15 and 16 November 2023

WELCOME TO THE OPEN SESSION OF THE 170TH PLENARY OF THE FEEDAP PANEL

EUROPEAN FOOD SAFETY AUTHORITY

170TH PLENARY OF THE FEEDAP PANEL

Chair: Prof. Vasileios Bampidis

EUROPEAN FOOD SAFETY AUTHORITY

AGENDA OPEN SESSION – 15 NOVEMBER

No.	ITEM
6.	Welcome and Apologies for absence
7.	Brief introduction of Panel Members
8.	Presentation of the EFSA guidelines for Observers
9.	Update on the Guidance on studies concerning the safety of use of the additive for users
10.	New mandates
11.	Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission/EURL
12.	FEED Team and FEEDAP Panel general planning
13.	Risk assessment of microorganisms intentionally added to the food chain
14.	MoPS
15.	Criteria for the quantification of the active agent(s) in the additive

AGENDA 15 NOVEMBER

No.	ITEM
1.	Welcome and Apologies for absence
2.	Adoption of the agenda
3.	Declarations of Interest
4.	Report on written procedures since the 169th Plenary meeting
5.	Scientific outputs submitted for discussion and possible adoption
	OPEN SESSION – 15 NOVEMBER
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13.	Risk assessment of microorganisms intentionally added to the food chain
14.	MoPS (Microorganisms Pipeline Service)
15.	Criteria for the quantification of the active agent(s) in the additive

AGENDA 16 NOVEMBER

No.	ITEM
	OPEN SESSION – 16 NOVEMBER
16.	Update of the Guidance on the assessment of the efficacy of feed additives
17.	Chemicals Strategy for Sustainability and One Substance One Assessment – Impact to EFSA
18.	Update on the confidentiality assessment of feed additives' applications
19.	Update on pre-application activities and completeness check of feed additives applications
20.	AOB/General EFSA activities
20.1.	NAMs (New Assessment Methodologies)
21.	Questions & Answers
22.	Closure of meeting

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Coffee break 16:00 – 16:30

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GUIDELINES FOR OBSERVERS FOR OPEN PLENARY MEETINGS

FEEDAP Panel Open Plenary

15-16 November 2023

EUROPEAN FOOD SAFETY AUTHORITY

GUIDELINES FOR OBSERVERS FOR OPEN PLENARY MEETINGS

Observers may:

- submit questions upon registration
- ask questions during the meeting, when the Chair grants the opportunity
- gain insights on scientific discussions and procedures at EFSA
- witness collegial decision-making first-hand
- report on the proceedings of the meeting, while any reference to participants should respect their reputation and professional integrity

GUIDELINES FOR OBSERVERS FOR OPEN PLENARY MEETINGS

Observers may not:

- hinder the work of the Panel
- engage in the discussion, drafting, deliberation of the scientific output at hand
- attempt to influence the meeting participants, in particular members of the Panel
- distribute or request the circulation of any documents
- make a written transcript or record the meeting

GUIDELINES FOR OBSERVERS FOR OPEN PLENARY MEETINGS

The minutes of the open plenary meeting are published on the EFSA website following the open plenary.

No audio/video-recordings of the open plenaries are made hence, if not followed live, information regarding the meeting discussions and outcomes can be only obtained through the meeting minutes that will be published on the EFSA website.

EFSA does its best to ensure the quality of the its web-casted open plenaries, however, due to the reliance on internet and other technical systems outside EFSA's control, streaming can be disrupted.

IMPORTANT FOR REMOTE OBSERVERS

EFSA would like to inform all the registered remote observers that **the link** you receive to connect to the EFSA meeting has a unique identifier, RESERVED FOR YOU IN PERSON to connect to the given meeting.

PLEASE DO NOT SHARE OR FORWARD the link to anyone else, as this may lead to unauthorized remote access.

Should you notice anything abnormal or unexpected in the course of your connection to the EFSA meeting, please contact either the Meeting Moderator in Questions chat or EFSA technical chat via the platform available throughout the meeting.

GUIDELINES FOR OBSERVERS FOR OPEN PLENARY MEETINGS

Q&A sessions:

- Chair may grant observers the opportunity to ask questions either after they have observed a discussion on a given topic or at the end of the open plenary meeting, on other topics which fall within the remit of the Panel
- If members of the Scientific Committee or the Scientific Panel are unable to answer questions from observers during the meeting, they may resubmit their questions to EFSA through the #AskEFSA service on the EFSA website.

ENJOY THE MEETING

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GUIDANCE ON THE ASSESSMENT OF THE SAFETY OF FEED ADDITIVES FOR THE USERS- OUTCOME OF THE PUBLIC CONSULTATION

FEEDAP Plenary meeting - Open session

15 November 2023

Fabiola Pizzo

EUROPEAN FOOD SAFETY AUTHORITY

GENERAL INFORMATION

Draft Guidance prepared by the WG on Toxicology (work started in 2020)

- Paul Brantom
- Andrew Chesson
- Birgit Dusemund
- Alberto Mantovani
- Francesca Marcon
- Ruud Woutersen

GENERAL INFORMATION

Endorsed by the FEEDAP Panel on 4 July 2023

Public consultation → from 27 July 2023 to 15 September 2023

to receive input from the scientific community and all interested parties

OUTCOME PC

EFSA received a total of 45 comments from 10 interested parties

(five industry association, three private companies, one consultant organisation and one anonymous)

The FEEDAP Panel prepared an **updated version of the guidance** on the assessment of the safety of feed additives for the users considering the questions/comments received (when considered appropriate).

The comments received and the EFSA's replies are included in an **Annex** and will be published.

Implementation: **3 months** after adoption

EFSA and its FEEDAP Panel wish to thank all stakeholders for their contributions

COFFEE BREAK

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NEW MANDATES

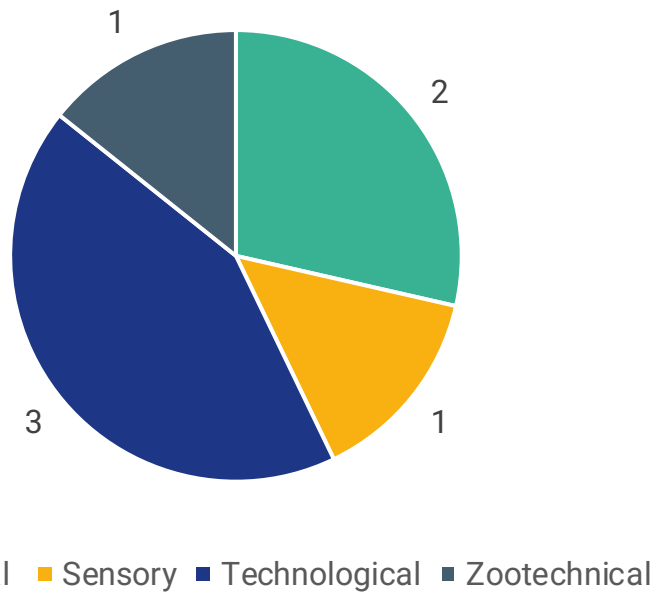
Davide Guerra

EUROPEAN FOOD SAFETY AUTHORITY

NEW APPLICATIONS UNDER REG. 1831/2003

EFSA-Q	FEED number	Subject	Article
EFSA-Q-2023-00551	FEED-2023-18810	TechnoCare® 50 (*Bacillus licheniformis* DSM 33806 and *Weizmannia faecalis* DSM 32016) for piglets (suckling and weaned), pigs for fattening, sows and physiologically related minor growing and reproductive porcine species	14
EFSA-Q-2023-00674	FEED-2023-19273	Clinoptilolite of volcanic origin (E567) for all terrestrial animal species	4
EFSA-Q-2023-00688	FEED-2023-18246	4-Hydroxy-2,5-dimethylfuran-3(2H)-one (2b13010) for cats and dogs	13
EFSA-Q-2023-00704	FEED-2023-19452	Perlite (E599) as anticaking agent for all terrestrial animal species	4
EFSA-Q-2023-00705	FEED-2023-14790	Inositol (3a900) for fish and crustaceans	14
EFSA-Q-2023-00712	FEED-2023-19630	L-lysine sulphate produced by *Corynebacterium glutamicum* for all animal species	4
EFSA-Q-2023-00715	FEED-2023-18730	*Saccharomyces cerevisiae* (NBRC 0203) and *Lacticaseibacillus rhamnosus* (NBRC 3425) for all animal species	4

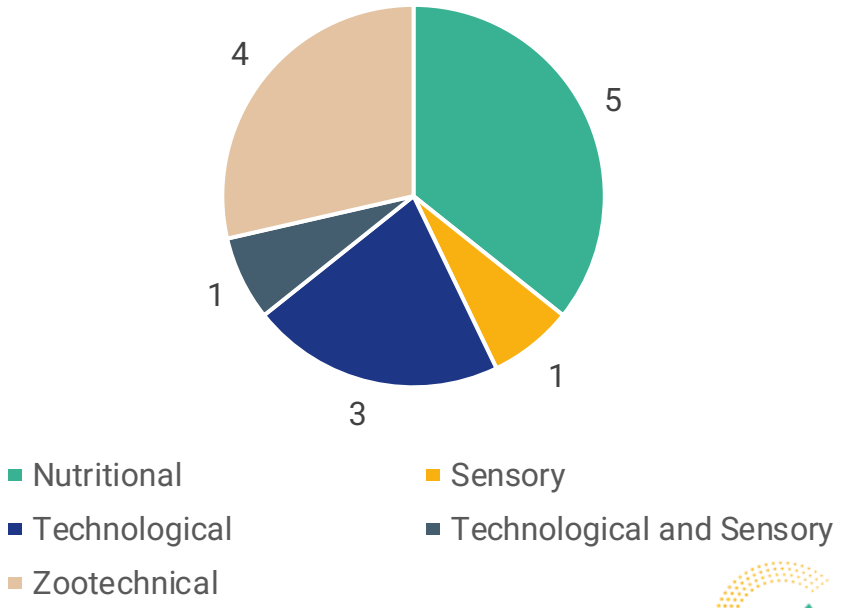
Article	Number
4	4
13	1
14	2
Total	**7**



VALID APPLICATIONS UNDER REG. 1831/2003

EFSA-Q	FEED number	Subject	Article	Valid
EFSA-Q-2023-00298	FEED-2022-7710	Lactosil (*Lactiplantibacillus plantarum* 14D/CSL - CECT 4528) for all animal species	4	26/09/23
EFSA-Q-2023-00355	FEED-2023-16200	*Levilactobacillus brevis* 16680 for all animal species	14	28/09/23
EFSA-Q-2023-00454	FEED-2023-15650	Bovacillus® (*Bacillus paralicheniformis* DSM33902 + *Bacillus subtilis* DSM33903) for dairy cows for milk production and other dairy ruminants (sheep, goat, buffalo etc.)	4	28/09/23
EFSA-Q-2023-00254	FEED-2023-15312	Quantum® Blue (preparation of 6-phytase (EC 3.1.3.26) produced by a genetically modified strain of *Trichoderma reesei* (CBS 126897)) for poultry, weaned piglets, pigs for fattening and sows	4, 14	29/09/23
EFSA-Q-2022-00873	FEED-2022-10610	L-threonine produced by fermentation with *Corynebacterium glutamicum* KCCM80367 for all animal species	4	02/10/23
EFSA-Q-2022-00882	FEED-2022-6311	L-tryptophan produced by fermentation with *Corynebacterium glutamicum* KCCM80346 for all animal species	4	02/10/23
EFSA-Q-2023-00440	FEED-2023-15311	Lanthan One (lanthanum carbonate octahydrate) for dogs	4	02/10/23
EFSA-Q-2023-00362	FEED-2023-13176	*Loigolactobacillus coryniformis* DSM34345 for all animal species	4	09/10/23
EFSA-Q-2023-00483	FEED-2023-14631	Lutein-rich extract of *Tagetes erecta* for turkeys for fattening	4	09/10/23
EFSA-Q-2023-00207	FEED-2023-13997	L-isoleucine for all animal species	4	11/10/23
EFSA-Q-2023-00409	FEED-2023-15991	Vitamin B12 or cyanocobalamin produced by *Ensifer adhaerens* CGMCC 21299 for all animal species	4	16/10/23
EFSA-Q-2023-00539	FEED-2023-17122	Fumaric acid for all animal species	4, 14	16/10/23
EFSA-Q-2023-00518	FEED-2023-14370	Pantothenic acid as calcium D-pantothenate and D-panthenol for all animal species	14	19/10/23
EFSA-Q-2023-00544	FEED-2023-17710	*Lacticaseibacillus paracasei* NCIMB 30151 for all animal species	14	19/10/23

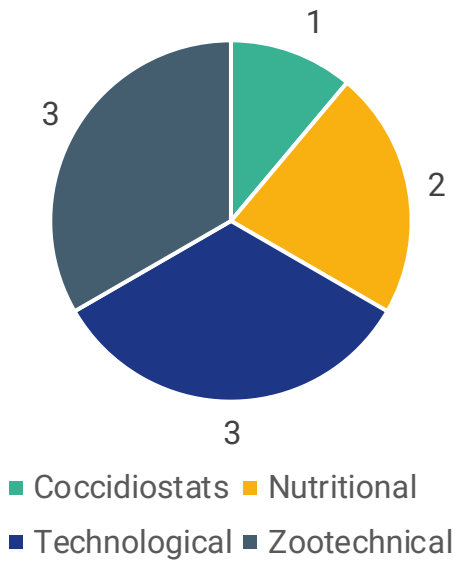
Article	Number
4	9
14	3
4, 14	2
Total	**14**



NEW APPLICATIONS UNDER REG. 178/2002

EFSA-Q	FEED number	Subject	Article	Valid
EFSA-Q-2023-00520	FEED-2023-17890	Beta-Xylanase / Beta-Glucanase / *Talaromyces versatilis* IMI 378536 / DSM 26702 (Rovabio® Advance)	29	26/09/23
EFSA-Q-2023-00545	FEED-2023-17170	Natupulse® TS/Natupulse® TS L (endo-1,4-beta-D-mannanase, EC 3.2.178) for all growing poultry species (chickens for fattening, turkeys for fattening and minor growing poultry species and other poultry for fattening (e.g. ducks, geese, pheasants, quail, guinea fowl, ostrich) and ornamental birds	29	26/09/23
EFSA-Q-2023-00519	FEED-2023-16812	Nilablend™ 200G (lasalocid A sodium and nicarbazin) for chickens for fattening	29	16/10/23
EFSA-Q-2023-00638	FEED-2023-18293	Sepiolite (E562) as feed additive for all animal species	29	16/10/23
EFSA-Q-2023-00354	NA	Cashew nut shell liquid for all animal species	29	23/10/23
EFSA-Q-2023-00668	FEED-2023-18292	Plexomin® L-Fe (Ferrous lysinate sulfate) for all animal species	29	23/10/23
EFSA-Q-2023-00694	FEED-2023-18711	BioCell® (*Saccharomyces cerevisiae* DBVPG 48 SF) for horses, pigs and ruminants	29	30/10/23
EFSA-Q-2023-00677	FEED-2023-17116	Phyllite, natural mixture of minerals of metamorphic origin for all animal species	29	received
EFSA-Q-2023-00693	FEED-2023-18430	Vitamin B2/Riboflavin produced by *Eremothecium ashbyi* CCTCCM 2019833 for all animal species	29	received

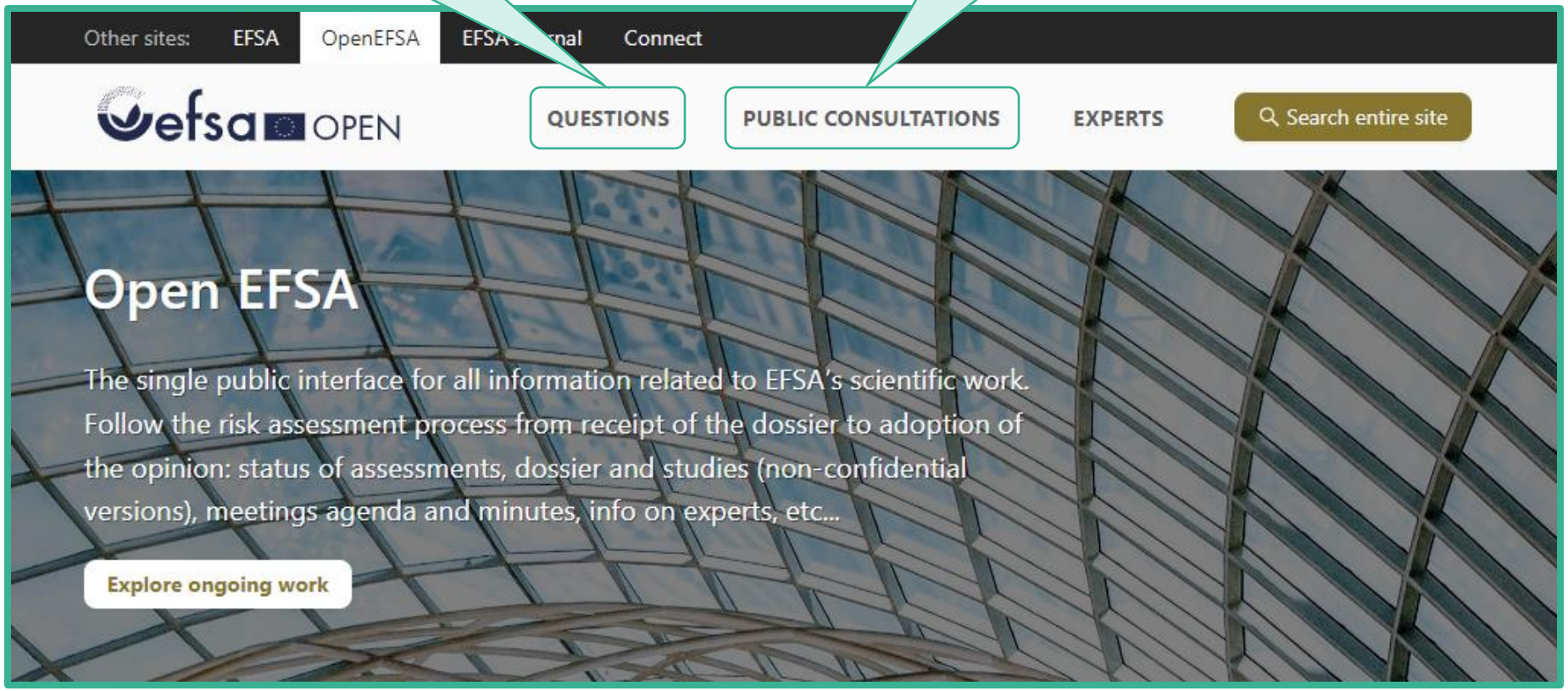
From June 2023



ONLINE RESOURCES

General information
RA timeline and events
Supporting documents
…and more

Status of PC
Files under PC
Comments received



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FEEDBACK FROM SCIENTIFIC COMMITTEE

GUIDANCE

efsa JOURNAL

ADOPTED: 20 September 2023

doi: 10.2903/j.efsa.2023.8312

Guidance on protocol development for EFSA generic scientific assessments

EFSA Scientific Committee (SC),

- **Available online**

efsa JOURNAL

Annex to: Guidance on protocol development for EFSA generic scientific assessments. doi:10.2903/j.efsa.2023.8312

Annex A – Template for EFSA protocols

FEEDBACK FROM EFSA

- SP/SC Members Feedback Survey
  - Panel Expert Mutual Assessment process (2018-2024)
  - Launched: mid-December 2023, open for 1 month
  - Results presented to Panels/SC: April-June 2024

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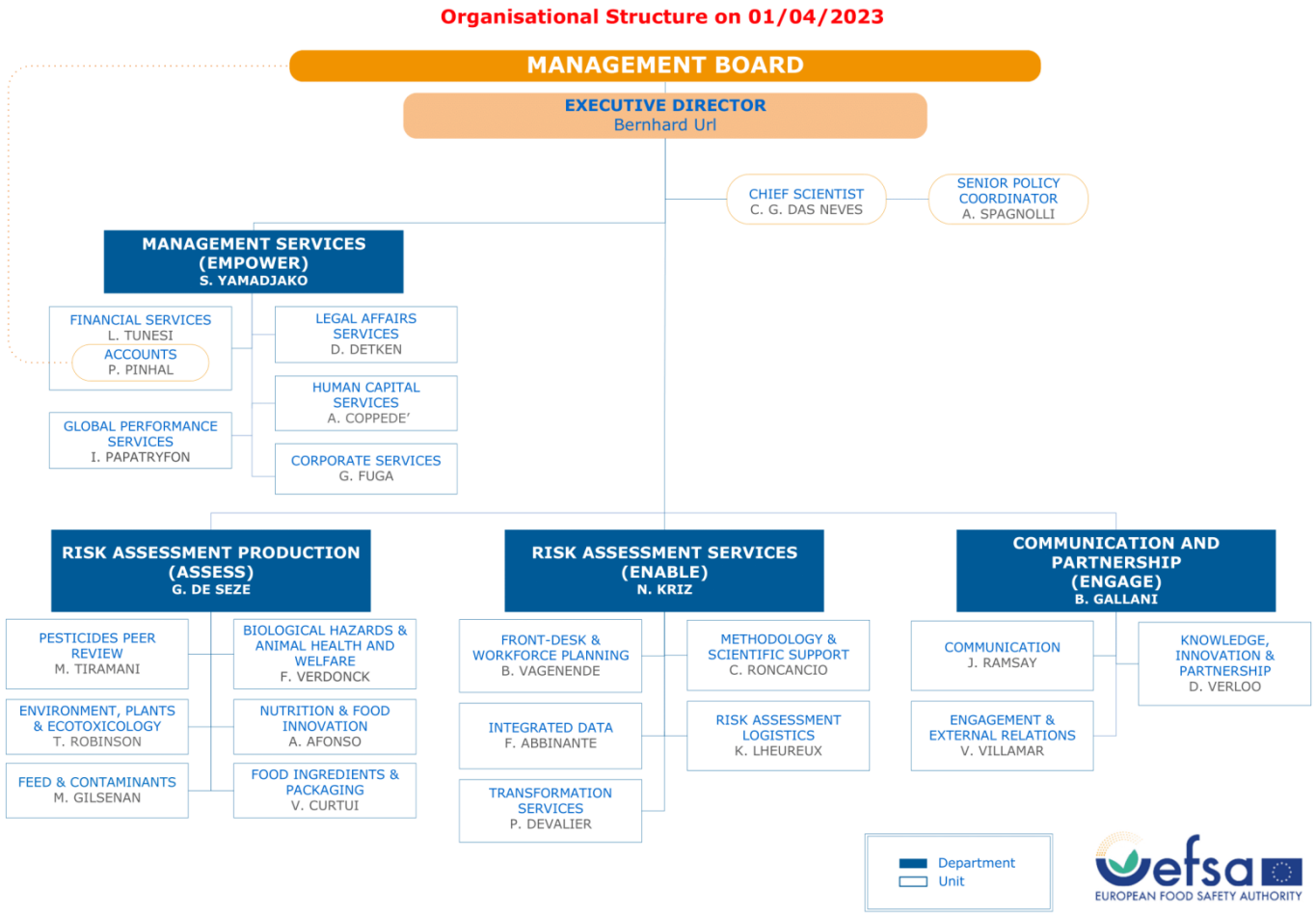
FEEDAP PANEL - FEEDCO

- FEEDAP Panel: Substances/products that are intentionally added to feed

- FEEDCO Unit as of 1/1/2022
  - Two teams
  - Providing support to two Panels (FEEDAP – CONTAM)
  - Mary Gilsenan - HoU



FEEDAP PANEL AND FEED TEAM - NEW

FEED TEAM

FEEDAP PANEL

WG on Characterisation

WG on Microbiology

WG on Toxicology

WG on Environment

WG on Animal Nutrition

WG on Flavourings

- Perform assessment of data on the characterisation and physico-chemical and technological properties of feed additives (except microorganisms)
- Ensure that the FEEDAP technical guidance on the characterisation is up to date
- Ensure harmonisation for cross-cutting issues and the proper implementation of horizontal EFSA guidance documents

FEEDAP PANEL AND FEED TEAM

FEED TEAM

FEEDAP PANEL

- Adoption/Endorsement of SO
- 6 Plenary meetings in 2023

WG on Characterisation

WG on Microbiology

WG on Toxicology

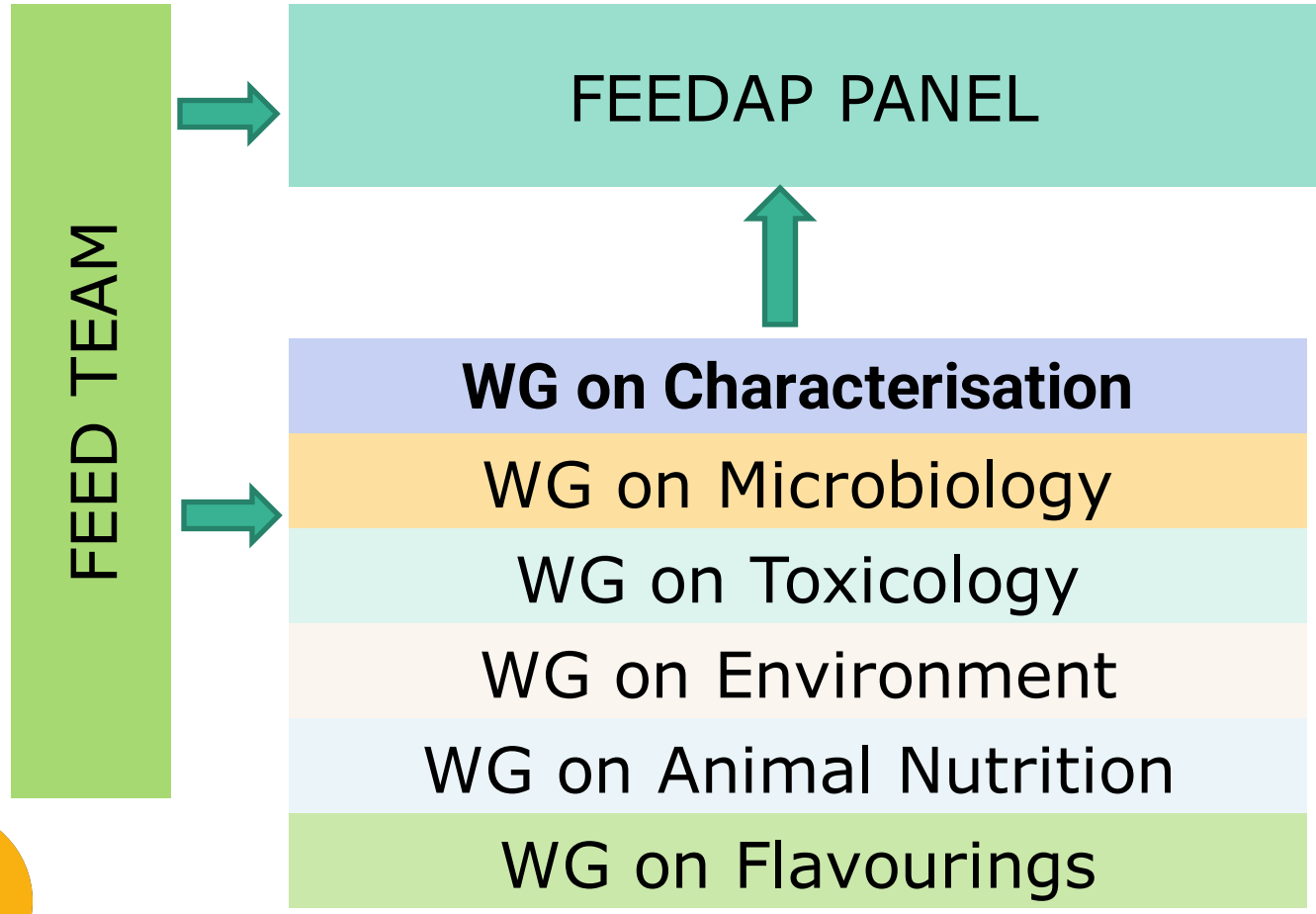
WG on Environment

WG on Animal Nutrition

WG on Flavourings

- WG include Panel members and external experts
- Drafting of Scientific Opinions
- 82 WG meetings in total for 2023

FEEDAP PANEL AND FEED TEAM – EXTERNAL SUPPORT



External support

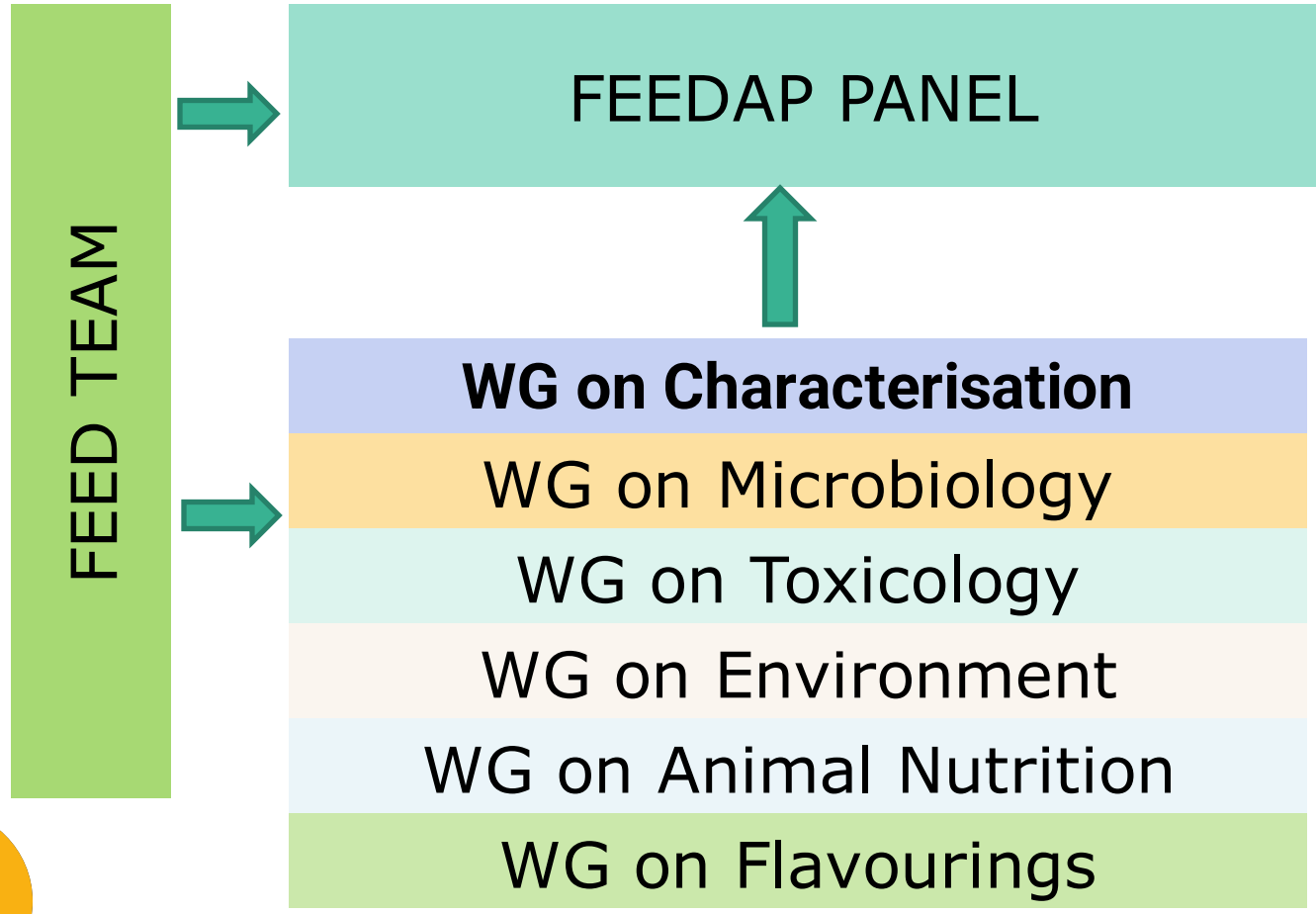
- Individual Scientific Advisor

Provide preliminary completeness check of dossiers

Provide advice in relation to risk a-assessment (e.g. literature analysis, systematic review, supporting an expert knowledge elicitation

Data validation, data extraction, data appraisal, collation and processing, summarizing and analysis

FEEDAP PANEL AND FEED TEAM – EXTERNAL SUPPORT



External support

- Individual Scientific Advisor

- **GP/EFSA/FIP/2022/01:** Grant involving MS competent authorities in the preparation of draft opinions (specific sections or in full) for four regulatory domains: food enzymes, food flavourings, food additives and feed additives

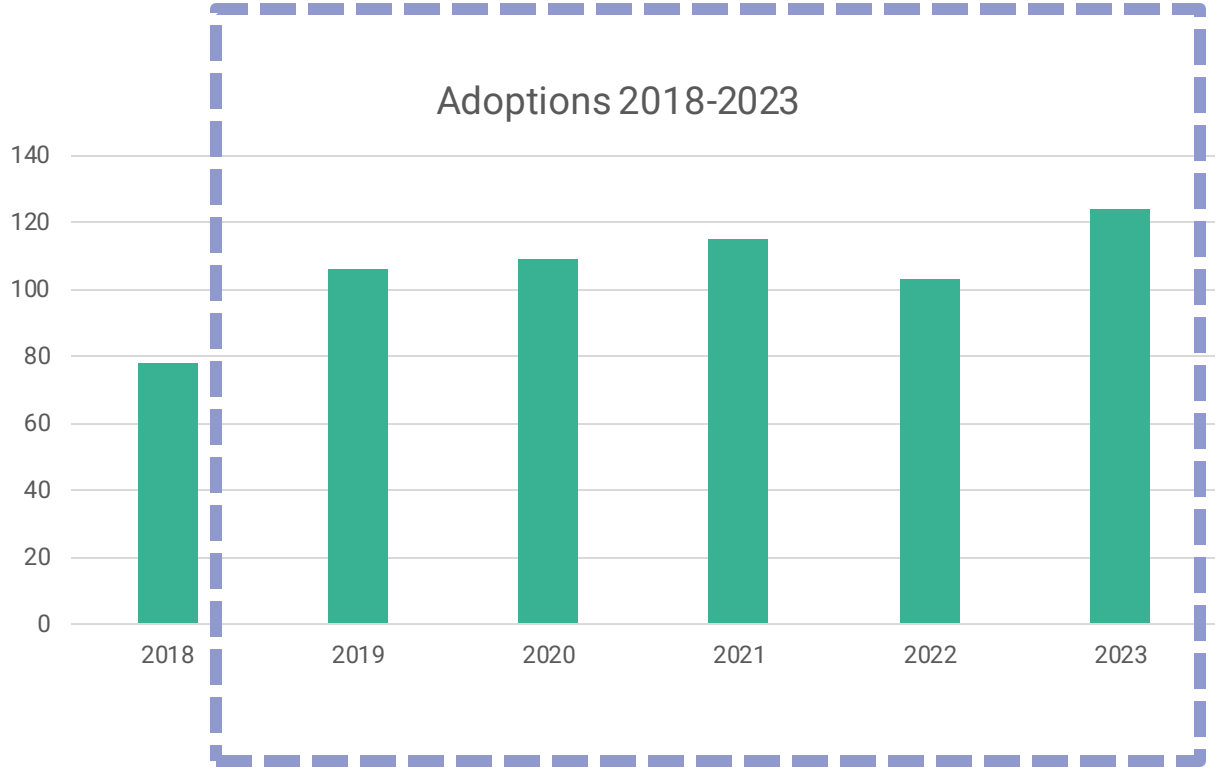
WORKPLAN

- **Applications – current work**
- Guidance update
    - Guidance on Efficacy
    - Guidance on Microorganisms – Statement
- Other on-going work

APPLICATIONS – WORK AHEAD

Assessment of applications under Regulation (EC) No 1831/2003

- New additives, new uses, modifications of the authorisation, renewals
- Last 5 years – more than 100 adoptions per year
- Circa 30% of renewals
- 2023 – Percent of Post-transparency ~ 50%



APPLICATIONS WORK AHEAD

- Re-evaluation dossiers?
  - Number of dossiers/questions not closed ca 29
  - Most of them sensory additives - flavours
- Re-evaluation of Flavourings
  - Assessment of chemically defined (CD) substances was done first
    - A total of 596 substances to be assessed – 595 assessed
    - Circa 200 may require follow up opinions
  - Assessment of Botanically defined (BD) substances followed
    - A total of 187 substances to be assessed – 62 assessed (~ 30%)
    - Work plan to finish the assessments in 2026

WORKPLAN

- Applications – current work
- **Guidance update**
    - Guidance on Efficacy
    - Guidance on Microorganisms – Statement
- Other on-going work

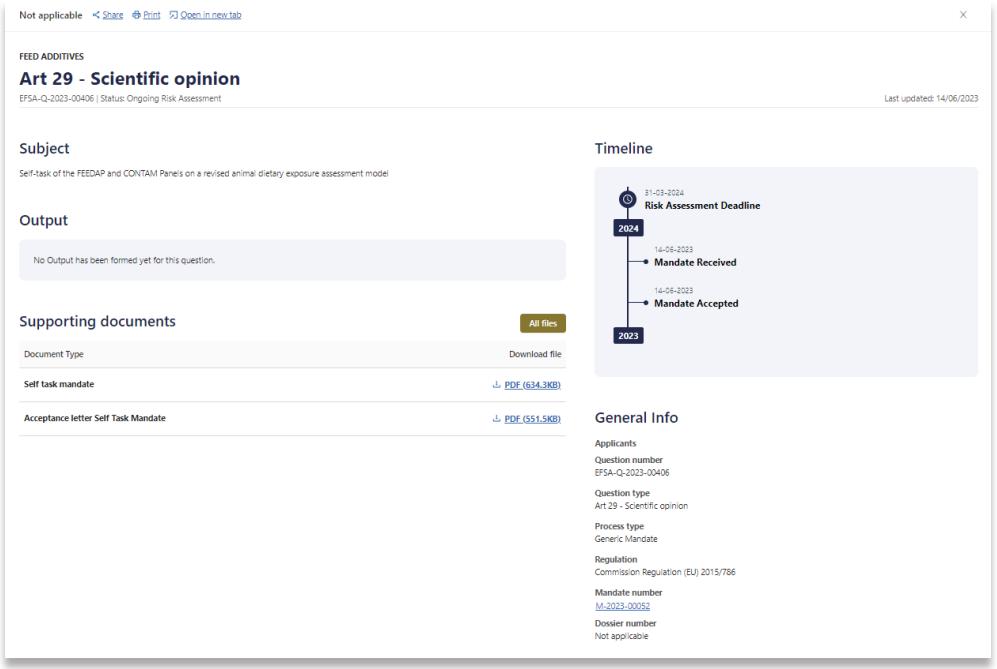
On-going

WORKPLAN

- Applications – current work
- Guidance update
    - Guidance on Efficacy
    - Guidance on Microorganisms – Statement
- Other on-going work

FEEDAP – CONTAM - FEEDCO

Self-task of the FEEDAP and CONTAM Panels on a revised animal dietary exposure assessment model



- Risk assessments in generic mandates (e.g., contaminants) require the study of the exposure of animals
- Model scenarios currently being used require update
- The current scenarios will be revised and updated to have up-to-date, and where possible a more flexible approach, scenarios to use in the risk assessment

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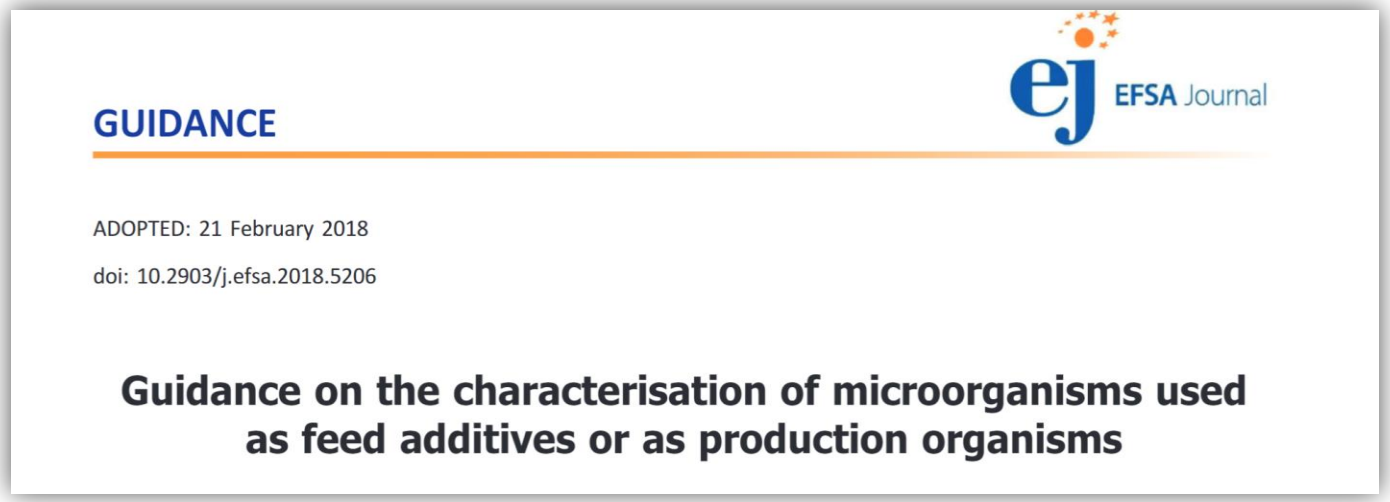
GUIDANCE ON MICROORGANISMS – WGS STATEMENT



GUIDANCE

EFSA Journal

ADOPTED: 21 February 2018

doi: 10.2903/j.efsa.2018.5206

Guidance on the characterisation of microorganisms used as feed additives or as production organisms

Statement WGS 2021

Update in 2018:

- Introduction of new requirements for the data – WGS, thresholds for DNA detection
- Comprehensive merging of well-established guidances

GUIDANCE ON MICROORGANISMS – WGS STATEMENT

- Current practices and most frequent questions
- Expanding the scope – new taxonomic units
- Phenotypic antimicrobial susceptibility

Table 2: Microbiological cut-off values (mg/L)

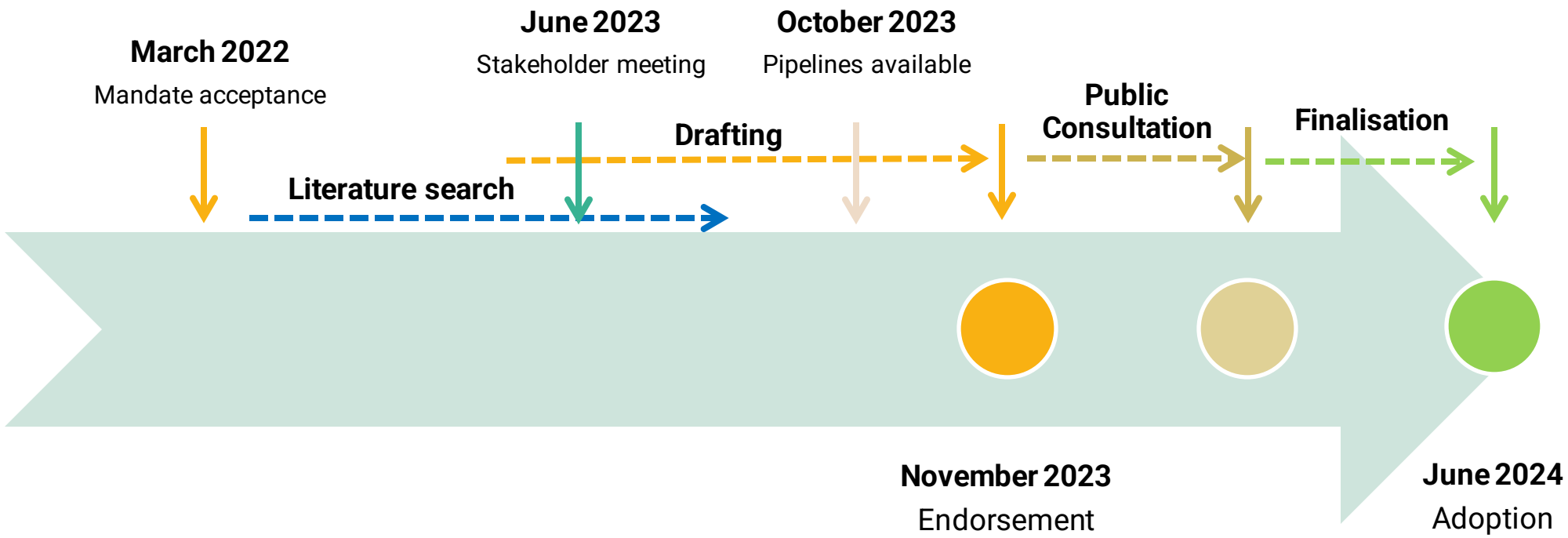
	Ampicillin	Vancomycin	Gentamicin	Kanamycin	Streptomycin	Erythromycin	Clindamycin	Tetracycline	Chloramphenicol	Tylosin	Ciprofloxacin	Colistin	Fosfomycin
Lactobacillus obligate homofermentative[a]	2	2	16	16	16	1	4	4	4	n.r.	n.r.	n.r.	n.r.
Lactobacillus acidophilus group	1	2	16	64	16	1	4	4	4	n.r.	n.r.	n.r.	n.r.
Lactobacillus obligate heterofermentative[b]	2	n.r.	16	64	64	1	4	8[c]	4	n.r.	n.r.	n.r.	n.r.
Lactobacillus reuteri	2	n.r.	8	64	64	1	4	32	4	n.r.	n.r.	n.r.	n.r.
Lactobacillus facultative heterofermentative[d]	4	n.r.	16	64	64	1	4	8	4	n.r.	n.r.	n.r.	n.r.
Lactobacillus plantarum/pentosus	2	n.r.	16	64	n.r.	1	4	32	8	n.r.	n.r.	n.r.	n.r.
Lactobacillus rhamnosus	4	n.r.	16	64	32	1	4	8	4	n.r.	n.r.	n.r.	n.r.
Lactobacillus casei/paracasei	4	n.r.	32	64	64	1	4	4	4	n.r.	n.r.	n.r.	n.r.
Bifidobacterium	2	2	64	n.r.	128	1	1	8	4	n.r.	n.r.	n.r.	n.r.
Pediococcus	4	n.r.	16	64	64	1	1	8	4	n.r.	n.r.	n.r.	n.r.
Leuconostoc	2	n.r.	16	16	64	1	1	8	4	n.r.	n.r.	n.r.	n.r.
Lactococcus lactis	2	4	32	64	32	1	1	4	8	n.r.	n.r.	n.r.	n.r.
Streptococcus thermophilus	2	4	32	n.r.	64	2	2	4	4	n.r.	n.r.	n.r.	n.r.
Bacillus	n.r.	4	4	8	8	4	4	8	8	n.r.	n.r.	n.r.	n.r.
Propionibacterium	2	4	64	64	64	0.5	0.25	2	2	n.r.	n.r.	n.r.	n.r.
Enterococcus faecium	2	4	32	1,024	128	4	4	4	16	4	n.r.	n.r.	n.r.
Corynebacterium **and other Gram-positive**	1	4	4	16	8	1	4	2	4	n.r.	n.r.	n.r.	n.r.
Enterobacteriaceae	8	n.r.	2	8	16	n.r.	n.r.	8	n.r.	n.r.	0.06	2	8

- Bacteria - yeasts
- Where possible/needed at species level
- List of antibiotics

GUIDANCE ON MICROORGANISMS – WGS STATEMENT

- EFSA statement on WGS data requirements
  - In use in the risk assessment
  - Document subject to update to consider:
    - New developments/uses in the technologies/tools
    - Knowledge gained in the initial implementation and during the development of pipelines

TIMELINE - INITIAL



GUIDANCE ON MICROORGANISMS – WGS STATEMENT

Scientific work

Antimicrobial susceptibility

- Literature search
- BIOHAZ Panel statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes

Expanding the scope

- New expertise, new needs
- Extend to other categories of products (e.g., biomasses)

Consolidation of statement on whole genome sequence data

- Work on-going together with the discussions above and knowledge gained

GUIDANCE ON MICROORGANISMS – WGS STATEMENT

Where we are

Antimicrobial susceptibility

- Literature search and title/abstract screening done; full text screening ongoing

Novelties (e.g., new groups):

- Bacteriophages and microalgae
- Viruses

Consolidation of statement on whole genome sequence data

AGENDA OPEN SESSION – 15 NOVEMBER

No.	ITEM
6.	Welcome and Apologies for absence
7.	Brief introduction of Panel Members
8.	Presentation of the EFSA guidelines for Observers
9.	Update on the Guidance on studies concerning the safety of use of the additive for users
10.	New mandates
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15.	Criteria for the quantification of the active agent(s) in the additive

MICROORGANISMS PIPELINES SERVICE (MOPS)

EUROPEAN FOOD SAFETY AUTHORITY

MOPS PROJECT IN A NUTSHELL

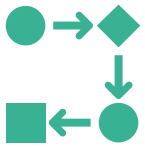
SCOPE

Develop and implement 3 pipelines (bacteria, yeasts/filamentous fungi, viruses) for the analysis of WGS data. The tool can be used for risk assessment (RA) purposes.

WHY

- Address the needs of different risk assessments domains
- Comprehensive microorganisms RA
- Standardised microorganisms WGS based data analysis

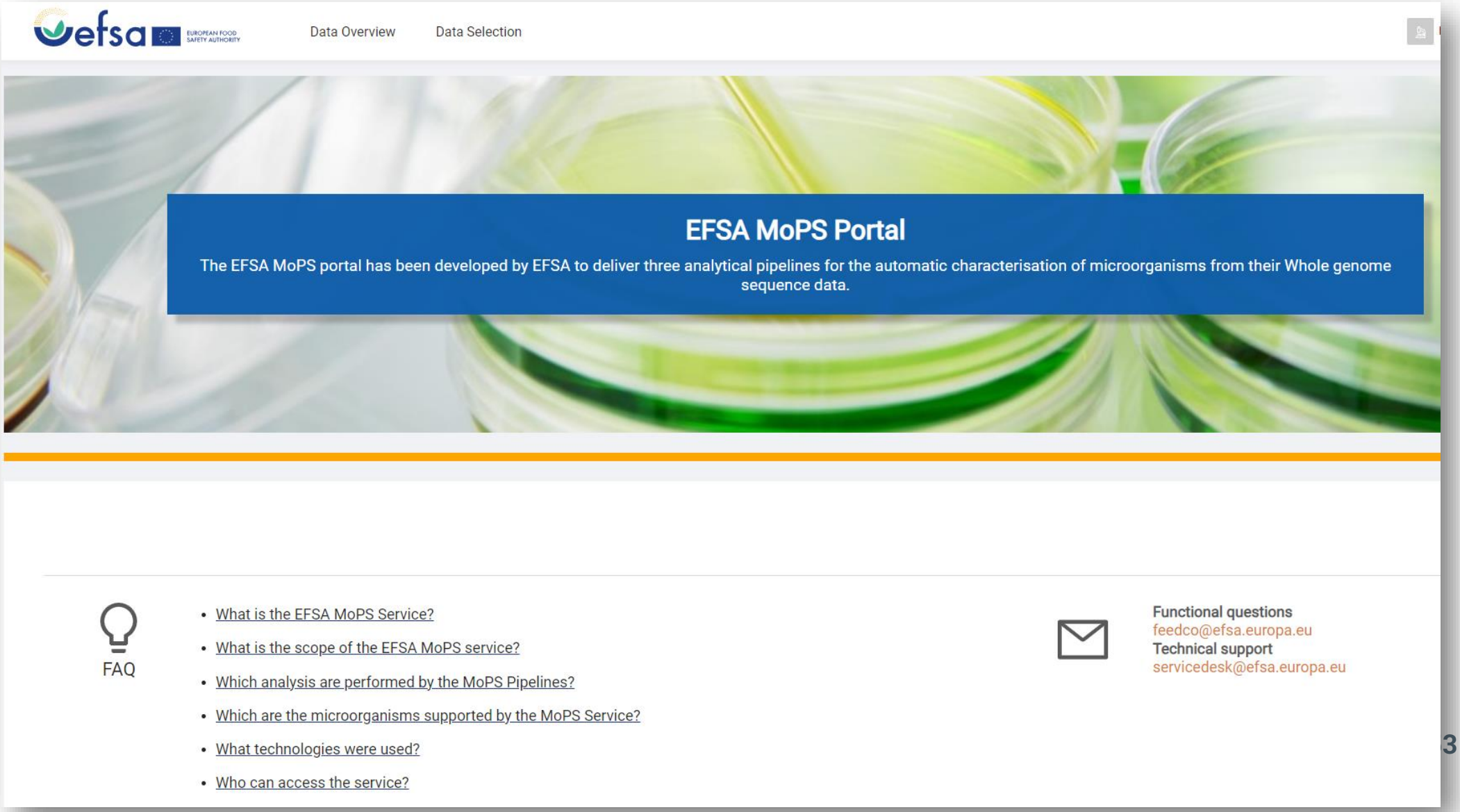
HOW



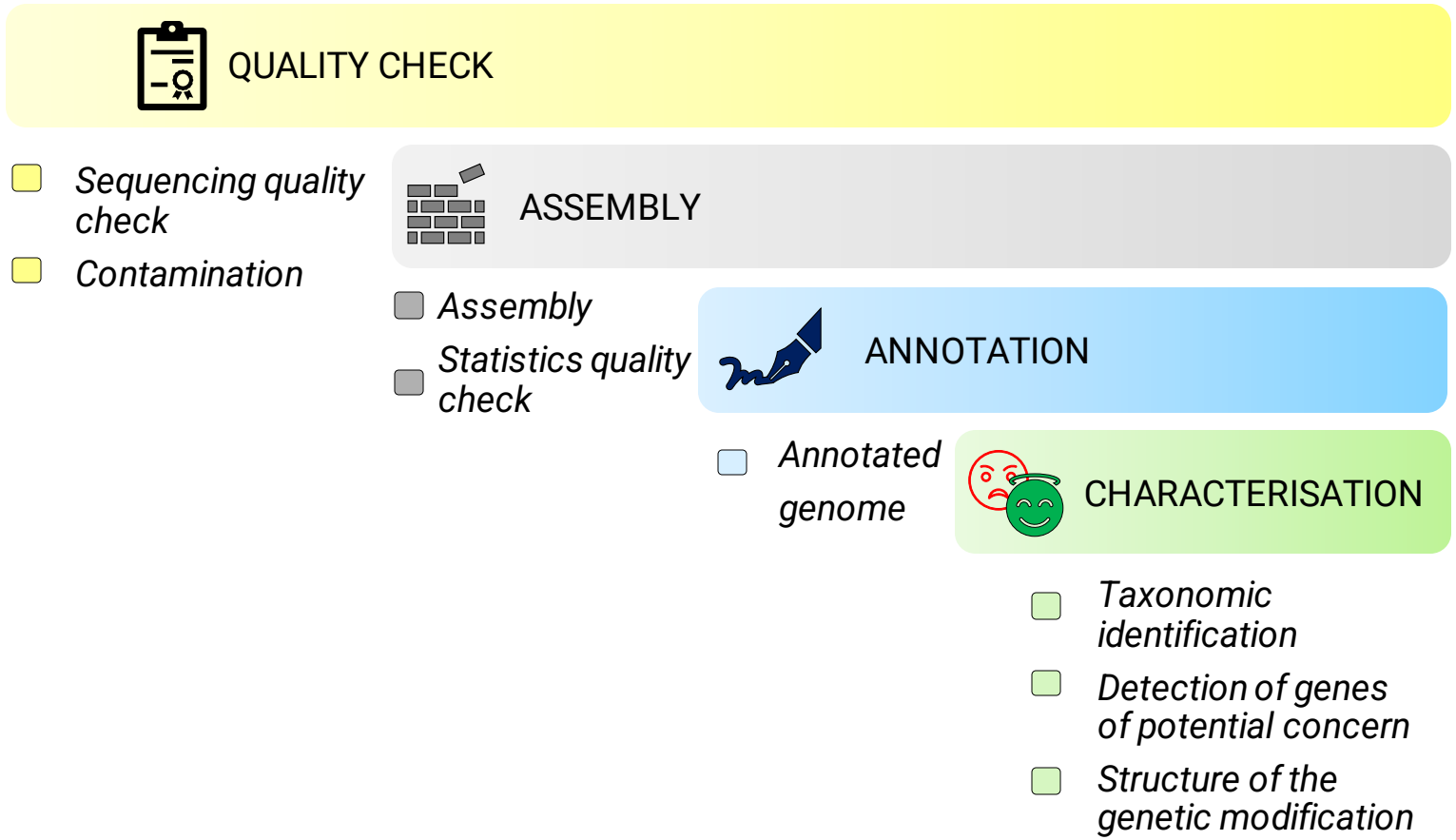
- Build a secure and confidential environment
- Perform the sequence quality check of the WGS data
- Use the WGS data to taxonomically identify and characterise the microorganism

- Taxonomic identification
- Genetic modification characterisation
- Detection of genes of potential concern

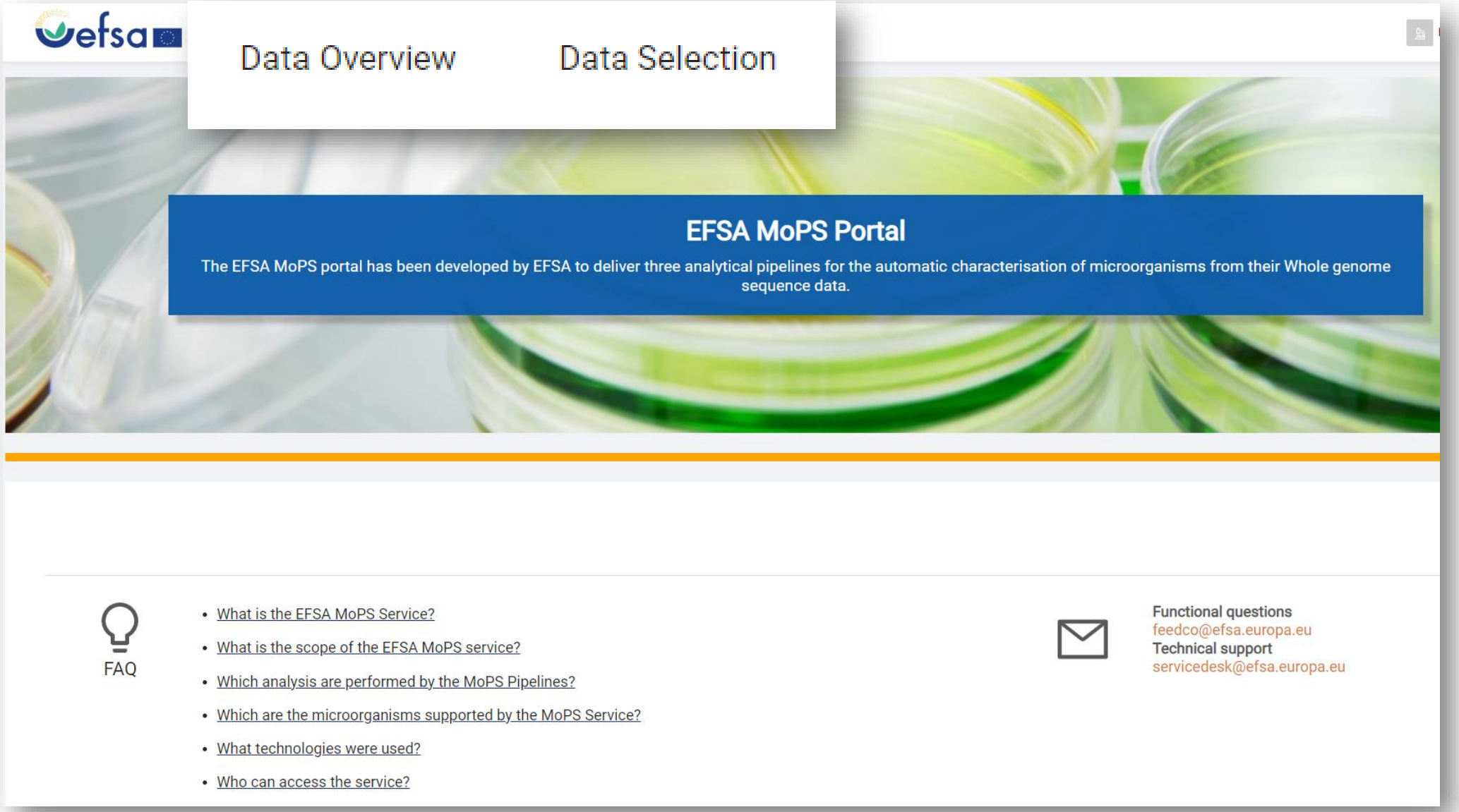
MOPS PORTAL


efsa
EUROPEAN FOOD SAFETY AUTHORITY
Data Overview
Data Selection
EFSA MoPS Portal
The EFSA MoPS portal has been developed by EFSA to deliver three analytical pipelines for the automatic characterisation of microorganisms from their Whole genome sequence data.
FAQ
What is the EFSA MoPS Service?
What is the scope of the EFSA MoPS service?
Which analysis are performed by the MoPS Pipelines?
Which are the microorganisms supported by the MoPS Service?
What technologies were used?
Who can access the service?
Functional questions
feedco@efsa.europa.eu
Technical support
servicedesk@efsa.europa.eu

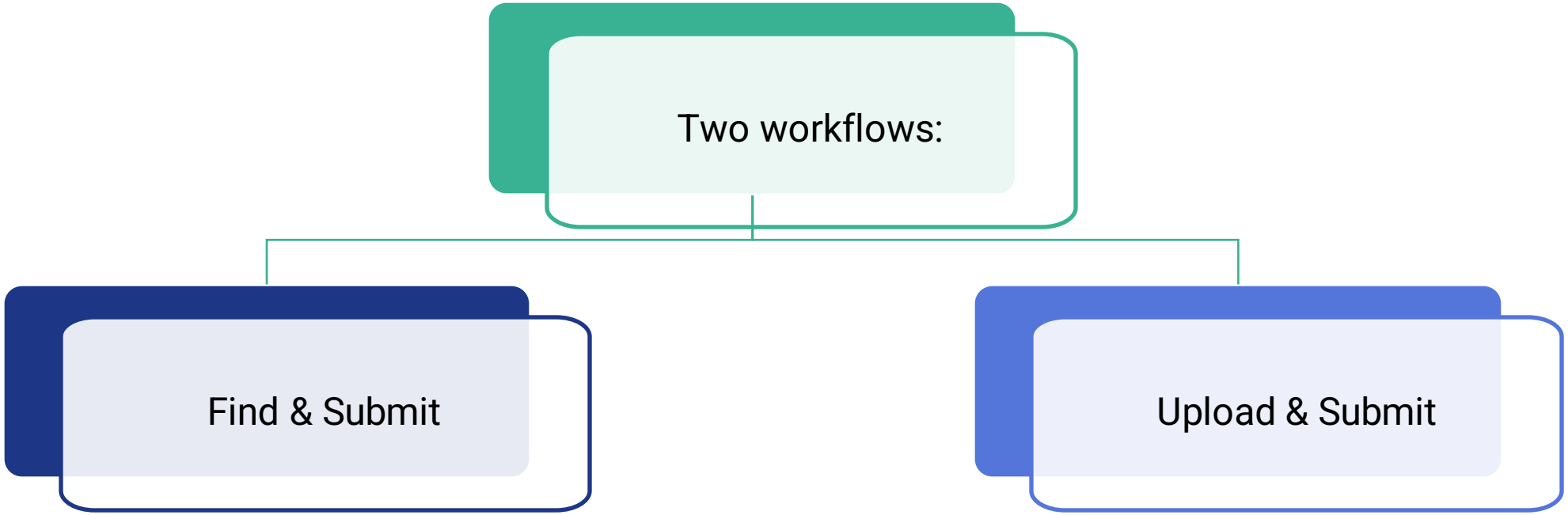
PIPELINES – STEP BY STEP



MOPS PORTAL HOMEPAGE – DATA OVERVIEW & DATA SELECTION



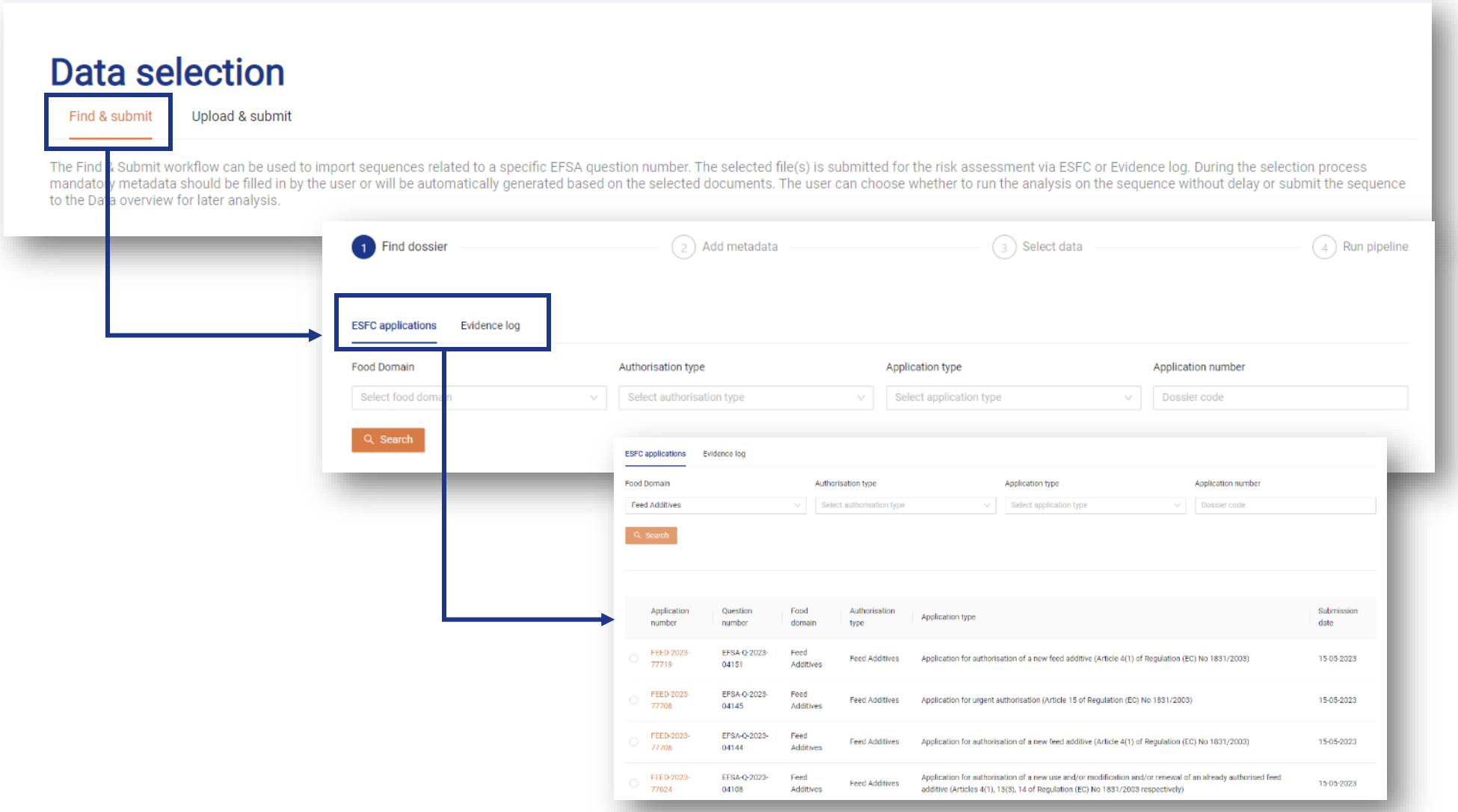
DATA SELECTION



- Applications
- Upload public sequences

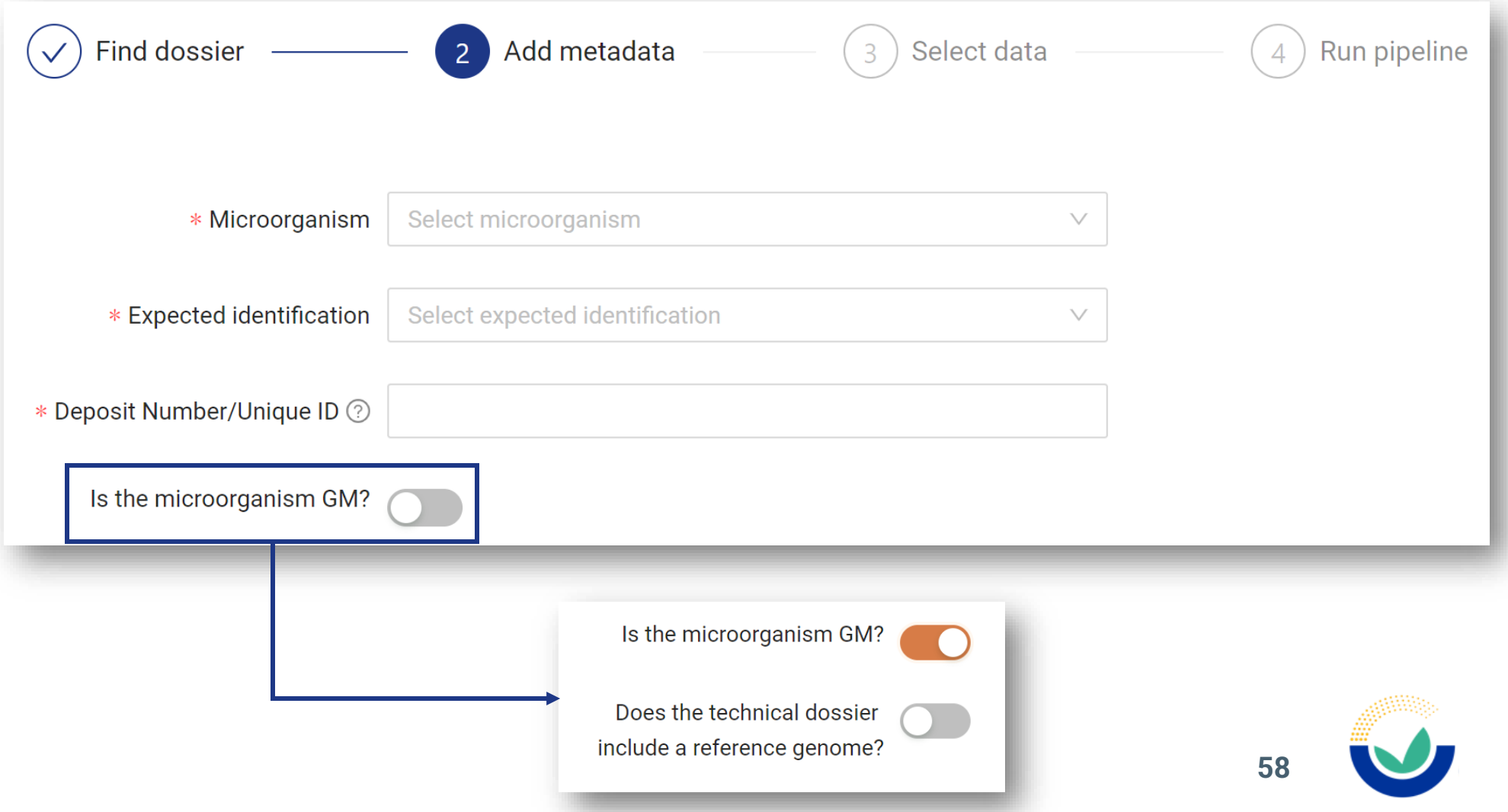
DATA SELECTION – FIND & SUBMIT

1 Select the dossier



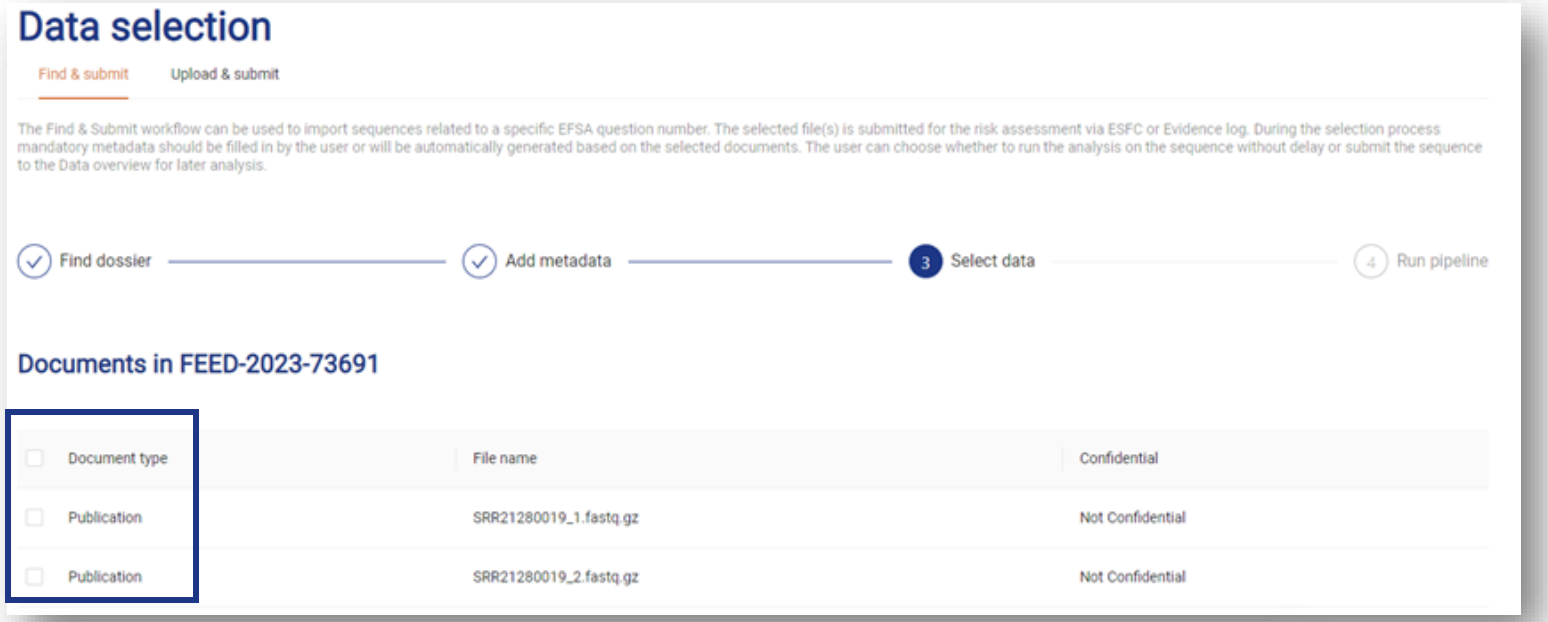
FIND & SUBMIT - METADATA

2 Add metadata

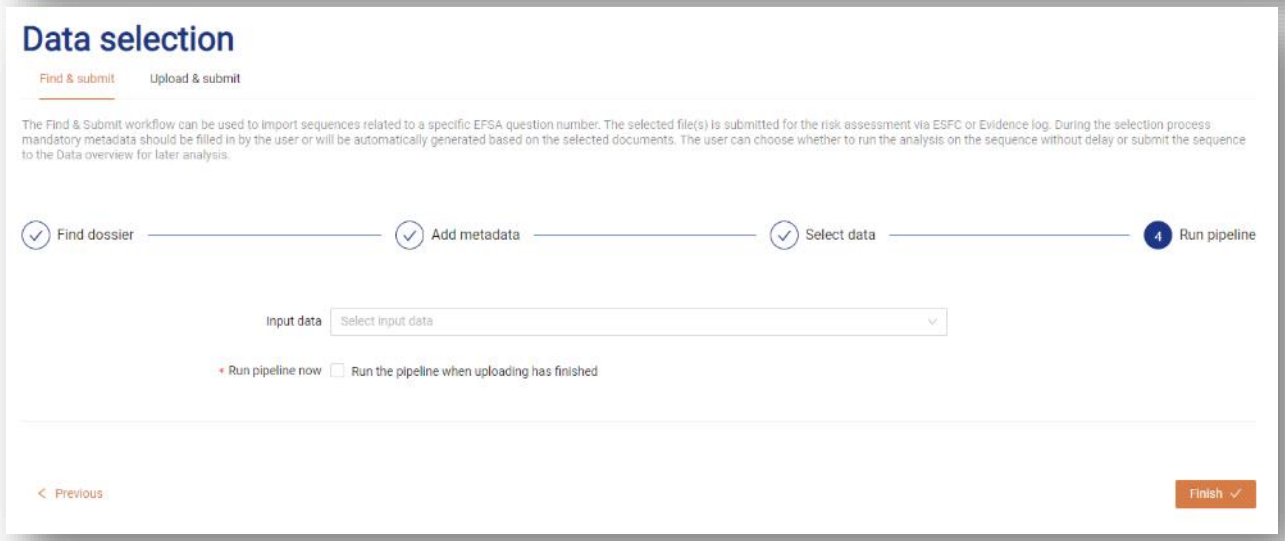


FIND & SUBMIT – DUMMY DATA

3 Select data



4 Finish

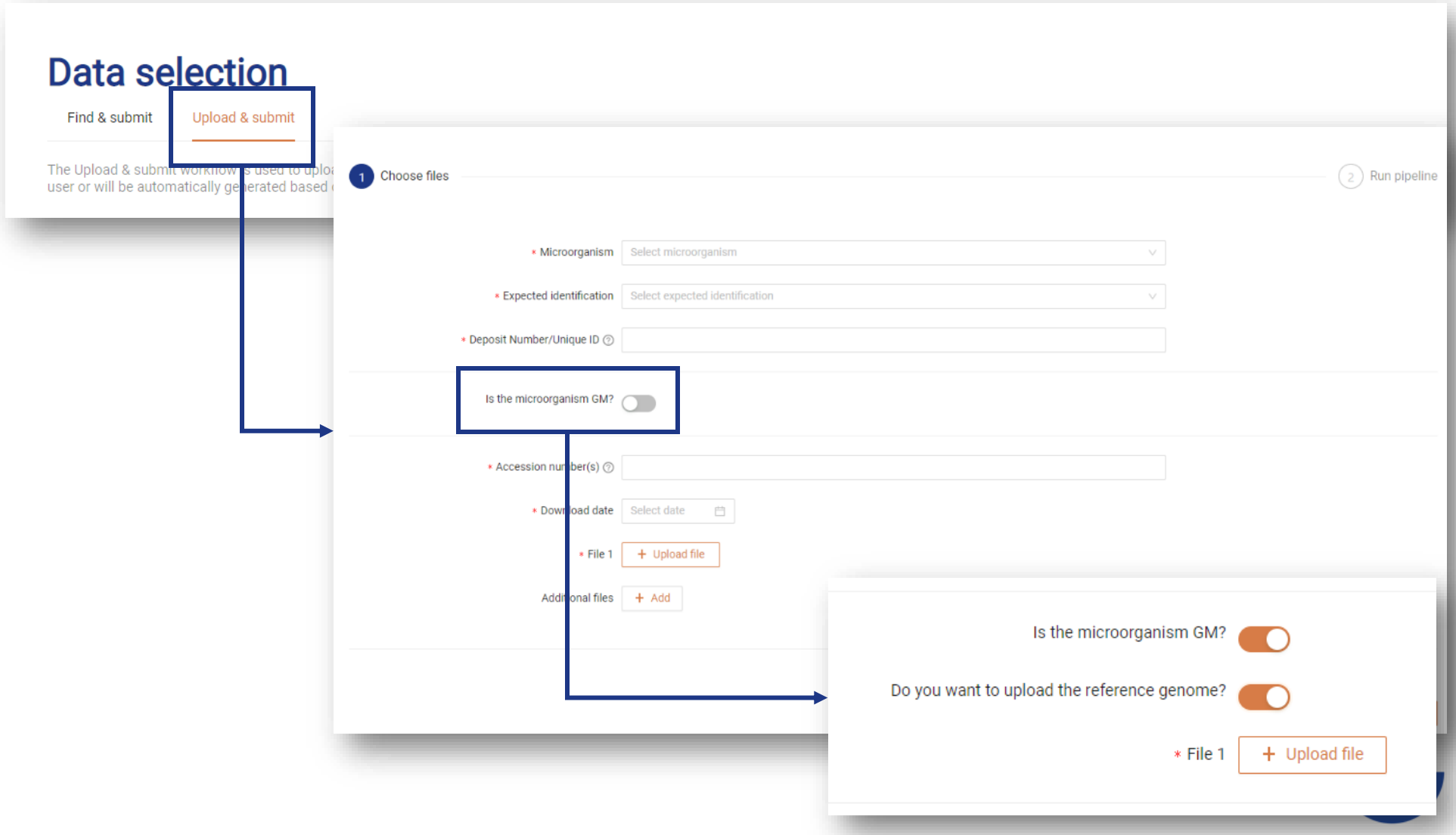


DATA SELECTION – UPLOAD & SUBMIT

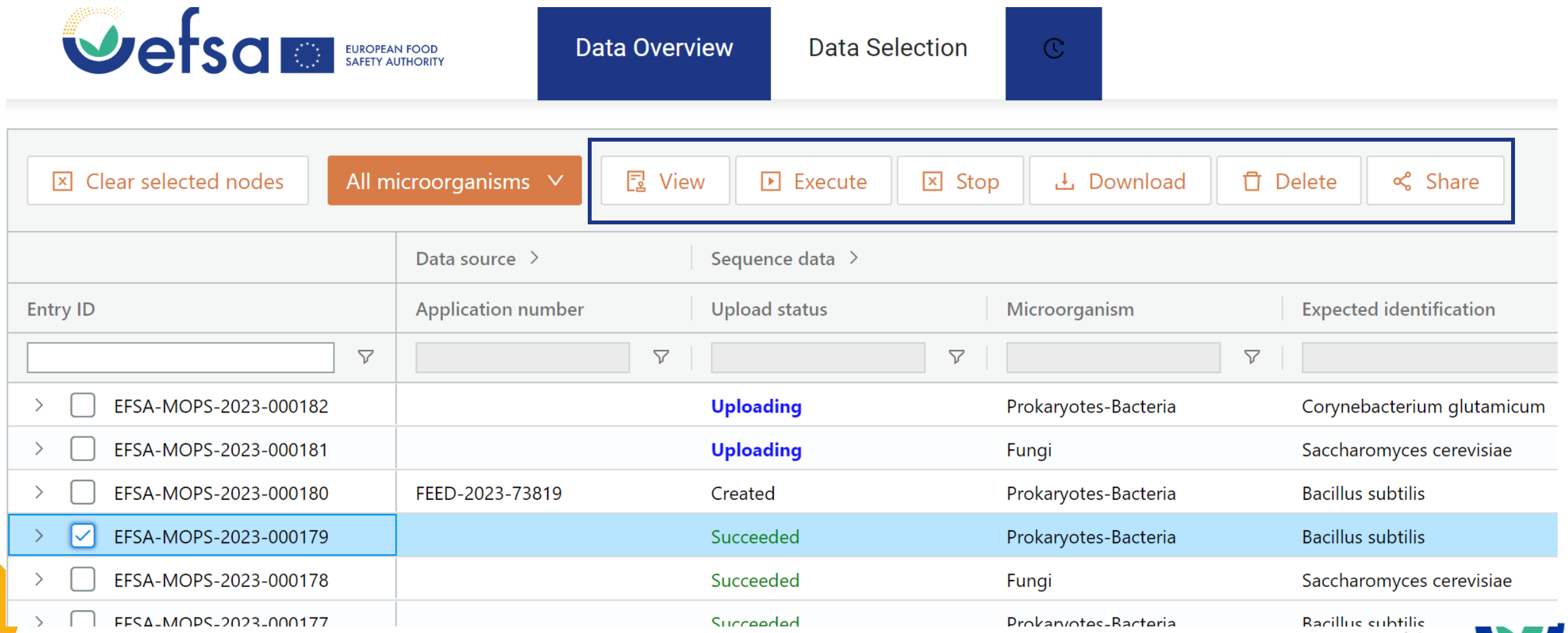
2 Add metadata

3 Upload files

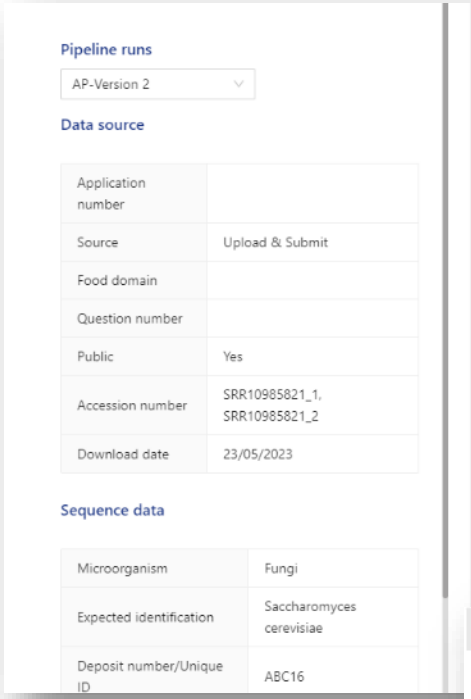
4 Finish

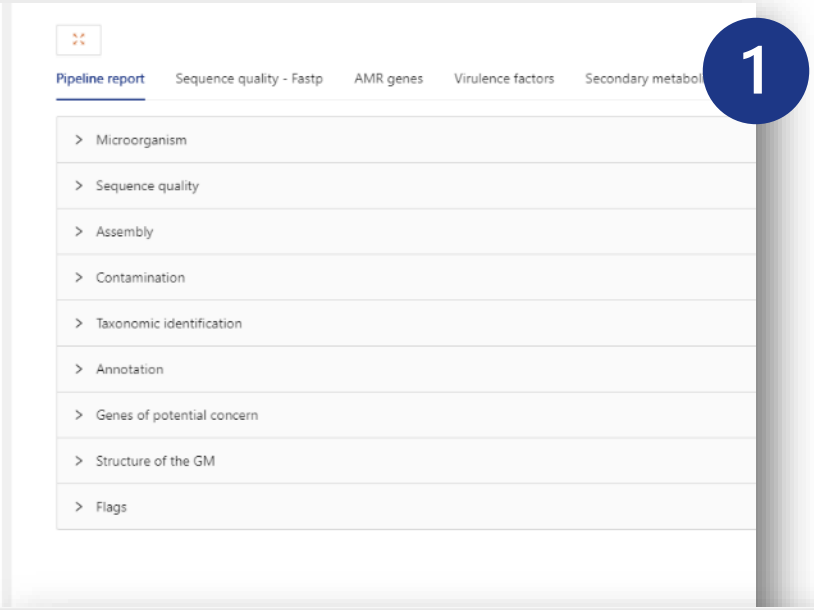


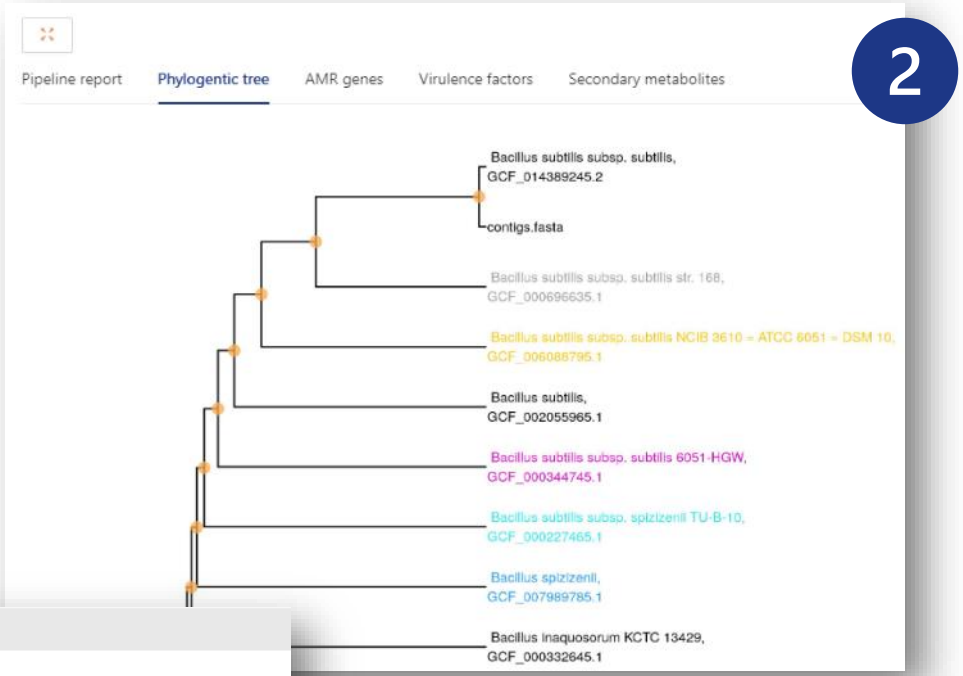
DATA OVERVIEW – DUMMY DATA

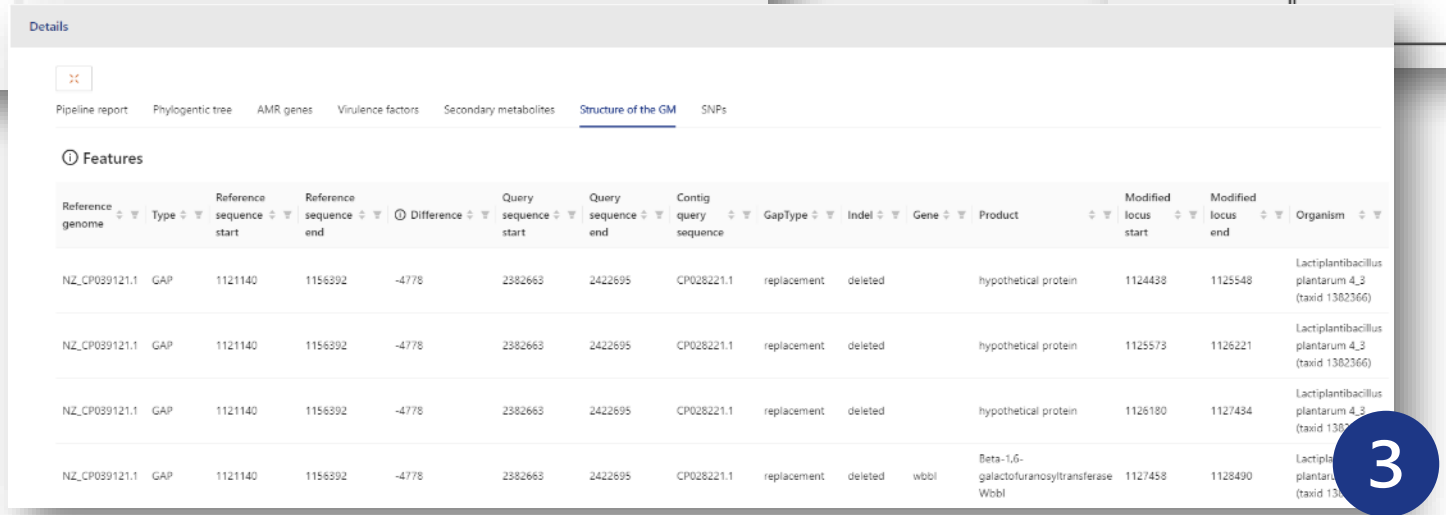


REPORTS – DUMMY DATA









NEXT STEPS – FUTURE OPPORTUNITIES

- Pipelines maintenance and update
- Developments to cover new needs (e.g., analysis, groups of microorganisms)
- Open pipelines

AGENDA OPEN SESSION – 15 NOVEMBER

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PROPOSED CRITERIA FOR THE QUANTIFICATION OF THE ACTIVE AGENT(S) COMPOSING A FEED ADDITIVE

FEEDAP Open Plenary Meeting
15th November 2023

EUROPEAN FOOD SAFETY AUTHORITY

PROPOSED CRITERIA FOR THE QUANTIFICATION OF THE ACTIVE AGENT(S) COMPOSING A FEED ADDITIVE

- **Active agent(s): any viable microorganism intended to be used as/in a feed additive that provides the intended effect.**

- Commission Regulation (EC) No 429/2008: The **qualitative** and **quantitative** batch to batch variation of the active substance(s)/agent(s) shall be determined.

- Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017):
  - The applicant should propose a specification of the product as it relates to the concentration of the active substance(s)/agent(s). Evidence should be provided by the analysis of at least five independent production batches that this specification is satisfied in practice.

PROPOSED CRITERIA FOR THE QUANTIFICATION OF THE ACTIVE AGENT(S) COMPOSING A FEED ADDITIVE

- Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017):
  - If the additive is a mixture of active substances or agents, each of which is clearly definable (qualitatively and quantitatively), the active substances/agents must be described and the proportions in the mixture given.

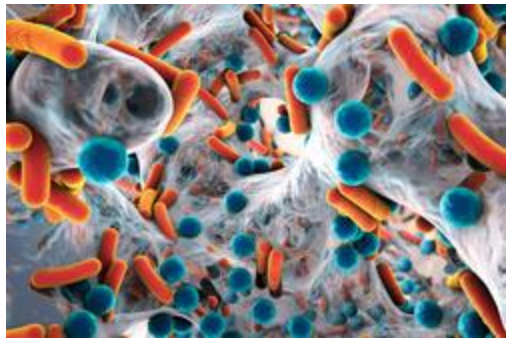
Need to determine the active agent(s) composing the additive in qualitative terms, and not only quantitative.

PROPOSED CRITERIA FOR THE QUANTIFICATION OF THE ACTIVE AGENT(S) COMPOSING A FEED ADDITIVE

Applicable to:

- Additives containing one active agent

- Additives containing more than one active agent.




THANK YOU

END OF SESSION

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efsa
EUROPEAN FOOD SAFETY AUTHORITY

15 and 16 November 2023

WELCOME TO THE OPEN SESSION OF THE 170TH PLENARY OF THE FEEDAP PANEL

EUROPEAN FOOD SAFETY AUTHORITY

AGENDA OPEN SESSION – 16 NOVEMBER

No.	ITEM
16.	Update of the Guidance on the assessment of the efficacy of feed additives
17.	Chemicals Strategy for Sustainability and One Substance One Assessment – Impact to EFSA
18.	Update on the confidentiality assessment of feed additives' applications
19.	Update on pre-application activities and completeness check of feed additives applications
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20.1	NAMs
21.	Questions & Answers
22.	Closure of meeting

Coffee break 10:30 – 10:50

Lunch break 12:30 – 14:00

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Update of the Guidance on the assessment of the Efficacy of feed additives

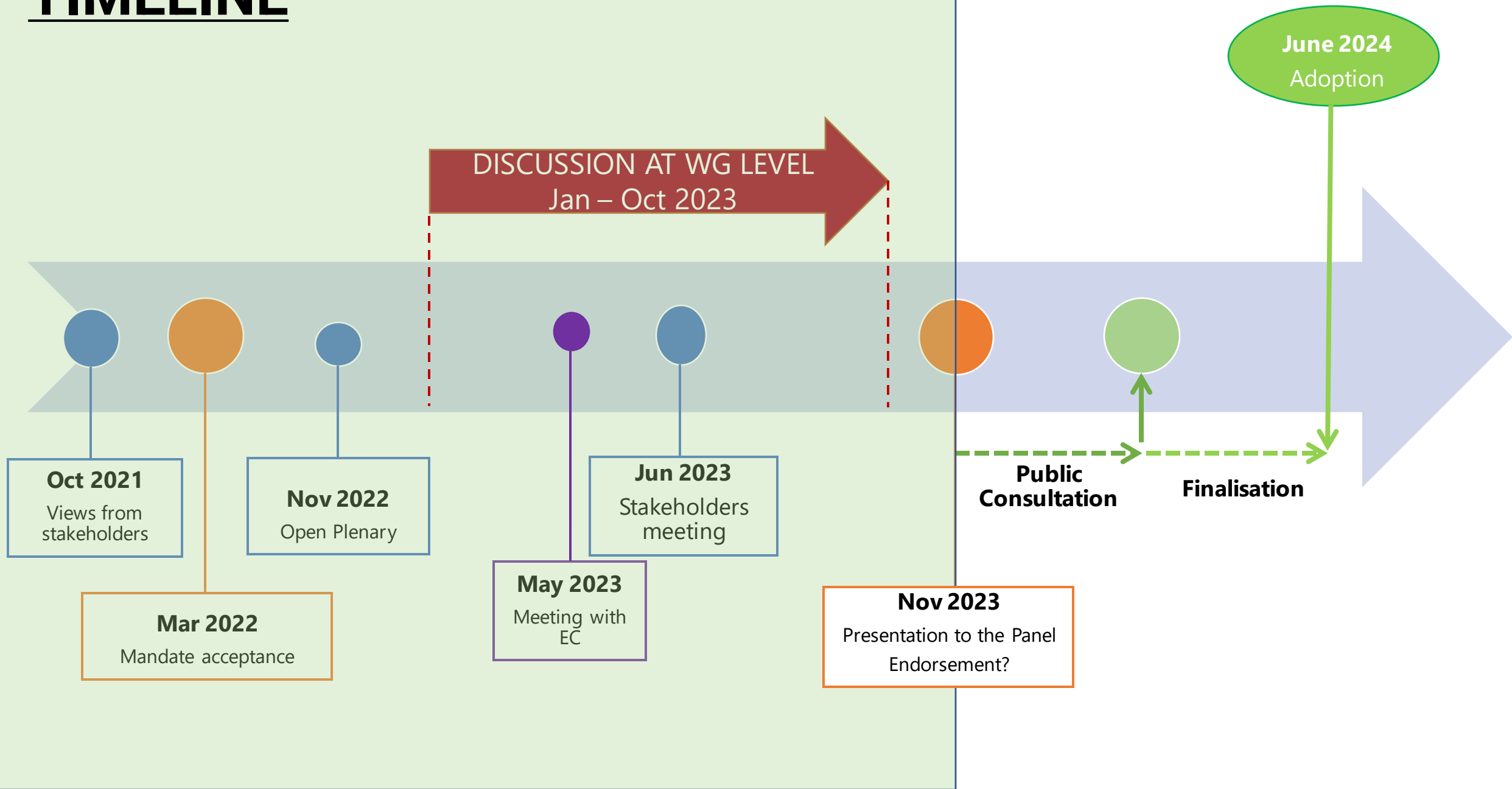
Open Plenary – EFSA FEEDAP Panel
16 November 2023

EUROPEAN FOOD SAFETY AUTHORITY

BACKGROUND

- **Regular update** of the Guidance to complement Regulation (EC) No 429/2008 → directions and clarifications to assist applicants in the preparation and submission of technical dossiers
- **New functional groups** included in Regulation (EC) No 1831/2003
- **Green Deal**: focus on additives that are beneficial for the environment and animal welfare
- To move forward within the **3 Rs** approach
- Revision of different aspects based on **experience**

TIMELINE


June 2024
Adoption
DISCUSSION AT WG LEVEL
Jan – Oct 2023
Oct 2021
Views from stakeholders
Mar 2022
Mandate acceptance
Nov 2022
Open Plenary
May 2023
Meeting with EC
Jun 2023
Stakeholders meeting
Nov 2023
Presentation to the Panel
Endorsement?
Public Consultation
Finalisation

WHAT IS NEW?

Criteria for functional groups included in Reg. 1831/2003

- Hygiene condition enhancers
- Physiological condition stabilisers

Certification of compliance of animal studies with the EU Welfare legislation

WHAT HAS BEEN UPDATED/REVISED?

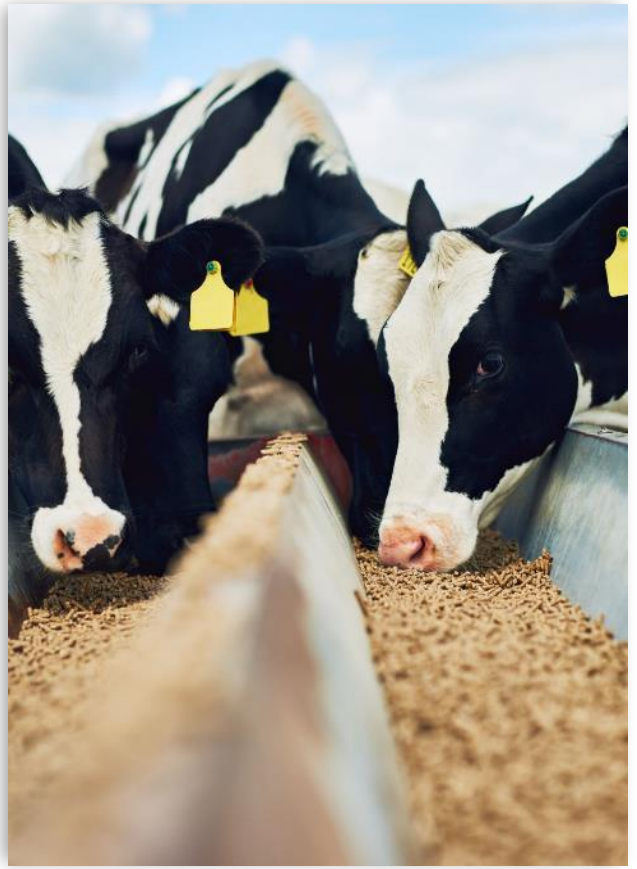
Revision and clarification of requirements for certain functional groups

- Nutritional additives
- Silage additives
- Substances which favourably affect the environment
- Coccidiostats and histomonostat

Higher flexibility in experimental design of *in vivo* trials

Refinement / reduction of the number of animal studies

Others (insects, animal health, independence…)



Refinement / reduction / flexibility

Table 5: Minimum number of independent studies and target species required for the assessment of efficacy in applications covering multiple species/categories

Application for	Number of studies required and species
All growing poultry species (chickens for fattening, turkeys for fattening and minor growing poultry species)	3 in chickens for fattening
All poultry species (chickens/hens, turkeys and minor growing and reproductive)	3 in chickens for fattening 3 in laying hens
All growing pigs (piglets, pigs for fattening and minor growing porcine)	3 in weaned piglets 3 in pigs for fattening
All pigs (piglets, pigs for fattening, sows and minor growing and reproductive porcine species)	3 in weaned piglets 3 in sows
All growing ruminants (calves, cattle for fattening, sheep and goats for fattening, other minor growing ruminants)	3 in calves 3 in cattle for fattening
All ruminants (calves, cattle for fattening, cows, sheep and goats for fattening and dairy production, other minor ruminants growing and reproductive)	3 in calves 3 in cows
All fin fish	3 in salmonids (salmon or trout) 3 in other species (1 study in each)
Crustaceans	3 in shrimp/crustaceans
Rabbits (growing and reproductive)	3 covering both growing and reproductive animals

Application for:	Number of studies required and species
All poultry for fattening and reared for laying/breeding	3 in chickens for fattening or 2 in chickens for fattening + 1 in turkeys for fattening
All poultry	2 in chickens for fattening 2 in laying hens
All *Suidae* for fattening and reared for reproduction	3 in weaned piglets/pigs for fattening(1)
All *Suidae*	1 in weaned piglets 1 in pigs for fattening 2 in sows
All bovines, ovines, caprines, cervids and camelids for fattening and reared for reproduction	3 in calves/cattle for fattening(1) or 1 in calves + 1 in cattle for fattening + 1 in lambs/kids
All bovines, ovines, caprines, cervids and camelids for milk production	3 in dairy cows or 2 in dairy cows + 1 in dairy sheep/goat
All bovines, ovines, caprines, cervids and camelids	1 in calves 1 in cattle for fattening 2 in cows
All rabbits	3 covering both growing and reproductive animals
All fin fish	2 in salmonids (salmon or trout) 1 in another carnivore fish species 1 in an herbivore fish species
All crustaceans	3 in shrimp/crustaceans
All terrestrial species	3 combining chickens for fattening and laying hens + 3 combining weaned piglets/pigs for fattening and sows + 3 combining calves/cattle for fattening and cows
All aquatic species	1 salmonid + 1 in another carnivore fish species + 1 herbivore fish species + 1 crustacean/mollusc

Refinement / flexibility

Table 6: Minimum duration of long-term efficacy studies

Category	Definition of the animal category	Start	Minimum duration
Piglets (weaned)	Young animals having completed the suckling period	≤ 7 days after weaning	42 days 35 days if growth rate is ≥ 0.5 kg/day
Pigs for fattening	Animals intended for meat production until day of transport to slaughterhouse	≤ 35 kg	Until slaughter, but not less than 70 days
Sows	Female animals having been inseminated/mated	Insemination/ mating	For effects on reproduction: two cycles (from insemination/ mating until weaning). For effects on piglets, preferably at least 2 weeks before parturition until weaning
Chickens for fattening	Birds raised for fattening	1 day of age	35 days
Laying hens	Productive female birds held for egg production purposes	22–25 weeks of age	84 days
Turkeys for fattening	Birds raised for fattening	1 day of age	84 days
Calves	Calves which are reared for reproduction, veal production or beef production	1–4 weeks of age	56 days
Cattle	Bovine animals that have completed the weaning period	Full development of rumination but ≤ 6 months of age	84 days
Cows	Lactating cows	4–8 weeks after calving	84 days
Lambs/kids	Young animals reared for reproduction or meat production	1–4 weeks of age	56 days
Sheep/goats	Lactating animals	4 weeks after parturition	84 days
Salmon and trout	Growing salmonids	Trout ≥ 10 g Salmon ≥ 50 g	84 days
Rabbits	Rabbits that are reared for reproduction or meat production	1 week after birth	42 days
Breeding does	Does that have become pregnant at least once	Insemination/ mating	For effects on reproduction: Two cycles For effects on kits: preferably from 2 weeks before parturition until end of weaning period.
Cats, dogs and other non-food-producing animals			28 days

Category	Start of the study	Minimum duration
Chickens for fattening	1 day of age	35 days
Laying hens	<30 weeks of age and ≥90% laying rate	84 days
Turkeys for fattening	1 day of age	84 days
Piglet (weaned)	≤ 7 days after weaning	42 days 35 days if growth rate is ≥ 0.5 kg/day
Pig for fattening	≤35 kg	Until slaughter, but not less than 70 days
Sow	For effects on reproduction: from insemination/mating ~~For effects on lactation or in piglets:~~	For effects on reproduction: two full reproduction cycles For effects on lactation or on piglets: until the end of weaning period but not less than 28 days
Calf	< 6 weeks of age	56 days
Cattle for fattening	Full development of rumination and ≤ 12 months of age	84 days
Dairy cow	< 16 weeks after parturition and Milk yield ≥ 30 kg/d	84 days
Lamb/kid	< 8 weeks of age	56 days
Dairy ewe/goat	<8 weeks after parturition	84 days
Rabbit		42 days
Breeding doe	For effects on reproduction: from insemination/mating For effects on kits: preferably from two weeks before parturition	For effects on reproduction: Two cycles For effects on kits: until end of weaning period.
Salmon and trout	Trout ≥ 10 g Salmon ≥ 50 g	84 days
Honeybee		28 days
Other insects		Whole production cycle
Cat, dog and other non food-producing animals		28 days

Draft Guidance

COFFEE BREAK

AGENDA OPEN SESSION – 16 NOVEMBER

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FEEDAP Panel Plenary Meeting
16th November 2023

CHEMICALS STRATEGY FOR SUSTAINABILITY AND ONE SUBSTANCE ONE ASSESSMENT – IMPACT TO EFSA

Gloria LÓPEZ-GÁLVEZ

Food Ingredients and Packaging (FIP) Unit

EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE

1. INTRODUCTION
2. 1S1A EFSA's ACTIVITIES
3. LEGISLATIVE PROPOSALS
4. SUMMARY
5. Q&A

Chemicals Strategy for Sustainability (CSS)
One Substance One Assessment (1S1A)
Promotional activities

- Presentation to Management Board
- Presentation to Advisory Forum and its groups
- Presentation to Scientific Committee and Scientific Panels
- Presentation to Other Stakeholders
- Various internal activities

1. INTRODUCTION: CSS and 1S1A

Chemicals Strategy for Sustainability (CSS)

October 2020

EU Green Deal

'Toxic-Free Environment'

Stronger EU legal framework to address pressing environmental and health concerns

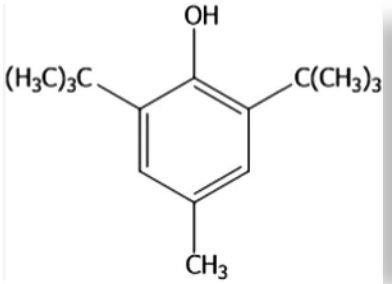
Simplifying and consolidating the legal framework.-
One Substance One Assessment

Innovating for safe and sustainable EU chemicals

Establishing a comprehensive knowledge base on chemicals

Providing a model to inspire chemicals management globally

ONE SUBSTANCE ONE ASSESSMENT (I)



Butylated hydroxy toluene (BHT)

IUPAC name: 2,6-di-tert-butyl-p-cresol

CAS number: 128-37-0

TODAY:

One Substance, SIX Assessments (one per use)

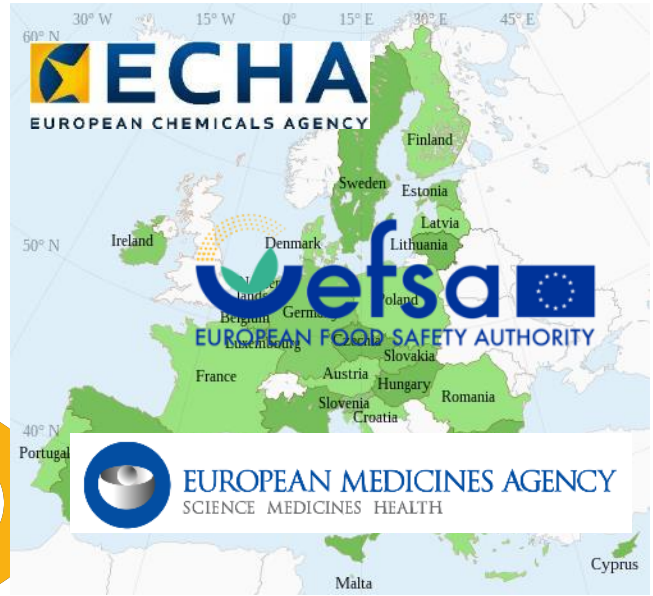
- **Food Contact Material**
- **Feed additive**
- **Industrial chemical**
- **Food Additive**
- **Medicine-excipient**
- **Cosmetic**

TOMORROW:

One Substance, ONE Assessment with all uses

- *Synchronised*
- *Same dataset*
- *Best use of resources*
- *No duplication, no risk of divergencies*
- *Facilitate the regulatory management*

ONE SUBSTANCE ONE ASSESSMENT (II)



TRANSPARENCY

- Stakeholders are timely informed and have access to underlying data

Initiation	Allocation	Data	Methodologies
• Synchronised and coordinated • Assessments of groups of substances	• Clear responsibilities • Making best use of available resources and expertise • Good governance and cooperation	• Easily findable, accessible, interoperable, secure, of high quality • Shared and reused by default	• Coherent • To the extent possible harmonised • Hazard assessment centralised under CLP Regulation

Tomorrow

One substance, one assessment

European Commission

(Slide taken from EC Presentation to 80th Advisory Forum Meeting)

2. ONE SUBSTANCE ONE ASSESSMENT (1S1A)
EFSA’s Activities

Early identification of cross-cutting substances

Piloting 1S1A; Analysis/Lessons learnt

Procurement Study to map Data Requirements and Risk Assessment Methodologies

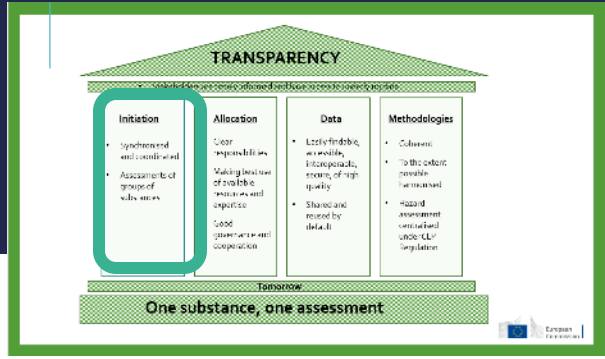
Contribution to the EU-Common Data Platform on Chemicals (EU-CDPC)

OTHER: Focused 1S1A Inter-Agencies meetings

Participation in various 1S1A preparatory activities led by EC: Repository of HBGV, Joint discussions with European Commission and Member States

IDENTIFICATION O -CUTTING SUBSTANCES

Available databases and tools
Future: EU-CDPC



10 Self-mandates

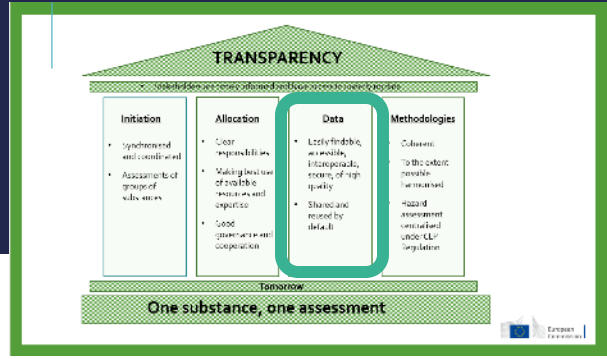
70 Generic mandates

Procedure to involve relevant Agencies in place (Mandate Dialogue phase)

WORK on SUBSTANCE IDENTIFIERS

350 **Applications for Regulated products mandates**

DATA SHARING / DATA USE AND RE-USE



- **Feed additives**
- **Food Contact Materials**
- **Food additives, food enzymes and food flavourings**
- **Plant protection products**

efsa EUROPEAN FOOD SAFETY AUTHORITY

- **Registration, Evaluation, Authorisation and Restriction of Chem**
- **Classification, labelling and packaging of substances and mixtu**
- **Biocidal products**

ECHA EUROPEAN CHEMICALS AGENCY

- **Medicinal products for human use**
- **Medicinal products for veterinary use**

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

- **Safety of Toys**
- **Cosmetic products**

European Commission

- **Member States**

Food/Feed Risk assessments

Legal

- Remove obstacles for reuse of data and better streamline flow of data

❖**Common open data platform on chemicals**

❖Making data available in appropriate **formats:**

- IUCLID for hazard and use data; IPCHEM for monitoring data

PILOTING 1S1A: DIVERGENCY ON DATA REQUIREMENTS

From the Pilot assessment being run: Drinking water Directive and Food Contact Matl's

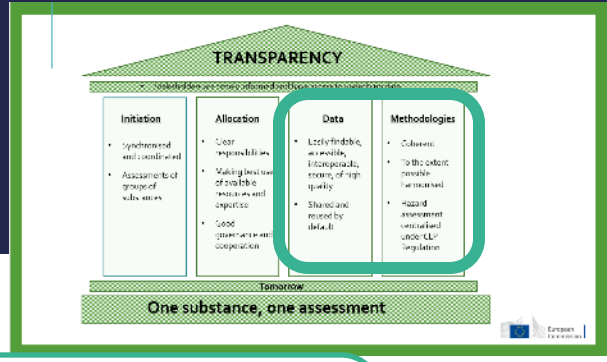
EFSA[1]	ECHA-REACH[2]
Two tests are requested: • Bacterial Reverse mutation assay (OECD TG 471) • *In vitro* micronucleus test (OECD TG 487)[3]	
↓ *If both tests are negative*	↓
NO GENOTOXIC POTENTIAL	**A third test is requested:** • *In vitro* gene mutation in mammalian cells (OECD TG 476/OECD TG 490)
	↓ *If the test is negative*
	NO GENOTOXIC POTENTIAL

(1) Requirements from Scientific Opinion of the EFSA's Scientific Committee of 2011 and Clarifications of some aspects in 2017

(2) Requirements from REACH Regulation, Annex VII (SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE) and Annex VIII (SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE)

(3) Until September 2022, the choice of '*In vitro* cytogenicity study in mammalian cells' or '*In vitro* micronucleus study' was possible for the second genotoxicity test. From September'22 only the '*In vitro* micronucleus study' is required as second test, and no choice is possible. Thus, the Decision of the ECHA's Member State Committee in its June 22's meeting approximates the approaches of the two Agencies.

ALIGNMENT DR AND RAM



PILOT findings

- Food Contact Material and Drinking Water (EFSA Sci. Ctee Guidance *vs* REACH)
- Data requirements for genotoxicity screening do not fully match

PROBLEM

- There might be other areas with misalignments in DR and RAM
- Work via Outsourcing. **Procurement Subject:** "Mapping of DR and RAM linked to the regulatory frameworks and remits of the relevant EU Agencies (ECHA, EFSA and EMA) and EC Scientific Committees (SCCS and SCHEER)"

RESULTS

- Expected by November 2023
- To be critically revised in the context of 1S1A

Work on GUIDANCEs
Joint GUIDANCEs

3. ONE SUBSTANCE ONE ASSESSMENT (1S1A) Legal Proposals

‘REVISION - CLASSIFICATION LABELLING AND PACKAGING REGULATION’

Revision CLP Regulation. Adopted 19/12/2022.

1) Delegated Act - *Change of Annex I*. Introducing NEW hazard classes

2) Proposal for a revision of the CLP Regulation – *Change of body text* :
   - NEW: Right for the Commission to develop CLH proposals
   - NEW: **Empowerment for Agencies** ‘*The Commission may ask ECHA or EFSA* ***to prepare a proposal for harmonised classification and labelling*** *of substances and, `[…].*’

METHODOLOGIES AND DATA

The Commission will:

- ensure that the CLP Regulation is the **central piece for hazard classification** and allows the Commission to initiate harmonised classifications[76];

‘RE-ATTRIBUTION OF TASKS’

Reallocation of tasks derived from the 1S1A implementation and from EC Scientific Committees

Tasks to EFSA, to contribute in:

- Operation and governance of the EU-CDPC
- Adopting formats and preparing controlled vocabularies
- Early Warning and Action System on Chemicals

COOPERATION
MS and Agencies

Preventing/Avoiding
DIVERGING OPINIONS

‘CHEMICAL DATA’

- **EU-Common Data Platform on Chemicals**
- **Data inter-operability, data use and re-use, removal of legislative barriers**
  Crucial element in the success of 1S1A
- **CSS Indicators**

EU-COMMON DATA PLATFORM ON CHEMICALS

ECHA
EUROPEAN CHEMICALS AGENCY

Hosting data on CHEMICALS

Studies Notification

Control vocabularies, dictionaries, formats

Academic Studies

'Analytical' Tools (QSAR Toolbox, data analytics, Query functions, exposure models)

Status on Regulatory Processes
Extended (P)ACT
Extended EUCLEF

Outcomes of the assessments

Repository of health limit values

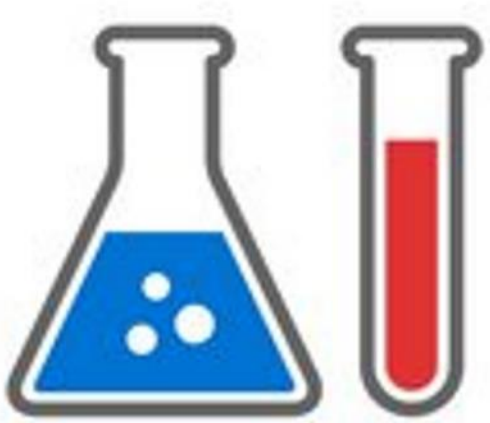
Central database(s) with regulatory submissions

IUCLID 6

Occurrence data

4. SUMMARY/Take-home messages

SUMMARY



- Legislative Proposals to be adopted
- CHANGES in the way of working
- Identification of Cross-cutting substances
  Substance Identifiers
- Data Sharing/Data re-use
  STANDARD Data formats
  INCREASED interaction with sister Agencies/MS
- Towards Alignment Data Requirements and RA Methodologies:
  Joint Working groups / Joint Guidance

Q&A

5. Discussion / Questions and Answers

AGENDA OPEN SESSION – 16 NOVEMBER

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CONFIDENTIALITY ASSESSMENT IN THE CONTEXT OF FEED ADDITIVES

Federica BRUNO
Gunda KRIZ
Legal Affairs Services

EUROPEAN FOOD SAFETY AUTHORITY

UNDERLYING PRINCIPLES

- Proactive disclosure of application dossiers
- Confidentiality as exception to transparency
- Burden of proof on applicants
- Non-disclosure of information claimed confidential pending decision-making

PROCEDURAL REQUIREMENTS – CLOSED POSITIVE LIST - I

Confidentiality requests only on items on closed positive list

For the feed additives sector:

- **Article 18(3) of Regulation 1831/2003 - Sectoral legislation**

a. the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) of, and Annex I to Regulation (EC) No 1831/2003;

b. specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment;

PROCEDURAL REQUIREMENTS – CLOSED POSITIVE LIST - II

Article 39(2) of Reg 178/2002 - General Food Law

a. the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
b. commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
c. commercial information revealing sourcing, market shares or business strategy of the applicant;
d. quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;

PROCEDURAL REQUIREMENTS – CLOSED POSITIVE LIST - III

Article 39(e) of Regulation 178/2002

- 2. names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information
- 3. personal data in accordance with the provisions of Article 3(1) of Regulation (EU) No 2018/1725

NB: name and address of the applicant shall always be made public (Article 39e(1) of Regulation 178/2002)

CONFIDENTIALITY CLAIMS SUBSTANTIVE REQUIREMENTS

- **Identifying** clearly the information claimed confidential, by (i) referring to all elements claimed confidential (ii) locating them in the document (page/paragraph/line)
- Indicating the **legal basis (grounds)**
- **Explaining** why the item should be kept confidential

- Information **not publicly available**
- **Potential harm to a significant degree**
  - Information acquired legitimately
  - Negligible harm – rebuttable presumption
  - Novelty – rebuttable presumption
- Clarification on whether information claimed confidential falls under "**environmental information**" (Art 2 of Aarhus Regulation)

LESSON LEARNT – SUBMISSION OF DOCUMENTS – I

Confidential version and **public** version must **always be submitted and should match**

Earmarking of confidential version **should match blackening** of non-confidential version – invest in a good redaction tool that allows earmarking rather than highlighting confidential information

Ensure that **information claimed confidential in one part is not visible in another part** of the document

Use a **redaction tool which** ensures that the redacted information is **irreversibly blackened**

LESSON LEARNT – SUBMISSION OF DOCUMENTS – III

Do not include watermark 'confidential' on parts of documents that you do **not claim confidential**

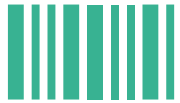
Properly name documents in order to distinguish between confidential and non-confidential version

Avoid confidential information in the file name of the non-confidential version

LESSON LEARNT – SUBMISSION OF DOCUMENTS – II

Where possible, **use redaction tools that have a proper earmarking functionality** and that allow you to save an earmarked version which could be easily modified and/or transformed into a redacted version

Whenever possible, perform **four-eyes checks** to ensure that you have correctly identified the all the items for which you are requesting confidential status



Where possible, **avoid using scanned documents**: they might hamper the search of the items you are willing to claim confidential

LESSON LEARNT – SUBMISSION OF DOCUMENTS – IV

Masking of personal data included in the submission of confidentiality requests

- ✓ Enables EFSA to support request by adopting a positive decision
- ✓ Personal data is sanitised in the non-confidential version published online

Masking of personal data is not included in the submission of confidentiality requests

- ✗ Personal data remains visible in the non-confidential version published online
- ✗ Applicant may be held accountable for any infringement of the rules

LESSON LEARNT – SUBMISSION OF CONFIDENTIALITY REQUESTS - I

Identify parts on which confidentiality is requested in a **clear and consistent manner**

Justification must support **elements earmarked/masked** as confidential in documents submitted

1

One confidentiality request per document per legal ground

LESSON LEARNT- SUBMISSION OF CONFIDENTIALITY REQUEST(S) - II

Quote the excerpt if short, otherwise **precisely identify** the location(s) of the information item(s) claimed confidential in the confidentiality request, at least by referring to the **name of the document**, **page** and **number of the paragraph**

Avoid claims like "throughout the document", "on all pages" if this is not the case

Tailored justification to each element claimed confidential based on the ground invoked (no copy-paste or generic justification), **referring to items in closed positive list**.

LESSON LEARNT- SUBMISSION OF CONFIDENTIALITY REQUEST(S) - III

Refer to the correct legal basis. When the qualification is not self-evident, **you must justify why this element falls under that legal basis**

No unfounded confidentiality requests or requests on **publicly available information**

Ensure all applicable **conditions** are ticked or **justification is provided**

SPEEDING UP THE PROCESSING TIMES

- Provide functioning e-mail address and ensure **business continuity** (e.g. referring to functional mailbox, ensure messages forwarded to colleagues in absence)

- **Faster reply** to EFSA`s requests for clarifications **=** **faster processing** of your confidentiality requests

- If you **agree with EFSA`s draft decision + reply immediately** to EFSA expressing explicitly your agreement **= faster issuance of the final decision**

IMPLEMENTATION OF THE CONFIDENTIALITY DECISION

Analysing the confidentiality decision and **identifying the conclusions on the confidential status of each item** claimed confidential by the applicant

- Only items granted confidential status are blackened
- Item for which a confidentiality request was rejected are disclosed

- **EFSA** carries out the sanitisation
- Applicants may submit amended documents on voluntary basis

FOCUS POINT: METHODS OF ANALYSIS

- **Confidentiality requests related to Methods of analysis** should be **submitted** under the dossier section **"Methods of analysis and reference samples"**
- Information related to company know-how **can be claimed under Article 39(2)(a) of Regulation (EC) No 178/2002** and not under Article 18(3)(a) or 18(3)(b) of Regulation (EC) No 1831/2003
- Note that the **reference to "methods of analysis" under Article 18(3)(b) refers specifically to the impurities of the active substance** and not to the general methods of analysis
- The **detailed protocol and the performance characteristics** (i.e. the outcome of the validation/verification) of the methods of analysis proposed for official control **are published in the EU Reference Laboratory (EURL) report** and therefore **cannot be claimed confidential**
- It is up to Applicants to only claim confidentiality for company know-how – CRs for **fully blackened documents will be rejected in their entirety**

FOCUS POINT: STUDY PLAN

- Article 18(3)(a) of Regulation (EC) No 1831/2003
  - The study plan for studies demonstrating the efficacy of a feed additive does not include results, conclusions or discussion – restrict claims to the actual study plan
  - Apply the same principle to safety studies

FOCUS POINT: NOTIFICATION OF STUDIES

- Reply timely to consultations on extract from notification of studies database
- Clearly indicate
  - The study to which the claim relates
  - The information claimed confidential
  - The column in which this information is located in the extract
  - The legal ground under which confidentiality is claimed
- Ensure the conditions listed in Article 10 of EFSA's Practical Arrangements concerning Transparency and Confidentiality are addressed

CHANGES MADE TO THE SUBMISSION TOOL I

- ✓ Submissions related to **FEED Additives Inconclusive opinions moved** from Portalino **to ESFC** on 27/07/2022

- ✓ **Partial acceptance/rejection** of a CR **now visible** in the Annex of the downloadable draft/final confidentiality decision (columns “EFSA considerations” and “EFSA decision”)

CHANGES MADE TO THE SUBMISSION TOOL II

✓ **Condition boxes layout and submission improved**

- labelling of conditions changed
- pop-up information to clarify conditions
- condition box “not publicly available” added
- justification field available if condition not satisfied

✓ **Fields** “potential harm”, worthiness of legal protection”, “environmental information” and “Novelty” **no longer required for CRs related to personal data**

REPLY TO QUESTIONS - I

"Are there any activities planned to facilitate the handling of the process related to the Confidentiality Assessment?"

- Concrete feedback is invaluable for optimizing the process
- Update of user guide on confidentiality

REPLY TO QUESTIONS - II

"Re the transparency matter the CFL (EC) No 178/2002 Article 39(2)(a) states:
the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety. As in-house analytical methods and their validation data are often integrated parts of the quality control of the manufacturing process and hence developed for such reasons, can analytical methods and their validation data be asked to be treated as confidential under the above article?"

- Confidentiality is granted to all in-house methods except for the type of method (UV, HPLC, etc)
- For internationally recognized methods, the reference/procotol number (e.g. EN/ISO number) should be disclosed

LUNCH BREAK

AGENDA OPEN SESSION – 16 NOVEMBER

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Update on Pre-application activities and Completeness check of Feed additives applications

170th Plenary meeting of the FEEDAP Panel

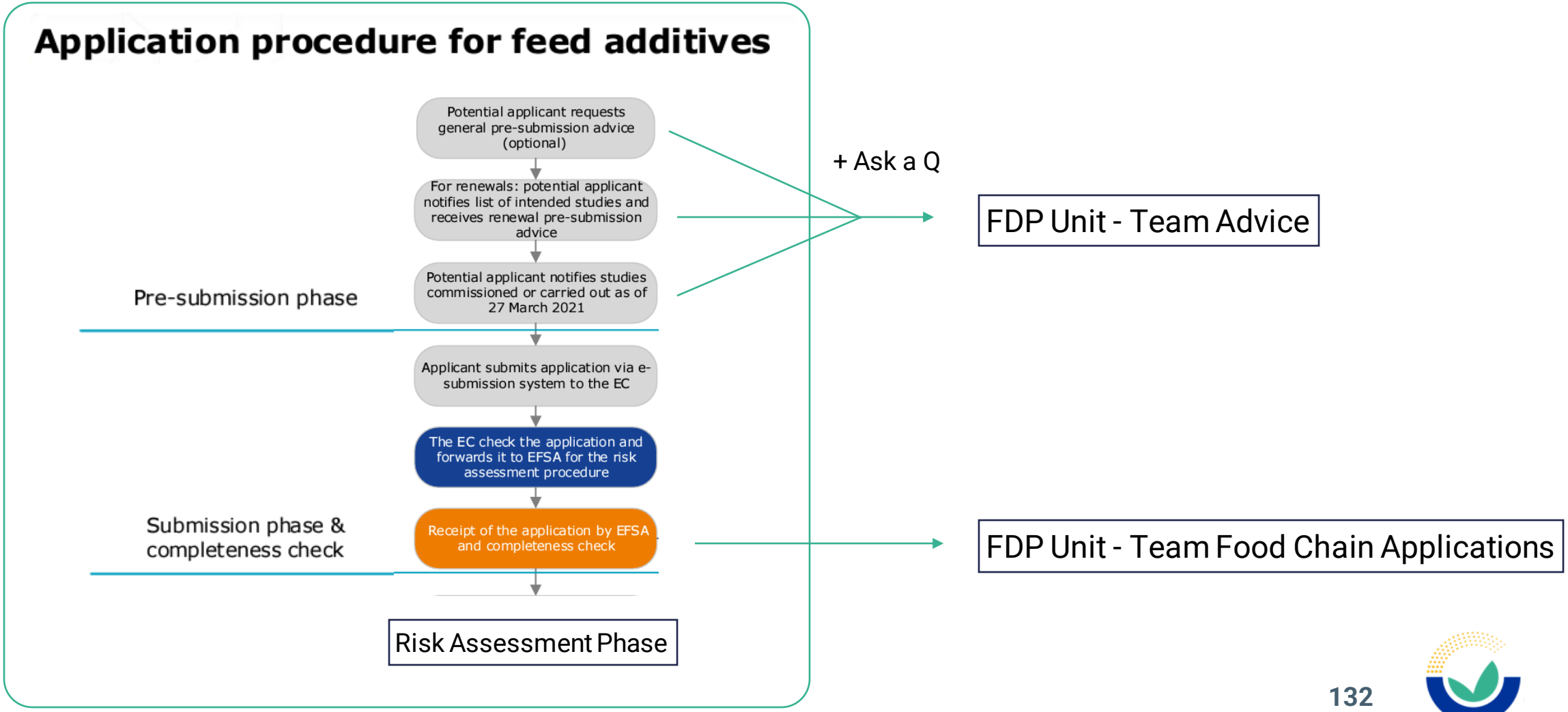
16/11/2023

Irene BARATTO and Oscar GONZALEZ

Front-Desk & Workforce Planning Unit

EUROPEAN FOOD SAFETY AUTHORITY

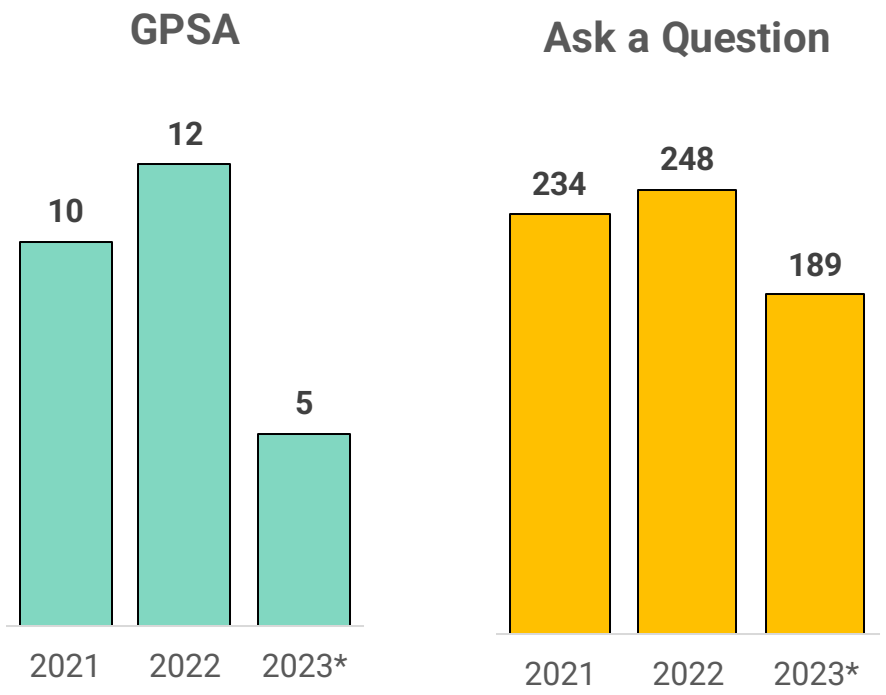
OUTLINE OF THE PRESENTATION



Pre-submission phase & Ask a Question

GENERAL PRE-SUBMISSION ADVICE AND ASK A QUESTION

Trend - GPSA requests and Ask a Question received on FEED ADDITIVES since 27/03/21



* 2023: data as of 9/11/23

- Potential applicants are encouraged to request EFSA's support via the GPSA to solve their questions while preparing an application.
- Requesters* are mostly satisfied with the service provided:
  - quality of the response: 86%
  - timeliness of the response: 75%

  Suggestions for improvement are being analysed
- Pilot ongoing on specific measures for SMEs
  - Faster service (half of the standard time)
  - Advice provided preferably in a tele-meeting

* Results referred to all the food domains (satisfaction survey is anonymus)

HOW TO ADDRESS QUESTIONS TO EFSA: GPSA & ASK A QUESTION

General Pre-submission Advice

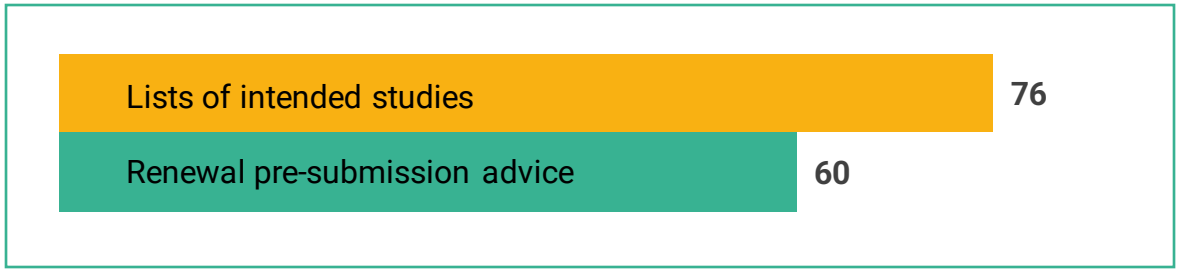
- Available for all kind of applications. Even if non mandatory, it is highly recommended
- Can be requested any time before submitting the application
- Written advice given within 30 working days, 35 if in a tele-meeting. Half of the time if requester is an SME
- Only a succinct summary of the advice is published together with the application upon its validation
- Non-committal for the applicants nor for EFSA and its Scientific Panels

Ask a Question

- Not necessarily related to an application
- Can be requested any time, not only before submitting the application
- Written replies within 15 working days. 7 for question submitted by an SME
- Questions out of scope are those related to rules and content for a future application and to risk management and interpretation of EU legislation

RENEWAL PRE-SUBMISSION ADVICE (RPSA)

Lists of Intended studies submitted and RPSA provided since 27/03/21



Highlights on RPSA requests (Article 32c(1) GFL) following the update of the Q&As on Practical Arrangements

- Applicants should consider to submit analyses to assess the identity/composition of a product and analyses to determine physico-chemical properties as part of the list of intended studies in order to benefit of the RPSA
- Before commissioning/starting such analyses, there is no need to notify them with a view to comply with Article 32b of the GFL, since they are exempted from study notification obligations

NOTIFICATION OF STUDIES

Highlights on Notification of studies following the update of the Q&As on EFSA's Practical Arrangements

- The update has been made building upon the practical experience to date with a view to the continuous enhancement of the implementation of Article 32b GFL, in particular with respect to ensuring an appropriate balance with the administrative requirements which need to be satisfied by applicants and the need for EFSA to have prior knowledge of the studies performed by an applicant
- Certain analytical measurements are exempted from notification of study obligations (Question 4): analyses to assess the identity/composition of a product, including the determination of its impurities and whole genome sequencing, and analyses to determine physico-chemical properties
- For those analytical measurements that have been previously notified: **no need for the applicants to withdraw those notifications** from Connect.EFSA (EFSA will not check anymore the notified information).
- For questions on the Q&A update, please contact EFSA via the Ask a question tool

Completeness Check

Completeness Check

- **STEP 1** - Reception: Processing dossier
- **STEP 2** – Completeness check
- **STEP 2.1** - Request for missing information
- **STEP 2.2** - Reception of missing information
- **STEP 3** - Validation of the application

COMPLETENESS CHECK – SCOPE AND REMITS

Guarantee high quality applications checking the compliance with relevant EFSA Guidance documents and Regulations.
Duration of 30 wds plus Requests for Information (RFI), if necessary.

Administrative compliance[1]

- Administrative data complete and correct
- Dossier correctly structured
- IPR information
- Accessibility of documents
- Categorisation of documents

Scientific compliance[2]

- Scientific data complete and in line with the requirements
- Consistency of scientific data

Sanitization of confidential and personal data[3]

- Permanent and consistent sanitization of documents
- Personal data not visible in public version

NoS obligations compliance[4]

- Compliance with the requirements and consistency with EFSA NoS database
- Justifications for notified studies not included or withdrawn
- Justifications for studies not notified or notified in delay

[1] Administrative guidance for the preparation of applications on additives for use in animal nutrition
[2] EFSA Scientific guidance documents
[3] Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain
[4] Regulation (EC) No 178/2002 (Art.32b)

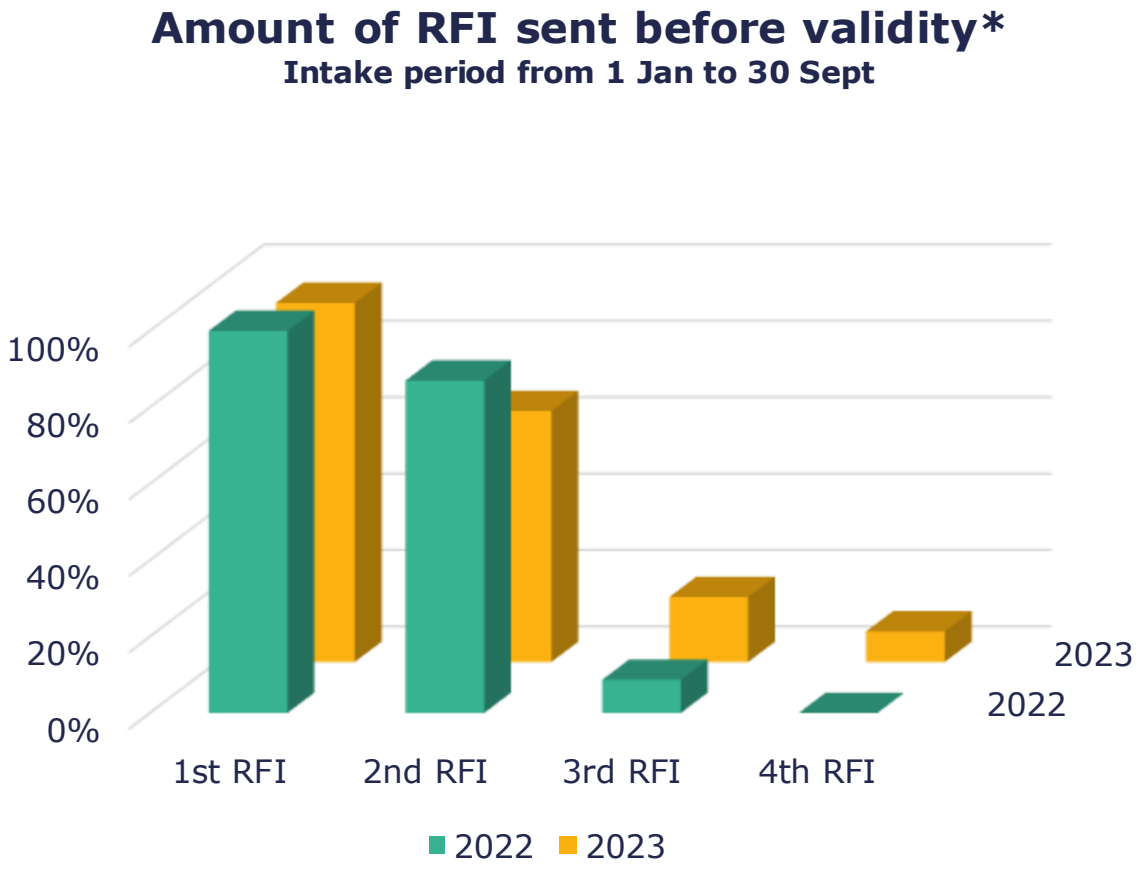
FEED APPLICATIONS TREND INTAKE PHASE 2022 AND 2023

Year	Withdrawal	Non Validity	Requests for extensions of deadlines	Clarification teleconferences
2022	1	2	34%	1
2023	0	0	28.5%	6

- Decreased average time from receipt to validation of an application from **96 days** (intake Jan-Sept 2022) to **87 days** (Jan-Sept 2023).

(1) Validated in the period until 15 of November

ISSUES DURING COMPLETENESS CHECKS – REQUESTS FOR INFORMATION (RFI)



Year	First RFI	Second RFI	Third RFI	Fourth RFI
2022	100%	87%	8.7%	0%
2023	94%	65.7%	17%	8%

- The average number of RFI sent per application was **1.95** in 2022 period, while, in 2023, it decreased to **1.25**.
- The main topics of an RFI are still: sanitization of documents, NoS obligations and IPR/admin issues.

*Referred to applications validated in the periods from 1 Jan to 31 Oct 2022 and 2023

SUBMISSION OF COMPLEMENTARY INFORMATION FOLLOWING EFSA INCONCLUSIVE OPINION

- New workflow in ESFC in place since **June 2023**
- Since June 2023, all submissions have been received through ESFC
- Portalino is still in place for submissions uploaded before June 2023 and not yet finalised
- From 1 Jan 2023 to 31 Oct 2023: **19** submissions received; **18** have been validated

QUESTIONS AND ANSWERS RECEIVED IN ADVANCE

"In the last update of August 2023 of the Questions and Answers on EFSA's Practical Arrangements, it is mentioned that analyses to assess the identity/composition of a product and physico-chemical properties don't need anymore to be notified on EFSA portal.

- *Please could you confirm when this statement is applicable?*
- *Do you plan to update the practical arrangements?*

QUESTIONS AND ANSWERS FROM THE AUDIENCE

STAY CONNECTED

Visit the **Toolkit** page with the **Highlights** section to stay updated on the IT portals

Join our **LinkedIn group** for information and news

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NEW APPROACH METHODOLOGIES (NAMS): CASE STUDY ESSENTIAL OILS AS FEED ADDITIVES

FEEDAP Plenary meeting - Open session

16 November 2023

Paola Manini

EUROPEAN FOOD SAFETY AUTHORITY

EFSA ONGOING PROJECTS ON NAMS

NAMS4NANO: EFSA NAMs roadmap data integration nanomaterials

(case studies and guidance)

Practical implementation NAMs - RA of pesticide metabolites

(QSAR and read across)

Environmental neurotoxicants (testing for DNT and NT in in vitro assays)

AOP for ED

New approach methodologies for RA of chemicals in food (ADME4NGRA)

Inter-human variability in toxicodynamic

Integrating new approaches in chemical risk assessment

(case studies)

Protein Safety

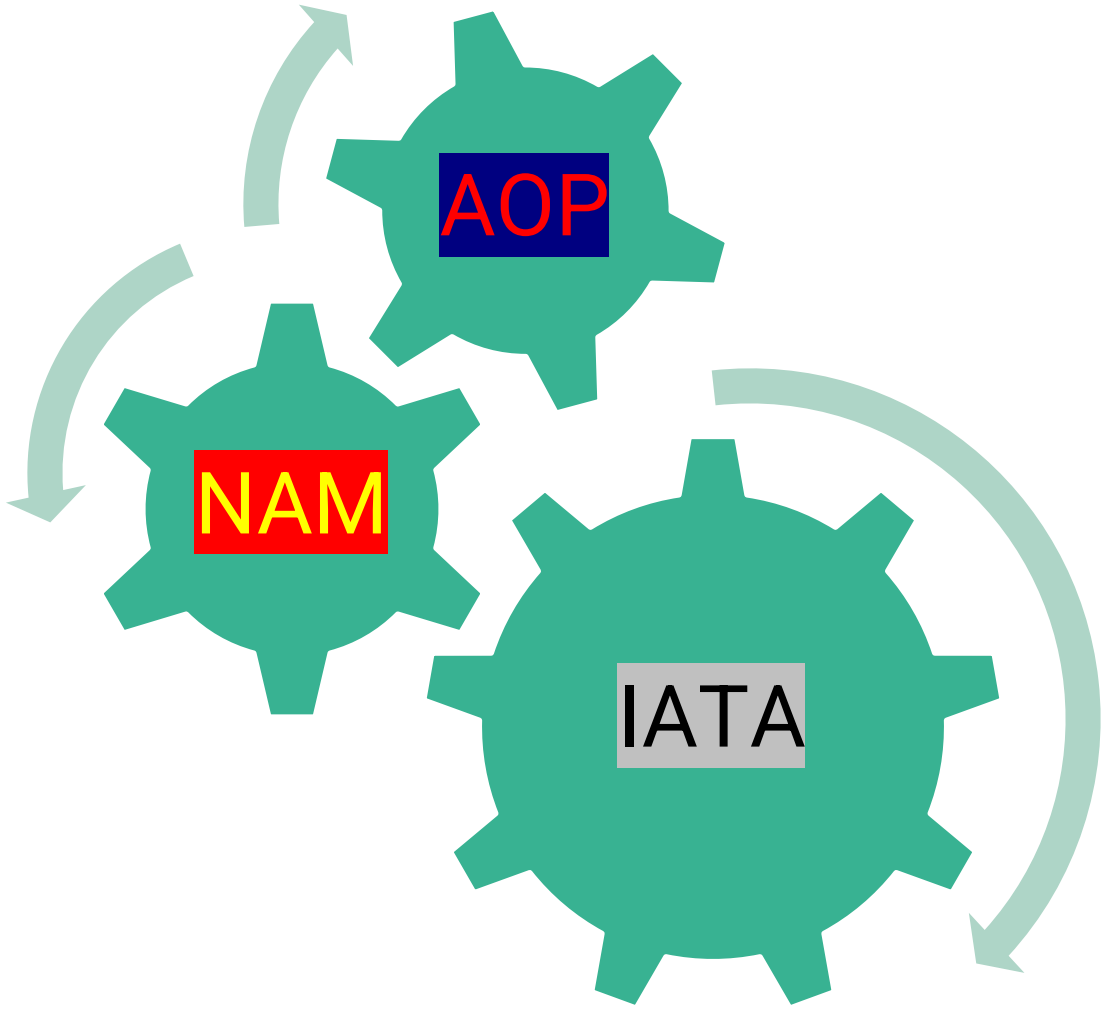
TGX-MAP

(translational quantitative TG mechanism based AOP mapping for human NAM based RA)

Brian Health

(NAMs to study developmental glial cell toxicity)

A COMMON APPROACH AND TANGIBLE OUTCOMES



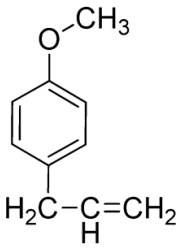
- **Fill data gaps** in chemical risk assessment without generating new *in vivo* data (NAMs case studies)
- Move towards a **mechanistic-based risk assessment** (NAMs case studies)
- Enhanced **acceptance/confidence to use NAMs data**, IATA and biomarker data in the derivation of Health Based Guidance Values
- Promote internationally **harmonised guidance** (use IATA as a best practice reference)
- Minimise/replace **animal testing**

RE-EVALUATION OF BOTANICAL FEED FLAVOURINGS

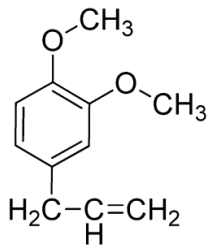
- The FEEDAP Panel is currently (re)-evaluating about **200 botanical preparations** (essential oils, oleoresins, extracts, tinctures) as feed additives
- About **30%** of the preparations contains substances that are both genotoxic and carcinogenic, e.g. *p*-allylalkoxybenzenes (estragole, methyl eugenol, safrole, elemicin, myristicin, etc.), with concentrations ranging from 0.001% to >10%
- Other preparations from *Citrus* species contain furocoumarins (<1%) and perillaldehyde (~0.02%)

P-ALLYLALKOXYBENZENES

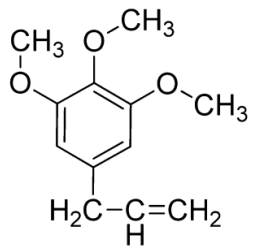
- Genotoxic and carcinogenic compounds
- *p*-Allylalkoxybenzenes induce DNA adducts with different potency
- Estragole, methyleugenol, and safrole induce liver cancer in rodents at high doses
- *p*-Allylalkoxybenzenes are present in herbs and spices (fennel, basil, nutmeg, anise, etc.), essential oils and foods
- Human background exposure exist



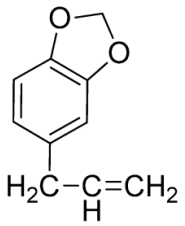
Estragole



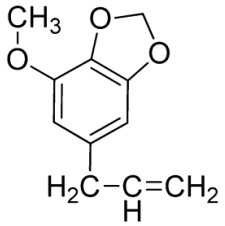
Methyleugenol



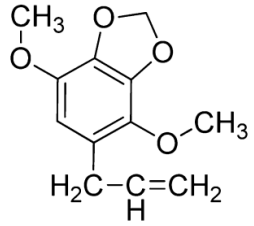
Elemicin



Safrole



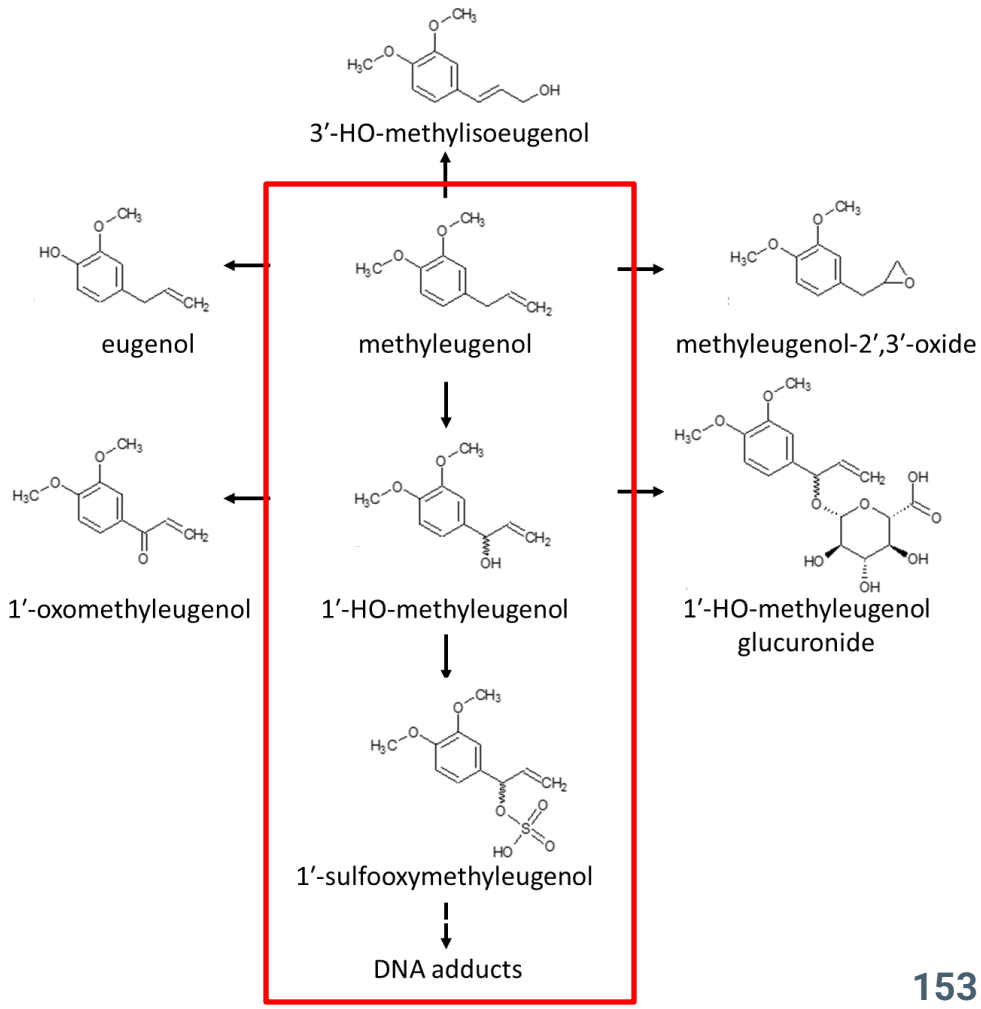
Myristicin



Apiole

METABOLIC ACTIVATION OF *P*-ALLYLALKOXYBENZENES

- Bioactivation pathway
  - Hydroxylation by CYP450 enzymes
  - Conjugation with sulfate catalysed by SULTs
  - Unstable sulfate-conjugate
  - Formation of a carbocation responsible for DNA adducts
- Other metabolic pathways represent detoxification



THE FEEDAP GENERAL APPROACH

- General approach to assess the **safety for the target species** of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as feed additives

  https://www.efsa.europa.eu/sites/default/files/2021-05/general-approach-assessment-botanical-preparations-containing-genotoxic-carcinogenic-compounds.pdf

  Endorsed by the FEEDAP Panel during the 153rd Plenary meeting of 17-18 March 2021, after consultation of the SC in November 2020

- **Three possible scenarios** identified depending on the availability of data from carcinogenicity studies in rodents from which a $BMDL_{10}$ can be derived
  - The margin of exposure (MOE) approach
  - The threshold of toxicological concern (TTC) of 0.0025 µg/kg bw per day for DNA-reactive mutagens and/or carcinogens
  - A comparative intake from other dietary sources

  In all cases: indicative of low concern, low probability of risk

SCENARIO I: MARGIN OF EXPOSURE (MOE) APPROACH

a) For substances for which carcinogenicity studies in rodents are available, from which a $BMDL_{10}$ can be derived, the MOE approach (EFSA, 2005; EFSA SC, 2012) can be applied

   i. Similar to human risk assessment, a combined (total) margin of exposure (MOET) ≥ 10,000, when comparing estimated exposure to genotoxic and/or carcinogenic substances with a $BMDL_{10}$ from a rodent carcinogenicity study, would be indicative of a low concern for the target species (EFSA SC, 2019a)

   ii. an MOE(T) > 100 when comparing estimated exposure with a reference point based on non-neoplastic endpoints is considered more appropriate more appropriate for **animals for fattening**, which are maintained for less than one third (or 20%) of natural lifespan

Applied to preparations containing *p-allylalkoxybenzenes* (estragole, methyleugenol, safrole, etc.)

THE REFERENCE POINT FOR MOE(T) APPROACH

A group $BMDL_{10}$ for *p*-allylalkoxybenzenes

- The FEEDAP WG on feed flavourings examined the available data (carcinogenicity studies, DNA adducts) for *p*-allylalkoxybenzenes (estragole, methyleugenol, safrole, myristicin, elemicin, apiole, dillapiole)
- The data indicate differences in the potency (i.e., methyleugenol >safrole >estragole >myristicin >elemicin >dillapiole) but do not allow do not allow to derive relative potency factors: all compounds considered ***equally potent***
- In a worst-case scenario, the FEEDAP Panel selected the $BMDL_{10}$ of 22.2 mg methyleugenol/kg bw per day, derived from a carcinogenicity study in rat (NTP, 2000) by applying model averaging, as ***reference point for the group***

CONSUMER SAFETY: PRINCIPLES

- *p*-Allylalkoxybenzenes are **naturally present** in plants and are extracted during the manufacturing of essential oils
- Parts of plants (e.g. fruit) used as spices and their essential oils are added to a wide range of food categories for flavouring purposes
- The EFSA SC recommends that "*in principle substances which are both genotoxic and carcinogenic should not be deliberately added to foods or used earlier in the food chain if they leave residues which are both genotoxic and carcinogenic in food*" (EFSA, 2005)
- This is reflected in the FEEDAP general approach: "*Precondition for the applicability of this approach is the availability of ADME/residue data for the food-producing animal species to consider possible carry-over of genotoxic and/or carcinogenic substances to the animal-derived food products in the assessment of consumer safety* (EFSA FEEDAP Panel, 2021)"

CONSUMER SAFETY: CURRENT APPROACH

- No data on **residues** in products of animal origin are available for botanical flavourings, however the absence of residues is linked to the sensitivity of the analytical method used (< limit of detection/quantification)
- Unrealistic assessment assuming that residues are present at the LOD
- The assessment of consumer safety is based on **assumptions:**
- The individual components are extensively metabolised and are not expected to accumulate in tissues and products
- No increase of human background exposure
- This assumption is also applied to methyleugenol, safrole and estragole, based on the evidence available on the absorption, distribution, metabolism and excretion in laboratory animals
- **New approach methodologies (NAMs)** to fill the data gaps and inform the risk assessment of combined exposure to multiple chemicals

NAMS: CASE STUDY ON ESSENTIAL OILS

- Contract title: Case Studies NAMs_ Essential oils as feed additives
- Contract Number: OC/EFSA/SCER/2021/14
- Contractor: Wageningen Food Safety Research
- Status: *ongoing*
- Project kick-off meeting: 24 January 2022
- Duration: 2 years
- Interim meetings (4) with the participation of experts
- Final report: end of November 2023
- Final workshop: January 2024

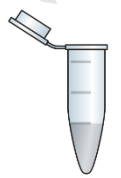
GOALS OF THE PROJECT

- Design and conduct a set of NAM-based experimental studies, using an IATA (Integrated Approach to Testing and Assessment)
  - assess qualitative and quantitative differences and similarities in metabolic competences across different species (food-producing animals and cats) by generating ***in vitro* metabolism data**
  - assess potential matrix modulation of the bioactivation
  - *in vitro* to *in vivo* extrapolation of the results using **physiologically based kinetic (PBK) models** and making the comparison among species
- Prioritised compounds: estragole, methyleugenol, safrole, elemicin and myristicin
- Prioritised species: chicken, pig, cow, rat, human, cat
- Prioritised compounds to study matrix effects: terpenes (limonene, α-pinene, 1,8-cineole)

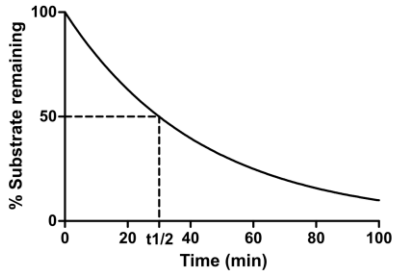
NAMS: EXPERIMENTAL PROTOCOL

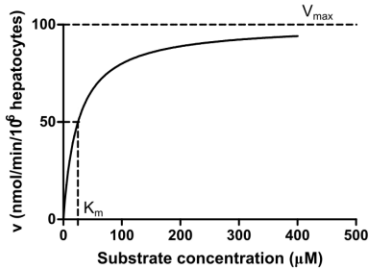
substrate

S9 or microsomes+cofactors or primary hepatocytes



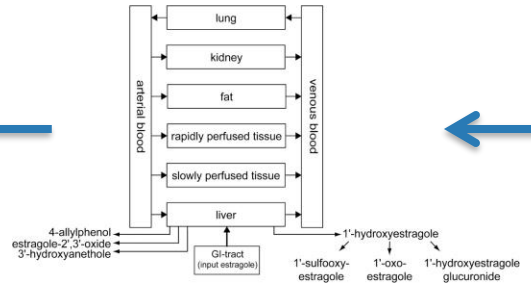
Incubation 37°C





Metabolic rate constants

+ physiological parameters
+ partition coefficients



PBK models for the different species

Predictions:

- Formation reactive metabolite(s)
- Species differences
- Transfer from feed to food
- Relative potency among *p*-allylakoxybenzenes
- Matrix modulation

Liver samples (rat, human, pig, chicken, bovine and cat) CYP450 enzyme activity tested, quality check

Synthesis of metabolites (1'-hydroxy- and 1'-acetoxy as surrogate for 1'-sulfooxy-metabolite)

Phase I and Phase II metabolism: 1'-hydroxylation and 1'-sulfonation

APPLICATION TO THE RISK ASSESSMENT OF BOTANICALS

The results will be used to **inform/refine** the risk assessment of feed additives containing *p*-allylalkoxybenzenes with respect to

I. the species differences in the formation of the sulfate conjugate, with special attention to cats
II. the transfer of the compounds and their 1'-hydroxymetabolites from feed to food, including milk and eggs
III. the differences in the relative potency of the different *p*-allylalkoxybenzenes
IV. the effect of other constituents of the mixture on bioactivation
V. the uncertainty in the results obtained

AGENDA OPEN SESSION – 16 NOVEMBER

No.	ITEM
16.	Update of the Guidance on the assessment of the efficacy of feed additives
17.	Chemicals Strategy for Sustainability and One Substance One Assessment – Impact to EFSA
18.	Update on the confidentiality assessment of feed additives' applications
19.	Update on pre-application activities and completeness check of feed additives applications
20.	AOB/General EFSA activities
20.1	NAMs
21.	Questions & Answers
22.	Closure of meeting

QUESTIONS & ANSWERS

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END OF MEETING

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