EFSA Draft Guidance for Public Consultation: on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin

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Introduction and Background

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This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

Introduction

1. EFSA discussed the possible update of the document 'Guidance on the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption' at the 39th Plenary meeting of the EFSA Panel on Food Contact Materials, Enzymes and Processing aids (CEP Panel). The purpose of the update was to provide more/further detail on the data and information that should be provided by an applicant to EFSA.

2. During the public consultation process the COT has an opportunity to provide comment on the draft guidance. Particular attention is drawn to section 4 of the guidance document, which describes the requirements for toxicological testing (see paragraph 26 onwards of this document).

3. Members are invited to comment on the guidance, and also to advise on whether they agree with EFSA's approach for the requirements for the toxicological assessment. **The deadline for comments is 5th February 2025**

so it will not be possible to take any additional comments following the meeting. Members are also invited to provide comments on the draft guidance document, to be submitted to EFSA.

4. The consultation has been shared with FCM JEG Members who did not have any comments.

Background

5. This document provides a summary of the EFSA guidance on submitting data to evaluate the safety and efficacy of substances used to remove microbial surface contamination from foods of animal origin intended for human consumption. This includes information on the technical aspects of the substance, consumer exposure assessment, toxicological and ecotoxicological impact, efficacy in removing microbial contamination, and the potential for acquired reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials induced by the substance.

6. The guidance is applicable to chemical substances, biological agents, or a combination of both, used to decontaminate foods of animal origin, and applies to a wider range of foods such as beef carcasses, pork meat, and processed foods such as cheese. It details the data and information required for the evaluation of the safety and efficacy of these substances for consumers and the environment.

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Existing authorisations and evaluations (Section 2, page 8)

7. The 2025 draft has been updated to include requirements for information on any existing evaluations and authorisations of the proposed decontaminating substance, including details of the evaluating body and the date of evaluation. This includes any relevant data/studies generated/conducted in the context of other regulatory frameworks.

Identity and specifications (Section 3.1, page 8)

Chemical substances (Section 3.1.1, page 8)

8. This section has been updated to incorporate chemical substances originating from biological sources (e.g. proteins), including requirements to identify the source (e.g. genus, species, variety, strain, part of a plant source, such as roots or leaves, and organ or tissue of an animal source), and include any known toxicants that may be present in the source material. Additionally, solutions comprised of mixtures with unidentified constituents must be characterised according to constituent activity.

Biological Agents (Section 3.1.2, page 9)

9. The proposed guidance has now been expanded to include biological agents as potential decontaminating agents. This includes their characteristics, safety profile, and efficacy under relevant conditions. for further details on these requirements.

10. Specific information required for the characterisation and assessment of bacteriophages used in decontamination solutions include:

Microorganism Characterisation

- Origin and History: Applicants must provide the origin and any genetic modifications of the production strain and/or the bacteriophage.
- Taxonomic Identification: Accurate taxonomic identification of both the production strain and the bacteriophage is crucial.
- Antimicrobial Resistance: Information is required on the presence of genes in the production strain and/or bacteriophage that confer resistance to clinically relevant antimicrobials or encode the production of such antimicrobials.

Toxigenicity and Pathogenicity

11. The following information is required to be submitted:

- Assessment of the production strain and bacteriophages for toxigenicity, pathogenicity, and infectivity.
- Investigation for the presence of toxin-encoding genes, virulence factors, lysogeny genes, and genetic elements involved in transduction.
- Determination of the host range of bacteriophages on relevant bacterial species.

12. Additionally, the following product and safety considerations are required:

- Information is required on the presence of viable cells, genetic material, toxins, toxic metabolites, and clinically relevant antimicrobials that may remain in the final product.

Bacteriophage-Specific Information

- Genome length and particle size of the bacteriophage.
- Form of the bacteriophage in the product (e.g., free, encapsulated) and details of encapsulation (if applicable).
- Concentrations of bacteriophage formulations (phage titers), volumes applied, and absolute numbers of phages delivered.
- Purity specifications of the bacteriophage solution, including impurities and analytical methods.
- Storage and shelf-life conditions for maintaining bacteriophage activity.
- Bacteriophage activity under different conditions (temperature, pH, water activity, NaCl concentration) assessed through plaque assays and/or planktonic killing assays.
- Decontamination approach (passive/active).

Manufacturing process, including any specific processing procedures (Section 3.2, page 9)

13. This section outlines the key aspects of how the decontamination solution will be used. A detailed description of the manufacturing process is required in order to define the critical points that may have an influence on the purity and impurities of the decontaminating substance.

14. The draft document clearly distinguishes between the active agents (chemical or biological) and the final solution applied to the food surface, which may include other components. The draft also clarifies that "reduction" encompasses both the physical removal and inactivation of microorganisms, whereas the 2010 version primarily used the term "removal".

Conditions of use of the decontamination solution (section 3.3, page 10)

15. With regard to the decontamination process, the following details are required to be included:

- Point(s) in the processing lines in which the decontamination solution is intended to be applied, including any instances of repeated treatments.
- Details of application methods of the decontamination solution (e.g. dipping, spraying).
- Application conditions, including the volume of solution used, concentration of the active substance(s), temperature and pH of the solution and the target, duration of treatment and applied pressures.
- Approximate volume of the solution per mass and surface area of treated food should be specified.
- Subsequent removal of the decontamination solution from the food and the conditions used should be described, if applicable (for example by washing or trimming of the treated area).
- Recycling of the decontamination solution or substance(s) thereof, the conditions used, should be described, if applicable.
- Amount of decontamination solution running off per time should be specified (e.g. in litres per day).
- Bacteriophage consideration: both the duration of the application and the time needed for the agents to contact their host bacteria and kill them should be described.

Methods of analysis (section 3.4, page 10)

16. This section focuses on the analytical methods used. All methods used for microbial analysis should be provided, including protocols, validity and performance parameters. In terms of substance measurement, methods for the measurement of all substances in the decontamination solution applied and their reaction products that may remain in the treated food and in the wastewater should be provided.

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Assessment of safety to humans (Section 4, page 11)

17. This provides a more detailed overview of the safety assessment requirements. This is a general summary, and specific requirements and procedures may vary depending on the nature of the decontaminating substance and the specific circumstances of the application.

18. For chemical substances, consumer exposure and toxicological assessments are required as part of the safety assessment.

Consumer Exposure Assessment (Section 4.1.1, page 11)

19. The updated guidance provides further information on exposure assessment methodologies and details the use of exposure assessment tools available.

Determining Residue Levels

20. Conservative Approach: applicants are required to estimate the amount of the substance and its reaction products remaining on the food based on the amount of decontamination solution applied per unit of food mass or surface area.

21. More Refined Estimation: Determine the amount of solution retained on the food surface more precisely through gravimetric analysis using small food specimens with a high surface-to-mass ratio.

22. Consider Reaction Products: applicants should account for any potential reaction products formed in the food during or after treatment.

Utilising EFSA Tools

23. Applicants should use the EFSA Comprehensive Food Consumption Database: This database provides detailed information on food consumption patterns across different population groups in EU Member States.

24. The applicant is required to use the Pesticide Residue Intake Model, revision 4 (PRIMo 4) exposure assessment tool. This online tool, designed for pesticide residue assessments, can be used to estimate consumer exposure by combining individual consumption data with residue data for the decontaminating substance. It considers individual dietary habits, body weight, and food consumption patterns.

25. An uncertainty analysis on data availability and exposure assessment should also be provided in line with the recommendations of the EFSA Guidance on Uncertainty Analysis in Scientific Assessments (EFSA SC, 2018).

Toxicological Assessment (Section 4.1.2, page 12)

26. The toxicological assessment of decontaminating substances requires a comprehensive approach, beginning with a detailed description and justification of the chosen testing strategy. This involves explaining the rationale behind including or excluding specific types of *in vitro* or *in vivo* toxicity studies, while applying a tiered approach and the principles outlined in the EFSA FAs guidance (EFSA FAF Panel, 2024). The basis for the assessment thereby lies in the toxicological data for each component of the decontamination solution, including not only the main substance but also any impurities and reaction products that might remain in the treated food. These data are required for both hazard identification and hazard characterisation and should include dose-response relationships derived from full study reports. However, a complete hazard characterisation may not be necessary for reaction products and impurities if a Threshold of Toxicological Concern (TTC) approach is applicable.

27. While assessments conducted under other regulatory frameworks (e.g., ECHA, EMA, FSA, or FDA) can be valuable, EFSA requires the submission of the original data and guaranteed data ownership. If only summaries are available, they can serve as supportive information but not as the basis for the risk assessment.

28. For substances already authorised for direct addition to food within the EU, such as Food Additives, the assessment can often use existing toxicological data. In these cases, the applicant must confirm compliance with relevant EU specifications and provide information on existing authorisations and evaluations. This information should include the evaluating body, the date of evaluation, a summary identifying critical studies and their no observed adverse effect levels (NOAELs), lowest observed adverse effect level (LOAELs) or benchmark dose lower confidence limit (BMDL) values, and any health-based guidance values (HBGV) along with the uncertainty factors (UF) applied and any other uncertainties noted in the evaluation. For already authorised substances, any changes in the manufacturing process, specifications, or conditions of use will require safety concerns to be addressed, either through new data or a scientific

justification explaining why new data are not required.

29. When dealing with substances not authorised for use in food within the EU, a more extensive toxicological assessment is required. This includes data to evaluate genotoxicity, toxicokinetics, and other forms of toxicity beyond genotoxicity. This includes subchronic, chronic, reproductive and developmental toxicity, and carcinogenicity. These endpoints are typically assessed through *in vitro* and *in vivo* experimental studies. Full reports of these studies, along with epidemiological studies, their compliance with international or national guidelines or Good Laboratory Practice (GLP), and any deviations from these, should be submitted. In line with the 3R principles (replacement, reduction, and refinement), the tiered approach should be applied for toxicokinetic and toxicity testing, using animal testing only until sufficient information is available for hazard characterisation.

30. Genotoxicity testing, referred to as Tier 0, should follow the specified testing strategy and be conducted for each individual component of the decontamination solution. Substances that raise concerns about genotoxicity are not assessed further. For those that do not, a minimal dataset is required under Tier I. If the Tier I data are sufficient for toxicity assessment and no triggers for higher tiers exist, no further studies are needed. However, substances that are absorbed or demonstrate toxicity in Tier I tests will require Tier II testing.

31. Tier III testing is reserved for a case-by-case basis to investigate specific endpoints needing further clarification from Tier I and II results. Additional studies, including human data if available, can be incorporated into the evaluation. It is important to note that the testing strategy for toxicokinetics and toxicity offers more flexibility compared to genotoxicity testing due to the wider range of potential datasets. This entire approach aims to identify a Reference Point (e.g., NOAEL or BMDL) and derive an HBGV using appropriate uncertainty factors. For risk characterisation, human exposure to the decontaminating substance is compared to the HBGV. If an HBGV cannot be derived, a margin of exposure (MoE) approach could be considered.

32. For reaction products and impurities with an available Reference Point or HBGV, potential exposure is calculated based on a limit value and then prorated to the exposure estimates for the decontaminating substance. This estimated exposure is then compared to the available reference point or HBGV of the undesirable impurity. When sufficient toxicological data are lacking, non-testing methods such as read-across, computational methods (structural activity relationship, SAR; quantitative structural activity relationship, QSAR), and the TTC

approach can be used for a preliminary assessment. If the TTC approach is used and the worst-case consumer exposure estimate is below the TTC of the relevant Cramer class, and genotoxicity can be ruled out, no further data are needed. For genotoxic compounds without carcinogenicity data, or if genotoxicity cannot be ruled out, consumer exposure should not exceed the TTC for genotoxic and carcinogenic compounds. For reaction products and impurities that are both genotoxic and carcinogenic, the MoE approach may be applied.

33. For biological agents proposed as decontaminating substances the EFSA guidance on the risk assessment of microorganisms (EFSA Scientific Committee, 2024) should be consulted. If multiple formulations are proposed, all should be tested. For bacteriophage-based solutions, requirements include characterising the bacteriophage and/or production strain, demonstrating the absence of viable cells and, if applicable, DNA from the production strain in the final product, and evaluating the impact on the gut and food/feed microbiome. Finally, the applicant must describe the reactions and fate of the decontaminating agents on treated foods, including quantifying residual levels of the active agent.

34. Allergenicity assessment is also required for bacteriophages or their components. If a component of the decontamination solution is a potential allergen, specific data requirements should be followed.

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Efficacy of pathogen reduction (Section 5, page 16)

35. Decontamination efficacy is established by demonstrating a statistically significant and consistent reduction in the prevalence and/or numbers of target pathogenic microorganisms compared to a control, while considering the inherent variation between experiments or batches of naturally contaminated foods. The control sample is either treated with water (if the decontamination method could have a rinsing effect, such as with meat carcasses) or left untreated (if the treatment doesn't replace a water treatment, such as with ready-to-eat food). It is crucial to consider the enumeration error, particularly when log reductions are below 1 log, as this can affect the interpretation of the results.

36. The dossier supporting the efficacy should include both existing experimental work from the literature and new experiments specifically conducted for the dossier ("in-house studies"). A comprehensive description of how existing studies were identified (search strategy, databases used, search limits, etc.) is essential for transparency and assessment of the evidence. Studies must be relevant to the intended treatment, focusing on the target pathogens and applying the decontaminating substance under the specified conditions. This includes details on the application stage (e.g., along the processing line), the specific application method (spraying, dipping, etc.), the concentration and temperature of the solution, and the pressure and duration of the treatment, all within the intended range of parameters. A proper control, treated with water or left untreated (with justification), is mandatory. The testing should assess at least one target pathogen, or relevant indicator microorganisms (such as Enterobacteriaceae, coliforms, or *E. coli*), immediately after treatment and optionally during storage and at the end of shelf-life. The study design and setting (laboratory, pilot-scale, or industrial) should be clearly defined.

37. The dossier should present a well-structured and coherent argument for the use of the decontamination solution. This argument must be supported by studies demonstrating the efficacy of pathogen reduction and an evaluation of the potential development of acquired reduced susceptibility to the formulated product. All studies should be performed using the specific solution for which authorisation is sought, covering all intended formulations and concentrations. Processing conditions used in efficacy evaluations must mirror the intended use conditions, ensuring even distribution of the substance. Pilot or in-plant studies are preferred over laboratory-scale studies as they better reflect real-world conditions. Experimental data is required to justify the proposed concentration of the product formulation, showing the effect of different concentrations on the target pathogens. While the primary focus is on target pathogens, data on indicator microorganisms can be valuable for assessing overall efficacy.

38. Each study must include a comparison of pathogen prevalence and/or numbers between the food treated with the decontamination solution and the control group (water-treated or untreated). The control should ideally differ only in the presence or absence of the decontaminant. Comparisons between water-treated and untreated samples can provide supporting evidence of the rinsing effect. Artificial inoculation studies must use diverse strains or strain cocktails of the target pathogens, including reference strains and strains isolated from the target food. The inoculum should be evenly distributed, and sufficient time should be allowed for bacterial attachment before treatment. The inoculum level should

be high enough to allow for quantification of log reductions. Sampling should occur at key time points: before treatment, immediately after treatment, and optionally during storage and at the end of shelf-life. Validated reference methods or other acceptable methods should be used for pathogen detection and enumeration, with recovery techniques for stressed cells. A validated neutralisation method (ISO 18593:2018) or removal of the formulated product is essential. For phage-based treatments, specific neutralisation methods such as centrifugation may be used. In pilot-scale or industrial settings, potential redistribution of organisms due to liquid treatments needs evaluation.

39. The study design must be justified in relation to the intended use of the product and should incorporate sound statistical methodology to test the efficacy hypothesis. The sample size must be justified, considering the expected effect size, significance level, study power, and measurement variance. Statistical tests (e.g., ANOVA, t-test) are required for in-house studies, using independent experimental trials with independent samples to increase statistical power. Factors that may influence efficacy (e.g., organic load, pH, temperature) must be identified, along with methods for controlling and monitoring these parameters during operation. The potential for acquired reduced susceptibility must be evaluated.

40. For each experiment, detailed information must be provided, including the experimental setting, contamination type, substance, application method, product type, treatment characteristics (concentration, temperature, duration, pH, pressure), contamination characteristics (bacterial group, strain origin, inoculum preparation), analytical methods (detection/enumeration method, sampling method, limits of detection and quantification), treatment and storage conditions, and outcome reporting (number of samples, microbial concentration, number of positive samples, log10 reduction calculations, and statistical analysis). Mean log10 reductions and their 95% confidence intervals should be reported, and the statistical methods used, including handling of negative samples, should be clearly stated.

41. This section outlines the requirements for evaluating the potential for decontamination substances (chemical or biological) to induce reduced susceptibility in target and non-target microorganisms, and the implications for resistance to other biocides and therapeutic antimicrobials. For bacteriophages, the focus is solely on resistance development in target species. If reduced susceptibility to the decontaminant is observed, further investigation is needed to determine if it promotes cross-resistance (where one mechanism confers resistance to multiple antimicrobials) or co-resistance (where resistance genes

are linked). Priority for cross-resistance evaluation should be given to biocides used in the same industrial settings. The goal is to understand the relationship between reduced susceptibility to the decontaminant and resistance to other antimicrobials, including the potential for multiple resistance development. Due to the complexity of this issue, there are no universal guidelines, requiring case-by-case analysis using diverse sources of information. These requirements apply even to substances with a history of safe use.

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Chemical Substances (section 6.1, page 23)

42. A literature review is required to assess the potential for the chemical substance and formulated product to induce reduced susceptibility to itself, other biocides, and/or resistance to therapeutic antimicrobials in target and non-target species (gram-positive and gram-negative, including *E. coli* and *enterococci*) at working and sub-inhibitory concentrations. If concerns are identified, further testing is required. If no or acceptable concerns are identified, no further testing is needed at this stage, but a post-market evaluation plan is required.

43. Laboratory tests are needed to evaluate the potential for the chemical substance and formulated product to select for reduced susceptibility. Initial screening should mimic real-world conditions, including sublethal dilutions, short exposure times, and relevant environmental factors. Testing should use control strains, publicly available target pathogens (e.g., *Campylobacter*, *Salmonella*, *Listeria*, *Staphylococcus*), indicator bacteria (e.g. *E. coli*, *enterococci*), and non-target microorganisms. Minimal inhibitory concentration (MIC) and minimal bactericidal concentration (MBC) determinations should be performed, along with data supporting permanent changes in bacterial susceptibility. *In vitro* evolution studies are also required. This initial screening should ideally be validated in the processing plant or a similar setting. Recovered strains should be tested for MIC and MBC against the chemical substance and formulated product.

44. If reduced susceptibility is observed, further testing is required to assess cross-resistance and co-resistance to other biocides and therapeutic antimicrobials. For human pathogens, this should specifically address co-resistance and cross-resistance to biocides and representative antimicrobial classes used in human infection treatment. If concerns are identified, genetic analysis is required. If no or acceptable concerns are identified, no further testing

is needed at this stage, but a post-market evaluation plan is required.

45. Genetic analysis is crucial for understanding the molecular mechanisms of decreased susceptibility, including point mutations, resistance gene acquisition, and changes in gene expression. If no molecular mechanisms of concern are found, a post-market evaluation and long-term monitoring plan are required.

46. A post-market resistance surveillance plan is required, including aspects of the in-plant screening. Data from other markets should also be submitted. If the decontaminant is released into the environment, a post-market monitoring plan is required to assess long-term effects on resistance development in the environment, including sampling of wastewater and relevant indicator microorganisms.

Biological Agents (section 6.2, page 23)

47. For biological agents, the EFSA guidance on the characterisation and risk assessment of microorganisms used in the food chain (EFSA Scientific Committee, 2024) should be followed, particularly regarding antimicrobial resistance genes and antimicrobial production. For bacteriophages, the search should cover both the phage genome and the host bacterial strain. The potential for bacterial resistance to phages and co-selection of resistance to therapeutic antimicrobials must be addressed.

48. A literature review is required on phage-bacteria coevolution, fitness costs of resistance, risk of resistance emergence, and the molecular basis of resistance, including *in vitro* and *in situ* studies under working conditions. If unacceptable concerns are identified, the evaluation is discontinued. If knowledge is insufficient, further testing is needed. If no or acceptable concerns are identified, no further testing is needed at this stage, but a post-market evaluation plan is required.

49. Laboratory tests are required to evaluate the potential for resistance emergence in target strains to the biological agent under various conditions. Initial screening should simulate realistic processing environments, examining the interaction of the bacteriophage and its formulated products under diverse conditions. Screening for phage-resistant bacteria should be performed. The stability and persistence of resistant strains should be demonstrated. Phenotypic characterisation of resistant isolates is needed. The initial screening should be validated in the processing plant or a similar setting.

50. Phenotypic characterisation of resistant isolates should include assessing cross-resistance and co-resistance to therapeutic antimicrobials and chemical biocides. If concerns are identified, genetic analysis is required. If unacceptable concerns are identified, the evaluation is discontinued. If no or acceptable concerns are identified, no further testing is needed at this stage, but a post-market evaluation plan is required.

51. Mechanisms of bacterial resistance to phages, therapeutic antimicrobials, and reduced susceptibility to biocides should be examined using whole genome sequencing or other appropriate methods. The potential for horizontal gene transfer should be assessed. If no molecular mechanisms of concern are found, a post-market evaluation and long-term monitoring plan are required.

52. A post-market resistance surveillance plan is required, including regular sampling and testing of target bacterial strains for susceptibility to the phages. Data from other markets should be submitted.

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Environmental risk assessment (Section 7, page 26)

53. If the decontaminant is released into the environment, a monitoring plan is required to assess long-term effects on resistance development in the environment, including sampling of wastewater and relevant indicator microorganisms.

Chemical Substances (Section 7.1, page 26)

54. Minimum data requirements include physical-chemical properties (water solubility, log Kow, vapor pressure, ionisation potential) and adsorption/desorption screening (unless adsorption potential is low or rapid decomposition occurs). A ready biodegradability study is also needed unless high reactivity or rapid hydrolysis is demonstrated. Data must cover the substance and all relevant reaction products.

55. Hazard assessment requires toxicity tests on algae (green algae and cyanobacteria), invertebrates, and fish (acute toxicity tests initially, potentially

chronic for specific modes of action). An activated sludge respiration inhibition test is required unless the substance is readily biodegradable, and test concentrations are within expected sewage treatment plant influent levels. Toxicity tests are not needed if complete transformation occurs during application/treatment or for endogenous substances whose environmental concentration/distribution is not significantly altered.

56. All available toxicological data should be considered. Non-testing approaches such as (Q)SAR and read-across can be used if models are scientifically valid and well-documented. Data from other sources can be used if original data and ownership are provided.

57. Environmental exposure assessment can follow the emission scenario document for biocidal disinfectants in food/feed areas. Wastewater from slaughterhouses is assumed to be pre-treated before release. Substance release to wastewater is assumed to be 100% by default but can be reduced with data. Disintegration and elimination during pre-treatment are 0% by default but can be increased with data. Predicted effect concentration (PEC) calculation uses the release to wastewater as input for model calculations. If the substance or its products bind to sludge/sediment, the assessment should extend to soil and sediment.

58. Predicted no effect concentration (PNEC) derivation for aquatic organisms and sewage treatment plant (STP) microorganisms is described in the guidance on the Biocidal Products Regulation (ECHA, 2017a), the REACH guidance (ECHA, 2008a) and the EFSA guidance for feed additives (EFSA FEEDAP Panel, 2019). The equilibrium partitioning method can be used for soil and sediment PNEC derivation.

59. Risk assessment uses a tiered approach. If the PEC/PNEC ratio is < 1, no further assessment is needed unless log Kow ≥ 3, in which case secondary poisoning risk is assessed. Secondary poisoning assessment involves bioaccumulation potential assessment, toxicity assessment, and risk characterisation. If the PEC/PNEC ratio is ≥ 1, a more refined PEC and/or PNEC can be calculated.

60. Substances with Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) potential require special attention due to uncertainty. A separate hazard-based assessment is needed, following REACH Annex XIII criteria and methodology. Screening is performed first, comparing information with screening thresholds. Potential PBT/vPvB substances

undergo further assessment using REACH Annex XIII criteria. Persistent/very Persistent (P/vP) assessment is conducted first, based on degradation half-life data. If the P/vP criterion is met, Bioaccumulative/very Bioaccumulative (B/vB) assessment follows, including new information. If the substance is not vPvB but meets Persistent (P) and Bioaccumulative (B) criteria, the Toxic (T) criterion is evaluated using standard aquatic toxicity studies and data for human health hazard classification.

61. It should also be considered whether substances meet criteria for persistent, mobile and toxic (PMT), very Persistent and very Mobile (vPvM0, and endocrine disrupting (ED) classifications under the CLP Regulation.

Biological Agents (section 7.2, page 30)

62. The EFSA guidance on microbial risk assessment should be followed for environment risk assessment (ERA) of non-genetically modified and genetically modified bacteriophages (EFSA Scientific Committee, 2024) . The environment considered is the receiving environment.

63. An ERA is needed for non-genetically modified bacteriophages that are not common members of the receiving environment's microbiome. Non-genetically modified bacteriophages carrying acquired antimicrobial resistance (AMR) genes, toxin genes, and/or virulence factors are considered a risk. Genetically modified bacteriophages require case-by-case ERA, evaluating potential adverse effects of the new traits on the receiving environment.

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Questions for the Committee

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3. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination -Section 4
4. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination -Section 5
5. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination -Section 6
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9. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Abbreviations
10. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Annex A

64. Members are asked to consider the consultation document and provide any comments.

a) Do Members have any comments on the toxicological assessment section?

b) Any other comments?

Secretariat

January 2025

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In this guide

10. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Annex A

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Abbreviations

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9. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Abbreviations
10. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Annex A

AFC	Food additives, flavourings, processing aids and materials in contact with food
AMR	Antimicrobial Resistance
B/vB	Bioaccumulative/very Bioaccumulative
BIOHAZ	Biological Hazards
BMDL	Benchmark Dose Lower Confidence Limit
CAS	Chemical Abstracts Service
CEP	Food Contact Materials, Enzymes and Processing Aids
CI	Confidence interval
CLSI	Clinical And Laboratory Standards Institute
FDA	Food and Drug Administration
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority

EMA	European Medicines Agency
ERA	Environment Risk Assessment
EUCAST	European Committee On Antimicrobial Susceptibility Testing
FAs	Food Additives
FCM	Food Contact Materials
FDA	Food and Drug Administration
FEEDAP	Additives and Products or Substances used in Animal Feed
FSA	Food Standard Agency
FSMS	Food Safety Management System
GLP	Good Laboratory Practice
HACCP	Hazard Analysis And Critical Control Points
HBGV	Health-Based Guidance Values
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOAEL	Lowest Observed Adverse Effect Level
MBC	Minimal Bactericidal Concentration

MIC	Minimal Inhibitory Concentration
MOE	Margin of Exposure
MOI	Multiplicity of Infection
NaCl	Sodium Chloride
NOAEL	No-Observed-Adverse-Effect-Level
OECD	Organisation for Economic Co-operation and Development
P/vP	Persistent/very Persistent
PCR	Polymerase Chain Reaction
PBT	Persistent, Bioaccumulative And Toxic
PCR	Polymerase Chain Reaction
PFU	plaque-forming unit(s)
PE	Population Equivalents
PEC	Predicted Effect Concentration
PMT	Persistent, Mobile And Toxic
PNEC	Predicted No Effect Concentration
QAF	(Q)SAR assessment framework

RPCDs	Raw Primary Commodity Derivatives
RTE	Ready-to-Eat
QPS	Qualified Presumption Of Safety
qPCR	Quantitative Polymerase Chain Reaction
QSAR	Quantitative Structural Activity Relationship
REACH	Registration, Evaluation, Authorisation And Restriction Of Chemicals
RP	Reference Point
RTE	Ready to eat
SC	Scientific Committee
SOP	Standard Operation Procedure
STP	Sewage Treatment Plant
TDI	Tolerable daily intake
TTC	Threshold of Toxicological Concern
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products
vPvB	Very Persistent And Very Bioaccumulative
WGS	Whole Genome Sequencing

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Annex A

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10. EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Annex A

Outline of EFSA consultation document

Secretariat

January 2025

EFSA Draft Opinion for Public Consultation:

Abstract

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Section 2

Section 3

Section 4

Section 5

Section 6

Section 7

Section 8

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Glossary

Abbreviations