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"India has a unique opportunity to exert global leadership by facilitating the timely approval and deployment of biotech fiber, feed, food and fuel crops."

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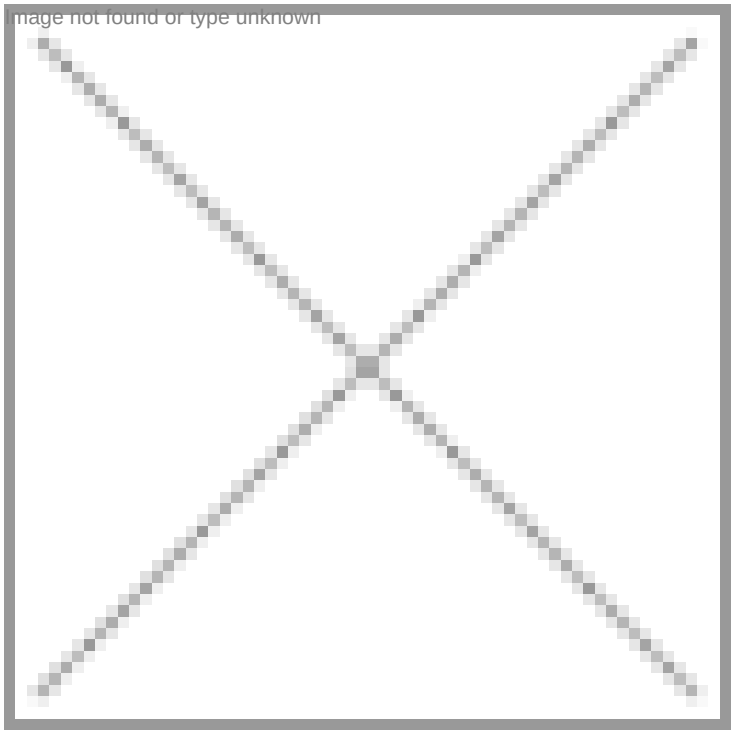

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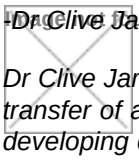


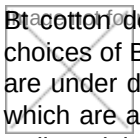
-Dr Clive James

Dr Clive James, an internationally renowned agricultural scientist founded ISAAA in 1990, which facilitates the acquisition and transfer of agricultural biotechnology applications from the industrial countries, for the benefit of resource poor farmers in the developing countries. On the occasion of the 5th anniversary of Bt cotton in India, he shares his thoughts on the way forward for India.

India has the maximum acreage of Bt cotton in Asia (3.8 million hectares compared to China's 3.5 million) as per the latest ISAAA findings for 2006. What is the way forward for India now?

Biotech crops offer India substantial benefits in the near term and provide the opportunity for the country to strengthen its world leadership in the adoption of biotech crops. This will ensure its competitive advantage globally in terms of crop production and coincidentally biotech crops can contribute to economic growth, a better environment and more importantly to the alleviation of poverty and hunger. The way forward for India is first to significantly increase its area of Bt cotton in the next few years so that the gains can be shared with even more Indian cotton farmers, cotton textile workers and consumers. Cotton impacts the lives of 60 million people in India and is a major export for the country. Future gains from Bt cotton can be

substantially greater than those achieved in 2006, as more Indian farmers adopt the superior Bt cotton technology. The most recent public sector study on Bt cotton by Dr Gandhi et al confirms an average yield gain of 31 percent, a significant reduction of 39 percent in the number of pesticide sprays and an 88 percent increase in profit, equivalent to $250 per hectare for the 2004 growing season. Prior to the introduction of Bt cotton in India in 2002, Indian cotton yields were one of the lowest in the world. However, after the introduction of Bt in 2002 cotton yields increased from 308 kg per hectare in 2001-2002 to 450 kg per hectare in 2005-2006, a 46 percent increase in yield, with most of the increase attributed to Bt cotton. In turn, exports of raw cotton from India soared from 0.9 million bales in 2005 to 4.7 million bales in 2006, the highest ever. The number of companies in India selling Bt cotton increased from one in 2002 to 15 in 2006, giving farmers a broad choice of Bt cotton products to choose from.



Bt cotton developed by the public sector in India is at an advanced stage of development and will give the farmer more choices of Bt cotton hybrids to select-those developed by either the public sector or the private sector. About 15 biotech crops are under development by both the public and private sector including mustard hybrids and nutritionally enhanced potatoes, which are at an advanced stage of development. Leading traits in new biotech crops include pest and disease resistance as well as delayed ripening in fruit and vegetables. Further, the development of golden rice as a contribution to remedy Vitamin A deficiency and longer-term programs with focus on salinity and drought resistance in rice, the most important food crop in India and more importantly the principal food crop of the poor, holds much promise. An advanced collaborative program between the private and public sector program features the development of both hybrid and open-pollinated Bt Brinjal (eggplant) resistant to fruit and shoot borer, which sometimes requires insecticides every other day. Brinjal is a very important vegetable crop that is grown on 5,00,000 hectares in India and supplies 25 percent of the calorie needs of resource-poor farmers, who cultivate on average 0.26 hectares of eggplant, which is also a major cash crop. Bt brinjal is expected to double yields, reduce pesticides by half, and deliver an increased income to small farmers equivalent to over $400 million per year at the national level and this will be a substantial contribution to the alleviation of their poverty.

In summary, India has a unique opportunity at this time to exert leadership at the global level by facilitating the timely approval and deployment of a chronology of biotech fiber, feed, food and fuel crops that can coincidentally ensure that crop production in India is competitive in an increasingly globalized world; contribute to economic growth; a safer environment and contribute to food, feed, fiber and fuel; and most important contribute to the alleviation of poverty and hunger for its people. In spite of the significant success of Bt cotton, there are some who believe that this technology poses a risk to India. Based on the consistent body of evidence accumulated in India and 21 other countries by about 45 million farmers over an 11-year period, the evidence is clear that this technology offers substantial benefits to India. On the contrary, the greatest risk associated with this technology for India is not to use it.

According to the ISAAA 2006 report, the global transgenic crop cultivation breached the 100 million hectare mark in 2006. However, there is reluctance in the acceptance of GM technology by the masses globally. Why is it so?

One of our characteristics as people is that we do not handle change very well, and we are usually more comfortable with the status quo, which may be the least safe situation, but we are creatures of habit and resist change. Witness the resistance to pasteurized milk and irradiation of food when first introduced-in both cases it took time for society to change its view and embrace the new technologies, which offered significant advantages over the conventional technology being applied at that time. Biotech crops are no different and hence the sharing of knowledge to inform society about the new science is a top priority. A better-informed society will be able to engage in a transparent knowledge-based decision-making process, which will allow a more objective evaluation of the attributes of biotech crops and their potential contribution to society.

Surveys confirm that the more knowledgeable society is about biotech crops the more acceptable biotech crops are to society. Recent surveys in the US, where 300 million people have consumed biotech food for more than 10 years without a single incident related to food safety, report that biotech crops were not even on the list of concerns about food, whereas concerns such as pesticide residues and allergies were significant issues to many people. In fact, survey results indicate that people would preferentially select biotech products if they contained omega 3 oils because of the substantial nutritional and health benefits they offer. Omega 3 biotech products are expected to be in the market in about five years, subject to timely regulatory approval.

It is very important to recognize that 3.6 billion people living in 22 countries that planted officially approved biotech crops-which is more than half the world's population of 6.5 billion-consumed GM crop produce as food, feed and fiber in 2006. These crops generated significant benefits in terms of improved production, significant economic environmental as well as socioeconomic benefits; in developing countries biotech crops have contributed to the alleviation of poverty and hunger. The planting of 102 million hectares by over 10 million farmers in 2006 is clear evidence of the high level of acceptance of biotech crops and their products globally. Furthermore, another 29 countries have approved biotech crops for import for food/feed bringing the total number of countries that have already approved biotech crops to 51 countries representing 70 percent of

the global population. This represents a high level of acceptance which has increased every single year for the last 11 years and is expected to continue to increase in the future, as more countries approve and adopt biotech crops.

It is clear that the technology is here to stay. In fact, it has increased at an unprecedented rate by double digit growth every single year for the last 11 years, making it the fastest adopted crop technology in recent history. It is a vote of confidence of farmers who have made approximately 45 million independent decisions to increase their plantings of biotech crop every single year since commercialization began in 1996, a remarkable acceptance record, by any standard.

Many GM products are mired in regulatory issues. How can the regulatory process be made simpler without compromising on the safety aspect? How feasible is it to evolve global regulatory guidelines along with global awareness programs?

The complexity of the regulatory environment for biotech or GM crops results from two aspects of over-regulation-the data needs for applications and the long delays and unnecessary repetitiveness of regulatory review.

Data requirements: The original data requirements for the general release are derived from "points to consider" produced between 1986 and 1992 in a technical working group of the Organisation for Economic Co-operation and Development (OECD). These data needs were further refined in national regulations around the world. The OECD guidelines deliberately took a comprehensive view of the matter, meaning that many questions are repetitive and unnecessarily detailed.

A major precedent set in these guidelines was that the unit of regulatory review is the event, i.e., the specific combination of a particular new gene insert in a particular place in the plant genome. As a consequence, every new genetically modified line resulting from introducing the same gene into a plant has to be reviewed and treated as a completely new product. For example, there are several Bt maize events on the market, using the same or almost identical new gene, and all of these have had to produce a completely new biosafety assessment and regulatory application file. Experience, with these multiple events, shows that there is no good reason to maintain this overcomplicated
requirement.

A review to agree that the unit of regulation should be the phenotype and the gene inserted, not the event, would greatly reduce the amount of data needed without compromising safety in any way.

Another major source of complexity and resource waste is the lack of MAD (mutual acceptance of data). There is a totally unnecessary requirement by many national bodies to reproduce data on safety through institutions in their own country. It ignores the fact that much greater national benefits can be drawn from the expeditious deployment of the biotech or GM crops to the farmers.

Regulatory delays: Once a comprehensive biosafety file has been developed, and regulatory applications have been filed, the initiative moves from the applicant to the regulatory bodies. Regulations worldwide have legally agreed time limits for review and decision-making. While applicants are held to these, authorities almost without exception disregard these time limits, making it impossible for the applicants to make informed plans for the next steps in their activities.

This is counter-productive in two ways. First, it delays applications unreasonably. This time loss represents a loss of benefits for farmers who are supposed to benefit from the products and also a loss of income for the applicant, including interests on capital invested. For public institutions, there is another damaging result: unreasonable delays of the regulators often result in public projects running out of funding, leading to many promising projects being abandoned simply because they run out of money.

The current initiative in India to explore the streamlining of the evaluation process of biotech crops is welcome and could significantly benefit developers of biotech crops, farmers and consumers in India by eliminating the opportunity cost associated with regulatory delays. The Union Minister of Agriculture has encouraged the streamlining of the process for the same reasons cited above.

Rolly Dureha