READY FOR EFSA'S NEW GUIDANCE? BUILD A FIT FOR PURPOSE FEED ADDITIVE DOSSIER—FROM MICROORGANISM TO SUBMISSION

24 June 2026

EUROPEAN FOOD SAFETY AUTHORITY

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- Use Teams Chat for questions.
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POST-EVENT RESOURCES

Access to Recording & Materials

- The presentation and a Q&A document will be available soon on the EFSA website.

Feedback Survey

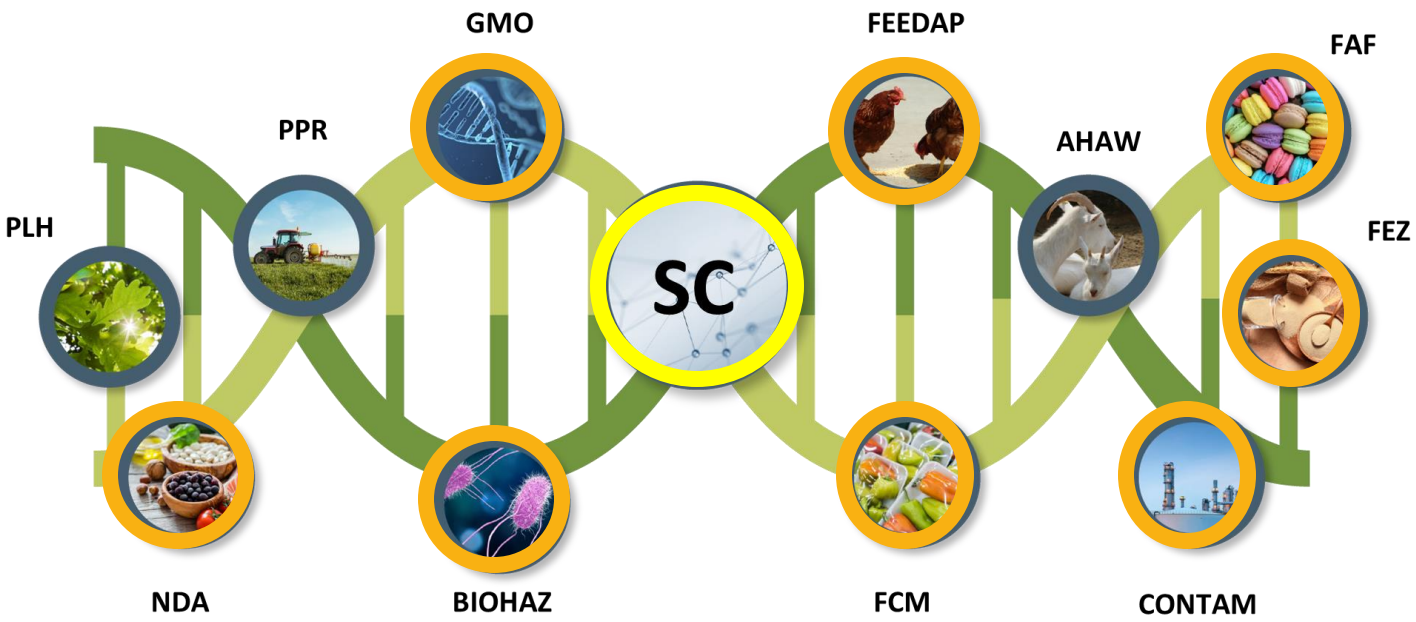
- A feedback survey link will be sent – your input is appreciated.

PROGRAMME

Introduction, updates on the new guidance, common pitfalls 30 min presentation + 15 min Q&A
Break: *5 min*
Breakout I: Antimicrobial resistance and production 10 min presentation + 20 min Q&A
Breakout II: Fermentation-derived products, presence of viable cells and DNA 10 min presentation + 20 min Q&A
Breakout III: Whole genome sequence data for strain identification and GM characterisation 10 min presentation + 20 min Q&A
Break: *10 min*
Closing session and final Q&A

UPDATES ON THE GUIDANCE

GUIDANCE DEVELOPMENT




Adopted: 24 September 2025

DOI: 10.2903/j.efsa.2025.9705

GUIDANCE

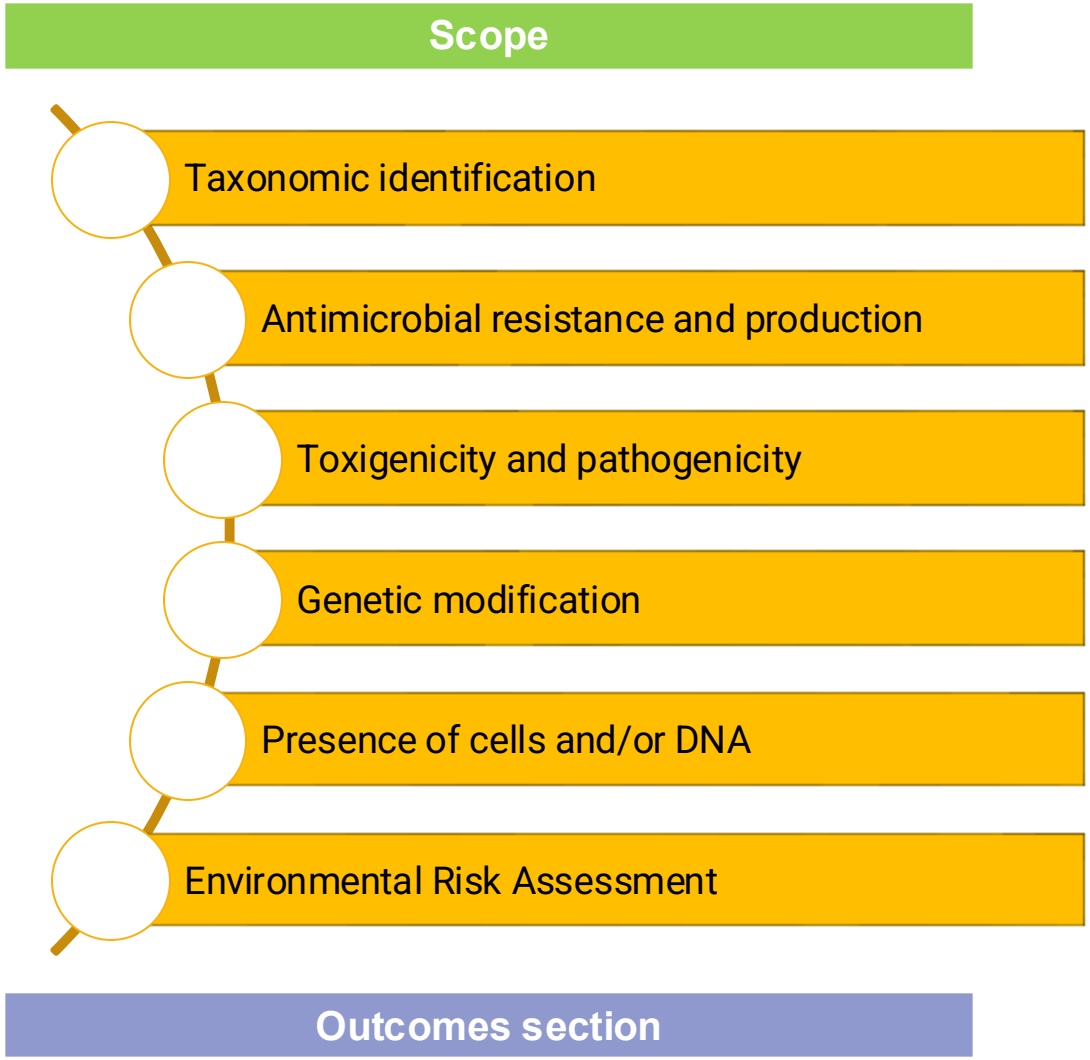
efsa JOURNAL

Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain

EFSA Scientific Committee | Susanne Hougaard Bennekou | Ana Allende | Angela Bearth | Josep Casacuberta | Laurence Castle | Tamara Coja | Amélie Crépet | Thorhallur Ingi Halldorsson | Ron Hoogenboom | Pikka Jokelainen | Helle Katrine Knutsen |

- Document endorsed by all the relevant EFSA Panels in 2024.
- Public consultation Nov 2024 – Feb 2025.
- Adoption by the Scientific Committee in September 2025.
- Published on 4th of November 2025.
- Date of application **1st April 2026.**

GUIDANCE - TABLE OF CONTENTS



- Background, products at stake
- Data requirements – what and how
- Predictability of the risk assessment

SCOPE - NOVELTIES

- Taxonomic groups and products under scope:
  - E.g. **microalgae, viruses (including bacteriophages).**
  - E.g. products of interest produced from microorganisms GM or not, such as **biomasses.**

- Clarifications:
  - Principles/concepts applied to the qualified presumption of safety (QPS) approach.
  - Cases where other guidance/legal requirements apply.

GUT MICROBIOME

The possible impact of the products under scope on the gut microbiome, should be considered in certain cases (e.g. when an adverse effect can be anticipated based on the body of knowledge, or when their use is expected to have effects on the gut microbiome of animals or humans), and will be assessed on a case-by-case basis. Examples of adverse effects on the gut microbiome include, e.g. colitis, diarrhoea or shedding of pathogenic microorganisms.

EFSA's initiatives to build capacity for Microbiome-Informed Risk Assessment – Roadmaps & Projects.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Search

JOURNALS SUBJECTS

efsa SUPPORTING PUBLICATIONS OPEN ACCESS

External scientific report | Open Access

Roadmap for the integration of gastro-intestinal (GI) tract microbiomes (human and domestic animal) in risk assessments under EFSA's remit

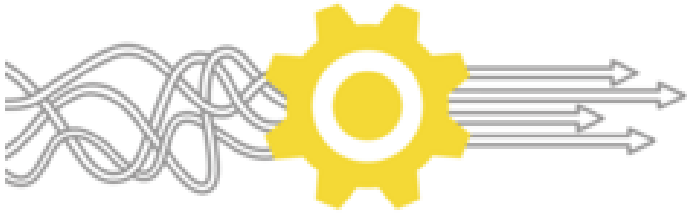
Francisco Javier Moreno, Florencio Pazos, Manuel Garrido-Romero, Cyrielle Payen, Gonzalo Borrego-Yaniz, Mónica Chagoyen, Nieves Corzo, Martine Denis ... See all authors

First published: 21 February 2024 | https://doi.org/10.2903/sp.efsa.2024.EN-8597 |

VIEW METRICS

Accessibility issue? Request accessibility update.

Question number: EFSA-Q-2020-00406
This publication is linked to the following EFSA Supporting Publications article:
https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2024.EN-8602/full



CHARACTERISATION OF THE MICROORGANISM

- All strains should be deposited in an internationally recognised culture collection.
- Origin and history of modifications of the strain should be reported.
- All the bioinformatic analyses should not be older than **2 years** at the time of submission of the application. Maintained/curated databases should be used.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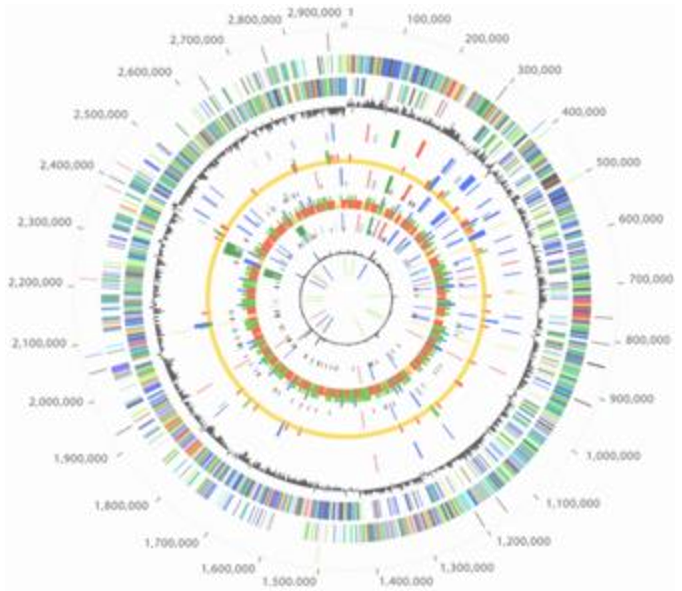
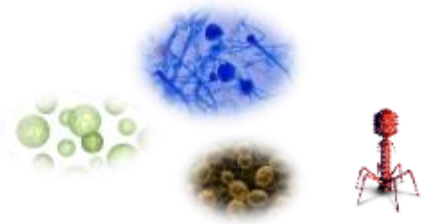
STATEMENT
efsa JOURNAL

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

European Food Safety Authority (EFSA)



TAXONOMIC IDENTIFICATION



Scope and approach:

- All strains need to be taxonomically identified.
- Identification at species level following international rules and nomenclature.
- Based on WGS data, except for microalgae (combination of morphological and DNA sequencing information of selected genetic markers).

ANTIMICROBIAL RESISTANCE

Bacteria and bacteriophages

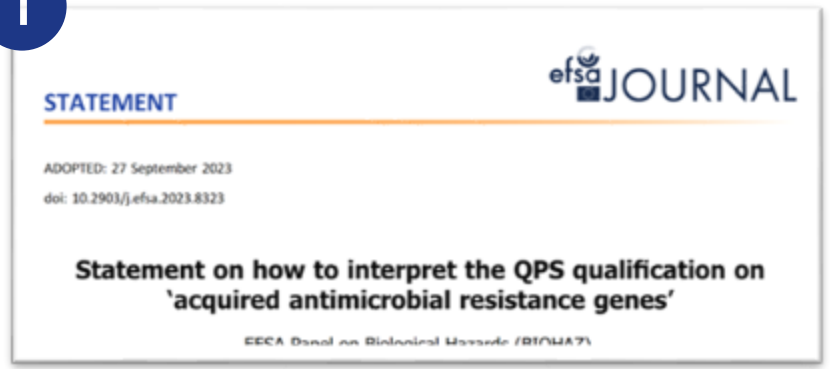
Assessment of **genes that may confer resistance to antimicrobials** of medical and veterinary importance (WHO and WOAH) → "therapeutic antimicrobials"

Scope: bacteria, and bacteriophages and their host strain(s)

Approach:

- **Step 1: WGS analysis** (≥2 databases)
  - Identify potential AMR genes ("hits")
  - Distinguish intrinsic vs acquired resistance
- **Step 2: phenotypic test**
  - When AMR gene is acquired

1


STATEMENT

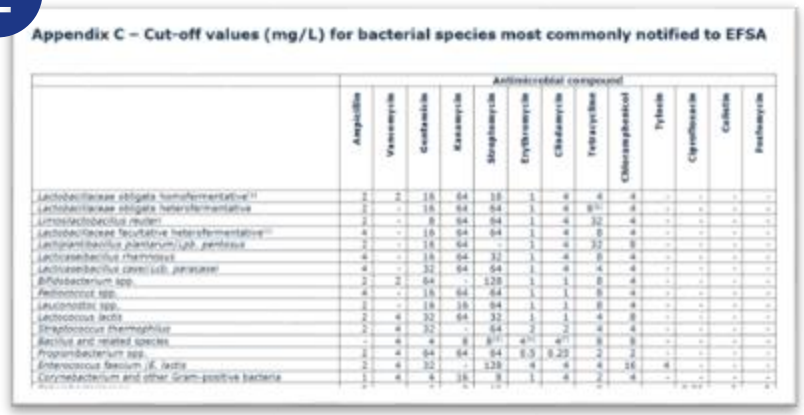
efsa JOURNAL

ADOPTED: 27 September 2023

doi: 10.2903/j.efsa.2023.8323

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

2


Appendix C – Cut-off values (mg/L) for bacterial species most commonly notified to EFSA

ANTIMICROBIAL RESISTANCE

Yeasts and filamentous fungi

Scope: active agents and production strains (if presence of viable cells not excluded)

Approach: phenotypic test

- ✓ Susceptibility to ≥2 antifungals (ideally belonging to two classes with distinct molecular mode of action)

Appendix D – Cut-off values (mg/L) for fungal species most commonly notified to EFSA

	Antimicrobial compound[a]								
	Nucleotide analogue	Polyene		Imidazole	Triazole 1st generation		Triazole 2nd generation		
	Flucytosine	Amphotericin B	Nystatin	Ketoconazole	Fluconazole	Itraconazole	Voriconazole	Posaconazole	Isavuconazole
Saccharomyces cerevisiae	1	4	64	1	32	4	1	2	0.125
Aspergillus flavus/oryzae	-	8	128	-	IR[b]	4	2	1	8
Debaryomyces hansenii	-	-	-	-	8	2	0.125	-	-
Kluyveromyces marxianus	2	4	-	-	2	0.5	0.0625	0.25	-
Pichia kudriavzevii	64	4	-	-	IR[b]	2	2	2	2
Clavispora lusitaniae	2	2	-	-	4	0.5	0.0625	0.125	-

PRODUCTION OF ANTIMICROBIAL SUBSTANCES

Scope: Active agents (excluding bacteriophages), production strains and strains used to produce biomasses

Approach: Genomic + phenotypic test (always)

- ✓ **WGS:** interrogation for genes/gene clusters involved in antimicrobial biosynthesis

(≥1 database).

  - Follow-up (if hits identified): quantify antimicrobial production (supernatant or final product)

- ✓ **Phenotypic test:** inhibitory activity following internationally recognised methods (e.g., EUCAST)

(≥6 reference/indicator strains).

  - Follow-up (if positive): further analysis to exclude production of therapeutic antimicrobials.

TOXIGENICITY AND PATHOGENICITY

Scope: QPS species are excluded (unless qualifications apply)

Approach: Body of knowledge, development of the strain, history of use… (literature search)

Specific requirements for each taxonomic group:

- ✓ **Bacteria:** WGS analysis (≥1 database) + Phenotypic test (if hits identified)
  - ❑ Taxonomic units with specific tests (i.e. *Bacillus* spp, *B. cereus*, *E. faecium* and *E. lactis*)
- ✓ **Yeasts and filamentous fungi:** WGS analysis (≥1 database) + Phenotypic test (if hits identified)
- ✓ **Viruses:**
  - ❑ Host (range/infectivity)
  - ❑ Non-intended species (Infectivity/absence of adverse effects)
  - ❑ Bacteriophages (WGS analysis: lysogeny, transduction…)
- ✓ **Microalgae and other protists:** Phenotypic test

GENETIC MODIFICATION

- Characterisation mainly based on WGS comparison – i.e., the focus is on the new trait(s).
- The most appropriate reference to be used in the WGS alignment is the non-GM strain from which the GMM strain under assessment is derived – **parental strain.**
- Any **gene(s) of concern** should be clearly indicated.
- **QPS approach** may still apply provided that i) the strain belongs to a TU included in the QPS list; ii) qualifications are fulfilled; iii) the modification does not introduce safety concerns.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VIABLE CELLS AND DNA

- The **test item** should be representative of the final product(s).
- **Raw data** should be submitted (e.g., pictures of the gels/plates).
- Requirements extended to bacterial **host strains** in which phages are replicated.

Presence of viable cells

Culture based method

What to do in case colonies are detected in the unspiked samples

Presence of DNA

PCR-based

Focus on genes of concern or recombinant DNA

Clarifications on the controls to be included

STRAINS WITH UNKNOWN ORIGIN

Limitations of WGS-based analysis
WGS may not be conclusive.

Approach to follow: worst-case scenario
In case of uncertainty, the strain is assumed to be genetically modified.

Required experimental evidence
Applicants must show absence of viable cells and DNA in the final product.

Safety assessment
The approach allows to conclude on product safety as concerns the strain

Minutes of the 186th FEEDAP Plenary Meeting

PITFALL: MISSING OR INCOMPLETE DATA

Typical signs in a dossier

- Missing sequence data.
- AMR outputs, strain deposition certificates, or appendices absent.
- Evidence referenced in the text but not supplied.

Information needed

- Provide a complete dataset index with file names.
- Include raw data, processed outputs and final interpretation.
- Cross-reference every appendix to the relevant dossier section.
- Check that strain identifiers are identical across all files.

Bottom line

Demonstrate completeness and consistency

PITFALL: INSUFFICIENT METHODOLOGICAL DETAIL

Typical signs in a dossier

- DNA extraction and sequencing strategy not properly described.
- Database names, versions, access dates or thresholds missing.
- PCR validation, controls or detection limits not reported.

Information needed

- State tools, versions, databases and run dates for each analysis.
- Report thresholds, acceptance criteria and quality controls.
- Describe sampling strategy and test item representativeness.

Bottom line

Demonstrate adherence to minimum quality standards

PITFALL: NON-COMPLIANCE WITH EFSA GUIDANCE

Typical signs in a dossier

- AMR searches run with non-required thresholds or default settings.
- Outdated, unmaintained or non-curated databases used.
- Taxonomic identification methods do not match the expected taxonomic unit.

Information needed

- Use maintained, curated databases and document the version used, respect time-frame of bioinformatic analyses.
- Apply the required thresholds.
- Confirm that taxonomic methods are appropriate for the strain.

Bottom line

Show compliance with EFSA requirements

PITFALL: SCIENTIFIC GAPS IN CHARACTERISATION

Typical signs in a dossier

- Incomplete species or strain identification.
- Lack of clonality check of genomes involved in assessment of nature of AMR gene (acquired vs intrinsic).
- Virulence, AMR, toxigenicity or antimicrobial production not assessed.
- Genetic modification history, inserted sequences or unintended changes unclear.

Information needed

- Present a complete strain identity and characterisation narrative.
- Compliance with provisions of EFSA BIOHAZ Statement on how to interpret the QPS qualification on ‘Acquired antimicrobial resistance genes’
- Explain genetic modifications and their intended purpose.

Bottom line

A complete dossier compliant with EFSA requirements should be submitted

PITFALL: INCONSISTENCIES IN THE DOSSIER

Typical signs in a dossier

- Strain origin, history or designation changes between sections.
- Different methods or results reported in the study report and summary.
- Updated analyses not reflected consistently across appendices.

Information needed

- Avoid in-house identifiers or provide a clear list of equivalence.
- Detailed methodology, study reports and raw data (if applicable).

Bottom line

Clear, consistent and detailed information.

Q&A SESSION

BREAKOUT 1:

ANTIMICROBIAL RESISTANCE AND PRODUCTION

ANTIMICROBIAL RESISTANCE

Target microorganims

- Bacteria
- Bacteriophages and their host strains

Assessment – WGS analysis

- Search for aquired genes that may confer resistance to therapeutic antimicrobials

Therapeutic antimicrobials

- Antimicrobials of medical and veterinary importance for humans and animals as defined by the World Health Organization (WHO) and World Organisation for Animal Health (WOAH), respectively

a

DATABASE INTERROGATION

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efsa JOURNAL

STATEMENT

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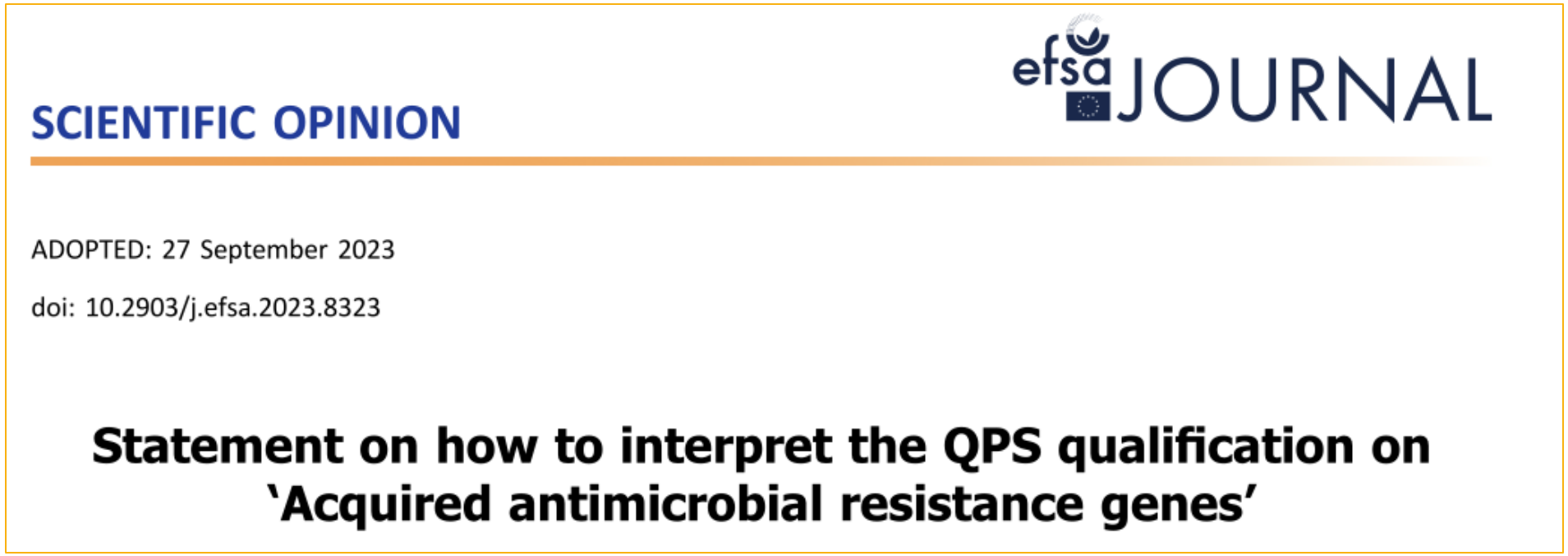
AMR GENE SEARCH

- Use of **two regularly updated databases.**
- The search should be conducted in the **complete genome of bacteria** (including any extrachromosomal elements) and **bacteriophages** (both in the genomes of the bacteriophage and the bacterial host strain).
- An **identity search** (e.g. BLAST) of the genes homologous to the AMR gene under investigation in the genome sequences selected as described above.
- A **positive control** gene expected to be present in all strains of the target group (e.g. a DNA replicon initiator) must be included.
- Query sequence hits with at least **80% identity** (at the protein level or nucleotide level as reported in the database) and **70% length** of the subject sequence should be considered for the differentiation between intrinsic and acquired.

a

ACQUIRED vs INTRINSIC RESISTANCE



SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 27 September 2023

doi: 10.2903/j.efsa.2023.8323

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

a

ACQUIRED vs INTRINSIC RESISTANCE

INTRINSIC GENE

- A gene inherent to strains of a bacterial species, limiting the action of antimicrobial agents. An AMR gene is considered ‘intrinsic’ when it is **shared by the vast majority of wild-type strains of the same species** and is **restricted to the chromosome.**
- **Intrinsic resistance is considered as of no concern** in the frame of the EFSA risk assessment purpose.

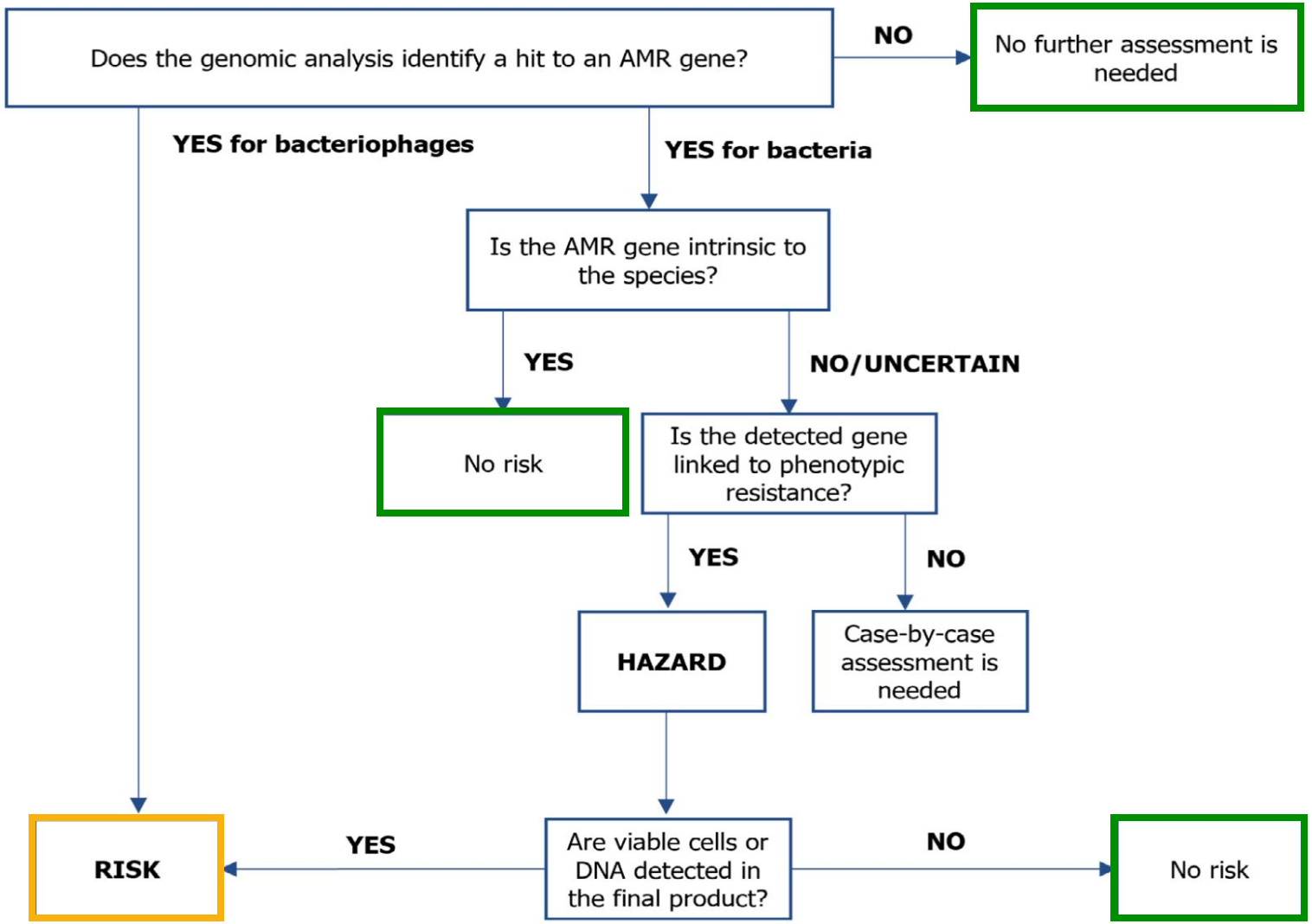
ACQUIRED GENES

- A resistance gene novel for the species under assessment, acquired through horizontal transfer, enabling a bacterial strain to survive or multiply in presence of concentrations of an antimicrobial agent higher than those that inhibit the growth of the majority of wild-type strains of the same species without this AMR gene.

ACQUIRED vs INTRINSIC RESISTANCE

- All available genome sequences of the species.
- If <30 strains, include sequences of more strains based on the applicant's own research.
- The quality of the WGS should be provided.
- Species identity of the strains should be verified (dDDH and/or ANI or phylogenomic).
- Isolates should be epidemiologically and/or ecologically unrelated.
- Demonstration of non-clonal relationship by phylogenomic based on SNP analysis, ANI distance, pangenome analysis.
- Metadata of the strains should be included in the analysis.

DECISION TREE ON THE RISK ASSESSMENT OF ANTIMICROBIAL RESISTANCE IN BACTERIA AND BACTERIOPHAGES



PHENOTYPIC TESTING FOR AMR: FUNGI

- **Scope:** Applies to all **yeasts and filamentous fungi** used as active agents and to those used as production strains if the potential presence of viable cells has not been excluded regardless of whether potential AMR genes have been identified/are present or not
- **Methodology:** MIC values are established following Appendix B and comparing them to **cut-off values** in Appendix D (or elsewhere as stated for bacteria)
- **Minimum testing requirements:** Susceptibility to **at least two commonly used therapeutic antifungal** compounds (ideally belonging to two classes with distinct molecular mode of action) should be shown. This would ensure that effective therapeutic options remain available in case of accidental fungal infections.
- **Note:** Since the mechanisms of developing resistance are different in fungi compared to bacteria conducting genomic analysis to elucidate the nature (acquired vs. intrinsic) of a particular antifungal resistance is not considered relevant.

PRODUCTION OF ANTIMICROBIAL SUBSTANCES

- **Focus:** The risk assessment focuses on **antimicrobials of medical and veterinary importance**.
- **Limitations:** Given the complexity and diversity of microorganisms assessed and microbial metabolites potentially produced by them, it is not possible to provide an extensive list of examples or case studies.
- **Approach:** WGS analysis can rule out the production of well-known antimicrobial substances for which the biosynthetic gene clusters are well-characterized. However, for antimicrobial compounds with unknown or not fully characterized genetic determinants, WGS alone may not detect their potential production. For this reason, a **combined approach using both WGS and phenotypic analysis** is considered the most reliable methodology.
- **Interpretation:** If a positive result is obtained in the phenotypic test, the **nature of the activity should be further investigated**. Only if the active agent is shown to produce antimicrobial substances of medical and veterinary importance, it is considered to be a risk.

Q&A

BREAKOUT 2: FERMENTATION-DERIVED PRODUCTS, PRESENCE OF VIABLE CELLS, AND DNA

PRESENCE OF VIABLE CELLS AND DNA IN THE FINAL PRODUCT

Scope

- Applies to biomasses and 'substances of interest' produced using **production strains**, including bacteriophages' host strains

Sampling requirements

- Samples of at least **1 g or 1 mL** representative of the final product
- Minimum **9 samples from at least 3 independent batches**
- Samples should originate from the **industrial-scale process.** Pilot-scale samples acceptable **only** if representative of industrial production
- For multiple processes or formulations:
  - Test each production process
  - Test the **most concentrated** formulation(s)

Documentation

- Manufacturing stage sampled must be specified
- Raw analytical data should be provided (e.g., plates, gels, of controls and samples)

PRESENCE OF VIABLE CELLS OF THE STRAIN

Applicable to

- Biomasses from GM and non-GM microorganisms
- Products produced using GM and non-GM strains
- Bacteriophages (testing for presence of the bacterial host strain)

Key requirements

- Detailed description of cell removal/inactivation during downstream processing
- Testing must use **culture-based methods**
- Cultivation-independent methods are not acceptable

Methodological considerations

- Recovery of stressed cells must be ensured. Use solid media with prolonged incubation (≥ 2× standard incubation time)
- Consider interference from contaminating microorganisms (enrichments not recommended)
- If colonies appear, molecular identification should confirm strain identity

Additional requirement

- For spore-forming strains, include appropriate germination procedures before culturing

PRESENCE OF VIABLE CELLS OF THE STRAIN

Controls for viable cell detection

- **Positive control**
  - Demonstrate that cultivation conditions support growth
  - Include product samples spiked with viable cells of the strain:
    - At least one tested batch
    - ≤ 100 CFU/g or mL

Interpretation

- Viable cells are considered **culturable cells**

Special cases

- Regulatory requirements may determine whether testing is needed for:
  - Non-GM production strains
  - Non-GM bacteriophage host strains

Bacteriophage products

- When propagated in pathogenic species, absence of host strain must be demonstrated in **25 g/mL samples** or according to applicable legislation

PRESENCE OF DNA FROM THE STRAIN

Applicable to

- GM production strains
- Non-GM strains carrying genes of concern (e.g., acquired AMR genes)
- Bacteriophage products produced in GM or gene-of-concern-containing host strains

PCR requirements

- Extract total DNA from samples
- Extraction method must recover DNA from all cellular forms:
  - Vegetative cells
  - Spores
- Appropriate lysis procedure required

Target sequence

- PCR target ≤ 1 kb (GM and non-GM strains)
- For GM and not-GM strains carrying genes of concern, target fragment must not exceed the size of the smallest gene of concern

PRESENCE OF DNA FROM THE STRAIN

Required controls and sensitivity tests

- Negative control (blank)
- Positive PCR control (purified genomic DNA of the strain)
- PCR inhibition control:
  - Genomic DNA added to DNA extracted from three batches of the product
- Limit of Detection:
  - DNA extracted from product/s spiked with dilutions of genomic DNA of the strain before DNA extraction

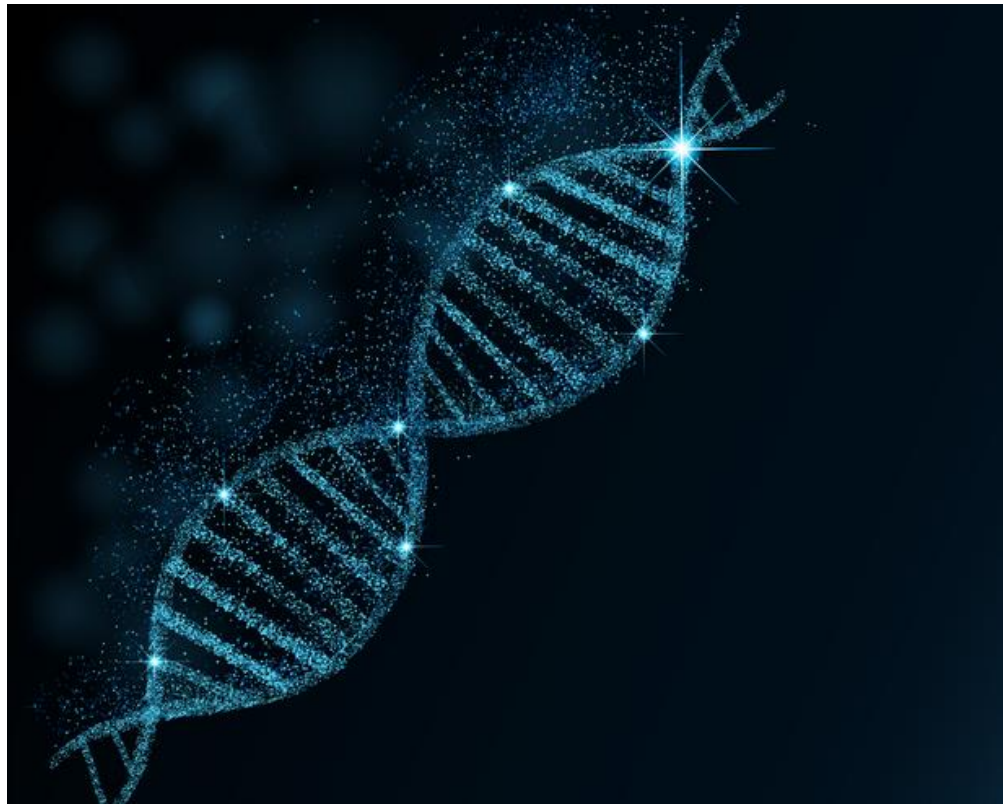
Sensitivity requirement

- Method must detect **≤ 10 ng total DNA per g or mL of product**

Q&A

BREAKOUT 3: WGS DATA FOR STRAIN IDENTIFICATION AND GM CHARACTERISATION

CORE CONCEPTS IN GENOMIC CHARACTERISATION



- Whole Genome Sequencing importance
- Strain as the main unit for characterisation purposes
- Fully closed genome requirement
- Recent bioinformatic analyses

GM*, non-GM microorganisms & those obtained with NGTs (see https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2024.8895)

*as defined in Article 2(2) of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. OJ L 106, 17.4.2001, p. 1–39

DATABASES

Quality Control of Reference Sequences in Databases

Reference sequences must undergo quality control, ensuring integrity and absence of contamination, and annotation accuracy for valid results.

Use of Curated Databases

Curated databases provide validated, maintained sequence data.

Up-to-date Bioinformatic Analyses

Bioinformatic analyses must be recent, less than two years old, to reflect current scientific information.

WGS – KEY CONSIDERATIONS

Thresholds definition

Quality Criteria

Data and Information for the Risk Assessment (Appendix A)

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efsa JOURNAL

STATEMENT

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

European Food Safety Authority (EFSA)

APPENDIX A

List of information and data to be provided

The below table lists the information and data that should be submitted to EFSA by the applicants in the technical dossiers in those applications for which WGS-based data analysis is required according to the relevant regulatory framework or guidance. This form should be duly completed and signed by the applicants at the time of submission.

Section	Item	Provided		Comments
		Yes	NA	
	Reporting of methodologies and outcomes			
2.1	**Microorganism and nucleic acid extraction**			
	Identifier for the microorganism/s subject of the application for authorisation (same used in other sections of the dossier)	☐	☐	
	Confirmation of the correspondence of the samples used for nucleic acid extraction, sequencing, WGS-based data analysis and results reported with the microorganism/s subject of the application	☐	☐	
2.2	**Sequencing and data quality control**			
2.2.1	**Library construction**			
	Library construction method (including the nucleic acid fragmentation method and any selection of fragments)	☐	☐	
2.2.2	**Sequencing strategy and quality control**			
	Sequencing strategy and instrumentation used (base-calling method, where applicable)	☐	☐	
	Trimming (where applicable), filtering, software version and parameters used, quality thresholds	☐	☐	
	Average read depth	☐	☐	
	Contamination in the sequencing data – Percent of reads assigned to unexpected organism/s Tool used, the software version and parameters used and results; the database used, its version and/or date of accession	☐	☐	
2.3	**De novo assembly and annotation**			
	Assembler software, version and parameters (including those applied in post-assembly processing)	☐	☐	

WGS BASED IDENTIFICATION

Bacteria

At species level (valid published name, International Code of Names of Prokaryotes, ICNP).

If not possible to identify to species level, designate a valid published genus name followed by ‘sp.’ based on phylogenetic comparison of whole genomic sequences to closest related species with valid published name.

Validly published names are updated in the List of Prokaryotic Names with Standing in Nomenclature (LPSN).

Yeasts and filamentous fungi

At species level (valid published name, International Code of Nomenclature for algae, fungi, and plants, ICNafp).

If not possible to identify to species level, designate a valid published genus name followed by ‘sp.’ based on whole genomic sequences or on multi-gene phylogenetic analysis to closest related species with valid published name.

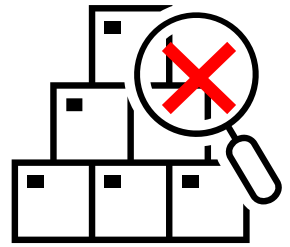
Validly published names are included in the MycoBank and Index Fungorum databases.

Viruses

At species level (valid published name, International Committee on Taxonomy of Viruses, ICTV).

By complete genome analysis and comparison of the sequence against maintained and up-to-date databases.

Microalgae and other protists



WGS GENETIC MODIFICATIONS DESCRIPTION – WHAT?

Purpose of Genetic Modification

Phenotypic and Metabolic Traits & Changes

Characterization of Inserted Sequences

Donor organism, DNA sequence with annotation of coding and non-coding regions, derived amino acid sequence and functions.

Codon optimised genes, chimeric/synthetic genes.

Characterization of Deletions and other modifications

Deletions, introduced substitutions, frameshift mutations or other edited sequences.

WGS GENETIC MODIFICATIONS DESCRIPTION – HOW?

Comparison of the WGS of the GMM with those of the non-GM reference strain – parental strain.

The origin and history of the parental strain including mutagenesis (conventional mutagenesis) steps should be reported.

Any gene of concern identified in the GMM by WGS alignment should be indicated.

GMM VS NON-GMM

Data requirements	How?	GMM	Non-GMM
WGS	Long and/or short reads technologies for most microorganisms	✓	✓
Taxonomic identification	Primarily based on WGS for most microorganisms	✓	✓
Genes of concern	WGS-based screening + additional testing where needed	✓	✓
Genetic modification characterisation	Primarily based on WGS for most microorganisms	✓	✗
QPS	TU included in the QPS list and qualifications fulfilled	✓	✓
Presence of viable cells	Culture based method	Fermentation products	Fermentation products
Presence of DNA	Mainly PCR-based	Fermentation products	Fermentation products, where relevant
ERA	Comparative approach	✓	Case-by-case

Q&A

CLOSING REMARKS

1. ANTIMICROBIAL RESISTANCE AND PRODUCTION

AMR – Bacteria

- **WGS-based screening** (≥2 DBs) for genes conferring resistance to **therapeutic antimicrobials.**
- Distinction between **intrinsic vs acquired** resistance is essential for interpretation.
- Phenotypic susceptibility test (MIC) when “acquired hits” identified.

AMR – Fungi

- **Phenotypic susceptibility test (MIC).**
- Demonstration of susceptibility to **≥2 antifungals (different classes).**
- **Genomic analysis not required.**

Production of antimicrobial substances

- Focus on **therapeutic antimicrobials.**
- **WGS-based screening** (≥1 DB) **+ Phenotypic activity test** (always both required).
- Positive activity → further characterisation needed.

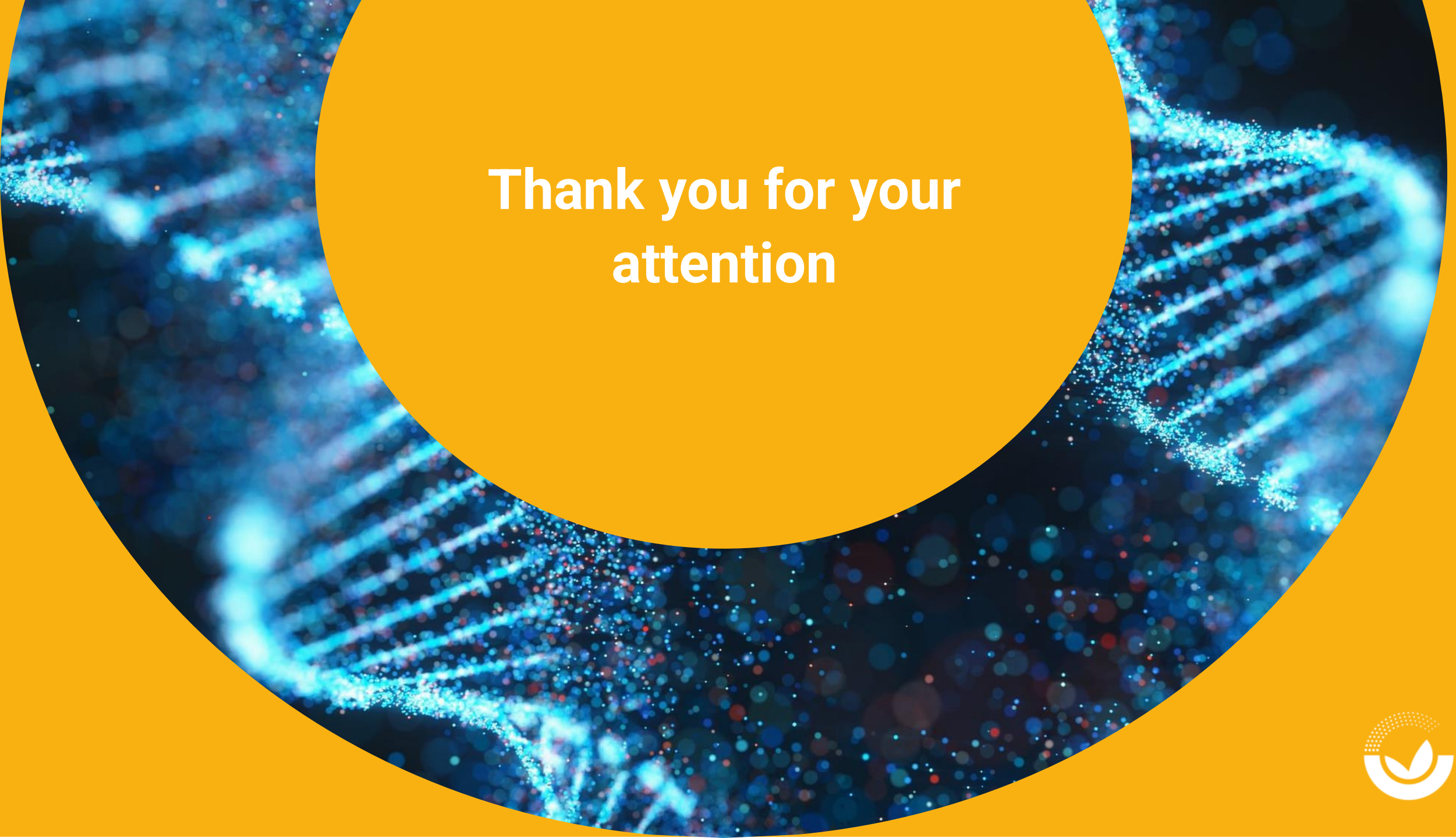
2. PRESENCE OF VIABLE CELLS AND DNA IN FERMENTATION-DERIVED PRODUCTS

- **Scope and sampling:** Characterise the final product and process, then test representative samples: ≥1 g or mL, 9 samples from ≥3 independent batches, covering relevant processes/formulations.
- **Viable cells:** Show absence using culture-based methods only; support recovery of stressed/spore-forming cells and include spiked positive controls plus strain-identity confirmation where colonies appear.
- **Residual DNA:** For GM strains or strains/hosts with genes of concern, extract total DNA, use PCR targets ≤1 kb with required controls, and demonstrate sensitivity ≤10 ng total DNA per g or mL.

3. WHOLE GENOME SEQUENCE DATA FOR STRAIN IDENTIFICATION AND GM CHARACTERISATION

- **WGS is the basis of microbial characterisation**: need for high-quality genomes, updated bioinformatic analyses, maintained/curated databases, following established thresholds and quality criteria.
- **Taxonomic identification**: mainly based on WGS, it should follow international nomenclature rules.
- **GM vs non-GM assessment**: data requirements are similar, but only GMM require full GM characterisation. Additional analyses (e.g., ERA, DNA/viable cells) are driven by type of micro and/or product type.

Q&A



Thank you for your attention

SUPPORT INITIATIVES FOR APPLICANTS

Services for applicants' page

General pre-submission advice	• **At any time before the submission** of a future application potential applicants can submit, via the Connect.EFSA portal, **questions on the rules and content of a future application.**
Ask a question tool	• **To increase understanding on general requirements for submitting applications, procedural steps, status of applications, use of tools.** Questions can be sent via the Connect.EFSA portal.
Clarification teleconference	• **During the completeness check or risk assessment phase**, requested via email by EFSA or the applicant. • **To clarify the rationale of questions and ensure understanding by the applicant**.
Dedicated support to SMEs	• Reply to requests submitted via Ask a question in 7 working days. • Reply to GPSA requests in half of the standard time and preferably in a telemeeting. • **Hands-on session in a telemeeting on the use of IT tools**. Can be requested via Ask a Question. • Possibility to request more than two clarification teleconferences.

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