EUROGROUP FOR ANIMALS

BRIEFING
February 2012

Animal welfare position on the obligatory use of the 90 day animal test for the authorisation of genetically modified food and feed

Overview

The Commission is presently drafting implementing rules concerning applications for authorisation of genetically modified food and feed, in accordance with regulation (EC) No 1829/2003. In the draft regulation, an issue of utmost animal welfare concern has been raised. The draft regulation calls for the obligatory use of an animal testing method which over many years has never yielded any additional significant or useful results. We strongly hope that the Commission has not bowed to pressure by certain member states to call for obligatory testing.

Our concerns

This risk assessment is currently carried out according to guidelines of European Food Safety Authority (EFSA). However, the proposed Implementing Regulation will drive the risk assessment. The issue is that the proposed regulation contains an obligation to always perform the repeated dose 90 –day oral toxicity study in rodents (Recitals 10, 11 and 12 and Annex II point 1.4.4.1). This test is designed to test the safety of simple substances for humans and animals. It involves subjecting the animals to repeat doses of a substance over a period of 90 days, resulting in high concentrations being fed which represent an unbalanced, unnatural diet. This making it difficult to compare results with the diet of humans. The test has always been carried out on a case-by-case basis determined by EFSA. The newly published EFSA guidance for risk assessment for food and feed from genetically modified plants (Published January 2012) places the repeated dose 90 –day oral toxicity study in rodents in a list of tests (OECD guideline 408) which may be selectively applied for toxicity testing. This guidance therefore maintains a case-by-case approach in order to decide whether a 90 days animal feeding study is needed.

From an animal welfare point of view it is important to maintain the case-by-case approach. Eurogroup finds the obligatory call a contradiction to the Commission's objective to reduce, refine and replace animal testing and to replace it with more modern, state-of-the-art science. There is no scientific reasoning behind the decision to make this test obligatory, it is purely political. In addition to the animal welfare concerns, it will add extra, unnecessary costs on industry.

Furthermore, the Commission wants to show it is flexible and for that reason has included a provision under Article 13 to review by 2016 the requirements of the 90 day study in case new scientific information is available. This will not solve the fundamental problem of additional testing. There is at the moment no scientific justification to impose the 90 day study in the first place. The Commission should rather focus on providing resources for the development of more state-of-the-art techniques which include the 3Rs, in particular testing strategies or tests based on 'omics' technology.

We urge Member States to carefully examine the draft regulation submitted by the European Commission and to support rules which keep the current situation, where a request to perform the 90 day study must in each case be based on a scientific opinion by EFSA.

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We call for Member States to support a decision which is driven by science and not by politics.

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Appendix

COMMISSION IMPLEMENTING REGULATION (EU) No …/..

of XXX

on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations (EC) No 641/2004 and (EC) No 1981/2006

(10) In accordance with the applicable guidance of the EFSA[1], the safety assessment of the genetically modified food or feed should include studies related to new components resulting from the genetic modification, the molecular characterisation of the genetically modified plant, the comparative analysis of the composition and the phenotype of the genetically modified plant compared to its conventional counterpart. Depending on the characteristics of the genetically modified plant and on the outcome of that first set of studies, the EFSA guidance indicates that it may be necessary to perform additional studies. In that respect, the EFSA considers that notwithstanding its limitations, a 90-day feeding study in rodents with whole food or feed is, when justified, the primary additional study to address uncertainties identified in the course of the safety assessment.

(11) It has, however, not been proved possible to define with the necessary precision the level of uncertainties which would require the submission of 90-day feeding studies in applications for genetically modified plants containing single transformation events. Therefore, in order to ensure a high level of protection of human and animal health, as well as to improve consumer confidence, such studies should be, for the time being, requested in all applications related to genetically modified plants with single transformation events and, where appropriate, on genetically modified plants containing stacked events.

(12) Studies to demonstrate that a genetically modified food or feed fulfils the requirements of Regulation (EC) No 1829/2003 involving the use of laboratory animals should be carried out in accordance with Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of the animals used for experimental and other scientific purposes[2] which will be repealed by Directive 2010/63/EU of the European Parliament and Council of 22 September 2010 regarding the protection of the animals used for scientific purposes[3], and should be kept to a minimum while ensuring an adequate demonstration of the safety of the genetically modified food or feed. The current uncertainties in relation to the need and design of 90-day feeding trials will be addressed by a large research project under the 2012 work programme of Theme 2 "Agriculture and Fisheries, Food and Biotechnologies" of the seventh Framework Programme for Research (FP7). The requirements regarding animal feeding trials in the context of GMO risk assessments should be reviewed in the light of the outcome of this project expected to be available by the end of 2015 at the latest. Other credible scientific knowledge which might be available at that time should also be taken into account.

Article 13
Review

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1 EFSA Journal 2011; 9(5):2150

2 OJ L 358, 18.12.1986, p. 1.

3 OJ L 276, 20.10.2010, p. 33.

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1. The Commission shall monitor the application of this Regulation, the developments in scientific knowledge on replacement, reduction and refinement of animal use in scientific procedures and the publication of new guidance from EFSA.
2. The Commission shall review the requirements of point 1.4.4.1 of Annex II on the basis of new scientific information. The results of this review shall be published by 30.6.2016 at the latest.

ANNEX II

SCIENTIFIC REQUIREMENTS FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED FOOD AND FEED

1.4.4. Testing of the whole genetically modified food and feed

The applicant shall primarily base its risk assessment of the genetically modified plant and derived food and feed on molecular characterisation, comparative agronomic, phenotypic and comprehensive compositional analysis, and the toxicological evaluation of the identified intended and unintended effects. Under the circumstances set out in points 1.4.4.1, 1.4.4.2 and 1.4.4.3 of this Section, specific toxicological studies with the whole genetically modified food and feed shall be carried out.

1.4.4.1. 90-day feeding study in rodents with whole genetically modified food/feed: sentinel study for toxicity and nutrition

The applicant shall include a 90-day feeding study with whole food and feed in rodents for the assessment of food and feed containing, consisting of or produced from genetically modified plants with a single transformation event or with stacked transformation events which are not obtained by conventional crossing of genetically modified plants containing a single transformation event.

In the case of stacked transformation events obtained by conventional crossing of genetically modified plants containing a single transformation event, a 90-day feeding study with whole food and feed in rodents shall be included for each genetically modified plant with a single transformation event of which it is obtained. An additional 90-day feeding study with whole food and feed in rodents with the genetically modified plant with the stacked transformation events shall be included where indications of potential adverse effects are identified during the assessment of (i) the stability of the inserts, (ii) the expression of the inserts and (iii) the potential synergistic or antagonistic effects resulting from the combination of the transformation events.

The protocol for 90-day feeding study in rodents with whole genetically modified food/feed shall be in compliance with the Guidance of the EFSA scientific committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed[4].

1.4.4.2. Animal studies with respect to reproductive and developmental toxicity testing

When information required in Sections 1.4.1, 1.4.2 and 1.4.3on the genetically modified food and feed suggest the potential for reproductive, developmental or chronic toxicity or in case of indications of adverse effects from the 90-day feeding study in rodents (such as functional and/or histological modifications of nervous, endocrine, reproductive or immunological tissues/organs), appropriate testing shall be performed. OECD protocols for reproductive, developmental and chronic toxicity testing (see Table 1 of Section 1.7) may be adapted for the purposes of testing the whole genetically modified food and feed.

Given that the 90-day feeding study in rodents is only designed to detect effects on adult reproductive organ weights and histopathology and that it does not detect other effects on reproduction or development, testing of the whole food and feed beyond a 90-day rodent feeding study shall be conducted where hazards in this respect have been identified.

[4] EFSA Journal 2011; 9(12):2438.