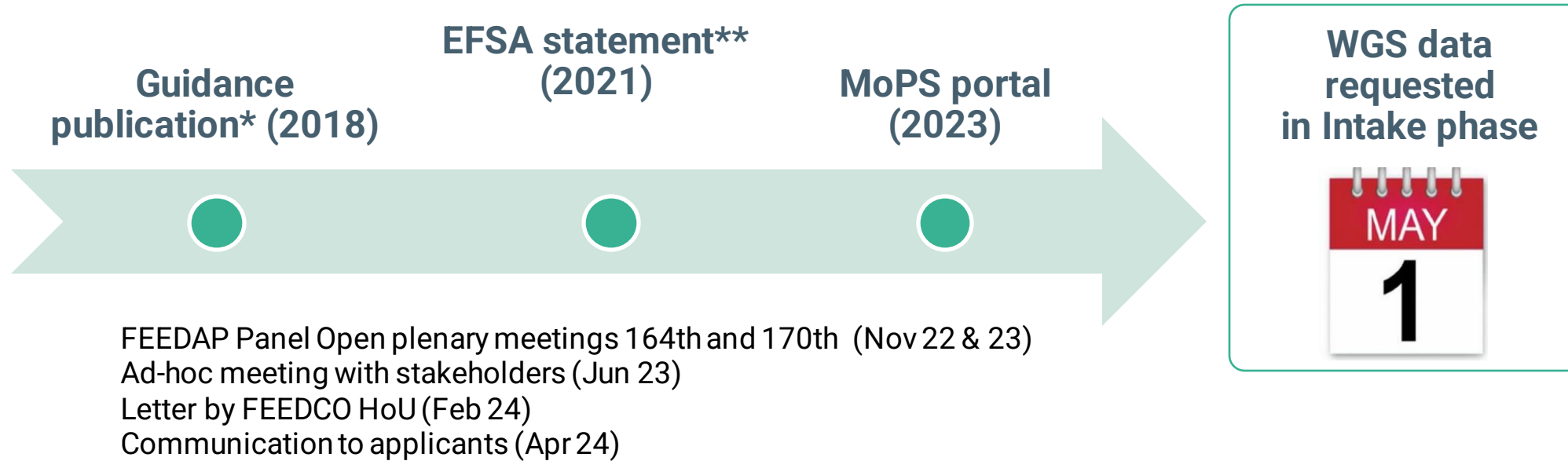




MICROORGANISMS PIPELINES SERVICE (MOPS)

OVERVIEW



Submission of WGS data

- WGS data are the raw data that would support the WGS-based analyses and the findings reported by the applicants.
- Like raw data of any other study, are relevant for the risk assessment and EFSA confirms the need to provide such data.
- Some applicants have been submitting WGS since the publication of the Guidance on the characterisation of microorganisms (2018). Data waiving applies as for other data.

*EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms (2018)

**EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (2021)

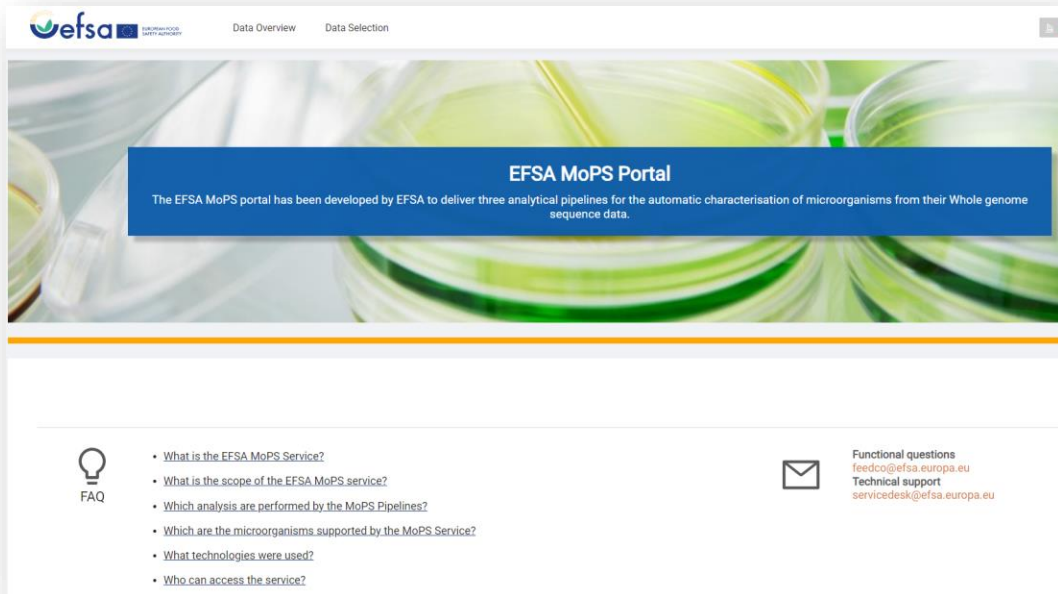


QUESTIONS FROM THE INDUSTRY – FASTA FILES

1. What is the purpose of the evaluation of FASTA files by EFSA?
2. Why is this level of detailed information necessary?
3. Can applicants request the deletion of FASTA files once their dossier has been evaluated?
4. How do you ensure that the analysis of FASTA files strictly adheres to the necessary requirements? For example, are FASTA files solely compared against public data and not against strains from other applications?
5. What is EFSA's data retention policy?



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 

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

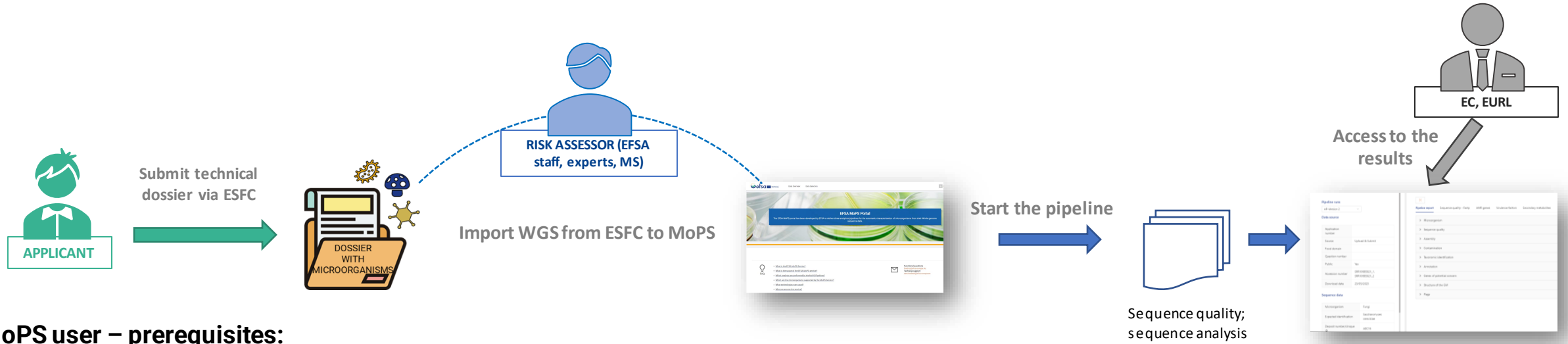
SUPPORTED FORMATS

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

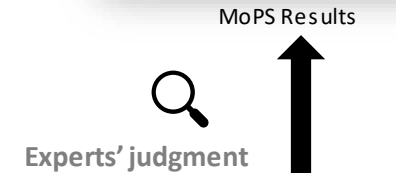
MoPS Security groups – main functionalities

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.



MOPS PROS

- **Speed up the RA**
 - Identify questions at an early stage
 - Target the questions
- **Standardised the RA**
 - Analyses according to EFSA requirements
- **Foster collaboration – open pipelines?**
 - Develop further
 - Identify new needs



strains development,
predictability of the assessment

VOLUNTEERS?



QUESTIONS FROM INDUSTRY – MOPS PURPOSE

- How does EFSA perceive the use of the EFSA MoPS portal in increasing the safety of food products on the EU market compared to the current status quo?
- Is the EFSA MoPS portal envisioned to be an optional commercial service for applicants who do not have the in-house technology to meet EFSA microorganism requirements?
- What tasks will the MoPS tool fulfill (e.g., strain identification/taxonomy, detection of virulence factors, antimicrobial resistance)? Will it address all of these, or anything else?
- Will the EFSA MoPS portal only perform analyses specified in the EFSA guidance, or will it allow for additional analyses not currently addressed in the guidance? If so, what additional analyses will be included, and why?



QUESTIONS FROM INDUSTRY – MOPS MANAGEMENT

- Who has access to the data in the EFSA MoPS portal, and who could gain access to the portal?
- How is the quality of the MoPS portal ensured?
- Which databases and algorithms are used, and are they kept in a secure environment?
- What are the input data requirements for the MoPS portal? What is the format for input and output data?
- How often is the tool updated? How does this affect the analysis submitted by applicants, and is there a risk of divergences in results due to updates? Can EFSA inform applicants during the evaluation process if an update to the MoPS tool affects their strain's compliance with specifications?
- It must be ensured that the results of the bioinformatic analysis from the MoPS portal are consistent with the analysis done by the company. What is the process for resolving discrepancies between EFSA's and the applicant's results?
- Which databases are used behind the MoPs tool, and is EFSA planning on publishing this information? It is unclear to us which databases and algorithms were used to build the MoPs tool, as we have not found any publicly available description of it.



QUESTIONS FROM INDUSTRY – DATA MANAGEMENT AND PROTECTION

- How is the confidentiality of proprietary whole genome production strain sequences guaranteed?
- How does EFSA ensure that unauthorised individuals cannot access the confidential data of production strains?
- When data are stored, are they used to train any further models? (This should not be the case for proprietary sequences.)
- If applicants use this tool, it implies using it before submitting the dossier and before claiming confidentiality on the data. This poses a risk when using an online platform. Will there be a downloadable version of the MoPS tool that applicants can use prior to submitting the dossier and claiming confidentiality, ensuring that the sequence is not stored on a cloud platform?

