Regulatory Compliance Guide
Food & Pharmaceutical Ingredients

EU & USA Markets | Updated January 2024

This guide provides an overview of key regulatory requirements for food additives and pharmaceutical ingredients in the European Union and United States markets. PharmaCo ensures all products meet or exceed applicable regulatory standards.

1. European Union (EU) Regulations

1.1 Food Additives (Regulation EC 1333/2008)

All food additives must be authorized and listed in Annex II of EC 1333/2008. Each approved additive receives an E-number. Common requirements include:

E-Number	Substance	Max Level (Example)	Applications
E330	Citric Acid	Quantum satis	Food, beverages
E270	Lactic Acid	Quantum satis	Food, dairy
E300	Ascorbic Acid	Quantum satis	Antioxidant, all foods
E415	Xanthan Gum	Quantum satis	Thickener, stabilizer
E211	Sodium Benzoate	150 mg/kg	Preservative
E202	Potassium Sorbate	200 mg/kg (general)	Preservative
E334	Tartaric Acid	Quantum satis	Acidulant, bakery

1.2 Pharmaceutical Products (Directive 2001/83/EC)

Pharmaceutical ingredients must comply with European Pharmacopoeia (Ph.Eur.) monographs. Key requirements:
• Certificate of Suitability (CEP) or Drug Master File (DMF)
• GMP certification (Good Manufacturing Practice)
• Batch-specific Certificate of Analysis (CoA)
• Compliance with Ph.Eur. testing methods

1.3 REACH Regulation (EC 1907/2006)

All chemical substances manufactured or imported >1 tonne/year must be registered.
• Registration dossier with ECHA (European Chemicals Agency)
• Safety Data Sheet (SDS) in local language
• Exposure scenarios for identified uses
• Downstream user obligations

2. United States (USA) Regulations

2.1 Food Additives (FDA 21 CFR)

Food additives must be either Generally Recognized as Safe (GRAS) or have FDA approval under 21 Code of Federal Regulations (CFR). Common categories:

CFR Citation	Substance	Status	Restrictions
21 CFR 184.1033	Citric Acid	GRAS	GMP conditions
21 CFR 184.1061	Lactic Acid	GRAS	GMP conditions
21 CFR 182.3013	Ascorbic Acid	GRAS	GMP conditions
21 CFR 172.695	Xanthan Gum	Approved	Max use levels
21 CFR 184.1733	Sodium Benzoate	GRAS	0.1% maximum
21 CFR 182.3640	Potassium Sorbate	GRAS	GMP conditions
21 CFR 184.1099	Tartaric Acid	GRAS	GMP conditions

2.2 Pharmaceutical Ingredients (FDA Drug Regulations)

Pharmaceutical excipients and active ingredients require compliance with USP-NF monographs:
• Drug Master File (DMF) Type II submission to FDA
• Current Good Manufacturing Practice (cGMP) certification
• United States Pharmacopeia (USP) or National Formulary (NF) compliance
• Inactive Ingredient Database (IID) listing for excipients
• Annual FDA establishment registration

2.3 FDA Prior Notice (Bioterrorism Act)

All food shipments to USA require electronic Prior Notice to FDA:
• Submit via FDA Prior Notice System Interface (PNSI)
• Required information: product details, manufacturer, shipper, receiver
• Submission timing: 2 hours (road), 4 hours (air/rail), 8 hours (sea)
• Confirmation Number (CN) required for customs clearance

3. EU vs USA: Quick Comparison

Aspect	European Union	United States
Food Additives	E-number system (EC 1333/2008)	CFR listing or GRAS status
Pharma Standards	Ph.Eur. (European Pharmacopoeia)	USP-NF (US Pharmacopeia)
Documentation	CEP or DMF (EU)	DMF Type II (FDA)
Import Requirements	Health certificate, EUR1	FDA Prior Notice, customs entry
Labeling	E-numbers mandatory on labels	Common names or CFR numbers
Maximum Levels	Specified per food category	GMP or specific limits
Testing	Ph.Eur. methods	USP methods
Registration	REACH (chemicals >1t/year)	FDA establishment registration

Disclaimer: This guide provides general information only and should not be considered legal or regulatory advice. Regulations are subject to change. For specific product compliance questions, please consult with PharmaCo regulatory affairs team at regulatory@pharmaco.com or consult with your legal counsel.

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