Mock EFSA Technical Dossier Summary

Portfolio Sample – Scientific & Regulatory Writing

Illustrative document prepared for portfolio purposes only.

Applicant: Not applicable (portfolio sample)
Ingredient name: Botanical Extract X (fictional)
Regulatory context: EFSA-aligned mock submission
Status: Sample document prepared for illustrative purposes only

1. Introduction

This technical dossier summary has been prepared as a **mock regulatory document** for portfolio purposes. It is intended to demonstrate scientific writing quality, regulatory awareness, and **familiarity with European Food Safety Authority (EFSA) guidance principles**.

This document does not represent a real regulatory application and contains no proprietary, confidential, or applicant-specific data.

2. Identity of the Substance

The substance under assessment is a **fictional botanical extract**, hereafter referred to as *Botanical Extract X*, derived from the aerial parts of *Plantus fictivus* (species name used for illustrative purposes only).

The extract is standardised based on its polyphenolic fraction, which constitutes the primary group of constituents of interest. The substance is intended for use as a nutritional component in animal feed.

3. Manufacturing Process

Botanical Extract X is produced using a controlled extraction process employing food-grade solvents. The manufacturing process includes raw material selection, extraction, purification, concentration, drying, and standardisation steps.

The process is designed to ensure:

- Consistent composition
- Absence of relevant contaminants
- Batch-to-batch reproducibility

Quality control measures are applied at critical stages of production.

4. Compositional Data and Specifications

The substance is characterised by defined specifications for active constituents and relevant impurities. Analytical methods are applied to verify compliance with these specifications.

Table 1. Proposed Specifications for Botanical Extract X

Parameter	Specification
Polyphenolic content	20–30% (w/w)
Moisture	≤ 5%
Heavy metals (Pb, Cd, Hg, As)	Below EU maximum limits
Pesticide residues	Below limits of detection
Microbiological contaminants	Compliant with feed safety standards

Batch analyses indicate consistency within the proposed specification ranges.

5. Intended Use and Conditions of Use

The substance is intended for inclusion in animal feed at a maximum proposed inclusion level of **X mg/kg complete feed** (value used for illustrative purposes).

The substance is not intended to exert pharmacological effects and is not classified as a veterinary medicinal product. No specific health claims are proposed.

6. Safety Assessment

6.1 Safety for the Target Species

The safety assessment for the target species is based on a weight-of-evidence approach, including available toxicological data, historical use considerations, and conservative exposure estimates.

Where direct tolerance studies are not available, safety margins have been derived from the highest relevant no-observed-adverse-effect level (NOAEL) identified in the literature.

Table 2. Safety Margin Calculation (Illustrative)

Parameter	Value
NOAEL	100 mg/kg bw/day
Estimated daily intake (target species)	10 mg/kg bw/day
Margin of safety	10

The calculated margin of safety is considered adequate under the proposed conditions of use.

6.2 Consumer Safety

Based on the nature of the substance, its metabolic fate, and the proposed inclusion levels, no safety concerns are identified for consumers of products derived from animals fed with the substance. No accumulation of relevant constituents in edible tissues is anticipated.

6.3 User Safety

Potential risks for users handling the substance have been considered. No specific hazards have been identified beyond those typically associated with powdered feed materials. Standard protective measures are considered sufficient.

6.4 Environmental Safety

Taking into account the botanical origin of the substance and its proposed use levels, no adverse effects on the environment are anticipated. The constituent compounds are expected to undergo natural degradation processes.

7. Efficacy Considerations

As this substance is intended as a nutritional component, no demonstration of efficacy beyond general nutritional contribution is required. No performance or health claims are proposed.

8. Overall Conclusion

Based on the available information and the conservative assessment approach applied, the use of *Botanical Extract X* under the proposed conditions does not raise safety concerns for the target species, consumers, users, or the environment.

This mock dossier summary illustrates the structure and scientific reasoning typically applied in EFSA-aligned submissions.

9. Disclaimer

This document has been prepared solely for **portfolio and illustrative purposes**. It does not represent a real regulatory submission and should not be interpreted as regulatory advice or an official safety assessment.

10. References

EFSA (European Food Safety Authority), 2012. **Guidance for the preparation of dossiers for the evaluation of feed additives.** EFSA Journal, 10(1):2537.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017. **Guidance on the assessment of the safety of feed additives for the target species.** EFSA Journal, 15(10):5021.

EFSA Scientific Committee, 2019. **Guidance on the use of the weight of evidence approach in scientific assessments.** EFSA Journal, 17(3):5639.

European Commission, 2009. **Regulation (EC) No 767/2009 on the placing on the market and use of feed.** Official Journal of the European Union, L 229, 1–28.

OECD (Organisation for Economic Co-operation and Development), 2018. **Guidance document on the reporting of defined approaches and individual information sources for hazard identification.** OECD Series on Testing and Assessment, No. 255.

Smith A., Jones B. and Taylor C., 2015. **Safety assessment of polyphenol-rich botanical extracts used in animal nutrition.** Journal of Animal Feed Science, 24(3), 201–212. *(Fictional reference)*

Brown D. and Green E., 2018. **Toxicological evaluation and margin of safety considerations for botanical feed ingredients.** Regulatory Toxicology and Pharmacology, 96, 123–131. *(Fictional reference)*