

THE ROLE OF EFSA IN THE PRE-MARKET AUTHORISATION OF NOVEL FOODS IN THE EU

Ermolaos Ververis, PhD

Scientific Officer
Nutrition & Food Innovation Unit



EFSA was established under EU law in 2002 following a series of food crises

TO

Improve the EU food safety system

Help ensure a high level of consumer protection

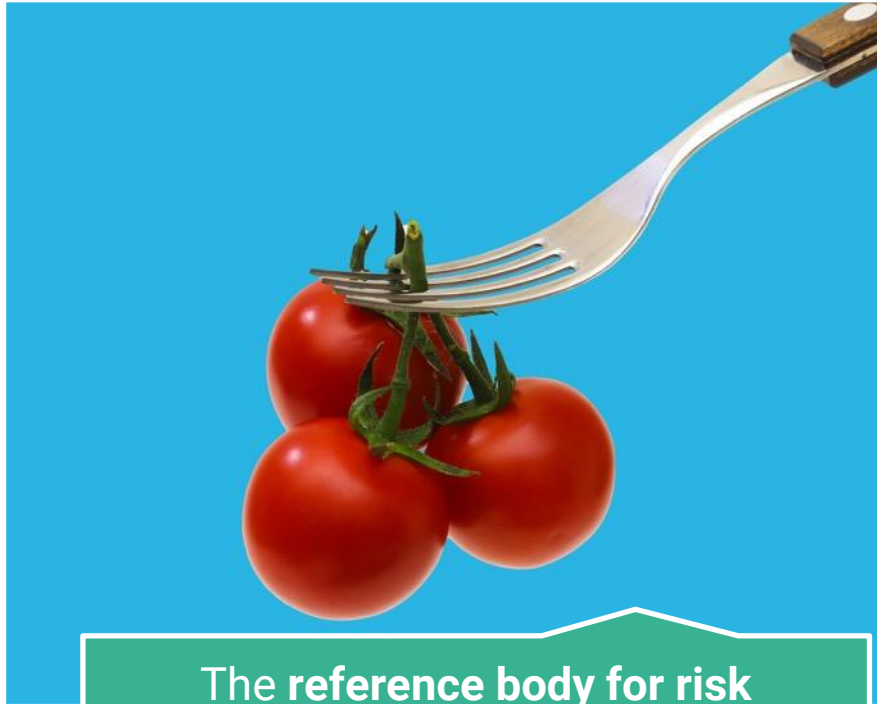
Restore and maintain confidence in the EU food supply

Clearly separate risk assessment and risk management functions

European Food Safety Authority



EFSA IS

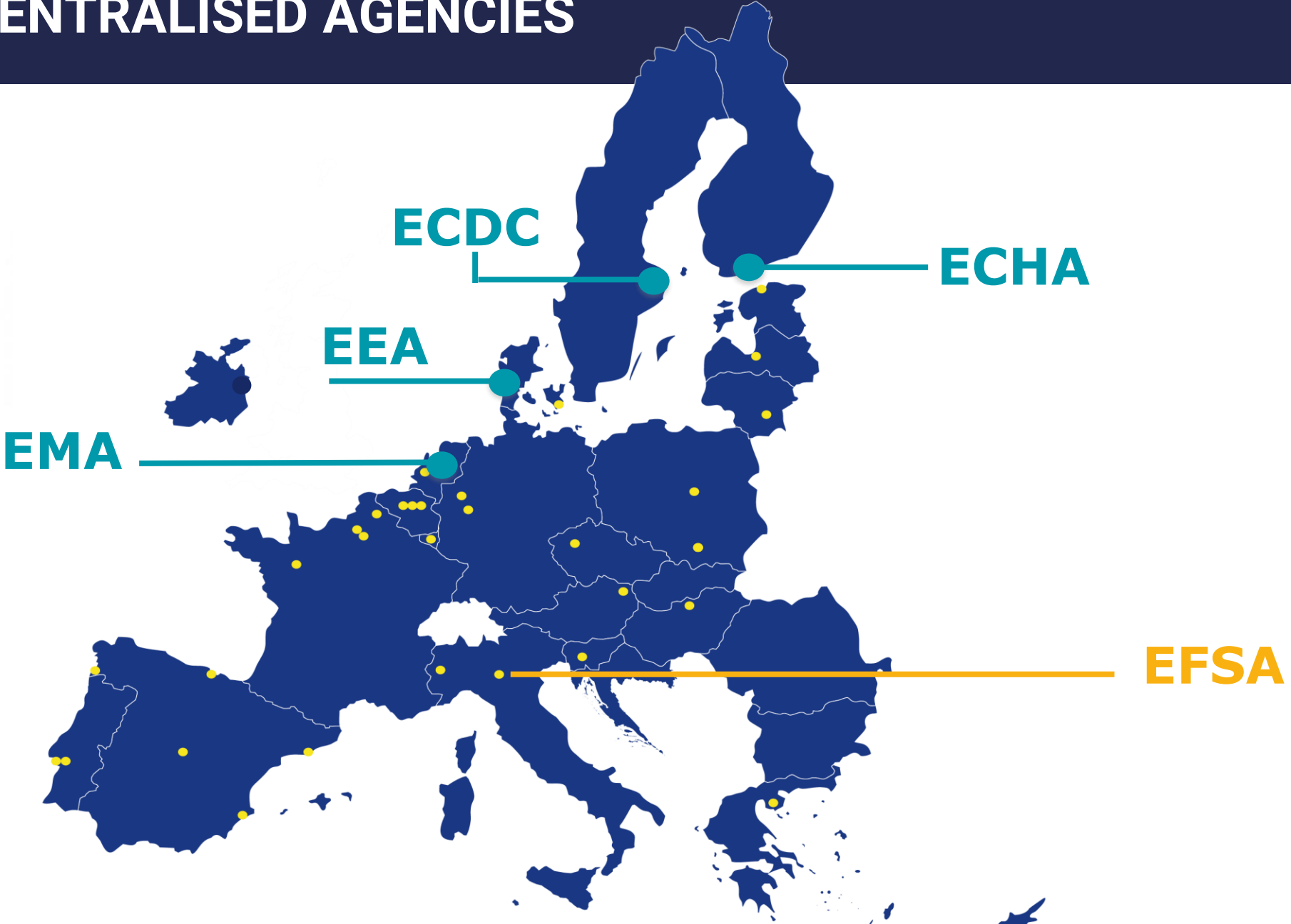


The **reference body for risk assessment** of food and feed in the European Union. Its work covers the entire food chain – from field to fork



One of a number of bodies that are **responsible for food safety in Europe**

EU DECENTRALISED AGENCIES



KEEPING FOOD SAFE IN THE EU





**EU NOVEL FOODS
FRAMEWORK**

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



NOVEL FOOD AUTHORISATION PROCEDURE IN THE EU



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**)






Decide on market authorisation
Integration to the **Union List of authorized novel foods**



EFSA'S MISSION & RESPONSIBILITIES IN THE NOVEL FOOD AREA

WHAT EFSA DOES NOT DO

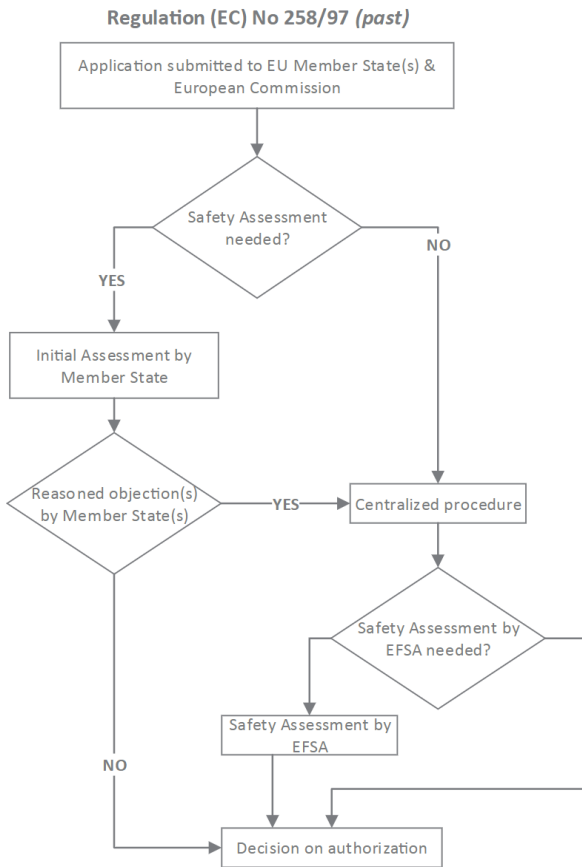
-  Develop food safety policies and legislation
-  Adopt regulations, authorise marketing of new products, define labelling
-  Enforce food safety legislation

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 FOODS REGULATION IN THE EU

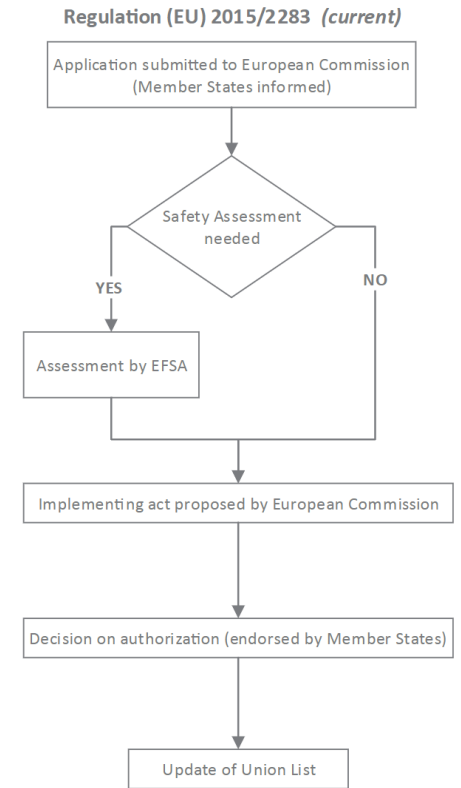


Risk assessment by Member States, European Commission and EFSA (*ad hoc*)

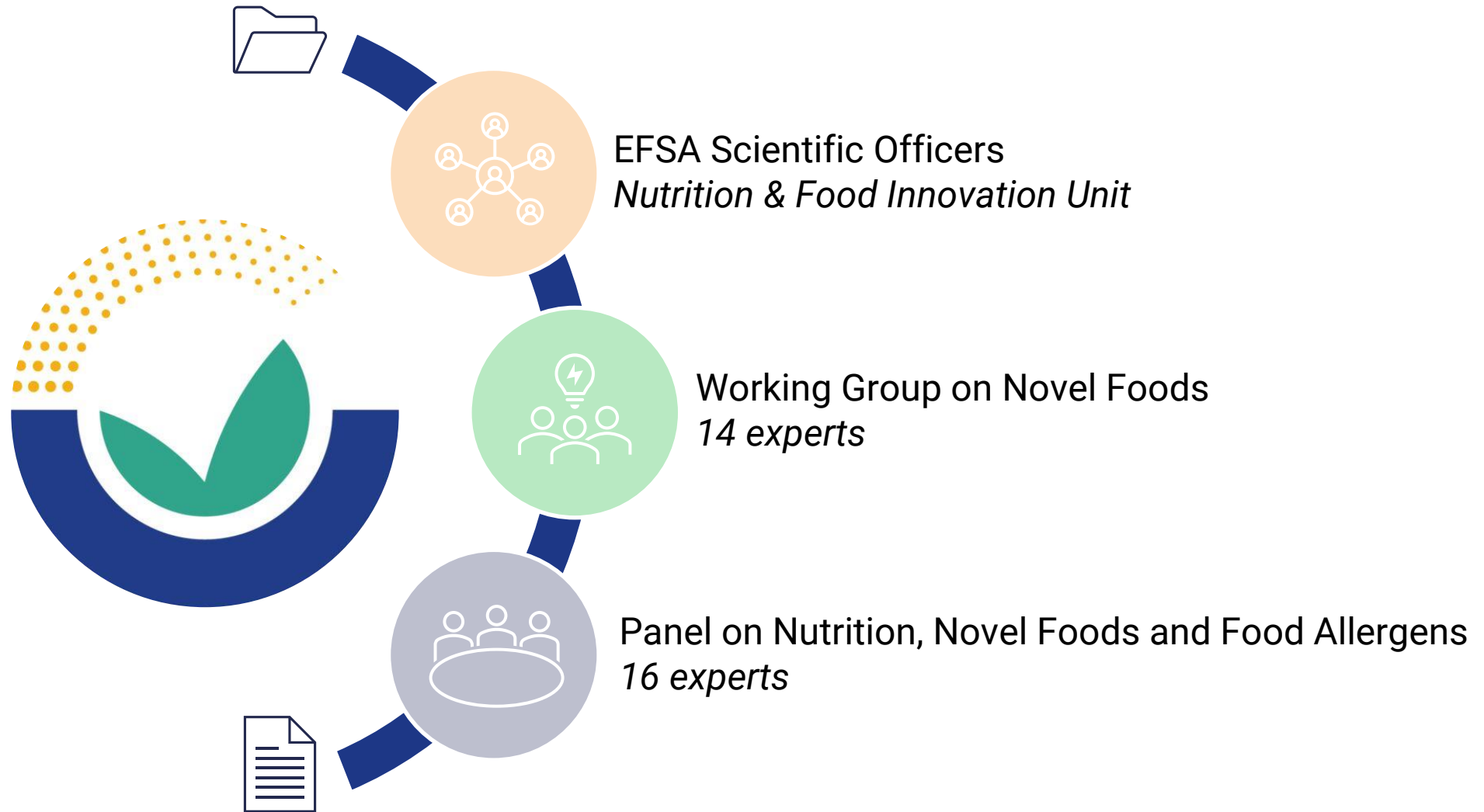
Regulation (EC) No 258/97

Regulation (EU) 2015/2283

From January 2018, centralised risk assessment by EFSA



RISK ASSESSMENT PROCESS



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

Adopted: 27 June 2024
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GUIDANCE

Guidance on the scientific requirements for an application for the authorisation of a novel food in the context of Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) | Dominik Torsten Bohn | Jacqueline Castenmiller | Stefaan de Henauw | Karen Ildiko Alexandre Maciuc | 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 Garciaarena | Gabriela Precup | Ruth Roldán Torres | Annamaria Rossi | Emanuela Turla | Silvia Valtueña Martínez | Ermolaos Ververis | Helle Katrine Knutsen

Correspondence: nif@efsa.europa.eu

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.

KEY WORDS

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

NEW
Administrative
guidance for the
preparation of
novel food
applications



FUNDAMENTAL PRINCIPLES



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



The novel food cannot be nutritionally disadvantageous



The efficacy of the novel food is not assessed



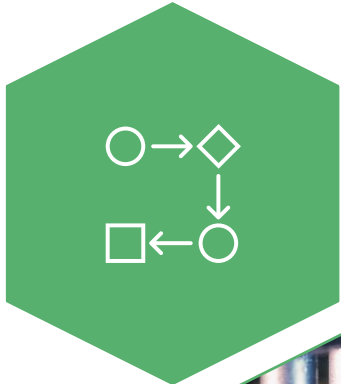
NOVEL FOODS IN THE EUROPEAN UNION

#OpenEFSA

NOVEL FOOD APPLICATIONS UNDER RISK ASSESSMENT



TRENDS IN THE NOVEL FOODS AREA



Novel carbohydrates

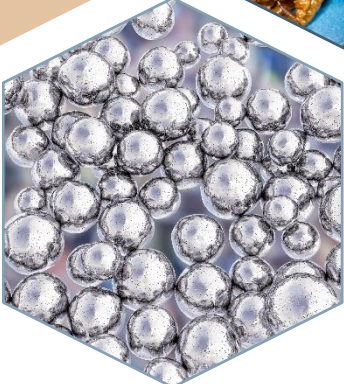
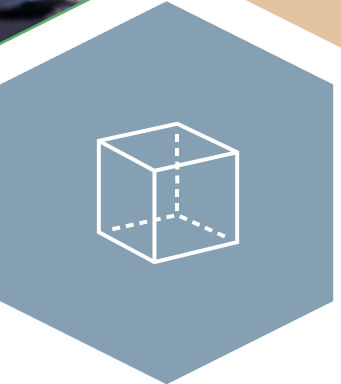


Novel proteins and their sources

New processes

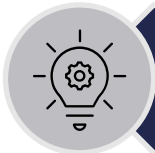


Nanomaterials



Plant extracts

NOVEL PROTEINS AND THEIR SOURCES



Traditional sources & novel processing*



insects



plants



algae



Novel sources



cell/tissue culture



fungi



by-products

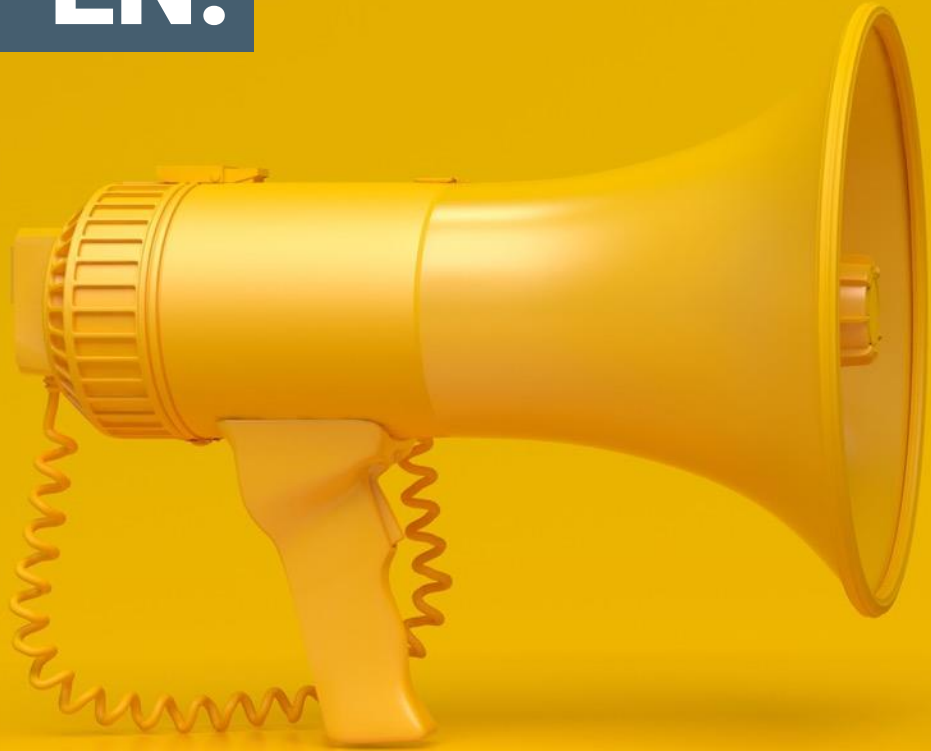
*Food processes not used within the EU before 15/05/1997, with a potential significant impact on the product

EFSA NOVEL FOOD RISK ASSESSMENT & UPDATED GUIDANCE

- **EFSA's Novel Food Scientific Guidance:** advice for applicants on preparing novel food application dossiers, with flexibility to tailor to specific products.
- **Guidance Update highlights:** reflect recent regulatory changes, advances in food science, and EFSA's experience in novel food risk assessment.
- **Risk assessment backbone: compositional analysis:** includes nutrient profile, microbiological aspects, contaminants, and substances of concern.
- **Impact of EFSA's Guidance & Safety Assessment:** supports food chain resilience, diversity, and safety by providing science-based advice for potential EU market approvals.
- **"Safe by design":** aligning innovation with EFSA's data requirements, early integration of safety into product development, simplifying/speeding-up pre-market authorization



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on applications for food
and feed products!**

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10 January 2025**



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QUESTIONS ?

