Regulatory Dossier — Sample Tables of Contents

How the evidence from your studies is structured for review. Section headings follow the legal structure in each market; contents are summarised.

A. EU / GB feed additive technical dossier

Structure of Annex II, Commission Regulation (EC) No 429/2008 (retained in GB). Submitted to EFSA (EU) or the FSA (GB) under Regulation (EC) No 1831/2003.

Section	Contents	Evidence we generate or compile
Section I	Summary of the dossier, including the public summary	Written summary of all sections
Section II	Identity, characterisation and conditions of use: composition, manufacturing, specifications, stability, analytical methods, proposed use levels	Batch analyses, stability studies, methods of analysis
Section III	Safety: target animals, consumers (where relevant), users/workers and the environment	Target-animal tolerance study, literature review, user-safety data
Section IV	Efficacy: studies showing the additive works at the proposed level	Efficacy studies in the target species (e.g. dogs, cats)
Section V	Post-market monitoring plan	Monitoring plan and reporting procedure

B. US GRAS notice for animal food

Seven-part structure of 21 CFR Part 570, Subpart E (§§ 570.225–570.255), submitted to FDA's Center for Veterinary Medicine.

Section	Contents	Evidence we generate or compile
Part 1	Signed statements and certification	Prepared with the notifier
Part 2	Identity, method of manufacture, specifications and physical or technical effect	Specifications, batch data, method of manufacture
Part 3	Target animal and human exposures	Intake and exposure estimates for dogs and cats
Part 4	Self-limiting levels of use	Palatability or technical limits, where relevant
Part 5	Experience based on common use in food before 1958	Historical-use evidence, where applicable
Part 6	Narrative: the basis for the GRAS conclusion	Safety narrative based on published and study data
Part 7	List of supporting data and information	Reference list and appendices

C. Claim substantiation file (all markets)

Kept on file to support on-pack and marketing claims; structure follows common industry practice.

Section	Contents	Evidence we generate or compile
1	Claim wording, product, species and markets	Final claim text per market
2	Regulatory position of the claim in each market	Claim classification review
3	Evidence summary: published literature	Literature or systematic review
4	Product-specific evidence	Feeding, digestibility or efficacy study report
5	Ingredient identity and dose in the finished product	Formulation and analytical verification
6	Conclusion and review date	Signed scientific sign-off

Illustrative sample only: data are fictitious and client details are redacted. Results relate only to the items tested. Not to be reproduced except in full.

Review times set in law: EFSA gives its opinion within six months of a valid application, extended whenever supplementary information is requested (Reg. (EC) 1831/2003, Art. 8). FDA responds to a GRAS notice within 180 days of filing, extendable by 90 days (21 CFR 570.265). Illustrative document only; not legal advice.

SAMPLE REPORT

Illustrative sample only: data are fictitious and client details are redacted. Results relate only to the items tested. Not to be reproduced except in full.