POLICY
PAPER
52

Biosafety Assurance for GM food Crops in India

NATIONAL ACADEMY OF AGRICULTURAL SCIENCES, NEW DELHI
DECEMBER 2011

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December 2011

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CITATION : NAAS 2011. "Biosafety Assurance for GM food Crops in India". Policy Paper No. 52, National Academy of Agricultural Sciences, New Delhi. pp 16.

EXECUTIVE COUNCIL 2011

Published by Mr H.C. Pathak, Executive Secretary on behalf of
NATIONAL ACADEMY OF AGRICULTURAL SCIENCES
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Preface

Genetically modified (GM) crops are the product of introduction of one or more well characterized genes in a crop plant using recombinant DNA technology. The genes introduced may belong to either a distant species or a closely related species or the same species. Based on their proven merit, the global acreage under GM crops swelled from 1.6 million hectare in 1996 to 148 million hectare in 2010. In India, Bt cotton today occupies nearly 9.5 million hectare, 86% of the country's total cotton area.

Yet, there is a strong opposition to the commercialization of GM crops in India and several other countries on the perceived grounds of their health and environmental unsafety. Whereas, from the deliberations of innumerable national and international symposia it has emerged that, while it is almost impossible to prove that the GM crops are completely safe, all experimental evidences and commercialization experiences during the last 15 years have revealed no risks.

In order to critically examine the current biosafety issues and the prospects of benefiting from the GM technology, the National Academy of Agricultural Sciences organized a Brainstorming Session on Biosafety Assurance for GM Food Crops in India on June 22, 2011. The main stakeholders – noted scientists and representative of public and private sectors and NGOs had participated. Based on detailed analyses of the available evidences, the Session concluded that GM technology is a powerful tool and the transgenic varieties of various crops so far commercialized are safe.

Since the GM approach is a dynamic process, it should be continuously enriched scientifically and evolved in a transparent and socially inclusive manner. This invaluable document addresses all issues of concern and contains science-based recommendations and concrete actions for safe, inclusive and judicious harnessing of the GM technologies for accelerated and sustained crop production.

On behalf of the Academy, I express my gratitude to Dr. Manju Sharma and Dr. P. Anand Kumar, respectively the convener and co-convener of the Brainstorming Session. The invaluable inputs of all the experts who participated and the efforts of Prof. P.K. Gupta and Prof. N.K. Singh who collated the views and information are gratefully acknowledged. Thanks are also due to Dr. C. Devakumar for the additional references and due revision of the document.

(R B Singh)
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Bio-safety Assurance for GM Food Crops in India

INTRODUCTION

GM (genetically modified) crops are the products of introduction of one or more well characterized genes in a crop plant using recombinant DNA technology, such that the gene introduced may belong to either a distant species (including prokaryotes), or a closely related species or even the same species (as in case of the so-called cisgenic plants); in some cases, the introduced gene may even be a synthetic gene or may result from targeted mutagenesis. In contrast, the conventionally-bred cultivars result from artificial selection, random mutagenesis, or due to intra- or interspecific (rarely intergeneric) hybridization leading to transfer of a number of uncharacterized genes from the same or a related alien species. Therefore, the major difference between GM crops and conventionally bred cultivars is in the technology for transfer, and in the nature of genes transferred [32].

The GM crops are perceived by many as a possible solution for the widely discussed problem of food and nutritional security, keeping in view the increasing world population associated with increasing poverty, hunger and malnutrition [4, 21, 27, 32]. However, there are organizations and individuals, who doubt the utility of GM crops, and consider them unsafe, unless these are proven to be safe on all fronts, according to the 'precautionary principle'. Despite this debate among the proponents and opponents of GM crops, the global land area occupied by GM crops has been continuously increasing during the last 15 years, and has increased from the initial mere 1.6 million ha in 1996 to 148 million ha in 2010 [19]. It is also known that in India Bt cotton has been a resounding success, now occupying ~9.4 million ha (85.5%) out of a total cotton area of ~11 milion ha. Although the remarkable success of Bt-cotton is attributed to its being a non-food fibre crop, in a recently published report it is emphasized that about 67% of the cotton seed is used as food or feed [6], thus suggesting that Bt protein is already in the food chain in India. It is also well known that besides Bt-cotton (primarily treated as a fibre crop), a number of GM food crops including corn, soybean, canola, potato and sugar beet are being grown world-wide without any report of their harmful effects either on the environment or on the health of non-target organisms including human beings.

At present all GM crop events undergo a rigorous biosafety and risk assessment before commercialization [8, 11, 16]. The events showing even the slightest of biosafety risks

are dropped at research and development stage itself. For instance, work on transgenic soybean expressing a sulphur-rich storage protein from Brazil-nut and transgenic chickpea expressing an alpha-amylase inhibitor of pea was discontinued [2, 26, 28].

Despite the above, there is a strong opposition to the commercialization of GM crops in several countries in Europe and Asia. The stated reason for this opposition is lack of sufficient evidence for biosafety of these GM crops, which are still perceived to be unsafe, both for the environment and human health. In accepting GM crops to be safe, unfortunately, we often like to adopt the 'precautionary principle' rather than the principle of "substantial equivalence", which shows that a GM food product is no different than its corresponding non-GM variety, except for the trait for which it has been modified [33]. Genetic modification in the case of GM crops is very precise and the protein synthesized by the transgene is well characterized and evaluated for its food safety and allergenicity. Conventionally-bred crop varieties also have a high degree of uncertainty about the types of changes introduced. For instance, a well known example of harmful effects of a cultivated crop variety is actually a traditionally bred insect-resistant variety of celery, which carried higher amounts of psoralens to deter insect predators and was found to produce skin rashes in occupational workers, who harvested this crop; no such documented example of a commercialized GM crop is available so far [32].

The question of biosafety of GM crops has been regularly discussed both at the national and international levels. A number of national seminars are organized on this subject every year. At the international level, starting from the year 1990, the *'International Symposium on the Biosafety of Genetically Modified Organisms'* (ISBGMO) is organized in alternate years, and the 12th ISBGMO is due in 2012.

During the deliberations of a large number of symposia, it has also been recognized that it is almost impossible to prove that GM crops are completely safe. However, we need to accept that all experimental evidence and the safe commercialization of GM crops during the last 15 years suggest that no risks are encountered in growing and consuming GM crops for food and other purposes. The objective of the brainstorming session organized on June 22 by the National Academy of Agricultural Sciences (NAAS) was to examine the current status of biosafety of GM crops both at the national and international levels and to find out how safe or unsafe the GM crops are in general, or on case-by-case basis and as to whether our present bio-safety evaluation system is adequate to ensure biosafety approval of GM crops. Also, it was proposed to prepare an action plan to change the perception of public and the policy makers, if there is sufficient evidence that GM crops are safe to be used for food and/or feed.

In this document, we first list the biosafety issues that needed to be addressed or are being addressed and record the experimental evidence for or against the biosafety of GM crops. We then list recommendations made at the brainstorming session to deal with the current controversies regarding the biosafety of GM crops. In the end, we propose an action plan to implement the recommendations made at the brainstorming session of June 22, 2011.

BIOSAFETY ISSUES

Following are some of the biosafety issues, which have been widely discussed at the national and international levels and continue to receive attention of scientists and the society at large:

- Pollen flow and horizontal gene transfer of transgene to wild relatives and bacteria
- Allergenicity and toxicity
- Invasiveness
- Development of resistance in insects
- Development of resistance in weeds against herbicides giving rise to superweeds
- Adverse effects on non-target organisms
- Loss of biodiversity
- Selectable and scorable markers involving antibiotic resistance
- Disruption of ecosystem
- Social, ethical and economic issues

We need to realize that the regulatory system available in different countries and particularly the one in India deals with all the above biosafety issues, before a GM crop event is recommended for commercial cultivation. The above issues have been widely discussed and experiments have been conducted to find out the possible risks involved. These issues have been discussed in some detail in a recent document entitled *"Agricultural Biotechnology-A Lot More than Just GM Crops"* brought out by International Service for the Acquisition of Agri-Biotech Applications (ISAAA) [17]. For majority of the above biosafety issues, no major risks have been found, although it

is accepted that no technology is entirely free of risks, so one has to examine the relative benefits and risks involved. Further, all GM events in a specific crop are not the same; therefore, each event in a specific crop needs to be evaluated on a case-by-case basis and no generalized statement can be made.

Experiments providing evidence for stated risks due to GM crops have also been published in the literature. Some important studies suggesting possible risks include the following: (i) adverse effect of Bt-corn on monarch butterfly [23]; (ii) contamination of land races due to Bt-corn [29]; (iii) adverse effect of lectin in GM potato on rats [13]; (iv) Aventis's Star-Link corn with Bt gene Cry9C, which had to be withdrawn from the market, although there was no evidence of any harmful effect [20]; (v) Adverse effect of herbicide resistant transgenic soybeans on the fertility of rats, as reported by Irina Ermakova from Moscow [12, 24]. In all these cases, subsequent studies showed that there were flaws in the experiments conducted and that the risks indicated were not justified, confirming once again that there were no real risks involved.

RECOMMENDATIONS

1. The GM technology is a powerful tool for developing future crop varieties with in-built genetic resistance to various biotic and abiotic stresses for reducing crop losses and enhanced input use efficiency, yield potential and quality traits. Their use will be crucial for the food and nutritional security of the country and therefore research on them must be continued with the aim of developing safer, more productive and nutritious food crops. However, this should be done in a more transparent and socially inclusive manner for wider public acceptance. Also, concerns of the opponents of GM technology should be addressed to allay the public concerns on food, environmental and economic security [7].

2. There is also scope for developing a range of GM food crops by transferring genes from one food crop to another or back into the same crop after suitable modification for enhanced or reduced expression levels. This concept is being promoted in Europe as 'Cisgenic' technology, which is a variant of the transgenic GM technology but has negligible food safety risk, and therefore may face less opposition/criticism [18].

3. The issue of bio-safety should not be a matter of individual opinion and undue fear or overconfidence. Therefore, the food and environmental safety of the specific GM crop events must be actually evaluated by the experts before their commercial release to the farmers. A very good system is already in place in

India for this purpose. It was shown that the present bio-safety evaluation system in India follows all the international bio-safety norms and standards and is one of the most stringent [1]. However, national capacity needs to be enhanced to handle a large number of samples expected with increasing number of new transgenic events.

4. All GM crop events will not require the same level of biosafety evaluation. The level of biosafety concern increases when genes are transferred from distant species to which humans and farm animals do not have prior exposure as food or feed. Therefore, the bio-safety is to be evaluated on a case-by-case basis and it will not be scientific to make generalized statements about the biosafety of all GM plants [22].

5. Regarding the concern for loss of crop biodiversity due to introduction of GM food crops, the danger is no more than many traditional varieties of wheat and rice going out of cultivation due to introduction of high yielding semi-dwarf varieties during nineteen hundred sixties and seventies, the so called era of Green Revolution. But this is a real concern and a way has to be found to compensate the farmers, who choose to participate in the process of *in situ* conservation of biodiversity of crop varieties. As far as possible, such diversity must be collected and deposited in the national gene bank at the earliest for the purpose of gene discovery and allele mining activities [15].

6. Another biosafety concern that has been widely discussed is the transfer of introduced gene to wild species through pollen. In this connection, a number of studies have been conducted and it was found that pollen flow does take place. However, this would not have much consequence unless a selection pressure is applied to the wild species leading to increase in the gene frequency [5, 25]. The consequences of gene transfer via pollen should be evaluated on a case-to-case basis and due precaution must be ensured.

7. The development of resistance in the insects against insecticides and that in the weeds against herbicides has also been widely discussed. It has been recognized that the development of such resistance is a normal phenomenon even during conventional plant breeding, and should be treated in the same manner [3].

8. A major point of concern among the farmers is also the monopolistic control of seed business by MNCs (multi-national companies), leading to sometimes exorbitantly higher cost of seeds [31, 35]. The solution to this problem is to encourage competition among the GM seed companies and even more

importantly to have mission-mode programs for the development of GM seeds in the public sector, which has yet to deliver a popular GM crop product. This may be partly due to insufficient support and lack of mission-mode approach for the development of GM technology in the public sector.

9. Access to seed of approved GM crops is another concern. Therefore, the government should make a policy for procuring the seeds of useful GM food crops and make them available to the needy farmers at an affordable cost in the same way as it does for fertilizer and diesel subsidy. In fact, future GM food crops with enhanced nutrient use efficiency will require less fertilizer, thus reducing the input cost of cultivation for the farmers. Similarly, GM technology is also seen as a solution to the energy crisis by producing more efficient GM crops for biofuel [10].

10. Currently our preparedness for risk assessment research is inadequate to provide scientific support to the regulatory process. Therefore, a **"National Institute of Bio-safety and Bio-Security"** should be created with state of the art infrastructure, human resource and research programs for conducting frontier research, capacity building in this field and providing policy support and technical advice to the government on this issue. Presently, although we have a good bio-safety evaluation system using standard protocols, there is very little basic research being conducted on the various aspects of the GM food crops in India. The risk assessment should also include the so called issue contamination needing of separation of GM food from non-GM foods and horizontal gene transfer etc. as advocated in the Occasional Paper of the Rajya Sabha Secretariat [30].

11. Education is a key to allay undue fear of GM food crops in the minds of public due to successful misinformation campaign by certain organizations. The public needs to be educated properly about the facts regarding both food safety and economic benefits of the GM food technology [14]. However, this will be more effective if the government promoted the GM crops developed by the public sector or that purchased from the private sector in the public interest, and is not perceived as a proxy to the multinational seed companies.

12. A major deficiency in India is also the lack of PPP (public-private partnership) for joint development and ownership of the GM food crop products. The products are coming almost entirely from the MNCs due to small size of the Indian seed companies *vis-s-vis* their R&D expenditure. This sometimes leads to lower public confidence particularly in the large section of poor farmers with limited resources for procuring agricultural inputs.

ACTION PLAN FOR THE DEVELOPMENT AND UTILIZATION OF GM FOOD CROPS

In view of the long gestation period for the development of useful GM crop events, and the high cost of research and development, there seems to be a need to have a sound biosafety evaluation and regulatory infrastructure. Following plan of action is suggested for this purpose:

1. Bio-safety Evaluation and Regulatory Mechanism

- The government should enact the proposed Biosafety Regulatory Authority of India (BRAI) legislation at the earliest for a single window regulation of GM crops. It should have a transparent time-bound decision making, similar to a citizen's charter, for rejection or acceptance of the GM crop events taking care of all the public concerns [9].
- ICAR should take a proactive role in the conduct and monitoring of biosafety-cum-evaluation trials as stipulated in the revised RCGM guidelines, so that no time is lost in bringing the elite GM crop material to the farmers.
- We need to strengthen the public sector laboratories conducting bio-safety evaluation and also promote establishment of accredited private sector bio-safety labs for crops and food products because we expect deluge of GM crop events in the coming future and our physical and administrative infrastructure should be commensurate with the demand.
- We need to strictly enforce the regulation on the ground because a good "Regulatory Act", if poorly implemented will bring disrepute to this wonderful technology. For example, experimental GM crop events should not land at farmer's hand for widespread cultivation before they are approved by the regulatory authority.
- GM crop events need to be classified, based on the perceived bio-safety risks and the level of regulation should be calibrated accordingly. For example, a gene coming from a food crop or another edible life form being transferred to another food crop need not go for an elaborate toxicity and allergenicity testing. Similarly, a protein coming from a distant source like soil bacterium but already tested extensively for toxicity and allergenicity, need not be tested again and again for this because it will unnecessarily delay the deployment of a benign gene for the benefit of society.

- We need to develop a mechanism for fast track clearance of GM crops with no perceived bio-safety risks, on the basis of the above categorization and biosafety evaluation.
- It may not be necessary to subject a GM crop to fresh bio-safety testing and evaluation process, or undergo bridge biosafety study, if it has resulted either from pyramiding of more than one approved GM events into a single variety or due to transfer of an approved event from one genetic background to another elite genetic background through molecular marker technology.
- We need to initiate research on integrated pest resistance management through gene technologies and crop management.
- We need to start studies on the potential of herbicide tolerant crop adoption on tillage practices.
- It is necessary to implement on priority and preferably in a network mode research studies on reproductive biology and potential impact of gene flow in native crops.
- Program should be initiated to inform and educate the policy makers, farmers and public about merits of GM crops for food security and potential benefits and risks of GM crops on biodiversity.
- Steps should be taken to harmonize the policies at the level of State and Central Governments so as to minimize the hindrance in conveying the benefits of proven pro-poor technologies to the farmers

2. Pre- and Post-release Monitoring and Evaluation of GM Crops

- Set up mechanisms for pre- and post release monitoring of cultivation of GM crops as a part of the BRAI to see that recommended practices are followed. This should be accompanied with the feed-back with respect to the accountability of the GM crop seeds.
- Have provision for adequate punishment for violation of specific guidelines built into the BRAI Act.
- We also need to initiate research on analysis of the impact of GM cotton adoption in India on (i) cotton genetic diversity, (ii) economic gain to the cotton farmers and (iii) development of insect resistance to the Bt gene.

3. Accessibility of Approved GM Seeds to the Farmers

- Strengthen the publicly owned national and State seed corporations for making the approved GM seeds available to the farmers at an affordable price.
- Fix MRP for the approved GM seeds so that no one is allowed to charge exorbitant price. The Government may consider to include all seeds including GM seeds under the category of the essential commodities in order to regulate the price of seeds.
- If required the seed prices may be subsidized to ensure affordability to the farmers in a way similar to the fertilizer and diesel subsidies. This will be required only if the cost of seed development and production is actually very high.
- Enact the long awaited 'Seed Bill' legislation for effective regulation of seed business in India while retaining the right of farmers to save seed [35].

4. Research and Development including PPP

- Although considerable work has been done in the public sector with respect to the development of GM crop events, these have not reached to the farmers. Hence, DBT and ICAR should consider establishment of separate Task Forces focusing on GM crops in a coordinated approach.
- We also need to constitute a Task Force of experts for in-depth analysis and prioritization of the crops, traits and genes for developing GM crops.
- Start mission mode projects for the development of elite GM crop events in the selected crops for selected traits in the public sector institutions with adequate financial support and monitoring of progress. There is need to strengthen selected institutions with proper tissue culture and transgenic greenhouse facilities with assured power supply.
- Sufficient grants should be provided for out-sourcing of bio-safety evaluation and regulatory approval of the elite events developed by the public sector institutions to competent professional services.
- Encourage private companies to take up joint R&D projects with the public sector with the aim of developing GM products with joint IPR protection. The products can then be commercialized by the seed companies (both private and public) on the basis of reasonable sharing of benefits.

- Added emphasis needs to be given on non-controversial and attractive GM crop events. For instance, the new (stronger) Golden Rice events need to be transferred to elite commercial cultivars with added features of better iron and zinc uptake, critical for the biosynthesis of β-carotene to vitamin-A. These could be used very effectively to garner public support for the GM food crops technology.
- Initiate GM crop projects for traits that will have positive impact on crop diversity. For instance, improvement in yield, adaptation, nutrition and consumer acceptability of "orphan crops" would provide attractive options to the farmers for crop diversification.

5. Education and Public Awareness

- Devise curricula for schools and universities incorporating modern concepts of genetic modification of crops and societal needs.
- Encourage interface of students, scientists and teachers; develop suitable models and modernize laboratory infrastructure for demonstration and skill development in the area of GM crops.
- Sensitise extension personnel on the usefulness of GM crop technology. Krishi Vigyan Kendras (KVKs) should be equipped to undertake this exercise.
- Train and educate the farmers at village/district level by inviting them to special training programs and demonstrate GM technology on the fields by frontline demonstrations (FLD).
- Connect to e-chaupals, radio and TV shows for education on benefits of the GM crop technology.
- Strengthen genome/DNA clubs under the Agriculture Technology Management Agency (ATMA)
- Prepare spokespersons and media outlets to interface with public and policy makers and also arrange "Road Shows" and "Workshops"
- Prepare fliers of frequently asked questions (FAQs) and their answers in Indian languages and distribute them widely. Knowledge-based articles/reviews also need to be published from time-to-time, particularly in popular science journals and newspapers. (Bring out DVDs on GM Crops both in English and other Indian languages)

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