NEWSLETTER

Latest Regulatory Update on Cultivated Meat and Fish in Japan

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1. Introduction

Japan's regulations governing cultivated meat and fish products are continuing to develop.[1] Since November 18, 2024, the Consumer Affairs Agency ("CAA") has been convening meetings of the Subcommittee on Novel Foods under the Food Sanitation Standards Council ("Subcommittee") to discuss guidelines and a regulatory framework for risk management relating to cultivated meat and fish.[2]

On February 21, 2025, at the third meeting of the Subcommittee, a working group led by Dr. Satoshi Kitajima of the National Institute of Health Sciences (serving as deputy chair) was formed to organize technical issues, including the distinction between hazards unique to cultivated meat and fish and those generally applicable to conventional food production. The group's draft summary report ("Summary") was released at the first Subcommittee meeting in FY 2025, which was held on July 25, 2025 ("Latest Meeting").

This newsletter provides an overview of the Summary and the expected development of the guidelines and regulatory framework, with a particular focus on topics of interest for food business operators ("FBOs") in this sector.[3]

2. Overview of the Guidelines

(1) Working Group Approach and Methodology

The Summary outlines the overall approach taken by the working group in developing its findings, including:

- Maintaining the general policy of assessing hazards based on each stage of production
- Simplifying the production stages from four categories to three
- Updating hazard descriptions for each stage, distinguishing between those specific to cultivated meat or fish and those common to conventional food production

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1 Currently, the Japanese regulatory development is focused on human food made with cultivated animal cells, such as cultivated meat and fish products. While the scope likely encompasses all animal cell-based cultivated foods, this article uses the simplified term "cultivated meat and fish" for ease of reference.

2 "Regulatory frameworks" refers to the overall method by which products reach the market, including whether individual applications, notifications, or approval procedures will be required (3rd Subcommittee meeting materials, p.9).

3 The author watched the live webcast of the Latest Meeting and incorporated its contents into this newsletter. However, as noted on the CAA's website, the webcast does not constitute an official record, and the official minutes will be published later. Until the final regulatory framework and/or guidelines are released, the information in this article remains subject to change.

- Identifying and classifying hazards that span multiple production stages, with express attention to their cross-stage natures
- Outlining the development of risk control checkpoints based on identified hazards

(2) Summary of Hazard and Checkpoint Policy

Cultivated meat and fish production processes have been streamlined into three stages. The table below summarizes key hazards and corresponding checkpoint development policies for each stage.[4]

Production Stage	Key Hazards	Checkpoint Development Policy
Cell Sourcing	• Phenotypic changes from cell immortalization • Toxicity or allergenicity from incorrect cell selection • Risks of toxins, pathogens, or drug residues from donor animals	• Confirm changes in cell characteristics or toxicity • Verify genetic consistency of selected cells • Confirm donor animal health and background
Cultivation (also related to cell sourcing)	• Residuals from culture media or scaffolds • Harmful substance production due to unintended differentiation and loss of cellular inconsistency during scale-up • Contamination by microbes or foreign matter	• Monitor and record effects of substances used • Monitor cell characteristics; confirm intended differentiation; adjust monitoring frequency based on scale • Implement hygiene controls based on HACCP/GMP
Food Processing	• Residual unapproved additives • Nutritional degradation or formation of inhibitory substances • Chemical/physical changes, potential tumorigenicity due to heat, etc.	• Address via existing additive regulations[5] • Evaluate changes and confirm nutritional impact • Confirm product stability and toxicity

[Note: In the original Japanese version, items considered unique to cultivated meat/fish are marked in red.]

(3) Next Steps

The Subcommittee has approved the general structure and content of the Summary. Therefore, FBOs should treat this Summary as a preliminary blueprint for the formal guidelines. The working group now will elaborate on specific hazards and develop detailed checkpoints. The results will be reviewed again by the Subcommittee before final guidelines are drafted. A concrete timeline was not specified, but based on prior meetings, an interim report is expected before the final version is released.[6] **The interim report is expected to provide important insights into the direction of the draft guidelines and regulatory framework**, and FBOs should monitor its content closely.

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[4] The descriptions in the table have been summarized and translated into English by the author based on Japanese-language source materials. The expressions used are based on the author's understanding and do not necessarily ensure scientific or linguistic precision. For accurate interpretation, please refer to the official meeting minutes when they become available (only available in Japanese).

[5] The document published by the CAA also notes the need to clarify from which stage in the production process cultivated meat and fish should be regarded as "food." This affects which inputs are defined as 'food additives' under the Food Sanitation Act, which applies only to substances used in the manufacturing of 'food.'

[6] This point has been discussed at previous meetings of the Subcommittee.

Once the official guidelines are finalized, FBOs likely will be required to obtain the necessary data to demonstrate the safety of cultivated meat and fish in accordance with the guidelines, and to provide appropriate explanations based on the relevant data. Therefore, FBOs should follow regulatory developments closely and prepare to ensure safety and accountability throughout the production process.

(4) Current Assessment

Considering that the cultivated meat and fish sector is an emerging field undergoing rapid scientific and technological development, it would be premature—and potentially counterproductive—to impose rigid regulatory measures, like a positive list of permitted substances, at this stage.[7] Based on the discussions observed thus far, it appears that both the Subcommittee and the CAA are proceeding with this in mind, to avoid similar pitfalls.[8] The working group's approach appears reasonable, in that the identified hazards are grounded in scientific assessments conducted by researchers actively engaged in the development and evaluation of the safety of cultivated meat and fish in Japan.[9] Moreover, the draft was developed with reference to reports and guidelines from international bodies, such as FAO/WHO and relevant overseas regulatory authorities, reflecting an intent to incorporate internationally recognized approaches.[10]

3. Development of the Regulatory Framework

As noted in the document published by CAA in connection with the Latest Meeting, the final regulatory framework will be determined by the CAA.[11] However, the Latest Meeting did not include an update on development of the framework. FBOs should continue to monitor ongoing discussions closely, because future deliberations will shape the details of the regulatory framework.[12]

End

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7 This point has been discussed at previous meetings and at the Latest Meeting of the Subcommittee.

8 The actual requirements will not be clear until the final version of the guidelines is published.

9 This point was clarified at the Latest Meeting.

10 This point is documented on page 2 of the materials provided in connection with the Latest Meeting.

11 During the 3rd meeting, Committee Member Matsuo commented that Japan should explore what regulatory options may be appropriate for cultivated meat and fish, taking into account the example of genome-edited foods, which are subject to a notification-based system. The secretariat acknowledged this understanding of the regulatory framework (3rd meeting minutes, p.13–14).

12 Based on previous discussions, it is expected that the interim report to be issued by the Subcommittee will also address the structure of the regulatory framework (p.19 of the 2nd meeting minutes).