Food Regulatory 101

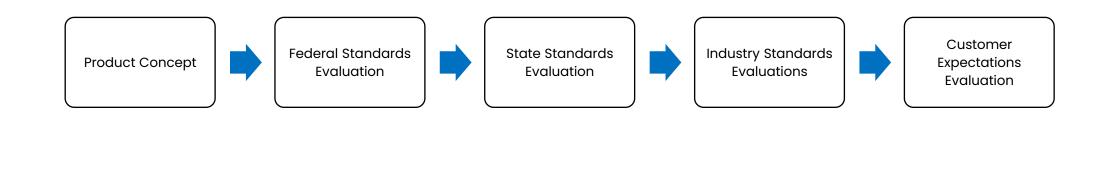
Abena Foli | 03.23.2023



Product Idea -> Formulation:

Product Formulation

- Are there federal standards governing your product idea (standards of identity)?
- Are there state guidelines governing your product idea?
- Are there industry standards for your product idea?
- Are there customer expectations governing your product idea?



Product Idea -> Formulation:

Standard of Identity Guidelines

- Permitted ingredients
- Ingredients standards
- Product standards
 - Microbial
 - Chemical
 - Physical
- Product Identity/Name
- Production standards



POKS

Formulation -> Production:

Self Production

- Home Production
 - Cottage Laws & Food Handlers Certificate
- Commercial Kitchen
 - Food Manufacturers License & Food Handlers Certificate

Formulation -> Production:

Co-Packing/Co-Manufacturing

- Confidentiality Agreement & NDA
- Manufacturer's Quality Documentation
- Food Safety Certification
- Letter of Guarantee
- Liability Insurance
- Food Manufacturer's License
- Supplier Verification Program

Production -> Food Safety:

Ingredients

- Supplier Verification Program
 - Documentation
 - Self Audit or 3rd Party Audit
- Raw Material Documentation
 - Product Claims
 - NFPs & Ingredient Statement
 - Safety Audit
 - Product Recall

Production -> Food Safety:

Production Facility

- FDA/USDA Registration & Inspections
- Food Safety Certifications
- Current Good Manufacturing Practices (cGMPs)
- Allergen & Testing Programs
- Hazard Programs
 - Hazard Analysis and Risk-Based Preventive Controls (HARPC)
 - Hazard Analysis Critical Control Point (HACCP)

Production -> Food Safety:

Ingredient & Facility Documentation

- Technical Data Sheet with 100g Nutritional Info
- Safety Data Sheet
- Food Safety Certification (SQF, BRC, AIB, ISO 22000)
- Allergen Statement
- Formula Breakdown (if composite ingredient)
- Bioengineered/GMO Statement
- HARPC/HACCP Plan with Process Flow Chart
- Certificate of Analysis (COA)

Product -> Labeling:

PDP Required

- Product Identity/Name
 - Standard of Identity
 - Common or Usual Name
 - Descriptive Name

Information Panel (IP) Required

- Nutrition Facts Panel (NFP)
- Ingredient Statement
- Allergen Statement
- Manufacturer/Distributor Info

- Net Quantity of Contents
 - Weight: NET WT 15 oz (420g)
 - Fluid: NET 12 fl oz (354 mL)

Nuanced details on sizing and placement

Product -> Labeling:

Federal & State Guidelines

- Standard of Identity Guidelines
- Product Formulation
 - Free from Claims
 - Ingredient Highlight Claim
- Regulated Claim
 - Nutrient Content
 - Health
 - Structure & Functional

Competitive Analysis

- Comparative Against Competitor
- Novel Substantive Claim
- 3rd Party Claims
 - non-GMO Verified
 - Organic
 - Gluten-Free

Q & A

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