



What's next on the  
fiber regulatory front?

As consumers learn more about the importance of their digestive health and maintaining an ideal weight, fiber has seen a resurgence in its dietary importance.

The global fiber market is now estimated by *Nutrition Business Journal* to be near

**\$3.7 billion,**

propelled by numerous trends around its functionality and health benefits.

But along with its rising health image, fiber is also in the regulatory spotlight as the U.S. Food and Drug Administration attempts to provide additional clarity with a new rule for fiber published in May of 2016. The Nutrition Facts Label final rule now defines dietary fiber as “non-digestible soluble and insoluble carbohydrates (with three or more monomeric units) and lignin that are intrinsic and intact in plants; [or] isolated or synthetic non-digestible carbohydrates (with three or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.”<sup>1</sup>

Along with a new definition, the rule changed the daily reference intake for fiber from 25 grams to 28 grams.

In the proposed rule, the FDA identified seven isolated or synthetic non-digestible carbohydrates that currently meet the new definition, including beta glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum and hydroxypropylmethylcellulose.

The new definition did not affirm a number of key isolated and non-digestible carbohydrates, including inulin (oligofructose/synthetic short-chain fructooligosaccharides), soluble corn fiber, Resistant Starch and oat hull fiber, as those are pending scientific review.

### A surprising rule

This short list was surprising, because many fiber ingredients have substantial scientific literature substantiation, according to Jacqueline Kuler, a partner with the law firm Amin Talati Upadhye in Chicago. She noted that the FDA likely left the ingredients out of the initial rule because they didn't feel prepared to make a definitive determination on them. “It seems a miss that they so narrowly defined ‘beneficial physiological effect’ to not include the balance of microflora.”

The agency did publish a draft guidance in November of 2016, entitled “Scientific Evaluation of the Evidence on the Beneficial Physiological Effect of Isolated and Non-Digestible Carbohydrates Submitted as a Citizen’s Petition (21 CFR 10.30) Guidance for Industry,” to communicate their thinking on the health effects of these carbohydrate ingredients. The guidance was finalized on March 1, 2018, and better refined the inclusion of subjects in studies.<sup>2</sup>

In the guidance, the FDA has explained that at least one of the following conditions would make a carbohydrate eligible for listing as a dietary fiber, including: lowering blood glucose and cholesterol levels, lowering blood pressure, improving laxation and bowel function or increasing mineral absorption in the intestinal tract. The agency also noted that other physiological endpoints could be considered in the future as scientific evidence is reviewed.<sup>2</sup>

Since the publication of the guidance, ingredient companies, especially manufacturers of inulin, were among the first to submit petitions with scientific information showing that their ingredients have extensive supporting clinical science to be considered. One petition on inulin-type fructans from chicory root fiber, for example, cited evidence to support that this ingredient provides many physiological effects, such as improved laxation and increased calcium absorption.<sup>3</sup>

## What do the changes mean for manufacturers?

The change in definition has also altered how fibers are included on the Nutrition Facts label. For example, once the compliance period goes into effect, if a product contains fiber from a non-reviewed novel fiber, say, cocoa and wheat flour, it may not be able to make a fiber claim because the fiber from cocoa and wheat flour may not be enough to meet the 10 percent minimum for daily value without the novel fiber.<sup>4</sup>

Kuler noted that they have not heard anything about how FDA's current scientific review of the newer submitted evidence is going, but that the recently proposed extension to the compliance dates may be an indication. (In October 2017, the agency announced its intention to extend the compliance dates from July, 2018, to January 1, 2020, for large companies; and for firms with revenues of less \$10 million, compliance would be pushed out an extra year to January 1, 2021.<sup>5</sup>)

In the meantime, companies with these excluded fiber ingredients are left in a sort of regulatory limbo. There is currently no definitive extension to the final rule, so inulin, for example, can still be labeled as fiber and included in the calculation of fiber until the FDA scientific review is complete and publicly released.

### Fibers currently included in dietary fiber definition

- Beta glucan soluble fiber
- Psyllium husk
- Cellulose
- Guar gum
- Pectin
- Locust bean gum
- Hydroxypropylmethylcellulose

### Fibers pending review

- Inulin (oligofructose/ synthetic short-chain fructooligosaccharides)
- Soluble corn fiber
- Resistant starch
- Oat hull fiber

#### References

<sup>1</sup> FDA.gov, "Questions and Answers for Industry on Dietary Fiber," March 1, 2018. <https://www.fda.gov/food/labelingnutrition/ucm528582.htm>

<sup>2</sup> FDA.gov, "Scientific Evaluation of the Evidence on the Beneficial Physiological Effect of Isolated and Non-Digestible Carbohydrates Submitted as a Citizen's Petition (21 CFR 10.30) Guidance for Industry," February 12, 2018. <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM528533.pdf>

<sup>3</sup> Gelski, J. "Inulin Companies Petition FDA for Fiber Status," *Food Business News*, September, 2016. [http://www.foodbusinessnews.net/articles/news\\_home/Regulatory\\_News/2016/09/Inulin\\_companies\\_petition\\_FDA.aspx?ID=%7B609D607C-BD03-4685-9450-CCC988402113%7D&cck=1](http://www.foodbusinessnews.net/articles/news_home/Regulatory_News/2016/09/Inulin_companies_petition_FDA.aspx?ID=%7B609D607C-BD03-4685-9450-CCC988402113%7D&cck=1)

<sup>4</sup> AIB International. "A Closer Look at FDA Definition of Dietary Fiber," August 22, 2016. <http://foodfirst.aibonline.org/foodfirst/2016/8/15/a-closer-look-at-the-fdas-definition-of-dietary-fiber>

<sup>5</sup> Van Laack, R. "FDA Proposed Jan. 1, 2020, as New Compliance Date for Nutrition Labeling." <http://www.fdalawblog.net/2017/10/fda-proposes-jan-1-2020-as-new-compliance-date-for-nutrition-labeling/>