Code of Practice for Safely Conducting Tastings of Cultivated Foods Prior to EU Approval

1. Introduction

The ability to successfully grow meat from a sample of cells was pioneered by a consortium of Dutch researchers brought together by funds provided by the Dutch government. This innovation was debuted to the world in 2013 and started a race around the globe that today has resulted in over 110 independent companies worldwide and more than $3B USD in private investment. Researchers involved in the original consortia founded two companies in the Netherlands (Mosa Meat and Meatable) that are working toward the pre-market regulatory approval necessary to sell cultivated meat.

To realize the economic and environmental potential of this new technology in the Netherlands, the Council of Ministers (ministerraad) awarded €60M in public money toward a €252M plan to build a thriving cellular agriculture ecosystem, based on a positive advise of the National Growth Fund (NGF) on 22 October 2022. The Ministry of Agriculture, Nature and Food Quality (LNV) submitted the plan. A new organization called Cellular Agriculture Netherlands (CAN) has been set up to coordinate and implement the plan approved, in close cooperation with the Ministry of LNV. The funds are collectively managed by the Ministry of Economic Affairs and Climate Policy, and the Ministry of Finance. These public funds will be used to create the conditions necessary by education, research and scaling up, to attract the researchers, workforce, entrepreneurs, and private capital necessary to make the Netherlands a global leader in the cellular agriculture space.

In line with this ambition, clear guidelines on how to conduct tastings / sensory evaluations (hereafter referred to as 'tastings') of new products[1] are an important enabling factor for the success of current companies and for those considering starting operations in the Netherlands. A majority of the Dutch House of Representatives (Tweede Kamer) affirmed this as a priority by adopting a motion (Motie De Groot-Valstar KST27428383) requesting the government to enter into consultation with companies

[1] These products are governed by EU regulations, which require a risk assessment by EFSA before European market introduction can be authorised.

developing foods based on animal cell-culture (e.g. meat and seafood) to enable pilot scale tastings of their novel products under controlled and safe conditions. As such, this document outlines a streamlined process for companies to get approval from an independent expert committee within CANS to conduct tastings and a code of practice to follow in order to ensure safety for prospective tasters.

2. Initial Considerations

In the European Union, newly developed foods need to be evaluated according to relevant European legislation before being approved to go to market, such as novel foods (EU novel food Regulation) and food produced from GMOs (EU GM food and feed Regulation).

Cultured meat is produced from animal cells that are expected to require nutrients and other constituents that are similar to those required by human beings. In principle, such nutrients are not expected to jeopardize the health of volunteer consumers.[2] Cell culture may require additional constituents such as modulators of growth or differentiation that can be low molecular weight compounds or substances of a proteinaceous nature. Safety of these would need to be assessed, taking into account levels of potential intake versus safety profiles.

Whereas novel foods are typically evaluated by EFSA for chronic consumption, tasting sessions are intended for a single or a few times only and in limited amounts. This involves a more proportionate risk assessment approach, versus a more extensive procedure done by EFSA.

As such, the risk assessment of cultured meat tastings can in essence follow the lines of argumentation of EFSA guidance (EFSA, 2016), albeit in a leaner form. Below, the necessary information for a tasting session is presented in an itemized way. A producer of food from cultured animal cells drafts an application for tasting sessions.

3. Information supporting safety of the cultured meat intended for tastings

A structured risk assessment which consists of a number of steps is required. The analysis should result in a comprehensive overall synthesis of the direct risks for the research subjects in this study. The risk considerations on the various issues listed below should be supported by up-to-date information and should be clearly described.

a. Description of the food from cultured animal cells:

[2] See for further information: Food safety aspects of cell-based food (fao.org)

- type of cells
- animal origin, history of consumption of the source
- deliberate modification of the cellular genome, if any. When GMO's are used in the production process, the company must have the proper permit from the Ministry of Infrastructure and Water Management overseeing the contained use of GMO's, and act accordingly.

b. Composition and production process of the cell-cultured meat or seafood:

Description of the culture process, including all constituents of the culture media, including growth factors, antibiotics, and other constituents. Constituents that are legally forbidden in food shall also not be permitted in the tasting sessions.

Information on relevant conservation and storage methods for the end product until tasting.

c. Documented safety information for all constituents:

- Identity, chemical and/or biological structure, composition
- Limit values from authoritative sources (EFSA, US-FDA, JECFA, EMA, etc.) or (for compounds with little safety information) the applicable TTC value[3]
- New substances with known or suspected genotoxic activity cannot be used
- The allergenicity risk associated with the consumption of the cultured product is considered not to be dissimilar to the source because biochemical characteristics of cultured cells are similar or identical to those of the same cells in the source tissue (eg chicken, beef, etc). While it is considered that newly introduced proteinaceous material can have allergenic properties, companies may minimize the risk by requesting all persons who intend to taste to declare in writing that they do not suffer from known allergies. The evaluation of allergenicity forms part of the risk assessment by the expert committee.

d. Content of the relevant components[4] in the product to be tasted:

[3] Use of the Threshold of Toxicological Concern (TTC) approach for constituents for which limited data are available may be instrumental. https://www.efsa.europa.eu/en/efsajournal/pub/5708

[4] Typical contaminants such as heavy metals, mycotoxins, PCBs, pesticides etc as per EC Regulation No 1881/2006 setting maximum levels for certain contaminants in foodstuffs are not expected to be present and need no consideration; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150731

- Microbiological status (measured[5]); the microbiological status should be in line with (Regulation EC No. 2073/2005 on microbiological criteria for (meat in) foodstuffs
- Amount to be ingested
- 'Calculated' or 'measured' content values
- Total amount per person and nominal amount per kg body weight (@ 70 kg)

e. Condensed information

All information should be condensed in a **Table,** including information from paragraphs 3 and 4, and identifying the intake / exposure for each constituent:

Constituent	**Total intake per person**	**Intake per kg of body weight**	**'calculated' or 'measured'**	**Safety level (ADI, TDI, TTC … etc)**	**Intake versus safety level:** - **Green** = safe - **Orange** = needs consideration

f. Any additional information can be requested by the Expert Committee. The Committee will react within a time frame of at most 30 days.

4. Participants

- All participants will be adults, apparently healthy and with no known allergies or underlying diseases and will not be pregnant (self-declared).

- Participation is strictly voluntary.

[5] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R2073 foodstuffs; https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R2073

- Informed consent needs to be registered prior to a tasting session.

- The EU General Data Protection Regulation (GDPR) applies.

- Participants will not be remunerated.

5. Information on the tasting session(s) of the cultured product intended for tasting

Records of the tasting session(s) will be kept as follows:

- Description of the setting: time, day, location (for instance, premises of the producer, or a facility dedicated to sensory evaluation; public access will be excluded).
- List of participants.
- Number of persons (maximum of 30 per tasting session).
- Cooking of the cultured meat, recipe, amount to be tasted.
- Availability of an emergency response officer (BHV) and a medical hotline.
- Registration of any adverse events occurring up to 2 weeks after the tasting event.
- Safety information as per the Table in paragraph 3.5
- All information provided by the industry for review by the Expert Committee is treated as confidential and proprietary.

6. The procedure of the tastings

The tastings can only be held in a controlled setting as described by the company: 'controlled environments' are suitable for food preparation; are either owned, leased or rented by the applicant company and are not accessible to the general public during tasting events.

- The manufacturer of the cell-cultured meat or seafood product provides (condensed) information as per the "Information supporting safety of the cell-cultured meat intended for tasting".
- The Table informs if any of the constituents may be ingested at levels above the initial threshold (**Orange** in the Table).
- The full product to be tasted will be assessed and the constituents that score **Orange** in the Table will be evaluated with extra attention. For constituents of concern, the intake will be appraised versus the established levels without concern (ADI, TDI, TTC etc). The expert committee may take into account the short duration of the exposure: ADI, TDI, TTC values are typically derived for

lifetime exposure whereas the tastings will be confined to 10 times maximum per person per year, thereby adding a considerable additional Margin of Safety.

7. Composition and mandate of the Committee of Experts

- The tastings will be evaluated and approved by an independent "Expert Committee for the safety evaluation of newly developed novel foods on the basis of animal cell culture" (Expert Committee) prior to the tasting events, based on the information provided by the company willing to organize a tasting
- The expert committee will be comprised of four individuals with the following expertise:
    - 1 toxicologist
    - 1 microbiologist
    - 1 physician
    - 1 expert on ethical issues
- The Expert Committee will be selected by CAN from a group of nominated experts (e.g. 2 toxicologists to choose from, etc) for the respective roles, thereby allowing for flexibility and differences in views.
- The Expert Committee will elect a chairperson amongst themselves and will be supported by an administrator from Cellular Agriculture Netherlands.
- The Expert Committee will evaluate the intended tastings before the actual tasting takes place.
- An approval for a tasting will comprise a maximum of 10 similar tasting sessions with a maximum of 30 persons per tasting and over a maximum time span of 1 year. In case more tastings are requested, a new application must be sent in. The Expert Committee will finally conclude that the tasting session is
    - "**safe** under the proposed conditions of tasting": viz. the tasting session conducted under the proposed conditions is not expected to present a health risk to participants. The tastings can go ahead as planned.
    - is "**not safe** under the proposed conditions of tasting", viz. it did not reach a conclusion on safety of the tasting session conducted under the proposed conditions. The tastings cannot go ahead.
- The expert committee needs to be unanimous across its 4 members in their approval of the tastings.
- The conclusion of the committee is final.

8. Publicity

- Tastings can be held in only a limited number of settings that are controlled by the applicant company, which are not accessible to the general public during tasting events. .

- Tastings will be attended by a predefined guest list: tasters and stakeholders.
- Actual tasting will only be permitted to designated and pre-selected tasters.
- Tastings may be attended by (potential) investors, journalists or regulators, and political stakeholders. Depending on the setting, publicity can be expected from journalists. Investors, regulators and political stakeholders might post information on social media.
- Tastings do not include large events that are open to the general public.
- The Ministries will inform the Second Chamber about the agreed Code of Practice. Via Public Access to Documents requests the CoP can become public in full or in abbreviated form.

9. Timeframe, scope and evaluation

- This Code of Practice is installed from 1 July 2023 onwards.
- This proposal is considered to be a pilot and is therefore valid for the period of one year with the possible extension of one more year.
- It is only applicable on the tastings held by cultivated meat and seafood companies with business operations in the Netherlands.
- After the period of one year the process of the tastings is to be evaluated by an independent (research) party, which will consult stakeholders involved.
- The parties involved in the preparation of the Code of Practice will discuss, based on the report of the independent party, the possibility and manner how to develop this Code of Practice into a general policy for tastings of novel foods.
- Once per year, CAN will publish a public report outlining the applicants for tastings in the previous 12 months and the total number of tastings conducted.

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