

No Two Twinkies Are Alike

Understanding the
“Reasonable Basis” Requirement
of Federal Menu Labeling

Presenters



- Jill Marchant, Associate General Counsel, DineEquity, Inc.
- Manages litigation for world's largest casual dining company, including Applebee's and IHOP brands
- Primary in-house counsel on defense of six consumer class actions over nutritional labeling of Weight Watchers-branded menu items
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Federal NLEA

- Nutrition Labeling & Education Act 1990
 - Nutrition Facts panel on packaged foods
 - The 80/120 Rule:
 - Analytical testing results must be at least 80% of stated values for vitamins and minerals
 - And no more than 120% of stated values for calories, fat, carbohydrates, sugar
 - Labeling was not required for restaurant foods
 - But for voluntary information, the FDA set the “reasonable basis” standard (Jan 1993)

NLEA

21 USC § 301 *et. seq.*

Nutrition Information

- **Statute:** 21 USC 343(q) requires nutrition information on packaged foods

e.g.



Nutrition Facts	
Serving Size: 8 fl oz (240 ml)	
Servings Per Container: 2.5	
Amount Per Serving	
Calories 0	
% Daily Value*	
Total Fat 0g	0%
Sodium 0g	0%
Total Carbohydrates 0g	0%
Protein 0g	

*Percent Daily Values are based on a 2,000 calorie diet.

- DOES NOT apply to restaurants. § 343(q)(5)(A)(1); 21 CFR 101.9(j)(2)(i)
- **Preemption:** State laws requiring nutrition information in restaurants are exempt from preemption. See § 343-1(a)(4).
- **Compliance Standard:** 20% variance under 21 CFR 101.9(g)(ii)

Nutrient Content Claims

- **Statute:** 21 USC 343(r) governs voluntary “claims” about nutrient content.

e.g. “low fat”
“100 calories”

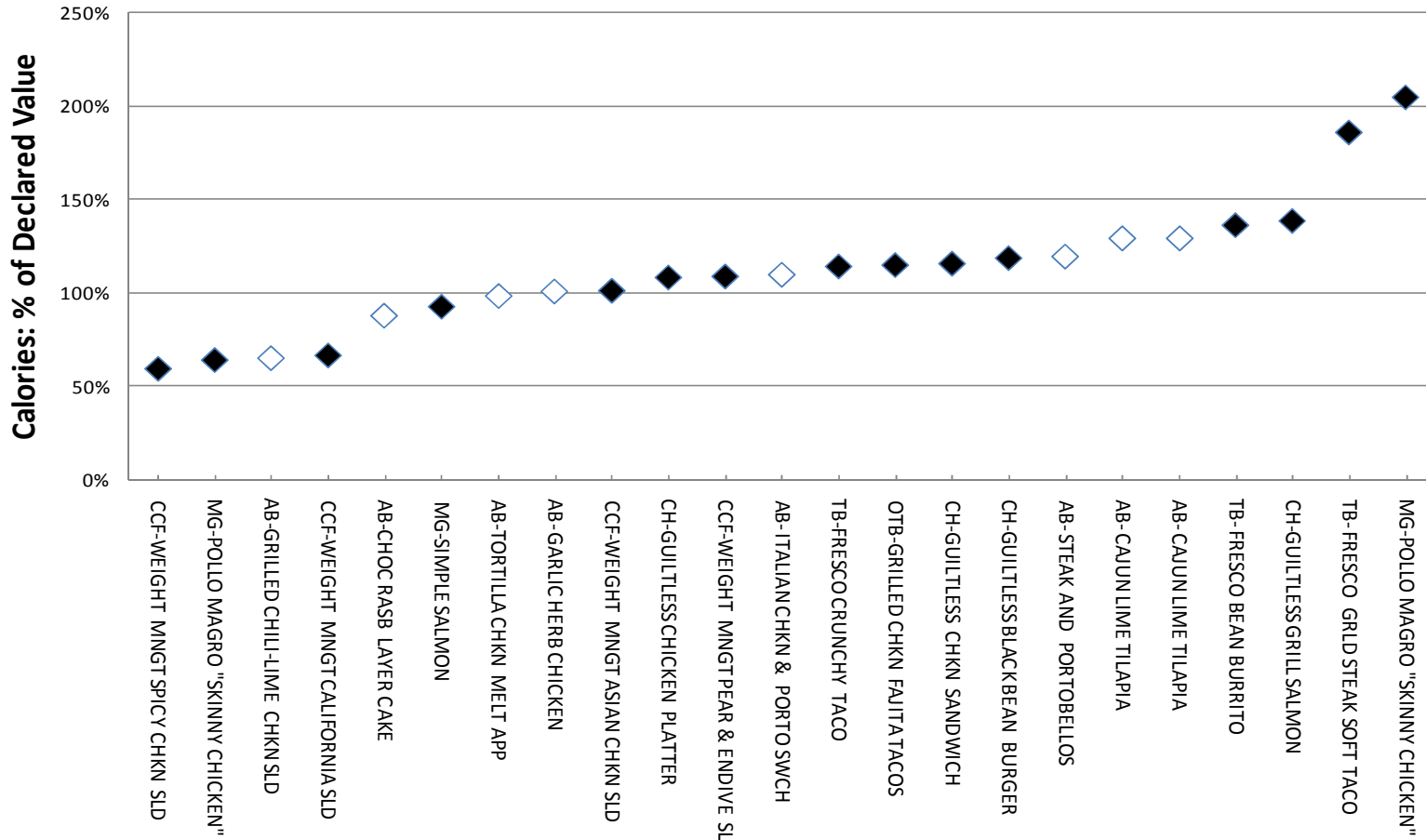
- DOES apply to restaurants
- **Preemption:** Non-identical state laws regulating claims are preempted. See § 343-1(a)(5).
- **Compliance Standard:** “Reasonable Basis” under 21 CFR 101.13(q)(5)(ii).

Packaged Food Varies

Food Product	Mean Fat per 100 g	Percent of Samples Exceeding Mean Fat Value by:						
		5%	10%	15%	20%	25%	50%	100%
Cheese Crust Pizza, Frozen	12.28	37.57	26.31	17.09	10.25	5.65	0.08	0.00
Meat Lasagna, Frozen	4.73	41.74	33.83	26.58	20.21	14.86	1.85	0.00
Meat Lasagna, Frozen low fat	2.23	44.49	39.09	33.90	28.99	24.44	8.31	0.28
Rice bowl with chicken, Frozen	1.56	44.75	39.58	34.60	29.87	25.45	9.33	0.41

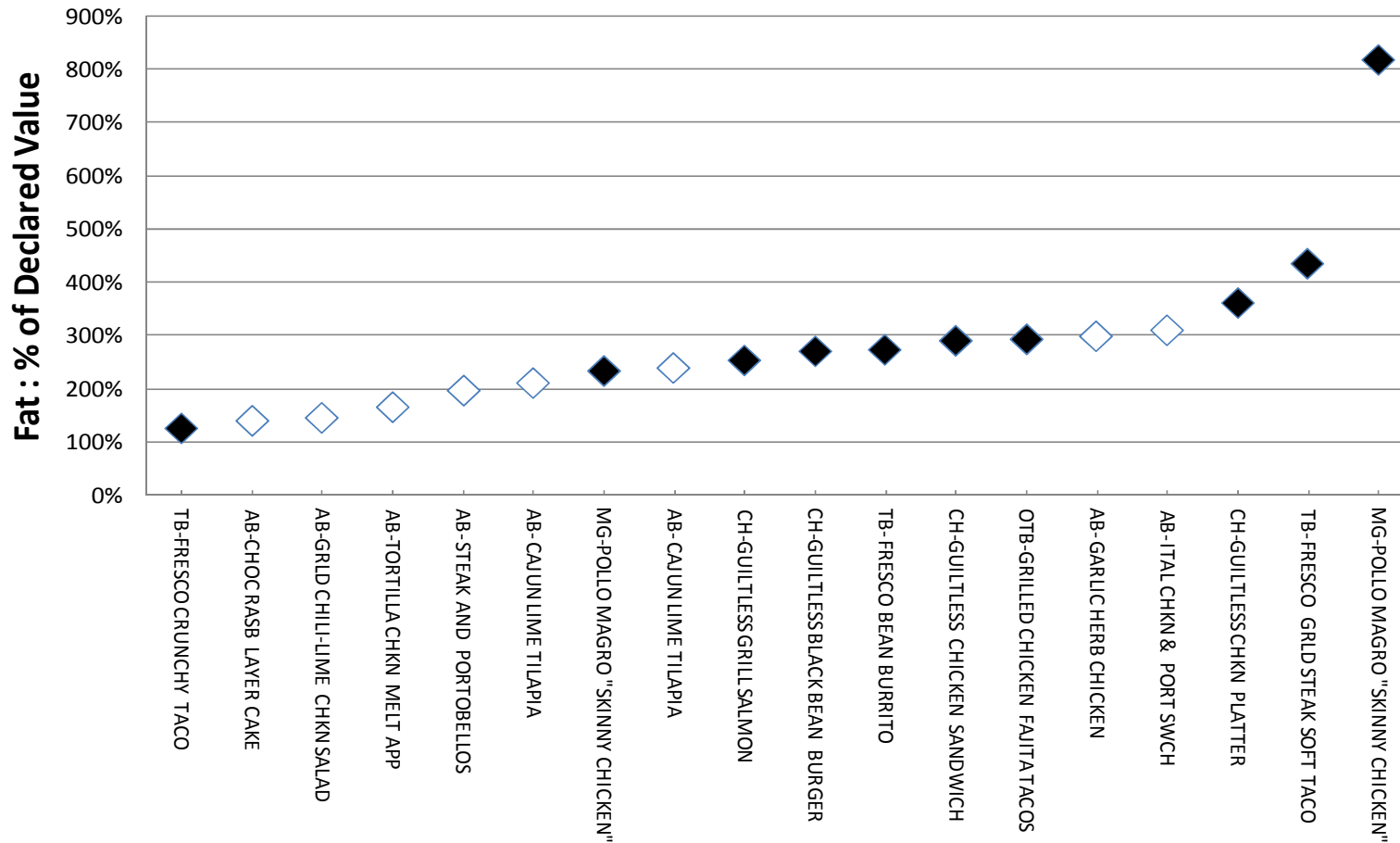
Restaurant Food Varies

Comparison of Actual and Declared Calorie Content
(Scripps data)



Low Fat Food Really Varies

Comparison of Actual and Declared Fat Content
(Scripps data)



Local and State Laws

- New York City (May 2008)
- San Francisco, CA (Jul 2008)
- Santa Clara County, CA (Sep 2008)
- King County, WA (Jan 2009)
- Multnomah County, OR (Mar 2009)
- Westchester County, NY (May 2009)
- Philadelphia, PA (Jan 2010)
- California (Jul 2009), preempting local laws

Local and State Laws (cont.)

- Massachusetts (2009)
- Maine (2009)
- Oregon (2009), preempting local laws
- Davidson County, TN (2008)
- Vermont (2010)
- New Jersey (2010)

Proposed Legislation

- Chicago
- New York State
- Arkansas
- Oklahoma
- District of Columbia
- Connecticut
- Hawaii
- Illinois
- Ohio
- Pennsylvania

Challenges to State/Local Laws

- First Amendment
- Federal preemption under the NLEA
 - *NY State Rest Ass'n I*, filed June 2007
 - NYC regulation of voluntarily provided information is preempted by NLEA
 - *NY State Rest Ass'n II*, filed Jan 2008
 - **New** NYC regulation **requiring** information is not preempted or barred by 1st Amendment
 - *Calif. Rest. Ass'n*, filed July 2008
 - Enforcement stayed; then statewide law enacted

Consumer Class Actions

- Chili's Guiltless Grill Menu
 - *Paskett v. Brinker Int'l* (TX, nationwide), dismissed voluntarily

- Applebee's Weight Watchers Menu
 - *Jones v. DineEquity* (CA, state) , ruling for Defendant; on appeal
 - *Kramer v. Applebee's* (KY state), inactive
 - *Curry v. Applebee's* (OH, state), ruling for Defendant
 - *Valiente v. Applebee's* (KS, nationwide), ruling for Defendant
 - *Jaramillo v. Applebee's* (IL, nationwide), ruling for Defendant
 - *Paskett v. DineEquity* (WA, state), dismissed with tolling agmt

- So far, no cases based on **mandatory** nutrition labeling

Federal Uniformity

- Bills proposed in 2008: MEAL and LEAN
- Federal Menu Labeling enacted as part of the Healthcare Reform Bill (PPACA) on March 23, 2010
- Preemption of non-identical state and local requirements was immediate
- FDA: immediate labeling nationally
 - Industry disagrees
 - FDA not yet enforcing, as a practical matter

Scope of Federal Requirement

- Chain Restaurants (20+ locations)
 - Must be under the same name
 - Other restaurants can opt-in
- Vending operators (20+ machines)
- FDA *proposes* to include:
 - Convenience stores
 - Movie theaters
 - Sidewalk carts
 - Trains and planes

Nutritional Info Required

- Menus and menu boards
 - Calories
 - Recommended daily calories (once FDA establishes)
 - Other information is available in writing
- In writing (e.g., handout, poster, computer)
 - Fat
 - Saturated Fat
 - Calories from Fat
 - Carbohydrates
 - Sodium
 - Cholesterol
 - Sugars
 - Dietary Fiber
 - Protein
 - Trans Fats?
 - Other attributes determined by FDA . . .

Reasonable Basis Standard

- Reasonable Method: Initial Numbers
 - Recipes and cookbooks
 - Nutrient databases
 - Laboratory analyses
 - Other reasonable means
- Reasonable Steps: Operations
 - Portion sizes are reasonably constant
 - Standardized recipes
 - Method of preparation adheres to basis

Issue #1: Whose Job Is This?

- The law applies to “restaurants.”
- Whether that means the brand or the franchisee may depend on the franchise or operator agreement.
- Hard not to share compliance responsibilities.
 - Brand might determine figures on menu.
 - But operator must also take reasonable steps to ensure operational adherence.

Issue #2: Disclaimers

- Many restaurants have had disclaimers for nutritional information for years.
- Some local laws (e.g., California) expressly permit disclaimers.
- FDA has not stated a position (but allows “additional disclosures”).
- Best to be clear, accurate, and brief so that consumers will read and understand it.
- Don’t distract from safety disclaimers.

Disclaimer Example

- **The nutritional analysis provided is comprised of data from Analytical Food Laboratories (an independent testing facility commissioned by Restaurant) combined with nutrient data from Restaurant’s suppliers, the United States Department of Agriculture and nutrient database analysis of Restaurant’s recipes using Food Processor SQL Nutrition Analysis Program from ESHA Research in Salem, Oregon. The rounding of figures is based on the Food and Drug Administration guidelines. Restaurant attempts to provide nutritional information regarding its products that is as complete as possible. Some menu items may not be available at all restaurants; test products, test recipes, limited time offers, or regional items may not be included. While menu item ingredient information is based on standard product recipes, variations may occur due to ordinary differences inherent in the preparation of menu items, local suppliers, region of the country and season of the year. Additionally, no products are certified as vegetarian. This listing is upgraded periodically in an attempt to reflect the current status of Restaurant’s products.**

Issue #3: Substitutions

- FDA does not require nutritional information for substitutions.
- May want to inform guests that substitutions will change nutritional values.
- Some chains train servers to remind guests of this, particularly for items specifically aimed at the nutrition-conscious.

Issue #4: Drive-Thru/To-Go

- Should not be an after-thought.
- Tendency to over-provision with condiments to please the guest.
- Solutions include:
 - Employee training
 - Asking guests when order is placed
 - Statement on menu card or other enclosure with meal

Issue #5: Buffers

- Tempting to add in some fat grams (or subtract out some protein grams) to be on the safe side.
- FDA standard does not allow this.
- Must use information available so that items can be compared across menus and restaurants. They will be variable, but it will average out.

Issue #6: Other Advertising

- Advertising nutritional information outside the mandated disclosure *may* create issues.
 - The law should be clear that if the mandated figure is X (e.g., because of rounding rules), then X can be advertised in other ways.
 - But consumer class actions are challenging this in the context of packaged foods and “zero grams trans fat” statements based on FDA rounding rules.

Issue #7: Lab Analyses

- Laboratory testing is not required or even preferred in the regulations.
- May be appropriate if underlying databases (or suppliers) need to be verified.
 - But generating data may create other issues.
 - Consider reasons for any analytical testing, particularly field testing.

Issue #8: Menu Printing

- Recipes can change, as can suppliers, in the middle of a menu cycle.
 - FDA has not addressed this.
- Major changes probably call for stickering.
- A disclaimer might note this issue.
- Short periods of time and minor changes are probably acceptable.
- Question of whether to revise on-line menu outside of menu cycle.

Issue #9: Multiple Suppliers

- Most chains strive for consistency.
- But cost and supply considerations can mean that there are different suppliers for different restaurants.
- Need to conform nutritionals to suppliers. If one supplier has more fat per gram of chicken than another, may need to consider making them consistent.
- Standard is flexible.

Issue #10: Training

- Reasonable steps include:
 - Reasonably constant portion size
 - Standardized recipes
 - Preparation method adhere to basis
 - E.g., baking instead of frying
- Address common errors in preparation
 - Wrong sauces, oils, dressings
 - Wrong measures
 - Missed ingredients (e.g., lemon wedge)
- Document training efforts

Issue #11: Documentation

- FDA standard requires production of documentation showing reasonable basis upon request by FDA.
 - May never have happened.
 - But could be important in litigation.
- Need collection/retention procedures.
 - Commercial databases often overwrite.
 - Data must be collected from multiple suppliers.

Additional Questions?



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