



**Cellular
Agriculture
Europe**

Item 3 – Update from sub-committees

**Regulatory Affairs Committee teleconference
Tuesday 26th March 2024 (3.00 – 5.00 pm CET)**



Event Report



APPROVED: 20 February 2024
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EFSA Scientific Colloquium 27: Cell Culture-derived Foods and Food Ingredients

European Food Safety Authority,

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Abstract

EFSA organised a scientific colloquium in May 2023 to (i) identify sectors in the agri-food system relevant to cell culture-derived foods and food ingredients, (ii) review the state of the art of relevant concepts, technologies, and derived products, and to (iii) discuss emerging safety and methodological aspects and their impact on EFSA's risk assessment approaches. The colloquium included an opening plenary session with internationally renowned experts who set the scene with presentations on the current state of cell culture-derived foods, including foods derived from precision fermentation. Subsequent discussions were organised in three break-out sessions, each aimed at exploring one of the following areas: a) "Food safety hazards associated



Timeframe

Draft guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

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General Info

Food Domain: Novel Foods

Consultation Type: PC on the draft scientific output before its adoption

Start Date: 15/02/2024

Deadline: 14/04/2024

Linked question: [EFSA-Q-2023-00442](#)

Documents

File Name	Size	
EFSA Draft Novel Food Guidance_Public consultation-updated.pdf	1.95 MB	Download

Comments



Novelties

No nutrition/health claims in section 1 (p.12)

Section 1.1.7 now subdivided into various sections:

1.5.1 *“Food consisting of, isolated from or produced from cell culture or tissue culture derived **from animals**”* (p. 17)

More detailed request under section 1.5.1

“Production process should be **thoroughly and completely** described” (section 2, p. 18)

Section 2 dedicated to production process much more detailed.

Expanded section 3 on compositional data, especially on stability 3.4 (p.25). New sub-section dedicated to “Impact of processing on the novel food in the proposed-for-use matrices” (section 3.4.1, p. 26)

Strong focus on nano.

Tiered approach more detailed under section 7 dedicated to *“Absorption, distribution, metabolism and excretion”*.

Toxicological info (section 8) now listed before nutritional info (section 9)

More detailed instructions on protein digestibility tests => **3** independently produced batches (section 9.4, p. 46)





Our comments

Section	Summary of comments
Section 1 - Identity	<ul style="list-style-type: none">- Disagreement with provision according to which NF shall bear no nutrition/health claim- Overall welcome new section 1.5.1 with detailed comments (i.e. inspection requirements' (513) should be better defined)
Section 2 – Production process	<ul style="list-style-type: none">- Consistency: Annex B shall say “specifications” instead of certificate of analysis- <i>“every material in contact with food during the production process”</i> should be clarified
Section 3 – Compositional data	<ul style="list-style-type: none">- Compositional variability: replace 5 batches with “at least 3 representative batches”- Tests to measure protein content shall be specified- Remark on stability study (i.e. 2 years)
Section 6 – Proposed uses and use levels	Dietex does not match with Union list or FAIM.



Our comments

Section	Summary of comments
Section 7 – Absorption, distribution, metabolism and excretion	EFSA should be more specific about digestibility studies
Section 8 – Toxicological information	<ul style="list-style-type: none">- Why no reference to QPS?- Add references to certain OECD studies
Section 9 – Nutritional information	EFSA should be more specific about protein digestibility tests.
Annexes	Annex B should say “specifications” and not certificates of analysis.



Our partners' comments

EuropaBio

- Focus on rDNA.
- Issue with “nano request”
- Whole genome sequence (WGS)
- Also focusing on Draft scientific opinion on new developments in biotechnology applied to microorganisms (deadline: 08/04).

Food Fermentation Europe

- New mandatory requirement for certificate of deposition for microorganisms
- Multiple new references to need for assessment of nano aspects

GFI Europe

- Consultation of GFI experts ongoing.



EFSA's Stakeholder webinar on the Novel Food Guidance – 21st March

- No interaction between presenters and the audience, certainly due to the high number of participants.
 - EFSA loudly insisted on the fact that no application dossier for a cell-cultured product derived from an animal has been filed in the EU yet.
 - The EFSA staff also loudly insisted on the need to have detailed information on the manufacturing process and compositional data.
 - EFSA admitted that the section dedicated to allergenicity could be updated further.
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When? Where? What?

- Monday 15th April btw 2.00 and 5.00 pm CET on TEAMS.
 - Agenda:
 - E-Submission Food Chain platform shall be included, exceptionally.
 - TG TOOLS members have until 27th March EOB to flag any topics (including ESFC) to cover.
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Thank you for your attention!
