MARKET ACCESS – GLOBAL FOOD CONTACT REGULATORY COMPLIANCE

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Health, Environmental & Regulatory Services (HERS)
FOOD PACKAGING SAFETY
FOOD PACKAGING DELIVERS SAFE AND QUALITY FOOD

• Preserves hygiene standard of food
  o Prevents cross contamination
  o Offers physical protection during food handling and storage
• Extends the shelf life of food products
  o Preserves the compositional integrity of food
  o Prevents microbial contamination
  o Reduce food waste
• Ease of transportation
• Meets consumer’s convenience requirements
• Packaging labels and prints provide a tool to communicate with consumers
FOOD PACKAGING INNOVATION

• The needs to eliminate food waste and improve global food security require novel food packaging methods and techniques to increase the shelf life of food
• Cost effectiveness demands reducing packaging weight, yet maintain same functional barrier
• Sustainability drives new and unconventional sources of raw materials for packaging
Small molecules are the main concern.
CONCERN WITH FOOD CONTACT MATERIALS

- Plastics materials are porous
- Small molecules in plastics can move out of the plastic and into food through migration
  - When a chemical is non-volatile, migration is by contact
  - When a chemical is volatile, migration can be by evaporation through air and absorption by food
MANAGE FOOD PACKAGING SAFETY AND PERCEPTIONS

- Government regulations
- Customer demand
- Consumer awareness
- Media exposure

THE SAFETY OF FOOD PACKAGING IS AS IMPORTANT AS THE SAFETY OF FOOD
GLOBAL FOOD CONTACT REGULATION
GLOBAL FOOD CONTACT REGULATIONS

Three major regulation systems
- US
- EU
- China

Other countries reference EU or FDA
- MURCOSUR and members states regulations
- Middle East countries
- Africa
- Australia and New Zealand

Other countries have different regulations
- Japan (is changing)
- South Korea
- India
- Etc.
Regulations may be different by countries and regions, however, the three main principles are the same.
FRAMEWORK REGULATION

Food packaging or food contact material:
• Should not endangerment of human health
• Should not change to food composition
• Should not change to organoleptic properties of food

Examples of Framework Regulations
• EU Regulation (EC) No 1935/2004
• China GB 4806.1 – 2016
• US FDA 21CFR174.5
GOOD MANUFACTURING PRACTICE (GMP) REGULATION

• Quality assurance and quality control systems in place to ensure consistent quality and safety of the product
• Manufacturing processes in place to avoid contamination in manufacturing
• Use of material at the level only to achieve technical function
• Materials have suitable purities for the intended uses

Examples of GMP Regulations
• EU Regulation (EC) No 2023/2006
• China GB 31603 – 2015
• US FDA 21CFR174.5
MATERIAL REGULATIONS

• Regulations to govern the use of specific materials
• May include positive list of material cleared or approved by government agencies
• May include loading limits or use restrictions
• May include compliance testing requirements

Examples of material regulations

EU
• Plastic Regulation (EU) No 10/2011
• And more

US FDA
• 21CFR177.1520 (polyolefin)
• 21CFR177.1630 (PET polymer)
• 21CFR175.300 (coating)
• And more

CHINA
• GB 9685-2016 (additive, colorants, etc.)
• GB 4806.6-2016 (resins)
• GB 4806.10-2016 (coating)
• And more
<table>
<thead>
<tr>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
<th>(7)</th>
<th>(8)</th>
<th>(9)</th>
<th>(10)</th>
<th>(11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCM</td>
<td>Ref. No</td>
<td>CAS No</td>
<td>Substance name</td>
<td>Use as additive or polymer production aid (yes/no)</td>
<td>Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)</td>
<td>FRF applicable (yes/no)</td>
<td>SML [mg/kg]</td>
<td>SML(T) [mg/kg] (Group restriction No)</td>
<td>Restrictions and specifications</td>
<td>Notes on verification of compliance</td>
</tr>
<tr>
<td>1</td>
<td>12310</td>
<td>0266309-43-7</td>
<td>albumin</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>12340</td>
<td>—</td>
<td>albumin, coagulated by formaldehyde</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>12375</td>
<td>—</td>
<td>alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>22332</td>
<td>—</td>
<td>mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>(17)</td>
<td>1 mg/kg in final product expressed as isocyanate moiety.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>25360</td>
<td>—</td>
<td>trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>ND</td>
<td>1 mg/kg in final product expressed as epoxy group. Molecular weight is 43 Da.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>25380</td>
<td>—</td>
<td>trialkyl acetic acid (C7-C17), vinyl esters</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>0,05</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EXAMPLE OF REGULATION – EU PLASTIC REGULATION (EU) NO 10/2011

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Part 174 — General provisions
Part 175 — Adhesives and Coatings
Part 176 — Paper and Paperboard
Part 177 — Polymers (e.g. 21CFR177.1630 – PET; 21CFR177.1520 – Polyolefins; etc.)
Part 178 — Adjuvants, Production Aids, Sanitizers (e.g. 21CFR178.2010 – additives, etc.)
Part 181 — Prior Sanctions
Part 182 — GRAS Substances
Part 184 — Direct Additives Affirmed as GRAS
Part 186 — Indirect Additives Affirmed as GRAS
Part 189 — Prohibited Indirect Additives
EXAMPLE – 21CFR177.1520 OLEFIN POLYMERS

• List of olefin polymers that at cleared by FDA, with description of:
  o Homopolymers (polymer of ethene, propene, and other alkene)
  o Copolymers (copolymer of ethene, propene, and other alkene)

• A List of additives cleared by FDA for use in these olefin polymers, in addition to the other additives listed in 21CFR178.xxxx

• Specifications of these olefin polymers must be met through compliance testing:
  o Density
  o Melting Point
  o Maximum extractable fraction in hexane
  o Maximum soluble fraction in xylene
GB 4806.6-2016 PLASTIC RESIN

Scope
This Standard applies to resins and resin blends used to produce food-contact use plastic materials and articles, including thermoplastic elastomer resins without vulcanization, and the mixtures thereof.

Definitions:
This Standard applies to resins and resin blends used to produce food-contact use plastic materials and articles, including thermoplastic elastomer resins without vulcanization, and the mixtures thereof.

Basic Requirements

• Plastic resins comply with GB4806.1
• Resin must be listed in Appendix A (a Positive list of 102 polymers)
• Sensory requirements
• Physicochemical specifications (SML, SML(T), QM)
• Additives must comply with GB 9685
• Migration test must follow GB 31604.1 and GB 5009.156
• Label requirement. Resin name(s) must be shown on the label
### Appendix A

#### Table A.1 Plastic resins permitted for use and the use requirements

<table>
<thead>
<tr>
<th>No.</th>
<th>Chinese Name</th>
<th>CASRN</th>
<th>Category Name</th>
<th>SML / QM mg/kg</th>
<th>SML(T) mg/kg</th>
<th>SML(T) Group No.</th>
<th>Other Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(3R)-3-羟基丁酸与 4-羟基丁酸共聚物 Butanoic acid, 3-hydroxy-,(3R)-, polymer with 4-hydroxybutanoic acid</td>
<td>125495-90-1</td>
<td>Poly(3HB-co-4HB), P(3,4HB)</td>
<td>5 (以 1,4-丁二醇计)</td>
<td>5 (as 1,4-butanediol)</td>
<td>30</td>
<td>The plastic materials or articles produced may not be used for contact with food containing ethanol; use temperature may not exceed 100 °C.</td>
</tr>
<tr>
<td>2</td>
<td>1,1,1,2,2,3,3-七氟-3-(三氟乙烯基)氧]丙烷与四氟乙烯的聚合物 Propane, 1,1,1,2,2,3,3-heptafluoro-3-[ (trifluoroethenyl)oxy]-, polymer with tetrafluoroethene</td>
<td>26655-0-5</td>
<td>PFA</td>
<td>0.05 (四氟乙烯：SML)</td>
<td>0.05 (tetrafluoroethylene: SML)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1,12-十二烷二酸与 1,6-己二胺的聚合物（聚十二烷二酰己二胺，聚酰胺 612） A polymer of 1,12-dodecanedioic acid and 1,6-hexanedianmine (polyhexamethylene)</td>
<td>26098-5-5</td>
<td>PA</td>
<td>2.4 (1,6-己二胺：SML)</td>
<td>2.4 (Hexamethylenediamine: SML)</td>
<td></td>
<td></td>
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</tbody>
</table>
## REGULATION COMPARISON - PLASTICS

<table>
<thead>
<tr>
<th>Regulated</th>
<th>US FDA</th>
<th>EU</th>
<th>China</th>
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</thead>
<tbody>
<tr>
<td>Polymer</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Monomer</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Additive for plastic</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Colorant for plastic</td>
<td>yes</td>
<td>no*</td>
<td>yes</td>
</tr>
<tr>
<td>Overall Migration Test</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Specific Migration Test</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

* Rely on EU member states regulation
NEW FOOD CONTACT SUBSTANCE: PRE-MARKET CLEARANCE

US FDA – Food Contact Notification
EU and China – Food Contact Substance Petition

Scope
a) New chemical or material
b) Expansion of existing uses
c) Manufacturing process change that cause significant impurity profile change
## Notification/Petition Package for Food Contact Substance (FCS)

<table>
<thead>
<tr>
<th>01</th>
<th>Physico-chemical Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chemical name &amp; CAS# of FCS</td>
<td></td>
</tr>
<tr>
<td>• Physical and chemical properties</td>
<td></td>
</tr>
<tr>
<td>• Technical function and use condition</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>02</th>
<th>Manufacture Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• List of starting materials</td>
<td></td>
</tr>
<tr>
<td>• Manufacturing process</td>
<td></td>
</tr>
<tr>
<td>• Impurity profile</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>03</th>
<th>Chemistry Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Stability and degradation</td>
<td></td>
</tr>
<tr>
<td>• Residue &amp; Migration test reports</td>
<td></td>
</tr>
<tr>
<td>• Estimated Dietary Intake (EDI) for FDA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>04</th>
<th>Toxicity Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Toxicity information base on migration/DC</td>
<td></td>
</tr>
<tr>
<td>• Comprehensive toxicology profile, when needed</td>
<td></td>
</tr>
<tr>
<td>• Derive Acceptable Daily Intake (ADI) for FDA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>05</th>
<th>Safety Narrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>• For FDA, Notifier demonstrate (C)EDI* &lt; ADI</td>
<td></td>
</tr>
<tr>
<td>• For EU or China, no Safety Narrative required, government agencies make safety decision</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>06</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Assess the potential environmental impact for FDA</td>
<td></td>
</tr>
<tr>
<td>• Provide other necessary information for EU and China</td>
<td></td>
</tr>
</tbody>
</table>

*(C)EDI – cumulative EDI*
## Pre-Market Clearance - Notification/Petition Process

<table>
<thead>
<tr>
<th>Information</th>
<th>US</th>
<th>EU</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical, physico/chemical and manufacturing information</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Exposure information</td>
<td>Dietary Concentration</td>
<td>Migration test data</td>
<td>Migration test data</td>
</tr>
<tr>
<td>Toxicity data requirements</td>
<td>Based on Dietary Concentration</td>
<td>Based on migration</td>
<td>Based on migration</td>
</tr>
<tr>
<td>Safety Narrative</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Environmental Assessment</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Duration</td>
<td>120 days</td>
<td>6 months – 18 months</td>
<td>unpredictable</td>
</tr>
<tr>
<td>Proprietary</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>

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03

COMPLY WITH FOOD CONTACT REGULATION
COMPLY WITH FRAMEWORK REGULATION

• Framework regulation ensures that even though there is no specific material regulations, manufacturers must do their due-diligence to ensure food contact materials and food packaging safety

• Compliance to regulations from other counties may be helpful

• If there are no other regulations, you may need to gain a better understanding of the material composition, conduct necessary testing, and do risk assessment

• May require sensory test
COMPLY WITH GOOD MANUFACTURING PRACTICE REGULATIONS

• Need a top down process with strong leadership commitment
• Quality system must be established for QA & QC
• Control process established to avoid contaminations
• Routine housekeeping activities to ensure hygiene standard in the manufacturing environment
• Management of change and corrective action plan
• Auditing and documentation

Reference: ISO/TS 22002-4
COMPLY WITH MATERIAL REGULATIONS

• Material formulation must be available

• Each ingredient in the formulation must have a regulatory compliance status

• Check use limitations in the regulation, including loading limits, use temperature, contact food type, etc.

• Conduct compliance testing when required
COMPLIANCE TESTING

• Overall migration test (US FDA; EU; China)
  a) Extractable type of testing
  b) Relatively simple analytical techniques by gravimetric

• Specific migration test (EU; China)
  a) Measure individual chemical
  b) More advanced analytical techniques are needed (GC/MS; LC/MS, etc.)

• Other testing (China)
  a) KMnO4 consumption
  b) Color elution test
  c) etc.
SUPPLY CHAIN RESPONSIBILITY

• Food Contact regulatory compliance is the supply chain’s responsibility
• GMP is applicable to material suppliers, package manufacturers, or end users
• Material formulation should be transferred from upstream to downstream in order to ensure accurate information is used for compliance determination
• Compliance test can be performed by material suppliers, package manufacturers, or end users
SUMMARY
FOOD CONTACT REGULATORY COMPLIANCE

• Comply with Framework regulation
• Comply with Good Manufacturing Practice regulation
• Comply with material regulations:
  o All ingredient are either Positive Listed or covered by a regulation
  o Meet use restrictions
  o Pass compliance testing
PRACTICAL SOLUTIONS FOR COMPLIANCE

• Involve your product stewardship, regulatory team, or third party consultant early in your food packaging or food contact material development
• Select regulatory cleared or Positive Listed materials to begin with
• Communicate your technical needs and application specifics to your material suppliers; and request Declaration of Compliance from your material suppliers
• When new material must be used to achieve specific technical function, push your supplier to file notification, or work with your supplier to file notification for government agencies clearance
• Establish GMP in manufacturing
• Rely on your supplier to complete compliance testing or do your own compliance testing

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Check out Intertek global food contact seminar in 2019