Singapore Food Agency

SFA's experience and perspectives on novel foods: regulatory framework, challenges, opportunities for collaboration

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Date : 29 Aug 2023

Platform : WOAH Food Safety CC Webinar

Singapore Food Agency

Vision

Safe Food for All

Mission

To ensure and secure a supply of safe food

A statutory board under the Ministry of Sustainability and the Environment (MSE)

New agency launched to strengthen food security and safety, from farm to fork

The new Singapore Food Agency will address all food-related issues, from food production to food hygiene. PHOTO: ST FILE

(straitstimes.com, 1 Apr 2019)

Joint responsibility for novel foods in Singapore

Science-based risk assessment and management system

- Defining and refining **regulatory pathways** for foods derived from new sources and production systems that ensure food safety while facilitating innovations.

Consumers

- Communicating **factual and scientific information** to consumers.
- **Managing feedback** from consumers on foods from new sources and production systems.

- **Sharing perspectives and knowledge** on safety assessment of novel foods with overseas agencies and international organizations.

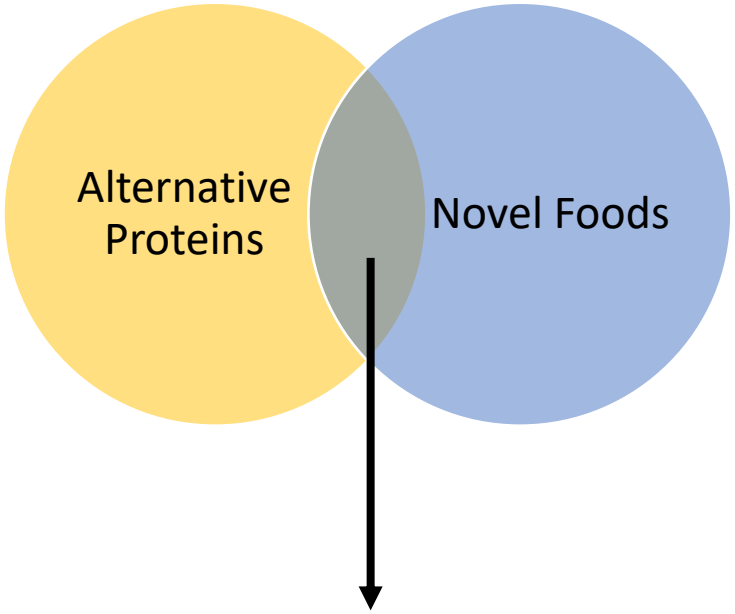
Partnership with industry and academia

- **Encouraging transparency** from industry so as to collectively build food safety capabilities.
- **Fostering** an environment that enables development of novel foods.

Some alternative proteins could be novel foods

Proteins from sources other than traditional livestock*

- **Plant-based** proteins
  - Unprocessed protein-rich plants (e.g. jackfruit)
  - Processed products (e.g. from wheat, pea, rice soy-based tofu, mung bean)
- **Mycoprotein**: Proteins derived from the dried cells of fungi (e.g. Quorn®)
- **Algae protein**: Derived from microalgae (e.g. spirulina)
- **Cell-based/cultured/cultivated meat**: Produced using cell culture without whole live animals



- Foods and food ingredients that **do not have history of use for human consumption**.
- History of use is taken to be a period of **20 years**.
- Also includes traditionally consumed food ingredients that are produced through **advances in biotechnology**.

Alternative protein	Are these novel food?	Examples
Cell-based meat	Yes	Cell-based beef, chicken, seafood
Acellular products from precision fermentation	Yes	β-lactoglobulin produced by GM yeast
Algae	Depending on species	*Chlamydomonas reinhardtii* algae
Fungal or plant-based proteins	Depending on species	Proteins derived from plants without history of use as food

**Adapted from World Economic Forum's "Meat: the Future Series – Alternative Proteins" (2019)*

Overview of SFA's regulatory framework for novel foods

Aim of regulatory framework is to create a system to identify potential risks and ensure these risks are appropriately managed.
Clear and scientifically validated safety assessment procedures help to support the food safety of food innovation.

Pre-market safety assessment

- Companies must provide **safety assessments** of their products and seek pre-market approval from SFA.
- Assessments must **identify risks** and ensure these risks are appropriately **managed** (e.g. Critical Control Points)

Review of safety assessment

- SFA will rigorously **review** safety assessments conducted by companies.
- Reviews are conducted with the **scientific advice** of the Novel Food Safety Expert Working Group.

Regulatory compliance

- The final product, as with any food that is imported, produced or manufactured for sale in Singapore, must meet the requirements under **Singapore's Food Regulations**.

Licensing production

- If the product is to be manufactured in Singapore, the establishment must be **licensed by SFA** and companies must put in place **systems and processes to ensure safety** of their products.

Risk comms

- Risk communication activities to **address perceived risks** of novel foods.
- Working with **third-party advocates** to assure consumers that approved novel foods that are safe.

Companies must conduct pre-market safety assessment before sale

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Pre-market safety assessment → **Review of safety assessment** → **Regulatory compliance** → **Licensing production** → **Risk comms**

Companies must provide **safety assessments** of their products and seek pre-market approval from SFA. Assessments must identify potential risks and ensure these **risks** are appropriately **identified and managed** (e.g. Critical Control Points).

Pre-submission consultations
Companies may request to discuss their safety assessment plan with SFA prior to submission

Novel Food Virtual Clinic
Held bi-monthly and open to all companies

Guidance document on Requirements for the Safety Assessment of Novel Foods
Examples of information companies should include in their pre-market assessment:

- Identity and characterization of the novel food
- Identities and chemical specifications of process inputs
- Manufacturing process
- Purity, allergenicity and toxicological data and intended uses of the novel food

Companies must conduct pre-market safety assessment before sale

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Pre-market safety assessment → **Review of safety assessment** → **Regulatory compliance** → **Licensing production** → **Risk comms**

Generalized cultured meat manufacturing process

Processes:	Cell line selection & adaptation	Cell proliferation	Scaffolding	Harvesting (concentration / washing)
Inputs:	Donor cells; Adaptation reagents	Growth media	Scaffold material	Processing aids
Biological considerations:	Infectious agents ▲	Infectious agents ■	Infectious agents ■	Infectious agents ▲ ■
	Cell line contamination ▲	Cell line contamination ■	Cell line contamination ■	Cell line contamination ▲ ■
Chemical considerations:	Chemicals used in selection & adaptation ●	Non-food grade media ●	Non-food grade scaffold material ●	Non-food grade processing aids ●
	Genetic engineering ●	Unintended metabolites ▲ ●	Chemical contaminants ▲ ●	Chemical contaminants ▲ ●

Risk mitigation strategies for food safety considerations are denoted as:

▲ Testing and analysis ■ Aseptic processing ● Risk assessment

SFA reviews novel food safety assessments made by companies

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Pre-market safety assessment → Review of safety assessment → Regulatory compliance → Licensing production → Risk comms

SFA **reviews** safety assessments by companies. To ensure safety assessments are rigorously reviewed. SFA has also established a Novel Food Safety Expert Working Group to provide scientific advice.

Ascertain food safety issues are addressed

- Identify food safety hazards
- Evaluate if information submitted is supported by scientific literature
- Evaluate whether risk mitigating steps are effective.
- Consider health impact of the novel food when consumed as intended.
- Estimate dietary exposure to novel food and evaluate impact on safety.

Establishment of a Novel Food Safety Expert Working Group to provide scientific advice

Experts with specializations in:

- Food science and engineering
- Nutrition
- Bioinformatics
- Epidemiology
- Public health
- Toxicology
- Microbiology

Regulatory compliance to ensure product safety

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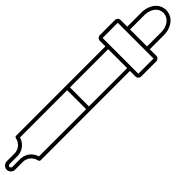
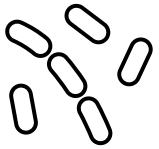
Pre-market safety assessment → Review of safety assessment → **Regulatory compliance** → Licensing production → Risk comms

The final novel food product, as with any food that is imported, produced or manufactured for sale in Singapore, must meet the requirements under **Singapore's Food Regulations**.

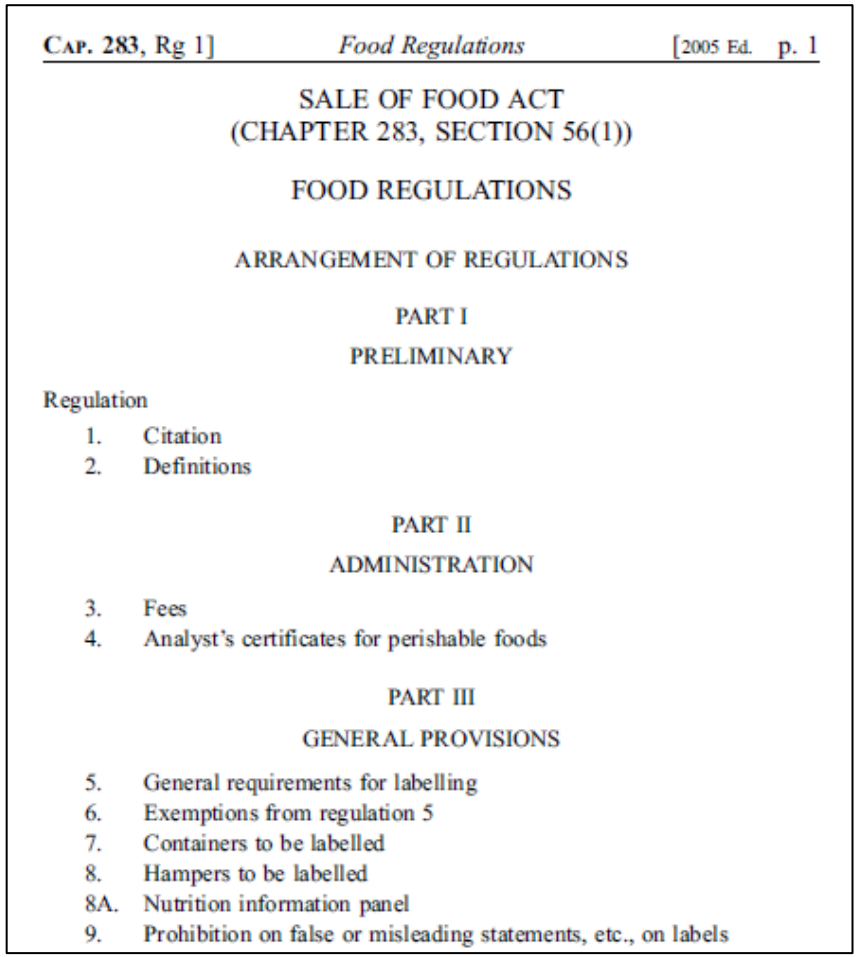


Chemical requirements
- Use of food additives
- Maximum levels for contaminants



Microbiological requirements
- Standards for ready to eat food

Labelling requirements
- General labelling requirements
- Use of health claims



CAP. 283, Rg 1] *Food Regulations* [2005 Ed. p. 1

SALE OF FOOD ACT
(CHAPTER 283, SECTION 56(1))

FOOD REGULATIONS

ARRANGEMENT OF REGULATIONS

PART I
PRELIMINARY

Regulation
1. Citation
2. Definitions

PART II
ADMINISTRATION

3. Fees
4. Analyst's certificates for perishable foods

PART III
GENERAL PROVISIONS

5. General requirements for labelling
6. Exemptions from regulation 5
7. Containers to be labelled
8. Hampers to be labelled
8A. Nutrition information panel
9. Prohibition on false or misleading statements, etc., on labels

Licensing requirements to ensure process safety

Pre-market safety assessment → Review of safety assessment → Regulatory compliance → **Licensing production** → Risk comms

If novel food is produced locally, SFA requires a detailed breakdown of the novel food production process to ascertain that companies have put in place systems and processes that **ensure safety** of their products before a licence is issued.

Existing licensing requirements for food production facilities +

Examples of requirements specific to novel food production

- Designated storage facility for sterile equipment and tools
- Provision of a designated media preparation room
- Cold storage facility for master cell bank and finished product
- Provision of a designated cell culture room

Risk communication activities to address perceived risks of novel foods

Pre-market safety assessment → Review of safety assessment → Regulatory compliance → Licensing production → Risk comms


Food for Thought

A digital publication by the Singapore Food Agency

Food Safety

A growing culture of safe, sustainable meat

For Singapore's food game plan to be truly successful, a robust and scientifically-based regulatory framework is needed to address the latest developments in the rapidly evolving field of novel food including cultured meat.

By Singapore Food Agency

Published 04 Jan 2021 | Updated 17 Jun 2021

Op-ed by Members of SFA's Novel Food Expert Working Group

Press briefing for SFA's first approval of cell-based meat

Identifying third-party advocates

Risk-at-a-glance article on novel foods published on SFA's website

Challenges on safety assessment of novel foods

As SFA talks to regulators, companies, and academics in the novel food ecosystem, we encounter recurring questions on safety assessment that may warrant further discussions.

Cultivated meat, seafood, milk

- What are the potential risks arising from genetic drift (from prolonged *in vitro* cellular growth)?
- What are the potential risks arising from use of bioactive molecules, growth factors, scaffolds, surfactants, processing aids, etc., that do not have a history of use in food?
- What are the possible effects of various methods (including genetic engineering) of cell line immortalization on food safety?

Precision fermentation

E.g.: milk proteins from GM yeast, food additives from GM bacteria

- Is there an internationally recognized list of microbial hosts that are considered safe?
- What is the tolerable limit for proteins and DNA residues in the final product?
- What is the extent of chemical characterization needed to show that the product is identical to the naturally occurring counterpart?

Addressing regulatory science challenges on safety assessment of novel food: FRESH

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FUTURE READY FOOD SAFETY HUB

https://www.ntu.edu.sg/fresh

Future Ready Food Safety Hub (FRESH) was established in Apr as a collaborative platform between SFA, academia and A*STAR^ to proactively build capabilities in food safety and risk assessment science.

R&D

Research, development and validation of new safety assessment protocols for novel foods and technologies, as well as support development of standards and regulations

TALENT DEVELOPMENT

Build up local expertise in food safety science and R&D, including undergraduates and graduates, and skills-development of professionals in food safety science

CONSULTANCY

Provide guidelines on newly developed risk assessment protocols, as well as assist companies to plan studies to ascertain safety of novel food products

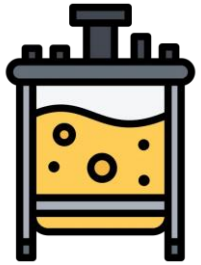
RISK COMMUNICATIONS

Work with SFA and industry to enhance Singapore's risk communications for novel food safety

^A*STAR stands for Agency for Science, Technology and Research, and is Singapore's leading public sector research agency

SFA is interested in the co-development of safety assessment criteria for new food sources and production systems (NFPS)

- Consumers are increasingly exposed to NFPS / novel foods, driven by strong public and private investments towards food sustainability and security goals.
- New foods introduce new risks that need to be addressed:
  - New proteins that may present adverse health effects
  - New or unexpected microbiological contaminants
  - New chemicals and processing aids that do not have history of safe use in food
- Challenges in addressing these new risks:
  - Lack of information on certain hazards in new foods
  - Lack of internationally accepted methodologies for safety assessment of new foods



International engagement: working together to address challenges on novel foods regulation and science

Roundtable on Novel Food Regulations (2019, 21, 22, 2023)
A platform for regulators, industry & researchers to raise awareness on new food production technologies, discuss challenges in safety assessment, and explore opportunities to advance the regulatory agenda.

Co-hosted an international consultation on cell-based foods with FAO (1 – 4 Nov 2022)
A group of 24 experts from 15 countries worked on identifying hazards associated with cell-based foods, and discussed terminologies and regulatory approaches.

Work towards development of internationally-recognised guidelines / standards that are important for food safety.

Highlight strategies and challenges in addressing safety issues associated with novel foods.

Singapore **International partners**

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Thank you