



Marketing in an Era of Transparency

Processing and Ingredient Sourcing:
Substantiating Claims
Means Knowing Your Supply Chain!

“Simple” is Surging!



“Featuring ‘clean’ product attributes on labels is paying off handsomely across a wide array of food, beverage and other CPG categories, Nielsen data confirm.

“For example, sales of products that make organic claims are up 10% compared to a year ago, sales of those making ‘all natural’ claims are up 7.8%, and sales of those claiming ‘no additives or artificial ingredients’ are up 8%, according to a new Nielsen report on clean labeling trends, including consumer behavior and sales results.

“In the food and beverages sector, across categories, products that had labels showing the claim “nothing artificial” saw sales rise 3.6% in the 52 weeks ended May 20, products claiming “all natural” were up 7.8%, and those claiming “free of additives and artificial ingredients” were up 8%.”

Marketing Daily, Media Post, 08/24/17

What Consumers Want / Don't Want

- Simple foods with ingredients they can understand, *i.e.*, knowing the “genealogy” of a food, as much as – or even more than – the food itself
 - Where it came from
 - How it was made
 - How it was handled
 - How the earth and its inhabitants were treated along the way
 - “Organic”, “rain-forest certified”
- Often, consumers want to know about what is not in a food, or what was not done to it:
 - “Non-GMO”
 - “No anti-biotics ever”
 - “Sustainable”
 - “Preservative-Free”
 - “Cage free”

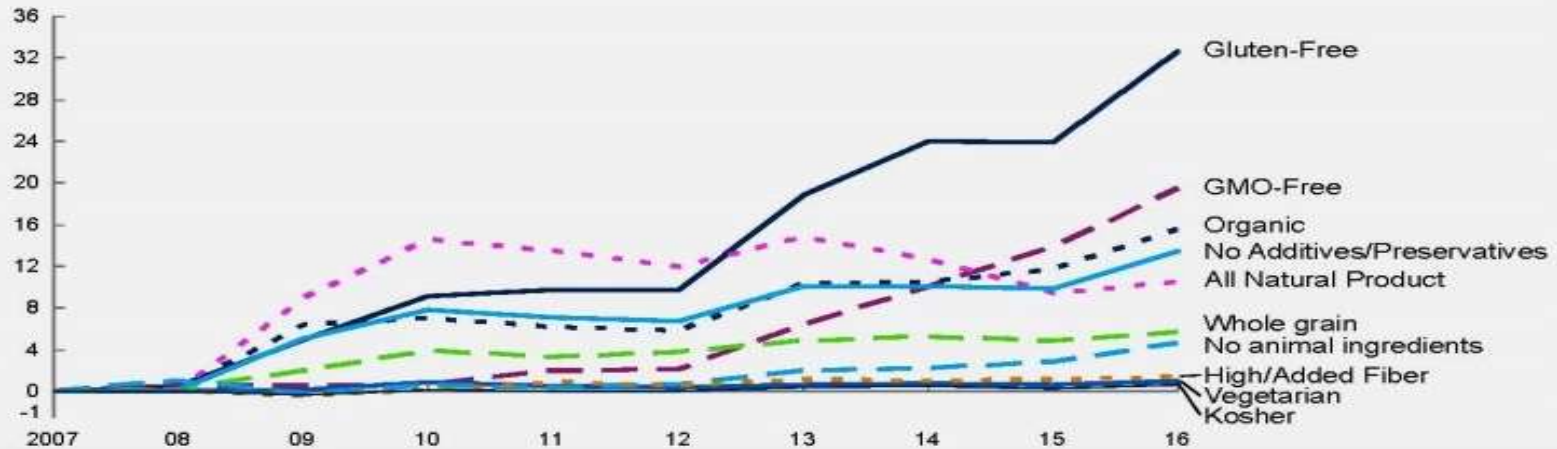
Product Claims Today



Trending Label Claims

Trending topics on product labels

Growth of label claims on food and beverage products (%), indexed to 2007



SOURCE: Mintel OMD

McKinsey & Company



Squarely “On-trend”

- From Skagit Valley
- USDA Organic
- Organic Almonds, from California
- Non-GMO certified
- No artificial colors or flavors

(Fiber not mentioned;
it's a good source!)

A Plea for the “Process Label”

“Under appropriate government or third party oversight, these ‘process labels’ can effectively bridge the information gap between producers and consumers, satisfy consumer demand for broader and more stringent quality assurance criteria and ultimately create value for both producers and consumers.”



- CAST Issue Paper 56

- <http://www.cast-science.org/download.cfm?PublicationID=283819&File=1030ac46417e576660c87b6b2553352b6624TR>

Embracing Transparency...

- Chicken of the Sea interactive digital traceability website
 - <https://chickenofthesea.com>
 - Where caught, fishing method, where processed and canned
- Hershey's website, with an "A to Z glossary" of all its ingredients, with easy-to-understand descriptions
- At egg and meat processing plants, cameras and picture windows to allow consumers to see how animals are treated in real time

Opportunities, Challenges!

- Claims about processing and sourcing can help food companies connect with consumers, especially those firms that are seeking greater “transparency”
- But such claims are tough to execute; they require:
 - Supply chains under strict control, visibility to the point of origin, constant oversight, validation, inspection and continuous monitoring
 - A well-defined processing / sourcing network reasonably designed to support the claim
 - Well-established, clearly delineated roles and responsibilities, with reliable documentation and record keeping

Seek Visibility!

- Supply chain visibility can be a challenge, especially across complex networks
 - Dairy producers, *e.g.*, purchase milk from “grass-fed” cows on many farms
- Recognized, credible third-party oversight, certification can solve many substantiation and transparency concerns



Third Party Certifiers



- The USDA Organic program sets a clear standard for processing claims;
- Non-GMO Project is a well-known third-party certification programs, but there are many others...

Certified Transitional!



Not organic, but
getting there,
year by year...

Kashi.
Newton Newton, looking
out at his Transitional
fields in Eastern Wyoming.



This cereal is not organic.

But hang on. That's the point.

The truth is, less than 1% of farmland in the US is certified organic, and transitioning conventional farmland to organic is difficult. Farmers like Newton (pictured above) often want to do it but they have to implement more costly methods for at least three years to become certified. And while that's good for all of us, it means farmers don't see a

return on their investment immediately, and they may be less motivated to make the change.

So, let's do something about it. The Kashi Transitional farms initiative was created so together we can help farmers like Newton transition their farmland. During Newton's three-year conversion process, we're buying some of his transitional grains—which are certified by Quality Assurance International to

ensure they are grown using sustainable practices that avoid genetically modified seed and synthetic pesticides or fertilizers. And we use them to make this cereal.

Our hope is to convert more acreage every year—which is why our Certified Transitional cereals will always be made with transitional grains. The more we all become aware, the more farmers we can help to make a difference together. Thanks for joining us.

Visit KashiStories.com to learn about how you can support the Transitional movement and keep the good taste flowing.



* Look for the mark of the movement.

Want a Sure Pathway?

- For a reliable way of ensuring a reasonable basis for your claim – and “Doing It Right” – look to the USDA’s Process Verified Program (“PVP”)
 - Operated by the Agricultural Marketing Service (“AMS”), longtime ally of agriculture and food processors
 - Experts trained to help validate quality systems



“PVP”: What is it?

- An audit-based, user-funded service providing **independent verification** that specific production practices or processing points are clearly defined, implemented and transparent
 - Based on the principle that a Quality Management System (“QMS”) is necessary to turn out products and services with a consistent and reliable level of quality
 - Under a PVP, a supplier's adherence to its own QMS is verified through independent audits conducted by qualified AMS auditors
- Labels remain subject to USDA oversight, but PVP approval can enable a nice claim!
 - “Process Verified Non-Hormone Treated”
 - “Process Verified Non-GMO”
 - “Process Verified Cage-Free Eggs”



PVP Facts



- Administered by USDA AMS, QAD, **Audit Services Branch (ASB)**.
- AMS has PVP's with over 50 livestock and seed companies, 70 poultry-related firms
- Granted PVPs to 12 companies for "Non-GMO"
- <https://www.ams.usda.gov/services/auditing/process-verified-programs>
- Approved claims:
 - Age- and source-verified
 - Non-hormone treated cattle
 - No use of antibiotics
 - Non-GE/GMO
 - Reduced use of antibiotics with applications to human medicine
 - Specific feeding claims
 - Accreditation for farms in "transition" farms to USDA Organic certification

“Non-GMO” Program

SunOpta's Process Verified Program



Practice Pointers!

- Define your “process” standard
 - Get a third party to back you up!
- Control your supply chain!
 - Contracting with suppliers?
 - Ask for inspection, auditing and verification rights
 - Conduct regular inspections / surprise visits
- Consider reaching out to USDA / AMS for guidance and support
 - Is PVP oversight and approval right for your network?

The Case for / Against Processing / Sourcing Claims

For:

- Inform
- Transparent
- Share values
- Interconnectedness
- Feeling of intimacy

Against:

- Sometimes subjective
- Negative inference
- Lack of science base
- Require investments in labels, websites and supply chain verification!

Be Transparent, but be Diligent!

- Process / Ingredient labeling can inform consumers about the “genealogy” of their food
 - Promote a sense of interconnectedness and a better understanding of agriculture
 - Consumers today feel it’s their right to know how their food is made and where it comes from!
- Be diligent in sourcing – and beware of potential misunderstanding
 - A process alone doesn’t promote well being
 - An ingredient doesn’t deliver a benefit just by being present
 - And it doesn’t mean a product is superior
 - Be clear about these things when labeling!

In Conclusion,
Use Thoughtfully!



FDLI Food Advertising, Labeling and Litigation Conference

Supply Chain Considerations and Marketing Claims

Miriam Guggenheim
Covington & Burling LLP

Communication and Transparency Among Your Supply Chain and Marketing Personnel are Critical!

- Consider how many of these popular claims depend on your supply chain
- The certified/verified claims may be easier or lower risk
 - Clear guidelines
 - Consistent process
 - Preemption, in some cases
- Same for those defined by FDA
 - Fat free/sugar free/excellent source
- But quality claims may be risky, and need diligence!



Play Defense While Marketing Creatively

- FTC requires marketers to substantiate all reasonable consumer takeaway messages, and courts follow this approach.
 - So you must consider not only what you mean to convey, but how else the claim might be perceived.
 - What does the claim promise? Are you delivering on that promise?
 - Don't just try to find "safe" words to suggest a message you can't say outright.
- In the current environment, you've got to think like a critic. Where are your weaknesses?
 - Stay on top of developments such as consumer fraud litigation, influential bloggers/TV personalities/"thought leaders", articles and exposés
 - What is known about an ingredient or process?
 - E.g., xanthan gum/citric acid considered non-natural ingredients. Many lawsuits.

“Natural”/“100% Natural”

- Yes, we’re still dealing with this!
- Supply chain considerations can have a significant impact on “natural” claims and litigation
 - Glyphosate pesticide residue cases
 - Challenges to “natural” claims on dairy products derived from milk from cows who may have been fed GE feed or treated with rBST
 - Some such cases are starting to get dismissed by reasonable judges, but still must consider risk/costs
 - May be able to lower risk by carefully crafting claim
 - In Nature Valley case, judge dismissed suit, noting in part that claim was limited to oats, not a 100% natural claim for the product
 - Don’t necessarily abandon claim, but make it knowingly



Alternatives to “Natural” Claims

- Pure, Simple, Wholesome, Clean
- What do these words mean? Are they really different from “natural”? What’s the consumer expectation?
 - This is the next phase of lawsuits; plaintiff lawyers treating them like “natural” claims
- What are your sourcing/supply chain considerations for such claims?
 - You may have few ingredients, but are they “simple”?
- Can you “clean up” your ingredient list? If so, is that enough?
 - Lawsuits against Minute Maid “Simply Orange” because of highly technical process used, though all ingredients came from orange
 - Shows growing sophistication of challenges



“No . . .”/“... Free”

- “No . . .”
 - artificial flavors/colors
 - preservatives
 - HFCS
 - artificial sweeteners?
- “... Free”
 - Gluten
 - Sugar
 - Fat
 - rBST?
 - GMO?
- Absolute claims can be risky, and more likely to draw scrutiny
- Those with regulatory definitions may be lower risk
- Do you need to substantiate all the way through the supply chain?
 - Yes!
 - Need to consider not just what you’re adding to your formulation
 - Otherwise, revise claim
 - E.g., “we don’t add preservatives to our product”
 - Narrow claim to particular ingredients about which you have details, e.g., “the cream in our ice cream comes from cows not treated with rBST”



Quality/Origin of Ingredients Claims

- Must all of the cherries come from Michigan?
- Must all of the vanilla come from Madagascar?
- Yes!
- So this requires communication and coordination with your supply chain
- Don't swap/modify based on price
- Build origin into your specs for the ingredient



Fruit/Vegetable Content Claims Are Particularly Sensitive



IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BARTOSZ GRABOWSKI,)	
Plaintiff,)	No. 17cv 5069
)	
v.)	
)	
DUNKIN' BRANDS, INC.,)	
Defendant,)	JURY DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, Bartosz Grabowski, individually and on behalf of all others similarly situated, by his attorneys, complains against Defendant Dunkin' Brands, Inc. ("Defendant") as follows:

NATURE OF THE ACTION

1. Plaintiff brings this class action lawsuit against Defendant pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.* ("ICFA"), and common law, based on Defendant's false and misleading business practices with respect to the marketing and sale of its "Glazed Blueberry" donuts or munchkins, "Blueberry Butternut"

Implications for Flavor Labeling Requirements



- Need to say “flavored”?
- Need to say “artificially flavored”?



“Made in USA”

- FTC standard – product must be “all or virtually all” made in the U.S.
 - all significant parts and processing that go into the product must be of U.S. origin, i.e., product should contain no, or negligible, foreign content
 - the product’s final assembly or processing must take place in the U.S.
- California standard:
 - finished product is made, manufactured, or produced in the United States, and
 - parts manufactured outside the United States do not exceed 5% of the final wholesale value of the finished product
- So sourcing is critically important! This is a content claim, not just about site of production
- Don’t tout foreign ingredients (e.g., Madagascar vanilla) if you’re also making a Made in USA claim!

Key Takeaways

- Ensure alignment among marketing, procurement, and supply chain
- Who leads? May vary, but presuming Marketing leads:
 - Determine what must be true in order for the desired claim to be truthful, not misleading, and substantiated
 - Do you need to consider processing aids?
 - Do you need more information from your suppliers?
 - Institutionalize these criteria so they cannot be changed without evaluation of the impact
 - Build criteria into specs, procurement systems
 - Communicate with your team and suppliers about why your desired specs/attributes are important
 - Documentation/recordkeeping will help substantiate your claim (but that's only after you've gotten a challenge)

Key Takeaways, cont.

- Match claim language to what you can confirm/substantiate
 - “No”/“free” claims are likely absolute, and may be more likely to invite scrutiny
 - Consider qualified claim if can’t confirm/lack transparency into supply chain
 - E.g., “we don’t add . . .”
- Say MORE, not less
 - Provide definitions and/or context for your claim
 - Shape the reasonable consumer take-away message
 - Helps make it more difficult to bring a legal challenge
- You may choose to retain a risky claim, but do so knowingly
 - Know the dollar value of the claim, where possible
 - Know the potential costs of a challenge

Thank you!

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Supply Chain Considerations for the Dietary Supplement Industry

Rend Al-Mondhiry
Associate General Counsel
Council for Responsible Nutrition

*Global supply chain, complex
ingredients, contract
manufacturers...what could possibly go
wrong?*



The Basics

- Is the product a dietary supplement?
 - Claims-driven, but also ingredient considerations
 - “A product intended to supplement the diet that contains **one or more dietary ingredients**”
 - 21 U.S.C. § 321(ff)(1)(A) – (F)
 - But is the ingredient old, or a new dietary ingredient (NDI) that must be notified to FDA?

Additional considerations



- For a pre-DSHEA ingredient, does a change in the manufacturing process make it “new”?
 - Consider whether the change impacts the identity of the ingredient (e.g., change to specifications needed to chemically characterize the ingredient) or the safety
- Does an exception to NDI notification apply?
 - Ingredients present in the food supply, e.g., GRAS or approved food additive, and not chemically altered (consider impact on identity or safety)

NDI or GRAS?

- FDA has signaled a narrowing of the definition of “dietary ingredient” under § 201(ff)(1)
 - Some novel ingredients (e.g., new probiotic strains) and certain synthetic ingredients (e.g., synthetic copies of botanicals) are not “dietary ingredients”
 - FDA Revised Draft NDI Guidance (2016)
 - Rather than submit an NDI notification, GRAS notice or self-affirmed GRAS to establish use in the food supply



Diligence in the Supply Chain

- Not only about safety but also ensuring **quality** and that the final product **meets label claims**
 - 21 CFR Part 111 requires manufacturers to ensure the **identity, purity, quality, strength and composition** of both their ingredients and their finished dietary supplements
- 100% identity testing requirement
 - Part 111 doesn't specify the exact test; "at least one appropriate test or examination..."
 - Authenticating some ingredients, e.g., botanicals, may require more than one test

Diligence in the Supply Chain

Who is responsible?

- FDA: “quality agreements cannot be used to delegate statutory or regulatory responsibilities”
- Compliance with FSMA
 - Some exemptions for supplement manufacturers , but still need to assure *supplier* compliance
 - Identify gaps, maintain documentation

What’s at stake?

- FDA, FTC, and state AG enforcement action
- Class action litigation
 - Increased retailer demands
- Consumer trust



Labeling Implications

- Claims such as “pure”, “clean”, or “natural”
 - Control for unintentionally added ingredients (e.g., glyphosate residues, GMOs, heavy metals)



Labeling Implications

- Was the correct plant part (e.g., root, stem, or leaf) used?
- Potency, stability testing
 - ConsumerLab tests and reviews
 - Labdoor “ratings” and “rankings”

Ginkgo Extract (*Ginkgo biloba*)
(Leaf)
(50:1 Standardized Extract,
min. 24% Ginkgo-
flavonglycosides and 6%
Terpene Lactones)

Organic Eleuthero
(*Eleutherococcus senticosus*)
(Root)



Labeling Implications

- Ingredient origin, sustainability claims
 - Panax ginseng (Korean ginseng) vs. Panax quinquefolius (American ginseng)

**100% Pure,
Sustainable Salmon**

*The fjords of Norway
and Scotland are home
to the sustainably
maintained salmon used
in PhosphOmega-3®.*



Best Practices

- Use approved, trusted suppliers
- Quality agreements with contract mfrs. to ensure compliance with cGMPs
 - *But cannot contract away responsibility*
- Confirm ingredient status and use the right test(s) to assure quality and verify label claims
- Consider third-party certifiers



Self-Regulatory Tools

- Standardized Information on Dietary Ingredients (SIDI) Protocol

<http://www.sidiworkgroup.com/>



- AHPA Guidance on Good Agricultural and Collection Practices and Good Manufacturing Practices for Botanical Materials

Thank you!

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The Science Behind the Supplements