Regulation of genetically modified organisms: has the time come to amend the law?

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Across the world, attempts at regulating the processes and products of recombinant DNA technologies, including genetically modified organisms (GMOs) had their origins in the famous Asilomar Conference in 1975. In this conference, scientists who had been involved in developing these revolutionary technologies gathered to discuss the potential dangers of creating GMOs, and they decided to implement a self-imposed moratorium on such research until more details became available from carefully planned experiments on the potential risks and consequences of the GMO technologies. The laws and regulations that were framed by the Indian Government in the 1980s on these technologies largely reflect the potential concerns that were voiced in the Asilomar Conference.

Broadly, three kinds of unintended potential harm from GMOs have been discussed in relation to the need for their regulation: to the health of researchers and workers who are involved in the development and distribution of GMOs and their products; to the health of humans or animals who are the direct consumers or users of the GMOs and their products, and to the ecology and environment, particularly in relation to the field release of GMOs, such as transgenic crops or insects. Some experts have also sought to employ arguments of economics (e.g. that yields from a particular GMO are not commensurate with the claims of the manufacturer or the cost of seed to the farmer) to criticize their release, but these are not relevant here.

In discussing the risks associated with GMOs, it is important to emphasize the qualifying adjectives 'unintended' or 'hitherto unknown'. In other words, what is it that is special to or unique about GMO traits and behaviour that are not seen in organisms (microbes, plants, animals) obtained by conventional breeding and mutagenesis technologies and which are not subjected to the additional level of regulation which is demanded of the GMOs? For example, even with the conventional technologies, there exist the dangers arising out of monoculture, including susceptibility to pathogens and biodiversity loss, or of farmers' exploitation by hybrid seeds producers, etc. Furthermore, the processes and products of the conventional technologies are also subject to regulation by statutory authorities in the Ministries of Health, Agriculture, Environment, etc. In the case of GMOs, this regulation continues to be retained, along with additional regulatory tiers imposed by the Review Committee on Genetic Modification (RCGM) and the Genetic Engineering Advisory Council (GEAC).

Sadly, any rational discussion on the subject of GMO regulation has been seriously hampered by polarization which has occurred between the proponents of the technology and its critics. The former include stakeholders such as biotech and seed producers, while the latter include NGOs and environmental activist groups. So much so that no scientist or expert who wishes to take a stand on this subject is immune from criticism that (s)he has been unduly influenced by one of the sides. This, of course, is unfortunate.

My own assessment is as follows. To my knowledge, in the three decades of regulation since the Asilomar Conference, there has been no clear uncontested (or consensual) validation of any example of unintended risks or consequences of GMOs anywhere in the world. This is true in the two-decade Indian experience as well. There have been several research publications claiming evidence of unintended damage from GMOs but most, if not all, of them have since been contested and several shown not to be valid. Furthermore, to my knowledge, no laboratory experiment so far has demonstrated to a universal level of acceptance any rational ground for believing that GMOs are inherently unsafe.

To continue this line of argument, perhaps the best example in my opinion of the broad safety of GMO technologies and products is what I could refer to as the 'controlled trans-Atlantic experiment'. To a rough approximation, over the last two decades, around 300 million people (and their livestock) of the developed world on the western side of the Atlantic Ocean have been exposed to GMOs and their products in their daily lives, whereas about the same number on the eastern side has been protected by their governments from such exposure. And it is arguable whether any difference exists between the two populations and regions in terms of human or animal health and environmental safety. One cannot but suspect that the decision of the European Union to keep out GMOs is primarily to serve as a non-tariff protectionist barrier against the import of agricultural produce into its territories.

I believe, therefore, that the time has come to ask why should the additional regulatory requirements for GMOs not be discontinued, and why should regulatory authorities such as RCGM and GEAC not be disbanded completely. In other words, perhaps it is now time for someone to stand up and state that this emperor is wearing no clothes. The additional regulatory hurdles for GMOs do impose considerable costs, both direct in terms of additional experiments and documentation to be provided by the producer to the regulatory authorities, and indirect in terms of missed opportunity costs and the imposition of high barriers against the entry of new and small players.

Of course, this is not to argue that GMOs are not to be regulated, only that they should be subject to the same regulations as are applicable for products obtained by conventional biological technologies. Furthermore, risks and consequences from GMOs which can be intended or foreseen should continue to be regulated, e.g. GMOs as potential biological warfare agents. This limited scope of additional regulation of GMOs would not require the RCGM and GEAC machineries.

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