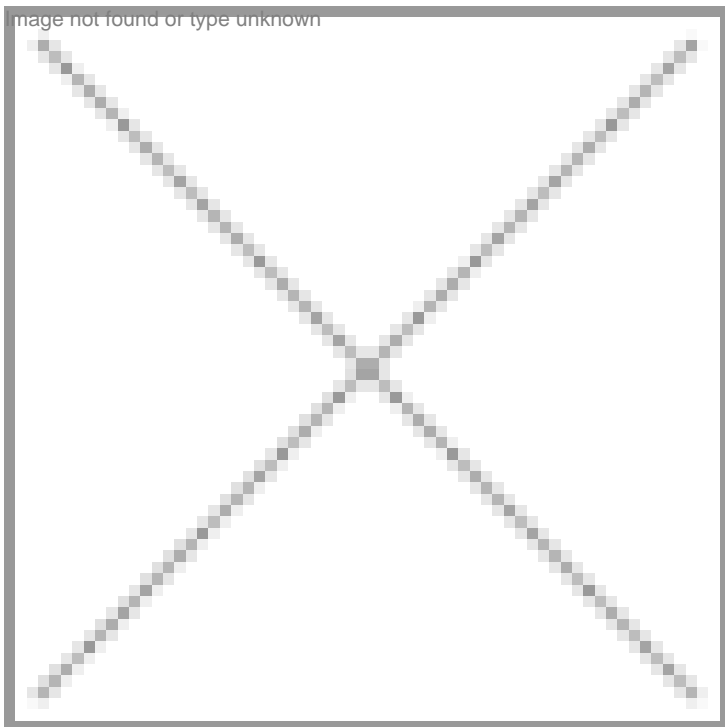


National Regulations Should Reflect Risks of GE Crops

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Acceptance of products and associated agricultural practices of the biotechnology industry is running into problems, probably due to the perception held by many scientists that the technical ability of biotechnology industry to produce safe genetically engineered (GE) crops has developed faster than the understanding of the underlying scientific principles of gene splicing. Consumers and scientists alike feel that the possible consequences for health and environment of the spread of GE crops are not properly understood and that without sufficient research funding and having generally agreed methodologies for assessing the unique risks of GE crops, we shall never be able to properly address them. It should not be surprising that societal concerns about genetic engineering of something as basic as our food and how they are produced are high and no matter of patronizing platitudes by the scientific, political and industrial establishments will make these concerns to go away.

Bizarre approach

The approach of the biotechnology industry to the safety of its products or the understanding how society perceives risk is bizarre. The harsh treatment of sceptics and dissident scientists does not demonstrate the establishment's great willingness to listen to views not in tune with their pre-set ideas. Openness is not much helped either that due to the high cost of biological testing, biotechnology companies only do minimal and superficial environmental and health risk assessments. Cost will also be a major factor in their reluctance to finance research to develop scientifically sound methodologies but rather they prefer to declare the present agricultural practices to grow GE crops as safe and that foods prepared from them present no risks for the consumer. The fact that in the decade since the introduction of GE crops only one human feeding study has been conducted and basic academic animal nutritional/toxicology studies published in peer-reviewed journals are also few and far between gives plenty of ammunition to those who oppose GE crops.

Presently there is an intensive scientific and legislative debate in many countries, including India, about the possibility of the large-scale growing of GE crops without jeopardizing the GE-free status of organically or conventionally grown crops. Pro-industry scientists advocate that even with cross-pollinating crop species only a few metres of separation distance between GE and non-GE crops will be adequate to prevent genetic pollution. However, in the laboratory to prevent the escape and proliferation of untested experimental GE organisms, all developmental work is strictly contained. Moreover, to guarantee the purity of certified seeds even the industry specifies considerably larger separation distances. Thus, for contract growers of certified hybrid seeds, such as hybrid corn, distances of 400 m or more are demanded. In contrast, the biotechnology industry proposes to release GE crops into the environment without adequate biological controls to prevent their dispersal or the artificial transgenes they express. According to their proposals, the strict safety guidelines that apply to GE organisms in the laboratory are not deemed to be necessary when these are grown in open fields, but without scientifically justifying this double standard in safety conduct. One might consider that even more stringent safety controls should be enforced in the natural environment than in the laboratory, particularly as we do not have a backup with products of this irreversible technology. Moreover, there is already sufficient evidence to show that engineered artificial gene constructs may undergo mutation and evolution to an end that we are not aware of, and therefore making the safety assessment of GE crops an exercise without a firm predictive scientific basis. Indeed, one cannot safety assess something that has not yet evolved.

Genetic contamination

In the absence of adequate methods to remove inserted transgenes, once the seeds are genetically contaminated, it will be nearly impossible to recover the original uncontaminated seed stock. Under the regulatory systems of most countries, testing of seeds for genetic contamination is done after the event and not before. In the USA and Canada the whole seed system has become contaminated after ten years of large-scale commercialisation of GE crops. Thus, even though only about one percent of the corn seeds sown in Iowa (USA) was StarLink, in the absence of adequate separation between the GE and non-GE cornfields and segregation of the seeds after harvest, about 50 percent of the corn produced contained the StarLink transgene, demonstrating that coexistence of GE and non-GE crops is impossible. The proposal by the MS Swaminathan Task Force that regions in India representing either primary or secondary centres of genetic diversity for major crops such as rice should be conserved for posterity as "agro-biodiversity sanctuaries" and "organic farming zones", is manifestly impractical and will not stop the genetic contamination of rice crops in other areas. In a democracy once the floodgates are opened it is impossible to control who grows what. It also means that other parts of the country will be opened up for GE crops. This therefore is nothing but a back door entry to introduce them by a slight of hand which, on the face of it, appears to give false assurances to people that there is no threat at all that genetic contamination will spread in the country.

Risks of GEOs

In order to satisfy the legitimate demands of the scientific community and society any large-scale growing of GE crops and their coexistence with crops grown using traditional and organic agricultural practices must be based on or at least take into account the scientific guidelines as laid out very recently in the authoritative ESA (Ecological Society of America) Report on the possible risks of GEOs (genetically engineered organisms) because these may create new, and more vigorous pests and pathogens; exacerbate the effects of existing pests through hybridisation with related transgenic organisms; harm non-target species of organisms; disrupt biotic communities, including agro- ecosystems; cause irreparable loss or changes in species diversity or genetic diversity. Therefore GEOs require greater scrutiny than crops produced by traditional breeding

We shall also have to consider that GEOs may pose risks to the environment because we have little or no prior experience with the trait and host combination; GEOs may proliferate and persist without human intervention; genetic exchange is possible between a transformed organism and non-domesticated organisms; trait confers an advantage to the GEO over native species in a given environment.

If these principles are not taken into account in proposed legislations, the large-scale growing of GE crops can irreversibly harm our environment by genetic contamination of our traditional crops and weeds by cross-fertilization and by horizontal gene transfer respectively. Moreover, in the absence of science-based regulation of the cultivation of pesticide-producing (i.e. Bt-toxin) GE crops, the development of resistance in pests to biopesticides which are also used in organic or traditional agriculture will be speeded up. The uncontrolled large-scale cultivation of herbicide-resistant GE crops will not only contaminate our environment but also lead to the creation of herbicide-resistant superweeds and thus increase rather than reduce the chemical-load of the land and endanger our clean water supply.

Transparency

It is therefore not unreasonable to suggest that the environmental and health risks or safety assessments of GE crops/foods should not be carried out only by biotechnology companies but it must also be verified by independent scientists through a transparent funding system. Any controlling legislation must also be based on these assessments and debated by all stakeholders in the society. The basic rule must be that, since we all want to live in a healthy and natural environment and eat foods which will not endanger our health, we are all entitled to scrutinise the evidence relating to the safety of GE crops. Secrecy is therefore against the public interest and unjustified. GE technology is irreversible and therefore we have to seriously weigh up the pros and cons of its introduction. In democracies it is the people's inalienable right that they should be able to decide whether society can afford to take on the very real risks and the possibly dangerous consequences of genetic engineering for the possibly vain hope of some future benefits for society.

GM Food Labels Should Not Be Misleading

The debate over foods derived from GM crops often touches on the subject of labeling. Ideally a label should not prejudice the consumer for or against the product.

Labeling of genetically modified food and processed food using GMOs is an equally important issue with respect to food safety. With food laws being re-written by the Government of India, the proposal to enact a Food Safety and Standards Bill, 2005 (draft Bill is under circulation for comments) which will repeal a number of the existing food laws and take out food safety from another eight Central and state laws, assumes significance. The Ministry of Food Processing must be complimented for bringing out a comprehensive legislation that brings food manufacturing, its sale, and safety under a single umbrella. The proposed Bill also provides for setting up of a National Food Safety and Standards Authority, as well as provisions for setting up a Food Appellate Tribunals at the Central and state levels, and a number of scientific panels and committees.

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The Bill is however, silent on the issue of labeling of food products whether these are genetically modified or not. The Bill advocates genetically engineered or modified food to mean food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology.

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Javali is a full fledged corporate law firm with niche expertise in IPR & Biotech law with offices in New Delhi, Bangalore and Mumbai.

Unfortunately, while the question seem simple, the issue is not, especially if the starting point of labeling includes the process rather than the final product. Issues such as safety, cost, truth in advertising, choice, fairness, science, trade-barriers,

regulatory responsibility, accountability, legal liability, among others are involved.

Labeling policies

Before any labeling rules can be implemented, governments would have to set up standards and services to conduct testing of the presence of GM ingredients; certification; and ensure that the quality standards are clear and achievable.

While it is easy to detect GM ingredients in products where the GM ingredient is the main ingredient (like tofu or popcorn), it would not be so easy to detect them in processed products like oils, sugars and starches, which no longer contain any novel DNA or proteins.

On another note, much of the food that is bought and consumed in developing countries is not packaged and consequently not labeled. Examples are soybean milk from a street vendor or fresh fruits and vegetables from the market.

Another issue that regulators have to grapple with is the wording: ideally a label should not prejudice the consumer for or against the product.

There is also the issue of whether the label would be useful or educational. To a homemaker who has heard little about the debate on GM food, a label that reads, "Made from genetically modified soybean" or "Grown from seed obtained through modern plant biotechnology" may create more confusion.

International Approaches to Labeling

Codex: The Codex Alimentarius Commission implements the joint FAO-WHO food standards program, the purpose of which is to protect the health of consumers and to ensure fair practices in the food trade. In view of this, it is pertinent to follow its rules and regulations in matters of food safety and labeling. The decisions made by Codex have profound effects on economics and health and well-being of citizens around the world. The fact that 165 nations are members of Codex and this membership represents 98 percent of the world's population, further illustrates the great influence Codex has.

USA: The US has based their position on the doctrine of 'substantial equivalence', where labeling would be necessary only if the food was not substantially equivalent to a conventional food based on composition, nutritional differences, toxicity and new factors like allergens and intended use.

European Union/ UK: The EU, (The UK, France, Austria, Denmark, Holland, Germany, Belgium, Finland, and Spain) position suggests a middle path, opposed to the US doctrine of substantial equivalence. It favored safety evaluation prior to market entry and mandatory labeling where the food can have an impact on health like the presence of allergens and substances not present in conventional foods.

Labeling Regulations in India

In some respects the existing Prevention of Food Adulteration Laws are more stringent as compared to Codex standards e.g., vegetables oils, butter and fats, permitted additives and food with special dietary uses.

Some of the laws for different types of products also come under prevention of Food Adulteration Act, 1954 & Rules 1955. However, some are voluntary and prepared by the Bureau of Indian Standards. Some of them are as follows:

Agmark (Agricultural Marketing)

• Agmark products are free from adulteration and conform to the scientifically laid down principles of purity. It ensures consumer protection.

• Each batch of Agmark products is pre-tested for quality in well-equipped lab by quality control and specially trained chemist.

Fruit Products Order, 1955

• It includes sanitary requirements of a factory manufacturing fruit products, specifications for the processing of various types of fruits, sauces, vinegar, pickles, sun-dried and dehydrated vegetables, onions etc. Rules have also been laid down on limits of poisonous metals in fruit products, permissible harmless food colors. Preservatives and food additives.

ISI Mark by BIS

â€¢ This is also voluntary. Any manufacturer can adopt it to ensure safety of the product.

Labeling Provisions

In the larger interest of our country, with the burden of feeding an ever-growing population, it is quite possible that genetically modified crops and food with their potential benefits will enter the market in a big way.

A reliable system of labeling demands an equally reliable system of monitoring ingredients through the production chain. Labels should tell consumers how and why these foods have been modified. The choice should be left to consumers who should make a choice on the basis of his/ her perception.

Verifiable Labeling

The proposed Food Bill should consider the aspect of labeling in terms of the future when GM food may actually be permitted by the government.

The only way to develop and maintain a labeling system that is truthful, not misleading, and verifiable is to ensure it is based on objective criteria, such as the actual composition of the food, and not on the method of manufacture.