

FINDING OF NO SIGNIFICANT IMPACT

A Food Allergen Labeling Notification (FALN 008), submitted by Unilever United States, Inc., requesting exemption from the allergen labeling requirements under section 403(w)(1) of the FD&C Act, as described in section 403(w)(7), for Ice Structuring Protein (ISP) preparation when used as a processing aid for frozen sauces of frozen meals at a maximum level of ppm in the frozen sauce, and as a texturizer in frozen novelty desserts limited to % in the finished product.

The Office of Food Additive Safety has determined that not making a determination under section 403(w)(7)(B) of the FD&C Act on this notification, resulting in no required labeling of this food ingredient as a major food allergen, will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on a review of the information provided in the Environmental Assessment prepared by Unilever, dated January 3, 2013, as discussed below.

The subject of the proposed action is a food ingredient derived from ocean pout (*Macrozoarces americanus*) produced by expression in the yeast *Saccharomyces cerevisiae* of a synthetic gene encoding a protein with an amino acid sequence identical to the ice structuring protein, ISP, Type III HPLC 12 found in the serum of ocean pout.

The food ingredient, ISP, is not sourced directly from the ocean pout. A gene coding for the ISP was assembled via *in vitro* methodologies and inserted into the yeast *Saccharomyces cerevisiae*, and not via direct transfer of a gene segment from the DNA of ocean pout. The food ingredient is produced through fermentation of the yeast expressing the ISP. Harvest and slaughter of the naturally occurring ocean pout species is not required to produce the food ingredient. Therefore, even if the use of the food ingredient increases as a result of the proposed action, no adverse impacts are expected on any naturally occurring species.

ISP preparation has been marketed in the United States since 2002. An exemption under a FALCPA Notification pursuant to section 403(w)(7) of the FD&C Act would permit the statement of ingredients on a food label to refer to ISP without referring to the name of a species of fish as required under section 403(w)(1) of the FD&C Act. Two categorical exclusions, neither of which is directly applicable here, refer to food labeling (21 CFR 25.30(k) and 25.32(p)). Unilever contends in the EA that this labeling change is similar to the result if a petition were granted under 21 CFR 10.30 to amend or revoke the label declaration of ingredients. An action resulting

in a labeling change requested under 21 CFR 10.30 is categorically excluded under 21 CFR 25.32(p), and therefore does not ordinarily require the preparation of an EA or Environmental Impact Statement (EIS).

The Office of Food Additive Safety considered that the food ingredient is produced by expression in yeast, with no impacts on the naturally occurring ocean pout species. Further, the food ingredient is a protein expected to be fully metabolized upon consumption. Therefore, even if an increase in the use of the food ingredient were to occur as a result of the proposed action, no significant impacts on the human environment would be anticipated as a result of the proposed action (which results in an exemption from labeling).

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