



Joan Baughan
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

Re: GRAS Notice No. GRN 000237

Dear Ms. Baughan:

The Food and Drug Administration (FDA, we) completed our evaluation of BASF Corporation (BASF)'s supplement to GRN 000237.¹ On May 10, 2017, we received the supplement dated April 28, 2017. The supplement addresses additional uses for alkyl polyglycosides (APG). We received clarifying information on April 22, 2018; November 1 and 6, 2018; May 24, 2019; October 31, 2019; and March 10, 2020.

We previously responded to GRN 000237 on October 14, 2008. We stated that we had no questions at that time regarding BASF's conclusion that APG is GRAS for use in the cleaning of foods, including fruits, vegetables, meat, and poultry products.²

In the supplement received May 10, 2017, BASF informs us of its view that APG is GRAS, through scientific procedures, for use in wash water for processing meat and poultry carcasses, and in washing fruits and vegetables, all without a potable water rinse. Specifically, BASF amends the concentration of APG that will be used in cleaning solutions and omits the use of a potable water rinse following treatment of foods with APG-containing cleaning solutions. In clarifying information, BASF revised the scope of the supplement and stated that the use of APG in wash water used for processing meat and poultry carcasses is limited to those situations where the application of APG is to be followed by some aqueous intervention such as treatment with non-APG wash or an antimicrobial treatment not including APG. The intended use includes APG as a component of wash solutions for meat carcasses (e.g., beef and pork), during butchering (including parts, trim, and organs), and for poultry (including whole and eviscerated carcasses, parts trim and organs) at up to 0.5% when followed by an aqueous intervention (e.g., an antimicrobial wash without APG or a chiller bath), at up to 2% for other products, including parts, trim, and organs, when followed by a potable water rinse, or

¹ BASF Corporation has acquired Cognis, the original notifier of GRN 000237. Thus, this letter refers to BASF as the notifier for GRN 000237.

² The use in meat and poultry products described in GRN 000237 includes use in caustic solutions at up to 5% APG for washing and dehairing meat carcasses (pork and beef) and poultry defeathering and use in solutions at up to 2% APG to wash meat (e.g., beef carcasses, after the hide is removed, to remove any extraneous hair, dirt, etc.) during butchering, all followed by a potable water rinse.

at up to 5% by weight for carcasses when followed by a potable water rinse. The intended use of APG also includes use in wash solutions at up to 1% for use on fruits and vegetables with or without a potable water rinse.

In the supplement to GRN 000237, BASF revises the estimates of dietary exposure to APG based on changes to the intended conditions of use, the resulting concentration on foods, and revised estimates of food consumption. BASF estimates dietary exposure to APG from use on fruits and vegetables to be 614 µg/kg body weight (bw)/day based on APG retention volume data presented in GRN 000237 (i.e., use of a 1% APG solution on fruits and vegetables without a subsequent rinse step). BASF estimates the dietary exposure to APG from use on poultry to be 264 µg/kg bw/day based on a retention volume of 0.5% APG cleaning solution on poultry (i.e., the maximum use level), average poultry carcass weight, daily consumption of poultry, and reductions to residual APG level due to additional processing (e.g., chiller bath). BASF estimates the dietary exposure to APG from use on beef to be 35 µg/kg bw/day based on retention volume of a 0.5% APG solution on beef carcasses i. e. the maximum use level, average carcass weight, daily consumption of beef, and reductions to residual APG level due to additional processing. BASF estimates the dietary exposure to APG from use of a 0.5% APG solution on pork carcasses to be 17 µg/kg bw/day based on pork consumption data and an assumption that APG residue on pork is similar to that on beef. BASF reports an additive estimate of total mean dietary exposure to APG from all intended uses to be 930 µg/kg bw/day (equivalent to 55.8 mg/person/day for a 60 kg individual). BASF states that these estimates of dietary exposure supersede those provided in GRN 000237, and that the revised conditions of use are not expected to result in an increase in exposure to APG.

BASF includes an update of the literature through January 2018. Through this time period, BASF found no new literature that contradicts their conclusion that APG is GRAS under its intended conditions of use.

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of the supplement to GRN 000237, we coordinated with the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS determines the efficacy and suitability of ingredients used in meat, poultry, and egg products, and prescribes safe conditions of use. Suitability relates to the ingredient's effectiveness in performing its intended technical effect and the assurance that the ingredient's use will not result in products that are adulterated or misleading for consumers.

FSIS has advised the following with respect to the statutes it administers:

FSIS has completed its review and has no objection to the use of APG at 0.5% by weight in wash water used on poultry, beef, and pork carcasses followed by an aqueous intervention of some kind.

Regarding labeling, FSIS would consider the substance a processing aid that does not require a labeling statement under the accepted conditions of use.

FSIS requested that we advise you to seek regulatory guidance from its Risk Management and Innovations Staff (RMIS) about the use of APG in meat, poultry, and egg products. You should direct such an inquiry to Dr. Melvin Carter, Director, RMIS, Office of Policy and Program Development, FSIS by email at Melvin.Carter@fsis.usda.gov.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of BASF's supplement concluding that APG is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing APG. Accordingly, our response should not be construed to be a statement that foods containing APG, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that BASF provided, as well as other information available to FDA, we have no questions at this time regarding BASF's conclusion that APG is GRAS under its intended conditions of use. This letter is not an affirmation that APG is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to the supplement to GRN 000237 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan
J. Carlson -S
Date: 2020.05.21 16:12:01
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Susan Carlson, Ph.D.
Director
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cc: Melvin Carter, Ph.D.
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