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EFSA Novel Food Draft Guidance Document Catch–up 25 March 24

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Anti-trust statement

The Group shall not enter into any discussion, activity or conduct that may infringe, on its part or on the part of its members, any applicable competition law. By way of example, participants shall not discuss, communicate or exchange any commercially sensitive information, including non-public information relating to prices, marketing and advertising strategy, costs and revenues, trading terms and conditions with third parties, including purchasing strategy, terms of supply, trade programmes or distribution strategy. This applies not only to discussions in formal meetings but also to informal discussions before, during and after meetings.

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Agenda

- Antitrust Statement
- EFSA Information Session on 21st March 2024 – Chairman's summary
- Member comments (5 minutes per Member max)
  - Overall impression of the draft guidance compared to previous version
  - EFSA Information Session – did you learn anything new?
  - Have you added your comments to the CAE comments table. What isare the major areas relative to cell agri to focus on
    - NF Guidance Draft Revision Comments.docx - Google Docs
  - Will you be adding comments to the table – by when
- Focus on key areas of the guidance
- Deadline for comments
- Logistics for response to EFSA
- EuropaBio and Food Fermentation Europe

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EFSA Webinar 21 March 24

- One way webinar – 3 h
- 844 registrants, 62 countries
- Private Sector 53%
- Session only had “questions” not “responses” to consultation yet (with the exception of toxicology)
- 181 questions by 76 registrants (only 16 on toxicology)
- EFSA and EU has still not seen any Cell-cultured meat applications (UK and Switzerland has)
- Noted the value of the Colloquium last year in Brussels
- The guidance is hoped to by June 24 EFSA Plenary then publication later

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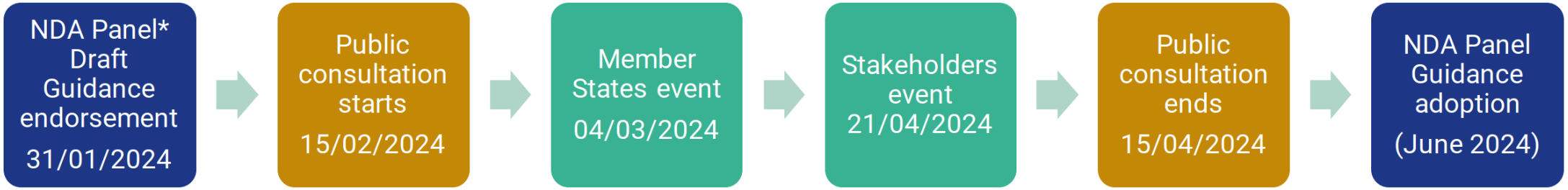
EFSA Timelines

Current Timeline



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

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Member States Meeting 4 March 20204

- A summary of the Member States meeting on 4th March is here: https://www.efsa.europa.eu/en/events/ad-hoc-meeting-member-states-and-observers-countries-draft-novel-foods-guidance
- Slides summarising key points of guidance are here: https://www.efsa.europa.eu/sites/default/files/2024-03/ermolaos-ververis-novel-food-guidance-update.pdf
- These slides were largely similar to the ones presented at the Info session. Additional details provided on intakes, ADME and toxicology
- Meeting slides and recording(?) available shortly on EFSA website

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Identity

- New sub- category
  - Foods consisting of, isolated from or produced from cell culture or tissue culture derived from animals
- Question on NFs from multiple sources – case by case, additives etc need to be essential to the stability/functionality of the NF
- Question on establishment of accepted purity lvels
- Strain led taxonomy
- Safety studies must be done on product representative

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Compositional Data

- Confirmed 5 batches
- If fed-batch/continuous, strong justification of samples takes and how representative of production – case by case
- Raw materials and processing aids NOT used before for food production need detailed specification and justification of food grade
- Selection of appropriate comparators

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Specifications

- Discussion on compositional data vs specification data. Specification must be representative

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History of Use/Proposed Use

- FAIM and DIETEX categories
- Different “frames” between additive intakes and novel foods

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ADME

- Very general
- Emphasis on comparative metabolism between animal models and human

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Toxicological Data

- Non-animal testing methods, not validated yet and so rely on in-vivo testing still
- Tox test article must be fully characterised and representative of process method used (even if it changes)
- Largely tier 1 data set (90 day + in vitro genotox)
- Macronutrients (CAE products) not really suitable for tox testing due to safety factors
- Comparative compositional data is key
- Knowledge on source and production yield factors important to calculate worst case exposures and base risk assessment on

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Allergenicity

- Always complex
- Discussion on tiered approach and protein digestibility
- Major vs minor allergens (not possible to distinguish)
- Member States reluctant to add new allergens to nutritional labelling reg. If you have a new one it will be very challenging
- Allergen section may be revised further following more discussion with Member States.
- Clearly a big area of concern