

Guideline for Food Safety Assessment of Foods Derived from Genetically Modified Plants with Stacked Traits

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(In case of any discrepancy between the Chinese text and the English translation thereof, the Chinese text shall govern.)

I. This Guideline applies only to foods produced using genetically modified plants with stacked traits obtained through conventional breeding between genetically modified plants that are already approved.

II. Classification of genetically modified plants with stacked traits:

A) Category I: plants with two or more traits that are unrelated.

B) Category II: plants with two or more traits that are related but with different modes of action.

C) Category III: plants with two or more traits that function in the same biosynthetic pathway.

III. Food safety assessment of foods derived from genetically modified plants with stacked traits belonging to category I and II.

A) The following bridging studies would need to be carried out to confirm that the stacked product is derived from the combination by traditional breeding of the single genetically modified events.

a. molecular characterization: a fingerprint-type Southern blot analysis, in comparison to the parental lines;

b. information on the expression of new proteins: analysis of gene expression in the stacked product to confirm that gene expression in relevant tissue(s) is comparable to that in the single genetically modified events; and

c. compositional analysis and agronomic variables: the compositional and agronomic analysis for the stacked product would be undertaken over a single growing season (4 sites), and relevant comparisons would be made either with the single-event genetically modified plants or with the non- genetically modified control of comparable genetic background.

B) Protein safety evaluation and animal feeding studies would need to be

conducted when necessary.

- a. If no changes to protein mode of action can be expected in the stacked product, no additional safety evaluation of the proteins and animal feeding studies would be required.
- b. If an interaction between the introduced proteins affecting their mode of action is expected, the need for additional studies should be evaluated on a case-by-case basis.

IV. Foods derived from genetically modified plants with stacked traits belonging to category III are considered as new genetically modified foods. A complete food safety assessment carried out in accordance with DOH guidelines is required.

V. Review process

Recognizing the rapid pace of development in the field of biotechnology, the approach to food safety assessment of foods derived from modern biotechnology should be reviewed when necessary to ensure that emerging scientific information is incorporated into the risk analysis. When new scientific information relevant to a risk assessment becomes available the assessment should be reviewed to incorporate that information and, if necessary, risk management measures adapted accordingly.