



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of Policy
and Program
Development

George Washington Carver Center
5601 Sunnyside Ave. STOP 5271
Beltsville, MD 20705-5271

JUL 26 2010

Mr. Gary Kushner
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Dear Mr. Kushner:

On January 19, 2007, the Food Safety and Inspection Service (FSIS) received a *Petition for Rulemaking to Allow Sodium Benzoate and Sodium Propionate as Antimicrobial Agents in Meat and Poultry Products* from Kraft Foods Global, Inc. The Petition requests a rule change to 9 CFR 424.21 to identify sodium benzoate and sodium propionate in combination with other ingredients as safe and suitable antimicrobial agents for *L. monocytogenes* control in ready-to-eat (RTE) meat and poultry products. Kraft requested that FSIS amend 9 CFR 424.21(c) to include the following specific uses:

Class of substance	Substance	Purpose	Products	Amount
Antimicrobial Agents	Sodium benzoate	To inhibit microbial growth	Various meat and poultry products	Up to 0.1% (by weight of total formulation) in combination with approved antimicrobial agents and adjuvants)
	Sodium propionatedo.....do.....	Up to 0.2% (by weight of total formulation) in combination with approved antimicrobial agents and adjuvants)

In support of this proposal, Kraft conducted research to show that the proposed use of these antimicrobial ingredients is safe and suitable. The research took into account the unique composition of diverse products such as hot dogs, bologna, ham, and turkey breast. Kraft developed an approach to predict the effect of antimicrobial ingredients on *L. monocytogenes* growth and confirmed the findings with tests of different formulations. Kraft assessed treated products for quality, analyzed the nutritional composition of planned formulations, and considered the status of sodium benzoate and sodium propionate as generally recognized as safe (GRAS) substances under Food and Drug Administration (FDA) requirements.

Kraft's research revealed that differences in product composition, especially moisture, can influence antimicrobial activity and formulation needs. Kraft identified three examples of types of formulations or antimicrobial ingredients as safe and effective for processed meat and poultry products:

1. A combination of 0.1% sodium benzoate and 0.1% sodium diacetate inhibits *L. monocytogenes* in some lower moisture products such as hot dogs.
2. A combination of 0.1% sodium benzoate, 0.15% sodium diacetate, and 0.2% sodium propionate inhibits *L. monocytogenes* in high moisture products such as ham.
3. A combination of 0.1% sodium benzoate, 0.15% sodium diacetate, 0.2% sodium propionate, and 0.56% Lem-O-Fos® inhibits *L. monocytogenes* in turkeys.

Subsequently, Kraft requested and received a waiver from FSIS to conduct sensory attribute tests using the antimicrobial ingredients at the levels described in the petition. Kraft's request required a waiver under 9 CFR § 303.1(h) and § 381.3(b) because the substances were not approved for use in 9 CFR § 424.21(c) and there is a prohibition on their use in meat because their use can conceal damage or inferiority, as described in 9 CFR § 424.23 (a)(3). FSIS regulations (9 CFR § 303.1(h) and § 381.3(b)) state that the Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in order to permit experimentation so that new procedures may be tested, provided that the waiver does not conflict with the purposes and provisions of the Federal Meat Inspection Act or the Poultry Products Inspection Act.

In regard to the substances not being listed as approved as safe and suitable in 9 CFR 424.21(c), FDA has informed FSIS that they have no objections at this time to the safety of the substances under the proposed conditions of use. In addition, the results from Kraft operating under this waiver have shown that the tested antimicrobial combinations had no negative impact on basic taste or flavor for hot dogs, bologna, ham, or turkey. Kraft showed that sodium benzoate and sodium propionate in combination with other ingredients are suitable antimicrobial agents for *L. monocytogenes* control in ready-to-eat (RTE) meat and poultry products. All additional data generated under the waiver will be used to further support the suitability of the substances to achieve the desired technical effect.

In regard to the prohibition of the use of the substances in 9 CFR § 424.23(a)(3), Kraft submitted three studies to address the concerns over the potential use of the substances to conceal damage or mask inferiority. First, Kraft assessed whether the proposed uses of sodium benzoate and sodium propionate would affect normal indicators of spoilage. Kraft conducted two shelf life studies to address the spoilage issue. Kraft found in both studies that there was very little difference in spoilage characteristics among treatments evaluated. Second, Kraft conducted a nutritional composition test. The company tested for moisture, protein, fat, ash, and sodium content. Kraft found other than a reduction in ash and an increase in moisture as lactate solids are replaced by water, there were no differences in nutritional composition between products with the substances in question and products without them. Finally, Kraft evaluated the efficacy and spoilage characteristics of sodium benzoate and sodium propionate in vacuum packaging or modified atmosphere packaging with nitrogen and carbon dioxide. Kraft found that the type of packaging did not have a technical effect on the efficacy and spoilage characteristics of sodium benzoate and sodium propionate. Kraft showed that there is consumer acceptance, that normal spoilage indicators were not masked, that nutrients were not adversely affected, and that product appearance was not changed as compared to untreated product.

Based on the evidence that you submitted from the studies and research that you have conducted, FSIS has decided to grant your petition. FSIS will propose to amend 9 CFR § 424.23(a)(3) to remove the use of these substances from the list of prohibited uses because of the data Kraft has submitted to FSIS that show that the use of these antimicrobial ingredients does not conceal damage or inferiority or make products appear better or of greater value under the proposed conditions of use. Therefore, pursuant to 9 CFR § 303.1(h) and § 381.3(b) and Federal Register Notice *FSIS Procedures for Notification of New Technology* (Docket No. 00-011N), the Office of Policy and Program Development (OPPD) will extend the in-plant trial period to allow the use of sodium benzoate and sodium propionate as antimicrobial agents in meat and poultry products to continue pending action to amend 9 CFR §§ 424.21(c) and 424.23(a)(3), provided that there is adherence to the petition's specific conditions of use.

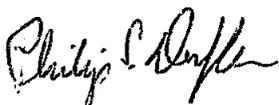
FSIS expects that any establishment formulating its products with the subject ingredients will obtain approval for a label that includes an accurate declaration of the ingredients in the appropriate order of predominance. The Labeling and Program Delivery Division (LPDD) must be notified in advance of any changes to product formulations through appropriate label modifications or re-approvals. Because Federal regulations currently prohibit the use of the subject ingredients, products in which these ingredients are to be used will be considered non-standardized and will need to be descriptively labeled to reflect the presence of the ingredients, e.g., "Ham, Water Added with Sodium Benzoate and Propionate." The reference to "with sodium benzoate and propionate" must be in print at least one-fourth the size of the largest print in the product name. Labels for these products need to be submitted to LPDD for temporary approval, which can be granted for a maximum of six months, according to the labeling regulations. In addition, products prepared using the ingredients under

the extended in-plant trial period need to bear a validated use-by or freeze-by calendar date on labeling. Establishments using the ingredients under the extended in-plant trial period are to maintain documents that provide the basis for how they determine an appropriate use-by or freeze-by date.

This extended in-plant trial period should not be considered as validation that the use of these ingredients in the products listed above will be effective in any particular official establishment. The use of these ingredients, as described in your petition, will need to be factored into the establishment's hazard analysis and if appropriate, incorporated into a Hazard Analysis and Critical Control Point (HACCP) plan or written Sanitation Standard Operating Procedures (SSOP) or other prerequisite program, validated for its application, and verified on an on-going basis for its effectiveness.

If you have any further questions, please contact Dr. John M. Hicks at (301) 504-0840 or john.hicks@fsis.usda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Philip S. Derfler". The signature is written in a cursive style with a large initial "P".

Philip S. Derfler
Assistant Administrator
Office of Policy and Program Development

cc:

Kenneth Petersen, Asst. Administrator, OFO
David Goldman, Asst. Administrator, OPHS
William Smith, Asst. Administrator, OPEER
Daniel Engeljohn, Dep. Asst. Administrator, OPPD
Rachel Edelstein, Director PID
Rosalyn Murphy-Jenkins, Director LPDD
Laura McKee, Director PDD