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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 December 25, 2025).

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The original Japanese discussion materials may be revised following the deliberations of December 25, 2025.

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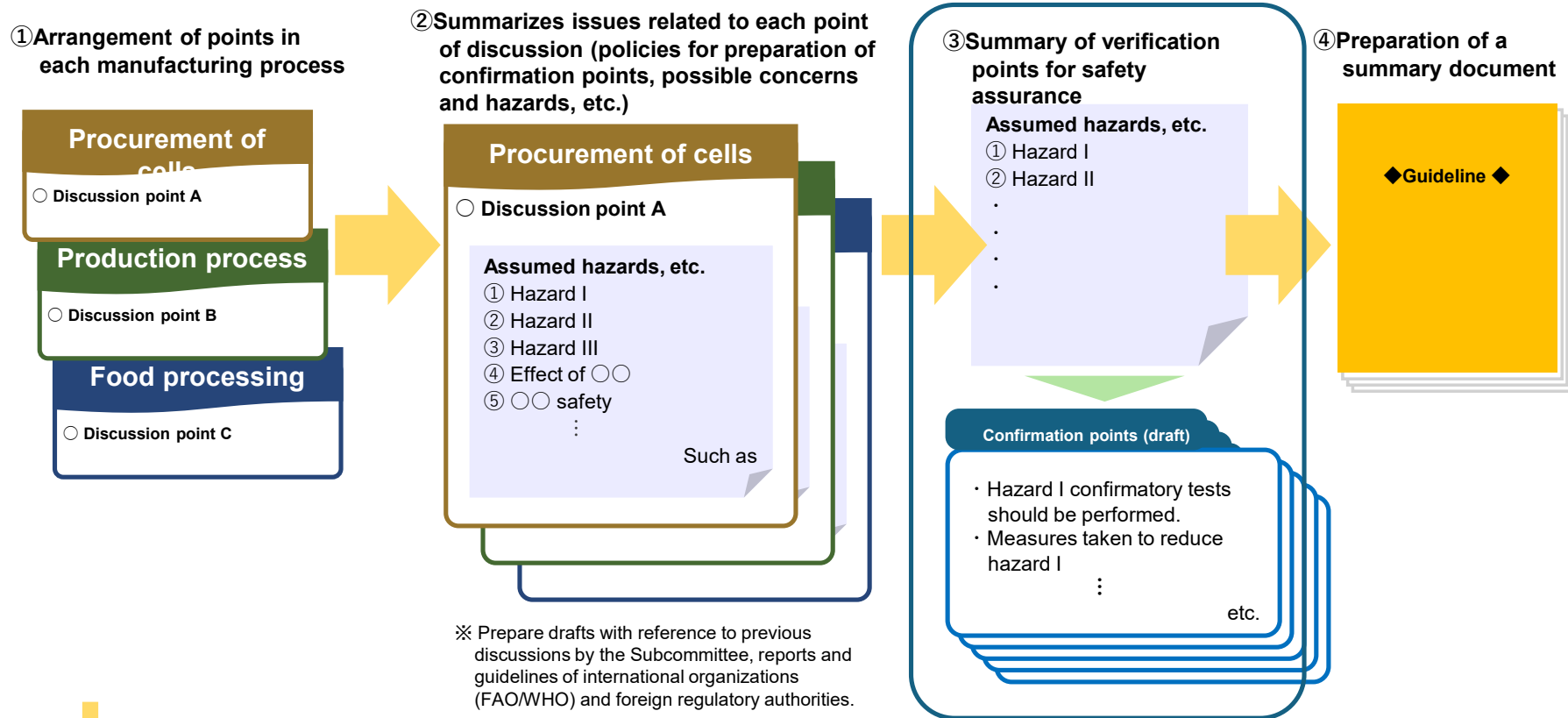
For readability, the layout, font size, color scheme, and other design elements may differ from the materials distributed at the meeting.

The source document is available here as of 25th December 2025:

https://www.caa.go.jp/policies/council/fssc/meeting_materials/review_meeting_004/044501.html

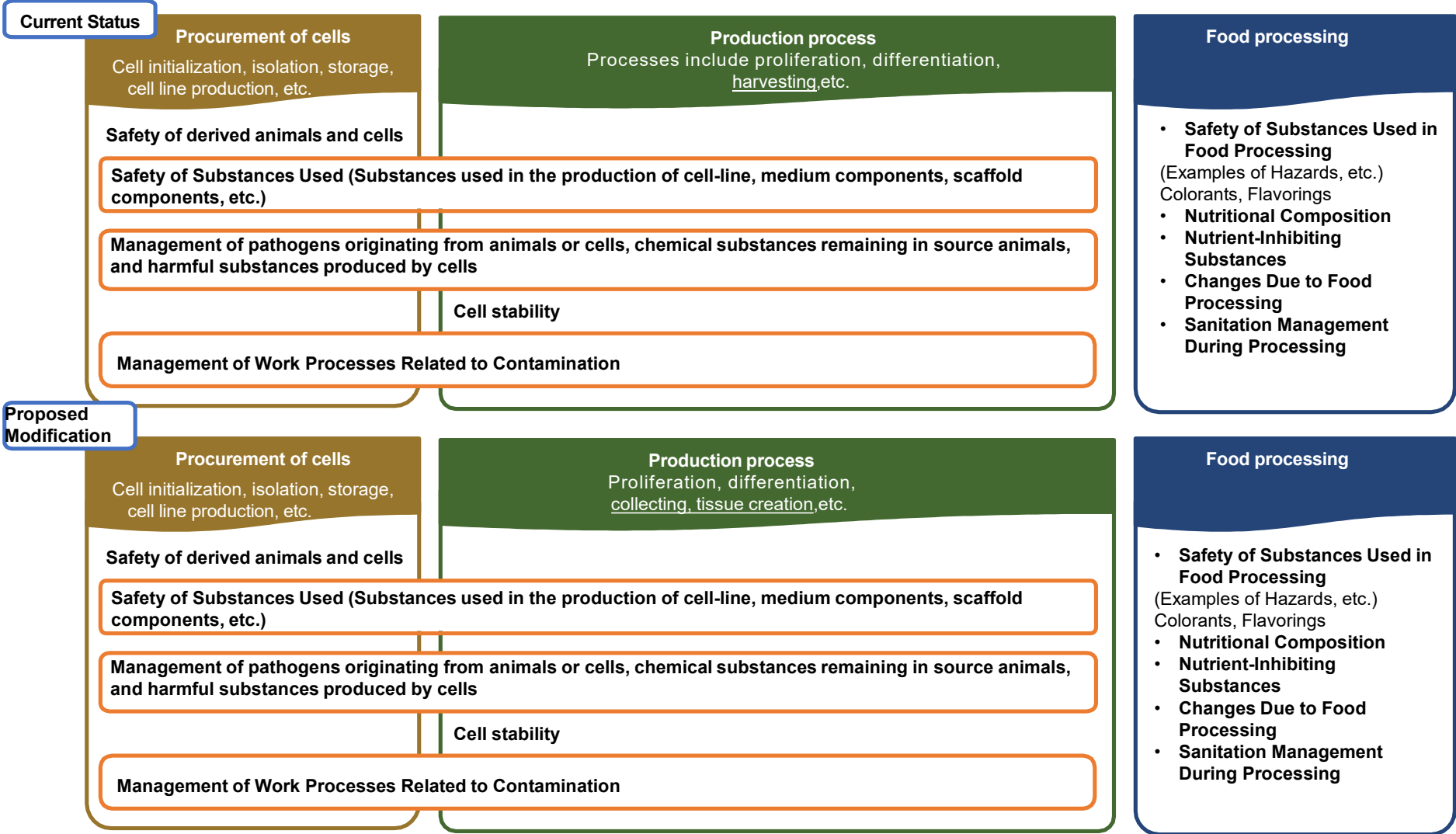
How to proceed with future discussions

- 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.

Revised Proposal for Organizing Key Safety Considerations Regarding “Cell-Cultured Food (Tentative Name)”



※In addition to the above, “cell-cultured food” → “cell-cultured food (tentative name)”

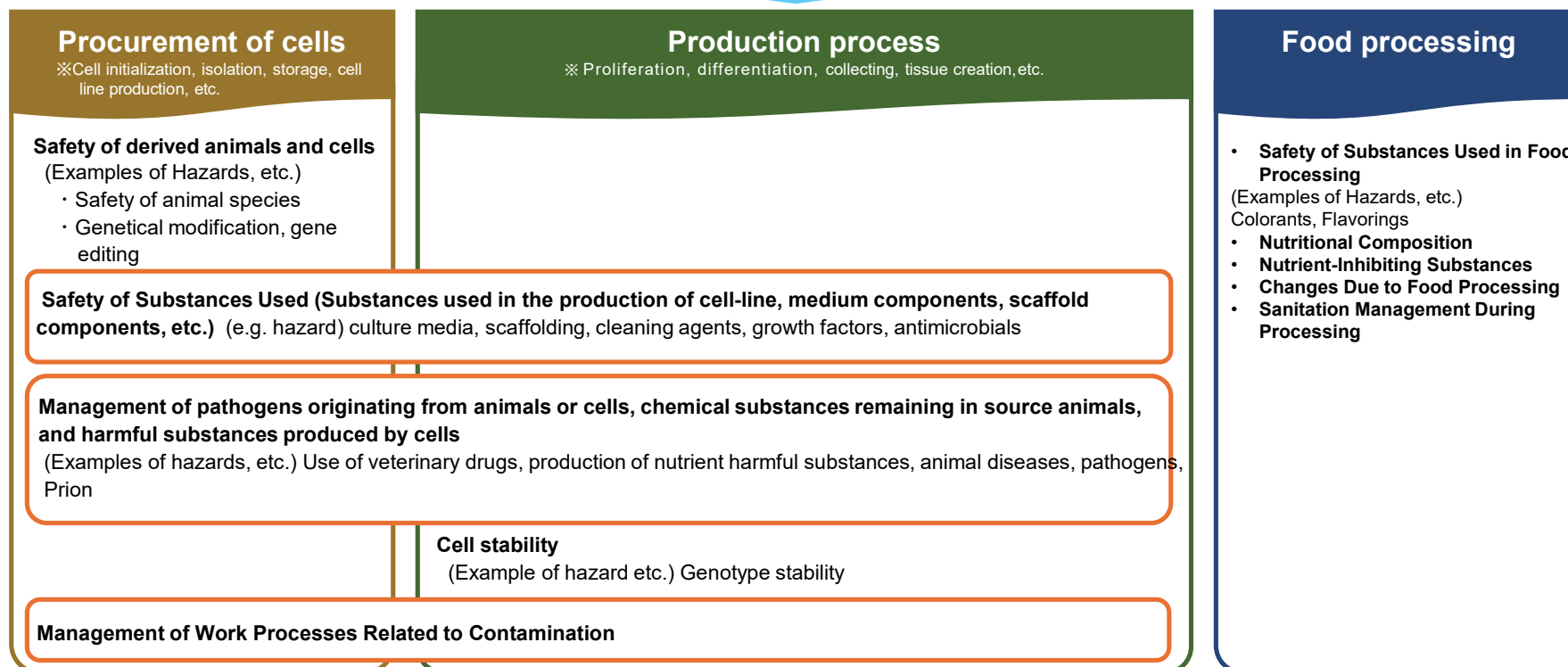
Organization of Key Issues for Safety Confirmation Regarding “Cell-Cultured Food (Tentative)”

Revised version

Regarding the safety confirmation of “cell-cultured food (tentative name),” focusing on the manufacturing process, we should discuss the items that need to be checked to ensure safety by narrowing down the potential hazards and concerns for each of the following points.

※ Future discussions and scientific findings will be taken into account to add, as appropriate.

Discussions that anticipate all possible hazards are considered essential for ensuring the safety of the final product and enabling consumers to safely consume “cell-cultured food (tentative name).”



※ In addition to the above, ① the name and scope of "cell culture foods" and ② the way of regulation (framework) based on the discussion of the Subcommittee are also examined.

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 substances in the final products
- Residues in the final product resulting from the transfer into cells and tissues when veterinary drugs and similar substances are used in the culture medium.
- Residues of allergenic substances in the final product.
- Transfer of pathogens, including prions derived from animal components, into the final product.

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 (such as water and air), and contamination by persistent pathogens due to insufficient sterilization of equipment and related items.
- Contamination from food contact materials.
- Heavy metal contamination
- Human error.
- Contamination with physical foreign objects (such as metal fragments and packaging materials).

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

6. Safety of Substances Used in Food Processing

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

Food
processing

7. Nutritional Composition

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

Food
processing

8. Nutrient-Inhibiting Substances

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

Food
processing

9. Changes Due to 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.

Food
processing

1. Organization of Issues Concerning the Safety of Source Animals and Cells (Anticipated Hazards and Related Considerations)

Blue Items considered to be points of concern (potential hazards)
Pink Items considered to be hazards (hazard factors)

(1) Items Considered Specific to Cultivated Foods			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
1	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.)	<p>Characteristics of cells used for cultivation (reference/standard cells)</p> <p>Appropriateness of the process for establishing cell lines (e.g., the purpose of cell line establishment, methods for creating a master cell bank, etc.)</p> <p>Whether cell line establishment leads to changes in cellular characteristics, such as effects on phenotype and function, accumulation of mutations, changes in cellular components, cell cycle, and proliferation rate</p> <p>In cases where genetic modification or genome editing is applied during cell line establishment, whether there is any generation of new bioactive substances, allergens, or similar compounds</p>	<p>Information on reference/standard cultured cells (e.g., cell cycle, proliferation rate, stability, etc.)</p> <p>Information on the cell line establishment process up to immortalization, including whether genetic modification or genome editing (e.g., for genetically modified or genome-edited foods) was performed</p> <p>Information on changes in cellular secretions resulting from cell line establishment</p>
2	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.)	<p>Whether the cell line is of the intended cell type</p> <p>Whether the methods used for cell identification, such as differentiation markers and characteristic markers, are appropriate</p> <p>Whether the cell sourcing and procurement process is appropriate, including whether there is any risk of misidentification by unintended cell types</p>	<p>Information on the establishment process up to cell line creation</p> <p>Information on confirmation of cell type identification</p> <p>Information on cell identification information</p>

1. Organization of Issues Concerning the Safety of Source Animals and Cells (Anticipated Hazards and Related Considerations)

(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
3	The toxicity and allergenicity of the selected cells themselves, as well as the bioactive substances such as hormones and cytokines produced by the cells.	<p>Whether there is an appropriate explanation and information regarding the identity of the selected cells (e.g., the rationale for selecting the body part of the animal [for cell sourcing] and cell type, information on dietary experience with the source animal, etc.).</p> <p>Whether the selected cells are known to produce bioactive substances or toxic substances (whether such substances increase concomitantly during cultivation will be confirmed in later processes).</p>	<p>Information on the source animal, tissue, and sampling site (including rearing conditions and dietary experience)</p> <p>(When using commercially available cell lines) information related to the origin of the cell line</p>
4	Toxic substances present in the source aquatic animals.	<p>(For primary cells)</p> <p>Whether there is an appropriate explanation and information regarding the identity of the selected cells (e.g., the rationale for selecting the body part of the animal [for cell sourcing] and cell type, information on dietary experience with the source animal, etc.).</p> <p>Whether there is any contamination by toxic substances contained in the source fish or shellfish (e.g., neurotoxins, shellfish toxins, histamine, etc.), and if contamination is present, whether it has been appropriately removed.</p>	<p>Information on the source fish or shellfish, tissue, and sampling site (including place of origin/aquaculture environment and dietary experience)</p> <p>(When using commercially available cell lines) information related to the origin of the cell line</p>
5	Diseases carried by the source animals, such as BSE (prions) and other diseases (including non-communicable diseases).	Described later	Described later
6	Pathogens derived from the animal species (such as bacteria and viruses)	Described later	Described later
7	Residues of veterinary drugs and other substances administered to the source animals.	Described later	Described later

To be discussed together with the following item described later: “(12) Transfer of pathogens, including prions, from animal-derived components into the final product (*)”.

*This relates to the points of concern/hazards, etc. under the issue: “Safety of materials used (materials used in cell line establishment, culture medium components, scaffold 9 components, etc.).”

2. Organization of Issues in “Safety of Substances Used (such as those employed in cell line establishment, culture medium components, and scaffold materials)” (Anticipated Hazards, etc.) (Draft)

(1) Items Considered Specific to Cultivated Foods			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
8	Changes in cell characteristics caused by substances used in the establishment of cell lines and related processes.	<p>Whether the conditions for the substances used (such as their purpose of use as culture medium components, concentrations, processing/treatment conditions, etc.) are appropriate.</p> <p>Whether the substances have an adequate level of safety assurance, including not only the absence of mutagenicity but also whether they do not exert undesirable effects on proliferative capacity, cell morphology, gene expression phenotype, cell stability, and related characteristics.</p>	<p>List of substances used</p> <p>Information on the general use of each substance, its purpose as a culture medium component, concentration, and processing/treatment conditions</p> <p>Information on changes or effects exerted by the substances on the cells</p>
9	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 substances in the final products	When substances other than food ingredients or food additives may carry over, whether appropriate removal and washing measures are implemented.	<p>Information on the presence/residues in the final product of substances not intended for use in foods</p> <p>If such substances carry over, information on their removal or inactivation</p>
10	Residues in the final product resulting from the transfer into cells and tissues when veterinary drugs and similar substances are used in the culture medium.	Whether appropriate removal and washing measures are implemented for components equivalent to veterinary medicinal products, and similar substances.	<p>Information on residue levels of components equivalent to veterinary medicinal products in the final product</p> <p>Information on the removal or inactivation of components equivalent to veterinary medicinal products, etc.</p>
(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
11	Residues of allergenic substances in the final product.	<p>Whether there are any culture medium components that could act as allergens</p> <p>Whether residues remain in the final product, and if so, whether appropriate mitigation measures are in place</p>	<p>In addition to the list of substances used, information on their allergenicity</p> <p>Information on allergen residues in the final product and on their treatment/handling</p>
12	Transfer of pathogens, including prions derived from animal components, into the final product.	Described later	

Regarding item 12, it should be discussed together with “⑤ Diseases carried by the source animal, such as BSE (prions) and other diseases (including non-infectious diseases),” “⑥ Pathogens attributable to the¹⁰ animal species (bacteria, viruses, etc.),” and “⑦ Residues of veterinary medicinal products, etc. administered to the source animal.”

3. Organization of Issues in “Management of Pathogens Originating from Source Animals and Cells, Chemical Residues in Source Animals, and Harmful Substances Produced by Cells” (Anticipated Hazards, etc.) (Draft)

(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
5		Although these are not confirmation points specific to cultured cell-based foods, it should be possible to verify—through certificates or similar documentation—that the hygienic conditions generally required for meat, fish, and shellfish are satisfied.	Information on the source animal, tissue, and sampling site Information on health management and disease status of the source animal (including country of origin, management status of BSE and other diseases, and evaluation documents)
6	Pathogens originating from the animal species (such as bacteria and viruses).	As discussed at the subcommittee meeting held in February of FY2024, confirmation that there is no contamination by bacteria, viruses, etc., that are generally required to be controlled. In addition, depending on the source animal, confirmation should also be made that there is no contamination by bacteria, viruses, etc., that cause animal-borne infectious diseases.	Information demonstrating assurance of sterility by PCR or equivalent methods Information on causative bacteria, viruses, etc. related to animal-borne infectious diseases carried by the source animal In the case of commercially available immortalized cell lines, certificates or similar documentation regarding sterility prepared by the supplier
7	Residues of veterinary drugs and other substances administered to the source animals.	(Compliance with residue limits, etc. for veterinary medicinal products is required.)	Information related to drug administration
12	Transfer of pathogens, including prions, from animal-based culture medium components.	Whether the culture media, etc. are ensured to be sterile. Whether culture medium components have any effect on the expression of retroviruses present in the cells.	Information related to assurance of sterility of culture media, etc.

4. Organization of Issues in “Stability of Cells”(Anticipated Hazards, etc.) (Draft)

(1) Items Considered Specific to Cultivated Foods			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
16	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.	<p>Whether the indicators established to confirm stability of cellular characteristics (such as cell proliferation, cellular phenotype, genetic stability, etc.) are appropriate, and whether the frequency of their measurement and recording is appropriate.</p> <p>Whether changes in the differentiation state and phenotype of the cells are appropriate.</p> <p>Whether a management system is in place that enables early detection of abnormalities that may lead to the production of harmful substances.</p>	<p>Description of the manufacturing process (including overview diagrams, etc.)</p> <p>Information on the stability of cell proliferation</p> <p>Information on the stability of cell phenotype</p> <p>Information on the genetic stability of the cells</p> <p>(Including test methods, monitoring timing, and frequency)</p>
17	Impact of large-scale cultivation on ensuring uniformity.	<p>Whether identification of the biological species and cell type is appropriately conducted for the cells at the time of harvest.</p> <p>Whether the implementation status and results of confirmation tests using marker genes are reported.</p> <p>Whether culture conditions and procedures to ensure uniformity have been established.</p> <p>Whether measures are in place to address mutations and contamination associated with large-scale cultivation.</p>	<p>Description of the manufacturing process (including overview diagrams, etc.)</p> <p>Information on performance evaluation indicators of the cells</p> <p>Information on confirmation of cell type identification</p> <p>Information on cell identification information</p> <p>Information on batch-to-batch variability</p>

5. Organization of Issues in “Management of Work Processes Related to Contamination” (Anticipated Hazards, etc.) (Draft)

(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)		
Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
18 Bacterial and fungal contamination from the environment (such as water and air), and contamination by persistent pathogens due to insufficient sterilization of equipment and related items.	<p>Whether the cleanliness of the culture environment and the management of water and air are appropriate.</p> <p>Whether sterilization and decontamination procedures for equipment and culture media are properly followed.</p> <p>Whether regular microbiological monitoring is conducted as a measure against contamination by e.g., mycotoxins and foodborne pathogens.</p>	<p>Information on environmental monitoring and hygiene programs</p> <p>Information on microbiological parameters</p>
19 Contamination from food contact materials.	<p>Whether the materials and hygienic management of containers and equipment used are appropriate.</p> <p>Whether cleaning and sterilization procedures are implemented.</p> <p>Whether there are test results confirming contamination originating from contact materials</p>	<p>Information on supplier management</p> <p>Information on materials, tools, equipment, etc. used (positive list for food-contact tools, containers, and packaging)</p>
20 Heavy metal contamination	<p>Whether raw materials and culture medium components meet heavy metal standards.</p> <p>Whether the transfer of heavy metals from manufacturing equipment and utensils is properly controlled.</p> <p>Whether results of periodic monitoring and analyses are recorded.</p>	<p>Information on supplier management</p> <p>Information on materials, tools, equipment, etc. used</p> <p>Levels/amounts of cadmium, lead, arsenic, and mercury</p>
21 Human error.	<p>Whether work manuals and SOPs are established, and compliance with them is confirmed.</p> <p>Whether records of personnel education and training are maintained.</p> <p>Whether measures to prevent cross-contamination (e.g., segregation of work areas, equipment control) are implemented.</p>	<p>Information on training, SOPs, and procedure handbook related to food safety</p>
22 Contamination with physical foreign objects (such as metal fragments and packaging materials).	<p>Whether manufacturing equipment and the work environment are appropriately managed.</p> <p>Whether packaging materials and equipments are properly controlled.</p> <p>Whether measures to prevent foreign matter contamination (e.g., metal detectors, filters) are implemented.</p>	<p>Equipment and material management procedures/manuals</p> <p>Records of implementation of measures to prevent foreign matter contamination</p> <p>Management information such as visual checks, etc.</p>

Prepare a process flow diagram of the manufacturing steps and implement HACCP.

Non-official translation, prepared by JACA

Organization of Issues in 6. “Safety of Substances Used in Food Processing”, 7. “Nutritional Composition”, and 8. “Anti-nutritional Factors” (Anticipated Hazards, etc.) (Draft)

6. Organization of Issues in “Safety of Substances Used in Food Processing” (Anticipated Hazards, etc.) (Draft)			
(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
23	Residues of unspecified food additives in the final product and their effects.	Whether any non-designated additives are used in the processing steps	Information on additives used in the processing steps
7. Organization of Issues in “Nutritional Composition” (Anticipated Hazards, etc.) (Draft)			
(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
24	Excesses or deficiencies of nutritional components.	Whether the contents of nutritional components are appropriate from the perspectives of safety and nutritional adequacy. Whether the composition of nutritional components is appropriate when compared with similar foods.	Information on the ingredient composition of the final product Information on nutritional component analysis of the final product (If necessary) comparative materials or evaluation reports comparing the product with similar foods
25	A composition different from that of conventional foods.		Information on the ingredient composition of the final product Information on nutritional component analysis of the final product (If necessary) comparative materials or evaluation reports comparing the product with similar foods
8. Organization of Issues in “Anti-nutritional Factors” (Anticipated Hazards, etc.) (Draft)			
(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
26	Production of anti-nutritional substances by cells.	Whether the final product contains excessive levels of anti-nutritional factors.	Information on the ingredient composition of the final product Information on nutritional component analysis of the final product
27	Residues of substances used in food processing or in culture media that possess anti-nutritional activity.		Information on the ingredient composition of the final product Information on nutritional component analysis of the final product

9. Organization of Issues in “Changes Resulting from Food Processing” (Anticipated Hazards, etc.) (Draft)

(1) Items Considered Specific to Cultivated Foods			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
28	Effects of changes in components during product processing and storage, and microbial contamination.	Whether the established processing and storage conditions are appropriate to prevent changes in product components and microbiological contamination. Whether the final product is free from microbiological contamination.	(If inactivation is planned through processing) information on processing and storage conditions Information on microbiological contamination of the final product
29	Tumorigenicity and oncogenicity.	(Tumorigenicity*) Whether the inactivation of immortalized cells is appropriate. Whether components derived from cell culture in the final product do not produce harmful substances as a result of abnormal proliferation, tumor formation, or similar processes. Whether changes in cellular characteristics due to metabolism in the body after ingestion are not anticipated. *In this subcommittee, tumorigenicity refers to cases in which cells constituting the product undergo tumor formation or similar changes. (Carcinogenicity*) Whether carcinogenic chemical substances, etc. are not present as residues or produced. *In this subcommittee, carcinogenicity refers to cases in which harmful substances showing mutagenicity or similar properties are produced by the cells constituting the product.	Information on the stability of cell proliferation Information on the stability of cell phenotype Information on the genetic stability of the cells (If necessary) information on tumorigenic potential (If necessary) information on genotoxicity testing (If necessary) information on long-term toxicity
(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
30	Effects of physical and chemical changes in components specific to cultivated foods.	Whether the processing and storage conditions are appropriate. Whether physical and chemical changes in components of the final product do not adversely affect safety or quality	List of substances used Residue levels in the final product of substances not intended for use in conventional foods Process control procedures/manuals for processing and storage Considerations regarding the safety of residues

Organization of Issues in “Sanitation Management During Processing” (Anticipated Hazards, etc.) (Draft)

(2) Items That Have Also Been of Concern in Conventional Foods (such as those managed under HACCP and GMP)			
	Draft of Anticipated Concerns and Potential Hazards	Confirmation points (draft)	Information to be submitted by the business operator (draft)
31	Contamination by microorganisms, chemical substances, etc. arising from each operation in the food processing steps	Although this is not a confirmation point specific to cultured cell-based foods, facilities must comply with the general hygiene management standards prescribed by law, including hygiene management standards based on HACCP, in order to be permitted to operate.	Information that enables confirmation of compliance with the standards for business licensing under the Food Sanitation Act (e.g., hygiene management plans, etc.).

Note: The “confirmation points (draft)” also include various regulations stipulated under existing legal frameworks, such as the Food Sanitation Act, including regulations related to the manufacture and sale of genetically modified foods, BSE, microbial contamination, and other relevant matters.