

Nutrition Labeling Challenges

Food and Drug Law Institute -- Annual Conference

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Dietary Fiber Definition



- Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants
- Isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health

Dietary Fiber Definition



- “Intrinsic” -- originating and included wholly within a food
- “Intact” -- “having no relevant component removed or destroyed”
- FDA -- “intrinsic and intact” includes non-digestible carbohydrates created during normal food processing (e.g., cooking, rolling, or milling)”



Approved Isolated or Synthetic Fibers



- Isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health:
 - [beta]-glucan soluble fiber
 - psyllium husk
 - cellulose
 - guar gum
 - pectin
 - locust bean gum
 - hydroxypropylmethylcellulose (HPMC)



Future FDA Actions on Dietary Fiber



- FDA took the position in the preamble that functional fibers in the IOM report (inulin, oligofructose, and fructooligosaccharides) do not demonstrate beneficial physiological effects
- Notice: seeking comments on available scientific data re fibers including: inulin, bamboo fiber, soy fiber, pea fiber, wheat fiber, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber
 - 81 Fed. Reg. 84595 (Nov. 23, 2016)

How to Get Listed as Approved Fiber



- Submit information re beneficial physiological effect to amend list of approved dietary fibers
- Draft Guidance (11/2016): FDA identified information needed to demonstrate beneficial physiological effects on human health

How to Get Listed as Approved Fiber



- “Beneficial physiological effects” include (but are not limited to):
 - Lowering total/LDL levels
 - Lowering post-prandial glucose levels
 - Reducing gut transit time and improving laxation (fecal output)
 - Reduced blood pressure
 - Increased satiety associated with reduced energy intake and with possible associated outcomes on body weight to be physiological endpoints.
- Only need one

How to Get Listed as Approved Fiber



- Final Guidance (3/2018) -- changes from draft:
 - Clinical studies in diseased populations may be considered if extrapolating to those without the disease is scientifically appropriate.
 - Petition can address a beneficial physiological effect from a combination of 2 non-digestible carbohydrates
 - Provides additional examples of physiological endpoints that FDA may consider
- Further clarification is needed re “intrinsic and intact” vs. “isolated or synthetic”
- No date for FDA responses re submissions for 26 added non-digestible carbohydrates

Added Sugars



- Mandatory
 - 1 gram or more added sugars per serving
 - OR
 - Claims made about sweeteners, sugars, added sugars or sugar alcohol content
- Declare grams and Percent Daily Value
- Daily Reference Value = 50g (adults and children ≥ 4 years)
- Basis --10% of daily calories from added sugars would help consumers maintain healthy dietary patterns



What are Added Sugars?

- Sugars either added during the processing of foods, or packaged as such
- Includes:
 - Sugars (free, mono- and disaccharides);
 - Sugars from syrups and honey; and
 - Sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type



What are Not Added Sugars?



- Not included in “added sugars”
 - 100% fruit or vegetable juice
 - Fruit or vegetable juice concentrated from 100% juices sold in that form to consumers;
 - Fruit or vegetable juice concentrates used towards the total juice percentage label declaration under 21 CFR 101.30 or for Brix standardization under 21 CFR 102.33(g)(2);
 - Fruit juice concentrates used to formulate the fruit component of jellies, jams, or preserves under standard of identities in 21 CFR 150.140 and 150.160; and
 - The fruit component of fruit spreads



Fruit/Vegetable Puree Concentrate



- Ingredient may or may not contain “added sugars”
 - If it contains all the components of a whole fruit/vegetable, and was processed to physically create smaller pieces or remove water, the sugars from the portion typically eaten and used are not considered added sugars -- “nutrient equivalency”
 - But if it no longer contains all the components of the portion typically eaten, and the sugars are concentrated, the ingredient is comparable to a juice concentrate
 - Terminology (“___puree concentrate”) can refer to either type of processing
 - FDA may seek evidence that the use of a puree concentrate process maintains nutrient equivalency

Claim re Amount of Protein (grams)



- “_____ g” Protein on PDP
 - Companies may be unaware that “_____g Protein” on PDP is a protein claim. and triggers the requirement to declare Percent Daily Value of protein
 - Companies may also be unaware that the protein must be tested using the PDCAAS methodology (protein digestibility-corrected amino acid score)
 - The calculation of Percent Daily Value may have to include a correction based on the PDCAAS result, depending on the source(s) of protein

Front-of-Package (FOP) Labeling



- Two main approaches:
 - Reductive -- snapshot of nutrient-specific information from labeled nutrition information
 - Evaluative -- interpretative compilation as a rating
- Mandatory FOP labeling proposed in Canada
 - Saturated fat, sugars, and sodium
 - Products with $\geq 15\%$ daily value for these nutrients
 - Would be effective in 12/2022
- FOP labeling -- required or being considered in a number of countries
- U.S.
 - The U.S. Trade Representative, in renegotiating NAFTA, is seeking to limit the ability of Canada, Mexico and the U.S. to impose mandatory FOP labeling that suggests health risks



THANK YOU

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NUTRITION LABELING CHALLENGES

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CHALLENGES FROM THE INSIDE

- Need for Clarity
 - Dates
 - Definitions
- Differing Recommendations re Sugar
 - Regulatory Priorities Abroad
- Uncertainty re Consumer Comprehension
- FOP in Canada
- Influence of Litigation

DATES AND DEFINITIONS

- FDA has a proposed rule to extend NLEA compliance dates to 1/1/20
- Pending Definitions
 - Dietary Fiber
 - Impact of NLEA on Healthy and Natural

DIETARY FIBER

- Are 26 added non-digestible carbohydrates fiber?
 - Suppliers convinced of beneficial physiological effects
 - FDA Guidance sets a high bar
- Some suppliers insist ingredients are intrinsic and intact
 - Does FDA agree?

DIETARY FIBER

- NLEA compliance when ingredient under consideration
 - Manufacturer Options
 - Reformulate
 - Omit from fiber calculations
 - Hound suppliers

ADDED SUGARS

- Reference Amounts
 - U.S. 50 gram DV
 - WHO and AHA 25 gram DV
 - Canada 100 gram DV total sugar
- Calculations
 - Mono and di-saccharides, but not poly saccharides
 - Fruit puree math

ADDED SUGARS

- Technical Considerations
 - Science of sugar consumption
 - FDA's position
 - Alternative sweeteners
 - Total versus added sugar
 - Contribution of inherent sugars
 - Juice
 - Dried fruit

ADDED SUAGRS

- Consumer Effects
 - Label Comprehension
 - Litigation

FOP LABELING

- Requirements vary by country
 - Scheduled to be mandatory in Canada
 - Still optional in EU and U.S.
 - Call outs vary by country
 - Formulation challenges

CHANGE MANAGEMENT

- Potential Outcomes
 - Reformulation
 - Retailer restrictions
 - Ingredient bans (e.g. partially hydrogenated oils)
 - Nutrient limits?
 - Changes to consumption patterns
 - Impact of consumer education/tools will

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Challenges and Developments in Nutrition Labeling – Added Sugars and Front-of-Pack Nutrition Rating Warnings

Nutrition Labeling and Front-of-Pack Nutrition Rating Warnings

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Outline of Presentation

- I. Added Sugars Labeling – US FDA
- II. Added Sugars Labeling – Health Canada
- III. Front-of Pack Nutrition Ratings – Health Canada
- IV. Implications for NAFTA negotiations

I. Added Sugars Labeling – US FDA

- On October 2, 2017, FDA extended the compliance deadline for updating the Nutrition Facts label from July 26, 2018 to **January 1, 2020** (January 1, 2021 for manufacturers with less than \$10 million in annual food sales).

I. Added Sugars Labeling – US FDA

- The agency explained in a *Federal Register* notice that it was taking this action, in part, because it tentatively determined that additional time would help ensure that all manufacturers be provided more guidance on certain technical questions FDA received after issuance of the final rules in 2016. Many of those questions involved the labeling of added sugars.

I. Added Sugars Labeling – US FDA

- Delay should be used to review consumer understanding.
- Added sugars labeling leads to consumer confusion.
- FDA's own survey research shows 24% of consumers would be misled by the proposed added sugars label.

I. Added Sugars Labeling – US FDA

- On March 2, 2018, FDA published draft non-binding guidance on:
 - The declaration of two (single ingredient) sugar products; Honey and Maple Syrup;
 - The FDA addressed the problem of requiring these foods to be listed as both “Total Sugars” and “includes Added Sugars;
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm595578.htm>

I. Added Sugars Labeling – US FDA

- Honey – A serving of honey from a honey jar would be listed on the Nutrition Facts label as “Added Sugars” and Total Sugars raising confusion.



I. Added Sugars Labeling – US FDA

- FDA's proposed solution is to permit a footnote explaining the nature of honey and maple syrup;
<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM596469.pdf>
- Examples of Nutrition Facts label with “†” symbol leading to a factual statement outside the box.

I. Proposed Footnote for Honey Doesn't Help Much

Nutrition Facts	
8 servings per container	
Serving size	1 cup (240ml)
Amount per serving	
Calories	110
% Daily Value*	
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 5mg	0%
Total Carbohydrate 27g	9%
Dietary Fiber 0g	0%
Total Sugars 25g	
Includes 23g Added Sugars	54%†
Protein 0g	
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 45mg	1%
<small>* 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.</small>	

† All these sugars are naturally occurring in honey.

Table Sugar – Added or Not?

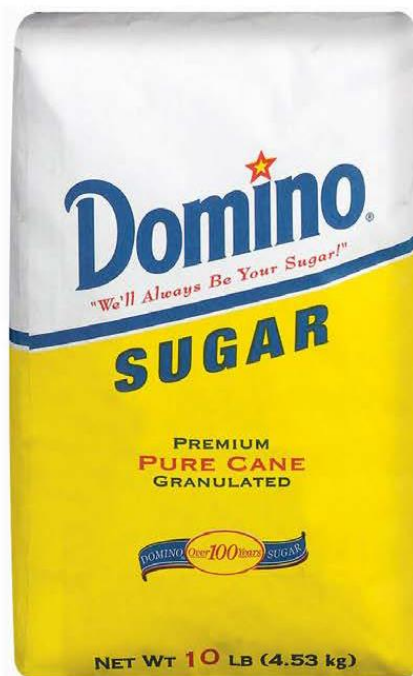


Table Sugar – Added or Not?

- A retail package of sugar would list the contents on the Nutrition Facts as Total Sugars and “Added Sugars” when common sense dictates otherwise.

II. Added Sugars Labeling – Health Canada

- Canada does not require disclosure of added sugars.
- Only requires a %DV for Total Sugars.
- Segway to differences in Canadian and US FDA Nutrition Facts labels.

II. Canada -- Old and New Nutrition Facts Labels with Sugars Content

ORIGINAL	
Nutrition Facts Valeur nutritive	
Per 250 mL / par 250 mL	
Amount Teneur	% Daily Value % valeur quotidienne
Calories / Calories 110	
Fat / Lipides 0 g	0 %
Saturated / saturés 0 g + Trans / trans 0 g	0 %
Cholesterol / Cholestérol 0 mg	
Sodium / Sodium 0 mg	0 %
Carbohydrate / Glucides 26 g	9 %
Fibre / Fibres 0 g	0 %
Sugars / Sucres 22 g	
Protein / Protéines 2 g	
Vitamin A / Vitamine A	0 %
Vitamin C / Vitamine C	120 %
Calcium / Calcium	2 %
Iron / Fer	0 %

NEW	
Nutrition Facts Valeur nutritive	
Per 1 cup (250 mL) pour 1 tasse (250 mL)	
Calories 110	% Daily Value* % valeur quotidienne*
Fat / Lipides 0 g	0 %
Saturated / saturés 0 g + Trans / trans 0 g	0 %
Carbohydrate / Glucides 26 g	
Fibre / Fibres 0 g	0 %
Sugars / Sucres 22 g	22 %
Protein / Protéines 2 g	
Cholesterol / Cholestérol 0 mg	
Sodium 0 mg	0 %
Potassium 450 mg	10 %
Calcium 30 mg	2 %
Iron / Fer 0 mg	0 %
*5% or less is a little, 15% or more is a lot *5% ou moins c'est peu, 15% ou plus c'est beaucoup	

New % Daily Value
for total sugars

New footnote
to help interpret
the % Daily Value

III. Front-of Pack Nutrition Ratings and Warnings

- Another major difference between Canada and the US is that Canada is moving ahead with rulemaking to standardize front-of-pack nutrition rating symbols and warnings.

<https://www.canada.ca/en/health-canada/programs/consultation-front-of-package-nutrition-labelling-cgi.html>

III. Front-of Pack Nutrition Ratings and Warnings

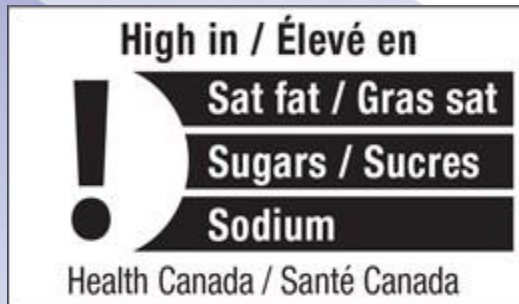
- FDA considered the issue in 2009-2011 but allowed a voluntary “Facts up Front” system developed by GMA/FMI to proceed.

<http://wayback.archive-it.org/7993/20171115001623/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm302720.htm>

III. Front-of-Pack Nutrition Ratings



III. Front-of-Pack Nutrition Warnings -- Canada's Options



III. Front-of-Pack Nutrition Warnings

- Front-of-Pack Nutrition Warnings are a reality.



IV. Implications for NAFTA Negotiations

- US trade negotiators are objecting to nutrition labeling warnings such as . . .
- Nutrient front-of-pack warnings/ratings
- Sugar warning labels
- Trump Administration/Congress trying to set new NAFTA agreement for fast track vote.

What's Down the Road?



Questions?

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