



Secretariat

O./ref.: WIV-ISP/BAC/2004_SC_165

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Concerns: Advice of the Belgian Biosafety Council on the reply of Syngenta of 28 July on the advice of the Biosafety Advisory Council of April 1, 2004 concerning the application Bt11 sweet maize under Regulation (EC) No. 258/97

Context

In its advice of April 1, 2004 on the application Bt11 sweet maize under Regulation (EC) No. 258/97¹, the Belgian Biosafety Advisory Council has made clear that no final decision on the safety assessment of Bt11 sweet maize can be taken, unless information definitively demonstrating the homology of the Bt11 sweet maize and field maize inserts is given. Information proving the equivalence between Bt11 sweet maize and field maize was formerly requested on 19 December 2003 (Ref. DA35848/L460/SG).

In order to demonstrate this equivalence, the notifier was requested to provide:

1. The *in planta* genomic DNA sequence of the Bt11 insert in sweet maize
2. An alignment of the DNA sequences of field maize and sweet maize, in correlation with the used transformation vector.
3. If sequence differences are observed between those two genomic DNA sequences, the impact of the observed differences on the nature and allergenicity of any of the recombinant proteins produced in the sweet maize product should be assessed.

Since the food application is supported by information generated with Bt11 field maize, the above-mentioned information is considered necessary by the experts of the Biosafety Advisory Council, since one can only state that the studies done for the Bt11 field maize are also valid for Bt11 sweet maize, in case molecular equivalence of the insert has been demonstrated.

The reply of the notifier on the advice of the Belgian Biosafety Advisory Council was received by the competent authority on 28 July 2004 and forwarded to the Belgian Biosafety Advisory Council.

¹ ref BAC/2004_SC_116 : <http://www.biosafety-council.be>



Scientific evaluation

In its reply, the notifier reports that the DNA sequence of the Bt11 sweet maize insert and a few hundred base pairs of the regions flanking the insert were determined and aligned with the DNA sequence of the insert and flanking regions of field maize.

Of the 7068 nucleotides sequenced, a total of eight changes in nucleotide were identified, none of them located in the coding sequences or promoters within the Bt11 insert. Two changes were identified in the maize genomic DNA flanking the insert, six in the insert itself. Within the insert, four nucleotide changes were detected in the intervening sequences and two in both copies of the NOS terminator.

In its previous report provided on 17 November 2003, the sequence of the Bt11 field maize insert was aligned with one determined by an independent party and shown to have ten nucleotide differences within the 6.2 kb insert and three in the genomic DNA sequence. Within the insert, three changes were identified in the intervening sequences and two in both copies of the NOS terminator and 5 in the Bt gene.

When comparing the location of the nucleotide differences in the schematic presentations of the sequenced Bt11 fragment obtained by the notifier and the independent party, it seems at first sight that some differences identified by the notifier (e.g. nucleotide differences in NOS terminator) correspond to the ones detected by the independent party, while others (e.g. 5 nucleotide differences in Bt gene) do not.

The final consensus sequence of the Bt11 insert was determined by the notifier by combining the data from three sequence operations to generate a consensus sequence. Individual base pair differences between the consensus sequence and the previously reported sequence were further studied in more detail. Any information on how the DNA sequence by the independent party was obtained is lacking.

Taking the protocol on how the sequencing is carried out, one can say that the final consensus sequence provided by the notifier is trust-worthy. Since none of the nucleotide changes were identified in the promoters or coding sequences, the functionality of the elements contained in the insert are expected to remain the same, and the expressed proteins to remain unchanged.



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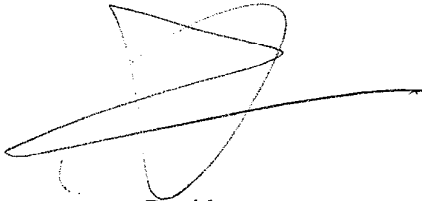
Conclusion

Taken into consideration that:

1. On 28 July 2004, the notifier provided the information requested on 19 December 2003 (Ref. DA35848/L460/SG).
2. Eight sequence inaccuracies were detected.
3. Equivalence at molecular level is demonstrated for Bt11 field maize and Bt11 sweet maize.
4. Given the molecular equivalence between Bt11 field maize and Bt11 sweet maize, one can conclude that the studies done for Bt11 field maize are also valid for Bt11 sweet maize.

Consequently, the Biosafety Advisory Council concludes that the molecular data provided in the Bt11 notification fulfil the Belgian requirements and therefore the marketing of Bt11 sweet maize can be considered safe having no adverse events for human and animal health..

Prof. D. Reheul



President

*Copie certifiée
conforme par le
secrétaire
11.10.2004*



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