Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Comments to EFSA/GMO/NL/2004/02

The risk assessment is dependent on sufficient analytical data to be available to allow the comparison to be made, i.e. the assurance of safety is relative to the components assessed for the particular comparator. We have evaluated the documentation presented, and have found that it is insufficient to perform a risk assessment. More information are therefore needed in order to determine substantial equivalence, and to determine any unexpected effects, e.g. pleiotropic effects, due to the genetically modification.

Compositional analyses:

Following documentations are lacking: analysis of the mineral Selenium, Vitamins A, B6, Niacin, Pantothenic acid, the secondary plant metabolite Ferulic acid, anti-nutrients DIMBOA and MBOA, and the metals Cadmium, Chromium, Mercury and Lead.

Statistically analysis:
In the report by The Nordic Council of Ministers called “Safety Assessments of Novel Food Plants - Chemical Analytical Approaches to the Establishments of Substantial Equivalence”, it is recommended that a sufficient number of samples should be analysed to allow for a proper statistical evaluation. Spread of measurements for the individual parameters should be comparable for the genetically modified plant and the non-modified plant, and a value range of 20% was suggested that should meet most of the natural variation range for the measured compounds. We have found that the statistical analysis from the different trial location is missing. The data from each location must be evaluated separately, and the mean values, standard deviation and the coefficient of variance “within location” for each component must be calculated.