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Agri Biotech Industry's Wish List

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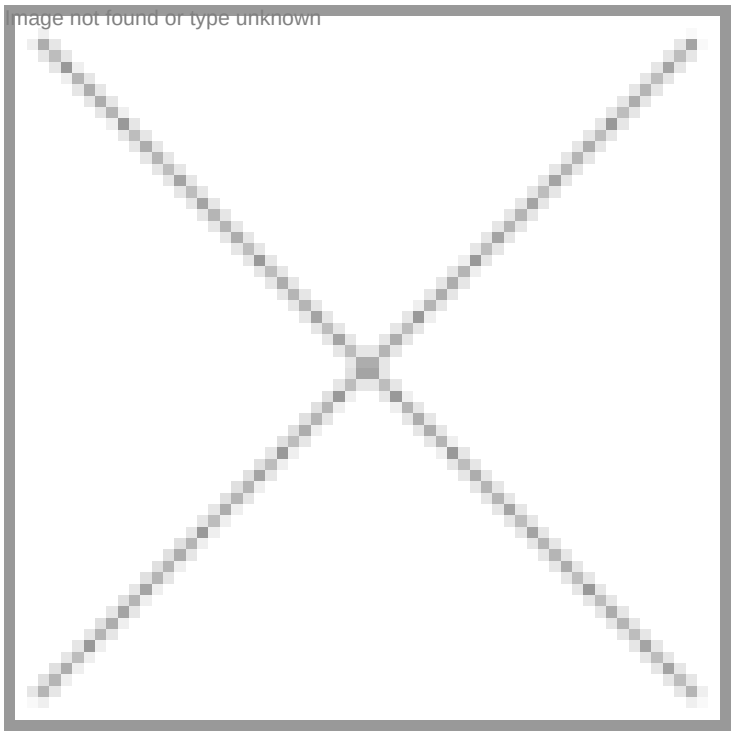

Agri Biotech Industry's Wish List

The agriculture industry contributes 22 percent to the Indian GDP and has been facing many problems. A major issue is that it is a highly regulated industry with a wide range of independent Acts and bureaucratic procedures. Kapil Sibal, minister for science and technology, during the first Biotech CEO Summit organized by *BioSpectrum* in Hyderabad on September 23, 2005, had asked the agri biotech companies to come out with a wish list so that he could take up the issues with the officials concerned. Some of the recommendations from the agri biotech industry are as follows:

The Patents Act: While the third amendment of the Patents Act has made it TRIPs compliant, there is an urgent need to amend the Manual of Patent Procedure and Practice on the lines of the industrialized nations quickly. This would facilitate proper examination of the patent applications.

Training of patent examiners: Crop Biotechnology is a very complex science and is relatively new to the Patent Examiners. Hence intensive training of the patent examiners designed at clarifying the complexities of the science would be required.

Protection of plant varieties and farmers rights: The Authority under the Act is just being established. It is meeting the industry representatives to ascertain their concerns, which is a step in the right direction. However, while implementing the Act, it is hoped that the Authority will fully integrate the concerns of all stakeholders in an equitable manner so that innovation and technology are given a push.

Approvals: We need to shift from hybrid-based approvals to event-based approvals, as is the practice in most countries. This will not only bring our system in harmony with the regulatory systems prevalent in other developed countries but will also make it faster and easier. Once the event has undergone the biosafety trials and found to be safe from all considerations, its positioning in any new hybrid should not pose any danger to the health of the environment, human beings and animals.

- The approval process for commercialization of approved events should not take more than two years as only agronomic evaluation is further required. Agronomic evaluation of the product can be part of post-approval monitoring, but should not be a pre-condition for approval. Approval of transgenic technology should solely be based on scientific evaluation of biosafety and validation of the specific claims made for the technology (efficacy testing).

- There is still an opportunity to reduce the time period required for approval of hybrids for an approved gene. In fact the total approval process for such hybrids should not take more than two years while it is taking three years now. We have to review why each trial is required for such hybrids including the ICAR trial of two years, the LST and the RCGM trials. This streamlining will help in bringing the approved products faster into the market thereby reducing the dependence of the farmer on unapproved products.

- There should be no restriction on commercialization of Herbicide Tolerant crops. Worldwide, HT crops have been the most accepted GM crops because of the economic benefits to the farmers. The same is applicable in India as well.

- Recognize the popular varieties as extant and effective varieties and accord them the same consideration as is given to the notified varieties. The Seed Act 1966 does not make notification a mandatory activity. The market share of the popular varieties is more than the notified varieties, signifying their superiority over the notified ones. It would, thus, be anachronistic not to recognize their value to the farmers. Definitional problems do exist, but these can be solved through dialogue with the industry.

- Time bound regulatory decisions (the whole process from first submission of application to final approval/denial) after all the field trials should not take more than 30 months.

Food and feed sector: The next decade would belong to the food and feed sector. The guidelines/protocols for the testing of food and feed products would need to be established and made transparent, credible, predictable and in line with FAO/WHO/Codex guidelines.

Drive against illegal seeds: The presence of illegal Bt cottonseeds in different parts of the country is more than that of the legal varieties. Apart from posing risks of biodisaster, they make a mockery of the regulatory system and the laws of the land. Firm State action to contain and restrict the illegal activities is called for.

R&D Priorities: These need to suit Indian requirements. There must be emphasis on biotic and abiotic stresses, increase in nutritional values and lengthening of the shelf life of agricultural products. There is no need to restrict R&D on soybean.

Biotech research is cost intensive and encouragement should be given to develop world-class facilities for biotech research. Set up biotech facility of International standard at five centers for supporting Bt research in private sectors at Hyderabad, Bangalore, Kharagpur, Pune and Delhi with latest equipment like sequencers.

Education and awareness campaigns: There is a need to carry the stakeholders along as agbiotechnology is a complex and a new science. Hence educational and awareness programs by the State is the need of the hour. An intensive outreach program is called for. The industry would be willing to assist the State in this endeavour in any manner that the Government desires.

Consumer acceptance and ownership of the technology: The involvement of the civil society is essential for the success of the program. The State must take initiative in this regard and ensure that the civil society understands the process of risk assessment and management and expresses confidence in its credibility. The industry is willing to fulfill any role assigned to it in this regard.

Duties and incentives: Apart from nine equipment (as per Customs Notification No. 11/2005â€“List 27A) that are being

exempted from Customs duty, the following equipment may also be considered under duty free equipment for import: PCR Machine /Real Time PCR, high speed refrigerated/non-refrigerated centrifuges, microscopes, incubator shaker, hybridization oven, growth chamber, lyophilyser, gel documentation system, high precision balance, HPLC, gas-chromatograph and high throughput dispensing system.

As per present policy, duty exemption is being granted on case-to-case basis. However, the following chemicals may also be treated under Duty Free Items that would help the biotech industry to speed up their R&D activities. The chemicals include Hygromycin B, Phosphinothricin/Bilaphos/BASTA, IPTG, TDZ (Thidiazuran), Zeatin, TRIS, AGAROSE (for electrophoresis), Acrylamide, Bis-Acrylamide, TEMED, Ammonium per sulphate, UREA, TAQ-Polymerase, Deoxy nucleotide triphosphates(dNTPs'), Restriction enzymes, Oligonucleotides, Gelrite, X-GlcA, DTT (Dithiothretol), NAD (Nicotine amide Adenine dinucleotide (free acid), X-Gal and SYBR-Green I .

There should be a single window clearance for setting up industry at every state. In lines of SEZ create Seed Production Zones (SPZs) to strengthen supporting infrastructure.

Exempt all taxes and duties (Sales Tax/Income Tax/TO tax, etc) for all GMO products using indigenous technology.

Simplify import of GMO seeds for research purposes.

Banks to consider biotech industry as priority sector and give loans at a concessional rate of interest, for longer gestation periods and with exemption from the collateral guarantees, since these industries are not very capital intensive but are research and technology driven.

Biopesticides: Wherever registration of biopesticides is required, it should be done by a separate Registration Board, rather than the Central Insecticides Board (CIB). It is hoped that the suggested new Registration Board may view biological inputs differently due to the different nature of the products. Otherwise, the process of registration should be simplified with fewer requirements for toxicology and chemistry data. Bio-efficacy may be given top priority for registering the products.

Currently, biopesticides, which are not under CIB schedules, should be allowed for marketing after it is ensured that they adhere to the quality and performance as per the claims made by manufacturers on the label.

A uniform policy should be implemented in all the states of India for research, development, manufacturing and marketing of biopesticides. Create a policy environment more conducive for the improved production of biopesticides and biofertilizers to enhance the use of these eco-friendly inputs.

In most of the states, biopesticides do not appear along with farm inputs in the Sales Tax or Commercial Tax schedules. They attract high tax rates. We suggest exemption of biopesticides from State and Central Sales taxes and also VAT wherever applicable and exemption from Excise Duty.

Because the biopesticides industry uses agriculturally beneficial microorganisms in their products, there are no significant pollution issues. Therefore, the clearance from the pollution control department should be made easy.

Allow contract research, contract manufacturing and consultancy services for biotech products (including biopesticides) to facilitate overseas clients to outsource their products of their brands and labels, under their licenses and IPRs.

Promote the concept of small and medium enterprises (SME) for the production of biopesticides rather than small-scale industries (SSIs).

Charges for testing, bio-efficacy, toxicology data and technology transfer should be made cheaper to facilitate small and growing biopesticides industry. It is therefore recommended that these services be rendered by ICAR, ICMR, SAUs, and other private/public toxicology institutions recognized by CIB-RC.

Quarantine facilities should be available at all air and sea ports to facilitate biotech products in terms of their technicalities and faster clearance.

Most of the tenders for biopesticides are not possible to go by the L1 concept since these are brand specific than product specific and differ largely due to potency. Dosage per unit area and application cost and methods should be the determinants.

Industrial subsidies of minimum 25 percent without upper ceiling may be considered for a fast growth of the biopesticides industry.

The above suggestions were given by RK Sinha, Executive Director, All India Crop Biotechnology Association (AICBA), PS

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