WRSS Food & Nutrition Insights®

Clean Label Conference

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# Labeling Fiber & Sugar: Maximizing Clean Label Advantages, Minimizing Class Action & Recall Risk

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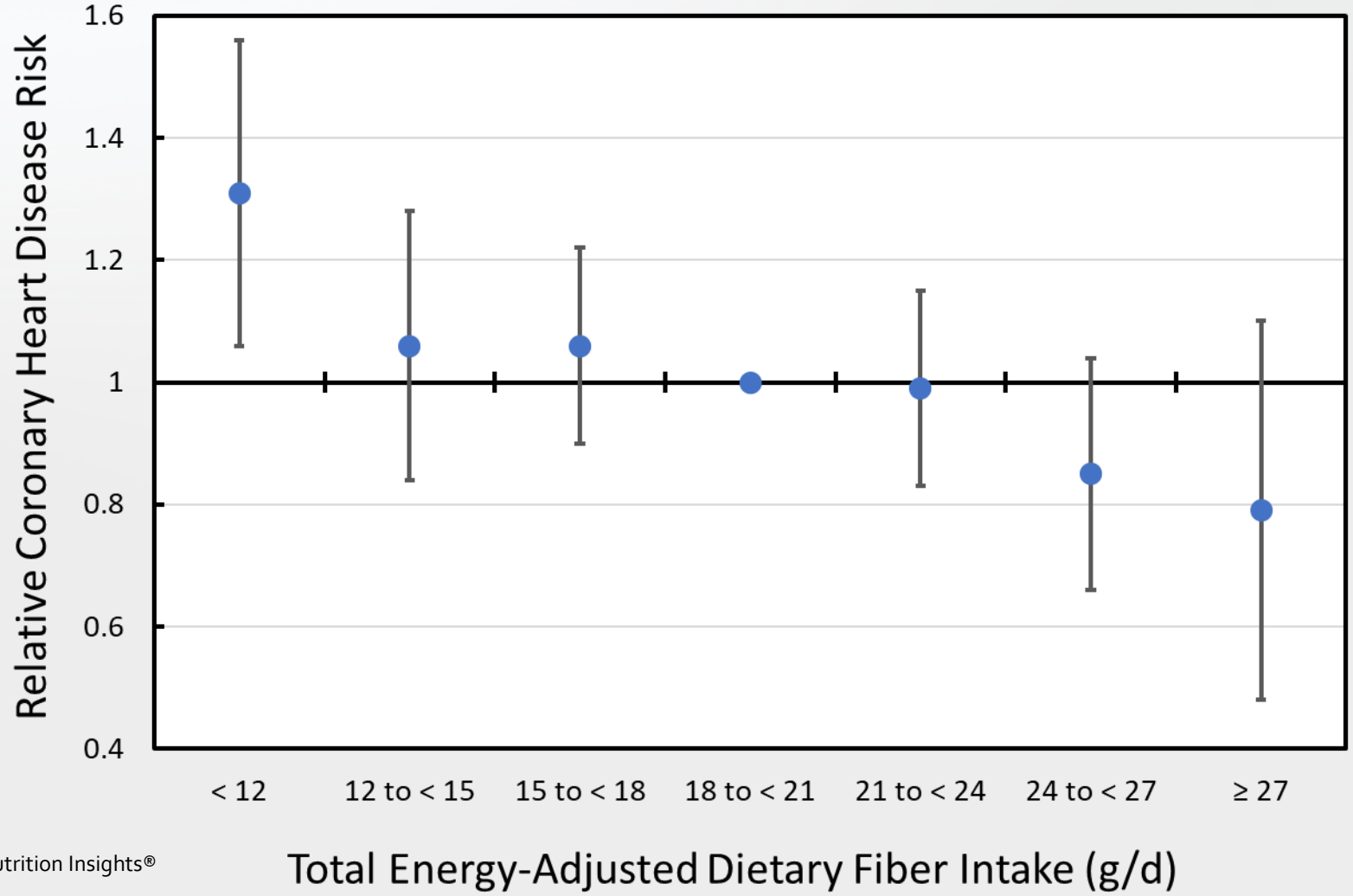
# Overview

- Importance of dietary fiber to human health.
- New FDA fiber regulations.
- Preferred analytical methods.
- Requirement for recordkeeping.
- Risks for not analyzing fiber.
- Avoiding added sugars.
- Risks for sugar claims.

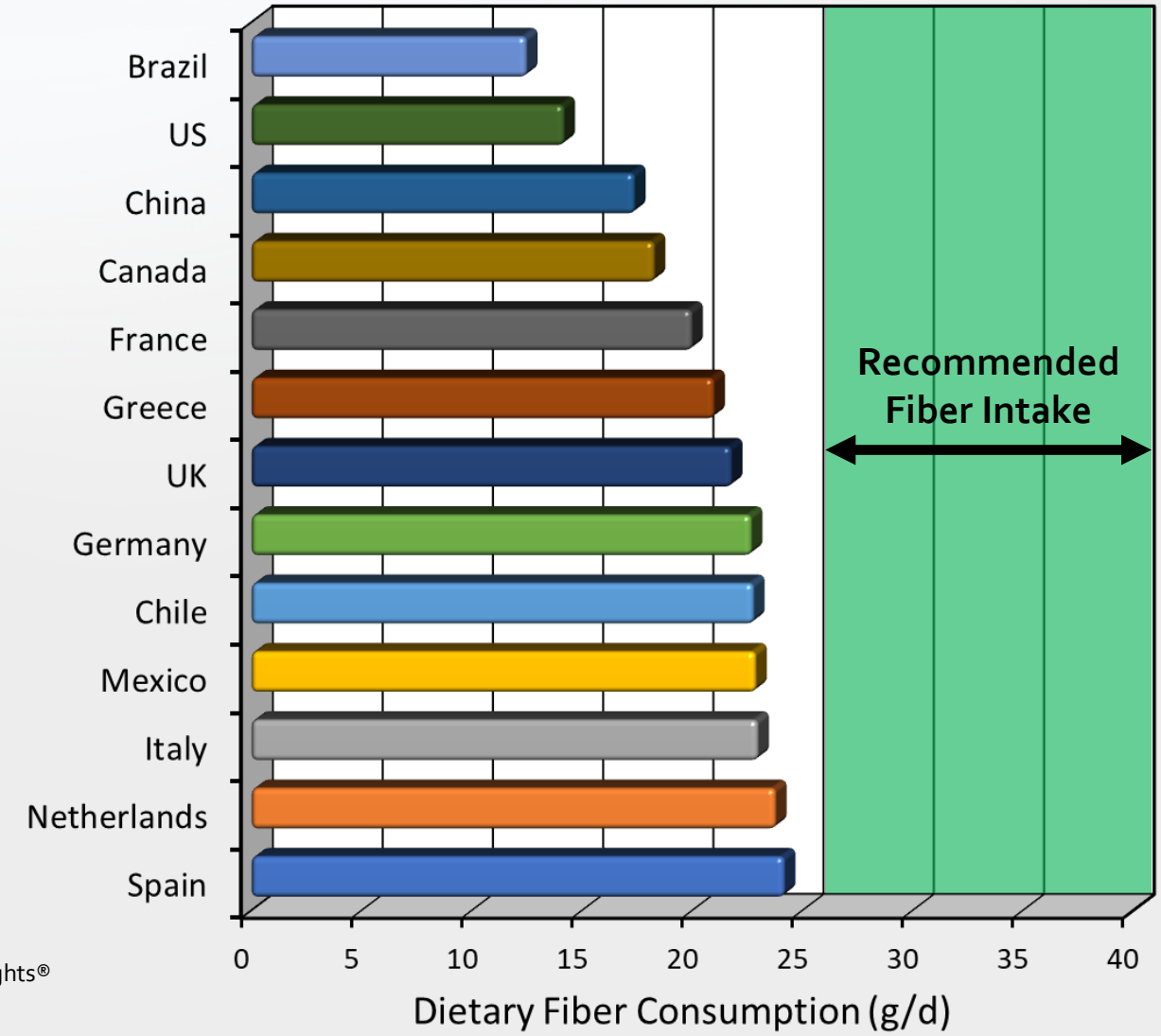
# Relative Risk of Death From Coronary Heart Disease






Pereira et al. 2004 Arch Intern Med 164:370-376.
*Courtesy of Prof. Joanne Slavin, University of Minnesota*

# Dietary Fiber Consumption Falls Short for Many Countries




Gray J. ILSI Europe Dietary Fibre Concise Monograph Series. 2006; Cho SS & Samuel P. Fibre Ingredients: Food Application. Thompson HJ, Brick MA. Adv Nutr. 2016 7:623-6.

# Keto-friendly means “Low Net Carb” foods

**Nutrition Facts**

Serving Size: 1 Donut (16g)
Servings Per Container: 24

| Amount Per Serving | Mix | Baked |
|---|---|---|
| **Calories** | 50 | 90 |
| Calories from Fat | 25 | 60 |
| | **% Daily Value**** | |
| **Total Fat** 3g* | **5%** | **11%** |
| Saturated Fat 0g | **0%** | **10%** |
| *Trans Fat 0g* | | |
| **Cholesterol** 0mg | **0%** | **23%** |
| **Sodium** 125mg | **5%** | **6%** |
| **Total Carbohydrate** 10g | **3%** | **4%** |
| Dietary Fiber 8g | **32%** | **32%** |
| Sugars 0g | | |
| **Protein** 1g | | |

10-8=2

net carbs*

*Some subtract sugar alcohols as well.

# New US FDA Dietary Fiber Regulations - Enforced July 1, 2020

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21 CFR 101.9(c)(6)(i)

| Regulation | FDA Old Rule | FDA New Rule |
|---|---|---|
| Daily Value (100%) | 25 grams per day | **28 grams per day** |
| **Good Source** of Dietary Fiber (**10% DV**) | 2.5 grams per serving | **2.8 grams per serving** |
| **Excellent Source** of Dietary Fiber (**20% DV**) | 5.0 grams per serving | **5.6 grams per serving** |
| Insoluble Calories | 0 Cal/g Insoluble Dietary Fiber | 0 Cal/g Insoluble NDC |
| Soluble Calories | 4 Cal/g Soluble Dietary Fiber | **2 Cal/g Soluble NDC** |
| Total Calories | 4 Cal/g Total Dietary Fiber | 4 Cal/g Total NDC |

NDC = Non-Digestible Carbohydrate

# New Definition of Dietary Fiber

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Dietary fibers are non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are:

1. **INTRINSIC AND INTACT**
   - Self-determined by Food Manufacturer
   - Due diligence concurrence with Ingredient supplier determination
2. **ISOLATED OR SYNTHETIC**
   - Determined by FDA based on a Citizen Petition

# Requirements for Intrinsic and Intact Dietary Fiber

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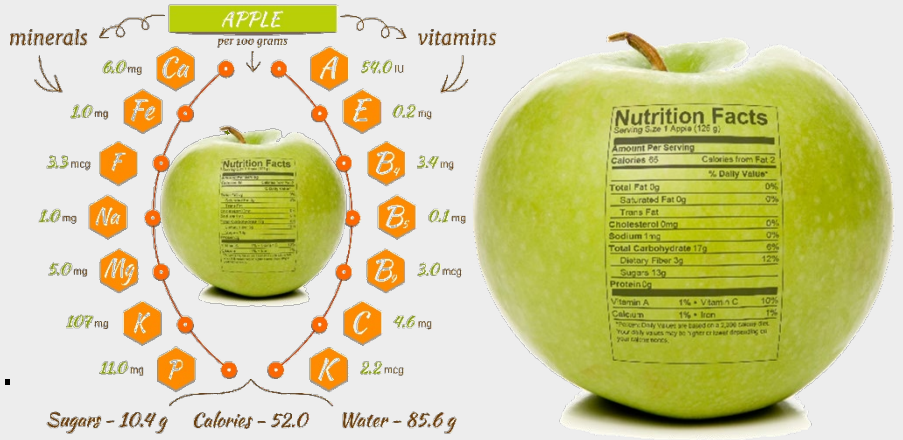
1. Intrinsic and Intact dietary fibers must contain all the same relevant components found in the whole plant.
    a) Intrinsic means the fiber originates and is included wholly within a food.
    b) Intact means that no relevant component has been removed or destroyed.
        i. To demonstrate that a dietary fiber is intact, any analytical method that can show all nutrients and bioactives remain after processing may be used.
            a. For example, methods that measure:
                1. dietary fiber;
                2. vitamins;
                3. minerals; and
                4. other relevant nutrients (protein, lignin, etc).




2. The I & I dietary fiber must be traditionally consumed by the US population (not novel).

# Examples of Intrinsic and Intact Dietary Fiber

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**Intrinsic and Intact Dietary Fibers**

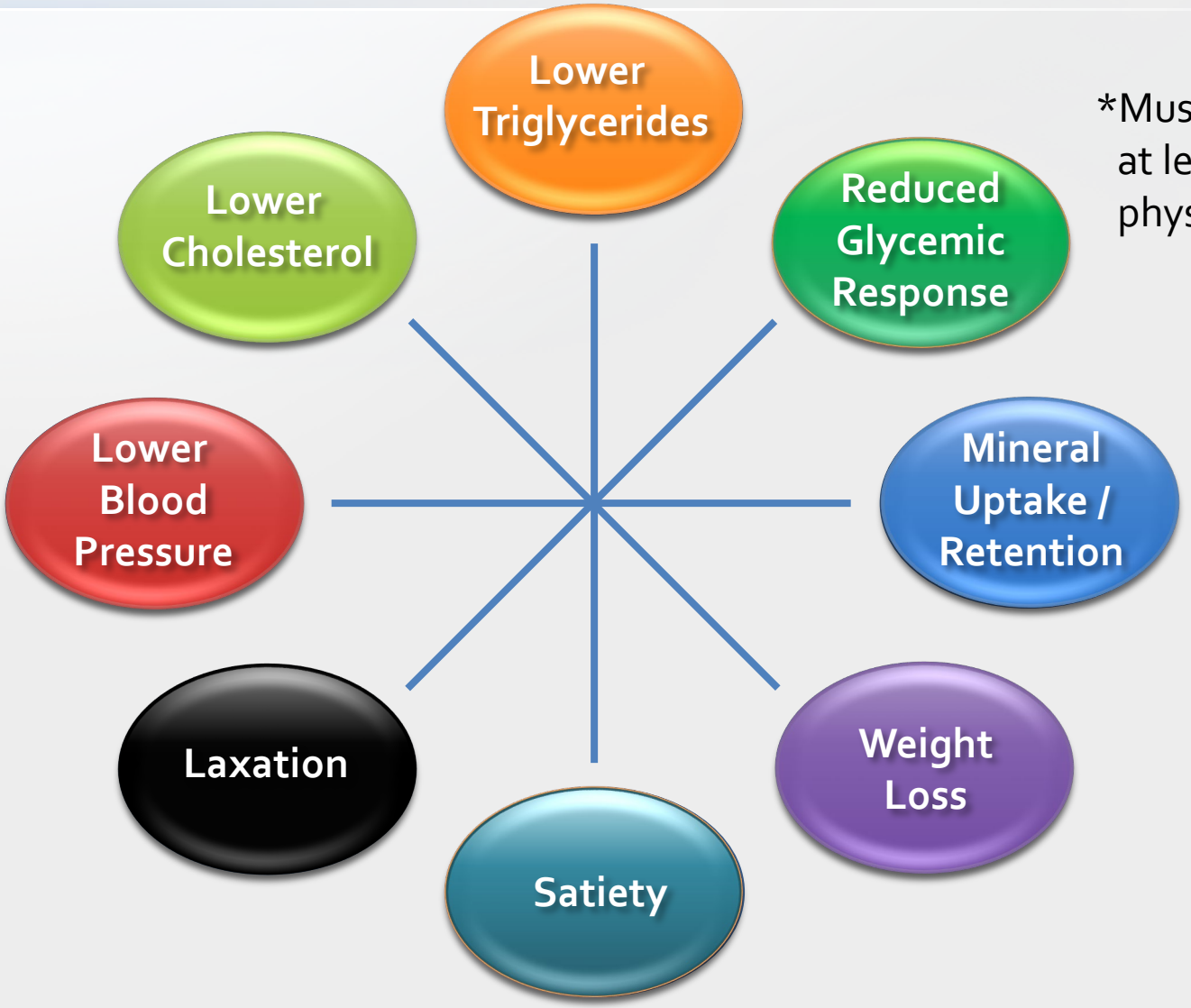
- Vegetables
- Whole grains
- Fruits
- Nuts
- Pulses
- Cereal bran
- Flaked cereal
- Flours

**Dietary Fibers which are not Intrinsic and Intact**

- Sugar Cane Fiber
- Apple Fiber
- Bleached Oat Hulls (Oat Fiber)

Isolated Fibers

# Isolated or Synthetic NDC must demonstrate a physiological benefit to health*




*Must demonstrate at least one physiological benefit.

# US Cereal β-Glucan Health Claim

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Diets that are low in saturated fat and cholesterol and that include:

**3 g** or more **per day of [beta]-glucan** soluble fiber from either whole oats or barley, or a combination of whole oats and barley.

**May reduce the risk of Heart Disease.**

21CFR101.81

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# FDA Recognized Isolated or Synthetic Dietary Fibers

## Originally approved with rule

- Beta-glucan soluble fiber
- Psyllium husk
- Cellulose
- Guar gum
- Pectin
- Locust bean gum
- Hydroxypropylmethylcellulose

## Added by Citizen Petition

- Mixed plant cell wall fibers (a broad category that includes fibers like sugar cane fiber, **oat fiber** and apple fiber, among many others)
- Arabinoxylan
- Alginate
- Inulin and inulin-type fructans
- High amylose starch (resistant starch 2)
- Galactooligosaccharide
- Polydextrose -- *(1 kcal/gram exception)*
- Resistant maltodextrin/dextrin
- Cross-linked phosphorylated RS4
- **Glucomannan (January 9, 2020)**
- Acacia [Gum Arabic] (Dec 17, 2021)

# Approved Fibers on the Clean Label Spectrum

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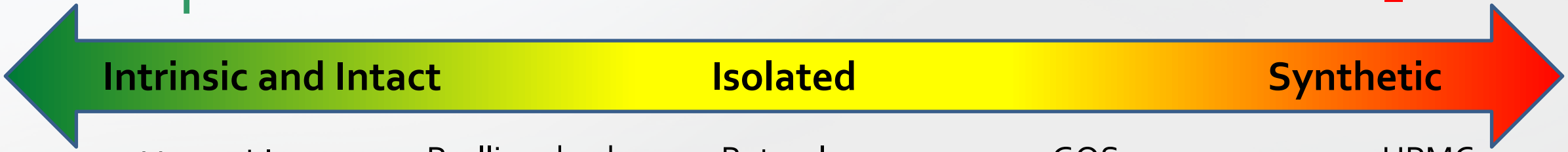
Positive +

Clean Label Perception

Negative -




- Vegetables
- Whole grains
- Fruits
- Nuts
- Pulses
- Cereal bran
- Flaked cereal
- Flours

- Psyllium husk
- Guar gum
- Pectin
- Locust bean gum
- Apple fiber
- Konjac fiber (glucomannan)
- Acacia gum

- Beta-glucan
- Cellulose
- Oat fiber
- Sugar Cane fiber
- Chicory Root fiber
- Alginate
- Arabinoxylan
- Resistant Wheat Starch ($RS_4$)
- Resistant Tapioca Starch ($RS_4$)
- Resistant Corn Starch ($RS_2$)

- GOS
- FOS
- Soluble corn fiber

- HPMC
- Polydextrose
- Resistant Maltodextrin

# How to Label Dietary Fiber under the New FDA Rules


1. Analyze your product by an official AOAC method like AOAC 2011.25 or AOAC 2017.16 for soluble and insoluble Non-digestible Carbohydrates (NDC).

**FDA Guidance**: Dietary Fiber equals "the total fiber that is quantified by analytical methods minus the amount that does not meet the dietary fiber definition."


2. Subtract the amount of recorded FDA approved dietary fiber from the total amount of Non-digestible Carbohydrates (NDC) analyzed.

# Analytical Methods for Measuring NDC

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## RS4 Starches

### Prosky Method

AOAC 985.29

### Lee Method

AOAC 991.43

\+

AOAC 2001.03

Recovers HPLC for DP≥3 to ~40

### McCleary Methods

#### CODEX Definition

AOAC 2009.01

AOAC 2011.25

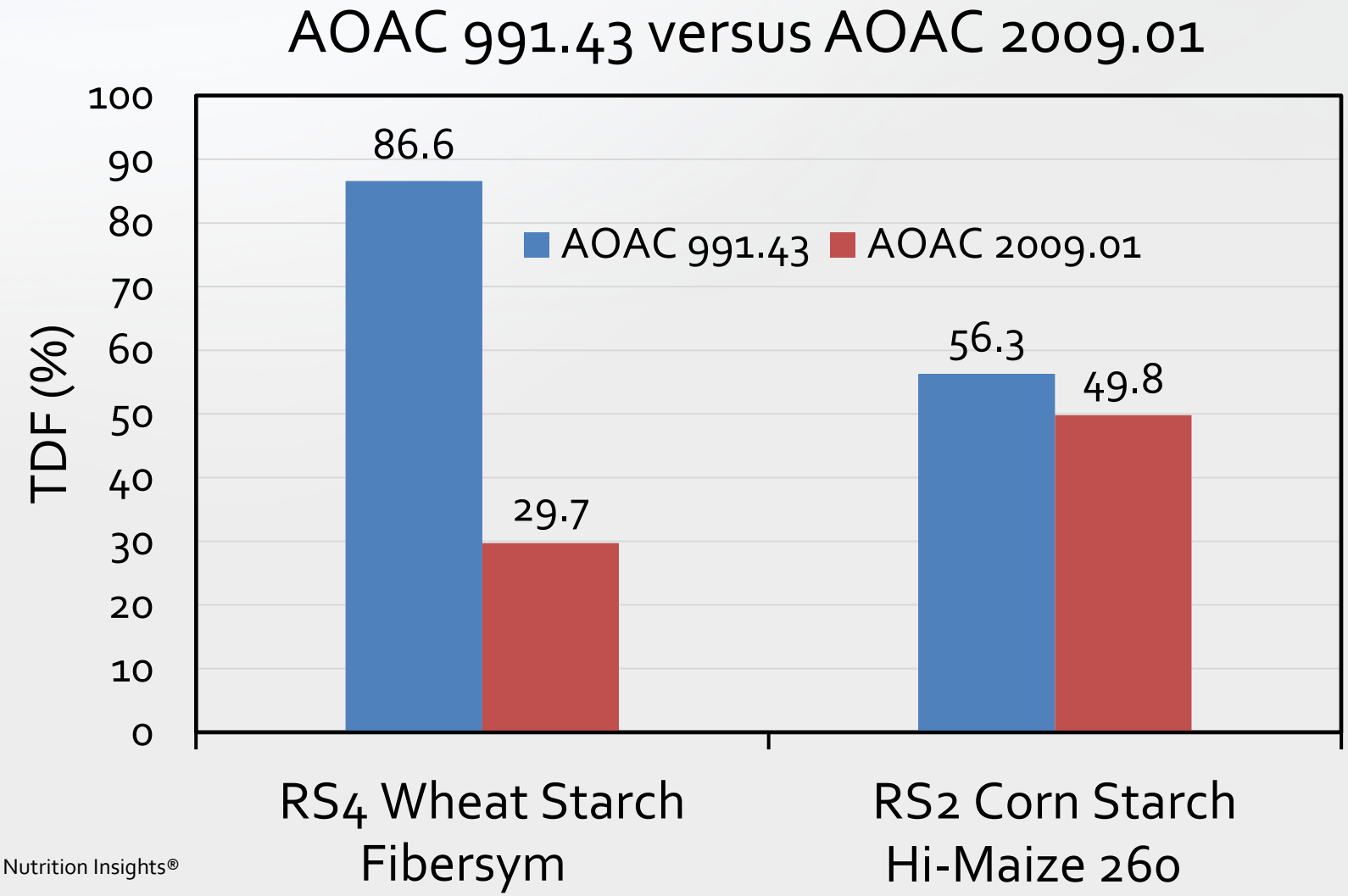
#### RINTDF

AOAC 2017.16*

Includes HPLC for DP≥3 to ~40

**Unacceptable Matrices:**
**Stevia** can cause interference with the chromatography. Samples containing **>2% stevia** will damage the instrument therefore cannot be run through this method.

# Difference in Total TDF for RS4 and RS2 Starches



# Inactivation of "Heat Stable" Alpha Amylase at 95°C

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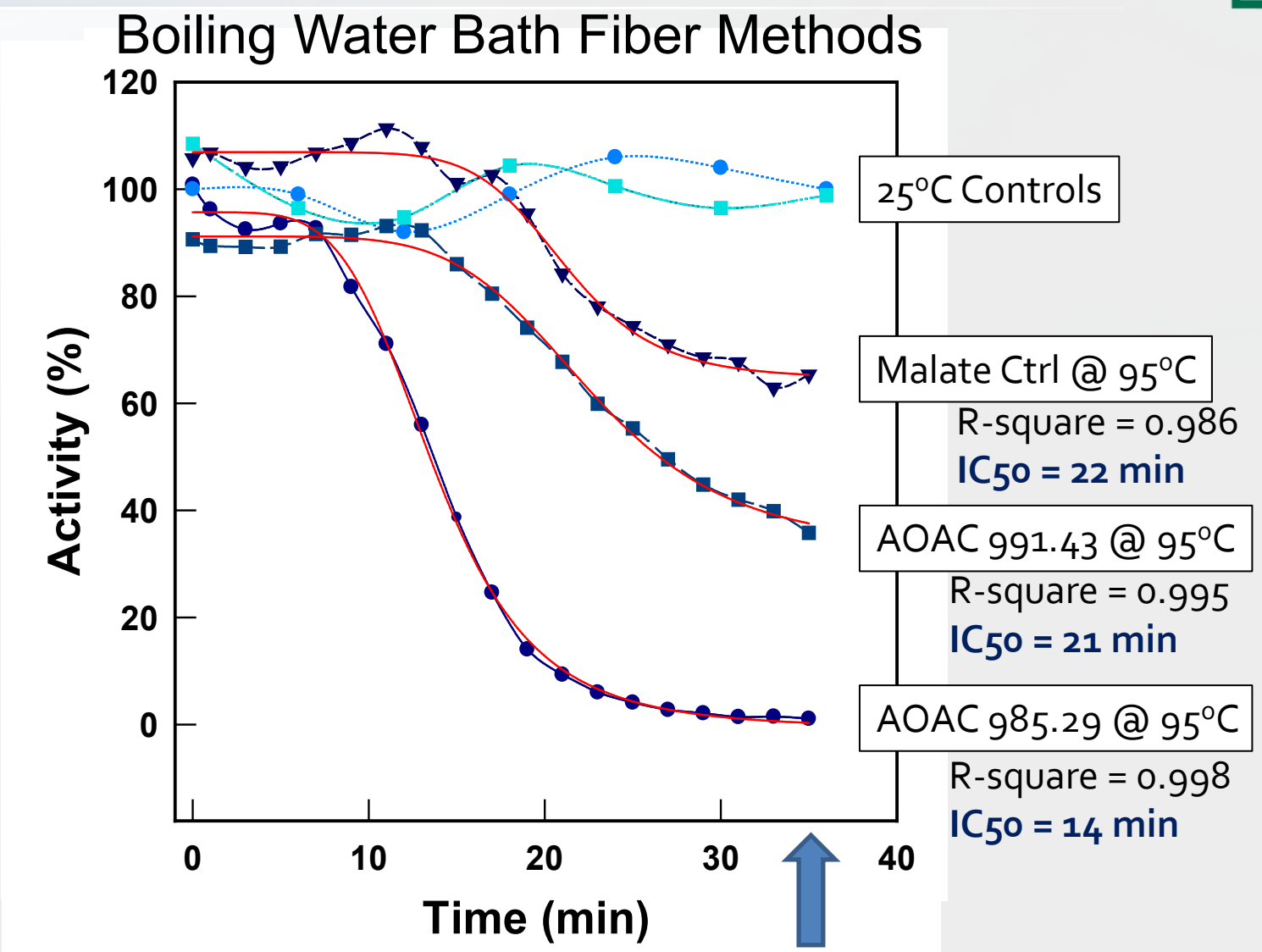
Alpha Amylase Activity measured by AOAC 2002.01 Ceralpha Assay

4-parameter Hill Plot fit:

$$y = \frac{\text{min} + (\text{max} - \text{min})}{(x / IC_{50})^{-\text{Hillslope}}}$$



# Considerations of using AOAC 991.43 for RS4

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## PROS

- Higher results for RS4 Starches and some RS2 Starches.
- FDA allowed method for NDC*.
- Quantification supported by an *In Vivo* study.
  - Iacovou, M. et al. (2017) *In vivo* digestibility of cross-linked phosphorylated (RS4) wheat starch in ileostomy subjects. *Bioactive Carb. Dietary Fibre*. **12:** 25-36.

## CONS

- Higher results may be a digestion artifact.
- Digestion not consistent with human physiology (boiling water bath).
- Limited 3rd Party Lab availability of method in combination with 2001.03.

*NDC = Non-digestible Carbohydrate

# Analytical Methods for Measuring NDC

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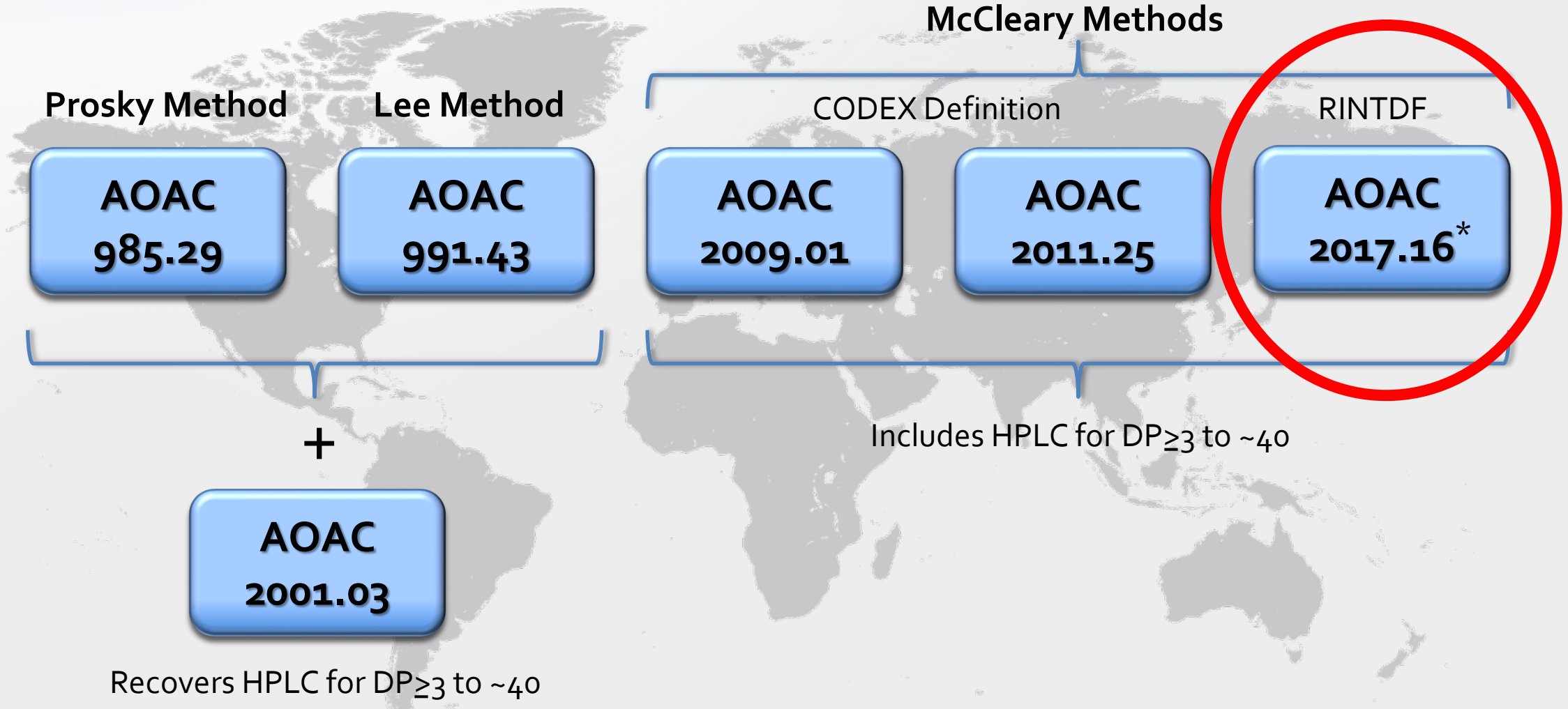
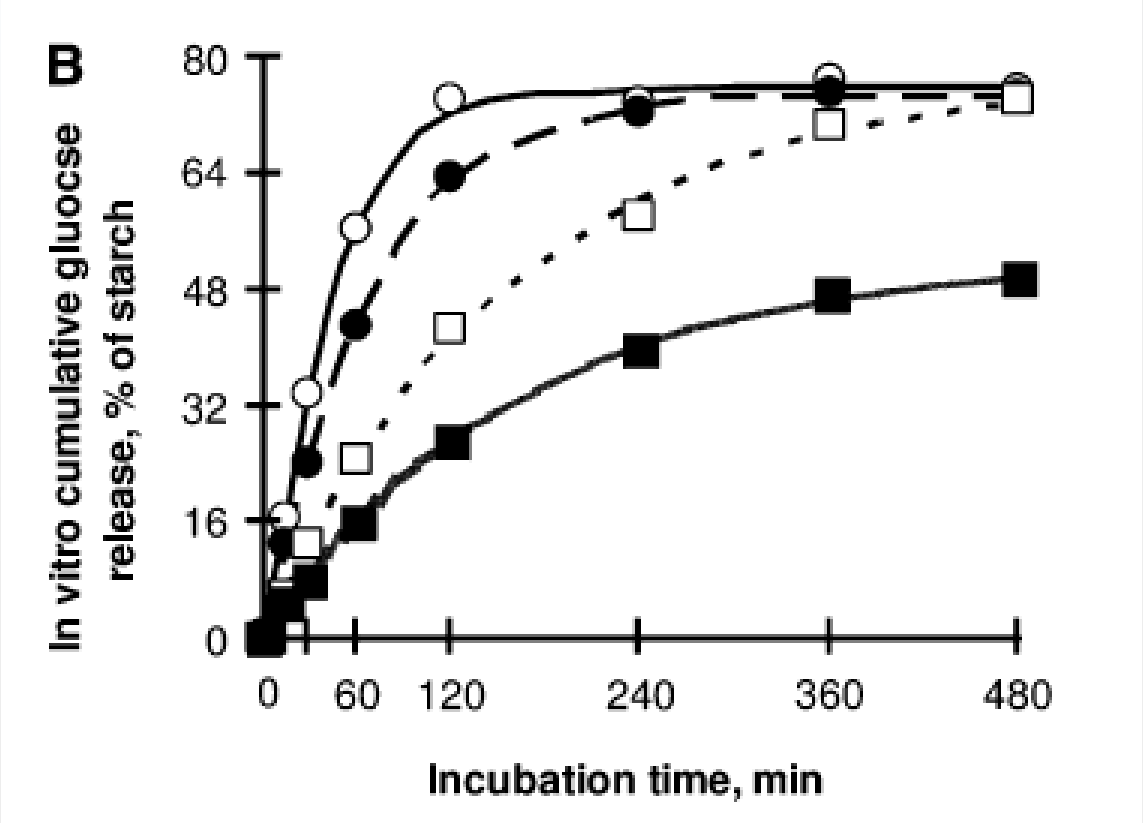
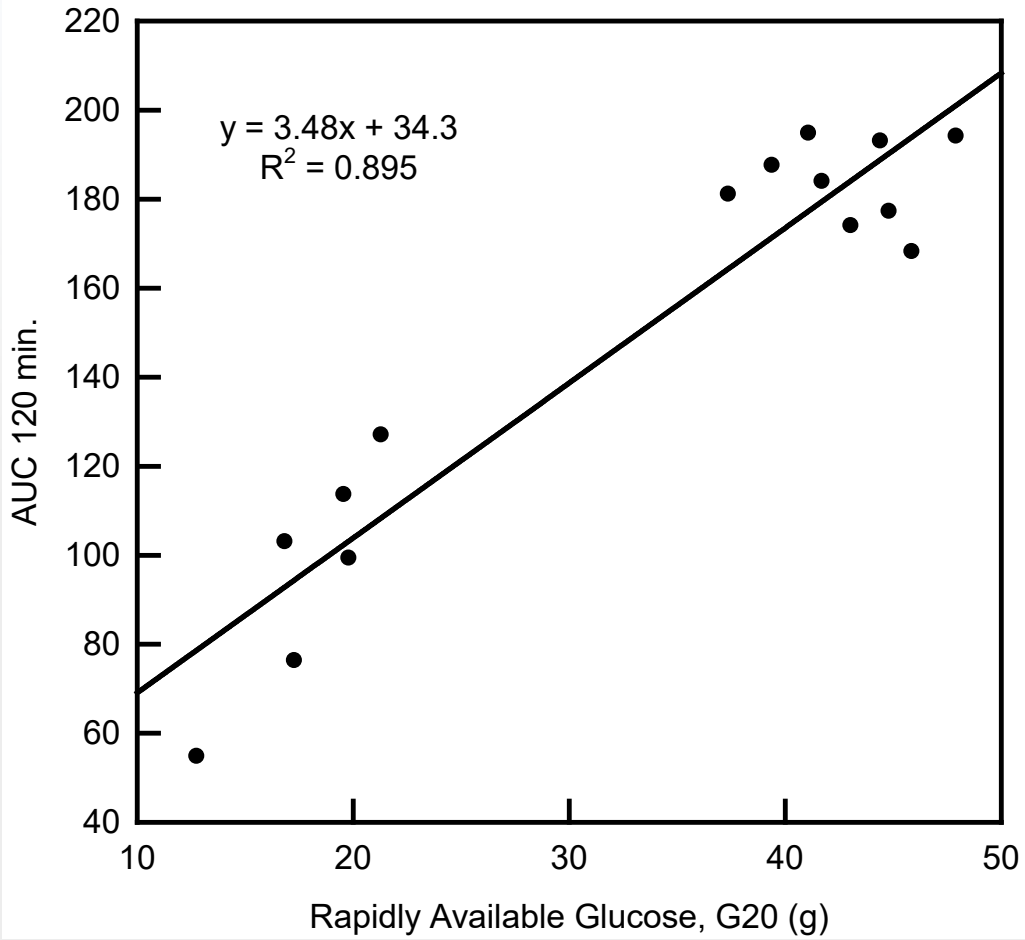


# Englyst Method – Measures rate of glucose release from starch by enzymatic digestion



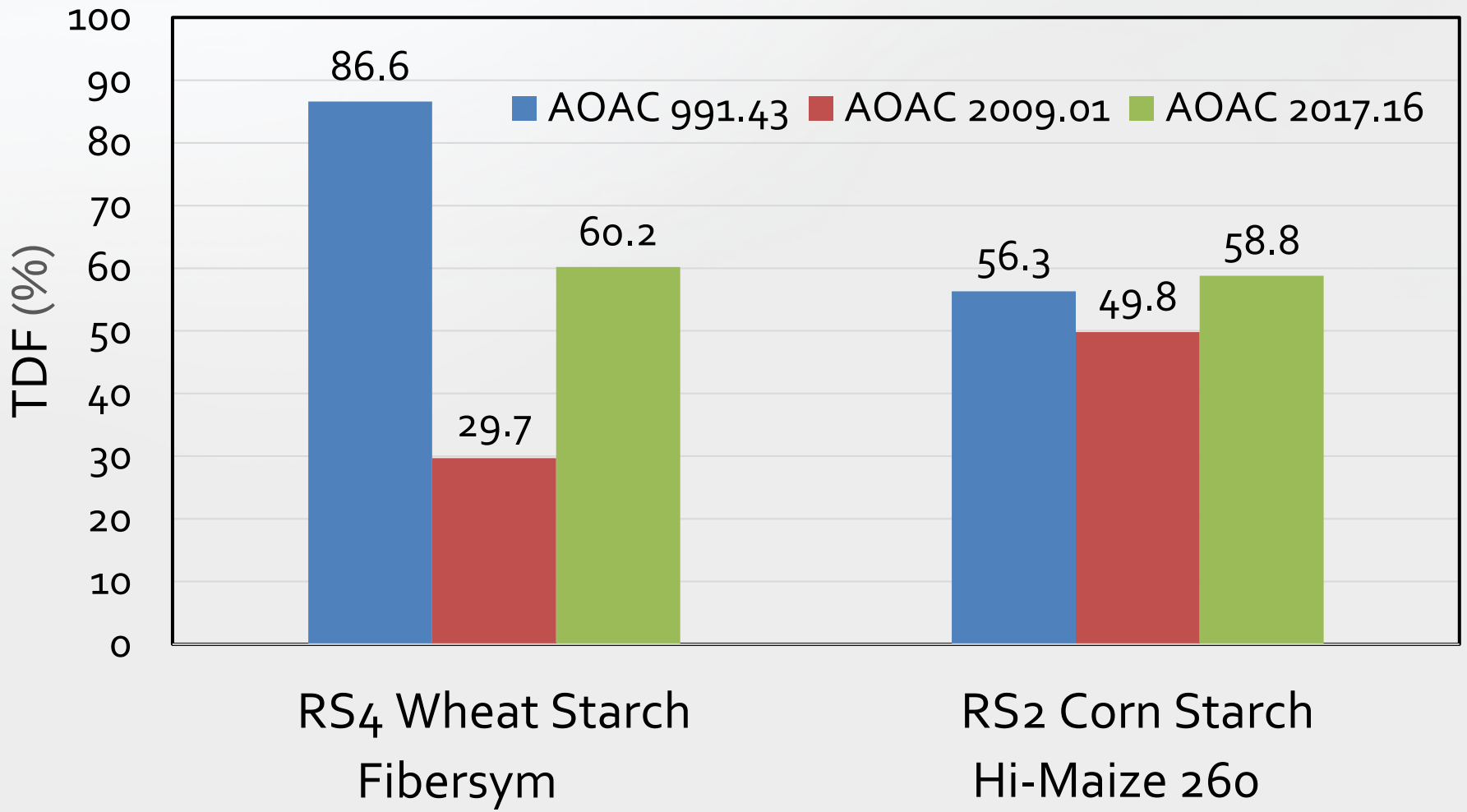

From: Van Kempen, et al. (2010) In Vitro Starch Digestion Kinetics, Corrected for Estimated Gastric Emptying, Predict Portal Glucose Appearance in Pigs. *Journal of Nutrition* **140(7)**, 1227-1233.

# Englyst Starch Method - Correlation to Human Glycemic Response




| Matrix | G20 (g) | AUC 120 min. |
|---|---|---|
| Corn Cereal | 12.73 | 54.87 |
| Oat Cereal 1 | 16.81 | 103.12 |
| Multigrain Cereal 1 | 17.25 | 76.38 |
| Oat Cereal Mod 1 | 19.54 | 113.74 |
| Wheat Cereal 1 | 19.77 | 99.45 |
| Rice Cereal 1 | 21.27 | 127.14 |
| Chocolate Wheat Cereal 1 | 37.35 | 181.19 |
| Chocolate Wheat Cereal 2 | 39.37 | 187.67 |
| Wheat Cereal 2 | 41.06 | 194.88 |
| Oat Cereal Mod 2 | 41.68 | 184.06 |
| Wheat Cereal 4 | 43.02 | 174.15 |
| Wheat Cereal 3 | 44.39 | 193.17 |
| Oat Cereal 2 | 44.79 | 177.34 |
| Multigrain Cereal 2 | 45.85 | 168.32 |
| Rice Cereal 2 | 47.89 | 194.24 |

# Equivalence and Improved Recoveries by AOAC 2017.16 Fiber Method



# Loss of Dietary Fiber during processing:

## How one can be misled by database derived Nutrition content

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- $RS_4$, $RS_2$ Starches lost with heat and moisture.
  - 10 -50% of insoluble fiber can be lost.
- Inulin/FOS losses.
  - Liquid format in storage.
  - With heat and acidic in processing.
- Resistant maltodextrins, SCF, Polydextrose, other.
  - Degradation with
    - Shear,
    - Maillard reactions, or
    - Enzymes

# Food Manufacturer Recordkeeping requirement


21CFR101.9f

- Records of food formulation must be kept when:
  - a mixture of approved dietary fiber and non-digestible carbohydrate (NDC) is present in either soluble, insoluble, or total dietary fiber fractions.
- Records must be made available to FDA on request
- Records must be maintained for a minimum of 2-years following the distribution of the product.
- Failure to make and keep the records means the food is misbranded.
  - Risk of recall
  - Risk of FDA enforcement action
  - Risk of class action lawsuit

# Reconciling Analytical NDC with Recorded Fiber


Analyze for NDC and compare to Records for added Dietary Fiber.

Is the Analyzed NDC equal to the Recorded Dietary Fiber?

No, Analyzed NDC is **less than** Recorded Dietary Fiber

Label only **Analyzed NDC** as Dietary Fiber. Excess Recorded Dietary Fiber cannot be claimed.

No, Analyzed NDC is **greater than** Recorded Dietary Fiber

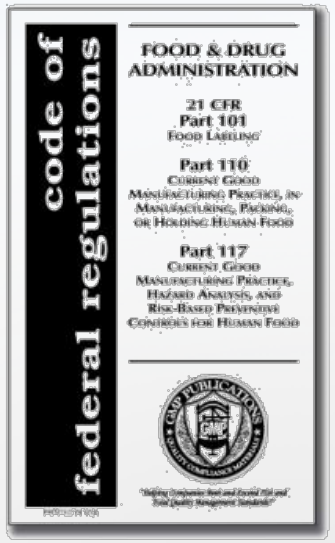
Label only **Recorded Dietary Fiber**. Excess Analyzed NDC is labeled as Carbohydrate but with alternative calories*.

Yes, **equal**.

Label all Analyzed NDC as Dietary Fiber.

*claiming alternative calories requires use of an analytical method which quantifies soluble and insoluble NDC.

# How Total Carbohydrates and Calories are Calculated




**Total Carbohydrates (g/100g)**

**=**

100 – Protein(g/100g) – Fat(g/100g) – Moisture(g/100g) – Ash(g/100g)

**Note:** Dietary Fiber and NDC are always included in Total Carbohydrates.

**Calories (kcal/serving)**

**=**

$(4^{\dagger} \times \text{Protein}^{*}) + (9^{\dagger} \times \text{Fat}^{*}) + (4^{\dagger} \times \text{Carbs}^{*}) - (2^{\dagger} \times \text{Soluble NDC}^{*}) - (4^{\dagger} \times \text{Insoluble NDC}^{*})$

$^{\dagger}$Units = kcal/g

$^{*}$Units = g/serving or g/100g

21CFR101.9(c)(1)(i)(C)

# How Analyzed NDC greater than Recorded Fiber impacts the Nutrition Facts Label

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**Nutrition Facts**

servings per container
**Serving size** **(41g)**

**Amount per serving**
**Calories** **120**

| | % Daily Value* |
|---|---|
| **Total Fat** 4g | **6%** |
| Saturated Fat 0.5g | **3%** |
| Trans Fat 0g | |
| **Cholesterol** 0mg | **0%** |
| **Sodium** 6mg | **0%** |
| **Total Carbohydrate** 14g | **5%** |
| Dietary Fiber 7g | **25%** |
| Total Sugars 7g | |
| Includes 3g Added Sugars | **6%** |
| **Protein** 20g | **16%** |
| Vitamin D 0mcg | 0% |
| Calcium 204mg | 15% |
| Iron 2mg | 10% |
| Potassium 504mg | 10% |

*The % Daily Value 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.

- **140** Cal, NDC **=** Recorded Dietary fiber
- **140** Cal, if 5 g Analyzed NDC **>** Recorded Dietary fiber
  (with use of **Total NDC Analytical Method; TDF = 4 Cal/g**)
- **130** Cal, if 5 g Soluble Analyzed NDC **>** Recorded Dietary fiber
  (with use of **Soluble/Insoluble NDC Analytical Method; SDF = 2 Cal/g**)
- **120** Cal, if 5 g Insoluble Analyzed NDC **>** Recorded Dietary fiber
  (with use of **Soluble/Insoluble NDC Analytical Method; IDF = 0 Cal/g**)

# Class Action Risk from Not Measuring Dietary Fiber



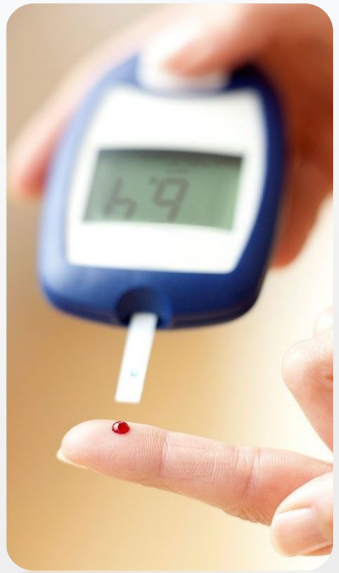
## IMO: The "Fiber" they said was too new to analyze


2013

- IMO = Isomaltooligosaccharide (enzymatically synthesized oligosaccharide)
- Analytical method could only measure ~20% of declared IMO as NDC.
- Manufacturer ignored analytical data and used dietary fiber content declared by ingredient supplier

# Class Action Risk from Not Measuring Dietary Fiber






- Customers observed:
  - blood sugar rise on consumption of product; and
  - discrepancy of measured dietary fiber with declared fiber on label.
- Class action lawsuit filed for misleading customers.
- Manufacturer changed to FDA recognized dietary fiber and settled for large sum.
- FDA subsequently did not approve IMO as dietary fiber due to insufficient evidence of physiological benefit.

# Minimizing Added Sugar with a Clean Label

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**Low Sugar** ⟹ **Low Net Carbs**

| | |
|---|---|
| **Total Carbohydrate** 21g | **8%** |
| Dietary Fiber 14g | **50%** |
| Total Sugars 1g | |
| Includes 0g Added Sugars | **0%** |
| Erythritol 3g | |

INGREDIENTS

**Erythritol**, Natural Flavors, Cocoa Butter. Contains Less Than 2% of the following: Sea Salt, Sunflower Lecithin, **Stevia Sweetener**, **Sucralose**.

# Clean Label Sweetener Examples

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## Natural Sweeteners

- Stevia
- Monk Fruit Extract
  - —Allulose
  - —Sugar Alcohols
- Agave
- Honey
- Maple Syrup

## Grain Syrups

- Rice Syrup
- Tapioca Syrup
- Oat Syrup

## Fruit & Vegetable Extracts

- Purees
- Juice
- Concentrates
- Powders

# Sugar Alcohol Alternative Calories

| Sugar Alcohol | Calories per gram |
|---|---|
| Isomalt | 2.0 |
| Lactitol | 2.0 |
| Xylitol | 2.4 |
| Maltitol | 2.1 |
| Sorbitol | 2.6 |
| Hydrogenated starch hydrolysates | 3.0 |
| Mannitol | 1.6 |
| Erythritol | 0 |
| Glycerol* | **4.3** |

- Include in Total Carbs
- Do not list in:
  - Total Sugars
  - Added Sugars
- Must list Sugar Alcohol if Sugar content claim made.

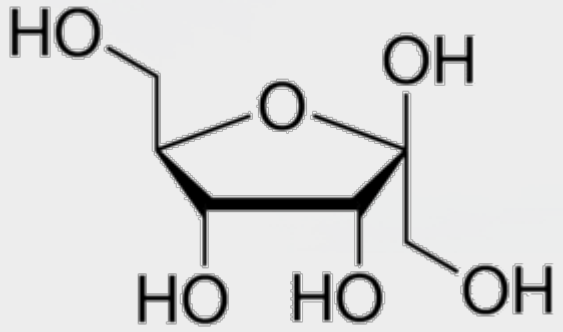
21CFR101.9

# Risks in Claiming and Analysis of Sugar Alcohols

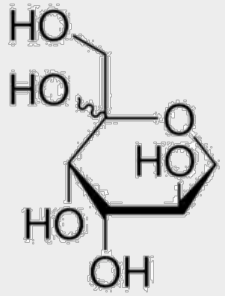
- Subtracting Sugar Alcohols from Net Carbs w/ significant calories.
  - Subject of Class Action Lawsuits.
  - Erythritol low risk = 0 Cal/g.
- Glycerol contains more calories than Total Carbs (4.3 Cal/g v 4 Cal/g).
  - Literature shows Glycerol can induce Insulin Response.
  - May be misleading to consumers to subtract from Net Carbs.
- Interference of some Sugar Alcohols with Labeling Sugars.
  - can trigger opportunistic Class Actions.
  - Use Gas Chromatography-FID to resolve interfering Sugar Alcohols.

# Allulose and other non-nutritive sugars

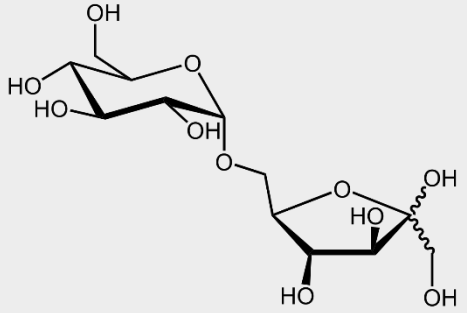
- Allulose is defined by FDA as a sugar (monosaccharide).
- Allulose is only 0.4 Cal/g.
- FDA enforcement discretion:
  - Allulose not included in Total Sugars.
  - Allulose not included in Added Sugars.
  - Must be included in Total Carbohydrates.
- FDA rulemaking pending on labeling other non-nutritive sugars.
  - D-tagatose.
  - Isomaltulose.
  - Others.



allulose



D-tagatose



Isomaltulose

# Using Grain Syrups as Sweeteners

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Rice, Tapioca, Oat

- Utilizes Enzymatic Hydrolysis of Grain Starch

> **(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results;**

**21CFR101.60(c)(2)(iii)**

- Good clean label solution.
- Must list sugar as added sugar.
- Must list enzymes unless inactivated.

# Using Fruit or Vegetable Extracts as Sweeteners

- Excellent way of adding natural sugar.
- Sugar added to product cannot exceed content of whole fruit.
  - Fruit concentrates.
  - Fruit powders.

> **(iii) "Added Sugars": …sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type.** **21CFR101.9**

# Clean Label Summary

- Dietary fiber content of a food product is dependent on food manufacturing process.
  - *Database calculations can be misleading*.
- New FDA guidance requires measurement of NDC by an Analytical Method for nutrition labeling.
- Food manufacturers must do their own due diligence on ingredients.
- Clean label options for avoiding added sugar labeling requires diligence.
- Not measuring NDC or Sugars and reconciling records can expose the food manufacturer to risk of:
  - Recall
  - FDA enforcement action
  - Class action lawsuit

# Thank you!

# Appendix

# Speaker Contact Information

Proudly representing Megazyme products in the USA

| Contact Information | |
|---|---|
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