

R K Trivedi
Executive Director



Ref. NSAI/2022/083

August 31, 2022

Dr. D K Yadava
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Krishi Bhawan
New Delhi 110001, India

Subject: Environmental release of RRF event in HT Cotton.

Dear Sir,

Greetings from National Seed Association of India!

The National Seed Association of India (NSAI), an apex association of Seed Industry, has made a joint representation along with Federation of Seed Industry of India (FSII) to Hon'ble Prime Minister of India on dated 03.06.2022 for speedy regulatory approval of New GM event in cotton so that the stagnant cotton productivity in the country could be enhanced.

We have learnt that GEAC is considering for release of RRF event (gene cp4epsps) in Herbicide Tolerant (Ht) cotton which had been earlier submitted to MoEFCC for biosafety evaluation. The application was submitted about ten years back and bio safety trials had also been conducted under the protocol and provisions of Environmental (Protection) Act, 1986. However, due to some reasons, the application was withdrawn and the process was not completed. Now, this application is again under active consideration of GEAC.

In this regard, we would like to bring to your kind notice that for event based approval of BT cotton traits under the Environment (Protection) Act, 1986 (EPA) and the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989, 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 itself to only new transgenic event, which is to be evaluated for biosafety and agronomic value and recommended for release. The decision taken in 91st meeting of the GEAC is as under-

“After detailed deliberations, it was agreed that the current practice of hybrid by hybrid approval does not involve any biosafety issues and therefore may be treated at par with the conventional cotton hybrids. However, the Committee also agreed that it would be prudent to formally register the information on Bt cotton hybrids at the Central Government level. On the process of operationalising the ‘event based approval mechanism, the following decisions were taken:

- The applicants (private/public sector organizations) who are interested in commercial cultivation of Bt cotton hybrids expressing approved events shall file applications along with affidavits to the ‘Standing Committee’ confirming/stating the following:
 - a) Confirmation of gene/ event through molecular characterization by the Licensor that the gene(s) which is being used is one of the approved events.
 - b) Level of protein expression in green house and field trials
 - c) Morphological characters using DUS descriptors

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d) Bio-efficacy data generated in laboratory conditions

- The 'event based approval mechanism' shall be applicable for Bt cotton hybrids expressing four events namely; cry 1Ac (MON 531 event), cry 1 Ac and Cry 2 Ab (MON 15985 Event, (cry 1 Ab + Cry Ac) GFM' and cry 1 Ac (Event1).

However, a Standing Committee was constituted under DBT to grant hybrid wise approval with a stipulation of LOC/NOC by trait developer. But, in 2017 this procedure was dispensed with and finally, as per the minutes of 132 meeting of GEAC dated 12.04.2017, it was decided by GEAC that after the event approval, ICAR will take up approval of new varieties / hybrids, carrying the biosafety cleared event, under Seeds Act, 1966 and Seed (Control) Order, 1983. The relevant paragraph (7.2) of minutes of 132 GEAC meeting reads as under:

“The Committee after detailed deliberations recommended transferring the entire responsibility of evaluation, approval, management and monitoring of Bt Cotton Hybrids to Indian Council of Agricultural Research (ICAR) in view of limited role of MoEF&CC and DBT and also recommended that hence forth the entire responsibility of confirmation of the presence or absence of the approved gene / event, level of protein expression etc. in Bt Cotton Hybrids would also be the sole responsibility of ICAR.”

Accordingly, ICAR has issued the guideline and protocol for evaluation under ICAR-AICRP trials for Bt cotton hybrids/varieties with bio-safety cleared transgenic events in April, 2017. Copies of the minutes of the 132 GC meeting of 12.04.2017 and the OM issued on 24.04.2017 by MoEF and the ICAR guideline on the protocol for evaluation of Bt cotton hybrid are attached.

We request that the similar procedure may be adopted for approval of the new event (RRF) in Ht cotton so that in a speedy way this event may be transferred in the new cotton hybrids/ varieties with high agronomic performance under Indian conditions and tested in ICAR system for approval for commercial cultivation.

Regards,

Yours sincerely,



R K Trivedi