



1600 Oregon Street, Muscatine, IA 52761, USA  
[grainprocessing.com](http://grainprocessing.com)

November 20, 2020

## **Citizen Petition Regarding Nutrition Labeling of Isomaltodextrin as a Dietary Fiber under the Resistant Maltodextrin category**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fisher Lane  
Room 1061  
Rockville, MC 20852

Dear Commissioner,  
Grain Processing Corporation submits this Citizen Petition in accordance with 21 CFR § 10.30 and 21 CFR § 10.20 to request that Isomaltodextrin(IMD) be included as Dietary Fiber under the Resistant Maltodextrin category in the Nutrition Facts label on foods and beverages and dietary supplements.

The basis for this request is set forth below.

### **A. Action Requested**

Grain Processing Corporation (GPC) requests the Commissioner to amend 21 CFR § 101.9(c)(6)(i) Nutrition Labeling of Food to include Isomaltodextrin as Dietary fiber under the Resistant Maltodextrin category in the Nutrition Facts label on foods and beverages and dietary supplements. Information to support this request is contained in this petition and as attachments that demonstrate that Isomaltodextrin is a Resistant Maltodextrin (with 3 or more monomeric units) that is the same as the substance recognized by FDA as Dietary Fiber.

### **Background**

Resistant Maltodextrin/Dextrin is approved as a dietary fiber by FDA based on several petitions in the industry. In the FDA Review of the Scientific Evidence on the Physiological Effects of Certain Non-Digestible Carbohydrates, it states Resistant Maltodextrin/Dextrin is a glucose oligosaccharide. Resistant Maltodextrin/Dextrin are composed of non-digestible oligosaccharides of glucose molecules that are joined by

digestible linkages and non-digestible  $\alpha$ -1,2 and  $\alpha$ -1,3 linkages. Common names used to identify Resistant Maltodextrin/Dextrin as an ingredient include soluble corn fiber, resistant dextrin, resistant wheat dextrin, soluble wheat fiber and wheat dextrin.

IMD is Generally Recognized as Safe (GRAS) as shown in GRAS Notification 610 for Isomaltodextrin with no limitation of use other than good manufacturing practice. GPC has reviewed the description of Resistant Maltodextrin/Dextrin and concluded with the justification below that the IMD is very similar in structure and digestibility to the approved Dietary fibers in the Resistant Maltodextrin category and therefore be considered as Resistant Maltodextrin/Dextrin.

Resistant Maltodextrin/Dextrins are synthetic non-digestible carbohydrates (with 3 or more monomeric units) that have physiological effects that are beneficial to human health. Resistant Maltodextrin/Dextrins meet the definition of dietary fiber as defined in 21 CFR101.9(c)(6)(i)

## **B. Statement of Grounds**

Under section 21 CFR 184.1444, Maltodextrin  $((C_6H_{10}O_5)_n$ , CAS Reg. No. 9050-36-6) is a non-sweet nutritive saccharide polymer that consists of D-glucose units linked primarily by  $\alpha$ -1,4 bonds and that has a dextrose equivalent (D.E.) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes.

### **Isomaltodextrin (IMD)**

IMD is produced through the action of enzymes on cornstarch, tapioca or other food starches. The initial processing steps are similar to those for maltodextrin but the process for IMD includes a step in which  $\alpha$ -1,6, and  $\alpha$ -1,3 linkages are formed.

### **Rationale for Listing of Resistant Maltodextrin as a Source of Dietary Fiber**

The detailed rationale for recognition of Isomaltodextrin as a Dietary Fiber under the Resistant Maltodextrin category is provided in Attachment A, "Scientific Evidence to Support the Labeling of Isomaltodextrin as Resistant Maltodextrin as a Source of Dietary Fiber in the United States": For FDA's review, all the references are included in Attachment A.

## **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 CFR § 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 petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

A handwritten signature in cursive script that reads "R. Thomas". The signature is written in black ink and is positioned above a horizontal line.

Rani Thomas

Senior Regulatory Affairs Manager

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