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CONTRACT PACKAGERS & MANUFACTURERS

# Food Contact Packaging Materials Regulation in a Nutshell

## A Webinar for CoMans and CoPacks, Their Suppliers, and Brands

**Wednesday, July 15, 2026**
**(2:00 PM - 3:00 PM) (EDT)**

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# Service, Solutions, Sustainability

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- Encourage the effective use of contract packaging services via innovation and flexibility
- Increase the industry profile, capabilities, innovation of its members


# MORE Leading CP/CMs are CPA Members

- **MORE RFQ**

**OVER 90**
**RFQ / MONTH**
**2018 Avg**

- **MORE growth**

**11.9% CAGR**
**5-year**

- **MORE networking** opportunities with hundreds of industry executives

**UP TO TEN**
**EVENTS**
**per year**

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[1] Summarize the basics of how food contact packaging materials are regulated

[2] Review the role of FDA compliance guarantees from suppliers and discuss how to read and improve them

[3] Discuss potential new legal changes about substances deemed Generally Recognized As Safe

# Eric F. Greenberg, P.C.

**Food and Drug Law**
**Packaging Law**
**Commercial Litigation**

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Our lawyers advise and represent food, drug, cosmetic and medical device manufacturers, and packaging manufacturers, converters and designers in all aspects of regulatory compliance and defense.

*The Eric F. Greenberg, P.C. firm is honored to be ranked in the prestigious*
***2026 Chambers Illinois Spotlight Guide for Food & Beverages: Chicago***

Our firm is a proud member of the *International Network of Boutique Law Firms.*

A Chicago-based law firm serving clients worldwide.

**www.ericfgreenbergpc.com**

**Eric F. Greenberg**
**Attorney**

Eric concentrates his practice in food and drug law, packaging law, and commercial litigation. His food and drug work has included regulatory counselling, new product development, negotiation with the U.S. Food and Drug Administration on numerous levels, handling recalls, and defending enforcement actions.

His packaging work includes legal representation for members of the packaging industry and acting as counsel to a wide range of consumer product companies, packaging manufacturers, package design firms, and others on regulatory and labelling requirements, and handles related contractual and litigation matters.

Eric is a member of the California Polytechnic State University, San Luis Obispo, where he teaches Packaging Laws and Regulations. He is a frequent speaker at industry conferences and seminars.

He serves as Legal Editor and monthly columnist for *Packaging World*.

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# Key Concepts

- FDA law defines food additives as a type of food.
- FDA law considers packaging materials that contact food to be food additives, unless they are GRAS or otherwise exempt.
- Food additives have to be used in a way that is consistent with their clearance for use.
- If they are used in a way that is not consistent with their clearance for use, the food they contact is “adulterated,” that is, unlawful.

# Key Definitions

Adulterated food =

Bears or contains an unsafe food additive

(defined as an additive, including a food contact material, that is used not in accordance with its clearances).

21 USC 342(a)(2)

# “Prohibited Acts” Federal Food, Drug and Cosmetic Act Sec. 301

- The law prohibits the introduction into interstate commerce of a food that is adulterated.
- Also the adulteration of food;
- Also the causing of adulteration;
- Also the receipt of, or delivery for introduction into commerce of, adulterated food.

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# Penalties for Prohibited Acts

Committing a “Prohibited Act” can subject companies and individuals to:

- Warning Letters
- Seizure
- Injunction
- Criminal Prosecution (jail and fines)
- Recall
- Detention of food
- Suspended registration
- Import Alert

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# To be compliant with FDA requirements, a use of a food contact material has to…

- Be consistent with one or another basis for clearance of its use;
- Not impart off-odor or taste or render the food otherwise unfit as food; and
- Be used in accordance with Good Manufacturing Practices (GMPs), meaning it’s of suitable purity and you’re not using more than necessary.

Food Additive

- Food Additive Petition
- Food Contact Notification (for Food Contact Substances)

Generally Recognized As Safe
(General Recognition of Safety)

Prior Sanction

Not a Component of Food

Threshold of Regulation

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# REMEMBER

- Food Additive regulations in the Code of Federal Regulations, Food Contact Notifications, GRAS Substances, Prior Sanctioned substances and Threshold of Regulation clearances ALL are subject to conditions and limits
- It's better to think of an approval of a USE of a substance rather than approval of a substance
- Conditions and limits can be on: amount of substance, foods it is used in, conditions of use.

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# To be compliant with FDA requirements, a use of a food contact material has to…

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- Not impart off-odor, taste or render the food otherwise unfit as food; and
- Be used in accordance with Good Manufacturing Practices (GMPs), meaning it’s of suitable purity and you’re not using more than necessary.

**SO… it’s wise to take some steps to make sure these things are true.**

Food Additive

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# General Recognition of Safety

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# General Recognition of Safety

Establish GRAS status through either

scientific procedures, *or*
common use in food before 1958.

GRAS substances are both

(1) demonstrably safe, *and*

(2) recognized as such by the relevant scientific community.

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# WHY GRAS MATTERS

**Because very low exposure levels to food contact materials are commonly and regularly considered GRAS by companies making, using or selling the materials.**

# GRAS ‘system’ has been….

….criticized in recent years and some movement has taken place to change it.

Recently, food packaging materials were the target of specific, potentially very troublesome proposals.

*MORE LATER*

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# Fundamentals of Product Stewardship

How to translate all this regulatory doctrine into everyday practice?

After all, you're not going to be seeking new approvals every day, but you do have to continuously assure that your products are compliant and deal with customer demands for information and guarantees and representations.

FDA food contact compliance is commonly only one of a long list of subjects of guarantees and representations.

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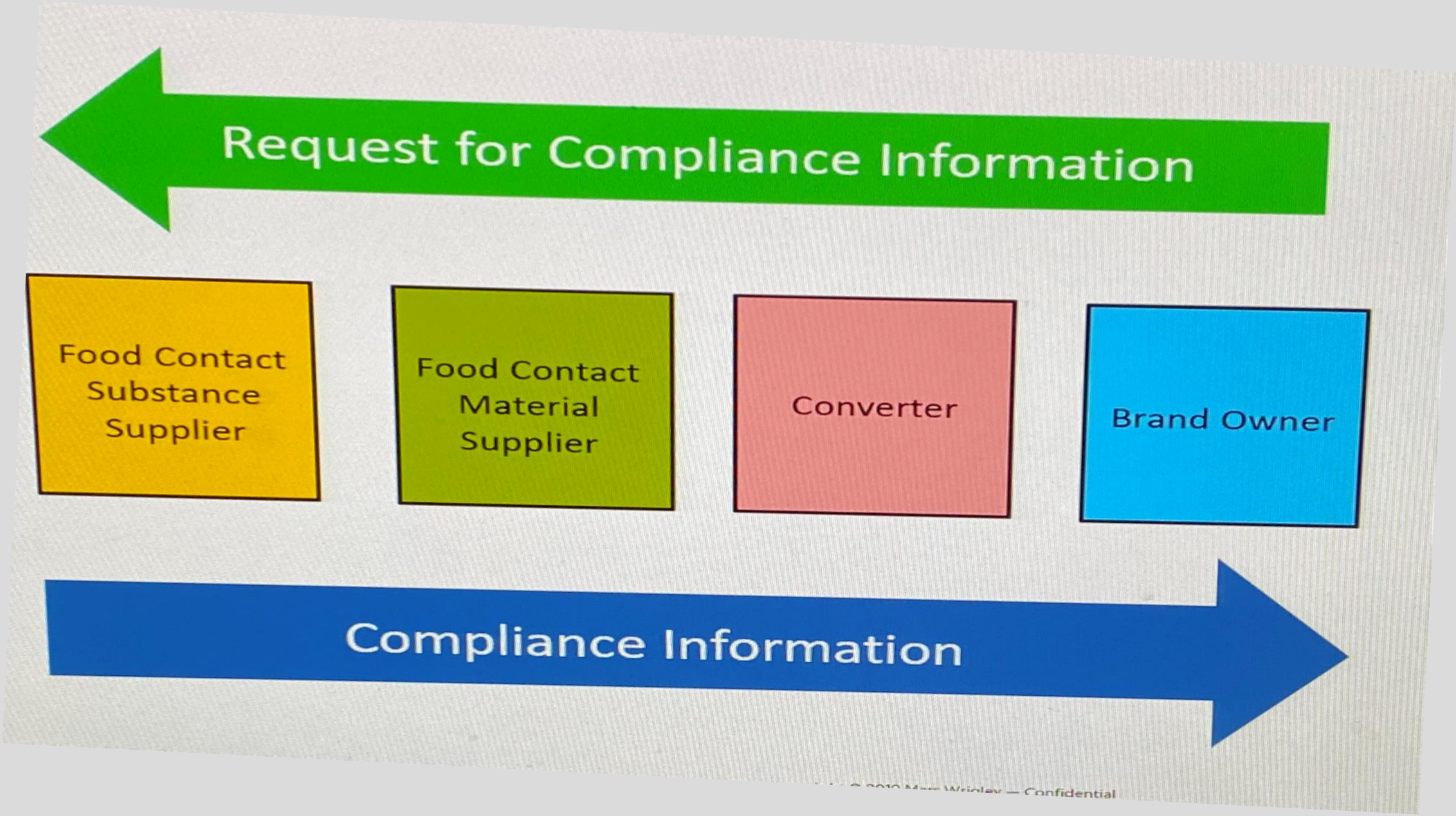
Request for Compliance Information
Food Contact Substance Supplier
Food Contact Material Supplier
Converter
Brand Owner
Compliance Information

# Some common topics of product stewardship guarantees or representations

1. FDA food contact compliance
2. CONEG Model Toxics law heavy metals (100 ppm limit on 4 heavy metals), and PFAS and Phthalates
3. Proposition 65 (carcinogens, reproductive toxins)
4. Bisphenol A
5. Dioxins
6. Natural rubber latex

…

# Some common topics of product stewardship representations CONT'd

7. Endocrine disruptors
8. Foreign requirements
9. Private standards requirements
10. Clean air act compliance at your facility
11. 'Sustainable' facility
12. Worker fairness
13. Support for Chicago Cubs
14. Etc……

# For each topic in product stewardship…

- You need to know WHY it's being asked about, and
- You need to know what the end-point is (Not present? Not present above a certain level? Not expected to migrate? Etc.)

# So, for example,

For many many individual substances, the specific question you will be asked is whether they are present at all in your materials.

# But, for example,

For **Proposition 65**

- You might be asked to promise no listed chemicals are added by you
- You might be asked to promise no listed chemicals are present
- You might be asked to promise no listed chemicals are present at levels that trigger the requirement of a Proposition 65 warning

# So, for example,

For **CONEG Model Toxics** legislation

- You might be asked to confirm that you don't use heavy metals*
- You probably will be asked to confirm that there are

  no more than 100 ppm of heavy metals in your material
- You might be asked if there

  - Are phthalates in your product, [A model state law, adopted in many states, prohibits packages or components with intentionally added phthalates (and no more than 100 ppm present)]

  - Are PFAS in your product [New model state law prohibits them from being intentionally added and must be NON-DETECT]

* Lead, cadmium, mercury, hexavalent chromium

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As for the FDA food contact compliance of packaging materials:

- Do you understand what supplier representations and guarantees say?
- Are you comfortable simply accepting supplier representations or guarantees, or do you want to know more, or even do more, to assure the food contact material's compliance?

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# Some examples of guarantee letters of varying quality…

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World's Finest Chemical Company
1 World's Finest Chemical Way, Chemtown, USA
(888)555-CHEM

**RE: Declaration of Compliance for FREPTOVIA**

To Whom it May Concern,

We hereby certify that FREPTOVIA complies with all laws.

Best regards,

World's Finest Chemical Company

World's Finest Chemical Company
1 World's Finest Chemical Way, Chemtown, USA
(888)555-CHEM

September 2, 2015

Mr. Chris Customer
Customer, Inc.
1 Customer Drive
Customerville, USA

**RE: Declaration of Compliance for FREPTOVIA**

Dear Mr. Customer,

We hereby certify that the FREPTOVIA that we supply to you complies with all U.S. laws governing food contact materials.

Best regards,

World's Finest Chemical Company

World's Finest Chemical Company
1 World's Finest Chemical Way, Chemtown, USA
(888)555-CHEM

September 2, 2015

Mr. Chris Customer
Customer, Inc.
1 Customer Drive
Customerville, USA

RE: Declaration of Compliance for FREPTOVIA

Dear Mr. Customer,

We hereby certify that the FREPTOVIA that we supply to you complies with FDA requirements about food contact materials, specifically 21 CFR Section 177.1520 Olefin polymers.

Best regards,

World's Finest Chemical Company

# “Best” example…



World’s Finest Chemical Company
1 World’s Finest Chemical Way, Chemtown, USA
(888)555-CHEM

September 2, 2015

Mr. Chris Customer
Customer, Inc.
1 Customer Drive
Customerville, USA

**RE: Declaration of Compliance for FREPTOVIA**

Dear Mr. Customer,

We hereby certify that the FREPTOVIA that we supply to you is a polypropylene that complies with FDA requirements about food contact materials, specifically 21 CFR Section 177.1520 (a)(1)(i), (b) and (c)(1.1a), provided it is used in accordance with cGMPs. As such, it can be used in contact with all food types under Conditions of Use A [High temperature heat-sterilized (e.g., over 212 deg.F)] through Condition of Use G [Frozen storage (no thermal treatment in the container)] as described in 21 CFR 176.170, Table 2.

**Heavy Metals**

This product is not intentionally formulated with heavy metals. Residuals that may be detected are expected to be less than 100 PPM total lead, cadmium, hexavalent chromium and mercury.

**California Proposition 65 ((Safe Drinking Water and Toxic Enforcement Act of 1986)**

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute.

**Bisphenol A**

This product is not manufactured or formulated with Bisphenol A (CAS# 80-05-7).

**Gluten**

This product is not intentionally manufactured or formulated with gluten; however, we do not analyze for these specific substances or compounds.

**Consumer Product Safety Improvement Act of 2008 (CPSIA)**

This product is not formulated with antimony, arsenic, barium, cadmium, chromium, mercury, lead or selenium. To the best of our knowledge, it does not contain these substances above the limits set in ASTM F 963-95, Section 4.3.5.2., Table 1.

**Food Allergens**

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish, tree nuts, mustard, celery, sesame, and/or wheat or gluten. No sulfates or sulfites are used in the synthesis of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this claim.

**Materials from Genetically Modified Organisms**

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO). This statement is based on information from our suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee this claim.

**Kosher**

One or more of the raw materials used in the manufacture of this product originated in whole or in part from animal sources. The animal sourced raw material(s) have been chemically altered from their original structure and have undergone significant chemical processing, and is/are therefore considered synthetic. Because of this modification and processing, kosher compliance is claimed for the above product containing the raw material(s) of animal origin.

**Phthalates**

This product is not intentionally manufactured or formulated phthalate substances; however, we do not analyze for these specific substances.

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# WHY GRAS MATTERS

**Because very low exposure levels to food contact materials are commonly and regularly considered GRAS by companies making, using or selling the materials.**

# General Recognition of Safety

There is no legal obligation to get FDA approval of a use of a substance on the ground that it is GRAS, and you don't even need to notify them

Some objections to that arrangement include:

- Lack of FDA knowledge
- No standards for quality of GRAS conclusion
- No standards for GRAS experts' conflicts of interest
  *NOW there are: Best Practices guidance*
- No real program for evaluations once substances are in the marketplace
- Special safety concerns about "nanomaterials." Are they GRAS if traditional form is GRAS?

# Current US Legal Issues

There is a proposed new federal law re GRAS substances, likely to require reporting of uses of substances based on independent GRAS, and possibly FDA approval

- Meanwhile, New York State law, awaiting governor's signature, would require such reporting, other states could follow
- Efforts underway to support federal changes that would preempt any state's laws
- New group, Food Contact Coalition, formed by former FDA-er Paul Honigfort and his new employer, Coca-Cola, to advocate for packaging within the GRAS efforts

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# Thank You!

# QUESTIONS?

contractpackaging.org