Dr. Kalyan B. Goswami

Executive Director

Ref. NSAI/2016/0145



Date: 22.12.16

Dr. Jeet Singh Sandhu
Deputy Director General (Crop Science)
Indian Council of Agricultural Research (ICAR),
Krishi Bhawan, New Delhi.

Dear Sir,

Sub: Developing procedure for Approval of new Bt cotton varieties and hybrids with biosafety cleared Transgenic events.

Ref:

- Minutes of 91st meeting of GEAC held on 14.01.2009 and Minutes of 130th meeting of GEAC held on 11.08.2016.
- 2. Our letter addressed to Dr. R S Paroda, Chairman, TAAS dated 09.08.16
- 3. Our letter addressed to JS (Seeds) submitting NSAI views and comments on draft guidelines, dated 22.08.2016
- 4. DDG letter addressed to Dr. SR Rao, DBT dated 16.09.2016
- 5. Shri RK Mishra letter addressed to Dr. SR Rao, DBT dated 26.10.2016
- 6. Our letter addressed to Chairperson, GEAC dated 05.12.2016
- Our letter addressed to DG-ICAR dated 05.12.2016

We draw your kind attention to the contents of the letters referred above, copies of which are also enclosed for your ready reference. NSAI has been opposing release of new Bt cotton varieties by the Standing Committee of GEAC with a stipulation of "No Objection Certificate" (NOC) / "Letter of Confirmation" (LOC) by trait developer leading to monopoly of cotton seed market and proposing for release of new cotton varieties or hybrids carrying the approved transgenic events under the procedures and processes existing in the country at the State and Central Government level under the Seeds Act and Seed (Control) Order, 1983. The involvement of GEAC or RCGM is not required for the same.

Under the Environment (Protection) Act (EPA) and the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms genetically engineered organisms or cells under EPA, RCGM and GEAC are empowered to evaluate for biosafety and agronomic use of the GM trait and recommend for approval of such events for the commercial release. As per the minutes of the 91st meeting of the GEAC dated 14.01.2009, it was decided to adopt Event Based Approval Mechanism (EBAM) which implies that GEAC will limit to a new transgenic event is to be evaluated for biosafety and agronomic value and recommended for release. However, a Standing Committee was constituted under DBT to grant hybrid wise approval with a stipulation of LOC/NOC by trait developer. Finally, as per the minutes of 130th meeting of GEAC dated 11.08.2016, it was also decided by GEAC that after the event approval, ICAR/DAC will take up approval of new varieties / hybrids carrying the biosafety cleared event under Seeds Act, 1966 and Seed (Control) Order, 1983.

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The NSAI has also been representing that the current mechanism of approving the hybrids or varieties by the Standing Committee of GEAC with a NOC stipulation is leading to monopoly and restricting the breeders' rights available under Section 30 and farmers rights under Section 39 of the PPVFR Act.

Based on the above facts, the following procedure of releasing GM events and subsequent release of new varieties / hybrids with these events would be ideal for the future.

- 1. RCGM and GEAC adopting "Event Based Approval Mechanism" wherein they approve a transgenic event of a crop after all the required tests for biosafety.
- 2. Post approval of a transgenic event, new varieties or hybrids carrying such events will be evaluated by the SAUs or ICAR so that the breeders of such varieties can obtain marketing permissions from the state licensing authorities.
- 3. The varieties / hybrids can also be submitted for evaluation under All India Coordinated Crop Improvement Project of ICAR for identification and notification as per the provisions of the Seeds Act, 1966.

Since all the transgenic varieties need to be labelled (informing the buyer), the particular event it is carrying, the developer of the transgenic event can make claim under Section 26 for benefit sharing from all the breeders.

As per the current practice prevailing in the Seed Industry, breeders of all new varieties are preferring to register them under the PPVFR Act to enjoy rights including commercialization rights in the market place.

The quality regulation of transgenic seeds is well defined through various notifications issued under Seeds Act, 1966 and Environment (Protection) Act, 1986 which can be enforced to maintain the quality standards so as to protect the interest of the farmers. The seed inspectors, seed analysts and the notified seed testing laboratories are delegated to undertake sampling and testing of transgenic cotton seeds also to ensure compliance to the provisions of EPA along with the Seeds Act and the Seed (Control) Order, 1983.

The CICR is the referral laboratory (through notification no. S.O. 1300(E) dated 12.11.2003 of DAC) which can carry out the gene expression and event confirmation tests to ensure only the varieties or hybrids with the approved event or taken into evaluation trials.

The above system

1. Will enable all breeders to continue breeding of a crop with a transgenic trait as and when it is approved by GEAC/MoEF and available for use. Release of a new GM trait in a crop shall not hamper or restrict breeding programs like incase of cotton since 2002.



- 2. With availability of varieties, farmers can also resort to saving, reuse, exchange or even selling his farm produced seeds
- 3. Developers of transgenic variety can claim benefit share from all the breeders who are using the trait under Section 26 of PPVFR Act and get suitable reward as decided by the PPVFR Authority.

The above system will balance the interest of breeders, farmers and the trait developers besides protecting the rights of all the three important stakeholders.

We request you to kindly bring the system into operation immediately by developing required guidelines that needs to be followed by applicants, the Project Coordinator (AICCIP) and all other concerned having stakes in Bt cotton.

Thanking you,

Yours sincerely,

Kalyan B. Goswami

Copies:

- 1. Shri R K Mishra, Additional Commissioner (Seeds), Dept. of Agriculture, Cooperation & Farmers Welfare, New Delhi
- 2. Dr. K R Kranthi, Director, CICR, Nagpur
- 3. Assistant Director General (Commercial Crops), ICAR, Krishi Bhavan, New Delhi
- 4. Dr A H Prakash, Project Coordinator, AICCIP, Regional Station, Lawley Road, Coimbatore 641 003