

Info session: (Re-)Evaluating Food Additives

DAY 1: 19 March 2024

SESSION 1 | Food additives re-evaluation: taking stock

(RE)-EVALUATIONS OF FOOD ADDITIVES: WHAT HAS HAPPENED SINCE WE LAST MET?

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Food Ingredients and Packaging Unit (FIP)

Food Additives and Flavourings Team

LONG TIME NO SEEING YOU!

- More than 4 years are gone since the last stakeholder event
 - A quick re-cap on the scope of the event
- A reflection on what has happened since:
 - Around us
 - For EFSA
 - For the (re)evaluation of food additives
- What can you expect from these two days

Technical stakeholder event: re-evaluation of authorised food additives - focus on sweeteners

3 December 2019, 00.00 (CET)
Paris, France

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Contents

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Background

As part of the ongoing re-evaluation of authorised food additives, under Regulation (EC) No 257/2010, EFSA is currently focussing on the safety assessment of sweeteners.

The Panel on Food Additives and Flavourings (FAF) has developed two draft protocols detailing the approach and the methodology that will be followed for performing all the risk assessment steps, from hazard identification and characterisation to exposure assessment for its coming re-evaluation of sweeteners.

A first public consultation on the protocol for hazard identification and characterisation closed on 19 September 2019. A second one on the methodology applicable to exposure assessment was launched on 9 October 2019. EFSA has invited the scientific community, stakeholders and other interested parties to provide feedback via the online submission tool on EFSA's website by 22 November 2019.

Given the complex nature of the subsequent evaluations and the potentially high public interest in this area of work, EFSA is holding a public scientific meeting to engage in discussion with all the stakeholders and other relevant parties. The event provides an opportunity to complement the two consultations and gather additional feedback on the protocols prior to their implementation. The event



A WELCOME FROM FIP UNIT/FAF PANEL

Food Ingredients and Packaging Unit



Re-evaluation of food additives already permitted as of 20 January 2009

- Regulation (EC) No 257/2010
- Regulation (EC) No 1333/2008
- Regulation (EC) No 231/2012



New food additives and flavourings, changes to conditions, specification or restrictions of use

- Regulation (EC) No 1331/2008 (Common Authorisation Procedure)



Flavouring substances already available in the EU market

- Regulation (EC) No 1565/2000 (the «Procedure»)
- Regulation (EC) No 1334/2008



Smoke flavourings

- Regulation (EC) No 2065/2003

Food Additives and Flavourings Panel



FIRST TIME HERE?

26.3.2010 EN Official Journal of the European Union L 80/19

COMMISSION REGULATION (EU) No 257/2010
of 25 March 2010
setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives
 (Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives and amending Regulation (EEC) No 1831/2003 of the Council, in particular Article 32 thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) Regulation (EC) No 1333/2008 provides that the Commission shall, in accordance with Article 32 thereof, set up a programme for the re-evaluation of approved food additives in accordance with that Regulation.

(2) The Commission has already been requested or became otherwise available. As a consequence, those additives do not need to be re-evaluated again.

(3) The re-evaluation of food additives has already been started with the oldest evaluation procedure. The re-evaluation of certain colours has already been substantially the re-evaluation of other food additives, the deadlines laid down in this Regulation may be revised.

(4) Taking into account that sweeteners have the most recent evaluations they should be re-evaluated the last.

(5) The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria:

(a) The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria:

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(z) The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria:

Re-evaluation of already permitted food additives

- Regulation (EU) No 257/2010
- Approx 300 substances to be re-evaluated
- Before 31.12.2020



20 January 2009

31.12.2008 EN Official Journal of the European Union L 354/1

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 1331/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008
establishing a common authorisation procedure for food additives, food enzymes and food flavourings
 (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Whereas:

(1) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives and amending Regulation (EEC) No 1831/2003 of the Council, in particular Article 32 thereof, provides that the Commission shall, in accordance with that Article, set up a programme for the re-evaluation of approved food additives in accordance with that Regulation.

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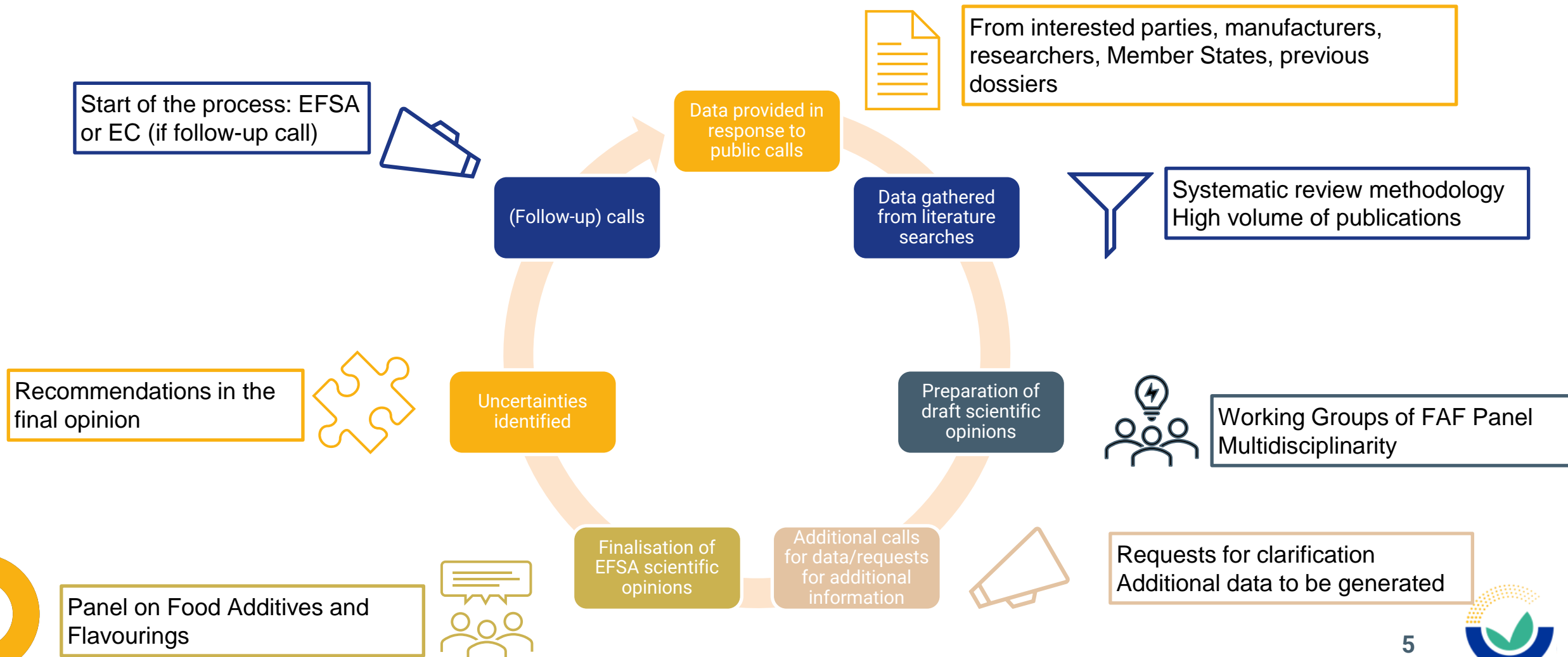
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New food additives applications

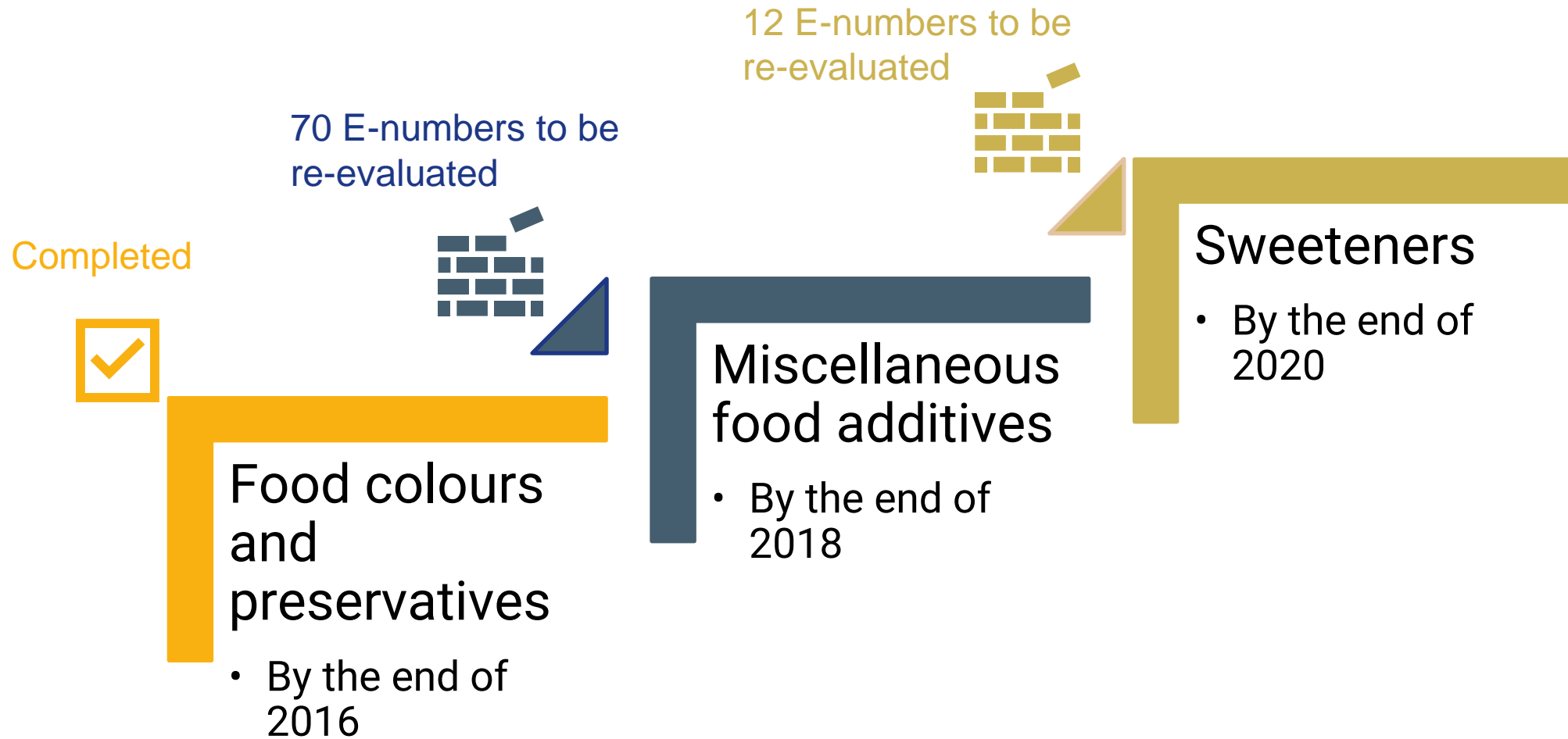
- Regulation (EC) No 1331/2008
- Amendment to Union list (new food additives, changes to uses, changes to manufacturing process)
- 9-month timeline to complete evaluation of dossiers



RE-EVALUATION OF FOOD ADDITIVES



RE-EVALUATION OF FOOD ADDITIVES

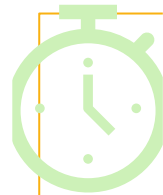


NEW APPLICATIONS: FOOD ADDITIVES/FLAVOURINGS

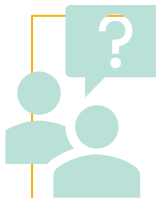


Dossiers are checked for completeness

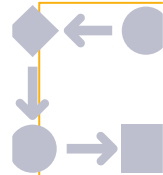
Data requirements in scientific guidance



Assessment does not start if dossier is not complete



Assessment can stop if need for additional information is identified

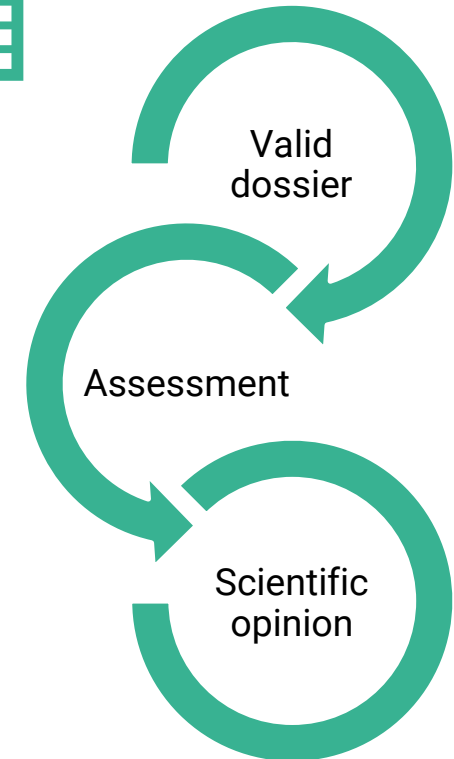


Linear process, focus on delivering on time

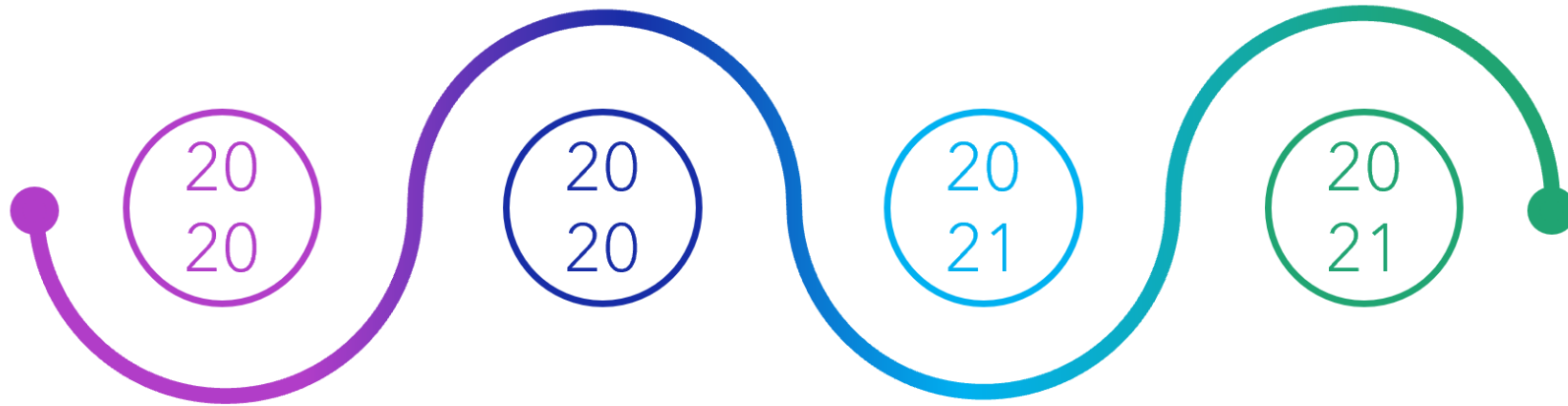
One mandate, one dossier, one applicant, one opinion



9-month timeline



AROUND US



COVID-19 PANDEMIC

New ways of working,
digital transformation

CHEMICAL STRATEGY FOR SUSTAINABILITY

Introducing the One
Substance One
Assessment concept

TRANSPARENCY REGULATION

Increased EFSA's
responsibilities towards
EU citizens.

EFSA's STRATEGY 2027

Science, Safe food,
Sustainability



TRANSPARENCY REGULATION MORE IN DETAIL

- The amendments introduced by the Transparency Regulation are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where EFSA delivers a scientific risk assessment.
- Changes introduced in Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings
- Applicable from 27 March 2021.

Pre-submission advice

- General pre-submission advice by the staff of EFSA at the request of a potential applicant

Notification of studies

- Obligation to notify studies commissioned or carried out by business operators to support an application or notification

Format of submissions

Transparency

- Provisions on the public disclosure, by EFSA, of all scientific data, studies and other information supporting applications, with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties

Confidentiality

- Specific procedural requirements for the submission of confidentiality requests and the assessment thereof by EFSA



TRANSPARENCY REGULATION AND RE-EVALUATION

- Regulation (EU) No 257/2010 on the re-evaluation of food additives has been amended to align to the changes introduced by the Transparency Regulation
 - See previous slides
- Applicable from 27 March 2021 and to data and information submitted to EFSA or the Commission in relation to [re-evaluation procedures launched and follow-up steps taken from that date.](#)

Follow-up of EFSA opinions

- Where, on the basis of the information referred to in Article 4, EFSA cannot confirm the safety of a food additive, of its uses or levels of use or recommend changes to the specifications, the Commission may take or request EFSA to take further steps, including the organisation of calls for data, in order to complete the safety assessment.
- Where the data and information requested in accordance with paragraph 1 has not been submitted or where it does not allow to confirm the safety of the food additive, of its uses or levels of use or specifications, the food additive may be removed from the Union list in accordance with the procedure referred to in Article 10(3) of Regulation (EC) No 1333/2008.



FOLLOW-UP TO THE RE-EVALUATION



EC Follow-up calls open:

Call for technical data on celluloses (E 460-465; E468-469)

Call for technical data on phosphoric acid-phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)

Call for technical and scientific data on the re-evaluation of sodium aluminium silicate (E 554)



EC Calls for data closed

Glutamic acid and glutamates (E 620-625)

Potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252)

Tartaric acid and tartrates (E 334-337; E354) + Metatartaric acid (E 353)

Chlorophylls & chlorophyllins (E 140(i), E 140(ii))



Ongoing assessment

Infants and young children:

- Silicon dioxide (E 551)
- Guar gum (E 412)
- Tocopherols (E 306-309)
- Carrageenan (E 407)
- Esters of mono- and diglycerides of fatty acids (E 472c)

General population:

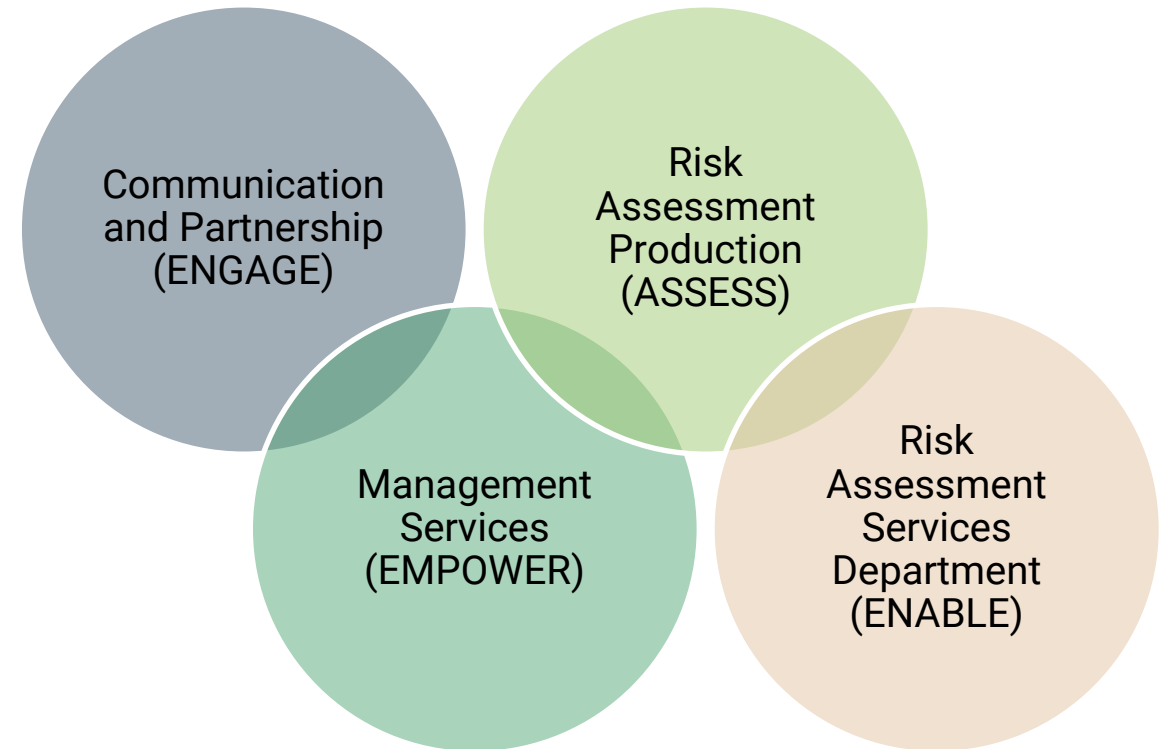
- Iron oxides (E 172)
- Silver (E 174)
- Gold (E 175)
- Silicates and talc (E 552-553a,b)
- Processed Eucheuma seaweed (E 407a)
- Esters of mono- and diglycerides of fatty acids (E 472a-b;d-f)

Vegetable carbon (E 153)

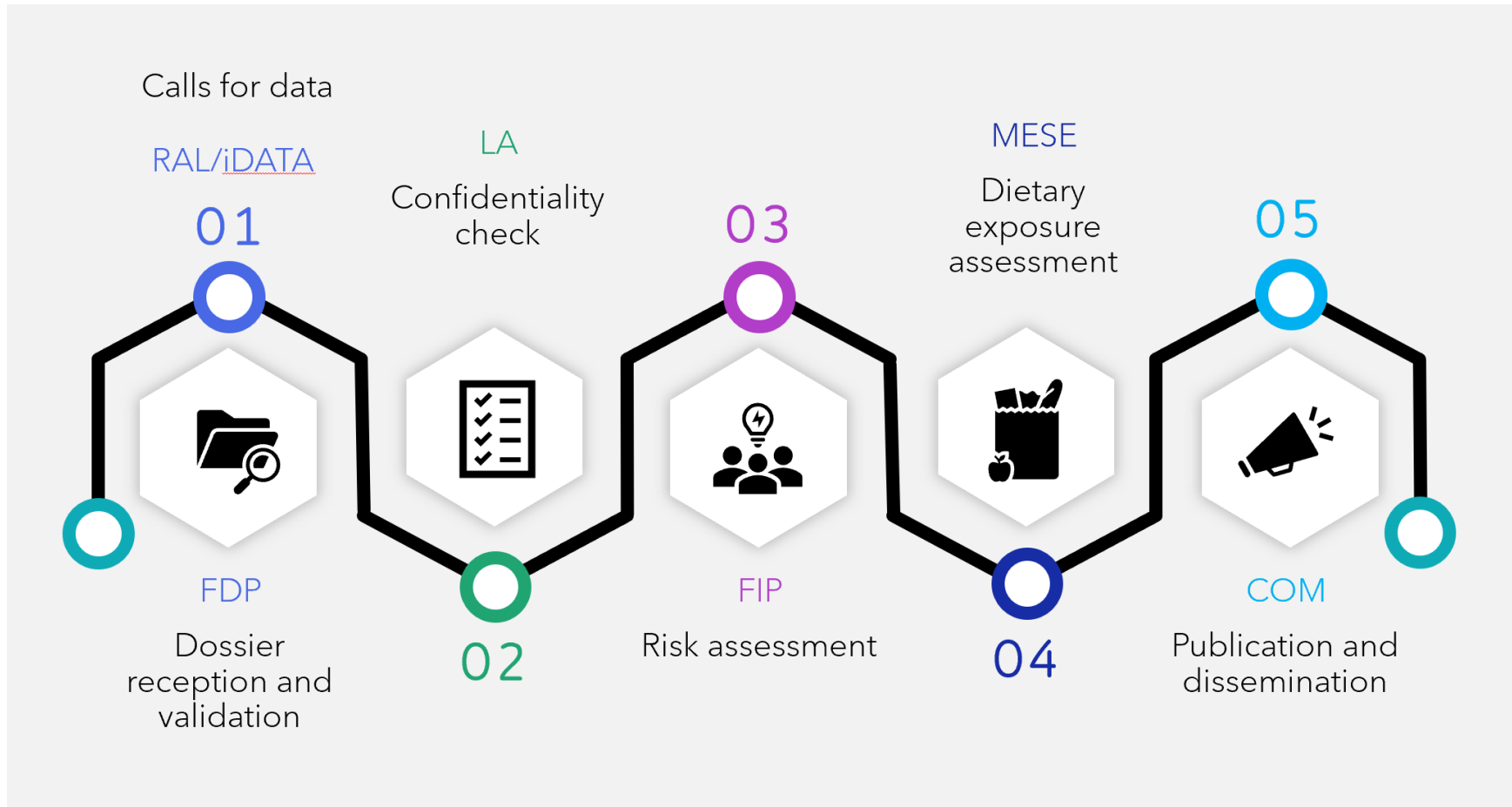


WHAT HAPPENED IN EFSA

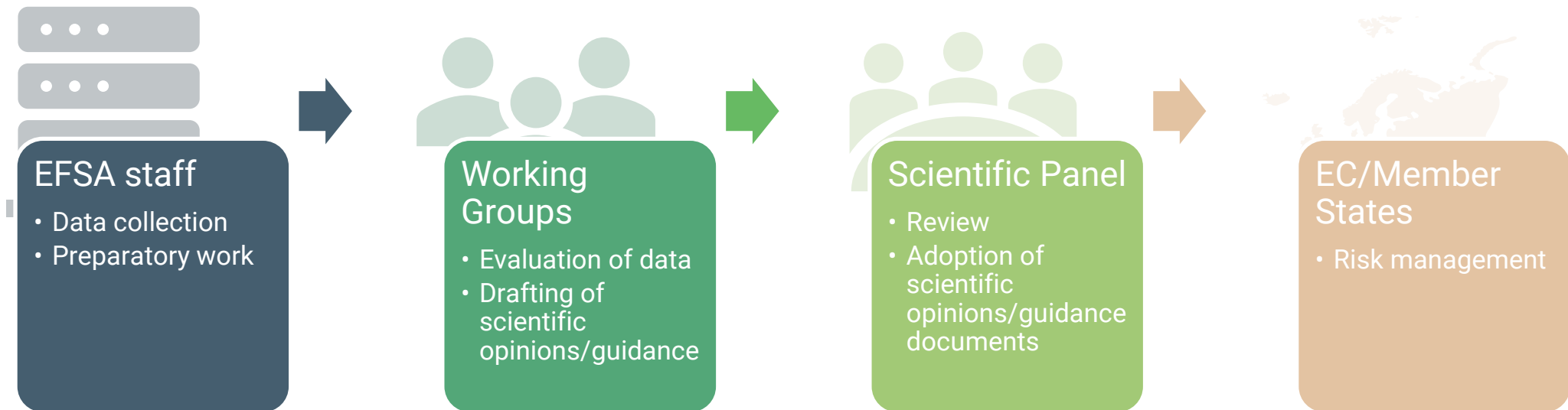
- In January 2022 EFSA underwent a re-organisation of its structure
- All 10 scientific Panels of EFSA currently supported by the staff working in the ASSESS Department
- ENABLE Department supports the work of the Scientific Committee and development of cross-sectorial methodologies and guidance.



HOW WE WORK



HOW WE WORK



AN EVOLVING SCENARIO

SCIENTIFIC OPINION

Guidance on onco-genicity assessment

Abstract

Keywords:

Question number:

Competence in area:

SCIENTIFIC OPINION

Certification of some aspects related to genotoxicity assessment

Abstract

Keywords:

Question number:

Competence in area:

STATEMENT

Genotoxicity assessment of chemical mixtures

Abstract

Keywords:

Question number:

Competence in area:

Botanicals

Genotoxicity



Nanotechnology

Guidance on technical requirements for regulated food and food product applications to establish the presence of small particles including nanoparticles

Abstract

Keywords:

Question number:

Competence in area:

Gut microbiota

Guidance on risk assessment of nanomaterials to be applied in the food and food chain: human and animal health

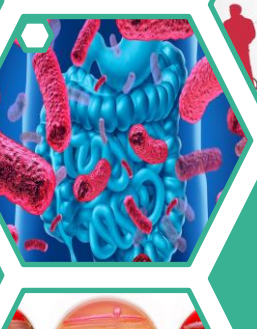
Abstract

Keywords:

Question number:

Competence in area:

Epidemiological data



Production organisms/enzymes

Consultation Details

Draft Guidance of EFSA's Scientific Committee on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments

Submit comments

General Info

Food Domain: Risk Assessment/Methodology

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

Start Date: 19/04/2021

Deadline: 03/04/2024

Linked questions: Q15A-Q2019-2020

Documents

Document Name	Size
Scientific Committee Guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments	5.38 MB

Download

GUIDANCE

Scientific Guidance for the submission of dossiers on Food Enzymes

Abstract

Keywords:

Question number:

Competence in area:



PROGRESS ON THE FA RE-EVALUATION PROGRAMME

2020

Re-evaluation

- Tartaric acid and tartrates (E 334-337; 354)
- Metatartaric acid (E 353)
- Stearyl tartrate (E 483)
- Hydrogenated poly-1-decene (E 907)
- Dimethyl polysiloxane (E 900)
- Aluminium silicates (E 554, E 555)
- Polyvinylpyrrolidone (E 1201), polyvinylpolypyrrolidone (1202)
- Polydextrose (E 1200)

Follow-up

- Ascorbyl palmitate [E 304(i)]
- Starch sodium octenyl succinate (E 1450)
- Lecithins (E 322)
- Pectins (E 440)

2021

Re-evaluation

- Thaumatin (E 957)

Follow-up

- Titanium dioxide (E 171)
- Mono- and diglycerides of fatty acids (E 471)

2022

Re-evaluation

- Neohesperidine DC (E 959)

Follow-up

- Polyglycerol polyricinoleate (E 476)
- Polyglycerol esters of fatty acids (E 475)
- Glycerol (E 422)
- Sulfur dioxide and sulphites (E 220-224; E 226-228)
- Sodium carboxy methyl cellulose (E 466)
- Locust bean gum (E 410)

2023

Re-evaluation

- Erythritol (E 968)

Follow-up

- Xanthan gum (E 415)
- Sucrose esters of fatty acids (E 473)
- Indigotine, indigo carmine (E 132)
- Calcium carbonate (E 170)
- Glycerol esters of wood rosins (E 445)
- Quillaia extract (E 999)



LATEST FOOD ADDITIVES APPLICATIONS



Buffered vinegar



Oat lecithin



Monk fruit



Jagua blue



Steviol glycosides



Carbomer



Glucolipids from
Dacryopinax
spathularia



Blue galdieria algae



Synthetic
oligonucleotides



Soy leghemoglobin



Pea fibre
concentrate



Pectin rich extract
from Coffea
arabica



Rice bran/hulls



ADDITIONAL ACTIVITIES



Renewal of FAF Panel (2024-2029)



Revision of the guidance on food additives



Support to the EC on the monitoring of FA & FF



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