The regulatory management of GMOs in South Africa

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As early as 1990, South Africa together with other developing countries entered the arena of agricultural biotechnology. Recognising that the issues and concerns around genetic modification involve scientific, economic, social, trade and political aspects, the South African Committee for Genetic Experimentation (SAGENE) was established.

This committee was responsible to advise government, industry and the public, on the safety of activities involving genetically modified organisms (GMOs). Approvals for such activities were granted under an amendment of the Regulations of the Agricultural Pests Act, 1983 (Act No. 36 of 1983).

Since 1999, activities involving GMOs have been regulated under the Genetically Modified Organisms Act, 1997 (Act No.15 of 1997). The Act is administered in the Department of Agriculture, Forestry and Fisheries.

The scope of the GMO Act includes all activities involving genetically modified organisms. Thus, it covers the imports, exports, transit, development, production, use and storage. Before a decision on the use of GMOs is made, a multidisciplinary risk assessment process is undertaken involving a scientific Advisory Committee and the cross-governmental decision-making body, the Executive Council.

These assessments focuses on all potential risks the GMO may pose to humans, animals and the environment. These are carried out in line with the prescripts of international standard setting bodies. Potential socio-economic impacts are also considered. In contrast to safety issues, socio-economic impacts have a very strong local context, as a result, no harmonised standards exists for potential socio-economic impacts.

Recently, the Secretariat of the Cartagena Protocol on Biosafety (CPB) undertook several consultations to consolidate countries' experiences and views on the socio-economic considerations relevant to the application of GMOs. The final synthesis of these considerations were reported at the meeting of parties to the Cartagena Protocol on Biosafety in India in October 2012.

What is the GMO act for?

The GMO act provides for the regulation of different classes of use of a GMO including development in the laboratory or glasshouse (contained use), the use as food and feed (commodity clearance), limited environmental release (field trials) and commercial release (general release).

It is important to note that no general release authorisation is granted unless performance and safety data generated under various South African environmental conditions are obtained. Every authorisation is subject to specific conditions; compliance to these conditions is monitored by the inspection services of the Department of Agriculture, Forestry and Fisheries (DAFF).

When technology holders obtain commodity or commercial release, traders or importers are still required to obtain an import or export authorisation every time a transboundary movement of commodity or seed consignments takes place.

This does not mean additional safety assessments would be undertaken; it merely serves as a means to monitor the imports or exports and ensures that the importers adhere to strict conditions of use and the rules of importing countries.

To ensure a fully participatory process, public comments are solicited on all environmental release or commodity clearance activities. The general public receives notice of these intended activities through advertisements placed in newspapers as prescribed.

For general release or commodity clearance applications, the public will be informed through notices placed in three newspapers with a national circulation, whilst field trials must be notified in two newspapers circulated in the immediate release area and one newspaper with national circulation. The public may submit comments to the Office of the Registrar within 30 days from the date on which the public notice was published.

Relevant non-confidential information relating to a particular application may be accessed via the procedure as stipulated under the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000). The application process and the contact details of the Deputy Information Officers may be obtained on the website of DAFF. Information on authorisations granted under this Act is also published on the departmental website. Non-confidential minutes are also available at the same location for publication consumption.

The South African legislation is also aligned to the Cartagena Protocol on Biosafety which is a protocol which emanates from the Convention on Biological Diversity. The objective of the Cartagena Protocol on Biosafety is *"to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (genetically modified organisms in the SA context) resulting from 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 trans boundary movement"*.

The protocol is therefore concerned with the common steps to be undertaken between exporting and importing during the trans boundary movement between two countries.

South Africa has already commercialised three genetically modified crops, namely maize, cotton and soybean. These crops have been modified to be resistant to certain insects and/or tolerant to certain herbicides. Field trials aimed at ultimate general release authorisation continue for new GM maize, cotton and sugar cane. In the health sector, several clinical trials are being carried out with GM vaccines aimed at HIV and tuberculosis. Several GM animal vaccines are already available in South Africa.

The application of the GMO Act allows South Africa to conduct a science-based case-by-case assessment of the potential risks that may arise from the use of a particular GMO. In addition, this enables the country to collect information on the impact and implications of deliberate release of a particular GMO. To date, evidence suggests that the act allows the authorities in South Africa to effectively manage activities involving GMOs.

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