



December 12, 2024

Randall Shultz  
Vice President of Research  
InnerPlant, Inc.  
202 Cousteau Place  
Suite 150  
Davis, CA 95618

RE: NPC 000020; LanFP1

Dear Mr. Shultz,

This letter is in response to InnerPlant's early food safety evaluation of the protein LanFP1, from the lancelet *Branchiostoma floridae*, expressed in a new plant variety under development. LanFP1 is a green fluorescent protein (GFP), the chromophore of which absorbs high energy light (blue) that is re-emitted as fluorescence of lower-energy light (green). You submitted your evaluation to the Food and Drug Administration (FDA) under our guidance to industry, "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."<sup>1</sup> We received your evaluation on August 2, 2024, and we received additional information on November 4, 2024. In this letter and in the guidance, the term "food" refers to both human and animal food. All materials relevant to this evaluation have been placed in a file designated NPC 000020. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in the Human Foods Program.

Based on your early food safety evaluation, it is our understanding that InnerPlant has concluded that the potential inadvertent presence in the food supply of low levels of LanFP1 would not raise food safety concerns. We have completed our evaluation of your submission, and we have no questions at this time regarding InnerPlant's conclusion.

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<sup>1</sup> Accessible from <https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties>

In 1996, FDA issued guidance on consultation procedures for foods derived from new plant varieties.<sup>1</sup> The submission of an early food safety evaluation for a new protein is not meant to substitute for a biotechnology consultation or other appropriate regulatory process with FDA about food derived from a new plant variety. We anticipate that InnerPlant will participate in appropriate regulatory review processes prior to marketing food derived from new plant varieties expressing LanFP1.

Sincerely,

Andrew

J. Zajac -S

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by Andrew J.  
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Andrew Zajac  
Director  
Innovative Foods Staff  
Human Foods Program