

GeneWatch UK comments on EFSA Draft Guidance on the risk assessment of food and feed from genetically modified animals

September 2011

BACKGROUND

The timing and purpose of this document are unclear. Production of GM mammals is likely to use cloning as a technique which potentially allows transgenic lines to be produced relatively quickly and cheaply, yet the use of cloning remains a subject of intense debate due to the many severe abnormalities and high abortion rate in offspring. EFSA should explain how this document relates to initiatives from the European Parliament regarding cloning and to the European Group on Ethics' Opinion on cloning. Since the production of multiple generations of animals is needed for the testing discussed in the report, this issue cannot be left to one side. Production of GM fish raises important issues about impact on wild populations. This is particularly the case for wild salmon populations. For example, the North Atlantic Salmon Conservation Organisation (NASCO) states in the Williamsburg Declaration: "*In view of the current lack of scientific knowledge on the impact of transgenic salmonids on wild salmon stocks, the use of transgenic salmonids should be considered a high-risk activity. There should be a strong presumption against any such use*". Yet, again, EFSA appears to want to begin at the point of assuming production is ethical and acceptable. This Guidance is premature until these important issues have been addressed.

INTRODUCTION

This section refers to enhanced nutritional characteristics and better resistance to pathogens as potential benefits of future applications, but the document is weak on the assessment of nutritional claims and says nothing about impacts on pathogens. Altered nutritional content can be harmful if safe upper levels of nutrients are exceeded and this can be an issue for some subpopulations but not others, so predicting impacts is notoriously difficult. As numerous recent trials of supplements, especially antioxidants, have shown, the net effect of altered nutrients on morbidity and mortality may be harmful, even when animal studies and observational evidence has predicted otherwise. This issue needs to be addressed. Altered disease transmission also has complex consequences, such as potential evolution of pathogens and viruses to become more virulent. Given the potential of many animal viruses to mutate and become dangerous to humans, this area also needs in-depth consideration.

GENERAL PRINCIPLES

Bees should be excluded from this guidance and treated separately as GM insects and invertebrates raise a whole range of additional issues which cannot be properly considered in this document. Rapid breeding and spread of such species leads to concerns about gene transfer, reversibility, and complex interactions between multiple species, pathogens and predators and prey. These issues may mean that open releases require international oversight.

FOOD AND FEED RISK ASSESSMENT

1.1.3 Objectives: Exposure assessment

Post-market monitoring for products with altered nutritional quality would not identify past problems found with supplements, such as increased mortality and cancer risk associated with high doses of beta-carotene (see Cochrane Review). Yet, inclusion of increased beta-carotene levels or other nutrients in food could lead to people being put at increased risk without their knowledge. The EC has yet to set upper safe levels for many nutrients due to lack of data. EFSA must explain how it will address this issue here, since animal studies are known to be inadequate. Vulnerable subpopulations may also exist (e.g. the elderly for folate, haemochromatosis patients for iron, babies and children).

1.2 Elements to be considered

Bioavailability of nutrients to humans, including impacts on vulnerable subpopulations, must be included. Altered disease transmission and any potential feedback to altered evolution of viruses or pathogens must also be listed.

2.1.2 Molecular characterisation.

Information on upper safe limits of any altered nutrients and on vulnerable subpopulations must be included. Expected impacts on pathogens must also be included.

2.1.3 Comparative analysis

Multigenerational data must be provided, including information on spontaneous abortions and stillbirths. Disease transmission must be included, including methods to model and validate long-term effects such as evolution of pathogens. For nutritionally-altered foods, the variety of human diets and the existence of vulnerable subpopulations must be considered. The inclusion of uptake of trace elements (p. 21) is welcome, but this will require testing in multiple environments (e.g. pigs eating different diets, fish grown in different aquacultures) as the availability of e.g. cadmium may vary. The potential of the animal to bioaccumulate substances such as heavy metals or radioactive substances should be part of the analysis. Data such as nutrient and anti-nutrient content versus time on feeding lot may be needed.

2.1.4 Toxicological assessment

The proposed assessment is insufficient to assess the potential effects of possible increased uptake of trace elements on human and animal health. Animal studies are often poor predictors of impacts on human health. Dose-response curves based on the totality of information available in the literature are needed. Lack of data and gaps and uncertainties should be explicitly identified.

2.1.6 Nutritional assessment

Animal studies are poor predictors of human nutrition. Reference should be made to the type of data required to substantiate food claims, such as impacts on human biomarkers and dose-response curves. This is particularly important where the nutritional content of food or feed is intentionally altered. The totality of evidence available to assess health impacts must be considered, e.g. data relevant to setting upper safe levels as nutrients, such as data available from clinical trials of supplements. Lack of data and gaps and uncertainties should be explicitly identified. Impacts on vulnerable populations must be explicitly considered. Impacts of altered feed composition on human

and animal nutrition must also take account of different management practices (e.g. significantly altered fat composition between grain-fed and pasture-fed meat).

2.2 Exposure assessment

Exposure assessments must take account of the variety of human and animal diets and the existence of vulnerable subpopulations.

2.3 Issues for risk characterisation

Altered biological pathways must be identified and gene-environment interactions assessed, since nutrient and trace metal levels may be affected by multiple pathways and vary in different environments. Information on risk characterisation of altered nutrients and altered pathogen transmission (including potential for pathogens to evolve in response to the genetic modification) must be included in this section.

ASSESSMENT OF ANIMAL HEALTH AND WELFARE

The inclusion of multi-generational studies is important, yet conducting these studies in themselves raises ethical issues. In circumstances where large numbers of deformed offspring, stillbirths and spontaneous abortions are expected (e.g. in farm animals) EFSA must explain why it believes such experiments are ethical in the first place. The issue of altered disease transmission and long-term potential consequences, such as the evolution of viruses, is entirely omitted but must be included in this section. Impacts on human health and welfare of relevant animal diseases (and their evolution) must also be considered.

POST-MARKET MONITORING

The inclusion of a requirement for traceability is essential. However, post-market monitoring is completely inadequate to identify nutritional problems in the general population or in vulnerable subgroups, for which observational data is notoriously unreliable. EFSA must develop the guidance to include pre-market assessment of such issues. It is difficult to understand why GM functional foods appear not to require human feeding trials, since human data is required under food claims legislation.