

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

EFSA GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GM PLANTS CONTAINING STACKED TRANSFORMATION EVENTS

1. The attached guidance document was published by EFSA on 25 July and sets out the information that is required when assessing plants that contain two or more "stacked" events. The GMO Panel confirms that plants containing stacked events will be assessed on a case by case basis and, in addition to consideration of the individual events, the assessment will focus on
 - (a) stability
 - (b) expression of the events; and
 - (c) potential interactions between the events.
2. The document details the specific information that is required in order to examine these factors in terms of molecular analysis, compositional analysis, safety assessment (food and feed) and environmental risk.
3. This document will be used by EFSA's GMO Panel when reviewing and updating its current Guidance Document for risk assessment of genetically modified plants and derived food and feed.
4. EFSA's approach is consistent with the conclusions reached by the ACNFP at its meeting in July 2003, when the Committee advised that it was not sufficient to rely on data on the parental lines and the potential for interactions between the sets of inserted genes should be examined on a case by case basis. This type of approach was subsequently adopted by EFSA's GMO Panel and was endorsed by the ACNFP in July 2005.

**Secretariat
September 2007**

Annex attached:

Annex 1: Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events (16 May 2007)
Available from:
http://www.efsa.europa.eu/EFSA/ScientificOpinionPublicationReport/efsa_locale-1178620753812_GuidanceDocuments.htm

Guidance Document of the Scientific Panel on Genetically Modified Organisms
for the risk assessment of genetically modified plants containing stacked
transformation events

Adopted on 16 May 2007