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Citizen Petition to Request Adoption of Calorie Value for "Resistant Maltodextrin A"

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fisher Lane
Room 1061
Rockville, MD 20852

Dear Commissioner,

On behalf of Tate & Lyle Ingredients Americas LLC ("Tate & Lyle" or "we"), a leading global provider of food ingredients, and in accord with 21 CFR § 10.30, the undersigned submits this petition under sections 403(q) and 701(a) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to amend 21 CFR §101.9(c)(1)(i)(C) to assign a calorie value of 0.2 kcal/ gram of fiber to a sub-type of resistant maltodextrin composed primarily of non-digestible oligosaccharides of glucose molecules (minimum of 70%) that are joined by 1,4, 1,6, 1,2 and 1,3 linkages, with a ratio of 1-4 to 1-6 linkages that is less than 2.2. For purposes of this petition, this sub-type of maltodextrin is referred to as "resistant maltodextrin A." The basis for our request is set forth below.

A. Action Requested

Tate & Lyle requests the Commissioner to amend 21 CFR §101.9(c)(1)(i)(C) to assign "resistant maltodextrin A" a calorie value of 0.2 kcal/gram of the fiber portion. "Resistant maltodextrin A" is a sub-type of resistant maltodextrin dietary fiber. Information to support this request is contained in this petition and as attachments that demonstrate that "resistant maltodextrin A" has a calorie value of 0.2 kcal/ gram of fiber, based on results of a high quality clinical study. The beneficial physiological effects of resistant maltodextrin have previously been reviewed by FDA, and the Agency has announced its intent to add resistant maltodextrin to the dietary fiber definition in § 101.9(c)(6)(i) through the Agency's

regular rulemaking process. See *The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels; Guidance for Industry; Availability*, 83 FR 27894 (June 15, 2018).

Paragraph (c)(1)(i)(C) of 21 CFR §101.9 currently states as follows:

> Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9-11. A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

Paragraph (c)(1)(i)(C) would be amended to state as follows (new text is underlined):

> Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9-11. A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used, <u>except as provided in paragraph (c)(1)(i)(G) of this section</u>. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

Further, new paragraph (c)(1)(i)(G) would be added, stating as follows:

> Using the general factor of 0.2 kcal/gram of the fiber portion for resistant maltodextrin that is composed primarily of non-digestible oligosaccharides of glucose molecules (minimum of 70%) that are joined by 1,4, 1,6, 1,2 and 1,3 linkages, with a ratio of 1-4 to 1-6 linkages that is less than 2.2.

Pending completion of the rulemaking requested in this petition, Tate & Lyle further requests that the Agency announce its intent to exercise its enforcement discretion for the use of a general factor of 0.2 kcal/gram of the fiber portion for "resistant maltodextrin A" when determining "Calories" on the Nutrition and Supplement Facts labels.

Background

On May 27, 2016, FDA published a final rule to revise the Nutrition Facts label. In this rule, FDA amended §101.9(c)(1)(i)(C) to state that the calorie value of soluble fiber to be used in nutrition labeling is 2

kcal/g. In the preamble to this rule, FDA stated that it recognizes that fermentation of fibers can yield different calorie values and that a fermentable fiber is not equivalent to a soluble fiber. FDA agreed that exceptions could be considered for changing the calorie value of a soluble non-digestible carbohydrate when the difference in energy value is significant and when the evidence is established by science. FDA indicated that the Agency would evaluate any requests for exceptions on a case-by-case basis in a request to amend § 101.9(c)(1)(i)(C) in determining the calorie value of the fiber as part of the total carbohydrate calorie amount. See *Food Labeling: Revision of the Nutrition and Supplement Facts Labels: Final Rule*, 81 FR 33742 at 33867 (May 27, 2016).

B. Statement of Grounds

The purpose of this petition is to ask FDA to amend § 101.9(c)(1)(i)(C) to assign "resistant maltodextrin A" a calorie value of 0.2 kcal/gram of fiber portion based on the scientific evidence provided in Attachment A. In contrast to the manufacturing process for other resistant maltodextrins, the process for "resistant maltodextrin A" controls the ratio of certain types of linkages that contribute a calorie value that is significantly lower than 2 kcal/gram, specifically one tenth of that value.

The difference between 2 kcal/gram and 0.2 kcal/gram would also have a significant impact in nutrition labeling of foods and food product development. For example, for a food containing 3 grams of fiber (a good source), a fiber with 0.2 kcal/gram would enable a declaration of 0.5 kcals from the fiber rather than the 6 kcals from a fiber that has 2 kcal/gram. This difference would be especially important to food product developers who are trying to formulate to a specific total calorie value (e.g. a 100 calorie serving) while also providing a good source of fiber. The calorie difference becomes even more pronounced in foods that have higher fiber contents, such as excellent source of fiber levels or higher.

"Resistant maltodextrin A," a fiber supplying significantly less than 2 kcal/g, is a dietary innovation that can contribute to public health by helping to increase fiber intake and decrease calorie intake among consumers. It can be used to help replace higher calorie sugars and fats in many foods and it supplies dietary fiber, which is lacking in the American diet. A food ingredient such as this would enable consumers to make lower calorie choices among frequently consumed foods such as beverages, bars and dairy products, among others, while also increasing dietary fiber intake. FDA's recognition that "resistant maltodextrin A" is a sub-type of resistant maltodextrin dietary fiber that has a lower calorie value would therefore align with public health goals as well as FDA's stated flexible and science-based approach to food product labeling.

Characteristics of "Resistant maltodextrin A"

"Resistant maltodextrin A" is a lower calorie sub-type of resistant maltodextrin ((C6H10O5)n, CAS Reg. No. 9050-36-6), that provides 0.2 kcal per gram of fiber and complies with 21 CFR 184.1444. It is a non-sweet source of dietary fiber, composed primarily of non-digestible oligosaccharides of glucose molecules (minimum of 70%) that are joined by 1,4, 1,6, 1,2 and 1,3 linkages, with a ratio of 1-4 to 1-6 linkages that is less than 2.2. It is prepared as a white powder or concentrated solution produced from a glucose solution obtained from a suitable food starch, using safe and suitable acids and/or enzymes. The glucose solution undergoes polycondensation of at least one monosaccharide or linear saccharide oligomer. The polycondensation is carried out at a solids concentration of at least 70% and temperature of at least 40°C in the presence of a suitable catalyst. The linkage ratio of finished product is determined by the partially methylated alditol acetates (PMAA) derivatization method for GC-MS as reported by York et al. (Methods Enzymol. 1986; 118:3-40).

Evidence Supporting a Calorie Value of 0.2kcal/Gram for "Resistant maltodextrin A"

The evidence to support a calorie value of 0.2 kcal/ gram of fiber for "resistant maltodextrin A" is detailed in Attachment A, "Evidence to Support the Use of 0.2 kcal/g fiber for 'Resistant maltodextrin A' in Nutrition Labeling." This document includes a review of the scientific evidence regarding the calorie value of "resistant maltodextrin A."

The scientific evidence reviewed in Attachment A demonstrates that PROMITOR® Soluble Corn Fiber, a commercial example of "resistant maltodextrin A," has a calorie value of 0.2 kcal/gram of fiber portion. This is based on a high quality clinical study of breath hydrogen production. In light of the evidence presented in Attachment A, FDA should recognize "resistant maltodextrin A" as a lower calorie sub-type of resistant maltodextrin, with a calorie value of 0.2 kcal/gram of the fiber portion.

C. Environmental Impact

The actions requested in this Petition are not within any of the categories for which an environmental assessment is required pursuant to 21 CFR Section 25.22. Additionally, the actions requested in this Petition are exempt from the requirement of an environmental assessment pursuant to 21 CFR Section 25.30(k). Furthermore, the undersigned do not believe that the actions requested in this Petition would have any environmental impact.

D. Economic Impact

An economic impact report is required only when requested by the Administration and such report has not been requested. 21 C.F.R. § 10.30(b).

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition**.**

Sincerely,

Lore W. Kolberg, MS RDN
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List of Attachments

Attachment A
Evidence to Support the Use of 0.2 Kcal/G Fiber for "Resistant Maltodextrin A" in Nutrition Labeling. Prepared by Tate & Lyle, July, 2019. Unpublished.

Attachment B
Summary of Breath Hydrogen Study: A Randomized, Double-Blind, Crossover Study to Determine the Available Energy from PROMITOR® Soluble Corn Fiber. Prepared by Tate & Lyle, July, 2019. Unpublished. (PRE-PUBLICATION---RESTRICTED)

Attachment C
Human Studies that Have Evaluated the Energy Value of Other Resistant Maltodextrins