# CODEX Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Animals

## Session 1: Food safety aspects of regulations for genetically engineered/modified animals

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# Outline

- Background
- Scope of the Animal Guideline
- Key elements of the assessment approach
- Final word on applying the Animal Guideline

# Background

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS

CAC/GL 68-2008

**Developed by the *Ad hoc* Intergovernmental Taskforce on Foods Derived from Biotechnology**

- Adopted in 2008

**The Guideline applies to r-DNA animals in general**

- Does not focus on specific classes of animals – e.g. fish, birds etc.

**Plant Guideline used as a model**

- Deviations in language only where scientifically justified based on biological differences between plants and animals

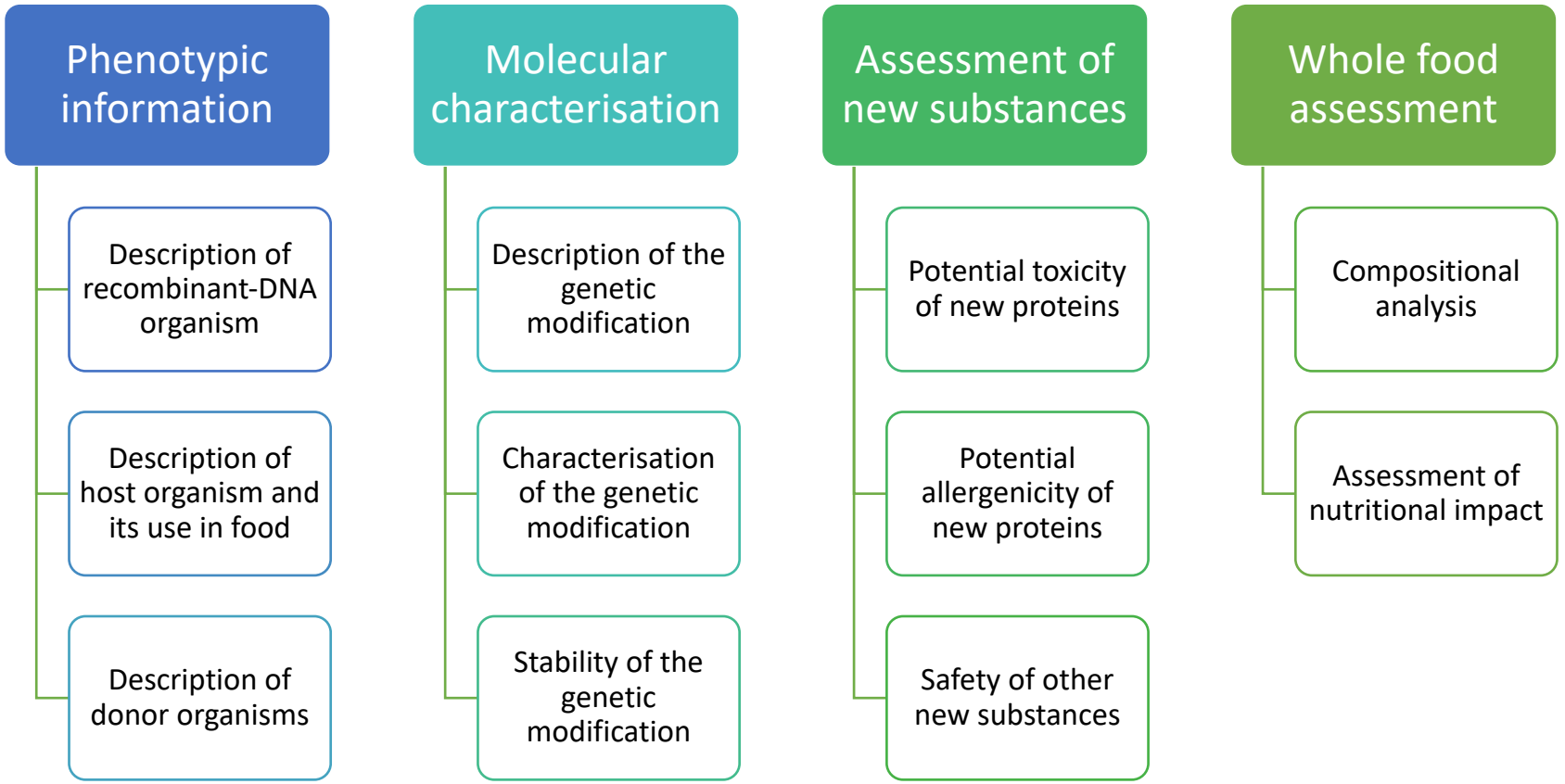
**Informed by two FAO/WHO Expert consultations**

- *Safety assessment of food derived from GM animals, including fish* (2003)
- *Safety assessment of food derived from recombinant DNA animals* (2007)

# Guideline scope

| | |
|---|---|
| Addresses only food safety and nutritional issues | • Excludes animal welfare, environmental risks, safety of rDNA animals used as feed<br>• Deliberately silent on use of guideline for determining safety of rDNA animals for non-food use |
| Applies to foods from animals with a safe history of use as sources of food | • Consistent with the Plant Guideline |
| Designed for food derived from recombinant-DNA animals | • Developed for animals bearing heritable rDNA constructs<br>• Does not preclude guideline being used for animals bearing non-heritable rDNA constructs but additional considerations may apply |
| Approach could be applied to foods from animals altered by other techniques | • Other techniques not specified but could for example be applied (or parts of it applied) to food from gene edited animals |

# Basic Codex framework




Flexible, case by case assessment
Comparisons to conventional foods
Focus on intended plus any unintended changes

# Animal Guideline – what's different?

| | |
|---|---|
| **Terminology/definitions** | • new terms introduced and definition for conventional counterpart revised |
| **Genetic modification/Molecular characterisation** | • different information requirements to reflect the different processes used in the development of recombinant-DNA animals |
| **Safety assessment considerations** | • new elements added (health status of rDNA animal) or revised (assessment of potential toxicity), some removed (evaluation of metabolites) |
| **Compositional analyses** | • substantially revised to reflect differences in approach to compositional analysis for animal species compared to plants |
| **Other considerations** | • revised section on accumulation of substances significant to human health to make it more applicable to animals |

# Terminology and definitions

- Host now recipient animal prior to the genetic modification
  - "host' not appropriate in the context of rDNA animals given the breeding process that occurs following the initial transformation event
- Initial rDNA animal (founder animal) and final rDNA animal used for food
  - some founder animals are mosaics – additional breeding required to ensure the insertion is germ-line transmissible
  - focus of the food safety assessment is on the final rDNA animal
- Conventional counterpart definitions
  - Definition revised to better reflect animal breeding practices

> ***"Conventional Counterpart"*** — an animal breed with a known history of safe use as food from which the recombinant-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food derived from such animals[4].

# Expressed substances

- Assessment of potential allergenicity (including Annex) remains the same as in the Plant Guideline
- Assessment of potential toxicity has been expanded to include bioactivity
  - recognises that some modifications to animals may involve the expression of bioactive substances (e.g. hormones such as GH in AquAdvantage Salmon)
  - the assessment should therefore include consideration of whether such substances may be active in humans, taking into account impacts of processing/cooking
  - the assessment may also be informed by the health status of the rDNA animal
- The general approach to the assessment of potential toxicity remains the same as the Plant Guideline

# Compositional analysis

- Has been substantially modified to remove reference to field trials and their design as this is not applicable to animals
- Informed by the 2003 FAO/WHO Expert Consultation on the *Safety assessment of food derived from GM animals, including fish*
- Changes introduced include reference to the following:
  - choice of comparator - ideally matched in husbandry/housing conditions, age, sex, parity, lactation, laying cycle etc but may not always be possible
  - more than one comparator may be necessary
  - number of samples may be limited
  - likely to be large variation between animals, even those raised under the same husbandry conditions

# Applying the Codex rDNA Animal Guideline

- Limited examples of rDNA animals for food use exist
- Applying the Codex Animal Guideline no different to applying the Plant Guideline
- A few different or changed elements BUT
- Same approach, same concepts and principles apply
  - Flexible, case-by-case assessment
  - Comparisons to conventional foods
  - Focus on intended and unintended changes – new or altered hazards relative to conventional counterpart

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