

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

ACCIDENTAL CULTIVATION OF Bt10 MAIZE IN THE USA

Purpose

This paper informs members of the action taken following the discovery that the unauthorised transformation event Bt10 was present in commercial maize varieties used by farmers in the US, in place of the authorised Bt11 event.

Background

1. At the end of 2004 the agricultural biotechnology company Syngenta informed US regulators that maize containing an unauthorised GM event, Bt10, was present in seed supplied to farmers during the 2001-2004 seasons. The affected varieties were all field maize, rather than sweetcorn.
2. Syngenta had discovered that Bt10 was present in a very small number of its Bt11 corn breeding lines. The novel proteins produced by Bt10, which cause the maize to be both insect resistant and herbicide tolerant, are reported to be identical to those produced by the commercialised Bt11 event. The contamination appears to have occurred at an early stage in the development of a corn breeding line that was used commercially to supply farmers in North America. The bulk of the commercial planting was in the USA; a small area was planted in Canada, but Canada is a net importer of maize grain and there is no evidence that this was used for export.
3. EU member states and the European Commission were informed of this contamination on 22 March 2005, when an article appeared in *Nature* (Annex 1). The Commission immediately wrote to Syngenta and to the US authorities expressing their concern over the delay in providing information and requesting further data.
4. Based on the acreages sown with Bt10 maize, it is estimated to have accounted for 0.025% of the US maize harvest during 2001-2004. Unsegregated US exports of maize and maize products, comprising a mixture of GM and non-GM varieties, could therefore have contained a small proportion of Bt10. Bt10 products would have been channelled to countries where Bt11 is approved for import. Bt11 corn is approved for food and feed use and for cultivation in the United States, Canada,

Argentina, Japan, South Africa, and Uruguay. It is approved for import for food and feed use in the European Union, although in reality the EU imports very little maize grain from the US. As Bt10 maize was mistakenly grown in place of Bt11, US maize products from protected non-GM sources would not be affected.

5. A smaller quantity of Bt10 maize has been grown in Canada, although it is reported that this was used for domestic consumption and not exported. In addition to commercial cultivation of Bt10 maize in North America, affected seed was supplied for use in small-scale trial plantings in South America and in the EU (France and Spain). In the EU, these trial plantings are subject to authorisation under the legislation on deliberate release of GMOs (Directive 2001/18/EC) and the resulting produce is destroyed, not used commercially.

Genetic identity of Bt10

6. Bt10 is identical to Bt11 in that the same plasmid was used to transform each line. The purpose of the transformation was to introduce genes coding insect resistance (*Cry1Ab* from *B. thuringiensis*) and tolerance to the herbicide glufosinate ammonium (*pat* from *Streptococcus viridochromogenes*). Only the Bt11 line was progressed further and commercialised. Unlike Bt11, Bt10 also includes an ampicillin resistance gene (*bla*) which was present in the plasmid as a bacterial selection marker¹.
7. Syngenta has sequenced the portion of the inserted DNA in Bt10 that includes the *Cry1Ab* and *pat* genes, including the regulatory sequences. These data show that the sequence is identical to that in Bt11 apart from a small number of nucleotide differences in the non-coding sequences contained within the insert

Safety assessments

8. Following the discovery of the misidentified maize lines, Syngenta provided safety data to the relevant authorities (USDA, EPA and FDA²). The size and immunoreactivity of the *Cry1Ab* and PAT proteins from Bt10 were compared with those from Bt11 using Western blotting. At the time the incident was made public, the US authorities had completed their assessment and concluded that the novel proteins present in Bt10 were identical to those in Bt11 and there was no safety concern.
9. As the *bla* gene is controlled by a bacterial promoter, it is predicted that this gene will not be expressed in plant tissues. This Committee has recently updated its factsheet on the use of antibiotic resistance marker genes and

¹ Earlier submissions for authorisation of Bt11 maize used DNA from Bt10 as a positive control in tests designed to demonstrate that the *bla* gene was not present in Bt11

² US Department of Agriculture, Environmental Protection Agency and Food and Drug Administration

has confirmed that, even in the unlikely event that other micro-organisms may acquired resistance to ampicillin from GM plants, the effect on the overall frequency of ampicillin resistance would be insignificant.

10. These data were also reviewed by scientists at EFSA, in consultation with the chair of EFSA's GMO Panel. EFSA issued a statement on 12 April (Annex 2). This statement notes that further data would be required for a full safety assessment. EFSA has not confirmed the identity of the novel proteins but points out that, although EFSA has advised against the presence of the *bla* gene in commercial GM crops in the EU (see paper ACNFP/66/1), it has accepted the food and feed use of other GM products containing the gene and its presence in Bt10 is not necessarily a concern.

Regulatory action

11. As a result of this contamination, Member States attended emergency meetings in Brussels on 12 and 15 April 2005 to agree harmonised action to prevent maize or maize products derived from Bt10 being placed on the market in the EU. At the meeting on 15 April there was a vote in favour of an emergency measure requiring imports of corn gluten feed and brewers grain from the United States to be certified as free of the unauthorised Bt10, as these are the imported products considered most likely to be contaminated. Commission Decision 2005/317/EC was formally adopted on 18 April and came into force the following day.
12. Following agreement of Community action on 15 April 2005, Food Standards Agency officials issued an advice to feed merchants, compounders and others, in the UK, advising them to quarantine any relevant animal feed material in their possession, pending testing to demonstrate that Bt10 maize was not present.
13. No action has been taken in relation to food products as the European food industry has stated to the Commission that US maize products for food use are from protected non-GM sources. Member States have been asked to monitor products on the market and, if any GM maize products are found, to conduct tests for the presence of Bt10. The Food Standards Agency has begun this process by asking the Food and Drink Federation and from the British Retail Consortium to identify whether any ingredients from GM maize are in current use.

Detection method

14. As Bt10 is an unauthorised event and had not been commercialised, there was no specific detection method when the incident was first notified to the EU authorities. Development of such a test was requested by the European Commission as a priority and Syngenta arranged for the commercial laboratory GeneScan to develop a suitably sensitive and specific method. The EC Joint Research Centre in Ispra, Italy completed its

validation of this method (based on qualitative PCR) on 22 April, when it published details of the method and the validation report³. Reference material from Bt10 maize has now been made available to control laboratories in the UK and other Member States.

**Secretariat
May 2005**

Annexes attached:

Annex 1 – *Nature* article on Bt10 (22 March 2005).

Annex 2 – EFSA statement on Bt10 (12 April 2005).

³ Details of the method and its validation are published on the JRC's GMO website at <http://gmo-crl.jrc.it>.

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Nature article on Bt10 (22 March 2005).

This document is available at:

<http://www.nature.com/news/2005/050321/full/nature03570.html>

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EFSA statement on Bt10 (12 April 2005).

This document is available at:

http://www.efsa.eu.int/press_room/press_statements/884_en.html

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