SUPPORTING AND MANAGING FOOD INNOVATION

Workshop On Biotechnology and the Future of Food, Ensuring Food Safety, Security and Sustainability

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Prof. Samuel Godefroy, Ph.D. | *Food Risk Analysis and Regulatory Policies, Université Laval, Canada*

GFoRSS
Global Food Regulatory Science Society

IUFoST

GFoRSS is a disciplinary organization of IUFoST

Food Regulatory Requirements for Novel Foods and Ingredients

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

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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)

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

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Novel Food, Ingredients and Processes

❑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

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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
defəˈniSH(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

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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

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Australia and New Zealand Definition

Standard 1.5.1 of the Australia New Zealand Food Standards Code defines "Novel food means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to:

a. the potential for adverse effects in humans; or

b. the composition or structure of the food; or

c. the process by which the food has been prepared; or

d. the source from which it is derived;

e. patterns and levels of consumption of the food; or

f. any other relevant matters.

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Novel Food is defined as food not consumed to any significant degree in the EU prior to May 1997 (when the first Novel Food legislation entered into force). This can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU.

❏Novelty:

"novel food" means:

a substance, including a microorganism, that does not have a history of safe use as a food; **a food that has been manufactured, prepared, preserved or packaged by a process** **that has not been previously applied to that food, and causes the food to undergo a major change**; and **a food that is derived from a plant, animal or microorganism that has been genetically modified** **such that** the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism

Safety Considerations for Novel Foods / Processes

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.

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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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Characteristics of Novel Food Regulatory Requirements

❑Novelty:

- No Split Policy

- **Division 28 of the Food and Drug Regulations Specifies the requirements for Novel Foods**

- Mandatory Pre-market Notification

- 45 Days to Issue Requests for Additional Information

- Timelines to receive a letter of no objection are much longer

❑**A positive list of novel foods that have been authorized such as**

- https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html

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Safety Assessment Considerations….

❑Same Considerations as those discussed internationally

❑Biosafety considerations are also studied, in the form of an environmental assessment to be conducted to review the possible effect of the new food on the environment

❑Requirements of information attesting to the safety of the conditions of production: not introducing new hazards.

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Considerations of Modernization

❑Recommendations - to Exclude from the novelty definition – genetic modification that does not lead to:

- **Alterations in endogenous proteins**, such that it would resemble (may have significant homology) with a known allergen or toxin relevant to human health

- An increase in levels of a known endogenous allergen or toxin or anti-nutrients

- Changes on key nutritional composition and/or metabolism

- Changes in the food use
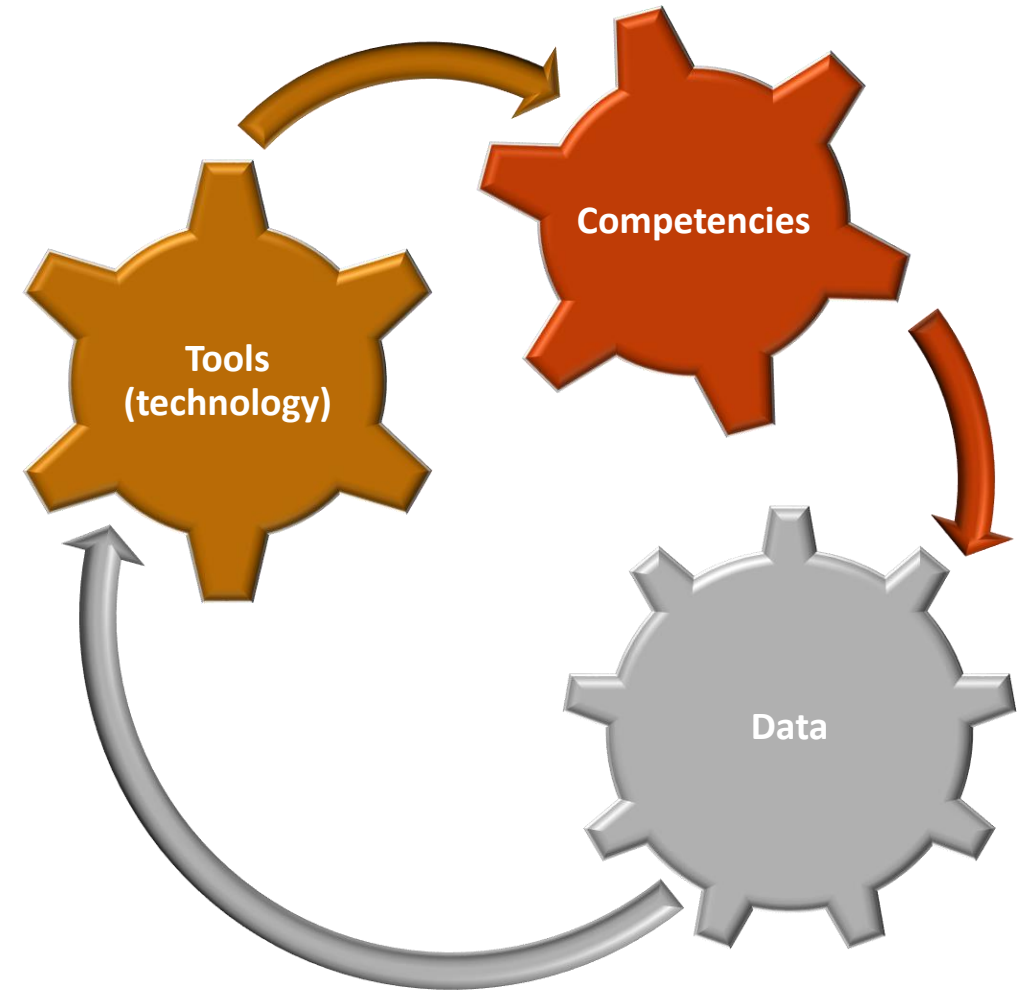
- Insertion of foreign DNA

IMPORTANT

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❑Regions most impacted by climate change / food insecurity are the least equipped.

❑Unequipped food regulatory authorities:

- Assessment.
- Management.
- Communication.

❑Ability to use / compare data.

❑Ability to manage large datasets.

❑Ability to update risk / safety assessment methodologies.

❑Ability to cope with technological innovation.

Tools (technology)

Competencies

Data

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❑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 for Collaboration

❑Opportunities to consider collaborative mechanisms to support assessment and formulation of Risk Management Measures

❑Opportunities for:

- Public-private collaborations.

- Regional collaborations.

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Concluding Remarks

☐ **Effectiveness of Food Regulatory Systems:**

- Enabling the Management of (Food)
- Novelty Supports Food Security and Sustainability of Food Systems

☐ **Learning from the Cell-Cultured Meat Example**

☐ **Opportunities for Enhanced Collaboration**