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Novel foods risk assessment process & challenges

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158th NDA Panel Plenary meeting
Open to observers

EUROPEAN FOOD SAFETY AUTHORITY

OVERVIEW OF THE PRESENTATION

WHAT IS A NOVEL FOOD IN THE EUROPEAN UNION?

Foods or ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997

- New production process
- New or modified molecular structure
- From microorganisms, fungi or algae
- From plants or their parts
- Vitamins and minerals from new process / nanomaterials
- Of mineral origin
- From animals or their parts
- Cell or tissue cultures derived from the living
- Engineered nanomaterials
- Exclusive use in food supplements prior to May 1997

EFSA'S MISSION & RESPONSIBILITIES IN THE NOVEL FOOD AREA

WHAT EFSA DOES NOT DO

- Develop food safety policies and legislation
- Adopt regulations, authorise marketing of new products, define labelling
- Enforce food safety legislation

WHAT EFSA DOES

- Provide independent scientific advice and support for EU risk managers and policy makers on safety
- Develop and provide up-to-date Guidance
- Communicate independently and timely on risks associated with the food chain
- Promote scientific cooperation

NOVEL FOOD AUTHORISATION PROCEDURE IN THE EU

European Commission

efsa EUROPEAN FOOD SAFETY AUTHORITY

European Commission

Submit a dossier according to the Novel Food (NF) or Traditional Food (TF) Guidance

Validate the dossier

Mandate EFSA to carry out the risk assessment (NF only)

NF: 9 months
TF: 4 months

Carry out the risk assessment (NF)

May request additional information to the applicant (NF) or raise duly reasoned safety objections (TF)

Within 7 months after EFSA's publication: EC sends draft implementing act to the PAFF Committee

Decide on market authorisation

Integration to the Union List of authorized novel foods

PAFF: Standing Committee on Plants, Animals, Food and Feed

FUNDAMENTAL PRINCIPLES OF NOVEL FOOD RISK ASSESSMENT

The novel food shall be safe under the proposed conditions of use

The novel food shall not be nutritionally disadvantageous

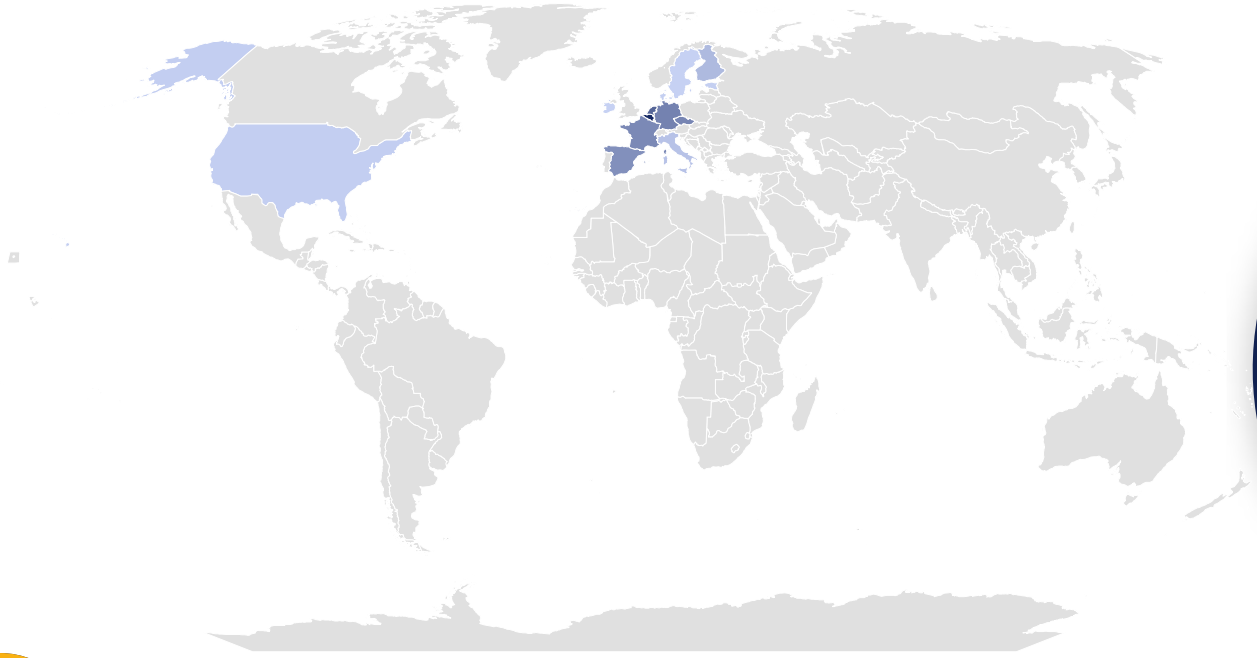
The efficacy of the novel food is not assessed

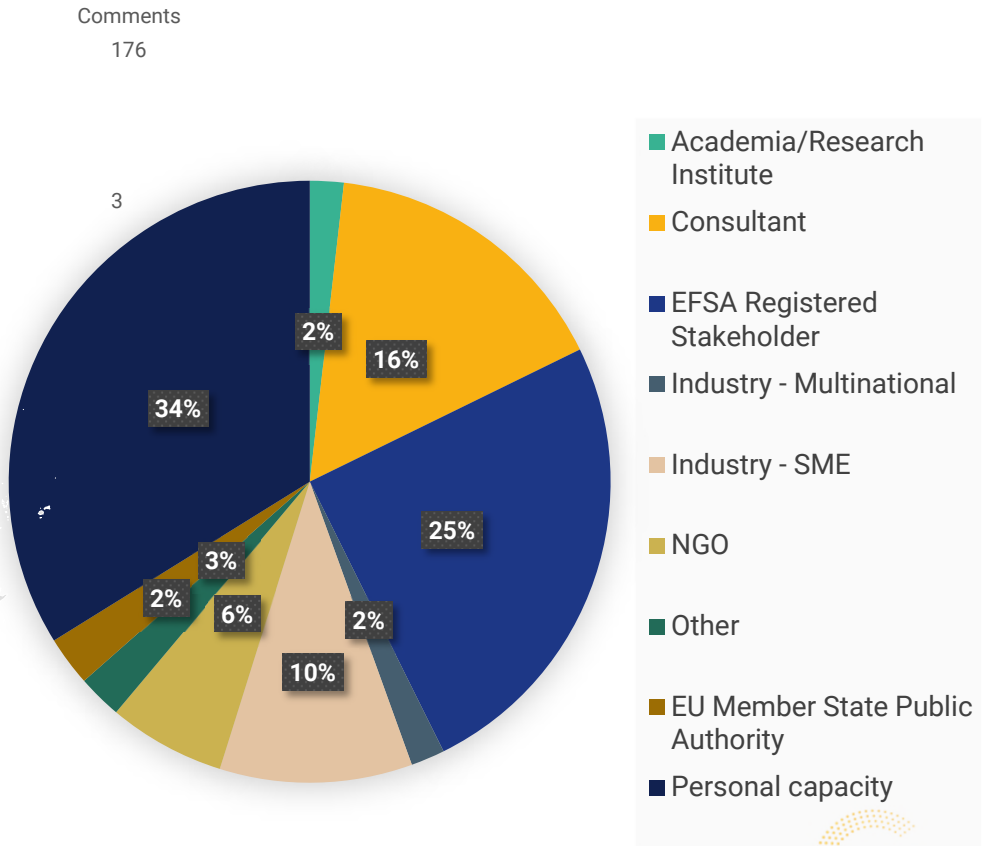
UPDATED EFSA NOVEL FOOD SCIENTIFIC GUIDANCE

EFSA's experience

- Centralised assessment of multiple & heterogeneous novel food dossiers (since 2018)
- New EFSA cross-cutting guidance applicable
- Risk assessment methodological developments
- Engagement & feedback from stakeholders

PUBLIC CONSULTATION – 715 COMMENTS RECEIVED





UPDATED EFSA NOVEL FOOD SCIENTIFIC GUIDANCE

- Introduction
- Identity of the novel food
- Production process
- Compositional data
- Specifications
- History of use of the novel food and its source
- Proposed uses and use levels, anticipated intake
- Absorption, distribution, metabolism, excretion
- Toxicological information
- Nutritional information
- Allergenicity
- Conclusions

Update EC request: June 2023

↓

Public consultation on the draft Guidance: Feb –Apr 2024

↓

Adoption by the EFSA NDA Panel: June 2024

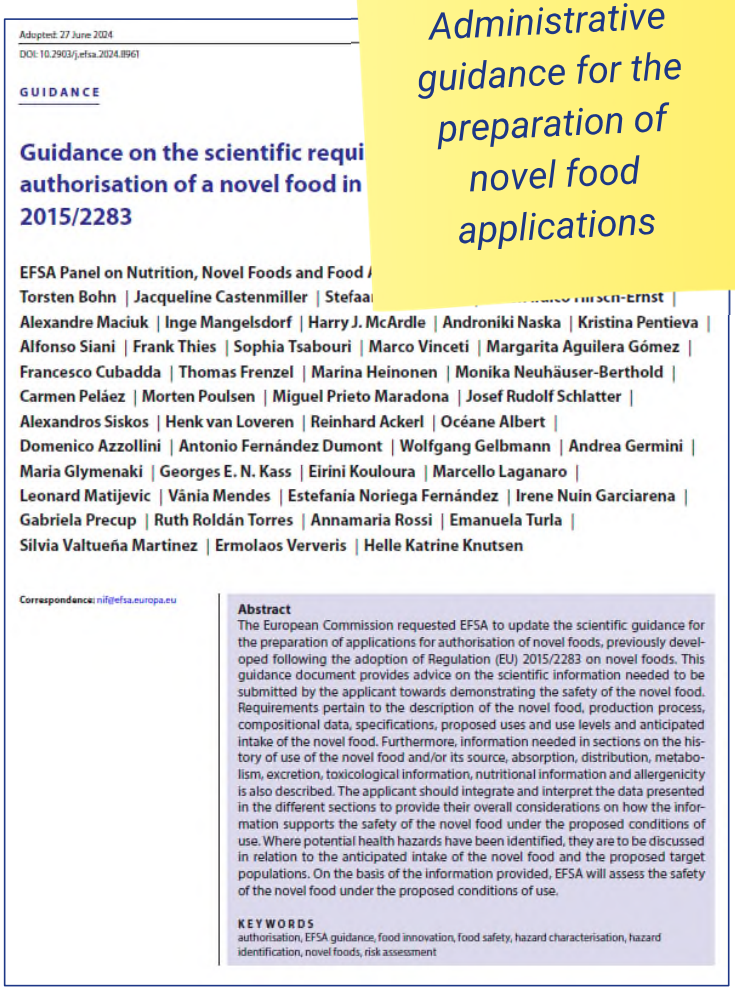
↓

Publication: September 2024

↓

Implementation: February 2025

NEW Administrative guidance for the preparation of novel food applications



Adopted: 27 June 2024
DOI: 10.2903/j.efsa.2024.8961

GUIDANCE

Guidance on the scientific requi… authorisation of a novel food in … 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food A… | Torsten Bohn | Jacqueline Castenmiller | Stefaa… | Alexandre Maciuk | Inge Mangelsdorf | Harry J. McArdle | Androniki Naska | Kristina Pentieva | Alfonso Siani | Frank Thies | Sophia Tsabouri | Marco Vinceti | Margarita Aguilera Gómez | Francesco Cubadda | Thomas Frenzel | Marina Heinonen | Monika Neuhäuser-Berthold | Carmen Peláez | Morten Poulsen | Miguel Prieto Maradona | Josef Rudolf Schlatter | Alexandros Siskos | Henk van Loveren | Reinhard Ackerl | Océane Albert | Domenico Azzollini | Antonio Fernández Dumont | Wolfgang Gelbmann | Andrea Germini | Maria Glymenaki | Georges E. N. Kass | Eirini Kouloura | Marcello Laganaro | Leonard Matijevic | Vânia Mendes | Estefanía Noriega Fernández | Irene Nuin Garciarena | Gabriela Precup | Ruth Roldán Torres | Annamaria Rossi | Emanuela Turla | Silvia Valtueña Martinez | Ermolaos Ververis | Helle Katrine Knutsen

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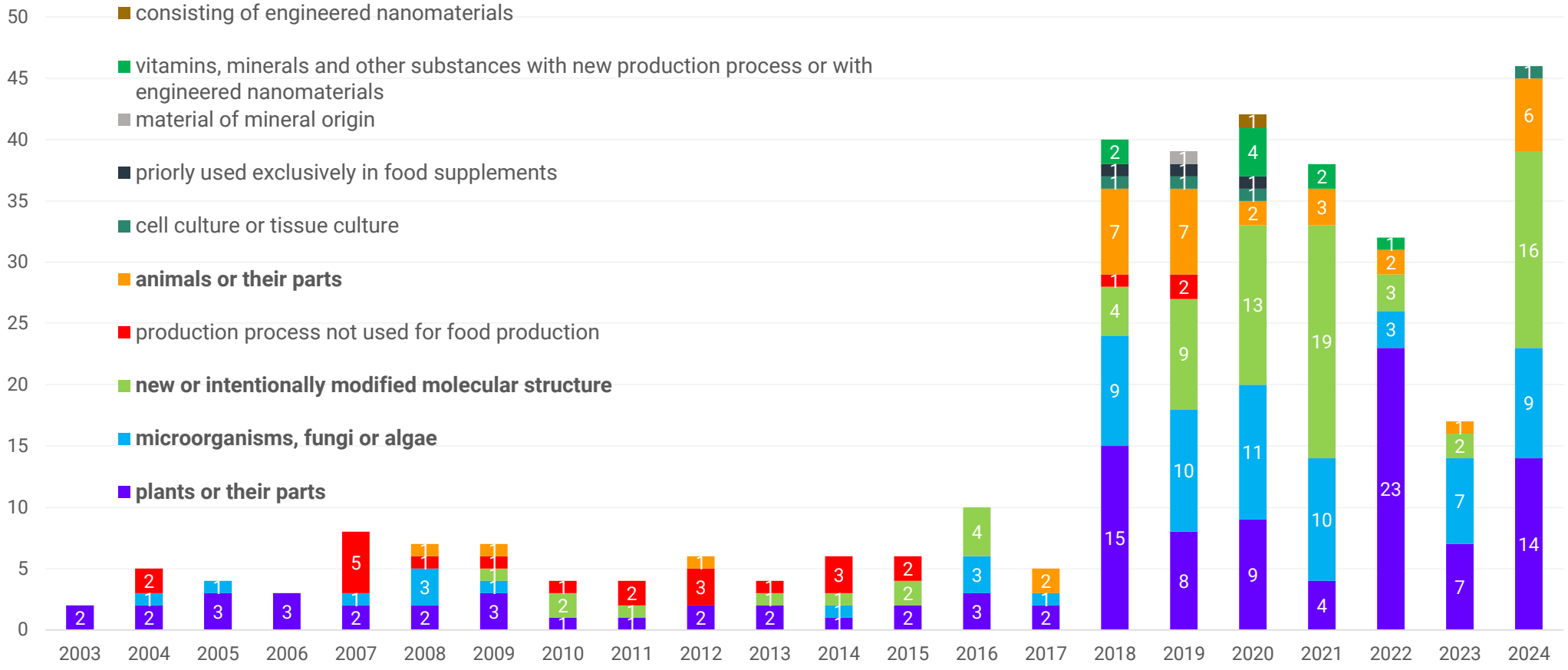
Abstract
The European Commission requested EFSA to update the scientific guidance for the preparation of applications for authorisation of novel foods, previously developed following the adoption of Regulation (EU) 2015/2283 on novel foods. This guidance document provides advice on the scientific information needed to be submitted by the applicant towards demonstrating the safety of the novel food. Requirements pertain to the description of the novel food, production process, compositional data, specifications, proposed uses and use levels and anticipated intake of the novel food. Furthermore, information needed in sections on the history of use of the novel food and/or its source, absorption, distribution, metabolism, excretion, toxicological information, nutritional information and allergenicity is also described. The applicant should integrate and interpret the data presented in the different sections to provide their overall considerations on how the information supports the safety of the novel food under the proposed conditions of use. Where potential health hazards have been identified, they are to be discussed in relation to the anticipated intake of the novel food and the proposed target populations. On the basis of the information provided, EFSA will assess the safety of the novel food under the proposed conditions of use.

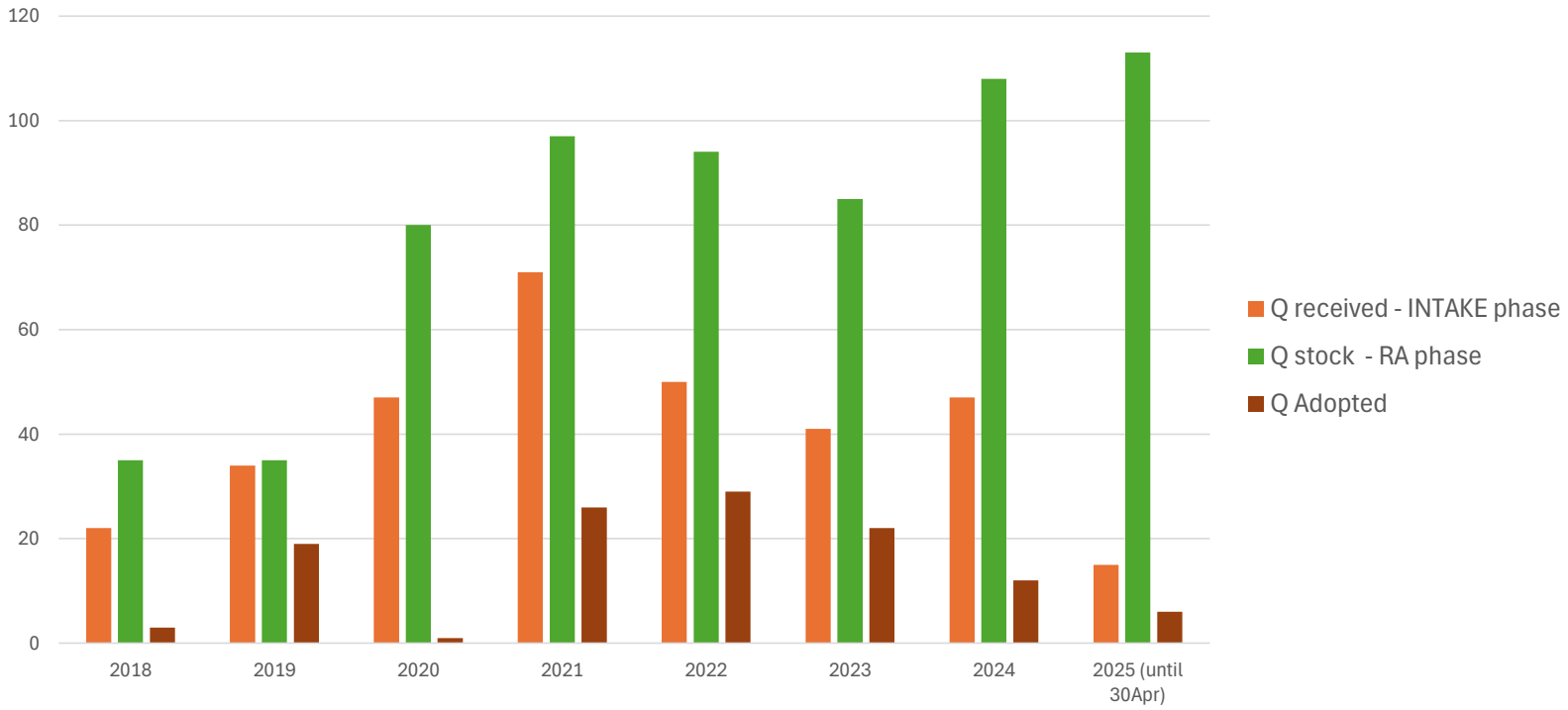
KEYWORDS
authorisation, EFSA guidance, food innovation, food safety, hazard characterisation, hazard identification, novel foods, risk assessment

NOVEL FOOD APPLICATIONS - EFSA'S RISK ASSESSMENT



*The figures refer to applications that entered EFSA's Risk Assessment

NOVEL FOOD APPLICATIONS - EFSA'S RISK ASSESSMENT



Average time RA with clock stop days	Average RA time excluding clock stop days	No additional EFSA requests average	No applicants extension request average
647 [105-1924]	222	4.41	2.26

MAIN OBSERVATIONS

- Regulatory requirements are sometimes misunderstood or overlooked
- Existing scientific opinions and relevant regulatory outputs are not always consulted
- Cross-cutting guidance documents may be implemented inconsistently or insufficiently
- Data collection on the novel food and its safety-relevant characteristics is occasionally inadequate
- Compositional analyses may be incomplete or contradict existing literature
- Discrepancies may exist between laboratory results (e.g., certificates of analysis) and data presented in the main dossier

MAIN OBSERVATIONS

- Over-reliance on history of use or non-representative literature-based toxicological data
- Studies are not submitted, without a scientifically sound justification
- The tiered toxicity testing approach is not always correctly or fully applied
- Study results may lack sufficient interpretation or elaboration
- Findings are not always contextualized within the broader scientific or regulatory framework
- Evidence is not consistently integrated across dossier sections
  (e.g., compositional data not informing the need for toxicological or allergenicity studies)

STAKEHOLDER ENGAGEMENT: PAST ACTIVITIES AND FUTURE PLANS

- More than 500 articles

- 54 media requests
- 5 interviews

International Collaborations *(e.g., FAO/WHO)*

EFSA's Scientific Colloquium 27 "Cell culture-derived foods and food ingredients"

11 May 2023, 09.00 - 12 May 2023, 12.30 (CEST)
Brussels, Belgium and online
Share:

Participation in Scientific Conferences

Participation in International Fora

FUTURE OUTLOOK: CHALLENGES & OPPORTUNITIES IN THE NOVEL FOOD RISK ASSESSMENT

- Heterogeneity of products and applicants
- Speed of Risk Assessment and regulatory process for authorization
- Development of user-friendly templates for interoperable data submission
- Development of Training material on the Novel Food Guidance
- EFSA - supported projects for development risk assessment methodologies
- New Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain (adoption foreseen in 2025)
- Ongoing update of the guidance document for the risk assessment of nanomaterials and materials containing small/nano particles in the food and feed chain
  Workshop on risk assessment of nanomaterials and materials containing small/nanoparticles in the food and feed chain (deadline to register: May 12, 2025)

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EUROPEAN FOOD SAFETY AUTHORITY