THE DECISION DOCUMENT: THE EXECUTIVE COUNCIL UNDER THE GMO ACT

Name of the applicant: Monsanto South Africa (Pty) Ltd

Title of the application: Application for general release of maize MON87460 x MON89034 x NK603, reference number 39.4.1/Monsanto - 17/1724.

Short description of the genetic modification

The genetically modified (GM) MON87460 x MON89034 x NK603 maize event was developed by conventional breeding between MON87460, MON89034 and NK603 events. MON87460 expresses cold shock protein B (CspB) from *Bacillus subtilis* and NptII protein that confers tolerance to drought and resistance to kanamycin/neomycin respectively. MON89034 expresses the cry1A.105 and cry2Ab2 protein that confers protection against certain lepidopteran insect pests and NK603 expresses the 5-enolypyruvylshikimate-3-phosphate synthase (EPSPS) protein that confers tolerance to glyphosate.

Purpose of the use: General release-use of a GMO as food, feed, processing and planting in South Africa.

Human and animal risk evaluation

The assessment concluded that there were no significant differences in composition that would lead to changes in the nutritional value of MON87460 x MON89034 x NK603 compared with conventional maize. The host or donor organisms are not pathogenic and the maize event MON87460 x MON89034 x NK603 is unlikely to display any particular toxicological activities and no allergic risks are apparent that would exceed those linked to conventional maize

Environment risk evaluation

The risk of harm arising from plant to plant gene transfer from MON 87460 × MON 89034 × NK603 is negligible. Field trials with MON 87460 × MON 89034 × NK603 were approved at four trial locations (Hopetown, Orania, Lutzville and Malelane) for the 2014/2015, 2015/2016, 2016/17 and 2017/18 planting seasons. However, the drought data specifically the kernel count per row and kernel count per ear data showed that there were no statistically significant differences between MON 87460 × MON 89034 × NK603 and the conventional maize. Moreover, the yield benefits associated with the MON 87460 × MON 89034 × NK603 maize event were inconsistent and in some trials the GM maize event had lower yields than the conventional maize. The insect

resistance data presented was insufficient since it was only collected from the Malelane trial site which only had natural infestation for the 2014/2015 and 2015/2016 planting seasons.

Conclusion

The data provided in the application is insufficient to demonstrate the efficacy of the drought-tolerant and insect resistant of MON 87460 × MON 89034 × NK603 maize event.

Decision

The Executive Council does not approve the general release of maize MON87460 x MON89034 x NK603.

Dr JB Jaftha
Chairperson of the Executive Council: Genetically Modified Organisms Act (Act No. 15 of 1997)