

Innspill til EFSA GMO Extranet

Søknad EFSA/GMO/DE/2010/82 – MIR162

A. General comments

The extensive labelling of basic biosafety data related to the biology of the maize MIR162 as "Confidential business information (CBI)" is unacceptable.

This practice limit independent verification and access to data on the: protein level of Vip3Aa20 and PMI 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 7.09 Allergenicity

According to the applicant the epitope test shows that Vip3Aa20 protein does not share structurally and immunologically relevant amino acid sequence similarities with known allergens, and that the Vip3Aa20-protein has no similarities to IgE epitopes of allergenic proteins. However, Vip3Aa-proteins bind in a similar way as Cry-protein to receptor(s) in epithelial cells in insect larvae gut (Sena *et al.* 2009, Abdelkefi-Mesrati *et al.* 2010). Due to uncertainty about the nature of the receptor, it should be characterized to ensure that these are not similar to human receptors in the intestine.

References:

Abdelkefi-Mesrati, L., Boukedi, H., Dammak-Karray, M., Sellami-Boudawara, T., Jaoua, S. & Tounsi, S. (2010).
Study of the *Bacillus thuringiensis* Vip3Aa16 histopathological effects and determination of its

outative binding proteins in the midgut of *Spodoptera littoralis*. J. Invertebrate Pathology – *in press*.

Sena, J.A.D., Hernandez-Rodriguez, C.S. & Ferré, J. (2009). Interaction of *Bacillus thuringiensis* Cry1 and Vip3A proteins with *Spodoptera frugiperda* midgut binding sites. Appl. Environ. Microbiol. 75, 2236-2237.