



ADDRESSING THE ASSESSMENT AND MANAGEMENT OF NOVEL (INNOVATIVE) FOODS/FEEDS AND NOVEL INGREDIENTS IN A GLOBAL ENVIRONMENT

EFSA Conference 2022

22 June 2022

*Food Regulatory Requirements for
Novel Foods and Ingredients*

Implications for Developing Nations

*Challenges and Opportunities of
Collaborative Efforts to Assess and
Manage Novel Food, Ingredients and
Processes*



Addressing Food Security and Sustainability Challenges

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❑ New food sources and production systems:

- Cell-based food production.
- Plant-based protein alternatives.
- Edible insects
- Marine-based food alternatives:
 - Jellyfish, seaweed.

❑ Addressing imperatives of circular economy: Recycling.



Novel Food / Processes – Definition (s)

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There are many definitions of Novel Foods / Processes used internationally by various food regulatory agencies reflecting various policies



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❑ Novel Foods: represent generally products developed through **new** technologies, **new** sources or sourced from exotic locations with limited to no previous history of safe, traditional use

❑ Real and/or Perceived Safety Issues: **Pre-market Approach is privileged**

Examples: Novel Proteins (Insect sources, Algae, etc..)

Examples Novel Processing technology:

- Aseptic
- High pressure
- Nanotechnology
- Fermentation
- Culturing



Novel Food – Definition (s)

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Novel Foods may also be defined in some parts of the world by the way in which they are produced using **new novel technologies, including genetic modification**, but also techniques such as ultra high pressure, **pulsed electric field processing**, pressure-assisted thermal sterilisation, and more recently by **fermentation and culturing**, etc.

def·i·ni·tion
defəˈniʃH(ə)n

noun

a statement of the exact meaning of a word, especially in a dictionary.

THE NOVELTY APPROACH IS A MATTER OF FOOD REGULATORY POLICY

General Consensus on Pre-market Oversight



Introduction of Hazards and Possible Resulting Risks⁸⁸

PRINCIPLE
Foods are Inherently Safe Products

Post-market Rules

- ❑ General provisions against adulteration and other unsanitary practices
- ❑ Limits for selected contaminants in food
- ❑ Nutrition and other labelling provisions

Regulatory Requirements
Set Rules related to
Safety and Quality

Pre-market Oversight

- ❑ Pre-approval of added substances, e.g. additives
- ❑ Pre-approval of novel processes, e.g. GMOs
- ❑ Pre-approval of foods destined to specific subsets of the population, e.g. infant formula

R I S K

I. Safety Assessment

- ☐ Possible introduction of new hazards:
 - Antinutrients.
 - Toxins.
 - New allergens.
- ☐ Changes in the hazard / risk profile.
- ☐ Production conditions.
- ☐ Effectiveness, as claimed.



II. Perception of Safety or the Lack Thereof: Challenges of Risk Communication

Assessment based on:

- ☐ Food chemical safety, toxicology, exposure.
- ☐ Food microbial safety.
- ☐ Nutritional considerations.
- ☐ Allergenicity.

Assessment of conditions of production:

- ☐ Safety.
- ☐ Environmental / Biosafety considerations.



Data Requirements for the Safety Assessment Novel Foods¹¹

Factors (to be) Assessed:

- ❑ History of use as a food in other countries.
- ❑ Composition, particularly levels of anti-nutrients and naturally-occurring toxins.
- ❑ Method of preparation and specifications.
- ❑ Potential for allergenicity.
- ❑ Metabolism/toxicokinetic data.
- ❑ Animal toxicity studies.
- ❑ Human tolerance studies.



Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms

Guidelines for the Safety Assessment of Novel Foods

Guidelines for the Safety Assessment of Novel Foods

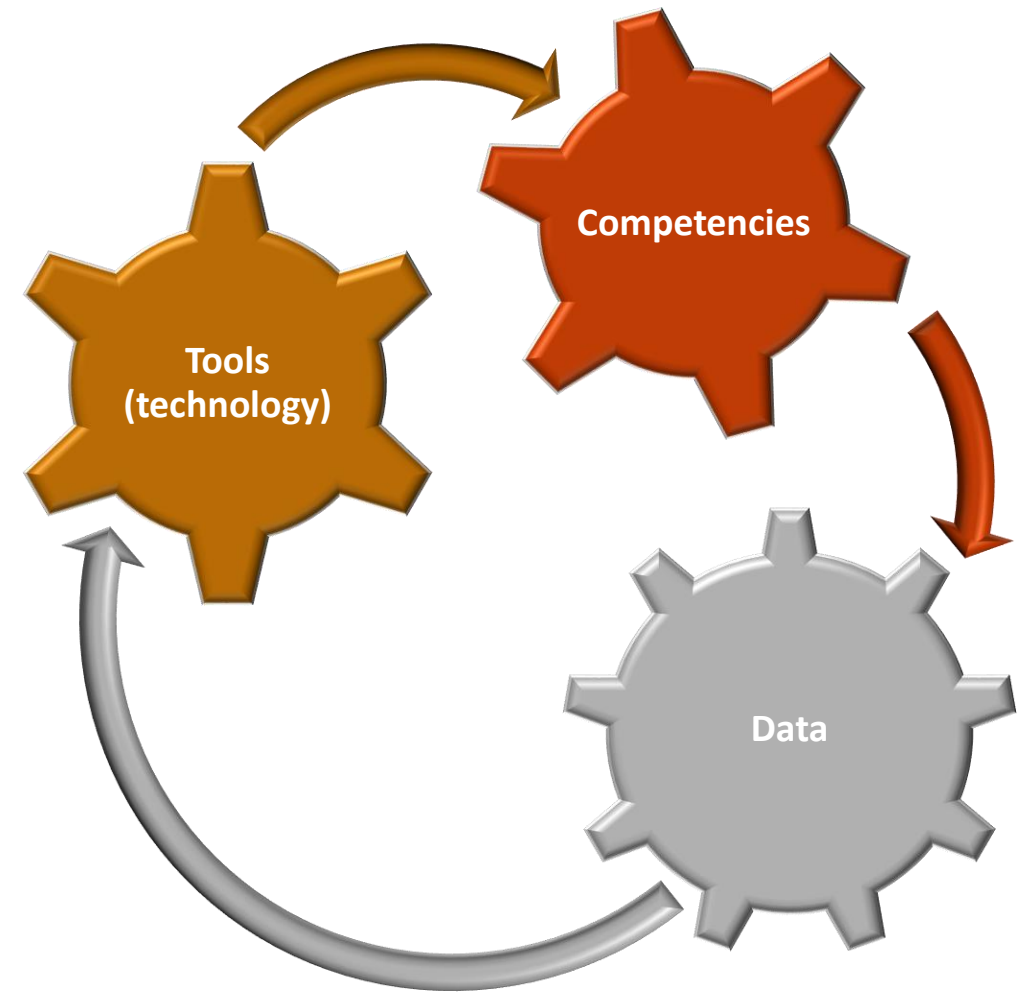
Food Directorate
Health Products and Food Branch
Health Canada
June, 2006

[\(PDF Version - 237 K\)](#)

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- ❑ Ability to use / compare data.
- ❑ Ability to manage large datasets.
- ❑ Ability to update risk / safety assessment methodologies.
- ❑ Ability to cope with technological innovation.



Challenges: Ability to Address This Globally

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- ❑ Regions most impacted by climate change / food insecurity are the least equipped.
- ❑ Unequipped food regulatory authorities:
 - Assessment.
 - Management.
 - Communication.



Some of the limitation for all Food Competent Authorities¹⁴

- ❑ Ability to conduct some of the toxicity studies:
 - Including whole food feeding studies (relevance ? Feasibility)
- ❑ Ability to predict allergenic potential and associated risk management measures
- ❑ Ability to assess exposure – Need to rely on existing data:
 - Occurrence and
 - Food consumption studies.



- ❑ Opportunities to consider collaborative mechanisms to support assessment and formulation of Risk Management Measures
- ❑ Opportunities for:
 - Public-private collaborations.
 - Regional collaborations.



**Effectiveness of Food Regulatory
Systems Enabling the Management of
(Food) Novelty Supports Food Security
and Sustainability of Food Systems**



