



# Singapore's Regulatory Framework for Novel Foods

20th Anniversary of the Food Safety Commission of Japan, 1 Sep 2023

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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](http://straitstimes.com), 1 Apr 2019)

# Strategies to ensure a supply of safe food for Singapore



## 1. Diversify Import Sources

- Reduces risk of reliance on any one supply source

Over 90% of supply is imported.



## 2. Grow Local

- Helps mitigate our reliance on imports and serves as a buffer during supply disruptions to import sources
- Transform agri-food industry into one that is highly productive, employing climate-resilient and sustainable technologies

30 by 30







## 3. Grow Overseas

- Support our companies to expand and grow overseas so that their produce can potentially be exported to Singapore

# What are novel foods?

- Currently no internationally harmonized or accepted definition

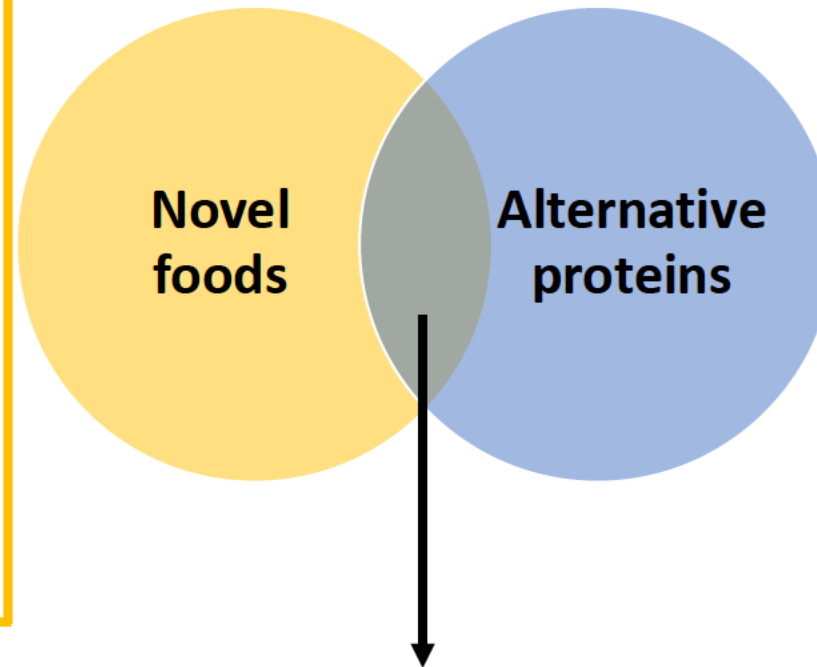
<p>European Union (EU)</p> 	<p>Canada</p> 	<p>Australia, New Zealand</p>  
<ul style="list-style-type: none"> <li>▪ Food that had <b>not been consumed to a significant degree</b> by humans in the EU before 15 May 1997</li> <li>▪ Can be newly developed, innovative food, food produced using new technologies and production processes as well as food which is/has been traditionally eaten outside of EU</li> </ul>	<ul style="list-style-type: none"> <li>▪ A substance, including a microorganism, that <b>does not have a history of safe use as a food</b></li> <li>▪ 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</li> <li>▪ A food that is derived from a plant, animal or microorganism that has been genetically modified</li> </ul>	<ul style="list-style-type: none"> <li>▪ Non-traditional food that requires an assessment of the public health and safety considerations</li> <li>▪ Non-traditional food: food/substance derived from food/any other substance that <b>does not have a history of human consumption</b> in Australia/ New Zealand</li> </ul>



# SFA's perspective on novel foods

## Novel foods

- 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**.



## Proteins from sources other than traditional livestock\*

- **Plant-derived** proteins (e.g. processed products from wheat, pea, rice, soy, mung bean)
- **Mycoprotein**: Proteins derived from the dried cells of fungi (e.g. Quorn®)
- **Algae protein**: Derived from microalgae (e.g. spirulina)
- **Insect protein**
- **Cell-based/cultured/cultivated meat**

Alternative protein	Are these novel food?	Examples
Cell-based meat	Yes	Cell-based beef, chicken, seafood
Proteins from biomass/precision fermentation	Depending on species and process	β-lactoglobulin produced by GM yeast
Algae	Depending on species	<i>Chlamydomonas reinhardtii</i> algae
Insect proteins	Depending on species	Black soldier fly larvae
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)

# Considerations in regulation of novel food

- ✓ Food safety is the principal consideration of SFA
  - Reliance on food imports- Need for an anticipatory stance
  - Science-based risk assessment and risk management
- ✓ Regulatory pathways that protect consumers while facilitating innovations that can help food security
- ✓ Regulations must be supported by other strategies:

## Build consumers' awareness

- Communicate factual and scientific information to consumers.



## Leverage on partnership

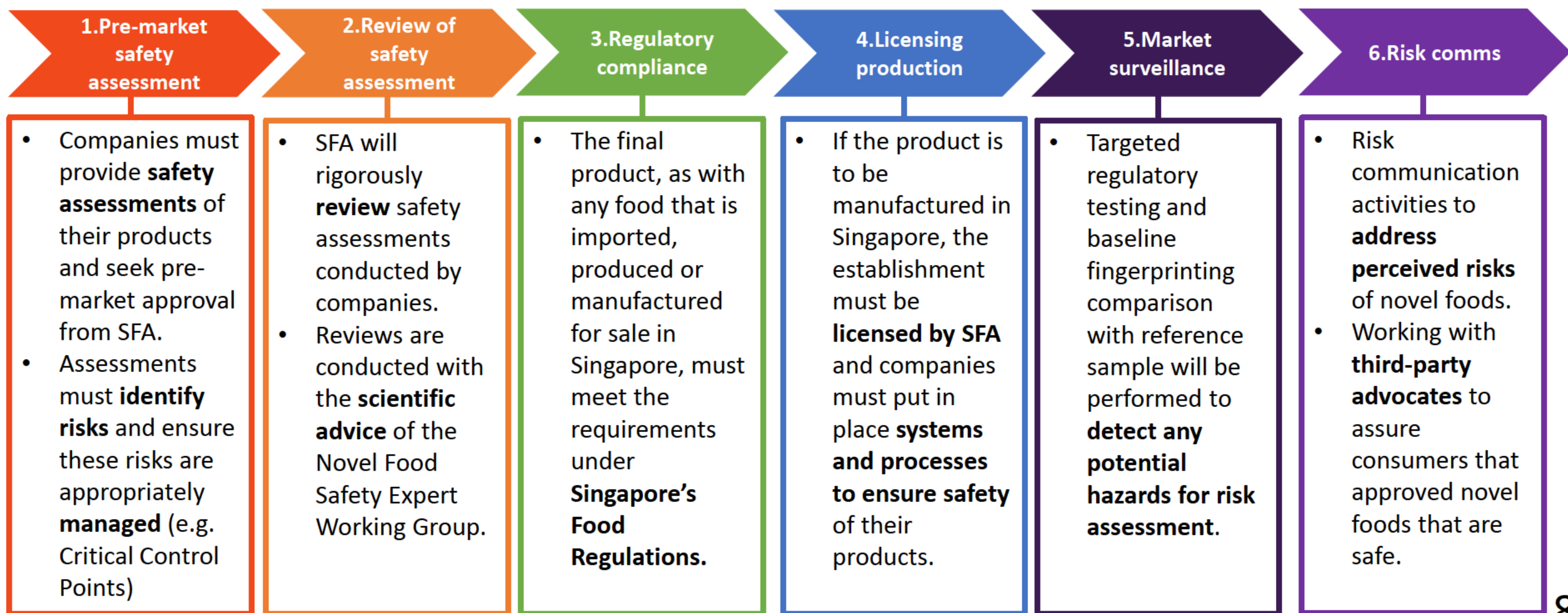
- Encourage transparency from industry
- Support R&D by academia so as to collectively build food safety capabilities.
- Engage and share with overseas agencies and international organizations

# Public consultation on Novel Foods in 2018

- Engaged stakeholders (local food manufacturers, importers, academia etc.):
  - Proposed regulatory framework for novel foods and food ingredients- Requirement for pre-market approval
- Public consultation helps to improve transparency, gain public's confidence and acceptance towards novel foods
- There was support for our proposal

# 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.



# 1. Pre-market safety assessment of novel food by the company

- Companies must conduct and **submit a safety assessment for SFA's review**
- Assessments must **identify risks** and ensure these risks are appropriately **managed** (e.g. Critical Control Points)

Information on SFA's requirements for the safety assessment of novel food is available on the SFA website



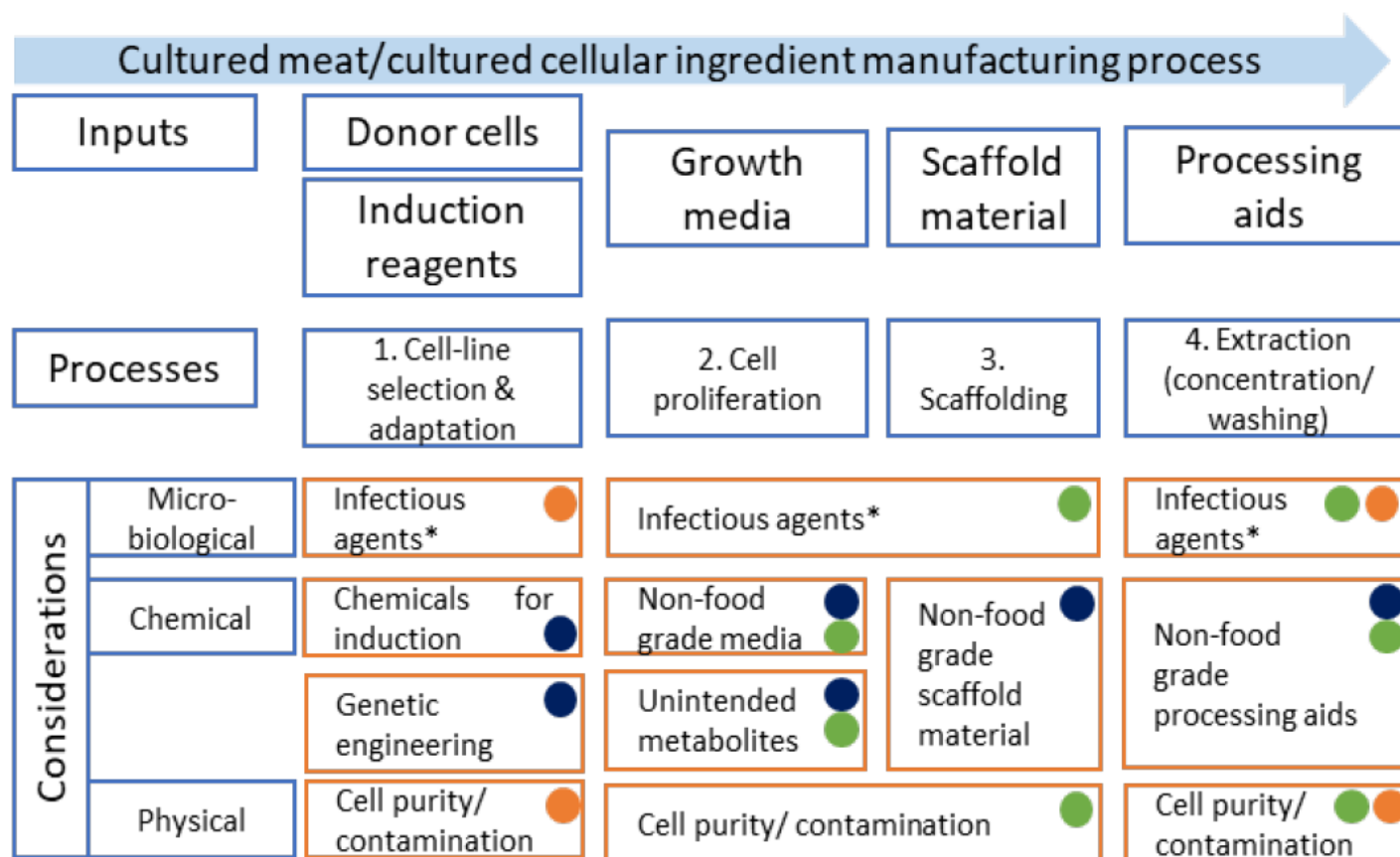
## Guidance document on Requirements for the Safety Assessment of Novel Foods

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



## 2. Review of safety assessment by SFA (Risk assessment approach)



- Information submitted must be supported by scientific literature or studies
- Safety and health impact of the novel food when consumed as intended, including dietary exposure

\*Examples: viruses, bacteria, fungi, prions (only for animal-based materials at risk)

Risk mitigation of hazards arising from the considerations are according to the legend below:

● Testing    ● Aseptic processing    ● Risk assessment



# Establishment of Novel Food Safety Expert Working Group

- Established in March 2020 to ensure rigorous review of the safety assessments
- Diverse specialization fields to allow for holistic assessment of novel food's safety

Chair



**Prof John Lim**  
*Executive Director, Centre  
of Regulatory Excellence,  
Duke-NUS Medical School*



**Adj A/Prof Annie Ling**  
*Health Promotion  
Board  
Epidemiology*



**Adj A/Prof Chow  
Wai Leng**  
*Ministry of Health  
Public Health*



**Prof Eric Chan**  
*National University of  
Singapore  
Pharmacology, Toxicology*



**Prof Zhou Weibiao**  
*National University of  
Singapore  
Food Science*



**Prof William Chen**  
*Nanyang Technological  
University  
Food Science*



**A/Prof Yew Wen Shan**  
*National University of  
Singapore  
Precision fermentation,  
microbiology*



**Asst Prof Ching Jianhong**  
*Duke-NUS Medical  
School  
Metabolomics*



**Prof Christiani  
Jeyakumar Henry**  
*A\*STAR  
Nutrition*



**A/Prof Tan Soo Yong**  
*A\*STAR  
Biobanking, molecular  
pathology, cancer  
genomics*



**Adj Prof Sebastian  
Maurer-Stroh**  
*A\*STAR  
Bioinformatics  
(Allergenicity prediction)*

### 3. Regulatory compliance to ensure product safety

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

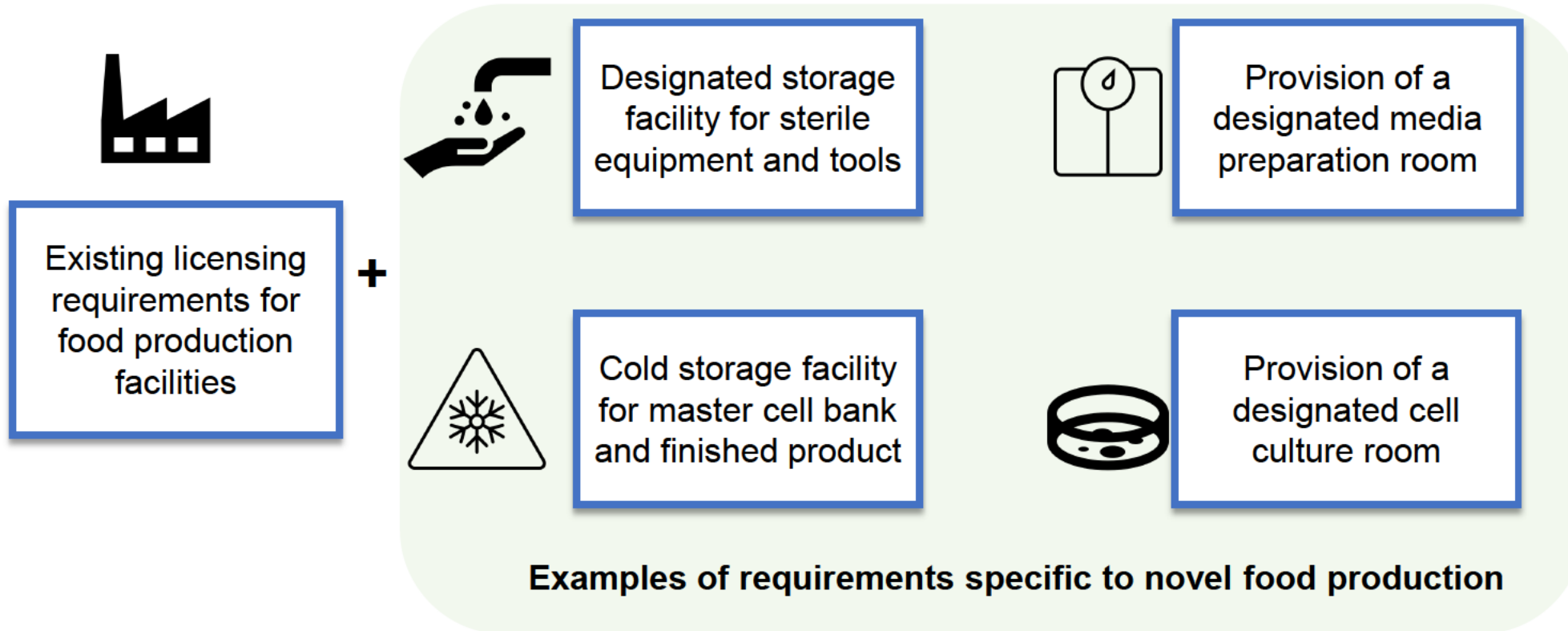
- General labelling requirements
- Use of health claims

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	



## 4. Licensing of local production to ensure process safety

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.



- Takes reference from licensing of biomedical/ pharmaceutical manufacturers in Singapore.
- One licensed cell-based production facility to date

# Advisory Panel for Novel Food Production Facility

- Established in June 2023 to review the licensing requirements for novel food production facility:
  - Enhance the rigor to ensure food safety but yet not add to production costs.
  - Need to delineate the requirements based on the type of novel food production, e.g. cultivated meat production vs. microbial fermentation, given their different technical considerations



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*Group Manager, Open  
Innovation  
Nestle R&D Center*



**Prof Zhou Weibiao**

*Head, Department of  
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*CEO, FoodPlant  
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*Director, Audit and  
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Polytechnic*



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Yong**

*Associate Professor  
Department of  
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School of Medicine, NUS*



- Testing of end product by SFA to ensure compliance with requirements under Singapore's Food Regulations.
- Baseline fingerprinting comparison with reference sample of cell-based meat?

SFA's approval is for the use of a specific cell-based meat or novel food as an ingredient in specific food products.

Should the company wishes to extend the use of this ingredient in more of their food products, they must provide the additional requisite information for SFA's evaluation (e.g. changes in exposure as a result of the new products entering the market)

Should there be any new manufacturing processes that may change the original safety review by SFA, the company must also provide requisite information for SFA's evaluation.



Pre-market  
safety  
assessment

Review of safety  
assessment

Regulatory  
compliance

Licensing  
production

Market  
surveillance

6. Risk comms

## 4. Risk communication activities to address perceived risks of novel foods such as cell-based meat

Label the product  
packaging with  
qualifying terms

F&B outlet must  
communicate true  
nature of food

**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

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

Others- Third-party  
advocates, social media





# Challenges in regulation of novel foods (1/2)

Given that novel foods is a nascent and rapidly evolving industry, regulatory agencies continue to face challenges even with a regulatory framework in place:



## Keeping pace with innovation

Current case-by-case safety assessment approach may be outpaced in the dynamic novel foods ecosystem



## Lack of internationally harmonized guidelines/standards on:

- a) **Risk assessment-** Difficult to achieve due to differing stages of regulatory preparedness of countries
- b) **Regulation of novel food production facilities-** Different requirements may be need for different types of novel food. Need to ensure food safety but yet not add to production costs.
- c) **Labelling of novel foods-** No harmonisation of terminologies for novel food products.



## Risk communication

Susceptibility of consumers to misinformation and strong biased opinions

# Challenges in regulation of novel foods (2/2)

Given that novel foods is a nascent and rapidly evolving industry, regulatory agencies continue to face challenges even with a regulatory framework in place:



## **Genetic drift**

Potential for formation of undesirable substances due to genetic instability (e.g. toxin, allergens, hormones). No harmonized method for risk assessment of genetic instability and no acceptable scientific approach for safety assessments of cellular output.



## **Use of unorthodox ingredients during production process**

Difficulties in assessing food safety risks associated with use of inputs in culture media such as biologics (e.g. growth factors) and small molecules



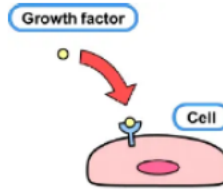
## **Detection of novel foods**

Difficulty in differentiating novel food from conventional foods in the market and changes that companies may make to the original product approved.

# To prepare for these challenges, SFA is deepening our knowledge on the fundamental science of novel foods

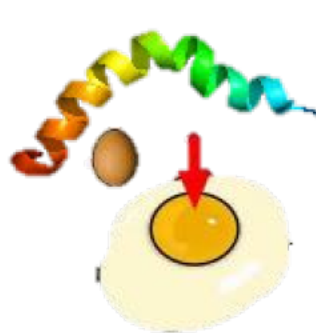
**1. *In vitro* test for food safety of media components that are never used in food before (e.g. growth factors)**

*SFS 1.0 project with A/P Tan Soo Yong (A\*STAR)*



**2. *In vitro* test for allergens to ensure that allergens are not overproduced in cell-based meats compared to conventional counterparts**

*SFS 1.0 project with A/P Chew Fook Tim (NUS)*



Level of egg yolk allergen in cultured chicken meat?

Will I get allergic reaction from consuming cultured chicken meat?



**3. Non-targeted capability for identification and characterization of foodborne hazards in alternative protein-based novel foods**

*SFS 1.0 project with Adj A/P Jayantha Gunaratne (A\*STAR)*

**4. New Approach Methodologies**  
E.g. Non-animal-based methodologies (NAMs) to deepen the science and generate data for toxicity and allergenicity assessment

# Building an integrated ecosystem to facilitate food innovations

- Multi-government agency efforts to support agri-food start-ups and enterprises



Image source: Nurasa

Food Tech Innovation Centre was established to accelerate the commercialization of agri-food technologies, including alternative proteins, in Singapore



<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<sup>^</sup> to proactively build capabilities in food safety and risk assessment science.

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



# International collaborations will help to minimize trade barriers and allow novel foods to contribute to a supply of safe food globally.



**Singapore**

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

Highlight strategies and challenges in addressing safety issues associated with cell-based food.



**International partners**



**SFA Roundtables for Novel Food Regulations (2019, 2021, 2022, upcoming Oct 2023)** - An annual discussion platform for regulators, industry & researchers



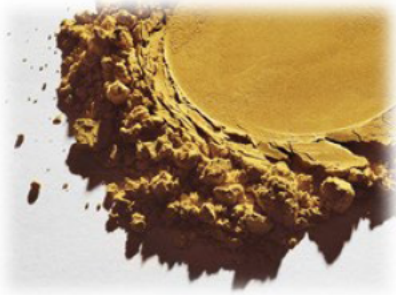
**SFA Co-hosted an international consultation on cell-based foods with FAO (1 – 4 Nov 2022)- 24 experts from 15 countries**



**“New Food Sources and Production Systems” (NFPS) at Codex Alimentarius Codex 45- Active contribution by Singapore to discussion**

# Novel food approved by SFA

- SFA's Novel Food Regulatory Framework applies not only to cell-based meat but other novel food products as well



Source: Solar Foods



**Solein®**  
*Biomass Fermentation*  
Solar Foods (Finland)



Source: Remilk



**Beta-lactoglobulin**  
*Precision Fermentation*  
Remilk (Israel)



Sources: Very Dairy, Coolhaus



**Beta-lactoglobulin**  
*Precision Fermentation*  
Perfect Day (USA)



Source: Nature's Fynd



**Mycelium**  
*Biomass Fermentation*  
Nature's Fynd (USA)





# Thank you

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