90TH ADVISORY FORUM
MADRID, 30NOV-01DEC 2023

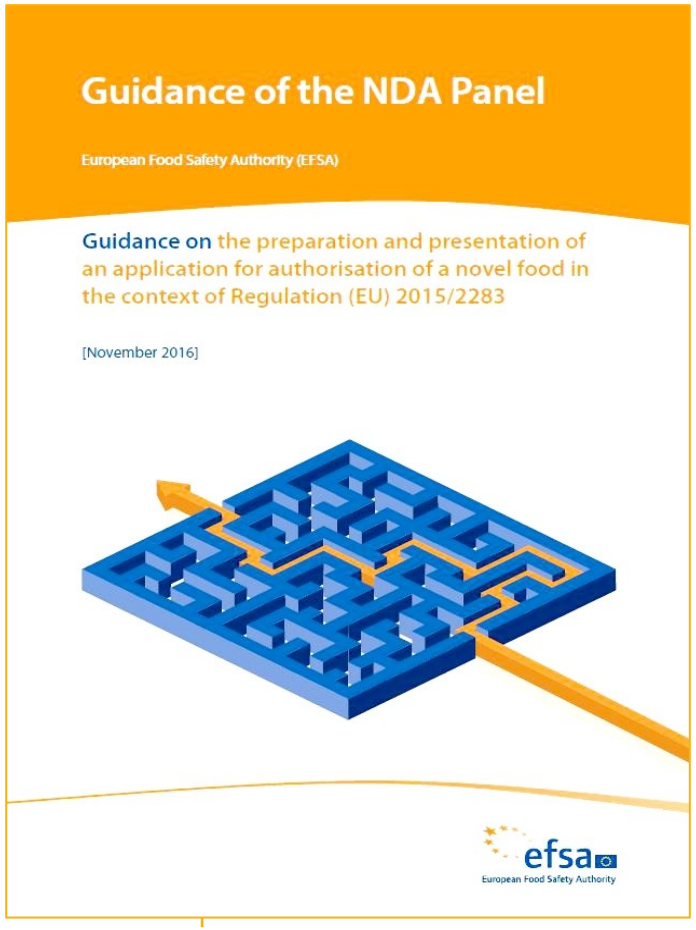
# EFSA GUIDANCE ON NOVEL FOODS

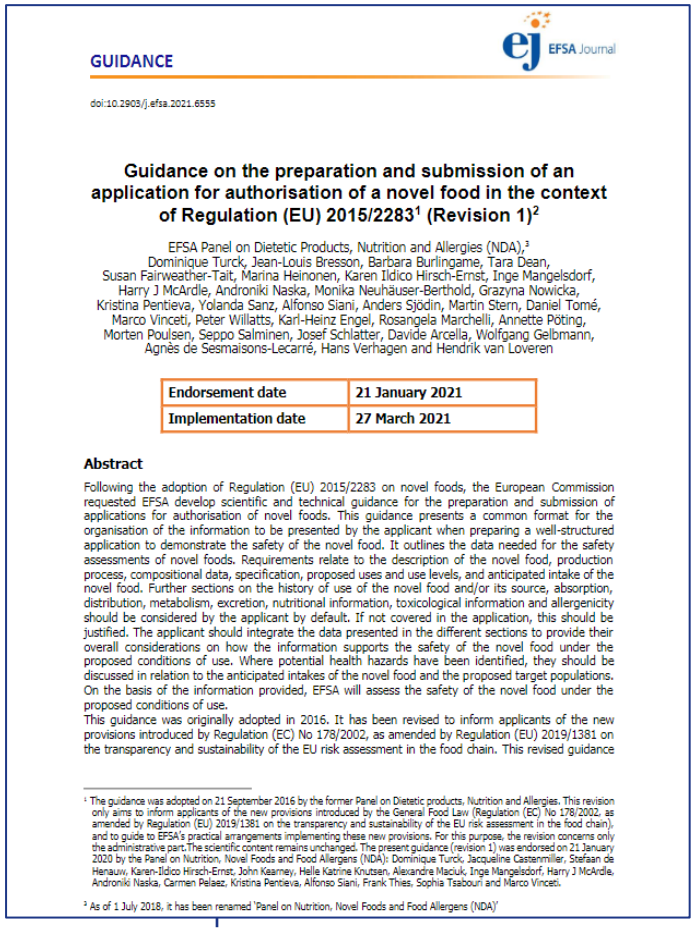
Ermolaos Ververis

Scientific Officer
Nutrition & Food Innovation Unit

EUROPEAN FOOD SAFETY AUTHORITY

# EFSA GUIDANCE ON NOVEL FOODS



GUIDANCE

EFSA Journal

doi:10.2903/j.efsa.2021.6555

**Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283[1] (Revision 1)[2]**

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA),[3] Dominique Turck, Jean-Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Marco Vinceti, Peter Willatts, Karl-Heinz Engel, Rosangela Marchelli, Annette Pöting, Morten Poulsen, Seppo Salminen, Josef Schlatter, Davide Arcella, Wolfgang Gelbmann, Agnès de Sesmaisons-Lecarré, Hans Verhagen and Hendrik van Loveren

| | |
|---|---|
| Endorsement date | 21 January 2021 |
| Implementation date | 27 March 2021 |

**Abstract**

Following the adoption of Regulation (EU) 2015/2283 on novel foods, the European Commission requested EFSA develop scientific and technical guidance for the preparation and submission of applications for authorisation of novel foods. This guidance presents a common format for the organisation of the information to be presented by the applicant when preparing a well-structured application to demonstrate the safety of the novel food. It outlines the data needed for the safety assessments of novel foods. Requirements relate to the description of the novel food, production process, compositional data, specification, proposed uses and use levels, and anticipated intake of the novel food. Further sections on the history of use of the novel food and/or its source, absorption, distribution, metabolism, excretion, nutritional information, toxicological information and allergenicity should be considered by the applicant by default. If not covered in the application, this should be justified. The applicant should integrate 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 should be discussed in relation to the anticipated intakes 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.
This guidance was originally adopted in 2016. It has been revised to inform applicants of the new provisions introduced by Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain. This revised guidance

[1] The guidance was adopted on 21 September 2016 by the former Panel on Dietetic products, Nutrition and Allergies. This revision only aims to inform applicants of the new provisions introduced by the General Food Law (Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain), and to guide to EFSA's practical arrangements implementing these new provisions. For this purpose, the revision concerns only the administrative part.The scientific content remains unchanged. The present guidance (revision 1) was endorsed on 21 January 2020 by the Panel on Nutrition, Novel Foods and Food Allergens (NDA): Dominique Turck, Jacqueline Castenmiller, Stefaan de Henauw, Karen-Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri and Marco Vinceti.

[2] As of 1 July 2018, it has been renamed 'Panel on Nutrition, Novel Foods and Food Allergens (NDA)'

**2015**
Regulation (EU) 2283/2015

**2016**

**2018**
Regulation (EU) 2283/2015 comes into force

**2021**

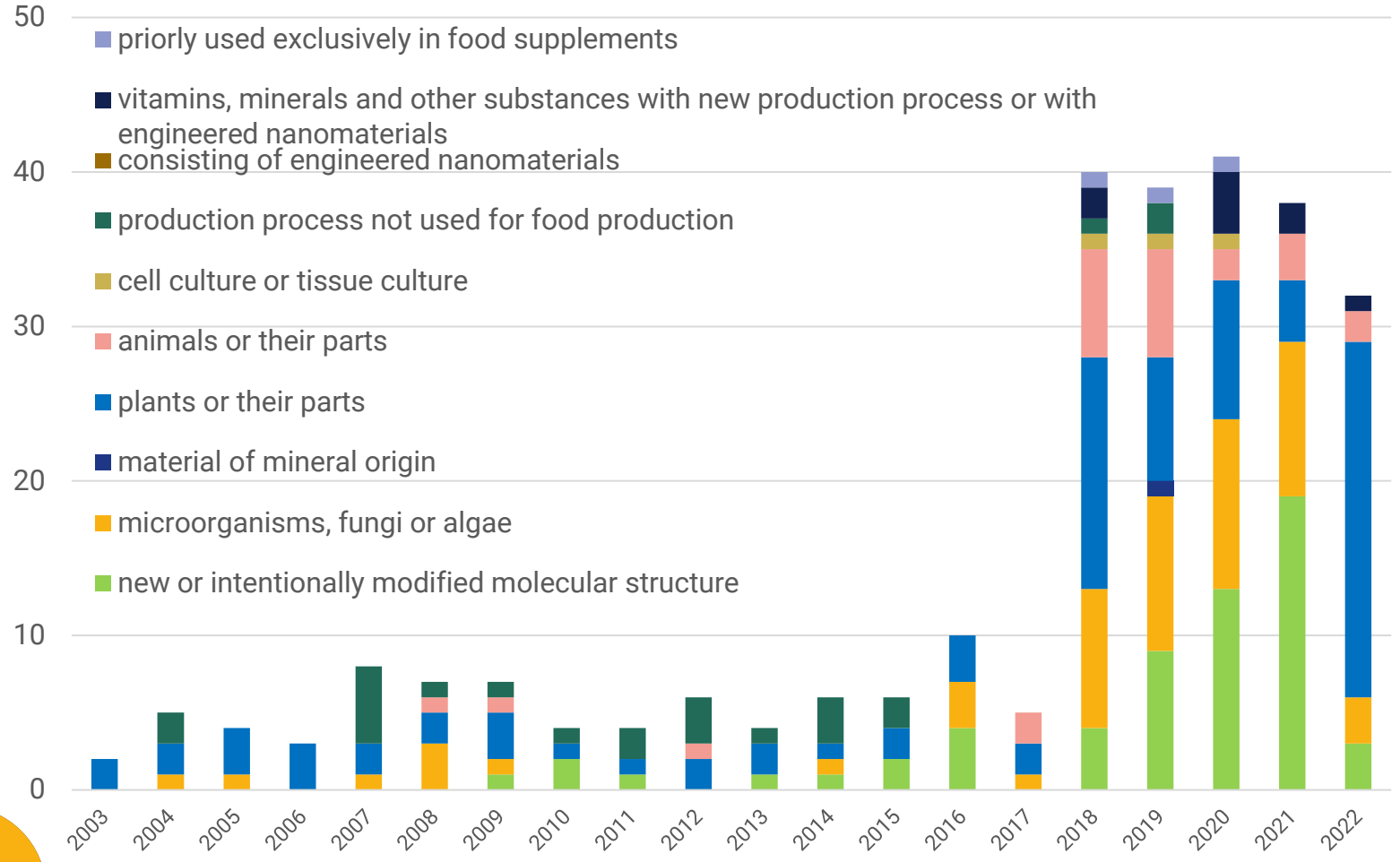
**2024**

# EFSA GUIDANCE ON NOVEL FOODS -UPDATE

## EFSA Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

- Mandate from EC received & accepted by EFSA: June 2023
- Deadline: June 2024
- Considerations:
  - Regulatory Updates: Implementing Regulation (EU) 2017/2469
  - EFSA's experience
  - Advances in science and technologies

# EFSA GUIDANCE ON NOVEL FOODS -UPDATE




**Number of Novel Food dossiers validated for EFSA's Risk Assessment**
Adapted from: Ververis et al. (2020), Novel foods in the European Union: Scientific requirements and challenges of the risk assessment process by the European Food Safety Authority. *Food Research International*, 137, 109515.

## EFSA's experience

- Centralised assessment of multiple & heterogeneous novel food dossiers
- New EFSA cross-cutting guidance applicable
- Risk assessment methodological advances
- New EFSA tools
- Engagement & feedback from stakeholders (e.g., EFSA Scientific colloquium in cell culture derived foods)

# EFSA GUIDANCE ON NOVEL FOODS -UPDATE

## Main points to be updated

- Additional Identity qualifiers for specific NF categories
- Specific production process requirements for specific NF cases
- Enhance instructions for fit-for-purpose compositional data
- Tools and methodological approaches for exposure assessment
- Further insights on nutrition-relevant testing requirements, including the area of novel proteins
- Updated tiered toxicity and ADME* approach
- Allergenicity testing requirements for specific NF cases



* ADME: Absorption, Distribution, Metabolism & Excretion

# EFSA GUIDANCE ON NOVEL FOODS -UPDATE

## Current Timeline


* NDA Panel: EFSA Panel on Nutrition, Novel foods and Food Allergens

# EFSA GUIDANCE ON NOVEL FOODS -UPDATE

## An opportunity for further collaboration between EFSA and Member States within the NF Risk Assessment framework

- EFSA identified several partners (art.36 list organisations) to entrust the tasks of contributing to the preparatory work of NF Risk Assessment
- Multiple Areas of Scientific expertise

- New call 2024: preparatory work and drafting of the scientific outputs
- **Framework partnership agreement**
- **Contract to be signed in 2025**

Our current partners

- AGES Wien (AT)
- CER Groupe (BE)
- CNR Rome (IT)
- CREA Rome (IT)
- CSIC Madrid (ES)
- CSIC Sevilla (ES)
- INYTA (Consortium)
- Sciensano (BE)
- UniParma (IT)
- UniThessaloniki (GR)

# STAY CONNECTED

SUBSCRIBE TO
efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
Careers.efsa.europa.eu – job alerts

LISTEN TO OUR PODCAST
Science on the Menu –Spotify, Apple Podcast and YouTube

FOLLOW US ON TWITTER
@efsa_eu @methods_efsa
@plants_efsa @animals_efsa

FOLLOW US ON LINKEDIN
Linkedin.com/company/efsa

FOLLOW US ON INSTAGRAM
@one_healthenv_eu

CONTACT US
efsa.europe.eu/en/contact/askefsa

efsa
EUROPEAN FOOD SAFETY AUTHORITY