5 and 6 June 2024

WELCOME TO THE OPEN SESSION OF THE 174TH PLENARY OF THE FEEDAP PANEL

EUROPEAN FOOD SAFETY AUTHORITY

174TH PLENARY OF THE FEEDAP PANEL

Chair: Prof. Vasileios Bampidis

EUROPEAN FOOD SAFETY AUTHORITY

AGENDA OPEN SESSION – 5 JUNE

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8.	Welcome and Apologies for absence
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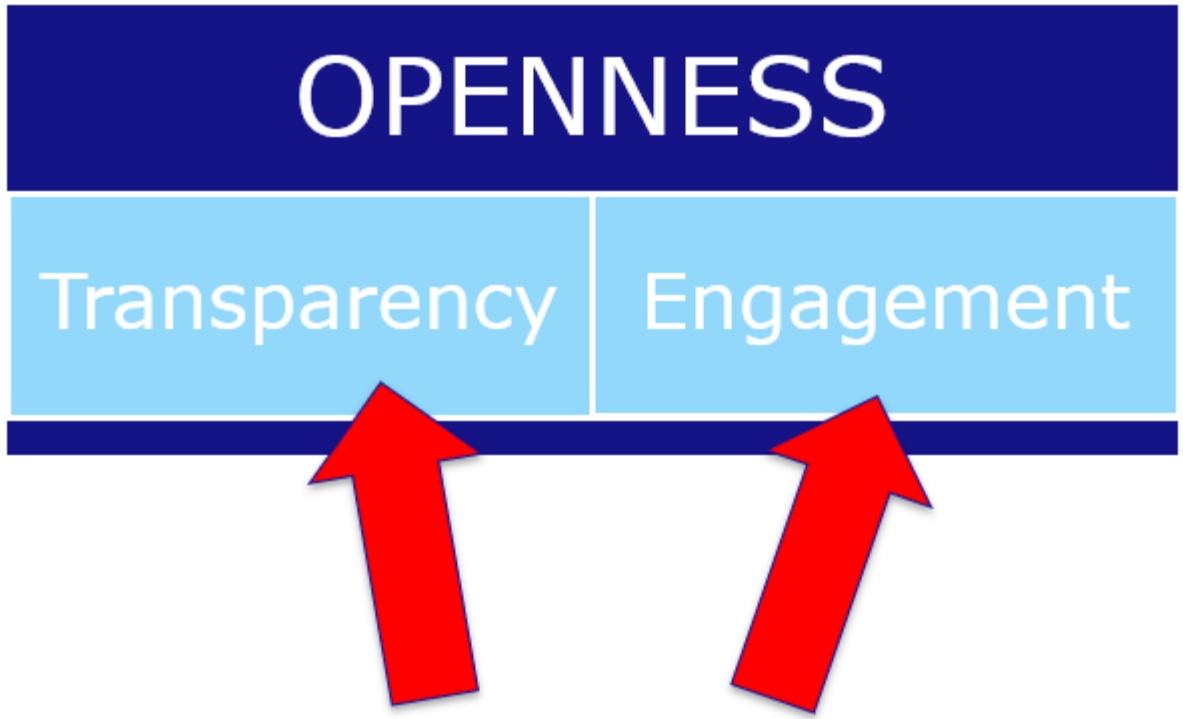
GUIDELINES FOR OBSERVERS FOR OPEN PLENARY MEETINGS

EUROPEAN FOOD SAFETY AUTHORITY

EFSA STRATEGIC OBJECTIVE



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 only be obtained through the meeting minutes** that will be published on the EFSA website.
- EFSA does its best to ensure the quality of 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 OBSERVERS CONNECTED ONLINE

- 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 of forward the link to anyone else, as this may lead to unauthorised remote access.

- Should you notice anything abnormal or unexpected in the course of your connection to the EFSA meeting, please contact the Meeting Moderator via the chat.

GUIDELINES FOR OBSERVERS FOR OPEN PLENARY MEETINGS

Q&A sessions:

- The Panel Chair may grant Observers the opportunity to ask questions either after a discussion on a given topic, or at the end of the day, or at the end of the OPEN Plenary meeting, on other topics which fall within the remit of the Panel.
- During the meeting, Observers are invited to post their question into the chat box.
- Priority will be given to questions submitted at the time of registration. Additional questions raised during the meeting may be addressed, if time permits, in the order of submission.
- Questions posted in the chat box not answered during the meeting, will be answered in the Minutes of the Plenary.
- If Observers have questions after the OPEN Plenary, they are invited to submit their questions to EFSA through the #AskEFSA service on the EFSA website.

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ON-GOING ACTIVITIES IN RELATION TO APPLICATIONS: UPDATES FROM FDP UNIT

Team Advice and Team Applications
Food Chain

FDP Unit

05/06/2024

EUROPEAN FOOD SAFETY AUTHORITY

OVERVIEW

Pre-submission phase and support to applicants

- LinkedIn campaign on tools – trend in GPSA
- Communication to applicants – request for WGS data in Completeness Check
- Upcoming support initiatives for feed applicants

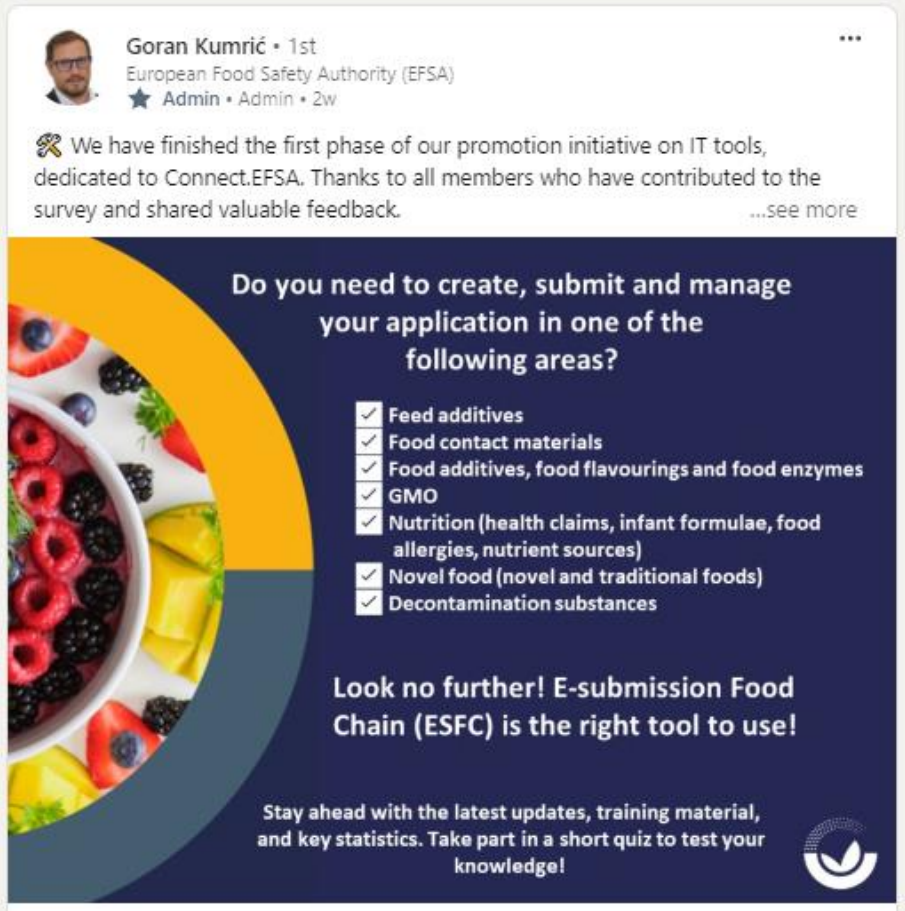
Intake phase

- Trends in applications received 2023-2024
- Completeness check status (average time for CCs and RFI analysis)
- New naming convention for applications subject

Pre-submission phase & Support to Applicants

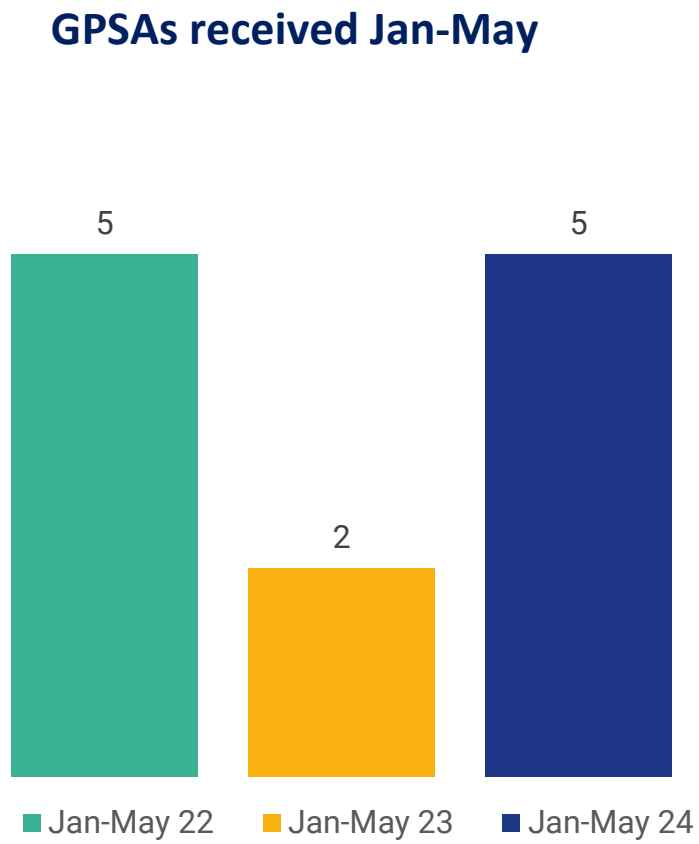
LINKEDIN CAMPAIGN ON TOOLS - CONNECT.EFSA

LINKEDIN CAMPAIGN ON TOOLS - ESFC



TREND IN GENERAL PRE-SUBMISSION ADVICE

- 5 GPSA requests in FEED received so far this year (same amount than in Jan - Dec 2023)
- Change in the trend after communication campaign in LinkedIn – Support to applicants channel



COMMUNICATION TO APPLICANTS: REQUEST FOR WGS

16/04 – EFSA communicates to applicants the request to submit WGS as of 01/05

EFSA will request applicants to submit whole genome sequence data **during the completeness check / suitability check** phase:

- applications involving microorganisms in FEED, GMO, FIP, Novel foods and Nutrition
- applications submitted as of 1 May and those submitted before, but 1st RFI is not issued yet on 1 May
- WGS data may be granted confidential status

1st RFI -

Reactions from applicants:

- Letter from **AMFEP, FEFANA and EuropaBio** on 19 April, replied via email 16 May + ad-hoc meeting 29 May
- Five web queries via **Ask EFSA**

UPCOMING SUPPORT INITIATIVES FOR FEED APPLICANTS

EFSA Administrative Guidance on Feed Additives:

Imminent update:

- Assessment of feed additives consisting of or containing nanoparticles (171st Plenary meeting of the FEEDAP Panel)
- Additional clarification based on questions received and experience in completeness check (applicable to all food domains)

FDP participation in sectorial events targeted to FEED applicants:

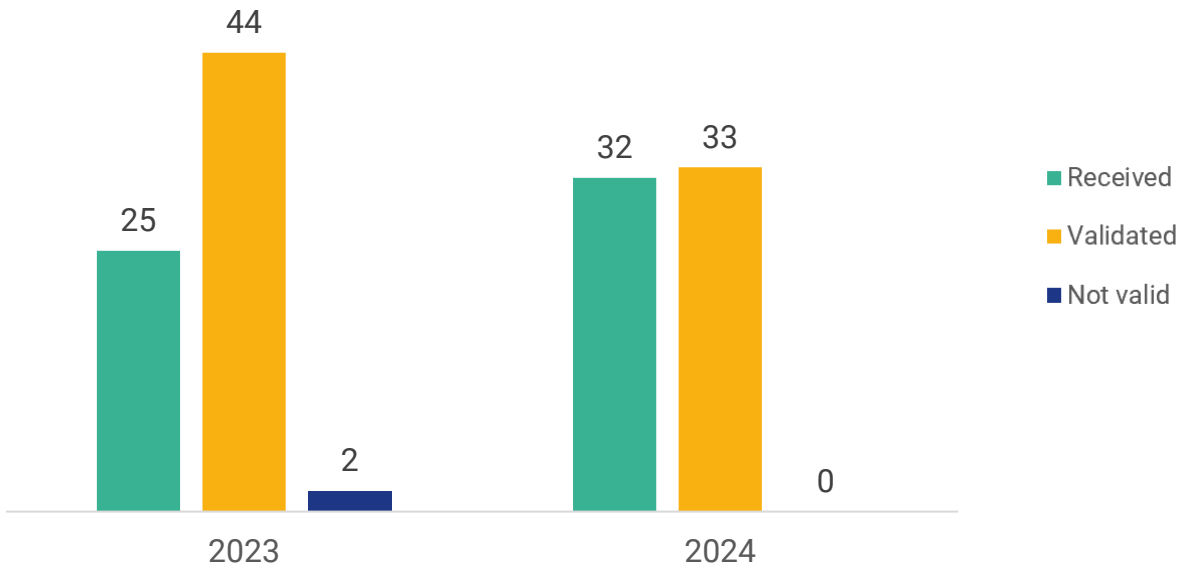
- **FEDIAF** Annual Congress (13 June) – online presentation on ***EFSA services to support applicants***
- FDP is open to present in sectorial events attended by FEED applicants, particularly in those with a significant participation of SMEs

Completeness Check

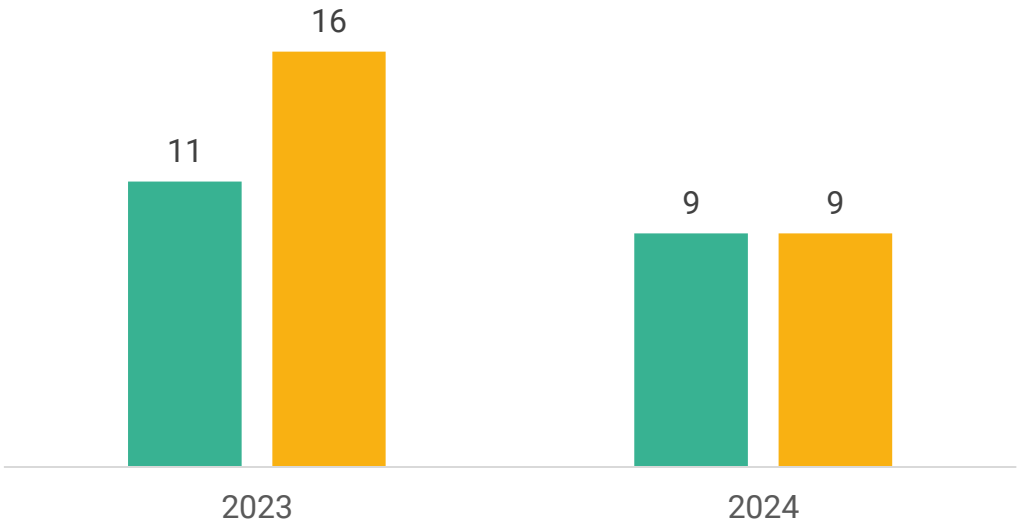
APPLICATIONS TREND 2023-2024

FEED applications

Data from the 1st January to 3rd of June



Data submissions after EFSA inconclusive opinion

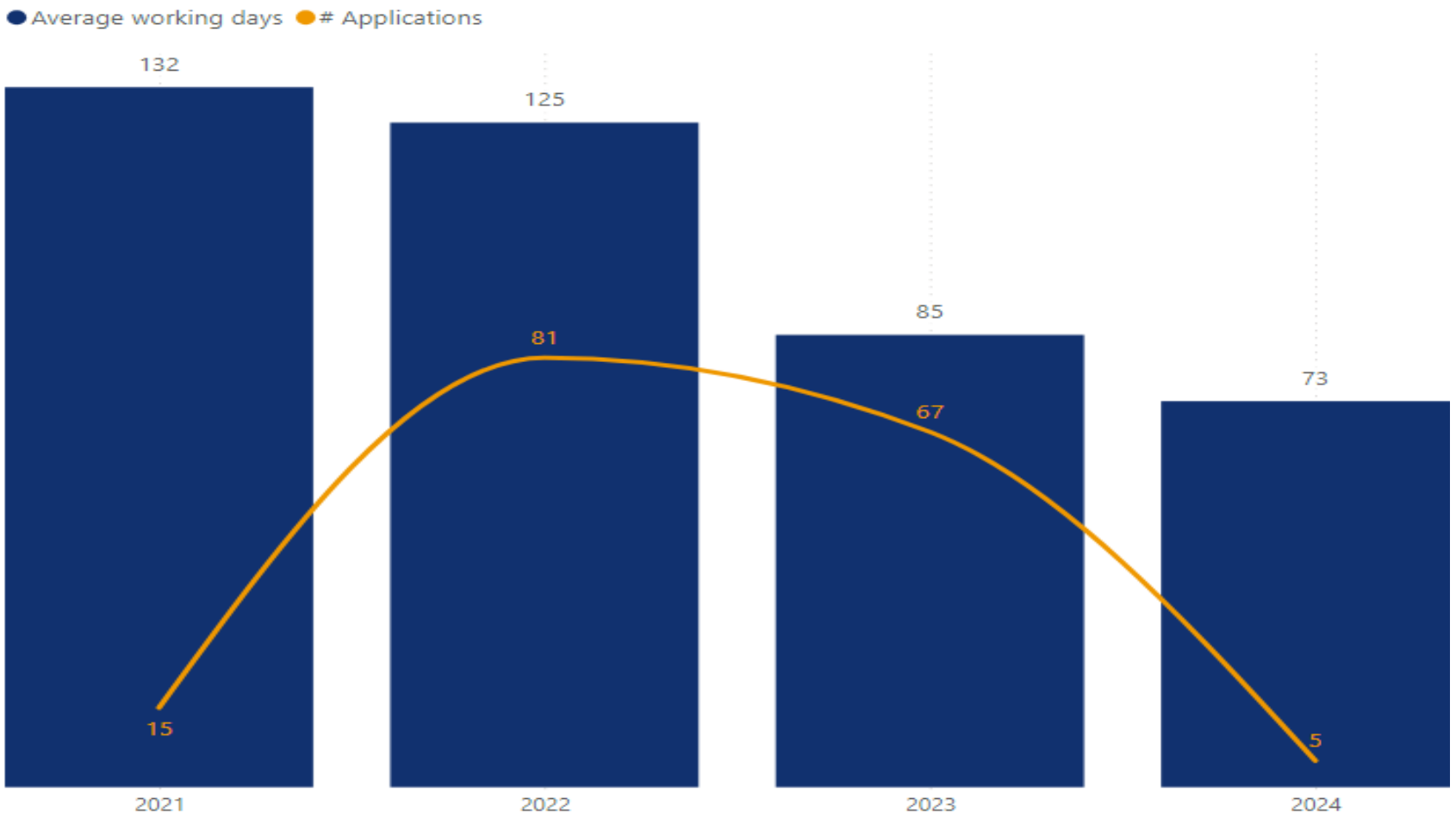


FEED applications under CC: 27

Data submissions under CC: 0

AVERAGE WORKING DAYS FROM RECEPTION TO VALIDATION

Average working days from reception to validation over the years



NEW NAMING CONVENTION FOR FEED APPLICATIONS SUBJECT

From May 2024 a new naming convention has been applied for applications subject in Open.EFSA. All post-Tr applications subjects have been updated.

Information displayed in the applications subject:

- Active substance name (Trade name for Coccidiostats and Histomonostats only)
- EC ID authorisation number for additives already authorised
- Producing strain latin name and strain number, if applicable
- Feed additive categories
- Target species
- Regulation article

Example: *Application for L-isoleucine (EC ID XXXXX) produced with Genus species (Deposit number) as a nutritional additive for all animal species [article 13].*

STAY CONNECTED

Join our LinkedIn group:

"EFSA support to applicants"

A space where you will find:

- Information and support materials
- Updates on the developments and progress of IT tools and platforms
- Alerts on new training material and upcoming events
- Clarifications to the most frequently asked questions received by applicants
- A space for interaction with your peers

https://www.linkedin.com/groups/9083910/

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CONFIDENTIALITY ASSESSMENT IN THE CONTEXT OF FEED ADDITIVES

5 JUNE 2024

Francesca VOLPI
Gunda KRIZ
Legal Affairs Services

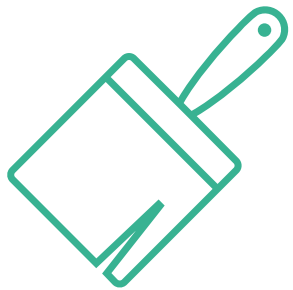
EUROPEAN FOOD SAFETY AUTHORITY

LESSONS LEARNT – SUBMISSION OF DOCUMENTS – I

Earmarking of confidential version **should match blackening** of non-confidential version

Invest in a **good redaction tool** that facilitates the task

LESSONS LEARNT – SUBMISSION OF DOCUMENTS – II



Use redaction tools that have a proper earmarking functionality and allow you to save an earmarked version which can easily be transformed into a redacted version

Avoid yellow/red highlights in the confidential version

LESSONS LEARNT – SUBMISSION OF CONFIDENTIALITY REQUESTS - I

1

One confidentiality request (CR) per document per legal ground

Choose legal ground that fits information best

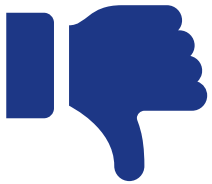
Do not select each legal ground that could be applicable

LESSONS LEARNT- SUBMISSION OF CONFIDENTIALITY REQUESTS - II

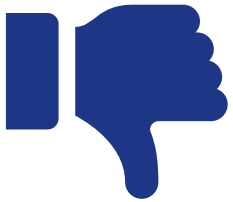
Confidentiality Excerpt and Section:

Provide a direct quote if very 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** (rather than % of page).

LESSONS LEARNT- SUBMISSION OF CONFIDENTIALITY REQUEST(S) – II CTD



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



Avoid repeating the same information under ‘Excerpt and ‘Section’

LESSONS LEARNT- SUBMISSION OF CONFIDENTIALITY REQUEST(S) – II CTD

✓ **Example 1**

- **Excerpt:** 'Joe Black, ADM Research Analytical Manager'
- **Section:** Pages 1, 3 and 5

✓ **Example 2**

- **Excerpt:** 'names, email addresses and signatures'
- **Section:** Pages 1 to 22

✓ **Example 3**

- **Excerpt** 'According to the Commission Regulation (…) already authorized as feed additives'
- **Section:** 'Section 2.1, page 3, paragraph 2 to page 4 paragraph 5'

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 and speeding up risk assessment process

- If you **agree with EFSA`s draft decision + reply immediately** to EFSA expressing explicitly your agreement **= faster issuance of the final decision - EFSA indicates 2 deadlines in notification email**

ONE DOSSIER, TWO PROCESSES!

CONFIDENTIALITY ASSESSMENT (CA) PROCESS

RISK ASSESSMENT (RA) PROCESS

- run in parallel
- ensure reply concerns the correct process
- resubmission of documents not possible via ESFC for CA process

CLARIFICATION: CONFIRMATORY APPLICATION

CONFIRMATORY APPLICATION = APPEAL AGAINST FINAL CONFIDENTIALITY DECISION

- Click ‘Start confirmatory application’ button in **ESFC if you wish to appeal**
- **Email** confidentialityrequestassessment@efsa.europa.eu **if** wish to confirm that **you agree** with the confidentiality decision

STEPS TAKEN BY EFSA TO PROVIDE BETTER GUIDANCE

- ✓ Update of communication templates
- ✓ Collaboration with DG SANTE to improve ESFC user experience

Suggestions for improvement welcome

UPDATE: NOTIFICATION OF STUDIES

SPEEDING UP THE PROCESS

- ✓ **Where all confidentiality requests on NoS extract are approved**, no longer separate (draft/final) decision
- ✓ Outcome of assessment communicated in notification email for draft and final decision

GENERAL UPDATE: EFSA ACTIVITIES

AVOIDING MISUNDERSTANDINGS

- ✓ Update of communication templates
- ✓ Collaboration with DG SANTE to improve ESFC user experience

Suggestions for improvement welcome!

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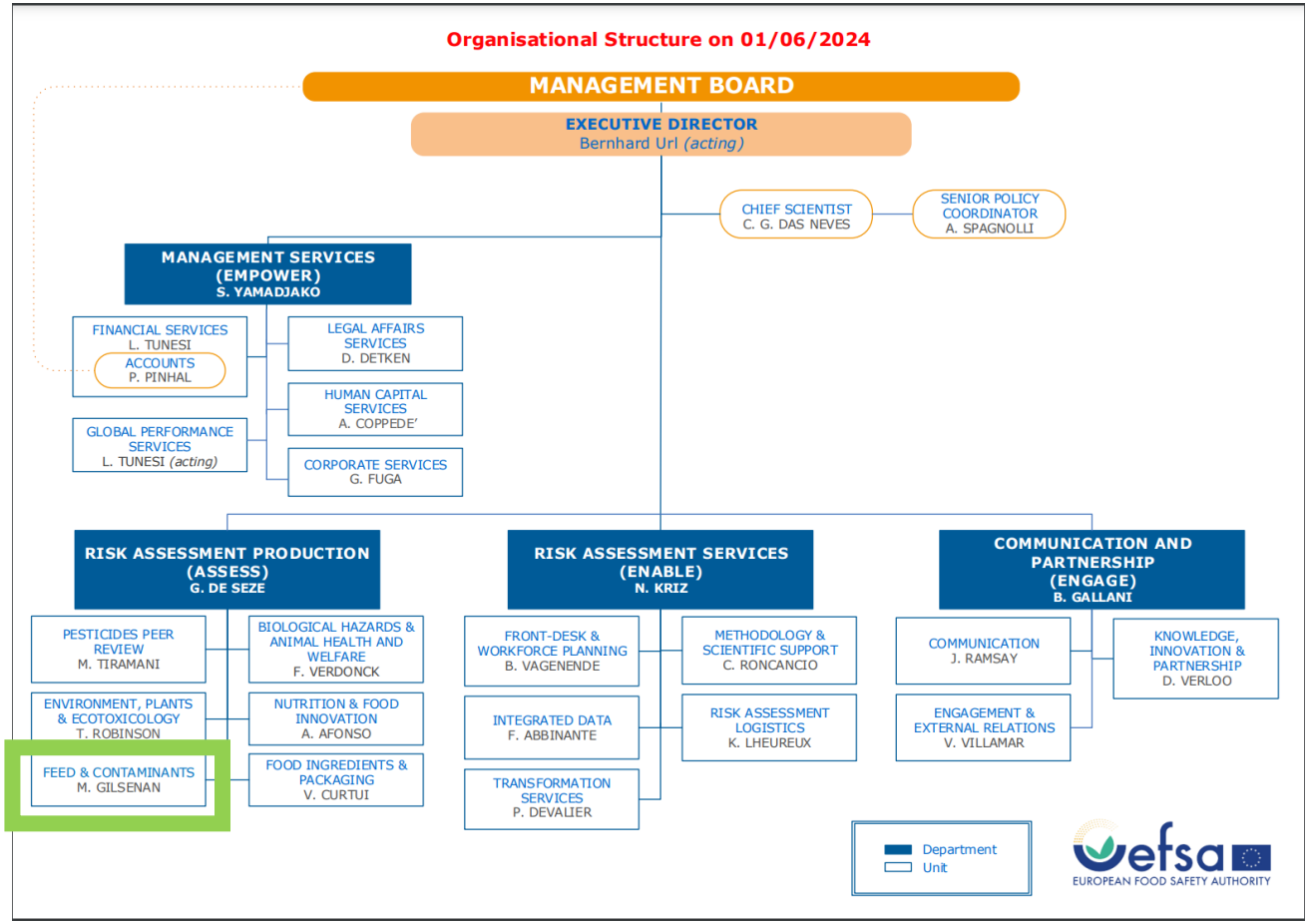
FEEDAP PANEL UPCOMING WORK

EUROPEAN FOOD SAFETY AUTHORITY

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

FEED TEAM

FEEDAP PANEL

WG on Characterisation

WG on Microbiology

WG on Toxicology

WG on Environment

WG on Animal Nutrition

WG on Flavourings

FEEDAP PANEL AND FEED TEAM

FEED TEAM

FEEDAP PANEL

- Adoption/Endorsement of SD
- 9 Plenary meetings in 2024

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
- 43 WG meetings – Until June

FEEDAP PANEL AND FEED TEAM – EXTERNAL SUPPORT

FEED TEAM

FEEDAP PANEL

WG on Characterisation

WG on Microbiology

WG on Toxicology

WG on Environment

WG on Animal Nutrition

WG on Flavourings

External support

- Individual Scientific Advisor
- GP/EFSA/FIP/2022/01:

FEEDAP PANEL

- Current Mandate of the FEEDAP Panel (2018-2024) comes to an end

Vasileios Bampidis (Chair)
Giovanna Azimonti (Vice-Chair)
Roberto Edoardo Villa (Vice-Chair)
Maria de Lourdes Bastos
Henrik Christensen
Mojca Durjava
Birgit Dusemund
Maryline Kouba

Marta López-Alonso
Secundino López Puente
Francesca Marcon
Baltasar Mayo
Alena Pechová
Mariana Petkova
Fernando Ramos
Ruud Woutersen

- New Mandate 2024 – 2029 - Inaugural Plenary meeting 2-4 July

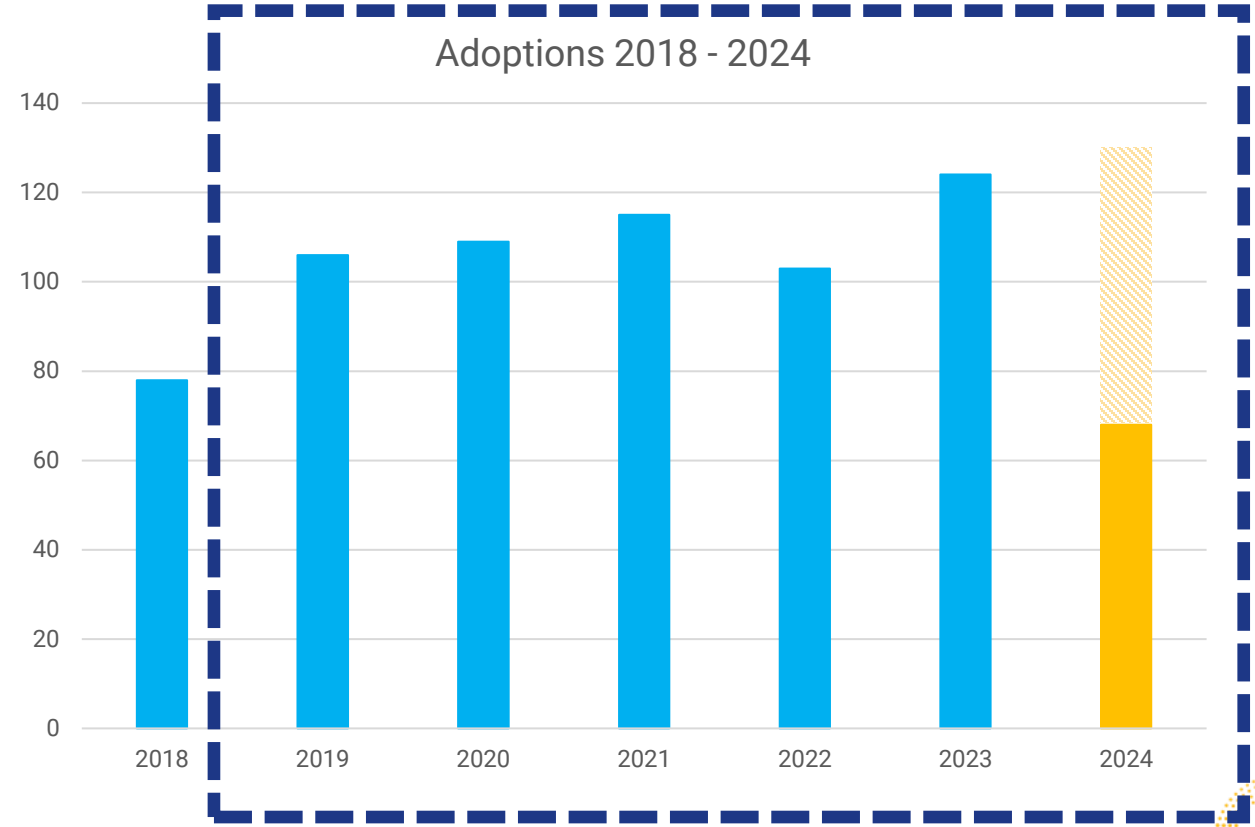
WORKPLAN

- Applications – current work
- Guidance update
- 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
- Jan – May 2024 68 opinions adopted; expected 130 opinions
- At present, ~ 50% post-transparency



WORKPLAN

- Applications – current work
- Guidance/technical documents
    - Guidance on Efficacy
    - Guidance on Microorganisms – Statement – MoPs
    - Tailored requirements to address nano-aspects
- Other on-going/future work
    - Selenium
    - Exposure scenario
    - ERA trace elements

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OVERVIEW

- Guidance on the Characterisation of microorganisms – FEEDAP Panel 2018
- Whole Genome Sequence statement
- Micro-organisms pipelines – stakeholder meeting
- Antimicrobial Resistance

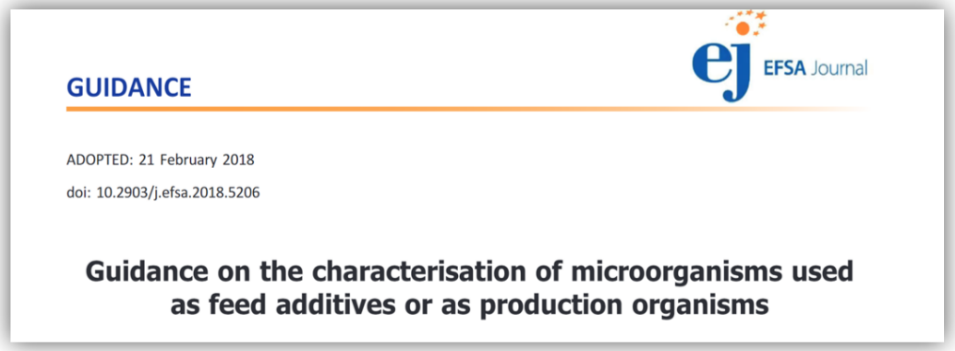
GUIDANCE ON MICROORGANISMS

EUROPEAN FOOD SAFETY AUTHORITY

GUIDANCE UPDATE

FEEDAP OPEN PLENARY MEETING NOVEMBER 2022

Characterisation of microorganisms


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

Update in 2018:

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

Statement WGS 2021

GUIDANCE UPDATE

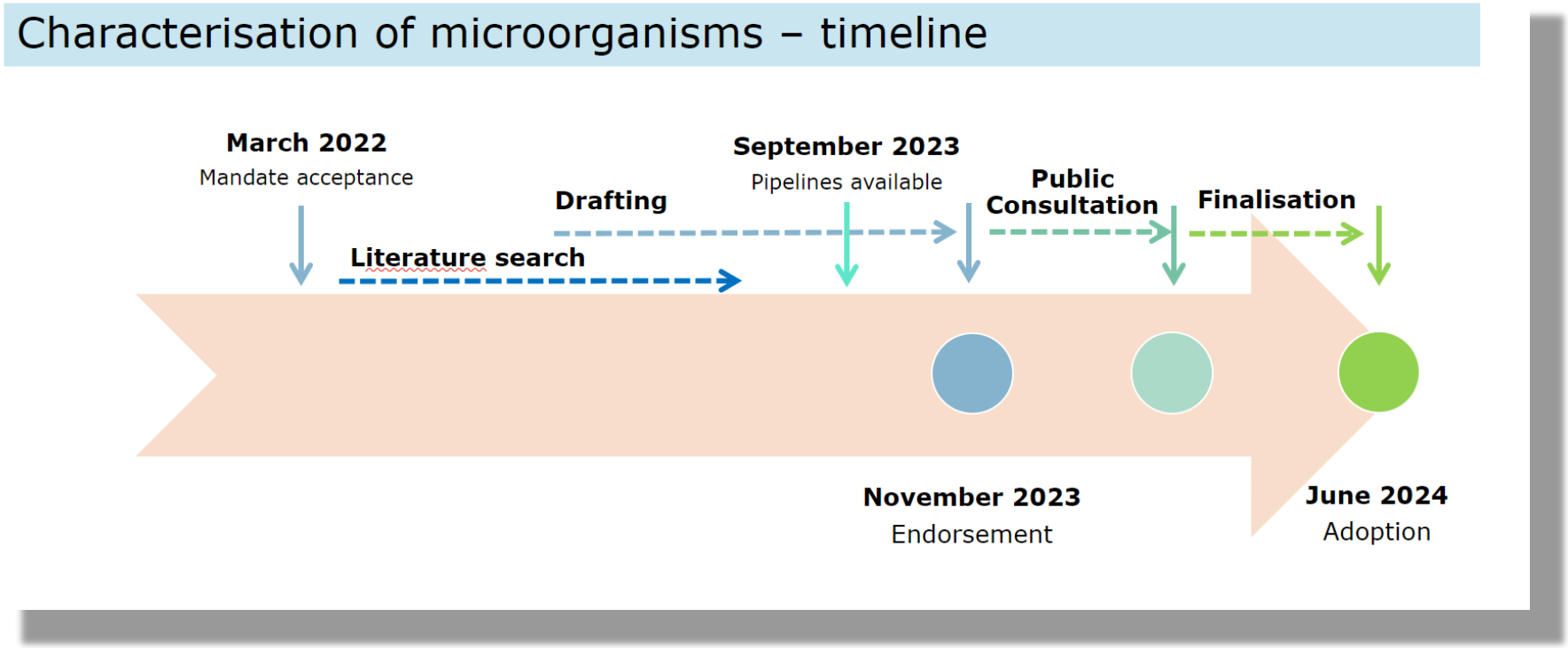
FEEDAP OPEN PLENARY MEETING NOVEMBER 2022

Characterisation of microorganisms – Update to…

- Current practices and most frequent questions
- Check the need for update on the phenotypic antimicrobial resistance thresholds

GUIDANCE UPDATE

FEEDAP OPEN PLENARY MEETING NOVEMBER 2022



NOVEMBER 2023 – SCIENTIFIC COMMITTEE

Different Sectors – Similar Products – One Approach for the aspects in common

NOVEMBER 2023 – SCIENTIFIC COMMITTEE

"A new mandate was presented to the SC in relation to the risk assessment of microorganisms that are used in the food chain for different purposes. The assessments are linked to requests for authorisation of the products under the applicable Regulations. The products evaluated may contain the microorganism, be prepared from, or obtained with the microorganism, and the microorganisms can be genetically modified or not.

EFSA considers it **necessary to have one scientific guidance document detailing the requirements for the risk assessment of microorganisms that could be applied across sectors.**

As the SC plays a major role in harmonising practices across areas, it was proposed that the SC prepares a guidance document on the risk assessment of microorganisms used in the food chain to be applied across sectors.

The **SC agreed on the proposal and a self-task will be prepared**. At this regard, **it is intended that the WG on Microbiology from the FEEDAP Panel with experts from other Panels** will prepare the draft guidance for the consideration of the relevant EFSA Panels and finally for the **endorsement and adoption by the Scientific Committee**."

EFSA GUIDANCE ON MICRORGANISMS

EFSA Guidance for the characterisation of microorganisms used as such or used to obtain/produce products used in the food chain to set the basis for the risk assessment of these products across areas

- Taxonomic groups of interest (current/future), genetically modified or not, and the different types of products
- Characterisation of the microorganism and resulting products in relation to the microorganism they are obtained/produced from/with; consideration on the impact on the receiving environment/s

Should be prepared considering i) existing guidance/reference documents and practices, ii) Needs – current and future, and iii) Up to date scientific knowledge

FEEDAP VS NEW GUIDANCE

- The New Guidance should contain all the elements that are currently present in the FEEDAP guidance - little exceptions may be expected for area specific requirements
- Enlarged to consider new taxonomic groups, products, and aspects that may require development (e.g., ERA)
- Once the new guidance is adopted by the SC – applicable to feed additives

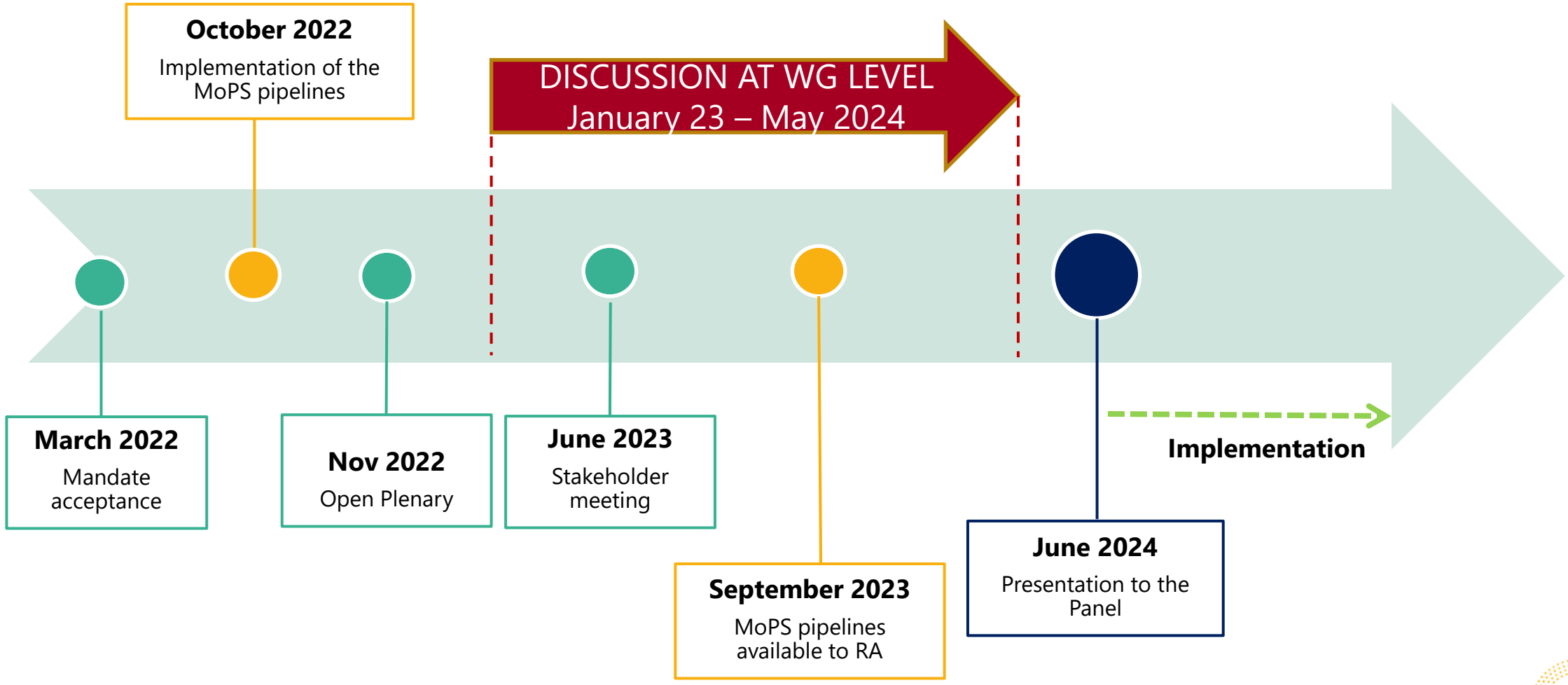
EFSA STATEMENT ON THE REQUIREMENTS FOR WGS ANALYSIS OF MICROORGANISMS INTENTIONALLY USED IN THE FOOD CHAIN

EUROPEAN FOOD SAFETY AUTHORITY

BACKGROUND

- **Regular update**
  - To assist applicants in the preparation and submission of technical dossiers
- **New technologies and uses**
  - Based on the scientific developments in the area
- **Experience gained during implementation**
  - Recurrent questions and knowledge gained via MoPS

TIMELINE


October 2022
Implementation of the MoPS pipelines
DISCUSSION AT WG LEVEL
January 23 – May 2024
March 2022
Mandate acceptance
Nov 2022
Open Plenary
June 2023
Stakeholder meeting
September 2023
MoPS pipelines available to RA
June 2024
Presentation to the Panel
Implementation

NOVELTIES/REVISIONS

Requirements for viruses, including bacteriophages

Use of WGS for detection of pathways involved in antimicrobial production

Provision of complete genomes (hybrid assembly – short + long reads): a MUST for bacteria and viruses; RECOMMENDED for yeasts/filamentous fungi

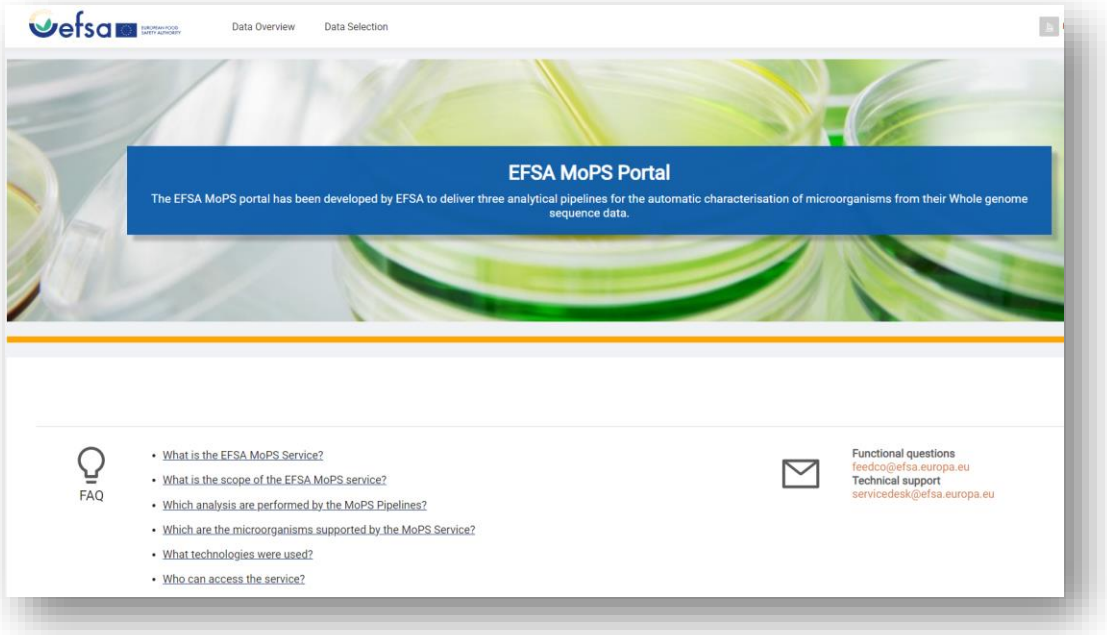
ANI analysis as a way to taxonomically identify yeasts and filamentous fungi

Requirements for WGS raw data formats and naming conventions

MICROORGANISMS PIPELINES SERVICE (MOPS)

EUROPEAN FOOD SAFETY AUTHORITY

MOPS PORTAL



WHAT, WHY, HOW

WHAT:

EFSA platform for the analysis of WGS data from bacteria, yeasts/filamentous fungi and viruses.

WHY:

- Preparedness – build in-house capacity, double-checks on a case-by-case basis, address new developments in the area
- Harmonisation – standardised WGS based data analysis

HOW:

By developing 1 portal, 3 bioinformatics pipelines, a secure and confidential environment

MOPS PIPELINES

STATEMENT

EFSA Journal

ADOPTED: 2 March 2021

doi: 10.2903/j.efsa.2021.6506

EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain

European Food Safety Authority (EFSA)

WGS QUALITY CHECK

- ✓ *Sequencing quality check*
- ✓ *Contamination*

ASSEMBLY

- ✓ *Assembly*
- ✓ *Statistics quality check*

ANNOTATION

- ✓ *Annotated genome*

CHARACTERISATION

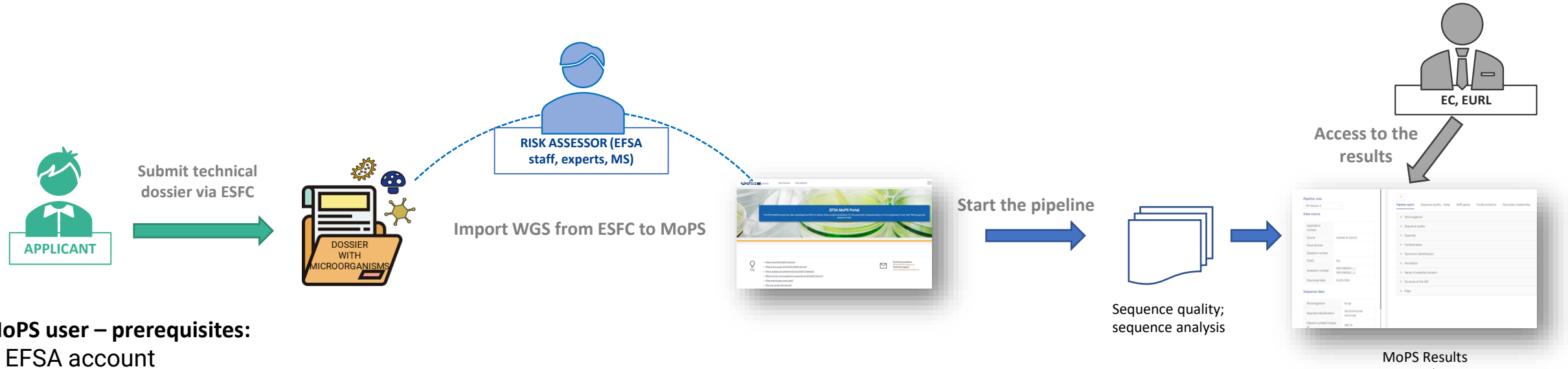
- ✓ *Taxonomic identification*
- ✓ *Detection of genes of concern*
- ✓ *Characterisation of the genetic modification*

SUPPORTED FORMATS

Assembled genomes: *.fasta, *.fna, *.fa, *.fsa_nt , *.fasta.gz, *.fna.gz, *.fa.gz, *.fsa_nt, *.fsa_nt.gz

Raw reads: *.fastq.gz, *.fq.gz, *.fastq, *.fq

MOPS – HOW DOES IT WORK?



MoPS user – prerequisites:

- ✓ EFSA account
- ✓ Already access to technical dossier
- ✓ MoPS security group

MoPS Security groups – main functionalities
Upload WGS data, run and control their analyses, visualise and download pipelines' results, share the results of an analysis with any other MoPS user.
Upload WGS data, run and control their analyses, visualise pipelines' results but not download them, share results with selected MoPS users working in the same regulatory domain in EFSA.
Upload WGS data, run and control their analyses, visualise pipelines' results but not download them or share them.
Visualise pipelines' results shared with them.

TECHNICAL MEETING WITH STAKEHOLDERS (29/05/2024)

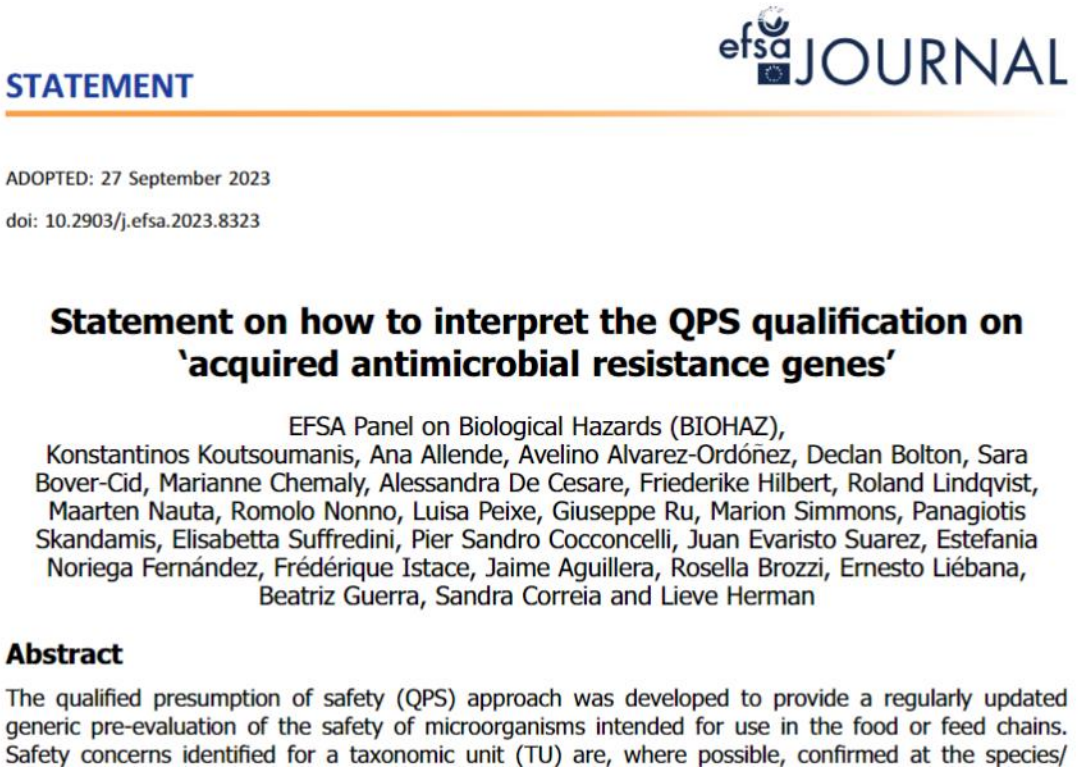
- **Sequence data submission**
  - WGS data are the raw data that support the WGS-based analyses and the findings reported by the applicants; relevant for the risk assessment
- **MoPS**
  - Bioinformatics tools and databases used, MoPS users, main functionalities, data management
- **MoPS opportunities: open codes vs open portal**
  - Piloting phase: open codes – transparency of the bioinformatics codes, feedback on what works well/what can be changed, new areas and possible improvements
  - Future: make the portal available. How? To be discussed

OTHER RELATED ACTIVITIES

EUROPEAN FOOD SAFETY AUTHORITY

STATEMENT ON HOW TO INTERPRET THE QPS QUALIFICATION ON ACQUIRED ANTIMICROBIAL RESISTANCE GENES

- *The strains should not harbour any acquired antimicrobial resistance (AMR) genes to clinically relevant antimicrobials*
- Relevant also for non-QPS organisms
- Bioinformatic approach



efsa JOURNAL

STATEMENT

ADOPTED: 27 September 2023

doi: 10.2903/j.efsa.2023.8323

Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes'

EFSA Panel on Biological Hazards (BIOHAZ), Konstantinos Koutsoumanis, Ana Allende, Avelino Alvarez-Ordóñez, Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Alessandra De Cesare, Friederike Hilbert, Roland Lindqvist, Maarten Nauta, Romolo Nonno, Luisa Peixe, Giuseppe Ru, Marion Simmons, Panagiotis Skandamis, Elisabetta Suffredini, Pier Sandro Cocconcelli, Juan Evaristo Suarez, Estefania Noriega Fernández, Frédérique Istace, Jaime Aguillera, Rosella Brozzi, Ernesto Liébana, Beatriz Guerra, Sandra Correia and Lieve Herman

Abstract

The qualified presumption of safety (QPS) approach was developed to provide a regularly updated generic pre-evaluation of the safety of microorganisms intended for use in the food or feed chains. Safety concerns identified for a taxonomic unit (TU) are, where possible, confirmed at the species/

GENOME BASED IDENTIFICATION OF ‘INTRINSIC’ AMR GENES

- A **sufficient number of high-quality complete genomes of strains of the species** should be interrogated for the presence of the specific AMR gene
- Genome sequences present in **publicly available databases** or provided by the applicant may be used
- Isolates should be properly **identified** and **independent**
- Requirements for **sequencing and data quality control** are set in the EFSA Statement on WGS analysis of microorganisms intentionally used in the food chain

AMR gene can be considered ‘**intrinsic**’ if it is present in the chromosome of **the vast majority** of the wild type strains of a bacterial species

AGENDA OPEN SESSION – 5 JUNE

No.	ITEM
Start of open session 14:00	
8.	Welcome and Apologies for absence
9.	Brief introduction of Panel Members
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Coffee break 16:00-16:30	
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IMPLEMENTATION OF THE NANO GUIDANCE DOCUMENTS - UPDATE 2024

05/06/2024

efsa
EUROPEAN FOOD SAFETY AUTHORITY

EFSA GUIDANCE DOCUMENTS ON NANO RISK ASSESSMENT

'GD on nano-RA'

GUIDANCE

EFSA Journal

ADOPTED: 30 June 2021

doi: 10.2903/j.efsa.2021.6768

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

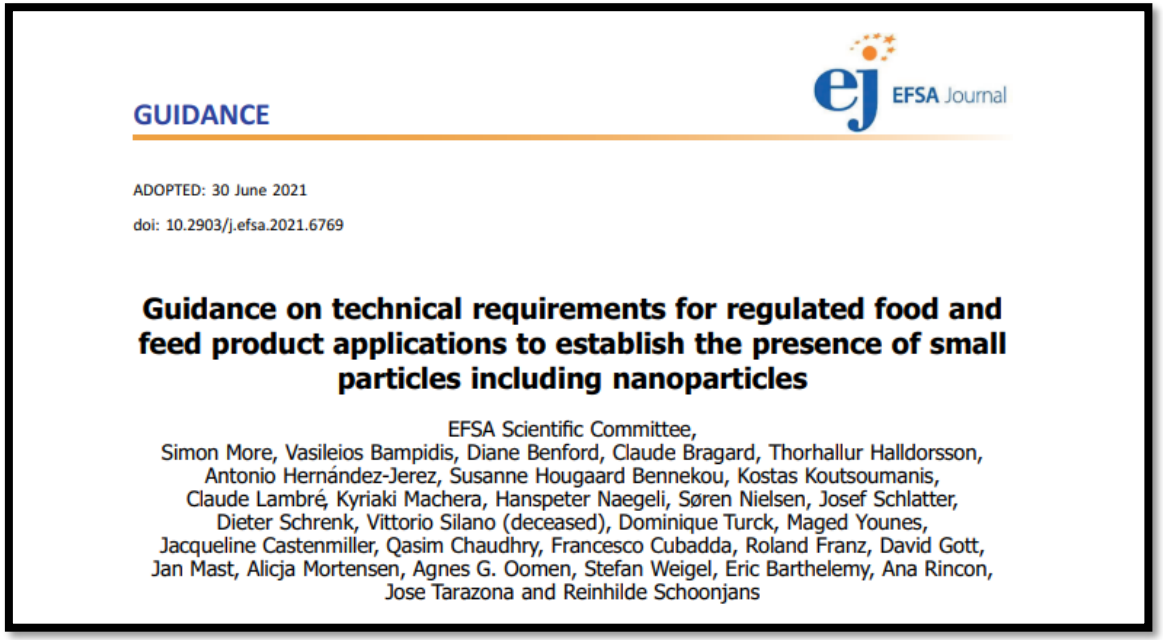
EFSA Scientific Committee,
Simon More, Vasileios Bampidis, Diane Benford, Claude Bragard, Thorhallur Halldorsson, Antonio Hernández-Jerez, Susanne Hougaard Bennekou, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Hanspeter Naegeli, Søren Nielsen, Josef Schlatter, Dieter Schrenk, Vittorio Silano (deceased), Dominique Turck, Maged Younes, Jacqueline Castenmiller, Qasim Chaudhry, Francesco Cubadda, Roland Franz, David Gott, Jan Mast, Alicja Mortensen, Agnes G. Oomen, Stefan Weigel, Eric Barthelemy, Ana Rincon, José Tarazona and Reinhilde Schoonjans

- Applicable for materials that
  - meet the definition of engineered nanomaterial
  - consist of or contain a fraction of small particles
  - nanostructured materials, including materials formulated in the form of nanocarriers

- Contains the principles how to conduct a nano-specific risk assessment

EFSA GUIDANCE DOCUMENTS ON NANO RISK ASSESSMENT

'GD on particle-TR'



GUIDANCE

EFSA Journal

ADOPTED: 30 June 2021

doi: 10.2903/j.efsa.2021.6769

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

EFSA Scientific Committee,
Simon More, Vasileios Bampidis, Diane Benford, Claude Bragard, Thorhallur Halldorsson, Antonio Hernández-Jerez, Susanne Hougaard Bennekou, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Hanspeter Naegeli, Søren Nielsen, Josef Schlatter, Dieter Schrenk, Vittorio Silano (deceased), Dominique Turck, Maged Younes, Jacqueline Castenmiller, Qasim Chaudhry, Francesco Cubadda, Roland Franz, David Gott, Jan Mast, Alicja Mortensen, Agnes G. Oomen, Stefan Weigel, Eric Barthelemy, Ana Rincon, Jose Tarazona and Reinhilde Schoonjans

- Considered a starting point to provide a strategy for the risk assessment including 'conventional' materials

- Contains appraisal routes and decision criteria
- Contains detailed methodology for solubility/dissolution testing and particle size determination
- Contains principles how to assess 'existing safety studies' originally designed for addressing conventional materials

EFSA GUIDANCE DOCUMENTS ON NANO RISK ASSESSMENT

feed additives designed to be nano:
not yet received by EFSA

The implementation focused on:

Identify feed additives that may contain a fraction of nano-particles and may require a nano-specific assessment

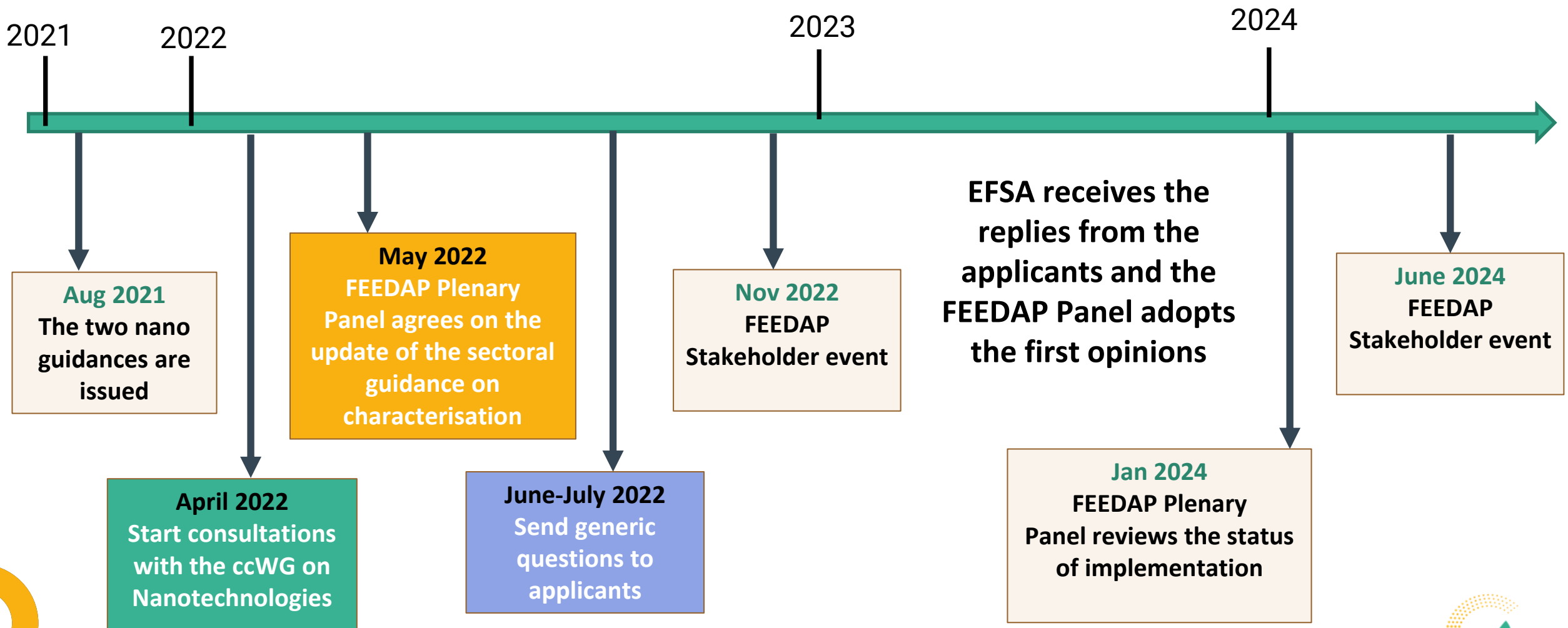
IMPLEMENTATION STRATEGY - 2022

Update the guidance on the Characterisation of feed additives

Send question to applicants to apply the Guidance on Particle-TR

Consult the cross-cutting WG on Nanotechnologies

MAIN MILESTONES



AIM OF TODAY'S PRESENTATION

- Provide an overview of the work of the FEEDAP Panel regarding the implementation and the lessons learnt
- Inform on the updated strategy
- Reply to questions received from stakeholders

LESSONS LEARNT

Strategy pillar	Main findings
Sending implementation question on nano safety and nano characterisation, i.e., "Safety evaluation strategy and corresponding testing strategy"	- Applicants have capacities to address the characterisation of feed additives in line with the GD on particle-TR (particle size distribution and solubility) - Applicants have difficulties to address the safety assessment of feed additives when nano-specific aspects should be also considered

LESSONS LEARNT

Strategy pillar	Main findings
Consulting the ccWG on Nanotechnologies	- A proper characterisation of the test item is fundamental in all studies and should include the characterisation of the fraction of small/nano particles - The additives of mineral origin that belong to certain class of silicate minerals (e.g., clays) are considered as nanostructured and in principle the risk assessment should consider nano-specific aspects

LESSONS LEARNT

Strategy pillar	Main findings
Update the sectorial guidance on the Characterisation of feed additives	- The requirement to assess the presence of small/nano particles should be added in the current sectoral FEEDAP GD. - Clarity is needed on the type of substances that fall under the remit - Clarity is needed for the additives which are authorized with a composition or are a mixture of more active substances/other ingredients/etc.

DECISION OF THE FEEDAP PANEL – UPDATED STRATEGY

FEEDAP Panel decision on the way forward in the 171th Plenary

8. Other scientific topics for information and/or discussion

8.1. Assessment of feed additives consisting of or containing nanoparticles

The FEEDAP Panel discussed experience gained to date on the implementation of the Scientific Committee Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health[5] and of the Scientific Committee Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles[6] for the safety assessments of feed additives.

The FEEDAP Panel agreed to continue characterising feed additives to determine the presence of small particles, including nano particles, based on the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles.

In order to assess potential risks associated with the presence of nanoparticles, the Panel agreed that there is a need for practical guidance tailored to feed additive safety assessments which considers safety for the target species, users, consumers and the environment, to complement the principles described in the above guidance documents on risk assessment of nanomaterials to be applied in the food and feed chain.

Until such detailed guidance is available, the FEEDAP Panel agreed that, for any ongoing or new mandates, the risk assessment of feed additives will follow the currently available sectorial guidance documents. The Panel will update this approach when practical guidance on the risk assessment of nanomaterials relating to feed additives is available.

- a practical guidance tailored to the feed additives safety assessments is needed
- until such detailed GD is available, the risk assessment will follow the sectorial FEEDAP GDs
- continue the characterisation to determine the presence of small/nano particles in line with particle-TR

UPDATED STRATEGY IN PRACTICE

Until a new tailor-made GD is issued for feed additives, the RA will follow sectorial guidances and the following apply for ADR and new safety studies:

- **ADR questions:**

If not properly characterised, additional data request will **be limited** to the characterisation of the small/nano fraction when this is considered relevant.

➢ further criteria to establish the need to characterise the fraction of small/nano particles is currently under development

- **New safety studies to be sent to EFSA:**

Until further guidance is developed, for substances that may have a fraction of small/nano particles, the studies (e.g. tolerance studies) can follow conventional designs; however, the characterisation of the test item should allow to establish if the material tested contained or not a fraction of small/nano particles.

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Open session 2024

RENEWAL APPLICATIONS FOR COCCIDIOSTATS AND HISTOMONOSTATS: "SAFETY FOR THE TARGET SPECIES"

Alberto Navarro Villa

efsa
EUROPEAN FOOD SAFETY AUTHORITY

REQUIREMENTS FOR THE RENEWAL OF FEED ADDITIVES - SAFETY

On regard of the safety for the target species, consumers, users and environment ‘The GD for the renewal of authorisation of feed additives’ establishes the following GENERAL REQUIREMENTS :

Post-Marketing monitoring plan - if requested in the authorisation

Reports of adverse effects including incidents/accidents for target animals consumers, users and environment

Additional evidence to support the safety of the additive such as extensive **literature searches** and/or **new studies**

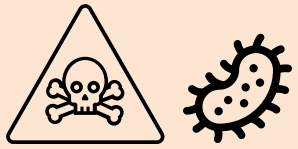
In the context of the renewal of coccidiostats for the Safety for the target species:

If no evidence for safety concerns exist…

Report of adverse effects
+
ELS
_____
Sufficient evidence to support the safety for the target species

PARTICULARS OF COCCIDIOSTATS & HISTOMONOSTATS AS FEED ADDITIVES

Feed additives with a relatively high toxicity

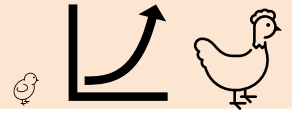


Narrow margin of safety

- Often < 10
- Occasionally without margin of safety

Target species (mostly) Poultry

- Terrestrial species with the greatest performance improvement throughout the years accompanied by an increased feed consumption (i.e. higher exposure to FA)



During the assessment of the safety for the target species in renewal applications of coccidiostats, the following was noted:

(i) Often, the original assessment based on tolerance studies dated 1980-2000 (not compliant with current GD)

(ii) The exposure of the target animal to the coccidiostat under assessment would differ in the modern chicken for fattening

(iii) Differences in exposure in modern chicken might alter the conclusions stablished in previous opinions relative to the tolerance and the margin of safety of the target animals to the coccidiostat

(iv) Safety concerns raised for the same substance in the context of other assessments

LEADING TO POTENTIALLY CONTRASTING SITUATIONS…

A) Concluding positively - target species:

Application	Margin of Safety	Previous assessement	Data submitted for the renewal	Other data considered	Outcome
Coccidiostat A	<3	TAS conducted in 2000's Not according to current GD Considerably lower performance compared to modern birds	PostMarketing Monit. ELS – no concerns No New TAS	None	Positive conclusion

B) Concluding negatively – target species:

Application	Margin of Safety	Previous assessement	Data submitted for the renewal	Other data considered	Outcome
Coccidiostat B	<3	TAS conducted in 2000's Not according to current GD Considerably lower performance compared to modern birds	PostMarketing Monit. ELS – no concerns No New TAS	Detected Safety concerns for the target species from a new application (Art.4). New TAS study (following new GD)	Negative conclusion

DECISSION OF THE FEEDAP PANEL

The FEEDAP Panel agreed (172nd Plenary meeting of the FEEDAP Panel)

- The FEEDAP Panel considers that for applications for the renewal of the authorisation of coccidiostats, tolerance studies in the relevant target species are required.

- These tolerance studies should be performed according to the most updated guidance document at the time of submission of the renewal of the authorisation and should not be older than 3 years at the time of submission.

- Applicants should use these tolerance studies to collect samples for residue determination following the most up to date analytical methods for an updated assessment of consumer exposure

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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-2024-00222	FEED-2021-1791	*Pediococcus pentosaceus* NCIMB 12674 for all animal species	4
EFSA-Q-2024-00223	FEED-2024-23950	Potassium iodide (No 3b201) and calcium iodate anhydrous (No 3b202) for all animal species	14
EFSA-Q-2024-00245	FEED-2024-23810	Neohesperidine dihydrochalcone for piglets and pigs for fattening, calves, sheep, fish and dogs	14
EFSA-Q-2024-00246	FEED-2024-23132	Neohesperidine dihydrochalcone for piglets and pigs for fattening, calves, sheep, fish and dogs	14
EFSA-Q-2024-00259	FEED-2023-18991	*Lactobacillus acidophilus* D2/CSL (CECT4529) for laying hens	14
EFSA-Q-2024-00260	FEED-2024-22093	*Saccharomyces cerevisiae* NCYC R404 for dairy cows for milk production	14
EFSA-Q-2024-00262	FEED-2023-18412	CAPSOZYME SB PLUS (alpha-galactosidase (EC, 3.2.1.22) and endo-1,4-beta-xylanase (IUB 3.2.1.8)) for weaned piglets	4
EFSA-Q-2024-00263	FEED-2022-7531	Belfeed B MP/ML (Endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136) for gestating sows	4
EFSA-Q-2024-00273	FEED-2024-24633	25-hydroxycholecalciferol as nutritional additive for salmonids, other fish species and all other animal species	4
EFSA-Q-2024-00287	FEED-2023-19272	Guanidinoacetic acid as zootechnical additive for chickens and turkeys for fattening and reared for laying and breeding	4
EFSA-Q-2024-00301	FEED-2024-26492	Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,3-beta-glucanase (EC 3.2.1.6) as zootechnical additives for chickens for fattening and reared for laying, laying hens, turkeys for breeding purposes, for fattening and reared for breeding and minor poultry species	14
EFSA-Q-2024-00302	FEED-2024-25871	L-Carnitine (3a910) and L-Carnitine L-tartrate (3a911) as nutritional additives for all animal species	14

Category	Art. 4	Art. 14	Total
Nutritional	1	2	3
Sensory	0	2	2
Technological	1	0	1
Zootechnical	3	3	6
Total	**5**	**7**	**12**

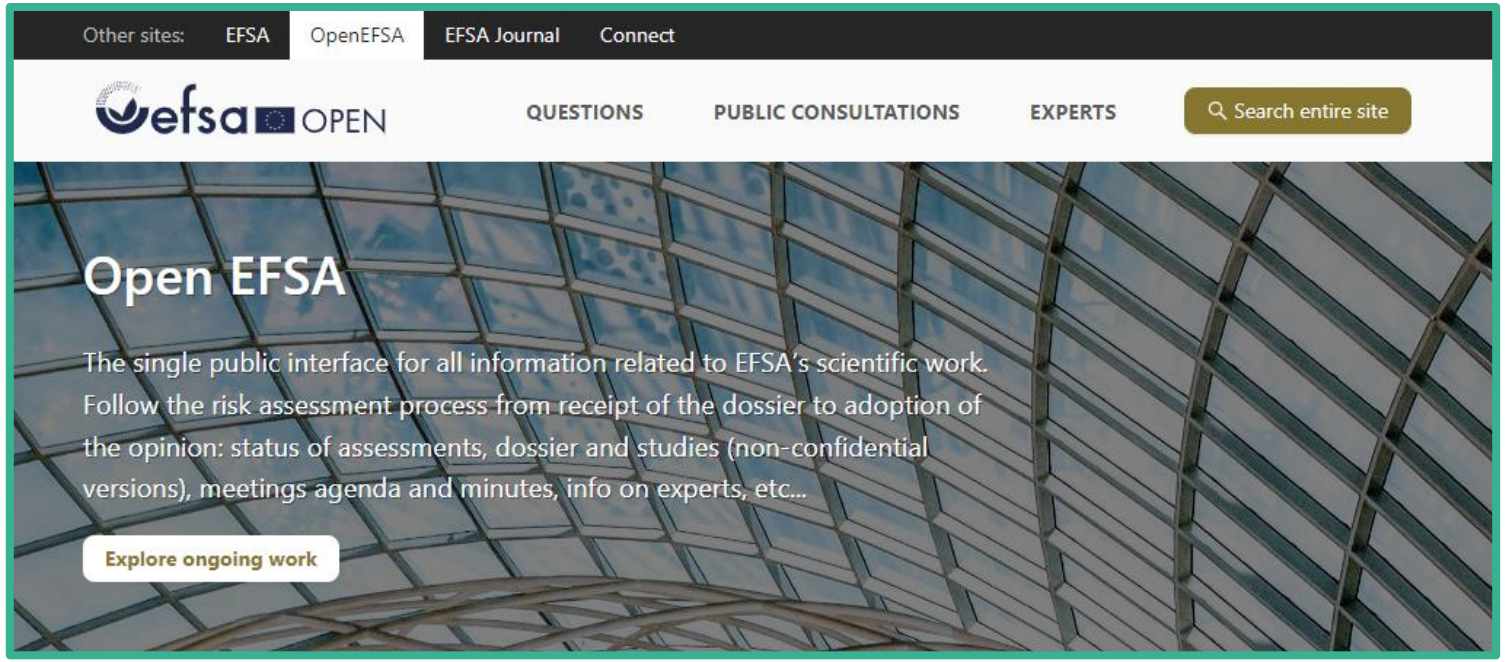
VALID APPLICATIONS UNDER REG. 1831/2003

EFSA-Q	FEED number	Subject	Article	Valid
EFSA-Q-2023-00451	FEED-2023-17004	FlorEquilibre® Chien (*Lactobacillus acidophilus* CNCM I-3231, *Ligilactobacillus salivarius* CNCM I-3233, *Lactiplantibacillus plantarum* CNCM I-3232, *Lacticaseibacillus rhamnosus* CNCM I-4427, *Bifidobacterium animalis* subsp. *lactis* CNCM I-3993) for dogs and other non-food-producing animals	4	29/04/24
EFSA-Q-2023-00857	FEED-2023-14471	Bonvital (*Enterococcus lactis* DSM 7134) for sows	14	10/04/24
EFSA-Q-2023-00867	FEED-2023-18114	GalliPro® Fit 10 (*Bacillus subtilis* DSM32324, *Bacillus subtilis* DSM32325 and *Bacillus amyloliquefaciens* DSM25840) for all poultry species for laying and for breeding	4, 13	13/05/24
EFSA-Q-2023-00887	FEED-2023-19751	YEA-SACC, YEA-SACC TS (*Saccharomyces cerevisiae* CBS 493.94) for dairy cows and minor dairy ruminant species, cattle for fattening and minor ruminant species for fattening	14	06/05/24
EFSA-Q-2023-00898	FEED-2023-18634	Riboflavin (Vitamin B2) and Riboflavin (Vitamin B2) (80% feed grade) produced by *Bacillus subtilis* VBB18049 for all animal species	4	13/05/24
EFSA-Q-2024-00001	FEED-2023-19411	Plexomin L-Cu (Copper lysinate sulfate) for all animal species	4	10/04/24
EFSA-Q-2024-00005	FEED-2023-20151	L-arginine for all animal species	4	18/04/24
EFSA-Q-2024-00007	FEED-2023-20870	MoNa (Molybdenum compound) for pollinator insects	4	16/05/24
EFSA-Q-2024-00031	FEED-2023-20170	L-histidine and L-histidine monohydrochloride monohydrate from *Corynebacterium glutamicum* KCCM80389 for all animal species	4	25/04/24
EFSA-Q-2024-00032	FEED-2023-20791	L-valine (min.98%) from *Corynebacterium glutamicum* KCCM80365 for all animal species	4	22/04/24

Category	Art. 4	Art. 14	Art. 4 + 13	Total
Nutritional	4	0	0	4
Nutritional and Sensory	2	0	0	2
Zootechnical	1	2	1	4
Total	**7**	**2**	**1**	**10**

NEW APPLICATIONS UNDER REG. 178/2002

EFSA-Q	FEED number	Subject	Category	Article	Valid
EFSA-Q-2024-00212	FEED-2024-21671	BLIS K12 (*Streptococcus salivarius* K12) for pets and other non food-producing animals	Technological	29	17/04/24
EFSA-Q-2024-00226	FEED-2024-24976	CanBiocin k-9 Heritage Probiotic Blend for dogs	Zootechnical	29	13/05/24
EFSA-Q-2024-00275	FEED-2023-20432	Bafasal® (Preparation of Bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097) for all avian species	Zootechnical	29	06/05/24



EFSA

FUTURE GENERIC MANDATE FOR THE ASSESSMENT OF THE SAFETY OF TRACE ELEMENTS FOR THE ENVIRONMENT

J. Tarrés-Call

Scientific Officer FEEDCO Unit

EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE

- i) the need,
- ii) scope,
- iii) status of the work
- iv) indicative timelines

NEED

- 8 Trace elements currently authorised as nutritional additives
- All authorised at a maximum use level
- Applicants request authorisation at the maximum authorised use level
- Renewal of authorisations and applications for new additive
- The FEEDAP Panel guidance on the safety of feed additives for the environment of 2019 describes new approaches
- Data gaps on natural background concentration of some trace elements or for some compartments
- Assessment is based on the information provided in the dossier.
- Need to have a standardised environmental risk assessment for a given trace element.

SCOPE

- Safety for the environment of the current maximum authorised levels of cobalt, copper, iodine, manganese, molybdenum, selenium and zinc
- …on the basis of available data or new data
- …for the target species for which the trace element is currently authorised

WHERE ARE WE?

- Mandate received and we are finalising the last administrative steps.
- Stakeholder meeting
- Sources of available data and the possibility of generating new data are being explored
- Organising the execution of the mandate (WG)

INDICATIVE TIMELINESS

Generic scientific opinion to be adopted within 2 years.

QUESTIONS?

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FEEDBACK FROM THE SCIENTIFIC COMMITTEE

V. Bampidis
Chair FEEDAP Panel

EUROPEAN FOOD SAFETY AUTHORITY

119TH PLENARY SCIENTIFIC COMMITTEE

- **Adoption**
  - Guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments
  - Guidance on risk benefit assessment
- **Endorsement for public consultation**
  - Scientific report for the feasibility study for a guidance on **biomarkers of effect**
- **Endorsement for Panel consultation**
  - Draft guidance on **read across**
- **New mandates**
  - Revision of the guidance documents for risk assessment of nanomaterials and materials containing nanoparticles in the food chain
  - Revision of the guidance on default values in the absence of actual data
  - New guidance for the characterisation of microorganisms

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Coffee break 16:00-16:30	
13.	Update on the assessment of feed additives with regards to the presence of nanoparticles
14.	Renewal of coccidiostats
15.	Update on new mandates since the previous meeting
16.	Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission/EURL
17.	Answers to questions from Observers
End of open session 18:00	

5 and 6 June 2024

WELCOME TO THE OPEN SESSION OF THE 174TH PLENARY OF THE FEEDAP PANEL

EUROPEAN FOOD SAFETY AUTHORITY

AGENDA OPEN SESSION – 6 JUNE

No.	ITEM
Start of open session 09:00	
18.	Update on the guidance on efficacy
Coffee break 10:00-10:30	
19.	Safety of feed additives containing selenium for the consumers
20.	Revised animal dietary exposure assessment model
21.	Any other business
22.	Answers to questions from Observers
End of open session 12:30	

UPDATE OF THE GUIDANCE ON THE ASSESSMENT OF THE EFFICACY OF FEED ADDITIVES

Open Plenary – EFSA FEEDAP Panel

6 June 2024

EUROPEAN FOOD SAFETY AUTHORITY

OUTCOME PUBLIC CONSULTATION

- Launched: 1 December 2023
- Finished: 9 February 2024
- 164 comments received
- 21 interested parties:
  - Four industry associations
  - Eleven private companies
  - One consultant organisation
  - Three Governmental organisations
  - Two individuals on personal capacity

SOME INSIGHTS

- Thank you – intense and challenging exercise
- Input received from many stakeholders
- Many changes applied to the endorsed document
- Repeated comments

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CONSUMER SAFETY OF FEED ADDITIVES CONTAINING SELENIUM

efsa
EUROPEAN FOOD SAFETY AUTHORITY

CURRENT AUTHORISATION MAXIMUM CONTENT OF SELENIUM

- **The maximum authorised concentration of selenium in complete feed (for any animal species) is currently:**
  - **Total selenium (0.5 mg Se/kg complete feed):**
    - Maximum content established with Directive 70/524/EEC
      - **Inorganic selenium (sodium selenite/sodium selenate)**
        - Maximum content up to 0.5 mg Se/kg complete feed
      - **Organic selenium (0.2 mg Se/kg complete feed)**

AUTHORISED FEED ADDITIVES CONTAINING SELENIUM

Inorganic selenium

- Sodium selenite
- Sodium selenate

Organic selenium

- DL-selenomethionine
- Hydroxy-analogue of selenomethionine
- L-selenomethionine
- Zinc-L-selenomethionine
- Selenomethionine produced by *Saccharomyces cerevisiae* (several strains)

NEW TOLERABLE UPPER INTAKE LEVEL FOR SELENIUM

The former UL for selenium (300 µg /day (adults)) has been revised by the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) in **2023**

Population category	**New UL** µg/day
Adults	**255**

4-6- months	45
7-11 months	**55**
1-3- years	**70**
4-6 years	**95**
7-10 years	**130**
11-14 years	**180**
15-17 years	**230**

MODIFIED CONSUMER EXPOSURE METHODOLOGY

- The **currently** authorised maximum contents of selenium **were based** on assessments in which consumer exposure was estimated based on the **food basket described in the Regulation (EC) No 429/2008**, or refined scenarios based on the same food basket.

- Since 2017, consumer exposure should be estimated based on:
  - Consumption data of edible tissues and products as derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database)
  - Residues (deposition data) in tissues (muscle, liver, kidney and fat (skin and fat for poultry)) from poultry, pigs and ruminant, fish flesh, eggs (laying hens) and milk (dairy cows)
  - For chronic exposure assessments, the total relevant residues will be combined for each individual with the average daily consumptions of the corresponding food commodities, and the resulting exposures per food will be summed in order to obtain total chronic exposure at individual level (standardised by using the individual body weight). The mean and the higher percentile (usually the 95th percentile) of the individual exposures will be subsequently calculated for each dietary survey (country) and each age class separately

MANDATE FROM THE EUROPEAN COMMISSION

- The Commission requests EFSA to deliver a new opinion on the **safety for the consumers of selenium (Se)** when used in feed additives, in accordance with Article 13 (1) of Regulation (EC) No 1831/2003. The purpose of the requested opinion is to determine whether the **conditions for authorisation** set out in that Regulation, with regard to the safety for the consumers of relevant animal products, **is still met for the existing authorisations of additives containing selenium as active substance**, on the basis of available information and data.
- Should it prove necessary to request supplementary information or data to the applicants of the existing authorisations, the nature and details of those information and data should be specified by EFSA in its opinion.

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