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Protocol for a Systematic Review of Microbiological Hazards in Novel Foods

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ADMINISTRATIVE INFORMATION

Support - European Food Safety Authority (project NP/EFSA/NIF/2024/02).

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202550074

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 May 2025 and was last updated on 24 May 2025.

INTRODUCTION

Review question / Objective The review question was formulated as follows: what is the occurrence of the microbiological hazard “X” in the Novel Food “N”?
This review question is of descriptive nature as is enquires about a condition of interest (microbiological hazards) in a food population (Novel Foods). This question has a simple PO (population and outcome) structure with key elements that can be broken down as follows:
• Population: Novel Foods
• Outcome: Occurrence of a microbiological hazard.

Rationale The objective of this systematic review is to determine which microbiological risks are, or could be, associated with the consumption of novel foods. The outcome of this systematic review will contribute to improving the risk assessments that The European Food Safety Authority (EFSA) performs on the safety of Novel Foods upon request by the European Commission.

Condition being studied Ocurence of microbiological hazards in Novel Foods.

METHODS

Search strategy Constraints in the search strategy:
• Fields: Title, Abstract and Keywords
• Dates: No temporal constraint
• Languages: English
• Publication type: Primary research studies (i.e., studies generating new data), conference abstracts or posters if they contain primary data and PhD theses and dissertations.
Keywords/Search Strings:
A dual search strategy will be developed including a “NF specific” and a “NF generic” search

strategy/search strings. The list of keywords and the structured search strings for Scopus, Web of Science and PubMed are reported as Supplementary material. These search strings will be manually translated to Spacenet language for patent (grey literature) searches.

a. NF-specific search strategy

The "NF-specific" search strategy was designed to narrow down the search on the NF under study since the term "novel foods" is commonly used in the literature but not necessarily to describe products falling under Regulation (EU) 2015/2283. Thus, specific keywords defined for each NF under study will be included in the first search block.

The second search block will include a series of keywords related to microbial hazards and/or microbiological studies.

The third block will include the term "Food"

The three search blocks will be combined in the search string by using the Boolean operator "AND".

Independent searches will be conducted for each NF.

b. NF-generic search strategy

The "NF generic" strategy was intended to complement the "NF-specific" one, towards a broader coverage of potentially relevant hits from the consulted literature sources. Thus, a list of keywords related to the term Novel Food will be included in the first search block.

The second search block wil include a series of keywords related to microbial hazards and/or microbiological studies.

The third block will includes the term "Food"

The three search blocks will be combined in the search string by using the Boolean operator "AND".

Study Selection:

Study selection will be performed and documented using the web-based systematic review software DistillerSR.

Searches will be carried out on the selected databases, and then imported to Distiller. DistillerSR Duplicate Detection tool will be used to find and quarantine duplicates. Studies retrieved through the extensive literature searches will be screened for relevance using a two-step approach:

A) Title and abstract screening

In the first step, screening will be performed by two reviewers independently, based on the information contained in the title and abstract, by applying the eligibility criteria indicated below.

Articles marked as irrelevant by the two reviewers will be excluded without proceeding to the full-text analysis. In case of a lack of consensus among the reviewers or if the two experts have doubts about a specific document, a conservative approach will be followed to ensure completeness, and the document will be considered for full text screening.

B) Full-text screening

Full text of the publications considered relevant after the first step will be screened for inclusion/exclusion by two reviewers independently by applying the eligibility criteria indicated below. Any disagreement will be reconciled by consulting a third reviewer, which will took the ultimate decision on inclusion or exclusion.

Participant or population Novel Foods. The term Novel Foods (NFs) was limited to those products falling under Regulation (EU) 2015/2283 at the time the searches were carried out (19/05/2025), including: (i) Authorized NFs included in the Union list ; (ii) NFs currently under suitability check or risk assessment by EFSA (summary / non-confidential version of the dossier available on the Open EFSA portal); (iii) Products with NF status following consultation pursuant to Article 4(2) of the Regulation (EU) 2015/2283 (https://food.ec.europa.eu/food-safety/novel-food/consultation-process-novel-food-status_en); and (iv) Products that will need an authorisation under the NF Regulation as per the EU NF status catalogue (https://ec.europa.eu/food/food-feed-portal/screen/novel-food-catalogue/search).

Intervention Not applicable.

Comparator Not applicable.

Study designs to be included Primary research studies (i.e., studies generating new data), conference abstracts or posters if they contain primary data and PhD theses and dissertations.

Eligibility criteria Excusion criteria (EC):

-EC 1: Documents to be excluded according to report characteristics (full text not available or not in English; reviews, books and book chapters, letters to the editor…).

-EC 2: Studies/experiments not reporting/quantifying microbiological hazards and/or indicators of them.

-EC 3: Studies not associated to NFs as defined above or where food chain stage/storage period where/when samples were taken for analysis is not specified.

-EC 4: Studies not presenting results on prevalence (sample size and number of positive samples) or concentration (sample size and measure of concentration).

-EC 5: Microbiological method not indicated/referenced.

-EC 6: Documents with general speculation, general description, or historical description of NF,

or microbial hazards, or any other document that cannot be included according to the eligibility criteria and cannot be excluded according to the above-mentioned criteria.

Information sources Scientific literature databases. The following databases will be used:
• PubMed/MEDLINE (https://www.ncbi.nlm.nih.gov/PubMed)
• Web of Science (https://www.webofknowledge.com)
• SCOPUS (https://www.scopus.com/)
Grey literature. Sources included are listed below:
• Patents: Spacenet search engine (https://worldwide.espacenet.com/).
• Websites and on-going research and research results registers. Searches will be conducted in websites of relevant organizations (e.g. research organizations, working groups, commercial, stakeholders, and national agencies). This included: FoodDrinkEurope, FEFAC (European Feed Manufacturers' Federation), EuropaBio, ILSI (International Life Sciences Institute), FDA, US EPA (Environmental protection agency), Health Canada, FSANZ (Food Standards Australia New Zealand) and the China Food and Drug Administration. Likewise, searches were also carried out in project registers specific to the search question using databases such as CORDIS and professional networks (technical meetings, conferences, fairs, funders…).
• As a source for NF specifications/characteristics:
o Union list of authorized Novel Foods (https://food.ec.europa.eu/safety/novel-food/authorisations/union-list-novel-foods_en).
o EFSA Scientific Opinions on the safety of NFs
• As a source for NF production processes:
o Repository of NF production processes reported by Martínez et al. (2024).
• As sources of regulations, analytical methods, and maximum admissible limits:
o Websites of relevant organizations (EU DG Santé (EU General Directorate on Health and Food Safety), EFSA, FDA (Food and Drug Administration), Health Canada, FSANZ (Food Standards Australia New Zealand), the China Food and Drug Administration) and associations (e.g. European Algae Biomass Association: EABA).
Reference lists. The reference list at the end of relevant publications will be checked to identify studies that have not been retrieved.

Main outcome(s) Microbiological Hazard (per Novel Food):
o Biological hazard (including species and group/serogroup…)
o Type (pathogen or indicator)
o Concentration/Prevalence (per food chain stage and/or storage time)
o Source
o Maximum limits suggested/reported.

Additional outcome(s) • Product characteristics:
o NF Form (powder, syrup, solution…)
o NF physico-chemical characteristics (per food chain stage and/or storage time)
o NF composition (per food chain stage and/or storage time).
o Processing steps
o Shelf-life.
• Sampling plan (when reported (e.g. for observational studies):
o Sampling plan
o Sampling size

• Analytical method:
o Name and description of the method
o Regulatory reference method
o Sample size
o LOQ/LOD
o Sensibility
o Specificity

Data management Specifically designed Excel spreadsheets will be used for data extraction.

Quality assessment / Risk of bias analysis The methodological quality of each included study will be critically appraised. Each study will undergo a standardized assessment, checking whether it meets a predefined list of characteristics. This information will be embedded in the same file for data extraction.
Two independent reviewers will score each study against risk of bias. The following issues will analyzed: Selection bias, Detection bias, Reporting bias and Other bias (the later one including methodological quality assessment). The studies will be judged on three categories of bias: high, low and unclear. As a criterion, a global riskof bias score will not be used; instead, articles for which a high risk will be determined in any of the four evaluated aspects will be excluded. Disagreements regarding scores will be resolved by discussion and consultation with a third reviewer when needed.

Strategy of data synthesis The information retrieved will be used to build a database in the framework of EFSA Project NP/EFSA/NIF/2024/02: MICROHAZ – Microbiological Hazards in Novel Foods.

Subgroup analysis Results obtained will also be anylized on the basis of the following subgroups:

o NF product (including species and variety)
o NF category (according to 258/97 or 2015/2283).
o NF status (authorized, Under RA/suitability check, consultation process).
o NF origin (animal, plant, fungi, synthetic…)
o NF intended use: Whole/Ingredient/Supplement and food categories.

Sensitivity analysis Not applicable.

Language restriction Only documents in English will be considered.

Country(ies) involved Spain and Portugal.

Keywords Novel Foods; microbiological hazards; foodborne pathogens; risk assement, hazard identification.

Dissemination plans The results of this Systematic Review will be published in the EFSA Journal (link to be provided).

Contributions of each author

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