Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Innspill EFSAnet 11/06-08

Maishybrid Bt11 x MIR604
EFSA/GMO/UK/2007/50

COMMENTS OR OBJECTIONS TO THE PLACING ON THE MARKET OF A GMO UNDER REGULATION 1829/2003

A. General comments

The extensive labeling of basic biosafety data related to the biology of the corn hybrid as "Confidential business information (CBI)" is unacceptable.
This unacceptable practice limit independent verification and access to data on the: protein level of the EPSPS in the recombinant plant, details on the comparative Southern-blot analyses, expression levels of the transgene-encoded proteins in plants grown under various conditions, and for data from the compositional analysis. Most applications do not contain CBI claims on such data, and it is unclear how these data exhibit high value to competing companies given the broad intellectual property rights protection in place for the use of these traits.

Indiscriminate use of CBI claims is in direct conflict with and hinders a transparent risk communication, creating unnecessary insecurity regarding the application. Thus, the applicant must remove the CBI claims from most if not all parts of the application. Remaining CBI claims, if any, needs to be justified by an explicit and specific statement on why such claims are necessary.

D, 07.01. Comparative assessment

No compositional analysis of Bt11 x MIR604/MIR604xGA21 maize, but only of the triple stack Bt11 x MIR604 x GA21 is included in application EFSA/GMO/UK/2007/48/ EFSA/GMO/UK/2007/50. In this regard, the applicant refers to the EFSA Guidance Document for the risk assessment of stacked transformation events (EFSA 2007), that “as long as each event in the highest number of stacked events has been risk assessed the risk assessment of the stacked events might also be applicable to GM stacks containing fewer of these events”. However, in line with the case-by-case principle of the risk assessment outlined in European regulations, we highly recommend that the applicant should also conduct and

submit a sufficient analysis with Bt11 x MIR604/MIR604xGA21 maize in order to receive robust data on the actual composition in the maize hybrid. With regard to a final assessment, further information is required, because the information provided is not considered sufficient to support the conclusion of a substantial equivalence of Bt11 x MIR604/MIR604xGA21 maize and conventional maize, which is the basis of further conclusions in application EFSA/GMO/UK/2007/48/ EFSA/GMO/UK/2007/50. The applicant should be asked to provide a robust and reliable data basis for composition to assess potential interactions between the parental events. Plant material should be sampled during a minimum of three growing seasons and at six locations representing different environmental conditions. The environmental conditions should be documented and provided with the application. A summarising statistical analysis should address the between-site variation of all parameters. According to the EFSA Guidance Document for the risk assessment of stacked transformation events (EFSA 2007), appropriate comparators for the GM plant containing stacked events should include parental GM lines and isogenic lines. The applicant is asked to include the parental GM lines Bt11 maize, MIR604 maize /MIR604 maize, GA21 maize in the study design at the same study.

7.9 Allergenicity

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Scientific studies, also very recent ones, have shown that the Cry1Ac protein is a potent systemic and mucosal adjuvant, which is an enhancer of immune responses. The GMO Panel of the Norwegian Scientific Committee for Food Safety find it difficult, based on the available data, to assess whether kernels from maize Bt11 x MIR604 may cause more allergenic reactions than food and feed from unmodified kernels. As the different Cry proteins are closely related, and in view of the experimental studies in mice, the GMO Panel finds that the likelihood of an increase in allergenic activity due to Cry1Ab and mCry3A protein in food and feed from maize Bt11 x MIR604 cannot be excluded. Thus, the Panel's view is that as the adjuvant effect of Cry1Ab and mCry3A with reasonable certainty cannot be excluded, the applicant in relation to a possible adjuvant effect of Cry1Ab and mCry3A must comment upon the mouse studies showing humoral antibody response of Cry1A proteins. Further, although the Cry1Ab and mCry3A protein is rapidly degraded in gastric fluid after oral uptake, there is also the possibility that the protein can enter the respiratory tract after exposure to e.g. mill dust. Finally, rapid degradation is no absolute guarantee against allergenicity or adjuvanticity.

References:

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