Scientific Works. Series C. Veterinary Medicine. Vol. LXXII (1), 2026
ISSN 2065-1295; ISSN 2343-9394 (CD-ROM); ISSN 2067-3663 (Online); ISSN-L 2065-1295

RECENT ADVANCES IN QPS MICROORGANISMS FOR FOOD AND FEED SAFETY, A PUBLIC HEALTH OVERVIEW

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Abstract

The 2006 EU ban on antibiotic growth promoters (AGPs) in animal feed marked a pivotal shift toward sustainable alternatives like probiotics, regulated under EFSA's Qualified Presumption of Safety (QPS) framework to ensure food and feed safety. Recent 2026 QPS updates expanded approvals for bacteriophages and select microalgae while excluding others due to safety gaps, supporting One Health strategies amid persistent challenges from feed contaminants (mycotoxins, heavy metals), zoonotic risks in novel plant/insect-based feeds, and AMR transmission. This overview synthesizes post-AGP impacts - initial 1-3% growth dips and 4-6% cost rises, offset by probiotics achieving 70-90% AGP efficacy - alongside regulatory evolution, key research gaps in long-term microbiome effects and climate-resilient forages, and practical implications for veterinary public health surveillance from farm to fork.

Key words*: Qualified Presumption of Safety (QPS), antibiotic growth promoters (AGPs), food safety, feed contaminants, One Health.*

INTRODUCTION

Public health faces ongoing uncertainties in how feed contaminants (e.g., mycotoxins, heavy metals) affect food-producing animals and enter the human chain (Sapkota et al., 2007). Questions persist on optimizing sustainable feeds like insect proteins or algae while ensuring nutritional balance across species (Kittitunyapong et al., 2025).

The 2006 EU ban on antibiotic growth promoters (AGPs) in animal feed aimed to curb antimicrobial resistance (AMR) while maintaining livestock productivity. Initial short-term challenges included 1-3% drops in growth rates, 4-6% production cost increases, and rises in enteric diseases like necrotic enteritis in poultry and post-weaning diarrhea in pigs, offset by compensatory therapeutic antibiotic use (up 10-30%). Long-term, strategies such as enhanced biosecurity, vaccines, and alternatives stabilized performance, with overall antibiotic sales declining 25-50% by 2020.

Probiotics emerged as leading AGP replacements, outperforming prebiotics (2-5% FCR gains) and phytogenics (0-8%) *via* competitive exclusion and immunomodulation, achieving 70-90% of AGP efficacy in commercial settings. EU Regulation (EC) No 1831/2003 governs probiotics as "gut flora stabilisers," requiring EFSA FEEDAP approval based on safety, efficacy, and species-specific data. EFSA's Qualified Presumption of Safety (QPS) framework streamlines this for notified taxonomic units meeting unambiguous taxonomy, safety history, and AMR criteria.

Recent 2026 QPS updates notably included bacteriophages at the species level and microalgae like *Microchloropsis gaditana* ("production purposes only", absent viable cells), while excluding filamentous fungi and denying *Bacillus thermoamylovorans* and *Aurantiochytrium acetophilum* due to insufficient knowledge. These advances support One Health-aligned sustainable feed innovations, balancing veterinary public health, food safety, and productivity post-AGP era.

In this context, the paper presents an analysis of the evolution of QPS microorganisms in Europe, in order to highlight recent advances and the results of research made in the last 20 years.

MATERIALS AND METHODS

To ensure a comprehensive understanding of recent advances in Qualified Presumption of Safety (QPS) microorganisms for food and feed safety, a rigorous literature search strategy was employed.

Databases such as PubMed, Scopus, Web of Science, and Google Scholar were utilized, alongside EFSA-specific repositories and veterinary journals *via* CAB Abstracts, to access peer-reviewed studies, regulatory documents, and grey literature.

The search focused on specific keywords and phrases including "Qualified Presumption of Safety" OR "QPS microorganisms", "antibiotic growth promoters" OR "AGPs ban EU", "probiotics animal feed", "feed contaminants" OR "mycotoxins aquaculture", "zoonotic risks novel feeds", "One Health feed safety", and "EFSA QPS updates 2024-2026", combined with Boolean operators (AND/OR/NOT) and filters for publication dates (2003-2026) to capture post-AGP ban developments.

Inclusion criteria prioritized English-language peer-reviewed articles, EFSA opinions, and reviews on veterinary public health implications; exclusions covered non-relevant human-only studies or pre-2003 data. Reference lists of key papers (e.g., EFSA QPS updates) were hand-searched for additional sources, yielding over 150 initial hits refined to 50 core references.

RESULTS AND DISCUSSIONS

The practical implications of unresolved main topics include the long-term effects of antibiotic residues in feed on microbiome resistance in ruminants and poultry, climate-resilient forages (e.g.: How to breed feeds minimizing methane emissions without reducing productivity?) and zoonotic pathogen transmission *via* novel plant-based feeds in aquaculture and livestock (Al-niaeem et al., 2026).

These gaps drive One Health approaches, emphasizing surveillance from farm to fork. For instance, EU regulations highlight needs for better data on dioxins and prions in recycled feeds. Research prioritizes HACCP integration with emerging feeds to close these knowledge voids.

Zoonotic pathogen transmission risk *via* novel plant-based feeds in aquaculture and livestock was recently detected (Al-niaeem et al., 2026).

Novel plant-based feeds in aquaculture and livestock aim to replace traditional fishmeal and soy, but they introduce potential zoonotic risks through contamination and health impacts on animals. Current research highlights indirect rather than direct transmission pathways.

Plant-based aquafeeds, like those from corn, wheat, and soy, are prone to mycotoxin contamination from fungi such as *Aspergillus* species, leading to aflatoxins that impair fish health, immunity, and growth. These toxins increase fish susceptibility to bacterial pathogens like *Aeromonas* and *Klebsiella*, which are zoonotic and can infect humans *via* contaminated seafood. Anti-nutritional factors in feeds may also weaken gut barriers, potentially amplifying pathogen loads (Mauad et al, 2025; Gruber-Dorninger et al., 2025; Glencross et al., 2020).

Shifting to novel plant proteins in livestock feeds carries contamination risks during storage or transport, though direct zoonotic pathogen survival (e.g., viruses like ASFV) is more noted in animal-derived feeds. Plant materials can harbor pathogens *via* fecal or environmental contamination, indirectly boosting zoonotic spillover in intensive systems. Phytogenic additives show promise as antibiotic alternatives but do not eliminate baseline risks from feed quality (Shepon et al., 2023; Holden, 2021; Aminullah et al., 2025; Jones et al., 2029).

Risk assessments emphasize sourcing contaminant-free plants, heat processing feeds, and monitoring mycotoxins. Insect-based novel feeds (e.g., black soldier fly larvae) enhance immunity and disease resistance without evident zoonotic amplification. Adopting One Health surveillance for feed chains can prevent transmission (Kannan et al., 2022; Glencross et al., 2020; Shepon et al., 2023; Mauad et al., 2025).

Unanswered questions on antibiotic use in livestock feeds persist due to gaps in long-term data, regulatory variations, and emerging resistance patterns. These challenges are central to veterinary public health and One Health initiatives (Ghimpețeanu et al., 2022; Zheng et al., 2025).

Key uncertainties include the exact degree to which antibiotic-resistant bacteria (ARB) from medicated feeds transfer to humans *via* meat, milk, or environmental pathways like manure runoff (Enshaie et al., 2025; Myers et al., 2022). Questions remain on whether sub-therapeutic doses in feed select for resistance genes more aggressively in ruminants versus poultry microbiomes (Ghimpețeanu et al., 2022).

It's unclear how effectively non-antibiotic feed additives (e.g., probiotics, essential oils) match growth promotion benefits across diverse livestock species under commercial stress conditions (Zheng et al., 2025). Long-term studies are needed on whether these substitutes reduce overall antimicrobial resistance (AMR) without compromising animal welfare or food productivity (Myers et al., 2022).

Challenges persist in quantifying the crossover-use of human antibiotics in animal feeds, especially in low-resource settings, and its residue impacts on food safety (Myers et al., 2022). Debates continue on optimal withdrawal periods and composting efficacy to eliminate residues like tetracyclines from manure before field application. Harmonizing global surveillance for feed-related AMR genes also lacks standardized protocols (Enshaie et al., 2025).

EU rules on antibiotic use in animal feed strictly prohibit antibiotics as growth promoters in animal feed to curb antimicrobial resistance. This ban, effective since 2006, covers all species including livestock and poultry (CABI News, 2005; EU, 2003).

Regulation (EC) No 1831/2003 bans antibiotics like monensin sodium, salinomycin sodium, avilamycin, and flavophospholipol for non-therapeutic growth promotion in feed (CABI News, 2005). The European Food Safety Authority (EFSA) evaluates additives, authorizing only those proven safe for animals, humans, and the environment with species-specific maximum dosages (EU, 2003).

Regarding their therapeutic and non-therapeutic use, antibiotics remain allowed solely for disease treatment or prevention under veterinary prescription (Regulation (EU) 2019/6), not for yield enhancement (AGRINFO, 2023). Post-2026 import rules extend this to third-country exports, requiring certification against growth promoter use (AGRINFO, 2023; Colli et al., 2025).

Maximum residue limits (MRLs) apply where needed, backed by routine feed and foodstuff testing plus post-market surveillance (CABI News, 2005). Violations trigger market withdrawal, aligning with One Health goals in veterinary public health.

The 2006 EU ban on antibiotic growth promoters (AGPs) had modest, mostly short-term effects on livestock growth rates and farming costs, with studies showing quick adaptation through alternatives like improved hygiene and probiotics (LEI, 2007).

Livestock growth rates dipped initially by 1-3% in poultry and pigs due to higher feed conversion ratios (FCR), but stabilized within 1-2 years as farmers optimized diets and biosecurity (LEI, 2007; Laxminarayan et al., 2015). No long-term productivity losses were widely reported; EU broiler and layer output remained competitive post-ban.

Feed costs rose slightly (2-5%) from increased feed intake and additive prices, contributing to overall production cost hikes of 4-6% for broilers and 11-13% for layers by 2010-2012 (compounded with other regulations like welfare rules) (LEI, 2007). These were offset by market premiums for antibiotic-free meat and efficiency gains (Table 1).

Table 1. Comparative impacts post-2006 AGP ban

Sector	Growth impact	Annual cost impact	Adaptation time
Broilers	-1-2% short-term (LEI, 2007)	+4-6% total (LEI, 2007)	1 year
Pigs	Minimal (~1%) (Laxminarayan et al., 2015)	+1-3% feed (McEwen et al., 2017)	<2 years
Layers	-2% FCR (LEI, 2007)	+11% cumulative (LEI, 2007)	2 years

The 2006 EU ban on antibiotic growth promoters (AGPs) yielded mixed long-term effects on antibiotic resistance, with reductions in specific resistances offset by rises in others due to compensatory therapeutic antibiotic use (Wen et al., 2022; Casewell et al., 2003).

Enterococcal resistance to banned AGPs like avoparcin, virginiamycin, and tylosin declined significantly in animal feces and human carriers within 3-5 years post-ban, as selection pressure lifted. Denmark's monitoring showed sustained drops in macrolide and streptogramin resistance among indicator bacteria by 2010 (Casewell et al., 2003).

Therapeutic antibiotic use rose 10-30% initially in pigs and poultry to manage diseases like necrotic enteritis and post-weaning diarrhea, elevating resistances to tetracyclines, aminoglycosides, and macrolides – key human medicines. Long-term data (to 2020s) indicate persistent higher AMR in *Salmonella* and *Campylobacter* from farms versus pre-ban levels, though overall EU AMR trends stabilized with hygiene improvements (McEwen et al., 2017; McEwen et al., 2018; Karen et al., 2019).

No uniform decline in total AMR occurred; benefits were compound-specific while prophylactic gaps drove broader therapeutic reliance, complicating One Health goals. Recent surveillance suggests net stabilization by 2020, but vigilance continues amid import pressures (Laxminarayan et al., 2015).

Strategies like improved biosecurity, alternative feed additives, and stricter therapeutic antibiotic controls helped mitigate rises in resistance after the EU's 2006 AGP ban (Laxminarayan et al., 2015; McEwen et al., 2017).

Farmers upgraded housing ventilation, all-in-all-out systems, and cleaning protocols, reducing pathogen loads (e.g., *Clostridium perfringens* in poultry) by 20-50%, which curbed the need for prophylactic antibiotics. Denmark's national action plan mandated farm audits, stabilizing overall AMR by 2015 (McEwen et al., 2017).

Feed additives like probiotics, prebiotics, organic acids, and phytogenics partially replaced AGPs, maintaining growth while lowering therapeutic antibiotic use in pigs by 15-25% long-term. Vaccines against key diseases like post-weaning diarrhea and necrotic enteritis further decreased reliance on drugs like tetracyclines (Laxminarayan et al., 2015).

The EU's 2006 AGP ban initially increased therapeutic antibiotic use in pigs and poultry due to heightened disease susceptibility, but long-term trends showed overall declines through adaptive measures.

Therapeutic use spiked short-term (e.g., Denmark saw +20-30% in tetracyclines and macrolides for post-weaning diarrhea in weaners during 2000-2002), as AGPs had masked gut infections like *E. coli* and *Clostridium* (Table 2). By 2010-2020, total use dropped 40-60% across the EU *via* vaccines, zinc oxide (later restricted), and probiotics, stabilizing below pre-ban levels (Casewell et al., 2003; McEwen et al., 2017).

Poultry saw milder initial rises (10-20% in medicated feed for broilers against necrotic enteritis), concentrated in northern Europe, but no sustained increase due to rapid vaccine adoption and biosecurity. EU-wide sales data indicate broiler therapeutic use fell ~25% by 2018, aided by Regulation (EU) 2019/6 benchmarking (McEwen et al., 2018).

Table 2. Trends in short and long term

Species	Short-Term Change	Long-Term Change	Main Drivers (McEwen et al., 2017)
Pigs	+20-116% (2000-02)	-50% (to 2020)	Vaccines, hygiene upgrades
Poultry	+10-20% (2006-08)	-25% (to 2018)	Alternatives, fewer outbreaks

The EU AGP ban did not reduce human vancomycin-resistant enterococci (VRE) infections as reductions in veterinary antimicrobial use, including AGPs, did not consistently translate into immediate, uniform declines in human VRE infections, due to multiple intervening factors such as hospital prescribing practices, infection control, and broader antimicrobial resistance dynamics.

Post-ban assessments (up to 2003) showed declines in VRE carriage among human fecal carriers and in animal indicators like enterococci from pig/poultry feces, linked to avoparcin withdrawal in 1997. However, clinical VRE infections in hospitals did not decrease and even rose in parts of Europe, driven by increased vancomycin use for MRSA treatment rather than animal sources (Casewell, 2003).

Scandinavian data (e.g., Denmark) confirmed rapid drops in animal VRE reservoirs after phased bans, but no parallel reduction in human cases where VRE was already rare (Table 3).

Table 3. Factors of changes

Aspect	Observed change (Casewell, 2003)	Primary driver
Animal VRE carriage	Sharp decline	Ban on avoparcin/virginiamycin
Human fecal carriage	Modest decline	Reduced food chain exposure
Clinical infections	No decline/increase	Hospital vancomycin overuse

Transmission from food animals to humans proved limited, with hospital selection pressures dominating (Casewell, 2003).

After the full 2006 EU AGP ban, animal health issues primarily emerged as short-term increases in specific gut and enteric diseases, though most were managed through alternatives (Huyghebaert et al., 2011; McEwen et al., 2017). Necrotic enteritis caused by *Clostridium perfringens* surged initially in broilers (up to 20-30% higher incidence in some flocks), linked to wet litter and higher feed intake without AGPs suppressing subclinical infections. Subclinical dysbiosis also raised footpad dermatitis and hock burn rates temporarily (Huyghebaert et al., 2011; McEwen et al., 2017).

Post-weaning diarrhea (PWD) from *E. coli* and *Rotavirus* increased markedly in weaners (10-50% more cases in Denmark and Netherlands during 2006-2008), as AGPs had controlled pathogen overgrowth (Table 4). This led to higher mortality (1-3%) and growth setbacks before vaccines and acidifiers took hold (McEwen et al., 2017; Laine et al., 2004).

Table 4. Resolution factors

Species	Main Issue	Duration	Mitigation (Huyghebaert et al., 2011; McEwen et al., 2018)
Poultry	Necrotic enteritis	1-2 years	Vaccines, organic acids
Pigs	Weaning diarrhea	2-3 years	Probiotics, zinc oxide (pre-2022 ban)

Industry-wide, diseases were transient, with no lasting epidemics due to rapid biosecurity upgrades and feed reformulation.

Probiotics played a key supportive role in mitigating animal health issues after the EU's 2006 AGP ban by stabilizing gut microbiota and reducing pathogen loads in pigs and poultry (Huyghebaert et al., 2011; Krysiak et al., 2021). Strains like *Lactobacillus* and *Bacillus* species competed with pathogens such as *Clostridium perfringens* (causing necrotic enteritis) and *E. coli* (post-weaning diarrhea), lowering incidence by 20-40% in trials. They improved feed efficiency and reduced subclinical dysbiosis, partially filling the AGP gap without promoting resistance and inducing gut health stabilization (Krysiak et al., 2021; Sachdeva et al., 2025; McEwen et al., 2018).

In broilers, probiotics cut mortality from enteric diseases by enhancing intestinal barrier function and immune modulation, with meta-analyses showing 5-10% better weight gains versus untreated controls post-ban. Piglet studies confirmed fewer diarrhea days (down 30%) when dosed early, aiding weaning transitions (Sachdeva et al., 2025; Abd El-Hack et al., 2022).

Probiotics worked best alongside vaccines, organic acids, and biosecurity – not as standalone replacements – achieving 70-90% of AGP performance in commercial settings. EFSA-approved multi-strain products proved most effective for sustained use (Krysiak et al., 2021; Abd El-Hack et al., 2022).

Probiotics generally outperform prebiotics and phytogenics as AGP alternatives in livestock, particularly for gut health and growth performance, based on post-EU ban studies (Agustono et al., 2025; Shehata et al., 2022).

Probiotics (live microbes like *Lactobacillus*) directly colonize the gut, reducing pathogens by 20-40% and improving FCR by 5-10% versus controls, often surpassing AGPs in poultry trials. Prebiotics (e.g., MOS, FOS) selectively feed beneficial bacteria, yielding milder gains (2-5% FCR improvement) with less consistency across flocks (Table 5).

Phytogenics (essential oils, oregano) provide antimicrobial effects *via* direct pathogen inhibition but show variable results (0-8% growth boost), limited by volatility and dosage sensitivity (Agustono et al., 2025; Shehata et al., 2022; Applegate et al., 2010; Idowu et al., 2025).

Table 5. Mechanisms and consistency

Alternative	Mechanism (Shehata et al., 2022; Applegate et al., 2010)	Growth benefit	Consistency	Cost-effectiveness
Probiotics	Competitive exclusion, immunomodulation	High (5-10%) (Agustono et al., 2025)	High in pigs/poultry	Moderate
Prebiotics	Substrate for native microbiota	Moderate (2-5%)	Medium (species-dependent)	Low
Phytogenics	Direct antimicrobials, appetite stimulation	Variable (0-8%)	Low (dose/ environment-sensitive)	High short-term

Probiotics excel in multi-strain formulations for sustained effects, while combinations (synbiotics: probiotics + prebiotics + postbiotics) often yield best results in commercial EU settings post-2006 (Sachdeva et al., 2025).

EU probiotics in animal feed are regulated as "gut flora stabilisers" under zootechnical additives *via* Regulation (EC) No 1831/2003. Only EFSA-approved strains with proven safety, efficacy, and quality reach the EU positive list after rigorous dossiers covering

identity, target species, and residue risks (Anadón et al., 2006; Lallemand Animal Nutrition, 2010; Biosafe, 2025; Regulation (EC) No 1831/2003).

Manufacturers submit data to EFSA's FEEDAP Panel, proving no harm to animals, users, consumers, or the environment - often leveraging QPS status for common strains like *Lactobacillus* or *Bacillus* to streamline review. Authorizations specify dosages, species (e.g., pigs, poultry), and claims like performance improvement, with 5-10-year renewals based on post-market monitoring (Anadón et al., 2006; Lallemand Animal Nutrition, 2010, von Wright, 2005).

Examples include *Pediococcus acidilactici* MA18/5M (Bactocell®) for broilers and *Saccharomyces cerevisiæ* CNCM I-1077 (Levucell® SC) for ruminants and piglets (Table 6). Multi-strain products must demonstrate synergy; non-QPS microbes face full genotoxicity testing (Lallemand Animal Nutrition, 2010; Biosafe, 2025).

Table 6. Important categories

Category	Examples	Target Species
Gut Flora Stabilisers	*Lactobacillus rhamnosus*, *Enterococcus fæcium* (Lallemand Animal Nutrition, 2010)	Poultry, pigs
Zootechnical	*Bacillus subtilis*, *S. cerevisiæ* (Biosafe, 2025)	Ruminants, aquaculture
Conditions	Dosage 10^{8-10} CFU/kg, species-specific (Anadón et al., 2006)	All food animals

EFSA maintains an official register of authorized feed additives, including probiotics classified as "gut flora stabilisers" or zootechnical additives under Regulation (EC) No 1831/2003. No single exhaustive public list exists in one document, but approved strains are detailed in EFSA opinions and commercial databases like the EU Feed Additives Register (EFSA, 2013; EFSA BIOHAZ Panel, 2026; PIGdk, 2024; Regulation (EC) No 1831/2003).

Common EFSA-authorised probiotic strains for animal feed include:

- *Bacillus subtilis* DSM 25841, C-3102 (e.g., in BioPlus YC, GalliPro, Calsporin) for pigs, poultry (PIGdk, 2024).
- *Bacillus amyloliquefaciens* DSM 25840 (e.g., in SolPreme) for pigs (PIGdk, 2024).
- *Bacillus velezensis* (formerly *B. subtilis*) NCIMB 30180 (Calsporin) for multiple species (PIGdk, 2024).
- *Enterococcus fæcium* strains like NCIMB 10415 (Bonvital, Fecinor) for piglets, poultry (PIGdk, 2024).
- *Lactobacillus acidophilus*, *L. helveticus*, *L. bulgaricus*, *L. lactis*, *Streptococcus thermophilus*, *E. fæcium* (Probiotic LACTINA®) for chickens, piglets at $\leq 1\times10^{10}$ CFU/kg (EFSA Journal, 2013).
- *Saccharomyces cerevisiæ* strains like MUCL 39885 (Biosprint), CNCM I-1077 (Levucell SC) for pigs, ruminants (PIGdk, 2024).

The EU Feed Additives Register (*via* EFSA or Commission websites) contains the latest, as approvals specify strains, dosages (often 10^{8}-10^{10} CFU/kg), and target animals. QPS-status microbes (e.g., many *Bacillus, Lactobacillus*) expedite approval if safety data aligns. Multi-strain products require individual efficacy proof (EFSA BIOHAZ Panel, 2026; Biosafe, 2025; EFSA, 2025).

EFSA's 2025 QPS updates expanded the list of qualified presumption of safety (QPS) taxonomic units for probiotic strains, facilitating faster approvals for animal feed use (Nicolle N., 2026; EFSA, 2025, 23:e9169).

Bacteriophages became eligible for QPS status at the species level for the first time, opening doors for phage-based probiotics targeting specific pathogens without disrupting microbiomes. *Microchloropsis gaditana* and *Chlamydomonas reinhardtii* joined the list with "for production purposes only" qualifications, while *Candida oleophila* was added for similar uses. *Lacticaseibacillus huelsenbergensis* and *Serratia plymuthica* received preliminary positive assessments pending full data (Nicolle N., 2026; EFSA , 2025, 23:e9169).

Qualifications were streamlined, extending QPS to certain genetically modified microorganisms (GMMs) if the parental strain qualifies and modifications pose no added risks – crucial for innovative feed probiotics.

Figure 1 illustrates the EFSA Qualified Presumption of Safety (QPS) evaluation process for probiotic microorganisms in animal feed, highlighting decision points that streamline approvals for safe strains like *Lactobacillus* while requiring full assessments for others.

Antimicrobial resistance genes must now be proven non-transferable and intrinsic to the species (Table 7). Denials included *Bacillus thermoamylovorans* (insufficient data) and *Bacillus thuringiensis* (safety concerns) (Nicolle N., 2026; EFSA, 2025, 23:e9169; EFSA, 2026, 24 (1) e9823).

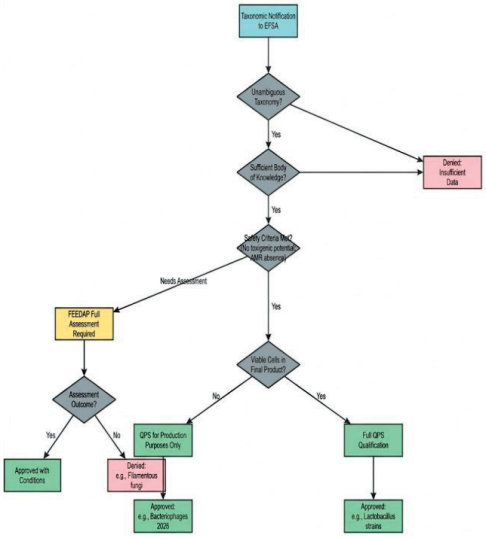


Figure 1. EFSA QPS process for probiotic microorganisms in feed

Microchloropsis gaditana received QPS recommendation with the qualification "for production purposes only," suitable for feed applications where viable cells are absent in the final product. *Bacillus thermoamylovorans* was denied QPS status due to insufficient body of knowledge, lacking extensive safety data and whole-genome sequencing for the type strain (EFSA Journal. 2026;24(1):e9824).

Table 7. Implications for probiotics

Update Category (Nicolle N., 2026; EFSA BIOHAZ Panel, 2026)	Examples	Feed Relevance
New QPS TUs	Bacteriophages, *Microchloropsis gaditana*	Pathogen control, microalgae feeds
GMM Extension	Parental QPS strains with safe edits	Precision probiotics for pigs/poultry
Reassessments	*L. huelsenbergensis* (approved)	Gut stabilisers post-AGP ban

EFSA's BIOHAZ Panel evaluated these as first-time notifications in their January 2026 update (notifications until September 2025). *M. gaditana* (formerly *Nannochloropsis gaditana*), a microalga, met taxonomy, safety history, and AMR criteria for production uses like biomass or enzymes (Table 8). *B. thermoamylovorans* failed on knowledge depth and strain identification, requiring full safety dossiers for feed authorisation (EFSA, 2026; 24(1): e9823; Nicolle, 2026).

Table 8. Comparison between strains concerning the QPS Status

Strain	QPS Status	Qualification/Reasons EFSA, 2026, 24(1):e9824; EFSA, 2026, 24(1): e9823)
Microchloropsis gaditana	Recommended	Production purposes only (safe, known)
Bacillus thermoamylovorans	Not recommended	Lack of body of knowledge, no WGS

"**Production purposes only**" is a key qualification in EFSA's QPS framework for microbial agents used in food/feed where viable cells must be absent from final products.

This qualification applies to taxonomic units (e.g., microalgae like *Microchloropsis gaditana*) employed in biosynthesis of additives such as enzymes, vitamins, or microbial biomass, ensuring no living cells reach consumers or animals. It recognizes safe histories of fermentation products despite limited direct exposure data for the live organisms themselves (Herman et al., 2019; EFSA, 2018, 16(7):e05315).

Applicants must demonstrate through validated methods (e.g., plate counts, viability assays) that viable cells of the production strain are undetectable (<1 CFU/g) in final feed/food items (Table 9). This covers inactivated biomass products too, streamlining approvals under Regulation (EC) No 1831/2003 without full genotoxicity testing (Herman et al., 2019; EFSA, 2022, 20(1):e07045).

Table 9. Examples in practice

Qualified strain/TU (EFSA, 2026, 24(1):e9824)	Use case	Verification needed
Microchloropsis gaditana	DHA-rich biomass	No viable cells post-harvest
Chlamydomonas reinhardtii	Production enzymes	<1 CFU/g in final additive

This supports One Health-aligned sustainable feeds while prioritizing consumer safety in veterinary public health contexts.

"Production purposes only" QPS qualifications apply to microorganisms used in manufacturing processes where no viable cells remain in the final food or feed product (EFSA, 2020, 18(7):e06174; EFSA, 2023, 21(1):7747).

This limits QPS to production of enzymes, additives, or biomass, requiring proof of <1 CFU/g viable cells *via* validated methods like plate counts. It enables safe histories for fermentation aids despite limited live-organism data (EFSA, 2023, 21(1):7747).

Table 10 shows examples of authorized microorganisms used only for production purposes.

- *Microchloropsis gaditana* for DHA biomass production (Herman et al., 2019).
- *Chlamydomonas reinhardtii* enzymes (Herman et al., 2019).
- *Candida oleophila* production uses (Herman et al., 2019).
- *Vibrio natriegens* and *Agrobacterium radiobacter*, recent 2026 additions (Herman et al., 2019).
- *Hæmatococcus lacustris* (pluvialis), astaxanthin (EFSA, 2024, 22(7):e8882).
- *Ogatæa polymorpha*, yeast for enzymes (EFSA, 2024, 22(7):e8882).
- *Bacillus circulans* with cytotoxicity absence (EFSA, 2024, 22(7):e8882).

Corynebacterium ammoniagenes, confirmed status.

Table 10. Examples of authorized microorganisms

Microorganism	EFSA update (EFSA, 2026, 24(1): e9823; EFSA Journal 2023, 21(1):7747)	Typical use
Microchloropsis gaditana	2026	DHA feeds
Chlamydomonas reinhardtii	2026	Enzymes
Hæmatococcus lacustris	Earlier	Pigments
Ogatæa polymorpha	Earlier	Fermentation aids

Certain taxonomic units are categorically excluded from EFSA's QPS evaluations, including "production purposes only" qualifications, due to inherent safety risks and taxonomic ambiguity. EFSA's BIOHAZ Panel excludes entire biological groups from QPS based on historical reviews showing unlikely qualification (EFSA, 2018, 16(7):e05315; EFSA, 2021, 19(1):e06377):

- Filamentous fungi (e.g., *Aspergillus*, *Fusarium*, *Aureobasidium pullulans*): mycotoxin production potential and complex taxonomy prevent presumption of safety (EFSA, 2018, 16(7):e05315; EFSA, 2021, 19(1):e06377).
- Bacteriophages: previously excluded (pre-2026); now eligible at species level but not production-only by default (EFSA, 2018, 16(7):e05315).
- *Enterococcus fæcium*: pathogenicity risks in humans/animals (EFSA, 2021, 19(1):e06377).
- *Escherichia coli* and *Streptomyces* spp.: opportunistic infections, antibiotic production traits (EFSA, 2020, 18(7):e06174).
- *Oomycetes* and *Clostridium butyricum*: toxin and ambiguous positioning concerns (EFSA, 2021, 19(1):e06377).

These groups require case-by-case, strain-level assessments by FEEDAP or other Panels under Regulation (EC) No 1831/2003, bypassing QPS streamlining due to "potentially harmful traits" identified in 2008-2013 updates (Table 11).

Notifications involving them are auto-excluded from biannual QPS lists (EFSA, 2020, 18(7):e06174; EFSA, 2018, 16(7):e05315).

Table 11. Comparison between excluded groups of microorganisms

Excluded group	Reason (EFSA, 2018, 16(7):e05315; EFSA, 2021, 19(1):e06377)	Assessment level
Filamentous fungi	Mycotoxins, taxonomy issues	Strain-by-strain
E. coli	Pathogenicity, AMR genes	Full dossier
Streptomyces spp.	Bioactive/toxin compounds	Case-by-case
Enterococci	Infection risks	Excluded entirely

"For production purposes only" QPS qualification applies to certain microorganisms under EFSA's Qualified Presumption of Safety (QPS) system, meaning they are safe when used solely for producing substances where no viable cells remain in the final product. Examples include:

- *Vibrio natriegens*, recommended for QPS status specifically "for production purposes only" (EFSA, 2025, 23(7): e9510; EFSA, 2026, 24(1): e9823).

- *Bacillus circulans*, granted QPS with the qualification "for production purposes only" (EFSA, 2023, 21(1):7747).
- *Hæmatococcus lacustris* (syn. *Hæmatococcus pluvialis*): QPS status with "for production purposes only" (EFSA, 2023, 21(1):7747).
- *Rhizobium radiobacter* (also noted as *Agrobacterium radiobacter*): Recommended for QPS "for production purposes only" (EFSA, 2026, 24(1): e9823; EFSA, 2024, 22(7):e8882).

This qualification ensures safety by requiring no viable production organisms in the end product, often for enzymes, additives, or biomass in food/feed chains. It's distinct from unqualified QPS, limiting use to non-viable applications (EFSA, 2025, 23(7):e9510).

Vibrio natriegens serves mainly as a fast-growing bacterial host for biotech production, particularly recombinant proteins and metabolites, rather than direct consumer products (Mojica et al., 2024; Hoffart et al., 2017).

Engineered strains like Vmax X2 produce challenging proteins such as cholera toxin (CT), GbpA from *Vibrio cholerœ*, heat-labile enterotoxin (LT) from *E. coli*, and fungal nematotoxin CCTX2 from *Coprinopsis cinerea*. These yield higher amounts (6- to 26-fold over *E. coli*) and simplify purification *via* secretion into media, aiding structure/function studies (Mojica et al., 2024).

Metabolic engineering enables pyruvate, 1,3-propanediol (productivity 2.36 g/L/h), L-alanine, citramalate, poly(3-hydroxybutyrate-co-lactate) [P(3HB-co-LA)], and cadaverine (up to 158 g/L, 14.4 g/L/h) (Wu et al., 2023; Sun et al., 2024; Zheng et al., 2025).

Targets include organic/amino acids under anaerobic conditions for high substrate uptake (Hoffart et al., 2017).

Primarily lab-scale for biotech R & D (e.g., 15N-labeling, perdeuteration for neutron studies), not yet commercial food/feed products due to its "production purposes only" QPS status limiting viable cells in finals. No widespread industrial commodities identified (Mojica et al., 2024; Thoma and Blombach, 2021; Hädrich et al, 2025; Xu et al., 2022).

Vibrio natriegens is primarily used as a recombinant host for producing challenging proteins, including enzymes and toxins, rather than natively producing specific enzymes at scale (Smith et al, 2024; Mojica et al., 2024).

- Cholera toxin (CT) and heat-labile enterotoxin (LT) are secreted *via* Type II secretion system, yielding 6- to 26-fold higher than in E. coli for structural studies (Mojica et al., 2024).
- GbpA (from *Vibrio cholerœ)* presents high-yield production and purification from media (Mojica et al., 2024).
- N-acetyl amino acid racemase, isoprene synthase, and ribonucleoside diphosphate kinase are expressed at 2.6- to 12-fold higher levels than in *E. coli* (Mojica et al., 2024).

Native enzymes are not well-documented for industrial use; focus is on its fast growth for biotech expression of heterologous proteins/toxins, aligning with "production purposes only" QPS. No commercial enzyme products identified beyond research (Smith et al, 2024; Thoma and Blombach, 2021; Hoffart et al., 2017).

The "Production purposes only" qualification for *Agrobacterium radiobacter* (syn. *Rhizobium radiobacter*) in EFSA's QPS list ensures safety by restricting its use to processes where no viable cells remain in the final food/feed product, such as enzyme or additive production (EFSA, 2026, 24(1):e9823).

This limitation addresses the species' body of knowledge (BoK) limitations, including its close relation to pathogenic *Agrobacterium* species (e.g., *A. tumefaciens* causing plant tumors) and opportunistic infections reported in immunocompromised humans, like bacteremia cases. Viable cells pose risks if consumed directly, but non-viable applications (e.g., filtrates) are deemed safe without full case-by-case assessment (EFSA, 2026, 24(1):e9823; EFSA, 2025, 23(7):e9510; EFSA, 2024, 22(7):e8882).

Added in recent 2025-2026 EFSA updates alongside *Vibrio natriegens*; contrasts with unrestricted QPS microbes. Applies to production strains verified absent of virulence factors or toxins (EFSA, 2023, 21(1):7747).

Recent EFSA updates to the QPS list for production microorganisms focus on taxonomic revisions, new inclusions with qualifications for production microorganisms, and safety

verification up to late 2025 (EFSA, 2024, 23(1):e9169; EFSA, 2026,24(1):e9823). These include:

- *Rhizobium radiobacter* is recommended for QPS with "for production purposes only" qualification (EFSA, 2024, 22(7):e8882).
- *Bacillus circulans* is added with "for production purposes only"(EFSA, 2023, 21(1):7747).
- *Hæmatococcus lacustris* (syn. *Hæmatococcus pluvialis*) is recommended for QPS with "for production purposes only"(EFSA, 2023, 21(1):7747).

Qualification changes

- *Bacillus velezensis*: "Absence of aminoglycoside production ability" withdrawn (EFSA, 2023, 21(1):7747).
- *Bacillus paralicheniformis* was updated to "absence of toxigenic activity" and "absence of bacitracin production ability" (EFSA, 2023, 21(1):7747).

No major changes to existing QPS TUs in the April-September 2024 period; list updated for taxonomy accuracy. Ongoing notifications (e.g., 54 in 2024) assessed for feed additives and enzymes, with production-only limits ensuring no viable cells in finals (EFSA, 2024, 23(1):e9169; EFSA, 2026, 24(1):e9823).

CONCLUSIONS

The transition away from antibiotic growth promoters has successfully shifted livestock production toward a more sustainable ecological framework.

By integrating advanced biosecurity and gut flora stabilizers, the industry has balanced animal health with public safety, stabilizing antimicrobial resistance without sacrificing long-term productivity.

Future resilience depends on the continued evolution of safety assessment frameworks, particularly as novel microbial technologies and alternative proteins enter the food chain. Harmonized global surveillance and the exploration of indirect zoonotic pathways will be essential to maintaining a secure, farm-to-fork production system in a changing climate.

The post-AGP era highlights the value of evolving microbial strategies in balancing productivity with food safety and environmental resilience.

Integrated surveillance systems, such as HACCP frameworks, alongside global harmonization efforts, offer pathways to address persistent challenges like indirect zoonotic risks and climate impacts on feed systems.

Prioritizing research into novel feed sources and regulatory alignment for emerging technologies will further advance One Health principles, ensuring sustainable veterinary practices from farm to fork.

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