

# Innspill til EFSA GMO Extranet

## Søknad EFSA/GMO/NL/2011/92 – maishybrid 1507 x 59122 x MON810 x NK603

### D,07.08

#### Toxicology

The applicant has performed acute testing separately for each Cry protein. However, the doses vary from 576 to 2700 mg/kg bw. Standard test dose according to OECD guideline 401 is up to 2000 mg/kg bw or to a toxic effect occurs. Moreover, the applicant has not performed acute studies using the combination of all Cry proteins to detect possible combinatorial effects as being either additive or synergistic. Relevant feeding studies with the maize hybrid in domestic animals including farm fish and mammals have not been performed. A 90-day toxicity study with the maize hybrid should have been performed according to OECD guideline 408 following the guidance for a repeated dose 90-day toxicity study as provided by EFSA (EFSA 2011).

#### Reference

EFSA (2011) Scientific Opinion of the Scientific Committee on guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. EFSA Journal 9(12):2438

### D,07.09

#### Allergenicity

According to Table 30 in the application, EFSA/GMO/NL/2011/92, maize consumption is as high as 150 g/person/day in some European countries, for instance Italy. Endogenous allergens (lipid transfer protein and trypsin inhibitor) in maize have been reported in human serum samples from persons with maize allergy (Pastorello et al. 2000, 2003). There is a possibility that Cry proteins may increase intestinal epithelial permeability and thus allow potential bystander allergens to induce an allergic reaction. The quadruple maize hybrid contains four different Cry proteins. It cannot be excluded that the combination of Cry proteins in this manner may exert an adjuvant effect on the intestinal epithelium by increasing its permeability (Norwegian Scientific Committee for Food Safety 2012).

#### References

- Norwegian Scientific Committee for Food Safety (2012) Health risk assessment of the adjuvant effects of Cry-proteins in GM food and feed.  
[http://www.vkm.no/eway/default.aspx?pid=277&trg=Content\\_6504&Main\\_6177=6504:0:31,2365&Content\\_6504=6187:1914443::0:6271:1:::0:0](http://www.vkm.no/eway/default.aspx?pid=277&trg=Content_6504&Main_6177=6504:0:31,2365&Content_6504=6187:1914443::0:6271:1:::0:0)
- Pastorello et al. (2000) The maize major allergen, which is responsible for food-induced allergic reactions, is a lipid transfer protein. *J. Allergy Clin. Immunol.* 106:744-751.
- Pastorello et al. (2003) Lipid-transfer protein is the major maize allergen maintaining IgE-binding activity after cooking at 100 degrees C, as demonstrated in anaphylactic patients and patients with positive double-blind, placebo-controlled food challenge results. *J. Allergy Clin. Immunol.* 112:775-783.