

SUMMARY OF FOOD SAFETY ASSESSMENT

FOR EVENT NK603 x T25

A) Description of the recombinant-DNA plant;

Common name : Maize
Family name : Gramineae
Genus : Zea
Species : Maize

Common : Maize or Corn

B) Description of the host plant and its use as food;

Zea mays, Maize and corn refer to *Z. mays ssp. mays*. Other subspecies of *Zea mays* are referred to as Teosintes. Maize is an annual grass growing up to 4m tall. The female inflorescences, ears develop in leaf axils on the stalk, which terminates in the male inflorescence, the tassel. The broad leaf sheaths are overlapping around the stalk and leaves arranged in two opposing rows along the stalk. Maize is the world's leading cereal after rice and wheat. Hence maize is not considered a pest anywhere in the world.

C) Description of the donor organism(s);

Donor organism used to develop NK 603 x T25, *Naturally occurring soil borne bacterium* that produces crystal- like proteins ('Cry' proteins). Cry proteins binds to specific receptors.

D) Description of the genetic modification(s);

Maize NK 603 and T25 were combined by conventional crossing to produce maize NK 603 x T25 without new combinations being involved. Maize NK603 x T25 contains several genetic elements of bacterial origin. These are (1) the coding sequence of the CP4 epsps gene from *Agrobacterium sp. CP4*; (2) the coding sequence of the pat gene from *Streptomyces viridochromogenes*; (3) two nopaline synthase (nos)-terminator sequences, each with a length of 300 bp, from the Ti plasmid of *A. tumefaciens*; (4) a sequence of 665 bp of the 3' prime end of the β -lactamase gene as is present on plasmids of *Escherichia coli*; and (5) two sequences of 611 bp and 1 176 bp from the pUC cloning vector used in *E. coli*, the latter sequence including the origin of replication (ori). Bioinformatic analyses confirmed, except for the pat gene, high sequence identities between the above-mentioned sequences and the origin from which they were derived. Owing to codon optimisation, the pat gene showed insufficient sequence identity with bacterial sequences to facilitate homologous recombination.

Genetic elements in the expression cassettes of the events stacked in maize NK603 x T25

Event	Promoter	5' Leader	Transit peptide	Coding region	Terminator
NK603	P-Ract1 (<i>Oryza sativa</i>)	I-Ract1 (<i>O. sativa</i>)	TS-CTP2 (<i>Arabidopsis thaliana</i>)	CP4 epsps (<i>Agrobacterium sp.</i>)	nos (<i>Agrobacterium tumefaciens</i>)
	P-e35S	I-Hsp70 (<i>Zea mays</i>)	TS-CTP2 (<i>Arabidopsis thaliana</i>)	CP4 epsps I214p (<i>Agrobacterium sp.</i>)	nos (<i>Agrobacterium tumefaciens</i>)
	T25(a)	35S (<i>CaMV</i>)	- (<i>Streptomyces viridochromogenes</i>)	<i>pat</i>	35S (<i>CaMV</i>)

(a): The insert also contains the following elements: 616 bp of the pUC18 cloning vector including 5 bp of the *bla* gene at the 5' of the expression cassette; and 1 841 bp of the pUC18 plasmid including a 665-bp 3' fragment of the *bla* gene and the ori, and 346 bp of the 35S promoter at the 3' end of the expression cassette. The remainder of the *bla* gene (about 25 %) is not present in the insert. No element was specifically introduced to optimize expression.

E) Characterization of the genetic modification(s);

PCR and Southern Blot.

F) Safety assessment:

a) Expressed substances (non-nucleic acid substances);

Toxicity: The two-event stack maize did not show any compositional difference from its conventional counterpart that would require further assessment as indicated in the EFSA report no. 13(7):4165, page 13.

Allergenicity: the EFSA GMO Panel previously evaluated the safety of the CP4 EPSPS and PAT proteins, and no concerns about allergenicity were identified in the context of the applications assessed. Therefore, no indications of safety concerns regarding the overall allergenicity of maize NK603 × T25 have been identified so far.

b) Compositional analyses of key components;

Likelihood of adverse effects being realized is considered low because:

- Hazards associated with NK603 × T25 are no greater than those associated with conventional maize-So hazard characterization cannot change as a result of containing such genes as food, feed or processing and commercial release. The safety assessment identified no concerns regarding the potential toxicity of the newly expressed proteins CP4 EPSPS and PAT in maize NK603 × T2
- Dispersal and survival characteristics have not changed in comparison to the conventional counterpart.
- Invasiveness of natural environments and persistence in the environment has not changed in comparison to the conventional counterpart. 4114 was agronomically comparable to the conventional maize.

c) Evaluation of metabolites;

These are the same as the conventional counterpart. The intended trait of maize NK603 × T25 is herbicide tolerance, with no intention of altering the nutritional parameters. Comparison of maize NK603 × T25 composition with that of its conventional counterpart did not identify differences that would require a safety assessment as found by EFSA.

d) Food processing;

Same as the conventional counterpart. No alterations with heat- Stable

e) Nutritional modification;

Metabolites in the modification are not shown as there are the same as the conventional counterpart so no recommendations other than procedures that might apply to the conventional maize.

G) Other considerations

Agronomic and phenotypic characteristics are unchanged in maize NK603 × T25.

In conclusion the objective of each safety assessment is to provide a guarantee, in the light of the best available scientific knowledge, that the food does not cause harm to animal or human health and the biodiversity when prepared, used and/or eaten according to its intended use. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In principle, therefore, the result of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed and if so to make well-informed and appropriate decisions.

Public Consultation/Comments;

Nothing has been received so far after the advert was placed in the media-National and Daily mail.