Overview of EFSA Requirements for Novel Food Applications

Portfolio Sample – Regulatory White Paper

Illustrative document prepared for portfolio purposes only.

Document type: Regulatory white paper
Regulatory framework: Regulation (EU) 2015/2283
Status: Mock document prepared for portfolio use only

1. Purpose

This white paper provides an overview of the **key requirements for novel food applications** submitted under Regulation (EU) 2015/2283. It is intended to support regulatory planning and dossier preparation by summarising core data elements and common challenges encountered during submission.

2. Scope of Novel Food Regulation

Novel foods are defined as foods that were not consumed to a significant degree within the European Union before 15 May 1997. Applications must demonstrate safety under the proposed conditions of use and address nutritional considerations where relevant.

3. Key Components of a Novel Food Dossier

A complete novel food application typically includes:

3.1 Identity of the Novel Food

- Chemical or biological identity
- Source material and taxonomic classification (if applicable)
- Physical and chemical characteristics

3.2 Production Process

- Description of manufacturing steps
- Quality control measures
- Identification of critical processing parameters

3.3 Compositional Data

- Main constituents and variability
- Impurities and contaminants
- Batch-to-batch consistency

3.4 Safety Assessment

- Toxicological data
- Exposure assessment
- Margin of safety considerations

3.5 Nutritional Information

- Nutritional profile
- Potential nutritional disadvantages
- Interaction with existing dietary patterns

4. Common Challenges in Dossier Preparation

Frequent challenges include:

- Insufficient characterisation of complex ingredients
- Limited toxicological datasets
- Inadequate justification of exposure estimates
- Inconsistencies between dossier sections

Early regulatory strategy and data gap analysis are critical to mitigating these risks.

5. Conclusion

Understanding EFSA expectations and structuring data accordingly is essential for successful novel food applications. Clear documentation, conservative risk assessment, and internal consistency remain central to regulatory acceptance.

6. Disclaimer

This document is provided for **illustrative portfolio purposes only** and does not constitute regulatory advice.