

# Proposed Rules

Federal Register

Vol. 65, No. 232

Friday, December 1, 2000

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 319

[Docket No. 98-103-2]

#### Importation of Artificially Dwarfed Plants in Growing Media From the People's Republic of China

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of reopening and extension of comment period.

**SUMMARY:** We are reopening and extending the comment period for our proposed rule that would amend our regulations to allow artificially dwarfed (penjing) plants of the genera *Buxus*, *Ehretia* (Carmona), *Podocarpus*, *Sageretia*, and *Serissa* to be imported into the United States from the People's Republic of China in an approved growing medium subject to specified growing, inspection, and certification requirements. This action will allow interested persons additional time to prepare and submit comments.

**DATE:** We invite you to comment on Docket No. 98-103-1. We will consider all comments that we receive by December 20, 2000.

**ADDRESSES:** Please send four copies of your comment (an original and three copies) to: Docket No. 98-103-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 98-103-1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Wayne D. Burnett, Senior Import Specialist, Phytosanitary Issues Management Team, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236; (301) 734-6799.

#### SUPPLEMENTARY INFORMATION:

##### Background

On September 20, 2000, we published in the **Federal Register** (65 FR 56803-56806, Docket No. 98-103-1) a proposed rule to amend our regulations governing the importation of plants and plant products to allow artificially dwarfed (penjing) plants of the genera *Buxus*, *Ehretia* (Carmona), *Podocarpus*, *Sageretia*, and *Serissa* to be imported into the United States from the People's Republic of China in an approved growing medium subject to specified growing, inspection, and certification requirements.

Comments on the proposed rule were required to be received on or before November 20, 2000. We are reopening and extending the comment period on Docket No. 98-103-1 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments. We will consider all comments that we received between September 20, 2000, and December 20, 2000.

Further, interested persons may now obtain the qualitative, pathway-initiated pest risk assessment for this action, titled "Pest Risk Assessments, Penjing Plants from China," on the APHIS web site at: <http://www.aphis.usda.gov/ppq/pim/>.

**Authority:** Title IV, Pub. L. 106-224, 114 Stat. 438, 7 U.S.C. 7701-7772; 7 U.S.C. 166 and 450; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 21st day of November 2000.

**Craig A. Reed,**  
Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00-30597 Filed 11-30-00; 8:45 am]

BILLING CODE 3410-34-U

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Parts 381 and 424

[Docket No. 98-062P]

#### Performance Standards for On-line Antimicrobial Reprocessing of Pre-Chill Poultry Carcasses

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing to amend its poultry products inspection regulations to allow, on a voluntary basis, the on-line reprocessing of pre-chill carcasses that are accidentally contaminated with digestive tract contents during slaughter. FSIS is proposing that, to permit this on-line reprocessing of visibly contaminated birds, the treated carcasses must meet pre-chill performance standards for *Salmonella* and *E. coli* that are significantly lower than the existing criteria for verifying process control for *E. coli* and the pathogen reduction performance standards for *Salmonella* for chilled poultry. The proposed change will allow contaminated poultry carcasses, including turkeys, to remain on the main processing line for treatment, rather than having to be moved off the main line. Birds with no visible contamination may undergo the same antimicrobial treatment, but they will remain subject to the Agency's pathogen reduction performance standards and process control criteria already in place for raw chilled product. Birds whose entire carcass is affected with contamination or are mutilated will not be permitted to be processed on-line. Under this proposal, establishments doing on-line antimicrobial reprocessing will need to do so in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in 9 CFR part 417. This proposed rule is in response to petitions from Rhodia Inc., of Cranbury, New Jersey, and Alcide Corporation of Redmond, Washington.

**DATES:** Comments must be received on or before January 30, 2001.

**ADDRESSES:** Submit written comments to the FSIS Docket Clerk, Room 102, Cotton Annex Building, 300 12th Street,

SW., Washington, DC 20250-3700. Interested persons are requested to submit an original and two copies of comments concerning this proposal. Written comments should be sent to the Docket Clerk at the address shown above and should refer to Docket Number 98-062P. Copies of all comments submitted in response to this proposal will be available for public inspection in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

Patricia F. Stolfa, Assistant Deputy Administrator, Regulations & Inspection, Office of Policy, Program Development, and Evaluation, FSIS, at (202) 205-0699 or FAX (202) 401-1760.

**SUPPLEMENTARY INFORMATION:** FSIS is responsible for ensuring that poultry products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. Under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451-470), FSIS provides mandatory inspection of poultry and poultry products distributed in interstate and foreign commerce and in designated States and U.S. territories. Inspection of poultry slaughtering establishments is intended to ensure that fresh, ready-to-cook poultry and parts are not adulterated or misbranded.

**Poultry Reprocessing**

FSIS estimates that 2 percent of inspected poultry carcasses are reprocessed. This estimate is based on approximately two years of in-plant data collection and represents the national average. The Agency requires that poultry with cut, contaminated surfaces be reprocessed by trimming, and poultry with uncut, contaminated inner surfaces be reprocessed by trimming alone or in combination with other methods, such as washing or vacuuming. After viscera removal, the contaminated carcasses are hung on a designated area of the retain rack. Carcasses are then transferred to the reprocessing station where they are suspended to prevent contamination during trimming and washing. The crops are removed, and external carcass surfaces are thoroughly washed. The contaminant is removed, and the reprocessed carcass is rinsed with water containing 20 ppm chlorine. After further examination by plant personnel, clean carcasses are lotted and made available for reinspection by FSIS inspectors. Carcasses found by the FSIS inspectors to be not adulterated are passed for human consumption.

Reprocessing procedures must be submitted in writing to FSIS. FSIS field

personnel are authorized to grant approvals for reprocessing stations to include 60-day provisional approvals (experimental under section 381.3(b)) to permit method development and data accumulation via MPI Bulletin 78-40 ("Disposition of Contaminated Poultry Carcasses," 3/28/78). Provisional approvals can be refused or revoked if the establishment cannot maintain consistently effective results. Final approvals must be based in part upon data from 20 consecutive days of successful operations.

The statutory basis for poultry reprocessing is section 6(c) of the PPIA (21 U.S.C. 455(c)) which provides that carcasses, parts, and products that may be reprocessed be made not adulterated, need not be condemned and destroyed if reprocessed under the supervision of an inspector and found to be not adulterated. The methods used to reprocess carcasses have changed over time. In the early 1960's, FSIS prohibited reprocessing by washing of poultry carcasses. This meant that contamination had to be removed by trimming. As a practical matter, the entire back of contaminated carcasses often had to be cut out and discarded.

In 1975, an Agriculture Research Service (ARS) study showed that the microbial profile of thoroughly washed carcasses previously contaminated with digestive tract contents was no different than the microbial profile of uncontaminated birds. Industry responded by requesting that FSIS permit contamination to be removed by washing. Industry also supplied data to demonstrate that washing also removed visible specks of internal contamination.

Citing newer technology that made the present procedure of trimming "unsuitable," on August 19, 1977, the Food Safety and Quality Service (now FSIS) proposed (42 FR 41873) to permit the reprocessing of internally contaminated carcasses if two conditions were met. First, each establishment must receive approval from FSIS of the off-line reprocessing procedure (trimming, vacuuming, or washing singly or in various combinations) and equipment. Second, the surface of each reprocessed carcass must be treated with a chlorinated water solution. A final rule, issued on March 8, 1978 (43 FR 12846), reduced the chlorine requirements from 50 ppm to 20 ppm and clarified some information about the areas designated for reprocessing.

During the 1970's and 1980's, the industry made significant technological advances and increased its process control capabilities. The development of automated evisceration equipment and

improvements in genetics, nutrition health, and flock management permitted the poultry industry to present uniform lots of birds to inspectors faster than inspectors could inspect them using traditional methods. In the 1980's, the Agency developed new inspection procedures, including New Line Speed (NELS) and Streamlined Inspection System (SIS) for chickens and the New Turkey Inspection (NTI) system, which shifted quality control responsibilities to the plant and relied more heavily on monitoring and verification than in the past. Inspection was now conducted in two distinct phases—a post-mortem inspection phase and a reinspection phase.

Under the current regulations, any carcass of poultry accidentally contaminated during slaughter with digestive tract contents will not be condemned if promptly reprocessed in a designated area off-line under the supervision of an inspector and found to be not adulterated. Under provisions of § 381.91, carcasses of poultry contaminated with volatile oils, paints, or any other substance that renders the carcass adulterated will be condemned. In addition, any organ or other part of a carcass that has been accidentally mutilated in the course of processing will be condemned, and if the whole carcass is affected, the whole carcass will be condemned.

**Advantages of On-Line Versus Off-Line Reprocessing**

Although FSIS' regulations require any visibly contaminated poultry carcass to be reprocessed at an approved reprocessing station away from the main processing line, there has been concern that pathogenic organisms may be spread by the off-line reprocessing technique (Beuchat, LR, and JH Ryu, *Produce Handling and Process Practices*, 1997). This technique involves a significant amount of product handling and provides an opportunity for cross-contamination.

On-line reprocessing of pre-chill poultry would provide great benefits to poultry slaughtering establishments. Production rates could increase considerably if such reprocessing were permitted. An increase in annual revenues resulting from an increase in the production rate would more than offset any one-time investment for the purchase and installation of equipment needed to reprocess on-line. The Agency does not foresee that any establishment would need to reduce its linespeeds as a result of on-line reprocessing, although the FSIS inspector-in-charge has discretion to reduce linespeeds, when necessary.

The benefits to be derived from on-line reprocessing include substantial reductions in pathogens on dressed, ready-to-cook poultry. A reduction in contamination, coupled with an antimicrobial treatment, would result in reduced microbial loads on dressed poultry carcasses. Because carcasses without visible contamination would undergo the antimicrobial treatment if reprocessing was done on-line, most poultry products would benefit from on-line reprocessing. There would be added assurance that reprocessed poultry are free of contamination and unlikely to be a cause of cross contamination when introduced into the chiller system.

Industry is aware of the potential benefits to be derived from on-line reprocessing. Consequently, over the last several years, companies have been exploring various methodologies. The first to come forward with data from trials performed at five plants (Choctow Maid, Carthage, MS; Perdue Farms, Rockingham, NC; Wayne Farms, Jack, AL; Choctow Foods, Forrest, MS; and Amick Farms, Batesburg, SC) was Rhodia, Inc., whose system uses trisodium phosphate (TSP). Rhodia's data show that its on-line reprocessing system can achieve pathogen levels significantly lower than the Agency pathogen reduction performance standards and process control verification criteria.

In addition, Alcide Corporation has developed the Sanova™ Continuous On-line Processing (COP) antimicrobial intervention process for poultry, which uses acidified sodium chlorite. FSIS is aware that other companies in addition to Rhodia and Alcide are doing in-plant testing and may soon be coming forward with data on the effectiveness of their antimicrobial systems.

#### TSP as a Processing Aid

Rhodia Inc., Rhone-Poulenc, Inc., its parent company, and Stauffer Chemical Company, its predecessor company, have conducted tests on the efficacy of various processes using solutions of food-grade TSP as a processing aid on raw meat and poultry carcasses for the purpose of reducing the numbers and prevalence of various pathogenic microorganisms. TSP is listed by the Food and Drug Administration (FDA) as generally recognized as safe (GRAS) for multiple-purpose use in accordance with good manufacturing practices (GMP) (21 CFR 182.1778). As part of the testing of TSP, numerous laboratory, plant, and commercial trials have been conducted pre-chill and post-chill in slaughtering operations for beef and

poultry (chicken and turkey) and for poultry giblets.

The trials tested both TSP spray/drench systems using inside/outside birdwashers (IOBW) and TSP immersion/application techniques using a drag through tank. Each of the commercial plant trials consistently demonstrated the efficacy of TSP in reducing prevalence and levels of Aerobic Plate Counts (APC's), *Campylobacter*, *E. coli*, and *Enterobacteriaceae* on meat and poultry.

The efficacy of a TSP rinse combined with a chlorine rinse in reducing the prevalence and levels of pathogenic bacteria on poultry is well documented by Rhodia. From the data submitted by Rhodia, it appears that APC's can be reduced up to 1.5 log<sub>10</sub> cycles (i.e., just less than 99 percent); *Campylobacter* prevalence can be reduced from 78.6 percent to 41.6 percent, a 37 percent reduction; *E. coli* and *Enterobacteriaceae* can be reduced to below the level of detection; and *Salmonella* can be reduced to below 1 percent of the total number of birds sampled.

#### Petition for Approval of TSP on Raw, Chilled Poultry Carcasses

In 1992, Rhone-Poulenc petitioned FSIS for approval of the use of TSP on raw, chilled poultry carcasses. The petitioner included data in its petition to demonstrate that the use of TSP is effective in reducing the prevalence of bacteria, including pathogenic bacteria, on raw, chilled poultry products. FSIS evaluated the petitioner's request and concluded that the treatment leaves virtually no residues in or on the product.

FSIS also determined that the use of TSP requested by the petitioner was suitable for its intended purpose as an antimicrobial processing aid, and that the use of this substance on raw, chilled poultry carcasses at the stated level would not render the treated product adulterated, misbranded, or otherwise not in accordance with the requirements of the PPIA. In a final rule issued on July 29, 1996 (61 FR 39273), FSIS amended the poultry products inspection regulations (formerly in § 381.147; now in the table in § 424.21(c)) to add "antimicrobial agents" as a new class of substance for use on poultry products and to include TSP as an approved antimicrobial agent whose use is limited to raw, chilled poultry carcasses.

#### In-Plant Trials of On-Line Reprocessing

Because of the antimicrobial efficacy demonstrated by TSP on chilled poultry in commercial poultry slaughter

operations, Rhodia requested and received authorization from FSIS to conduct in-plant trials of the use of TSP for on-line reprocessing of pre-chill carcasses. FSIS regulations (§ 381.91(b)(1) and (2)) require that the carcasses be reprocessed off-line under the supervision of an FSIS inspector.

Under the FSIS-approved protocol, a TSP treatment using an IOBW for the on-line reprocessing was tested. In the first stage of the approved protocol, visible contamination was removed from carcasses prior to zero tolerance verification by using one or more IOBW with a water spray containing 20 ppm chlorine. In the second stage, carcasses passed through another IOBW where a TSP antimicrobial rinse was applied.

Two separate phases of sampling took place in each trial at five plants. Phase 1 was conducted over a 4-week period and involved extensive sampling, in part, to verify proper startup of the system. Phase 2 was conducted over an 8-week period and involved collecting a lesser number of samples on a random basis.

The trials were conducted within the following operating parameters:

(1) There was strict compliance with FSIS regulatory policy, including the zero tolerance for fecal matter (9 CFR 381.65(e)), and with the existing pre-chill finished product standards (9 CFR 381.76, Table 1).

(2) Birds whose entire carcass was affected with contamination were not eligible for on-line reprocessing with TSP. These carcasses were reprocessed off-line in accordance with 9 CFR 381.91.

(3) The temperature of the TSP treatment solution did not exceed the carcass temperature at the time of treatment, and the treatment solution was applied by spraying/drenching carcasses up to 15 seconds.

(4) The TSP concentration levels were between 8 and 12 percent, with a critical limit of not less than 8 percent.

The 960 samples generated at each plant were divided equally among three sampling points. "A" samples were taken randomly from "normal" on-line fully eviscerated carcasses with no visible contamination before they underwent the first IOBW rinse for on-line reprocessing. The "A" samples, therefore, can be considered the control samples because they represented the actual bacterial load on carcasses proceeding on-line during days the sampling was conducted. "B" samples were taken from visibly contaminated carcasses that would normally have been reprocessed off-line but that were marked and allowed to be reprocessed on-line. "C" samples were obtained

from carcasses after they were reprocessed off-line, where they underwent procedures such as vacuuming, washing, or trimming, singly or in combination, and treated with chlorinated water. All samples were frozen and shipped to laboratories for analysis by AOAC/BAM analytical methods.

### Results of Trials

The data submitted to FSIS in support of Rhodia's petition show that the combined effects of the TSP and chlorine rinses substantially reduced the average APC's and *Enterobacteriaceae* counts and the prevalence of *Campylobacter*, *E. coli*, and *Salmonella* on treated sample carcasses. Specifically, the data show that:

- On-line TSP reprocessing achieved a 1 log<sub>10</sub> greater reduction in average APC's than normally reprocessed on-line carcasses before the chiller ("A" samples) and a one-half log greater reduction in average APC's than off-line reprocessed carcasses before the chiller ("C" samples).

- The average prevalence of *Campylobacter* on normal on-line carcasses before the chiller ("A" samples) was 78 percent, and the average prevalence was 80 percent for off-line carcasses before the chiller ("C" samples). There was a 32 percent reduction in *Campylobacter* prevalence for TSP reprocessed birds. (There were no *Campylobacter* samples tested in Phase 2 of the trials).

- On-line TSP reprocessing resulted in less than a 1.0 percent prevalence for *E. coli*. On-line carcasses in the control group ("A" samples) had an average *E. coli* prevalence of 97 percent before the chiller, and off-line reprocessed carcasses ("C" samples) averaged a 22 percent prevalence rate before the chiller.

- TSP on-line reprocessing reduced the prevalence for *Enterobacteriaceae* to 1.0 percent of carcasses. The average prevalence of *Enterobacteriaceae* on normal on-line pre-chilled carcasses ("A" samples) was 98 percent, and the average prevalence was 81 percent for off-line reprocessed pre-chilled carcasses ("C" samples).

- *Salmonella* prevalences were based on more than 1,200 samples each of the normal on-line carcasses, the TSP on-line reprocessed carcasses, and the off-line reprocessed carcasses. Less than 0.5 percent of the on-line carcasses treated with chlorine and TSP rinses were positive for *Salmonella*. On-line pre-chilled carcasses ("A" samples) averaged a prevalence of 30 percent, and off-line reprocessed pre-chilled

carcasses ("C" samples) averaged a 22 percent prevalence.

### Establishing a Pathogen Reduction Standard for On-Line Reprocessing Systems

In its petition, as noted above, Rhodia presented data from frozen samples that showed that the TSP rinse, in combination with a chlorinated water system, achieved substantial microbial load reduction on treated carcasses. Rhodia Inc., asked that FSIS amend its rules to provide for the on-line reprocessing of poultry with a substance or reprocessing system that has demonstrated, with statistically significant validating data generated under conditions of in-plant trial tests, the ability to reduce the pre-chill prevalence of *Salmonella* to less than 0.5 percent and to reduce the pre-chill prevalence of *E. coli* to less than 1.0 percent on frozen samples.

The on-line reprocessing of carcasses would occur after FSIS post-mortem inspection (in non-HACCP Inspection Models project plants) and the removal from the slaughter/processing line of carcasses extensively contaminated with digestive tract content or fecal material, condemned poultry carcasses, and parts or organs that are obviously unwholesome or unfit for human food. The removal of processing defects (nonconformances such as digestive tract contents, lungs, hair, feathers, bruises, scabies, airsacculitis, and others listed in § 381.76) is unchanged by this proposed rule and would continue to occur before on-line antimicrobial processing and before carcasses enter the chiller tank.

Under this proposal, carcasses with visible digestive tract contamination, including fecal contamination, would be permitted to remain on-line and would be treated with an antimicrobial agent before entering the chiller. Carcasses with extensive digestive tract contamination would continue to be eligible for reprocessing off-line but would not be eligible for on-line reprocessing.

FSIS is not proposing the specific pre-chill *Salmonella* and *E. coli* standards because, at this time, various antimicrobial treatments have been demonstrated to have differing effects. FSIS does intend to establish one or more pre-chill performance standards that establishments using on-line reprocessing with an antimicrobial treatment will be required to meet. FSIS invites comment, especially in the form of additional data, on the specific performance standards that establishments should be required to meet.

*E. coli* continues to be the best microbial indicator for fecal contamination. *Salmonella* is the most frequently occurring foodborne pathogen, and it is widely associated with raw poultry. Because *E. coli* contamination is largely preventable, and because the current *E. coli* and *Salmonella* requirements contained in § 381.94 were met or exceeded in the commercial on-line reprocessing trials, FSIS believes that these organisms would be appropriate for pre-chill performance standards for reprocessing on line.

Under provisions of the HACCP final rule, FSIS requires all poultry slaughter establishments to test carcasses for generic *E. coli* using an AOAC approved method of analysis to verify process control for fecal contamination. The rule establishes testing frequencies based on production levels. The HACCP final rule does not require establishments to conduct their own testing for *Salmonella*, but FSIS tests product and reports the results to establishments. FSIS has published guide books for sampling for both *E. coli* and *Salmonella* (footnotes 1 and 3 in § 381.94). The guidebooks are available in the Docket Room (See ADDRESSES) and on the FSIS web page at <http://www.fsis.usda.gov>. FSIS believes that establishments operating on-line antimicrobial reprocessing systems for pre-chilled carcasses should follow the guidelines for sample collection for the pre-chill pathogen reduction performance standards for *E. coli* and *Salmonella* in accordance with footnotes 1 and 3 in 9 CFR 381.94.

### Campylobacter

In 1999, the National Advisory Committee on Meat and Poultry Inspection requested that the National Advisory Committee for Microbiological Criteria for Foods evaluate options for defining a performance standard for *Campylobacter*. *Campylobacter* is the most frequent cause of bacterial foodborne illness in the United States. It is estimated that between 60 and 80 percent of chilled whole birds sampled at processing facilities are contaminated with the microorganism. The National Advisory Committee for Microbiological Criteria for Foods expressed concern in defining a *Campylobacter* standard, in part, because of the paucity of data on the relationship among *Campylobacter*, other microorganisms (e.g., *Salmonella* and generic *E. coli*), and poultry. For example, there are no available on-farm or slaughter intervention strategies designed to eliminate *Campylobacter*, and a new method developed by the Agricultural Research Service to detect

and quantify *Campylobacter* has not yet been fully assessed and compared against the current method used by FSIS. Consequently, FSIS believes that there are insufficient data to establish a performance standard for *Campylobacter* as part of this proposed rulemaking for on-line antimicrobial reprocessing of pre-chill poultry carcasses. However, FSIS is interested in establishing such a standard for this pathogen and is seeking comment and data regarding this issue.

#### Alcide's Petition for Acidified Sodium Chlorite

In January 1999, FSIS granted interim approval to the Alcide Corporation of Redmond, Washington, to permit the use of Sanova™ equipment using acidified sodium chlorite as an antimicrobial treatment for reducing microbial levels on raw poultry carcasses. The Agency's approval did not extend to the use of the equipment and acidified sodium chlorite for on-line reprocessing of contaminated poultry. FSIS stated in the January 1999 letter that it would eventually add the substance to the chart specifying the food ingredients approved for use in the preparation of meat and poultry products under the heading "Antimicrobial agents" for pre-chilled poultry carcasses at § 424.21(c).

In November 1999, FSIS received a petition from Alcide requesting that the Agency conduct rulemaking to approve the use of its Sanova™ continuous on-line processing (COP) system, which uses acidified sodium chlorite as an antimicrobial treatment for on-line reprocessing of contaminated poultry. The process can be used in conjunction with an IOBW, but an IOBW is not a requirement of the system. The COP system features a spray cabinet to deliver an antimicrobial treatment of acidified sodium chlorite (500 to 1200 ppm sodium with citric acid) to poultry carcasses before the carcasses are chilled.

FSIS intended to initiate rulemaking to amend the chart to include acidified sodium chlorite until a recent final rule (64 FR 72168) and a Memorandum of Understanding with the Food and Drug Administration (FDA) on the listing of food ingredients (MOU; FDA/FSIS Regarding the Listing of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products, January 2000) were issued. The documents provide that FDA will list in its regulations in title 21 of the Code of Federal Regulations (CFR) all food ingredients and sources of radiation that are safe for use in the production of meat and poultry

products. FSIS, through a separate rulemaking activity, intends to delete the chart in § 424.21(c), and the contents of the chart will be appended to 21 CFR. Meanwhile, FDA amended its food additive regulations to provide for the safe use of acidified sodium chlorite as an antimicrobial agent in the processing of red meat carcasses (63 FR 11118), on red meat parts and organs (65 FR 1776), in poultry processing (64 FR 26841), and on poultry carcass parts (65 FR 16312).

Alcide also requested that any regulatory proposal on performance standards for on-line reprocessing of poultry be deferred until FSIS has had the opportunity to evaluate Alcide's petition. The Agency has reviewed Alcide's petition and the accompanying data. The Agency's review of the test results from Alcide indicates that the COP system achieves an average reduction in *Salmonella* prevalence of 27.27 percent, and an average reduction of *Campylobacter* prevalence of 25.6 percent. Alcide's samples were fresh and chilled, not frozen. Of the 1,070 post-COP treated carcasses sampled in the five establishments, an average of 34 percent were negative for *E. coli*, and 66 percent were positive. Assuming that 10 or fewer cells of *E. coli* are considered as a limit of detection, the estimated prevalence in the sampling is 26.4 percent. If the samples were frozen, Alcide estimated that freezing would reduce the number of organisms in a sample by 1 log<sub>10</sub> (i.e., 90 percent) resulting in only 5.4 percent of the samples having a count greater than 10.

Unlike the Rhodia data that were quantitative and focused on absolute levels of reduction (i.e., less than 0.5 percent of the treated samples were positive for *Salmonella*), Alcide's data documented degrees of reduction (i.e., there was an average reduction by 27.27 percent of the prevalence of *Salmonella* on the treated samples). Alcide's data appear to document statistically significant food safety enhancements achieved at the five test establishments, without establishing specific numerical performance standards as Rhodia did through its petition. Therefore, at this time, the Agency has not been able to equate the results of the data from the two petitions. Nonetheless, because the Agency has decided to go forward with this rulemaking, it has granted the Alcide petition, in part, except for the company's request to use non-quantitative performance standards. FSIS is seeking public comment on performance standard levels and hopes to receive further data that are relevant to this issue. It also seeks comment on

whether it is possible to equate the Rhodia and Alcide data.

#### National Chicken Council Data

Meanwhile, a third set of data was submitted to the Agency by the National Chicken Council (NCC). The NCC conducted testing in five establishments regarding the commercial application of TSP. The NCC data, like the Rhodia data, show that on-line antimicrobial reprocessing is superior to off-line reprocessing, and that the prevalence of *E. coli* and *Salmonella* can be reduced considerably. In contrast to the Rhodia data, however, the NCC data show that freezing the samples has an impact on the prevalence and counts of *E. coli* and results in lower numbers. Although the prevalence of *Salmonella* was lower in frozen samples than in refrigerated samples in the NCC study, the difference between frozen and refrigerated samples was not statistically significant. NCC asserted that its sampling (1,840 samples were analyzed for *Salmonella* spp, and 1,320 were analyzed for *E. coli*) demonstrated that the 0.5 percent pre-chill performance standard for *Salmonella* and the 1.0 percent pre-chill performance standard for *E. coli* were not achievable following TSP application in commercial operations.

NCC's study was conducted in four stages. Carcass rinses of whole birds were performed at three designated sites along the production line: pre TSP (post IOBW), post TSP, and post-chill. The sample types included "visually clean/no TSP," "visually contaminated/with TSP," and "visually contaminated/off-line reprocessed/no TSP." All carcass rinses were tested for the presence or absence of *E. coli* and *Salmonella* using validated rapid screening methods. Carcass rinses were kept chilled on wet ice or refrigerated until transported to the laboratory. Frozen samples were held on dry ice for 18 to 24 hours and thawed before setting. Positive results were confirmed biochemically and serologically.

Because the NCC data results are substantially different from the Rhodia data, the Agency is seeking comment on what should be the new pre-chill performance standards in order to balance public health benefits for consumers and achievable goals that encourage establishment participation. The Agency also is seeking comments on the issue of the effect freezing has on samples and any other aspects of the NCC data. The data are available in the FSIS Docket Room and on the FSIS web page.

The NCC data point out another factor. Currently, even in plants where

TSP or the Sanova system is in use, birds that are grossly contaminated, and then reprocessed off-line, enter the chiller without the TSP or Sanova treatment. This fact is significant because there is sometimes a higher prevalence of *Salmonella* in these plants post-chill than pre-chill. Thus, FSIS requests comment on whether it should include, as a condition for permitting on-line reprocessing, that all birds entering the chiller, including those reprocessed off-line, be treated with the antimicrobial intervention.

### Environmental Impact

There are increasing environmental concerns associated with the use of nutrients, particularly nitrogen, phosphorus, and potassium, in agricultural systems. In response to the growing body of evidence about the relationship among solid nutrient loadings, nutrient transport off-sites, and surface and ground water quality, USDA's Natural Resources Conservation Service (NRCS) and other Federal agencies have revised their policies for delivering nutrient management and issued new technical guidelines.

In agriculture, the greatest focus is on the inputs of nutrients in the form of fertilizers that exceed outputs of nitrogen and phosphorus in the form of crops and manure production. High densities of poultry plants in some areas in the United States have generated concerns about manure production exceeding the needs of crops to which the manure is applied. The density of animals on the land is directly related to nutrient flows to aquatic ecosystems.

In addition, there is a concern about the introduction of additional substances into the agricultural production process, particularly in view of NRCS's stated goal of reducing nutrients used in agricultural production. However, the waste water of the more than 80 poultry establishments that are engaged in on-line reprocessing operations with TSP is handled routinely by existing water treatment systems or recycled as by-products without entering the plant's systems, municipal water systems, or the ground water.

However, would establishments operating under more restrictive state environmental laws and regulations incur additional costs as a result of on-line reprocessing operations? Are such operations restricted in some States? FSIS would like the public to comment on the environmental impacts associated with on-line reprocessing operations.

### Request for Comments

FSIS has decided to publish this proposed rule and to solicit comments on the exact performance standard that it should adopt. Although the Agency is not now proposing specific performance levels, FSIS is giving the public an opportunity to comment on and provide data that would support adopting a particular performance level as the standard.

The Agency is aware that not all antimicrobial substances or processing systems for poultry pre-chill may be capable of attaining the pathogen reduction levels Rhodia claims to have achieved in its trials. FSIS is proceeding with this proposal because it considers pathogen reduction to be one of its primary goals, and data supplied to date appear to show significant improvements in the ability to reduce microbial contamination of poultry. FSIS remains open to considering other new technologies or treatments, and alternate standards, in developing a final rule. In recent years, trials with TSP and other substances have proliferated. FSIS would like to accommodate any technology that is safe and will significantly reduce the prevalence of *E. coli*, *Salmonella*, and other microorganisms on poultry carcasses pre-chill.

In developing an appropriate standard, the Agency believes that poultry contaminated with digestive tract contents must be held to a more rigid pathogen reduction standard than product that is not visibly contaminated because digestive tract contents are a source of pathogens and other microorganisms. Furthermore, physical removal of visible contamination does not necessarily remove significant levels of these pathogens and other microorganisms, as evidenced by the Rhodia trials involving off-line reprocessed pre-chill carcasses.

Persuasive data that support specific performance standards for on-line reprocessed visibly contaminated poultry pre-chill will be the basis for the final rule. The Agency would like public consideration of the following questions: Should the performance standards be based on organisms other than *E. coli* and *Salmonella*? What is the appropriate standard if chilled (*i.e.*, not frozen) samples are submitted for laboratory analysis?

It is important to emphasize that Rhodia used frozen, not chilled, laboratory samples in its in-plant trials. Data obtained by Rhodia on the effects of freezing whole carcass rinse samples indicated that there was no difference between frozen or chilled TSP treated

samples. All TSP treated samples were negative for *E. coli*, *Enterobacteriaceae*, and *Salmonella*. These results are based on a 2-day split sampling and testing study at a plant conducting on-line reprocessing using TSP. A copy of these results is available to the public for review in the FSIS Docket Room (See **ADDRESSES**). No data were obtained regarding frozen *Campylobacter* samples. *Campylobacter* cells are sensitive to freezing and generally die off when subjected to temperatures at or below freezing.

If adopted, the performance standards should not only significantly improve a single establishment's performance but also should lower the national baseline, compelling improvements in process control and pathogen reduction by all establishments. FSIS is interested in hearing from the poultry industry, industry-related organizations, the scientific community, academia, consumers, consumer groups, and other interested persons before developing a final rule.

### The Proposed Rule

FSIS is proposing to amend the poultry products inspection regulations at 9 CFR 381.91 by adding a new subsection (c) that would allow poultry carcasses contaminated with digestive tract contents during slaughter to remain on the main processing line along with uncontaminated carcasses for treatment with an antimicrobial agent before the chiller. FSIS also is proposing to amend the chart in 9 CFR 424.21(c) to extend the use of antimicrobial agents to pre-chill poultry carcasses.

Because FSIS is proposing to hold the visibly contaminated carcasses to more rigorous performance standards than apply to other birds, plants would need to establish verification and validation procedures as part of their HACCP system requirements. As part of the plant's on-going verification procedures, FSIS expects that plants will identify the visibly contaminated carcasses to distinguish them from the uncontaminated carcasses before the birds proceed down the processing line in order that the visibly contaminated carcasses can be sampled separately from the other birds after the treatment. Furthermore, FSIS expects that plants will identify an appropriate sampling frequency for verification as part of the HACCP system requirements.

In addition, in accordance with § 417.5(a)(1), establishments will need to include in their hazard analyses validating data, generated under conditions of in-plant commercial operations, demonstrating that the on-

line reprocessed contaminated poultry carcasses achieve the proposed pre-chill standards that FSIS adopts.

Establishments would establish critical control points for the use of the antimicrobial treatment based on the determinations that they make as part of their reassessment.

FSIS is not proposing to change the requirement in § 381.65(e) that carcasses contaminated with visible fecal material not enter the chilling tank or to change the finished product standards in § 381.76(b)(3). In addition, under the proposed regulation, on-line reprocessed carcasses, as well as the on-line non-contaminated carcasses, must comply with the criteria for verifying process control (*E. coli* testing) and with the pathogen reduction performance standards for *Salmonella* in accordance with § 381.94 of the poultry regulations.

The Agency emphasizes that this proposal would neither mandate on-line reprocessing by all establishments nor establish the use of specific equipment and antimicrobial aids to reprocess pre-chilled poultry carcasses on-line.

Finally, the Agency requests comments on amending the chart in § 424.21(c) to extend the use of trisodium phosphate to "pre-chill" poultry carcasses.

#### Cost of the Proposal

The economic impact of this rule is likely to be minimal because of the voluntary nature of the practice this proposal would authorize. An establishment will use on-line reprocessing if it is consistent with the objectives of the firm, conforms with plant configuration, provides increased efficiency in achieving product standards, improves product characteristics, and other factors. The poultry industry is highly competitive; an increase in product price by a single producer is likely to result in a loss of market share. A firm is not likely to purchase new equipment that will increase overall production costs or reduce profits.

The cost for a poultry plant to adopt an acceptable on-line reprocessing system will vary from plant to plant and will be contingent on the location, physical structure, and age of the plant and the adaptability of the equipment. Available information indicates that the capital cost per line ranges from \$10,000 to more than \$55,000, with an average cost of \$35,600, which is close to the manufacturer's estimate for a single line cost of \$30,000.

Operating costs associated with on-line reprocessing systems also can vary significantly as a result of plant size, number of lines, processing capacity,

plant configuration, and other factors. Rhodia estimates that the TSP application cost will be about 0.2 cents per pound for an average chicken slaughter plant. The application of other antimicrobial substances may vary slightly in cost. Plant data suggest that total annual operating costs, which include labor, water softener, TSP, and water, are very close to the manufacturer's estimate. Available information suggests annual operating costs of about \$125,000 per line for an average plant. Costs associated with off-line reprocessing would be expected to decline following installation of on-line reprocessing equipment because of reduced labor and other operating requirements. Available data suggest the decrease in operating costs because of reduced off-line reprocessing is about \$70,000 per line, somewhat more than half of the increase in operating costs associated with TSP on-line reprocessing. The available plant information suggests that about two-thirds of the plants would not experience any change in sewage treatment. The remaining third would be required to perform additional treatment at the plant to meet discharge limits. Two-thirds of the plants would show no change in water use, while the remaining plants will have to increase use by 1 to 2 gallons per bird, or about 10 percent.

For the average plant, the net present value of capital costs and the net change in operating costs of TSP on-line reprocessing is about \$1.2 million over a 10-year period using a discount rate of 7 percent. Based on the assumptions that the average plant processes about 200,000 birds per day, that an average bird has a dressed weight of 3.6 pounds, and the plant operates an average of 255 days per year over the next 10 years, the increase in total production costs is slightly more than .2 cents per pound. The capital costs amortized over a 10-year period are minimal on a per pound basis. The costs to the poultry processing industry would accrue to plants engaged in slaughter, either exclusively or in combination with processing. In 1996, there were 281 federally inspected plants of this description. Only one Federal-State cooperative inspection plant is currently engaged in poultry slaughter. If all such plants voluntarily install an on-line reprocessing system, the total cost to the poultry industry would be about \$345 million over a 10-year period.

The cost of a TSP on-line reprocessing system represents an insignificant portion of the retail price per pound of poultry. If there is any increase in the retail price of poultry, it will be modest

and offset by consumer confidence that the product presents lower microbial risks.

#### Cost Impact on Small Entities

The impact of the proposed rule on small establishments is likely to be minimal given that it is voluntary. A firm will adopt the practice if it is consistent with its objectives. The limited evidence available does not indicate that small firms would be at a disadvantage if on-line reprocessing were a uniformly accepted practice. The initial capital costs and net change in operating costs do not appear to be related to plant size. In addition, the magnitude of the costs, \$1.2 million over 10 years, would not represent a significant share of overall costs for small firms.

#### Request for Comments on Economic Impact

The Agency would like comment from the public and especially from poultry firms that are currently engaged in TSP or acidified sodium chlorite reprocessing on the costs presented in this document. Are the economic assumptions valid? Do the decreases in operating costs for reduced off-line reprocessing appear to be reasonable? The Agency expects that on-line reprocessing will provide establishments with considerable economic advantages related to cost savings gained from no longer having to reprocess birds off-line. What levels of savings would accrue to plants adopting on-line reprocessing operations? How much will the proposed new standards for *Salmonella* and *E. coli*, if implemented, contribute to higher costs for product sampling? If the pathogen reduction standards become tighter, can compliance costs be expected to increase? Because adopting on-line reprocessing is voluntary, the amounts of the increase are difficult to determine. FSIS also would like to hear from the public about whether the Agency should consider deleting the provisions for off-line reprocessing in § 381.91(b)(1) and (2) if on-line reprocessing is implemented. FSIS would like comments on the economic impact on both large and small establishments if such actions were taken.

#### Industrial Hygiene Survey

At the request of FSIS, because of concerns raised by in-plant inspectors, an industrial hygiene survey was conducted in 1999 by an independent firm to evaluate potential dermal, ocular, respiratory, or other exposure of inspectors to TSP while working with



TSP-treated poultry or around TSP treatment facilities. The study did not address TSP exposure to plant employees, whose job activities differ significantly from those of inspection employees. Based on interviews and observations of inspectors and sampling results, the risk of bodily contact with significant quantities of TSP solution is minimal for slaughter line inspectors. They are not present when the TSP solution is prepared and inspect and handle the birds prior to TSP application. This indicates no alkalinity, TSP contact, or dermal hazard. The survey results also show no respiratory or ocular hazard from ambient TSP dust or mist in the plant.

Other inspectors who perform a variety of tasks throughout the plant may come into contact with small quantities of TSP solution when conducting pre-chill finished product standard checks and Acceptable Quality Level (AQL) giblet checks. There is also the potential for transient ocular exposure. The survey recommends the mandatory use of safety glasses when performing activities where exposure to TSP occurs and PVC or natural rubber gloves when handling poultry post TSP application. It encourages the consideration of barrier creams on a voluntary basis, routine washing at signs of TSP solution contact, and awareness of emergency lavage for accidental eye contact. The study recommends that federally inspected establishments provide emergency eyewashes within a limited distance from TSP use areas and training regarding these recommendations.

Rhodia Inc. conducted a later study in June 1999 to monitor the effects of TSP exposure on both plant and inspection employees at four locations in 46 plants. The study concluded that there were no safety risks to either plant or inspection employees from exposure to TSP. Food Safety Benefits of On-line Reprocessing.

Scientific and public concern about microbiological contamination of poultry products has expanded from the processing of such products to conditions under which poultry are slaughtered to pre-slaughter poultry production. FSIS has encouraged the scientific community and the industry to develop slaughter and processing methods and treatments that would yield raw poultry products that are as free as practicable of pathogenic bacteria.

The use of TSP and other antimicrobial rinses would not eliminate the need for continued careful handling of raw poultry products. However, by allowing the visibly contaminated carcasses to remain on-

line, all carcasses are subject to further rinsing and antimicrobial treatment. The result will be lesser risks because of reduced pathogen prevalence on contaminated poultry carcasses. Not handling contaminated carcasses in off-line reprocessing may reduce the risk of foodborne pathogens from cross-contamination of the contaminated carcasses.

#### **Executive Order 12866**

FSIS has determined that this regulatory proposal is not a significant rule under Executive Order 12866 and, therefore, it has not undergone review by the Office of Management and Budget.

#### **Alternatives**

Executive Order 12866 requires that FSIS identify and assess alternative forms of regulation. FSIS considered two alternatives to this proposed rule: (1) Not proposing to allow for the on-line reprocessing of contaminated carcasses and (2) proposing to require plants to perform on-line reprocessing of pre-chill contaminated carcasses and establishing specific numerical performance standards that the reprocessed poultry must meet using a mandated antimicrobial treatment or process. FSIS rejected both alternatives for the reasons explained below.

#### **Failing To Propose**

FSIS is committed to reducing the levels of microbial pathogens in poultry products. On-line reprocessing of poultry in commercial trials using solutions of TSP/chlorine and acidified sodium chlorite has been shown to be a highly effective method of reducing the microbial levels of raw poultry to levels substantially below the performance standards and criteria established by the pathogen reduction/HACCP final rule.

#### **Mandating Procedures, Materials, and Methods**

FSIS is proposing to give all establishments the option of adopting on-line reprocessing of visibly contaminated birds. By not mandating that all plants adopt on-line reprocessing, FSIS is recognizing that there are other solutions to reducing bacterial loads that may be more appropriate and cost-effective for small plants. There are many possible solutions for pathogen reduction of raw poultry and poultry products, and the industry continues to seek out new products and equipment that will be effective.

Pathogen reduction is central to the FSIS food safety strategy. However,

eliminating as many prescriptive or command-and-control regulations as possible also is an important part of the overall strategy for updating and improving inspection in light of HACCP. Therefore, there will be no mandate proposed for establishments to use TSP or any other substance as the antimicrobial reprocessing aid.

Various substances have undergone trials to determine their potential as antimicrobial processing agents. Such substances include acidified sodium chlorite; organic acids such as lactic, acetic, and formic acids; chlorine dioxides; and ozone. Plants will be free to use other products that have demonstrated their efficacy in reducing levels of microorganisms in in-plant commercial trials. This is consistent with the Agency's strategy of encouraging the industry to take advantage of new technology to reduce the risks associated with the consumption of meat and poultry products.

#### **Executive Order 12988**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule would provide for the on-line reprocessing of poultry carcasses accidentally contaminated with digestive tract contents during slaughter.

States and local jurisdictions are preempted under the PPIA from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different from, those imposed under the PPIA. States and local jurisdictions also are preempted under the PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected poultry products that are in addition to, or different than, those imposed under the PPIA. States and local jurisdictions, however, may exercise concurrent jurisdiction over poultry products that are misbranded or adulterated under the PPIA or, in the case of imported products, which are not at such an establishment after their entry into the United States. States and local jurisdictions also may make requirements or take other actions that are consistent with the PPIA, with respect to any other matters regulated under the PPIA.

Under PPIA provisions, States that maintain poultry inspection programs must impose requirements on State inspected products and establishments that are at least equal to those required under the PPIA. These States, however, may impose more stringent



requirements on such State-inspected products and establishments.

#### Additional Public Notification/Request for Comments

FSIS has considered the potential civil rights impact of this proposed rule on minorities, women, and persons with disabilities. FSIS anticipates that this proposed rule will not have a negative or disproportionate impact on minorities, women, or persons with disabilities. However, proposed rules generally are designed to provide information and receive public comments on issues that may lead to new or revised Agency regulations or instructions. 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 proposed rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update.

FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to more than 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

FSIS has reviewed the paper and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Establishments choosing to reprocess poultry on-line using an antimicrobial treatment before the chiller will need to do so in accordance with 9 CFR Part 417. Accordingly, establishments will reassess their HACCP plans as

prescribed in § 417.4(a)(3). Also, in accordance with § 417.5(a)(1), establishments will need to generate and maintain validating data, generated under conditions of in-plant commercial operation, demonstrating that the reprocessing substance or system resulted in product that meets any performance standard that FSIS adopts. Based on the determinations establishments make as part of their reassessments, they may establish critical control points for the use of the antimicrobial treatment.

*Estimate of Burden:* The Agency estimates that it will take 8 hours for establishments to reassess their HACCP plans and to prepare the validating data they will include in their hazard analysis. For purposes of this paperwork analysis, FSIS will assume that all establishments will establish a critical control point for the use of the antimicrobial treatment. Accordingly, an establishment will spend about 5 minutes a day (250 days) completing one monitoring record and 2 minutes a day filing the record for one HACCP plan.

*Respondents:* Meat and poultry product establishments.

*Estimated Number of Respondents:* 80.

*Estimated Number of Responses per Respondent:* 1 for HACCP reassessment; 250 for monitoring records, and 250 for filing the record.

*Estimated Total Annual Burden on Respondents:* 2,974.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, FSIS, USDA, Room 109 Cotton Annex Building, Washington, DC 20250-3700.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the method and assumption used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who respond, including through use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Mr. Puricelli at the address above and to the Desk Officer for Agriculture, Office of Information and Regulatory

Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

#### List of Subjects in 9 CFR Parts 381 and 424

Poultry and poultry products.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR part 381 as follows:

#### PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for 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.

2. Section 381.91 would be amended by adding paragraph (c) to read as follows:

##### § 381.91 Contamination.

\* \* \* \* \*

(c) In lieu of the provisions in paragraph (b) of this section, any poultry carcass contaminated during slaughter with digestive tract contents may remain on the main processing/slaughter line and be reprocessed while on-line through use of an antimicrobial technique, in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter. Validating data, generated under conditions of in-plant commercial operations, must demonstrate that the visibly contaminated carcasses that are reprocessed on-line meet the pre-chill performance standard of \_\_\_\_\_. Birds whose entire carcass is contaminated by digestive tract contents under paragraph (b)(1) of this section or birds that have been mutilated under paragraph (a) of this section may not remain on the main processing/slaughter line and may not be reprocessed using the on-line antimicrobial technique.

#### PART 424—PREPARATION AND PROCESSING OPERATIONS

3. The authority citation for 9 CFR part 424 continues to read as follows:

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

4. The table in § 424.21(c) would be amended by adding an entry for "Antimicrobial agents for use as secondary additives" after the entries for "Antimicrobial agents" to read as follows:

##### § 424.21 Use of food ingredients and sources of radiation.

\* \* \* \* \*

(c) \* \* \*

Class of substance	Substance	Purpose	Products	Amount
* Antimicrobial agents for use as secondary additives.	* Trisodium phosphate .....	* To reduce microbial levels during reprocessing.	* Raw, chilled or pre-chilled poultry carcasses.	* 8 to 12%; in conjunction with a water spray containing 20 ppm chlorine; solution to be maintained between 45–55°F after chilling and applied by spraying chilled or pre-chilled carcasses for up to 15 seconds in accordance with 21 CFR 182.1778.
*	*	*	*	*

\* \* \* \* \*

Done at Washington, DC, on: November 22, 2000.

**Thomas J. Billy,**

*Administrator.*

[FR Doc. 00–30497 Filed 11–30–00; 8:45 am]

**BILLING CODE 3410–DM–P**

## DEPARTMENT OF ENERGY

### Office of Energy Efficiency and Renewable Energy

#### 10 CFR Part 430

[Docket Number EE–RM/STD–00–550]

**RIN 1904–AB08**

#### Energy Conservation Standards for Distribution Transformers

**AGENCY:** Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Proposed rule; notice of extension of comment period.

**SUMMARY:** On October 6, 2000, the Department of Energy (DOE or Department) published a Notice of public workshop and availability of the Framework Document for Distribution Transformer Efficiency Standards. 65 FR 59761. The document announced that December 1, 2000, would be the closing date for receiving public comments and information on the matters addressed in the Framework Document and on other matters relevant to consideration of energy conservation standards for distribution transformers. On November 1, 2000, during the public workshop on the energy efficiency rulemaking process for distribution transformers, several stakeholders requested that the comment period be extended. The Department agrees to extend the

comment period closing date until January 16, 2001.

**DATES:** Comments must be received on or before January 16, 2001.

**ADDRESSES:** Written comments are welcome. Please submit written comments to: Ms. Geraldine Paige, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, “Energy Conservation Program for Consumer Products: Energy Conservation Standards for Distribution Transformers, Docket No. EE–RM/STD–00–550”, EE–41, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Telephone: (202) 586–9130; Telefax: (202) 586–4617. You should label comments both on the envelope and on the documents, and submit them for DOE receipt by January 16, 2001. Please submit one signed copy and a computer diskette (WordPerfect 8) or 10 copies (no telefacsimiles). The Department will also accept electronically-mailed comments, by e-mail to [Geraldine.Paige@ee.doe.gov](mailto:Geraldine.Paige@ee.doe.gov), but you must supplement such comments with a signed hard copy.

**FOR FURTHER INFORMATION CONTACT:** Carl Adams, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE–41, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9142, e-mail: [carl.adams@ee.doe.gov](mailto:carl.adams@ee.doe.gov), or Edward Levy, Esq., U.S. Department of Energy, Office of General Counsel, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9507, e-mail: [Edward.Levy@hq.doe.gov](mailto:Edward.Levy@hq.doe.gov).

Issued in Washington, DC, on November 27, 2000.

**Dan W. Reicher,**

*Assistant Secretary Energy Efficiency and Renewable Energy.*

[FR Doc 00–30641 Filed 11–30–00; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### 12 CFR Part 8

[Docket No. 00–29]

**RIN 1557–AB90**

#### Assessment of Fees; National Banks; District of Columbia Banks

**AGENCY:** Office of the Comptroller of the Currency, Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Office of the Comptroller of the Currency (OCC) proposes to amend its assessment regulation to clarify that the OCC has authority to charge a national bank when the OCC conducts a special examination of a third party that provides services to the bank. The proposal applies in the same way to a District of Columbia bank and to a Federal branch or agency.

**DATES:** Comments must be received by January 2, 2001.

**ADDRESSES:** Please direct your comments to: Communications Division, Office of the Comptroller of the Currency, 250 E Street, SW., Third Floor, Washington, DC 20219, Attention: Docket No. 00–29; Fax number (202) 874–5274 or Internet address: [regs.comments@occ.treas.gov](mailto:regs.comments@occ.treas.gov). Comments may be inspected and photocopied at the OCC’s Public Reference Room, 250 E Street, SW., Washington, DC, between 9 a.m. and 5 p.m. on business days. You can make an appointment to inspect comments by calling (202) 874–5043.

**FOR FURTHER INFORMATION CONTACT:** Mitchell E. Plave, Senior Attorney, Legislative and Regulatory Activities Division, (202) 874–5090.