Preparing for the FDA's Menu Labeling Regulations and Implementation Best Practices

ESHA Research

April 11, 2017





About ESHA Research

ESHA Research was established in 1981 with the goal of providing a comprehensive nutrition database with few missing values.

Our Solutions Include

- Food Formulation & Labeling Software
- Restaurant Menu Analysis & Labeling Software
- Supplement Formulation & Labeling Software
- Nutrition & Diet Analysis Software
- Consulting Services





Genesis R&D

Food Analysis & Labeling Software

- Released in 1991
- Pre & Post 2016 Label formats
- Product Development
- Menu Analysis
- Nutrient Analysis
- Nutrient Search
- Reporting Features
- Audit Trails

- US, Canada, Mexico, & EU Label Formats
- Labeling & Compliance
 - Allergen Statements
 - Ingredient Statements
 - Nutrient Content Claims





Upcoming Webinars

Importing Supplier Ingredients with ESHA Port | May 16, 2017

During this webinar we explore how the newest version of the ESHA Port workflow utility can help you streamline data from ingredient suppliers into your Genesis R&D program database.

The Buzz on FDA's Definition of Added Sugars | May 30, 2017

As food manufacturers prepare for compliance there is still some confusion regarding the definition of Added Sugars and how to calculate this new mandatory label nutrient. On May 30th, we will discuss what is considered an Added Sugar (and what is not), best practices for documentation, and Genesis R&D user tips for achieving compliance.

Top 10 Genesis R&D User Tips for Success | June 20, 2017

Take your Genesis R&D functionality to the next level. Taken from user suggestions, this webinar will cover tips and tricks that will help you get the most of Genesis R&D.

To register or view archived webinars please visit: www.esha.com/news-events/webinars





Today's Agenda

During this 45 minute webinar we will cover:

- Overview of the Regulations
 - Timeline for Compliance
 - Nutrient Requirements
 - Menu Board Display Requirements
 - Documentation
- Genesis R&D
 - Recipe Analysis
 - Reports

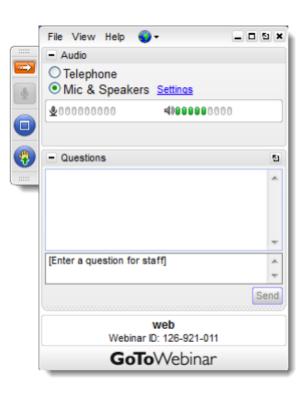






Please Note!

- ✓ The webinar is being recorded
- ✓ We will email a copy of the slide deck
- ✓ All webinars available on our website
- ✓ Submit your questions in the GoToWebinar control panel







Menu Labeling Timeline For Compliance

Labeling provisions in the ACA (Affordable Care Act) require that restaurants and other retail food establishments provide access to nutrition information.

- Final Guidance Published May 5, 2016
- FDA will begin enforcing regulations May 5,
 2017



Who Has to Comply?

- Covered Establishments
 - Bakeries
 - Chain Restaurants
 - Coffee Shops
 - Fast Food Establishments
 - Grocery Stores
 - Retail Food Establishments
 - Vending Machines

"Restaurants and similar retail food establishments if they are part of a chain of 20 or more locations, doing business under the same name (regardless of ownership—aka franchises), offering for sale substantially the same menu items, and offering for sale restaurant-type foods."





Who is Not Covered?

- Establishments with fewer than 20 locations
- Food trucks
- Sidewalk carts
- Trains and airlines

Note: Any establishment not covered may, however, voluntarily register to be covered. You must use Form FDA 3757.



What Food Items Are Covered?

Restaurant-Type Foods

- Any standard menu items
- Any foods routinely included on menu or menu boards
- Combination Meals
- Self-service food (grab and go)
- Food on display
- Salad Bars
- Alcoholic Beverages







Foods that are Exempt

- Alcohol on display behind the bar (not on menu or menu board)
- Custom order
- Daily Special
- Market Test (fewer than 90 consecutive days)
- Temporary Menu Item (fewer than a total of 60 calendar days)





Required Information - Calories

- Shown on Menu Boards/Drive-Through/Kiosk
- Number of (Rounded) Calories
- Calories or Cal must appear at top of column in type size no smaller than name or price of menu item





Required Information - Calories

- For menu items that have variable options, you must declare either both options (when there are only two variables) separated by a slash or, for items with more than two choices, you must list the caloric range.
- Different flavors or varieties that are listed as a single item
 - Slash 2 options (150/250 calories)
 - Range 3 or more (150-300 calories)





Listing Calories Examples

Variable Options

- (grilled or fried) 350/550 Calories \$7.99
- (grilled/baked/fried) 350-550 Cal \$7.99

Combination Meals

- Cheeseburger, salad or chips 450/550 Calories . . .\$4.79
- Cheeseburger, salad, fruit or chips, 450-550 Calories . .\$4.79





Listing Calories Examples

Multi-Serving

- Entire standard menu item
- Can list per individual unit (slice of pizza) but must include total number of units is included and the menu item is normally prepared and served in discrete units (whole pizza cut into slices)

EXAMPLE: PIZZA

EXAMPLE

On your menu board, you must declare calories for each item as prepared (example: 200 cal/slice, 8 slices). In addition, you must declare the calories for each additional topping available (example: roasted garlic, 5 cal/slice).

Listing Calories Examples

Multiple Toppings

- If individual toppings are not listed range of calories can be used
- If toppings are individually listed toppings must have specific calorie declaration but can be grouped if declaration is the same

Pizza

Small (12")	500 cal
Medium (14")	750 cal
Large (16")	1000 cal

Toppings

	Small	Medium	Large
Pepperoni	200	300	400
Sausage	250	350	450
Green Peppers	15	20	25





Self-Serve & Foods on Display

3 Different Options:

- Sign adjacent to clearly associated with the corresponding food (including calories directly on the package of grab and go)
- 2. Sign attached to sneeze guard
- Single sign or placard listing calorie declaration for several food items (but must be located where consumer can view the information while making selection)
 - 300 calories per muffin
 - 200 calories per scoop of potato salad
 - 140 calories per 12 fluid ounces (small)





Beverage Bar

- Must state number of calories in full volume of cup as served without ice at beverage bar
- If covered establishment has a drive-through calories should reflect standard fill line with ice added
- Some restaurants will need two sets of calories – one for the beverage bar (without ice) and one to fill line (with ice)



Statement Requirements

	Succinct Statement "2,000 calories a day is used for general nutrition advice but calorie needs vary"	Statement of Availability "Additional nutrition information available upon request"
Menu	Bottom of each page	First page only
Menu Boards Victorial Control	Each rotating page	Bottom of each rotation
Grab & Go	On label or on sign in close proximity and visible while ordering	On label or on sign in close proximity and visible while ordering

Drive-through

- Same requirements as Menu Boards
- Beverages must state number of calories ordinarily dispensed to standard fill with ice
- Succinct Statement and Statement of Availability required







Written Information

Written nutrition information must include the nutrients that are currently required in the Nutrition Facts label (1990) on packaged foods (except vitamins & minerals)

- Total calories
- Calories from Fat
- Total fat
- Saturated Fat
- Trans Fat
- Cholesterol
- Sodium
- Total carbohydrate
- Dietary Fiber
- Sugars
- Protein

1990 Label

	ntainer Ab	out 8	
Amount Per Servin	ng		
Calories 230	Cal	ories fron	n Fat 72
		% Dail	y Value
Total Fat 8g			12%
Saturated Fat	1g		5%
Trans Fat 0g			
Cholesterol 0	mg		0%
Sodium 160mg			7%
Total Carbohy	ydrate 37	'g	12%
Dietary Fiber	4g		16%
Sugars 1g			
Protein 3g			
			400
Vitamin A			10%
Vitamin C			8%
Calcium			20%
Iron			45%
 Percent Daily Value Your daily value may your calorie needs. 			
	Calories: Less than	2,000	2,500
Total Fat		65g	80g

Written Nutrition Format

- Posters
- Tray Liners
- Counter Cards
- Signs
- Handouts
- Booklets
- Computer/Kiosk (inside restaurant cannot direct customer to the internet)







Changes to Menu Items

- Requirements of the rule are to provide accurate and timely information
- If calorie and other information not accurate, the food will be considered misbranded
- Update the menu board, contact the FDA or use a temporary solution as in packaged goods.





Menu Labeling vs. 2016 Nutrition Facts

ACA - Menu Labeling

- Effective May 5, 2016 –
 Enforcement May 5, 2017
- All restaurants, grocery and convenience stores with 20 or more locations
- Must provide calorie declarations for all standard, combination and variable menu item

NLEA - Nutrition Facts Label

- Effective July 26, 2018
- All manufacturers with more than \$10 million in annual sales
- Manufacturers with less than \$10 million have until July 26, 2019
- Must convert from 1990
 NLEA to 2016 label





Menu Labeling vs. 2016 Nutrition Facts

Nutrient or Regulatory Topic

2016 NLEA

ACA

Calories	✓	✓
Calories from Fat	*	✓
Total Fat	✓	✓
Sat Fat	✓	✓
Trans Fat	✓	✓
Cholesterol	✓	✓
Sodium**	✓	✓
Total Carb	✓	✓
Dietary Fiber**	✓	✓
	(Beneficial to human health)	
Sugars (Total Sugars)	✓	✓

✓- Required

V- voluntary

O- not listed

➤- removed

Menu Labeling vs. 2016 Nutrition Facts

Nutrient or 2016 NLEA ACA Regulatory Topic Added Sugar ✓ - Required **Protein** V- voluntary Calcium Iron O- not listed **Potassium ×**− removed Vitamin A Vitamin C Vitamin D** Serving size determined by RACC, Nutrition information is RACC which has been re-evaluated to determined by size of the item as usually prepared and offered for more accurately reflect modern sale, not according to RACC portion sizes % Daily Values * * DVs have been updated for www.esha.com Sodium, Fiber and Vit D

In-Store vs Corporate Headquarters

Upon request, the following information must be provided to FDA:



On-Site Information

- Method of Preparation
- Additional Nutrition Information
 - Total Calories, Calories from Fat, Total Fat, Sat Fat, Trans Fat, Cholesterol, Sodium, Total Carbohydrate, Dietary Fiber, Sugars, and Protein
- Statement certifying method of preparation



Information at Corporate Headquarters

- Detailed description of means to determine nutrition information (software, cookbook, Lab)
- Copy of the recipe
- Lab Data (if used)
- Data used to derive nutrient values for individual ingredients
- Statement certifying that information is complete & accurate





Determining Nutrition Content

- Nutrient Databases
 - Name, version of database
 - Software
- Laboratory Analysis
- Nutrient Facts label
- Cookbooks
- Other Reasonable Means







Food Menu and Food Menu Report

Food Menu

Create your menu

Food Menu Report

- Display Calories and mandated nutrients
- Prices entered
- Allergens
- Ingredient statements, or characteristics such as "gluten free".





Genesis R&D Training

Advanced Genesis Workshop | April 25-26, 2017 | Washington, DC

This workshop covers advanced topics in detail such as new FDA labeling regulations, due diligence and documentation for transitioning to the new labels, new program features, PDCAAS (protein digestibility score), range formulas, advanced labels, and more

Genesis Professional Training (Canadian Specific) | April 27-28, 2017 | Toronto, ON

This training session will cover the essentials of Genesis R&D including creating ingredients and recipes/formulas, reporting, best practices, and basic labeling features.

Genesis Professional Training | May 9-10, 2017 | Lombard, IL

This training session covers the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, obtaining nutrition analysis, analysis reporting, best practices, and basic labeling features.

Genesis Professional + Menu Labeling Training | May 18-19, 2017 | Chicago, IL

This training session covers ingredient creation and recipe/menu building, best practices, and analysis reporting specific to restaurants, grocery stores, and those who have to comply with the FDA's Menu Labeling regulations.

For more information including cost and availability, please contact our training coordinator by phone at 503-585-6242or by email at **training@esha.com**.



Questions?

Contact Us!

Phone: 503-585-6242

Email: sales@esha.com

Helpful Resources

LinkedIn: bit.ly/ESHA-LinkedIn

Blog: www.esha.com/blog

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