FDA Update on the Post-market Assessment of Tara Flour

Constituent Update

May 15, 2024

Today, the U.S. Food and Drug Administration (FDA) posted on its website its determination that tara flour in human food does not meet the <u>Generally</u> <u>Recognized As Safe (or GRAS)</u> standard and is an unapproved food additive. The FDA's assessment of the ingredient is detailed in a <u>memo</u> added to the agency's <u>public inventory</u>. Increased transparency of our assessment of ingredients in the food supply is part of our approach to enhance <u>food chemical safety</u>.

Under the <u>Federal Food</u>, <u>Drug</u>, <u>and Cosmetic (FD&C) Act</u>, any ingredient used or intended for use in food must be authorized by the FDA for use as a food additive unless that use is <u>Generally Recognized As Safe or GRAS</u> by qualified experts or meets a listed exception to the <u>food additive</u> <u>definition</u> in the FD&C Act. An unapproved food additive is deemed to be unsafe under the FD&C Act.

In 2022, Daily Harvest used tara flour in a leek and lentil crumble product which was associated with roughly 400 adverse event reports. The firm took prompt action to voluntarily recall the product and conduct their own root cause analysis, during which they identified tara flour as a possible contributor to the illnesses. To date, the FDA has found no evidence that tara flour caused the outbreak; however, it did prompt the agency to evaluate the regulatory status of this food ingredient.

The FDA's evaluation revealed that there is not enough data on the use of tara flour in food, or a history of its safe use, to consider it GRAS. There is no food additive regulation authorizing the use of tara flour in food. Uses of food ingredients that are not GRAS, not authorized as food additives, and not excepted from the <u>Federal Food</u>, <u>Drug</u>, <u>and Cosmetic (FD&C) Act</u>'s food additive definition are unapproved food additives. Food that is, or contains, an unsafe food additive is considered adulterated.

FDA's Continued Monitoring of Tara Flour in the Food Supply

Manufacturers who are considering using tara flour as an ingredient in food are responsible for ensuring that its use is safe and lawful and are

encouraged to consult with the FDA. At this time, the FDA is not aware of evidence that shows that tara flour is a food ingredient being developed domestically or that there are any products containing tara flour that are currently being manufactured in the U.S.

The FDA instituted screening at ports of entry for tara flour used as an ingredient in imported food or imported for sale in bulk. The agency has not detected any recent shipments of tara flour in imported products as of today.

The FDA remains committed to monitoring new ingredients in the food supply to ensure they meet relevant safety standards. The FDA's assessment of chemicals in the food supply is part of our commitment to food safety and public health.

Additional Information

- Post-market Determinations that the Use of a Substance is Not GRAS
- FDA Update on Post-market Assessment of Certain Food Ingredients
- <u>Understanding How the FDA Regulates Food Additives and GRAS</u>
 <u>Ingredients</u>