

Possible implications of a recent gazette notification on *Bt*-cotton scenario in India

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According to a new Central Government gazette notification S.O.1813 (E) dated 18 May 2016, titled 'Licensing and Formats for GM Technology Agreement Guidelines, 2016', significant changes were proposed by the Ministry of Agriculture, that if implemented could have had far reaching consequences on cotton scenario in India. However, the Ministry suspended the gazette on 24 May 2016 and invited public comments within 90 days for a possible re-consideration and revision. It remains to be seen, as to which aspects of the gazette would be retained that may re-shape policies which could have a positive influence on the cotton sector.

Bt-cotton contains one or more genes derived from the soil bacterium *Bacillus thuringiensis* and introduced into the cotton genome through genetic modification (GM). The genes express insecticidal proteins in the plant parts and are generally referred as Cry (crystal) proteins which are toxic to leaf-eating caterpillar pests, more specifically to the three species of cotton bollworms. '*Bt*-cotton' event Mon-531 (*cry1Ac* gene) was first approved by the Genetic Engineering Approval Committee (GEAC), Ministry of Environment, for commercial cultivation in India on 26 April 2002. Subsequently in 2006, three new *Bt*-cotton GM events, namely MON-15985 (Bollgard-

II®, *cry1Ac* + *cry2Ab2* genes), event-1 (*cry1Ac* gene) of JK seeds and GFM event (fusion gene with *cry1Ab* + *cry1Ac* sequences) of Nath seeds were approved for commercial cultivation. *Bt*-cotton event BNLA-601 of UAS Dharwad was approved in 2008 and event MLS-9124 of Meta-Helix Life Sciences was approved in 2009. So far six *Bt* cotton events have been approved for commercial cultivation in India and are being marketed by 49 Indian seed companies under licence agreements from Monsanto. Though six different *Bt*-cotton events have been approved thus far in India, currently more than 95% of the cotton area in the country is covered by

only Monsanto's two-gene (*cry1Ac* + *cry2Ab2*) *Bt* event called Mon-15985.

The trait value or royalty thus far has been about 20% of the sale price of *Bt*-cotton hybrid seeds. Over the past five years until 2015, a packet of 450 g Bollgard-II seeds was being sold for Rs 930. Recently, the Central Government issued orders under the Cotton Seeds Price (Control) Order, 2015, to fix the maximum sale price (MSP) of Bollgard-II at Rs 800, including royalty of Rs 49, for a packet of 450 g seeds. The Central Government in exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955 (10 of 1955) made the Cotton Seeds Price (Control) Order, 2015 to fix the MSP as well as the price components of the MSP, namely the 'trait value' and the 'seed value' of GM cotton with an objective to provide farmers with seeds at a fairly reasonable and affordable price.

The new gazette specifies that 'for all new GM Trait License agreements to be executed henceforth, the upfront fee shall be as mutually agreed but subject to the maximum ceiling not exceeding Rs 25 Lakhs payable in two equal annual instalments'. The gazette also specifies in clause 4(2) that 'for a new GM Trait, commercialized hereafter, the maximum trait value may be up to 10% of Maximum Sale Price (MSP) of GM cotton seeds as fixed by the Central Government, for the initial period of five years from commercialization. From the sixth year onwards, it shall taper down every year @ 10% of initial trait value'. The gazette also states that 'the Licensor shall transfer GM Trait to the licensee within fifteen days of receipt of first instalment of upfront fee'. However, as of now the above clauses of the gazette may not have any immediate implication because currently there are no new GM events that are available for fresh commercialization by any company.

Interestingly, the gazette states that the 'commercial life of the GM Traits is considered as 10 years subject to review in case of efficacy of trait is lost earlier'. According to Clause 4(3) of the gazette 'any GM Trait which loses its efficacy as reported by States and verified by the Indian Council of Agricultural Research (ICAR) shall not be eligible for any trait value whatsoever' even if it is under patent. Recent studies conducted by ICAR-CICR (unpublished data) unequivocally showed that the pink bollworm has de-

veloped resistance to Bollgard-II. Based on the data, as applicable under Clause 4(3) of the gazette, both Bollgard and Bollgard-II will be deemed ineligible for any trait value or royalty in view of the ICAR-CICR findings based on insect resistance bioassays conducted by the Institute with pink bollworm populations collected from 39 districts across 10 cotton growing states. Results showed that pink bollworm populations in 15 districts of six states (Gujarat, Telangana, Andhra Pradesh, Madhya Pradesh, Maharashtra and Karnataka) have developed resistance to Bollgard (*Cry1Ac*) and Bollgard-II (*Cry1Ac* + *Cry2Ab2*). Therefore the results may lead to the ineligibility of royalty claim by the licensor.

According to Clause 3(7) of the gazette, all the existing 'GM trait license agreements' dealing with the production and sale of GM cotton seeds and payment of 'trait value' to the concerned licensor shall become invalid, inoperative and shall have to be executed in the new format within 30 days from the date of publication of these guidelines. Based on this clause, the Indian seed companies could sign fresh agreements with Monsanto, but will not have to do upfront payment or any further royalty in view of the fact that both Bollgard and Bollgard-II are unlikely to guarantee protection against the pink bollworm. If the companies do not sign any fresh agreement, they can still sell their *Bt*-cotton hybrids because the gazette also declares that transgenic varieties become the intellectual property of the breeder or company who has developed it, irrespective of the source of the GM event. Further, the licensees may license the transgenic variety developed by them under the agreement having intellectual property rights under the Protection of Plant Varieties and Farmer's Rights Act, 2001, to any other company. Thus seed companies and plant breeders can now sell or sub-license such varieties for commercial use and also for further improvement through plant breeding.

The most important clause in the gazette is 3(5) which states that the licensor shall not refuse grant of a license to any eligible seed company or institution. The licensor shall transfer the GEAC-approved GM trait within 30 days of application to the applicant, failing which it is deemed to have been automatically transferred. Further, the gazette specifies that the licensor shall not re-

strain the licensee from getting similar or other GM traits or any other technology from other technology developers. Thus, the gazette is likely to ensure a level playing field for all licensors and licensees because of the elimination of several restrictive clauses previously imposed by multinational companies in bilateral agreements between licensors and licensees. These clauses may have a significant impact on the cotton scenario. By enforcing compulsory licensing by licensors for any licensee, the gazette provides opportunities for public sector institutions as licensees to incorporate any new GM technology into open-pollinated varieties.

It is only in India that technology developers and seed companies have thus far restricted the *Bt*-cotton technology only in the form of 'F-1 *Bt*-hybrids' without permitting the deployment of '*Bt*' in open pollinated '*Bt*-varieties'. 'F-1 *Bt*-hybrids' serve as tools of 'value-capture' to ensure that farmers are compelled to buy freshly produced hybrid seed every year, and cannot use the farm saved F-2 seed for sowing, since it would result in a crop with genetic segregation and heterogeneity. Cultivators in other countries enter into agreements with the seed companies, that they would not reuse the farm saved seeds of the open pollinated '*Bt*-varieties'. The Indian Seed Act, 1966 empowers farmers to reuse and distribute farm saved seeds. Therefore any such agreements between technology providers or seed companies with farmers in India to restrict them from reusing farm saved seeds would be deemed illegal. Thus 'hybrids' were a natural choice for deployment of *Bt*-technology in India, which is not the case elsewhere in any other country, except China where *Bt*-hybrids have been cultivated in a small area, mostly for experimentation.

Until now, public sector institutions of ICAR and State Agricultural Universities did not have access to *Bt*-technologies of the private sector for being used in open-pollinated varieties, because of which excellent varieties developed by the Government institutions over the past 15 years were deprived of available GM technologies that were developed by the private sector. Due to the presence of the '*GM-Bt*' in them, many inferior *Bt*-hybrids had a competitive edge over the best of non-*Bt* varieties which were thus unable to reach farmers who preferred *Bt*-technology for its powerful control

efficacy on bollworms. While *Bt*-varieties have contributed significantly in other countries through efficient bollworm control leading to yield enhancement and insecticide reduction, Indian data show that even after saturation of the country's area with *Bt*-hybrids after 2010, India's global rank never increased above 32nd with at least 24 countries being ahead of India in spite of not having access to *Bt* technology. India's average cotton yields at 510 kg lint per hectare are way below the average 904 kg/ha of rest of the world. Over the past 10 years after 2006, India's National average yields either declined or were stagnant, despite the introduction of three new GM events, including the more potent dual gene (*cry1Ac + cry2Ab*) Bollgard-II technology in 2006; despite the increase of *Bt*-area from 38% in 2006 to more

than 92% after 2010; despite the addition of more than 1000 new *Bt*-hybrids after 2006 and despite more than doubled usage of fertilizers and insecticides in 5 years after 2006. This was primarily due to the unsuitability of hybrid cotton in at least 60% of India's cotton area, mainly in rain-fed region, that was under open pollinated varieties prior to the introduction of *Bt*-cotton in India in 2002. Deployment of *Bt*-technology in the elite public sector varieties would have made a huge difference to production and productivity, mainly in the rain-fed regions of the country. Short duration compact-statured varieties under high density cultivation are better suited for rain-fed conditions since they escape terminal drought, which the long duration hybrids are vulnerable of, especially in Maharashtra and Telangana states which

together have 50% of India's cotton area, almost all of which is predominantly rain-fed. If implemented, the non-restrictive clause of the gazette will provide Indian farmers with access to open pollinated *Bt*-cotton varieties in addition to the existing *Bt*-hybrids. Further, in the absence of any restrictions on pyramiding of various approved events, good products can be developed by stacking events belonging to different companies to enhance sustainable efficacy of *Bt*-cotton by intelligent pyramiding of toxins with different modes of action.

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