



NATIONAL BIOSAFETY AUTHORITY

PRESS RELEASE ON MON 15985 EVENT (BT COTTON) APPLICATION

We wish to let the public know that National Biosafety Authority (NBA) has approved environmental release of MON 15985 event (commonly known as Bt Cotton) for the purposes of conducting limited National Performance Trials (NPTs). This follows an application submitted by Monsanto Kenya Ltd in October 2015 seeking NBA approval for **“environmental release, cultivation and placing on the market”**.

The decision to approve was informed by the outcome of food and feed safety assessment, consideration of socio-economic issues, environmental risk assessment as well as analysis of public comments received. This was done in compliance with the Biosafety Act, 2009.

What does the approval mean?

Whereas the applicant had sought approval for “environmental release, cultivation and placing on the market” of Bt cotton (MON15985), the NBA has granted approval only for limited environmental release. This approval is for environmental release only for the purpose of conducting National Performance Trials (NPTs), collecting compositional analysis data as per guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants (KS CAC/GL 45-2003), carrying out tests for presence of aminoglycoside-3"-adenyltransferase (aadA) proteins in cotton seed and leaf tissues, concurrently for MON 15985 event in cotton varieties in Kenya. This approval is not granted to allow for cultivation, importation or placing on the market of Bt Cotton (MON 15985).

Approval conditions

Approval is granted subject to the applicant meeting the following conditions:

1. Prior to establishment of NPT sites, conduct an Environmental Impact Assessment (EIA) and submit an Environmental and Socio Impact Assessment (ESIA) Project Report to NEMA for review and approval;
2. Comply with other existing national laws and policies relevant to this approval;
3. Provide a detailed Biosafety Stewardship Program and Monitoring Roadmap to NBA for approval;
4. Provide compositional analysis as per the guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants (KS CAC/GL 45-2003) on Kenyan MON 15985 event in cotton varieties adapted to Kenya's agro-ecologies;
5. Carry out tests for presence of aminoglycoside-3"-adenyltransferase (aadA) proteins on cotton seed and leaf tissues on Kenyan MON 15985 event in cotton varieties adapted to Kenya's agro-ecologies;

Once the Applicant has complied with the approval conditions, they may submit an Application for consideration to NBA for commercialization and placing on the market of MON 15985 Bt cotton.

What happens during Environmental release trials and thereafter?

KEPHIS is responsible for conducting the National Performance Trials (NPTs) and the Distinctness, Uniformity and Stability (DUS) tests before variety release. For GM crops, KEPHIS conducts these tests only after NBA approves the GM event.

What happens during National Performance Trials (NPTs)?

The NPT is a mandatory process for all plant varieties whether GM or conventional to provide information on Value of Cultivation and Use (VCU). By law, new varieties are required to go through laid down variety testing and release protocols under the supervision of KEPHIS. If materials carrying



the just approved Bt cotton (MON 15985) event perform as well as the local check during NPTs and are also characterized as distinct, uniform and stable (DUS), then they will be eligible for being considered and approved as varieties by the National Variety Release Committee (NVRC) for commercial cultivation.

What will be role of NBA during NPTs?

During NPTS, NBA will constantly and independently evaluate the data generated by the applicant. This approval will be revoked and trial sites terminated by NBA if new information becomes available that Bt cotton poses unacceptable risks to human health or the environment.

Will Bt cotton seeds be available to farmers during NPTs?

This approval **will not** permit the applicant to provide seeds to farmers for planting, sale, for human food or animal feed. When the Applicant has demonstrated successful NPTs they will submit an Application to NBA for approval to that effect.

How long will this process take before seeds become available to farmers?

It is the Cabinet Secretary, Ministry of Agriculture who officially releases all crop varieties (Whether GM or conventional) on advise of KEPHIS and NVRC in line with Seed and Plant Varieties Act, Cap 326 and not NBA. This is a process that takes two to three years.

What happens once the seed is commercialized in Kenya?

If GM cotton variety(s) is released, NBA and other Government agencies monitors it for 20 years to assess whether there are any post release adverse effects.



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Date.....2/9/16.....

CHIEF EXECUTIVE OFFICER