



NOVEL FOODS PARTNERSHIP – CALL FOR PROPOSALS (EUBA-EFSA-2024-NIF-01)

AGENDA

Part 1 "Presentation of the call" – 10:00 - 10:55

10:00 - 10:05 – Welcome & housekeeping rules

10:05 - 10:20 – Objectives of the call and tasks to be performed

10:20 - 10:35 – Financial procedures and requirements

10:35 - 10:50 – Q&A (based on questions written in the chat)

10:50 - 10:55 – Close and instructions to join Part 2



10:55-11:05 – BREAK

Part 2 "Partner discovery" – 11:05 - 12:00

Reserved for Article 36 delegates | SEPARATE LINK TO CONNECT!

11:05 - 11:10 – Welcome & housekeeping rules

11:10 - 11:55 – Tour de table and follow-up interactions

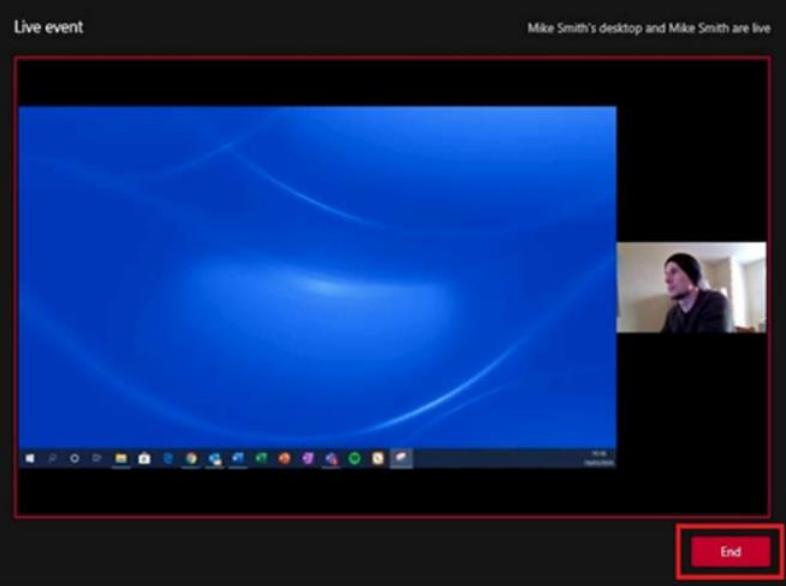
11:55 - 12:00 – Close



HOUSE-KEEPING RULES

- You are **automatically connected** to the audio broadcast. One-way audio (**listen only** mode);
- The **event is in English**. Questions should be submitted **in English** via the **Q&A chat**;
- This event is **being recorded** and recordings will be published on EFSA's website;
- After the event, attendees will receive a **link to a survey** to evaluate the EFSA's event & services.

Presentation window



Live event Mike Smith's desktop and Mike Smith are live

Live event Q&A

Featured: **My questions**

Ask a moderator

Questions won't be visible to everyone until a moderator approves them

Your name (optional):

Ask a question:

Post as anonymous

Q&A box: For any questions related to the topic or unexpected IT issues

3



WHAT IS EFSA?

- The reference body for **risk assessment of food and feed** in the European Union
- Provides **scientific basis** for laws and regulations to protect European consumers from food-related risks **from farm to fork**
- Established in Parma, Italy



WHAT IS A NOVEL FOOD?



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

- Phenylcapsaicin
- Ice-structuring protein

New synthetised or isolated compounds



New sources



- UV-treated yeast or mushrooms
- Milk products fermented with *B. xylanisolvans*

New processes & technologies



- Haskap berries
- Cacao pulp
- Coffee leaves

Traditional foods (non-EU countries)



NOVEL FOOD CATEGORIES | REGULATION (EU) 2015/2283

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



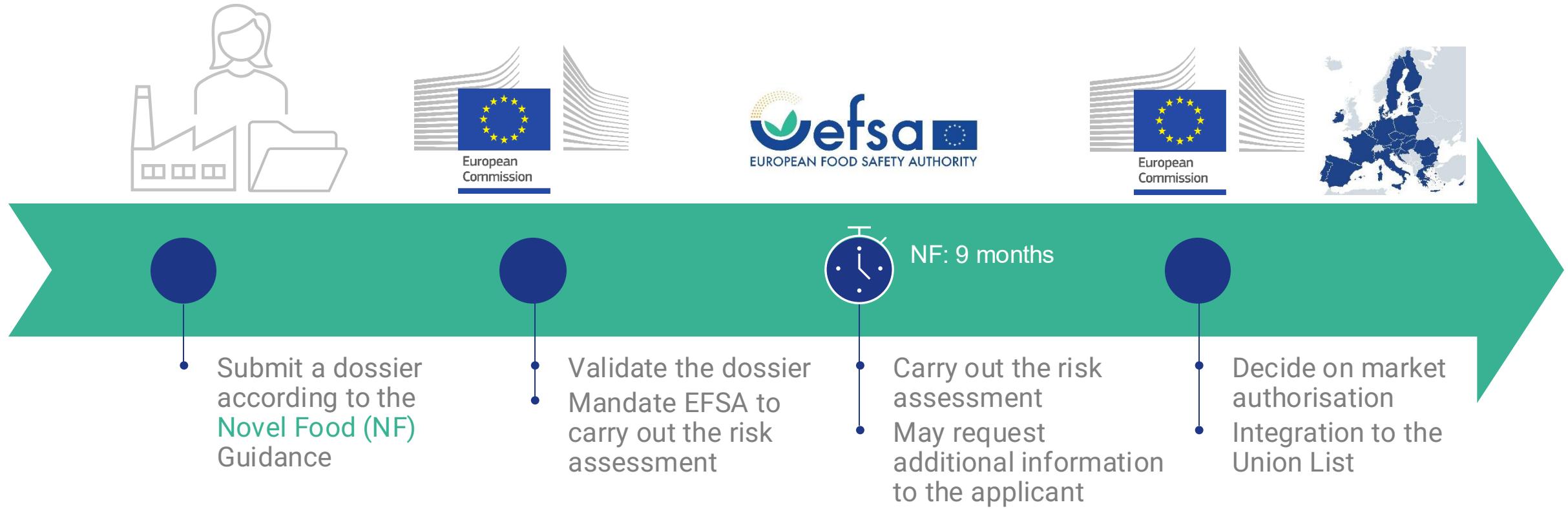
Engineered nanomaterials



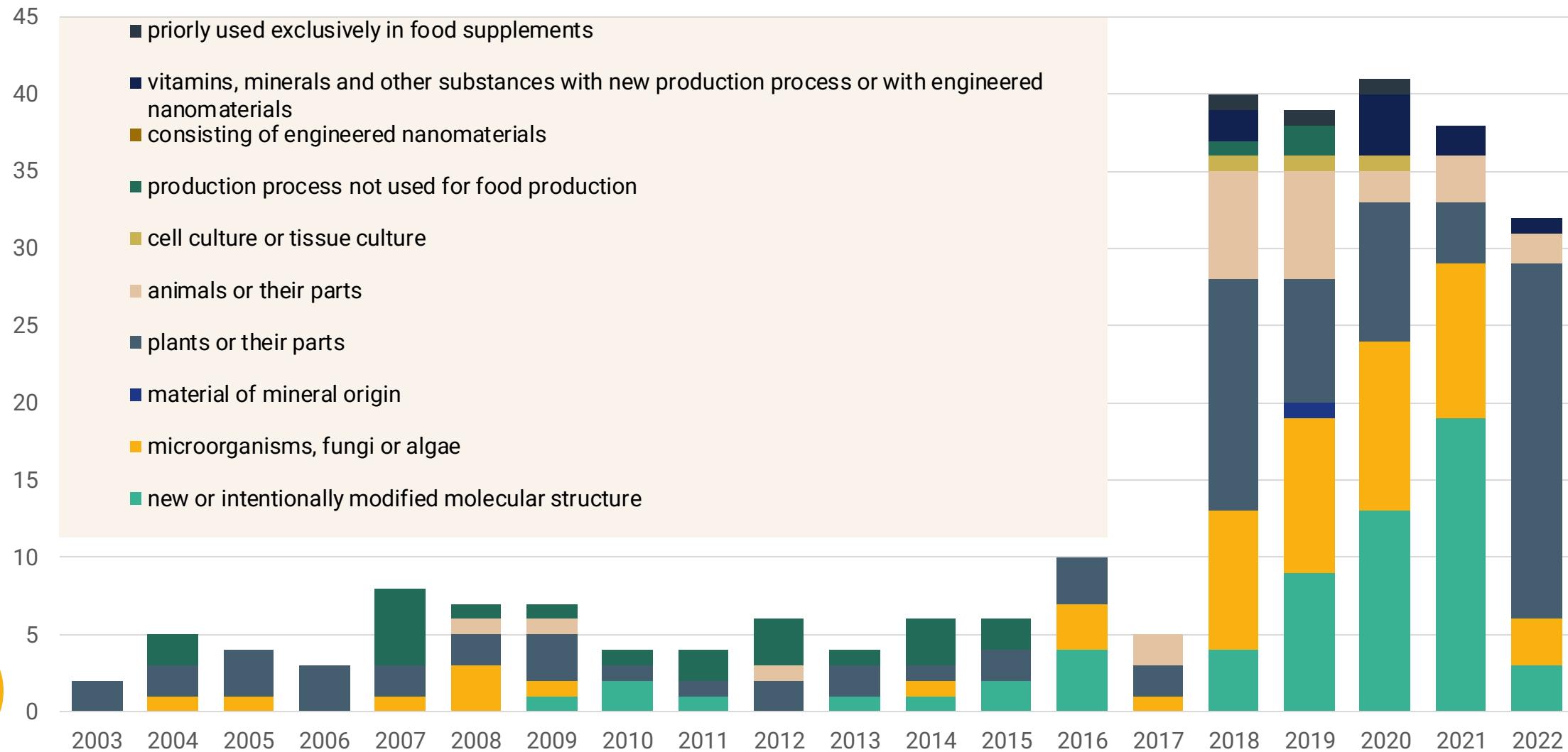
Exclusive use in food supplements prior to May 1997



NOVEL FOOD AUTHORISATION PROCEDURE



NOVEL FOOD APPLICATIONS



THE CALL

CALL FOR PROPOSALS AND GUIDE FOR APPLICANTS

Call reference: EUBA-EFSA-2024-NIF-01

Call title: Contribution to the Risk Assessment of Novel Foods and Nutrient Sources in the EU.

Restricted to **the list of competent organisations** established by the Authority's Management Board in application of Article 2 the Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the Authority's remit.

Brief description of the call objectives and key messages: EFSA is responsible for EU risk assessments of materials from farm to fork. With this Call for Proposals, EFSA is launching a new opportunity to involve **competent organisations** in the assessment of Novel Food (NF) dossiers submitted to EFSA under Regulation (EU) 2015/2283 and the preparation of scientific opinions (specific sections or in full) for the NF regulatory domain. The objective of this call is to identify and award a four-year Framework partnership agreement (FPA) to one or more competent organisations or consortia thereof that can provide capacity and expertise (chemistry, microbiology, biotechnology, food technology, nutrition, ADME, exposure and toxicology) that are relevant for the assessment of NF technical dossiers.



KEY POINTS OF THE CALL

- **Entire dossiers** are outsourced – no splitting into individual lots/sections
- **Full range of competencies/ expertise plus capacity** needed
- Deliverables are **complete draft Scientific Opinions** – not just preparatory work
- Based on data in dossier – **no laboratory work** (analyses etc.) foreseen
- **Limited number of partners/consortia** (not obligatory but encouraged)
- **Additional budget for coordination activities** – scientific and administrative
- **Time-constraints**, 4 months, owing to legal framework



EXPERTISE NEEDED

- Should cover **all areas/sections** of the novel food technical dossier
 - ✓ Chemistry
 - ✓ Microbiology
 - ✓ Biotechnology / food technology
 - ✓ Nutrition
 - ✓ ADME
 - ✓ Exposure
 - ✓ Toxicology / Pharmacology
 - ✓ Human studies / Epidemiology
- Depending on type of NF, similarities to **chemical risk assessment**



NOVEL FOOD GUIDANCE <-> DATA/EXPERTISE REQUIREMENTS

- Administrative data
- 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 (ADME)
- Nutritional information
- Toxicological information
- Allergenicity
- Conclusions

SCIENTIFIC OPINION

 ej EFSA Journal

ADOPTED: 21 September 2016

doi: 10.2903/j.efsa.2016.4594

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

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Morten Poulsen, Seppo Salminen, Josef Schlatter

Agnès de Sesmaisons-Lecarré, Hans Verh

Abstract

Following the adoption of Regulation (EU) 2015/2283 of the European Commission requested technical guidance for the preparation and presentation of novel foods. This guidance presents a common format for the application to assist the applicant in preparing a safety of the novel food. The application should be outlined the data needed for the safety assessments of covered in all applications relate to the description, compositional data, specification, proposed uses and uses of food. Further sections on the history of use of the distribution, metabolism, excretion, nutritional information should be considered by the applicant by default. If not justified. The applicant should integrate the data presented overall considerations on how the information supports proposed conditions of use. Where potential health hazards discussed in relation to the anticipated intakes of the novel food. On the basis of the information provided, EFSA will assess the proposed conditions of use.

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GUIDANCE

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) 2015/2283¹ (Revision 1)²

EFSA Panel on Dietetic Products, Nutrition and Allergies³

Dominique Turck, Jean-Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Illdico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, An Marco Vinceti, Peter Willatts, Karl-Heinz Engel, Rosangela Marchelli, Annette Potting, 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 to develop scientific and practical guidance for the preparation and the 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. Furthermore, history of use, distribution, metabolism, excretion, nutritional information, toxicological information and allergenicity should be considered by the applicant by default. If not 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

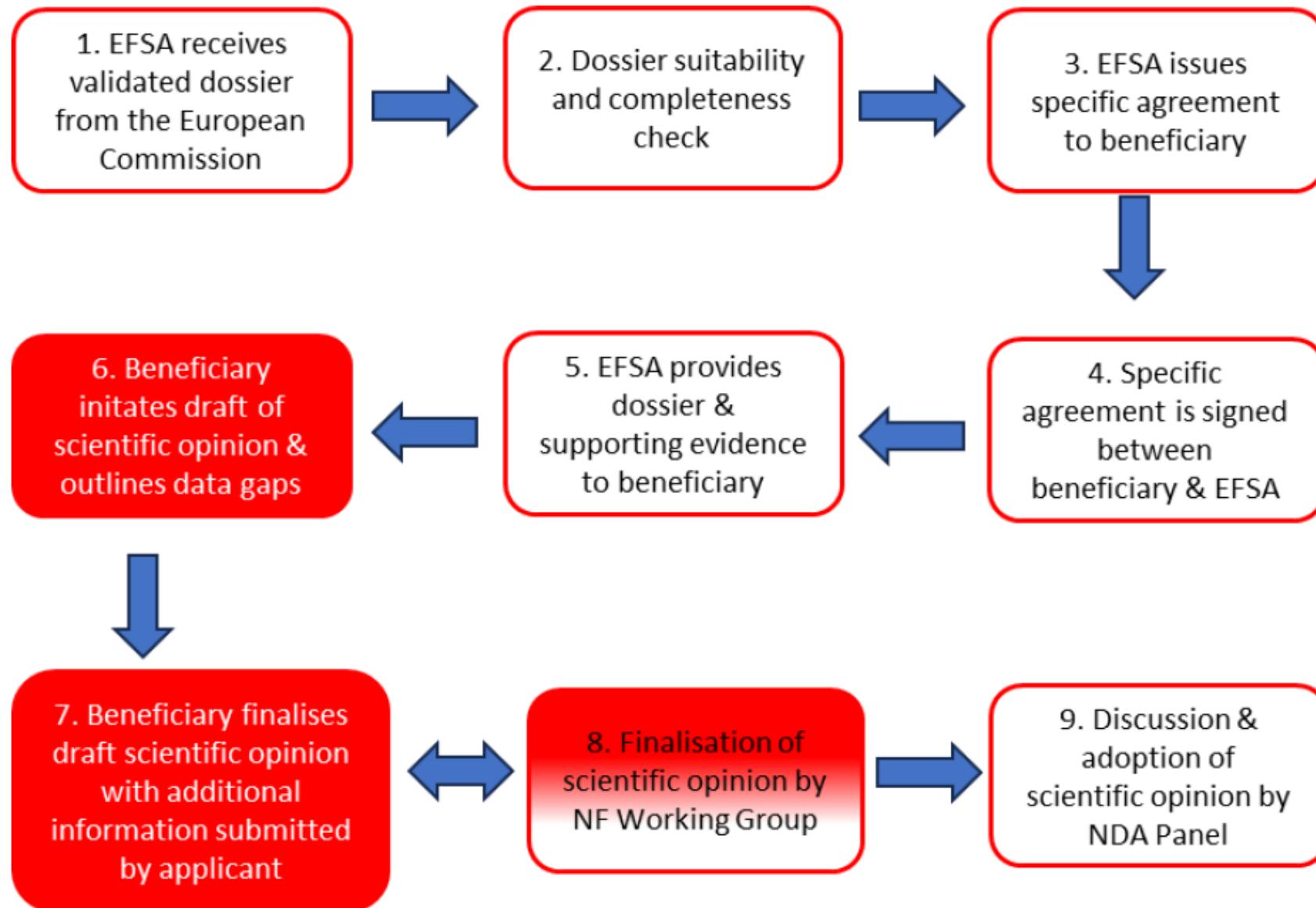
¹ The guidance was adopted on 21 September 2016 by the former Panel on Dietetic products, Nutrition and Allergies. This revision only aims to inform applicants of the new provisions introduced by the General Food Law (Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain), and to guide to EFSA's practical arrangements implementing these new provisions. The revision concerns only the sections on history of use, distribution, metabolism, excretion, nutritional information, toxicological information and allergenicity. It is not intended to change the safety assessment of the novel food. It is valid from 21 January 2020 by the Panel on Nutrition, Novel Foods and Food Allergens (NDA). Dominique Turck, Jacqueline Castenmiller, Stefan de Henauw, Karen-Didier Hirsch-Ernst, Helle Katrine Knudsen, Alexandre Maslik, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Camille Peeters, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Toubour and Marco Vinceti.

² As of 1 July 2016, it has been renamed 'Panel on Nutrition, Novel Foods and Food Allergens (NDA)'.

www.efsa.europa.eu/efsa/journal

EFSA Journal 2021;19(3):6555

WORKFLOW OF THE SCIENTIFIC ASSESSMENT



CALL FOR PROPOSALS



Call launched in June 2024; It will lead to a cascade of FPAs - Framework Partnership Agreements - with a maximum of 3 FPAs

Only art. 36 organisations can apply as partners – [full list here](#)



Overall estimated budget: EUR 3.5 million
Financing Not Linked to Costs: no need to justify incurred costs



Framework partnership agreement duration: 48 months



Applications in **consortium** are not mandatory but are welcome



USE OF EU FUNDING & TENDER OPPORTUNITIES PORTAL



Launched on the Funding and Tender Opportunities portal.

Deadline for submission of offers: 21/11/2024



Hard copy paper applications will **not be accepted**. Only electronic applications using the [EU Funding and Tenders portal](#) will be accepted.



The Funding and Tender Opportunities portal includes a feature allowing for the search of partners



N.B.: any organisation can access the Portal and its “Partner search announcement” section, but remember that only art. 36 organisations ([link to the list of art. 36 organisations](#)) can apply to this call as partners (other organisations can be involved as subcontractors for non-core tasks).

THANK YOU FOR ATTENDING PART 1!

- All submitted questions—whether addressed during the webinar or not—will be answered in writing in a **clarification document published alongside the call text and on the webinar page** within a few days.
- The **recording of Part 1** will be available on the EFSA website within a few days.
- Please take few minutes to fill out the **evaluation survey that you will receive after the event**. Your feedback is essential to improve our future events.

Participants in Part 2 “Partner Discovery” are invited to join the session using the dedicated link to Part 2 they received by e-mail.



BREAK

**PLEASE CONNECT TO PART 2
“PARTNER DISCOVERY” SESSION
AT 11:00**



STAY CONNECTED

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