Balanced regulation of biotech

There are too many regulatory bodies for biotechnology. Their functions overlap, giving rise to delays in the approval processes and a tendency to avoid responsibility. A single-window clearance mechanism that looks into all aspects, including bio-safety, would be an improvement,

says **BHASKAR BALAKRISHNAN.**

The ecological impact of Bt Brinjal on existing species of the vegetable and their biodiversity needs to be examined.

The recent move to release Bt-Brinjal for commercial production in India has ignited controversy and debate. Rapid advances in gene sequencing and manipulation technology are driving a dramatic transformation in the life sciences. As is often the case, regulatory mechanisms have been left far behind in this revolution.

The ability to rapidly and inexpensively sequence genes and manipulate them has given us the ability to move genetic material reliably and precisely across the species barrier. Earlier, one had to do this painstakingly by breeding within a species and depending on random mutations or changes in genes. Human, animal, and plant life forms all share the same DNA genetic code made up of the four amino acids A, T, G, and C. At the molecular level all life is the same.

Genes are responsible for a variety of functions of the organism, such as production of proteins, reproduction, regulation, etc. Genes with a desirable attribute can be removed from one life form and transplanted into another. The limitation so far is that while we can sequence genomes easily, our ability to relate the structure to function (which can involve interactions among many parts of the genome) is still limited, and is the focus of intense research activity. Work is in progress to artificially synthesise genes independently of life forms.

NEED FOR REGULATION

This technological revolution has many sides. Plants, animals, bacteria and viruses can be modified by genetic insertions or modifications for a variety of useful functions. These include products useful for human and animal health applications, higher productivity, pest and drought resistance, and even food with beneficial nutrients or supplements.

Other applications include organisms that can absorb pollutants or CO_2, produce fuels from sunlight, etc. Human health applications cover a wide field of diagnostics, therapeutic techniques, including the fight against cancer, degenerative diseases, regeneration of tissues and organs, etc. It seems possible to solve many of our problems. Applications such as DNA-based identity, verifying descent, propensity for diseases, etc are already available.

The dark side of this revolution needs mentioning. Enemies of humanity could pervert this science to engineer new and dangerous life forms and unleash them upon unsuspecting populations, in a form of bioterrorism.

Accidental or uncontrolled release of modified life forms from labs could cause great harm. Just as the IT revolution had its dark side in the form of cybercrime and cyber terrorism, biotech, too, has this aspect. This makes it necessary to have in place regulatory systems at national and international levels.

We are talking here of a regulatory system that regulates scientific research as well as its technological applications. Research, by definition requires a flight of imagination and thinking out of the box. Regulation should not stifle the scientific spirit of enquiry.

In this sense, biotech regulation needs to be flexible and open-minded. The classic criteria of a good regulatory system should also be met – so that it balances the interests of producers and consumers of knowledge, services and products, and safeguards the public interest, while promoting the healthy and balanced development of the sector as a whole.

The biotech revolution in India needs an efficient regulatory system. The present system is the outgrowth of ad hoc regulatory mechanisms built up piecemeal, since 1989, to deal with issues as and when they would arise.

The system includes many entities under several Ministries such as Biotechnology, Environment, Health, Agriculture, Food Processing, Commerce, and involves several pieces of legislation.

MONITORING AGENCIES

The entities involved are the Recombinant DNA Advisory committee (RDAC), Review Committee on Genetic Manipulation (RCGM), Institutional Biosafety Committees (IBSC), Genetic Engineering Approval Committee (GEAC), Drugs Controller-General of India (DCGI), the Health Ministry Screening Committee (HMSC), among others .

All these entities function independently under different departments of the Government of India, and work at their own pace. Some of their functions overlap. This results in inordinate delays in the approval processes, and a tendency to shift responsibility. India's regulatory system was accused of stifling the biotech industry with its red tape. The Mashelkar-led Task Force on recombinant pharma, set up to look into this problem, made a number of recommendations in 2006, including setting up of a single National Biotechnology Regulatory Agency (NBRA), for providing a single-window mechanism for giving various regulatory approvals, including those concerning bio-safety issues. This was also the recommendation of the M. S. Swaminathan led Task Force on agro-biotechnology.

The Department of Biotechnology (DBT)'s National Biotechnology Development Strategy (NBDS), approved in 2007, envisages the NBRA as an "independent, autonomous and professionally-led body to provide a single-window mechanism for biosafety clearance of genetically modified products and processes".

The DBT published an establishment plan for the NBRA (May 2008) and a draft NBRA Bill (July 2008). The Bill is pending and should be approved at the earliest, so that our regulatory system can be cleaned up. This can give a further boost to India's biotech sector which crossed the $2.5 billion mark during 2007–08 with a CAGR over the past five years of over 30 per cent.

BT BRINJAL CONTROVERSY

In the meantime, the controversy over the GEAC's clearance for commercial cultivation of Bt Brinjal raises some issues. There are many other transgenic plant varieties that are pending approval by the GEAC. The controversy mirrors the international divide on this subject between the EU on one side, and the US on the other. The EU is strongly opposed to commercial transgenic crops, and in fact demands certification that imported food is "GM-free". We do not have a credible system of testing and certifying GM-free material. This could become a non-tariff barrier to our agri-exports to the EU.

Bt Brinjal would be the first food crop to be released commercially in India, in contrast to Bt-cotton, which is not a food crop. India is the second largest producer of brinjal in the world, and has some 2000 varieties. Bt Toxin is produced by the bacillus thuringiensis, which occurs abundantly in nature, in soil and on plants. The toxin produced by the transgene in Bt Brinjal and Bt Cotton has been considered a safe, environment-friendly biopesticide, which is not harmful to humans. Moreover, the pesticide is confined to the plant and is active only against pests that feed on it. It has been widely used as a pesticide against mosquito larvae (Cuba), and is toxic only to a few specific insect orders. The European Food Safety Authority found a 2007 study commissioned by Greenpeace indicating liver damage in rats to be insignificant.

The ecological impact of Bt Brinjal on existing species of brinjals and their biodiversity needs to be carefully examined.

There are several examples of accidental introduction of alien plant species that have proliferated out of control – which is why we have plant quarantine regulations. The risks of the trans-gene "leaking out" through hybridisation to related plant species and the consequent impact need to be assessed.

Therefore, more scientific studies on real-world consequences of Bt transgenics are needed. The experience of other transgenic crops released in various countries could provide some guidance. In the meantime, caution should be exercised.

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