March 14, 2005

USDA, FSIS, OPPD, NTS
1400 Independence Ave., SW
Room 2932 South Building
Washington, DC 20250-3700


To the New Technology Office:

This letter of notification and protocol are sent for approval and endorsement by the New Technology Staff (NTS) in order that meat and poultry establishments listed herein can proceed with test production of uncured and cured RTE meat and poultry products using the following GRAS ingredient individually, or in combination, to achieve an antimicrobial effect, particularly against L. monocytogenes. The GRAS ingredients include calcium, potassium and/or sodium sorbate, sorbic acid, propionic acid, sodium propionate, sodium benzoate and benzoic acid. This letter also serves to request that products produced during the test phase be considered as acceptable for commerce without specific label requirements until formulations are confirmed, e.g., within six months as was done for development of RTE meat and poultry products reformulated with lactate and diacetate to retard the growth of L. monocytogenes.

Notification

How the new technology affects food safety?
The use of calcium, potassium and/or sodium sorbate, sorbic acid, propionic acid, sodium propionate, sodium benzoate and benzoic acid, individually or in combination, to prevent growth of L. monocytogenes in RTE meat and poultry products will further enhance food safety of these RTE products. These antimicrobial agents will specifically move more RTE meat and poultry products from Alternative 3 to Alternative 1 or 2 categories by inhibiting the growth of L. monocytogenes, a pathogen that has the potential to contaminate RTE meat and poultry products.

Why the new technology will not jeopardize the safety of Federal inspection personnel.
The use of calcium, potassium and/or sodium sorbate, sorbic acid, propionic acid, sodium propionate, sodium benzoate and benzoic acid, individually or in combination, to formulate RTE meat and poultry products follows daily existing practices of adding lactate and diacetate, salt and other such ingredients used in preparation of such products. Calcium, potassium and/or sodium sorbate, sorbic acid, propionic acid, sodium propionate, sodium benzoate and benzoic acid are common antimicrobials that are GRAS, are used in preparation of many food products, and pose no danger as raw materials during storage and handling.

Why the new technology will not require a waiver of any Agency regulation or inspection procedures.
The use of calcium, potassium and/or sodium sorbate, sorbic acid, propionic acid, sodium propionate, sodium benzoate and benzoic acid, individually or in combination, to prevent growth of L. monocytogenes in RTE meat and poultry products is allowed under 9 CFR 424.21 (b)(2), which allows the use of GRAS substances. FSIS may choose to include these substances in 9 CFR 424.21 (c) for their proven antimicrobial efficacy in RTE meat and poultry products as the data are developed to validate that use of these substances in commercial operations parallels their proven use in laboratory research as antimicrobial agents similar to lactate and diacetate.
Although sorbic acid and its salts are prohibited for use in cooked sausages or other meat (9 CFR 424.23 (a)(3)), this regulation pertains to substances that conceal damage or inferiority or make products appear better or of greater value (9 CFR 424.23 (a)). The application proposed in this letter of notification in no way is proposed to conceal damage or inferiority, or make the product appear better or of greater value. FSIS will need to approve new labeling to account for the use of these GRAS antimicrobials. The requested approval for in-plant trials will assist in generating the data to enable industry to make a science-based decision regarding the application of these antimicrobial agents to various RTE meat and poultry products.

*Any prior approvals by other federal agencies of the substances.*

Sorbic acid and its calcium, potassium and sodium salts, benzoic acid, sodium benzoate, propionic acid, and sodium propionate are GRAS when used in accordance with Good Manufacturing Practices (21 CFR 182, 21 CFR 184 sections 1021, 1081, 1733, and 1784). Benzoic acid and sodium benzoate are limited to 0.1%. In fact, when used in combination, their total concentration is limited to the highest level permitted for one of the ingredients (21 CFR 184.1(d)); thus, when benzoate or benzoic acid is included in a mixture, the total of all ingredients can not exceed 0.1% according to current regulations.

Submitted by:

American Meat Institute
Dr. Skip Seward
1150 Connecticut Avenue NW
12th Floor
Washington, D.C. 20036

Phone: 202-587-4249
E mail: sseward@meatami.com

**Protocol**

*Descriptive title and statement of purpose for the in-plant trial.*

**Title:** Use of calcium, potassium and/or sodium sorbate, sorbic acid, propionic acid, sodium propionate, sodium benzoate and benzoic acid, individually or in combination, to prevent growth of *L. monocytogenes* in RTE meat and poultry products.

**Purpose:** Demonstrate that laboratory results demonstrating that the antilisterial efficacy, and lack of impact on sensory characteristics of the RTE meat and poultry products, from use of calcium, potassium and/or sodium sorbate, sorbic acid, propionic acid, sodium propionate, sodium benzoate and benzoic acid, individually or in combination, is duplicated for commercially processed products.

*Sponsors and facilities for the trial.*

The following establishments have indicated a willingness to formulate selected products using the GRAS chemicals to assess sensory characteristics and, in some instances, to supply formulated products to academic researchers that will evaluate the commercial formulations for inhibition of growth of *L. monocytogenes*.

Uncured oven roasted turkey breast for the trial will be produced by Sara Lee Foods at their Cincinnati, Ohio facility, establishment 89, at 3241 Spring Grove Avenue. The management contact for the trial is Stu Oliver, Vice President Quality Assurance (513-853-1413). The project coordinator is Rodolfo Estrada, Research Scientist, (513-853-8966). Other RTE uncured meat and poultry products, as well as RTE cured products also would be candidates for production runs depending on the results of laboratory studies, cost-benefit ratios, and other analyses.

Cured sausage-type products and ham (water-added) products for the trial will be produced by Berks Packing Company, Inc., at their Reading, Pennsylvania facility, establishment 8782, P-8782, at 307 Bingaman Street. The management contact for the trial is Ralph Weise, V.P. Food Safety (610-376-7291, ext. 486); the Quality Control Manager, Matt Bauer (ext. 432) will assist in coordinating the project.

Cured smoked sliced ham for the trial will be produced by Land O’ Frost at the Searcy, Arkansas facility, establishment 500A, at 911 Hastings Avenue. The management contact for the trial is John Butts, V.P. Research (708-474-7100). The project coordinator is Warren Nicholson, Director Product Development (501-268-2473).

*Experimental design.*

Uncured poultry products (e.g., turkey) and cured pork products will be prepared with sorbic acid and its calcium, potassium and sodium salts, benzoic acid, sodium benzoate, propionic acid, and sodium propionate, individually or in combinations. Concentrations of these GRAS chemicals will be between 0.05 and 0.2%; although if benzoic acid or sodium benzoate is used in the formulation, the total concentration of all of these GRAS chemicals will be \( \leq 0.1\% \) (21 CFR 184.1(d)). Generally these antimicrobials will be added to products as ingredients.
during blending, forming, tumbling, marinating, enhancing or tenderizing operations. Products will be split for microbiological, chemical and organoleptic analyses.

Microbiological analyses will track standard plate count data throughout the shelf life of the product. For selected products, establishments may choose to conduct inoculation studies with L. monocytogenes at suitable off-site laboratories for validation studies. Chemical analyses will be done to determine the accuracy of the projected uptake of the GRAS chemicals during the processing steps used in the preparation of the selected RTE meat or poultry product. Organoleptic analyses will be done by in-house sensory experts to assess whether or not there are significant changes to the organoleptic properties of the RTE meat and poultry products under test.

Test subjects and control articles.

No human subjects will be involved save for those helping to evaluate the organoleptic properties of products containing the GRAS ingredients. Control products without the GRAS chemicals will be prepared for comparative purposes.

Type and frequency of tests, analyses and measurements to be made.

Microbiological assays will be done for SPC: 0 time, end-of-shelf life, and midpoint to the end-of-shelf life. Chemical assays (HPLC or alternate method) will be done for GRAS chemicals: 0 time & end-of-shelf life. Organoleptic analyses will be done to determine whether the GRAS chemicals have a negative impact on key sensory attributes when used at levels required for antimicrobial efficacy.

Records to be maintained.

All production records will be maintained to ensure all products manufactured with the GRAS chemicals are segregated and labeled appropriately. All research and associated production records, including microbiological, chemical and organoleptic analyses, will be maintained for a minimum of 12 months.

Statistical methods for data analyses.

No unusual statistical methods will be used. It is possible, depending on the number of repetitive analyses done, that mean and standard deviations will be obtained for concentrations of GRAS chemicals found in the product. Some in-house sensory labs may choose to use a T-test or similar method to determine if there is a statistical difference between test and control samples.

Time period for the trial.

Production of test product samples will occur over a six-month period following approval by the FSIS NTS and labeling office for test product production and sale.

Research data.

Industry reports that while lactate and diacetate have proven effective in controlling the growth of L. monocytogenes in some RTE meat and poultry products there remain products, e.g., uncured products, where sensory characteristics preclude the use of these chemicals at concentrations necessary to ensure growth is inhibited or remains below one log throughout the shelf life of the products. Research has shown sorbate, benzoate and propionate salts have inhibited the growth of Gram-positive pathogens such as Clostridium botulinum, Staphylococcus aureus, and L. monocytogenes in media and in meat systems (El-Shenawy & Marth, 1991; Tompkin et al, 1974; Wederquist et al, 1994; Samelis et al, 2001; Islam et al, 2002a, 2002b; Choi & Chin, 2003).
In preliminary, unpublished work done by U. Wisconsin researchers, dissolved sorbate, propionate and benzoate salts demonstrated the most consistent and effective inhibitory activity against *L. monocytogenes* when compared to 65 individual or combination chemical treatments. For example, *L. monocytogenes* did not grow in wiener or turkey slurries containing 0.25% potassium sorbate, benzoic acid or propionic acid held at 4 or 10 °C for four weeks. Combinations of these chemicals (0.05% of each component in the following combinations: benzoate-propionate and benzoate-sorbate) prevented growth of *L. monocytogenes* on bologna stored at 4 °C for 12 weeks, compared to increases in cell numbers of over three logs for control products without these antimicrobials (personal communications, Dr. Glass, U. Wisconsin Food Research Institute).

**Prior approvals from Federal agencies.**

Sorbic acid and its calcium, potassium and sodium salts, benzoic acid, sodium benzoate, propionic acid, and sodium propionate are GRAS when used in accordance with Good Manufacturing Practices (21 CFR 182, 21 CFR 184 sections 1021, 1081, 1733, and 1784). Benzoic acid and sodium benzoate are limited to 0.1%. In fact, when used in combination, their total concentration is limited to the highest level permitted for one of the ingredients (21 CFR 184.1(d)); thus, when benzoate or benzoic acid is included in a mixture, the total of all ingredients can not exceed 0.1%.

**References**


