

## Høringssvar til EFSA: Risikovurdering av mat og fôr fra genmodifiserte dyr

Høringssvaret ble lagt inn på EFSA's nettsider 30.9.2011. Kommentarene ble lagt inn under de paragrafene de hører til.

### **Background as provided by EFSA**

When doing risk assessments for genetically modified animals, ethical and socio-economic issues must be taken into account in the assessment. Issues concerning ethics, sustainability and benefits to society are just as important here as when it comes to GM plants. Other important concerns than for GM plants also arise.

#### **1.1.2. Hazard characterization**

Second paragraph:

It is absolutely essential that:

- a) the hazard characterization work is performed by independent institutions and investigators.
- b) it is demanded, without exceptions, that the applicants are submitting "suitable test materials" to these independent institutions and investigators.

#### **1.1.3. Exposure assessment**

Line 5: add "route", i.e. "...significant source and route of exposure."

#### **1.1.4. Risk characterisation**

This section needs a definition of the concept "risk"! Section heading should be "Risk identification and characterisation"

#### **1.2.**

f. should be made broader by phrasing it: ".....bioactivity and immunogenicity (including allergenicity) of gene products,....."

### **2.1. Hazard identification**

When developing guidance for the risk assessment of food and feed from GM animals EFSA should build upon what is already done with the guidance document for food and feed for genetically modified plants and the experience that has been gained.

Making tests that are scientifically valid is essential. Food safety experiments should be designed to give information about long-term effects such as potential allergies or effects on gut function.

Independent researchers and institutions should conduct the safety testing. It is a problem in terms of trust and credibility that the testing is conducted not by independent investigators, but by the industry itself. However, the producers/applicants should still cover the expenses for the testing. Furthermore, it is absolutely imperative that applications are not even considered until the applicant has submitted the biological materials necessary for proper safety testing, including conventional counterparts.

#### **2.1.2.1**

e. Viruses are not microorganisms, and accordingly this section should be phrased: "when microorganisms or virus vectors are used,..."

#### **2.1.2.2.2.**

NB! Point g. should name the types of "further analyses" that "may be needed". Profiling techniques should in our opinion be compulsory!

A new point h should be added, e.g.:

"h. microRNAs produced from any of the inserted DNA sequences"

#### **2.1.2.2.3.**

Page 15, third paragraph, line 5 "endogenous RNA(s), protein(s) and or specific metabolite(s)". Add: "by relevant profiling techniques."

#### **2.1.2.3.**

Third bullet point: "...new toxins or immunogens/allergens."

#### **2.1.4.3 Assessment of newly expressed proteins**

For studies of the potential toxicity of a newly expressed protein, the protein itself must be tested. Proteins produced by microorganisms may differ in amino-acid sequence, post-translational modification, immunological reactivity, enzymatic activity etc.

Addition to First paragraph, first sentence: "...should be assessed, *and also whether these proteins form complexes with proteins or other endogenous macromolecules.*"

#### **2.1.4.6 Assessment of the whole GM food/feed derived from GM animals**

As for GM plants toxicological tests should be done on food from the GM animal.

Characterization of the newly expressed proteins and toxicological studies of single proteins are not sufficient.

Under the condition that the average lifetime expectancy for a lab rat is 2,5-3 years, a feeding period of 90 days constitutes approximately 1/10 of the test animal lifetime. In humans chronic disease may develop over a timespan of 20-50 years from triggering exposure or start of continuous exposure to debut of symptoms. It is essential that the recommended duration of feeding studies be adjusted according to this. Multi-generational lifetime studies should be required in some cases. Feeding studies should include testing of antibodies directed against the protein(s) expressed from the transgene(s).

#### **2.1.5.1 Assessment of immunogenicity/allergenicity of the newly expressed protein**

For studies of the potential allergenicity of a newly expressed protein, the protein itself must be tested. Proteins produced by microorganisms may differ in amino-acid sequence, post-translational modification, immunological reactivity, enzymatic activity etc.

If the protein(s) expressed from the transgene(s) give rise to humoral or cellular immune reactions in the humans or animals exposed through consumption, skin contact or inhalation, this is a matter of concern whether the reactions are accompanied by symptoms

or not. Hence, tests for specific antibodies and lymphocyte reactivity to the transgenic protein(s) should always be included.

### **2.1.6 Nutritional assessment**

Feeding studies for nutritional assessments should always be conducted because composition analyses based on total protein content, fat, vitamins etc may hide subtle, but biologically significant differences. Also complex formation between transgene and endogenous macromolecules may contribute. See also comments to chapter 2.1.2.2.2 on profiling techniques and microRNA .