Food Contact Regulations in the U.S. and the EU: Overview of Essentials

James Lee & Scott Stephens

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Mr. Lee is responsible for the research and analysis of various statutes and regulations of the U.S. and Canada, which pertain to environmental compliance, hazard communication, chemical products, food additives, food contacts and pharmaceuticals. Mr. Lee also monitors and updates database content for 3E Ariel products and provides regulatory and legal information support to clients.

Mr. Stephens is in charge of tracking environmental, health and safety regulatory developments in the European Union in support of 3E’s flagship WebInsight, as well as Integrated Data products. His duties include keeping a large set of regulatory databases up to date, expanding regulatory coverage to meet client needs, fielding client questions concerning European EHS regulations, producing regulatory guidance for external and internal customers, and providing regulatory support for product development initiatives.
I. Food Contact Regulatory Framework

II. GRAS, Prior Sanctioned, Secondary Direct Food Additives, and Other Exemptions

III. Food Contact Notification (FCN)
Food Contact Regulatory Framework
What are Food Contacts?

• A.K.A. "indirect" food additives
• Substances used in food-contact articles, and including adhesives and components of coatings (Part 175), paper and paperboard components (176), polymers (177), and adjuvants and production aids (178)
• Substances that may come into contact with food as part of packaging or processing equipment, but are not intended to be added directly to food
• 21 CFR Parts 175, 176, 177, and 178
## Regulatory History

<table>
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<td>Prior sanctioned by FDA or USDA before the enactment of the Food Additives Amendment</td>
<td>Before 1958</td>
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<td>Food additives approval system encompassing food packaging</td>
<td>After 1958</td>
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<td>Food Contact Notification (FCN) program</td>
<td>After 1997</td>
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21 CFR 174-186

1) Direct food additives
2) Indirect food additives (food contact substances)
   - Premarket Approval via the Food Additive Petitions (2-4 years or longer for FDA approval)
3) Generally Recognized as Safe (GRAS)
Three Types of Regulations for Food Contact Materials in 21 CFR

1) Particular types of packaging (e.g. paperboard)
2) Specific polymers (e.g. polyurethane resins)
3) Use of substances by technological function (e.g. emulsifiers and antioxidants)
Food Contact Substances

- Food Additives
- GRAS
- Prior Sanctioned
- Secondary Direct Additives

FCS
GRAS, Prior Sanctioned, Secondary Direct Food Additives, and Other Exemptions
**Generally Recognized as Safe**

1) Statutory exemption from the food additive premarket approval
2) Non-exhaustive lists in 21 CFR 182, 184, and 186
3) GRAS Notices
4) GRAS as “direct additives” considered as GRAS as “indirect additives”
Prior Sanctioned

- Prior sanctioned by FDA or the USDA before the Food Additives Amendment in 1958
  
  1) Statutory exemption from the premarket approval
  
  2) Status dependent on the existence of pre-1958 letter or other acceptance
  
  3) No complete list of the prior sanction letters
  
  4) Listed food contacts in 21 CFR 181
Secondary Direct Food Additives

- **Listed in 21 CFR 173**
  - Substances whose functionality is required during the manufacture or processing of a food and are ordinarily removed from the final food. Although some residuals might carry over to the final food, residuals must not exhibit any technical effects.
  - Exempt from premarket approval.
  - Examples: acetone, acidified sodium chlorite, per oxyacids, and boiling water additives.
Other Premarket Exemptions

• Not Reasonably Expected to Become a Component of Food or the “No Migration” (Statutory exemption)

• Threshold of Regulation (Non-statutory exemption)

• Housewares Exemption (Non-statutory)

• Basic Resin Doctrine (Non-statutory)
Food Contact Notification (FCN)
What is an FCN?

- Premarket notification for a food contact substance
- Established by the Food and Drug Administration Modernization Act of 1997 (FDAMA)
- FDA has 120 days to review a submission for the new use.
- 21 CFR 170.100 to 170.106
- Form 3480 may be submitted electronically
- No user fee
- Proprietary: effective only for the listed manufacturer
What Can Be in an FCN?

- **Three possible groups**

1) Indirect food additives – e.g., polymers, starting materials, adjuvants
2) Secondary direct additives – e.g., ion exchange resins, boiler water additives
3) Others (not “food additives”) – e.g., antimicrobials, GRAS, substances not reasonably expected to migrate to food
What Cannot Be in an FCN?

- **Five general no’s**
  
  1) Direct food additives
  2) FCS formulation consisting of cleared materials
  3) New recycling technologies
  4) Carcinogens
  5) Not meeting GMP requirement
Who May Submit an FCN?

- A manufacturer or supplier of an FCS
  1) Supplier – any person supplying an FCS: “companies supplying to themselves for manufacture of a food-contact material”
  2) A notifier company but not necessarily the producer of the product
  3) FCNs may be filed by companies that “supply the product to themselves” for further modification
When Should You Submit an FCN?

• When other methods to establish FDA clearance are not available
• Proprietary concerns
• Customer assurance
• Company preference

- Not acceptable if:
  - Cumulative dietary exposure > 1 ppm
  - Unreviewed cancer studies or not clearly negative for carcinogenicity
  - Substances already regulated for the same use
Data Required for an FCN

- Chemistry
- Toxicology
- Environmental Assessment

1) Chemistry data
2) Intended conditions of use data
3) Migration and exposure data
### FDA Review Phases

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<th>Phase I (21-45 days)</th>
<th>Phase II (45-120)</th>
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<td>Receipt date established</td>
<td>Acceptance determined 10 working days to respond to deficiencies Withdrawal (info protected)</td>
<td>Acknowledgement letter Final reviews Final letter FCN website listing</td>
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Outcome of Successful FCN

1. Acknowledgement Letter
2. Effective Letter
3. Listing on FCN Website

- Identity of the FCS
- Name of the notifier
- Name of the manufacturer/supplier
- Intended use of the FCS
- Limitations/specifications
Your food contact material shall be covered by:

1) Reg. in 21 CFR 174-179
2) Meeting GRAS status
3) Prior Sanctioned
4) Threshold of Regulation Exemption Request
5) Other Exemptions
6) Or FCN
I. Food Contact Materials (FCM) Legislation in European Union
II. General Requirements for All FCMs in EU
III. Harmonized EU Measures for Specific FCMs
IV. Highlights of National FCMs Legislation
V. Recent Developments in EU FCMs Regulation
Overview of EU legislation on FCMs

  - GMP 2023/2006/EC
- Plastic Materials
  - Elastomers & Rubber
    - Nitrosamines (EC) No 450/2009
  - Epoxy Derivatives 1895/2005/EC
- Recycled Plastics (EC) No 282/2008
- Plastics Regulation (EU) No 10/2011
- Ceramics 84/500/EEC
- Regenerated Cellulose Film 2007/42/EC

Materials:
- Paper & Board
- Glass
- Wood
- Cork
- Metals & Alloys
- Textiles
- Adhesives
- Printing Inks
- Ion-exchange Resins
- Silicones
- Varnishes & Coatings
- Waxes
Overview of EU legislation on FCMs

General Requirements For All FCMs

- Regenerated Cellulose Film 2007/42/EC
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Overview of EU legislation on FCMs

EU-Wide Specific Measures

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GMP 2023/2006/EC
Overview of EU legislation on FCMs

Legislation & Guidelines at Member State Level + International Organizations


- GMP 2023/2006/EC
- Active and Intelligent Materials (EC) No 450/2009
- Nitrosamines 93/11/EEC
- Epoxy Derivatives 1895/2005/EC
- Elastomers & Rubber

Plastic Materials

- Plastic Regulation (EC) No 282/2008
- Recycled Plastics (EU) No 10/2011

- Ceramics 84/500/EEC
- Regenerated Cellulose Film 2007/42/EC

Miscellaneous Materials

- Paper & Board
- Glass
- Wood
- Cork
- Metals & Alloys
- Textiles
- Adhesives
- Printing Inks
- Silicone
- Varnishes & Coatings
- Waxes
General Requirements for All FCMs


GMP 2023/2006/EC

Regenerated Cellulose Film 2007/42/EC

Ceramics 84/500/EEC

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General Requirements for All FCMs

Framework Regulation (Regulation 1935/2004/EC)

- General safety requirements
- EU-wide measures for specific FCMs
- Labeling
- Authorization procedure
- Traceability system
- Declaration of compliance for EU-wide specific measures
- Safeguard measures procedure
- Inspection and control measures
Applies to:
• Packaging, and
• Conveyor belts, kitchen/tableware, food production equipment, etc.

In scope are materials and articles:
• Already in contact with food
• Intended to be brought in contact with food
• Expected to come into contact with food or transfer their components to food (under normal and foreseeable use)
Does not apply to:

• Fixed water supply equipment (i.e. water utility infrastructure)
• Coverings/coatings consumed with food (e.g. cheese rinds, meat coverings)
• Antiques
General safety requirements

• No release of constituents into food at levels harmful to human health
• No change in food composition, taste and odor in an unacceptable way
• Must not mislead consumer (labeling, advertising)
Commission authorized to adopt EU-wide measures for specific FCMs

• Annex I outlines scope of possible FCMs
• Currently, specific measures exist for:
  • Plastics
  • Recycled plastics
  • Regenerated cellulose film
  • Ceramics
  • Active and intelligent materials
  • Epoxy derivatives
  • Nitrosamines
Labeling requirements

• Name and address of manufacturer, processor or seller
• Special instructions
• Clear language easily understood by consumers
• Phrase “for food contact” or specific indication or symbol:
Authorization for EU-wide specific measures

- Application submitted to member states
- Assessed by EFSA
- Once authorized, may be used by any company
- Authorizations can be modified or suspended
- Companies required to inform Commission on new scientific data/information
Traceability system

- System in place allowing traceability
- At all stages of production and distribution
- All materials, including substances and products
- Available to competent authorities on demand
Declaration of compliance

For EU-wide specific measures:
• Written declaration confirming product’s compliance with applicable rules supplied
• Appropriate documentation available to demonstrate such compliance
• Documentation to be made available to competent authorities on demand
• In absence of specific measures, member states can adopt national provisions to require declarations of compliance
Safeguard measures

• Temporary suspension or restriction of authorized FCM by member state (MS)
• Commission takes decision to either adapt specific EU legislation or ask MS to withdraw suspension/restriction (e.g. BPA in Denmark, France)
Inspection and control measures

• Member states charged with enforcing EU and national legislation (Regulation 882/2004/EC applies to FCMs)
• Commission ensures implementation of legislation by member states
• Rapid Alert System on Feed and Food (RASFF)
Good manufacturing practices

• Quality assurance system
• Quality control system
• Documentation covering manufacturing process
EU Measures on Specific FCMs

  - GMP 2006/EC
  - GMP 2023/2006/EC

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**Plastic Materials** (Regulation 10/2011/EU)
- most comprehensive specific measure
- establishes Union List of substances permitted in manufacture of plastic FCMs
- Union Guidelines (version 1.1 – 1 Jan 2016)

**Recycled Plastic Materials** (Regulation 282/2008/EC)
- Regulates processes for recycling plastics
- Establishes authorization application procedure
- Recycling processes authorized by Commission after EFSA assessment
- Union list of authorized processes foreseen
Active and Intelligent Materials
(Regulation 450/2009/EC)
• specific rules apply for their specific purposes
  (exempt from general inertness rule in 1935/2004/EC)
• Union list foreseen (Almost 50 substances submitted for authorization)

Ceramics Directive (84/500/EEC)
• Limits on Pb, Cd migration
• Test methods
Regenerated Cellulose Film (Directive 2007/42/EC)
• Uncoated RCF, RCF coated with cellulose or coated with plastics
• RCF composition restricted to substances in Annex II
• Plastic coatings to comply with Regulation 10/2011/EU

Epoxy Derivatives (Regulation 1895/2005/EC)
• Bans BFDGE, NOGE
• SMLs for BADGE and derivatives
• Covers plastics, coatings and adhesives

Nitrosamines (Directive 93/11/EC)
• Limits release of N-nitrosamines in rubber teats and soothers
National Legislation & Standards

- Regenerated Cellulose Film 2007/42/EC
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- Waxes
• Regulation 1935/2004/EC allows for member state regulation of FCMs

• Fragmented, confusing patchwork of regulations, guidelines and standards across 28 member states
### SUMMARY OF THE NATIONAL LEGISLATION

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# National Legislation & Standards

### Table: EU Legislation & Standards for Food Contact Materials

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National Legislation & Standards

Germany
Federal Institute for Risk Assessment (BfR)
Recommendations on FCMs

Netherlands
Commodities Act Regulation on Packaging and Consumer Products, 14 March 2014

Italy
Ministry of Health Decree of 21 March 1973

Council of Europe
Standards under the Partial Agreement
Recent Regulatory Developments

• FCM Foresight Project (Commission’s JRC)

• “For industry, harmonized rules at EU-level were clearly preferable. It was stated that divergent MS rules and risk assessments would hinder rather than foster the functioning of the internal market.” - Conclusion of EU Presidency workshop on FCMs- Luxembourg, October 2015
Quick Demo of WebInsight Search
How 3E Can Help

- **3E Tools and Services for Food Contact Compliance**
  - Ariel WebInsight™ enables you to search and identify food contact/packaging substances
  - Ariel WebInsight™ and Regulatory Monitoring have the latest news on FDA rules; WebInsight has full texts of regulations and guidance documents
  - Regulatory Consulting Services can assist you with food contact notification.
  - Ariel Logic™ can help with all other food additive compliance needs.
How helpful was this webinar in increasing your basic knowledge about food contact regulations in the US and the EU?

A) A lot  
B) A little  
C) Not helpful
What topics of webinars do you want to see more from 3E Company?

A) GHS-related regulations (e.g., HCS 2012 and EU CLP)
B) Chemical management laws (e.g., TSCA and REACH)
C) Food-related regulations (e.g., food contact and FSMA)
D) Cosmetic and drug regulations (e.g., FDCA and EMA regs)
E) Lifecycle management (e.g., ROHS and WEEE)
Poll Question 3

Are you interested in speaking with a 3E specialist regarding assistance in Food Contact Regulatory compliance?

A) Yes
B) No
Upcoming Webinars

• Best Practices in SDS and Product Data Management
  March 24 at 8am PST

• 3E Expands Our Regulatory Consulting Services to Help Meet Your Business Needs
  April 7 at 8am PST

• REACH in Asia – What You Need to Know
  April 14 at 8am PST
Upcoming Events

- **Indiana Safety and Health Conference & Expo**
  March 21, 2016 (Indianapolis, IN)

- **NSC Texas Safety Conference & Expo**
  March 21, 2016 (San Antonio, TX)

- **GlobalChem 2016**
  March 22, 2016 (Washington, DC)

To learn more about upcoming events or to register—please go to 3ecompany.com
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Questions?