Food Packaging Forum

Workshop – 5 October 2017
Zürich, Switzerland

Packaging Safety Challenges | Supply Chain Communication

Jim Huang
Director, Food Contact Materials
Global Scientific & Regulatory Affairs
The Coca-Cola Company
Atlanta, Georgia, USA

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

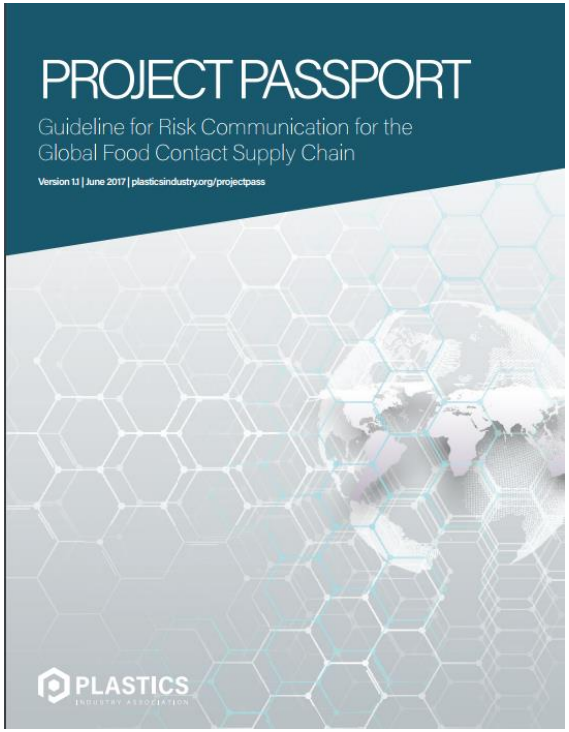
Food Packaging Forum

Workshop – 5 October 2017
Zürich, Switzerland

Risk Communication in the Supply Chain

Jim Huang
Director, Food Contact Materials
Global Scientific & Regulatory Affairs
The Coca-Cola Company
Atlanta, Georgia, USA

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



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

PLASTICS
INDUSTRY ASSOCIATION

Risk Analysis

Codex Alimentarius Commission, ‘‘Codex Alimentarius Commission Procedural Manual, 21st Edition,’’ 2013.

78 Federal Register 3646, “Proposed Rule: cGMP and Hazard Analysis and Risk-Based Preventative Control,” 2013.

Regulation (EC) No. 178/2002, “General principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety,” 2002.

1. Risk analysis is universal to public health protection

Risk Analysis		
1. Risk Assessment	**2. Risk Management**	**3. Risk Communication**

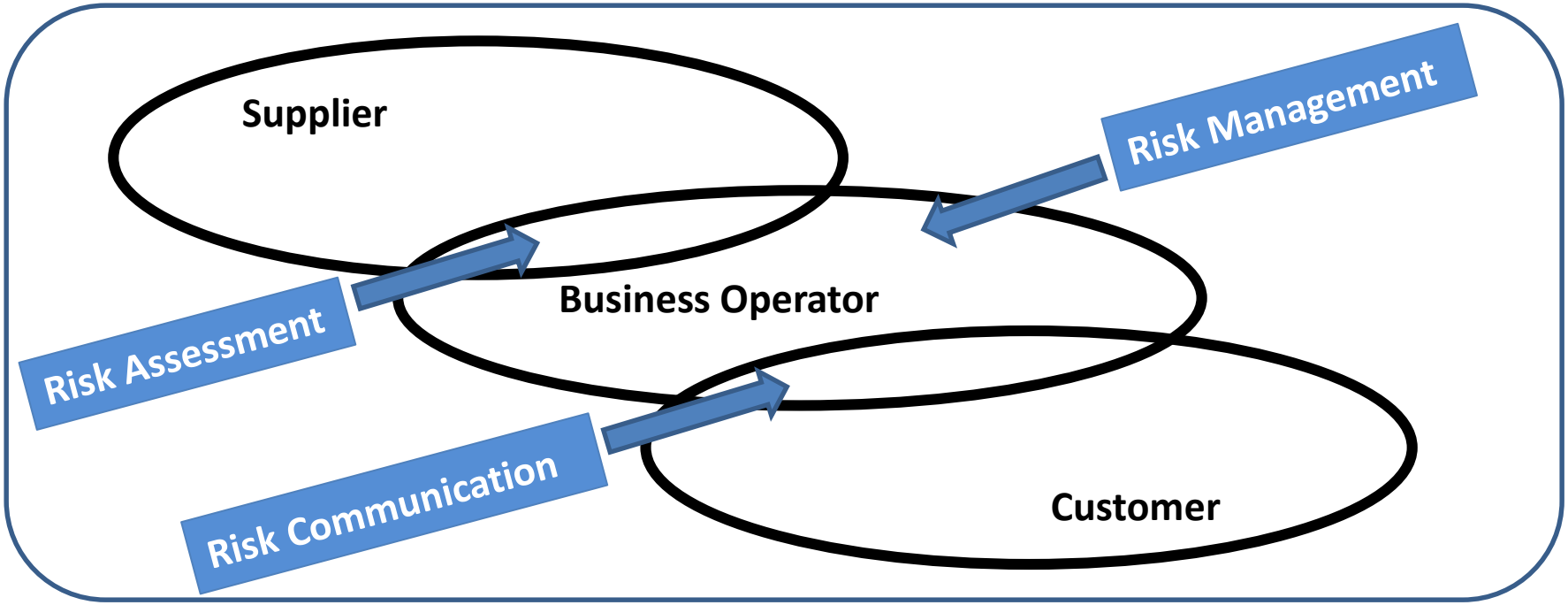
Codex Alimentarius Commission, ‘‘Codex Alimentarius Commission Procedural Manual, 21st Edition,’’ 2013.

78 Federal Register 3646, “Proposed Rule: cGMP and Hazard Analysis and Risk-Based Preventative Control,” 2013.

Regulation (EC) No. 178/2002, “General principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety,” 2002.

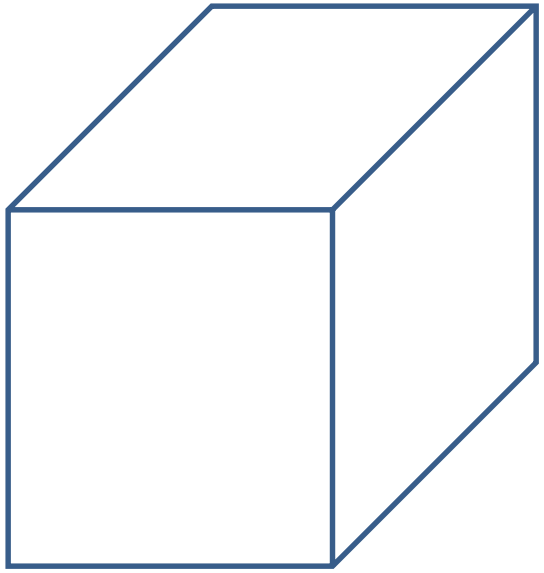
2. Risk communication is an integral part of risk analysis

Risk Analysis		
1. Risk Assessment	2. Risk Management	3. Risk Communication



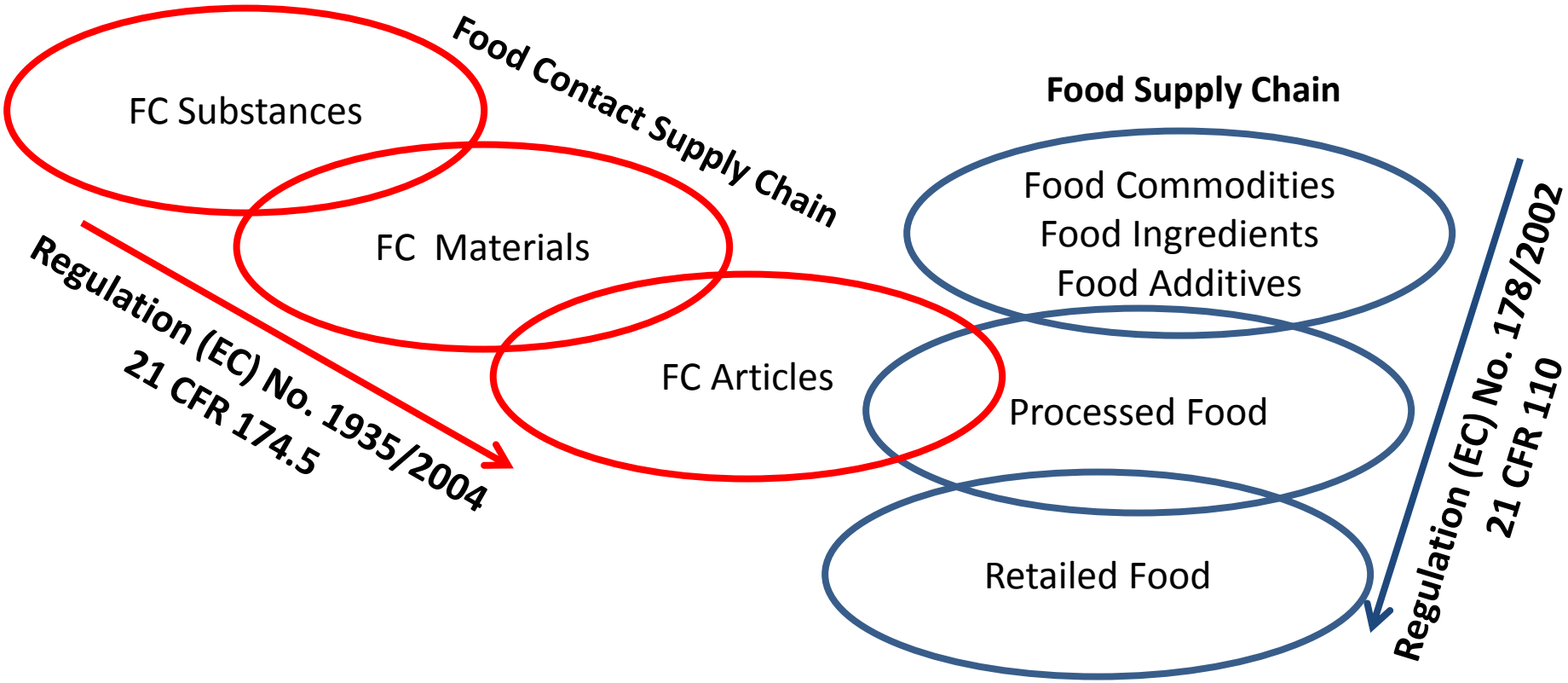
3. No business operator can do supply chain risk analysis alone

3. Risk Communication		
3.1 People	3.2 Process	3.3 Content



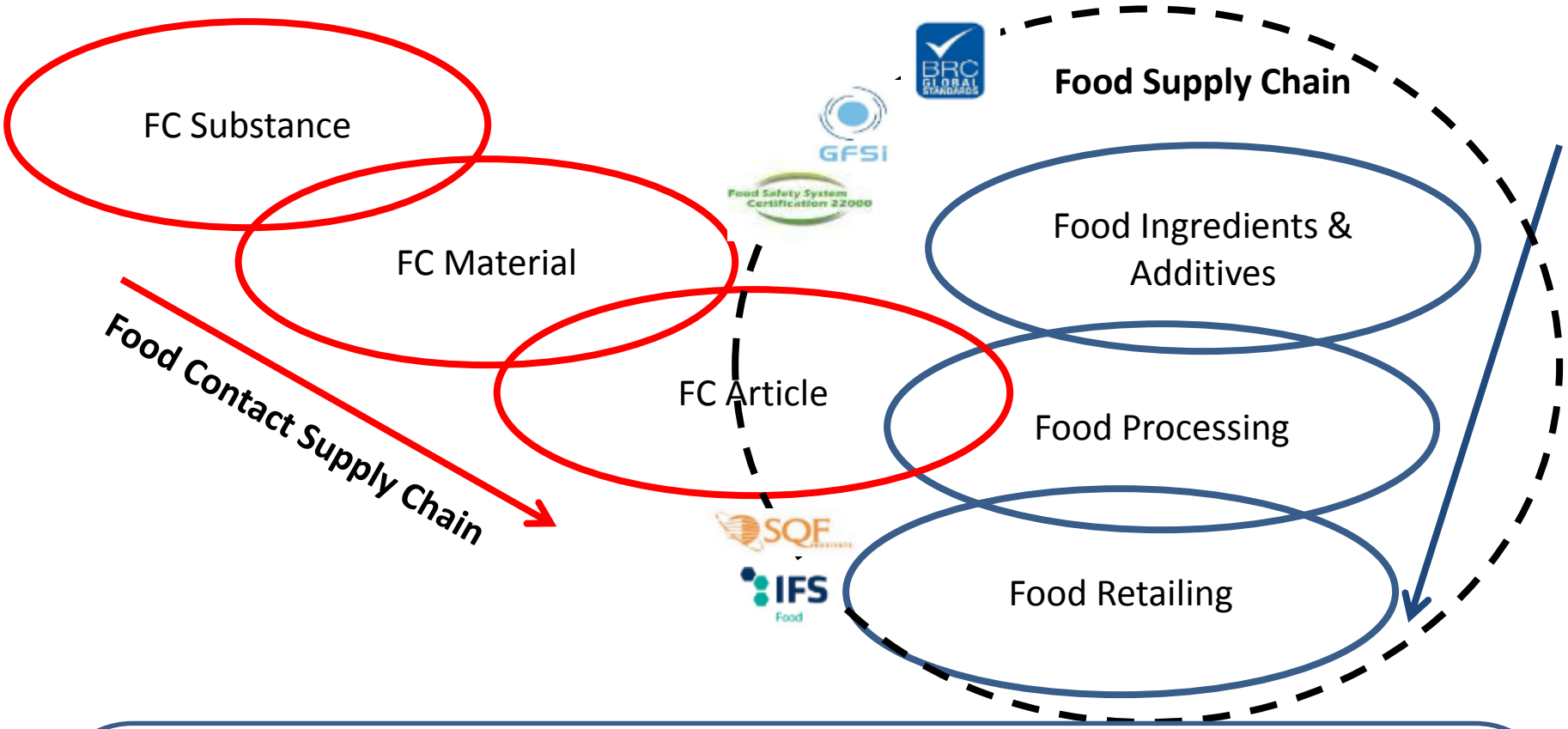
4. Communication has 3 elements: people, process and content

3.1 People



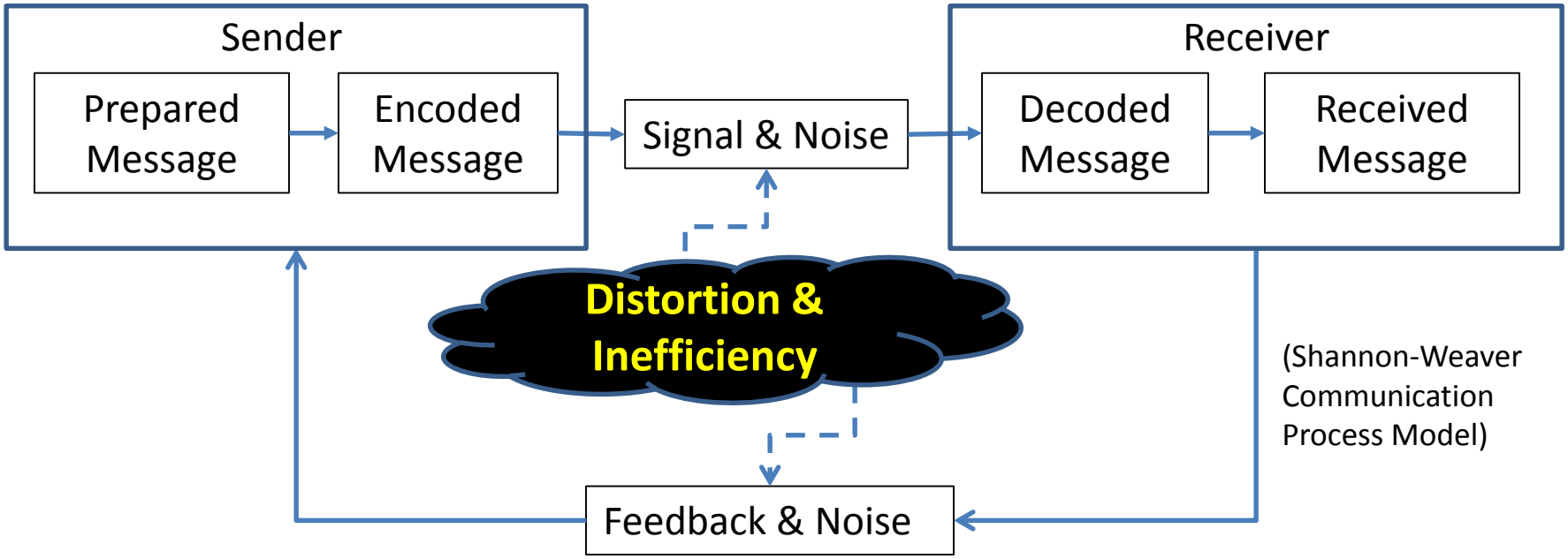
5. Authors may not know the intended audience, or vice versa

3.1 People



6. Food safety auditors are getting more involved in food contact

3.2 Process



(Shannon-Weaver Communication Process Model)

7. Message received is often not the message prepared

3.3 Content		
3.3.1 Semantics	3.3.2 Pragmatics	3.3.3 Syntax

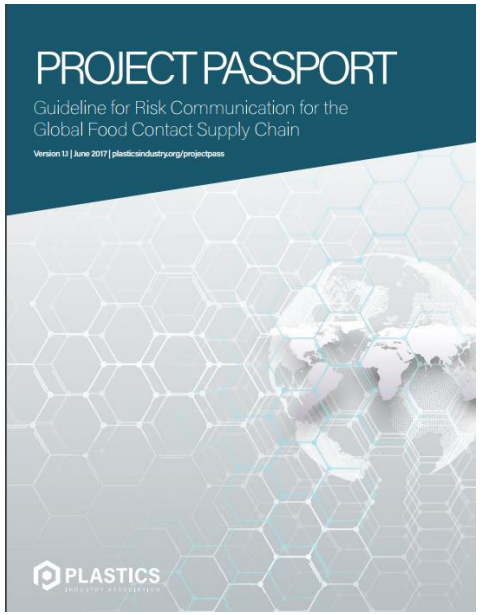
8. Content is a multidimensional linguistic entity:

Semantics – is the text precise and unambiguous?

Pragmatics – is the context defined and understood?

Syntax – is the structure streamlined and consistent?

PROJECT PASSPORT
PROGRAM



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.

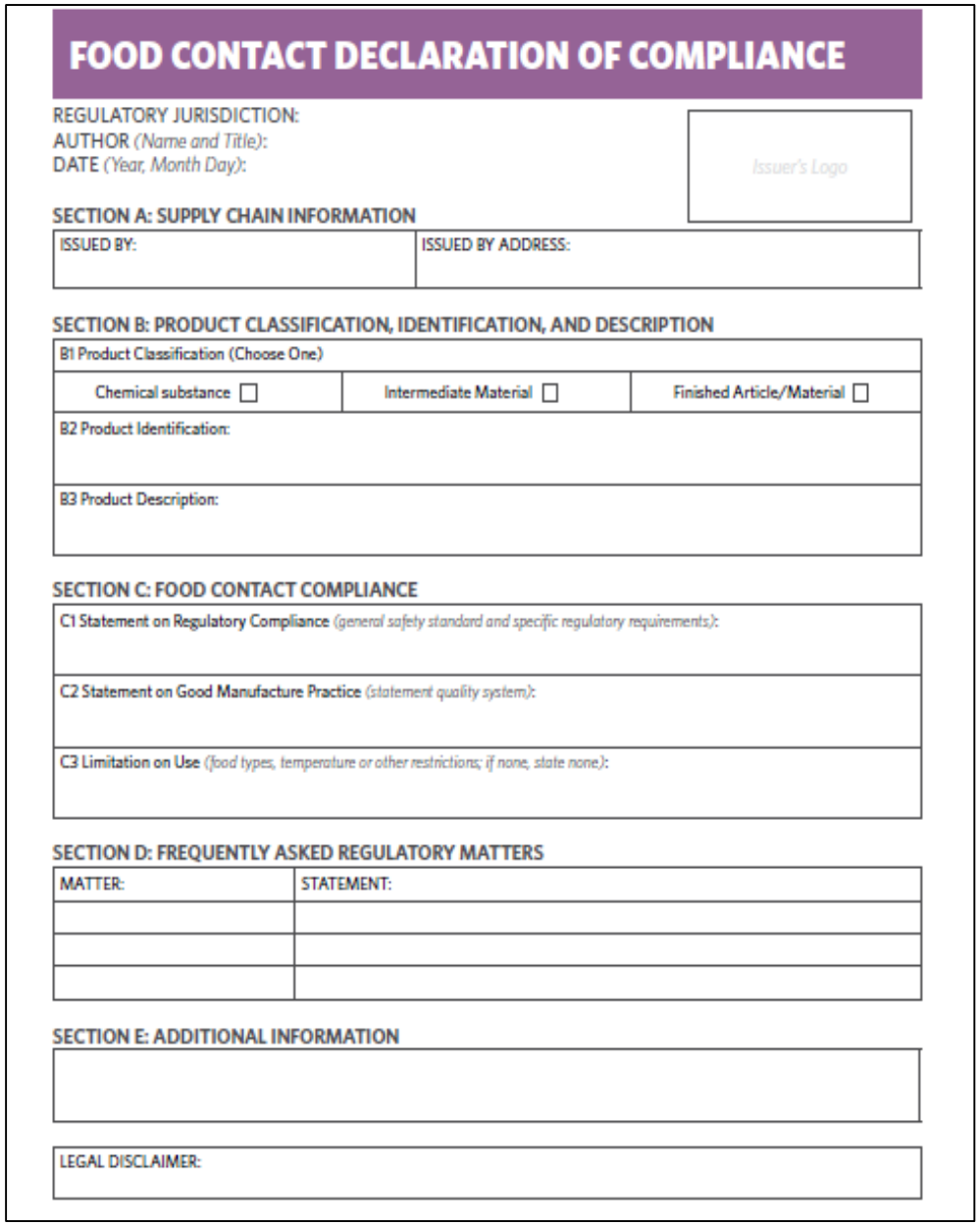
http://www.plasticsindustry.org/projectpass

PROJECT PASSPORT
PROGRAM

Feature 1: Syntax

Organization matters.

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



FOOD CONTACT DECLARATION OF COMPLIANCE

REGULATORY JURISDICTION:
AUTHOR *(Name and Title)*:
DATE *(Year, Month Day)*:

Issuer's Logo

SECTION A: SUPPLY CHAIN INFORMATION

ISSUED BY:	ISSUED BY ADDRESS:

SECTION B: PRODUCT CLASSIFICATION, IDENTIFICATION, AND DESCRIPTION

B1 Product Classification (Choose One)		
Chemical substance ☐	Intermediate Material ☐	Finished Article/Material ☐
B2 Product Identification:		
B3 Product Description:		

SECTION C: FOOD CONTACT COMPLIANCE

C1 Statement on Regulatory Compliance *(general safety standard and specific regulatory requirements)*:
C2 Statement on Good Manufacture Practice *(statement quality system)*:
C3 Limitation on Use *(food types, temperature or other restrictions; if none, state none)*:

SECTION D: FREQUENTLY ASKED REGULATORY MATTERS

MATTER:	STATEMENT:

SECTION E: ADDITIONAL INFORMATION

LEGAL DISCLAIMER:

PROJECT PASSPORT
PROGRAM

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

B1. Product Classification

B1 Product Classification (Choose One)		
Chemical substance ☐	Intermediate Material ☐	Finished Article/Material ☐

Select one of the three options in the supply chain hierarchy to clarify the position in the supply chain: Chemical Substances, Intermediate Material, or Final Article/ Materials. For reference, please confer with the table below:

	Chemical Substance	Intermediate Material	Final Article/Material
Product Marketing	The product is marketed by its chemical identity and its purity profile characteristic to the chemical manufacturing processes.	The product is marketed by its performance attributes derived from its proprietary formulation and/ or manufacturing processes.	This product is manufactured to have a defined shape and surface, and is marketed by its readiness for use in food contact.
Product Readiness	The product requires one or more manufacturing steps in order to be used in contact with food.	The product requires one or more manufacturing steps in order to be used in contact with food.	The product may be used alone or as a component of another final article/ material intended for manufacturing, processing, packing, packaging or holding of food and beverage for consumption.
Product Use and Suitability	As a substance, the product may have end uses other than food contact. Its suitability for food contact use needs to be assessed by the downstream purchaser.	As a material, the product may have end uses other than food contact. Its suitability for food contact use needs to be assessed by the final manufacturer of the article.	As a final article/ material, the product has the specific end use in food contact. Its suitability for food contact is assured by the manufacturer, subject to any applicable limitations on the type(s) of food and the condition(s) of use.
Product Examples	Functional additives, colorants, fillers, etc. (Under US FDA's definition, this may also include polymers.)	Plastic Resins, masterbatches, concentrates, substrates (plastics, foil, paper, etc.), adhesives & coatings, waxes, etc.	Packaging films & bags, bottles & containers, caps & closures, single- or repeat-use plates & cups, utensils & cookware, etc.

PROJECT PASSPORT
PROGRAM

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

C2. The statement on good manufacturing practice

C2 Statement on Good Manufacture Practice

For a product marketed in the US, the following statements have been prepared for possible adoption:

Statement A: Food Contact Article

This product is manufactured in compliance with 21 CFR 174.5, which sets forth the general provisions on good manufacturing practices applicable to indirect food additives. This compliance statement is further based upon the manufacturing facilities' adherence to good manufacturing practices consistent with the Food, Drug and Cosmetic Act as amended. Food processors may use this product to meet their safety and suitability obligations under 21 CFR 110(b)(13)(iii) if the temperature and food type restrictions are observed.

Statement B: Food Contact Substance or Material

This product is manufactured in compliance with 21 CFR 174.5, which sets forth the general provisions on good manufacturing practices applicable to indirect food additives

For a product marketed in the EU, the following statements have been prepared for possible adoption:

Statement C: Food Contact Materials and Articles

This product is manufactured in accordance with relevant requirements in Commission Regulation (EC) 2023/2006, which laid down the good manufacturing practice for materials and articles intended to come in contact with food.

Caution: If a product is not manufactured in accordance with 21 CFR 174.5 or Commission Regulation (EC) 2023/2006, then Food Contact Declaration of Compliance should not be issued. See Quick Guide #8.

PROJECT PASSPORT
PROGRAM

SECTION C: FOOD CONTACT COMPLIANCE

C1 Statement on regulatory compliance
C2 Statement on good manufacture practice
C3 Statement on suitability (food types, temperature or other use restrictions)

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

PROJECT PASSPORT
PROGRAM

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

PROJECT PASSPORT
PROGRAM

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 use 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).

PROJECT PASSPORT
PROGRAM

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

PLASTICS
INDUSTRY ASSOCIATION

1425 K Street NW., Suite 500
Washington, DC 20005

Phone: 202.974.5200
Fax: 202.296.7005

Food Packaging Forum

Workshop – 5 October 2017

Zürich, Switzerland

Thoughts on Packaging Safety Challenges

Jim Huang

Director, Food Contact Materials

Global Scientific & Regulatory Affairs

The Coca-Cola Company

Atlanta, Georgia, USA

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

Food Contact Materials (FCM) & Articles

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

Annex I, Regulation (EC) No. 1935/2004

The Framework Regulation provides the list of groups of materials and articles for food contact.

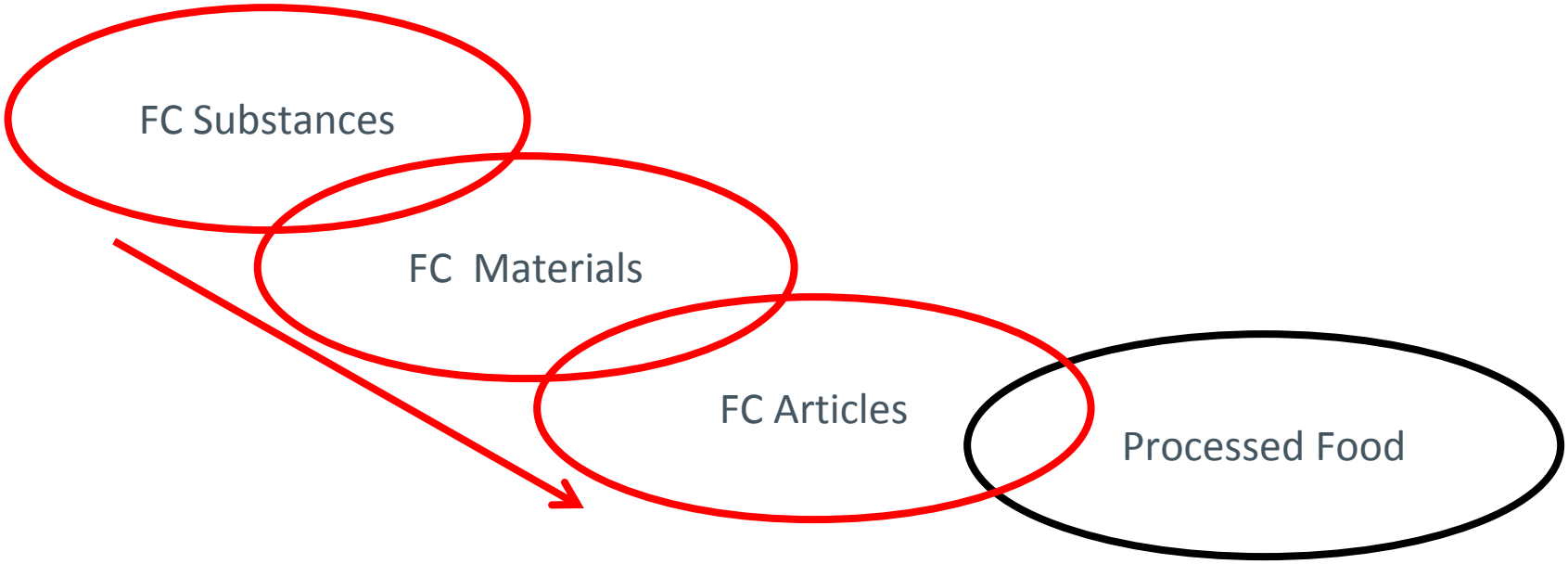
Food Contact Substance (FCS)

Federal Food, Drug, and Cosmetic Act § 409(h)6	
any **substance**	that is **intended for use**
as a component of **materials**	used in
manufacturing, packing, **packaging**, transporting, or **holding food**	if such use
of the substance	is not **intended to have**
any technical effect in **such food**	[as consumed]

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)**

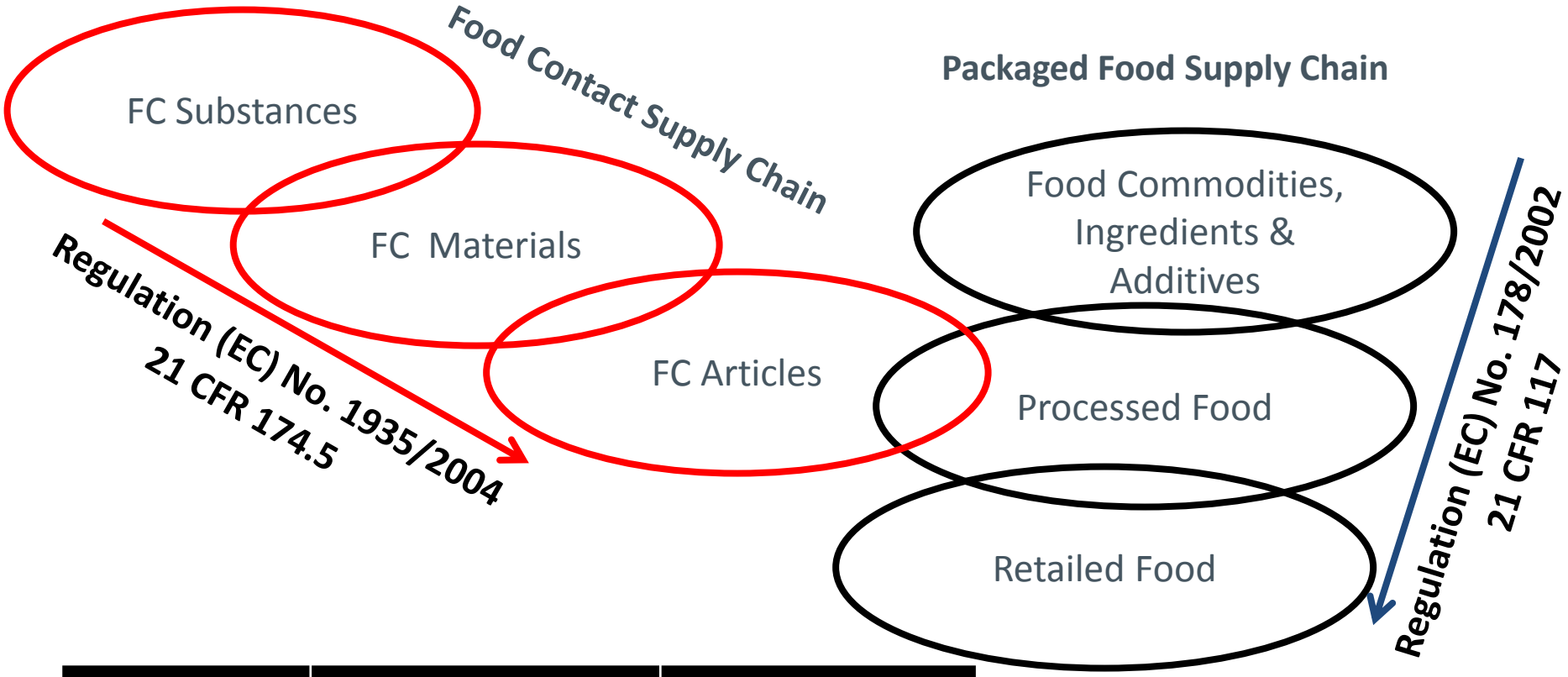
Packaging Supply Chain



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**

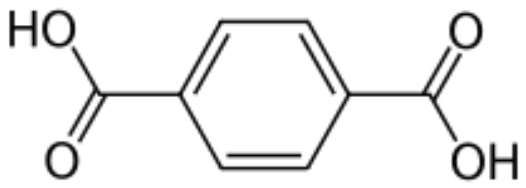
Food Contact vs. Packaged Food



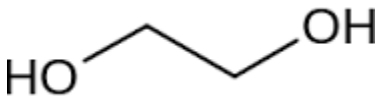
	Food Contact	Packaged Food
Supply Chain	Petrochemical & Mineral	Agricultural
Major Disciplines	Toxicology Chemistry Materials Science Chemical Engineering	Toxicology Nutrition Food Science Microbiology

An example: "S-PET"

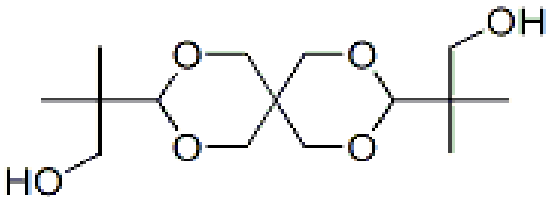
(Spiroglycol-modified polyethylene terephthalate)



Terephthalic acid, TPA



Ethylene glycol, EG



Spiro glycol, SPG

ALTESTER Copolyester

Product Description

ALTESTER is amorphous copolyester with excellent appearance and clarity. Its most outstanding features are excellent hydrolytic stability, and heat resistance.

Key Attributes

(1) Good heat resistance
(2) Excellent clarity
(3) Lower specific Gravity.
(4) Ease of processing

(5) Excellent hydrolytic stability

Applications

Injection Molding
Blow Molding
Extrusion Molding

Typical Properties of ALTESTER

		ALTESTER S2000	ALTESTER S3000	ALTESTER S4500	PET	PET-G
Specific Gravity	g/cm³	1.28	1.27	1.24	1.34	1.27
Tg	℃	95	100	110	82	83
Flexural Yield Strength	MPa	90	92	96	85	70
Flexural Modulus	GPa	2.5	2.5	2.5	2.2	2.1
Elongation @ Break	%	220	200	140	250	130
Izod Impact Strength, Notched	J/m	25	25	24	20	100
Total Transmittance	%	91	91	91	90	91
Haze	%	1	1	1	5	1

MITSUBISHI GAS CHEMICAL COMPANY, INC.
Mitsubishi Building, 5-2,Marunouchi 2-chome Chiyoda-ku,
Tokyo 100-8324, Japan
TEL : +81-3-3283-4902 FAX : +81-3-3214-0930

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

β,β,β',β',-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.

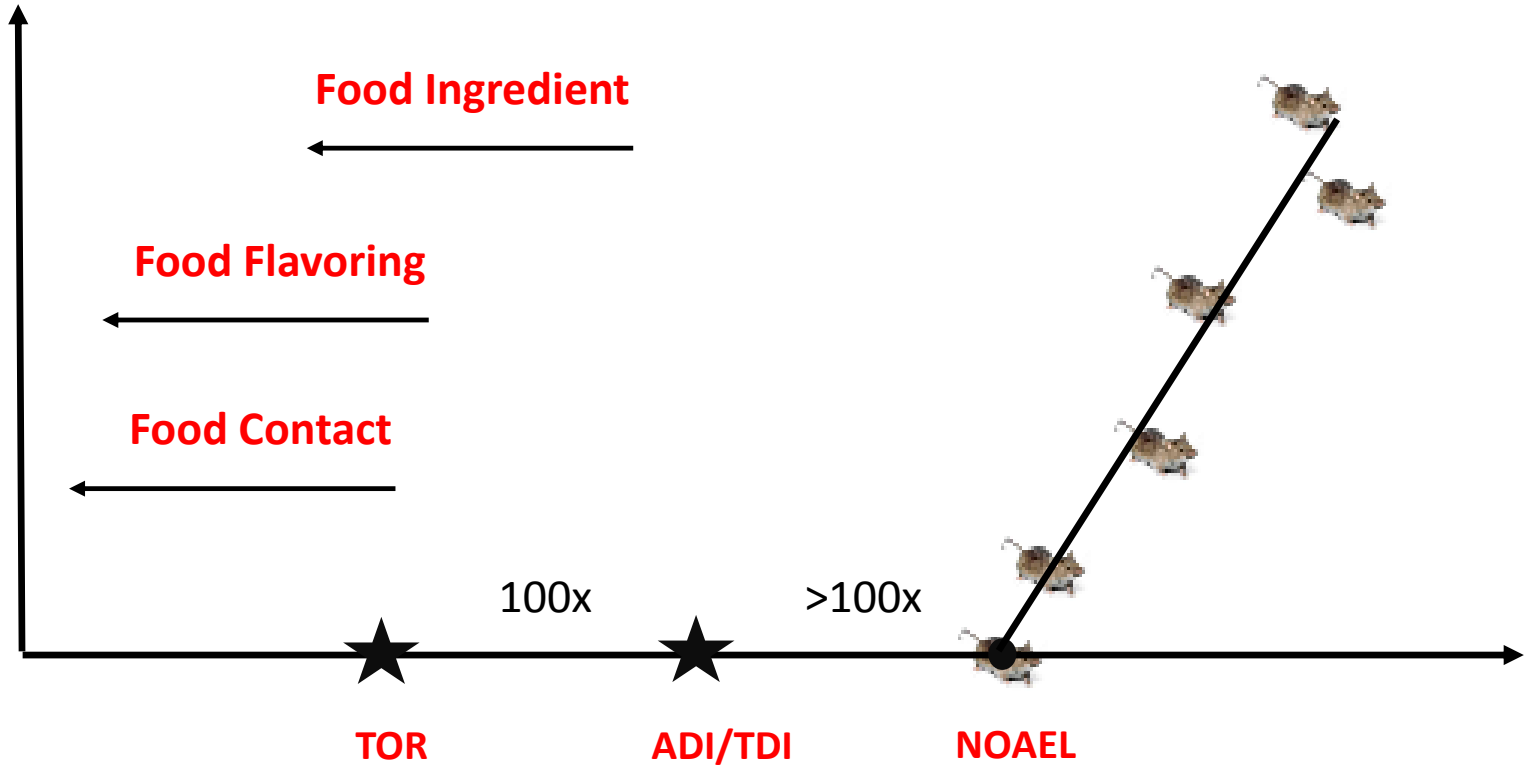
Summary

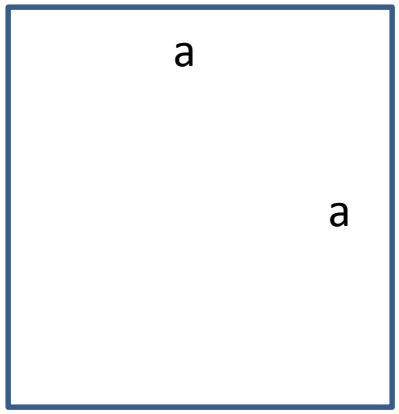
1. Both the US and the EU authorities have determined the same polymer to be safe for food contact, and both have laid down safety parameters for compliance purposes.

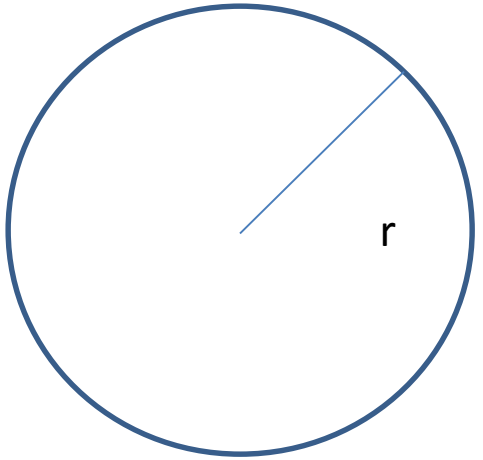
2. The parameters used to establish safety are distinct from one another, and harmonizing the requirements is not possible since the approaches are different.

    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







$$A_1 = a^2$$

$$A_2 = \pi r^2$$

$$A_1 = A_2$$

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

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

$\sqrt{\pi}$ = 1.772453850905516027298167483341…….

$\frac{1}{\sqrt{\pi}}$ = 0.564189583547756286948079451560 7…….

10^{-9}

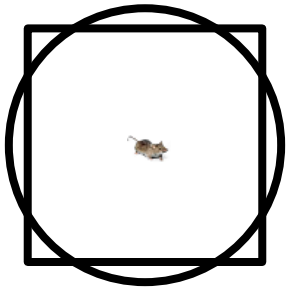
Observation

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

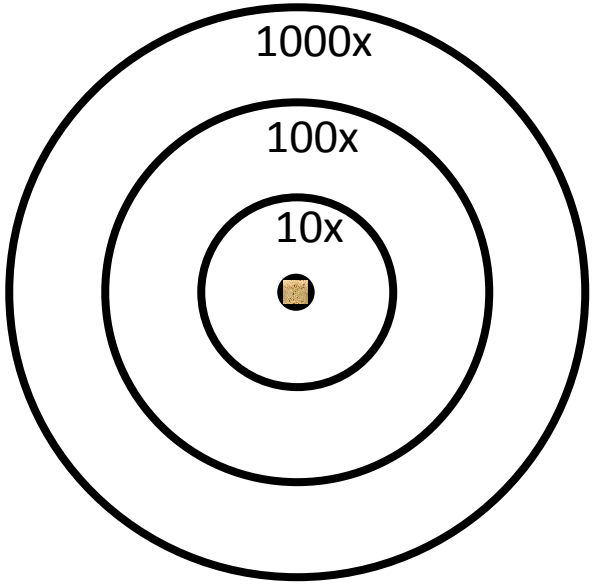
2. The parameters used to establish safety are distinct from one another, and harmonizing the requirements is not possible since the approaches are different

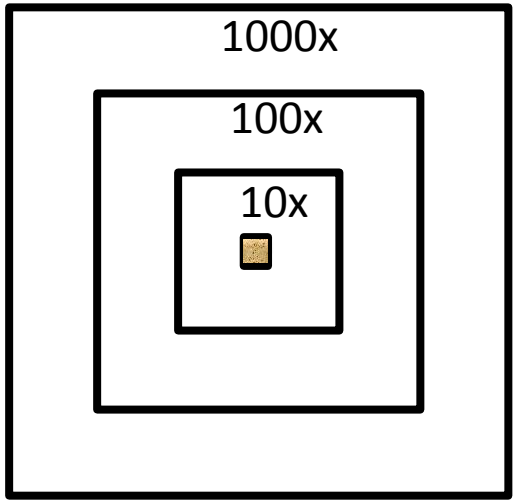
    1. **EU – *a posteriori* chromatography (migrations of monomer and of oligomers)**
    2. **US – *a priori* stoichiometry (% of glycol units) & physical dimension**

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



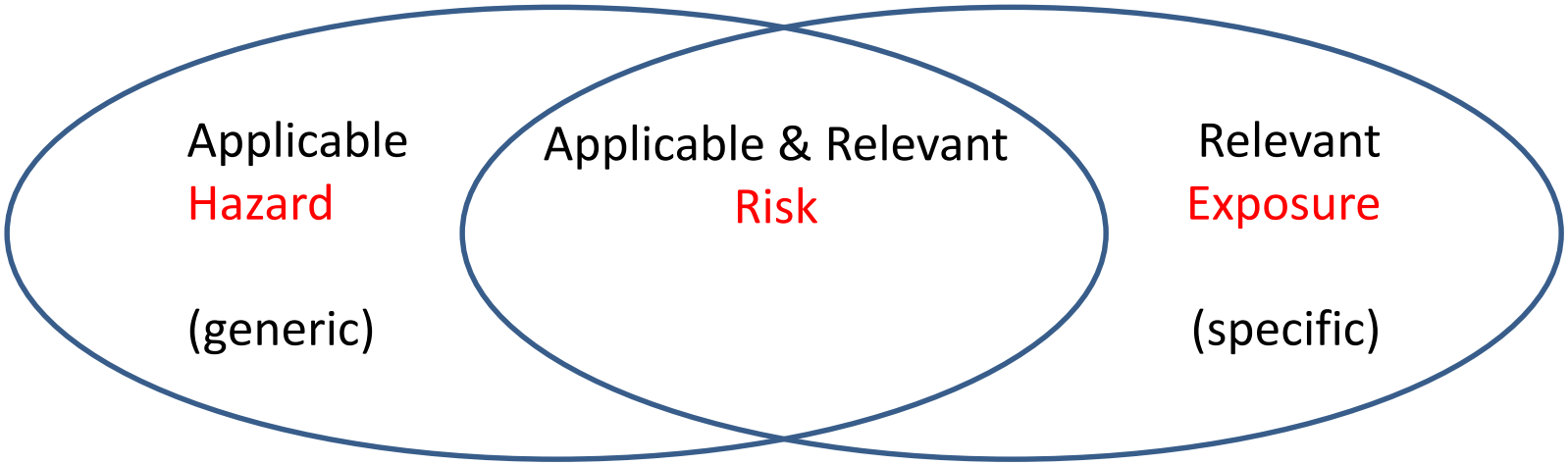
Question #1: Which is more protective?





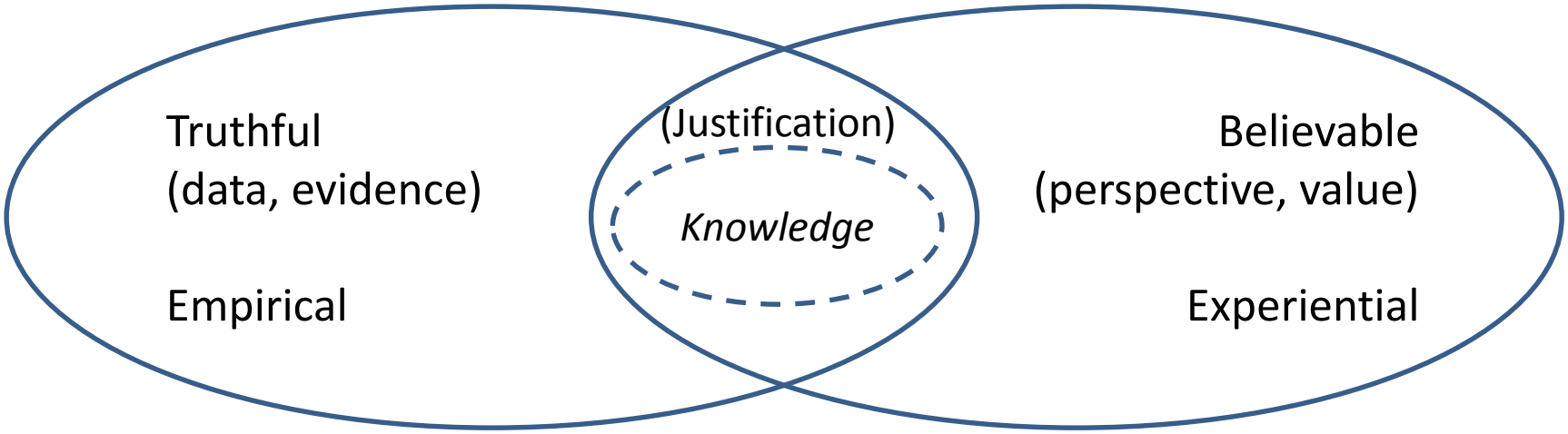
Can we communicate safety in a way that transcends political borders?

Question #2: What is more helpful?



Can we communicate the message with clarity *and* empathy?

Question #3: What is more effective?



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