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# The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels: Guidance for Industry

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**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Food Safety and Applied Nutrition**

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# The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## I. Introduction

This guidance is intended to identify for manufacturers specific, additional isolated or synthetic non-digestible carbohydrates that we intend to propose adding to the list of those that meet our regulatory definition of "dietary fiber" (21 CFR 101.9(c)(6)(i)). This guidance also is intended to advise manufacturers of our intent to exercise enforcement discretion relative to the declaration of these isolated or synthetic non-digestible carbohydrates as a dietary fiber on Nutrition Facts and Supplement Facts labels, and for the use of a caloric value for polydextrose of 1 kcal/g, pending completion of a rulemaking regarding revising our regulations. The following isolated or synthetic non-digestible carbohydrates are subject to our intent to exercise enforcement discretion: mixed plant cell wall fibers; arabinoxylan; alginate; inulin and inulin-type fructans; high amylose starch (resistant starch 2); galactooligosaccharide; polydextrose; and resistant maltodextrin/dextrin.

This guidance is effective immediately because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

# II. Background

Before 2016, FDA regulations did not define the term "dietary fiber" for purposes of the Nutrition Facts or Supplement Facts labels. In the *Federal Register* of May 27, 2016 (81 FR 33742), we published a final rule amending our Nutrition Facts and Supplement Facts Labels regulations (hereafter referred to as "the final rule"). The final rule, among other things, defines dietary fiber as 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 (21 CFR 101.9(c)(6)(i)). The final rule also identifies seven non-digestible carbohydrates that we have determined have beneficial physiological effects for human health and that therefore can be declared as dietary fiber on Nutrition and Supplement Facts labels. The seven non-digestible carbohydrates identified in § 101.9(c)(6)(i) are:

- [beta]-glucan soluble fiber (as described in § 101.81(c)(2)(ii)(A));[2]
- psyllium husk (as described in § 101.81(c)(2)(ii)(B));
- cellulose;
- guar gum;
- pectin;
- locust bean gum; and
- hydroxypropylmethylcellulose.

Interested parties can ask us to list additional isolated or synthetic non-digestible carbohydrates that meet the definition of dietary fiber in § 101.9(c)(6)(i). For example, a manufacturer who wants FDA to amend the list of isolated or synthetic non-digestible carbohydrates that meet the definition of dietary fiber can submit a citizen petition under 21 CFR 10.30.

In the *Federal Register* of November 23, 2016 (81 FR 84516), we announced the availability of a draft guidance titled, "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry" (2016 draft guidance).[3] We announced the availability of

[2] Beta-glucan soluble fiber and psyllium husk are included in the definition of "dietary fiber" because they are the subject of a health claim and not because of their status as an "intrinsic or intact" or "isolated or synthetic" non-digestible carbohydrates.

[3] See Docket No. FDA-2016-D-3401.

the final guidance in the *Federal Register* of March 2, 2018 (83 FR 8997).[4] The March 2018 final guidance explains FDA's current thinking on information needed when submitting a citizen petition and the scientific review approach we plan to use for evaluating scientific evidence to determine whether an isolated or synthetic non-digestible carbohydrate that is added to food has a physiological effect that is beneficial to human health.

In the *Federal Register* of November 23, 2016 (81 FR 84516), we also announced the availability of a document titled "Science Review of Isolated and Synthetic Non-Digestible Carbohydrates" (2016 science review), which summarizes clinical studies associated with 26 isolated or synthetic non-digestible carbohydrates.[5] In addition, we published a separate notice in the *Federal Register* requesting the submission of scientific data, information, and comments to help us evaluate the beneficial physiological effects to human health of isolated or synthetic non-digestible carbohydrates that are added to food (81 FR 84595).

FDA has received several citizen petition requests to list additional isolated or synthetic non-digestible carbohydrates. We evaluated the strength of the scientific evidence using the same factors that we set forth in the March 2018 final guidance. We based our scientific evaluation for isolated or synthetic non-digestible carbohydrates on data and information provided by: (1) citizen petitions;[6] (2) the publicly available scientific literature; (3) comments that we received in response to our notice requesting scientific data, information;[7] and (4) comments that we received on the 2016 science review.[8] Our summaries and evaluations of the published clinical studies for the non-digestible carbohydrates for which we intend to exercise our enforcement

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[4] Available at: https://www.fda.gov/downloads/Food/GuidanceRegulations/GuidanceDocumentsRegulatoryInformation/UCM528533.pdf.

[5] See Docket No. FDA-2016-N-3389.

[6] Docket No. FDA-2016-P-1674, "Citizen Petition Regarding the Listing of PROMITOR® Soluble Corn Fiber as a Source of Dietary Fiber," submitted by Tate & Lyle Ingredients Americas LLC; Docket No. FDA-2016-P-2377, "Citizen Petition Regarding Nutrition Labeling of Fibersol® Resistant Maltodextrin as a Dietary Fiber," submitted by Archer Daniels Midland Company; Docket No. FDA-2016-P-2736, "A Citizen Petition Requesting that FDA Amend 21 CFR §101.9(c)(6)(i) to Recognize that Inulin-Type Fructans Derived from Chicory Root Qualify as Dietary Fiber for Purposes of Nutrition Labeling," submitted by Hyman, Phelps & McNamara, P.C. on behalf of Beneo, Cosucra Groupe Warcoing, S.A., and Sensus B.V.; Docket No. FDA-2016-P-2860, "A Citizen Petition Regarding the Inclusion of Inulin-Type Fructans Extracted from Chicory Root in the Definition of Dietary Fiber," submitted by General Mills; Docket No. FDA-2016-P-3070, "A Citizen Petition to Request the Commissioner of Food and Drugs to Add Soy Fiber to the List of Isolated or Synthetic Non-digestible Carbohydrates that Have Been Determined by FDA to Have Physiological Effects that Are Beneficial to Human Health at 21 CFR 101.9(c)(6)(i)," submitted by DuPont Nutrition & Health; Docket No. FDA-2016-P-3311, "Citizen Petition Regarding the Listing of Polydextrose as a Source of Dietary Fiber and the Caloric Value of Polydextrose for Use in Nutrition Labeling and Claims," submitted by Tate & Lyle Ingredients Americas LLC and DuPont Nutrition & Health; Docket No. FDA-P-2017-0970, "A Citizen Petition Requesting that FDA Amend 21 C.F.R. § 101.9(c)(6)(i) to Recognize Rice Bran Derived Products that Contain Rice Bran Fiber and Other Components of Rice Bran as Containing Dietary Fiber for Purposes of Nutrition Labeling, submitted by RiceBran Technologies; and Docket No. FDA-2016-P-4233, "A citizen petition requesting that Phytocel™ and Kfibre™ sugarcane flour made from whole sugarcane be classified as a dietary fiber for label declaration purposes," submitted by KFSU Ltd.

[7] FDA. "Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request for Scientific Data, Information, and Comments" (81 FR 84595; November 23, 2016), and see Docket No. FDA-2016-N-3389.

[8] FDA. "Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates," November 2016. Available at: https://www.fda.gov/Food/LabelingNutrition/ucm525656.htm.

discretion appear in a document entitled "Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates."[9]

# III. Discussion

Based on our review of the citizen petitions, comments that we have received, and our independent evaluation of the available scientific data, we intend to propose to add eight new isolated or synthetic non-digestible carbohydrates to § 101.9(c)(6)(i) because we have tentatively determined that they have physiological effects that are beneficial to human health.

We intend to exercise enforcement discretion for the declaration of dietary fiber, pending completion of a rulemaking regarding revising our regulations, if the declaration includes one or more of the following eight isolated or synthetic non-digestible carbohydrates, when present in a food and included in the amount of dietary fiber declared on the Nutrition or Supplement Facts label:

- mixed plant cell wall fibers;[10]
- arabinoxylan;
- alginate;
- inulin and inulin-type fructans;
- high amylose starch (resistant starch 2);
- galactooligosaccharide;
- polydextrose; and
- resistant maltodextrin/dextrin.

Many of the 26 non-digestible carbohydrates we reviewed (e.g., sugar cane fiber and oat hull fiber) are considered to be mixed plant cell wall fibers.[11] While some isolated non-digestible carbohydrate ingredients are added to foods and listed as a specific non-digestible carbohydrate (e.g., cellulose), they may also be added and listed as part of a mixed plant cell wall fiber (e.g., sugar cane fiber). We have evaluated the beneficial physiological effects of specific, isolated non-digestible carbohydrates that also may be part of a mixed plant cell wall fiber (e.g., cellulose and pectin). We have determined that each of these individual isolated non-digestible carbohydrates (e.g., cellulose and pectin) has a beneficial physiological effect. Therefore, we intend to consider "mixed plant cell wall fibers" as a general category of isolated non-digestible carbohydrates.

[9] Available at: https://www.fda.gov/downloads/Food/LabelingNutrition/UCM610139.pdf.
[10] While not an exhaustive list, examples of mixed plant cell wall fibers are provided in our science review (Id.).
[11] For purposes of this guidance, mixed plant cell wall fibers are ingredients that contain two or more of the following plant cell wall fibers in varying proportions: cellulose; pectin; lignin; beta-glucan; and arabinoxylan. Mixed plant cell wall fibers may include variable amounts of vitamins, minerals, and macronutrients depending on the methods that may be used for isolating and extracting the fiber. See the discussion of mixed plant cell wall fibers in Appendix A and our science review titled "Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates," June 2018. Available at: https://www.fda.gov/downloads/Food/LabelingNutrition/UCM610139.pdf.

FDA's regulations at 21 CFR 101.9(c)(1)(i)(C), regarding the required declaration of nutrient levels on a food label, provide a caloric value of 2 kcal/g for soluble non-digestible carbohydrates. Based on our review of the scientific evidence,[12] including evidence provided in a citizen petition,[13] we intend to propose to amend this caloric value for polydextrose to 1 kcal/g in a future rulemaking. In the interim, we intend to exercise enforcement discretion with respect to the use of a caloric value of 1 kcal/g for polydextrose on Nutrition and Supplement Facts labels under § 101.9(c)(1)(i)(C).

Section 101.9(g) requires manufacturers to make and keep records to verify the amount of non-digestible carbohydrates added to food that do not meet the definition of dietary fiber. However, consistent with our intent to exercise enforcement discretion, when a mixture of dietary fiber and one or more of these eight added non-digestible carbohydrates (that are not currently listed as a "dietary fiber" in the definition in § 101.9(c)(6)(i)) are present in a food, we do not expect manufacturers to make and keep records in accordance with § 101.9(g)(10) and (11) to verify the declared amount of one or more of these eight added non-digestible carbohydrates in the label and labeling of food.

# IV. References

We have placed the following reference on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see it at that location between 9 a.m. and 4 p.m., Monday through Friday. As of June 5, 2018, FDA had verified the Web site address for the references as hyperlink from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after June 5, 2018.

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. "Review of the Scientific Evidence on the Physiological Effects of Non-Digestible Carbohydrates." June 2018. Available at: https://www.fda.gov/downloads/Food/LabelingNutrition/UCM610139.pdf.

[12] *Id.*

[13] Docket No. FDA-2016-P-3311, "Citizen Petition Regarding the Listing of Polydextrose as a Source of Dietary Fiber and the Caloric Value of Polydextrose for Use in Nutrition Labeling and Claims," submitted by Tate & Lyle Ingredients Americas LLC and DuPont Nutrition & Health.

# V. Appendix A – Intrinsic and Intact Non-Digestible Carbohydrates and Mixed Plant Cell Wall Fiber Ingredients

In this guidance, we announce our intent to exercise enforcement discretion with respect to eight additional non-digestible carbohydrates (NDCs) relative to the declaration of these NDCs as a dietary fiber on Nutrition and Supplement Facts labels. We include a reference in this guidance that provides our science review of the eight additional NDCs (titled "Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates") (2018 enforcement discretion science review). This Appendix addresses several issues related to NDCs that we consider to be intrinsic and intact, or that we consider to be a mixed plant cell wall fiber ingredient. A full discussion of mixed plant cell wall fibers can be found in the document entitled "Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates."

The 2016 draft guidance, titled "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry," stated that we did not consider NDCs obtained from non-food sources, such as stems, branches, and trunks of trees, edible hulls and husks, seaweed, and fungus, to be intrinsic and intact. We recognize that certain seaweeds and fungi are considered foods. Therefore, consistent with the dietary fiber definition, the intrinsic and intact NDCs found in seaweed and fungi, consumed as food, meet the dietary fiber definition. There are, however, NDCs that may be isolated from food sources or that are isolated from non-food sources that are not intrinsic and intact, such as cellulose from wood pulp. Therefore, we intend to review the available scientific evidence for isolated NDCs obtained from food and non-food sources to determine whether any of them have a physiological effect that is beneficial to human health. The 2016 draft guidance provided examples of "intrinsic and intact" NDCs (e.g., cereal bran, cocoa powder, flours) and NDCs (e.g., resistant starch) that are created during the normal processing of food (e.g., flaked corn cereal). For many other products, determining whether the processing that a plant undergoes would no longer result in an "intrinsic and intact" dietary fiber or would be an "isolated" NDC would be difficult, unless we evaluated the particular NDC and its processing method. For example, many plants contain a variety of NDCs, with common ones primarily being present in plant cell walls (e.g., cellulose, hemicelluloses, and pectin), in addition to lignin.[14] The content and profile of these mixed plant cell wall fibers can vary depending on the processing methods that are used to extract the NDCs from a particular type of plant, which, in turn, often makes it difficult to determine whether or not a particular NDC is intrinsic and intact, particularly when the processing methods used to extract the NDC or the composition of the ingredient are unknown.

[14] Marlett JA. Content and composition of dietary fiber in 117 frequently consumed foods. *Journal of the American Dietetic Association* 1992;92:175-186; Kumar V, Sinha AK, Makkar HPS et al. Dietary roles of non-starch polysaccharides in human nutrition: A review. *Critical Review in Food Science and Nutrition* 2012;52:899-935.

We recognize that different types of processing methods can result in different degrees of isolation, even among aqueous or chemical extraction methods.[15] In reviewing the literature, the plant cell wall fibers, cellulose and pectin, as well as lignin, are present in de-hulled soybeans that are used for producing soy protein concentrates.[16] Therefore, the plant cell wall fibers present in concentrates, such as soy protein concentrates, provide physiological effects that are beneficial to human health.

Some NDCs, such as plant cell wall fibers (e.g., corn hull fiber), can have the same name, but are subject to different types of processing and the name may not be indicative of whether the NDC is "intrinsic and intact" or "isolated." We have addressed this in this 2018 enforcement discretion guidance, where we state that we intend to consider enforcement discretion for mixed plant cell wall fibers as dietary fiber.

The 2018 final guidance, titled "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry" (2018 final guidance), provides additional information regarding the NDCs that we consider to be isolated and not intrinsic and intact. The remaining isolated NDC ingredients, (i.e., not currently listed in the definition of "dietary fiber" or included in the "mixed plant cell wall fiber" category of isolated fibers) have a specific chemical structure as defined by their carbohydrate composition and non-digestible bond linkages. Consistent with the 2018 final guidance, the 2018 enforcement discretion science review includes the scientific evidence for such chemically specific ingredients (e.g., inulin, alginate, and polydextrose).

[15] Production of soy protein concentrates involves the use of defatted soy flour which is further processed to remove other macronutrients, such as sugars, and minerals, resulting in minor changes to the fiber content (Wang H, Johnson LS, Wang T. Preparation of soy protein concentrate and isolate from extruded-expelled soybean meals. *Journal of the American Oil Chemist's Society* 2004; 81:713-717).

[16] Li B, Lu F, H Nan et al. Isolation and structural characterization of okara polysaccharides. *Molecules* 2012;17:753-761; Tsai, AC, Mott EL, Owen GM et al. Effects of soy polysaccharide on gastrointestinal functions, nutrient balance, steroid excretions, glucose tolerance, serum lipids, and other parameters in humans. *American Journal of Clinical Nutrition* 1983;38:504-511.