

EFSA Draft Guidance for Public Consultation: on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface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

# Annex A

## In this guide

### [In this guide](#)

1. [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Introduction and Background](#)
2. [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination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 2 and 3](#)
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 [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination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 [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination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 [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination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](#)
6. [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination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 7](#)
7. [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - Questions for the Committee](#)
8. [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination - References](#)
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 [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination -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 [EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination -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](#)

## **Outline of EFSA consultation document**

**Secretariat**

**January 2025**

### **EFSA Draft Opinion for Public Consultation:**

#### **Abstract**

#### **Section 1**

Introduction (Section 1, page 5),

Background (Section 1.1, page 6),

Terms of Reference (Section 1.2, page 6),

Public consultation (Section 1.3, page 7),

Interpretation of the Terms of References (Section 1.4, page 7).

#### **Section 2**

Information on existing authorisations and evaluations (Section 2, page 8).

#### **Section 3**

Technical data (Section 3, page 8),

Identity and specifications (Section 3.1, page 8),

Chemical substance(s) (Section 3.1.1, page 8),

Biological agent(s) (Section 3.1.2, page 9),

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

Decontaminating substances (Section 3.2.1, page 9),

Decontamination solution (Section 3.2.2, 10),

Conditions of use of the decontamination solution (Section 3.3, 10),

Methods of analysis (Section 3.4, page 10).

## **Section 4**

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

Chemical substances (Section 4.1, page 11),

Consumer exposure assessment (Section 4.1.1, page 11),

Toxicological assessment (Section 4.1.2, page 12),

Biological agent(s) (Section 4.2, page 15).

## **Section 5**

Efficacy of pathogen reduction (Section 5, page 16).

## **Section 6**

Potential emergence of acquired reduced susceptibility to the decontamination substance and/or other biocides and/or resistance to therapeutic antimicrobials (Section 6, page 20),

Chemical substance(s) (Section 6.1, page 21),

Literature review for assessing the potential for emergence of reduced susceptibility to the chemical substance and/or other biocides and/or resistance to therapeutic antimicrobials (Section 6.1.1, page 21),

Laboratory tests for assessing the emergence of reduced susceptibility to the chemical substance (Section 6.1.2, page 22),

Analysis of “cross-resistance” and “co-resistance” between the chemical substance and other biocides and/or therapeutic antimicrobials (Section 6.1.3, page 22),

Genetic analysis (Section 6.1.4, page 23),

Post-market evaluation and long-term monitoring (Section 6.1.5, page 23),

Biological agent(s) (Section 6.2, page 23),

Literature review for assessing the potential for emergence of resistance to the biological agent and therapeutic antimicrobials or reduced susceptibility to chemical biocides (Section 6.2.1, page 23),

Laboratory tests for assessing the potential emergence of resistance to the biological agent (Section 6.2.2, page 24),

Analysis of “cross-resistance” and “co-resistance” between the biological agent and other biocides and/or therapeutic antimicrobials (Section 6.2.3, page 24),

Genetic analysis (Section 6.2.4, page 24),

Post-market evaluation and long-term monitoring (Section 6.2.5, page 25),

Standards and methodologies (Section 6.3, page 25).

## **Section 7**

Environmental risk assessment (Section 7, page 26),

Chemical substance(s) (Section 7.1, page 26),

Data requirements (Section 7.1.1, page 27),

Environmental exposure assessment (Section 7.1.2, page 28),

Environmental hazard assessment (Section 7.1.3, page 28),

Environmental risk assessment (Section 7.1.4, page 28),

Assessment of persistent, bioaccumulative and toxic and/or very persistent and very bioaccumulative substances (Section 7.1.5, page 29),

Biological agent(s) (Section 7.2, page 30).

## **Section 8**

References (Section 8, page 31).

## **Appendices (page 35)**

Appendix A-1. Tiered approach for toxicokinetic and toxicity testing (from EFSA Food).

Additives guidance (EFSA FAF Panel, 2024) (page 35).

Appendix A-2. Genotoxicity testing strategy recommended by the EFSA Scientific Committee (EFSA Scientific Committee, 2011) (page 36).

Appendix A-3. Overview of the surveys, countries, population classes and methods of dietary data collection considered in the chronic exposure assessments in the PRIMo 4 tool (page 37).

## **Glossary**

(p. 43).

## **Abbreviations**

(p.47).