EFSA Draft Guidance for Public Consultation: on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface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

Section 2 and 3

In this guide

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 EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination -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

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.