

Innspill til EFSA GMO Extranet søknad EFSA/GMO/UK/2009/76

15. mai 2010

D.07.08

Toxicology

In the acute toxicity studies in mice, the applicant has used single doses of Pj Δ 6D- and Nc Δ 15D-protein (4.7 mg/kg body weight and 37.3 mg/kg body weight, respectively). According to the OECD guideline 401 "Acute oral toxicity", a limit test at one dose level of at least 2000 mg/kg bodyweight should be carried out. In the OECD guideline 423 it is recommended to use 3 doses.

According to toxicological practice NOAEL is the lowest dose where there is no adverse effect, i.e. at least one higher dose has to give an adverse effect. The Norwegian GMO Panel is of the opinion that the applicant, in order to exclude any acute health effects of the newly introduced proteins, should have performed an acute toxicity test on mice with at least 2000 mg/kg bodyweight with purified Pj Δ 6D- and Nc Δ 15D-protein.

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Allergenicity

According to the technical dossier, the accurate pH level in the pepsin test is not given. The pH level of the gastric acid of children below the age of two is higher than the general population. As these proteins can be a part of the food of young children or patients with ulcer (Utersmayer & Jensen-Jarloom 2008), the applicant is asked to give the accurate pH level of the pepsin test.

According to the applicant, the epitope test show that there are no similarities to IgE epitopes of allegetic proteins. The Norwegian GMO Panel asks the notifier to elaborate whether these proteins have immunogenic potential to elicit strong IgG-response.