TOWARDS A WORKABLE MOPS

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amfep
association of manufacturers & formulators of enzyme products

EuropaBio®
The European Association for Bioindustries

FEFANA
Specialty Feed Ingredients Industry

Overview Of Issues And Impact

Risks for confidentiality & IP

- External submission of WGS required/no downloadable tool option
- Unclear data handling and storage

IP leaks

- Core company IP at risk of being captured illegally by rogue actors, putting the very existence of EU biotech companies at risk

Requirements proportionality

- Analysis beyond EFSA guidance

Tool readiness

- Low assembly quality
- Rushed tool testing
- Lack of tool versatility

Delayed RA

- Additional questions
- Longer EFSA review times
- MoPS output inconsistent with internal analyses due to tool current shortcomings

Negative impact on

Competitiveness

Innovation

Efficient use of EFSA and applicant resources

Time to successful completion of RA

without improving safety.

Overview Of Issues And Impact

1

High confidentiality and IP risks due to external WGS submission

- Choice for companies to run MoPS internally and submit only the report
- Strong data handling safeguards for external data submission option

2

Current misalignment between MoPS requirements and existing EFSA guidance

MoPS tool reflecting EFSA guidance

3

Pilot phase has shown there are currently still issues that need to be resolved

Extended dialogue phase before a soft launch

Issue #1: Framing the Issue

1

EFSA is requesting highly confidential WGS information to be uploaded to their online MoPs tool as a requirement for product safety evaluation.

Whole genome sequence information of a biotech company's microorganism collection is **strictly confidential** and **fundamental proprietary information**.

Companies should have the choice between a:

- A downloadable MoPS tool with strong integrity safeguards and programming supporting portability
- External submission of data, provided strong confidentiality safeguards are clarified and ensured

Issue #1: Deep dive & Solutions

1 High confidentiality and IP risks due to external WGS submission

Data submission obstacles

- Companies' protection of IP and IT may prevent upload of ultra-sensitive core IP data to external servers.
- EU submissions impossible for part of the sector in the case of an external tool.

High risk linked to data handling and storage

- When external submission is possible, **handling of strictly confidential data-related aspects must be clarified** to ensure in-house IT compliance:
  - Data upload process: Is the transfer route encrypted, and if so, how?
  - Data processing: Is the query/bioinformatics analysis encrypted, and how? What technical and organizational measures ensure confidentiality and data security during processing?
  - Data deletion: Is the deletion process verified?
  - Logging: Are all processing steps and the deletion of data logged?

Suggested approach

- **Option for a downloadable MoPS tool with appropriate integrity safeguards** to be used within an in-house, security-validated IT environment, and subsequently uploading the generated report into the dossier.
- **Strong safeguards and audit trails for data handling operations** should be put in place. Transparency of the audit trail can be further discussed.

Issue #2: Deep dive & Solutions

2 Aligning MoPS requirements with existing EFSA guidance

The MoPS tool assesses certain features that go beyond the requirements in the EFSA WGS guidance. This causes inconsistency and unnecessary burden.

Examples

- QPS strains are assessed for e.g. virulence factors, 2nd metabolites and plasmids although it is not a requirement.
- The report outputs not only the species but also phylogenetic relationships sometimes to subspecies.

Suggested approach

- **MoPS tool to reflect guidances**: **each piece of the output should be connected to a requirement in the guidance**, together with corresponding cutoffs.
- Before run initiation, allow for an **extended parameter selection** such as QPS status to initiate an amended run specifically for QPS strains.
- Allow for **database selection** to give the option which databases to consult.

Issue #3: Deep dive & Solutions

3 Extended development phase to facilitate the delivery of a robust, reliable and well-tailored tool enhancing trust and usability

Limited time provided to test major new functionalities (e.g., GM module) does not allow to validate pipeline correctness.

Persisting discrepancy between **quality of assemblies** obtained through the **tool vs. in-house:** false "red flags" cause **cascading issues** across modules.

Suggested approach

- **Allow more time for tool evaluation and dialogue**, along with transparent handling of the pipeline, tooling, and testing criteria.
- **Upload of in-house assemblies together with the WGS to be supported**. Checks can be put in place to ensure that the assembly uploaded is stems from the reads provided.
- Create a **dynamic dialogue forum** between EFSA and industry to continuously secure that MoPS is based on state of the art algorithms. Set **clear milestones and success criteria** for implementation of new algorithms, databases etc.

Thank You

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