Taste trials guidance

Guidelines on the conduct of taste trials involving novel foods or foods produced by novel processes.

Purpose

Novel foods must be authorised before they can be placed on the GB market. The definition of ‘placing on the market’ is broad and may include free of charge or one-off transfers such as trade samples. Novel food taste trials, where the intention is to conduct research to develop the novel food, may be permitted for unauthorised novel foods. If the intention of a tasting trial is to publicise a product or a company brand, then the tasting may amount to the unlawful placing on the market of an unauthorised novel food.

The FSA and FSS recommend that as best practice, taste trials are guided by advice published by the Advisory Committee on Novel Foods and Processes (ACNFP). Companies may communicate the fact they have conducted a taste trial after it has taken place through media activity, provided such publicity is ancillary to the main purpose of the trial as research and development. Companies might also consider conducting taste trials in a closed venue that is not accessible to the public so that individuals who are not part of the taste trial cannot access the trial.

The purpose of this guidance page is to provide a summary that follows the principles of the ACNFP’s guidance to help companies conduct taste trials for novel foods or foods produced by novel processes, supporting the design of trials for research and development purposes that are safe and ethical.

Key definitions

Novel Food

Regulation (EU) 2015/2283 defines a 'novel food’ as a food or ingredient that has not been significantly used for human consumption within the EU or the United Kingdom before 15 May 1997. This includes but is not limited to low-calorie fat replacers, cell cultivated products (CCPs) and certain functional foods (for further definitions of novel foods see Article 3 of Assimilated Regulation 2015/2283 or Novel foods authorisation guidance on the FSA website).

Placing on the Market

Placing an unauthorised novel food on the market is unlawful. ‘Placing on the market’ is defined in Regulation (EC) 178/2002 as including any form of transfer, whether free of charge or not. For example, giving away trade samples may constitute unlawful ‘placing on the market’. However, taste trials of unauthorised novel foods may be permissible where the trial takes place as part of the research and development phase of production because the foods are not considered to have been placed on the market

Referral protocol

The FSA and FSS recognise that the Advisory Committee on Novel Foods and Processes is of the opinion that, in general, there is no need for protocols or documents for taste trials to be referred to it for consideration, or to the FSA and FSS, provided certain criteria are met:

- Health & Safety: Ensure the trial poses no hazard to human health through a risk assessment. If necessary, seek independent professional advice to confirm this.
- Ethics Committee Approval: The trial protocol should be reviewed and cleared by an independent Ethics Committee.
- Record Keeping: Maintain detailed records of the trial (see below for specifics).
- GMO Notification: If the trial involves the release of genetically modified organisms (GMOs), follow the appropriate notification and clearance procedures.

Risk assessment

Companies should, as best practice, conduct a thorough risk assessment before proceeding with a taste trial, as is recommended in the ACNFP guidelines. They should consider the likely levels of intake and the extent of safety information available for the novel food. Companies should consider the risks to vulnerable groups such as under 18s, pregnant or immunosuppressed individuals from participating in taste trial, and, if necessary, seek independent professional advice to assure the risk assessment.

The FSA and FSS recommend that, as best practice, companies undertake comprehensive evaluations to ensure the safety of participants prior to conducting a taste trial. Utilising the Novel foods authorisation guidance on the FSA website, the following areas are highly recommended for inclusion in a robust risk assessment. Please note that this is only an indicative list and that companies should develop their own matrices for evaluating the risks:

- Microbiological contamination
- Allergenicity
- Acute toxicity
- Genotoxicity

Companies should not proceed with taste trials if they hold limited safety information on the areas listed above, or otherwise identified through their risk assessment process.

Companies should screen for, and exclude, individuals with known food allergies, intolerances, underlying medical conditions, or gastrointestinal disorders from participating in the taste trials.

Ethics committees

Any relevant legal requirements relating to the performance of studies on human subjects must be adhered to.

Companies conducting taste trials should consider seeking review from an independent ethics committee to ensure the most up-to-date ethical considerations of studies on human subjects are followed. These committees exist within major industrial companies or externally, such as those at universities or medical schools.

Ethics Committees should have the technical expertise to assess the trial’s impact on participants’ welfare and the study’s objectives. They should also include lay members to represent community interests.

Ensure full informed written consent is obtained from all volunteers. Provide clear, understandable information about the trial, including any known adverse reactions to the novel food.

If appropriate, inform the volunteers' general practitioners (GPs) about their participation in the study.

The UK Government has produced guidelines advising on the structure and function of local research ethics committees (see Additional Support and Information).

Record keeping

Keep comprehensive records of the trial, including:

- Names and health status of participants
- Details of the novel food being tested
- Any adverse effects reported by participants, with follow-up and medical investigation if necessary
- Retain these records for 30 years

Follow the guidelines on adverse reactions as outlined by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) Report on Adverse Reactions to Food and Food Ingredients (2000). Available from the COT Secretariat on request.

Release to the environment

Contained Use of Genetically Modified Organisms (GMOs)

If the novel food production involves GMOs, where required notify the Health and Safety Executive (HSE) under The Genetically Modified Organisms (Contained Use) Regulations 2000. If conducted in Scotland, where required compliance with the genetically modified organisms (contained use) regulations 2014 and notify both HSE and Scottish Government.

For taste trials involving GMOs, if required ensure a valid notification is submitted to the HSE regarding the premises where taste trials are to take place. Individual trials need notification only if the GMO poses a higher risk than the non-modified organism. If conducted in Scotland, where required compliance with the genetically modified organisms (contained use) regulations 2014 and notify both HSE and Scottish Government

Deliberate Release of GMOs

If required, obtain specific consent for environmental release from the Secretary of State for the Environment or the relevant devolved authorities.

Additional support and information

The FSA and FSS recommend that, as best practice, taste trials are guided by advice published by the Advisory Committee on Novel Foods and Processes (ACNFP).

Any tasting that is not conducted for the purpose of research and development may be considered an unauthorised placing on the market and may be subject to enforcement action by the relevant local authority. Therefore, it is advisable to contact the relevant local authority in whose area the tasting is to be held and inform them the trial will be conducted and how the guidance is being adhered to.

For further information on contained use of GMOs in Scotland, see Scottish Government's Agriculture and the Environment policy.

For resources advising on the structure and function of local research ethics committees, see:

- Department of Health (DH, 1991b). Circular on local research ethics committees. London: Department of Health, 1991.
- Research Governance Framework for Health and Social Care.