# The Buzz on FDA's Definition of Added Sugar

## ESHA Research

May 30, 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

**Top Genesis R&D User Tips for Success Part 1 | June 20, 2017**
Take your Genesis R&D functionality to the next level. Taken from user suggestions, this 2-part webinar series will cover tips and tricks that will help you get the most of Genesis R&D.

**Genesis R&D Supplements 1.2 Overview| July 1, 2017**

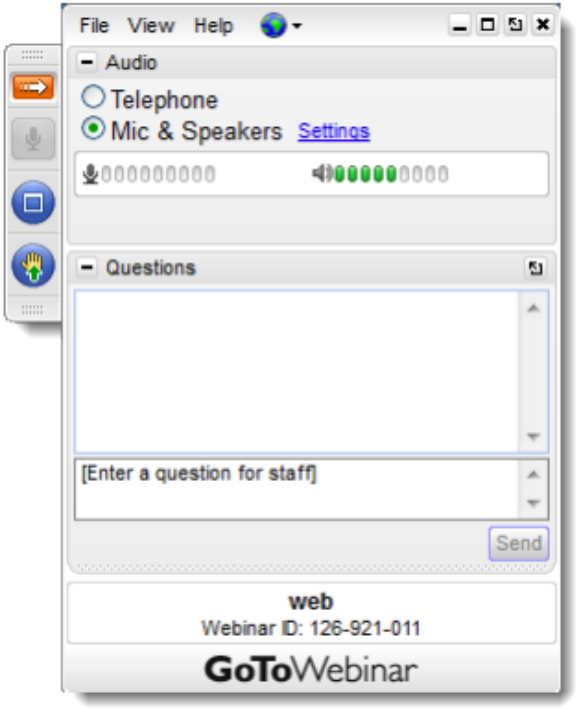
During this webinar, we will showcase the newest features of Genesis R&D Supplements and demonstrate how to create labels for protein powders and fish oil tablets, enter and track costs for blends, when and how to use the new "Promote" option for listing ingredients, and other program enhancements.

**Top Genesis R&D User Tips for Success Part 2 | July 18, 2017**
Take your Genesis R&D functionality to the next level. Taken from user suggestions, this 2-part webinar series 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](www.esha.com/news-events/webinars)

# Please Note!

- ✓ The webinar is being recorded
- ✓ All webinars available on our website
- ✓ Submit your questions in the GoToWebinar control panel




# Today's Agenda

During this 45 minute webinar we will cover:

- FDA's Definition of Added Sugars
- Brix Values
- Fruit Juice Concentrate
- Incidental vs Purposeful Hydrolysis
- Sugars left after Fermentation
- Non-enzymatic browning
- Documentation
- Q&A

# Timeline for Compliance

- The compliance date for the updated Nutrition Facts labels will be July 26, 2018, for companies with more than 10 million dollars in annual food sales

**OR**

- July 26, 2019, for companies with less than 10 million dollars in annual food sales.

# Added Sugars

- New mandatory label nutrient
  - Requires “Includes X g Added Sugars” to be listed under “Total Sugars” to help consumers understand how much sugar has been added to the product.
- The DV is 50 g and 10% of total calories
- Lab analysis can only test for Total Sugars but cannot distinguish the difference between added sugars and naturally occurring sugars.

# Added Sugars Defined

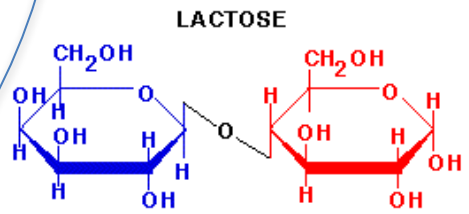
Sugars that are either added during the processing of foods or packaged as such and includes sugars (free, mono- and disaccharides), sugars from syrups and sugars concentrated from fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice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

- Honey
- Molasses
- Corn Sweetener
- Sugar
  - Raw sugar, brown sugar, cane sugar, beet sugar, dextrose, fructose, glucose, invert sugar, lactose, maltose, malt sugar, trehalose, turbinado, sucrose, galactose
- Syrup
  - High fructose corn syrup, malt syrup, crystalline fructose, maple syrup
- Juice Concentrates* (in some cases)

## Sugar as component of whole food

## Sugars contributing to empty calories

**Total Sugar**



# Added Sugar– Fruit Juice Concentrate

*"Except that, fruit or vegetable juice concentrates…*

- from 100 percent juices sold to consumers
- used towards the total juice percentage label declaration
- used for Brix standardization
- used to formulate the fruit component of jellies, jams, preserves or fruit spreads

*….shall not be labeled as added sugars"*

# Added Sugar– Fruit Juice Concentrate

- Apple juice concentrate reconstituted to 100% Juice or less *is not added sugar.*
- Apple juice concentrate added to any product, when sugar content would **exceed** sugar in same volume of same type of juice concentrate *is added sugar.*

# Added Sugar - Fruit Juice Concentrate

## 100 g Fruit Cup

- 33.33% diced peach
- 33.33% diced pear
- 33.33% diced pineapple

- 30% diced peach
- 30% diced pear
- 30% diced pineapple
- 10% apple juice concentrate (46% sugar)

# Genesis R&D Foods - Spreadsheet Report

## Fruit Cup #1

| Item Name | Quantity | Measure | Cals (kcal) | Prot (g) | Carb (g) | Fib(16) (g) | Sugar (g) | SugAdd (g) |
|---|---|---|---|---|---|---|---|---|
| Fruit Cup | 1 | Serving | 43.67 | 0.65 | 11.10 | 2.15 | 8.33 | 0 |
| peaches, fresh, sliced | 33.3333 | Gram | 13.00 | 0.30 | 3.18 | 0.48 | 2.70 | 0 |
| asian pear, fresh, 2 1/4" x 2 1/2" | 33.3333 | Gram | 14.00 | 0.17 | 3.55 | 1.20 | 2.35 | 0 |
| pineapple, fresh, chunks | 33.3333 | Gram | 16.67 | 0.18 | 4.37 | 0.47 | 3.28 | 0 |
| Total | 1 | Serving | 43.67 | 0.65 | 11.10 | 2.15 | 8.33 | 0 |

# Spreadsheet Report

## Fruit Cup #2

| Item Name | Quantity | Measure | Cals (kcal) | Prot (g) | Carb (g) | Fib(16) (g) | Sugar (g) | SugAdd (g) |
|---|---|---|---|---|---|---|---|---|
| Fruit Cup plus 10 g apple juice concentrate | 1 | Serving | 66.80 | 0.61 | 16.84 | 1.96 | 12.10 | 3.45 |
| peaches, fresh, sliced | 30 | Gram | 11.70 | 0.27 | 2.86 | 0.43 | 2.43 | 0 |
| asian pear, fresh, 2 1/4" x 2 1/2" | 30 | Gram | 12.60 | 0.15 | 3.20 | 1.08 | 2.12 | 0 |
| pineapple, fresh, chunks | 30 | Gram | 15.00 | 0.16 | 3.94 | 0.42 | 2.96 | 0 |
| juice concentrate, apple, 46% sugar | 10 | Gram | 27.50 | 0.02 | 6.85 | 0.03 | 4.60 | 3.45 |
| Total | 1 | Serving | 66.80 | 0.61 | 16.84 | 1.96 | 12.10 | 3.45 |

# 100 g Fruit Cup

- 33.33% diced peach
- 33.33% diced pear
- 33.33% diced pineapple

- 8 g total sugar
- 0 g added sugar

- 30% diced peach
- 30% diced pear
- 30% diced pineapple
- 10% apple juice concentrate (46% sugar)


- 12 g total sugar
- 3 g added sugar

# 100 g Fruit Cup


| QTY Juice Conc. (g) | % Sugar in Conc. | Sugar in Conc. (g) | % Sugar in SS Juice | Sugar in SS Juice (g) |
|---|---|---|---|---|
| 10 | 46.00% | 4.6 | 11.50% | 1.15 |

**4.6 g sugar in Conc. – 1.15 g sugar in SS = 3.45 g added sugar per 100 g**

# Degrees Brix

- Degrees Brix is the sugar content of an aqueous solution
- 1 degree Brix is 1 gram of sucrose in 100 grams of solution
- Can be used to calculate added sugar when using fruit juice concentrates

# Brix Chart FDA

| Juice | Minimum brix at 100% juice |
|---|---|
| Acerola | 6 |
| Apple | 11.5 |
| Apricot | 11.7 |
| Banana | 22 |
| Blackberry | 10 |
| Blueberry | 10 |
| Boysenberry | 10 |

| Juice | Minimum brix at 100% juice |
|---|---|
| Casaba Melon | 7.5 |
| Cashew (Caju) | 12 |
| Celery | 3.1 |
| Cherry, dark, sweet | 20 |
| Cherry, red, sour | 14 |
| Crabapple | 15.4 |
| Cranberry | 7.5 |

21CFR101.30

# Calculation Method Example

## **Step 1**: Information Collection

| Item | Sugar Content of Conc. (%) | % By Weight | Sugar Content of SS Juice (%)* |
|---|---|---|---|
| Apple juice concentrate | 46.00% | 10.00% | 11.50% |
| Mango Juice concentrate | 39.00% | 10.00% | 13.00% |
| Pear juice concentrate | 24.00% | 20.00% | 12.00% |
| | | | * Use Brix as estimates |

On a 100 g basis

# Calculation Method Example

## **Step 2**: Calculate Concentration Factor

**Formulas Needed:**

1. Concentration Factor = B/A
    - A = Final weight of actual reconstituted juice blend
    - B = Final weight of juice blend if reconstituted to 100% juice

2. Final weight of juice blend if reconstituted to 100% juice (B)
    - B = Grams of Juice Concentrate in 100 g + Grams of Water Needed to Reconstitute to SS Juice

3. Grams of Water Needed to Reconstitute to SS Juice
    - B = (Grams of Sugar from Concentrate / Percent Sugar in SS Juice) – Weight of Juice Concentrate in 100 g

# Calculation Method Example

## **Step 2 (cont.)**: Calculate Concentration Factor

**Formula**: Concentration Factor = B/A

- A = 100 g (*We know this is based on 100 g)
- B = 40 g + 70 g = 110 g

| Item | % By Weight | Weight of Juice Conc. In 100 g | Sugar from Concentrate (g) | H2O Needed to Reconstitute to SS (g) |
|---|---|---|---|---|
| Apple juice concentrate | 10.00% | 10 | 4.6 | 30 |
| Mango Juice concentrate | 10.00% | 10 | 3.9 | 20 |
| Pear juice concentrate | 20.00% | 20 | 4.8 | 20 |
| | | 40 | 13.3 | 70 |

**Concentration Factor: 110/100 = 1.1**

# Calculation Method Example

## **Step 3**: Calculate Sugar in SS Juice Blend

**Formula**: $\frac{\text{Sugar (g) from Concentrate}}{\text{Concentration Factor}}$

| Item | Weight (g) Juice Concentrate | Sugar Content of Concentrate (%) | Sugar from Concentrate (g) |
|---|---|---|---|
| Apple juice concentrate | 10 | 46% | 4.6 |
| Mango Juice concentrate | 10 | 39% | 3.9 |
| Pear juice concentrate | 20 | 24% | 4.8 |
| | | | 13.3 |

$$\frac{13.3\text{ g}}{1.1} = 12.09\text{ g}$$

# Calculation Method Example

**Step 4**: Calculate Added Sugar

**Formula**: Total Sugar – Sugar in SS Juice Blend

13.3 – 12.09 = 1.21 g added sugar per 100 g

**Step 5**: Adjust for Actual Serving Size

$$\frac{1.21\text{ g}}{100\text{ g}} = \frac{X}{240\text{ g}} \qquad X = \text{2.9 g added sugar per 240 g}$$

# Mono- and Disaccharides

**Monosaccharides**

Monosaccharides are the simplest carbohydrates and are often called single **sugars**. They are the building blocks from which all bigger carbohydrates are made.

- Fructose
- Galactose
- Glucose

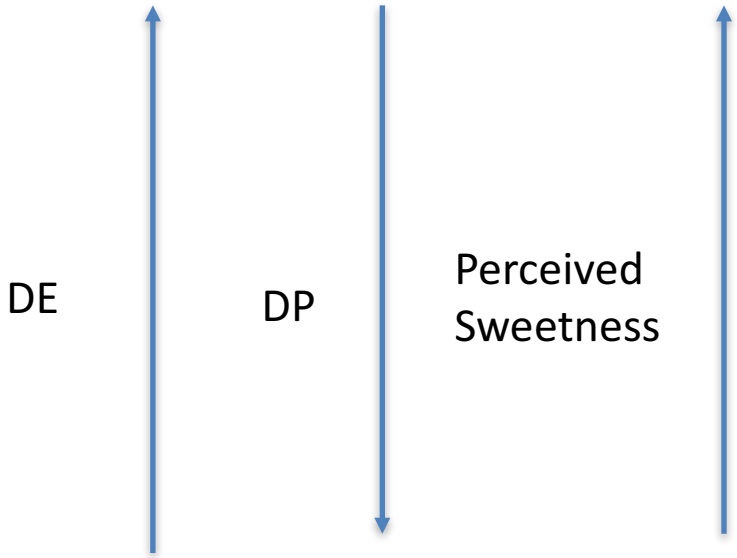
**Disaccharides**

A disaccharide is a sugar (a carbohydrate) composed of two monosaccharides.

- Sucrose (table sugar) = glucose + fructose
- Lactose (milk sugar) = glucose + galactose
- Maltose (malt sugar) = glucose + glucose

# Incidental vs. Purposeful Hydrolysis

- Definitions
  - **Hydrolysis**: the chemical breakdown of a compound due to reaction with water.
  - **DP1 & DP2**: Refer to Degrees of Polymerization
  - **DE**: Dextrose Equivalency is a measure of the amount of reducing sugars present in a sugar product, expressed as a percentage on a dry basis relative to **dextrose**
- Why do these matter? They relate to sweetness and sugar in your product, and thus added sugar.



# Hydrolysis

- This can create varying levels of mono- and disaccharides with degrees of polymerization at 1 or 2
- Some may contain for example 8%-9% mono and disaccharides and can contribute to sweetness
- Rounding rules apply:  <0.5 g / serving can round to 0
- So your ingredient singularly may not push your total past 0.5 but cumulatively they might

# How this Pertains to the Regulations

- If a manufacturer is purposely using hydrolysis to produce a sweetening effect, *yes this is considered added sugars.*

- If, as an incidental by-product sugars are created during the hydrolysis step, the FDA in the draft guidance would *not consider that added sugar as it would be captured in the total sugar value.*

# Maltodextrin and Corn Syrup Solids

Corn syrup solids >20 DE

Maltodextrin <20 DE

- Maltodextrin itself is not considered an added sugar unless it is purposely manufactured for a sweetening effect
- Per 100 g of Maltodextrin if the spec sheet shows 4 g of sugar – record 4 g of added sugar per 100 g in Genesis

# Purees/Pastes Etc.

- The main rule of thumb here is does the ingredient maintain the nutritive integrity you would find in the whole food
- Just because something is named “paste” does not give it automatic exemption
- If it meets the requirement above it is not considered an added sugar

# Sugars After Fermentation

- Manufacturers need to document the amount of sugar being added to the initial formulation
- As well as any methods used to determine final sugar levels
- Analytical lab tests can also be used to determine final sugar level which can be used as the added sugar content

# Non-Enzymatic Browning

- Enzymatic browning: a chemical process which occurs in fruits and vegetables by the **enzyme** polyphenoloxidase, which results in brown pigments
- Non – Enzymatic Browning: a process that also produces the brown pigmentation in foods, but without the activity of enzymes. The two main forms of non-enzymatic browning are caramelization and the Maillard reaction

# Non-Enzymatic Browning

- Similarly to fermentation it can be difficult to predict the amount of sugars present after such processes as caramelization
- FDA recommends in draft guidance a lab test to determine final sugar content which can be used as added sugar value
- Documentation, as always, is required

# Added Sugar - Lactose

Example: dehydrated milk powder vs. purified lactose

- Lactose is defined as a sweetener under CFR 168.22
- Dairy ingredients, except lactose as defined in § 168.122, are not included in the definition of added sugars.

# Documentation

Manufacturers are required to make and keep records to verify the mandatory declaration of added sugars – especially with a combination of both naturally occurring and added sugars

- Nutrition analysis records (database/lab analysis)
- Supplier spec sheets
- Any mathematical calculations performed

# ESHA Database

ESHA is populating as many items with Added Sugars as possible in the ESHA database (these are items assigned ESHA Codes) from data provided so far. This is an on-going process and data will continue to be populated in updates.

This includes:

- For ingredients defined as Added Sugars by the FDA (such as sugars, honey, syrups, dextrose, fructose, sucrose, etc.) ESHA is populating the Added Sugar value from the Total Sugar value.
- For whole food ingredients that contain naturally occurring sugars that are not considered Added Sugars, (such as fruits, vegetables, grains) ESHA is populating the Added Sugar value with a “0” value.
- Data is being populated for mixed foods for which suppliers have indicated Added Sugars values as well as foods whose Added Sugars content can clearly be determined as zero by ingredient statements. Total Sugars might be greater than or equal to Added Sugars.
- At this time, if the Added Sugars data is unavailable or cannot be determined, the Added Sugars field in the ESHA database will be blank. Users will want to populate as needed.

# Guidance for Industry

**Draft Guidance Documents**

We monitor draft guidance carefully, and do not implement draft guidance into our software programs until the FDA has finalized the guidance. Our goal at ESHA is to provide solutions that follow the FDA's regulations and delay implementing compliance solutions that run the risk of changing when final documentation is published.

At this time, ESHA is reviewing the most recent FDA Draft Guidance documents, and we are consulting the FDA with regards to how the draft guidance should be used, interpreted, and implemented into our software.

# Genesis R&D Helpful Tips

- View the Spreadsheet Report to display Ingredients with missing values.
  - Turn on the “us_label_mandatory” set of Nutrients to View.
- Use the F5 Search to search for ingredients by Added Sugars content.
  - Added Sugars is > = 0 shows all foods with Added Sugars populated.
  - Added Sugars is > 0 shows all foods containing Added Sugars that report Added Sugars so far.
- Utilize audit trails, reports, and notes for documentation

# Genesis R&D Training

**Advanced Genesis Workshop | June 22-23, 2017| Las Vegas, NV**

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 | July 18-19, 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.

**Advanced Genesis Workshop | Sept 19-20, 2017| Lombard, IL**

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 + Menu Labeling Training | August 15-16, 2017 | Washington, DC**

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. Additionally, we will discuss how Genesis R&D helps you comply with the 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?

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