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Food Packaging and Labeling: Crucial, Controversial, and Changing

Chicago Section IFT

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Ignite Glass Studios 401 N Armour St., Chicago, IL 60642

Eric F. Greenberg, P.C.

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



ERIC F. GREENBERG, P.C.
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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.



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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.

Cornell Law School, 1983
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**Food Packaging and Labeling:
Crucial, Controversial, and Changing**

Food Packaging and Labeling

AGENDA

FOOD PACKAGING

Emerging new legal pressures on packaging as such and food contact materials:

- Slack Fill
- Environmental Label Claims
- Plastics bans
- Proposed packaging labeling
- GRAS controversy – re ingredients and packaging materials

FOOD LABELING

Most important current food labeling controversies:

- Nutrition Facts
- ‘Natural’ and other claims: Regulators & Class Actions
- ‘Clean Label’

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FOOD PACKAGING

Emerging new legal pressures on packaging as such and food contact materials:

- Slack Fill

Slack Fill

Slack fill = empty space inside a package

Sometimes it's considered misleading to consumers, if container that does not allow the consumer to fully view its contents and there's no 'function' for the empty space.

Slack fill class-action lawsuits -- state-law-based cases alleging misleading packaging due to slack fill -- have become something of a cottage industry in recent years.





Original 4oz Pepper Tin

3oz of pepper in
Original 4oz Tin

3oz of pepper in
Original 4oz Tin



‘Non-functional’ is bad.

Functional (that is, OK) – per FDA – if needed for:

- the **protection** of the contents of the package;
- the **requirements of the machines** used to enclose the contents in the package;
- **settling** during shipping and handling;
- the need for the package to perform a **specific function**;
- the food is packaged in a **reusable container** with empty space as **part of the presentation** of the food; or
- inability to increase the fill level or reduce the package size because, for example, the size is **necessary to accommodate food labeling requirements or discourage theft**.

A slack fill tale



Class action case against
Mondelez International, Inc.
re
SOUR PATCH
WATERMELON CANDY



Plaintiff alleged that the company filled boxes of its Sour Patch Watermelon Candy with only enough candy to fill about half of the box, thereby misleading consumers

Alleged violation of a New York State consumer protection law.

Mondelez said that the box isn't misleading because consumers "can plainly feel and hear the existence of empty space in the box upon reasonable inspection." (The candy boxes were closed and opaque.)



Mondelez made the argument that the box wasn't misleading because the quantity of contents was properly revealed on the label, and pointed the court to earlier decisions under California law that found that "food packaging cannot be materially misleading so long as it displays the net weight and lists the number of pieces inside the package."



The court rejected that argument, saying that its interpretation was that a company had 2 separate legal obligations, first, to label the contents accurately and second, to package products in a non-misleading way.



The court quoted FDA as saying that “to rule that an accurate net weight statement protects against misleading fill would render the prohibition against misleading fill...redundant.”

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- Environmental Label Claims



Q: Which regulatory agency issued guidelines about making environmental claims on labels, in advertising and other promotional materials?

A: Environmental Protection Agency?

Q: Which regulatory agency issued guidelines about making environmental claims on labels in advertising and other promotional materials?

~~A: Environmental Protection Agency?~~

A: The **Federal Trade Commission**, which regulates trade and tries to protect consumers against deceptive and false business practices.



Green Guides address...

- General Environmental Benefit Claims
- Carbon Offsets
- Certifications and Seals of Approval
- Compostable Claims
- Degradable Claims
- Free-Of Claims
- Non-Toxic Claims
- Ozone-Safe and Ozone-Friendly Claims
- Recyclable Claims
- Recycled Content Claims
- Refillable Claims
- Renewable Energy Claims
- Renewable Materials Claims
- Source Reduction Claims

Green Guides dodge...

“natural” claims

“organic” claims

“sustainability” claims



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Green Guides dodge...

“natural” claims

“organic” claims

“sustainability” claims



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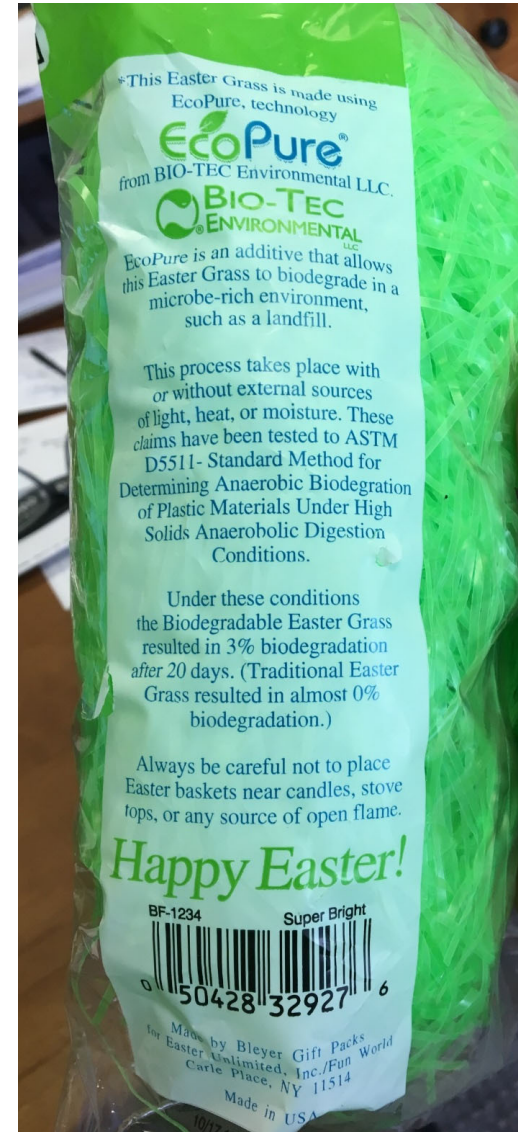
Advice about environmental claims:

You actually have a rather good amount of freedom to word your claims, but

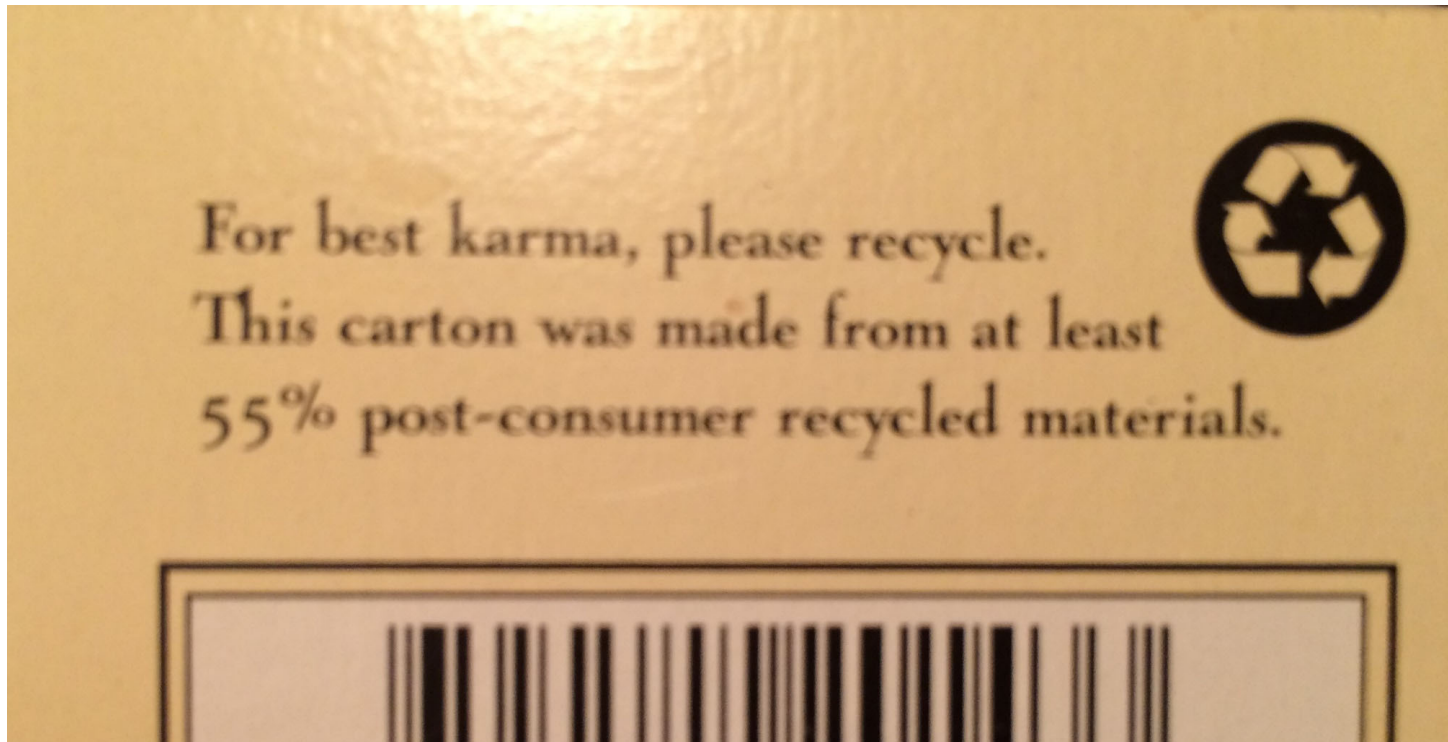
remember that implied as well as explicit claims are expected to meet the regs and guidance.

Often, wordier claims are better than short ones or symbols from the point of view of regulatory compliance...

...because it's easier to substantiate a very specific claim than a broad one.



An example of a company taking advantage of the available flexibility



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FOOD PACKAGING

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- Slack Fill
- Environmental Label Claims
- **Plastics bans**

The ground has shifted, in a bad way



ERIC F. GREENBERG ATTORNEY-AT-LAW

If anyone asks you in the next few months what the big new legal trend affecting packaging is, I suggest you tell them it's the "Worldwide Plastics Smackdown." Say it like that and they'll be certain to remember what you said. That kind of attention and vigilance on the packaging industry's part could be necessary in years to come.

Plastic articles, from any single-use item to drinking straws, have rather quickly become the subject of a proliferation of adverse new laws and company policies.

Many people probably heard of Starbucks' decision to stop using drinking straws, but that high-profile private action helped bring wider attention to a pattern that had already emerged in which governments and companies are moving away from plastics. A common motivation appears to be the problem of plastic ocean debris.

Bans on packaging materials or articles are virtually always misguided, simply because it is just about never true that a specific packaging material or structure is all bad, or so bad that the bad outweighs the good. This being real life, after all, materials and structures typically carry both advantages and disadvantages.

Bans are sort of the death penalty for a material or a product. Taxes and restrictions on materials or products are more like prison sentences, that is, part-way measures intended to reduce usage but stopping short of complete bans. But they can certainly hurt, too, and should only be imposed if the facts clearly justify such actions.

For decades, the debate over environmental issues and packaging has led to frustration for packaging makers and users, primarily because the public sees packaging after its useful life and thinks of it as waste, giving little if any thought to that useful life. Packagers know that consumer product packaging provides multiple benefits at once, including safety, efficiency, convenience, communication, marketing, and no doubt others. They also know that consciousness about environmental issues, and in some cases, legal strictures, have led packaging makers and converters to adopt enormous improvements in recyclability, recycled content, degradability, source reduction and safety of packaging. Far from being resistant to these pressures, the packaging industry overall has responded with dramatic changes and improvements.

Right now, though, single-use plastics appear to be a primary target of legislators in many different locations. Examples abound and are quickly gaining higher profile. Here are some:

- Seattle recently banned single-use plastic straws and utensils, except if needed for medical reasons. Recyclable straws for dine-in or takeout meals are OK. (They banned many uses of expanded polystyrene back in 2009.)

- Malibu, CA, now prohibits retail stores and restaurants from using single-use plastic straws, stirrers, and cutlery (and it banned expanded polystyrene, too, starting back in 2005, broadening the prohibition to items including packaging materials, meat and fish trays, egg cartons,

and shipping containers unless compostable or recyclable.)

- Plastic carryout bag bans have popped up in many localities, including the entire State of California, as of late 2016. The state's law calls for groceries and other food stores, pharmacies, convenience stores, and liquor stores to provide reusable or recycled paper bags and charge at least 10 cents for them.

The plastics industry's big trade group, the Plastics Industry Association, has, not surprisingly, got a lot to say on these topics. While the group agrees that debris in the oceans is a real issue that needs to be addressed, it says it's essentially a problem of plastics entering the marine environment, not a problem of the plastics as such, and calls for "additional focus on recycling, advances in waste management, energy recovery and non-mechanical recycling technologies."

The plastics group calls for more "investment in a new generation of waste management solutions, especially in China and other countries who have been the primary processors of scrap plastic recycling, make significant policy changes that require the U.S. to make new investments."

United Nations Environment, which coordinates the United Nations' environmental activities "assisting developing countries in implementing environmentally sound policies and practices," issued a report in June, called "Single-Use Plastics, A Roadmap for Sustainability."

The 104-page report begins by acknowledging that "Plastic is a miracle material," but asserts that "Plastic packaging accounts for nearly half of all plastic waste globally."

The report says, "More than 60 countries have introduced bans and levies to curb single-use plastic waste" and contains a survey of actions that governments around the world have taken against plastics. The report says, "The most common single-use plastics found in the environment are, in order of magnitude, cigarette butts, plastic drinking bottles, plastic bottle caps, food wrappers, plastic grocery bags, plastic lids, straws and stirrers, other types of plastic bags, and foam take-away containers."

The organization says, "Plastic bag bans, if properly planned and enforced, can effectively counter one of the causes of plastic overuse," but they'd also like to see governments address causes by improving "waste management practices and introduce financial incentives to change the habits of consumers, retailers and manufacturers, enacting strong policies that push for a more circular model of design and production of plastics. They must finance more research and development of alternative materials, raise awareness among consumers, fund innovation, ensure plastic products are properly labelled and carefully weigh possible solutions to the current crisis."

In short, there seems to be increasing momentum in the direction of opposition to plastics products, world-wide. All packagers would be well-advised to stay alert and get involved in these public policy debates in order to minimize misguided measures. **PIW**

Eric Greenberg can be reached at greenberg@efg-law.com, or visit his firm's Web site at www.ericfgreenbergpc.com.

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- Proposed packaging labeling

August 2016

A proposal to require food makers to put the names of the “packaging ingredients” used to make their packaging ON THE FOOD LABEL

WHAT'S IN THE PACKAGE?

Unveiling the Toxic Secrets of Food and Beverage Packaging



A REPORT BY CLEAN WATER ACTION AND CLEAN WATER FUND • AUGUST 2016



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GRAS = Generally Recognized As Safe

WHY GRAS MATTERS

Because GRAS is the status many ingredients and even food contact materials have that makes them lawful in food.

GRAS is....

(1) Safety,

PLUS

(2) General recognition

- Safety = reasonable certainty of no harm
- Scientific procedures OR common use in food since before 1958

GRAS status doesn't require FDA confirmation, so

- Companies may use substances in food based on their own determination that the use is GRAS
- Industry groups, international standards, customer demands, also play a role, so there is some knowledge and oversight
- FDA is not aware of all uses of substances on the basis of GRAS determinations

Have substances that were considered GRAS ever been then NOT considered GRAS?

YES

- 2015 FDA finalized its withdrawal of Generally Recognized As Safe status for partially hydrogenated oils (PHOs).
- 1980s they un-GRAS'd some uses of sulfiting agents
- 1970s when they took similar action against substances like cyclamates, saccharin and brominated vegetable oil.

What substances might be next?

- Caffeine?
- Salt?
- Sugar?
- Packaging polymers?

Tonight's #1 Understatement:

Not everyone likes GRAS

Recent years have seen objections raised and suggestions for changes in law and regulation from government studies and advocacy groups.

More legal or regulatory changes may arrive in coming years.

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FOOD LABELING

Most important current food labeling controversies:

- **Nutrition Facts**

The distinctive Nutrition Facts box on many food labels is perhaps the most identifiable FDA-required label element.

Nutrition Facts	
Serving Size 2/3 cup (55g) Servings Per Container About 8	
Amount Per Serving	
Calories 230	Calories from Fat 72
% Daily Value*	
Total Fat 8g	12%
Saturated Fat 1g	5%
<i>Trans Fat</i> 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	12%
Dietary Fiber 4g	16%
Sugars 1g	
Protein 3g	
Vitamin A 10%	
Vitamin C 8%	
Calcium 20%	
Iron 45%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g

OLD

Nutrition Facts	
8 servings per container Serving size 2/3 cup (55g)	
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
<i>Trans Fat</i> 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars 20%	
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

NEW

Effective date July 26, 2016, and Compliance date of January 1, 2020, for manufacturers with more than \$10 million in food sales and January 1, 2021, for manufacturers with less than \$10 million in annual food sales

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- ‘Natural’ and other claims: Regulators & Class Actions

What is commonly known about 'natural?'

That FDA has no definition for it.



FDA has 'no definition' for 'natural' ?

That FDA has no definition for it.

Myth!

It's not as if they haven't said **ANYTHING** about what it means...

FDA has 'no definition' for 'natural' ?

“A food that may be labeled as “natural” is one to which “nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, the food that would not normally be expected to be in the food”

NLEA regulation preamble, from 1993

FDA has 'no definition' for 'natural' ?

AND if you're dealing with FLAVORS and how to describe them on the principal display panel of the a food label there is a regulation on that: 21 CFR 101.22(a)(3)):

Natural flavor

Artificial flavor

WONF

etc....

Natural

The big issues today come up because of foods claiming to be 'all natural' or 'made from natural ingredients' or simply 'natural,' and challenges from STATE LAW-BASED CLASS ACTIONS asserting that various product characteristics make the food NOT NATURAL, therefore DECEPTIVE.

Examples

- GMO Ingredients
- Synthetic Ascorbic Acid and Citric Acid
- HFCS is not natural
- Herbicide traces

Natural

- Are these cases successful?
- Sometimes, but not always
 - Depends to some degree on the specific state's laws and case decisions
 - Depends on if the label feature sued about is PREEMPTED by federal (FDA) requirements

Natural – some civil case examples

IN RE: GENERAL MILLS GLYPHOSATE LITIGATION, Federal Court in Minnesota, 2017

Here, Plaintiffs claim that glyphosate is a synthetic chemical and that a reasonable consumer would not expect a product labeled as being “Made with 100% Natural Whole Grain Oats” to contain a synthetic biocide.

Plaintiffs claim that Defendant breached its promise that its Products would contain “100% Natural Whole Grain Oats,” because the Products contained trace amounts of glyphosate.

Each of Plaintiffs’ claims depends on the statement “Made with 100% Natural Whole Grain Oats” being misleading, false, deceptive, fraudulent, or misrepresentative solely because trace amounts of glyphosate are found in the Products.

IN RE: GENERAL MILLS GLYPHOSATE LITIGATION, Federal Court in Minnesota, 2017

“The Court concludes that Plaintiffs have failed to plausibly allege that the statement “Made with 100% Natural Whole Grain Oats” means, or could be interpreted by a reasonable consumer to mean, that there is no trace glyphosate in Nature Valley Products. It is implausible that a reasonable consumer would believe that a product labelled as having one ingredient – oats – that is “100% Natural” could not contain a trace amount of glyphosate that is far below the amount permitted for organic products. The Court further concludes Plaintiffs fail to state a claim because Defendant did not represent or warrant that Nature Valley Products would be free from trace glyphosate.”

“The Court concludes that it is not plausible to allege that the statement “Made with 100% Natural Whole Grain Oats” means that there is no trace glyphosate in Nature Valley Products or that a reasonable consumer would so interpret the label. It would be nearly impossible to produce a processed food with no trace of any synthetic molecule.”

Natural – some civil case examples

Finding a claim based on “All Natural” label on pasta to be implausible and noting that “the reasonable consumer is aware that Buitoni Pastas are not springing fully-formed from Ravioli trees and Tortellini bushes”

Pelayo v. Nestle USA, Inc., 989 F. Supp. 2d 973, 978 (C.D. Cal. 2013)

FDA asked for public comments to help it define 'natural'...

...over 2 years ago.

- Whether it is appropriate to define the term “natural,”
- If so, how the agency should define “natural,” and
- How the agency should determine appropriate use of the term on food labels.

FDA commissioner Scott Gottlieb said they may have more to say 'soon' in March 2018

Public comments closed in 2016 – **7,690** comments received

So, for now....

- 1. Be guided by FDA's guidance principles and the regulation if flavorings are involved.**
- 2. Research case decisions especially in specific states of interest re the meanings that have been given to 'natural' to help you assess the risk.**

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What Does Clean Label Mean?

It means whatever consumers think it means at any given moment in history.

- That doesn't mean it's not important, or a valid venture for the company –
- Of course it is!
- Just that it's a more multifaceted and changeable concept than might be understood.

A SNAPSHOT OF THE FINDINGS

“Clean label” understanding is broad, not deep

Nearly 60% of the respondents say they are aware of clean label products but far fewer have a deep understanding of what the term means. But it doesn't seem to matter. Nearly 8 in 10 say they are at least somewhat likely to seek out these products even though they aren't certain what the term means. When prompted to define “clean label” products in their own language, respondents most often associate the term with ingredients, especially those that they perceive as natural. Smaller segments connected clean label with

products containing ingredients that they are familiar with and labels they can easily read and understand.

“Clean Label” catching on as a trend, but without a clear definition

One approach:

The Clean Label Project™ - A business that tests foods for BPA, acrylamide, heavy metals, antibiotics, pesticides. Focusing on ‘long-term exposure to low levels of environmental and industrial contaminants’

‘...we think the new frontier of food safety is food toxicity.’

“Clean Label Project™ uses data and science to reveal the true contents of America’s best-selling consumer products. Products are tested in an accredited analytical chemistry laboratory for 130 harmful environmental and industrial contaminants and toxins. Results are published as Product Ratings.”



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Questions?



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