

The host or donor organisms are not pathogenic, and there is no reason for the GM maize to demonstrate pathogenic properties. Therefore it is highly unlikely that event DAS-40278-9 would display any particular toxicological activities; and no allergenic risks are apparent that would exceed those linked to the unmodified wild type maize plant, which has a low allergenic potential.

Environment risk evaluation

This application is for a Commodity Clearance so no cultivation is anticipated. However, should some spillage occur along transit routes, this is unlikely to be problematic as maize is not known to be weedy or invasive. The DAS-40278-9 maize event can be killed with herbicides other than 2,4-D or fop class of chemicals.

No public comments were received.

Conclusion

The following conclusions was made from data provided in the application, the maize event is substantial equivalent, and has a low environmental risk and there is adequate scientific reason to support that the introduced trait is safe in imported grain and is nutritionally adequate for human and animal consumption.

Decision

The Executive Council approves the Commodity Clearance of maize DAS-40278-9.

DECISION DOCUMENT

Summary of the Application

Name of the applicant: Dow AgroSciences Southern Africa (Pty) Ltd

Title of the application: Application for commodity clearance of GM maize event DAS-40278-9, reference number DowAgroSciences -12/002.

Short description of the applicant's request

The intended use: Commodity Clearance for the import of maize grain derived from transgenic event DAS-40278-9, which contains the transgenic protein aryloxyalkanoate dioxygenase (AAD-1) for tolerance to 2,4-D and 'fop' (aryloxyphenoxypropionate) herbicides.

Purpose of the use: food, feed and processing for the South African market.

Short description of the genetic modification

Herbicide tolerant GM maize line DAS-40278-9 contains the transgene aryloxyalkanoate dioxygenase (*aad-1*) from the soil bacterium *Sphingobium herbicidovorans*, conferring tolerance to 2,4-D and 'fop' herbicides. The *aad-1* gene was introduced to *Zea mays* via whisker-mediated transformation and is under the maize ubiquitin promoter. The transgenic line was backcrossed with elite lines and DAS-40278-9 was selected for commercialisation.

Human and animal risk evaluation

The equivalence of the AAD-1 protein derived from plants and from the bacterial system (*Pseudomonas fluorescens*) used for the subsequent toxicological testing was demonstrated; (a) 15-day acute toxicity study in mice and 28-day repeat dose study in mice showed no evidence of toxicity; (b) the AAD-1 protein is heat labile and loses 99% of its immune-reactivity when heated for 30 minutes to temperatures of between 50 and 95 °C which occurs during the processing of maize grain; (c) safety of donor organism: *Sphingobium herbicidovorans*, is not known to be pathogenic or toxic.

The protein is from a non-allergenic source, lacks structural and sequence homology with known allergens as evidenced by bioinformatics studies with both the AAD-1 protein and flanking sequences. The AAD-1 protein is rapidly digested in simulated gastric fluid and would constitute a small proportion of the total protein present in the grain.

The compositional analysis data was within the range observed for commercial maize. The Feeding study indicated no differences between broilers fed with grain derived from DAS-40278-9 and several control lines.

There were no significant differences in composition that would lead to changes in the nutritional value of DAS-40278-9 compared with commercial maize hybrids. This was supported by the 42-day broiler feeding study where nutritional equivalence of the DAS-40278-9 and several control lines was demonstrated.