



Dr. Ahmad Parveez Ghulam Kadir
Malaysian Palm Oil Board
6, Persiaran Institusi
Bandar Baru Bangi
43000 Kajang, Selangor
MALAYSIA

Re: GRAS Notice No. GRN 001009

Dear Dr. Kadir:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 001009, which we filed on August 25, 2021. We received this request on May 22, 2022.

The subject of the notice is water-soluble palm fruit extract (wsPFE) for use as an ingredient in cookies, nonalcoholic beverages and beverage bases, milk- and non-milk-based meal replacement drinks, instant coffee, instant tea, ready-to-drink (RTD) tea beverages, specialty RTD coffee drinks, dairy product analogs, margarine, ice cream, frozen dairy desserts, cereal and granola bars, protein bars, milk-based beverages (including flavored milks, smoothies), yogurt, yogurt drinks, fermented milks, nuts and nut products, fruit juices and nectars, fruit drinks and ades, vegetable juices and blends, chocolate and gummy candies, and cocoa syrup at levels ranging from 0.11% to 2.67%, and in sugar substitutes at levels between 10% and 40%. The notice informs us of Malaysian Palm Oil Board's view that these uses of wsPFE are GRAS through scientific procedures.

In a teleconference on May 10, 2022, we discussed various remaining questions, including those related to: the composition of wsPFE, including the polyphenol and carbohydrate profiles; the method of manufacture and residual impurities; heavy metal specifications and the presence of arsenic in wsPFE; estimates of dietary exposure to wsPFE and its impurities; suitability and relevance of pesticide residue analyses and limits provided in the notice; the approach to establishing safety, whether via compositional (constituent-based) narrative or determination of an acceptable daily intake based on studies conducted using the article of commerce; the lack of clear scientific rationale given for use of a reduced safety factor (less than 100); the differences in composition (e.g., for polyphenols) between wsPFE and the test material used in published toxicology studies; the reference to polyphenols as a chemical class coupled with the lack of information to support the assumption that all constituents classified as polyphenols would exhibit a similar safety profile; the lack of information establishing the typical estimates of dietary intake of oil palm fruit; the lack of sufficient data bridging the proximate and phytochemical composition of wsPFE to those of other

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polyphenol-containing sources (e.g., dates); and other deficiencies requiring clarification. Due to the extent of these deficiencies, we recommended that MPOB should request that we cease to evaluate GRN 001009. In an email dated May 22, 2022, you requested on behalf of MPOB that we cease our evaluation of GRN 001009.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001009 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan
J. Carlson -S
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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