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# Part III

# Department of Agriculture

## Food Safety and Inspection Service

**9 CFR Part 310, et al.**

**Food Ingredients and Sources of Radiation Listed or Appproved for Use in the Production of Meat and Poultry Products; Final Rule**

**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Parts 310, 318, 319, 381 and 424**

**[Docket No. 88–026F]**

**RIN 0583–AB02**

## Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to harmonize and improve the efficiency of the procedures used by FSIS and the Food and Drug Administration (FDA) for reviewing and listing or approving the use of food ingredients and sources of radiation in the production of meat and poultry products. Except in very limited circumstances, FDA will list in its regulations in title 21 of the Code of Federal Regulations (CFR) food ingredients and sources of radiation that are safe for use in the production of meat and poultry products. Requests for approval to use food ingredients and sources of radiation not currently permitted under title 9 or title 21 of the CFR in the production of meat and poultry products will have to be submitted to FDA.

This action will eliminate the need for separate FSIS rulemakings. FSIS will limit substance-specific rulemakings under the authority of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA) to those necessary to establish specific prohibitions or limitations on the use of food ingredients and sources of radiation in the production of meat or poultry products. Such rulemakings might be necessary where a standard of identity or composition prohibits or limits the use of an ingredient, when use of the ingredient is not expected in the product, *e.g.,* adding milk to hamburger, or use of the ingredient would result in the product being adulterated or misbranded.

FSIS is also consolidating various existing regulations on food ingredients and sources of radiation into a single, new part, 9 CFR Part 424, applicable to both meat and poultry establishments. This will include combining the separate listings of food ingredients approved for use in meat and poultry products into a single table (9 CFR 424.22(c)) and eliminating unnecessary differences in the listings. FSIS has not made any substantive changes in the consolidated language.

**EFFECTIVE DATE:** January 24, 2000.

**FOR FURTHER INFORMATION CONTACT:** Robert C. Post, Ph.D., Labeling and Additives Policy Division, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0279.

**SUPPLEMENTARY INFORMATION:**

### Current FDA/FSIS Process for Listing Food Ingredients and Sources of Radiation for Use in the Production of Meat and Poultry Products

Food ingredients and sources of radiation used during the production of meat and poultry products are subject to regulation by FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA). However, FSIS also has jurisdiction to regulate the use of those food ingredients and sources of radiation used in the production of meat and poultry products under the FMIA and the PPIA (*see* 21 U.S.C. 601(m)(2) and 21 U.S.C. 453(g)(2)).

Under the current system, someone interested in using a new food additive or color additive, or a new use or use level of a regulated food ingredient or source of radiation in the production of a meat or poultry product, must submit a petition to FDA requesting the listing of that use. The petition must contain data demonstrating the safety of the intended use of the food ingredient or source of radiation. FDA reviews the petition to determine the safety of the use of the food ingredient or source of radiation, and considers whether it has its intended technical effect at the requested level of use. After completing its review, FDA provides FSIS with an advisory opinion on whether the food ingredient or source of radiation is safe for the requested use in the production of meat or poultry products. At that point, FSIS reviews the suitability of the food ingredient or source of radiation for use in the production of meat or poultry products and conducts notice-and-comment rulemaking.

The process being adopted in this final rule will provide the same level of consumer protection without the delays inherent in the current system. It was in recognition of these delays that FSIS and FDA initiated this rulemaking and the companion FDA rulemaking.

### Background

On December 29, 1995, FSIS published a proposed rule in the **Federal Register** titled ''Substances Approved for Use in the Preparation of Meat and Poultry Products'' (60 FR 67459). In it, FSIS proposed to amend the Federal meat and poultry products inspection regulations containing the procedures for reviewing the safety and suitability of substances used in meat and poultry products so they would correspond with the procedures used by FDA. Under the proposal, FSIS's regulations would have reflected the fact that it and FDA would simultaneously review petitions for the listing of substances for use in the production of meat and poultry products. In the same issue of the **Federal Register** (60 FR 67490), FDA proposed to make parallel changes to its regulations.

FSIS proposed to stop adding, in most cases, to its own regulations that list substances suitable for use in the production of meat and poultry products. Instead, the proposal envisioned that future FDA regulations would specify whether a substance listed or approved for use in foods under the FFDCA could be used in the production of meat or poultry products. In addition, under the proposal, current FDA regulations that list the use of a substance in foods generally, and that do not preclude meat and poultry product uses, would confer authority to use those substances in the production of meat and poultry products unless expressly prohibited by FSIS. In place of its own regulations, FSIS proposed to amend 9 CFR Parts 310, 318, 319, and 381 to include appropriate cross-references to the listings of substances permitted for use in the production of meat and poultry products in title 21 of the CFR.

FSIS stated that, as a matter of policy, all substances listed by FDA as Generally Recognized as Safe (GRAS) for general use in food in 21 CFR Parts 182 and 184 would be considered by USDA to be acceptable for use in meat and poultry products, unless restricted for such use by FSIS. For substances not listed by FDA as GRAS in 21 CFR Parts 182 or 184, FSIS proposed to continue to evaluate, in consultation with FDA, a manufacturer's basis for claiming that the food ingredient is GRAS and is suitable for use in meat or poultry products. FSIS also proposed to continue to offer advice to manufacturers regarding the suitability for specific uses of substances listed in title 21 of the CFR for general use in the production of foods or for use in meat or poultry products only. Except for formulation and processing procedure data for proprietary mixtures, which would be kept confidential, FSIS stated

that it intended to make its responses and related correspondence available to the public.

Under the proposal, all petitions for rulemaking to permit new substances or new uses or use levels of substances in the production of foods—including meat and poultry products—would be sent to FDA. The proposal reflected the fact that a petition needs to be submitted when a substance: (1) is not expressly listed for meat or poultry product uses in title 9 of the CFR, or in title 21 of the CFR, Parts 172–180; (2) is not a GRAS substance listed in Part 182 or 184 of title 21 of the CFR for general use in foods; or (3) cannot be demonstrated to FSIS, which consults with FDA as necessary, to be GRAS for particular meat or poultry product uses. It stated that FDA would evaluate the petitions in consultation with FSIS if any prospective use of a food additive, color additive, or GRAS substance, would be in meat or poultry products.

FSIS stated that it intended to review its listings in title 9 of the CFR of substances, within three to five years of a final rule in this proceeding, to eliminate those listings that duplicate FDA's listings in title 21 of the CFR. Because of current and anticipated resource constraints, FDA proposed to amend its regulations in title 21 of the CFR to provide that it would include meat and poultry product uses only in response to a petition, *i.e.,* a food additive, color additive, or GRAS affirmation petition, and that it would not move wholesale FSIS's listings of substances from title 9 of the CFR to title 21 of the CFR.

FSIS proposed to continue regulating the use of substances in meat and poultry products and to conduct the same reviews that it has been conducting, if and when necessary. For example, FSIS standards of identity or composition, in specific cases, could restrict uses of substances, or FSIS could determine that the use of a substance could adulterate a particular product or lead to a misbranded product. FSIS tentatively found that its ability to continue to regulate food ingredients was important so that it could prohibit or restrict the use of specific food ingredients in meat or poultry products. However, FSIS does not expect that it will have to take such action regularly because FDA's statutory authority, exercised according to the Memorandum of Understanding (MOU) between FDA and FSIS, will provide a means of imposing appropriate limitations on uses of food ingredients in meat and poultry products. (A draft version of the MOU was published as an appendix to the proposal. *See* 60 FR 67467.)

To provide direction to its inspection program personnel, FSIS proposed to maintain a comprehensive listing in its directive system of substances authorized for use in the production of meat and poultry products under title 9 or title 21 of the CFR. FSIS proposed to include in the listing:

a. Substances listed in title 9 of the CFR;

b. Substances listed for meat or poultry product uses in FDA food additive, color additive, GRAS, or prior-sanction listings;

c. Approved color additives in 21 CFR Parts 73, 74, and 82, food additives listed in 21 CFR Parts 172–173 and 180, prior-sanctioned substances approved by part 181, and GRAS substances approved by 21 CFR 182 and 184, if permitted for general use in or on foods (including meat and poultry products) in accordance with good manufacturing practice, unless meat or poultry product uses of these additives or substances are otherwise precluded; and

d. FDA food additive, color additive, GRAS, and prior-sanctioned substance listings that provide for meat and poultry product uses and are promulgated after the proposal becomes final.

FSIS also proposed to provide similar information to inspected establishments and other interested persons in the form of guidelines.

**Memorandum of Understanding**

FDA and FSIS have entered into an MOU establishing procedures to jointly respond to petitions to use food ingredients and sources of radiation in the production of meat and poultry products. Under the terms of the MOU, petitions to use a food or color additive or GRAS substance in the production of meat or poultry products will be evaluated for safety by FDA and for suitability by FSIS. FDA will be the submitter's regulatory contact. A copy of the MOU is appended to this final rule.

**Discussion of Comments**

FSIS received 22 comments in response to the proposed rule. Trade associations submitted eleven, industry eight, and a governmental organization, professional association, and consulting firm each submitted one. Most commenters generally favored the proposal and supported the efforts of FSIS and FDA to streamline the system to list or approve food ingredients used in meat and poultry products. Two commenters opposed the proposal. The following is a discussion of the relevant issues raised in the comments.

1. Despite the general support for the proposal, many commenters took issue with FSIS's proposal to prohibit the use of GRAS substances in meat and poultry products unless the substance is listed in parts 182 or 184 of title 21 of the CFR or in title 9 of the CFR. They stated that FSIS's prohibition of the use of unlisted GRAS substances in meat and poultry products is unreasonable because FDA has said that it is impractical to list all such substances in FDA regulations. The commenters maintained that all GRAS food substances, whether or not listed in FDA or FSIS regulations, should be permitted in meat and poultry products, provided that they are used in accordance with good manufacturing practice. One commenter requested that the policy currently in place for the self-determination of GRAS status of substances used in FDA-regulated foods be applied to food ingredients used in FSIS-regulated meat and poultry products. Another commenter expressed concern that permitting firms to make GRAS self-determinations would allow the use of unknown food ingredients in meat and poultry products.

Self-determinations of GRAS status present significantly different problems for FSIS than FDA. FDA's regulatory authority over products that contain an ingredient that a manufacturer views as GRAS begins when such products enter commerce and requires that FDA find that such products are adulterated. In contrast, FSIS must be able to find that a product is not adulterated *before* it will apply the mark of inspection that is necessary for the product to enter commerce. Thus, while a manufacturer of an FDA-regulated product may determine that use of a substance is GRAS, taking a calculated risk that FDA will not disagree, the manufacturer of an FSIS-regulated product which uses the same substance will not be eligible for the mark of inspection if FSIS has no basis for concluding that use of the substance would not adulterate the product. To be eligible for the mark of inspection for its products, a manufacturer must show that the use of the ingredients in its products has been shown to be safe under some provision of FDA law or has a history of safe use.

On April 17, 1997, FDA published in the **Federal Register** a proposal to replace the current GRAS affirmation petition process with a notification procedure. Under the proposed notification procedure, any person may notify FDA that he/she has determined that a particular use of a substance is GRAS. Upon receiving such a notification, FDA will evaluate whether the submitted notice provides a sufficient basis for a determination that

the use is GRAS, and whether information in the notice or otherwise available to FDA raises issues that lead FDA to question whether use of the substance is GRAS. If FDA elects not to question the determination, it will send the person a letter to that effect.

In the near future, FSIS intends to publish a proposal that will reflect FDA's GRAS notification proposal as it implicates GRAS food ingredients permitted for use in meat and poultry products. If both proposals are adopted, FSIS will accept self-determinations of GRAS status if an establishment that relies on the determination has on file in the establishment a copy of a letter from FDA that states that FDA does not question the determination, and the establishment makes the letter available to FSIS inspection program personnel. However, FSIS is retaining the right to evaluate self-determinations of GRAS status for suitability and will do so if it deems such an evaluation is required for any reason. FSIS is currently continuing to perform evaluations of self-determined GRAS substances to ascertain that the substances are suitable for use in meat and poultry products.

2. Many commenters asserted that food ingredients listed or approved for general food use under FDA regulations should be permitted for use in meat and poultry products unless otherwise restricted by other FDA or FSIS regulations.

FSIS agrees. As stated in the proposal, color additives approved by 21 CFR Parts 73, 74, and 82; food additives listed in 21 CFR Parts 172–173 and 180; prior-sanctioned substances approved by part 181; and GRAS substances approved in 21 CFR 182 and 184 may be used in meat and poultry products provided that the food ingredient is permitted for general use in or on foods (which includes meat and poultry products) and is used in accordance with good manufacturing practice, unless the meat or poultry product uses of the food ingredient are otherwise specifically precluded or not specifically allowed by product standards.

3. Many commenters that supported the efforts of FSIS and FDA to streamline the system for listing or approving food ingredients used in meat and poultry products stated that FSIS should participate in FDA's process to regulate food ingredients to ensure that such ingredients listed or approved for use in or on meat and poultry products are appropriate for such use. However, a few felt that FSIS should be completely eliminated from this process. One commenter stated that FSIS is not equipped to perform a separate safety evaluation for food ingredients, and that FSIS's review would be inconsistent with the goal of streamlining the review process. Others felt that dual evaluations would significantly lengthen the review process, and therefore, one agency or the other should conduct evaluations entirely, but not both.

Most commenters felt that FDA, not FSIS, should be responsible for reviewing food ingredient petitions, despite concerns that ''the FDA petition process system is burdensome and slow, because FDA is required to evaluate all substances for use in food, including meat and poultry products.'' One commenter lamented the loss of a quick response by FSIS to submitters, while another suggested that FSIS accept ''informal advisory letters'' from FDA. This commenter suggested that FSIS could use these letters, which prescribe the appropriate use of food ingredients, to determine the appropriate use of such ingredients without requiring a rulemaking proceeding to be completed before the ingredient may be used in meat and poultry products.

FDA has broad jurisdiction over all food, except to the extent exceptions have been created by statute, and primary authority for determining the safety of food ingredients for use in meat and poultry products. FSIS's jurisdiction is more specific: It is limited to regulating the production and distribution of meat, poultry, and egg products. Because of its extensive statutory authority to regulate the safety of food ingredients and sources of radiation that may be used the production of food, FDA has developed the scientific staff, the institutional expertise, and the regulatory structure to ensure that food ingredients and sources of radiation that may be used in the production of foods are safe. Therefore, FDA and FSIS have agreed that FDA is the agency to whom manufacturers should submit petitions for the use of food ingredients and sources of radiation.

Requiring petitions to be submitted to FDA will not delay the listing of food ingredients or sources of radiation for use in meat and poultry products. Instead, the single petition, joint review, and single rulemaking procedure should decrease the time it takes to list or approve a food ingredient or source of radiation for use in meat or poultry products by eliminating the current time-consuming, duplicative, sequential rulemaking process.

Currently, food additives, as defined in 21 U.S.C. 321(s), may not be used in meat or poultry products unless they are listed for use under the FFDCA. A manufacturer is first required to petition FDA to list the food additive for its intended conditions of use or for use in food in general. In response to the petition, FDA amends its regulations in title 21 of the CFR to provide for the use of the substance. Once FDA has acted, the manufacturer must then petition FSIS for approval of the food additive for use specifically in meat or poultry products, unless the manufacturer has submitted data supporting its use in such products in its original petition to FDA (*see* 9 CFR 318.7(a)(2)). In such a case, use is generally permitted unless a standard of identity or other regulation precludes it. After FSIS has completed its evaluation and approved the food additive for use in meat and poultry products, FSIS must amend its regulations in title 9 to include the permitted use before the food additive can actually be used in a meat or poultry product.

Sometimes, however, a manufacturer does not submit a food additive petition to FDA for use of a substance in meat or poultry products. Instead, it contacts FSIS directly, asking that FSIS approve the use of the food additive in meat or poultry products. When this happens, FSIS, rather than the submitter, is put in the position of having to approach FDA to obtain approval for the use of the food additive in food generally under the FFDCA. Therefore, though FSIS, and not the submitter, approaches FDA, FDA still conducts a safety evaluation of the food additive and amends its regulations as necessary under the FFDCA before FSIS begins its own process. Duplicative reviews and rulemaking cannot be avoided under the current system.

The new system will eliminate the need for a manufacturer to submit two petitions, one to each agency, for the listing or approval to use a food additive or color additive, or source of radiation, in the production of meat or poultry products. Manufacturers will tender only one petition, to FDA, as they have always had to do under the tenets of the FFDCA. After FDA has completed its general food safety evaluation, it will inform FSIS of its determination. Consistent with the requirements that FDA's statutory authority has always necessitated, FDA, not FSIS, will amend its regulations to provide for the use of the food or color additive or other substance, when such regulation is necessary. FSIS will, as indicated, modify its directive and guidelines to reflect the new food ingredient or source of radiation or its new use or level. These new procedures will speed up the review process and eliminate the need

for duplicative listings in FSIS's regulations.

4. One commenter asked why inquiries regarding substances that are not affirmed or listed as GRAS in title 21 of the CFR should be sent to FSIS if FDA will ultimately be required to issue a GRAS regulation before the substance may be used.

At the time of the proposal, FDA and FSIS determined that FSIS is best suited to provide advice regarding whether a substance could be used in meat or poultry products. Therefore, the agencies tentatively decided that inquiries about the use of unlisted or unaffirmed GRAS substances in meat and poultry products should be directed to FSIS.

After further discussions with FDA, the two agencies have decided that because the statutes under which FDA operates require FDA approval of ingredients whose use is not GRAS, FDA is better suited than FSIS to provide advice regarding whether a substance not listed as GRAS is safe for use in meat or poultry products. Therefore, inquiries concerning the use in specific meat or poultry products of substances that are not affirmed by FDA as GRAS or otherwise listed in 21 CFR Part 182 or 184, or of food and color additives listed or approved in title 21 regulations for general use in foods, or for use in meat or poultry products generally, including mixtures of such food and color additives, should be addressed in writing to FDA.

5. In the proposed rulemaking, FSIS stated that it would review its lists of food ingredients and sources of radiation approved for use in meat and poultry products in title 9 of the CFR over the next three to five years and eliminate those that duplicate FDA's listing in title 21 of the CFR. However, FSIS also declared its intention to retain those regulations that prohibit uses of specific food ingredients to protect the public health and consumers from product adulteration and misbranding under the FMIA and PPIA; and to promulgate new prohibitions or limitations as necessary.

While one commenter favored this dual approach, five others felt that FDA should cover all past, present, and ''future ingredient approvals and restrictions'' for use in meat and poultry products in title 21 of the CFR. A third group of commenters requested that FSIS maintain a comprehensive listing of food ingredients approved for use in meat and poultry products either under title 9 of the CFR or in another FSIS publication as guidance to inspection program personnel and industry. One commenter who opposed the proposal stated that while the ''new food additive approval system'' might decrease the bureaucracy involved in getting food ingredients listed for use in meat and poultry products, it could also negatively affect traditional products produced by smaller processors because such processors rely on FSIS staff to guide them in properly using FDA-approved food ingredients in their products.

FSIS generally agrees with those commenters who stated that FSIS's tables of approved substances in title 9 of the CFR should be eliminated because they are not as complete as FDA's food ingredient listings. FSIS has decided, however, to retain them in title 9 of the CFR until FDA completes the amendments of its regulations in title 21 of the CFR to include all food ingredient and sources of radiation uses in meat and poultry products. While this may not happen for some time, due to current and anticipated resource constraints within FDA, FSIS believes it is the best way to ensure that food ingredients not listed or approved for use in meat and poultry products will not be used. FSIS will also publish a directive for inspection program personnel, and a set of guidelines for members of both the meat and poultry industry and the public, that will contain the food ingredients listed or approved for use in meat and poultry products.

6. One commenter recommended that FSIS conduct a total review of all existing ''food additive'' limitations and restrictions before the proposal is finalized, to determine their efficacy. All current food additive limitations and restrictions are based on scientific data that were reviewed by FSIS and FDA before each additive was listed or approved for use in meat and poultry products. The commenter presented no basis for concern about the reviews that were done. Therefore, there is no basis for changes to the limitations or restrictions unless new data are presented that support modifying a listed or approved use. It would take years of effort to review all of the actual data supporting each limitation or restriction, and FSIS has no intention of conducting a total review of existing substance limitations and restrictions.

7. A commenter stated that it was unclear whether FSIS's review process for processing chemicals not regulated under the FFDCA, such as sanitizing and cleaning agents for food-contact equipment and utensils, will continue once this final rule is adopted.

It will not. On February 13, 1998, FSIS announced in the **Federal Register** that it is eliminating its prior approval requirements for nonfood compounds and proprietary substances. ''Proprietary substances'' contain a combination of ingredients, some of which are not identified on the containers by common or chemical name, or by some other means. While approval of nonfood compounds and proprietary substances before their intended use provides some assurance to meat and poultry product processors that the use of these compounds and substances would not result in the adulteration of food products, provided they are properly used, this type of prior approval program is inconsistent with the new food safety strategy and approach set forth in the ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' (61 FR 38806).

Under these regulations, meat and poultry establishments are responsible for developing and implementing HACCP plans incorporating the controls necessary and appropriate to produce safe meat and poultry products. Consequently, establishments, not FSIS, will be responsible for ensuring that the nonfood compounds and proprietary substances they use are lawful, safe, and effective.

FSIS intends to maintain a small staff with expertise in nonfood compounds and proprietary substances. This staff will be responsible for issuing technical guidance, particularly to small and very small meat and poultry establishments, as the need arises. FSIS began eliminating the prior approval system for nonfood compounds and proprietary substances in autumn 1998.

8. A commenter suggested that FSIS eliminate the Proprietary Mix Committee (PMC) and set up third-party review of ''food additives.'' The PMC provides a voluntary identification service to ingredient manufacturers. The PMC evaluates the proprietary formula and process for making an ingredient mix, confirms the identity and regulatory use status of the ingredients, and identifies appropriate labeling and use requirements for the mix. The PMC then sends the information, in writing, back to the requestor. This ''PMC letter,'' which is used during the prior label approval process by meat and poultry product processors manufacturing products containing proprietary mixes, provides verification of the appropriate ingredient labeling information to FSIS.

Ingredient manufacturers are not required by the meat and poultry regulations to have a PMC letter before getting meat and poultry product labels approved by FSIS. It is a voluntary service offered by FSIS. For this reason, and because the PMC works in

conjunction with the prior label approval system, it will continue to function as long as FSIS has a prior label approval system. If, and when, FSIS eliminates that system and replaces it with a generic label approval system (which was discussed in the final rule on prior label approval, 60 FR 67443), FSIS will also consider eliminating the PMC.

9. One commenter, who provided qualified support for the proposal, felt that 9 CFR 318.1(d), which would require labels for preparations containing ''chemicals'' limited by 21 CFR 73, etc., or by 9 CFR Chapter III, Subchapter A, to show the percentage of the ''chemical'' in the preparation, was unnecessary and should be deleted. The commenter contended that such a requirement conflicts with FDA's regulations for labeling GRAS substances (21 CFR 184.1(f)(2)), which permit proprietary composition information to be excluded from the label if other information on the label will enable the user to comply with the given regulatory limitations. According to the commenter, proposed 9 CFR 318.1(d) would require the manufacturer to reveal confidential information to FSIS-inspected establishments or to decline to sell the preparation to them. The commenter asserted that if the information on the label instructs the user how to properly use the product and to comply with the regulatory limits, then public health and safety are not compromised. Therefore, the commenter contended, the regulation is not necessary. The commenter suggested that deletion of 9 CFR 318.1(d) will make FDA's and FSIS's regulations consistent and will allow manufacturers to use the same label on identical products destined for both FSIS-inspected establishments and FDA-regulated establishments.

To some extent, FSIS agrees with the commenter. Contrary to the commenter's assertion, however, section 318.1(d) does *not* require the ingredient manufacturer to disclose proprietary information to FSIS-inspected establishments. It requires that labels on containers of preparations used in hog scalding water or the denuding of tripe bear the common or chemical name of the preparation. If the preparation contains a chemical that is specifically limited by current section 318.7(c)(4), the label must show the percentage of the chemical in the preparation.

After further consideration, FSIS believes that 9 CFR 318.1(d), as currently written, is a command-and-control provision because it tells chemical manufacturers what information they must provide on the labels of their products. This is inconsistent with FSIS's announced policy of removing command-and-control provisions wherever feasible.

Therefore, FSIS has decided to amend section 318.1(d) to require that labels or labeling on containers of hog scald water or tripe denuding preparations bear adequate directions to ensure use in compliance with any limitations prescribed in 9 CFR or 21 CFR. This action will make FDA's and FSIS's regulations consistent and will allow manufacturers to use the same label on identical products destined for both FSIS-inspected establishments and FDA-regulated establishments.

10. The commenters that did not support the proposal expressed concern that FDA's petition system is more complicated and confusing than FSIS's system. One commenter stated that it would be confusing and time-consuming to have to search through five parts of title 21 of the CFR to find the status of a food ingredient.

While FDA and FSIS acknowledge that some confusion may arise from the placement of listed or approved food ingredients and sources of radiation in different parts of title 21 of the CFR, the public will be better served by having the permitted uses consolidated in one title of the CFR. Rather than searching through two separate titles of the CFR, 9 *and* 21, to find the permitted uses of a food ingredient or source of radiation, interested parties will only have to survey one, title 21.

**Combined Language**

For the past several years, FSIS has been reviewing its regulatory procedures and requirements to determine which are still needed and which ought to be modified, streamlined or eliminated (*see* FSIS Docket No. 95–008A, ''FSIS Agenda for Change: Regulatory Review''; 60 FR 67469). This review is an integral part of FSIS's initiative to modernize its food safety regulations and reflects FSIS's commitment to achieving its goal of having fewer, clearer, and user-friendly regulations.

In the course of drafting this final rule, FSIS identified various meat and poultry regulations that, within the context of FSIS's regulatory streamlining initiative, need revision. FSIS decided to consolidate some of those regulations. The consolidation did not involve any substantive changes.

FSIS added a new Part 424, titled Preparation and Processing Operations. This new part, to the extent possible, combines the meat and poultry products inspection regulations affected by this rule. As a result, these rules are the same for both meat and poultry products, unless there is a specific reason for having different rules or language.

**The Final Rule**

Under this final rule, FSIS is ending duplicative rulemaking activities regarding the use of food ingredients and sources of radiation in the production of meat and poultry products. FSIS is amending the Federal meat and poultry products inspection regulations in 9 CFR Parts 310, 318, 319, and 381 to include appropriate cross-references to title 21 (Chapter I, Subchapter A and Subchapter B) listings of food additives, GRAS substances, color additives, and prior-sanctioned substances permitted for use in meat and poultry products.

As amended, 9 CFR 310.20 includes appropriate references to food ingredient listings and approvals in title 21 of the CFR. The requirements governing the saving of livestock blood have not been changed. The new amendment to 9 CFR 318.1 eliminates the requirement that labels on hog scalding or tripe denuding preparation containers show the percentage of chemicals in the preparations that are specifically limited as to amount permitted to be used, if any, by 21 CFR or 9 CFR. The labels will need to bear only adequate use directions to ensure that such use is in compliance with all provisions of 21 CFR or 9 CFR.

Section 318.7(d)(2) of 9 CFR is amended to add a reference to title 21 of the CFR. In addition, this section has now been transferred to a new part and renumbered. (*See* Part 424, Preparation and Processing Operations, section 424.23, Prohibited uses, paragraph (a)(3).) As in the proposal, the paragraph does not change the prohibitions of and restrictions on the food ingredient uses in meat.

Proposed 9 CFR 318.7(a)(4) and 381.147(f)(2)(iv) listed addresses for inquiries concerning the status of food ingredients intended for use in or in contact with meat or poultry products. Proposed 9 CFR 318.7(a)(5) and 381.147(f)(2)(v) listed addresses for inquiries concerning the use in meat or poultry products of food ingredients not listed in the title 21 regulations. In this final rule, these provisions have been combined and moved to section 424.21, Use of substances, paragraphs (b)(5) and (b)(6). No substantive changes have been made to these provisions.

Proposed 9 CFR 318.7(a)(1)–(3) and 9 CFR 381.147(f)(1) and (2) have also been combined in this final rule and placed in section 424.21, paragraphs (b)(1)–(3).

Again, no substantive changes have been made.

Section 318.7(b), Use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon, has been moved in its entirety to section 424.22, Certain other permitted uses, paragraph (b), while section 318.7(c) has been moved in its entirety to section 424.22(c) and combined with section 381.147(f)(4) to create one list of food ingredients approved for use in meat and poultry products. Where possible, FSIS has combined meat and poultry listings for a specific chemical into one listing. No substantive changes have been made to these provisions.

New part 424 prescribes the rules for the preparation or processing of meat and poultry products (*see* section 424.1, Purpose and Scope). The rules are intended to prevent the adulteration and misbranding of meat and poultry products at official establishments. The statements contained in section 424.1 merely advise the public of the purpose and scope of the rules FSIS administers.

FSIS is also including in Part 424 section 424.22 (formerly 9 CFR 318.7(b) and (c), and 9 CFR 381.147(f)(4)), which covers certain other permitted uses of ingredients in meat, and section 424.23, which lists prohibited uses of ingredients in meat and poultry products (formerly 9 CFR 318.7(d)).

**Executive Order 12988**

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different from, those imposed by the FMIA and the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are within their jurisdiction and outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

This rule is not intended to have retroactive effect.

Under this rule, administrative proceedings will not be required before parties may file suit in court challenging this rule.

**Executive Order 12866 and Regulatory Flexibility Act**

This final rule has been determined to be significant and has been reviewed by OMB under Executive Order 12866. In accordance with 5 U.S.C. 603, FSIS has also conducted a regulatory flexibility analysis regarding the impact of the rule on small entities.

This final rule will replace the current government process for listing or approving the use of food ingredients and sources of radiation in meat and poultry products, which involves consecutive rulemakings by FDA and FSIS, with a ''one-stop'' procedure under which sponsors of new food or color additives, other substance uses, or sources of radiation in meat and poultry products will have to petition only FDA under the requirements of the FFDCA. FDA has always had the statutory authority for approving ingredients. FDA will conduct any required rulemaking on the matter in consultation with FSIS. FDA's rule will specify any uses or use restrictions unique to meat or poultry products.

This final rule modifies existing FSIS regulations concerning the listing or approval of food ingredients and sources of radiation used in the production of meat and poultry products that needlessly duplicate effort and expenditures by government and the regulated industry. These existing regulations require sequential rulemakings by FDA and FSIS to permit a new food ingredient and source of radiation, or a new use of a previously approved food ingredient or source of radiation to be used in meat or poultry products. The cost to industry and government of these rulemaking procedures includes the costs to industry arising from the delay in the introduction of new ingredients, or new food products. These costs create a disincentive for technological innovation and new product development. The existing process, therefore, negatively affects economic growth.

**Benefit-Cost Assessment**

The public benefits conferred by this rulemaking include, principally, those associated with the more timely regulatory listing or approval of food ingredients and sources of radiation used in the production of foods and those associated with having the ingredients themselves available for use more quickly. The benefits of ingredients added to meat and poultry products include the technical effects on the characteristics of food products, the uses of the ingredients in food processing, and a greater variety of foods in the marketplace. Public health benefits include the greater availability of food through preservation techniques and improved food safety through, for example, antimicrobial treatments of raw product and the use of curing solutions in processed products. The benefits conferred by the availability of ingredients and this rulemaking will marginally increase the ingredients' uses.

The public benefits of regulating food ingredients and sources of radiation, generally, will not change. These include, principally, the prevention of adulteration or misbranding of food products. Consumers are provided assurances that the products they buy do not contain food ingredients whose use(s) ought, for various reasons, to be prohibited, and food ingredients that have been listed or approved have not been used improperly in foods. This final rulemaking will not affect such benefits because (1) FDA will continue to approve food ingredients and sources of radiation, and conduct safety reviews (when required by the FFDCA) of food ingredients and sources of radiation proposed for use in the production of foods, including—in consultation with FSIS—meat and poultry products, and (2) FSIS will continue to exercise its in-plant inspection and other regulatory authorities to prevent the marketing of adulterated or misbranded meat and poultry products. Therefore, elimination of the duplicative FSIS rulemaking process involved in listing or approving food ingredients or sources of radiation for use in meat and poultry products will probably save the regulated industry between $400,000 and $600,000 a year over and above the savings the government itself will realize in administrative costs. (According to industry representatives, the cost of filing one food ingredient petition is approximately $100,000. This includes research and administrative costs.)

Other less calculable benefits arise through the removal of a disincentive to innovate. With the potential expansion of uses of listed or approved food ingredients that will result from the easing of the current regulatory burden, new product development and marketing are encouraged.

This final rule will not have a significant economic impact on a substantial number of small entities. Obtaining approval for the use in the production of meat and poultry products of new food ingredients or sources of radiation, or for new uses of previously listed or approved food ingredients or sources of radiation, will

be simpler, faster, and less costly for both industry and the Federal government than under the current system.

Under the final rule, separate petitions to FSIS will no longer have to be submitted. FSIS will permit food ingredients and sources of radiation to be used in products under its jurisdiction based on FDA's title 21 regulations permitting such uses. Those food additives and color additives *not* approved for meat and poultry product use under current FDA regulations will require only one petition for rulemaking—to FDA.

FSIS currently receives only four to six petitions per year for the listing or approval of food ingredients for use in meat and poultry products. Approximately 75 percent of these petitions are from large commercial entities. Therefore, the final rule will not have a significant effect on a substantial number of small entities. Furthermore, all users of the Federal regulations concerning the addition of food ingredients to foods will benefit by having fewer, clearer regulations. Thus, there will be a reduction in the duplication of effort and attendant costs for all concerned.

**Public Notification and Request for Data**

The public is asked to provide additional information on the effect of this final rule on minority ownership and operation of affected establishments, employment, and consumers, and other related impacts. The information being requested includes professional journal articles, research reports, industry data, and other similarly reliable information. Public involvement in all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this final rule, FSIS will announce the publication of this final rule in the **Federal Register** in the FSIS Constituent Update.

FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

**Paperwork Requirements**

No new paperwork requirements are associated with this final rule. The effect of the rulemaking will be to substantially reduce the information collection from private sources concerning proposed uses of food ingredients in meat or poultry products. Persons seeking Federal government listing or approval of food additives and color additives for use in the production of meat or poultry products will have to petition only FDA, rather than both FDA and FSIS, as they now do. Thus, the current, duplicative information collection requirement will be eliminated.

**List of Subjects**

*9 CFR Part 310*

Meat inspection.

*9 CFR Part 318*

Food additives, Food packaging, Meat inspection.

*9 CFR Part 381*

Food additives, Food packaging, Poultry and poultry products.

*9 CFR Part 424*

Food additives, Food packaging, Meat inspection, Poultry and poultry products.

For the reasons set out in the preamble, 9 CFR parts 310, 318, 319 and 381, are amended, and part 424 is added, to read as follows:

## PART 310—POST-MORTEM INSPECTION

1. The authority citation for part 310 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

2. Section 310.20 is revised to read as follows:

### § 310.20 Saving of blood from livestock as an edible product.

Blood may be saved for edible purposes at official establishments provided it is derived from livestock, the carcasses of which are inspected and passed, and the blood is collected, defibrinated, and handled in a manner so as not to render it adulterated under the Federal Meat Inspection Act and regulations issued pursuant thereto. The defibrination of blood intended for human food purposes shall not be done with the hands. Anticoagulants may be used in accordance with 21 CFR Chapter I, Subchapter A and Subchapter B, or by regulation in 9 CFR Chapter III, Subchapter A or Subchapter E.

## PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

3. The authority citation for part 318 continues to read as follows:

**Authority:** 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

4. Section 318.1(d) is revised to read as follows:

### § 318.1 Products and other articles entering official establishments.

* * * * *

(d) To ensure the safe use of preparations used in hog scalding water or in the denuding of tripe, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B, or 9 CFR Chapter III, Subchapter A or Subchapter E.

* * * * *

### § 318.7 [Removed]

5. Section § 318.7 is removed.

## PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

6. The authority citation for 9 CFR Part 319 continues to read as follows:

**Authority:** 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

### § 319.100 [Amended]

7. The first sentence of § 319.100 is amended by removing ''§ 318.7(c)(1) and (4) of this subchapter'' and adding in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

### § 319.106 [Amended]

8. Paragraph (d)(2) of § 319.106 is amended by removing ''in accordance with § 318.7(c)(4) of this subchapter'' and adding in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

**§ 319.140 [Amended]**

9. The second and third sentences of § 319.140 are amended by removing ''§ 318.7(c)(4) of this subchapter'' and adding in its place ''a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

**§ 319.145 [Amended]**

10. Section 319.145 is amended as follows:

A. In paragraph (a)(4), remove ''in the chart following § 318.7(c)(4),'' and add in its place ''in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B'';

B. In paragraph (b)(6), remove ''the chart of substances in § 318.7(c)(4) of this subchapter.'' and add in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

**§ 319.180 [Amended]**

11. Section 319.180 is amended as follows:

A. In the first sentence of paragraph (a), remove ''§ 318.7(c)(4) of this chapter,'' and add in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.'';

B. In the first sentence of paragraph (b), remove ''§ 318.7(c)(4) of this chapter,'' and add in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.'';

C. In the first sentence of paragraph (e), remove ''§ 318.7(c)(4) of this subchapter.'' and add in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

**§ 319.303 [Amended]**

12. The second sentence of paragraph (a)(3) of § 319.303 is amended by removing ''§ 318.7(c)(4) of this subchapter'' and adding in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

**§ 319.700 [Amended]**

13. Section 319.700 is amended as follows:

A. In paragraphs (a)(4), (a)(5), and (a)(6), remove ''§ 318.7(c)(4) of this chapter'' and add in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.'';

B. In the first sentence of paragraph (a)(7), remove ''§ 318.7(c)(4) of this chapter,'' and add in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Parts 73, 74, 81, or 82,'';

C. In the first sentences of paragraphs (a)(9) and (a)(10), remove ''§ 318.7(c)(4) of this chapter,'' and add in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

## PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

14. The authority citation for 9 CFR Part 381 continues to read as follows:

**Authority:** 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

**§ 381.120 [Amended]**

15. The fourth and sixth sentences of § 381.120 are amended by removing ''§ 381.147'' and adding in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

16–17. Section 381.145, paragraph (i), is revised to read as follows:

**§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.**

* * * * *

(i) To ensure the safe use of preparations used in poultry scald water, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B or 9 CFR Chapter III, Subchapter A or Subchapter E.

**§ 381.147 [Removed]**

18. Section 381.147 is removed.

**§ 381.171 [Amended]**

19. The first and second sentences of § 381.171, paragraph (b), are amended by removing ''§ 381.147 of this part'' and adding in its place ''a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.''

## SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

20. Subchapter E is amended by adding a new Part 424 to read as follows:

## PART 424—PREPARATION AND PROCESSING OPERATIONS

**Subpart A—General**



**Subpart C—Food Ingredients and Sources of Radiation**



**Authority:** 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

### Subpart A–General

**§ 424.1 Purpose and scope.**

This part of the regulations prescribes rules for the preparation of meat and the processing of poultry products. The rules in this part further the purposes of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by, among other things, preventing the adulteration or misbranding of meat and poultry products at official establishments. 9 CFR Chapter III, Subchapter A, Parts 318 and 319, Subpart C of this part, and 21 CFR Chapter I, Subchapter A or Subchapter B, specify rules for the use of certain food ingredients (e.g., food additives and color additives) and sources of radiation that may render meat or poultry products adulterated or misbranded.

### Subpart C—Food Ingredients and Sources of Radiation

**424.21 Use of food ingredients and sources of radiation.**

(a)(1) *General.* No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, part 318 or part 319 of this chapter, or by the Administrator in specific cases.

(2)(i) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment or imported from a foreign country listed in § 381.196(b), and have been inspected and passed in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed for use as human food in

a manner approved by the Administrator in specific cases and detached ova may be used in the processing of poultry products if the processor demonstrates that such ova comply with the requirements of the Federal Food, Drug, and Cosmetic Act.

(ii) Liquid, frozen, and dried egg products used in the processing of any poultry product shall have been prepared under inspection and be so marked in accordance with the Egg Products Inspection Act.

(3)(i) Carcasses, parts thereof, and products of cattle, sheep, swine, goats, or equines may be used in the processing of poultry products only if they were prepared in the United States in an official meat packing establishment or imported from a foreign country listed in § 327.2(b), were inspected and passed in accordance with the Federal Meat Inspection Act and the regulations under such Act (subchapter A of this chapter), and are so marked.

(ii) Pork from carcasses or carcass parts used as an ingredient in poultry products that has been found free of trichinae, as described under § 318.10 (a)(2), (e) and (f) of the Federal meat inspection regulations (9 CFR 318.10 (a)(2), (e) and (f)), is not required to be treated for the destruction of trichinae.

(iii) Poultry products containing pork muscle tissue which the Administrator determines at the time the labeling for the product is submitted for approval in accordance with part 381 of the regulations in subchapter A or upon subsequent reevaluation of the product would be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product or otherwise, shall be effectively heated, refrigerated, or cured to destroy any possible live trichinae, as prescribed in § 318.10(c) of this chapter, at the official establishment where such products are prepared. In lieu of such treatment of poultry products containing pork, the pork ingredient may be so treated.

(b)(1) *Food ingredients and sources of radiation.* Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry products in 21 CFR Chapter I, Subchapter A or Subchapter B, shall be listed for such use under this chapter, subject to declaration requirements in parts 316 and 317, or Subparts M and N, of Part 381 of this chapter, unless precluded from such use or further restricted in parts 318 or 319, or Subparts O and P, of Part 381 of this chapter, or unless such use otherwise results in the adulteration or misbranding of meat or poultry products. Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry products in 21 CFR Chapter I, Subchapter A or Subchapter B, may be listed or approved for such use under this chapter by the Administrator in § 424.21, subject to declaration requirements in parts 316 and 317, or Subparts M and N, of Part 381 of this chapter.

(2) No food ingredients or sources of radiation may be used in the preparation of any meat or poultry product, for any purpose, unless the use is listed or approved in 21 CFR Chapter I as a direct food additive (21 CFR Part 172), a secondary direct food additive (21 CFR Part 173), indirect food additive (21 CFR Parts 174–178), radiation source (21 CFR Part 179), an interim-listed direct food additive (21 CFR Part 180), a prior-sanctioned substance (21 CFR Part 181), a Generally Recognized As Safe (GRAS) substance (21 CFR Parts 182 or 184), or by a regulation in this chapter. Part 319 of this chapter also specifies other food ingredients that are acceptable in preparing specified products.

(3) No food ingredient, the intended use of which is to impart color in any meat or poultry product, shall be used unless such use is approved in 21 CFR Chapter I as a color additive (21 CFR Parts 73, 74, 81, and 82) or in a regulation in this chapter.

(4) Petitions to amend 21 CFR Chapter I to provide for uses of food additives, or other substances or sources of radiation necessary in the preparation of meat or poultry products, or food ingredients used to impart color to product, should be sent to the Food and Drug Administration, in accordance with the provisions of 21 CFR Parts 71 or 171, as appropriate.

(5) Inquiries concerning the regulatory status under the Federal Food, Drug, and Cosmetic Act of any articles intended for use as components of, or in contact with, meat or poultry products, may be addressed to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204, or the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development and Evaluation, Washington, DC 20250–3700.

(6) Inquiries concerning the use in specific meat or poultry products of substances that are not affirmed by the Food and Drug Administration as Generally Recognized as Safe (GRAS) or otherwise listed in 21 CFR Part 182 or Part 184, or of food or color additives listed in 21 CFR regulations for general use in foods or for use in meat, or poultry products, generally, including mixtures of such substances or additives, should be addressed to the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development and Evaluation, Washington, DC 20250–3700.

(c) The food ingredients specified in the following chart are approved for use in the preparation of meat products, provided they are used for the purposes indicated, within the limit of the amounts stated, and under other conditions specified in this part and Part 317 of this chapter. Part 319 of this chapter specifies other food ingredients that are acceptable in preparing specified meat products. This chart also contains food ingredients that are acceptable for use in poultry products, provided they are used for the purpose indicated, within the limits of the amounts stated and under other conditions specified in this part. No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, or by the Administrator in specific cases.

| Class of substance | Substance | Purpose | Products | Amount |
|---|---|---|---|---|
| Acidifiers | Acetic acid | To adjust acidity | Various meat and poultry products [2]. | Sufficient for purpose.[3] |
| | Citric acid | do | do | Do. |
| | Glucono delta-lactone | do | do | Do. |
| | Lactic acid | do | do | Do. |
| | Phosphoric acid | do | do | Do. |
| | Tartaric acid | do | do | Do. |

| Class of substance | Substance | Purpose | Products | Amount | |
|---|---|---|---|---|---|
| Anti-coagulants | Citric acid | To prevent clotting | Fresh blood of livestock | 0.2 percent with or without water. When water is used to make a solution of citric acid added to the blood of livestock, not more than 2 parts of water to 1 part of citric acid shall be used. | |
| | Sodium citrate | .....do | .....do | Not to exceed 0.5 percent based on the ingoing weight of the product. When water is used to make a solution of sodium citrate added to livestock blood, not more than 2 parts of water to 1 part of sodium citrate shall be used. | |
| Antifoaming agent | Methyl polysilicone | To retard foaming | Soups (meat and poultry) | 10 ppm. | |
| | | .....do | Rendered fats (meat and poultry). | Do. | |
| | | .....do | Curing pickle (meat and poultry). | 50 ppm. | |
| Antimicrobial agents | Trisodium phosphate | To reduce microbial levels | Raw, chilled poultry carcasses | 8 to 12 percent; solution to be maintained at 45 °F. to 55 °F. and applied by spraying or dipping carcasses for up to 15 seconds when used in accordance with 21 CFR 182.1778. | |
| Antioxidants and oxygen interceptors. | Ascorbyl palmitate | To retard rancidity | Margarine or oleomargarine | 0.02 percent (by wt. of finished product) individually or in combination with other antioxidants approved for use in margarine. | |
| | Ascorbyl stearate. | | | | |
| | BHA (butylated hydroxyanisole) | .....do | Dry sausage | 0.003 based on total weight. | 0.006 percent in combination with other antioxidants for use in meat. |
| | | .....do | Rendered animal fat or a combination of such fat and vegetable fat. | 0.01 percent | 0.02 percent in combination with other antioxidants for use in meat. |
| | | .....do | Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs. | 0.01 percent based on fat content. | 0.02 percent in combination with other antioxidants for use in meat, based on fat content. |
| | | .....do | Dried meats | 0.01 percent based on total weight. | 0.01 percent in combination with other antioxidants for use in meat. |
| | | .....do | Margarine or oleomargarine | 0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine. | |

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| | .....do ..... | Various poultry products ..... | 0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content. | |
| BHT (butylated hydroxytoluene) | .....do ..... | Dry sausage ..... | 0.003 percent based on total weight. | 0.006 percent in combination with other antioxidants for use in meat. |
| | .....do ..... | Rendered animal fat or a combination of such fat and vegetable fat. | 0.01 percent | 0.02 percent in combination with other antioxidants for use in meat. |
| | .....do ..... | Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs. | 0.01 percent based on fat content. | 0.02 percent in combination with other antioxidants for use in meat, based on fat content. |
| | .....do ..... | Dried meats ..... | 0.01 percent based on total weight. | 0.01 percent in combination with other antioxidants for use in meat. |
| | .....do ..... | Margarine or oleomargarine ..... | 0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine. | |
| | .....do ..... | Various poultry products ..... | 0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content. | |
| Dodecyl gallate ..... | .....do ..... | Margarine or oleomargarine ..... | 0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine. | |
| Glycine ..... | .....do ..... | Rendered animal fat or a combination of such fat and vegetable fat. | 0.01 percent | 0.02 percent in combination with other antioxidants for use in meat. |
| Octyl gallate ..... | .....do ..... | Margarine or oleomargarine ..... | 0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine. | |
| Propyl gallate ..... | .....do ..... | Dry sausage ..... | 0.003 percent based on total weight. | 0.006 percent in combination with other antioxidants for use in meat. |

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| | .....do | Rendered animal fat or a combination of such fat and vegetable fat. | 0.01 percent | 0.02 percent in combination with other antioxidants for use in meat. |
| | .....do | Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs. | 0.01 percent based on fat content. | 0.02 percent in combination with other antioxidants for use in meat, based on fat content. |
| | .....do | Dried meats | 0.01 percent based on total weight. | 0.01 percent in combination with other antioxidants for use in meat. |
| | .....do | Margarine or oleo-margarine | 0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine. | |
| | .....do | Various poultry products | 0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content). | |
| Resin guaiac | .....do | Rendered animal fat or a combination of such fat and vegetable fat. | 0.01 percent | 0.02 percent in combination with other antioxidants for use in meat. |
| TBHQ (tertiary butylhydroquinone). | .....do | Dry sausage | 0.003 percent based on weight. | 0.006 percent in combination only with BHA and/or BHT. |
| | .....do | Rendered animal fat or a combination of such fat and vegetable fat. | 0.01 percent | 0.02 percent in combination only with BHA or BHT. |
| | .....do | Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs. | 0.01 percent based on fat content. | 0.02 percent in combination only with BHA and/ or BHT, based on fat content. |
| | .....do | Dried meats | 0.01 percent based on total weight. | 0.01 percent in combination only with BHA and/or BHT. |
| | .....do | Margarine or oleo-margarine | 0.02 percent alone or in combination only with BHA and/or BHT, based on oil or fat content. | |
| | .....do | Various poultry products | 0.01 percent based on fat content (0.02 percent in combination only with BHA and/or BHT, based on fat content). | |

| | | | | |
|---|---|---|---|---|
| | Tocopherols | .....do | Rendered animal fat or a combination of such fat and vegetable fat. | 0.03 percent. A 30 percent concentration of tocopherols in vegetable oils shall be used when added as an antioxidant to products designated as ''lard'' or ''rendered pork fat.'' |
| | | .....do | Dry sausage, semidry sausage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausages, pregrilled beef patties, and restructured meats. | Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants. |
| | | .....do | Various poultry products | 0.03 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content). |
| Artificial Sweeteners | Saccharin | To sweeten product | Bacon | 0.01 percent. |
| Binders and Extenders | Agar-agar | To stabilize and thicken | Thermally processed canned and jellied meat food products. | 0.25 percent of finished product. |
| | Algin | To extend and stabilize product. | Breading mix; sauces (meat only) and various poultry products. | Sufficient for purpose in accordance with 21 CFR 172.5. |
| | A mixture of sodium alginate, calcium carbonate and calcium lactate/lactic acid (or glucono delta lactone). | To bind meat pieces | Restructured meat food products. | Sodium alginate not to exceed 1.0 percent; calcium carbonate not to exceed 0.2 percent; and lactic acid/calcium lactate (or glucono delta-lactone) not to exceed 0.3 percent of product formulation. Added mixture may not exceed 1.5 percent of product at formulation. Mixture ingredients must be added dry. |
| | A mixture of sodium alginate, calcium carbonate, lactic acid, and calcium lactate. | To bind poultry pieces | Ground and formed raw or cooked poultry pieces. | Sodium alginate not more than 0.8 percent, calcium carbonate not more than 0.15 percent; lactic acid and calcium lactate, in combination, not more than 0.6 percent of product formulation. Added mixture may not exceed 1.55 percent of product at formulation. The mixture must be added in dry form. |
| | Bread | To bind and extend product | Bockwurst | 3.5 percent individually or collectively with other binders for use in meat. |
| | | .....do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders for use in meat. |
| | | .....do | Spaghetti with meat balls and sauce, spaghetti with meat and sauce and similar products. | 12 percent individually or collectively with other binders for use in meat. |
| | Carboxymethyl cellulose (cellulose gum). | To extend and stabilize product. | Baked pies (meat only) and various poultry products. | Sufficient for purpose in accordance with 21 CFR 172.5. |
| | Carrageenan | To extend and stabilize product. | Breading mix; sauces (meat only) and various poultry products. | Sufficient for purpose in accordance with 21 CFR 172.5. |
| | | To prevent purging of brine solution. | Cured pork products as provided in 9 CFR 319.104(d). | Not to exceed 1.5 percent of product formulation; permitted in combination only with soy protein concentrate, combination not to exceed 1.5 percent of product formulation; in accordance with 21 CFR 172.620, 172.623, and 172.626. |

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| Carrageenan, Locust bean gum, and Xanthan gum blend. | .....do ..... | .....do ..... | In combination, not to exceed 0.5 percent of formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, 172.626, 184.1343, and 172.695. |
| Cereal ..... | To bind and extend product ... | Sausages as provided in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders for use in meat. |
| | .....do ..... | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders for use in meat. |
| Dried milk ..... | .....do ..... | Sausages as provided for in 9 CFR Part 319. | 3.5 percent individually or collectively with other binders for use in meat |
| Dried skim milk, calcium reduced. | .....do ..... | Sausages as provided in 9 CFR 9 CFR Part 319. | Do. |
| | .....do ..... | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders for use in meat. |
| Enzyme (rennet) treated with calcium reduced dried skim milk and calcium lactate. | .....do ..... | Sausages as provided for in 9 CFR Part 319. | 3.5 percent total finished product (calcium lactate required at rate of 10 percent of binder.) |
| | .....do ..... | Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products. | Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 10 percent of binder). |
| Enzyme (rennet) treated with sodium caseinate and calcium lactate. | .....do ..... | Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products. | Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 25 percent of binder). |
| Food starch modified ..... | To prevent purging of brine solution. | Cured pork products as provided for in 9 CFR 319.104(d). | Not to exceed 2 percent of product formulation in ''Ham Water Added'' and ''Ham with Natural Juices'' products; not to exceed 3.5 percent of product formulation in ''Ham and Water Product—X percent of Weight is Added Ingredients'' products; permitted in combination only with soy protein concentrate, with combination of modified food starch at 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in accordance with 21 CFR 172.892. |
| Gelatin ..... | To bind and extend product ... | Various poultry products ..... | Sufficient for purpose in accordance with 21 CFR 172.5. |
| Gums, vegetable ..... | .....do ..... | Egg roll (meat only) and various poultry products. | Sufficient for purpose in accordance with 21 CFR 172.5. |
| Isolated soy protein ..... | .....do ..... | Sausage as provided for in 9 CFR Part 319, bockwurst. | 2 percent. |
| | .....do ..... | Imitation sausages; nonspecific loaves; soups; stews (meat only) and various poultry products. | Sufficient for purpose in accordance with 21 CFR 172.5. |
| | .....do ..... | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders for use in meat. |
| | .....do ..... | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products. | 12 percent individually or collectively with other binders and extenders for use in meat. |
| | To prevent purging of brine solution. | Cured pork products as provided for in 9 CFR 319.104(d). | Not to exceed 2 percent of product formulation, not permitted in combination with other binders approved for use in cured pork products. |

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| Methyl cellulose | To extend and stabilize product (also carrier). | Meat and vegetable patties; various poultry products. | 0.15 percent. |
| Sodium caseinate | To bind and extend product | Imitation sausages, nonspecific loaves, soups, stews (meat only). | Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5. |
| | do | Sausages as provided for in 9 CFR Part 319. | 2 percent in accordance with 21 CFR 182.1748. |
| | do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders and extenders for use in meat in accordance with 21 CFR 182.1748. |
| | do | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products. | 12 percent individually or collectively with other binders and extenders for use in meat in accordance with 21 CFR 182.1748. |
| | To prevent purging of brine solution. | Cured pork products as provided for in 9 CFR 319.104(d). | Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products, in accordance with 21 CFR 182.1748. |
| | To bind and extend product | Various poultry products | 3 percent in cooked product, 2 percent in raw product, in accordance with 21 CFR 172.5 and 182.1748. |
| Soy flour | do | Sausages as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat. |
| | do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders and extenders for use in meat. |
| | do | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products. | 12 percent individually or collectively with other binders and extenders for use in meat. |
| Soy protein concentrate | do | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat. |
| | do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders and extenders for use in meat. |
| | do | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products. | 12 percent individually or collectively with other binders and extenders for use in meat. |
| | To prevent purging of brine solution. | Cured pork products as provided for in 9 CFR 319.104(d). | Not to exceed 3.5 percent of product formulation; permitted in combination only with modified food starch, with combination of modified food starch at 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in combination only with carrageenan, combination not to exceed 1.5 percent of product formulation. |
| Starchy vegetable flour | To bind and extend product | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat. |
| | do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders and extenders for use in meat. |

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| Tapioca dextrin | .....do | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277. |
| | .....do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277. |
| | .....do | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products. | 12 individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277. |
| | .....do | Various poultry products | Sufficient for purpose in accordance with 21 CFR 184.1277. |
| Vegetable starch | .....do | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat. |
| | .....do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders and extenders for use in meat. |
| Wheat gluten | To bind and extend product | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1322. |
| | .....do | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders for use in meat, in accordance with 21 CFR 184.1322. |
| | .....do | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products. | 12 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1322. |
| | .....do | Various poultry products | Sufficient for purpose in accordance with 21 CFR 184.1322. |
| Whey, Dry or dried | To bind or thicken | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat. |
| | .....do | Imitation sausages, nonspecific loaves, soups, stews (meat only). | 8 percent individually or collectively with other binders and extenders for use in meat. |
| | .....do | Chili con carne, chili con carne with beans, pork or beef with barbecue sauce. | 8 percent individually or collectively with other binders and extenders for use in meat. |
| | .....do | Various poultry products | Sufficient for purpose in accordance with 21 CFR 184.1322. |
| Whey, Reduced lactose | To bind or thicken | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat. |
| | .....do | Imitation sausages, nonspecific loaves, soups, stews (meat only). | Sufficient for purpose in accordance with 21 CFR 172.5. |
| | .....do | Chili con carne, chili con carne with beans, pork or beef with barbecue sauce. | 8 percent individually or collectively with other binders and extenders for use in meat. |
| Whey, Reduced minerals | .....do | Sausage as provided for in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat. |
| | .....do | Imitation sausages, nonspecific loaves, soups, stews (meat only). | Sufficient for purpose in accordance with 21 CFR 172.5. |
| | .....do | Chili con carne, chili con carne with beans, pork or beef with barbecue sauce. | 8 percent individually or collectively with other binders and extenders for use in meat. |

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| | Whey protein concentrate | .....do | Sausage as provided in 9 CFR Part 319, bockwurst. | 3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c. |
| | | .....do | Imitation sausages, nonspecific loaves, soups, stews. | Sufficient for purpose in accordance with 21 CFR 184.1979c. |
| | | .....do | Chili con carne, chili con carne with beans, pork or beef with barbecue sauce. | 8 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c |
| | | To bind meat pieces | Restructured meat food products, whole muscle meat cuts. | 3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c. |
| | Xanthan gum | To maintain: uniform viscosity; suspension of particulate matter, emulsion stability; freeze-thaw stability. | Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes. | Sufficient for purpose in accordance with 21 CFR 172.5. |
| | | .....do | Various poultry products, except uncooked products or sausages or other products with a moisture limitation established by Subpart P of Part 381. | Sufficient for purpose |
| Bleaching Agent | Hydrogen peroxide | To remove color | Tripe (substance must be removed from product by rinsing with clear water). | Sufficient for purpose. |
| Catalysts (substances must be eliminated during process). | Nickel | To accelerate chemical reaction. | Rendered animal fats or a combination of such fats and vegetable fats. | Do. |
| | Sodium amide | Rearrangement of fatty acid radicals. | .....do | Do. |
| | Sodium methoxide | .....do | .....do | |
| Chilling Media | Salt (NaCl) | To aid in chilling | Raw poultry products | 700 lbs. to 10,000 gallons of water. |
| Coloring Agents (artificial) | Coal tar dyes (FD&C certified) | To color products | Various poultry products | Sufficient for purpose. |
| | Color additives listed in 21 CFR Part 74, Subpart A of Part 82, Subpart B (operator must furnish evidence to inspector in charge that color additive has been certified for use in connection with foods by the Food and Drug Administration). | To color casings or rendered fats; marking and branding product. | Sausage casings, oleomargarine, shortening, marking or branding ink on product (meat only). | Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt and sugar). |
| | Titanium oxide | To whiten | Canned ham salad spread and creamed-type canned meat products. Poultry salads and poultry spreads. | 0.5 percent. |
| Coloring Agents (natural) | Alkanet, annatto, carotene, cochineal, green chlorophyll, saffron and tumeric. | To color casings or rendered fats; marking and branding product. | Sausage casings, oleomargarine, shortening, marking or branding ink on product (meat only). | Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar). |
| | Annatto, carotene | To color products | Various poultry products | Sufficient for purpose. |
| Curing accelerators (must be used only in combination with curing agents). | Ascorbic acid | To accelerate color fixing or preserve color during storage. | Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products. | 75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product). |

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| | Citric acid or sodium citrate ... | To accelerate color fixing or preserve color during storage. | Cured pork and beef cuts, cured comminuted meat food product, cured comminuted poultry or poultry products. | May be used in cured meat products or in 10 percent solution used to spray surfaces of cured meat cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used. May be used in cured poultry products to replace 50 percent of the ascorbic acid or sodium ascorbate that is used. |
| | Erythorbic acid ..... | To accelerate color fixing or preserve color during storage. | Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products. | 75 oz to 100 gal pickle at 10 percent pump level; 3/4 oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product). |
| | Fumaric acid ..... | .....do ..... | Cured, comminuted meat, poultry or meat and poultry products. | 0.065 percent (or 1 oz to 100 lb) of the weight of the meat, poultry or the meat or poultry byproducts before processing. |
| | Glucono delta lactone ..... | .....do ..... | Cured, comminuted meat or meat food product. | 8 oz to each 100 lb of meat or meat byproduct. |
| | | .....do ..... | Genoa salami ..... | 16 oz to 100 lb of meat (1.0 percent). |
| | Sodium acid pyrophosphate ... | .....do ..... | Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst and similar products. | Not to exceed alone or in combination with other curing accelerators for use in meat the following: 8 oz in 100 lb of meat, or meat and meat byproducts, content of the formula; nor 0.5 percent in the finished product. |
| | Sodium ascorbate ..... | To accelerate color fixing or preserve color during storage. | Cured pork and beef cuts, cured comminuted meat food product, cured comminuted poultry or poultry products. | 87.5 oz to 100 gal pickle at 10 percent pump level; 7/8 oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product). |
| | Sodium erythorbate ..... | To accelerate color fixing or preserve color during storage. | Cured pork and beef cuts, cured comminuted meat food products, cured comminuted poultry or poultry products. | 87.5 oz to 100 gal pickle at 10 percent pump level; 7/8 oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.) |
| Curing Agents ..... | Sodium or potassium nitrate .. | Source of nitrite ..... | Cured meat products other than bacon. Nitrates may not be used in baby, junior, and toddler foods. Cured, comminuted poultry or poultry products. | 7 lb to 100 gal pickle; 3 1/2 oz to 100 lb meat or poultry product (dry cure); 2 3/4 oz to 100 lb chopped meat or poultry. |

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| | Sodium or potassium nitrite (supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly). | To fix color | Cured meat and poultry products. Nitrites may not be used in baby, junior, or toddler foods. | 2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb meat or poultry product (dry cure); ¼ oz to 100 lb chopped meat, meat byproduct or poultry product. The use of nitrites, nitrates or combination shall not result in more than 200 ppm of nitrite, calculated as sodium nitrite in finished product, except that nitrites may be used in bacon only in accordance with paragraph (b) of this section. |
| Denuding Agents (may be used in combination. Must be removed from tripe by rinsing with potable water.). | Lime (calcium oxide, calcium hydroxide). | To denude mucous membranes. | Tripe | Sufficient for purpose. |
| | Sodium carbonate | .....do | .....do | Do. |
| | Sodium citrate | .....do | .....do | Do. |
| | Sodium gluconate | .....do | .....do | Do. |
| | Sodium hydroxide | .....do | .....do | Do. |
| | Sodium persulfate | .....do | .....do | Do. |
| | Sodium silicates (ortho, meta, and sesqui). | .....do | .....do | Do. |
| | Trisodium phosphate | .....do | .....do | Do. |
| Emulsifying Agents | Actylated monoglycerides | To emulsify product | Shortening and various poultry products. | Sufficient for purpose. |
| | Diacetyl tartaric acid esters of mono-and diglycerides. | .....do | .....do | Do. |
| | Glycerol-lacto stearate, oleate, or palmitate. | .....do | .....do | Do. |
| | Lecithin | To emulsify product (also as an antioxidant). | Oleomargarine, shortening, various meat and poultry products. | 0.5 percent in oleomargarine, use in other products—sufficient amount for emulsification. |
| | Mono and diglycerides (glycerol palmitate, etc.). | To emulsify product | Rendered animal fat or a combination of such fat with vegetable fat; oleomargarine. | Sufficient for purpose in lard and shortening; 0.5 percent in oleomargarine. |
| | | .....do | Various poultry products | Sufficient for purpose. |
| | Mono and diglycerides of fatty acids esterified with any of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts; the sodium sulfoacetate derivatives of these mono and diglycerides. | .....do | Margarine or oleomargarine | 0.5 percent. |
| | Polyglycerol esters of fatty acids (polyglycerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of § 172.854(a) of the Food Additive Regulations). | .....do | Rendered animal fat or a combination of such fat with vegetable fat when use is not precluded by standards of identity of composition; oleomargarine. | Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5 percent for oleomargarine. |
| | Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate). | .....do | Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods (meat only). Rendered poultry fat or a combination of such fat with vegetable fat. | 1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 percent. |
| | Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate). | .....do | Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods (meat only). Various poultry products. | 1 percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 percent. |
| | 1,2-propylene glycol esters of fatty acids. | .....do | Margarine or oleomargarine | 2.0 percent. |
| | Propylene glycol mono and diesters of fats and fatty acids. | .....do | Rendered animal or poultry fat or a combination of such fat with vegetable fat. | Sufficient for purpose. |
| | Stearyl-2-lactylic acid | .....do | Shortening to be used for cake icings and fillings (meat only). | 3.0 percent. |

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| | Stearyl monoglyceridyl citrate | .....do | Shortening | Sufficient for purpose |
| Film Forming Agents | A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethyl-cellulose, and corn syrup solids. | To reduce cooler shrinkage and help protect surface. | Freshly dressed meat carcasses. Such carcasses must bear a statement ''Protected with a film of water, corn syrup solids, sodium alginate, calcium chloride and sodium carboxymethyl-cellulose.''. | Formulation may not exceed 1.5 percent of hot carcass weight when applied. Chilled weight may not exceed hot weight. |
| Flavoring Agents; Protectors and Developers. | Artificial smoke flavoring | To flavor product | Various (meat and poultry)[2] | Sufficient for purpose. |
| | Autolyzed yeast extract | .....do | .....do | Do. |
| | Benzoic acid (sodium, potassium and calcium salts). | To retard flavor reversion | Margarine or oleomargarine | 0.1 percent individually, or if used in combination with other flavoring agents for use in meat or with sorbic acid and its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods). |
| | Calcium lactate | To protect flavor | Cooked semi-dry and dry products including sausage, imitation sausage, and nonspecific meat food sticks. | 0.6 percent in product formulation. |
| | Citric acid | .....do | Various poultry products | Sufficient for purpose. |
| | | Flavoring | Chili con carne | Do. |
| | Corn syrup solids; corn syrup; glucose syrup. | To flavor product | Various poultry products, sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham. | Do. |
| | Dextrose | .....do | Sausage, ham and cured products. | Do. |
| | Diacetyl | .....do | Oleomargarine | Do. |
| | Disodium guanylate | .....do | Various meat and poultry products.[2] | |
| | Disodium inosinate | .....do | .....do | Do. |
| | Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of *Pediococcus cerevisiae*. | To develop flavor | Dry sausage, pork roll, thuringer, lebanon bologna, cervelat, and salami. | 0.5 percent. |
| | Harmless lactic acid producing bacteria. | To prevent the growth of *Clostridium botulinum*. | Bacon | Sufficient for purpose. |
| | Hydrolyzed plant protein | To flavor product | Various meat and poultry products.[2] | Do. |
| | Isopropyl citrate | To protect flavor | Oleomargarine | 0.02 percent. |
| | Malt syrup | To flavor product | Cured meat products | 2.5 percent. |
| | | .....do | Various poultry products | Sufficient for purpose. |
| | Milk protein hydrolysate | .....do | Various meat and poultry products.[2] | Do. |
| | Monoammonium glutamate | .....do | .....do | Do. |
| | Monosodium glutamate | .....do | .....do | Do. |
| | Potassium lactate | .....do | Various meat and meat food products, poultry and poultry food products, except infant formula and infant food.[2] | Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639. |
| | Smoke flavoring | To flavor product | Various meat and poultry products. | Sufficient for purpose. |
| | Sodium acetate | .....do | Various meat and poultry products. | Not to exceed 0.12 percent of formulate in accordance with 21 CFR 184.1721. |
| | Sodium diacetate | .....do | .....do | Not to exceed 0.1 percent of formulate in accordance with 21 CFR 184.1754. |
| | Sodium lactate | .....do | Various meat and meat food products, poultry and poultry food products, except infant formula and infant food.[2] | Not to exceed 2 percent of formulation in accordance with 21 CFR 184.1768. |
| | Sodium sulfoacetate derivative of mono and diglycerids. | .....do | Various meat and poultry products.[2] | 0.5 percent. |
| | Sodium tripolyphosphate | To help protect flavor | ''Fresh Beef,''[2] ''Beef for further cooking, ''Cooked Beef,'' Beef Patties, Meat Loaves, Meat Toppings, and similar products derived from pork, lamb, veal, mutton, and goat meat which are cooked or frozen after processing. | 0.5 percent of total product. |

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| | Sodium tripolyphosphate and sodium mixtures, metaphosphate, insoluble; and sodium polyphosphates, glassy. | .....do | .....do | Do. |
| | Sorbitol | To flavor, to facilitate the removal of casings from product, and to reduce caramelization and charring. | Cooked sausage labeled frankfurter, frank, furter, wiener, and knockwurst; cured pork and pork products, as provided for in 9 CFR Part 319. | Not to exceed 2 percent of the weight of the formula excluding the formula weight of water or ice, when used in accordance with 21 CFR 184.1835. |
| | Starter distillate | To help protect flavor | Oleomargarine | Sufficient for purpose. |
| | Stearyl citrate | .....do | .....do | 0.15 percent. |
| | Sugars (sucrose and dextrose) | To flavor product | Various meat and poultry products. | Sufficient for purpose. |
| Gases | Carbon dioxide liquid | Contact freezing | Various poultry products | Do. |
| | Carbon dioxide solid (dry ice) | To cool product | Chopping of meat, packing of product. | Sufficient for purpose. |
| | | To cool product or facilitate chopping or packaging. | Various poultry products | Do. |
| | Nitrogen | To exclude oxygen from sealed containers. | Various meat and poultry products. | Do. |
| | Nitrogen, liquid | Contact freezant | .....do | Do. |
| Hog Scald Agents (must be removed by subsequent cleaning operations). | Caustic soda | To remove hair | Hog carcasses | Sufficient for purpose. |
| | Dicotyl sodium sulfosuccinate | .....do | .....do | Do. |
| | Dimethylpolysiloxane | .....do | .....do | Do. |
| | Disodium-calcium ethylenediaminetetra-acetate. | .....do | .....do | Do. |
| | Disodium phosphate | .....do | .....do | Do. |
| | Ethylenediaminetetra-acetic acid (sodium salts). | .....do | .....do | Do. |
| | Lime (calcium oxide, calcium hydroxide). | .....do | .....do | Do. |
| | Potassium hydroxide | | | Do. |
| | Propylene glycol | .....do | .....do | Do. |
| | Soap (prepared by the reaction of calcium, potassium, or sodium with rosin or fatty acids of natural fats and oils). | .....do | .....do | Do. |
| | Sodium acid pyrophosphate | .....do | .....do | Do. |
| | Sodium carbonate | .....do | .....do | Do. |
| | Sodium dodecylbenzene sulfonate. | .....do | .....do | Do. |
| | Sodium gluconate | .....do | .....do | Do. |
| | Sodium hexametaphosphate | .....do | .....do | Do. |
| | Sodium lauryl sulfate | .....do | .....do | Do. |
| | Sodium mono and dimethylnaphthalene sulfonate (molecular weight 245–260). | .....do | .....do | Do. |
| | Sodium n-alkylbenzene sulfonate (alkyl group predominantly C12 and C13 and not less than 95 percent C10 and C16). | .....do | .....do | Do. |
| | Sodium pyrophosphate | .....do | .....do | Do. |
| | Sodium silicates (ortho, meta, and sesqui). | .....do | .....do | Do. |
| | Sodium sulfate | .....do | .....do | Do. |
| | Sodium tripolyphosphate | .....do | .....do | Do. |
| | Sucrose | .....do | .....do | Do. |
| | Triethanolamine dodecylbenzene sulfonate. | .....do | .....do | Do. |
| | Trisodium phosphate | .....do | .....do | Do. |
| Miscellaneous | Adipic acid | To acidify | Margarine or oleomargarine | Sufficient for purpose. |

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| Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate singly or in combination, under quality control. | To delay discoloration | Fresh beef cuts, fresh lamb cuts, fresh pork cuts. | Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq. inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041) or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq. inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751). |
| Calcium disodium, EDTA (calcium disodium ethylenediaminetetraacetate. | To preserve product and to protect flavor. | Margarine or oleomargarine | 75 ppm by weight of the finished oleomargarine or margarine. |
| Calcium propionate | To retard mold growth | Pizza crust | 0.32 percent alone or in combination based on weight of the flour brace used. |
| | do | Fresh pie dough (poultry only) | 0.3 percent of calcium propionate or sodium propionate alone, or in combination, based on weight of flour used. |
| Citric acid | To preserve cured color during storage. | Cured pork cuts | Not to exceed 30 percent in water solution used to spray surfaces of cured cuts, prior to packaging, in accordance with 21 CFR 184.1033. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to product). |
| Citric acid (sodium and potassium salts). | To acidify | Margarine and oleomargarine | Sufficient for purpose. |
| d- and dl-alpha-tocopherol | To inhibit nitrosamine formation. | Pump-cured bacon | 500 ppm; by injection or surface application. |
| Dipotassium phosphate | To decrease the amount of cooked out juices. | Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.. | For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product. |
| Disodium phosphate | do | do | Do. |
| Glycerine | Humectant | Shelf stable meat snacks | Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320. |
| Hydrochloric acid | To acidify | Margarine or oleomargarine | Sufficient for purpose. |
| Lactic acid (sodium and potassium salts). | do | do | Do. |
| L-Tartaric acid (sodium and sodium potassium salts). | do | do | Do. |
| Monopotassium phosphate | To decrease the amount of cooked out juices. | Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.. | For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product. |
| Monosodium phosphate | do | do | Do. |
| Phosphoric acid | To acidify | Margarine or oleomargarine | Sufficient for purpose. |
| Potassium bicarbonate | To alkalize | Margarine or oleomargarine | Sufficient for purpose. |
| Potassium carbonate | do | do | Do. |

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| Potassium pyrophosphate ..... | To decrease the amount of cooked out juices. | Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.. | 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product. |
| Potassium sorbate ..... | To retard mold growth ..... | Dry sausage ..... | 10 percent in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing. |
| Potassium tripolyphosphate ... | To decrease the amount of cooked out juices. | Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations. | 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product. |
| Propyl paraben (propyl p-hydroxy-benzoate). | To retard mold growth ..... | Dry sausage ..... | 3.5 percent in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing. |
| Silicon dioxide ..... | Processing aid/dispersant ..... | Tocopherol containing bacon curing mixes. | At level not to exceed 4.0 percent in the dry mix. |
| Sodium acid pyrophosphate ... | To decrease the amount of cooked out juices. | Meat food products except where other prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.. | For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product. |
| Sodium bicarbonate ..... | To neutralize excess acidity, cleaning vegetables. | Rendered fats, soups, curing pickle (meat and poultry). | Sufficient for purpose. |
| | To alkalize ..... | Margarine or oleomargarine .... | Do. |
| Sodium carbonate ..... | .....do ..... | .....do ..... | Do. |
| Sodium citrate buffered with citric acid to a pH of 5.6. | To inhibit the growth of micro-organisms and retain product flavor during storage. | Cured and uncured, processed whole muscle meat and poultry food products, e.g., ham, chicken breasts. | Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751. |
| Sodium hydroxide ..... | To alkalize ..... | Margarine or oleomargarine .... | Sufficient for purpose. |
| | To decrease the amount of cooked out juices. | Poultry food products containing phosphates. | May be used only in combination with phosphate in a ratio not to exceed one part sodium hydroxide to four parts phosphate. |
| | .....do ..... | Meat food products containing phosphates. | May be used only in combination with phosphates in a ratio not to exceed one part sodium hydroxide to four parts phosphate; the combination shall not exceed 5 percent in pickle at 10 percent pump level; 0.5 percent in product. |
| Sodium metaphosphate, insoluble. | .....do ..... | Meat food products except where other prohibited by the meat inspection regulations, and poultry food products except where otherwise prohibited by the poultry products inspection regulations. | For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product. |
| Sodium polyphosphate, glassy | .....do ..... | .....do ..... | Do. |
| Sodium proprionate ..... | To retard mold growth ..... | Pizza crust ..... | 0.32 percent alone or in combination based on weight of the flour brace used. |

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| | | .....do | Fresh pie dough (poultry only) | 0.3 percent of calcium proprionate or sodium proprionate alone, or in combination, based on weight of flour used. |
| | Sodium pryophosphate | To decrease the amount of cooked out juices. | Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations. | For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product. |
| | Sodium tripolyphosphate | .....do | .....do | Do. |
| | Sorbic acid (sodium, potassium, and calcium salts). | To preserve product and to retard mold growth. | Margarine or oleomargarine | 0.1 percent individually, or if used in combination or with benzoic acid or its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods). |
| | Tricalcium phosphate | To preserve product color during dehydration process. | Mechanically deboned chicken to be dehydrated. | Not to exceed 2 percent of the weight of the mechanically deboned chicken prior to dehydration, in accordance with 21 CFR 182.1217. |
| Poultry scald agents (must be removed by subsequent cleaning operations). | Alpha-hydro-omega-hydroxy-poly (oxyethylene) poly (oxypropylene) (minimum 15 moles) poly (oxyethylene) block copolymer (poloxamer). | To remove feathers | Poultry carcasses | Not to exceed 0.05 percent by weight in scald water. |
| | Dimethylpolysiloxane | .....do | .....do | Sufficient for purpose. |
| | Dioctyl sodium sulfosuccinate | .....do | .....do | Do. |
| | Dipotassium phosphate | .....do | .....do | Do. |
| | Ethylenediaminetetra-acetic acid (sodium salts). | .....do | .....do | Do. |
| | Lime (calcium oxide, calcium hydroxide). | .....do | .....do | Do. |
| | Polyoxyethylene (20) sorbitan monooleate. | .....do | .....do | Not to exceed 0.0175 percent in scald water. |
| | Potassium hydroxide | .....do | .....do | Sufficient for purpose. |
| | Propylene glycol | .....do | .....do | Do. |
| | Sodium acid phosphate | .....do | .....do | Do. |
| | Sodium acid pyrophosphate | .....do | .....do | Do. |
| | Sodium bicarbonate | .....do | .....do | Do. |
| | Sodium carbonate | .....do | .....do | Do. |
| | Sodium dodecylbenzene-sulfonate. | .....do | .....do | Do. |
| | Sodium-2-ethylhexyl sulfate | .....do | .....do | Do. |
| | Sodium hexametaphosphate | .....do | .....do | Do. |
| | Sodium hydroxide | .....do | .....do | Do. |
| | Sodium lauryl sulfate | .....do | .....do | Do. |
| | Sodium phosphate (mono-, di-, tribasic). | .....do | .....do | Do. |
| | Sodium pyrophosphate | .....do | .....do | Do. |
| | Sodium sesquicarbonate | .....do | .....do | Do. |
| | Sodium sulfate | .....do | .....do | Do. |
| | Sodium tripolyphosphate | .....do | .....do | Do. |
| | Tetrasodium pyrophosphate | .....do | .....do | Do. |
| Proteolytic Enzymes | Aspergillus flavus oryzae group. | To soften tissue | Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts. | Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product. |
| | Aspergillus oryzae | .....do | .....do | Do. |
| | Bromelin | .....do | .....do | Do. |
| | Ficin | .....do | .....do | Do. |
| | Papain | .....do | .....do | Do. |
| Refining Agents (must be eliminated during process of manufacturing). | Acetic acid | To separate fatty acids and glycerol. | Rendered fats (meat only) | Sufficient for purpose. |
| | Bicarbonate of soda | .....do | .....do | Do. |
| | Carbon (purified charcoal) | To aid in refining of animal fats. | .....do | Do. |
| | Caustic soda (sodium hydroxide). | To refine fats | .....do | Do. |
| | Diatomaceous earth; Fuller's earth. | .....do | .....do | Do. |

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| | Sodium carbonate | .....do | .....do | Do. |
| | Tannic acid | .....do | .....do | Do. |
| Rendering agents | Tricalcium phosphate | To aid rendering | Animal fats | Do. |
| | Trisodium phosphate | .....do | .....do | Do. |
| Synergists (used in combination with antioxidants). | Citric acid | To increase effectiveness of antioxidants. | Any meat product permitted to contain antioxidants as provided for in this part. | Not to exceed 0.01 percent based on fat content. |
| | | .....do | Poultry fats | 0.01 percent alone or in combination with antioxidants in poultry fats. |
| | Malic acid | .....do | Lard and shortening | 0.01 percent based on total weight in combination with antioxidants for use in meat products only. |
| | | .....do | Poultry fats | 0.01 percent alone or in combination with antioxidants in poultry fats. |
| | Monoglyceride citrate | .....do | Lard, shortening, fresh pork sausage, dried meats and poultry fats. | 0.02 percent. |
| | Monoisopropyl citrate | .....do | Lard, shortening, oleomargarine, fresh pork sausage, dried meats. | Do. |
| | | .....do | Poultry fats | 0.01 percent poultry fats. |
| | Phosphoric acid | .....do | Lard, shortening, and poultry fats. | 0.01 percent. |
| Tenderizing agents | Aspergillus flavus oryzae group. | To soften tissue | Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts. | Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product. |
| | Aspergillus oryzae | .....do | .....do | Not more than 3 percent of a of a 0.8 molar solution. |
| | Bromelin | .....do | .....do | Do. |
| | Calcium chloride | .....do | .....do | Do. |
| | Magnesium chloride | .....do | .....do | Do. |
| | Papain | To soften tissue | Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts. | Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product. |
| | Potassium chloride | .....do | .....do | Not more than 3 percent of a 2.0 molar solution. |
| | Potassium, magnesium or calcium chloride. | .....do | .....do | A solution of approved inorganic chlorides injected into or applied to raw meats or poultry cuts shall not result in a gain of more than 3 percent above the weight of the untreated product. |

[1] [RESERVED]

[2] Information as to the specific products for which use of this additive is approved may be obtained upon inquiry addressed to the Labeling and Additives Policy Division, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[3] Provided, that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under §§ 317.4 or 381.32.

[4] Special labeling requirements are prescribed in 381.120 for raw poultry chilled in a medium with more than 70 lbs. of salt to 10,000 gals. of water.

**§ 424.22 Certain other permitted uses.**

(a) Under appropriate declaration as required in parts 316 and 317 of this chapter, the following substances may be added to meat:

(1) *General.* Common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other food and color additives specified in the chart in paragraph (c) of this section may be added to meat under conditions, if any, specified in this part or in part 317 of this chapter.

(2) *Artifical flavorings.* Other harmless artificial flavorings may be added to meat, with the approval of the Administrator in specific cases.

(3) *Coloring matter and dyes.* Coloring matter and dyes, other than those specified in a regulation permitting that use in this chapter or in 21 CFR Chapter I, Subchapter A and Subchapter B, may be applied to meat mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.

(b) *Use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon.*

(1) *Pumped bacon.* With respect to bacon injected with curing ingredients and massaged bacon, sodium nitrite shall be used at 120 parts per million (ppm) ingoing or an equivalent amount of potassium nitrite shall be used (148 ppm ingoing); and 550 ppm of sodium

ascorbate or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 ppm of sodium ascorbate or sodium erythorbate.

(i) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the Thermal Energy Analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be collected and analyzed by gas chromatography. Presumptive positive results must be confirmed by mass spectrometry before being considered positive. If during the interval required for the Department to analyze the confirmatory samples by gas chromatography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitrosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA shall proceed in its confirmation analysis on the original samples taken for confirmation. If any one of the original samples collected by USDA for confirmation is found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to ensure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Bacon subsequently produced shall not be retained because of nitrosamines if the operator of the establishment makes adjustments in the processing of the product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department. However, if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of the product. All tests of pumped bacon for nitrosamines under this paragraph (b)(1)(i) shall be made on pumped bacon cooked at 340 degrees F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in a sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 ppb.

(ii) Notwithstanding the provisions of paragraph (b)(1)(i) of this section, sodium nitrite may be used at:

(A) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 500 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used, provided the establishment has a partial quality control program as provided in Sec. 318.4(d) that results in compliance with this provision, or

(B) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the growth of botulinum toxin at a level sufficient for the purpose of preventing the growth of botulinum toxin, provided the establishment has a partial quality control program as provided in Sec. 318.4(d) that results in compliance with this provision.

(C) The Department shall collect samples of bacon from establishments producing under paragraph (b)(1)(ii) of this section and analyze them for the level of nitrosamines. Samples shall be randomly selected throughout the production of a lot. The actual sampling plans and methods of analysis that are used will result in approximately the same likelihood as under paragraph (b)(1)(i) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10 ppb. In the event of a presumptive positive result, the establishment shall become subject to the provisions of paragraph (b)(1)(i) of this section.

(2) *Immersion cured bacon.* Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(3) *Bacon made with dry curing materials.* With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

### § 424.23 Prohibited uses.

(a) *Substances that conceal damage or inferiority or make products appear better or of greater value.* No substance may be used in or on any meat if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is. Therefore:

(1) Paprika or oleoresin paprika may not be used in or on fresh meat, such as steaks, or comminuted fresh meat, such as chopped and formed steaks or patties; or in any other meat consisting of fresh meat (with or without seasoning).

(2) Paprika or oleoresin paprika may be used in or on chorizo sausage and other meat in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.

(3) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausages or any other meat; sulfurous acid and salts of sulfurous acid shall not be used in or on any meat; and niacin

or nicotinamide shall not be used in or on fresh meat product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate may be used in or on any product, only as provided in 9 CFR Chapter III.

(b) *Nitrates.* Nitrates shall not be used in curing bacon.

Done at Washington, DC, on December 13, 1999.

**Thomas J. Billy,**

*Administrator.*

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