

February 24<sup>th</sup> 2005**Maize MON863 x MON810,****EFSA/GMO/2004/03**

Comments to EFSA concerning genetically modified maize MON863xMON810 from the Norwegian Scientific Panel on Genetically Modified Organisms.

Vazques-padron et al have shown that intragastric administration of crystalline and soluble Cry1Ac induced systemic and secretory antibody response, i.e. they detected high levels of systemic IgG and IgM, and secretory IgA antibodies. After intragastric immunization with crystalline Cry1Ac together with either hepatitis virus antigen or bovine serum albumin, they observed adjuvant effect on the anti-Cry1A mucosal immune response.

The GMO Panel finds it difficult to assess whether the genetically modified maize MOM863xMON810 is more allergenic than unmodified control plants. As the amount of Cry3Bb1 is about 60 µg/ g fresh weight (Table 3, page 15, Part II, Summary (2004), see References), the Panel requests that Monsanto comments these publications, and that Monsanto also comments the possibility for an adjuvant response following the intake of maize products containing active Cry1Ab and Cry3Bb1 proteins.

**References:**

Part II, Summary (2004), Application for authorization of MON863xMON810 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed. Monsanto Company.

Prasad S.S.S.V. & Shethna, Y.I. (1975) Enhancement of immune response by the proteinaceous crystal of *Bacillus thuringiensis* var *thuringiensis*. *Biochim. Biophys. Res. Commun.* 62, 517-521.

Vazquez-Padron RI. Martinez-Gil AF. Ayra-Pardo C. Gonzalez-Cabrera J. Prieto-Samsonov DL. de la Riva GA. (1998) Biochemical characterization of the third domain from *Bacillus thuringiensis* Cry1A toxins. *Biochemistry & Molecular Biology International.* 45(5):1011-20.

Vazquez RI. Moreno-Fierros L. Neri-Bazan L. De La Riva GA. Lopez-Revilla R. (1999) *Bacillus thuringiensis* Cry1Ac protoxin is a potent systemic and mucosal adjuvant. *Scandinavian Journal of Immunology.* 49: 578-84.

Vazquez-Padron RI. Gonzales-Cabrera J. Garcia-Tovar C. Neri-Bazan L. Lopez-Revilla R. Hernandez M. Moreno-Fierro L. de la Riva GA. (2000a). Cry1Ac protoxin from *Bacillus thuringiensis* sp. *kurstaki* HD73 binds to surface proteins in the mouse small intestine. *Biochemical & Biophysical Research Communications*. 271:54-8.

Vazquez-Padron RI. Moreno-Fierros L. Neri-Bazan L. Martinez-Gil AF. de-la-Riva GA. Lopez-Revilla R.( 2000b). Characterization of the mucosal and systemic immune response induced by Cry1Ac protein from *Bacillus thuringiensis* HD 73 in mice. *Brazilian Journal of Medical & Biological Research*. 33,147-55.