maize would germinate and thrive, weeds and parasites such as Striga would be killed.

Virus resistance

Many plants are susceptible to diseases caused by viruses, which are often spread by insects (such as aphids) from plant to plant across a field. The spread of viral diseases can be very difficult to control land crop damage can be severe. Insecticides are sometimes applied to control populations of transmitting insects, but often have little impact on the spread of the disease. Often the most effective methods against viral diseases are cultural controls (such as removing diseased plants) or plant varieties bred to be resistant (or tolerant) to the virus, but such strategies may not always be practical or available. In response, Scientists have discovered new genetic engineering methods that provide resistance to viral disease where options were limited before:

- In the US, several varieties of squash and zucchini resistant to three important viral diseases have been developed and commercialized.
- Beginning in 1992, a devastating outbreak of Papaya Ring Spot Virus (PRSV) swept through the papaya plantations of Hawaii - papaya production dropped 40% over 5 years. Researchers in Hawaii and at Cornell University developed two GE (genetically-engineered) varieties of papaya resistant to PRSV. Papaya growers in Hawaii have been able to grow GE virus resistant papaya since 1998.
- Scientists are currently developing virus-resistant crops for Africa, including cassava, maize and sweet potato.

Delayed fruit ripening

Delaying the ripening process in fruit is of interest to producers because it allows more time for shipment of fruit from the farmer's fields to the grocer's shelf, and increases the shelf life of the fruit for consumers. Fruit that is genetically engineered to delay ripening can be left to mature on the plant longer, will have longer shelf-life in shipping, and as mentioned before, may last longer for consumers. It becomes possible to demand a higher premium for the fruit as it is available when no other similar cultivars are available on the market. This is also the case for earlier-ripening fruit.

Foods with improved nutritional value

Researchers are using biotechnology for the development of foods with improved nutritional value. Genetic modification can be used to produce crop s that contain higher amounts of vitamins to improve their nutritional quality. Genetically altered "golden rice," for example, contains three transplanted genes that allow plants to produce beta-carotene, a compound that is converted to vitamin A within the human body: vitamin A deficiency - the world's leading cause of blindness - affects as many as 250 million children. Biotechnology has also been use d to alter the content of many oil crops, either to increase the amount of oil or to alter the types of oils they produce. Biotechnology could also be used to upgrade some plant proteins now considered incomplete or of low biological value because they lack one or more of the 'essential' amino acids. Examples include maize with improved protein balance and sweet potatoes with increased total protein content. Reducing toxicity of certain foods is also a goal of biotechnology. For example, reduction of the toxic cyanogens in cassava has been shown to be possible and could be produce d in the future[17,18].

Increased profits

In general, studies indicate that farmers' profits increase as they adopt GM seeds. The ERS study found that in most cases there is a statistically significant relationship between an increase in the use of GM seeds and an increase in net returns from farming operations.[19] For example, the ERS found that, on average, GM soybean crops produced a net value of $208.42 per planted acre, while other crops produced a value of $191.56 per planted acre[20]. The ERS also found a "significant increase" in net returns for herbicide-tolerant cotton crops and Bt cotton crops.

Use of marginalised land

A vast landmass across the globe, both coastal as well as terrestrial has been marginalised because of excessive salinity and alkalinity. A salt tolerance gene from mangroves (*Avicennia marina*) has been identified, cloned and transferred to other plants. The transgenic plants were found to be tolerant to higher concentrations of salt. The *gut*D gene from *Escherichia coli* has also been used to generate salt-tolerant transgenic maize plants. Such genes are a potential source for developing cropping systems for marginalised land [21] and agricultural land for which only lower quality water (brackish water) is available.

Tolerance to biotic and abiotic stresses

The development of crops that have built-in resistance to biotic and abiotic stress would help to stabilise annual production. For example, Rice Yellow Mottle Virus (RYMV) devastates rice in Africa by destroying much of the crop directly, with a secondary effect on any surviving plants that makes them more susceptible to fungal infections. As a result, this virus has seriously threatened rice production in Africa. Conventional approaches to the control of RYMV using traditional breeding methods have failed to introduce resistance from wild species to cultivated rice. Researchers have used a novel technique that mimics 'genetic immunisation' by creating transgenic rice plants that are resistant to RYMV[22]. Resistant transgenic varieties are currently entering field trials to test the effectiveness of their resistance to RYMV. This could provide a solution to the threat of total crop failure in the sub-Saharan African rice-growing regions.

Pharmaceuticals and vaccines from transgenic plants

Vaccines are available for many of the diseases that cause widespread death or human discomfort in developing countries, but they are often expensive both to produce and use. The majority must be stored under conditions of refrigeration and administered by trained specialists, all of which adds to the expense. Even the cost of needles to administer vaccines is prohibitive in some countries. As a result, the vaccines often do not reach those in most need. Researchers are currently investigating the potential for GM technology to produce vaccines and pharmaceuticals in plants. This could allow easier access, cheaper production, and an alternative way to generate income. Vaccines against infectious diseases of the gastro-intestinal tract have been produced in plants such as potato and bananas[23]. Another appropriate target would be cereal grains.

An anti-cancer antibody has recently been expressed in rice and wheat seeds that recognises cells of lung, breast and colon cancer and hence could be useful in both diagnosis and therapy in the future[24]. Such technologies are at a very early stage in development and obvious concerns about human health and environmental safety during production must be investigated before such plants can be approved as speciality crops. Nevertheless, the development of transgenic plants to produce therapeutic agents has immense potential to help in solving problems of disease in developing countries.

Genetic modification of animals

A transgenic animal is an animal that carries a foreign gene that has been deliberately inserted into its genome, so that it has characteristics that it would not normally have, through transplantation techniques. The characteristics are then transferred to its offspring.

Several many biotechnology applications have been incorporated into animal breeding programmes to accelerate genetic improvements which confer commercial traits (include increasing wool production in transgenic sheep, leaner meat from pigs, pigs with "environmentally-friendly" manure, increasing milk production, altering milk composition to be lactose-free, disease resistance, reproductive efficiency, increased feed utilization and growth rate, improved carcass composition, improved milk and meat production) to animals[25,26,27,28].

Genetically-modified fish (it is easier to manipulate fish genes) is already commercially available in the USA for aquariums – the Glofish, a *Zebra danio* which has been modified to produce a red fluorescent protein. Other examples are Atlantic Salmon which grows 400-600% faster on 25% less feed.

Transgenic animals are used primarily for pharmaceutical research, which is a topic of much debate, due to concerns about the appearance of new diseases[29].

Applications in technology development for research purposes

Molecular markers - Traditional breeding involves selection of individual plants or animals based on visible or measurable traits. By examining the DNA of an organism, scientists can use molecular markers to select plants or animals that possess a desirable gene, even in the absence of a visible trait. Thus, breeding is more precise and efficient. For example, the International Institute of Tropical Agriculture (IITA)has used molecular markers to obtain cowpea resistant to bruchid (a beetle), disease-resistant white yam and cassava resistant to Cassava Mosaic Disease, among others. Another use of molecular markers is to identify undesirable genes that can be eliminated in future generations.

Molecular diagnostics - Molecular diagnostics are methods to detect genes or gene products that are very precise and specific. Molecular diagnostics are used in agriculture to more accurately diagnose crop/livestock diseases.

Tissue culture - Tissue culture is the regeneration of plants in the laboratory from disease-free plant parts. This technique allows for the reproduction of disease-free planting material for crops. Examples of crops produced using tissue culture include citrus, pineapples, avocados, mangoes, bananas, coffee and papaya.

Genetic engineering – described above.

3. Technology or Application Life Cycle: Status and Expected Development in 2020 and 2025

Table 1: Life Cycle

Technology Area	Current application in agriculture	Expected applications in agriculture by 2020	Expected applications in agriculture by 2050
Agricultural biotechnology/genetics	DNA mapping. Disease resistance. Improved yield. Crop production in marginal/unsuitable areas	Improved abiotic stress (e.g. water efficient maize). GM crops specifically developed for small-scale farmers. Crops with enhanced nutritional content, e.g. sorghum with increased levels of lysine, Vitamin A, iron and zinc. Crops with increased yields.	Weed & insect control. Human vaccine production and antibodies in plants. Animal gene modification

The status of genetically engineered crops

In the United States, the Animal and Plant Health Inspection Service (APHIS), which is the equivalent of South Africa's Biosafety SA regulates the development and release of transgenic crops. APHIS classifies phenotypic traits under AP (agronomic properties), BR (bacterial resistance), FR (fungal resistance), HT (herbicide tolerance), IR (insect resistance), MG (marker gene), NR (nematode resistance), OO (others), PQ (product quality), and VR (virus resistance) categories. APHIS issued a total of 2192 permits for different phenotypic traits in 2013. Other traits (OO), herbicide tolerance (HT) and agronomic properties (AP) topped the category by contributing 34.5, 21.9 and 20.1 percent[30] respectively (Figure 1 below). Permits for other traits also topped in year 2014 with more than 75% of total permit issued. One permit can contain multiple phenotypes of phenotype categories while each phenotype category may include one to several traits.

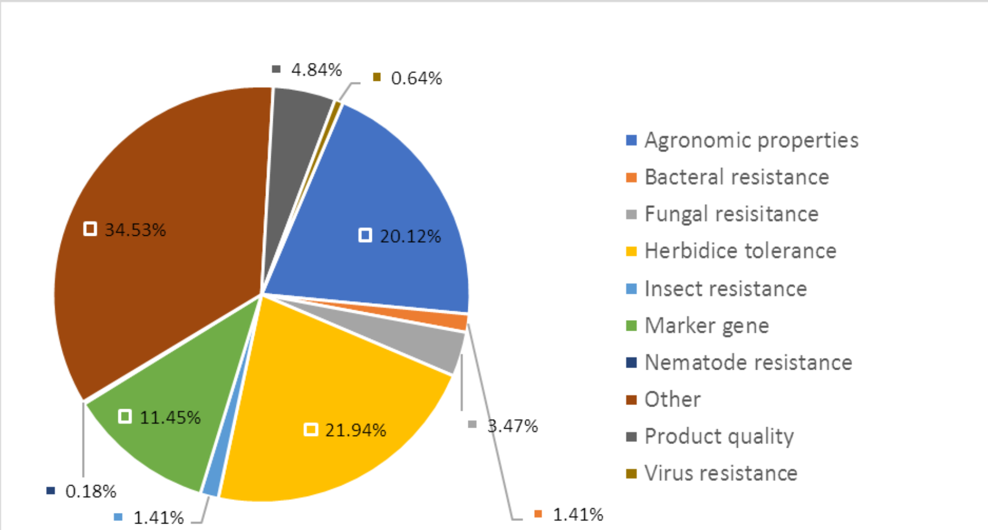

Figure 1: Permits for different phenotypic traits in 2013 (USA)[31]

More recent (2016)[32] global statistics and facts are the following (updated in 2017):

- Number of hectares of biotech crops planted globally: 185.1 million (100-fold increase since 1996
- Number of famers planting biotech crops: 18 million
- Number of countries planting biotech crops: 26
- For the past five years, developing countries have planted more biotech crops than the industrial countries (Table 2). In 2016, 19 developing countries planted 54% (99.6 million hectares) of the global biotech hectares, while 7 industrial countries took the 46% (85.5 million hectares) share.

Table 2 below shows the global areas of GM plantings by country (million hectares).

Table 2: Ranking of global GM plantings by country (million hectares)

Rank	Country	2015	2016
1	USA	70.9	72.9
2	Brazil	44.2	49.1
3	Argentina	24.5	23.8
4	Canada	11.0	11.6
5	India	11.6	10.8
6	Paraguay	3.6	3.6
7	Pakistan	2.9	2.9
8	China	3.7	2.8
9	South Africa	2.3	2.7
10	Uruguay	1.4	1.3
11	Bolivia	1.1	1.2
12	Australia	0.7	0.9
13	Philippines	0.7	0.8
14	Myanmar	0.3	0.3
15	Spain	0.1	0.1
16	Sudan	0.1	0.1
17	Mexico	0.1	0.1
18	Colombia	0.1	0.1
19	Vietnam	<0.1	<0.1
20	Honduras	<0.1	<0.1
21	Chile	<0.1	<0.1
22	Portugal	<0.1	<0.1
23	Bangladesh	<0.1	<0.1
24	Costa Rica	<0.1	<0.1
25	Slovakia	<0.1	<0.1
26	Czech Republic	<0.1	<0.1
	TOTAL	**181.5**	**179.7**

Notes: Shaded: countries which planted >50, 000 hectares

From Table 2 above, South Africa ranks 9th in the world, and is classified as biotech-mega, having planted more than 50, 000 hectares along with others.

The status of GM crops in South Africa

The status of GM crops in South Africa is summarized below[33]:

- Since 1999, 393 permits were issued for confined trials on 10 different crops types
- 2.9 million ha of GM crops were planted in South Africa in 2013
- 87% of maize in South Africa is GM (Insect Resistant and/or Herbicide Tolerant)
- 92% of Soybean is GM (Herbicide Tolerant)
- 100% of cotton is GM (Herbicide Tolerant and/or Insect Resistant)

Permit types have been issued in South Arica in the period 1999 to 2014. These are illustrated in Table 3 below.

Table 3: Number of permit types issued in South Africa (1999-2014)

	Number of permits issued
Export	1749
Import	1442
Commodity clearance	535
General release	19
Field trials	418
Contained use	56
Total	**4219**

Source: Adapted from Biosafety SA.

Table 4 shows the number of permits issued by GM trait and permit type for maize cotton and soybean only (major GM crops in South Africa)

Table 4: Permits issued (number) by GM trait and permit type in South Africa

	Field Trial Permits			**General Release Permits**		
	IR/HT	**HT**	**IR**	**IR/HT**	**HT**	**IR**
Maize	68	22	98	6	2	3
Cotton	40	29	38	2	2	2
Soybean	-	23	-	-	1	-

Notes: IR/HT (Insect Resistant/Herbicide Tolerant); HT (Herbicide Tolerant); IR (Insect Resistant)

Source: Adapted from Biosafety SA.

Adoption by developing countries

The FAO data[34] on developing countries showed more than thousand different GMOs under various stages of commercialization (Table 5).

Table 5: Number of genetically modified organisms (GMOs) in developing countries under different stages of development[35]

Region (GMOs)	**Experimental phase**	**Field trial**	**Commercial phase**	**Not specified**
Asia (679)	453	119	33	74
Africa (85)	39	36	10	-
Latin America and Caribbean (306)	99	185	15	7
Europe (28)	18	6	2	2
Near East (51)	31	16	2	2
Grand total (1149)	640	362	62	85

Since 1996 the increase in acreage of transgenic crops in industrial countries has moderated but the pace of planting these crops in developing countries has accelerated. The total area planted in genetically engineered crops has increased from 1.7 million hectares in 1996 to 175 million hectares in 2013 reflecting a remarkable increase in global hectarage of genetically engineered crops by 100-fold. In 2013, transgenic crops were grown in a total of 27 countries where the top ten countries each grew more than 1 million hectares. Eighteen million farmers, in 27 countries, have planted 175 million hectares (432 million acres) in 2013 and will likely exceed 40 countries.

4. Business Eco-System View

To have efficient breakthroughs in the field of genetic engineering, it is necessary to use bioinformatics tools along with high speed throughput technologies so that multiple genes can be identified and used in the field of genetic engineering. Secondly, the collection of useful genes also becomes possible with the discovery of synthetic biology so that the creation and alteration of numerous genes is possible. Third, the insertion, removal or alteration of the transgenes in the genome is now possible through site-specific genome editing techniques[36].

Overlapping technologies are therefore:

- Synthetic biology
- Biorefinery and biofuels
- Protein transition
- Food design
- Bioinformatics.

5. Benefits and Risks

Benefits[37]

Increased crop productivity

Biotechnology has helped to increase crop productivity by introducing such qualities as disease resistance and increased drought tolerance to the crops. it is now possible to select genes for disease resistance from other species and transfer them to important crops. For example, researchers from the University of Hawaii and Cornell University developed two varieties of papaya resistant to papaya ringspot virus. This was achieved by transferring one of the virus' genes to papaya to create resistance in the plants. Seeds of the two varieties, named 'SunUp' and 'Rainbow', have been distributed under licensing agreements to papaya growers since 1998.

Further examples come from dry climates, where crops must use water as efficiently as possible. Genes from naturally drought-resistant plants can now be used to increase drought tolerance in many crop varieties.

Enhanced crop protection

Farmers use crop-protection technologies because they provide cost-effective solutions to pest problems which, if left uncontrolled, would severely lower yields. As mentioned above, crops such as corn, cotton, and potato have been successfully transformed through genetic engineering to make a protein that kills certain insects when they feed on the plants. The protein is from the soil bacterium *Bacillus thuringiensis*, which has been used for decades as the active ingredient of some “natural” insecticides.

Improvements in food processing

The first food product resulting from genetic engineering technology to receive regulatory approval, in 1990, was *chymosin*, an enzyme produced by genetically engineered bacteria. It replaces calf rennet in cheese-making and is now used in 60 percent of all cheese manufactured. Its benefits include increased purity, a reliable supply, a 50 percent cost reduction, and high cheese-yield efficiency.

Improving the tolerance of plants to biotic stresses

The introduction of resistance to heavy metals, salt, cold, and drought into crop plants has become a topic of major economic interest for agriculture. Genetically engineered drought- and salt-tolerant plants could provide an avenue to the reclamation of farmlands lost to agriculture because of salinity and a lack of rainfall[38].

The plant as a factory to produce useful molecules

A particularly fruitful area of research for the current interests of plant biotechnology concerns the improvement of the quality of plant products. One can now alter the principal biosynthetic routes of the higher plants almost “at will” to make them synthesize new types of fatty acids, starch, and proteins. Their metabolite content, which is indispensable to animal and human nutrition (e.g. vitamins, essential amino acids), may also be modified. This is also the case for metabolites posing a problem to developing industrial applications (e.g. lignin, the principal constituent in wood, which poses problems in the paper industry).

Improved nutritional value

Genetic engineering has allowed new options for improving the nutritional value, flavour, and texture of foods. Transgenic crops in development include soybeans with higher protein content, potatoes with more nutritionally available starch and an improved amino acid content, beans with more essential amino acids, and rice with the ability produce beta-carotene, a precursor of vitamin A, to help prevent blindness in people who have nutritionally inadequate diets. Examples of crops that have already been genetically modified with with nutritionally improved macro- and micronutrient traits (novel protein, fibre, carbohydrates, novel lipids, vitamins, minerals phytochemicals, and antinutrients such as allergens and toxins) that may provide nutritional benefits, for consumers and animals are given in other references[39,40].

Better flavour

Flavour can be altered by enhancing the activity of plant enzymes that transform aroma precursors into flavouring compounds. Transgenic peppers and melons with improved flavour are currently in field trials.

Fresher produce

Genetic engineering can result in improved keeping properties to make transport of fresh produce easier, giving consumers access to nutritionally valuable whole foods and preventing decay, damage, and loss of nutrients. An example is transgenic tomatoes with delayed softening that can be vine-ripened and still be shipped without bruising. Research is under way to make similar modifications to broccoli, celery, carrots, melons, and raspberry. The shelf life of some processed foods such as peanuts has also been improved by using ingredients that have had their fatty acid profile modified.

Environmental benefits

When genetic engineering results in reduced pesticide dependence, there is less pesticide residues on foods, there is reduced pesticide leaching into groundwater, and there is minimized farm worker exposure to hazardous products. With *Bt* cotton's resistance to three major pests, the transgenic variety now represents half of the U.S. cotton crop and has thereby reduced total world insecticide use by 15 percent. Also, according to the U.S. Food and Drug Administration (FDA), "increases in adoption of herbicide-tolerant soybeans were associated with small increases in yields and variable profits but *significant decreases* in herbicide use".

Ecological benefits of GM crop cultivation

While the adoption of *Bt*-maize has resulted in only modest reductions in insecticide applications due to the small area of conventional maize treated with insecticides, the commercial cultivation of *Bt*-cotton has proven to have resulted both in a significant reduction in the quantity and in the number of insecticide applications. In addition to direct environmental benefits resulting in fewer non-target effects and in reduced pesticide inputs in water, demonstrable health benefits for farm workers have been documented in several countries due to less chemical pesticide spraying in *Bt*-cotton.

The adoption of genetically modified herbicide tolerant (GMHT) crops has allowed the use of a single broad-spectrum herbicide that may reduce the need for herbicide combinations or chemicals that require multiple applications. The two main herbicides used when growing GMHT crops (glyphosate and glufosinate) are generally less toxic to human health and the environment than many of the herbicides they replace.

The adoption of GMHT crops has also facilitated the change to conservation tillage agriculture. Growers using conservation tillage have reduced their tillage operations, thus preventing soil erosion, soil degradation and runoff of chemicals.

Benefits for developing countries

Genetic engineering technologies can help to improve health conditions in less developed countries. Researchers from the Swiss Federal Institute of Technology's Institute for Plant Sciences inserted genes from a daffodil and a bacterium into rice plants to produce "golden rice," which has sufficient beta-carotene to meet total vitamin A requirements in developing countries with rice-based diets. This crop has potential to significantly improve vitamin uptake in poverty-stricken areas where vitamin supplements are costly and difficult to distribute, and where vitamin A deficiency leads to blindness in children.

Crops

Interspecific hybridisation allows the combination of favourable traits from different species and has been used successfully in, for instance, the development of New Rice for Africa (NERICA) varieties, by crossing high-yielding Asian rice with African rice which thrives in harsh environments, using embryo rescue and other culture techniques. NERICA varieties are estimated to be cultivated annually on about 200,000 ha of upland areas in sub-Saharan Africa[41].

Marker-assisted selection is still at a relatively early stage in its application for key subsistence crops in many developing countries, although it has begun to produce some significant results, such as the development of a pearl millet hybrid with resistance to downy mildew disease in India[42] and flood-resistance rice in Asia[43].

Micropropagation is used for the mass clonal propagation of elite lines or disease-free planting material. Many developing countries have significant crop micropropagation programmes and are using it in a wide range of subsistence crops, such as micro-propagated sweet potato in the Hwedza District (Zimbabwe), where the technology was adopted by 97% of the farmers, including both poorer and better off farmers, contributing to household food security[44].

Biotechnology also offers important tools for the diagnosis of plant diseases of both viral and bacterial origin. Immuno-diagnostic techniques as well as DNA-based methods are commercially applied for this purpose in some developing countries[45]. Additionally, biotechnologies such as molecular markers, cryopreservation and in vitro slow growth storage are extensively used for the characterisation and conservation of plant genetic resources in developing countries[46].

Microbial-based biotechnologies are also important in the crop sector. Biofertilisers are used in developing countries both to augment the nutritional status of crops and as alternatives to chemical supplements. For example, biopesticides formulated with the spores of the fungus *Metarhizium anisopliae* var. *acridum* have been used successfully to control migratory locusts in countries such as Timor-Leste and Tanzania[47].

Fisheries and aquaculture

It is expected that, soon, aquaculture will produce more fish for direct human consumption than capture fisheries. Disease outbreaks are a serious constraint to aquaculture development. Better management of intensive systems is needed, and biotechnologies are assisting in this task - immunoassay and DNA-based diagnostic methods are currently applied for pathogen diagnosis in the aquaculture sector of developing countries.

Forests

Forests and other wooded areas perform key economic and ecological functions, such as the provision of goods and livelihoods, as well as the protection of soils, regulation of water and absorption of carbon. For management of naturally regenerated forests, DNA-based and biochemical markers are available for a growing number of tropical species. Today, findings are available to guide operational forest management plans, albeit limited to a few hundred tree species that are managed in naturally regenerated tropical forests.

Agro-industry

Agro-industries provide a means of converting raw agricultural materials into value added products Food processing converts relatively bulky, perishable and typically inedible raw materials into more useful, shelf-stable and palatable foods or potable beverages. Processing contributes to food security by minimising waste and loss in the food chain and by increasing food availability and marketability. Biotechnology as applied to food processing uses fermentation and microbial inoculants to enhance properties such as the taste, aroma, shelf-life, texture and nutritional value of foods[48,49]. Traditional methods of genetic improvement such as classical mutagenesis and conjugation can be applied to improve the quality of microbial cultures. Hybridisation and genetic modification are also used for the improvement of yeast strains used in food processing[50]. These technologies only now beginning to be applied in developing countries for the improvement and development of starter cultures.

Livestock

Livestock contribute directly to livelihoods worldwide, providing not only food, but also non-food products, draught power and financial security. They contribute 40% of the global value of agricultural output[51], and this proportion is expected to increase.

Conventional technologies and biotechnologies in livestock have contributed immensely to increasing productivity, particularly in developed countries, and can help to alleviate poverty and hunger, reduce the threats of diseases and ensure environmental sustainability in developing countries. A wide range of biotechnologies are available and have already been used in developing countries in different sectors of animal science. In animal reproduction and breeding, artificial insemination (AI) has perhaps been the most widely applied animal biotechnology, particularly in combination with cryopreservation, allowing significant genetic improvement for productivity, as well as the global dissemination of selected male germplasm. It is applied at some level in most developing countries, primarily in dairy cattle and peri-urban areas where complementary services including milk marketing are available.

In animal nutrition, biotechnologies are often based on the use of micro-organisms, including those produced through genetic modification. Fermentation technologies are used to produce nutrients (such as particular essential amino acids or complete proteins) or to improve the digestibility of animal feeds. Microbial cultures are used to increase the quality of silage for animal feed or to improve digestion, when fed as probiotics or prebiotics. Amino acids and enzymes appear to be the most prominent and widespread nutrition-related biotechnology products used in developing countries. India and China for example have developed local industries to produce amino acids and enzymes.
Probiotics are live micro-organisms which, when administered in adequate amounts, confer a health benefit on the host[52] .They are used in animal nutrition in several developing countries, mostly in monogastrics. Prebiotics on the other hand are non-viable food components that confer a health benefit on the host associated with modulation[53].

Risks – Health-related issues

Allergens and toxins

A major safety concern raised about genetic engineering technology is the risk of introducing allergens and toxins into otherwise safe foods. The Food and Drug Administration (FDA) checks to ensure that the levels of naturally occurring allergens in foods made from transgenic organisms have not significantly increased above the natural range found in conventional foods. Transgenic technology is also being used to remove the allergens from peanuts, one of most serious causes of food allergy.

Antibiotic resistance

Antibiotic resistance genes are used to identify and trace a trait of interest that has been introduced into plant cells. This technique ensures that a gene transfer during genetic modification was successful. The use of these markers has raised concerns that new antibiotic-resistant strains of bacteria will emerge. The rise of diseases that are resistant to treatment with common antibiotics is a serious medical concern of some opponents of genetic engineering technology.

Environmental and ecological issues

Potential gene escape and superweeds

There is a school of thought that transgenic crops might crosspollinate with related weeds, possibly resulting in “superweeds” or "superbugs" that become more difficult to control and, over time, become resistant to GM seeds and crops and to other herbicides and pesticides, for example the transfer of pollen from glyphosate-resistant crops to related weeds can confer resistance to glyphosate.

There is also the concern that genetic engineering could conceivably improve a plant’s ability to “escape” into the wild and produce ecological imbalances or disasters. This is supported by research that suggests that weeds and bugs could possibly evolve into resistant organisms. Gene movement from crop to weed through pollen transfer has been demonstrated for GM crops when the crop is grown near a closely related weed species.[54]

Impacts on “nontarget” species

Another concern centering on impacts of biotechnology is possible harm of GM seeds and crops to other, beneficial organisms, necessitating the rigorous testing before being made commercially available. *Bt* corn, for instance, produces a very specific pesticide intended to kill only pests that feed on the corn. In 1999, however, researchers at Cornell University found that pollen from *Bt* corn could kill caterpillars of the harmless Monarch when windblown onto milkweed leaves. Subsequent research has indicated that the actual level of *Bt* on milkweed plants in a real-life scenario do not reach the levels that produce a toxic result in the larvae, and that under real-life conditions Monarch butterfly caterpillars are highly unlikely to encounter pollen from *Bt* corn that has drifted onto milkweed leaves, or to eat enough of it to harm them[55].

Identity preservation in the field

Potential cross-pollination of GM seeds onto non-GM crops is also a concern to farmers, particularly those farmers that certify their crops as non-GM crops or organic crops. There is evidence that such cross-pollination is already occurring. Plants with GM characteristics have been found in conventional crops as well as in crops that have been grown using only organic farming practices, for example corn and soybean crops[56,57]

Identity preservation from field to market

Another concern for farmers who are not currently planting GM crops is preserving the identity of their non-GM crops as those crops move from farm to market. Currently, bulk agricultural trading facilities are not able to separate GM crops from traditional crops. Shipments of corn and soybeans originating at these facilities cannot be guaranteed as "GM-free." The inability to segregate crops may lead to a situation where all products are de-valued (particularly in the international market, as discussed below) because they cannot be certified GM-free[58].

Insecticide resistance

Another concern related to the potential impact of agricultural biotechnology on the environment involves the question of whether insect pests could develop resistance to crop-protection features of transgenic crops. There is fear that large-scale adoption of *Bt* crops will result in rapid build-up of resistance in pest populations. Insects possess a remarkable capacity to adapt to selective pressures, but to date, despite widespread planting of *Bt* crops, no *Bt* tolerance in targeted insect pests has been detected.

Reliability of research results

Traits relevant for animal production are under the control of several genes, and so researchers have struggled to achieve reliable and consistent improvements.

Limitations of transgenic animals and the discipline of transbenics

Despite its numerous applications he development and use of transgenic animals has limitations, namely:

- The modification of important biological processes due to insertional mutations;
- Unregulated gene expression which causes the inappropriate (levels of types) of gene products.;
- The possibility of side effects in transgenic animals like arthritis, dermatitis and cancer[59].

Social concerns

Labelling

Some consumer groups argue that foods derived from genetically engineered crops should carry a special label. In the USA, these foods currently must be labelled only if they are nutritionally different from a conventional food.

"Terminator" technology

In developing countries, many farmers who are not growing hybrids save harvested seeds for replanting the next year's crop. A technology has been developed that might be used to prevent purchasers of transgenic crop seeds from saving and replanting them. Such "terminator" seeds are genetically engineered, along with other improvements more acceptable to farmers, to produce plants with seeds that have poor germination. This forces farmers who otherwise save seed to purchase it if they wish to use these improved commercial varieties. These farmers cannot take advantage of improvements brought about by genetic engineering without being brought into the economic cycle that profits the seed companies. Without profit incentive, however, these companies are unlikely to invest in improving crops. Clearly, it is a difficult and divisive social issue.

Ethical issues

The main reasons against the application of transgenic technologies on animals are listed as follows:

- Transgenic biotechnology is the cause of great suffering to animals.
- Using animals to produce pharmaceutical proteins is inhumane
- The integrity of species in having a right to exist as a separate is questioned
- The introduction of human genes into animals and vice-versa, is confusing the definition of "humanness"[60]

Food safety

Uncertainties concerning the adequacy of regulatory safeguards

The largest controversy surrounding the regulation of GM foods has been labelling. Currently, the FDA requires labelling only when the food product has been changed in its composition, safety, or nutritional quality.[61]

Transgenic crops and their resulting foods in the United States are extensively researched and reviewed by three federal government agencies: the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). Each agency is responsible for a different part of the review process.

Considerations about food from genetically engineered crops have raised a host of questions about effects on the environment, economic impacts, and ethics. However, perhaps the most fundamental question about such food is whether it is safe and wholesome to eat. Before field testing any new transgenic crop in the USA, companies and research institutions must register with USDA for field testing permission. Researchers must ensure that pollen and plant parts of the tested plants are not released into the environment during this period. Transgenic crops must also pass scrutiny of the EPA, which has the authority to regulate all new pesticides and genetically engineered crops, as it is concerned with potential impacts on nontarget species and endangered or threatened species. Finally, any foods derived from transgenic crops must pass FDA inspection. Current law requires that foods from transgenic organisms must be labelled as such if their nutritional content or composition differs significantly from their conventional counterparts or if they pose any health risks. Both the National Academy of Sciences and the FDA have determined that, in general, foods derived so far from genetically engineered organisms are as safe or safer than conventional counterparts. The main concern is remaining vigilant for potential allergens.

Food safety assessment[62]

Previously established principles for assessing food safety still apply for products of biotechnology. Moreover, these products can be judged on their individual safety, allergenicity, toxicity and nutrition rather than their method of production. The intent of this comparative approach is to establish whether the new food is "as safe as" its conventional counterpart.

International discussion and expert consultations have resulted in a consensus on the specific safety issues that should be considered when evaluating these new foods. They include the following:

- The Parent Plant: Knowledge of the biology of the plant and its history of safe use as a food
- The Gene Source: Information about the natural history of the source organism of a new gene
- Nutrition: Food safety assessments consider the potential for any change in nutritional composition of food
- Allergens: The potential of accidentally introducing a new allergen into a food is an important safety concern.
- Toxins: The possibility that new toxins may have been introduced into a food is also tested

Environmental safety[63]

The objective of environmental safety assessment is to identify and evaluate any additional risks associated with the release and cultivation of these new plants in comparison with a conventional crop variety that has a history of safe use. Assessing the environmental safety of a biotech plant requires an understanding of the biology of the plant itself and the practices used in its cultivation. This knowledge is important in identifying and evaluating potential environmental risks and in designing any appropriate risk management measures. Most countries use similar environmental risk assessment approaches, which include, evaluating the role of the introduced gene in the plant, evaluating possible unintended secondary effects on non-target organisms, investigating the possibility of environmental persistence and invasion, the potential spread of newly introduced traits to related plants, and potential impacts on biodiversity.

6. Potential Economic, Social, Ecological and Political Developments and Impacts

Economic developments and impacts

The global value of biotech crops

According to Cropnosis, the global market value of biotech crops in 2016 was US$15.8 billion. This value indicates that there was a 3% increase in the global market value of biotech crops from 2015, which was US$15.3 billion. This value represents 22% of the US$73.5 billion global crop protection market in 2016, and 35% of the US$45 billion global commercial seed market. The estimated global farmgate revenues of the harvested commercial "end product" (the biotech grain and other harvested products) are more than ten times greater than the value of the biotech seed alone.

GMO legislation in South Africa

South Africa has an active Genetically Modified Organism (GMO) industry in which the country's genetically modified crop comprised 1.4 million hectares in the 2006/07 season in which 1 million hectares were planted to maize and the remainder comprising of soybean and cotton. South Africa's position is strongly contested by several watchdog organisations. South Africa's Genetically Modified Organism Act (No 15 of 1997) looks to enhance GMO productivity to enhance food security especially considering global environmental change. In this regard, with agricultural security as a cornerstone, South Africa has embarked on a significant biotechnology research initiative and in 2001 published its National Biotechnology Strategy, with the objectives of promoting biotechnology research and development (R&D) and marketing of biotechnology products in South Africa.

Intellectual Property considerations

Intellectual property protection can be conferred in relation to plant materials in several ways:

- The US model of plant patents, which are distinct from normal (utility) patents
- Through allowing normal patents on plants or parts thereof, such as cells
- Through patenting plant varieties as is the practice in the US and in few other countries (for example, not in the EU)
- Through applying a *sui generis* form of plant variety protection (PVP), such as plant breeders' rights (as in the EU or the US) or other modalities

- Through allowing patents on DNA sequences, and gene constructs including the gene, plants transformed with those constructs, the seed and progeny of those plants.

In addition, patents are widely used to protect the technologies which are employed in research on plant genomics.

Developing countries have possibly three options for meeting their obligation to protect plant varieties under TRIPS. They may adopt one or a combination of the following:

- UPOV style legislation based on the 1978 or 1991 Convention (although they may now only join the 1991 Convention)
- Another form of sui generis system, including or not landraces
- Patents on plant varieties

Special attention should be paid to international conventions that may affect innovation in agriculture. These conventions include Trade Related Intellectual Property (TRIPs), patent law, plant variety protection and the Convention on Biological Diversity (CBD). To be effective, these conventions should be consistent with each other to reduce any distortions in the promotion of innovation by farmers, public research institutions, and for-profit corporations

Social Developments and Impacts

Sustainable GMO technologies for Africa

To successfully unlock the potential of GM technology, it should be packaged into a final product that, in addition to the sustainability aspects listed above, is also relevant and accessible to ensure adoption and continued use. Defining sustainability in this holistic way and integrating these considerations from an early stage into a GM research and development programme will not only help with the development of safe, sustainable products, but will also improve the efficiency of the innovation process because flawed products can be discarded at an early stage.

To ensure the sustainable adoption and use of GMOs in a particular environment, these aspects should be considered proactively during the development process of the specific product. The integrated, proactive assessment of both the biosafety and socioeconomic aspects, i.e. a continuous sustainability assessment, of a new GMO is therefore critical to ensure the development of sustainable products for African agriculture that will impart a real benefit to the adopters of the technology, as shown in Figure 4 below.[64]

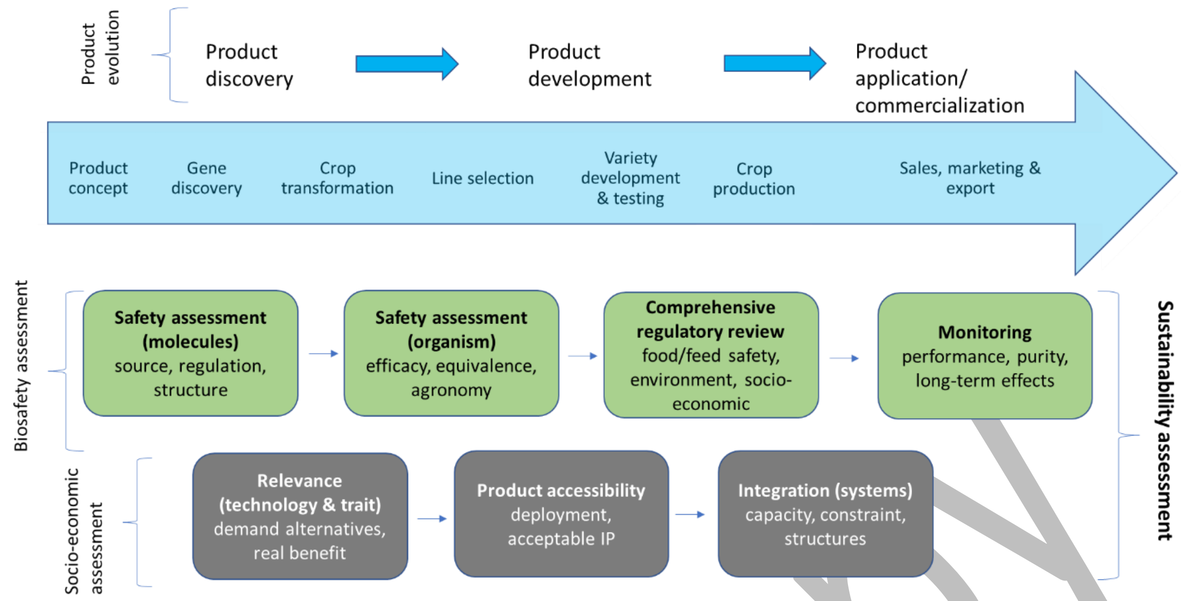

Figure 4: Integration of sustainability assessment during a GMO R7D and commercialization programme

In Figure 4, the product evolution lifeline is illustrated, from concept to market. However, safety assessments of the molecules, organism, as well as review of the regulatory environment, monitoring of long-term effects, alignment of traits with needs, accessibility issues and integration systems (once marketed) are also to be considered, as the product evolution lifeline is being developed. This is to ensure that throughout the development process, benefits to the end-user may be realized.

Implications to the farmer

The farmer that elects to engage in the use of GMOs faces the following direct and specific risks, categorized as

(i) Production risks (seed cost and availability, pest and disease risk, yield risk, cross-pollination risk, management risk and,

(ii) Marketing risks (transportation risk, storage risk, testing risk, market outlet risk, price risk).

Farmers would need to adopt a combination of strategies to reduce yield and price risks. The prominent strategies include crop yield and revenue insurance contracts, and marketing and futures contracts, as well as improving market capacity to handle biotech and non-biotech commodities separately. Each of these are explained briefly below, and would need to be considered by policy-makers to ensure the successful marketing and commercialization of biotech products.

Crop Yield and Revenue Insurance Contracts

Crop yield and revenue (i.e., crop revenue, income protection, revenue assurance) insurance contracts are designed to protect farmers against yield and price risks.

Production and Marketing Contracts

Production and marketing contracts, whose purpose would be to ensure the flow of product with specific traits and delivery terms, set a fixed price and/or outlet for a crop before harvest. Such contracts could reduce marketing and price risks to farmers and others involved in the marketing chain.

Futures Contracts

A more refined futures contract that distinguishes biotech and non-biotech products may very well provide farmers with a method for reducing price risks.

Mitigating price risks beyond the farm gate

Efficient production and marketing system linking producers and consumers would mitigate risks beyond the farm gate.

Market Information

A marketing system designed to provide information regarding prices, delivery locations, and export demand may help farmers in making timely decisions.

Testing and Certification

Development of tests to verify the biotech status of produce, that acceptable to all stakeholders will improve marketing efficiency and will benefit both consumers and producers.

Labelling of biotech products

Labelling would provide information to consumers, allow them a choice between biotech and non-biotech content, and help them avoid exposure to potential allergens. Labelling with full disclosure would be a step toward more informed decision making and would provide a way to increase consumers' acceptance of this new technology, by reducing the market uncertainty for biotech foods, and therefore reducing risks to biotech crop producers.

Global agreement on health and biosafety standards

If a science-based global approach is established to assess the risks to agriculture, the environment, and health, and to develop acceptable standards, then consumers' reluctance toward biotech products might be reduced. The development of sound safety regulations and establishment of standards acceptable to the global community are important for the efficient marketing of biotech products and perhaps full realization of biotechnology's potential, as wells as the sales and marketing of biotech produce.

Agriculture and rural development in South Africa

South African legislation is based on the South African constitution, and in the case of agriculture provision has been made for rural development along the following guidelines:

- Enhancing food security
- Providing a conducive environment for agricultural production and economic returns
  - Enhancing agricultural productivity and farmer's incomes
  - Diversification of agricultural production systems
  - Agrarian reform and measures to secure equitable access to land by both genders
  - Infrastructure development to enhance distribution to markets
- Reducing poverty through rural development
- Integrating rural development strategies into Poverty Reduction Strategies (PRSPs) or other economic/development strategies and the empowerment of local rural communities, especially those living in poverty and their organizations
- Supporting main driving forces for economic growth and social development in rural areas (e.g. agriculture, small and medium enterprise development, employment and other non-agricultural sector) as well as improving access to basic services and infrastructure in rural areas (e.g. adequate shelter, education, employment opportunities, health, sanitation, energy)
- Reducing the environmental impact of agricultural production
- Improving access to international agricultural markets

Environmental Developments and Impacts

This section has been dealt with above, under Risks as Environmental and Ecological Issues.

Political Developments and Impacts

Developing a Biosafety System

Biosafety South Africa (BSA), launched on 18 February 2010, is a national biosafety service platform falling under the auspices of the Department of Science and Technology (DST). BSA is publicly funded from the coffers of the DST through the Technology Innovation Agency. The aim of the organisation is to support the development of innovative, safe and sustainable product development within the South African biotechnology sector. However, the BSA is committed to the commercialization of locally developed biotechnology products through private-private partnerships.4. The organisation is thus involved in trying to create a strong South African biotechnology sector, through a biosafety platform.

BSA provides the following services:

- Assistance with regulatory applications, e.g. registration of GM facilities and the trial release of a GMO.
- Development of a service provider network for all necessary analyses that should be undertaken for permit applications.
- Provision of advice to developers of GM technology at an early stage regarding the biosafety requirements and implications of their projects to help ensure an integrated approach to GM research and development.
- Publication of user-friendly guidance documents and checklists for all regulatory applications.
- Assistance with conducting required risk assessments by informing applicants about the regulators' expectations and the necessary support structures that need to be in place to generate the required data. BSA also assists stakeholders with validating information and evaluating applications to support the applicant.
- Ad hoc consultation and assistance as required.

All GMO activities (R&D, import/export, production, consumption) within South Africa are regulated under the country's GMO Act (Act No 15 of 1997), GMO Amendment Act (Act No 23 of 2006), GMO Act Regulation (No R. 120 of 2010), so that the minimum standards of safety and sustainability are met in respect of food, the environment and socio-economic aspects.

South Africa is legally bound to the Cartagena Protocol on Biosafety (CPB), supplemented by the Convention on Biological Diversity (CBD), and under the governance of the CPB, South Africa is obliged to adhere to the following regulations of the CPB[65]:

a. The movement of living modified organisms across borders
b. Risk assessment procedures
c. The biosafety clearing rules
d. Capacity building, and,
e. Public awareness

The link to the GMO Act (DAFF) and other South Africa government departments (Health, Environmental Affairs, Trade and Industry) is shown below in Figure 5.

Potential Impact		Legislation	Application of legislation
Human and animal health and safety	GMO Act	Foodstuffs, Cosmetics and Disinfectants Act	Labelling requirements for GM-containing foods
		Occupational health and Safety Act	Health and safety of workers and other persons involved with activities of GMOs
Environmental safety		National Environmental Management and Biodiversity Act	Regulates possible impacts of GMOs on biodiversity
		National Environmental Management Act	Provides general guidance on the criteria that may trigger an EIA for GMOs, the objectives of such an EIA and procedures to follow
Socio-economic viability		Consumer Protection Act	Introduced compulsory labelling requirements for all GM goods

Figure 5: Illustration of cross-cutting by the GMO Act with other national departments (South Africa)[66]

For countries seeking to develop a national biosafety system, it must be emphasized that there is no model for a single best approach. The issues to be considered can be broadly divided into six elements, which are briefly discussed below.

(i) National inventory and evaluation

An inventory and evaluation of national priorities, agricultural policies, existing regulatory regimes, and national scientific and technical capacities, is an ideal prerequisite to the development and implementation of biosafety-related policies and regulations. This national appraisal provides a means to identify and characterize available resources and regulatory infrastructures, assess their adequacy for supporting a biosafety system, and identify gaps where capacities need to be strengthened.

(ii) National policies and strategies

A national biosafety policy or strategy provides a set of principles to guide the development and implementation of a biosafety system and should describe the goals and objectives of the regulatory framework. Direction on many of the fundamental issues and public policy choices that must be considered during the development of regulations can be provided by such a strategy. Examples of these issues include the extent to which social, ethical, and economic factors should be considered, the social acceptability of biotechnology and its products, and linkages with other national policies on food, agriculture, and economic development.

(iii) Scientific knowledge, skills and capacity base

The human resource environment that both enables and limits biosafety implementation is shaped by the scope and quality of: competency in the biological sciences; expertise in information acquisition, communications, and management; and, experience in critical thinking, analysis, and decision-making. These capacities have an overriding influence on the development and implementation of a biosafety system. Addressing capacity needs is the top priority for many developing countries.

Building a strong base of scientific knowledge in support of the regulatory system, and development of core competencies in biotechnology product evaluation, are fundamental to any national biosafety system. These activities allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management, inspection, and monitoring.

(iv) Development of regulations

Decisions on an appropriate regulatory framework should be informed by the national inventory and evaluation, and through extensive consultation with stakeholders, including the public. This is particularly true if a country chooses to incorporate non-safety issues into its decision-making process.

(v) Implementation of regulations

The central issues around the implementation of biosafety regulations involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication within existing financial, technical, and human resource constraints. Decisions made during the implementation phase directly affect the costs associated with assessing and managing risks and ensuring compliance with regulations.

(vi) Cross-cutting issues

Cross-cutting issues are those that are common to each of the five preceding elements and they are often the most challenging factors to address and resolve. They are, however, the issues that will ultimately dictate the scope of a national policy on biosafety, and the conversion of policy into practice. Cross cutting issues affect the implementation of the system designed to assess biosafety, and perhaps more importantly, those non-technical factors that are crucial to public acceptance and confidence in the decisions that are made by government on behalf of the people.

The twin issues of public information and participation have to do with the degree of transparency in a regulatory system, and the degree to which the public has input either into the formulation of regulatory policy or into specific regulatory decisions. Transparency refers to the extent to which governments provide information on why and how certain products are regulated, how risk assessments are performed and decisions made, and as well, the conclusions and decisions that have been reached. Transparency can also involve the perceived independence and objectivity of the regulatory decision-makers.

Human, financial and infrastructure resources largely determine the scientific and administrative capacity of any country; they obviously influence any biosafety related policy or program. Funds must be available to develop and implement a national biosafety system; to support the infrastructure required, such as buildings, labs, equipment, and computers; to facilitate communication and public participation; to train scientific and regulatory personnel; and to foster the research required to assure that risk assessments are sound.

Annexure 1 illustrates the alignment of Genetics with the key policy mandates of DAFF, articulated in the NDP, and APAP, and illustrates where Genetics and possibly technologies of the future may be used to support the delivery of the South African governments proposed interventions as articulated in the APAP.

7. Conclusions

Genetically modified (GM) commercial crop species are few (soybean, corn, cotton and canola) with agronomic characters (traits) directed against some biotic stresses (pest resistance, herbicide tolerance or both) and created by multinational companies. The time-to-market of the next biotech plants will not only depend on science progress in research and development (R&D) in laboratories and fields, but also primarily on how demanding regulatory requirements are in countries where marketing approvals are pending. Regulatory constraints, including environmental and health impact assessments, have increased significantly in the past decades, delaying approvals and increasing their costs. This has sometimes discouraged public research entities and small and medium size plant breeding companies from using biotechnology and given preference to other technologies, not as stringently regulated.

Be that as it may, R&D programmes are flourishing in developing countries, boosted by the necessity to meet the global challenges that are food security of a booming world population while mitigating climate change impacts. Biotechnology is key to these imperatives and several plants are currently being tested for their high yield despite biotic and abiotic stresses, including plants with higher water or nitrogen use efficiency, tolerant to cold, salinity or water submergence.

Food security is not only a question of quantity but also of quality of as well as the need for these foods to be available to the neediest. Staple food types are therefore being developed with nutritional traits, such as biofortification in vitamins and metals using biotechnology, and this is in the main being invested into by large multinational seed companies, in collaboration with public institutions, private entities and philanthropic organizations in developing countries. These partnerships are particularly present in Africa. In developed countries, plant biotechnology is also used for non-food purposes, such as the pharmaceutical, biofuel, starch, paper and textile industries, where plants are modified to produce molecules with therapeutic uses, or with an improved biomass conversion efficiency, or producing larger volumes of feedstocks for biofuels [67].

8. Synthesis and key trends from the literature

The acceptance of transgenic crops and products will depend on positive public perception of this technology, particularly where compliance with regulation and biosafety standards is concerned. Transgenic crop agrobiotechnology industry faces hurdles such as consumer concerns on health risks and environmental safety and barriers to world-wide trade. Long term effects of GE foods must be rigorously researched but equally, the field-testing and marketing of GM products must be done to prevent lawsuits.

The cost (approximately US$100 - 136 million[68],[69]) of developing and obtaining authorization for the commercialization of a transgenic trait limits the development of transgenic crops to traits wide interest. As a result, agro-based companies like Monsanto, Dupont, Syngenta, Dow Agro, and Bayer Crop Science have the difficult task of generating profit for shareholders while they are also sensitive to the farming community and consumer demands.

Agronomic traits like herbicide resistance, pest resistance and drought tolerance have been commercialized, and continue to enjoy high adoption rates in many developing countries.
Successful commercialization and marketing of transgenic crops and products has become dependent on the implementation of international standards and trade policies among nations. related to this is that private corporations and research institutions should decide to share GM technology, now held under strict patents and licensing agreements, with responsible scientists for use for hunger alleviation and to enhance food security in developing countries. In addition, special exemptions should be given to the world's poor farmers to protect them from inappropriate restrictions in propagating their crops[70].

The need for poor farmers in developing nations to gain access to food through the application of intensive production practices of staples such as maize, rice, wheat, cassava, yams, sorghum, plantains and sweet potatoes is therefore elevated.

Socio-economic trends affected by biotechnology[71]

- Over the last century, agricultural technologies have been developed that require greater levels of capital investment and fewer numbers of people to produce the nation's food.
- Farmers are involved in the production of undifferentiated (unprocessed) raw commodities while the profit and opportunities in the food system have shifted to the

companies that sell farm inputs such as seeds, farm equipment, fertilizer, herbicides, and pesticides and to those that process, package, and market food.

- The impacts of GM crops typically emphasize economic benefits to farmers in the form of labour savings, reduction in inputs, and yield increases.
- Other changes and impacts on family farms and rural communities include a shift in the returns on production from labour to capital. Capitalists use technology to gain a larger share of the value of their product at the expense of labour. A new technology lowers costs and eventually dominates the industry. Those who work in the industry are then forced to accept wages offered by the owners of the technology.
- The development of new seed and chemical packages through biotechnology has emerged from private research and private–public collaborations. Public sector scientists may have limited knowledge with which to support extension education programs, with a consequence that extension, and potentially agricultural cooperatives, may gradually be reduced to playing a secondary role in farm change.
- The private–public research collaborations that generate new biotechnologies may also lead to a restructuring of the relationship between farmers and researchers.
- Many agriculturally-based rural communities will continue the ongoing process of shrinkage and consolidation, as producers and local supply and marketing firms continue to decline in numbers.
- With the advent of agricultural biotechnology products, some of which are promoted as environmentally friendly (such as herbicide-resistant crops), the farmer is likely to incur increased costs and risks without assurance of gains. The use of expensive genetically engineered seeds does not guarantee a commensurate increase in yields. Furthermore, supply companies and firms licensing genetically engineered organisms are adept at charging what markets will bear, with the economic benefits arising from these technologies likely to be accrued by those holding the patents.
- The level of investment required, the increased risk, and the need for higher levels of management mean that larger and more capitalized farmers will likely benefit disproportionately.
- The proliferation of new genetically engineered products and processes may inhibit the ability of farmers to make educated choices with respect to crops and inputs appropriate to their regions and cropping systems.
- Biotechnology will continue and accelerate the trend toward increasing concentration of power in a small number of large multinational corporations. Development and commercial control of agricultural biotechnology will be in the hands of corporations that transcend geographic boundaries.
- The increased concentration of research funds, scientific talent, and intellectual property at a small number of public and private institutions will become more common. While the public sector was the primary investor in agricultural research

prior to the 1980s, the private sector now funds more agricultural research than the public sector and the gap continues to grow. The university and the private sector have very different goals for research and ways of pursuing those goals[72].

- The new agricultural biotechnologies are also contributing to a changing collaborative relationship between universities and for-profit companies. The new types of university–industry relationships in biotechnology are generally more varied, wider in scope, and more publicly visible than relationships in the past.
- Several analysts have predicted that biotechnology will have an unfavourable impact on the rural poor in Africa, Asia, and Latin America while benefiting relatively well-off farmers in those regions. As farms become larger and fewer, more people both in absolute numbers and as a percentage of the population in developing countries are being affected. Those who are affected are more likely to be much worse off to begin with and are more vulnerable to displacement[73].
- Developed nations might use the new technology to undercut traditional developing country exports such as vanilla, sugar, cocoa butter, and other important cash crops. In principle, any commodity that is consumed in an undifferentiated or highly processed form could be produced using new biotechnological processes and therefore product substitutions could be easily introduced.
- Another concern is that biotechnology will increase disparities between developed and developing nations. With the shift in applied research and associated product development from the public to the private sector, the benefits from the new biotechnologies may become less widely available. Furthermore, the products developed are unlikely to be the ones that are important to developing countries, particularly in the tropics.
- If world agriculture, and developing countries, are to benefit from the many potential advantages of GM technology, it will be important to promote capacity building in risk management. To be effective, the following objectives must be included:
    - Build sufficient scientific and technical human resources in each country to enable it to assess the relative benefits and the risks of GM technology;
    - Strengthen local and global infrastructure;
    - Monitor and evaluate the short mid and long-term effects of transgenic plants and share data between all relevant countries;
    - Develop simple techniques to readily and reliably distinguish non-transgenic and transgenic plants where necessary.
- The emergence of transgenic technology has allowed for the possibility of diversifying animal production techniques, as well as provide alternatives to produce biopharmaceuticals for human use.

- Extensive safety guidelines should be developed for the commercial exploitation of recombinant proteins, the prevention of transmission of pathogens from animals to humans, as well as for the management and control of environmental issues.

End Notes

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