When Natural Isn't Good for You: Managing Food Safety, Litigation & Regulatory Risk

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Question: What is “Clean” Labeling?

• Answer: No “clean definition.” In part, a response to misunderstanding or lack of knowledge regarding food science and safety

• Industry should not encourage the use of “clean” label nomenclature – nothing dirty about labels

• But – clear pressure on industry from consumers and advocacy groups
What Is a “Clean Label”?

• No “big” words - can the consumer pronounce it?
  – Ingredients (although, there are exceptions if the ingredient is “hip” and sounds natural, e.g. “acai,” pronunciation gets a pass)
  – Additives, preservatives, colors (to some extent)
  – Flavors can get a bit of a pass here
  – Where processing techniques are indicated, back to the old “could grandma make it in the kitchen” question
What Is a “Clean Label”?

- It is a subjective term, influenced by consumer knowledge or lack thereof
- Example – xanthan gum
- Xanthan gum is the product of fermentation of sugars (glucose, sucrose, lactose, etc.)
- Depending on production technique, being marketed as an “all natural” ingredient
- Nonetheless, there has been some level of reformulation to remove xanthan gum, because it “sounds artificial”
  - Don’t tell folks who need “gluten-free” products about this
So What Else Does the Consumer Want?

- Price – however, there is some overlap with the market paying premium prices for organic and “natural”
- Taste
- Texture
- Health/healthy
- Shelf life
- “Minimal” processing
- SAFETY
Brass Tacks

• Labels still need to comply with FDA and FSIS requirements

• Ingredients
  – Still required to use the common and usual name of ingredients unless a regulation provides for a different term
    • “Sugar” is still “sugar” on the ingredients list, not “Andalusian summer’s breeze sugar”
    • “Corn syrup” is not an acceptable synonym for HFCS
    • “Modified” and other new ingredients – “milk protein”
Ingredient Labeling Exemptions Remain Limited

• Processing aids and certain incidental additives
  – Incidental additives and processing aids are present at “insignificant levels” AND have no function or technical effect in the finished product
  – An incidental additive is usually present because it is an ingredient of another ingredient, or a processing aid added to a food for its technical or functional effect in the processing
  – “Insignificant” – not defined, clearest example in regulations is sulfites, considered to be incidental only if present at less than 10 ppm
Flavors

- “Spices”
- “Flavor”
- “Natural flavor”
- “Artificial flavor”
- “Flavor Flav”
Overlap with Natural and Organic

- There is a “natural” overlap with “organic” products here.
- OFPA and Organic rules will generally get you to a similar place – but not necessarily - the “National List” currently allows (in certain processed organics):
  - Ammonium bicarbonate
  - Calcium hydroxide
  - Potassium carbonate
  - Tetrasodium pyrophosphate
  - And . . . xanthan gum (identified as a “synthetic”)
Overlap with Natural and Organic

• USDA and FDA Policies for Natural
  – Nothing artificial or synthetic (including all color additives regardless of source and flavors) has been included in or added to a food that would not normally be expected to be in the food
  – Processing taken into account – minimal processing – think “Grandma’s kitchen”
Issues and Concerns

• SAFETY
  – Clearly, this is the #1 concern
  – Formulation/process changes that affect shelf life, stability, need to be validated and reviewed in the context of final labeling
  – Preservatives – what effective alternatives are available – HPP, etc.
  – See recent recalls of Greek Yogurt
Issues and Concerns

• Formulation
  – Can the product be reformulated and still maintain the taste and texture expected by consumers
  – For example – some past attempts at low-sodium soups did not resonate with consumers
Issues and Concerns

• Labels must still be truthful and accurate
  – Cannot be “false or misleading in any particular”
  – Omission of material fact(s) can be misleading
  – Does reformulation negate or alter other claims on your label?
  – Nutrition information/claims
  – Health claims
FDA & FTC Enforcement

- **FDA**
  - Big emphasis on “Front of Package” claims
  - Food products claiming to treat or mitigate diseases;
  - Misleading “healthy” claims; etc.

- **FTC**
  - Increased scrutiny of foods
  - Associate Director for Advertising Practices has said:
    - “Health-related claims are becoming more prevalent in food advertising – so we are giving increased scrutiny to food advertising”
    - “Claims such as boost the immune system, assist with memory and brain function, boost metabolism, protect the heart, etc.”
    - “We have concerns with disease prevention or treatment claims not approved by FDA”
Additives Are Under Attack

- Pew Charitable Trusts (now at NRDC) – Food Additives Initiative
  - One paper published, several in the pipeline
  - Aggressive media campaign
- CSPI “Food Additives Mobile App”
  - CARAMEL COLORING - “But not so fast: Much of what goes by this innocent-sounding name is made with ammonia, or sulfites, or both.”
  - “Shopping was easy when most food came from farms. Now, factory-made foods have made chemical additives a significant part of our diet.”
- BTW – shopping was EASY when “most” food came from farms? Really? Dust Bowl anyone? Bueller?
Food Litigation

- The *%@! lawyers
- Plaintiffs’ bar is aggressively going after the food industry
- Big Food is the new Big Tobacco
  - the same lawyers who went after tobacco now have their sights set on food
- All the issues we’ve discussed are potential targets – omissions, ingredient names, processing – plaintiffs are using “consumer fraud” statutes to pursue labeling that “misleads” consumers
Food Litigation

- FDA is picking its labeling battles as a result of strained resources
- FDA has said “Natural” claims are a lower priority than e.g. food safety issues
- As a result, a gap has been created by FDA’s inaction on developing a definition of “Natural”
- Plaintiffs’ claims bar is filling that gap
“Natural” claims first targeted high-fructose corn syrup, artificial preservatives, products processed with unnatural ingredients, and now GMO ingredients.

Products targeted vary – chips, ice cream, yogurt, almond milk, canned tomato products

Class actions alleging:

- Violation of state consumer protection laws
- Fraud and misrepresentation
- Breach of express and implied warranties
- Unjust enrichment
Food Litigation

• Claims allege that plaintiff would not have bought the product if did not display “All Natural” on the label
• Damages alleged from higher prices paid for premium natural products
• Non-GMO cases – Some courts dismissed because plaintiffs did not plead reliance on “Natural” label, as other ingredients are also required to be on label
• Identifying ingredient as GMO is not required on the label, so this reliance issue is not present for plaintiffs
Food Litigation

- Sample of products at issue in GMO litigation:
  - Cereals
  - Chips
  - Crackers
  - Soups
  - Rapeseed/canola and soy oils

- Ingredients
  - Corn
  - Soy
Food Litigation

- Popular jurisdictions:
  - Northern District of California
  - Central District of California
  - Eastern District of New York
  - District of New Jersey
  - Southern District of Florida
Food Litigation

- Defenses in play:
  - Preemption under NLEA
  - Failure to state a claim for fraud or misrepresentation under *Iqbal* and *Twombly*, Rule 9(b)
  - Primary jurisdiction of FDA
  - Not suitable for class action because claims are too individualized, lack predominance
  - Lack of standing
Food Litigation

• Preemption rulings:
  – For products containing meat, courts are finding preemption as a result of USDA and FSIS label approvals
  – Generally finding no preemption under FDCA and NLEA
    • No express preemption in FDCA or NLEA
    • No implied preemption as FDA deferred taking regulatory action and therefore does not intend to occupy the field
Food Litigation

• FDA’s primary jurisdiction
  – Some courts finding FDA’s primary jurisdiction implicated and clearly not comfortable defining “natural”
    • Coyle v. Hornell Brewing Co., D.N.J., - In 2010, certified to FDA for an administrative determination of whether HFCS qualifies as a “natural” ingredient. FDA declined to provide guidance.
    • Cox v. Gruma Corp., N.D. Cal. – Referring to FDA determination of whether GMO ingredients are natural and staying case for six months
Food Litigation

- *Barnes v. Campbell Soup Co.*, N.D. Cal. – Staying case six months for referral to FDA because otherwise the court would risk “undermining, through private litigation, the FDA’s considered judgments.”


- Some courts are ruling primary jurisdiction is not applicable
  - *Krzykwa v. Campbell Soup, Co.*, S.D. Fla. – Court found primary jurisdiction doctrine did not apply, because FDA consistently refuses to rule on the meaning of the word “natural.”
Food Litigation

- Class action claims:
  - Inconsistent rulings on whether plaintiff claims are too individualized for class treatment
    - *Vitaminwater* case – Class certification denied as to monetary damages, class proceeding as to injunctive relief only
    - *Moro v. Barbara’s Bakery* – Denying preliminary injunction to enjoin label because monetary damages provide sufficient relief.
Food Litigation

- **Settlements**
  
  - 2012 – *Ben & Jerry’s* case (alkalized cocoa) – $5,000,000
  
  - 2012 – *Breyers* case (same) – $2,500,000
  
  - 2013 – *Trammell v. Barbara’s Bakery* (GMO) – $4,000,000 and removal of natural and artificial claims on labels and packaging on foods containing GMOs or artificial ingredients
  
  - 2013 – *Pappas v. Naked Juice Co.* (GMO) – $9,000,000 and changes to labels
Food Industry - Multiple Silos

- Research and Development
- Food Safety / Manufacturing / Processing
- Legal and Regulatory
- Policy and Government Affairs
- Advertising, Marketing & Communications
- Corporate and Commercial
Conclusions

- There is some need to respond to consumer demand
- Reformulation requires a holistic review
  - Safety
  - Shelf life
  - Product attributes
  - Related label claims
- Regulatory requirements must still be met
- Consider plaintiffs’ lawyers and misleading claims/omissions
- Don’t feed the clean-label trolls
- Meld Silos
- Education of consumers
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THANK YOU!