Code of Practice for
Safely Conducting Tastings of innovative fermentation-based food Prior to EU Approval

1. Introduction

For thousands of years, we have produced foods such as beer, wine, yogurt, cheese, and tempeh through fermentation. In recent decades, we have gained the ability to use microorganisms as single-cell production factories (precision fermentation) to produce substances like rennet and insulin. We can also leverage microorganisms themselves to generate large amounts of protein-rich food (biomass fermentation). Microorganisms—such as yeasts, fungi, bacteria, and microalgae—are now widely used to produce animal-free proteins, fats, vitamins, enzymes, and other essential compounds at a large scale. The development of these production methods and applications is accelerating rapidly, with several Dutch companies leading the way globally.

Driven by advancements in biotechnology and other technological fields, such as artificial intelligence, fermentation technology has evolved significantly, allowing for precise selection, analysis, and, if necessary, genetic modification of microorganisms to optimise production. This enables a more cost-effective and animal-friendly way of producing food and nutrients while significantly reducing its ecological footprint by using fewer resources and less land. Fermentation-based food production contributes to food security, as it requires less land, water and energy than traditional agriculture and supports a local, resilient food system. This approach allows for the efficient and controlled production of tailor-made nutrition (e.g. vegetarian or vegan alternatives, etc.).

Innovative fermentation-based foods are newly developed food ingredients[1], produced through biomass fermentation or precision fermentation. These ingredients have not yet been authorized for the EU market, either because they have not been consumed before or because they are produced using a novel, innovative technology.

[1] These products are governed by EU regulations, for example the Novel Foods Regulation (EC 2283/2015), which require a risk assessment by EFSA before European market introduction can be authorised.

In 2022, the Dutch government's National Growth Fund allocated €60 million to advancing precision fermentation. Until now, one key challenge is that tastings—essential for new product development—have not been permitted for innovative fermentation-based foods before market authorisation[2]. In response, Dutch Members of Parliament Meulenkamp (VVD) and Bromet (GL-PvdA) have put forward a broadly supported motion[3] urging the government to engage with Dutch biotechnology companies to allow controlled and safe tastings of products made by innovative fermentation, as defined above.

Tastings (also referred to as sensory evaluations) of newly developed foods are important for both existing companies and those considering starting operations in the Netherlands. Clear guidelines on how to conduct tastings safely and effectively are therefore essential to fostering innovation and maintaining the Netherlands' leadership in fermentation technology.

2. Initial Considerations

In the European Union, newly developed foods need to be evaluated for their food safety according to relevant European legislation before being authorized for market entry, such as the novel foods regulation (Regulation 2015/2283) or food produced from GMOs (Regulation No 1829/2003 and Directive No 2001/18/EG). Innovative fermentation-based food usually needs to go through this evaluation process.

Whereas newly developed foods are typically evaluated by EFSA for repeated consumption, tasting sessions are intended for a single or a limited number of intakes only, and in limited amounts. This calls for a proportionate risk assessment approach compared to the extensive risk assessment procedure conducted by EFSA. As such, the risk assessment of innovative fermentation-based food ingredient tastings can essentially follow the lines of argumentation of EFSA guidance (EFSA, 2024), albeit in a leaner form. Below, the necessary information for a tasting session is presented in an itemized format. A producer of an innovative fermentation-based food that has not received EU market authorisation, drafts an application for tasting sessions.

This document outlines a streamlined process for companies, hosted by Cellular Agriculture Netherlands (CAN), to get unanimous approval from an independent "Expert committee" for the safe tasting of newly developed foods on the basis of innovative fermentation, prior to market authorization.

[2] These challenges were investigated by Wageningen Economic and Social research in its report *Drempels en beleidsopties voor stimulering innovatie precisiefermentatie*, 15 mei 2024

[3] Parliamentary document number 36600-XIV-60, full text available via: https://www.tweedekamer.nl/kamerstukken/moties/detail?id=2024Z16189&did=2024D39215

3. Roles and responsibilities

In the context of this Code of Practice for the safe tasting of newly developed foods on the basis of innovative fermentation, prior to market authorization, there are several parties involved with different roles and responsibilities:

- Applicant: a company developing innovative fermentation-based food ingredient with a demonstrated presence in the Netherlands (e.g. with founders, employees, assets or operations), responsible for requesting a tasting of an innovative fermentation-based food ingredient by submitting an application with the relevant supporting information to the Expert Committee and carrying out the tasting after approval in a safe and responsible way
- Expert Committee: a committee of experts in several relevant domains that assesses the submission for tastings of an innovative fermentation-based food ingredient and that is responsible for deciding whether to approve it or not
- Cellular Agriculture Netherlands: the foundation and organization carrying out the National Growth Fund program and the independent host of the Expert Committee, also providing supporting service to facilitate the assessment of submissions
- Ministries of Agriculture, Fisheries, Food Security and Nature (LVVN) and Health, Welfare and Sport (VWS): the ministries that are responsible for setting up the pilot that facilitates the tastings of innovative fermentation-based food ingredients in a safe and responsible manner
- Wageningen Food & Biobased Research (WFBR): the organization tasked with the evaluation of the pilot for the process of the tastings of innovative fermentation-based food ingredients

4. Information supporting safety of the innovative fermentation-based food ingredients intended for tastings

A structured risk assessment which consists of a number of steps is required. The analysis should result in a comprehensive overall analysis 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 microorganism

- Unambiguous taxonomic identification of microorganism (full name, identity of strain).
- Qualified presumption of safety (QPS) status, if available.

- Generally Recognized as Safe (GRAS) status or existing evaluations in other geographies, if available.
- Deliberate modification of the microorganism, if any. When genetically modified microorganisms (GMOs) are used in the production process, the company must have the proper permit from the Ministry of Infrastructure and Water Management (or the equivalent foreign governing body, in case of (partial) production outside of the Netherlands) overseeing the contained use of GMOs, and act accordingly. The final product must not contain viable GMOs.

b. Description of the production process

Clear description of the production process (including production location) of the fermentation-based ingredient. Providing flow diagram, as well as a summary of main risks and their mitigation from a HACCP perspective or a HACCP plan or certification, and information on relevant conservation and storage methods for the food ingredient until tasting.

c. Documented safety information for the food ingredient

- Identity, chemical and/or biological structure and/or composition.
- Limit values from authoritative sources (EFSA, US-FDA, JECFA, EMA, etc.) or (for compounds with little safety information) the applicable TTC value).
- Substances with known or suspected genotoxic activity cannot be used.
- 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 food allergies. The evaluation of allergenicity forms part of the risk assessment by the Expert Committee.

d. Content of relevant components (e.g. (myco)toxins) in the food ingredient to be tasted:

- Microbiological status (measured[4]); the microbiological status should be in line with European legislation on microbiological criteria (Regulation EC No. 2073/2005) for

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

the relevant food category in the context of the proposed tasting

- 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 for the Expert Committee on confidential basis in a **Table,** including information from paragraphs 3c and 3d, and identifying the intake / exposure of the relevant components within the ingredient:

Component	**Total intake per person**	**Intake per kg of body weight**	**'calculated' or 'measured'**	**Safety level (ADI, TDI, TTC … etc)**	**Intake versus safety level[5]:** - **Green** = safe - **Orange** = needs consideration

f. Any additional information can be requested by the Expert Committee. The Expert Committee can request the applicant to discuss the scope of any additional information and strives to request additional information in one instance.

5. Participants

- All participants will be adults, apparently healthy and with no known food allergies or underlying diseases and will not be pregnant (self-declared).
- Participation is strictly voluntary and on invitation only.
- Informed consent needs to be obtained from the participant prior to a tasting session which will be

[5] For further clarification: the percentage resulting from total intake vs the safety level should show that the maximum intake for a participant in a tasting is (substantially) below the safety threshold.

arranged and properly documented by the applicant.

- In such informed consent, the applicant will inform participants about the type of ingredient they will taste and provide instructions in case of any adverse events.
- The EU General Data Protection Regulation (GDPR) applies.
- Participants will not be remunerated.

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

The applicant requesting approval for tastings will keep records of the tasting session(s) 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).
- Preparation of food as served, recipe of food, amount of food and ingredient 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.e
- All information provided by the applicant for review by the Expert Committee is treated as confidential and proprietary.

7. The process in case of adverse events

In case of an adverse event after a tasting, the following procedure is followed :

- The participant of a tasting informs the applicant of any adverse event within two weeks after the tasting.
- The applicant informs a participant that they need to contact their own General Practitioner in case of any adverse event.
- The applicant subsequently liaises with a participant experiencing a possible adverse event to determine potential root causes or other variables or factors that are relevant to a possible adverse event.

- The applicant informs CAN within two working days of being notified of an adverse event, CAN will in turn inform other authorities.
- The applicant liaises with CAN on any further actions to be taken.

8. The procedure of the tastings

The tastings can only be held in a controlled setting as described by the applicant: '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 food provides (condensed) information as per the "Information supporting safety of the innovative fermentation-based food ingredient intended for tasting".
- The Table informs if any of the components may be ingested at levels above the initial threshold (**Orange** in the Table).
- The food product to be tasted will be assessed and the components that score **Orange** in the Table will be evaluated with extra attention. For components of concern, the intake will be appraised versus the established levels without concern (ADI (acceptable daily intake), TDI (tolerable daily intake), TTC (threshold of toxicological concern) etc). The Expert Committee may take into account the short duration of the exposure: ADI and TDI values are typically derived for lifetime exposure whereas the tastings will be confined to 10 times maximum per person per year, thereby applying a proportionate Margin of Safety.

9. Composition and mandate of the Committee of Experts

- The tastings will be evaluated and approved by the already existing Expert Committee prior to the tasting events, based on the information provided by the company willing to organise a tasting
- The Expert Committee is comprised of a Chair plus four individuals with the following expertise:
    - 1 toxicologist
    - 1 microbiologist
    - 1 physician
    - 1 expert on ethical issues
- The Expert Committee is 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 elects a Chair amongst themselves and is supported by an administrator from CAN.

- Experts having a conflict of interest shall not be nominated as a member of the Expert Committee. To avoid such conflict of interest, each candidate for the Expert Committee shall determine whether or not any application on the agenda for a certain meeting leads to a potential conflict of interest. A conflict of interest includes but is not limited to experts having (i) a financial interest in the applicant company and/or (ii) an active employment contract with the applicant company. Each expert is himself/herself responsible, taking into account his/her professional standards, to decide if a conflict of interest is present or likely to be perceived present in the public opinion. In cases of doubt, CAN will make a decision about the participation of the expert in the Committee or with regards to a certain application.
- Applicants are responsible for arranging a non-disclosure agreement via CAN, with each of CAN, WFBR and the Expert Committee.
- The dossier will be confidentially managed and stored in a digital environment facilitated by CAN for safekeeping and evaluation by the experts, who will have exclusive access thereto.
- In case of sufficient dossier quality and no restrictive interests, the dossier will be considered.
- Each expert conducts a focused and efficient evaluation of submitted dossiers as per his/her area(s) of expertise. The committee examines key safety aspects leveraging their expertise in toxicology, microbiology, medicine, and ethics. The experts aim for a concise yet comprehensive assessment of potential risks. This evaluation ensures a thorough understanding of risks, aiding in swift and well-informed decisions regarding the safety of the planned tastings.
- One or more (digital) meetings will be organised, to allow experts to articulate their opinion within the setting of the Expert Committee. These meetings also give the possibility to formulate a compiled list of additional questions for the applicant, if needed, that are key to finding a substantiated advice.
- A representative of CAN will provide support as an administrator to support the committee in administrative tasks and coordination, ensuring a smooth and efficient evaluation process. This person will also be tasked with the creation of minutes and further record-keeping of the process for future reference.
- 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 submitted. The Expert Committee will finally conclude that the tasting session is
    - "**approved** 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.

    - "**not approved** under the proposed conditions of tasting", viz. it did not reach a positive 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 members in their approval of the tastings.
- In cases the Expert Committee is unable to reach a definitive conclusion based on the available information, the outcome will be considered "**inconclusive**". the Expert Committee may set a meeting with the applicant company to discuss all concerns and/or request further information from the applicant in written. Upon its request, the applicant company will subsequently have an opportunity to address the Expert Committee's concerns. A new evaluation will be conducted once the requested information has been submitted.
- When a definitive conclusion on safety is made, a formal report (letter, stating the conclusion) signed by the Chair will be sent by the CAN representative to the applicant.
- The applicant can only set the date(s) of the tasting after the approval is given by the Committee.
- Once set, the date(s) of the tasting(s) will be communicated timely, at least two weeks prior to the tasting, by CAN to the Ministry of LVVN, VWS and the independent (research) party.

10. 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 Code of Practice will become public.

11. Timeframe, scope and evaluation

- This Code of Practice is installed from (*timing to be decided*) 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 tastings held by companies producing innovative fermentation-based foods that have a presence in the Netherlands that is more substantial than just a business entity. An

applicant needs to provide information on its presence in and connection with the Netherlands, for example by demonstrating the number of employees active in the Netherlands, its assets (e.g. IP, facilities) and/or operations it has (e.g. R&D, production, HQ, business development, etc.) in the Netherlands. In cases of doubt, CAN decides whether or not an applicant is eligible to submit a dossier for a tasting.

- 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 evaluation 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.
- A company willing to organise a tasting applies via an email address provided by CAN (tastings@cellulaireagricultuur.nl) and submits comprehensive information to CAN for evaluation.
- Upon receiving the application, CAN enables a confidential data environment.
- The receipt of an application is communicated as soon as possible by CAN to the applicant.