Animal Biotechnology

EFSA guidance document on GM animals

Antonio Fernandez Dumont
Scientific Officer EFSA

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SCIENTIFIC OPINION

Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects[1]

EFSA Panels on Genetically Modified Organisms (GMO) and Animal Health and Welfare (AHAW)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This document provides guidance for the risk assessment of food and feed containing, consisting of or produced from genetically modified (GM) animals, as well as for the health and welfare assessment of these animals, within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The assessment strategy seeks to deploy appropriate approaches to compare GM animals and derived food and feed with their respective comparators. The health status of a food/feed producing animal has traditionally been considered as an important indicator of the safety of derived foods/feed and therefore comparative analysis of the phenotypic characteristics of the GM animal with the traditionally-bred animal, including health and physiological parameters, is considered an important component in the risk assessment. The document addresses the molecular

https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2501

General principles for the Risk Assessment

- Aim of RA: to provide evidence on whether or not the GM animal-derived food/feed is as safe as the comparator(s)
- Substantial equivalence (WHO 1991): methods and approaches to compare the GMO and derived products with their comparator
- Assumption: traditionally-bred animals have a history of consumption as food/feed for consumers or animals
- Where no comparator(s) can be identified: a comprehensive safety and nutritional assessment of the GM animal-derived food/feed should be carried out
- Differences with GM plants: only allowing animals with acceptable health and welfare status to enter the food/feed supply is an essential step for ensuring safe food/feed

Hazard identification and characterisation

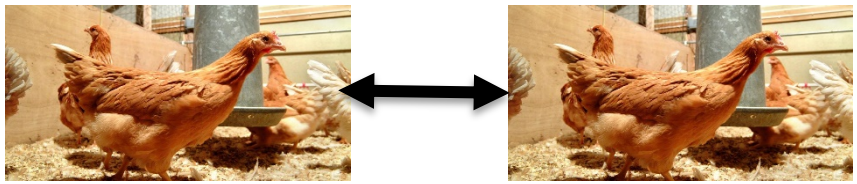
- **Molecular characterisation**
  - Providing data on the structure of the genetic modification, expression and stability of the intended trait(s) and indicating whether it raises safety issues

  - Including data of potential unintended proteins/products, new toxins or allergens, and the potential mobilisation of the insert
  - Evaluating the info considering its capacity to impact on human and animal health (toxicological/allergenicity/nutritional impact)

Hazard identification and characterisation

- **Comparative analysis**

Comparative approach



"non-GM" "GM"

- Identifying biologically relevant differences in phenotypic and compositional characteristics between the GM animal and its comparator(s)
- Taking into account natural variation
- Assessing differences with regards to their possible effects on both human and animal health (toxicological/allergenicity/nutritional impact)

Hazard identification and characterisation

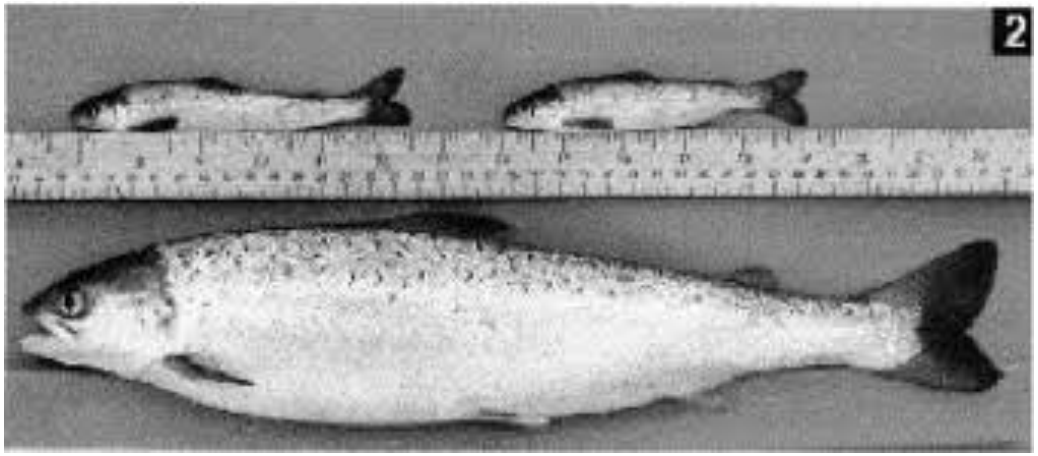
- **Toxicological/Allergenicity assessment**
  - Evaluating potential adverse effects identified in previous sections of the safety assessment
  - Assessing potential adverse effects of newly expressed protein(s) and other new constituents resulting from the genetic modification
  - Comparing natural constituents of the GM versus its comparator(s) and assessing potential differences
  - Identifying potential toxicological/allergenic adverse effects and investigating its intrinsic nature via *in vitro* and/or *in vivo* studies, whenever relevant

Hazard identification and characterisation

- **Nutritional assessment**
  - demonstrating that introducing the GM animal-derived food or feed into the market is not nutritionally disadvantageous to humans or animals
  - Assessing:
    - the nutritional relevance of newly expressed proteins and other new constituents
    - the changes in the levels of nutritionally important endogenous constituents in the GM animal-derived food/feed
    - the potential alterations in the total diet for the consumers/animals
    - that unintended effects of the genetic modification previously identified have not adversely affected the nutritional value of the GM animal-derived food/feed

Exposure assessment

- Estimating the expected intake is an essential element in the risk assessment of GM food/feed
- Also required for the nutritional evaluation
- Providing info on the intended function, the dietary role, and the expected level of use of the GM animal-derived food/feed product(s)

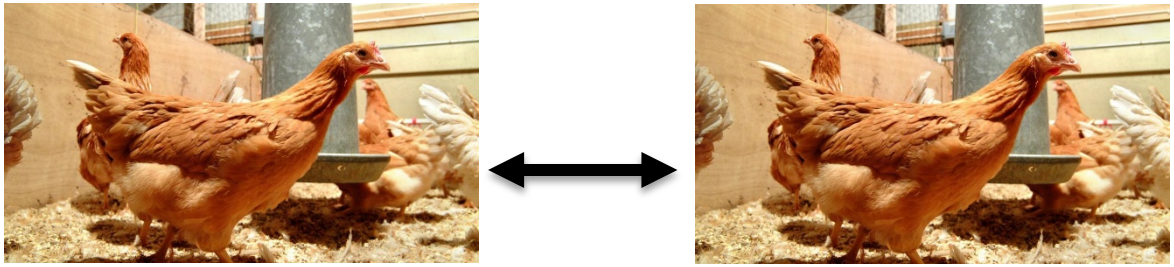


Risk characterisation/PMM

- Informing whether:
  - consumption of GM animal-derived foods/feed is as safe for humans/animals as the consumption of comparator(s)
  - the GM animal-derived food/feed is not nutritionally disadvantageous for the consumer/animal
  - the health of the GM animals is the same or no worse than its comparators
- A PMM should address the following questions:
  - is the product use as predicted/recommended?
  - are known effects and side-effects as detected during the pre-market risk assessment as predicted?
  - does the product induce unexpected side effects?

Concluding remarks

Comparative approach



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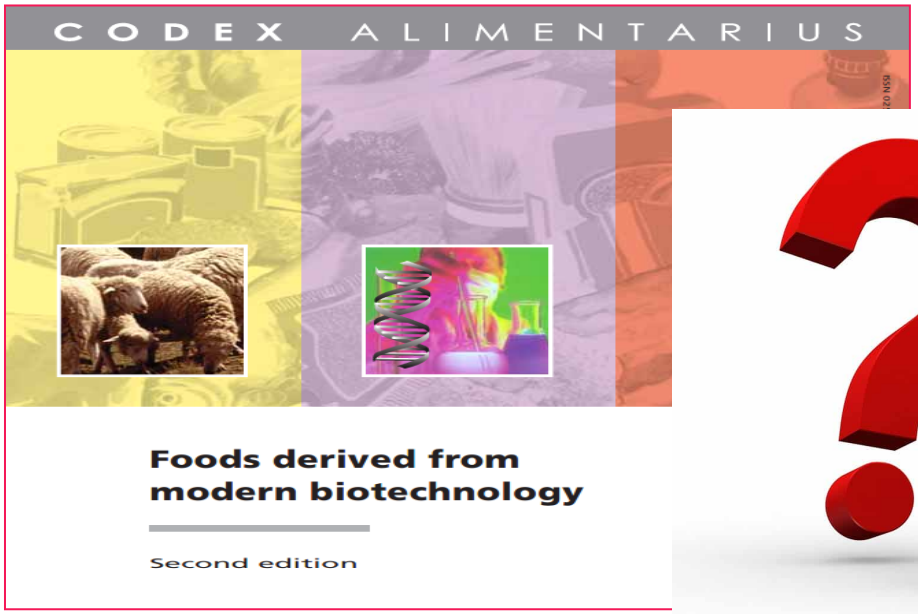

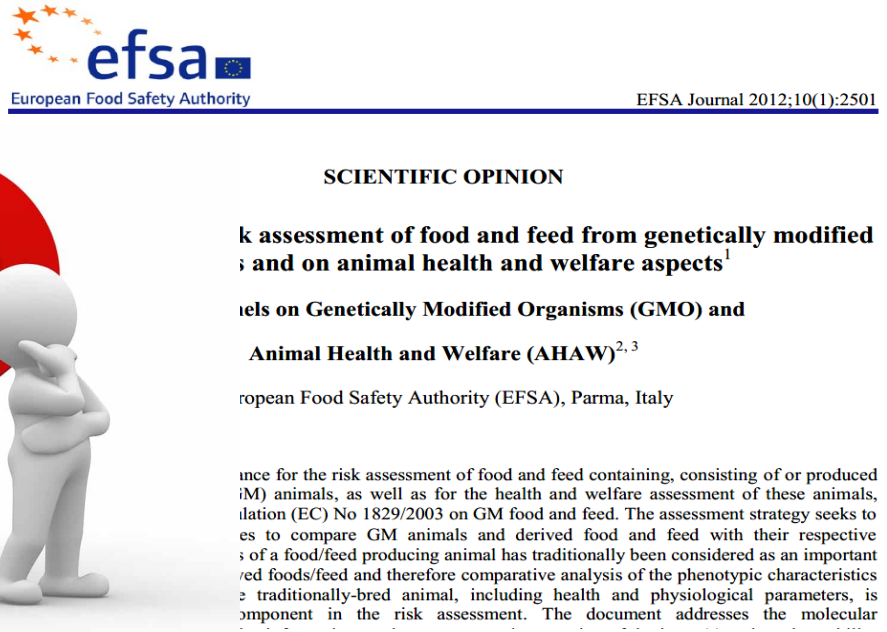

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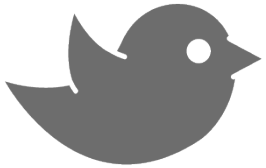

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