FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food/Feed Safety Assessment of Biotech Animals

Genetic engineering and genome editing

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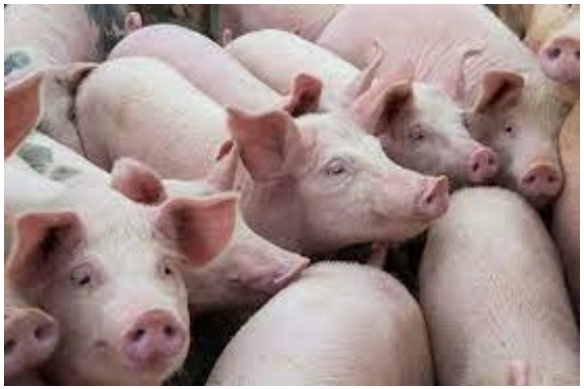
The Science, the Opportunities and Regulation of Animal Biotechnology:
Genetic Engineering (GE) and Genome Editing (GnEd)

Outline

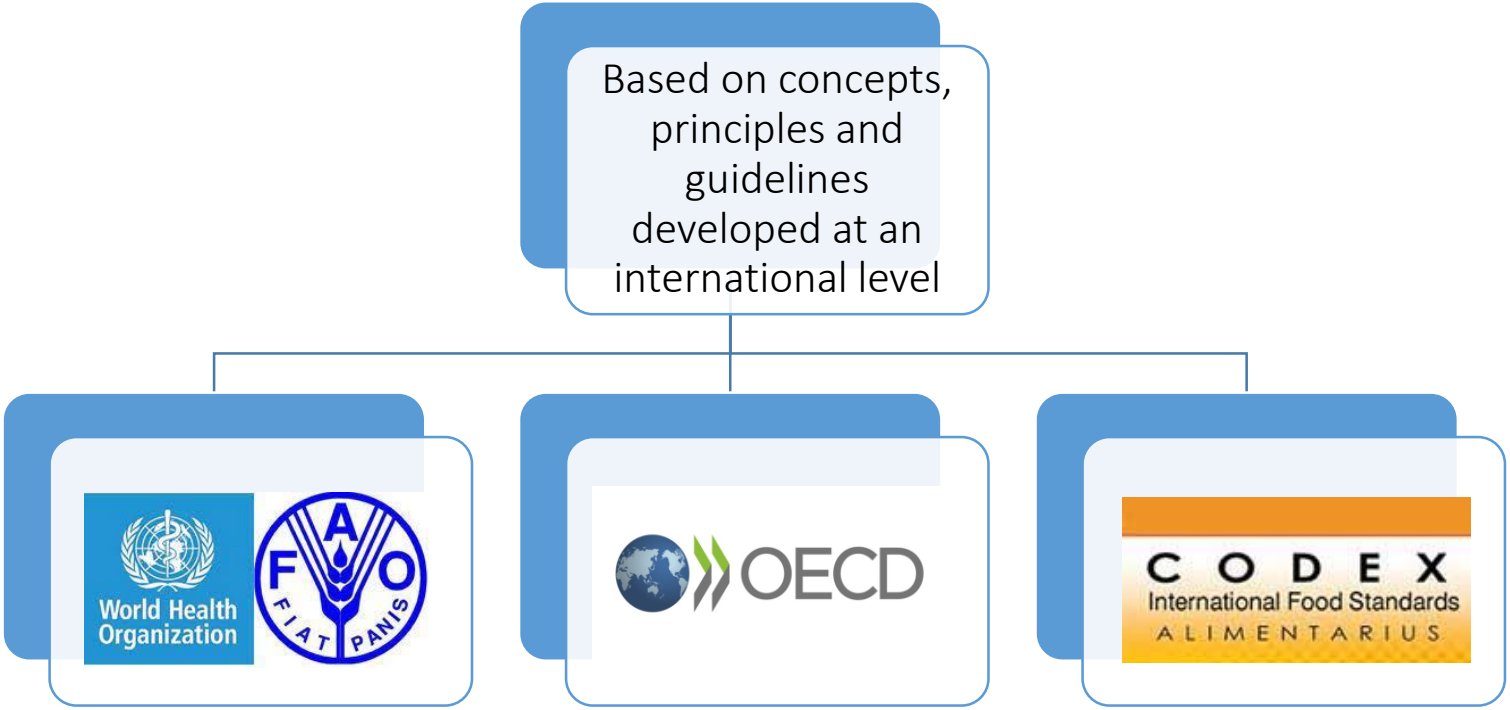
- Background
- Concepts and principles
- Key elements of the assessment
- Applying the safety assessment approach

Biotech animals as food/feed

- Limited regulatory experience assessing the safety of biotech animals for food/feed
- Limited examples of biotech animals that have received regulatory approval
  - AquAdvantage Salmon
  - GalSafe® Pig
- Some genome edited animals may be classified as not GMOs



Food safety assessment



Concepts, principles and guidelines

FOODS DERIVED FROM MODERN BIOTECHNOLOGY
Second edition

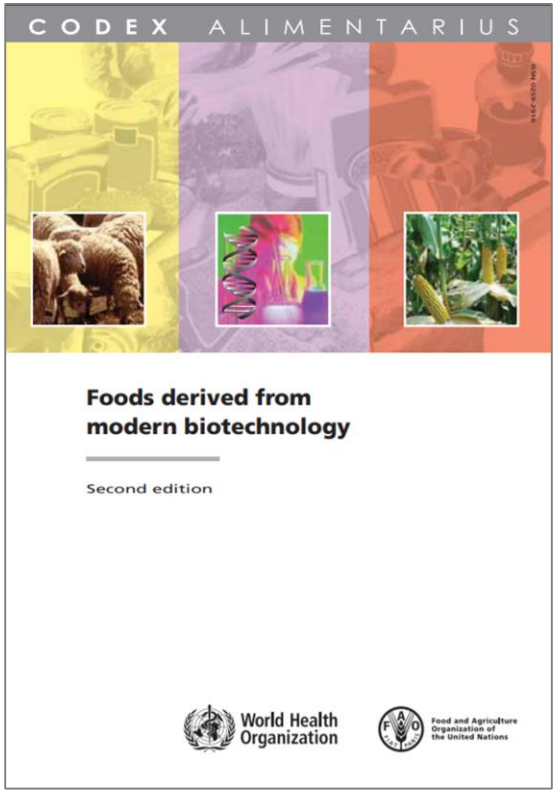
PREFACE

PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY
CAC/GL 44-2003

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS
CAC/GL 45-2003

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS PRODUCED USING RECOMBINANT-DNA MICRO-ORGANISMS
CAC/GL 46-2003

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS
CAC/GL 68-2008



Basic approach

Characterised by:

- Flexible, case-by-case assessment
- Consideration of the intended as well as the unintended effects
- Comparison to conventional counterpart with a history of safe use as food
- Identification of new or altered hazards

Key elements of the assessment

Phenotypic information

- Description of the host animal and its use in food
- Description of modified animal
- Health status of the modified animal

Molecular characterisation

- Description of the genetic modification
- Description of the methods used to produce the modified animal
- Characterisation of the genetic modification
- Stability of the introduced trait(s)

Assessment of new substances

- Assessment of potential toxicity or bioactivity
- Assessment of possible allergenicity

Whole food/feed assessment

- Compositional analysis
- Assessment of nutritional impact

Applying the safety assessment

- Designed for food from animals with a history of safe use as food
- Designed primarily for animals bearing heritable rDNA constructs
- Approach could be adapted to apply to food/feed from animals altered using other techniques, e.g. genome editing

Streamlining the approach

- Approach characterised by flexible, case-by-case assessment
- Intent is for the safety assessment approach to be modified to suit the type of food and specific genetic modification being evaluated.
- Implicit in this flexibility is that data requirements can be adjusted or simplified to suit the specific case under assessment without compromising safety.
- As familiarity increases, there is greater potential for streamlining of the assessment approach (increased regulatory experience, more examples)

Potential areas for streamlining

- Knowing when its appropriate to simplify an assessment is challenging with animals because of limited examples and regulatory experience
- Parts of the safety assessment that may be simplified:
  - phenotypic assessment, e.g. where the host has previously been used for other modifications
  - molecular characterisation, e.g. where the construct is one that has been previously used
  - assessment of new substances, e.g. where the modification does not result in expression of a new protein or the trait is one that has been previously assessed in a different line/species
  - compositional analyses where sample numbers are limited

In summary

- The safety assessment approach for animals is similar to that used for plants
- Very few examples of biotech animals for food use, and very limited regulatory experience in their assessment
- Some aspects of the food safety assessment of biotech animals may be more challenging compared to plants, e.g. compositional analysis
- The assessment approach is intended to be applied in a flexible way taking into account the type of food and the specific genetic modification

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