



Robert Rankin
International Food Additives Council
750 National Press Building
529 14th Street NW
Washington, DC 20045

Re: GRAS Notice No. GRN 000668

Dear Mr. Rankin:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000668. We received the notice, dated July 25, 2016, that you submitted in accordance with the agency's proposed regulation, proposed 21 Code of Federal Regulations (CFR) 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal) on September 15, 2016, and filed it on September 21, 2016. We received amendments containing additional safety information on November 18, 2016, December 15, 2016, January 10, 2017, January 20, 2017, and January 31, 2017.

FDA published the GRAS final rule on August 17, 2016 (81 FR 54960), with an effective date of October 17, 2016. As GRN 000668 was pending on the effective date of the GRAS final rule, we requested additional information consistent with the format and requirements of the final rule. We received an amendment responding to this request on November 18, 2016.

The subject of the notice is sodium formate. The notice informs us of the view of International Food Additives Council (IFAC) that sodium formate is GRAS, through scientific procedures, for use to support the growth of microorganisms (including *Streptococcus*, *Lactobacillus*, and *Leuconostoc* species) during the production of fermented dairy or soy products at a level not to exceed 20 mg/kg sodium formate in the starting milk or soy beverage.

IFAC discusses the identity of sodium formate (CAS number 141-53-7), the sodium salt of formic acid. Sodium formate is a white crystalline powder.

IFAC describes the manufacture of sodium formate as the reaction of carbon monoxide or formic acid with sodium hydroxide in an aqueous solution. The manufacturing process includes filtration, evaporation, and drying steps to yield the final product. The final product contains $\geq 98\%$ sodium formate and $\leq 2\%$ water.

IFAC provides specifications for sodium formate that include limits for arsenic (≤ 1 mg/kg) and lead (≤ 0.1 mg/kg). IFAC provides certificates of analysis for ten consecutive lots of sodium formate to demonstrate compliance with these specifications.

IFAC states that sodium formate is intended for addition into microbial food cultures that are used during the production of fermented dairy or soy products, including cheese and yogurt. IFAC states that formic acid occurs at variable concentrations in milk and finished dairy products, including yogurt and cheese. IFAC explains that the addition of sodium formate does not increase the concentration of formic acid at the end of fermentation above that present

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

normally and will not increase the background exposure to formate or formic acid. However, IFAC estimates the additional dietary exposures to formic acid that would result from the intended use of sodium formate to be 0.105 mg/kg bodyweight (bw)/day and 0.0033 mg/kg bw/day for a 60-kg person from the consumption of cheese and yogurt, respectively. Therefore, IFAC estimates that the total additional dietary exposure to formic acid from cheese and yogurt consumption would be 0.108 mg/kg bw/day.

IFAC discusses information relevant to the safety of sodium formate. IFAC notes that FDA has affirmed sodium formate and formic acid as GRAS for packaging use in 21 CFR 186.1756 and in 21 CFR 186.1316, respectively. IFAC discusses information available since the 1976 safety assessment from its literature search conducted through December 2016, noting the search did not find information contradicting the affirmations. IFAC states that multiple other countries and authoritative bodies have found sodium formate and formic acid acceptable for certain uses in human food, including France, Australia/New Zealand, Denmark, the European Union, and the European Food Safety Authority. IFAC also notes that the Joint Food and Agriculture Organization/World Health Organization's Expert Committee on Food Additives established an acceptable daily intake for formic acid of 0-3 mg/kg bw/day. Additionally, IFAC states that formate is a normal component of intermediary one-carbon metabolism, being a by-product of acetate production. Thus, in healthy human subjects, low levels of formate are found in blood from normal metabolism, as well as from external sources through the diet.

IFAC includes the report of a panel of individuals (IFAC's GRAS panel). Based on its review, IFAC's GRAS panel concluded that sodium formate is safe under the conditions of its intended use.

Based on its estimation of potential dietary exposure and safe levels of intake, IFAC concludes that sodium formate is GRAS for its intended use.

Standards of Identity

In the notice, IFAC states its intention to use sodium formate in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

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

Section 301(II) 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(II)(1)-(4) applies. In our evaluation of IFAC's notice concluding that sodium formate is GRAS under its intended conditions of use, we did not consider whether section 301(II) or any of its exemptions apply to foods containing sodium formate. Accordingly, our response should not be construed to be a statement that foods containing sodium formate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).

Conclusions

Based on the information that IFAC provided, as well as other information available to FDA, we have no questions at this time regarding IFAC's conclusion that sodium formate is GRAS under its intended conditions of use. This letter is not an affirmation that sodium formate is GRAS under 21 CFR 170.35 for use to support the growth of microorganisms (including *Streptococcus*, *Lactobacillus*, and *Leuconostoc* species) during the production of fermented dairy or soy products at a level not to exceed 20 mg/kg sodium formate in the starting milk or soy beverage. 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 GRN 000668 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
**Michael A.
Adams -S**

Digitally signed by Michael A. Adams -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300042713,
cn=Michael A. Adams -S
Date: 2017.03.09 12:33:31 -05'00'

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition