Food Packaging Forum
Workshop – 5 October 2017
Zürich, Switzerland

Packaging Safety Challenges | Supply Chain Communication

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The views expressed in the presentation are those of the speaker; they do not necessarily represent those of The Coca-Cola Company.
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Risk Communication in the Supply Chain

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PROJECT PASSPORT
Guideline for Risk Communication for the Global Food Contact Supply Chain
Version 1.1 | June 2017

Plastics Industry Association (PLASTICS)
Food, Drug, and Cosmetic Packaging Materials Committee
plasticsindustry.org/projectpass
Risk Analysis

1. Risk analysis is universal to public health protection


2. Risk communication is an integral part of risk analysis
3. No business operator can do supply chain risk analysis alone
3. Risk Communication

3.1 People

3.2 Process

3.3 Content

4. Communication has 3 elements: people, process and content
5. Authors may not know the intended audience, or vice versa
6. Food safety auditors are getting more involved in food contact
7. Message received is often not the message prepared
8. Content is a multidimensional linguistic entity:

   Semantics – is the text precise and unambiguous?
   Pragmatics – is the context defined and understood?
   Syntax – is the structure streamlined and consistent?
The stated goal of Project Passport is to improve risk communication in the supply chain. The current edition of the work product consists of three separate components:

a. **Form.** A form is provided to offer a basic syntax to organize the data elements. It is generic by design such that it can be adapted to different products marketed in various jurisdictions.

b. **Instructions.** These are basic explanations intended to provide the context to accompany the Form.

c. **Quick Guides.** These are topical guides interspersed throughout on select topics to provide added clarity on the Instructions.

http://www.plasticsindustry.org/projectpass
Feature 1: Syntax

Organization matters.

- Simple, one-page form for organizing data elements
- Readily adaptable to different products marketed in various jurisdictions
Feature 2: Pragmatics

Context matters.

- Conspicuous differentiation between substance vs. material vs. article made

- Clear distinction between food ingredient vs. food contact emphasized as appropriate
Feature 3: Semantics

Text matters.

- Instructions on food contact compliance in the US and the EU covered

- Additional topics of interest to food processors included

- Responses provided for possible adoption
Feature 4. Genericism

Regardless of the regulatory system, food contact compliance can be generically described in terms of

1. Safety – general safety framework & specific measure
2. Quality – type of good manufacturing practice
3. Suitability – use limitation in food type & temperature
Feature 5. Prioritization

Information is prioritized in the following order:

C. Regulatory Compliance, Food Contact
D. Regulatory Compliance, Non-Food Contact
E. Issue Management: Substance & Topics of Interest
Feature 6. Quick Guides

- Topical guides are interspersed throughout on select topics to provide added clarity on the instructions.

Quick Guide #7: Pathways to Pre-market Clearance in the US

Be aware that Effective Food Contact Substance Notification (FCN), Threshold of Regulation (TOR), Prior Sanction, GRAS status, or "no migration" exemption may be applicable.

Food Contact Substance Notifications (FCN) may be applicable. The notification process has replaced the Food Additives Petition since 2000. An effective FCN is proprietary to only the notifier, its licensees, and its downstream customers.

Threshold of Regulation (TOR) exemptions may be applicable. The exemptions have been issued by FDA since 1996 pursuant to 21 CFR 170.39. Prior Sanctions apply to substances for which the specific use in food was approved by U.S. FDA or USDA prior to September 6, 1958.

"GRAS" is an acronym for Generally Recognized as Safe and applies to substances generally recognized by qualified experts to be safe for the intended use. FDA maintains an inventory of notices that are given "no question" responses.

The "no migration" exemption may apply if a food contact substance is not reasonably expected to migrate to a food when used as intended. Cf. section 201(s) of the FD&C Act.

FDA also maintains a list of submissions for specific processes for post-consumer recycled plastics used in the manufacture of food contact articles that have received no-objection letters.

9 CFR 317.24 and 9 CFR 381.144 are USDA regulations for federally-inspected facilities implementing pre-requisite food safety programs on packaging materials, which are food contact articles. These regulations further reference the product guaranty in the enforcement section of FDA regulations (Cf. 21 CFR 7.12 and 7.13).
Thank you for your attention

For further information on “Guideline for Risk Communication for the Global Food Contact Supply Chain”, please contact Jim Huang, huang2@coca-cola.com

For further information on the Plastics Industry Association and the Food, Drug, and Cosmetics Packaging Materials Committee, please contact Kyra Douglas, kdouglas@plasticsindustry.org
Thoughts on Packaging Safety Challenges

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### Food Contact Materials (FCM) & Articles

<table>
<thead>
<tr>
<th>Number</th>
<th>Material Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Active and intelligent materials and articles</td>
</tr>
<tr>
<td>2</td>
<td>Adhesives</td>
</tr>
<tr>
<td>3</td>
<td>Ceramics</td>
</tr>
<tr>
<td>4</td>
<td>Cork</td>
</tr>
<tr>
<td>5</td>
<td>Rubbers</td>
</tr>
<tr>
<td>6</td>
<td>Glass</td>
</tr>
<tr>
<td>7</td>
<td>Ion-exchange resins</td>
</tr>
<tr>
<td>8</td>
<td>Metals and alloys</td>
</tr>
<tr>
<td>9</td>
<td>Paper and board</td>
</tr>
<tr>
<td>10</td>
<td>Plastics</td>
</tr>
<tr>
<td>11</td>
<td>Printing inks</td>
</tr>
<tr>
<td>12</td>
<td>Regenerated cellulose</td>
</tr>
<tr>
<td>13</td>
<td>Silicones</td>
</tr>
<tr>
<td>14</td>
<td>Textiles</td>
</tr>
<tr>
<td>15</td>
<td>Varnishes and coatings</td>
</tr>
<tr>
<td>16</td>
<td>Waxes</td>
</tr>
<tr>
<td>17</td>
<td>Wood</td>
</tr>
</tbody>
</table>


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**The Framework Regulation provides the list of groups of materials and articles for food contact.**
Federal Food, Drug, and Cosmetic Act § 409(h)6

<table>
<thead>
<tr>
<th>any substance</th>
<th>that is intended for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>as a component of materials</td>
<td>used in</td>
</tr>
<tr>
<td>manufacturing, packing, packaging, transporting, or holding food</td>
<td>if such use</td>
</tr>
<tr>
<td>of the substance</td>
<td>is not intended to have</td>
</tr>
<tr>
<td>any technical effect in such food</td>
<td>[as consumed]</td>
</tr>
</tbody>
</table>

The statutory definition offers, among other things,
- the concept of “intended use”
- the requirement of inertness
- the connection to food [as consumed]
- the hierarchy of supply chain (substance → material → article)
Each link in the food contact supply chain has a key value proposition:

- **Substance** – compositional *purity*, usually to a known standard
- **Material** – formulary *complexity*, generally held as a trade secret
- **Article** – physical *utility*, safe, suitable & ready to package food
Packaging Safety Challenges

Food Contact vs. Packaged Food

<table>
<thead>
<tr>
<th></th>
<th>Food Contact</th>
<th>Packaged Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply Chain</td>
<td>Petrochemical &amp; Mineral</td>
<td>Agricultural</td>
</tr>
<tr>
<td>Major Disciplines</td>
<td>Toxicology</td>
<td>Toxicology</td>
</tr>
<tr>
<td></td>
<td>Chemistry</td>
<td>Nutrition</td>
</tr>
<tr>
<td></td>
<td>Materials Science</td>
<td>Food Science</td>
</tr>
<tr>
<td></td>
<td>Chemical Engineering</td>
<td>Microbiology</td>
</tr>
</tbody>
</table>
Packaging Safety Challenges

An example: “S-PET” (Spiroglycol-modified polyethylene terephthalate)

S-PET (“Altester”), introduced into the market circa 2010, is chosen to illustrate the differences between the two regulatory frameworks.
As regulated in the EU (1/2)

EFSA opinion, issued on October 20, 2014

Food Contact Material No 1052

\[ \beta,\beta,\beta',\beta',-\text{tetramethyl-2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol} \]

(CAS No 1455-42-1)

Intended Use

The substance is intended for use as a co-monomer at a maximum content of 50 mole % of the diol component for manufacturing polyesters specifically in partial replacement of ethylene glycol in poly(ethylene terephthalate) (PET). The final articles are intended to be in contact with all types of foodstuffs for long-term storage at room temperature including hot-fill/sterilisation for up to 30 min at 100 °C or for 2 hours at 70 °C.

Safety Assessment

...the use of SPG as a monomer in the production of polyesters, does not raise a safety concern for the consumer when the migration of the substance itself does not exceed 5 mg/kg food and the migration of the oligomers of less than 1000 Da does not exceed 50 µg/kg food (as SPG).
As regulated in the EU (2/2)

EC Commission Regulation, issued on August 24, 2016

Food Contact Material No 1052

β,β,β',β'-tetramethyl-2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol

(CAS No 1455-42-1)

Limitations, Restrictions and specifications

Only to be used as a monomer in the production of polyester.

The migration of SPG shall not exceed 5 mg/kg food and the migration of oligomers of less than 1000 Da shall not exceed 50 µg/kg food (expressed as SPG).

Notes on verification of compliance

When used in contact with non-alcoholic foods for which Table 2 of Annex III assigns food simulant D1, food simulant c shall be used for verification of compliance instead of food simulant D1;

When a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.
As regulated in the US

FCN No. 1135 (Effective April 20, 2012)

Food Contact Substance

1,4-benzenedicarboxylic acid, polymer with
1,2-ethanediol and
β,β,β',β',-tetramethyl-2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol
(CAS Reg. No. 102070-64-4).

Intended Use

As the basic polymer in the manufacture of films, coatings, and molded articles having a maximum thickness of 5 mm for single-use and repeated-use food-contact applications.

Limitations/Specifications

The FCS may be used in contact with all food types

(a) under Conditions of Use C through G where SPG is less than 30 mol% of total glycol units, and
(b) under Conditions of Use B through H where SPG is between 30 and 50 mol% of total glycol units.
Packaging Safety Challenges

Summary

1. Both the US and the EU authorities have determined the same polymer to be safe for food contact, and both have laid down safety parameters for compliance purposes.

2. The parameters used to establish safety are distinct from one another, and harmonizing the requirements is not possible since the approaches are different.

   1. EU – *a posteriori* chromatography (migrations of monomer and of oligomers)
   2. US – *a priori* stoichiometry (% of glycol units) & physical dimension
Observation: Food Ingredients vs. Food Contact

Packaging Safety Challenges

Food Ingredient

100x

TOR

Food Flavoring

100x

ADI/TDI

Food Contact

>100x

NOAEL
$A_1 = a^2$

$A_1 = A_2$

$a = r\sqrt{\pi}$

$A_2 = \pi r^2$

$r = \frac{a}{\sqrt{\pi}}$

$\sqrt{\pi} = 1.772453850905516027298167483341\ldots\ldots$

$\frac{1}{\sqrt{\pi}} = 0.5641895835477562869480794515607\ldots\ldots$
Packaging Safety Challenges

Observation

1. Both the US and the EU authorities have determined the same polymer to be safe for food contact, and both have laid down safety parameters for compliance purposes.

2. The parameters used to establish safety are distinct from one another, and harmonizing the requirements is not possible since the approaches are different.

   1. EU – *a posteriori* chromatography (migrations of monomer and of oligomers)
   2. US – *a priori* stoichiometry (% of glycol units) & physical dimension

3. The systemic incongruence creates compliance gaps, which are often perceived as safety gaps.
Packaging Safety Challenges

Question #1: Which is more protective?

Can we communicate safety in a way that transcends political borders?
Question #2: What is more helpful?

Can we communicate the message with clarity and empathy?
Packaging Safety Challenges

Question #3: What is more effective?

Truthful (data, evidence)

Empirical

(Justification)

Knowledge

Believable (perspective, value)

Experiential

Epistemology

Philosophy

The theory of knowledge, especially with regard to its methods, validity, and scope, and the distinction between justified belief and opinion.

Mid 19th century: from Greek epistēmē ‘knowledge’, from epistasthai ‘know, know how to do’.

Oxford English Dictionary

Can we cultivate a receptive framework before we communicate?
Thank you for your attention