

# FDA Issues Guidance Proposing to Add Eight Fibers to Dietary Fiber Definition

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Food, Beverage, and Dietary Supplements

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Today, FDA issued a guidance document announcing its intention to add eight new isolated or synthetic non-digestible carbohydrates (NDCs) to the regulatory definition of “dietary fiber.”<sup>1</sup> Until FDA completes a rulemaking to revise the “dietary fiber” definition, the agency intends to exercise enforcement discretion for the declaration of these eight NDCs as dietary fiber. In addition, the guidance states that intrinsic and intact NDCs found in seaweed and fungi (consumed as food) meet the definition of dietary fiber. The guidance is effective immediately.

## Background

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As part of its May 2016 revisions to the nutrition label for foods and dietary supplements, FDA defined “dietary fiber” as (1) soluble and insoluble NDCs (with three or more monomeric units), and lignin that are intrinsic and intact in plants, and (2) isolated or synthetic NDCs (with three or more monomeric units) that FDA determines to have a physiological effect that is beneficial to human health.<sup>2</sup>

In the final rule, FDA said it had reviewed over 20 isolated or synthetic NDCs, but concluded that, based on the information available to the agency at that time, only seven met its definition of dietary fiber. FDA subsequently issued the following dietary fiber documents: (1) the Science Review of Isolated and Synthetic Non-Digestible Carbohydrates; and (2) the Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition.<sup>3</sup>

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<sup>1</sup> *Guidance for Industry: The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels* (June 2018), available [here](#).

<sup>2</sup> See *FDA Issues Final Rules on Changes to Nutrition Labels*, Covington Client Alert (May 23, 2016), available [here](#).

<sup>3</sup> See *FDA Issues Dietary Fiber Guidance and Scientific Review of 26 Fibers*, Covington Client Alert (Nov. 30, 2016), available [here](#); *FDA Issues Guidance on Dietary Fiber and Added Sugars and Announces “Next Steps,”* Covington Client Alert (Mar. 5, 2018), available [here](#).

## Proposal to Add Eight Fibers to FDA’s “Dietary Fiber” Definition

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Based on FDA’s tentative determination that these eight NDCs have physiological effects that are beneficial to human health,<sup>4</sup> the agency intends to add the following NDCs to the regulatory definition of “dietary fiber”:

- Mixed plant cell wall fibers;
- Arabinoxylan;
- Alginate;
- Inulin and inulin-type fructans;
- High amylose starch (resistant starch 2);
- Galactooligosaccharide;
- Polydextrose; and
- Resistant maltodextrin/dextrin.

FDA will have to initiate a rulemaking to revise the “dietary fiber” definition, and, while the completion of that rulemaking is pending, the agency will exercise enforcement discretion with respect to the declaration of these eight NDCs as dietary fiber.

The guidance defines “mixed plant cell wall fibers” as a general category of isolated NDCs. Specifically, 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. FDA provides a non-exhaustive list of examples of mixed plant cell wall fibers that it intends to consider enforcement discretion for as dietary fiber: apple fibers, bamboo fibers, barley fibers, carrot fibers, citrus fibers, cocoa fibers, corn fibers (e.g., corn hull fiber), cotton seed fibers, oat fibers (e.g., oat hull fiber), pea fibers (e.g., pea hull fiber, pea seed coat fiber, inner cotyledon pea fiber), rice bran fibers, soy fibers (e.g., soy hull fiber, soy polysaccharide, soy cotyledon fiber), sugar beet fibers, sugar cane fibers, and wheat fibers.<sup>5</sup>

## Caloric Value for Polydextrose

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In addition, FDA intends to initiate a rulemaking to amend the caloric value for polydextrose (one of the newly approved dietary fibers) to 1 kcal/g, and will exercise enforcement discretion with respect to the use of this caloric value until the rulemaking is complete.

## Intact and Intrinsic NDCs Found in Seaweed and Fungi

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In FDA’s 2016 draft guidance on dietary fiber, the agency stated that it 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. The new guidance partly revises this

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<sup>4</sup> See *FDA Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates* (June 2018), which includes FDA’s science review of the eight NDCs listed herein, available [here](#).

<sup>5</sup> *Id.*

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position, by announcing that the intrinsic and intact NDCs found in seaweed and fungi (consumed as food) meet the dietary fiber definition.

Covington & Burling LLP continues to monitor developments in food labeling requirements, and in particular, FDA's actions on dietary fiber, added sugars, and other actions related to FDA's nutrition labeling. If you have any questions concerning food labeling developments discussed in this alert or other food regulatory matters, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

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