Nutrition applications

EFSA's revised guidance for food additive applications The European Food Safety Authority (EFSA) has published a revised guidance for food additive applications, applicable from 20 July 2026 across the EU. The update aligns technical and administrative requirements and introduces important changes that will directly impact dossier preparation for new additives and modifications to existing authorisations. A key development is the strengthened emphasis on data consistency: applicants are expected to provide analytical data across studies using the same production batches, unless deviations are scientifically justified. Specifications must follow the structured format in Appendix A, while use levels must be reported using dedicated Excel templates outlined in the administrative guidance. Notably, the revised toxicological testing strategy introduces a more flexible, tiered approach. Changes include repositioning in vitro genotoxicity within Tier I, shifting the 90-day study to Tier III, and incorporating OECD 422 for reproductive toxicity. EFSA also clarifies that applicants may enter higher tiers directly where justified by existing data, reinforcing a weight-of-evidence approach supported by NAMs, (Q)SAR, and in vitro studies. The guidance further underscores cross-referencing with EFSA's food enzyme (2021) and microorganism (2025) guidances, particularly for fermentation-derived additives, requiring careful navigation of overlapping requirements. Why it matters Overall, the update signals greater scientific flexibility alongside stricter data structuring, requiring companies to reassess gap analyses and ensure compliance with evolving EFSA expectation	**Retrospective review of 90-day toxicity studies for regulatory assessment of food enzymes** EFSA is advancing a significant reassessment of its guidance framework for food enzyme (FE) applications, with potential implications for both regulatory strategy and study design across the EU. Recent discussions, supported by a retrospective review of 90-day oral toxicity studies submitted between 2014 and 2026, indicate growing consensus that food enzymes present a low toxicological risk. Consequently, the routine requirement for 90-day rat studies is increasingly being questioned. Aligned with the EU's broader roadmap to phase out animal testing for chemical substances, EFSA's 2025–2026 self-task is exploring opportunities to waive these studies in specific cases and to integrate New Approach Methodologies (NAMs) and weight-of-evidence approaches into risk assessments. However, EFSA acknowledges that the transition away from conventional in vivo data presents scientific and regulatory challenges, particularly in addressing unknown hazards and ensuring robust safety conclusions. For industry stakeholders, this evolving guidance landscape underscores the importance of strengthened quality and manufacturing controls, as well as proactive engagement with alternative data strategies. Clearer guidance on data requirements, methodologies, and interpretation criteria is anticipated and will be critical for ensuring compliance. Why it matters Companies should closely monitor upcoming EFSA public consultations and stakeholder events expected in 2026, which will shape the future Catalogue of EFSA guidance and define expectations for FE dossiers in the EU regulatory framework.