

SUMMARY OF FOOD SAFETY ASSESSMENT FOR DP4114

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 DP 4114 was *Bacillus thuringiensis (Bt)*, 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);

Bt corn was created by inserting selected cry genes into the corn plant. Therefore, DP 4114 was genetically modified to produce the *cry1F*, *cry 34Ab1*, *cry35Ab1* and *pat genes*. The *cry1F* gene derived from the bacterium *Bacillus thuringiensis* sub sp. *aizawai*. This gene encodes a Cry1F insecticidal protein that controls specific lepidopteran pests on corn.

4114 maize was produced using *Agrobacterium tumefaciens* mediated transformation of Pioneer proprietary inbred line PHWWE(Pioneer 2011) The *A.tumefaciens* strain LBA4404 used to develop 4114 was made non-pathogenic by removing tumor inducing (Ti) DNA sequences. The disarmed *A. tumefaciens* carried a binary plasmid vector PHP27118. In vitro selection of transformation events was based on tolerance to the herbicide bialaphos which is rendered nontoxic to plant tissues by the presence of PAT proteins. The T-DNA had four expression cassettes: *cry1F*, *cry 34Ab1*, *cry35Ab1* and the *pat genes* cassette.

Its important to note that in addition to the above genetic elements the inserted T-DNA also contains short noncoding DNA sequences called polylinkers which contain restriction enzyme recognition sites for cloning purposes.

E) Characterization of the genetic modification(s);

Southern blot analysis shows a single intact PHP27118 T-DNA (Pioneer 2011) inserted into the genome of 4114 maize and no region from the back borne plasmid PHP27118 was inserted. Event specific and gene specific end point PCR analysis for several generations was used to determine the stability of the introduced genes.

F) Safety assessment:

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

Toxicity: There are no known adverse effects detected based on extensive characterization. Agrobacterium- mediated plant transformation has been used widely for decades and has no known effects. The donor organism for the *cry1F*, *cry 34Ab1*, *cry35Ab1* and the *pat* genes are soil inhibiting bacteria. Neither of these bacteria are plant or human pathogens. Secondly the Cry1f, Cry 34Ab1, Cry35ab1 and the PAT proteins encoded by these genes do not cause disease or production of infectious agents in plants. The cauliflower mosaic virus (CaMV) in the promoter and terminator for the *pat* gene also do not cause disease symptoms in plants nor encode for infectious agents.

b) Compositional analyses of key components;

Likelihood of adverse effects being realized is considered low because:

- Hazards associated with 4114 are no greater than those associated with conventional maize-So hazard characterization cannot change as a result of containing Cry genes as food, feed or processing and commercial release. The comparators were non-transgenic near-isoline maize lines with about 99% genetic similarity to 4114 maize in compositional comparisons.
- 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. Therefore, a comprehensive evaluation of 4114 maize and controls showed no biologically meaningful differences for grain and forage compositions either for major nutrients(Pioneer 2011, Table 15-19, pp 104-117) or key nutrients in maize.

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

None

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.