

MEMORANDUM

From: Martin J. Hahn
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Re: FDA Issues Guidance Recognizing Eight Ingredients as Meeting the Dietary Fiber Definition

The Food and Drug Administration (FDA) has issued a guidance document that identifies eight ingredients that the agency has determined meet the regulatory definition of “dietary fiber.”^{1/} Specifically, FDA has recognized the following ingredients as meeting the dietary fiber definition: (1) mixed plant cell wall fibers; (2) arabinoxylan; (3) alginate; (4) inulin and inulin-type fructans; (5) high amylose starch (resistant starch 2); (6) galactooligosaccharide; (7) polydextrose; and (8) resistant maltodextrin/dextrin. In this guidance document, FDA also announced that it intends to extend enforcement discretion regarding the declaration of these eight isolated or synthetic non-digestible carbohydrates (NDCs) as a dietary fiber on Nutrition Facts and Supplement Facts labels pending completion of a formal rulemaking to revise the dietary fiber regulation to reflect these ingredients. In addition to the guidance document, FDA has also published a review of the scientific evidence on the physiological effects of these NDCs,^{2/} and has issued responses to several citizen petitions requesting that certain NDCs be added to the “dietary fiber” definition.

This memorandum provides a brief overview of FDA’s dietary fiber definition, and summarizes the key aspects of the guidance related to FDA’s determination that these eight ingredients meet the dietary fiber definition.

By way of background, FDA’s regulations define 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)

^{1/} See FDA Guidance for Industry, The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels, *available at* <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM610144.pdf>.

^{2/} Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates, *available at* <https://www.fda.gov/downloads/Food/LabelingNutrition/UCM610139.pdf>.

determined by FDA to have physiological effects that are beneficial to human health.” ^{3/} The regulation goes on to list all of the isolated or synthetic NDCs that FDA has determined to have beneficial physiological effects on human health, ^{4/} and FDA’s new guidance document reflects the agency’s intent to add to this list the eight ingredients identified above. As a part of the enforcement discretion, when a mixture of dietary fiber and one or more of these eight added NDCs are present in a food, FDA does **not** expect manufacturers to keep records in accordance with 21 C.F.R. §101.9(g)(10) and (11) to verify the declared amount of one or more of these eight added NDCs on a food label. While all companies should maintain records or other documentation that each of the fibers used in the product qualifies as “dietary fiber,” the records required under 21 C.F.R. §101.9(g)(10) and (11) must only be kept if the formulation involves a combination of both non-digestible carbohydrates that do and do not qualify as “dietary fiber” under the new definition.

In addition to recognizing these eight ingredients as meeting the definition of dietary fiber and extending enforcement discretion with respect to declaring these ingredients as dietary fiber pending the amendment of FDA’s regulations, FDA has provided clarification regarding mixed plant cell wall fibers as a category of NDCs, enforcement discretion specific to polydextrose, and an explanation of how the degree of processing can affect whether a NDC is considered intrinsic and intact, as discussed further below.

Mixed Plant Cell Wall Fibers as Category of NDCs

With respect to mixed plant cell wall fibers, FDA explains that this is a general category of isolated NDCs, and that “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. Further, FDA states that 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. FDA’s scientific review includes examples of mixed plant cell wall fibers, which the agency states is not intended to be an exhaustive list. ^{5/}

In Appendix A to the guidance, FDA explains that in reviewing the literature, the agency found that 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, and therefore, the plant cell wall fibers present in concentrates, such as soy protein concentrates, provide beneficial physiological effects to human health. FDA further explains that 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 therefore the name may not be indicative of whether the NDC is intrinsic and intact or isolated. For this reason, FDA has decided to extend enforcement discretion for mixed plant cell wall fibers as dietary fiber.

^{3/} 21 C.F.R. § 101.9(c)(6)(1).

^{4/} The seven NDCs that FDA has already determined have a beneficial physiological effect and are included in the regulation are: [beta]-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose.

^{5/} FDA’s examples of mixed plant cell wall fibers include: 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.

Polydextrose Enforcement Discretion

FDA is also intending to exercise enforcement discretion specific to the caloric value used to declare polydextrose in the Nutrition and Supplement Facts labels. FDA's regulations provide a caloric value of 2 kcal/g for soluble NDCs; 6/ however, based on the agency's review of the scientific evidence, it intends to propose a caloric value of 1 kcal/g for polydextrose, and is exercising enforcement discretion for the use of the 1 kcal/g value until the regulation is amended.

Impact of the Degree of Processing on Whether a NDC is Considered "Intrinsic and Intact"

Appendix A to the guidance discusses the degree to which a NDC can be isolated or synthesized from its original plant source but still be considered intrinsic and intact. First, FDA recognizes that the NDCs found in seaweed and fungi, consumed as food, meet the dietary fiber definition, contrary to a statement in FDA's 2016 Draft Guidance, Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition.

NDCs may be isolated from both food sources and non-food sources, such as cellulose from wood pulp, and FDA intends to review the available scientific evidence for isolated NDCs obtained from food and non-food sources to determine whether any of them have a beneficial physiological effect. FDA states that that for many 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 the agency evaluates the particular NDC and processing method. For example, FDA notes that the content and profile of mixed plant cell wall fibers can vary depending on the processing methods used to extract the NDCs, which makes it difficult to ascertain whether the NDC is intrinsic and intact, particularly if the processing methods are unknown.

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We will continue to monitor developments on FDA's determinations regarding dietary fibers and implementation of the new nutrition labeling rules. Please contact us if you have any questions regarding this or any other matter.

6/ 21 C.F.R. § 101.9(c)(1)(i)(C).