Cellular Agriculture Europe

Food Innovation in Europe: an industry perspective

EFSA Stakeholder Forum - Innovation in food safety: navigating the future together

Workshop 3: *"Science & Innovation for a Sustainable & Competitive European Food System"*

Wednesday 27th November 2024 in Brussels

Cellular Agriculture Europe

About Us

We are entrepreneurs, innovators, and food lovers who believe in a future where consumers have the opportunity to choose delicious, nutritious meat and seafood products made in a kinder way.

Foie gras by Gourmey

Hamburger by Mosa Meat

Fish finger by Bluu Seafood

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- Brussels-based association officially launched in December 2021.
- 18 ordinary members and 3 associated members from across Europe, Israel and UK that produce beef, pork, poultry, fish, foie gras, and fats.
- Registered stakeholder with EFSA and member of DG SANTE's Advisory Group on Sustainability of Food Systems.
- Collaborating with cellular agriculture associations across the globe. Global Cellular Agriculture Alliance with:

ASSOCIATION FOR MEAT, POULTRY AND SEAFOOD INNOVATION

APAC-SCA
Asia-Pacific Society for Cellular Agriculture

Aleph Farms

BLUU SEAFOOD

brunocell

Cell 4 Food

FISHWAY

Food Novelties

GOURMEY

MEATABLE

LABFARM

NEWFORM

MEWERY
growing meat with love

Mosa Meat

Re-Meat

SuperMeat

uncommon

TECH 4MEAT

UPSIDE FOODS

VITAL MEAT

Associated members

Alternative Proteins Association

Nestlé
Good food, Good life

ROSLIN Technologies

Authorisations and applications for cell-cultured products

A global perspective

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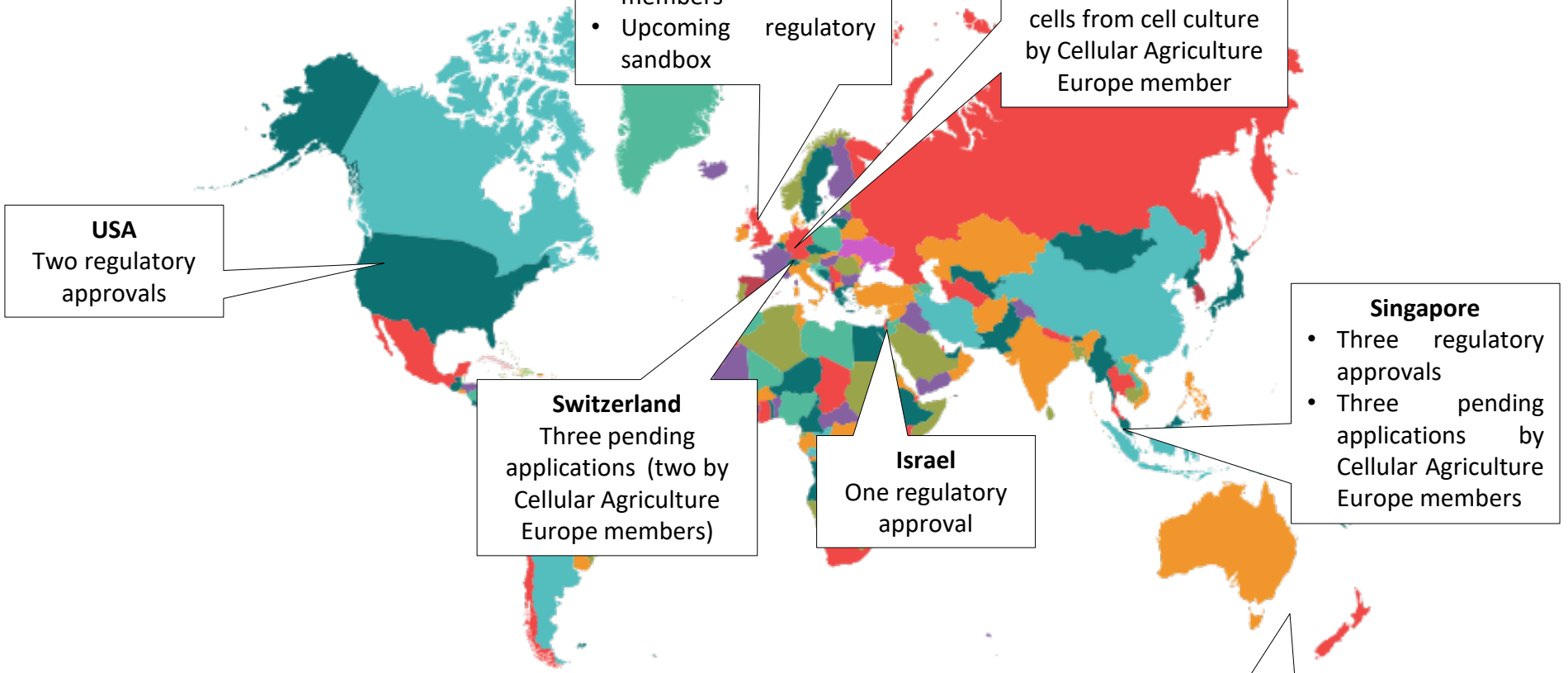

UK
- Three pending applications by Cellular Agriculture Europe members
- Upcoming regulatory sandbox

EU
One pending application for duck cells from cell culture by Cellular Agriculture Europe member

USA
Two regulatory approvals

Switzerland
Three pending applications (two by Cellular Agriculture Europe members)

Israel
One regulatory approval

Singapore
- Three regulatory approvals
- Three pending applications by Cellular Agriculture Europe members

Australia & New Zealand
One pending application

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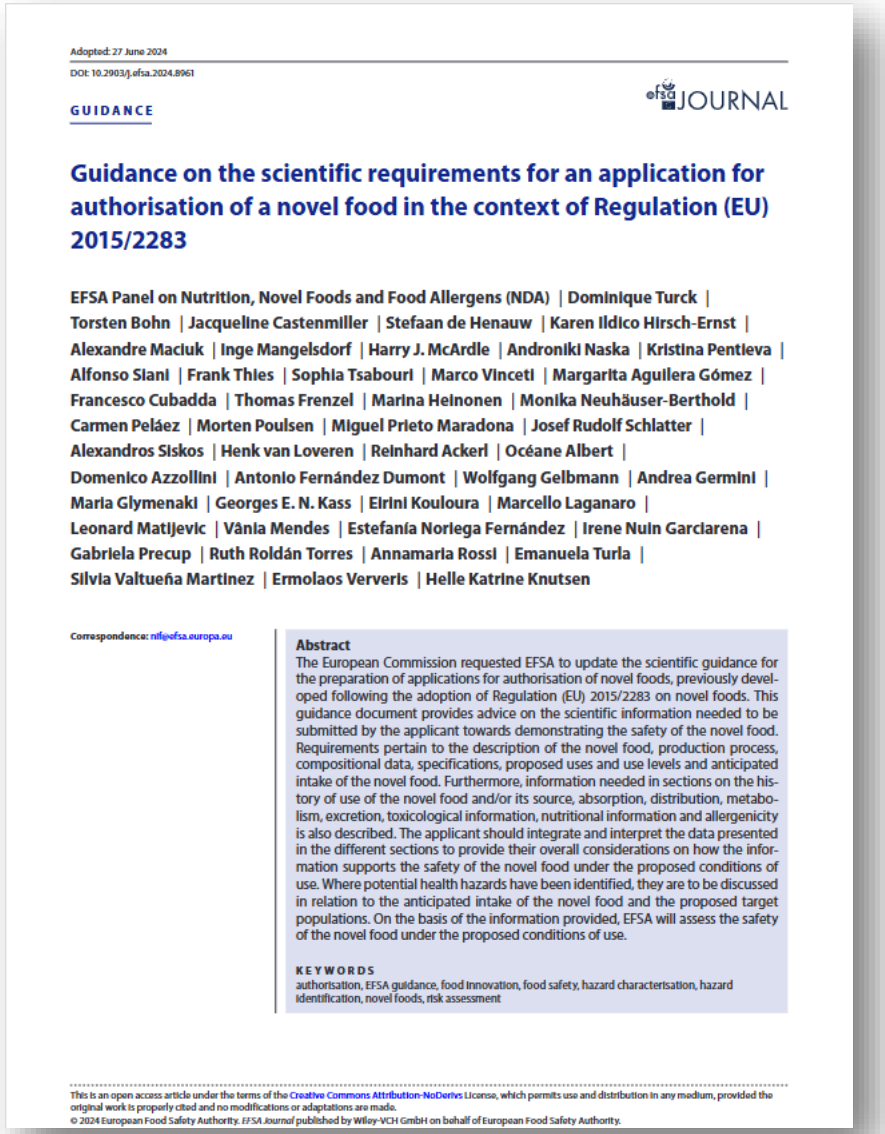
Guidance on novel foods

Our comments



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GUIDANCE

efsa JOURNAL

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

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) | Dominique Turck | Torsten Bohn | Jacqueline Castenmiller | Stefaan de Henauw | Karen Ildico Hirsch-Ernst | 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

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Characterisation and Identity

We welcome

Clarifications brought to final version

(i.e. reference to IUPAC nomenclature)

"No health or nutrition claims" pre-requisite no longer mentioned in final version

Regulatory issue on a case-by-case basis and that is part of the administrative process upon submission of a dossier

Reference to section 1.4 and Regulation (EC) No 853/200428 on specific hygiene rules for food of animal origin re cell lines & biopsies

Section 1.5.1 dedicated to "*Foods consisting of, isolated from or produced from cell culture or tissue culture derived from animals*"

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Production & compositional data

We welcome

Reference to *"Specifications **and/or** Certificates of analysis"* (Clarification also brought to Annex B)

3 batches required to demonstrate the absence or presence of enzymes

We note some stumbling blocks

"every material in contact with food during the production process"

Specify *"every material"* and "*production process*"?

Analytical data based on five representative batches

A challenge for start-ups!

Particles at nanoscale

Size or fraction of small particles (% in mass? In number?)

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Exposure assessment and ADME

We welcome

Possible scenario of double counting mentioned in section dedicated to estimate of exposure to undesirable substances and other substances of possible safety

We note some stumbling blocks

Final Guidance still refers to two systems for food categories: FAIM and Dietex

Leads to ambiguity

Methods required for digestibility studies?

In vitro models could '***substitute***' instead of '*complement*' in vivo models".

Reduction, replacement and refinement of animal studies (3R) important principle supported by EFSA

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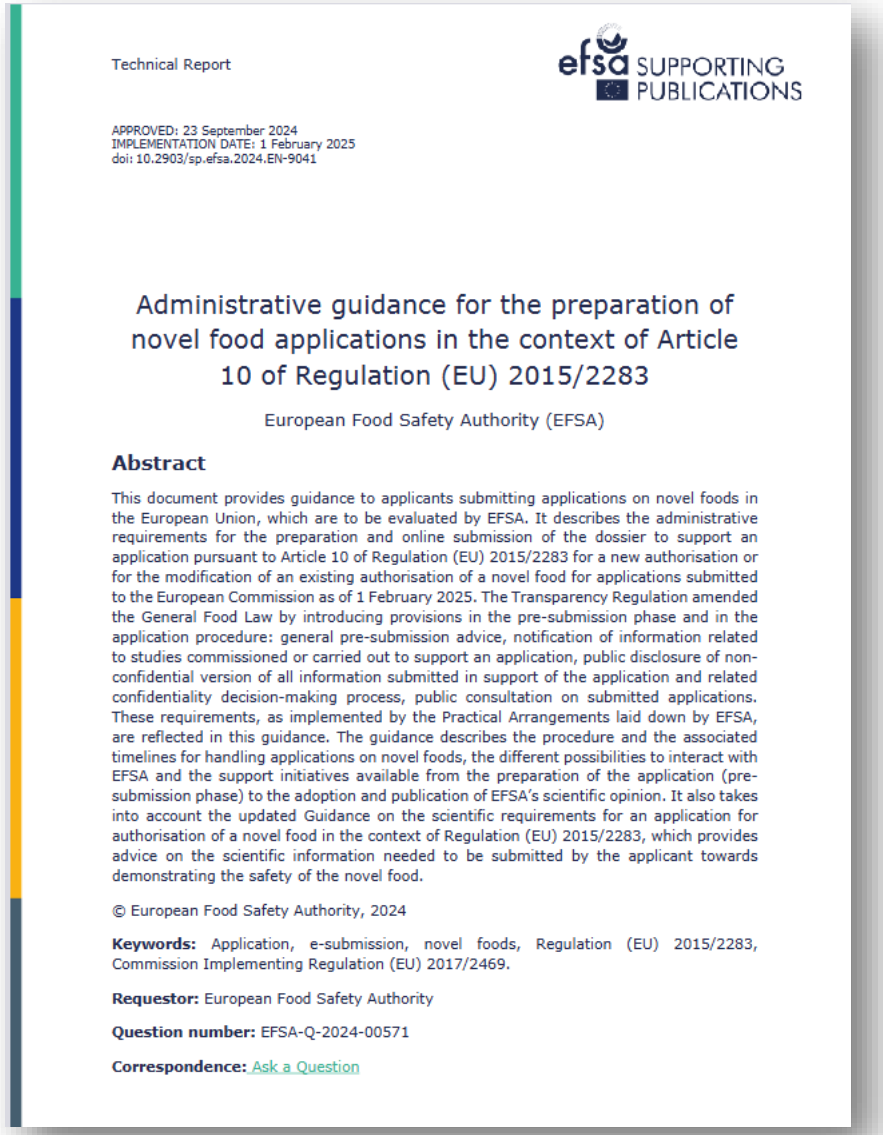
Guidance on novel foods and dossier preparation

General comments



Technical Report

efsa SUPPORTING PUBLICATIONS

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Administrative guidance for the preparation of novel food applications in the context of Article 10 of Regulation (EU) 2015/2283

European Food Safety Authority (EFSA)

Abstract

This document provides guidance to applicants submitting applications on novel foods in the European Union, which are to be evaluated by EFSA. It describes the administrative requirements for the preparation and online submission of the dossier to support an application pursuant to Article 10 of Regulation (EU) 2015/2283 for a new authorisation or for the modification of an existing authorisation of a novel food for applications submitted to the European Commission as of 1 February 2025. The Transparency Regulation amended the General Food Law by introducing provisions in the pre-submission phase and in the application procedure: general pre-submission advice, notification of information related to studies commissioned or carried out to support an application, public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process, public consultation on submitted applications. These requirements, as implemented by the Practical Arrangements laid down by EFSA, are reflected in this guidance. The guidance describes the procedure and the associated timelines for handling applications on novel foods, the different possibilities to interact with EFSA and the support initiatives available from the preparation of the application (pre-submission phase) to the adoption and publication of EFSA's scientific opinion. It also takes into account the updated Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283, which provides advice on the scientific information needed to be submitted by the applicant towards demonstrating the safety of the novel food.

Keywords: Application, e-submission, novel foods, Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2469.

Requestor: European Food Safety Authority

Question number: EFSA-Q-2024-00571

Correspondence: Ask a Question

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Pre-submission advice

- Our association **welcomes** EFSA's *Call for expressions of interest targeting SME–Novel Food potential applicants interested in receiving EFSA's advice,* closed on 31st October.
  - One of our members has expressed its interest in pre-submission advice.

- We call for a dialogue with EFSA staff that have relevant scientific expertise to discuss the content of the dossier and the safety data requirements (i.e., study designs).

- We do not expect EFSA to tell our members what to do, but rather discuss the **approach and strategy** and to provide **non-binding feedback**.

- Pre-submission advice can help applicant to prepare a more robust dossier and EFSA will have a **better understanding of the product and the approach taken by the applicant.**

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EFSA's call for proposals "Contribution to the Risk Assessment of Novel Foods and Nutrient Sources in the EU"

Some questions

Deadline was 21st November

- How many partnership agreements were signed?
- With which entities?

Transparency

- Applicants are not supposed to know if/when his/her dossier will first be assessed by an Article 36 entity: why?

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Thank you !

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