

You May (Soon) be Ready to Sell Your Cultured Meat, but are the Regulators?

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◆ **We serve clients in 26 countries**

KELLER AND HECKMAN'S SHANGHAI OFFICE

- ◆ **Our practice in China, and Asia generally, is regulatory in nature**
- ◆ K&H has prepared many applications for product approval before the following government agencies:
 - ◆ China National Health Commission (NHC)
 - ◆ Singapore Food Agency (SFA)
 - ◆ Food Standards Australia New Zealand (FSANZ)
 - ◆ Indonesia Food and Drug Authority (BPOM)





Existing China food regulatory updates are available on the K&H website:

<https://www.khlaw.com/CRM>

We also distribute articles focusing on the development of alternative proteins in Asia.

Special Focus on Alternative Proteins

- 07.20.2022 [South Korea Promotes Alternative Proteins in Its National Plan](#)
- 04.28.2022 [India: Another Booming Market for Alternative Proteins in Asia](#)
- 09.03.2021 [Japan is Contemplating the Future of Cell-based Meats](#)
- 05.06.2021 [China Releases First Group Standard for General Plant-Based Foods](#)
- 03.30.2021 [Asia's First Animal-Free Dairy Ice Cream: Another Alternative Protein Breakthrough](#)
- 02.01.2021 [Cultured Meat: Shaping the Future of Foods](#)
- 05.08.2020 [Plant-Based Foods: Exciting Technology, But Don't Overlook the Regulatory Considerations](#)

PUBLICATION 07.20.2022

South Korea Promotes Alternative Proteins in Its National Plan

To formulate a better regulatory environment for the alternative protein industry to thrive, the South Korean government is taking action to support the industry by including it in the National Plan 2022. Specifically, the Ministry of Food and Drug Safety (MFDS) is calling for accelerating the development of official guidance for alternative proteins by establishing:

Japan is Contemplating the Future of Cell-based Meats

Author: David J. Ettinger
Jenny Xin Li

The Japanese food authorities have been actively deliberating food regulatory matters regarding how to better use new technologies to diversify protein sources for consumers.

India: Another Booming Market for Alternative Proteins in Asia

Author: David J. Ettinger
Jenny Xin Li

With a massive population and religious culture rooted in vegetarianism, India's alternative protein industry has been developing at unprecedented speeds. At the same time, we have seen the local government grant funding to promote the research and development of cellular agriculture and introduce some regulatory changes that may indirectly impact alternative proteins.

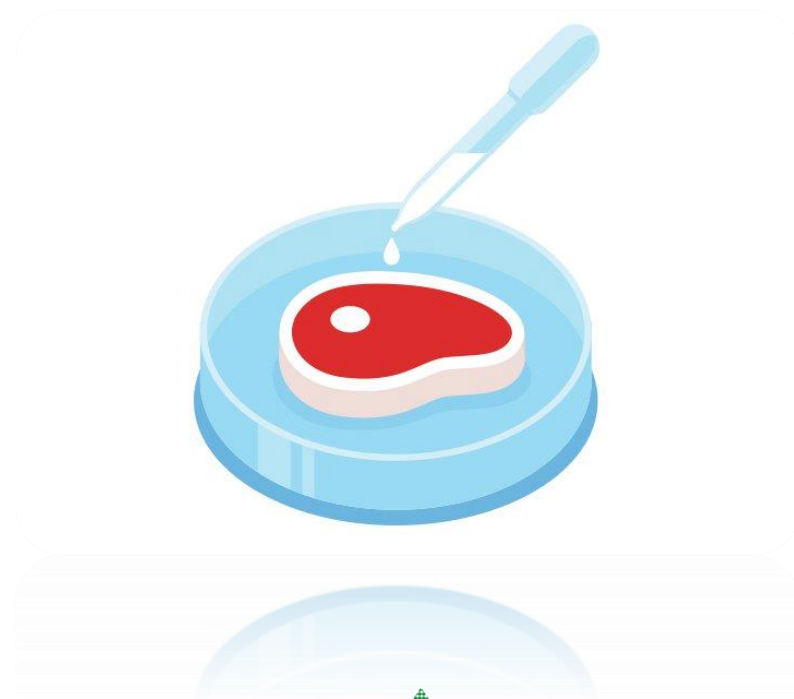
Important Note

The content of this presentation is not intended to as, and does not constitute, legal advice for particularized facts. Regulatory counsel should be consulted in advance for advice on any specific compliance issues.

Agenda

- I. Overall Picture of Cultured Meat in Asia-Pacific
- II. Country Review - Australia
- III. Country Review - Singapore
- IV. Country Review - South Korea
- v. Q&A Session





Part I Overall Picture of Cultured Meat in Asia-Pacific

Cultured Meat

- ❖ Cultured meat, also known as cultivated meat, cell-based meat, lab grown meat, etc. Countries may refer this type of food category differently.
- ❖ Cultured meat may also cover cell-based seafood.

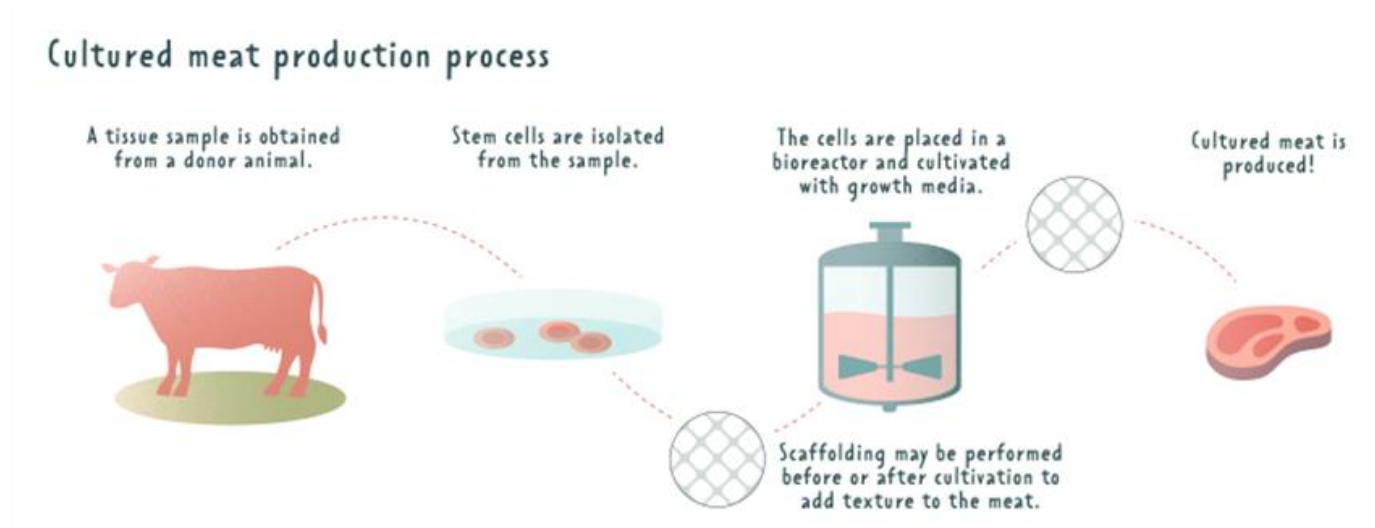


Image source: <https://sitn.hms.harvard.edu/flash/2022/meat-pie-in-the-sky-when-will-our-appetite-for-lab-grown-meat-be-satisfied/>

Overall Picture of Cultured Meat in Asia-Pacific

- Detailed guidelines for the safety assessment of cultured meat
- Approved the world's first cultured chicken

Singapore



- Existing framework for the review of novel foods/GM foods may cover cultured meat

Australia



- No guidelines concerning cultured meat at the current stage
- 2022 National Plan - establish a management system for cultured meat

South Korea



- Cultured meat is being taken seriously in China
- National Policy – MARA 14th Five-Year Plan for National Agricultural and Rural Science and Technology Development (2021-2025)

China



- ◆ Regulatory clearance — the official stamp that cultured meat is safe to eat — is probably the biggest hurdle to commercializing cultured meat.
 - ◇ Existing food regulatory framework of Singapore and Australia may cover the new area of cultured meat
 - ◇ South Korea announced its plan to establish guidelines for cultured meat evaluation
 - ◇ For certain Asian countries, such as China, there is no regulatory pathway to clear cultured meat at the current stage

Overall Picture of Cultured Meat in Asia-Pacific

- Not promulgated any new food regulations or standards for cultured meat
- Local authority appears to be open to engagement with stakeholders during the process of formulating the best approach to regulate cultured meat products

Japan



- Generally speaking, there is no preapproval requirement for ordinary foods in Hong Kong
- To date, the authority has not formulated any regulations that are specific to cultured meat
- Rapid development of other types of alternative proteins, e.g., animal-free dairy protein.

Hong Kong



- Not yet a regulatory pathway to clear cultured meat in India
- It is possible that such foods are likely to be regulated as “novel food”
- local government grant funding to promote the research and development of cellular agriculture

India



Local government is actively developing this area



Specific regulatory pathway to clear cultured meat at the current stage

Start with Singapore, Australia and South Korea – May be considered as ideal launch grounds for cultured meat



JUST's cell-based chicken nuggets.

JUST's cell-based chicken nuggets.

- ◆ Local government – supporting the development of cultured meat
 - ◆ Food authorities of Singapore and Australia encourage pre-submission consultation
 - ◆ South Korea released notice to invite enterprises to apply for the pre-review of application dossier for Genetically Modified (GM) food safety evaluation as well as novel food evaluation

Recent Developments regarding Cultured Meat in Asia-Pacific

- ◆ After Singapore approved the world’s first cultured chicken produced by Eat Just, Inc. in December 2020, recently, Eat Just announced to open Asia’s biggest lab-grown meat facility.

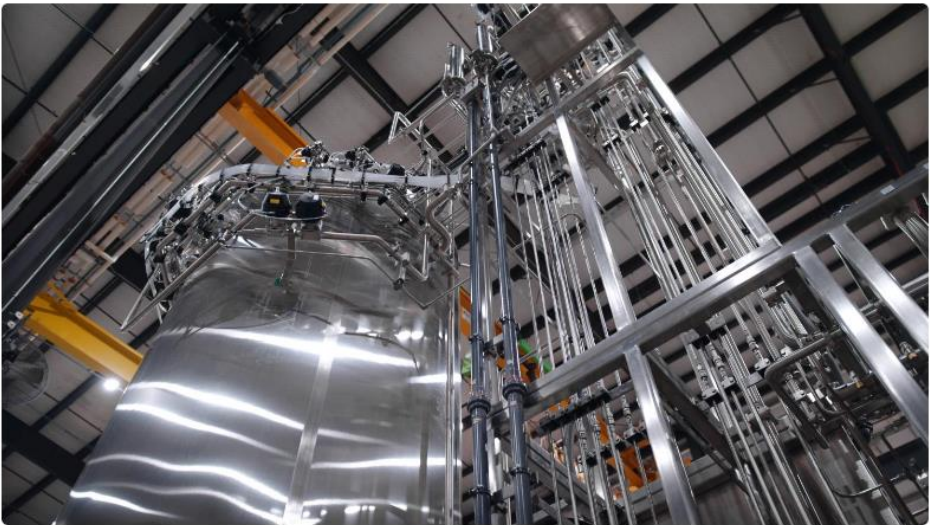
Eat Just to Open Asia’s Largest Cultivated Meat Facility in 2023

- Company is approved to sell its lab-grown chicken in Singapore
- Costs to be competitive against conventional meat by end 2030



Josh Tetrick Source: Eat Just Inc.

By Sing Yee Ong
June 10, 2022 at 3:17 PM GMT+8



File photo of a bioreactor used to produce cultivated meat. (Photo: GOOD Meat)



Recent Developments regarding Cultured Meat in Asia-Pacific

- ◆ Media reported conversations between FSANZ and cultivated meat company



Australians could see cultivated meat on shelves next year, with Food Standards Australia and New Zealand (FSANZ) anticipating an application from a company in the next few weeks.

In an exclusive interview with *Future Alternative*, Glen Neal, General Manager of Risk Management and Intelligence at FSANZ said the government agency has had conversations with a cultivated meat company that indicated it would be ready to file its application in around June of this year.

The conversations formed part of FSANZ's pre-application assistance program, which gives manufacturers advice on the application process and the material FSANZ requires in order to deem a product safe.




An array of companies are working towards biologically identical, lab-grown meat. Shutterstock

Australian company Vow is making pork and chicken, as well as kangaroo, alpaca and water buffalo meat using cells from animals. These products are not yet commercially available, though chef Neil Perry did use some of them to create a menu in 2020.

Recent Developments regarding Cultured Meat in Asia-Pacific

Space F Claims Korea's First Cultivated Chicken And Beef Prototypes Alongside New Pork 2.0

By  Amy Buxton — Published on Feb 10, 2022 — Last updated Feb 10, 2022

ALT PROTEIN | CELL-BASED NEWS | FUTURE FOODS



Cultivated beef meatballs. Photo by SpaceF.



3 Mins Read

After pioneering cultivated pork in March 2021, South Korean cellular agriculture startup Space F has unveiled a host of new innovation including an upgraded version of its existing cultivated pork prototype, a brand new cultivated beef prototype, presented as meatballs and a patty and their first cultivated chicken fillets and nuggets.

- ◆ South Korea Promotes Alternative Proteins in Its 2022 National Plan
- ◆ Local enterprise are developing technology for potential commercialization of cultured meats.

Challenges for Cultured Meat



- ◆ Public perception:
 - ◇ “Real meat” / “Fake meat”
 - ◇ Concerns about the end of conventional animal agriculture, distrust of companies producing cultured meat
 - ◇ Concerns about the taste, texture and appearance of cultured meat.
 - ◇ Price concerns
- ◆ Regulatory schemes:
 - ◇ No specific regulations; Under preliminary development
- ◆ Unique challenges:
 - ◇ Cost of production of cultured meat - difficult to predict
 - ◇ Lab contaminations



Part II - Australia



A Promising Market -- Australia

Potential market for Australian cellular agriculture products in 2035

Cellular agriculture market



\$105–210m

Base case

Assumes

- Australia 1% of global meat production
- 11% alt protein adoption rate by 2035
- 6–12% of alt protein as cell ag
- AU\$4/kg for cell ag products

\$2.3bn

Most optimistic case

Assumes

- Australia 5% of global meat production
- 16% alt protein adoption rate by 2035
- 20% of alt protein as cell ag
- AU\$4/kg for cell ag products

Overall synthetic biology

\$1.9bn

CSIRO¹⁵

In food and agriculture, includes

- Biomanufacturing sustainable alternatives to animal proteins
- Engineered crops for improved resilience and nutrition
- Biosensors for security and surveillance of ag conditions ag products

Food Governing Authorities & Food Laws in Australia



FSANZ

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the Food Standards Australia New Zealand Act 1991 (FSANZ Act).

FSANZ develops the Food Standards Code (“Food Code”) that regulate the use of ingredients, processing aids, food additives, vitamins and minerals etc.

The Food Code also covers the composition of some foods, such as dairy, meat and beverages as well as foods developed by new technologies such as genetically modified foods.

Food Standards Code

Chapter 1: Introduction and standards that apply to all foods

Chapter 2: Food standards

Chapter 3: Food safety standards (Australia only)

Chapter 4: Primary production standards (Australia only)

Schedules

PART 1.1 Preliminary

Standard 1.1.1 Structure of the Code and general provisions
Standard 1.1.2 Definitions used throughout the Code

PART 1.2 Labelling and other information requirements

Standard 1.2.1 Requirements to have labels or otherwise provide information
Standard 1.2.2 Information requirements – food identification
Standard 1.2.3 Information requirements – warning statements, advisory statements and declarations
Standard 1.2.4 Information requirements – statement of ingredients
Standard 1.2.5 Information requirements – date marking of food for sale
Standard 1.2.6 Information requirements – directions for use and storage
Standard 1.2.7 Nutrition, health and related claims
Standard 1.2.8 Nutrition information requirements
Standard 1.2.10 Information requirements – characterising ingredients and components of food

PART 1.5 Foods requiring pre-market clearance

Standard 1.5.1 Novel foods
Standard 1.5.2 Food produced using gene technology
Standard 1.5.3 Irradiation of food

PART 1.3 Substances added to or present in food

Standard 1.3.3 Processing aids
Standard 1.3.2 Vitamins and minerals
Standard 1.3.1 Food additives

PART 1.6 Microbiological limits and processing requirements

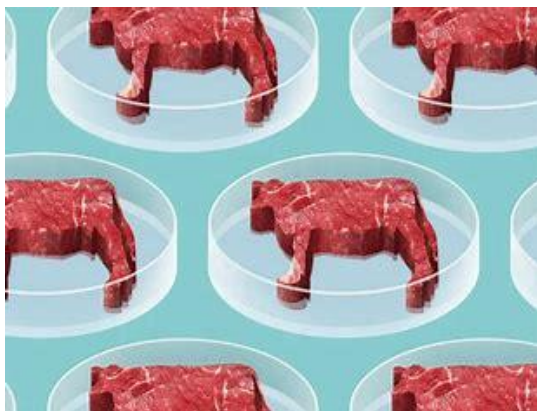
Standard 1.6.1 Microbiological limits in food
Standard 1.6.2 Processing requirements for meat [applies in Australia only]

PART 1.4 Contaminants and residues

Standard 1.4.1 Contaminants and natural toxicants
Standard 1.4.2 Agvet chemicals [applies in Australia only]
Standard 1.4.4 Prohibited and restricted plants and fungi



Regulatory Status



◆ What is cell-based meat?

- ◆ Cell-based meat is produced using animal cell culture technology, where meat is produced from animal cells using a combination of biotechnology, tissue engineering, molecular biology and synthetic processes.

- ◆ No specific standards or requirements for cell-based meat under the Food Code
- ◆ No approval has been issued by FSANZ for cell-based meat
- ◆ Cell-based meat may be captured within existing food standards in the Food Code, subject to pre-market approval

◆ Existing Standards of Relevance, e.g.,



- ◆ **Novel foods** - foods without a history of traditional human consumption in Australia and New Zealand (Standard 1.5.1)
- ◆ **Processing aids** – substances used to produce foods but which serve no technological function in the final food for sale
- ◆ **Food additives** – substances that serve a technological function in the final food for sale
- ◆ **Foods produced using gene technology** (Standard 1.5.2)
- ◆ **Vitamins and minerals**
- ◆ **Labelling** that indicates the true nature of the food
- ◆ **Food Safety requirements**
- ◆ ...

Filing an Application to Amend the Food Code

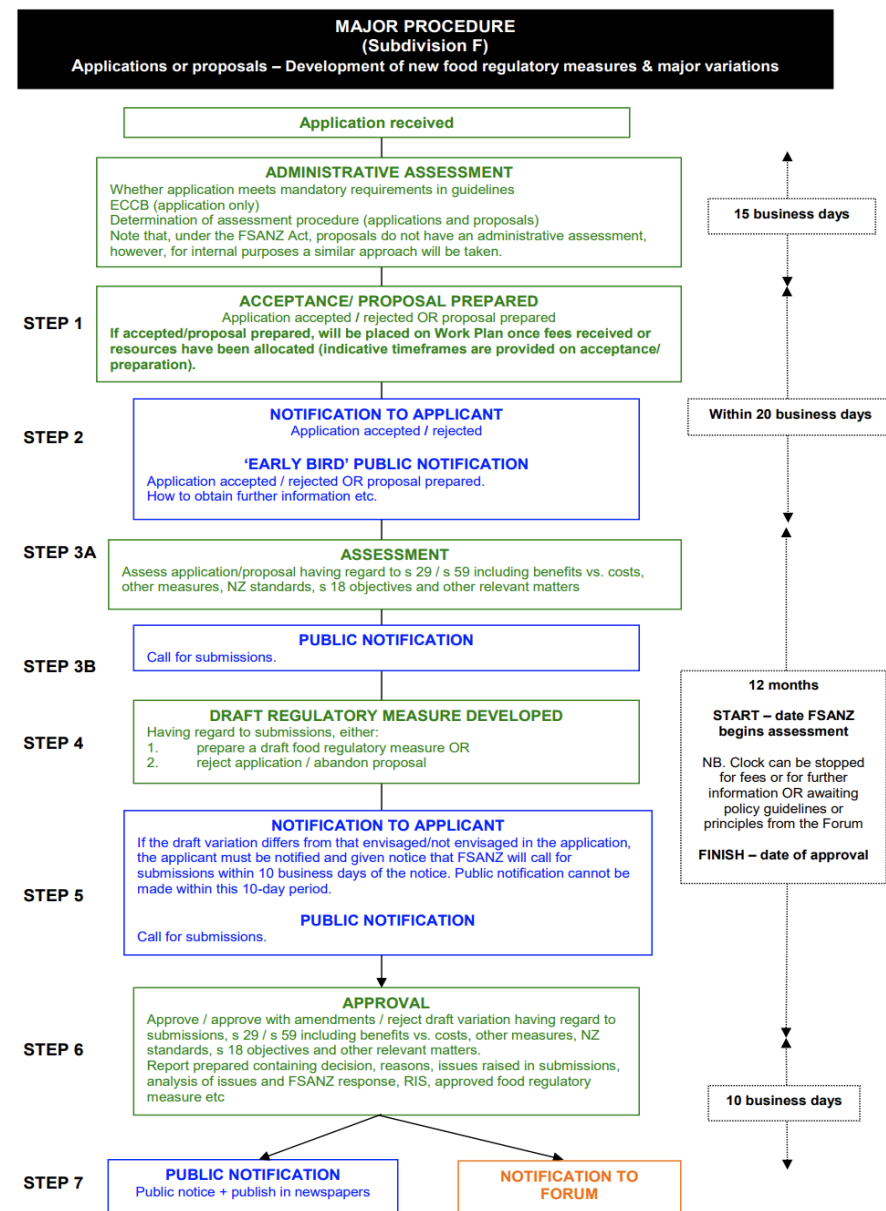
- ◆ “Novel food” – a **non-traditional food** that requires an assessment of the public health and safety considerations
- ◆ **Key element:** No history of human consumption in Australia (or New Zealand)



- FSANZ’s Advisory Committee on Novel Foods (ACNF) can make a recommendation about whether a food is “novel” in case you are not sure
- Applicants requesting approval of a novel food may also apply for a period of ‘exclusive’ use to apply to a brand or class of food for up to 15 months



Application Procedure



- ◆ General Procedure (9 months)
- ◆ Minor Procedure (3 months)
- ◆ Major Procedure (12 months)
- ◆ High level health claim variation (9 months)

A1186 – Soy Leghemoglobin in meat analogue products

Last updated: 24 December 2020

The purpose of the application is to allow the use of soy leghemoglobin derived from *Pastorisa* as a component in meat analogue products.

Approval Report - 15 December 2020 (PDF 1.4 mb) | (Word 268 kb)

Supporting document 1 - Risk and technical assessment report (PDF 1442 kb) | (Word 333 kb)

Supporting document 2 - Consumers and plant-based meat analogue products in Australia and New Zealand

(PDF 410 kb) | (Word 122 kb)

2nd Call for submissions - 6 August 2020 (PDF 433 kb) | (Word 220 kb)

Supporting document 1 - Risk and technical assessment report (PDF 433 kb) | (Word 228 kb)

Supporting document 2 - Consumers and plant-based meat analogue products in Australia and New Zealand

(PDF 117 kb) | (Word 88 kb)

Submissions (Zip 3.17 mb)

1st Call for submissions - 20 December 2019 (PDF 840 kb) | (Word 120 kb)

Submissions (Zip 14.1 mb)

Administrative Assessment Report – 27 August 2019 (PDF 282 kb) | (Word 64 kb)

Application (PDF 4.5 mb) | Appendices (Zip 22.8 mb)

Executive Summary (PDF 144 kb)



Dossier Preparation

◆ Checklist for a novel food application

- ◆ General requirements for application, e.g., purpose of the application, justification for the application
- ◆ Exclusive use of novel foods
- ◆ Technical information on the novel food
- ◆ Information on the safety of the novel food
- ◆ Information on dietary exposure to the novel food
- ◆ Information on the nutritional and health impact of the novel food
- ◆ Information related to potential impact on consumer understanding and behavior

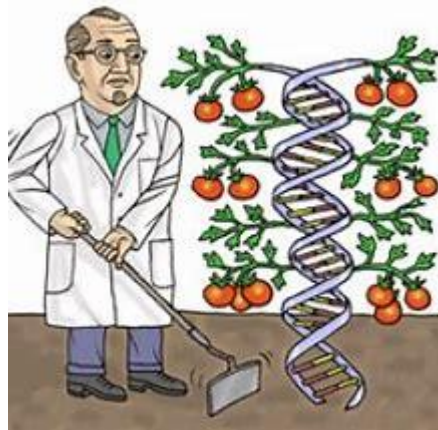
◆ Pre-Application Consultation

- ◆ FSANZ offers a pre-application service to industry



◆ Foods produced using gene technology

- ◆ **Data required for an application of food produced using gene technology**
 - ◆ General requirements for application, e.g., purpose of the application, justification for the application
 - ◆ Technical information on the food produced using gene technology
 - ◆ Characterization and safety assessment of new substances
 - ◆ Information related to the nutritional impact of the food produced using gene technology
 - ◆ Other information





Procedural and data requirements

- Confirm the proper procedure and data for the product

Pre-application consultation

- Engagement with FSANZ

Confidentiality

- Information included in the application

Exposure Assessment

- Dietary exposure assessment based on the local population

Part III - Singapore

The First Country Worldwide Cleared
Cultured Meat



World's First Cultured Meat Approval

- ◆ In December 2020, the world's first cultured chicken produced by Eat Just, Inc. was approved in Singapore, signaling the start of the global regulatory approval process to clear cultured meat.



Source: Eat JUST



Governing Food Authorities & Laws

- ◆ **Singapore Food Agency (SFA)**

- ◆ Responsible for all food-related regulations and issues

- ◆ **Key Food Regulations**

- ◆ ***Sale of Food Act (Chapter 283)***

- Fundamental food law ensuring food safety and proper information disclosure to consumers

- ◆ ***Food Regulations*** (under the Sale of Food Act)

- Setting forth specific food standards and specifications
- Labeling and advertising requirements

- ◆ ***Wholesome Meat and Fish Act 1999***



Food Regulations in Singapore

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
- 9A. Exceptions from prohibitions on claims on labels
- 9B. Limitations on making particular statements or claims on labels
10. Date marking
- 10A. Removal, etc., of date marking prohibited
11. Claims as to presence of vitamins or minerals
12. Misleading statements in advertisements
13. Food and appliances offered as prizes
14. Imported food to be registered

FOOD ADDITIVES

15. Food additives
16. Anti-caking agents

Informal Consolidation – version in force from 1/10/2021

Requirements in Food Regulations

- ◆ Safety and quality specifications for different food types (e.g., dairy products, meat products)
- ◆ Use of food additives
- ◆ MRLs of heavy metals, contaminants, pesticides, toxins and veterinary drugs
- ◆ Labeling (language, font size, nutrition claims, package, etc.)
- ◆ Packaging
- ◆ Others

Novel Foods Subject to Premarket Approval

Definition:

- “Foods and ingredients that do not have a history of safe use. Substances with a history of safe use are those that have been consumed as an ongoing part of the diet by a significant human population, e.g., the population of a country, for a period of **at least 20 years** and **without reported adverse human health effects**”
- Compounds chemically identical to naturally occurring substances but produced through advances in technology are considered novel foods

Novel foods to be produced, imported and/or sold must:

- Have received pre-market regulatory approval from SFA; and
- Meet the specifications and are produced per declared manufacturing process in the safety assessment; and
- Only used in the food categories specified in the approval per the proposed use levels for each food category described

Unassessed novel foods:

- No **offer for consumption** for the purpose of advertisement or in furtherance of any trade or business
- Allowed in **sensory evaluation studies** by companies and research institutions for R&D

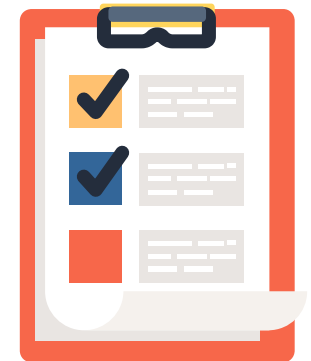


Safety Assessment of Novel Foods

Testing approach: not one-size-fits-all but hazard-based

All safety data disclosure: applicant must provide all available proprietary, confidential, or published scientific safety data, including both data in favor and not in favor.

1. Identity and source (including % of major components)
2. Purity and expected impurities
3. Tests conducted by an accredited laboratory per established testing protocols (LoD+LoQ specified)
4. All intended and unintended food processing materials and contact articles in the final product (“inputs”), including any potential metabolites
5. Safety assessment reports conducted for and/or by overseas food safety authorities
6. Intended use and exposure data
7. Demonstration of safety risk absence
8. Demonstration of toxicity absence
9. Metabolism or toxicokinetic studies (where relevant)
10. Allergenicity and/or allergen profiling (if present)
11. Manufacturing process
12. Training plans and records of staff members in training



Source: *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients* (last updated in April 2022)

Safety Assessment of Cultured Meat

In addition to what is required in regular novel food assessment:

- ◆ **Product characterization**

- ◆ Nutritional composition
- ◆ Comparison of residual anti-microbials, growth promoters and/or modulating factors against published levels

- ◆ **Information of all inputs**

- ◆ Cell lines or stem cells, and chemicals used for their induction
- ◆ Culture media, growth promoters, modulating factors and anti-microbials
- ◆ Scaffolding materials, solvents, enzymes, and processing aids

- ◆ **Manufacturing process**

- ◆ Aseptic processing steps established

Note: If GM organism/microorganism is used, additional information will be required, such as the description of the genetic modification process, safety of the host/recipient strain, genome characterization.



Application for Cultured Meat Approval



Testing

- No prescribed minimum batches to be tested, typically 3-5 non-consecutive batches
- No stability data required
- LRP-recognized laboratories

Safety Assessment

- No specified format
- SFA would initiate the evaluation by reviewing dossier prepared per specific reference documents and submitted to overseas regulatory agencies, e.g., US FDA, EFSA, FAO/WHO

Applicant

- Both domestic and foreign companies can be the applicant
- Applications can be directly submitted or through service providers, e.g., regulatory consultants or law firms

Application for Cultured Meat Approval



Data Submitted

Application data is kept confidential unless in response to public inquiry with applicant's consent

Approvals are not published; preview of press release by SFA is encouraged

Application Fee and Process

No review fee is charged by SFA

9-12 months review time (excluding responding to follow-up questions)



KH Insights



01

Confidentiality

Think early and plan for publication of non-sensitive info. to gain consumer trust

02

Application synergy

Overseas applications may ease the data burden in Singapore assessment

03

Pre-consultation

Regulatory consultation in advance is highly recommended

Part IV South Korea



Food Governing Authorities

Ministry of Food and Drug Safety (MFDS)

- Governing food safety matters
- Establishing food regulations, standards and specifications for foods
- Administrative approval of foods and food ingredients
- Investigating violations and implementing the recall



Ministry of Agriculture, Food and Rural Affairs (MAFRA)

- Supervision and management of agricultural food products
- Providing food industry infrastructure support, e.g., introducing projects for high added value food technology development
- Agencies under MAFRA governing specific food matters, e.g., APQA, NAQS, RDA



Ministry of Trade, Industry and Energy (MOTIE)

- Governing issues related to Living Modified Organism (LMO) Act, e.g., providing guidance on the development, production, import, export, sales, transportation, and storage of LMO



MAFRA –TASKS & Policy



(New industry promotion) To create new jobs and added value by reflecting social trends such as the changing demographics, net-zero and the post-Covid-19 era

- (Pet industry) to create new jobs in the service area such as animal welfare experts*, animal behavior correction specialists
 - * Notification of the 1st certification test ('21.11.26.) → test ('22.2.) → 1st certification (scheduled in '22.3.)
- (Promising food industry) to run functional food, future food*, food-tech majors to nurture experts to lead the promising food industry in the future (4 colleges in 2022)
 - * to train new food industry sectors for aging population, medical food and customized food

Support Food R&D

- Secure core technology competitiveness and support industrialization technology development to drive future food industry
- Project for high added-value food technology development
 - Support promising items' industrialization technology development including alternative food and customized food to take the lead in next-generation food market
 - Support technology development to provide safe and healthy food and improve confidence in food quality and safety
 - Support advanced food processing technique development including next-generation food packaging technology
 - Support smart food production and processing technology development
- Project for customized innovation food and naturally safe material technology development
 - Support products targeting new market in line with market trend and technology development with new technologies
 - Develop materials with alternative natural material-based ingredients instead of chemical additives

General Requirements - Food Category & Food Composition



◆ Korean Food Code

stipulates general food safety standards and specifications for the manufacturing, processing, usage, cooking, and storage of conventional foods in Korea.

◆ **Health Functional Food Act** regulates health functional foods separately.



- ◆ Use of **raw materials used in food** is regulated under the *Food Code*.

- ◆ **Ingredients used for manufacturing health functional food** (e.g., nutrients and functional ingredients) are managed by the *Health Functional Food Code*.

- ◆ **Food additives** to be used in food must satisfy relevant provisions in the *Food Additives Code*.

◆ Genetically modified foods

- ◇ In Korea, commercialization of GM foods will be conditioned upon a biosafety evaluation by MFDS.



Regulatory Status of Cultured Meat in South Korea

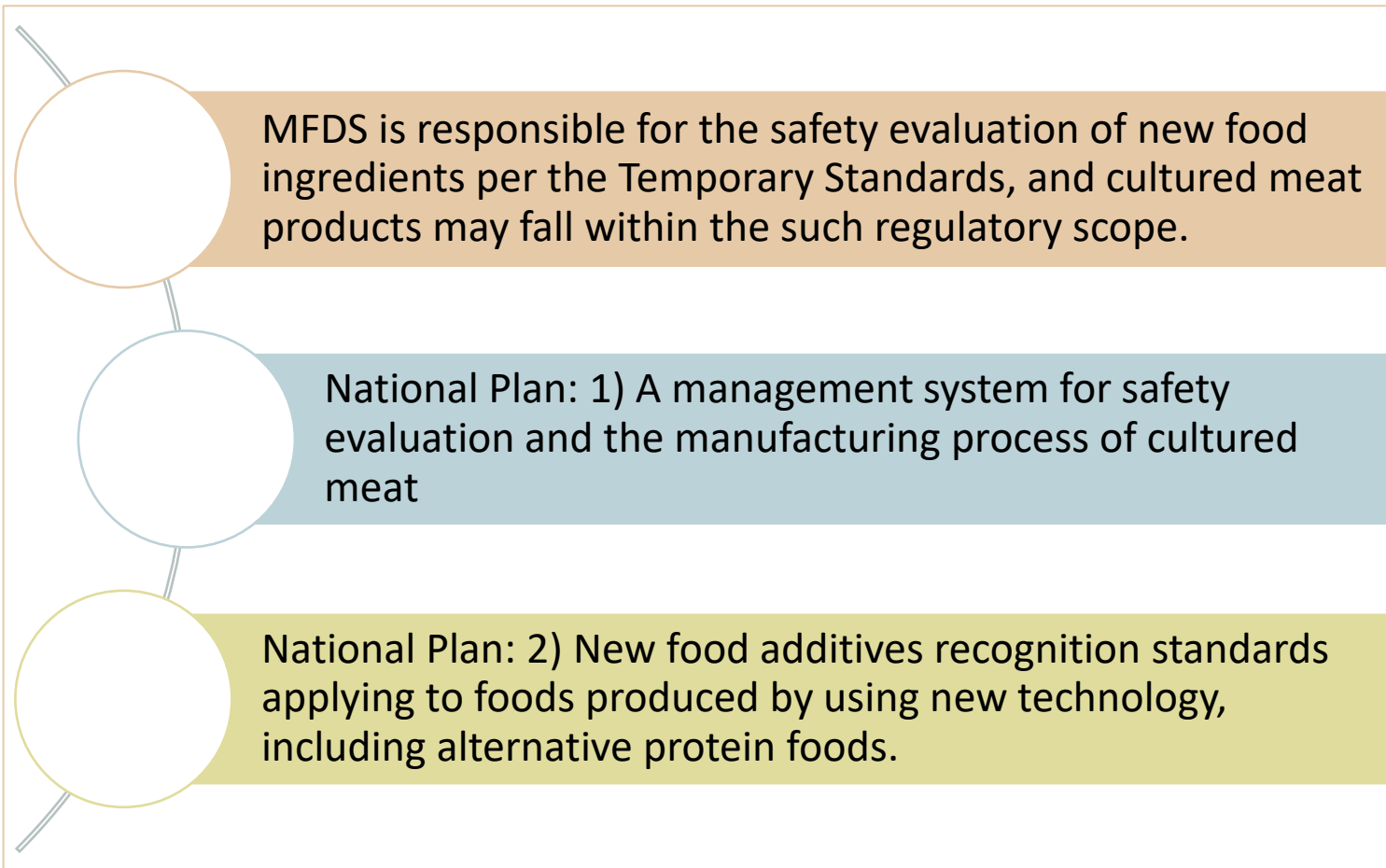


- ◆ **No** applicable food category specific to cultured meat products in the Food Code
- ◆ Raw materials of cultured meat products may **not** be considered as permissible food ingredients
 - ◆ Obtained by using new technology
 - ◆ Not have a history of safe use in Korea
- ◆ **MFDS is working on** the legal guidelines for cultured meat category





MFDS National Plan 2022



Prospective Regulatory Framework Specific to Cultured Meat Products

Annex 1 of the Temporary Standard requires the following items to be included in a new food ingredient application dossier:

- Summary of submitted data
- Data on the origin and development process, domestic and foreign recognition, usage status, etc.
- Data on the manufacturing process
- Data on the characteristics of raw materials
- Safety Data

More details for cultured meat application are expected to be released by MFDS

- Safety evaluation
- Development and production of cultured meat
- Manufacturing process of cultured meat



MFDS Notice – Pre-review Consultation in 2022



Technical Consultation For New Food Ingredients Application

- Providing guidance on new food ingredient recognition system, scope of submitted materials, such as toxicity test data
- One-on-one consulting service tailored to each company
- May shorten the actual review time of the ingredient

Technical Consultation For GM Food Application

- Providing guidance on dossier preparation, comments on the appropriateness of the submitted materials, product information, application form etc.
- Enterprises that are intended to apply for research and development of “new protein products” are explicitly encouraged by MFDS to submit their safety evaluation dossier for pre-review

유전자변형식품 안전성심사 자료 사전검토 신청서			
일반사항			
신청자(개발자)		주소	
		FAX	
담당자명	(연락처 :)		
신청 예정일		전자우편	
품목명	예) 유전자변형콩ABC	삼입유전자 및 특성	
신청 대상			
1) 안전성 심사 신청 경험이 없는 신청자(개발사, 대행사) 2) 새로운 단백질 발현 품목 3) 기타 희망하는 신청자(개발사, 대행사)			
사전 검토 사항			
1) 심사 항목별 제출자료 구비 여부 및 적정성 2) 신청서, 요약서, 자료(시험 보고서, 참고자료 등) 제출 요령 3) 기타 문의사항 질의 및 답변			
자료 확보 정도			
○ 사전검토 전 해당 항목의 불임 자료를 작성하여 신청서와 함께 제출하여야 함			
유전자변형 농축수산물	[불임 1]		
유전자변형 미생물	[불임 2]		
유전자변형 미생물 유래 식품첨가물	[불임 3]		
※ 심사자료 작성시 「유전자변형식품등의 안전성 심사 규정 해설서」를 참고할 수 있음 ※ 사전검토제도는 민원인의 심사자료 작성 및 제출 시 도움을 주고자 하는 것으로 법적 효력을 가지지는 않으며, 안전성			

KH Insights



Pre-review consultation

Get engaged with the food authorities

Per the case example provided in the MFDS notice, it takes one year for the recognition of new food ingredients on average; however, it may take about 8 months in the case of companies receiving customized consultation from MFDS.

Monitor the regulatory development

Internal discussion - Draft guidelines on safety evaluation of cultured meat

Guidance concerning cultured meat released in 2022?





Part V Q&A Session