Information Manual on Agricultural Biotechnology

agriculture,
forestry & fisheries

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Information Manual on Agricultural Biotechnology

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For further information please contact:

The Registrar
Genetically Modified Organisms Act
Private Bag X973
PRETORIA
0001

Tel: +27 12 319 6382
Fax: +27 12 319 6329

Content

Acronyms

Bt	*Bacillus thuringiensis*
FAO	Food and Agriculture Organization
DAFF	Department of Agriculture, Forestry and Fisheries
DNA	Deoxyribonucleic Acid
GM	genetically modified
GMO	genetically modified organism
GREP	Global Rinderpest Eradication Programme
SAGENE	South African Committee for Genetic Experimentation
WHO	World Health Organisation

Objectives of this manual

The objectives of this manual are to provide general information on agricultural biotechnology and serve as a source of information to extension officers within the agricultural sector. This manual will assist extension officers to provide farming communities with sufficient information to make informed decisions on the application of agricultural biotechnology products as only one of the agricultural tools that could be used to increase farm productivity, competitiveness and sustainability.

What is biotechnology?

Biotechnology is the branch of technology that uses living organisms in their natural or modified forms to create useful products. It can overcome production constraints that are more difficult and intractable with conventional breeding programmes by speeding up the process and providing farmers with disease-free planting material and crops that are resistant to pests and diseases. Biotechnology started in early farming societies with practices such as selective breeding to improve plants and animal breeds, and with fermentation to produce commodities such as beer, bread and wine.

Later applications which are well established, include, e.g. the production of life-saving antibiotics, including penicillin from the fungus *Penicillium*. Biotechnology has opened up unusual opportunities for improving the productivity, quality and sustainability of crop and animal husbandary, fisheries and forestry. It can be divided into two eras: traditional and modern biotechnology.

TRADITIONAL BIOTECHNOLOGY

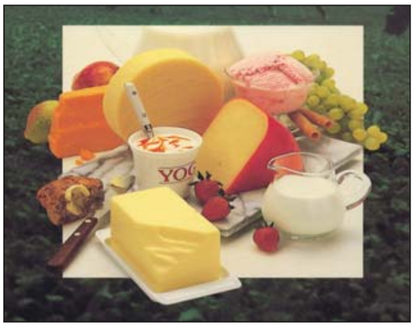
Traditional biotechnology dates back to early farming societies in which people collected seeds of plants with the most desired traits for planting the following year, currently known as selective breeding. As humans discovered more plant varieties and traits, they gradually became used to breeding specific plant varieties over several years and sometimes generations, to obtain desired traits such as disease resistance, better taste and higher yield.

As years went by people discovered how to make use of natural processes that occur all the time within living cells. They discovered that food matures in a way that changes its taste and content, and makes it less perishable. Through a process called fermentation, flour dough became leavened in the making of bread, grape juice became wine and milk turned into cheese.

Through different improved experiments it was later discovered that traits are transmitted from parents to offspring by independent and discrete units called genes. This provided the first indication of the crossing over from traditional to modern biotechnology.

Traditional beer

Wine



Milk products

Bread

MODERN BIOTECHNOLOGY

Modern biotechnology began with the discovery of the structure of deoxyribonucleic acid (DNA) and the way genetic information is passed from one generation to the other. This technique involves the intentional manipulation of genes to generate changes in the genetic make-up of an organism or produce new cells.

Before the discovery of genes and DNA, genetic changes in an organism were carried out at an organism level whereby a plant with a desired trait was cross-bred with other plants in the hope that through cross-breeding a desired trait would be transferred to the offspring of the parent.

In modern biotechnology, achieving a desired trait is done at a gene level whereby a gene responsible for the desired trait is identified, transferred and inserted into the organism at cell level to produce a genetic change. It has therefore become possible to introduce genes from a wide range of species and genera, irrespective of their ability to undergo sexual hybridisation.

What is agricultural biotechnology?

Biotechnology is one tool being used to address problems in all areas of agricultural production and processing. This includes plant breeding to increase and stabilise yields; to improve resistance to pests, diseases and abiotic stresses such as drought and cold; to enhance the nutritional content of food.

Agricultural biotechnology encompasses a range of research tools scientists use to manipulate and understand the genetic make-up of organisms for use in the production and processing of agricultural products. A technique making use of recombinant DNA, sometimes called genetic modification, has already been used to develop plants with novel traits, known as genetically modified plants.

Technologies such as artificial insemination and embryo transplantation have created worldwide access to high-quality genetic material. Although agricultural biotechnology is applied internationally, most of the research to date has taken place in developed countries.

Modern biotechnology applications take various forms such as tissue culture, marker-assisted selection and genetic modification. Genetic modification using recombinant DNA technology has opened unusual opportunities for increasing crop production. It is, however, not just in the field of plant transformation in which biotechnology has contributed to production. Disease surveillance and identification are also increasingly achieved using biotechnological methods.

BIOTECHNOLOGY TECHNIQUES

Tissue culture technique

Tissue culture is the cultivation of plant cells, tissue, or organs on specially formulated nutrient media. Under the right conditions, an entire plant can be regenerated from a single cell. Plant tissue culture is a technique that has been around for more than 30 years. Tissue culture is seen as an important technology for developing countries in the production of disease-free, high-quality planting material and the rapid production of many uniform plants.

Micropropagation, which is a form of tissue culture, increases the quantity of planting material to facilitate distribution and large-scale planting. In this way, thousands of copies of a plant can be produced in a short time. Micropropagated plants have been observed to establish more quickly, grow

Tissue culture

more vigorously and taller, have a shorter and more uniform production cycle, and produce higher yields than conventional propagates.

This technique only requires a sterile workplace, nursery, greenhouse, and trained manpower and is therefore applied in many developing countries. Plants important to developing countries that have been grown in tissue culture are oil palm, plantain, pine, banana, date, eggplant, jojoba, pineapple, rubber tree, cassava, yam, sweet potato and tomato.

Examples of the use of tissue culture in crop improvement in Africa include:

(i) A new rice plant type for West Africa (NERICA—New Rice for Africa)

Results from embryo rescue of wide crosses made between Asian rice (*Oryza sativa*) and African rice (*Oryza glaberrima*) followed by anther culture of the hybrids to stabilise breeding lines.

(ii) Disease-free bananas in Kenya

Bananas are produced clonally; mother plants are used to produce new shoots which give rise to "offspring" plants. If the mother plant is diseased, the offspring are also diseased with subsequent lower yields.

In Kenya, biotechnology is being tapped to tackle the problem *via* micropropagation, an original banana shoot tip is heat-treated to destroy infective organisms and then used through many cycles of regeneration to produce daughter plants. A single selection of tissue can be used to produce as many as 1 500 new, disease-free plants through ten cycles of regeneration without the use of any pesticides.

Genetic modification

It involves inserting specific foreign genes into a plant's genome with the aim of introducing a desired trait (e.g. resistance to a disease or tolerance to herbicide) using methods such as biolistics or *Agrobacterium*-mediated transformation. These traits include: drought tolerance, salinity tolerance, disease resistance, herbicide tolerance, pest resistance and improved micronutrients.

Growth-enhancement for human food production in aquaculture is the most common objective of current modifications. Another example of genetically modified fish for ornamental purposes is a fluorescent zebrafish which glows as a result of the skeletal muscle expression of a fluorescent protein.

In South Africa transgenic maize, cotton and soya-beans are available commercially. These have been modified for insect resistance and/or herbicide tolerance. Other research currently in progress include:

- Insect-resistant potatoes
- drought-tolerant maize
- enhanced herbicide-tolerant soya-beans
- virus-resistant cassava
- drought-tolerant groundnut
- virus-resistant sugar cane
- sugar cane with increased carbohydrate metabolism

The global area of approved biotech crops in 2008 was 125 million ha, an increase from 114,3 million ha in 2007. This 10,7 million ha is equivalent to an annual growth rate of 9,4 % in 2008. There are 13,3 million biotech crop farmers globally in 25 countries and 90 % or 12,3 million of these farmers represent small and resource-poor farmers in developing countries.

Insect-resistant maize (genetically modified)

Noninsect-resistant maize (conventional)

Other genetic modifications are aimed at:

- improving the product quality characteristics, for example:
  - enhanced vitamin A content in rice
  - increasing the beta-carotene and vitamin E in vegetable oils
  - altering the fatty acid composition in oils from soya and canola
- Antinutritional factors in plants such as cereals and legumes may contain varying quantities of substances that interfere with digestibility and nutrient absorption. In excess, these materials may even be toxic. Genetic modifications are aimed at reducing these antinutritional substances, for example:
  - phytate in cereals and legumes
  - glycoalkaloids in potatoes
  - gossypol in cottonseed, etc.
- Functional attributes for example:
  - firmer tomatoes for canning, or beans with less breakage, delayed ripening in tomatoes to extend the shelf-life.

Forestry biotechnology

Application of biotechnology in forestry is growing in scope. Research and development is carried out in a number of countries, focusing on a range of aspects.

Marker-assisted selection, genomics and genetic modification are some of the major categories of biotechnological activities applied in forestry. A number of countries are conducting field trials with GM trees. Most of the gene modifications are focused on gene stability, functional genomics or tissue culture, herbicide tolerance, wood chemistry and fertility-related issues. Populus, Pinus, Liquidambar and Eucalyptus are the most important tree genera that have been modified.

Livestock breeding

Technologies such as genomics and molecular markers are equally valuable in understanding, characterising and managing genetic resources in livestock and fisheries. Rapid advances in molecular biology and reproductive biology have provided new and powerful tools for further innovation in this area.

The main objective of reproductive biotechnologies for livestock is to increase reproductive efficiency and rates of animal genetic improvement. The genetic improvement of locally adapted breeds will be important in realising sustainable production systems within the broad spectrum of production environments in developing countries, and will probably best be realised by the strategic use of both nongenetic and genetic interventions.

Reproductive biotechnology in fisheries presents opportunities to increase growth rates and improve the management of farmed species and to limit the reproductive potential of genetically engineered species.

Disease diagnostics

Biotechnology has also allowed the development of diagnostics which has assisted farmers worldwide in managing different diseases affecting their crops and livestock. In this way it is possible to identify disease-causing agents, formulate intervention strategies and monitor control programmes more effectively than ever before. In molecular epidemiological surveillances, the origin of the pathogens (viruses, bacteria, parasites and fungi) can be traced through nucleotide sequencing, which may be important for effective control. For example, the molecular analysis of rinderpest viruses has been vital for determining the lineages circulating in the world and instrumental in aiding the Global Rinderpest Eradication Programme (GREP).

Marker-assisted breeding

Complex characteristics such as crop yield are usually influenced by many genes. Traditionally, plant breeders have selected plants based on their visible or measurable traits, called the phenotype. This process can, however, be difficult, slow, influenced by the environment, and costly—not only in the development itself, but also for the economy, as farmers suffer crop losses.

As a shortcut, plant breeders now use marker-assisted selection. To help identify specific genes, scientists use the so-called molecular markers. These markers are located near the DNA sequence of the desired gene. Because the markers and the genes are close together on the same chromosome, they tend to stay together as each generation of plants is produced. This linkage assists scientists to predict whether a plant will have a desired gene. If researchers can find the marker for the gene, it means the gene itself is present.

The benefit is allowing for a larger number of crossings to take place, with a higher chance of success, thereby increasing the efficiency and enhances of success of a breeding programme. This methodology has now to be integrated into the breeding programmes, as evidenced by work done at CIMMYT (Mexico) and successfully done by the SA Sugar Industry.

Regulation of GMOs in South Africa

An efficient and functional biosafety framework is essential to facilitate the effective regulation of GMOs in any country. An effective regulatory framework will inspire public confidence.

GENETICALLY MODIFIED ORGANISMS ACT, 1997 (ACT NO. 15 OF 1997)

Genetically modified organisms (GMOs) have been permitted in S A since 1992. In the absence of specific legislation to regulate activities involving GMOs, a Committee, known as the South African Committee for Genetic Experimentation (SAGENE), was established to advise Government, industry and the public on the application and safety of GMOs, especially in the agricultural sector. SAGENE evaluated the results of the risk assessments of GMOs in terms of food, feed and environmental impact. At that time, permits to conduct activities with GMOs were issued under an amendment of the Agricultural Pests Act, 1983 (Act No. 36 of 1983).

Knowledge and expertise acquired through this trial period allowed Government to develop and implement the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), which came into full operation in December 1999.

The main objectives of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) are to:

- provide for measures to promote the responsible development, production, use and application of GMOs
- ensure that all activities involving the use of GMOs (including importa-

tion, exportation, transit, development, contained use, storage, application, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequences to the environment, human as well as animal health

- give attention to the prevention of accidents and the effective waste management
- establish mutual measures for the evaluation and reduction of the potential risks arising from the activities involving the use of GMOs
- lay down the necessary requirements and criteria for risk assessments;
- establish a council for GMOs
- ensure that GMOs are appropriate and do not present a hazard to the environment
- establish appropriate procedures for the notification of specific activities involving the use of GMOs and to provide for matters connected therewith.

The GMO Act is administered by the Directorate Biosafety within the Department of Agriculture, Forestry and Fisheries (DAFF) which hosts the Office of the Registrar of the GMO Act.

The GMO Act also makes provision for establishment of two regulatory bodies, i.e. the Advisory Committee and Executive Council, which provide guidance and decisions respectively, relating to all activities of GMOs in S A. Members of the Advisory Committee are appointed by the Minister of Agriculture, Forestry and Fisheries and consist of ten scientists who are experts in various scientific fields relating to GMOs.

The Executive Council is the decision-making body and consists of senior officials from six government departments *viz*. the departments of Agriculture, Forestry and Fisheries, Health, Environmental Affairs, Labour, Trade and Industry and Science and Technology, as well as the chairperson of the Advisory Committee. With the implementation of the GMO Amendment Act, 2006 the Council will additionally include members from the Department of Water Affairs and the Department of Arts and Culture.

The objectives of the Council are to advise the Minister of Agriculture, Forestry and Fisheries on all aspects concerning activities relating to GMOs. Approved GMO activities are regulated by way of permits issued by the

Registrar and accompanying permit conditions are monitored for compliance by inspectors within the DAFF.

INTERNATIONAL OBLIGATIONS

S A acceded to the Cartagena Protocol for Biosafety in 2003. This is an international agreement that regulates the transboundary movement of GMOs.

The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

To ensure that S A is in compliance with all the provisions of the Protocol, the GMO Act has since been has amended. In terms of the protocol the Department of Environmental Affairs is the recognised focal point for SA while DAFF is the designated competent Authority tasked with the implementation of the provision of the protocol.

Are GMOs commercially available in South Africa?

Yes, S A commercialised its first genetically modified crops in 1997.

It is important to remember that a genetically modified crop would only be approved for commercial use in S A if it has been tested thoroughly for safety with regard to humans, animals and the environment, and therefore is regarded as safe as conventional crops.

The genetically modified crops that have obtained approval for commercial planting in SA are cotton, maize and soya beans.

All of the crops currently approved for commercial release contain traits of insect resistance or herbicide tolerance, or both. Information on the status of approved GMO Activities is attached (Annexure 2).

Special growing conditions for commercial genetically modified crops

Currently all genetically modified crops in S A have been modified to be either insect resistant or herbicide tolerant or to contain both of these traits. To prevent these traits becoming ineffective owing to the build-up of resistance, it is important to take special measures to prevent this from happening. This is one of reasons why farmers are required to sign special grower agreements or licences with the suppliers of GM seed whenever GM seed is purchased. This agreement requests the farmer to commit to specific planting requirements relevant to his or her GM crop.

The risk of ineffectivity is one of the reasons why famers are required to sign special growers' agreements or licences with the suppliers of GM seed whenever GM seed is purchased. This agreement requests the farmers to commit to planting a refuge insect resistance, and informs the farmer of the specific planting requirements relevant for his or her specific GM crop.

In agreements and guidelines for transgenic herbicide tolerant crops there are currently specific recommendations for herbicide applications in these crops. Weed resistance management is a greater issue and not confined to transgenic crops. The herbicides used in transgenic crops are also used in other non-GM situations and therefore the risk of weeds developing resistance to herbicides is universal wherever herbicides are used. Weed Resistance Management Practices have been designed for all herbicide use situations.

At this stage, specific planting requirements are only applicable to insect resistant maize and insect resistant cotton. These requirements form part of the insect resistant management strategy, which is a strategy to prevent the build-up of resistance of certain insects that feed on GM crops.

One essential component of the insect resistant management strategy is the creation of refuge areas. This involves the planting of a nontransgenic crop as a refuge or a host area, in the ratio of 4 to 25 ha for every 100 ha planted to the insect resistant crop. This refuge will produce susceptible adults who could mate with any adults that might be resistant to the delta endotoxin produced by the transgenic crop. Such mating will ensure that the offspring remain susceptible to the delta endotoxin, i.e. keep the tolerant types with the tolerant recessive genes recessive.

The plants in the host area must not contain any of the GM crop and may not be treated with a Bt type biopesticide but may be sprayed with any other insecticide that normally kills the insect. Spraying this insecticide is generally so ineffective that more than enough adults escape to be able to mate with any resistant types that may emerge from the transgenic crop that is in the proximity of the refuge area.

The following options for refuge requirements are applicable in S A are discussed below.

OPTION 1

Of the total area to be planted with Bt-maize or cotton, the farmer must plant at least 20 % with non-Bt (i.e. conventional) maize or cotton. This 20 % area acts as the refuge area and may be treated with any insecticide, except Bt-insecticides. This method is mostly used by the big commercial farmers.

OPTION 2

Of the total area to be planted with Bt-maize or cotton, the farmer must plant at least 5 % with non-Bt (i.e. conventional) maize or cotton. This 5 % area acts as the refuge area and may NOT be treated with any insecticide. This option is mostly used by small-scale farmers.

The refuge on each farm may be arranged in a number of configurations, which will offer flexibility to easily incorporate an effective maize or cotton refuge into farm operations. Some frequently used options can be seen in Fig 1, 2 and 3.

The following recommendations, irrespective if the farmer plants Bt-maize or Bt-cotton, are applicable to create a refuge area:

- A refuge is required on every farm where Bt maize or cotton is planted
- The refuge must be planted within 500 m and at the same time as the insect resistant maize or cotton

- The non-Bt (i.e. conventional) maize or cotton must be managed in the same manner as the insect resistant maize or cotton
- The refuge may only contain non-Bt maize or cotton. It may not be a mixture of insect resistant and conventional (non-insect-resistant) maize or cotton.

Any non-Bt (i.e. conventional) maize or cotton planted on a grower's farm within 500 m from insect resistant maize or cotton can serve as a refuge.

REFUGE CONFIGURATION OPTIONS WHEN PLANTING INSECT-RESISTANT MAIZE OR COTTON

See Fig. 1.2 and 3.

Do GMOs create farmer dependency on multinational companies?

The statement is often made that GM crops create farmer dependency on more expensive seeds from multinational companies and that the farmers may not keep any of the seed harvested. It is quite true that GM seeds are more expensive than conventional seed, but this is because the price includes a technology fee.

Independent surveys conducted in S A have shown that farmers have experienced a per hectare increase in yields and a reduction of pesticide costs, which outweighed the increase in seed costs.

Farmers may, as with conventional seed, keep GM harvested seed for replanting the following season. GM soya-bean farmers save and plant harvested seed for up to 2 seasons before they buy a new variety. Maize farmers plant a specific hybrid in each season, benefiting from the hybrid vigour that delivers optimum yields.

Although maize farmers may keep the seed harvested for replanting, they choose not to do this as the loss of hybrid vigour and segregation that takes place when planting F2 planting F2 generation seed in the following season. It is for this reason that most maize farmers buy new hybrid seed every year.

Refuge configurations options

FIG. 1 Block

Plant non-Bt maize strips or blocks within a Bt field

FIG. 2 Split planter

Split the planter to alternate four or more rows (six preferred) of non-Bt maize with Bt maize

FIG. 3 Perimeter maize

Plant field perimeters or end rows to non-Bt maize

Non-Bt maize   Bt maize

Some small-scale farmers plant saved seed over many years that are open pollinators and do not exhibit hybrid vigour. These are sometimes referred to as landraces. These landraces can, however, not compete with hybrid maize plants in terms of yield.

Cotton farmers, on the other hand, may also keep the harvested seed, but unless they have the ability to separate the fibre from the seed and are able to remove the linters from the seedcoat it is extremely difficult to establish a new crop from saved seed.

When a farmer sells his cotton to the gin for ginning machine separation of fibre from seed, he sells and is paid for both the seed and the fibre. The ginner then becomes the owner of this seed and sells it to the cotton seed oil extractors who produce cotton oil and animal feed stocks from the cotton seed "meat" and hulls. The farmer is therefore not in possession of the cotton seed anymore for replanting.

What are the debates on GMOs?

Direct and indirect concerns relating to the use of GM seeds and crops, as well as comment on these concerns, are briefly summarised below.

LOSS OF BIODIVERSITY

The diversity of traditional seeds that have been developed through a very sophisticated system of knowledge passed on over generations, over centuries by local farmers and indigenous people, is being replaced by genetically engineered and hybrid seeds.

Comment

Statements of "traditional seeds that are being developed over centuries by local and indigenous people that are carefully adapted and selected" and that "such diversity is destroyed when replaced with commercial seeds, both hybrid and GM varieties" can equally be applied to non-GM seeds. This is therefore not a concern only relating to the use of GMOs.

"GENETIC DRIFT" OR "BIOPOLLUTION" FROM GMOS

In addition to the loss of biodiversity as depicted above, an indirect consequence resulting from pollination between conventional and GM crops, is the occurrence of genetic drift, i.e. the movement of genes causing nontarget organisms to express unwanted genes, i.e. biopollution.

Comment

Gene transfer from any crop to wild species by means of pollen is a natural process that occurs constantly and is well known in conventional breeding. In addition, genetic drift can only occur between related crop species. South Africa does not have any wild crop species of the same taxonomic group as the GMOs currently approved in SA.

CREATION OF "SUPERWEEDS" AND "SUPERPESTS"

Concerns are often raised about major pests and weeds that have developed through only a few years of growing GM cotton, corn and potato in the USA, and that these pests and weeds force the farmers to spray crops with ever higher doses of herbicides and synthetic pesticides.

Comment

The fear that new, aggressive weeds could be created by genetically modified herbicide tolerant plants has not been confirmed to date. Likewise, pollen transfer from a field of GM plants to a neighbouring field of organic or conventional varieties must be differentiated according to plant species.

DAFF through an inspection service, also monitors all trials with GM crops to ensure that cross-pollination does not occur.

It is also important to note that the extent of pollen flow does not correspond to gene flow. In crops such as potatoes, which reproduce vegetatively, gene transfer has not been known to occur at all.

In S A, if the safety of a GMO cannot be demonstrated, the product is not approved. To date SA has not approved any GM crop that has sexually compatible relatives in this country. In the event that closely related exotics do exist, no evidence of outcrossing could be found. Importantly, cotton, soya-bean and maize are not invasive or problematic crops in SA.

NON-TARGET PESTS AND INSECTS ARE HARMED BY GMOS

Many GM plants have been developed to express a gene that was taken from *Bacillus thuringiensis* (Bt) that acts as a biological pesticide. Studies are often referenced about Bt corn that was deadly to the monarch butterflies. The concern is raised that it would kill beneficial pests and insects related to GM crops.

Comment

Since publication of a study by Cornell University that indicated that "pollen from GM corn" (Bt corn) "was deadly to monarch butterflies when it was spread onto milkweed plants which butterflies eat", many university researchers, including researchers at Cornell University, stressed that the study did not represent natural conditions. This was confirmed by a separate study from the University of Illinois, which indicated that monarch butterflies were not harmed by pollen from Bt corn in actual field conditions.

On the contrary, recent research shows that fields of Bt crops have more insects and a greater diversity of insect species.

CLAIMS OF INCREASED NUTRITIONAL VALUE OF GM CROPS ARE INCREASINGLY BEING QUESTIONED

Various GM crops are being promoted as being answers to curing diseases and nutritional deficiencies, e.g. golden rice. Golden rice has been engineered to contain large quantities of Vitamin A, a vitamin necessary for sight.

Research showed that a single serving of golden rice would not be adequate to eliminate the Vitamin A deficiency. Some people argue that focus should be placed on traditional crops that are rich in Vitamin A and not crops genetically engineered to contain higher quantities of Vitamin A.

Comment

There is absolutely no doubt that the genetic modification of crops has a huge potential for alleviating vitamin and other deficiencies that cause major health problems throughout the world. White rice is the staple food for most of the 3,5 billion people in the world. The kernels lack beta-carotene, without which the body cannot manufacture vitamin A. It has been stated that about 100 to 140 million children suffer from vitamin A deficiency and that more than half a million of them become blind every year. In addition, vitamin A deficiency also weakens the immune system and many children succumb to ailments such as pneumonia, measles and diarrhoea.

The "golden rice" mentioned in the paper contains beta-carotene, not vitamin A. Although the consumption of this rice may not provide the total recommended daily allowance, it constitutes a very important contribution towards eliminating vitamin A deficiencies. Further research in the field of genetic engineering could lead to even further progress in this regard.

HUMAN HEALTH AND FOOD SAFETY EFFECTS INCLUDE THE POTENTIAL FOR TOXICITY, ALLERGENICITY AND ANTIBIOTIC RESISTANCE

Because GM foods may contain genes that are not natural to the product, food allergies, often toxic, may result from consumption of these foods. GM foods may also have an impact on a person violating his or her religious or moral beliefs by imbibing foods that are contaminated with genes from allegedly sacred sources.

Comment

All crops naturally contain a variety of chemicals that act as a defence system against insects, bacteria, viruses and fungi. When eaten in small quantities, these chemicals pose no risk. During the assessment of GM crops, particular attention is paid to the compositional analysis of the GM crop compared to a conventional counterpart, and any additional components are tested thoroughly for their potential to cause allergies and toxicity.

Many conventional foods have the potential for toxicity and allergenicity. Genetically modified foods are, however, assessed so thoroughly that they can be considered to be as safe as conventional foods. In this regard, the Department of Health has kept abreast with and participated internationally in relevant work conducted by the Joint Food and Agriculture Organization (FAO)/World Health Organisation (WHO) Codex Alimentarius Commission.

Regulations on the labelling of foodstuffs derived by certain techniques of genetic modification were published by the Department of Health and also address moral and religious concerns.

Government's position on agricultural biotechnology

Government developed a National Biotechnology Strategy in 2001 to address the issue of biotechnology as it relates to all spheres where it is applicable. With the development of the Strategy mentioned, the importance of strengthening scientific and technological capacities in the field of biotechnology was highlighted. Through this strategy government recognises that biotechnology plays a very important role in alleviating poverty, but is aware of the potential risks involved in the application of biotechnology and is therefore sensitive towards concerns raised in this regard.

The S A government therefore embraces biotechnology with the proviso that the application of the technology is managed properly. In terms of agricultural biotechnology, legislation exists, which is aimed at addressing the potential risks associated with the introduction of GMOs.

Annexure 1

UNDERSTANDING THE GMO APPROVAL PROCESS

The Registrar for GMOs receives all applications for activities with GMOs. Once s/he is satisfied that the application is compliant with the provisions of the GMO Act, the application is forwarded to the Advisory Committee for risk assessments pertaining to food, feed and environmental impact. Based on the findings of the Committee, the application is recommended to the Executive Council for a decision.

The general public is also informed and consulted on intended activities relating to GMOs through notifications in major newspapers. Comments from the public are therefore considered in the process of evaluating any relevant application. If the Executive Council is satisfied that a certain activity with a GMO may be conducted, the Registrar is authorised by the Council to issue the necessary permit.

The application process is illustrated in Fig. 4

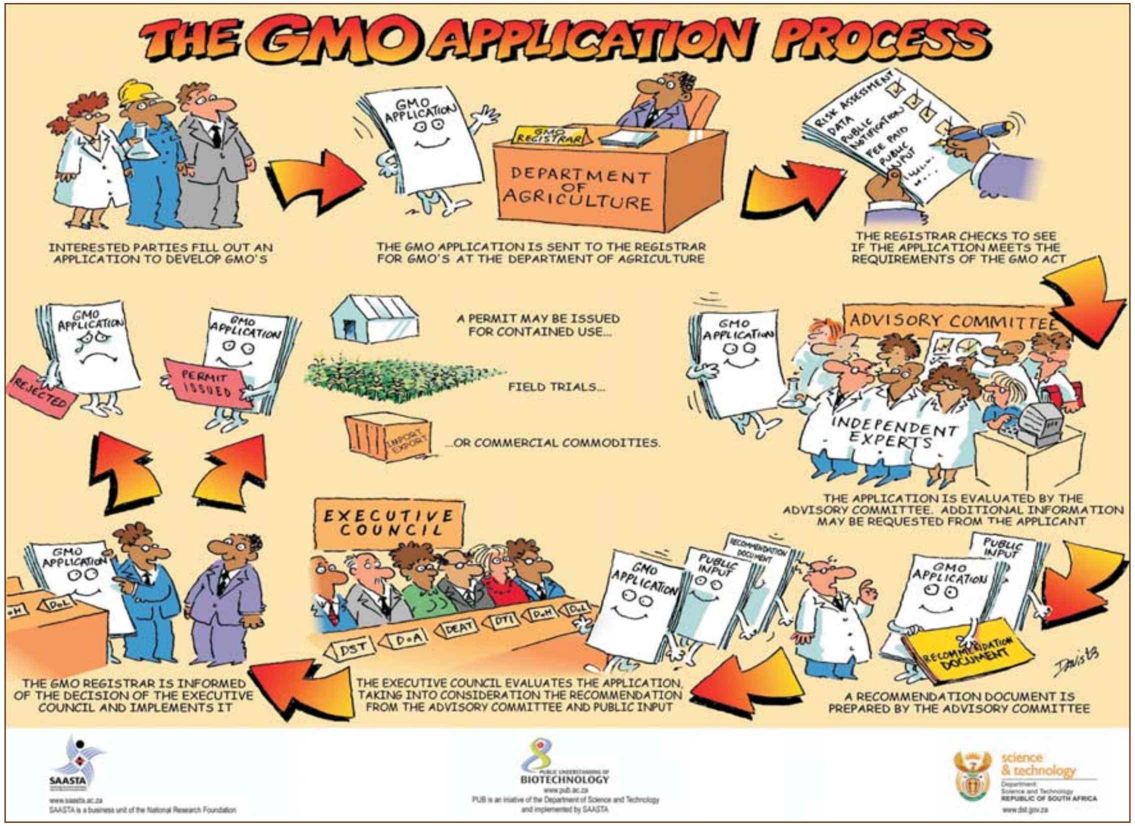


FIG. 4 The GMO application process [Acknowledgement: Public Understanding of Biotechnology (PUB)]

Annexure 2

GMO ACTIVITIES APPROVED UNDER THE GENETICALLY MODIFIED ORGANISMS ACT, 1997

GMOs approved for conditional general release

Use of the event: importation/exportation, commercial planting, food and/or feed

Event	Crop	Trait	Company	Year approved
Bollgard II X RR flex (MON15985 X MON88913)	Cotton	Insect resistant Herbicide tolerant	Monsanto	2007
MON88913 (RR flex)	Cotton	Herbicide tolerant	Monsanto	2007
MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2007
Bolgard RR	Cotton	Insect resistant Herbicide tolerant	Monsanto	2005
Bollgard II, line 15985	Cotton	Insect resistant	Monsanto	2003
Bt11	Maize	Insect resistant		2003
NK603	Maize	Herbicide tolerant	Monsanto	2002
GTS40-3-2	Soya-bean	Herbicide tolerant	Monsanto	2001
RR lines 1445 & 1698	Cotton	Herbicide tolerant	Monsanto	2000
Line 531 / Bollgard	Cotton	Insect resistant	Monsanto	1997
MON810 / Yieldgard	Maize	Insect resistant	Monsanto	1997

GMOs approved for commodity clearance (excludes events that have obtained general release clearance before commodity clearance)

Use of the event: importation for use as food or feed

Event	Crop	Trait	Company	Year approved
MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2004
MON810 x GA21	Maize	Insect resistant Herbicide tolerant	Monsanto	2003
TC1507	Maize	Insect resistant Herbicide tolerant	Pioneer Hi-Bred	2002
NK603	Maize	Herbicide tolerant	Monsanto	2002
GA21	Maize	Herbicide tolerant	Monsanto	2002
Bt11	Maize	Insect resistant	Syngenta	2002
T25	Maize	Herbicide tolerant	AgrEvo	2001
Bt176	Maize	Insect resistant	Syngenta	2001
Topas 19/2, Ms1Rf1, Ms1Rf2, Ms8Rf3	Oilseed rape	Herbicide tolerant	AgrEvo	2001
A2704-12	Soya bean	Herbicide tolerant	AgrEvo	2001

GMOs approved for trial release (Authorisations granted since implementation of the GMO Act in December 1999)

Use of the event: Importation/exportation/field/clinical trial evaluation

Event	Crop	Trait	Company	Year approved
MEDI-534	Vaccine	Intranasal vaccine	PPD	2009
NCo310	Sugar cane	Altered sugar content	SASRI	2009
Cotton Bollgard II x Gly-Tol x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	2009
Cotton Twinlink	Cotton	Insect resistant Herbicide tolerant	Bayer	2009
Cotton Twinlink x GlyTol	Cotton	Insect resistant Herbicide tolerant	Bayer	2009
SAAVI rMVA TBC-M456 vaccine	Vaccine	HIV vaccine	WITS	2008
GlyTol x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	2008
GlyTol	Cotton	Herbicide tolerant	Bayer	2008
T304-40	Cotton	Insect resistant Herbicide tolerant	Bayer	2008
GHB119	Cotton	Insect resistant Herbicide tolerant	Bayer	2008
BGII x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	2008
98140	Maize	Herbicide tolerant	Pioneer	2008

Event	Crop	Trait	Company	Year approved
Bt11 X MIR162	Maize	Insect resistant Herbicide tolerant	Syngenta	2008
MIR 162	Maize	Insect resistant	Syngenta	2008
MVA-Mbb85B	Vaccine	Measles vaccine	Triclinium	2007
HIV VIR201	Vaccine	HIV Vaccine	Triclinium	2007
AERAS 402	Vaccine	TB vaccine	Triclinium	2007
MON87460	Maize	Abiotic stress (drought tolerance)	Monsanto	2007
MRKAd5 HIV-1 gag/pol/ nef vaccine	Vaccine	HIV vaccine	WITS	2006
GA21X Bt11	Maize	Insect resistant Herbicide tolerant	Syngenta	2006
GA21	Maize	Herbicide tolerant	Syngenta	2006
MON89788 (RR2 Yield)	Soy-beans	Herbicide tolerant	Monsanto	2006
SST	Sugar cane	Sucrose metabolic pathway	SASRI	2006
Bt event (Mnandi)	Potato	Insect resistant	ARC	2006
Mon89034 and Mon89034 X NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2006
VRC-HIV DNA 1600V P and VRC-HICADV01 4-00-VP	Vaccine	HIV Vaccine	Triclinium	2006
Pleurocidin	Sugarcane	Antimicrobial	SASRI	2006

Event	Crop	Trait	Company	Year approved
SCMV	Sugar cane	Viral resistant	SASRI	2006
8H0019	Sugar cane		SASRI	2006
High Proline	Groundnut	Drought tolerant	ARC-GCI	2005
Cot 200/ Cry1Ab	Cotton	Insect resistant	Syngenta	2005
MVA 85A	Vaccine	TB Vaccine	Triclinium	2005
DAS 1507	Maize	Herbicide tolerant	Dow AgroScience	2005
Cot 102/ Cry1Ab	Cotton	Insect resistant	Syngenta	2004
Heb 134001-134100	Cotton	Herbicide tolerant	Syngenta	2004
VRX496	Vaccine	HIV vaccine	Cato Research	2004
MRK Ad5	Vaccine	HIV vaccine	MSD	2004
MVA ,IAVI 011	Vaccine	HIV vaccine	Triclinium	2003
1-2-3-3	Sugarcane	Increased carbohydrate content	SASEX	2003
MON88913 (RR flex/ enhanced RR)	Cotton	Herbicide tolerant	Monsanto	2003
MON88913 x Bollgard II	Cotton	Insect resistant Herbicide tolerant	Monsanto	2003
Safe Maize	Maize	Herbicide tolerant	CSIR	2003

Event	Crop	Trait	Company	Year approved
MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2003
3243M	Maize	Insect resistant	Syngenta	2003
Glyphosate resistant	Cotton	Herbicide tolerant	Syngenta	2003
P5CR	Soybean	Drought resistant	ARC	2002
COT102, lines 3169, 3826-3829	Cotton	Insect resistant	Syngenta	2002
Stacked Bt event	Cotton	Insect resistant	Calgene	2002
Stacked Bollgard II & RR (1445)	Cotton	Insect resistant Herbicide tolerant	Stoneville	2002
COT101, COT102, line 3169	Cotton	Insect resistant	Syngenta	2001
LL25	Cotton	Herbicide tolerant	Stoneville	2001
Bt event	Potato	Insect resistant	ARC	2001
TC6228	Maize	Insect resistant	Pioneer Hi-Bred	2001
ZMA101	Maize	Insect resistant Herbicide tolerant	Aventis	2001
Glufosinate ammonium	Sugar cane	Insect resistant Herbicide tolerant	University of Natal	2001
*Bt event	Potato	Insect resistant	First potato Dynamics	2001

Event	Crop	Trait	Company	Year approved
*NK603	Maize	Herbicide tolerant	Monsanto	2000
T25	Maize	Herbicide tolerant	AgrEvo	2000
RR	Wheat	Herbicide tolerant	Monsanto	2000
*TC1507 (DAS 1507)	Maize	Insect resistant	Pioneer Hi-Bred	2000
*Stacked Bollgard I & RR	Cotton	Insect resistant Herbicide tolerant	Monsanto	2000
*Stacked MON84006	Maize	Insect resistant	Monsanto	2000
*GTS40-3-2	Soya-bean	Herbicide tolerant	Monsanto	2000
*BXN	Cotton	Herbicide tolerant	Monsanto	2000
*Ms8Rf3	Canola	Herbicide tolerant	AgrEvo	2000
*GA21	Maize	Herbicide tolerant	Monsanto	2000
*Bollgard I	Cotton	Insect resistant	Monsanto	2000
*Bollgard II Line 15985	Cotton	Insect resistant	Monsanto	2000
*Bt 11	Maize	Insect resistant	Novartis (Syngenta)	1999

Note: The earliest year of approval under the GMO Act is provided

Approvals originally granted under an amendment of the Agricultural Pests Act, 1983 is indicated with an *

Approvals are granted for a specific period only. Therefore, not all the events listed above are being tested at this moment.

These tables are updated regularly to accommodate new approvals.

GMOs approved for contained use (Authorisations granted since implementation of the GMO Act in December 1999)

Use of the event: Importation, contained use

Event	Crop	Trait	Company	Year approved
ABS1	Sorghum	Nutritional composition	CSIR	2009
TC1507	Maize	Insect resistant	Pioneer	2009
98140	Maize	Herbicide tolerant	Pioneer	2009
98140 x Mon810	Maize	Insect resistant Herbicide tolerant	Pioneer	2008
Rolou A2:1 &A2:4 *Ornithogalum dubium* x thyrsoides	Ornithogalum	Viral resistant	ARC	2008
Bt	Potato (feeding study)	Insect resistant	ARC	2007
Lines 3.1 and 3.2 of Cultivar TMS60444	Cassava	Starch enhanced	ARC	2007
L-Phenylalanine	*E.coli* K12		SA Bioproducts	2006
Glutamicum L-serine	*Corynbacterium*		SA Bioproducts	2006
Glutamicum L-Valine	*Corynbacterium*		SA Bioproducts	2006
DAS 1507 (TC1507)	Maize	Herbicide tolerant	Dow Agroscience	2004
–	*C. glutamicum* AM919	Amino acid (isoleucine production)	SA Bioproducts	2003

Event	Crop	Trait	Company	Year approved
–	E.coli VNII	Amino acid (threonine) production	AECI Bioproducts (SA Bioproducts)	2003 1999
TC6228	Maize	Insect resistant	Pioneer Hi-Bred	2002
–	Sweet potato	Insect resistant	ARC	2002
–	Pathogen (*Zylophilus ampelinus*)	Bacterial blight formation in grapevine	ARC	2000
–	Granulovirus	Insect resistant	Capespan	2000
Bt event	Potato	Insect resistant	ARC	2000
–	E.coli XL1Blue	Protein expression for use in diagnostic test kits for syphillis	Natal Bioproducts	2000
–	Pathogen	Pathogen epidemiology	ARC	2000

Notes