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SCIENTIFIC OPINION

Update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The qualified presumption of safety (QPS) process was developed to provide a harmonised safety assessment approach to support EFSA Scientific Panels and Units. The QPS approach assesses the taxonomic identity, body of relevant knowledge and safety concerns of microorganisms intentionally added to the food and feed chain. Safety concerns identified for a taxonomic unit (TU) are, where possible, reflected by 'qualifications' that should be assessed at the strain level by EFSA's Scientific Panels. In total, 340 notifications were received between October 2022 and September 2025, of which, 190 were of microorganisms used for the production of feed additives, 87 for the production of food enzymes, food additives and flavourings, 3 for food contact materials, 22 as Plant Protection Products (PPPs) and 38 for novel foods. Bacteriophages, previously ineligible for the QPS status, are now eligible at the species level. The QPS list has been updated in relation to the most recent taxonomic insights and the qualifications were revised and streamlined. A BIOHAZ Panel Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes' was published and revised; the qualification 'for production purposes only' was extended to production strains or biomass; the qualification on genetic modified microorganisms (GMMs) was also extended to production strains, biomass or active agents, when the gene of concern is removed. Since 2023, *Chlamydomonas reinhardtii*, *Microchloropsis gaditana*, *Candida oleophila*, *Vibrio natriegens* and *Agrobacterium radiobacter* were recommended for QPS status with the qualification for '*production purposes only*'. *Clostridium tyrobutyricum* also but with the qualification '*absence of genetic determinants for toxin production*'. *Lacticaseibacillus huelsenbergensis* and *Lactobacillus paragasseri* (formerly included in *Lactobacillus gasseri*) were also included. *Bacillus sonorensis* was also recommended with the qualifications '*absence of bacitracin production ability*' and '*absence of toxigenic activity*'. *Bacillus thuringiensis* was not recommended for the QPS list due to safety concerns.

KEYWORDS

AMR, bacteria, bacteriophages, food and feed, microalgae, protists, QPS, qualification, qualified presumption of safety, risk assessment, viruses, yeast

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SUMMARY

The European Food Safety Authority (EFSA) asked the Scientific Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the qualified presumption of safety (QPS) list. The QPS list contains microorganisms, intentionally added to food and feed, which have received QPS status. The request included three specific tasks as mentioned in the Terms of Reference (ToR).

The QPS process was developed to provide a harmonised safety assessment approach to support EFSA Scientific Panels and Units. This process assesses the taxonomic identity, body of relevant knowledge and safety of microorganisms.

Safety concerns identified for a taxonomic unit (TU) are, where possible, confirmed at strain or product level, reflected as 'qualifications' that should be assessed at the strain level by EFSA's Scientific Panels. A generic qualification applies for all QPS bacterial TUs, 'the strains should not harbour any acquired resistance genes to therapeutic antimicrobials' (EFSA BIOHAZ Panel, 2023a).

The list of microorganisms is maintained and re-evaluated every 6 months in a BIOHAZ Panel Statement. The Panel Statement also includes the evaluation of newly notified microorganisms to EFSA in the context of technical dossiers for safety assessment, within the previous 6-month period. Since the last QPS Opinion (EFSA BIOHAZ Panel, 2023b), 6 Panel Statements have been published (part 18 to 23).

Every 3 years, an QPS opinion is published summarising the results of the Panel Statements published in that period. The Opinion also updates the QPS approach considering developments in microbial methodology (e.g. identification, typing, etc.), new scientific insights and new microbial applications in the food/feed chain.

The first ToR requires ongoing updates of the list of microorganisms notified to EFSA, in the context of a technical dossier for safety assessment. The updated *'Microbiological agents as notified to EFSA'* list can be found at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.3607183). In total, 340 notifications were received between October 2022 and September 2025, of which, 190 were of microorganisms used for the production of feed additives, 87 for the production of food enzymes, food additives and flavourings, 3 for food contact materials, 22 as PPPs and 38 for novel foods; 211 were bacteria, 81 filamentous fungi/ oomycetes, 38 yeasts, 4 protists, 3 microalgae, 3 viruses (1 was a bacteriophage).

The second ToR concerns the revision of the TUs previously recommended for the 'QPS list' and their qualifications. The articles were retrieved and assessed through an extensive literature search (ELS) protocol that can be found at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.3607188) together with the search strategies (https://doi.org/10.5281/zenodo.3607192). Since the last QPS Opinion (EFSA BIOHAZ Panel, 2023b), articles published from July 2022 to June 2025 were included in each of the 6 respective Panel Statements (part 18 to 23) and assessed.

Relevant information from the ELS includes case reports of human diseases, particularly infections or intoxications linked to the TU under assessment. The QPS status of TUs for which case reports were retrieved, has not been withdrawn due to the frequently incomplete description of the identification method, the lack of clear virulence determinants in their genomes, the extremely low incidence of infections when compared with the level of exposure to the concerned species, the underlying comorbidities of patients that predispose for opportunistic infections and the general lack of transmission evidence through food/feed sources.

From Panel Statement part 20 (EFSA BIOHAZ Panel, 2024b), the QPS TUs of bacteria, yeasts, microalgae, protists and viruses were checked every 6 months against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. Several corrections have been made in the QPS TUs names since then. The taxonomic update was also reflected in the ELS keywords of the subsequent cycle.

A BIOHAZ Panel Statement was published in 2023 and updated and republished in 2025 (EFSA BIOHAZ Panel, 2023a) to explain how the QPS qualification on 'acquired antimicrobial resistance genes' could be interpreted. A bioinformatic approach was proposed for demonstrating the 'intrinsic'/'acquired' nature of an AMR gene.

In the QPS list, the following qualification was added for all QPS status yeasts used as active agents (viable cells) for when they are used as production strains or as biomass (non-viable cells): *QPS applies for 'production purposes only' (the qualification 'for production purposes only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass)* (EFSA BIOHAZ Panel, 2025a).

The relation between QPS and genetically modified microorganisms, has been amended as follows:

- '*For genetically modified microorganisms (GMMs) for which the species of the parental/recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to the genetically modified strain(s) used as production strains, biomass or active agents* (EFSA BIOHAZ Panel, 2024a). *The QPS approach can also be followed if the qualifications for QPS are met due to the removal of a gene(s) of concern (e.g. AMR genes) by means of genetic modification*.' (EFSA BIOHAZ Panel, 2025a).
- The QPS concept can also be extended to GMMs generated by new genetic techniques (NGTs), and to more extensively genetically modified microorganisms deriving from synthetic biology. In the latter case, the QPS approach can be used for the risk assessment of chassis.

The QPS status cannot be automatically extended to species split from QPS taxonomic units based on new taxonomic insights. This is because the differences that justify the splitting might raise safety concerns.

For microorganisms that qualify for QPS, any adverse effect on the gut microbiome of humans and animals is assessed in the framework of the QPS evaluation based on the body of knowledge of the species to which the active agent belongs. For genetically modified active agents, the impact on the gut microbiome follows a case-by-case assessment.

The third ToR requires a (re)assessment of new TUs notified to EFSA, for their suitability for inclusion in the '*Updated list of QPS-recommended microorganisms for safety risk assessments carried out by EFSA*' at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.1146566).

Six Panel Statements have been published every 6 months, since the last QPS Opinion (EFSA BIOHAZ Panel, 2023b) and covering notifications received between October 2022 and September 2025. Thirty-eight TUs were considered for the assessment across Panel Statements part 18 to 23. From these 38, 7 were already evaluated in previous Panel Statements within this 3-years cycle and therefore were not re-evaluated. Eight of the remaining 31, were evaluated and recommended for inclusion on the QPS list, while 23 were evaluated but not recommended. The following eight TUs were recommended for the QPS status:

- *Chlamydomonas reinhardtii* – with the qualification for '*production purposes only*'
- *Microchloropsis gaditana* – with the qualification for *'production purposes only'*
- *Clostridium tyrobutyricum* – with the qualification *'absence of genetic determinants for toxin productio*n'
- *Rhizobium radiobacter*, synonym *Agrobacterium radiobacter* – with the qualification '*for production purposes only'*.
- *Lacticaseibacillus huelsenbergensis*
- *Bacillus sonorensis* – with the qualifications '*absence of bacitracin production ability*' and '*absence of toxigenic activity*'
- *Lactobacillus paragasseri* (formerly included in *Lactobacillus gasseri*)
- *Candida oleophila* – with the qualification for '*production purposes only*'

Filamentous fungi, streptomycetes, oomycetes, *Enterococcus faecium*, *Escherichia coli* (EFSA BIOHAZ Panel, 2020a), *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020b), *Klebsiella pneumoniae* (EFSA BIOHAZ Panel, 2024a), *Actinomadura roseirufa* and *Burkholderia stagnalis* (EFSA BIOHAZ Panel, 2024b) are excluded from the QPS assessments based on an ambiguous taxonomic position or on the possession of potentially harmful traits, and it is considered unlikely that any TUs within these groups would be granted QPS status in the foreseeable future. The assessment of members of the excluded biological groups needs to be carried out at strain level by the relevant EFSA Unit.

Previously and within this QPS 3-years cycle, bacteriophages were considered to be ineligible for the QPS status because of lack of a reliable taxonomic classification. As a new phylogeny-based taxonomy has been devised, allowing reconsideration of phage eligibility, the QPS concept was opened for bacteriophages at the species level. Bacteriophages used as production organisms may also get the QPS status with the qualification '*for production purposes only*' which would apply to products free of viable hosts and infective virions.

The taxonomic information, the body of knowledge and the safety of *B. thuringiensis*, including those used as biological agents, were assessed (EFSA BIOHAZ Panel, 2025b). Based on the assessment it was concluded that *B. thuringiensis* is not recommended for the QPS list due to safety concerns.

1 | INTRODUCTION

The qualified presumption of safety (QPS) approach was developed by the EFSA Scientific Committee to provide a generic concept for risk assessment within the European Food Safety Authority (EFSA) for microorganisms intentionally introduced into the food and feed chains, in support of the respective Scientific Panels and Units in the context of market authorisations for their use in food and feed and the requirement for a safety assessment by EFSA (EFSA, 2007; Herman et al., 2019). EFSA is requested to assess the safety of microorganisms used 'as such' or as production organisms for food and feed additives, food enzymes and food flavourings, plant protection products (PPPs), novel foods (NFs) or genetically modified microorganisms (GMMs). In each area, the risk assessment falls under specific EU legislations and the new EFSA microbial guidance (EFSA Scientific Committee, 2025) applies.

The list, first established in 2007, has been continuously revised and updated. A Panel Statement is published approximately every 6 months. These Panel Statements include the results of the assessment of relevant new scientific articles related to the taxonomic units (TUs) with QPS status. They also contain the assessment of newly submitted TUs to the EFSA Units on Feed and Contaminants (FEEDCO), Food Ingredients and Packaging (FIP), Nutrition and Food Innovation (NIF) and Pesticides Peer Review (PREV). Every 3 years, a QPS opinion is published summarising the results of the Panel Statements published in that period. The Opinion also updates the QPS approach considering developments in microbial methodology, new scientific insights and new microbial applications in the food/feed chain.

The QPS approach covers safety concerns for humans, animals and the environment. In the QPS concept, a safety assessment of a defined taxonomic unit (TU) is performed independently of the legal framework under which the application is made during a market authorisation process. Strains belonging to QPS TUs still require an assessment based on a specific data package by the relevant EFSA Scientific Panel, but the QPS status facilitates a fast-track evaluation (EFSA BIOHAZ Panel, 2023b, see also 1.4).

Safety concerns for a TU are, where possible, reflected as 'qualifications', which should be assessed at strain and/or product level by EFSA's Scientific Panels. The generic qualification '*the strains should not harbour any acquired resistance genes to therapeutic antimicrobials*' applies for all QPS bacterial TUs (EFSA BIOHAZ Panel, 2023a). The available definitions of 'acquired' and 'intrinsic' AMR genes and eventually, their distinction have triggered certain ambiguity in the interpretation of that generic QPS qualification by applicants and EFSA Panels and Units responsible for the risk assessment of the respective regulated products. The QPS working group and BIOHAZ Panel have decided to clarify these concepts of acquired and intrinsic AMR genes, considering the current body of knowledge on the genetic basis of these antimicrobial resistances and their clinical relevance (EFSA BIOHAZ Panel, 2023a, updated and amended in 2025).

1.1 | Background and Terms of Reference as provided by EFSA

A wide variety of microorganisms are intentionally added at different stages of the food and feed chain. In the context of applications for market authorisation, EFSA is requested to assess the safety of microorganisms when used either directly or as sources of food and feed additives, food enzymes, food flavourings, NFs, GMMs and PPPs.

EFSA's work on QPS activities began in 2004 when the Scientific Committee issued a scientific opinion in continuation of the 2003 working document '*On a generic approach to the safety assessment of microorganisms used in feed/food and feed/food production*' prepared by a working group consisting of members of the former Scientific Committee on Animal Nutrition, the Scientific Committee on Food and the Scientific Committee on Plants of the European Commission.[1] The document, made available for public consultation, proposed the introduction of the concept of Qualified Presumption of Safety (QPS), to be applied to selected groups of microorganisms. Microorganisms not considered suitable for QPS status would remain subject to a full safety assessment. EFSA management asked its Scientific Committee to consider whether the QPS approach could be applied to the safety assessment of microorganisms across the various EFSA Scientific Panels. In doing so, the Committee was required to take into account the response of stakeholders to the QPS approach. In its 2005 opinion (EFSA, 2005), the Scientific Committee concluded that the QPS approach could provide a generic assessment system that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food and feed chain. Its introduction was intended to improve transparency and ensure consistency in the approach used across the EFSA Panels. Applications involving a TU belonging to a species that falls within a QPS group do not require a full safety assessment.

Several TUs (usually species for bacteria, protists/microalgae and yeasts; families for viruses) have been included in the QPS list, either following notifications to EFSA, or proposals made initially by stakeholders during a public consultation in 2005, even if they were not yet notified to EFSA (EFSA, 2005). The EFSA Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and, in 2007, published a list of microorganisms recommended for the QPS list.

In their 2007 opinion (EFSA, 2007), the Scientific Committee recommended that a QPS approach should provide a generic concept to prioritise and to harmonise safety risk assessment of microorganisms intentionally introduced into the food and feed chain, in support of the respective Scientific Panels and EFSA Units in the frame of the market authorisations

[1] https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out178_en.pdf.

for their use. The same Committee recognised that there would have to be continuing provision for reviewing and modifying the QPS list and, in line with this recommendation, the EFSA Panel on Biological Hazards (BIOHAZ) took the prime responsibility for this and started reviewing annually the existing QPS list. In 2008, the first annual QPS update was published (EFSA, 2008).

In 2014, the BIOHAZ Panel, in consultation with the Scientific Committee, decided to change the revision procedure; the overall assessment of the TUs previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013) was no longer carried out annually but over a 3-year period. From 2017, the search and revision of the possible safety concerns linked to those TUs began instead to be carried out every 6 months through extensive literature searches (ELS). For instance, the update of the 2013 QPS list (EFSA BIOHAZ Panel, 2013) was done in 2016 (EFSA BIOHAZ Panel,2017). From 2016 on, the QPS list (https://doi.org/10.5281/zenodo.1146566) and the list of notifications to EFSA (https://doi.org/10.5281/zenodo.3607183) are constantly updated, independently from the QPS opinion, and are available at the Knowledge Junction in Zenodo. From 2016, the QPS opinion summarises the main results of the 3-year ELS on the QPS TUs, together with an update of the process for granting QPS status. In the meantime, every 6 months a Panel Statement, compiling the assessments for a QPS status of the microorganisms notified to EFSA requested by the Feed and Contaminants (FEEDCO) Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition and Food Innovation (NIF) Unit and the Pesticides Peer Review (PREV) Unit,[2] as well as the summary of each 6-month ELS exercise, has been produced and published. Each QPS Panel Statement contains the evaluations of the new notifications for microorganisms submitted for possible QPS status. It also contains the result of a standardised ELS performed every 6 months regarding possible new safety concerns related to the TUs already included in the QPS list. The data identified are used to inform decisions on whether any TU may or may not remain in the QPS list, and whether any qualifications need to be revised.

Establishing a QPS status is based on 4 pillars: [1] the taxonomic unit (TU) for which QPS is sought ('*taxonomic identification*'); [2] whether sufficient relevant information is available about the proposed TU to conclude on human/animal exposure via food/feed ('*body of knowledge*'); [3] whether the TU proposed contains known '*safety concerns*' and, finally, [4] the intended end use ('*intended use*'). If a hazard related to a TU is identified, which can be tested at the strain or product level, a 'qualification' to exclude that hazard may be established and added. The subject of these qualifications for the microbial strain under investigation is evaluated by the EFSA Unit to which the application dossier has been allocated. Absence of acquired genes coding for resistance to therapeutic antimicrobials for humans and animals is a generic qualification for all bacterial TUs; the absence of antimycotic resistance should be proven if the pertinent yeasts are to be used as viable organisms in the food and/or feed chain. The qualification '*for production purposes only*' implies the absence of viable cells of the production organism in the final product and can also be applied to food and feed products based on microbial biomass (EFSA BIOHAZ Panel, 2020a).

Because the QPS evaluation is, after its initial creation, only triggered through an application dossier notified to EFSA or through an internal request for particular reasons, the QPS list is not exhaustive.

In summary, the QPS evaluation provides a generic safety pre-assessment approach for use within EFSA that covers safety concerns for humans, animals and the environment. In the QPS concept, a safety assessment of a defined TU is performed independently of the legal framework under which the application is made in the course of an authorisation process. Although general human safety is part of the evaluation, specific issues relating to type and level of exposure of users handling the product (e.g. dermal contact, inhalation, ingestion) are not addressed. In the case of GMMs for which the species of the recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to genetically modified production strains (EFSA BIOHAZ Panel, 2018). The assessment of potential allergenic microbial residual components is beyond the QPS remit; however, it is reported if science-based evidence is available for a microbial species. These aspects are separately assessed, where applicable, by the EFSA Panel responsible for assessing the application.

The lowest TU for which the QPS status is granted is the species level for bacteria, yeasts and protists/microalgae, and family for viruses.

Filamentous fungi, bacteriophages,[3] streptomycetes, oomycetes, *Enterococcus faecium, Escherichia coli* (EFSA BIOHAZ Panel, 2020a), *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020b) *Klebsiella pneumoniae* (EFSA BIOHAZ Panel, 2024a), *Actinomadura roseirufa* and *Burkholderia stagnalis* (EFSA BIOHAZ Panel, 2024b) are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits of these biological groups, therefore requiring a specific assessment for each strain for which an application is made.

The **Terms of Reference** are as follows:

ToR 1: Keep updated the list of microorganisms being notified in the context of a technical dossier to EFSA Units such as FEEDCO, PREV, FIP and NIF,[4] for intentional use directly or as sources of food and feed additives, food enzymes and PPPs and GMMs for safety assessment.

ToR 2: Review TUs previously recommended for the QPS list and their qualifications when new information has become available. The latter is based on an update of the ELS aiming to verify whether any new safety concern has arisen that could require the removal of a TU from the list, and to verify if the qualifications still effectively exclude safety concerns.

[2]Units as in December 2022.

[3]Bacteriophages were excluded since 2020 and within this 3-years QPS cycle (2023–25) but this exclusion has been revised within this QPS opinion, please see Section 3.7.

[4]Units as in December 2022.

ToR 3: (Re) assess the suitability of new TUs notified to EFSA for their inclusion in the QPS list. These microorganisms are notified to EFSA in the context of technical dossiers for safety assessment and trigger a QPS assessment.[5]

1.2 | Interpretation of the Terms of Reference

In the current 3 years cycle of this mandate, the ToRs were addressed in the different Panel Statements published each 6 months, part 18 to part 23 (EFSA BIOHAZ Panel, 2023, 2024a, 2024b, 2025b, 2025a, 2026). The QPS list (https://doi.org/10.5281/zenodo.1146566) and the list of notifications to EFSA (https://doi.org/10.5281/zenodo.3607183) were updated each 6 months and are available at the Knowledge Junction in Zenodo. In this QPS opinion, a summary is made of these activities. The ELS searches strings and protocol, used to revise the published literature concerning possible safety concerns, are available at the Knowledge Junction in Zenodo (ELS protocol in https://doi.org/10.5281/zenodo.3607188 and the search strategies in https://doi.org/10.5281/zenodo.3607192).

Besides this summary, the QPS opinion focuses on the methodology used for updating the QPS list and assessing the notifications. It also indicates how the QPS status is currently applied in the microbial risk assessment of EFSA and suggests improvements on how it could be applied in the assessment of applications expected in the near future following new scientific developments in this area and on new microbial applications in the food chain.

1.3 | Use of the QPS status in microbial safety assessment by EFSA - the QPS approach applied to each EFSA food and feed safety risk assessment area

The microorganisms intended to be used in the food and feed chain encompass bacteria, yeasts, fungi, viruses (including bacteriophages), protists and microalgae.

The use of microorganisms within the EU agri-food sector requires, depending on the specific type of end-use regulation, a pre-market authorisation which is based on an EFSA risk assessment. These risk assessments are carried out in the context of applications for feed and food additives, food enzymes and flavourings, novel foods, plant protection products or genetically modified microorganisms.

The QPS concept is a cross-cutting safety concept used in the different risk assessment areas in EFSA. An EFSA '*Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain*' has aligned the requirements on the characterisation of microorganisms for applications underpinning the assessment of microorganisms in the different areas of the food chain (EFSA Scientific Committee, 2025). This guidance explains how the QPS status is used in the assessment of new applications. The QPS assessment process is triggered internally by EFSA after receiving an application for market authorisation (Figure 1). It cannot be triggered directly by an applicant. Applications sent to EFSA are checked for completeness before being distributed to the relevant EFSA Unit(s). Simultaneously, a list with all notified applications that include a microorganism (usually a strain) is shared with the Biological Hazards (BIOHAZ) Team, responsible for coordinating all activities related to the QPS process. If a strain belongs to a TU without a QPS status, which is not excluded from the QPS process (see 3.3.4) and has not undergone yet a recent QPS assessment (within the current QPS 3-years cycle), an assessment for a possible QPS status is initiated and the result included in the following QPS Panel Statement (see 1.4). Microorganisms that are excluded or without a QPS status are subject to a complete safety assessment, outside the QPS approach.

An interactive multimedia tool for more information about how the QPS process is carried out at EFSA can be found on https://www.efsa.europa.eu/en/applications/qps-assessment.

[5]Previous text 'These microorganisms are notified to EFSA and requested by the Feed Unit, the FIP Unit, the Nutrition Unit or by the Pesticides Unit'.

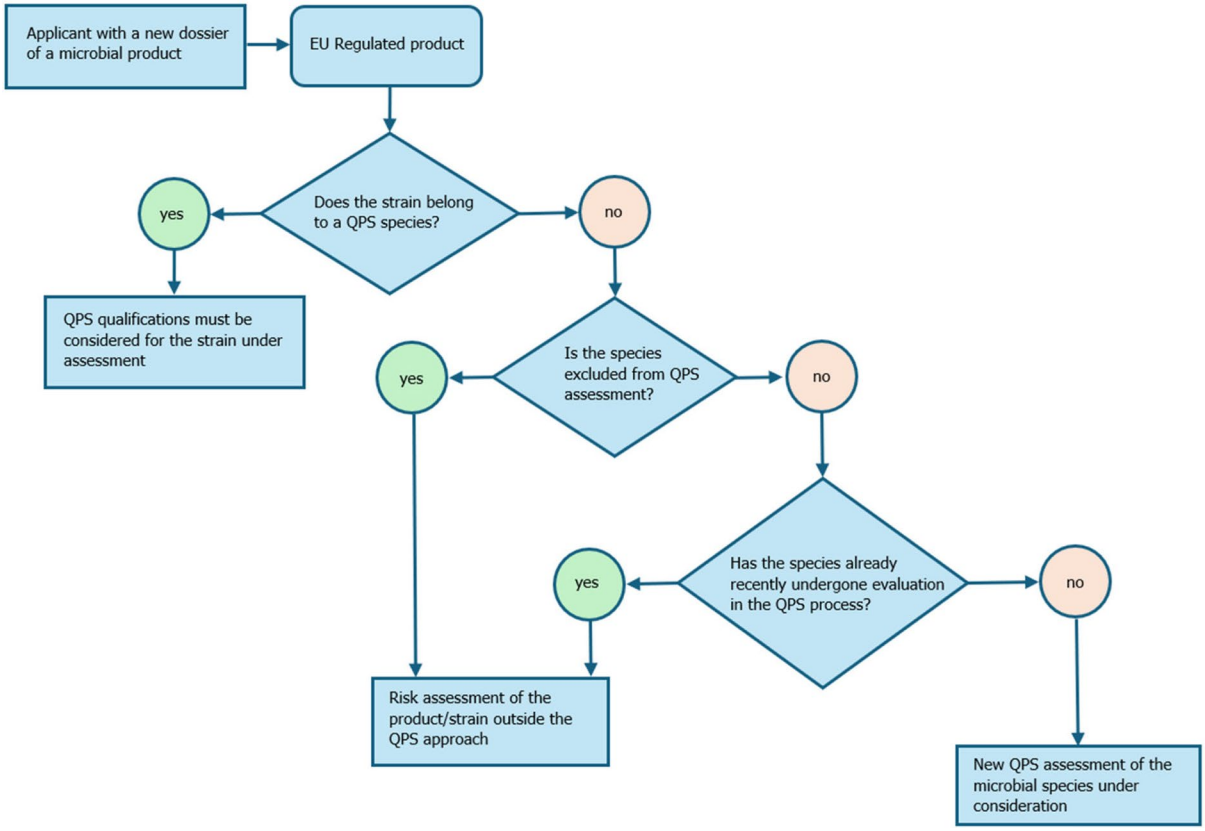


FIGURE 1 QPS process with the flow of decisions taken internally at EFSA during the risk assessment of a microbial product.

1.4 | Simplified safety assessment by EFSA for QPS microorganisms

Strains belonging to TUs with QPS status (species for all cases except for non-bacterial viruses for which is the family) and meeting the QPS qualifications are generally presumed safe for humans, animals and the environment without further studies.

For GMMs for which the species of the parental/recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to the genetically modified strain(s) used as production strains, biomass or active agents (EFSA BIOHAZ Panel, 2024a). The QPS approach can also be followed if the qualifications for QPS are met due to the removal of a gene(s) of concern (e.g. AMR genes) by means of genetic modification (EFSA BIOHAZ Panel, 2025a).

The following aspects of the EFSA risk assessment are not covered by the QPS status and have to be separately assessed, when applicable, by the EFSA Scientific Panel responsible for assessing the application: (1) exposure of users handling the product (e.g. dermal contact, inhalation, ingestion); (2) potential allergenicity of the microbe or its residual components or produced metabolites; (3) environmental hazards for PPPs and environmental risk assessment legally required for GMMs; and (4) hazards linked to the product formulation and/or the production and purification process.

The QPS status of microbial TUs provides a simplified safety assessment of microbial strains belonging to the QPS TUs with less data requirements. For these microorganisms and the metabolites they produce, no safety issues are expected. Therefore, data are generally not required for e.g. antimicrobial production, toxigenicity and pathogenicity (including infectivity) for humans and animals, environmental risks (for non-GM and non-PPPs) or for adverse effects on the gut microbiota (see EFSA Scientific Committee, 2025 for further details).

Strains belonging to a QPS TU still require an assessment based on a specific data package as requested by the EFSA Guidance (EFSA Scientific Committee, 2025). Requirements may include, for example, data confirming the taxonomic identification of the requested microbiological strain as belonging to the QPS TU. If the QPS status of the TU to which the strain belongs is defined with some qualifications, data confirming the compliance with these qualifications are required, e.g. the generic qualification for all QPS bacterial TUs in relation to the absence of acquired genes conferring resistance to therapeutic antimicrobials (antimicrobials of medical and veterinary importance[6]). Guidance on how to discriminate, between

[6]For the purpose of the assessment of antimicrobial susceptibility and production in EFSA, the antimicrobial substances considered are those of medical and veterinary importance for humans and animals as defined by WHO and WOAH, respectively ('medically important antimicrobials' as indicated in Table 1 and further detailed in Tables 2 and 3 (WHO, 2024) and 'veterinary critically important antimicrobial agents', 'veterinary highly important antimicrobial agents' and 'veterinary important antimicrobial agents' (WOAH, 2024)).

acquired and intrinsic AMR genes is provided in an EFSA Statement, (EFSA BIOHAZ Panel, 2023a). For *Bacillus* spp., the lack of toxigenic potential needs to be confirmed. The qualification '*for production purposes only*' needs to be met by submitting data excluding the presence of viable cells of the microorganism in the product under assessment in the concerned technical dossier. For GMMs, the safety of the genetic modification needs to be confirmed.

2 | DATA AND METHODOLOGIES

2.1 | ToR 1: Update of EFSA notifications list

Applications sent to EFSA are first checked for completeness at the Front-Desk and Workforce Planning (FDP) Unit, before being distributed to the respective Units. Simultaneously, a list with all notified applications that include a microorganism is prepared and shared monthly with the BIOHAZ Team. The list '*Microbial species as notified to EFSA*' (https://zenodo.org/doi/10.5281/zenodo.3607183) compiles all microorganisms notified to EFSA in the context of a technical dossier for safety assessment, from the beginning of the QPS exercise in 2007.

2.2 | ToR 2: Review of taxonomic units previously recommended for the QPS list and their qualifications

In reply to the ToR 2, on the revision of the TUs previously recommended for the QPS list and their qualifications, an ELS is conducted every 6 months. The protocol is available at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.3607188), and the Search strategies as well (https://doi.org/10.5281/zenodo.3607192). The references retrieved are checked to verify if any new safety concern has arisen that could require a change in the QPS status of the TU and result in a withdrawal from the list or a change in the respective qualifications.

The Title and Abstract screening step in this process was supported by a machine-assisted tool (DAISY) in DistillerSR. To do that, a Classifier was created de novo to answer the screening question. The training dataset used consisted of 564 random references (80% of the ones included and a number of the ones excluded that was five times the number of the included) from the QPS batches 18 and 19 (see Section 3.2.1) screened by two human reviewers in parallel, for which conflicts were reconciled by discussion. The total number of references in the training dataset was 94 in class Yes and 470 in class No. The classifier was validated against all the remaining references of the QPS batches 18 and 19. To assess the stability of the model, the entire process was run 23 times. The results of the model were compared with the combined judgement of the two experts after solving the conflicts. The specificity was always close to 0.99 and the sensitivity was in general above 0.75 with a lower value of 0.67 and a higher one of 0.88. The initial experts' agreement for the papers that were considered as relevant at Title and Abstract screening step for the QPS batches 18 and 19 was 50%. In this context, the results of the validation were considered stable and fit for purpose even in the worst-case sensitivity scenario recorded. To predict the outcome of the Title and Abstract screening step of a new batch of references a new classifier was then created de novo. The training dataset used consisted of 702 references (all the ones included and a random number of the ones excluded that was five times the number of the included) from the QPS batches 18 and 19. The classifier was validated using the DistillerSR built in three-fold cross-validation method. The Performances of the classifier confirmed the results recorded when validating the initial classifier also suggesting some improvements.

The Title and Abstract screening step was then performed in parallel by one Expert and the classifier on QPS batches 20, 21 and 22 (see Section 3.2.1).

To continuously improve the performance of the algorithm, conflicts between the Experts and the classifier were solved. In case of conflicts where the answer of the classifier had to be changed (after consultation with the concerned Expert), the reply was changed manually by the EFSA Scientific Officer in charge of the assessment which had administration rights on the DistillerSR project.

An assessment of the stability of the classifier was done by comparing its performance on QPS batches 20 and 21. The performance were similar in the two batches.

An updated classifier was then build using the information gained with the screening of batches 20 to 22. A first classifier was trained considering the information gained with the screening of batches 18, 19 and 20 and its performance were assessed predicting the results obtained in the screening of batch 21. Overall, the specificity of the Classifier was 0.99, while its sensitivity was > 0.98 when considering the results of the process up to the Article Evaluation step. Similar results were obtained when updating again the classifier using as training set batches from 18 to 21 and predicting the results of batch 22.

The classifier was then considered stable and fit for purpose to be used alone for screening references at Title and Abstract level. Hence, it was further updated by using as a training set the results of the screening process of batches from 18 to 22 and used as unique reviewer to screen the references of batch 23 at Title and Abstract level (see Section 3.2.1).

From Panel Statement part 20, the QPS TUs of bacteria, yeasts, microalgae, protists and viruses were checked every 6 months against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. The ELS for each Panel Statement included the updated names/synonyms as keywords. The methodology was

described in a Panel Statement (EFSA BIOHAZ, 2024b). The taxonomic update was also reflected in the ELS keywords of the subsequent cycle.

2.3 | ToR 3: Evaluation of a QPS recommendation for taxonomic units notified to EFSA

To address the ToR 3, (re)assessment of the suitability of TUs notified is carried out each 6-month period. These microorganisms are notified to EFSA in the context of an application for market authorisation for safety assessment and it may trigger a QPS assessment (see 1.3). Relevant databases, such as PubMed, Web of Science, CAB Abstracts, Food Science Technology Abstracts (FSTA) and Scopus, are searched for information related to the QPS assessment including taxonomic identification, body of knowledge and safety concerns in relation to virulence/pathogenicity and the environment. The searches performed are documented for each assessment. In the case the literature data and/or the taxonomic identity indicates the possible production of secondary metabolites of concern, the genetic potential for this production is investigated based on the analysis of the available whole genome sequences.

2.3.1 | Taxonomic identification

The TU for which the QPS status is granted corresponds to the species for bacteria, bacteriophages, yeasts, protists and microalgae and to the family for non-bacterial viruses. Only unambiguously defined biological TUs are considered for inclusion in the QPS list. Microbial taxonomy is a very dynamic discipline, recently supported mainly by phylogenetic analysis of housekeeping genes and whole genome relatedness [e.g. digital DNA–DNA hybridisation (dDDH), average nucleotide identity (ANI), phylogenomics, etc.] (EFSA Scientific Committee, 2025).

The resulting re-classifications of microorganisms have led to necessary adaptations in the QPS list, which is updated in successive QPS Statements.

Bacterial taxonomy

Taxonomic identity is based on internationally accepted nomenclature, overseen by the '*International Committee on Systematics of Prokaryotes*' (ICSP). The nomenclature of bacteria and their changes are covered by the '*International Code of Nomenclature of Prokaryotes*' (ICNP; 2022 and future updates),[7] after being proposed and validly published in the '*International Journal of Systematic and Evolutionary Microbiology*' (IJSEM) (formerly *International Journal of Systematic Bacteriology*) and are reported on the website: '*List of Prokaryotic Names with Standing in Nomenclature*' (LPSN) (Meier-Kolthoff et al., 2022)[8] which is an expert-curated authoritative resource for prokaryotic nomenclature. The 'Type (Strain) Genome Server' (TYGS) is a high-throughput platform for accurate genome-based taxonomy.[9]

Yeasts taxonomy[10]

The nomenclature and taxonomy of yeasts are covered by the '*International Code of Nomenclature for Microalgae, Fungi, and Plants*' (ICNafp); (Turland & Wiersema, 2024 and future updates) and can be found at the MycoBank database[11] and Index Fungorum databases.[12]

The distinction between a filamentous fungus and a yeast, and thus whether an organism would be eligible for QPS evaluation and status (yeasts), or not (filamentous fungi) is sometimes not clear-cut. Kurtzman (2011) define yeasts as follows: 'In summary, yeasts, whether ascomycetes or basidiomycetes, are generally characterised by budding or fission as the primary means of asexual reproduction and have sexual states that are not enclosed in fruiting bodies'. This definition implies that yeasts are not expected to belong to any other fungal phylum than ascomycetes and basidiomycetes. However, they considered that of the three lineages within the Ascomycota, only two contain yeasts, whereas the third (Pezizomycotina) does not. This is in line with the fact that typically, members of Pezizomycotina contain a high abundance of enzymes for secondary metabolism, which is generally in contrast to yeasts but similar to filamentous fungi (e.g. Naranjo-Ortiz & Gabaldón, 2019).

The decision whether a species should be considered to be a yeast or a filamentous fungus for QPS purposes is taken on a case-by-case basis, but applying the following general rules and limitations. A fungus may be subject to evaluation for QPS status if it (i) belongs to the phyla Ascomycota (excluding the Pezizomycotina) or Basidiomycota and (ii) is treated as a yeast by taxonomic literature.

[7]International Code of Nomenclature of Prokaryotes Prokaryotic Code (2022 Revision). Available at https://www.microbiologyresearch.org/content/journal/ijsem/10.1099/ijsem.0.005585#tab2.

[8]List of Prokaryotic Names with Standing in Nomenclature (LPSN). Available at: https://lpsn.dsmz.de/.

[9]Type (Strain) Genome Server (TYGS) available at https://tygs.dsmz.de.

[10]Under QPS approach, only yeasts are covered as filamentous fungi are excluded.

[11]https://www.mycobank.org/.

[12]Index Fungorum database (maintained by the Royal Gardens Kew). Available online: https://www.indexfungorum.org.

As supporting information, the taxonomy applied by internationally recognised microbial culture collections and databases is considered (e.g. Fungal Biodiversity Centre (CBS) – Fungi strains; https://wi.knaw.nl/page/fungal_table with the yeast page https://theyeasts.org/).

Viral taxonomy

For viruses, including bacteriophages, taxonomy and nomenclature are described by Turner (Turner et al., 2021) and maintained by the '*International Committee on Taxonomy of Viruses'* (ICTV).[13]

Updates are made annually, based on proposals of Study Groups and after adoption by the Executive Committee. These updates from the 10th Report of the ICTV, are available through the ICTV website (https://ictv.global/taxonomy). Despite the introduction of higher taxa there are no consequences for the currently approved taxa for QPS.

A species is the lowest taxon recognised by the ICTV. A strain is a genetic variant or subtype within a species with stable biological characteristics. In the case of baculoviruses, a species is based on a consensus sequence with > 95% sequence homology (Wennmann et al., 2019).

The taxonomic unit considered for the QPS approach for non-bacterial viruses (*Alphaflexiviridae, Potyviridae* and *Baculoviridae)* is the family level. For bacteriophages it is the species level (see 3.7) level.

Microalgae and other protists taxonomy

For microalgae and other protists, although currently there is no unanimously accepted classification, their nomenclature and taxonomy are covered by the MicroalgaeBase database[14] and the 'International Code of Nomenclature for microalgae, fungi, and plants' (ICNafp) and can be found at the NCBI taxonomy browser.[15]

GenBank ®, a NIH genetic sequence database containing an annotated collection of all publicly available DNA sequences (https://www.ncbi.nlm.nih.gov/genbank/) can be used as the basis for the assessment.

2.3.2 | Body of knowledge

The body of knowledge is mainly obtained through inspection of peer-reviewed papers published in journals and books that appear in scientific literature databases. To evaluate if the body of knowledge is sufficient to grant a TU QPS status, several aspects are taken into account, such as the robustness of available scientific evidence indicating a certain degree of exposure of humans and animals through food and feed use.

Aspects of the ecology of the microorganism are also taken into account. This includes the distribution of the TU in natural environments (e.g. as part of the human microbiota, of wild and farmed animals and in natural and cultivated plant ecosystems) and their colonisation ability and routes for dispersal. The body of knowledge also includes the history of the use of a TU in agricultural and food manufacturing systems and its related occurrence in the food and feed chains or in other sectors (e.g. biotechnological or medical applications). For this, information on the direct use of viable cells (e.g. as feed additives including those with 'probiotic' activity, food starter cultures, novel foods or PPPs), the use for production purposes (e.g. production of amino acids, biomass, enzymes, vitamins and polysaccharides) or its use in biotechnological or medical applications is examined. When detection in food or feed microbial communities is reported, its presence as a spontaneous contaminant versus its use as a main fermentative microorganism is considered.

2.3.3 | Safety concerns in relation to pathogenicity and virulence

TUs assessed for the QPS list should not represent a hazard to human or animal health, nor to the environment, when used within the food or feed chain.

Relevant information includes case reports of human diseases, particularly infections or intoxications linked to the TU under assessment. Additional important information considers host susceptibility - if reported diseases occur exclusively in individuals with underlying conditions predisposing to opportunistic infections (e.g. immunosuppression), these cases are not considered indicative of an intrinsic pathogenic potential of the TU. In this context, it is also relevant to determine whether transmission occurred through food or other routes (e.g. medical devices).

Studies indicating the presence of virulence factors (e.g. toxins and enzymes that might contribute to the pathogenicity of the microorganism) in the TU are also relevant for the identification of potential safety concerns. As WGS of microorganisms is becoming increasingly available, searching for the presence of genetic determinants encoding genes of concern has been incorporated in this assessment. The WGS also offers the opportunity to check if a TU mentioned in QPS relevant papers is correctly identified based on, for example, ANI or dDDH (EFSA, 2024a and future updates). WGS analysis is being

[13] https://ictv.global/taxonomy.
[14] https://www.algaebase.org.
[15] https://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi.

more systematically incorporated with the support of the Microorganisms Pipelines Project (MoPS), an EFSA tool that can be used to retrieve relevant information from available genomes of the TU under scrutiny.

Assessment of allergenicity of residual microbial components in microbial products (e.g. proteins, secondary metabolites, etc.) is beyond the QPS assessment remit; nevertheless, if there is science-based evidence for some microbial species related to well defined clinical cases, this is taken into consideration. Although general human safety is part of the evaluation, specific issues connected to the exposure of users handling the product (e.g. dermal, inhalation) are not addressed.

Reports of infection, intoxication or other diseases caused by the assessed TU in livestock are also relevant information for identifying potential safety concerns. As with safety concerns for humans, whether diseases are acquired through exposure via feed, or other routes (e.g. wounds, inhalation) is also relevant information.

The environmental safety assessment considers potential adverse effects on microorganisms present in the natural environment. The environmental risk assessment of PPPs is not included in the QPS assessment but is carried out by the Member State competent authority and peer reviewed by EFSA's Units dealing with PPPs based on the information in the application dossier.

2.3.4 | Microbial safety/opportunistic infections by QPS species

The pathogenicity potential of QPS species is investigated on a regular basis mainly by literature search analysis of:

- pathogenicity evidence from clinical cases and epidemiological data sources;
- functional characterisation of genes discovered in available genome sequences of TU with special attention to documented virulence factors and AMR determinants;
- experimental approaches using in vitro and in vivo model systems.

Opportunistic infections related to TUs on the QPS list are sporadically reported. Therefore, these are further investigated, leading to the following observations:

- The development of opportunistic infections is based both on the host factors and features of the microorganisms. These features are related to virulence potential and to exposure. The level of exposure and the severity of pre-existing host morbidity determine the probability of the occurrence of opportunistic infections. Thus, opportunistic infections would often result from the combination of these different aspects.
- In relation to the putative pathogens, the clinical reports frequently omit essential information on the isolation and identification of the associated microorganisms or describe procedures for identification that are not taxonomically appropriate. This results in uncertainty about the real identity of the claimed pathogens. Moreover, the co-detection of other microorganisms, including primary pathogens, is common. This suggests that in these cases either colonisation or sample contamination by the claimed QPS organism may have occurred. This questions the causality relation between the QPS organism and the adverse effect, making it impossible to determine its pathogenic character.
- For patients, the literature usually describes the main features of the cases with an emphasis on the clinical characteristics of the patient, including any pre-existing conditions and the final outcome. In most cases, the infections associated with QPS species occur in individuals who suffer severe impairment of their immune response due to one or several of the following conditions: prematurity, metabolic illnesses such as diabetes, lymphoma and other tumours, AIDS, previous infection by primary pathogens that could not be controlled by antimicrobials, illnesses that generate life threatening conditions, such as endocarditis, septicaemia, abdominal or thoracic organ malfunction, etc. Additionally, opportunistic infections are often associated with use of medical devices in the patients, e.g. catheters or parenteral nutrition.
- Moreover, the incidence of the infections is extremely low, especially when compared with the level of exposure: most of the species involved are widespread and common components of the microbial communities of the food system. As such, they can occur in spontaneous food fermentations and are commonly used as starter cultures for food and feed processing and, in most cases, are ingested alive in large amounts with no harm to the consumers. This is the case for several QPS species of the family *Lactobacillaceae*, the genera *Bacillus and Bifidobacterium* and the species *Lactococcus lactis* and *Saccharomyces cerevisiae*. In addition, bifidobacteria and lactobacilli are essential for the functioning of the digestive and urogenital tracts. Although the level of exposure to these microorganisms could potentially suggest a food or endogenous source for the infections, only very rarely can the putative etiological pathogens be ascribed to components of the diet or to presence among the human microbiota, and such infections are almost invariably linked to consumption of high doses of organisms within probiotic food supplements administered to greatly weakened patients.
- The WGS data available do not reveal clear virulence determinants in the genomes of the QPS microorganisms most frequently found associated with opportunistic infections.

To be highlighted that human 'probiotics' are not subject of a safety assessment by EFSA (and therefore not QPS assessed) unless they are introduced as a novel food/supplement or as a genetically modified microorganism.

In conclusion, although infection with QPS species is occasionally reported, their QPS status has not been withdrawn due to the frequently incomplete description of the identification method, the lack of clear virulence determinants in their genomes, the extremely low incidence of infections when compared with the level of exposure to the concerned species,

the underlying comorbidities of patients that predispose for opportunistic infections and the general lack of transmission evidence through food/feed sources.

Overall, current evidence does not indicate that microorganisms with QPS status pose a safety concern for healthy humans, animals or the environment under their intended conditions of use.

2.3.5 | Interpretation of the QPS qualification on 'acquired antimicrobial resistance genes'

For all bacterial TUs on the QPS list, the generic qualification '*the strains should not harbour any acquired resistance genes to therapeutic antimicrobials*' applies.

A Panel BIOHAZ statement was published in 2023 and updated and republished in 2025 (EFSA BIOHAZ Panel, 2023a) to explain how the QPS qualification on '*acquired antimicrobial resistance genes*' should be interpreted. This Statement was further used as basis for the EFSA *'Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain'* (EFSA Scientific Committee, 2025) and was applied to prepare a '*Catalogue of antimicrobial resistance genes in species of* Bacillus *used to produce food enzymes and feed additives*' (EFSA, 2024b).

In the '*Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes*' EFSA BIOHAZ Panel, 2023a), the terms 'intrinsic' and 'acquired' AMR genes were defined for the purpose of EFSA's risk assessments, and they apply to bacteria used in the food and feed chains. A bioinformatic approach (e.g. based on the pangenome analysis of a set of relevant strains of the TU) was proposed for demonstrating the 'intrinsic'/'acquired' nature of an AMR gene. 'Intrinsic' AMR genes should be considered as of no concern in the framework of the EFSA risk assessment purpose. 'Acquired' AMR genes coinciding with the corresponding antimicrobial phenotypic resistance should be considered as a hazard/ concern. If the presence of the 'acquired' AMR gene is not leading to phenotypic resistance, further case-by-case assessment is necessary.

3 | ASSESSMENT

3.1 | ToR 1: Update of EFSA notifications list

Between October 2022 and September 2025, a total of 340 notifications were received and analysed for a possible inclusion in the QPS process. Of these, 190 were for feed additives, 87 for food enzymes, food additives and flavourings, 3 for food contact materials, 38 for novel foods and 22 for plant protection products (PPPs). In terms of the types of organisms notified; 211 were bacteria, 81 filamentous fungi/oomycetes, 38 yeasts, 4 protists, 3 microalgae, 3 viruses (including 1 bacteriophage) (Table 1). The notification list, which is updated every 6 months, is publicly available (https://doi.org/10.5281/zenodo.3607183) (see Table 1).

TABLE 1 Notifications received by risk assessment area from October 2022 until September 2025, per type of microorganism (from QPS Panel Statements, part 18 to part 23)

	Microalgae	Bacteria	Bacteriophages	Filamentous fungi	Virus (non bacteriophages)	Yeasts	Protists	Grand Total
Feed additives	1	143		26		20		190
Food enzymes, food additives and flavourings		38		39		10		87
Food contact materials		3						3
Novel foods	2	20		6		6	4	38
Plant protection products		7	1	10	2	2		22
Grand Total	**3**	**211**	**1**	**81**	**2**	**38**	**4**	**340**

3.2 | ToR 2: Review of taxonomic units previously recommended for the QPS list and their qualifications

3.2.1 | Review of the taxonomic units by extensive literature search

The aim of the ELS carried out in response to ToR 2 (review of the recommendations for the QPS list and specific qualifications) was to identify any available studies reporting on safety concerns for humans, animals or the environment caused by QPS organisms.

Within the time frame of this Opinion, a total of six ELS exercises have been run, with searches made for the following periods of publication. The summary of the results was published every 6 months within the Panel Statements:

- From July to December 2022 (inclusive): Panel Statement part 18;
- From January to June 2023 (inclusive): Panel Statement part 19;
- From July to December 2023 (inclusive): Panel Statement part 20;
- From January to June 2024 (inclusive): Panel Statement part 21;
- From July to December 2024 (inclusive): Panel Statement part 22;
- From January to June 2025 (inclusive): Panel Statement part 23.

The 'Updated list of QPS-recommended biological agents for safety risk assessments carried out by EFSA' (previously '2022 QPS list', from this Opinion, '2025 QPS list') is available at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.1146566).

Within this 3-years period, after removal of duplicates, 49,509 records proceeded to the title and abstract screening step, resulting in the exclusion of 49,046 records. The remaining 463 records were deemed eligible for article evaluation step (full text), of which 219 were considered to report a potential safety concern and were further analysed.

The flow of records from their identification by the different search strategies (as reported in Appendix C) to their consideration as potentially relevant scientific articles for QPS is shown in Table 2.

No safety concerns that would change the QPS status of the TUs on the QPS list have been identified.

TABLE 2 Flow of records by the ELS search strategy step for the 3-year period (July 2022 until June 2025)

Species	Title/abstract screening step	Article evaluation step (screening for potential relevance)	Article evaluation step (identification of potential safety concerns)
Bacteria (total)	**30,398**	**198**	**98**
Bacilli	10,568	62	34
Geobacillus stearothermophilus	8	0	0
Bifidobacterium	2712	14	5
Carnobacterium divergens	34	0	0
Corynebacterium glutamicum	593	2	1
Gram negatives[a]	2832	4	1
Lactobacilli	8783	59	22
Lactococcus lactis	1385	30	9
Leuconostoc	765	23	9
Microbacterium imperiale	4	0	0
Oenococcus	187	0	0
Pasteuria nishizawae	2	0	0
Pediococci	1422	2	1
Propionibacterium	198	0	0
Streptococcus thermophilus	804	2	0
Viruses (total)	**1322**	**3**	**0**
Alphaflexiviridae/Potyviridae	679	2	0
Baculoviridae	643	1	0
Yeasts	**14,984**	**262**	**121**
Protist	**100**	**0**	**0**
Microalgae	**2705**	**0**	**0**
Total	**49,509**	**463**	**219**
Excluded	49,046	244	0

[a]*Gluconobacter oxydans/Xanthomonas campestris/Cupriavidus necator/Komagateibacter sucrofermentans/Agrobacterium radiobacter/Vibrio natriegens.*

3.2.2 | Update of the QPS TUs nomenclature

From Panel Statement part 20 (EFSA BIOHAZ Panel, 2024b) the QPS TUs of bacteria, yeasts, microalgae, protists and viruses were checked every 6 months against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. The taxonomic update was also reflected in the ELS keywords of the subsequent ELS cycle.

The following updates were done, summarised per Panel Statement:

Panel Statement part 21 (EFSA BIOHAZ Panel, 2025b):

The updated names, mentioned as correct names in the databases, for *Acidipropionibacterium acidipropionici* (previously *Propionibacterium acidipropionici), Shouchella clausii* (previously *Alkalihalobacillus claussii*), *Lederbergia lenta* (previously *Ledebergia lentus*), *Heyndrickxia coagulans* (previously *Weizmannia coagulans*) *and Phaffia rhodozyma* (previously *Xanthophyllomyces dendrorhous)* were included in the QPS list. Besides this, new synonyms were added for 25 bacteria and 9 yeast TUs. For two bacteria and four yeast TUs previous synonyms were removed because they were no longer valid. For protists and microalgae, all names are correct, but one synonym was removed because it is indicated as a different species. For more details see the QPS Panel Statement part 20 (BIOHAZ Panel, 2024b). These names/synonyms were used for the ELS search strategy for Panel Statement part 21.

Panel Statement part 22 (EFSA BIOHAZ, 2025a):

A swap has been made in the QPS list between *Agrobacterium radiobacter* (correct name) and *Rhizobium radiobacter* (synonym).

Panel Statement part 23 (EFSA BIOHAZ, 2026):

The following changes were made in the QPS list: (1) a swap between correct name and synonym resulting in *Lactibacillus rhamnosus* (correct name) and *Lacticaseibacillus rhamnosus* and *Lacticaseibacillus casei* subsp. *rhamnosus* (synonyms); (2) a swap between correct name and synonym resulting in *Bacillus circulans* (correct name) and *Niallia circulans* (synonym); (3) an update related to *Bacillus coagulans* becoming the correct name and *Weizmannia coagulans* and *Heyndrickxia coagulans* as synonyms.

3.2.3 | Streamlining of qualifications in the QPS list

The following qualification was added in the QPS list for all QPS status yeasts used as active agents (viable cells) when they are used as production strains or as biomass (non-viable cells): '*QPS applies for 'production purposes only' (the qualification 'for production purposes only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass)'* (EFSA BIOHAZ, 2025a).

The relation between QPS and genetically modified microorganisms, has been amended as follows: '*For genetically modified microorganisms (GMMs) for which the species of the parental/recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to the genetically modified strain(s) used as production strains, biomass or active agents* (EFSA BIOHAZ Panel, 2024a). *The QPS approach can also be followed if the qualifications for QPS are met due to the removal of a gene(s) of concern (e.g. AMR genes) by means of genetic modification*.' (EFSA BIOHAZ, 2025a).

3.3 | ToR 3: Evaluation of a QPS recommendation for taxonomic units notified to EFSA

3.3.1 | Evaluation of notified taxonomic units to EFSA

In response to ToR 3, the microorganisms notified to EFSA in the context of a technical dossier for safety assessment were (re)assessed for their suitability for inclusion in the QPS list. Of the 340 notifications received, 173 referred to microorganisms that already had the QPS status and were therefore not further evaluated. Similarly, 129 notifications concerning 81 filamentous fungi, 47 bacteria (comprising 7 *Enterococcus faecium*, 38 *E. coli* and 2 *Streptomyces* spp.) and 1 bacteriophage were not considered for QPS evaluation (Tables 3 and 4). The remaining 38 notifications were considered for assessment of the suitability of the respective TUs for inclusion in the QPS list. These included 31 bacteria, 2 yeasts, 3 microalgae and 2 protists (see Tables 3 and 4). Of these 38, 7 were already evaluated in previous Panel statements within this 3-years cycle and therefore were not reassessed.

The assessments of the respective TUs were published in the six Panel Statements (part 18 to 23), adopted at six-month intervals between June 2023 and December 2025 (see Table 5).

A total number of 31 TUs were assessed across Panel Statements 18 to 23. Of these, 8 were recommended for inclusion on the QPS list, while 23 were not (see Table 6).

TABLE 3 Notifications received by type of risk assessment area and by microbiological group from October 2022 until September 2025 (included in one of six Panel Statements, from part 18 to part 23)

Risk assessment area	Not evaluated		Evaluated[a]	Total
Microbiological group	**Already QPS**	**Excluded from QPS**		
Feed additives	**126**	**52**	**12**	**190**
Bacteria	106	26	11	143
Filamentous fungi		26		26
Microalgae			1	1
Yeasts	20			20
Novel foods	**9**	**16**	**13**	**38**
Bacteria	1	10	9	20
Filamentous fungi		6		6
Microalgae			2	2
Protists	2		2	4
Yeasts	6			6
Plant protection products	**4**	**12**	**6**	**22**
Bacteria	2	1	4	7
Bacteriophages		1		1
Filamentous fungi		10		10
Viruses	2			2
Yeasts			2	2
Food enzymes, food additives and flavourings	**33**	**47**	**7**	**87**
Bacteria	23	8	7	38
Filamentous fungi		39		39
Yeasts	10			10
Food contact materials	**1**	**2**		**3**
Bacteria	1	2		3
Total	**173**	**129**	**38**	**340**

[a]From these only 31 were subjected to a QPS assessment; the other 7 were already recently assessed and therefore not reassessed.

TABLE 4 Notifications received by microbiological group from October 2022 until September 2025 (included in one of six Panel Statements, from part 18 to part 23)

	Not evaluated			
Microbiological group	**Already QPS**	**Excluded in QPS**	**Evaluated**	**Total**
Bacteria	133	47	31	211
Bacteriophages		1		1
Filamentous fungi		81		81
Microalgae			3	3
Protists	2		2	4
Viruses*	2			2
Yeasts	36		2	38
Grand Total	**173**	**129**	**38**	**340**

*Used for plant protection.

TABLE 5 TUs notifications received for a QPS status per Panel Statement (PS)

Species[16]							
Panel Statements	18	19	20	21	22	23	Grand total
Bacteria	24	38	54	40	28	27	211
Actinomadura roseirufa			1				1
Akkermansia muciniphila			1				1
Anaerobutyricum soehngenii	1						1
Bacillus amyloliquefaciens		1	3		1		5
Bacillus licheniformis	1	2	7	3	4	1	18
Bacillus nakamurai				1			1
Bacillus paralicheniformis		1		1			2
Bacillus smithii						1	1
Bacillus sonorensis					1		1
Bacillus subtilis	1	4	7	4	3	3	22
Bacillus thuringiensis				1	1		2
Bacillus velezensis	1	2		1	1	2	7
Bifidobacterium animalis			1	1			2
Bifidobacterium longum			1				1
Burkholderia stagnalis			1				1
Burkholderia ubonensis		1					1
Caldibacillus thermoamylovorans						1	1
Clostridium tyrobutyricum		1					1
Corynebacterium glutamicum	4	2	11	3	7	2	29
Corynebacterium stationis					1		1
Ensifer adhaerens		1		1	1		3
Enterococcus faecium	4	1		1			6
Enterococcus lactis			1	1			2
Escherichia coli	2	5	10	8	4	9	38
Heyndrickxia coagulans						1	1
Klebsiella pneumoniae		1					1
Lacticaseibacillus huelsenbergensis				1			1
Lacticaseibacillus paracasei		1					1
Lacticaseibacillus rhamnosus	1		1	1			3
Lactiplantibacillus plantarum		2		1	1	1	5
Lactobacillus acidophilus			1	2			3
Lactobacillus paracasei			1				1
Lactobacillus plantarum		1					1
Lactococcus lactis		1				1	2
Lentilactobacillus buchneri	3	2	1			1	7
Levilactobacillus brevis	1	2					3
Ligilactobacillus salivarius			1	1		1	3
Limosilactobacillus fermentum		1					1
Loigolactobacillus coryniformis		1					1
Microbacterium arborescens			1				1
Parageobacillus thermoglucosidasius						2	2
Pediococcus acidilactici		1					1
Pediococcus pentosaceus	3			1	1		5
Pseudomonas putida		1					1
Pseudomonas stutzeri	1						1
Rhizobium radiobacter	1					1	
Serratia marcescens		2	1				3
Serratia plymuthica				1			1

(Continues)

[16]Species names are included as they were notified to EFSA. After the identification step, some names were found not to be the current correct names. The corresponding TUs correct names were the ones used for the QPS assessment.

TABLE 5 (Continued)

Species[16]							
Streptomyces aureofaciens			1				1
Streptomyces lydicus					1		1
Vibrio natriegens					1		1
Weizmannia faecalis		1	1			1	3
Xanthomonas campestris				6			6
Unnamed *(Coriobacteriaceae)*	1						1
Bacteriophages		**1**					**1**
Bacteriophage[17]		1					1
Filamentous Fungi	**8**	**26**	**15**	**12**	**11**	**9**	**81**
Antrodia camphorata						1	1
Aspergillus niger	2	2	2	4	1	1	12
Aspergillus oryzae		2		3			5
Aspergillus tubingensis		1	1	1			3
Beauveria bassiana					2		2
Eremothecium ashbyi			1				1
Lentinula edodes	1						1
Metarhizium brunneum		1					1
Metarhizium pingshaense		3					3
Moniliella pollinis						1	1
Mortierella alpina		1					1
Paecilomyces fumosoroseus					1		1
Penicillium citrinum	1						1
Talaromyces versatilis		1	2	2	1		6
Trichoderma afroharzianum		1					1
Trichoderma atroviride		2					2
Trichoderma citrinoviride	1						1
Trichoderma longibrachiatum	2	1		1			4
Trichoderma reesei	1	11	9	1	6	5	33
Rhizopus arrhizus						1	1
Microalgae	**1**	**1**				**1**	**3**
Chlamydomonas reinhardtii		1					1
Nannochloropsis gaditana						1	1
Nannochloropsis oculata	1						1
Protists	**1**		**1**		**1**	**1**	**4**
Aurantiochytrium acetophilum						1	1
Schizochytrium limacinum	1						1
Schizochytrium sp.			1		1		2
Virus		**1**			**1**		**2**
Adoxophyes orana granulovirus and Adoxophyes orana nucloepolyhedrovirus					1		1
Cryptophlebia peltastica Nucleopolyhedrovirus		1					1
Yeasts	**4**	**4**	**11**	**4**	**6**	**9**	**38**
Candida oleophila		1					1
Kluyveromyces lactis			1				1
Komagataella phaffii	1		2	1	2	7	12
Papiliotrema terrestris					1		1
Pichia pastoris		1					1
Saccharomyces cerevisiae	3	2	7	3	3		18
Yarrowia lipolytica			1			1	2
Kluyveromyces marxianus						1	1
Grand Total	**38**	**71**	**81**	**56**	**47**	**47**	**340**

[17]Bacteriophage of Potato Soft Rot Enterobacteriaceae (BPSRE).

TABLE 6 Overview of TUs assessed per Panel Statement and their final QPS status

Panel statements and species assessed	QPS status		
	No	**Yes**	**Grand total**
PS 18	**4**		**4**
Anaerobutyricum soehngenii	1		1
Nannochloropsis oculata	1		1
Pseudomonas stutzeri	1		1
Unnamed (*Coriobacteriaceae*)	1		1
PS 19	**7**	**3**	**10**
Burkholderia ubonensis	1		1
Candida oleophila		1	1
Chlamydomonas reinhardtii		1	1
Clostridium tyrobutyricum		1	1
Ensifer adhaerens	1		1
Klebsiella pneumoniae	1		1
Pseudomonas putida	1		1
Serratia marcescens	2		2
Weizmannia faecalis	1		1
PS 20	**4**	**1**	**5**
Actinomadura roseirufa	1		1
Akkermansia muciniphila	1		1
Burkholderia stagnalis	1		1
Microbacterium arborescens	1		1
Agrobacterium radiobacter		1	1
PS 21	**4**	**1**	**5**
Bacillus nakamurai	1		1
Bacillus thuringiensis	1		1
Enterococcus lactis	1		1
Lacticaseibacillus huelsenbergensis		1	1
Serratia plymuthica	1		1
PS 22	**2**	**2**	**4**
Bacillus sonorensis		1	1
Corynebacterium stationis	1		1
Papiliotrema terrestris	1		1
Vibrio natriegens		1	1
PS 23	**2**	**1**	**3**
Aurantiochytrium acetophilum	1		
Bacillus thermoamylovorans	1		1
Microchloropsis gaditana		1	1
Grand Total	**23**	**8**	**31**

3.3.2 | New QPS recommendations from October 2022 until September 2025

In five of the six Panel Statements parts 19, 20, 21, 22 and 23 (BIOHAZ Panel, 2024a, 2024b, , 2025b, 2025a, 2026) produced during this period, 9 new TUs were recommended for the QPS status (Table 7). *Lactobacillus paragasseri* was not notified but was also assessed because it was formerly included in *Lactobacillus gasseri*, a TU included in the QPS list.

TABLE 7 QPS new recommendations per TU group and TU, for notifications received from October 2022 until September 2025

TU Group/TU	QPS status	Qualification	PS
Microalgae			
Chlamydomonas reinhardtii	**Yes**	Recommended for QPS status with the qualification for 'production purposes only'	19
Microchloropsis gaditana	**Yes**	Recommended for QPS status with the qualification for 'production purposes only'	23
Bacteria			
Clostridium tyrobutyricum	**Yes**	Recommended for the QPS list with the qualification 'absence of genetic determinants for toxin production'. The strains should not harbour any acquired resistance genes to therapeutic antimicrobials.	19
Agrobacterium radiobacter, synonym *Rhizobium radiobacter*	**Yes**	Recommended for the QPS list with the qualification 'for production purposes only'. The strains should not harbour any acquired resistance genes to therapeutic antimicrobials.	20
Lacticaseibacillus huelsenbergensis	**Yes**	Can be granted the QPS status based on its close relatedness to several other QPS *Lacticaseibacillus* species The strains should not harbour any acquired resistance genes to therapeutic antimicrobials.	21
Bacillus sonorensis	**Yes**	Recommended for the QPS list with the qualifications 'absence of bacitracin production ability' and 'absence of toxigenic activity'. The strains should not harbour any acquired resistance genes to therapeutic antimicrobials.	22
Lactobacillus paragasseri (formerly included in *Lactobacillus gasseri*)	**Yes**	Recommended for the QPS list. The strains should not harbour any acquired resistance genes to therapeutic antimicrobials.	22
Vibrio natriegens		Recommended for the QPS status with the qualification for 'production purposes only'	22
Yeasts			
Candida oleophila	**Yes**	Recommended for the QPS status with the qualification for 'production purposes only'	19

3.3.3 | QPS assessment of *Bacillus thuringiensis*

Bacillus thuringiensis was assessed for inclusion in the QPS list by a separate ELS, in response to internal ad-hoc request (EFSA BIOHAZ Panel, 2025b). References published from January 2015 until July 2024, were searched in order to include all relevant literature since the previous BIOHAZ Panel Opinion on 'Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs' (EFSA BIOHAZ Panel, 2016). Besides the ELS, additional papers were included to interpret the data in a broader context than covered by the ELS search items. *B. thuringiensis* contains insecticidal proteins, the reason why *B. thuringiensis* is commercialised as a biocontrol agent pesticide. The taxonomic information, the body of knowledge and the safety of *B. thuringiensis*, including those used as biocontrol agents were assessed. Based on the assessment it was concluded that *B. thuringiensis* is not recommended for the QPS list due to safety concerns.

3.3.4 | New exclusions of TUs within this 3 years period

Other than filamentous fungi, streptomycetes, oomycetes, *Enterococcus faecium, Escherichia col*i (EFSA BIOHAZ Panel, 2020a), *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020b) already excluded before 2023, also *Klebsiella pneumoniae* (v), *Actinomadura roseirufa* and *Burkholderia stagnalis* (EFSA BIOHAZ Panel, 2024b) have been excluded from the QPS assessments within this 3-years QPS cycle, based on an ambiguous taxonomic position or on the possession of potentially harmful traits and it is considered unlikely that any TUs within these groups would be granted QPS status in the foreseeable future. The assessment of members of the excluded biological groups needs to be carried out at strain level by the relevant EFSA Unit.

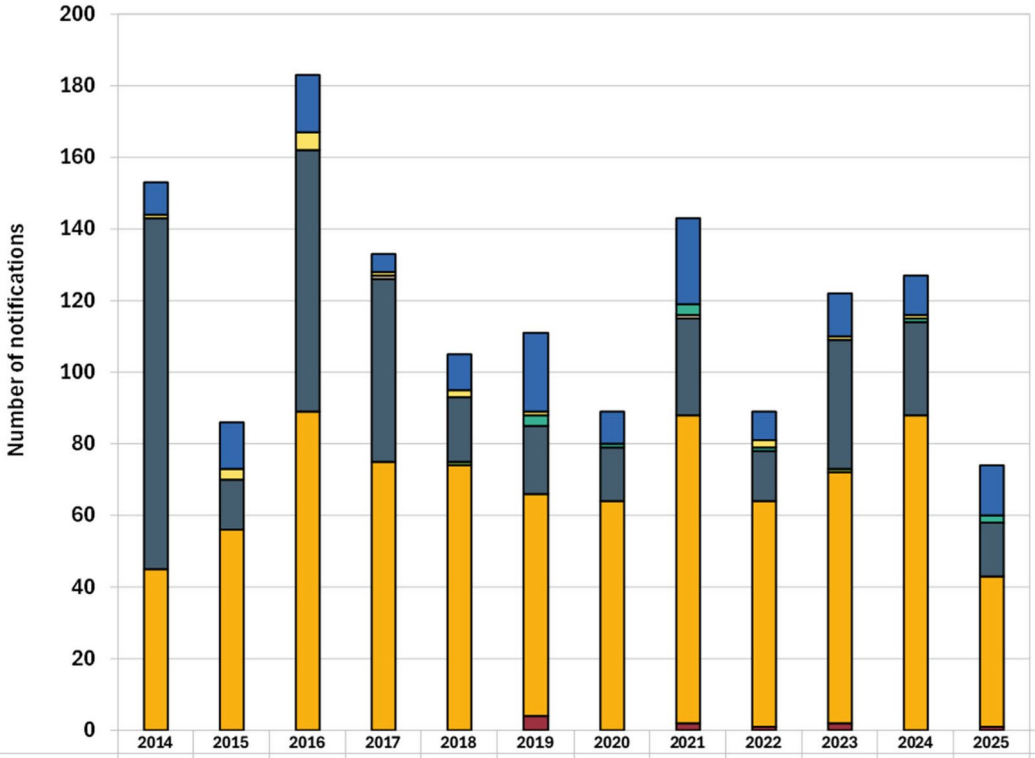
Previously and until the end of this 3-years QPS cycle, bacteriophages were also considered to be ineligible for the QPS status because of lack of a reliable taxonomic classification. However, as a new phylogeny-based taxonomy has been devised, it was reassessed for the QPS status (see Section 3.7).

The current list of microorganisms (or groups of microorganisms) excluded from the QPS process can be found on the 2nd spreadsheet of the QPS list at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.1146566).

3.3.5 | Overview of microbial notifications received and assessments made by EFSA between 2014 and 2025

As an addition to the analysis done for this 3-years QPS cycle and for this Opinion, an analysis was also conducted for the notifications received since QPS PS part 1 (EFSA BIOHAZ, 2014) until QPS PS part 23 (EFSA BIOHAZ, 2026).

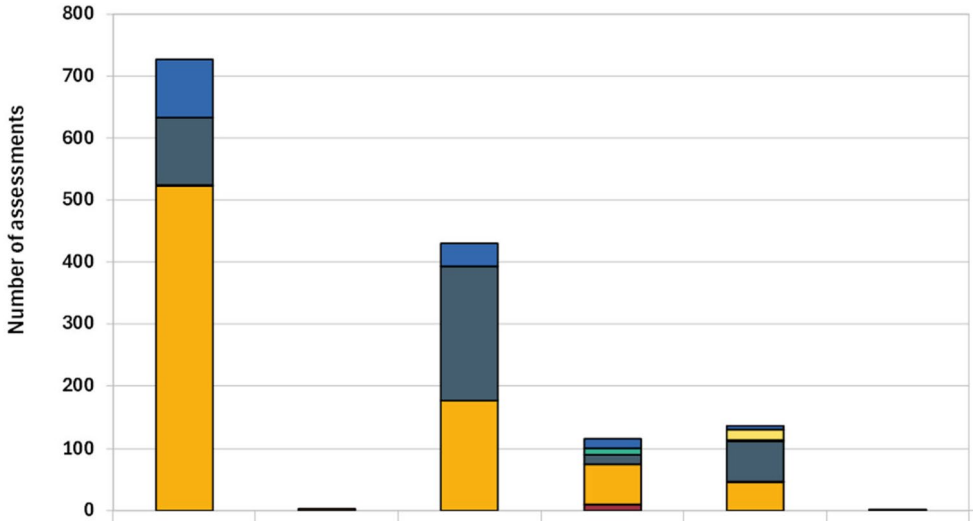
Figure 2 presents the number of notifications per microbiological group per year with a total of 1415 notifications of microbial species received by EFSA between 2014 and 2025 (Panel Statements part 1 until part 23). In terms of the types of organisms notified; 814 were bacteria, 406 filamentous fungi, 2 oomycetes, 152 yeasts, 11 protists, 10 microalgae, 17 viruses (non-bacterial viruses) and 2 bacteriophages. Filamentous fungi and bacteria consistently account for the majority of notifications. Over time, a gradual diversification in the range of notified microbiological groups is evident. Filamentous fungi show a decreasing trend while microalgae and protists, though less frequently reported, begin to appear intermittently in later years.



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	Grand total
Yeasts	9	13	16	5	10	22	9	24	8	12	11	14	153
Viruses	1	3	5	1	2	1			2	1	1		17
Protists						3	1	3	1		1	2	11
Oomycetes				1				1					2
Filamentous Fungi	98	14	73	51	18	19	15	27	14	36	26	15	406
Bacteriophages					1					1			2
Bacteria	45	56	89	75	74	62	64	86	63	70	88	42	814
Microalgae						4		2	1	2		1	10
Grand total	153	86	183	133	105	111	89	143	89	122	127	74	1415

FIGURE 2 Number of notifications per microbiological group per year (2014–2025).

Figure 3 shows the number of notifications per risk assessment area per microbiological group, between 2014 and 2025 (1415 notifications in total). Of these, 727 were for feed additives, 430 for food enzymes, food additives and flavourings, 3 for food contact materials, 116 for novel foods, 22 to plant protection products (PPPs) and 2 for genetically modified organisms (GMOs). Feed additives constitute the most notified category primarily involving bacteria (523) but also filamentous fungi (109), yeasts (94) and bacteriophage (1) followed by food enzymes, food additives and flavourings mainly with filamentous fungi (217) but also bacteria (176) and yeasts (37).



	Feed additives	Food contact materials	Food enzymes, food additives and flavourings	Novel Foods	Plant protection products	GMO	Grand Total
Yeasts	94		37	15	6	1	153
Viruses					17		17
Protists				11			11
Oomycetes					2		2
Filamentous Fungi	109		217	15	65		406
Bacteriophages	1				1		2
Bacteria	523	3	176	65	46	1	814
Microalgae				10			10
Grand Total	727	3	430	116	137	2	1415

FIGURE 3 Number of notifications per risk assessment area for each microbiological group (2014–2025).

From those 1415 notifications received by EFSA between 2014 and 2025, only 160 were subject to a QPS assessment as the rest corresponded to notifications of TUs already with a QPS status or related to TUs excluded from the QPS approach (e.g. filamentous fungi, oomycetes, *E. coli*, etc.. See Section 3.3.4). Figure 4 provides a temporal overview of the TUs notifications which were subject to a QPS assessment per year, for the period 2014–2025, categorised by the microbiological groups covered by the QPS approach: microalgae, bacteria, protists and yeasts. The data show that bacteria consistently account for the majority of TUs evaluations throughout the years with notable peaks observed in 2017 (20 evaluations) and 2014 (18 evaluations). From 2019 onwards, an increase in diversity among the evaluated microorganisms becomes apparent. Microalgae, protists and yeasts appear more frequently for the QPS assessment. The year 2019 marks the first instance in which all four groups were evaluated and stands out as the active year with the most assessments carried out.

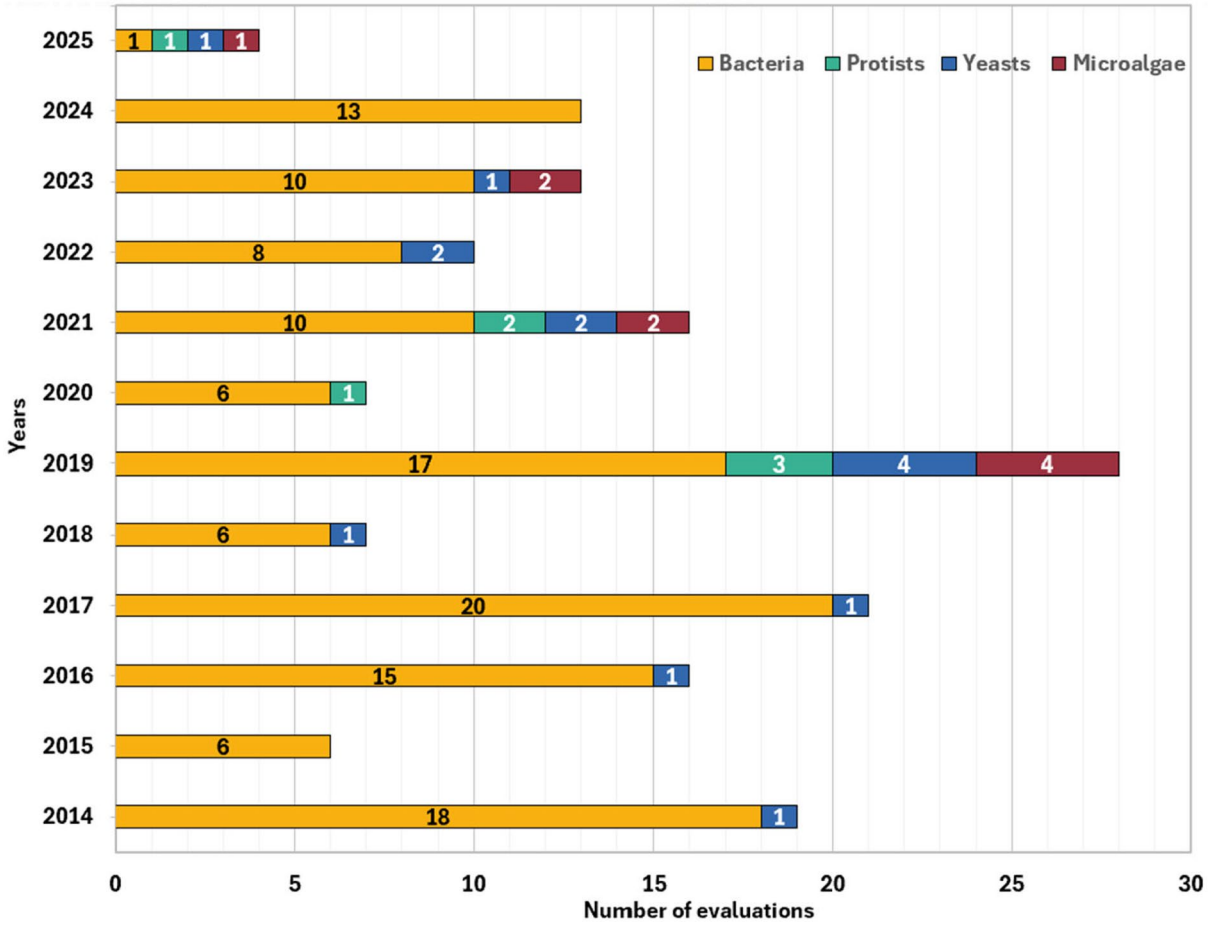
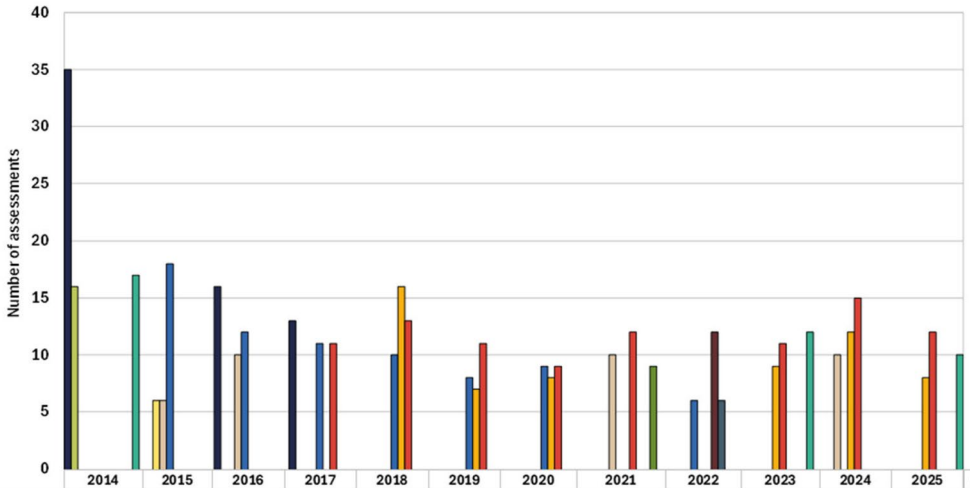


FIGURE 4 Number of notifications TUs subject to a QPS process, per risk assessment area for each microbiological group (2014–2025).

The last exercise that was done was to identify which were the TUs species most frequently notified to EFSA. The top three notified species per year were identified and are represented in Figure 5 with individual species represented by distinct colours (in a total of 416 notifications for a total of 1415 notifications received within this period). The data indicate both persistent patterns and temporal variations. Across the years, *Bacillus subtilis*, *Escherichia coli* and *Trichoderma reesei* were among the most recurrently notified species.



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	Grand Total
Aspergillus niger	35		16	13									64
Aspergillus oryzae	16												16
Bacillus amyloliquefaciens		6											6
Bacillus licheniformis		6	10					10			10		36
Bacillus subtilis		18	12	11	10	8	9		6				74
Corynebacterium glutamicum					16	7	8			9	12	8	60
Escherichia coli				11	13	11	9	12		11	15	12	94
Lactiplantibacillus plantarum									12				12
Lentilactobacillus buchneri									6				6
Saccharomyces cerevisiae								9					9
Trichoderma reesei	17									12		10	39
Grand Total	68	30	38	35	39	26	26	31	24	32	37	30	416

FIGURE 5 Top 3 TUs species notified to EFSA (2014–2025) per year.

Finally, the 5 TUs with the highest number of notifications received by EFSA between 2014 and 2025 were identified and are shown in Figure 6. The analysis shows that *Escherichia coli* is the most frequently notified species with a total of 113 notifications, followed by *Bacillus subtilis* (101 notifications) and *Aspergillus niger* (99 notifications). *Trichoderma reesei* and *Corynebacterium glutamicum* also exhibit notable frequencies, with 87 and 72 notifications, respectively. These five TUs sum up with 472 notifications for a total of 1415 notifications received within this period.

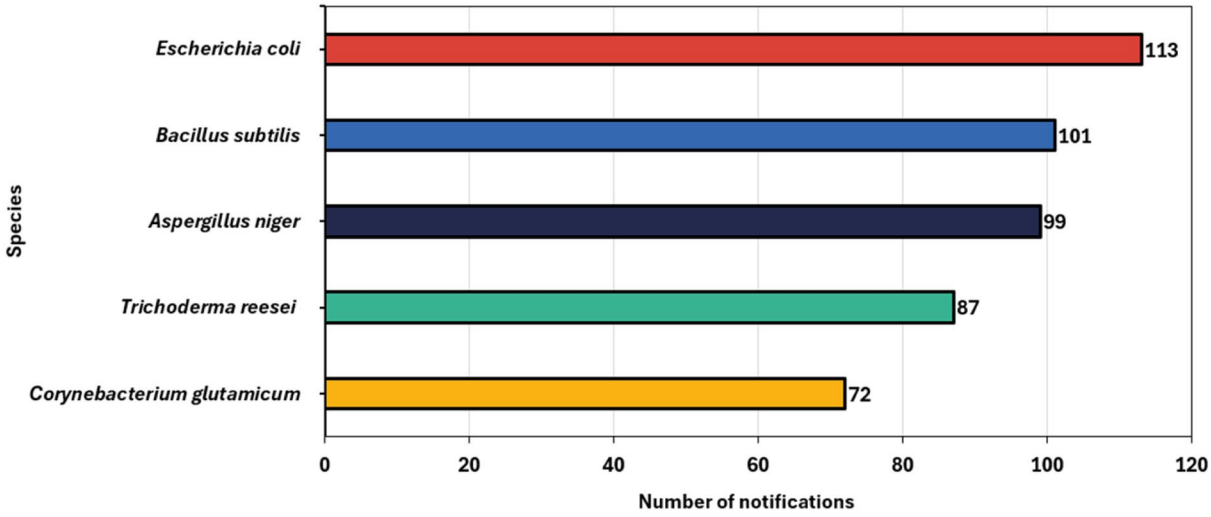


FIGURE 6 Top 5 TUs species notified to EFSA in the total period 2014–2025.

3.4 | QPS assessment of species detached/split from QPS microorganisms

The application of molecular techniques and, especially whole DNA sequence analysis, to the microbial taxonomy is revolutionising bacterial systematics, mainly by provoking splitting of standing species (Gupta et al., 2020; Patel & Gupta, 2020; Zheng et al., 2020). This has raised consultations to EFSA on whether the new species to those that hold the QPS status would share it, because their components were strains of the former taxonomic unit and were thus included into that consideration.

The QPS status cannot be automatically extended to species derived from QPS taxonomic units because, the differences that justify the splitting might raise safety concerns. The following QPS assessment will be followed for evaluating the new species:

- In the Identity section, the reasons for the splitting from the former species will be assessed.
- In the *Body of Knowledge* part, the information from the former species to which the split species belonged will be taken into account.
- For the *Safety Concerns* evaluation, genome sequences of the type strains of both the former and the split one will be assessed with emphasis on the analysis of the genes present in the DNA segments characteristic of the new species. The genome sequences will be assessed for genes/clusters encoding virulence, antibiotic resistance, antimicrobial production and other potentially harming determinants taking into account also their possible location on mobile elements.

The data analysed will lead to a conclusion on the incorporation of the new species to the QPS list.

3.5 | QPS, genetic modification, new genetic techniques and synthetic microbiology

In the EFSA opinions on new genetic techniques and synthetic biology the QPS concept is addressed and seen as an important tool in the risk assessment of engineered microbial cells and the products thereof. Thus, the QPS concept plays a crucial role in the microbial characterisation and risks assessment processes being applicable to GMMs used as production strains, biomass or active agents if the species of the parental/recipient strain qualifies for the QPS status and if the genetic modification does not give rise to safety concerns (EFSA BIOHAZ, 2024a). Thus, it is not expected that a QPS organism would contain gene sequences of concern that could be activated due to mutations. Consequently, for GM production strains belonging to taxonomic units with QPS status, toxicological studies are not generally required unless safety concerns not related to the strain fermentation arises elsewhere in the production process.

The QPS concept can also be extended to GMMs generated by new genetic techniques (NGTs), when the parent/recipient microorganism is on the QPS list and if the genetic modification does not pose risks, and to more extensively genetically modified microorganisms deriving from synthetic biology. In the latter case, the QPS approach can be used for the risk assessment of chassis. Chassis concept is central to contemporary synthetic biology. A 'chassis' is a naturally derived

or highly engineered organism repurposed to build, maintain and amplify the components necessary for deployment of synthetic biological systems and their applications (EFSA Scientific Committee, 2022). In the context of the QPS framework, the meaning of the term deals with live cells containing an editable genome. When a chassis meets the requirement of the QPS approach, the risk assessment should be focused on the effect of the genetic modification added to the chassis.

3.6 | Safety of strains in relation to the gut environment and its application in the QPS concept

The microbial safety assessment includes possible adverse effects of the product on the gut microbiome[18] and on the gut functions of humans and/or animals exposed to it. For microorganisms that qualify for QPS, any adverse effect on the gut microbiome of humans and animals is assessed in the framework of the QPS evaluation based on the body of knowledge of the species to which the active agent belongs (EFSA BIOHAZ Panel, 2023b). While no specific risks are expected based on this evaluation, current methodologies used in the reflected body of knowledge still have limitations in detecting and quantifying microbiome-related effects. Therefore, continuous refinement of assessment methods remains important. For GM active agents, the impact on the gut microbiome follows a case-by-case assessment. Examples of adverse effects on the gut microbiome include e.g. gut dysbiosis triggering colitis, diarrhoea or shedding of pathogenic microorganisms (EFSA Scientific Committee, 2025).

Currently, considering the complexity of the gut microbiome, universally accepted methodologies for accurately estimating the effects of microbial strains and their products on the microbiome's structure and metabolic activities are lacking. This includes methods for assessing potential adverse effects resulting from microbiome perturbations on gut functions (such as metabolic, barrier defence and immune functions). Critical endpoints, including the persistence and colonisation of microbial strains, as well as alterations in the structure and function of the gut microbiome, remain difficult to measure accurately. Consequently, there is a pressing need for the development of standardised methodologies to facilitate a more comprehensive understanding of how microbial products influence the gut microbiota and consequently the host. These methodologies would not only enable a more precise assessment of microbial safety but also contribute to elucidating the intricate interplay between microbial communities and host physiology.

To explore the possibilities to include the gut related safety aspects in EFSA risk assessment a study was subcontracted by EFSA (https://doi.org/10.2903/sp.efsa.2024.EN-8597) to perform a comprehensive and critical assessment of the evidence-based research about: (i) the impact of dietary compounds in the human and some domestic animals (poultry, ruminants and pigs) gut microbiome; (ii) the most representative in vitro and in vivo models of the human gut microbiota currently used in microbiome research studies; and (iii) the methodology used to measure changes in the microbiota. Also, a roadmap is proposed outlining how to: (i) strengthen the nascent evidence relating to effects on/by gut microbiomes in humans and domestic animals; and (ii) list identified key knowledge gaps and provide guidance recommendations on how to experimentally approach these urgent research needs. A multidisciplinary research strategy is proposed to provide key information to fill knowledge and methodology gaps.

3.7 | Inclusion of bacteriophages to the QPS assessment

In previous Opinions (EFSA BIOHAZ Panel, 2009, 2017, 2023a, 2023b, 2023c) bacteriophages were excluded from the QPS assessment, based on the impossibility of allocating them to precise TUs (genera and species). However, the ICTV has produced a phylogenetic tree for classification that comprises all viruses, including those that are only known by their genome sequences (https://ictv.global/taxonomy; Journal of General Virology ICTV Virus Taxonomy Profiles; ICTV Executive Committee, 2020; Koonin et al., 2020; Simmonds et al., 2017, 2024) that is widely accepted and used in the field. This fact has prompted a revision on the suitability of bacteriophages for the QPS consideration and has opened the QPS concept for bacteriophages at the species level.

The QPS assessment of bacteriophages, notified to EFSA, will be based on analysis of the main pillars, also used for the QPS assessment of other microorganisms. Following the same model, a general assessment of the identity, the body of knowledge and the safety requirements of bacteriophages amenable for the QPS consideration is explained in more detail.

The TU for QPS phage consideration will be the species because it is considered important to keep the containment of phage treatments, i.e. the bacteria onto which the phage is active, which ideally should be a single species, and this is best fulfilled through limitation of the TU to the lowest well defined taxonomic category.

[18]Definition of 'Microbiome' (FAO, 2023): Microbiome is the community of bacteria, fungi, archaea and other microorganism and their theatre of activity, which includes their interactions with each other and their respective environments. Microbiomes exist within and across all ecosystems, in plants, animals, soils, forests, oceans and, importantly, in humans. All vary enormously in composition and functions and over space and time but research, aided by technological advances in genomic sequencing, points to some broad patterns that may correlate to health or dysfunction for their hosts and host ecosystems. A growing corpus of evidence suggests that gut microbiome may be associated with many health and nutrition outcomes, including child stunting, obesity and overweight, cognitive functions, immune functions, among others.

Identity

The current virus classification launched by the ICTV is based on whole genome, proteome, gene allocation, the so called 'Virus Hallmark Genes' (VHGs), which are responsible for the key functions in virus replication (e.g.: nucleic acid polymerases) and other molecular comparisons. In addition, the type of cellular organisms that act as hosts for specific viruses (e.g.: prokaryotes vs. eukaryotes; animal vs. plant cells and subdivisions thereof) is taken into consideration. To complete the alignment, the new classification has adopted the taxonomic categories of cellular organisms, including the suffixes that characterise each of them and the Latin derived nomenclature, which has to be written in italics, down to the genus names (e. g.: Phylum *Uroviricota* for double stranded DNA viruses with tails that infect prokaryotic but not eukaryotic cells; family *Herelleviridae* for those, within that Phylum, that infect members of the Phylum *Bacillota* and present isometric capsids and contractile tails, linear, terminally redundant, non-permuted dsDNA genomes encoding a series of orthologous proteins and are obligatorily lytic).

Body of knowledge

The term bacteriophage comprehends more than 6000 species of viruses that infect exclusively bacterial cells and absolutely depend on their hosts for propagation. They probably are the most abundant biological entities on earth and are present wherever their hosts thrive (Abedon, 2009). Phages are extremely diverse, to the point that their genomes may reside on single or double stranded DNA or RNA molecules. However, more than 95% of phage species present dsDNA genomes and specialised structures, called tails, for recognition of their host surfaces and injection of their genomes into the host cells. They are grouped, within the Realm *Duplodnaviria*, into the Phylum *Uroviricota* (uros/tail in greek), Class *Caudoviricetes* and are, probably, monophyletic, as suggested by their major capsid protein common structure, but also by the relation between their portal proteins and terminase subunits (Koonin et al., 2020). Phages that harbour dsDNA genomes present DNA polymerases that correct possible complementarity mistakes introduced during replication. This contrasts with the lack of edition capacity of RNA polymerases, which generate many more genome variants (quasispecies). Since the species steadiness is crucial for the QPS consideration of any microorganism, having a dsDNA genome would be a requirement for any candidate phage.

Phages alternate between an extracellular, infective form, the **virion**, which presents a protein shell, the **capsid**, which surrounds and protects the genome and specifically recognises and attach, through the tail tip, to receptors in the host surface, as the first step towards infection. The nature of these receptors may vary from structural components of the cell wall, such as teichoic acids or the lipopolysaccharide, to surface proteins. As a consequence, each phage will only infect hosts that bear the appropriate receptor, which, in practice, limits its range of susceptible bacteria to members of single species or, at most, of similar species within a genus.

Once the phage is attached to the host-cell surface, a peptidoglycan hydrolase, located in the tail tip will ease its deepening into the wall and, possibly, contribute to the formation of the pore through which the phage DNA will reach the host cytoplasm.

The intracellular form of bacteriophages is exclusively composed of their genome, which is transcribed and translated by the cell metabolic machinery to produce phage enzymes (e.g.: genome polymerases) and structural proteins. The latter spontaneously assemble to form the capsids that will be filled with the newly produced genome molecules.

Phages may follow two development cycles once their genomes have entered the host cell; (i) the **lytic**, by which new progeny virions are produced and, usually, end with lysis of the host and (ii) the **lysogenic**, which frequently involves integration of the phage genome into that of the host and silencing of most phage genes through the action of a phage-encoded repressor protein. Phages that can only follow a lytic cycle are called **virulent**, while those that may undertake both the lytic and the lysogenic cycles are designed as **temperate**. While integrated, the genomes of temperate bacteriophages are known as **prophages** and are vertically transmitted to their host progeny. Double stranded DNA bacteriophages initiate replication of their genomes by two different mechanisms; one group presents terminal proteins in their 5′ ends that act as primase elements for replication and lead to the generation of two identical genomes ready for packaging into capsids. The rest generate genome concatemers by two alternative procedures: the rolling circle replication and the replication followed by recombination (the exact details of formation of the concatemers are out of the scope of this text). The extremes of the concatemers are recognised by specific enzymes called terminases that are located at the entrance of the empty capsids and that promote DNA packaging. Termination of packaging can occur by two alternative mechanisms; in the first case, the genome DNA presents a unique sequence (*pac*) that is recognised and cut by the terminase, leaving a concatemer end that can start a new packaging event. In some cases, a palindrome sequence of about 15 nucleotides long is recognised and the terminase produces staggered cuts in the two DNA chains, thus generating complementary monocatenary extensions (cohesive ends). In others, the bacteriophages present long terminally redundant non-permuted genomes (up to several kbp) into which the *pac* site is located. This packaging mechanism (recognition of *pac* sequences and generation of precise sequence ends) produces one unit genomes, which are identical to that of the progenitor phage. For other bacteriophages, packaging proceeds until the capsid is completely filled (headful mechanism); its capacity exceeds the genome size, thus allowing packaging of more than one unit genome and, most important, generating a new extreme of the concatemer that is different from the previous one. As a consequence, the extreme-recruiting function of the terminase has to be relaxed with respect to the DNA sequence that would be recognised, thus allowing packaging of almost any linear dsDNA into the capsid. At the end of the lytic cycle two phage-encoded proteins, the holin and the endolysin,

collaborate to breakdown the host cell, allowing for liberation of the newly produced virions. The holin produces pores in the cell membrane that allow passage of the endolysin to the periplasm, where it attacks the cell peptidoglycan and, in the case of Gram negative bacteria, the external membrane, which ends with osmotic lysis of the host.

The application of bacteriophages in the food and feed chains to reduce the concentration of food-borne pathogens and of spoilage microorganisms exploded at the onset of this century. The work was mainly focused on *Listeria monocytogenes*, *Salmonella enterica*, *Campylobacter* spp., *Escherichia coli* STEC, *Vibrio* spp. and *Staphylococcus aureus* for matrices of animal origin (Cooper, 2016; Holzer et al., 2025; Jordá et al., 2023; Yan et al., 2024) and on *Xantomonas* spp., *Pseudomonas syringae*, *Erwinia amylovora* and *Xillela fastidiosa* among those that infect plant crops (Braz et al., 2025; Czajkowski et al., 2025; Giovanardi et al., 2025). They have even been proposed as biocontrol agents for tap water systems (Hong et al., 2025), as slowly releasing safety elements from active packaging materials (Braz et al., 2025; Narayanan et al., 2024) and as part of synergistic treatments with high hydrostatic pressure (Shymialevich et al., 2024) and essential oil application (Giovanardi et al., 2025).

Complementarily, some phage-encoded proteins, mainly the endolysins but also depolymerases (which hydrolyze the glycocalyx polysaccharides that wrap the host cell, protecting it from infection and are also essential components of biofilms) and holins are being introduced as biocontrol agents in the food industry (Kim et al., 2025; Soto Lopez et al., 2025).

Lysis from within vs. lysis from without: In liquid food matrices, both bacteria and bacteriophages move freely, their encounter being a question of probabilities that depend on their respective concentrations. In addition, the progeny viruses are also dispersed, thus contributing to the effectiveness of the treatment, even with low initial phage concentrations (lysis from within). However, in solid matrices the harming bacteria become attached to the substrate. Usually, the level of contamination is not very high (10^2 to 10^4 cfu/g or /mm^2), which obliges the use of high phage concentrations (to the level of 10^9 pfu/g or /mm^2) to ensure adequate coverage of the food surface. This makes it possible that any bacterium cell is attacked by several bacteriophages at a time. The simultaneous formation of several pores to allow the injection of the phage DNAs may result in abolition of the proton-motive force across the membrane, inability to generate energy and death of the cell, which will impede the phage life cycle to proceed (lysis from without). Consequently, the particularities of phage application for food biocontrol may vary as a function of the physical characteristics of the matrices. In the case of liquids, relatively low phage concentrations can be applied, viral progenies will be produced, provided that the host metabolism can proceed and the bacterial elimination process would be sequential. For solid matrices, higher phage concentrations would be necessary and elimination of the contaminating cells will mainly rely on lysis from without, which is much faster, relatively independent of the conditions of application and of the metabolic state of the bacterium, possibly making it active even on persisters (Rodríguez-Rubio et al., 2013; Tarahovsky et al., 1994).

Safety concerns

Bacteriophages only infect bacteria and, consequently, they cannot be considered as direct pathogens for humans, animals or plants. Besides this, they are not spoilage agents since they do not have their own metabolism. Furthermore, living organisms and the environment are heavily exposed to bacteriophages; for example, they are being continuously consumed, especially with fermented foods, where bacteriophages active on the bacterial starters are common and may constitute the main cause of production failure (Mc Grath et al., 2007). They also parasitise the components of the normal microbiota, being produced in the body cavities, to the point that they are routinely used as indicators of faecal contamination in water and as reliable indicators of sewage good processing (Andrianjakarivony et al., 2023; Sabar et al., 2022; Singh et al., 2022).

The abundance and importance of environmental bacteriophages can be illustrated by their presence in seawater and in the rhizosphere by up to 10^7 virions/ml or 10^9 virions/g of soil. There, they fulfil essential roles in functioning of the organic matter and nutrient cycles, mainly by making available up to 1/3 of the organic matter of the cellular microbiota/day (Mayers et al., 2023; Wang et al., 2024; Weinbauer, 2004).

A common concern on the use of bacteriophages as biocontrol agents for food and feed is the possibility that they might reach the colon and disturb the homeostasis of the resident microbiota. In this respect the following has to be considered: (i) the presumptive pathogens/spoilage organisms to which a phage applied in the food and feed chain has to be active, are usually not members of the digestive microbiota and, as already indicated, bacteriophages have to specifically recognise receptors on the hosts surfaces, which limit their spectrum of susceptible bacteria from strains within one species to closely related species within a genus, making a cross infection thus improbable; (ii) bacteriophages are made out of proteins and nucleic acids and are susceptible to acidity and digestive enzymes (Bernela et al., 2025; Majewska et al., 2023; Vinner et al., 2017); consequently, passage throughout the digestive apparatus would inactivate them. The innocuousness of environmental bacteriophages let them pass mostly unnoticed in spite of their abundance. Their safety is also backed by their use in the food and feed chains for infectious disease prevention and treatment of agricultural plants and livestock, elimination of food-spoilage bacteria, accelerated ripening, etc. apparently without any related health problems to the consumers (Dong et al., 2024; Golban et al., 2025; Necel et al., 2025; Reyneke et al., 2024; Yan et al., 2024).

The absence of risks associated to direct phage actions does not exclude indirect safety concerns, mainly derived from their influence on the phenotypes of their bacterial hosts. Two situations may lead to these changes: lysogenic conversion and bacterial DNA generalised transduction. Lysogenic conversion is produced by temperate bacteriophages, which have to preserve the metabolism of their hosts, which would be needed for their persistence as prophages. Frequently, temperate bacteriophages harbour genes not involved in its own development but that confer advantages to their hosts and that

are expressed during lysogeny (Brüssow et al., 2004). Of special relevance are determinants that encode virulence factors, such as those that encode toxins (diphtheria, cholera, etc.), invasins and elements for adaptation to different hosts (Rohmer & Wolz, 2021), subversion factors of the immune system (Secor et al., 2020) and even antibiotic resistances (Cadamuro et al., 2025). Conversely, most virulent bacteriophages abolish the host capacity for production of its own proteins at the very early stages of development and they do so through a series of complementary mechanisms, such as host DNA and mRNA degradation, inactivation of the host RNA polymerase, etc. (several chapters of Calendar (Ed.) Calendar, 2006. The Bacteriophages) thus effectively killing the host much before its eventual lysis is produced. Generalised transduction is the acquisition of foreign DNA, encapsulated into a viral capsid, by bacterial cells. It only happens between related bacteria because the recognition constraints of the hosts by their bacteriophages apply here as well. The relatedness between the donor and the recipient bacteria would allow homologous recombination with the genome of the latter, expression of the new genes and modification of its phenotype. Transducing bacteriophages are those that fill their capsids by the headful mechanism, because their genome extremes vary due to the circular permutation of the genome DNA molecules being packaged, which obligates to have a relaxed recognition of the extreme of the incoming DNA. This contrasts with the strict recognition of the DNA ends performed by bacteriophages that package unit genomes, irrespectively that they present terminal proteins in their 5′ ends or because they have terminase strictly recognised *pac* sequences such as the long palindromic sequences that mark the cohesive ends (Borodovich et al., 2022).

Conclusions

The application of molecular techniques has allowed the International Committee on Taxonomy of Viruses to devise a comprehensive, phylogenetically based, classification of bacteriophages.

This has eliminated the main obstacle that precluded the consideration of bacteriophages, as candidates to the EFSA-QPS list. Consequently, the EFSA BIOHAZ panel opens the possibility of bacteriophages as biological entities amenable for QPS assessment with the following limitations:

(i) Double stranded DNA genome to ensure the fidelity of replication and avoid the typical quasispecies situation of RNA viruses,
(ii) Strictly lytic development for prevention of lysogen generation and lysogenic conversion,
(iii) One unit genome packaging with accurate identification of the DNA termini and processing by precise DNA recognition sequence terminases for prevention of phage transduction,
(iv) Host range limited to one or several related species within a genus to ensure containment of the treatment and
(v) Previous use in the food or feed chains with no reports on correlated health or environmental safety concerns.

The TU for the QPS evaluation is suggested to be the species to keep the containment of the treatments to the target bacteria. Bacteriophages used as production organisms may also get the QPS status with the qualification 'for production purposes only' which would apply to products free of viable hosts and infective virions.

The general qualification of absence of AMR[19] and virulence genetic determinants is applied to bacteriophages as well.

4 | CONCLUSIONS

Answer to the Terms of Reference (ToR)

ToR 1: *Keep updated the list of microorganisms being notified in the context of a technical dossier to EFSA Units (such as Feed, Pesticides, Food Ingredients and Packing, and Nutrition) for intentional use in feed and/or food or as sources of food and feed additives, enzymes and PPPs for safety assessment*.

- The '*Microbiological agents as notified to EFSA*' list (https://doi.org/10.5281/zenodo.3607183), comprises all microorganisms notified to EFSA in the context of a technical dossier for safety assessment, from the beginning of the QPS exercise in 2007. The list of microorganisms notified in the context of technical dossiers has been updated every 6 months with every Panel Statement.
- Every 3 years, a QPS opinion is published summarising the results of the Panel Statements published in that period. The Opinion also updates the QPS approach considering developments in microbial methodology, new scientific insights and new microbial applications in the food chain.
- In total, 340 notifications were received between October 2022 and September 2025, of which, 190 were of microorganisms used for the production of feed additives, 87 for the production of food enzymes, food additives and flavourings, 3 for food contact materials, 22 as PPPs and 38 for novel foods; 211 were bacteria, 81 filamentous fungi/ oomycetes, 38 yeasts, 4 protists, 3 microalgae, 3 viruses (including 1 bacteriophage).

[19]The generic qualification '*the strains should not harbour any acquired resistance (AMR) genes to therapeutic antimicrobials*' applies to all QPS bacterial TUs (EFSA BIOHAZ Panel, 2023).

ToR 2: *Review TUs previously recommended for the QPS list and their qualifications when new information has become available.*

- The list of QPS-recommended TUs is reviewed every 6 months, following an ELS strategy. The outcome of this task has been covered by each of the Panel Statements published from July 2023 onwards. The '*Updated list of QPS-recommended microorganisms for safety risk assessments carried out by EFSA*' ('QPS list') is available at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.1146566).
- Relevant information from the ELS includes case reports of human diseases, particularly infections or intoxications linked to the TU under assessment. The QPS status of TUs for which case reports were retrieved, has not been withdrawn due to the frequently incomplete description of the identification method, the lack of clear virulence determinants in their genomes, the extremely low incidence of infections when compared with the level of exposure to the concerned species, the frequent weakness of patients that predispose for opportunistic infections and the habitual lack of transmission evidence through food/feed sources.
- From QPS Panel Statement part 20 (EFSA BIOHAZ Panel, 2024b), the QPS TUs of bacteria, yeasts, microalgae, protists and viruses were checked every 6 months against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. Several corrections have been made in the QPS TUs names since then. The taxonomic update was also reflected in the ELS keywords of the subsequent cycle.
- A Panel BIOHAZ Statement was published in 2023 and updated and republished in 2025 to explain how the QPS qualification on 'acquired antimicrobial resistance genes' should be interpreted. A bioinformatic approach was proposed for demonstrating the 'intrinsic'/'acquired' nature of an AMR gene (EFSA BIOHAZ Panel, 2023).
- In the QPS list the following qualification was added for all QPS status yeasts used as active agents (viable cells) for when they are used as production strains or as biomass (non-viable cells): *QPS applies for 'production purposes only' (the qualification 'for production purposes only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass)* (EFSA BIOHAZ Panel, 2025b).
- The relation between QPS and genetically modified microorganisms, has been amended as follows:
  - '*For genetically modified microorganisms (GMMs) for which the species of the parental/recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to the genetically modified strain(s) used as production strains, biomass or active agents. The QPS approach can also be followed if the qualifications for QPS are met due to the removal of a gene(s) of concern (e.g. AMR genes) by means of genetic modification*.'
  - The QPS concept can also be extended to GMMs generated by new genetic techniques (NGTs), and to more extensively genetically modified microorganisms deriving from synthetic biology. In the latter case, the QPS approach can be used for the risk assessment of chassis.
- The QPS status cannot be automatically extended to species split from QPS taxonomic units based on new taxonomic insights. This is because the differences that justify the splitting might raise safety concerns.
- For microorganisms that qualify for QPS, any adverse effect on the gut microbiome of humans and animals is assessed in the framework of the QPS evaluation based on the body of knowledge of the species to which the active agent belongs. For GM active agents, the impact on the gut microbiome follows a case-by-case assessment.

ToR 3: *(Re)assess the suitability of TUs notified to EFSA not present in the current QPS list for their inclusion in that list.*

- Six Panel Statements have been published every 6 months, since the last QPS Opinion (EFSA BIOHAZ Panel, 2023b) and covering notifications received between October 2022 and September 2025. Thirty-eight TUs were considered for the assessment across Panel Statements part 18 to 23. From these 38, 7 were already evaluated in previous Panel Statements within this 3-years cycle and therefore were not re-evaluated. Nine of the remaining 31 were recommended for inclusion on the QPS list, while the other 22 were evaluated but not recommended. These are the TUs recommended for the QPS status:
  - *Chlamydomonas reinhardtii* – with the qualification for '*production purposes only*'
  - *Microchloropsis gaditana* – with the qualification for '*production purposes only*'
  - *Clostridium tyrobutyricum* – with the qualification *'absence of genetic determinants for toxin production'*
  - *Agrobacterium radiobacter*, synonym *Rhizobium radiobacter*- with the qualification *'for production purposes only'*
  - *Lacticaseibacillus huelsenbergensis*
  - *Bacillus sonorensis* – with the qualifications '*absence of bacitracin production ability*' and '*absence of toxigenic activity*'
  - *Lactobacillus paragasseri* (formerly included in *Lactobacillus gasseri*)
  - *Vibrio natriegens* – with the qualification *'for production purposes only'*
  - *Candida oleophila* – with the qualification for 'production purposes only'

All bacteria have also the qualification the strains should not harbour any acquired resistance genes to therapeutic antimicrobials'.

- Filamentous fungi, streptomycetes, oomycetes, *Enterococcus faecium*, *Escherichia coli* (EFSA BIOHAZ Panel, 2020a), *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020b), *Klebsiella pneumoniae* (EFSA BIOHAZ Panel, 2024a), *Actinomadura roseirufa* and *Burholderia stagnalis* (EFSA BIOHAZ Panel, 2024b) are excluded from the QPS assessments based on an ambiguous taxonomic position or on the possession of potentially harmful traits, and it is considered unlikely that any TUs within these groups would be granted QPS status in the foreseeable future. The assessment of members of the excluded biological groups needs to be carried out at strain level by the relevant EFSA Unit.
- Previously and within this QPS 3-years cycle, bacteriophages were considered to be ineligible for the QPS status because of lack of a reliable taxonomic classification. As a new phylogeny-based taxonomy has been devised, allowing reconsideration of phage eligibility, the QPS concept was opened for bacteriophages at the species level. Bacteriophages used as production organisms may also get the QPS status with the qualification 'for production purposes only' which would apply to products free of viable hosts and infective virions.
- *Bacillus thuringiensis* was not recommended for the QPS list due to safety concerns.

5 | RECOMMENDATION

None.

ABBREVIATIONS

AMR	antimicrobial resistance
ANI	average nucleotide identity
BIOHAZ	Scientific Panel on Biological Hazards
BLAST	basic local alignment search tool
dDDH	digital DNA–DNA hybridisation
DNA	deoxyribonucleic acid
ECOFF	epidemiological cut off value
ELS	extensive literature search
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FEEDCO	Feed and Contaminants Unit
FIP	Food Ingredients and Packaging Unit
FSTA	Food Science Technology Abstracts
GC	guanine-cytosine
ICNP	International Code of Nomenclature of Prokaryotes
ICSP	International Committee on Systematics of Prokaryotes'
ICTV	International Committee on Taxonomy of Viruses'
IJSEM	International Journal of Systematic and Evolutionary Microbiology'
GMMs	genetically modified microorganisms
LPSN	List of Prokaryotic Names with Standing in Nomenclature'
MGE	mobile genetic element
MIC	Minimal Inhibitory Concentration
MoPS	Microorganisms Pipelines Project
NDA Panel	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NGTs	new genetic techniques
NF	novel food
NIF	Nutrition and Food Innovation Unit
PPPs	plant protection products
PREV	Pesticides Peer Review
QPS	qualified presumption of safety
ToR	Terms of Reference
TU	taxonomic unit
TYGS	Type (Strain) Genome Server
VHGs	virus hallmark genes
WGS	whole genome sequence
WHO	World Health Organization
WOAH	World Organisation for Animal Health

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REFERENCES

Abedon, S. T. (2009). Phage evolution and ecology. *Advances in Applied Microbiology*, *67*, 1–45.

Andrianjakarivony, F. H., Bettarel, Y., & Desnues, C. (2023). Searching for a reliable viral indicator of Faecal pollution in aquatic environments. *Journal of Microbiology*, *61*(6), 589–602. https://doi.org/10.1007/s12275-023-00052-6

Bernela, M., Virmani, N., Bera, B. C., Vaid, R. K., Vashisth, M., & Anand, T. (2025). Development of an acid-protective polymer encapsulation formulation for Oral delivery of salmonella phages. *Viruses*, *17*(9), 1205. https://doi.org/10.3390/v17091205

Borodovich, T., Shkoporov, A. N., Ross, R. P., & Hill, C. (2022). Phage-mediated horizontal gene transfer and its implications for the human gut microbiome. *Gastroenterology Report (Oxford)*, *10*, goac012. https://doi.org/10.1093/gastro/goac012

Braz, M., Pereira, C., Freire, C. S. R., & Almeida, A. (2025). A review on recent trends in bacteriophages for post-harvest food decontamination. *Microorganisms*, *13*(3), 515. https://doi.org/10.3390/microorganisms13030515

Brüssow, H., Canchaya, C., & Hardt, W. D. (2004). Phages and the evolution of bacterial pathogens: From genomic rearrangements to lysogenic conversion. *Microbiology and Molecular Biology Reviews*, *68*(3), 560–602. https://doi.org/10.1128/MMBR.68.3.560-602.2004

Cadamuro, R. D., Elois, M. A., Pilati, G. V. T., Savi, B. P., Pessi, L., Jempierre, Y. F. S. H., Rodríguez-Lázaro, D., & Fongaro, G. (2025). Role of lysogenic phages in the dissemination of antibiotic resistance genes applied in the food chain. *Foods*, *14*(7), 1082. https://doi.org/10.3390/foods14071082

Calendar, R. (2006). *The bacteriophages*. ISBN: 0–19–514850-3. Oxford University Press.

Cooper, I. R. (2016). A review of current methods using bacteriophages in live animals, food and animal products intended for human consumption. *Journal of Microbiological Methods*, *130*, 38–47. https://doi.org/10.1016/j.mimet.2016.07.027

Czajkowski, R., Roca, A., & Matilla, M. A. (2025). Harnessing bacteriophages for sustainable crop protection in the face of climate change. *Microbial Biotechnology*, *18*(2), e70108. https://doi.org/10.1111/1751-7915.70108

Dong, C., Cui, S., Ren, J., Gong, G., Zha, J., & Wu, X. (2024). Engineering of bacteria towards programmed autolysis: Why, how, and when? *Microbial Cell Factories*, *23*, 293. https://doi.org/10.1186/s12934-024-02566-z

EFSA (European Food Safety Authority). (2005). Opinion of the Scientific Committee on a request from EFSA related to the *introduction of a qualified presumption of safety (QPS) approach for assessment of selected microorganisms referred to EFSA*. *EFSA Journal*, *3*(12), 226. https://doi.org/10.2903/j.efsa.2005.226

EFSA (European Food Safety Authority). (2007). Introduction of a qualified presumption of safety (QPS) approach for assessment of selected microorganisms referred to EFSA – Opinion of the scientific committee. *EFSA Journal*, *5*(12), 587. https://doi.org/10.2903/j.efsa.2007.587

EFSA (European Food Safety Authority). (2008). The maintenance of the list of QPS microorganisms intentionally added to food or feed - scientific opinion of the panel on biological hazards. *EFSA Journal*, *6*(12), 923. https://doi.org/10.2903/j.efsa.2008.923

EFSA (European Food Safety Authority). (2024a). EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain. *EFSA Journal*, *22*(8), 8912. https://doi.org/10.2903/j.efsa.2024.8912

EFSA (European Food Safety Authority), Peluso, S., Aguilera-Gómez, M., Bortolaia, V., Catania, F., Cocconcelli, P. S., Herman, L., Moxon, S., Vernis, L., Iacono, G., Lunardi, S., Pettenati, E., Gallo, A., & Aguilera, J. (2024b). Catalogue of antimicrobial resistance genes in species of Bacillus used to produce food enzymes and feed additives. *EFSA Supporting Publications*, *21*(7), EN-8931. https://doi.org/10.2903/sp.efsa.2024.EN-8931

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards). (2009). Scientific Opinion on the maintenance of the list of QPS microorganisms intentionally added to food or feed (2009 update). *EFSA Journal*, *7*(12), 1431. https://doi.org/10.2903/j.efsa.2009.1431

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards). (2013). Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update). *EFSA Journal*, *5*(11), 3449. https://doi.org/10.2903/j.efsa.2013.3449

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards). (2014). Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 1: Suitability of taxonomic units notified to EFSA until October 2014. *EFSA Journal*, *5*(12), 3938. https://doi.org/10.2903/j.efsa.2014.3938

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards). (2016). Scientific Opinion on the risks for public health related to the presence of Bacillus cereus and other Bacillus spp. including Bacillus thuringiensis in foodstuffs. *EFSA Journal*, *14*(7), 4524. https://doi.org/10.2903/j.efsa.2016.4524

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci, A., Allende, A., Bolton, D., Chemaly, M., Davies, R., Girones, R., Herman, L., Koutsoumanis, K., Lindqvist, R., Nørrung, B., Robertson, L., Ru, G., Sanaa, M., Simmons, M., Skandamis, P., Snary, E., Speybroeck, N., Ter Kuile, B., … Fernandez Escamez, P. S. (2017). Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. *EFSA Journal*, *5*(3), 4664. https://doi.org/10.2903/j.efsa.2017.4664

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci, A., Allende, A., Bolton, D., Chemaly, M., Davies, R., Girones, R., Koutsoumanis, K., Lindqvist, R., Nørrung, B., Robertson, L., Ru, G., Fernández Escámez, P. S., Sanaa, M., Simmons, M., Skandamis, P., Snary, E., Speybroeck, N., Ter Kuile, B., … Herman, L. (2018). Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 7: Suitability of taxonomic units notified to EFSA until September 2017. *EFSA Journal*, *5*(1), 5131. https://doi.org/10.2903/j.efsa.2018.5131

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Alvarez- Ordóñez, A., Bolton, D., Bover- Cid, S., Chemaly, M., Davies, R., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., & Herman, L. (2020a). Scientific Opinion on the update of the list of QPS- recommended biological agents intentionally added to food or feed as notified to EFSA (2017–2019). *EFSA Journal*, *18*(2), 5966. https://doi.org/10.2903/j.efsa.2020.5966

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Alvarez- Ordóñez, A., Bolton, D., Bover- Cid, S., Chemaly, M., Davies, R., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández

Escámez, P. S., & Herman, L. (2020b). Statement on the update of the list of QPS- recommended biological agents intentionally added to food or feed as notified to EFSA 12: Suitability of taxonomic units notified to EFSA until march 2020. *EFSA Journal*, *18*(7), 6174. https://doi.org/10.2903/j.efsa.2020.6174

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Álvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Nonno, R., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Suárez, J. E., … Herman, L. (2023a). Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes'. *EFSA Journal*, *21*(10), 8323. https://doi.org/10.2903/j.efsa.2023.8323

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Álvarez- Ordóñez, A., Bolton, D., Bover- Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Prieto Maradona, M., & Herman, L. (2023b). Scientific Opinion on the update of the list of qualified presumption of safety (QPS) recommended microorganisms intentionally added to food or feed as notified to EFSA. *EFSA Journal*, *21*(1), 7747. https://doi.org/10.2903/j.efsa.2023.7747

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Alvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Nonno, R., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., … Herman, L. (2023c). Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 18: Suitability of taxonomic units notified to EFSA until march 2023. *EFSA Journal*, *21*(7), 8092. https://doi.org/10.2903/j.efsa.2023.8092

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Alvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Nonno, R., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., … Herman, L. (2024a). Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 19: Suitability of taxonomic units notified to EFSA until September 2023. *EFSA Journal*, *22*(1), 8517. https://doi.org/10.2903/j.efsa.2024.8517

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Alvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Nonno, R., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., & Herman, L. (2024b). Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 20: Suitability of taxonomic units notified to EFSA until march 2024. *EFSA Journal*, *22*(7), 8882. https://doi.org/10.2903/j.efsa.2024.8882

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., Jacxsens, L., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Maradona, M. P., & Herman, L. (2025a). Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 22: Suitability of taxonomic units notified to EFSA until march 2025. *EFSA Journal*, *23*(7), 9510. https://doi.org/10.2903/j.efsa.2025.9510

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., Jacxsens, L., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Chemaly, M., Cocconcelli, P. S., Fernández Escámez, P. S., & Herman, L. (2025b). Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 21: Suitability of taxonomic units notified to EFSA until September 2024. *EFSA Journal*, *23*(1), 9169. https://doi.org/10.2903/j.efsa.2025.9169

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., Jacxsens, L., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Maradona, M. P., & Herman, L. (2026). Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 23: Suitability of taxonomic units notified to EFSA until September 2025. *EFSA Journal*, *24*(1), 9824. https://doi.org/10.2903/j.efsa.2026.9824

EFSA Scientific Committee, More, S., Bampidis, V., Benford, D., Bragard, C., Halldorsson, T., Hernández-Jerez, A., Bennekou, S. H., Koutsoumanis, K., Lambré, C., Machera, K., Mullins, E., Nielsen, S. S., Schlatter, J., Schrenk, D., Turck, D., Younes, M., Herman, L., Pelaez, C., … Cocconcelli, P. S. (2022). Scientific Opinion on the evaluation of existing guidelines for their adequacy for the food and feed risk assessment of microorganisms obtained through synthetic biology. *EFSA Journal*, *20*(8), 7479, 58 pp. https://doi.org/10.2903/j.efsa.2022.7479

EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., & Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. *EFSA Journal*, *23*(10), 9705. https://doi.org/10.2903/j.efsa.2025.9705

FAO. (2023). Four new reports highlight importance of the microbiome for food safety, soils and nutrition. Available online https://www.fao.org/newsroom/detail/four-new-reports-highlight-importance-of-the-microbiome-for-food-safety--soils-and-nutrition/en

Giovanardi, D., Biondi, E., Biondo, N., Quiroga, N., Modica, F., Puopolo, G., & Pérez Fuentealba, S. (2025). Sustainable and innovative biological control strategies against pseudomonas syringae pv. Tomato, pseudomonas savastanoi pv. Phaseolicola and Xanthomonas spp. affecting vegetable crops: A review. *Frontiers in Plant Science*, *16*, 1536152. https://doi.org/10.3389/fpls.2025.1536152

Golban, M., Charostad, J., Kazemian, H., & Heidari, H. (2025). Phage-derived endolysins against resistant *Staphylococcus* spp.: A review of features, antibacterial activities, and recent applications. *Infectious Disease and Therapy*, *14*, 13–57. https://doi.org/10.1007/s40121-024-01069-z

Gupta, R. S., Patel, S., Saini, N., & Chen, S. (2020). Robust demarcation of 17 distinct bacillus species clades, proposed as novel Bacillaceae genera, by phylogenomics and comparative genomic analyses: Description of Robertmurraya kyonggiensis sp. nov. and proposal for an emended genus bacillus limiting it only to the members of the subtilis and cereus clades of species. *International Journal of Systematic and Evolutionary Microbiology*, *70*(11), 5753–5798. https://doi.org/10.1099/ijsem.0.004475

Herman, L., Chemaly, M., Cocconcelli, P. S., Fernandez, P., Klein, G., Peixe, L., Prieto, M., Querol, A., Suarez, J. E., Sundh, I., Vlak, J., & Correia, S. (2019). The qualified presumption of safety assessment and its role in EFSA risk evaluations: 15 years past. *FEMS Microbiology Letters*, *366*(1), fny260. https://doi.org/10.1093/femsle/fny260

Holzer, K., Marongiu, L., Detert, K., Venturelli, S., Schmidt, H., & Hoelzle, L. E. (2025). Phage applications for biocontrol of enterohemorrhagic E. Coli O157:H7 and other Shiga toxin-producing Escherichia coli. *International Journal of Food Microbiology*, *439*, 111267. https://doi.org/10.1016/j.ijfoodmicro.2025.111267

Hong, P. Y., Mathieu, J., Cheng, H., Narayanasamy, S., Castillo, D. A., Goel, R., & Alvarez, P. J. (2025). Phage biocontrol in water treatment and reuse systems: A nascent field with significant innovation opportunities. *Current Opinion in Biotechnology*, *91*, 103242. https://doi.org/10.1016/j.copbio.20.

ICNP. (2022). International Code of Nomenclature of Prokaryotes Prokaryotic Code (2022 revision). Available online https://www.microbiologyresearch.org/content/journal/ijsem/10.1099/ijsem.0.005585#tab2

International Committee on Taxonomy of Viruses Executive Committee. (2020). The new scope of virus taxonomy: Partitioning the virosphere into 15 hierarchical ranks. *Nature Microbiology*, *5*, 668–674. https://doi.org/10.1038/s41564-020-0709-x

Jordá, J., Lorenzo-Rebenaque, L., Montoro-Dasi, L., Marco-Fuertes, A., Vega, S., & Marin, C. (2023). Phage-based biosanitation strategies for minimizing persistent salmonella and campylobacter bacteria in poultry. *Animals*, *13*(24), 3826. https://doi.org/10.3390/ani13243826

Kim, J., Liao, X., Zhang, S., Ding, T., & Ahn, J. (2025). Application of phage-derived enzymes for enhancing food safety. *Food Research International*, *209*, 116318. https://doi.org/10.1016/j.foodres.2025.116318

Koonin, E. V., Dolja, V. V., Krupovic, M., Varsani, A., Wolf, Y. I., Yutin, N., Zerbini, F. M., & Kuhn, J. H. (2020). Global organization and proposed Megataxonomy of the virus world. *Microbiology and Molecular Biology Reviews*, *84*(2), e00061-19. https://doi.org/10.1128/MMBR.00061-19

Kurtzman, C. P. (2011). Phylogeny of the ascomycetous yeasts and the renaming of Pichia anomala to Wickerhamomyces anomalus. *Antonie Van Leeuwenhoek*, *99*(1), 13–23. https://doi.org/10.1007/s10482-010-9505-6

Majewska, J., Miernikiewicz, P., Szymczak, A., Kaźmierczak, Z., Goszczyński, T. M., Owczarek, B., Rybicka, I., Ciekot, J., & Dąbrowska, K. (2023). Evolution of the T4 phage virion is driven by selection pressure from non-bacterial factors. *Microbiology Spectrum*, *11*(5), e0011523. https://doi.org/10.1128/spectrum.00115-23

Mayers, K. M. J., Kuhlisch, C., Basso, J. T. R., Saltvedt, M. R., Buchan, A., & Sandaa, R. A. (2023). Grazing on marine viruses and its biogeochemical implications. *MBiom*, *14*(1), e0192121. https://doi.org/10.1128/mbio.01921-21

Mc Grath, S., Fitzgerald, G. F., & van Sinderen, D. (2007). Bacteriophages in dairy products: Pros and cons. *Biotechnology Journal*, *2*(4), 450–455. https://doi.org/10.1002/biot.200600227

Meier-Kolthoff, J. P., Carbasse, J. S., Peinado-Olarte, R. L., & Göker, M. (2022). TYGS and LPSN: A database tandem for fast and reliable genome-based classification and nomenclature of prokaryotes. *Nucleic Acids Research*, *50*(D1), D801–d807. https://doi.org/10.1093/nar/gkab902

Naranjo-Ortiz, M. A., & Gabaldón, T. (2019). Fungal evolution: Major ecological adaptations and evolutionary transitions. *Biological Reviews of the Cambridge Philosophical Society*, *94*(4), 1443–1476. https://doi.org/10.1111/brv.12510

Narayanan, K. B., Bhaskar, R., & Han, S. S. (2024). Bacteriophages: Natural antimicrobial bioadditives for food preservation in active packaging. *International Journal of Biological Macromolecules*, *276*(Pt 2), 133945. https://doi.org/10.1016/j.ijbiomac.2024.133945

Necel, A., Dydecka, A., Topka-Bielecka, G., Wesołowski, W., Lewandowska, N., Bloch, S., & Nejman-Faleńczyk, B. (2025). What, how, and why? – Anti-EHEC phages and their application potential in medicine and food industry. *Journal of Applied Genetics*, *66*, 219–240. https://doi.org/10.1007/s13353-024-00918-4

Patel, S., & Gupta, R. S. (2020). A phylogenomic and comparative genomic framework for resolving the polyphyly of the genus *bacillus*: Proposal for six new genera of *bacillus* species, *Peribacillus* gen. Nov., *Cytobacillus* gen. Nov., *Mesobacillus* gen. Nov., *Neobacillus* gen. Nov., *Metabacillus* gen. Nov. and *Alkalihalobacillus* gen. Nov. *International Journal of Systematic and Evolutionary Microbiology*, *70*(1), 406–438. https://doi.org/10.1099/ijsem.0.003775

Reyneke, B., Havenga, B., Waso-Reyneke, M., Khan, S., & Khan, W. (2024). Benefits and challenges of applying bacteriophage biocontrol in the consumer water cycle. *Microorganisms*, *12*, 1163. https://doi.org/10.3390/microorganisms12061163

Rodríguez-Rubio, L., Martínez, B., Donovan, D. M., Rodríguez, A., & García, P. (2013). Bacteriophage virion-associated peptidoglycan hydrolases: Potential new enzybiotics. *Critical Reviews in Microbiology*, *39*(4), 427–434. https://doi.org/10.3109/1040841X.2012.723675

Rohmer, C., & Wolz, C. (2021). The role of hlb-converting bacteriophages in Staphylococcus aureus host adaption. *Microbial Physiology*, *31*(2), 109–122. https://doi.org/10.1159/000516645

Sabar, M. A., Honda, R., & Haramoto, E. (2022). CrAssphage as an indicator of human-fecal contamination in water environment and virus reduction in wastewater treatment. *Water Research*, *221*, 118827. https://doi.org/10.1016/j.watres.2022.118827

Secor, P. R., Burgener, E. B., Kinnersley, M., Jennings, L. K., Roman-Cruz, V., Popescu, M., Van Belleghem, J. D., Haddock, N., Copeland, C., Michaels, L. A., de Vries, C. R., Chen, Q., Pourtois, J., Wheeler, T. J., Milla, C. E., & Bollyky, P. L. (2020). Pf bacteriophage and their impact on pseudomonas virulence, mammalian immunity, and chronic infections. *Frontiers in Immunology*, *11*, 244. https://doi.org/10.3389/fimmu.2020.00244

Shymialevich, D., Wójcicki, M., & Sokołowska, B. (2024). The novel concept of synergically combining: High hydrostatic pressure and lytic bacteriophages to eliminate vegetative and spore-forming bacteria in food products. *Foods*, *13*(16), 2519. https://doi.org/10.3390/foods13162519.24.103242

Simmonds, P., Adams, M. J., Benkő, M., Breitbart, M., Brister, J. R., Carstens, E. B., Davison, A. J., Delwart, E., Gorbalenya, A. E., Harrach, B., Hull, R., King, A. M., Koonin, E. V., Krupovic, M., Kuhn, J. H., Lefkowitz, E. J., Nibert, M. L., Orton, R., Roossinck, M. J., … Zerbini, F. M. (2017). Consensus statement: Virus taxonomy in the age of metagenomics. *Nature Reviews Microbiology*, *15*, 161–168. https://doi.org/10.1038/nrmicro.2016.177

Simmonds, P., Adriaenssens, E. M., Lefkowitz, E. J., Oksanen, H. M., Siddell, S. G., Zerbini, F. M., Alfenas-Zerbini, P., Aylward, F. O., Dempsey, D. M., Dutilh, B. E., Freitas-Astúa, J., García, M. L., Hendrickson, R. C., Hughes, H. R., Junglen, S., Krupovic, M., Kuhn, J. H., Lambert, A. J., Łobocka, M., … Varsani, A. (2024). Changes to virus taxonomy and the ICTV statutes ratified by the international committee on taxonomy of viruses (2024). *Archives of Virology*, *169*, 236. https://doi.org/10.1007/s00705-024-06143-y

Singh, S., Pitchers, R., & Hassard, F. (2022). Coliphages as viral indicators of sanitary significance for drinking water. *Frontiers in Microbiology*, *13*, 941532. https://doi.org/10.3389/fmicb.2022.941532

Soto Lopez, M. E., Mendoza-Corvis, F., Salgado-Behaine, J. J., Hernandez-Arteaga, A. M., González-Peña, V., Burgos-Rivero, A. M., Cortessi, D., Vidigal, P. M. P., & Pérez-Sierra, O. (2025). Phage endolysins as an alternative biocontrol strategy for pathogenic and spoilage microorganisms in the food industry. *Viruses*, *17*(4), 564. https://doi.org/10.3390/v17040564

Tarahovsky, Y. S., Ivanitsky, G. R., & Khusainov, A. A. (1994). Lysis of *Escherichia coli* cells induced by bacteriophage T4. *FEMS Microbiology Letters*, *122*(1–2), 195–199. https://doi.org/10.1111/j.1574-6968.1994.tb07164.x

Turland, N. J., & Wiersema, J. H. (2024). Synopsis of proposals on nomenclature – Madrid 2024: A review of the proposals to amend the international code of nomenclature for algae, fungi, and plants submitted to the XX international botanical congress. *Taxon*, *73*, 325–404. https://doi.org/10.1002/tax.13114

Turner, D., Kropinski, A. M., & Adriaenssens, E. M. (2021). A roadmap for genome- based phage taxonomy. *Viruses*, *13*, 506.

Vinner, G. K., Vladisavljević, G. T., Clokie, M. R. J., & Malik, D. J. (2017). Microencapsulation of Clostridium difficile specific bacteriophages using microfluidic glass capillary devices for colon delivery using pH triggered release. *PLoS One*, *12*(10), e0186239. https://doi.org/10.1371/journal.pone.0186239

Wang, X., Tang, Y., Yue, X., Wang, S., Yang, K., Xu, Y., Shen, Q., Friman, V. P., & Wei, Z. (2024). The role of rhizosphere phages in soil health. *FEMS Microbiology Ecology*, *100*(10), fiae052. https://doi.org/10.1093/femsec/fiae052

Weinbauer, M. G. (2004). Ecology of prokaryotic viruses. *FEMS Microbiology Reviews*, *28*(2), 127–181. https://doi.org/10.1016/j.femsre.2003.08.001

Wennmann, J. T., Eigenbrod, M., Marsberg, T., Moore, S. D., Knox, C. M., Hill, M. P., & Jehle, J. A. (2019). *Cryptophlebia peltastica* nucleopolyhedrovirus is highly infectious to codling moth larvae and cells. *Applied and Environmental Microbiology*, *85*, e00795-19. https://doi.org/10.1128/AEM.00795-19

WHO (World Health Organization). (2024). WHO's list of medically important antimicrobials: A risk management tool for mitigating antimicrobial resistance due to non-human use. Available online: https://cdn.who.int/media/docs/default-source/gcp/who-mia-list-2024-lv.pdf?sfvrsn=3320dd3d_2

WOAH (World Organisation for Animal Health) . (2024). WOAH List of Antimicrobial Agents of Veterinary Importance. Available online: https://www.woah.org/app/uploads/2021/06/amended-91gs-tech-03-amr-working-group-report-en.pdf.June

Yan, J., Guo, Z., & Xie, J. (2024). A critical analysis of the opportunities and challenges of phage application in seafood quality control. *Foods*, *13*, 3282. https://doi.org/10.3390/foods13203282

Zheng, J., Wittouck, S., Salvetti, E., Franz, C., Harris, H. M. B., Mattarelli, P., O'Toole, P. W., Pot, B., Vandamme, P., Walter, J., Watanabe, K., Wuyts, S., Felis, G. E., Ganzle, M. G., & Lebeer, S. (2020). A taxonomic note on the genus lactobacillus: Description of 23 novel genera, emended description of the genus lactobacillus Beijerinck 1901, and union of Lactobacillaceae and Leuconostocaceae. *International Journal of Systematic and Evolutionary Microbiology*, *70*, 2782–2858. https://doi.org/10.1099/ijsem.0.004107

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