# Biotechnology and National Biosafety Policy in Africa

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# Introduction

Africa, in the light of its own priorities and circumstances, needs to determine how it will engage in biotechnology. Considering the overwhelming need to grow more food, fiber and feed in a productive, profitable and environmentally sustainable way, avenues need to be found to maximize the benefits and minimize any potential risks, associated with biotechnology.

“Africa is already in the biotechnology revolution. We should not be debating whether or not the continent should go for the technology but what specific policies and institutions are required to enable Africa to maximize benefits and minimize risks associated with genetic engineering.

# POLICY RELATED TO GENETIC MODIFICATION

Policy decisions must be made in the following areas when considering the regulation of GMOs and/or their products:

Intellectual property rights (IPR)
Biosafety
Trade
Food safety and consumer choice
Public research and investment
Transboundary movement of living modified organisms (LMOs)

# Policy Options for GM Crops

| | Promotional | Permissive | Precautionary | Preventative |
|---|---|---|---|---|
| **Intellectual property rights** | Full patent protection, plus plant breeders' rights under UPOV 1991 | PBRs under UPOV | PBRs under UPOV 1978, Which preserves farmers' privilege | No IPRs for plants or animals, or IPRs on paper that are not enforced. |
| **Biosafety** | No careful screening; only token screening or approval based on approvals in other countries | Case-by case screening for demonstrated risk, depending on intended use of product | Case by case screening; also for scientific uncertainties owing to novelty of GM process. | No careful case-by-case screening; risk assumed because of GM process |
| **Trade** | GM crops promoted to lower commodity production costs and boosts exports; no restrictions on imports of GM seeds or plant materials | GM crops neither promoted nor prevented imports of GM commodities limited in same way as non-GM in accordance with science-based WTO standards | Imports of GM seeds and materials screened or restrained separately and more tightly than non-GM; labeling requirements imposed on import of GM foods or commodities | GM seed and plant imports blocked; GM-free status maintained in hopes of capturing export market premiums |
| **Food safety and consumer choice** | No regulatory distinction drawn between GM and non-GM foods when testing or labeling for food safety | Distinction made between GM and non-GM foods on some existing food labels but not so as to require segregation of market channels | Comprehensive positive labeling of all GM foods required and enforced with segregated market channels | GM food sales banned or warning labels that stigmatise GM foods as unsafe to consumers required |
| **Public research investment** | Treasury resources spent on both development and local adaptations of GM crop technologies | Treasury resources spent on local adaptations of GM crop technologies, but not on development of new transgenes | No significant treasury resources spent on GM crop research or adaptation; donors allowed to finance local adaptation of GM crops | Neither treasury nor donor funds spent on any adaptation or development of GM crop technology |

# Intellectual property rights

This is a new policy area for many developing countries. The existence of IPR regulations is a requirement for companies wishing to spend large amounts of money on research and development (R&D) of GM products in any country. Patents, copyrights, breeders rights, etc. are the means whereby companies can recoup the investment they make into the development of new products. Without IPR companies are unlikely to make R&D investments.

# Biosafety

This too is a new policy area for many countries. Countries that have signed the Cartagena protocol on biosafety regulations put in place a mechanism whereby the environmental and consumer safety of GMOs is evaluated and decisions can be made on whether or not to allow a GMO to be used in a country

# Trade

These regulations are well established under the WTO. The regulations are designed to encourage trade and reduce unfair protection and exclusion. Whether these regulations are actually benefiting poor nations is the subject of much international debate.

# Food safety and consumer choice

These regulations exist in many countries and are mostly reactive to instances where foods are suspected of being unsafe. Food labeling requirements are also largely in existence and in general require that foods are labeled when they contain known allergens or are changed with respect to their nutrition, use or composition. The international standards for food safety and labeling are determined by Codex Alimentarius. This organization planed to release standards and labeling requirements for GM foods in early 2002.

# Public research and investment

While some applications of GM technology can be transferred to developing countries, the development of GM crops requires that the new traits are placed in the best germplasm for the growing area. This often requires that modifications be bred into local germplasm. National breeding programs are frequently the only source of specific germplasm and so need to get involved in identifying the most appropriate technology is transferred and tested in local conditions. This is especially true for crops that are not major commodities in the developed countries, like coconut, cassava, cowpea, yam, sorghum, etc. By getting involved in local crop improvements can ensure that the outcomes are made available for the benefit of their people

# Trans-boundary movement of living modified organisms

The movement of living organisms is largely covered by existing trade and pest control regulations. However, the Cartagena protocol on biosafety (CPB) has been specifically negotiated to ensure that living GMOs are not sent to countries without their approval and without a chance to review their human safety and environmental impact. Signatories to the CPB will have to bring their national legislation into line with the protocol's requirements. For many this will mean the development of biosafety regulations.

# Why are GMOs regulated?

Scientists have insisted that safety checks be carried out on GMOs from the very outset of the technology. This is to make sure that in transferring the genes no unwanted characteristics are obtained. When the first GMOs were ready for commercial release, companies requested governments to independently review the safety of the GMOs and approve their release. There independent assessments of GMO safety are known as biosafety reviews ad are routinely carried out on all new GMOs before they are released into the environment. Because GMOOs are living organisms, they are able to reproduce and spread once released. Thus , in addition to determining the safety of foods derived from GMOs, the biosafety process also investigates what impact these GMOs may have assessment of GMOs and to be able to approve or refuse their import, development or use. In order to take these decisions, countries need to have biosafety regulations that enable both the assessment of risk and decision making based on safety and non-safety issues.

# How governments regulate GMOs

The biosafety review process is largely a paper exercise, where governments ask local experts to assess the safety data accumulated by the applicant and determine whether enough information is present to assess the safety and impact of the GMO. Where important information is missing, the applicant is asked to collect the data before the review process proceeds. Where risk is identified, the chance of the hazard happening and the ability to manage the risk are assessed. As with all technologies, the risks are weighed against the benefits and a decision is taken on the overall safety of the GMO in its release environment. This scientific biosafeyt assessment is passed back to government where the final decision is taken and approval is given or withheld for release and use of the GMO.

# Steps towards establishing a biosafety framework

- A national policy on the use of modern biotechnology should be established to guide decisions taken about the use of GMOs;
- Development of a national biosafety framework should follow extensive consultation to ensure public awareness and input;
- Consultations within existing departments of environment, agriculture and health will ensure that the infrastructure is cross-sectoral efficient, cost-effective and implementable;
- An interim framework can be implemented using biosafety guidelines and an exiting permit system for approvals (e.g a plant pest Act) while the legislation for the final framework is being modified or developed;
- Implementing the biosafety administration will be facilitated by capacity-building in both the handling of GMO applications and biosafety review training;
- Reasonable fees charged to applicants can cover an efficient review

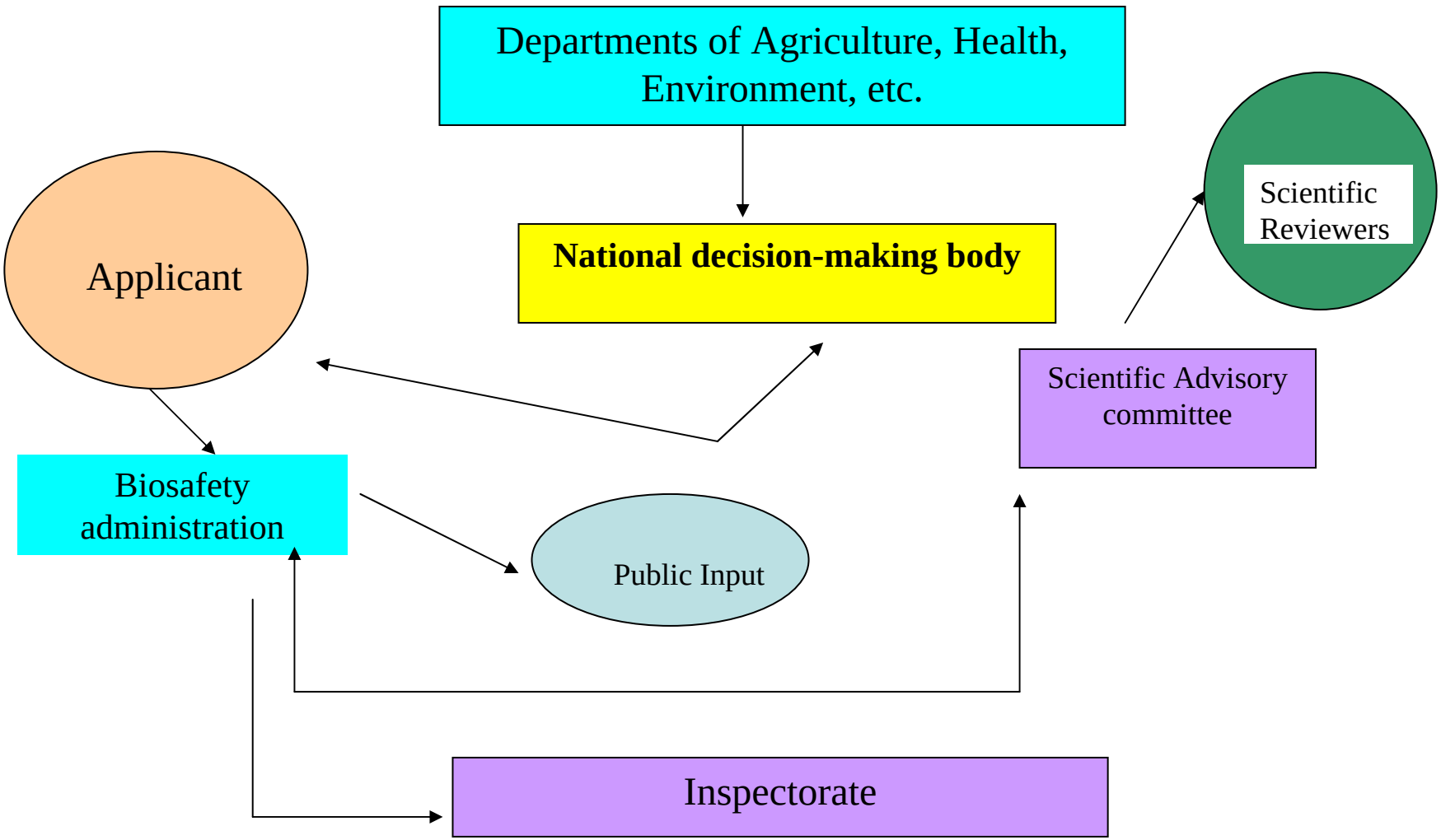
# Components of an effective biosafety framework

- When faced with applications for use of GMOs, governments need to implement an effective biosafety framework to ensure a science-based review of the safety issues and a review of other factors important in making a national decision. With hindsight, the following componts are considered desirable in a national biosafety framework (Figure 1):
- A single entry point for applications, whether for GM plants, animals or micro-organisms;
- An efficient biosafety administration for processing of applications (2 people once applications reach about 40 a year);
- A mechanism for ensuring for ensuring confidential handling of commercial information
- Access to a trained pool of scientific expertise to

# Components of an effective biosafety framework cont…

- A call for public input into the application;
- A single, transparent national decision-making body that can take into account the scientific risk assessment recommendations, the benefits, the public input and any national needs and priorities when making decisions;
- Development of a decision document that clarifies the safety issues of each GMOs, the conditions attached to specific releases and the reasons why decisions were made;
- Access to an inspectorate that can monitor whether release conditions are adhered to.

# Components of an interactive national biosafety framework



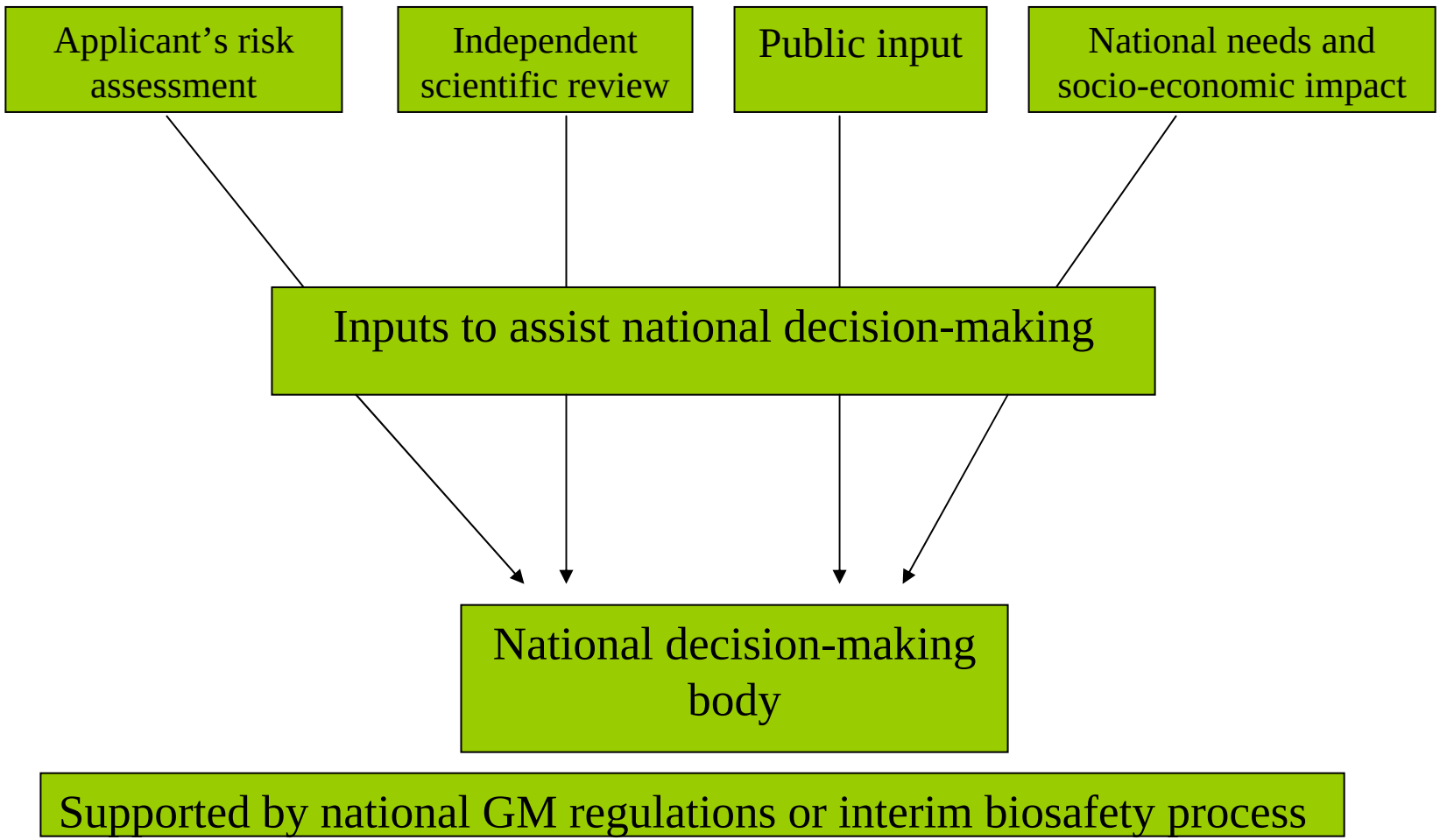
# Steps in reviewing an application for GMOs

1. Acknowledge receipt of the application
2. assess what the applicant requires approval for and the nature of the GMO;
3. select a group of scientists with the current expertise to review the safety of the proposal (about 5 scientists are needed for each proposal, depending on what the GMO is and what is will do)
4. Publicise the application and call for public input;
5. Schedule a meeting for the scientific group to review the application and make recommendations to the national decision making bondy regarding the activity, missing

# Steps in reviewing an application for GMOs Cont….

6. Where information is missing or clarification is needed, schedule a meeting with the applicant and the scientific review panel;
7. Call a decision-making meeting when the scientific and public input is available (Figure 2);
8. Once a decision had been made, prepare a decision document on the findings of the review and make this publicly available'
9. Notify the applicant and issue a permit where necessary;
10. Schedule an inspection of the release site during

# Information used in national decision making



# Some considerations for reviewers in national biosafety assessment process

**Human and animal safety**

Toxicity
Pathogenicity
Allergnicity
Digestibilty
Nutrition
Unexpected products
Gene stability
Other

**Environmental impact**

Living organisms
•Biodiversity
•Outcrossing
Weediness
Air, soil, water
Gene Stability
Other

**Non-safety issues**

Sustainable developmer
Farmers' privilege
Labour
Trade
Socio-economics
Ethics

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# Labeling and detection

Most food legislation already covers labeling of changes to the composition, intended use f nutrition of a food product. Labeling the process by which foods are developed, e.g. genetic modification, is fraught with problems. Firstly, it implies that the foods have some safety concerns which the public needs to be aware of. This is untrue as all GM foods must pass a safety approval process before being used in food products. Secondly, once food ingredients are processed and diluted in food products it is very difficult, if not impossible, to detect which foods are derived from GM. This makes regulating a process label impossible, Thirdly, the labeling regulations must be equally applicable in al food sectors, adding considerable burden to the informal food sector, which plays a critical role in African food security.

# Public awareness

Without a doubt, consumers need to be able to make informed choices about food and to know of any risks a food may have. It is important to address these needs in a way that will be feasible to implement, provide good information and not compromise the cost of food. Public information meetings. Posters in shops and clinics and informed extension workers in the agricultural and health sectors all provide ways of addressing public awareness.

# collaboration and linkages in Biosafety development in Eastern Africa

| | |
|---|---|
| • KENYA (ABSF + (Govt Agencies + UNEP GEF) | Draft Biotechnology and Biosafety Policy<br>Draft biotechnology and biosafety bill<br>Draft Biotechnology strategy<br>Enhancing of monitoring and inspection capacity |
| • UGANDA (ABSF + Govt Agencies + UNEP GEF) | Draft biotechnology policy<br>Draft biosafety bill |
| • TANZANIA (ABSF + Govrt agencies + UNEP GEF) | Draft biotechnology policy<br>Draft biosafety policy |
| • MALAWI (BIOEROC + Govt Agencies) | Biosafety Law |
| • ZAMBIA (BOSZ + Govt Agencies + UNEP GEF) | Biotechnology Regulations and Guidelines |
| • ETHIOPIA (HBF) + EARO | Biotechnology and Biosafety Policy |

# Biosafety Frameworks: Liability and redress challenges:

Historical Perspectives:-

Several conventions established to deal with liability and compensation for damage to persons, property and environment arising from potentially hazardous activities which include damage due to

- Oil pollution
- Nuclear incidents
- Carriage of hazardous and noxious substances at sea
- Most of conventions or treaties convened around
- Intentions is to control transboundary movement of hazardous waste
- States opted to channel liability to private parties rather than establish rules for state liability for transboundary damage (e.g. Insurance Companies)

# Challenges of linking GMO's to liability and redress issues

- Impact of GMO to environment uncertain
- Knowledge gap on GMO's interaction with environment uncertain
- Definition of damage with regard to GMO on environment unclear
- Lack of knowledge of activities that can be covered by instrument of liability and redress
- Limitations of issues such as standards, identification of persons liable for damage; setting time limits for bringing claims etc.
- During the period of 1990 – 1995 only a few countries had adopted GMO corps; policies issues not clearly developed. No emerging data from biotechnology and biodiversity research programs.

# Biosafety Laws Vs. Liability and Redress

- Linking biosafety laws to liability and redress can only be considered after taking into account scientific data emerging from biotechnology and biodiversity research programs

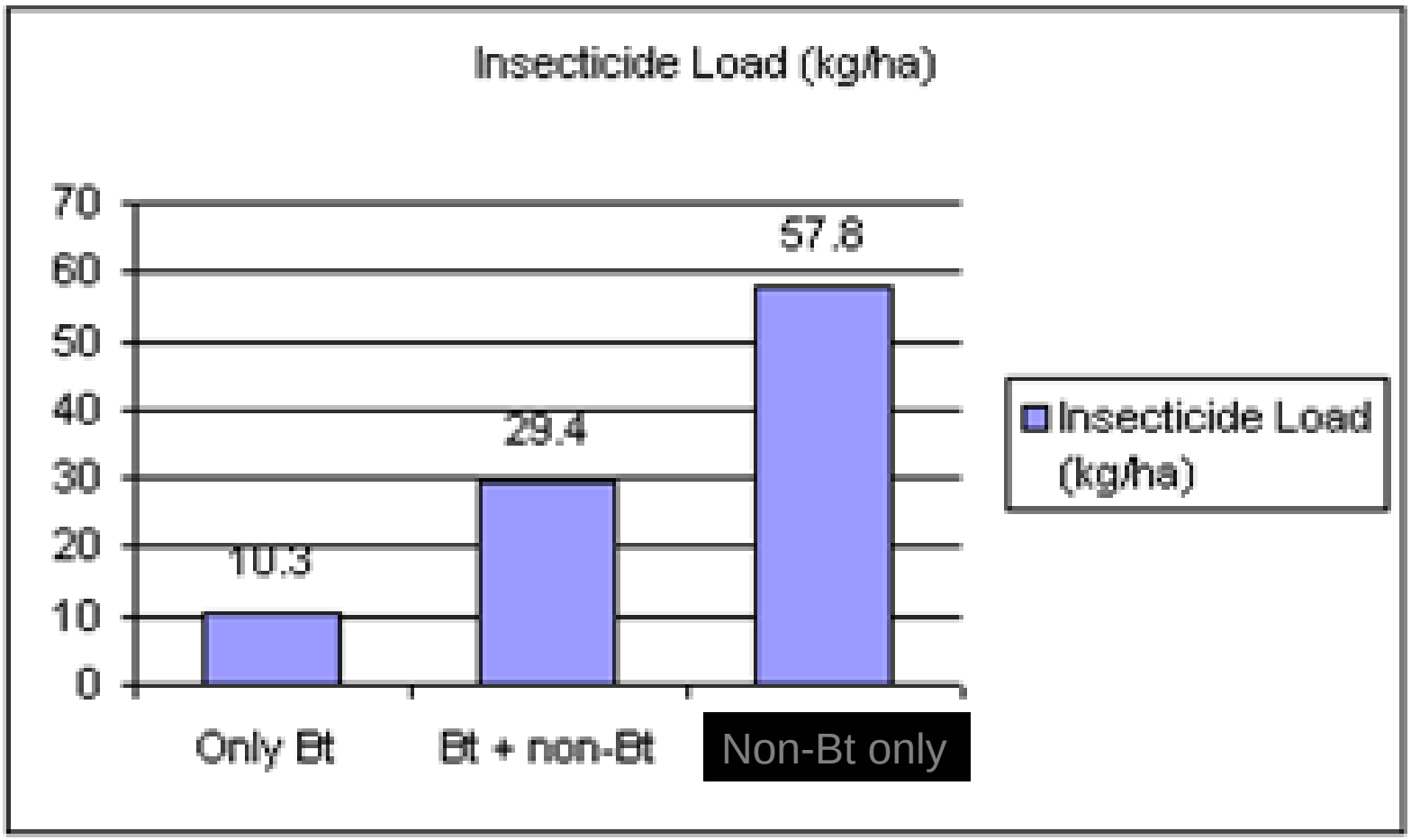
- Current emerging data from biotechnology and biodiversity intervention programs demonstrate biotech application to environment in may ways

# GM Products and Environment

- No evidence that GM crops harm environment or have potential to harm environment than current agricultural farming methods (e.g. Bt. Toxin Vs. Hycorrehiza interaction with sorghum)
- Evidence show that certain GM crops have environmental benefits because they reduce pesticide use (Markhatini flats, Bt cotton farmers data)
- GM crops also require less tilling of land (less danger of erosion)
- GM crops can also play an important role in making agriculture more sustainable and more productive
- Farmers want GM crops because they make crop production cheaper and enhance their own safety because crops require less positive (reduction in pesticide positioning)

# Socio-economic Benefit to Farmer

## Reduction of insecticide use and poisoning



# GM Crops and Food Safety

- To the best of current knowledge GM Foods and crops are as safe as conventional ones. Approval process requires many test of many years
- Nutritionists and other scientists do not know of any unresolved safety issues
- GM foods and corps are being improved or higher levels of vitamins, minerals, a biologically active phytochemials and other nutrients to provide better nutrition to consumers (e.g. vitamin A rice and Iron dense beans)

# GM Crops and Food Safety

- Many challenges currently in our goods can be eliminated though biotechnological approaches.
- Opponents of GM crops (GreenPeace, Sierra Club and Third World Network) only act on ideological, philosophical, or socio-ethical grounds have no factual evidence for their claims of negative health consequence or environmental impact
- Developing Countries: Plant breeders and farmers want access to Modern biotechnology to improve their crops. Biotechnology is simply another tool to increase productivity that could enhance eradication of hunger and poverty.

# Conclusions

- Uncertainty & knowledge gap cannot be the determining factor for liability and redress in biosafety for GMOs

- The determining factors for liability and redress for biosafety in GMOs must have a scientific basis

# For more information

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***Thank You***