

EU & EFSA Requirements for Low-Acid Foods

1. EU Regulatory Framework

- Regulation (EC) No 852/2004: General food hygiene requirements.
- Regulation (EC) No 853/2004: Hygiene rules for food of animal origin.
- Regulation (EU) 2017/625: Official control procedures and responsibilities of national authorities.
- Regulation (EC) No 178/2002: General Food Law—traceability, food safety, and risk management.

2. EFSA (European Food Safety Authority)

- EFSA provides scientific risk assessments for food safety, including thermal processing, microbiological risks, and novel technologies.
- EFSA opinions guide process validation standards and acceptable sterilization parameters (e.g., F_0 values).
- EFSA evaluations inform EU policy on thermal and aseptic processing safety.

3. Process & Product Requirements

- HACCP-based food safety systems are mandatory across the EU.
- Process validation must demonstrate commercial sterility and inactivation of pathogens such as *Clostridium botulinum*.
- Time, temperature, pressure, and container integrity must be continuously monitored and recorded.
- Facilities must use hygienic equipment design and maintain effective sanitation and environmental monitoring in aseptic zones.

4. Microbiological Criteria & Testing

- Processors must comply with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.
- Periodic product testing for *Clostridium botulinum* spores and spoilage indicators is expected.

- Environmental monitoring programs should verify control of high-risk areas.

5. Labelling & Traceability

- Regulation (EU) No 1169/2011 sets rules for nutrition, allergens, and other food information to consumers.
- Full traceability is required under Regulation (EC) No 178/2002 (one step back, one step forward).
- Recall procedures must be documented, functional, and tested.

6. Oversight & Audits

- Competent national authorities conduct official controls per Regulation (EU) 2017/625.
- Documentation of HACCP, validation, traceability, and sanitation programs must be available during inspections.
- Non-EU producers must provide evidence of equivalent hygiene and processing controls for imports.

7. Bonus Tips for Compliance

- Keep up to date with EFSA opinions and updated guidance documents.
- Review HACCP plans whenever products, processes, or regulations change.
- Maintain both digital and hard-copy backups of critical records.

For expert assistance with HACCP design, validation, or regulatory review:

Advanced Food-Tech Solutions | www.advfood.tech | info@advfood.tech