Note:
This document is an unofficial English translation of discussion materials used at the *Consumer Affairs Agency's Subcommittee on Newly Developed Foods under the Food Sanitation Standards Council* (meeting held on February 5th, 2026).

The translations were voluntarily prepared by the **Japan Association for Cellular Agriculture (JACA)** and are provided for reference purposes only. They are not official translations and may contain inaccuracies or omissions. For official information, please go to Consumer Affairs Agency's website.

The original Japanese discussion materials may be revised following the deliberations of February 5th, 2026.
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For readability, the layout, font size, color scheme, and other design elements may differ from the materials distributed at the meeting.

The source document is available here as of February 5th, 2026:
https://www.caa.go.jp/policies/council/fssc/meeting_materials/review_meeting_004/044980.html

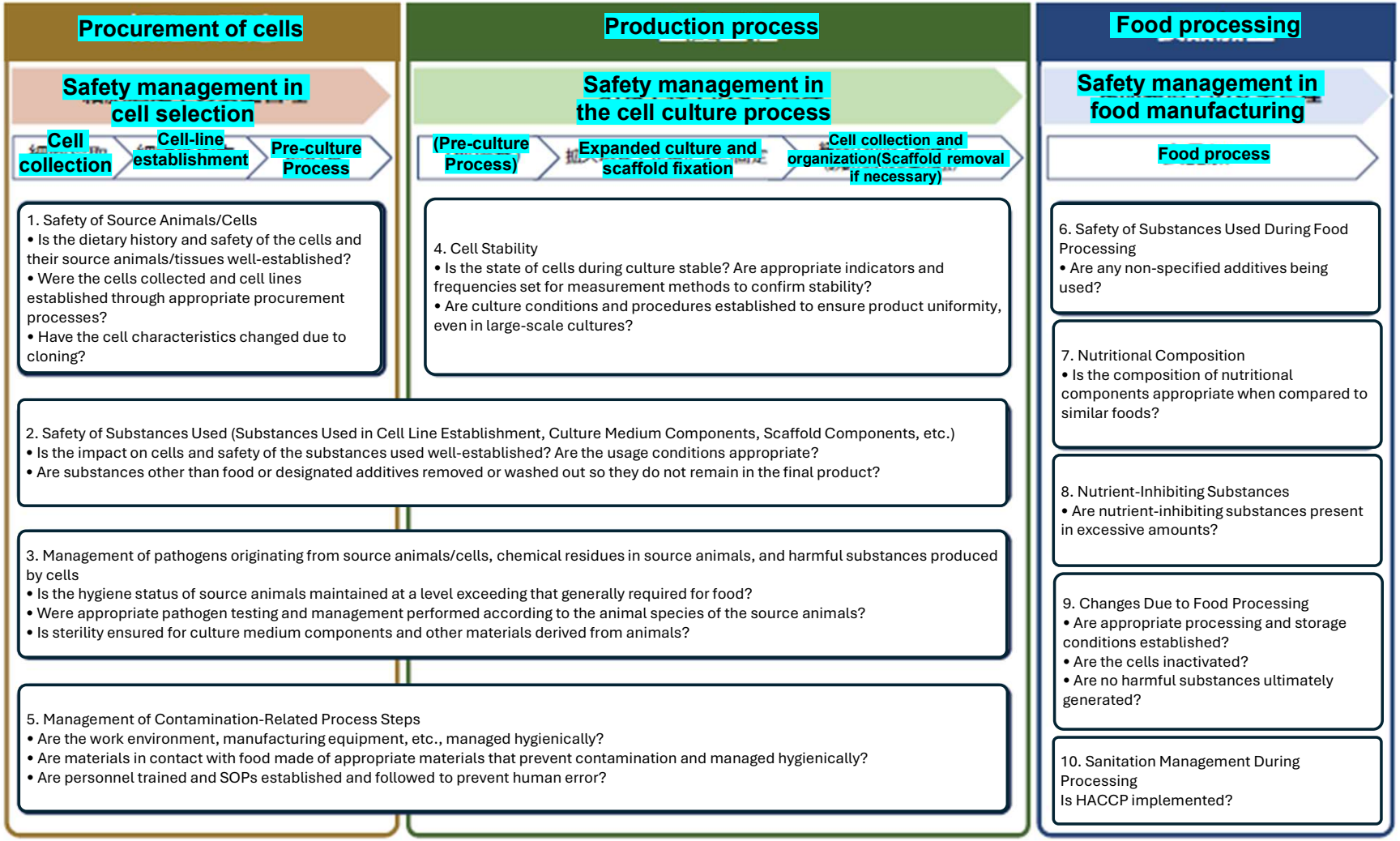
Also, please note that the materials translated were Reference Documents **2-1** and **2-2**. In addition, only selected slides were translated; not all slides were translated because some content was duplicated from the previous version.

Reference Document 2-1: *Key Points for Confirming the Safety of Cell-Cultured Foods (Provisional Name) (Revised Based on the Previous Subcommittee Meeting)* [PDF: 685.6 KB]「資料2-1 細胞培養食品(仮称)に係る安全性確認上のポイント(前回部会を踏まえ修正したもの)」
Reference Document 2-2: *Draft Outline of the Guidelines for Cell-Cultured Foods (Provisional Name), etc.* [PDF: 1.1 MB]「資料2-2 細胞培養食品(仮称)に係るガイドライン骨子(案)等」

Previous version can be found here: https://jaca.jp/2025/12/10967/

Reference 2-1 (p5)

Key Points for Safety Confirmation of Cell-Cultured Foods (Provisional Name)



※ The “Confirmation Points (Draft)” also include various regulations concerning the manufacture and sale of genetically modified foods, BSE, microbial contamination, etc., as stipulated within the framework of existing laws and regulations, including the Food Sanitation Act.

Non-official translation, prepared by JACA

Reference 2-1 (p5)

細胞培養食品（仮称）に係る安全性確認上のポイント

Pre-translation of the previous page

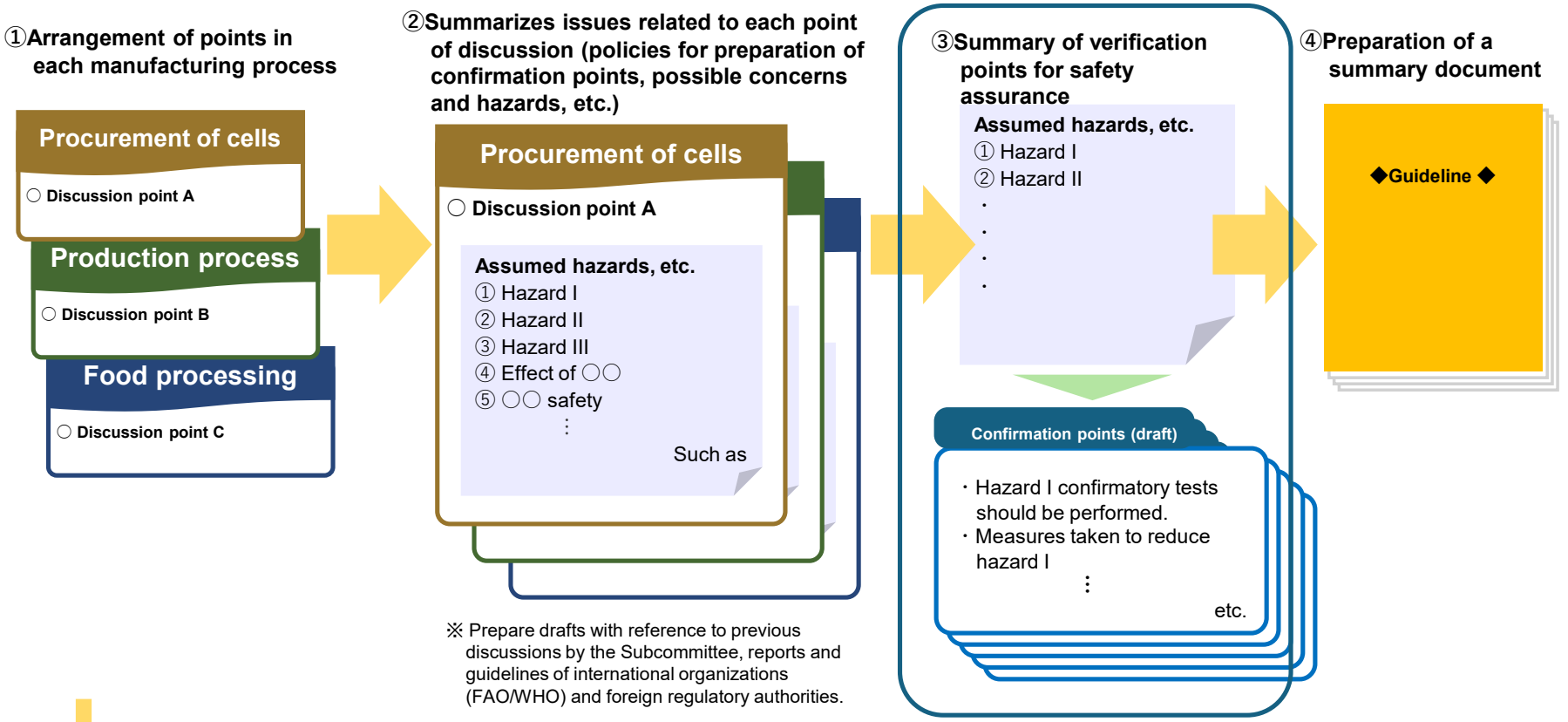
※「確認ポイント（案）」には、食品衛生法をはじめとする既存法令の枠組みにおいて定められる遺伝子組換え食品の製造・販売、BSE、微生物汚染等に係る各種規制も記載している。

Reference 2-2 (p2)

How to proceed with future discussions

○ To begin with, the concern and hazard, etc. are identified on all discussion points.

○ Subsequently, the "Summary of Confirmation Points for Safety Assurance" is carried out as items to be checked for concerns and hazards, etc., and as soon as the study work has been completed, the discussion will be carried out and the guidelines will be established.



＋ In addition, review the nomenclature used in the discussion, scope, and regulatory framework.

Non-official translation, prepared by JACA

Reference 2-2 (p3)

Outline of the Draft Guidelines

- The guidelines to be developed by this committee shall summarize the points manufacturers of cell-cultured foods (tentative name) should consider from the product design stage to ensure the safety of the final product.
- Additionally, they are planned to comprehensively cover design and manufacturing considerations for ensuring quality stability, the data to be collected, and procedures for administrative agencies.

Introduction
Section 1 General Provisions
1 Purpose
2 Nature, Positioning, and Scope of Application of These Guidelines
3 Definitions of Terms Used in These Guidelines

Section 2 Overall Overview
1 Product Overview
2 Development Background
3 Food Experience Status of Animals, etc., from Which Cells Are Derived

Section 3 Cell Properties, Characteristics, etc.
1 Cells/Tissues Serving as Starting Materials
2 Cell Characterization Analysis

Section 4: Risk Mitigation Measures through Manufacturing and Quality Control
1. Manufacturing Methods
(1) Details of Critical Manufacturing Steps, Contamination Prevention, Control Standards (HACCP-related), etc.
(2) Cell Stability
(3) Manufacturing Consistency/Process Evaluation/Validation (Including Re-evaluation upon Manufacturing Method Changes)
2. Safety of Substances Used in Manufacturing and Culture
(1) Culture Media/Scaffold Components
(2) Substances Used in Establishing Cell Lines
(3) Equipment, Containers, and Materials Used

Section 5: Comprehensive Considerations (or Comprehensive Evaluation?) Regarding the Product
1. Considerations Regarding Safety
2. Specifications of the Final Product
3. Information Regarding Allergens and Nutrition
4. Information Provided to Consumers

* Wording will be revised as appropriate based on future discussions.

Reference 2-2 (p3)

Pre-translation of
the previous page

ガイドラインの骨子案

○ 本部会が作成するガイドラインは、細胞培養食品（仮称）の製造事業者が製品設計の段階から最終製品の安全性を担保するために留意すべき事項をまとめたものとする。
○ 加えて、品質を安定させるための設計・製造上の留意点、収集すべきデータ、そして行政機関への手続き等について包括的に記載する予定としている。

はじめに

第１　総則
1　目的
2　本ガイドラインの性質・位置付け及び適用範囲
3　本ガイドラインでの用語の定義

第２　全体の概要
1　製品概要
2　開発の経緯
3　細胞が由来する動物等の食経験の状況

第３　細胞の性質、特性等
1　出発物質となる細胞・組織
2　細胞の特性解析

第４　製造管理、品質管理によるリスク回避の方策
1　製造方法について
（１）重要製造工程の詳細、汚染防止、管理基準（HACCP関係）等
（２）細胞の安定性
（３）製造の恒常性・プロセス評価／バリデーション（製造方法の変更時の再評価を含む）
2　製造・培養で使用される物質の安全性
（１）培地・足場成分
（２）株化細胞作製時に用いる物質
（３）使用される器具・容器・資材について

第５　製品に関する総合考察（or 総合評価？）
1　安全性に関する考察
2　最終製品の仕様について
3　アレルギー、栄養に関する情報
4　消費者への情報提供

※　文言は今後の議論を踏まえ適宜修正を行う

Reference 2-2 (p4)

Potential concerns, hazards, etc., identified during the subcommittee meeting

1. Safety of derived animals and cells

Procurement of cells

- Changes in Cell Characteristics Resulting from Cell Line Establishment Processes, Including Genetic Modification and Genome Editing (e.g., cellular components, growth rate, growth limits, etc.)
- Selection or Contamination of Incorrect Cells (e.g., in cases where the wrong cells are selected for cultivation, potential concerns include the toxicity or allergenicity of those cells, as well as any bioactive substances they may produce.)
- The toxicity and allergenicity of the selected cells themselves, as well as the bioactive substances such as hormones and cytokines produced by the cells.
- Toxic substances present in the source aquatic animals.
- Diseases carried by the source animals, such as BSE (prions) and other diseases (including non-communicable diseases).
- Pathogens derived from the animal species (such as bacteria and viruses)
- Residues of veterinary drugs and other substances administered to the source animals.

2. Safety of Substances Used (Substances used in the production of cell-line, medium components, scaffold components, etc.)

Procurement of cells | Production process

- Changes in cell characteristics caused by substances used in the establishment of cell lines and related processes.
- Transfer into cells and tissues of substances such as growth factors and hormones that are not expected to be used in conventional foods. The residuals of such substabces in the final products
- When components equivalent to veterinary drugs are used in culture media, residues may transfer into the final product via cellular and tissue uptake.
- Residues of allergenic substances in the final product.
- Transfer of pathogens, including prions derived from animal components, into the final product.

Reference 2-2 (p4)

Potential concerns, hazards, etc., identified during the subcommittee meeting

3. Management of pathogens originating from animals or cells, chemical substances remaining in source animals, and harmful substances produced by cells

Procurement of cells | Production process

- Pathogens originating from the animal species (such as bacteria and viruses).
- Residues of veterinary drugs and other substances administered to the source animals.
- Transfer of pathogens, including prions, from culture medium components.

4. Cell stability

Production process

- Unexpected differentiation into tissues or organs.Epigenetic changes. Production of harmful substances (such as allergens and bioactive substances) due to phenotypic changes such as cellular deterioration.
- Impact of large-scale cultivation on ensuring uniformity.

5. Management of Work Processes Related to Contamination

Procurement of cells | Production process

- Bacterial and fungal contamination from the environment (water, air, etc.), and contamination by pathogens due to inadequate sterilization of instruments and equipment.
- Contamination from food contact materials.
- Heavy metal contamination
- Human error.
- Contamination with physical foreign objects (such as metal fragments and packaging materials).

Reference 2-2 (p4)

Potential concerns, hazards, etc., identified during the subcommittee meeting

6. Safety of Substances Used in Food Processing

Food processing

- Residues of unspecified food additives in the final product and their effects.

7. Nutritional Composition

Food processing

- Excesses or deficiencies of nutritional components.
- A composition different from that of conventional foods.

8. Nutrient-Inhibiting Substances

Food processing

- Production of anti-nutritional substances by cells.
- Residues of substances used in food processing or in culture media that possess anti-nutritional activity.

9. Changes Due to Food Processing

Food processing

- Effects of changes in components during product processing and storage, and microbial contamination.
- Tumorigenicity and oncogenicity.
- Effects of physical and chemical changes in components specific to cultivated foods.

10. Sanitation Management During Food Processing

Food processing

- Microbial and chemical contamination arising from each operation in the food processing process, including contamination due to processing itself.

Reference 2-2 (p5)

Sections where anticipated concerns, hazards, etc., identified by the subcommittee are documented

Chapter 2 Overall outline
1.Product overview
2.Development history
3.Status of prior food consumption experience for the animals/seafood from which the cells are derived

(Concerns / hazards addressed in this section)
③ Toxicity or allergenicity of the selected cells themselves; physiologically active substances produced by the cells (e.g., hormones, cytokines)
④ Toxic substances present in the source seafood

Chapter 3 Properties and characteristics of cells
1. Cells/tissues used as starting materials

(Concerns / hazards addressed in this section)
③ Toxicity or allergenicity of the selected cells themselves; physiologically active substances produced by the cells (e.g., hormones, cytokines)
④ Toxic substances present in the source seafood
⑤・⑬ Diseases carried by the source animals, such as BSE (prions) and other diseases (including non-infectious diseases)
⑥ Pathogens attributable to the animal species (e.g., bacteria, viruses)
⑦・⑭ Residues of veterinary drugs, etc., administered to the source animals

2. Analysis of cell characteristics

(Concerns / hazards addressed in this section)
① Changes in cell characteristics (cell components, proliferation rate, proliferation limit, etc.) due to cell line establishment/immortalization processes, including genetic recombination and genome editing
② Selection or contamination with the wrong cells (if the cells to be cultured are mistakenly selected, the toxicity/allergenicity of those cells, physiologically active substances produced by the cells, etc.)

Chapter 4 Measures to avoid risks through manufacturing and quality management
1. About manufacturing methods
(1) Details of critical manufacturing steps, prevention of contamination, management standards (HACCP-related), etc.

(Concerns / hazards addressed in this section)
⑱ Bacterial/fungal contamination from the environment (water, air, etc.); contamination with pathogens due to insufficient sterilization of instruments, etc.
⑲ Contamination from food-contact materials
⑳ Heavy metal contamination
㉑. Human error
㉒. Inclusion of physical foreign matter (e.g., metal fragments, packaging materials)

(2) Cell stability

(Concerns / hazards addressed in this section)
⑯ Unexpected differentiation into tissues/organs, epigenetic changes, manifestation of toxicity due to cellular deterioration, and production of physiologically active substances, etc.

(3) Manufacturing consistency; process evaluation/validation (including re-evaluation when the manufacturing method is changed)

(Concerns / hazards addressed in this section)
⑰ Impact on ensuring product uniformity due to large-scale cultivation

2. Safety of substances used in manufacturing and cultivation
(1) Culture media and scaffold components

Concerns / hazards, etc. handled in this item
⑨Residues in the final product due to the transfer into cells/tissues of substances such as growth factors and hormones that are not assumed to be used in conventional foods
⑩ When components, etc. equivalent to veterinary drugs are used in the culture medium, residues in the final product due to transfer into cells/tissues
⑪ Residues of allergen substances in the final product
⑫, ⑮ Transfer of pathogens, starting with prions, from animal-derived components

(2) Substances used at the time of creating/establishing cell lines (immortalized cells)

Concerns / hazards, etc. handled in this item
⑧ Changes in cell characteristics due to culture materials used for, etc., producing/establishing cell lines

(3) Regarding the equipment, containers, and materials used

Concerns / hazards, etc. handled in this item
⑱ Contamination with pathogens due to insufficient sterilization of equipment, etc., ~
⑲ Contamination from food-contact materials; ⑳ Heavy metal contamination

(4) Substances used in food-processing steps

Concerns / hazards, etc. handled in this item
㉓ Residues of unspecified food additives in the final product and their effects

Reference 2-2 (p5)
Pre-translation of the previous page

部会において整理された想定される懸念点・ハザード等の記載位置

第２　全体の概要

1　製品概要
2　開発の経緯
3　細胞が由来する動物・魚介類の食経験の状況

この項目で扱う懸念点・ハザード等
- ③　選定した細胞そのものの毒性・アレルゲン性、細胞が産生するホルモン・サイトカイン等の生理活性物質
- ④　由来の魚介類に存在する毒性物質

第３　細胞の性質、特性等

1　出発物質となる細胞・組織

この項目で扱う懸念点・ハザード等
- ③　選定した細胞そのものの毒性・アレルゲン性、細胞が産生するホルモン・サイトカイン等の生理活性物質
- ④　由来の魚介類に存在する毒性物質
- ⑤⑬　BSE（プリオン）、その他疾患（非感染性疾患を含む）など由来動物が持つ疾病
- ⑥　動物種に起因する病原体（細菌、ウイルス等）
- ⑦⑭　由来動物に投与した動物用医薬品等の残留

2　細胞の特性解析

この項目で扱う懸念点・ハザード等
- ①　遺伝子組換え・ゲノム編集等を含む株化処理による細胞特性（細胞成分、増殖速度、増殖限度等）の変化
- ②　誤細胞の選定・混入（培養する細胞を誤って選定した場合、その細胞の毒性・アレルゲン性、細胞が産生する生理活性物質等

第４　製造管理、品質管理によるリスク回避の方策

1　製造方法について
（１）重要製造工程の詳細、汚染防止、管理基準（HACCP関係）等

この項目で扱う懸念点・ハザード等
- ⑱　環境（水、空気等）からの細菌・真菌汚染、器具等の不十分な滅菌による病原体の汚染
- ⑲　食品接触物質からの汚染
- ⑳　重金属汚染
- ㉑　人為的なミス
- ㉒　物理的な異物（金属片、包装資材等）の混入

（２）細胞の安定性

この項目で扱う懸念点・ハザード等
- ⑯　予期せぬ組織、器官等への分化、エピジェネティックな変化、細胞の劣化等による毒性の発現、生理活性物質等の産生

（３）製造の恒常性・プロセス評価／バリデーション
（製造方法の変更時の再評価を含む）

この項目で扱う懸念点・ハザード等
- ⑰　大規模培養による均一性担保への影響

2　製造・培養で使用される物質の安全性
（１）培地・足場成分

この項目で扱う懸念点・ハザード等
- ⑨　従来型の食品への使用が想定されない成長因子やホルモン等の物質の細胞・組織内への移行による最終製品への残留
- ⑩　動物用医薬品に相当する成分等を培地に使用した場合、細胞・組織内移行による最終製品への残留
- ⑪　アレルゲン物質の最終製品への残留
- ⑫⑮　動物由来成分からのプリオンをはじめとする病原体移行

（２）株化細胞作成時に用いる物質

この項目で扱う懸念点・ハザード等
- ⑧　株化細胞の作製等に使う培養資材による細胞の特性変化

（３）使用される器具・容器・資材について

この項目で扱う懸念点・ハザード等
- ⑱　～器具等の不十分な滅菌による病原体の汚染、
- ⑲　食品接触物質からの汚染、⑳　重金属汚染

（４）食品加工工程に用いる物質

この項目で扱う懸念点・ハザード等
- ㉓　未指定の食品添加物の最終製品への残留及びその影響

5

Reference 2-2 (p6) Sections where anticipated concerns, hazards, etc., identified by the subcommittee are documented

Chapter 5 Comprehensive considerations regarding the product (or comprehensive evaluation?)

1. Considerations regarding safety

Concerns / hazards, etc. handled in this item
㉙ Tumorigenicity / carcinogenicity
㉚ Effects of physical/chemical changes of components specific to cell-cultured foods

2. About the specifications of the final product

3. Information regarding allergy and nutrition

Concerns / hazards, etc. handled in this item
③ Toxicity / allergenicity of the selected cells themselves; physiologically active substances such as hormones/cytokines produced by the cells
⑪ Residues of allergen substances in the final product
㉔ Excess or deficiency of nutritional components
㉕ Composition different from conventional foods
㉖ Production by cells of substances that inhibit nutrition
㉗ Remaining of substances that have nutritional-inhibitory activity, which are substances used during food processing or substances used in media, etc.
㉘ Effects of changes in components, etc. during processing/storage of the product; microbial contamination
㉛ Contamination by microorganisms, chemical substances, etc. attributable to each operation in the food-processing process

Items to be included other than concerns / hazards, etc.

☐ Introduction (introductory section)
☐ Specific operation/implementation of the guideline (regulatory framework), scope of application (also, items not treated as cell-cultured foods) (Chapter 1 General Provisions, item 2)
☐ In the case that there is a change in the manufacturing method (Chapter 1 General Provisions, item 2)
☐ Glossary (Chapter 1 General Provisions, item 3)
☐ Product overview (Chapter 2 Overall outline, items 1 and 2)
☐ Overall picture of the manufacturing process (Chapter 4 Measures to avoid risks through manufacturing management and quality management)
☐ Provision of information to consumers etc.

Reference 2-2 (p6)
Pre-translation of the previous page

部会において整理された想定される懸念点・ハザード等の記載位置

第５　製品に関する総合考察（or 総合評価?）

1　安全性に関する考察

この項目で扱う懸念点・ハザード等
- ㉙ 造腫瘍性・腫瘍原性
- ㉚ 細胞培養食品特有の成分の物理的・化学的変化の影響

2　最終製品の仕様について

3　アレルギー、栄養に関する情報

この項目で扱う懸念点・ハザード等
- ③ 選定した細胞そのものの毒性・アレルゲン性、細胞が産生するホルモン・サイトカイン等の生理活性物質
- ⑪ アレルゲン物質の最終製品への残留
- ㉔ 栄養成分の過不足
- ㉕ 従来の食品とは異なる組成
- ㉖ 細胞による栄養阻害物質の産生
- ㉗ 食品加工時に使用する物質や培地等に使用する物質であって栄養阻害活性を有するものの残存
- ㉘ 製品の加工・保存中における成分等の変化の影響、微生物汚染
- ㉛ 食品加工の工程における各作業に起因する微生物、化学物質等による汚染

懸念点・ハザード等以外の記載すべき項目

- □ はじめに（イントロダクション）
- □ ガイドラインの具体的運用（規制のフレームワーク）、適用範囲（併せて細胞培養食品として扱わないもの）（第１総則の２）
- □ 製造方法に変更があった場合（第１総則の２）
- □ 用語集（第１総則の３）
- □ 製品概要（第２全体の概要の１、２）
- □ 製造工程の全体像（第４製造管理、品質管理によるリスク回避の方策）
- □ 消費者への情報提供

等

Reference 2-2 (p7)

（参考）

ガイドラインのイメージ

令和８年〇月

(Reference)

Illustration/Image of the Guideline

Reiwa 8, Month ◯ (i.e., [unspecified] month in Reiwa 8)

Reference 2-2 (p8)

Reference 2-2 (p9)

はじめに

「細胞培養食品（仮称）を取り巻く現状（国内外の研究、販売及び規制状況）」、「ガイドライン策定までの経緯」、「性質（第１パラ１、２を併せて参照）」等について記載。

第１　総則

１　目的

「作成の目的」等について記載。

２　本ガイドラインの性質・位置付け及び適用範囲

「ガイドラインの具体的運用（規制のフレームワーク）」、「適用範囲（併せて対象としない培養食品。）」、「製造方法に変更があった場合」等について記載。

※　今後の科学的知見の集積により現状、想定しないハザード等が生じた際には適時見直すことなどについても記載。

３　本ガイドラインでの用語の定義

（ガイドラインで使う単語の説明。）

第２　全体の概要

１　製品概要

（製品概要として、提示してもらう情報について記載。）

２　開発の経緯

「当該細胞培養食品の開発に至った背景」、「研究・開発の過程」、「想定される利用場面」、「海外における制度的な位置づけや承認・販売の状況」等について記載。

３　細胞が由来する動物等の食経験の状況

（この項目で扱う懸念点・ハザード等）
③　選定した細胞そのものの毒性
④　由来の魚介類に存在する毒性物質

第３　細胞の性質、特性等

１　出発物質となる細胞・組織

「原則」、「原料の適格性（ドナー動物を更新する場合（初代）、セルバンク等を構築する場合（不死化細胞、多能性幹細胞など））」、「ドナー動物に関する記録管理」について記載。

Introduction

Describe items such as: the current situation surrounding “cell-cultured foods (provisional name)” (domestic and overseas research, sales, and regulatory status), the background up to the formulation of the guideline, and the “nature/properties” (see also Chapter 1, paragraphs 1 and 2).

Chapter 1 General Provisions

1 Purpose

Describe items such as the “purpose of preparation/drafting.”

2 Nature/positioning of these guidelines and scope of application

Describe items such as: “specific operation of the guideline (regulatory framework),” “scope of application (including cultured foods not covered),” and “cases where there has been a change in the manufacturing method.”
Note: Also describe that, as scientific knowledge accumulates in the future, if currently unanticipated hazards, etc. arise, the guideline will be reviewed in a timely manner, etc.

3 Definitions of terms in these guidelines
(Explanation of the words used in the guideline.)

Chapter 2 Overall outline

1 Product overview

(As a product overview, describe the information that should be provided/presented.)

2 Development history

Describe items such as: the background leading to the development of the relevant cell-cultured food, the process of research and development, anticipated use situations, and the institutional positioning overseas as well as the status of approvals and sales.

3 Status of prior food-consumption experience of the source animals, etc. from which the cells are derived

(Concerns/hazards handled in this item)
③Toxicity of the selected cells themselves
④Toxic substances present in the source seafood

Chapter 3 Properties and characteristics of cells, etc.

1 Cells/tissues used as starting materials

Describe items such as: “principles,” “eligibility of raw materials (when renewing donor animals (primary); when establishing cell banks, etc. (immortalized cells, pluripotent stem cells, etc.)),” and “record management regarding donor animals.”

Reference 2-2 (p10)

（この項目で扱う懸念点・ハザード等）
③ 選定した細胞そのものの毒性
④ 由来の魚介類に存在する毒性物質
⑤⑬ BSE（プリオン）、その他疾患（非感染性疾患を含む）など由来動物が持つ疾病
⑥ 動物種に起因する病原体（細菌、ウイルス等）
⑦⑭ 由来動物に投与した動物用医薬品等の残留

2 細胞の特性解析
「原則」、「細胞の特性解析（細胞の集団、亜集団の特徴、各集団の形態学的特徴、微生物学的特徴、増殖特性、分化特性、生化学的指標、免疫学的指標、特徴的産生物質、その他特徴的な遺伝型又は表現型）」、「保存方法及び取り違え防止策」、「運搬方法と管理」、について記載

（この項目で扱う懸念点・ハザード等）
① 株化処理による細胞特性の変化
② 誤細胞の選定、混入

第4 製造管理、品質管理によるリスク回避の方策
1 製造方法について
（1）重要製造工程の詳細、汚染防止、管理基準（HACCP 関係）等
「製造方法（製造工程の全体像）」、「重要製造工程の詳細」、「モニタリング」、「管理基準（HACCP 関係）」について記載

（この項目で扱う懸念点・ハザード等）
⑱ 環境からの汚染について
⑲ 食品接触物質からの汚染について
⑳ 重金属汚染について
㉑ 人為的なミスについて
㉒ 物理的な異物の混入について

（2）細胞の安定性
「製造の恒常性」における「ゲノムの不安定性/核型異常の誘導」「純度試験」について記載する。

（この項目で扱う懸念点・ハザード等）
⑯ 予期せぬ組織、器官等への分化、エピジェネティックな変化、細胞の劣化等による毒性の発現、生理活性物質等の産生

（3）製造の恒常性・プロセス評価／バリデーション（製造方法の変更時の再評価を含む）
「製造の恒常性」における「プロセス評価/バリデーション」「細胞の洗浄・培地の除去工程」「不活化処理」「製造方法の変更時の再評価」について記載する。

(Concerns / hazards handled in this item)
③. Toxicity of the selected cells themselves
④. Toxic substances present in the source seafood
⑤, ⑬. Diseases carried by the source animals, such as BSE (prions) and other diseases (including non-infectious diseases)
⑥. Pathogens attributable to the animal species (bacteria, viruses, etc.)
⑦, ⑭. Residues of veterinary drugs, etc. administered to the source animals

2 Analysis of cell characteristics
Describe: “principles,” “analysis of cell characteristics (cell populations; characteristics of subpopulations; morphological characteristics of each population; microbiological characteristics; proliferative characteristics; differentiation characteristics; biochemical indicators; immunological indicators; characteristic produced substances; and other characteristic genotypes or phenotypes),” “storage methods and measures to prevent mix-ups,” and “transport methods and management.”

(Concerns / hazards handled in this item)
①Changes in cell characteristics due to cell line establishment/immortalization processing
②Selection of the wrong cells; contamination/mixing-in

Chapter 4 Measures for risk avoidance through manufacturing management and quality management
1 About manufacturing methods
(1) Details of critical manufacturing steps, contamination prevention, management standards (HACCP-related), etc.
Describe: “manufacturing methods (overall picture of the manufacturing process),” “details of critical manufacturing steps,” “monitoring,” and “management standards (HACCP-related).”

(Concerns / hazards handled in this item)
⑱. Contamination from the environment
⑲. Contamination from food-contact materials
⑳. Heavy metal contamination
㉑. Human error
㉒. Inclusion of physical foreign matter

(2) Cell stability
In “manufacturing consistency,” describe “genome instability/induction of karyotypic abnormalities” and “purity testing.”

(Concerns / hazards handled in this item)
⑯. Unexpected differentiation into tissues/organs, epigenetic changes, manifestation of toxicity due to cellular deterioration, and production of physiologically active substances, etc.

(3) Manufacturing consistency; process evaluation/validation (including re-evaluation when the manufacturing method is changed)
In “manufacturing consistency,” describe “process evaluation/validation,” “cell washing and culture-medium removal steps,” “inactivation treatment,” and “re-evaluation when the manufacturing method is changed.”

Reference 2-2 (p11)

（この項目で扱う懸念点・ハザード等）
⑰　大規模培養による均一性担保の影響

2　製造・培養で使用される物質の安全性
「原則」「培地成分」「足場成分」「フィーダー細胞」「セルバンク、材料の製造過程で履歴として使用された成分（原材料）」について記載する。

（1）培地・足場成分

（この項目で扱う懸念点・ハザード等）
⑨　培地・足場成分について
⑩　動物用医薬品に相当する成分等を培地に使用した場合、細胞・組織内移行による最終製品への残留
⑫⑮　動物由来成分からのプリオンをはじめとする病原体の最終製品への移行

（2）株化細胞作製時に用いる物質

（この項目で扱う懸念点・ハザード等）
⑧　株化細胞の作製等に使う培養資材による細胞の特性変化

（3）使用される器具・容器・資材について

（この項目で扱う懸念点・ハザード等）
⑱　環境（水、空気等）からの細菌・真菌汚染、器具等の不十分な滅菌による病原体の汚染
⑲　食品接触物質からの汚染
⑳　重金属汚染

（4）食品加工工程に用いる物質
「出荷物を構成する非細胞成分」における「食品添加物」「細胞保存液（中間体の出荷の場合）」について記載する。

（この項目で扱う懸念点・ハザード等）
㉓　未指定の食品添加物の最終製品への残留及びその影響

第５　製品に関する総合考察
1　安全性に関する考察
「情報提供について」における「構成細胞の生物学的特徴」について記載する。

（この項目で扱う懸念点・ハザード等）
㉙　造腫瘍性・腫瘍原性
㉚　細胞培養食品特有の成分の物理的・化学的変化

(Concerns / hazards handled in this item)
⑰. Impact on ensuring uniformity due to large-scale cultivation

2 Safety of substances used in manufacturing and cultivation
Describe: “principles,” “culture-medium components,” “scaffold components,” “feeder cells,” and “components used as part of the history in the manufacturing process of cell banks and materials (raw materials).”

(1)　Culture media and scaffold components

(Concerns / hazards handled in this item)
⑨. Regarding culture-medium and scaffold components
⑩. If components equivalent to veterinary drugs, etc. are used in the culture medium, residues in the final product due to transfer into cells/tissues
⑫, ⑮. Transfer into the final product of pathogens—starting with prions—from animal-derived components

(2) Substances used during establishment/creation of cell lines

(Concerns / hazards handled in this item)
⑧. Changes in cell characteristics due to culture materials used for, etc., producing/establishing cell lines

(3) Regarding the equipment, containers, and materials used

(Concerns / hazards handled in this item)
⑱. Bacterial/fungal contamination from the environment (water, air, etc.); contamination with pathogens due to insufficient sterilization of equipment, etc.
⑲. Contamination from food-contact materials
⑳. Heavy metal contamination

(4) Substances used in food-processing steps
In “non-cellular components constituting the shipped product,” describe “food additives” and “cell preservation solution (in the case of shipping intermediates).”

(Concerns / hazards handled in this item)
㉓. Residues of unspecified food additives in the final product and their effects

Chapter 5 Comprehensive considerations regarding the product
1 Considerations regarding safety
In “about information provision,” describe “biological characteristics of the constituent cells.”

(Concerns / hazards handled in this item)
㉙. Tumorigenicity / carcinogenicity
㉚. Physical and chemical changes of components specific to cell-cultured foods

Reference 2-2 (p12)

2　最終製品の仕様について
標準品と比較してリスク評価をする場合について記載

3　アレルギー、栄養に関する情報
「安定性について」における「設定する保存条件」、「微生物学的安定性」、「アレルゲン」、「安全性評価について」における「摂取許容量に関するまとめ」、「細胞成分（細胞の代謝産物）」について記載予定

（この項目で扱う懸念点・ハザード等）
③　選定した細胞そのものの毒性・アレルゲン性、細胞が産生する生理活性物質等
⑪　アレルゲン物質の最終製品への残留
㉔　栄養成分過不足
㉕　従来組成との比較について
㉖　細胞による栄養阻害物質の産生について
㉗　食品加工時の使用物質における栄養阻害活性について
㉘　変化の影響、微生物汚染
㉛　食品加工の工程における汚染について

4　消費者に情報提供すべき事項

2 About the specifications of the final product
Describe cases where risk assessment is conducted by comparison with a standard product.

3 Information regarding allergies and nutrition
It is planned to describe: in “Stability,” the “storage conditions to be set,” “microbiological stability,” and “allergens”; and in “Safety evaluation,” the “summary regarding tolerable intake,” and “cell components (cell metabolites).”

(Concerns / hazards handled in this item)
③ Toxicity/allergenicity of the selected cells themselves, and physiologically active substances, etc. produced by the cells
⑪ Residues of allergen substances in the final product
㉔ Excess or deficiency of nutritional components
㉕ Regarding comparison with conventional composition
㉖ Regarding production by cells of substances that inhibit nutrition
㉗ Regarding nutritional-inhibitory activity of substances used during food processing
㉘ Effects of changes; microbial contamination
㉛ Regarding contamination in the food-processing process

4 Matters on which information should be provided to consumers

More detail will be shared at JACA blog
https://jaca.jp/en/blog/