EFSA Draft Guidance for Public Consultation: on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface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 7

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 EFSA Draft Guidance for Public Consultation: submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination -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

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.