



**bonumose**

**WITH TAGATOSE, THE U.S. FDA  
LABELING OFFICE IS “OUT TO LUNCH”**

**ICQC, SEPTEMBER 2023**

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# “Total Sugars” & “Added Sugars”

- Public policy to inform consumers and discourage excess consumption of sugars
- U.S. FDA “total sugars” and “added sugars” regulations count all **monosaccharides** and **disaccharides**

<b>Nutrition Facts</b>	
8 servings per container	
<b>Serving size</b>	<b>2/3 cup (55g)</b>
<b>Amount per serving</b>	
<b>Calories</b>	<b>230</b>
<b>% Daily Value*</b>	
<b>Total Fat</b> 8g	<b>10%</b>
Saturated Fat 1g	<b>5%</b>
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
<b>Total Carbohydrate</b> 37g	<b>13%</b>
Dietary Fiber 4g	<b>14%</b>
Total Sugars 12g	
Includes 10g Added Sugars	<b>20%</b>
<b>Protein</b> 3g	
Vit. D 2mcg 10%	• Calcium 260mg 20%
Iron 8mg 45%	• Potas. 240mg 6%

\* 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.

# Healthy Rare Monosaccharides

- Tagatose and Allulose are rare monosaccharides with many documented health properties – **should be no public policy to discourage consumption**
- U.S. FDA October 2020: “[W]e should consider not only the chemical structure of sugars, but also other evidence, including their association with **dental caries** and how they are metabolized in the body” (e.g., **caloric contribution** and their **effect on blood glucose and insulin levels**), when determining whether a sugar should be included in the declaration of ‘Total Sugars’ on the label.”

# U.S. FDA Exempted Allulose



FDA announced the following criteria when exempting Allulose from “total sugars” and “added sugars”:

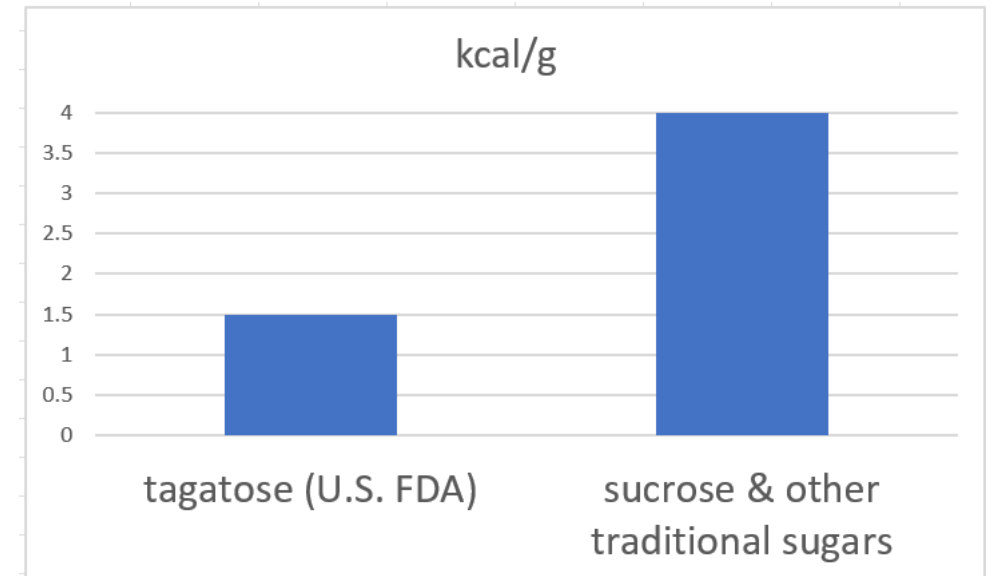
1. Does not cause dental caries
2. Does not increase blood glucose or insulin levels
3. Has “much less than 4 kcal/g”

FDA, October 2020

# Applying U.S. FDA's Criteria To Tagatose



1. Tagatose does not cause dental caries
2. Tagatose does not increase blood glucose or insulin levels
3. Tagatose has only 1.5 kcal/gram (per U.S. FDA)
  - 62% less than 4 kcal/gram
  - 62% less is indisputably “much less”



# U.S. FDA Arbitrarily Changed Its Criteria

- Based its decision solely on calories, ignoring other criteria
- Compared Tagatose's 1.5 kcal/g to Allulose's 0.1 kcal/g, not sucrose's 4.0 kcal/g
- Mistakenly said Tagatose's calories are "empty"
  - **Like soluble fiber**, Tagatose has calories because of its **prebiotic actions in the colon**



# U.S. FDA Acting Contrary To Public Health



- Tagatose can prevent and even treat diet-related diseases
  - But FDA's decision has a chilling effect on adoption of this important sugar alternative
  - Most leading food companies refuse to adopt tagatose until the labeling is changed
- Consumers will be misinformed about glycemic impact
- Consumers will be misinformed about fiber content

# U.S. FDA Bias?



*FDA internal email after FDA decided to deny Bonumose's request to count Tagatose under "fiber" grams*

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**From:** Moura, Fabiana <Fabiana.Moura@fda.hhs.gov>

**Sent:** Friday, May 28, 2021 9:51 AM

**To:** Fitzpatrick, Blakeley <Blakeley.Fitzpatrick@fda.hhs.gov>; Jurand, Deirdre <Deirdre.Jurand@fda.hhs.gov>; DeJesus, Vincent <Vincent.DeJesus@fda.hhs.gov>

**Subject:** RE: For Final Center Review/Clearance Bonumose fiber CP

The best news for this Memorial Day Weekend!!!!

Fabiana





THANK YOU

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