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April 2, 2001

FSIS Docket Clerk  
Room 102  
Cotton Annex Building  
300 12<sup>th</sup> Street SW  
Washington, DC 20250-3700

98-062P  
98-062P-10  
James T. Elfstrum

**Re: Docket No. 98-062P - Performance Standards for On-Line Antimicrobial Reprocessing of Pre-Chill Poultry Carcasses**

Dear Sir or Madam:

Rhodia Inc. submits these comments, in triplicate, in response to the above referenced proposed rule of the Food Safety & Inspection Service (FSIS) published in the *Federal Register* on December 1, 2000. 65 FR 75187 et. seq. FSIS proposes to amend its poultry products inspection regulation to allow, on a voluntary basis, the on-line reprocessing of pre-chill carcasses that are accidentally contaminated with digestive tract contents during slaughter.

In submitting these comments, it is Rhodia's intention to strongly support FSIS's proposal to allow such on-line reprocessing of accidentally contaminated pre-chill carcasses, and to urge the adoption of meaningful, numerical quantitative pre-chill performance standards, which must be continually met to utilize such voluntary on-line reprocessing. Rhodia also urges FSIS to clarify and adopt in the final rule the use of an FSIS approved antimicrobial agent for all reprocessing operations, whether on-line or off-line. On-line reprocessing provides significant economic and other benefits to the poultry processing industry. Likewise, use of the current best available, commercially achievable technology for on-line reprocessing can achieve pathogen reduction incidence rates for *Salmonella* and *Escherichia coli* that are substantially lower than the current post-chill performance standard and process control criterion for those organisms.

Rhodia strongly believes that FSIS's goals of continuing to achieve meaningful reduction in pathogens on raw poultry and of further minimizing the risk of foodborne illness to the consuming public will not be greatly enhanced without requiring pre-chill performance standards which the current best available on-line reprocessing technology has demonstrated to be commercially and economically achievable under poultry plant operations. Adoption of significantly low, achievable, numerical pre-chill performance standards will assure pathogen reduction and reduce the risk of foodborne illness to the consumer. Conversely, basing such pre-chill performance standards on achieving a percentage degree of pathogen reduction on an individual plant incidence rate will not guarantee that a significant overall national reduction in the pathogen will occur, or that an overall national decrease in risk of foodborne illness **will**



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occur. Compliance with such an imprecise standard would be difficult, at best, from an enforcement standpoint, and the lack of national uniformity of such a standard would be confusing to both the industry and the consuming public.

As will be shown in greater detail later in these comments, Rhodia has developed an overwhelming database from conducting pre-chill on-line reprocessing operations in more than 80 poultry slaughter plants during the past several years which show that the use of current available technology can reduce pathogens to levels substantially lower than the current national plant average reported by FSIS. Consequently, based on its experience with current achievable technology, and based on data from operating on-line reprocessing systems adjusted to meet FSIS's preferred sampling methodology, Rhodia believes overwhelming data exists for establishing specific pre-chill performance standards based on utilizing post-chill chilled sampling techniques which must be met for the voluntary utilization of on-line poultry reprocessing of a 5% incidence rate for *Salmonella* and a 5% incidence rate for *E. coli* (equal to or greater than 10 cfdml). Stated another way, 95% of samples tested for *Salmonella* presence should be negative and 95% of samples tested for *E. coli* presence should have counts less than 10 cfdml. It has been demonstrated that such pre-chill performance standards for poultry on-line reprocessing can be achieved under conditions of current poultry plant operations using safe and economical technology. For that reason, to establish any less effective performance standards would unnecessarily expose the consuming public to greater risk of foodborne illness, and would undermine FSIS's mission to upgrade the safety profile of meat and poultry products.

## I. Rhodia Experience with Antimicrobial Treatments and On-line Reprocessing

### A. FSIS Antimicrobial Use Approval for TSP

Rhodia, Inc., based in Cranbury, New Jersey is a large specialty chemical company whose primary business focus is on the production and marketing of basic chemical and basic food grade ingredients for a variety of industrial and commercial applications, including food uses. Over the years, Rhodia, Inc., and its predecessor companies, Rhone-Poulenc, Inc. and Stauffer Chemical Company (hereinafter referred to collectively as Rhodia), have devoted considerable resources to developing effective antimicrobial treatments, especially for use with meat and poultry products. In particular, during the late 1980s trisodium phosphate (TSP) was found in laboratory trials to have great efficacy against a number of pathogens common to meat and poultry. TSP is a common and safe food ingredient listed by the Food and Drug Administration as a substance generally recognized as safe for multipurpose food uses at 21 CFR 182.1778. Given its potential as an effective antimicrobial for meat and poultry applications, Rhodia worked closely with the industry and FSIS to test such application in a number of meat and poultry plants pursuant to FSIS mandated protocols. Rhodia then sought approval from



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FSIS for several specific uses of TSP as an antimicrobial agent for meat and poultry applications as follows:

- Post-Chill Poultry Carcasses--Based on multi-plant trial data which indicated that *Salmonella* incidence rates were reduced from 17% to less than 1%, that *E. coli* incidence rates were reduced from **94%** to less than 11%, and that similar reduction were achieved for coliforms, *Enterobacteriaceae*, and Aerobic Plate Counts, Rhodia petitioned **FSIS** for approval of use of TSP as an antimicrobial agent on post-chill carcasses. In **1992**, FSIS's Administrator granted interim approval for such use, and on July **29, 1996, (61 FR 39273)**, FSIS amended the poultry products regulation to add a new category of "Antimicrobial agents" to the table in what is now current section **424.21(c)** of the regulations, listing TSP **as** such an agent for use on raw, chilled poultry carcasses;
- Raw, Unchilled Poultry Carcasses--Following commercial plant trials conducted pursuant to FSIS developed protocols, data showed that incidence rates of *Salmonella* were reduced from an average level of **25%** to less than 1%, that incidence levels **of E. coli** of more than **78%** were reduced to below the level of detection, and that similar significant reductions were achieved in Aerobic Plate Counts, *Cumylobacter* and *Enterobacteriaceae* following pre-chill TSP treatment. Rhodia petitioned, and received interim approval from the FSIS Administrator in **1994**, for use of TSP as an antimicrobial agent on pre-chill poultry carcasses;
- Raw, Unchilled Poultry Giblets--Based on commercial plant trials in conformity with FSIS approved protocols which showed similar antimicrobial efficacy as in the above referenced whole carcass trial, in **1994** Rhodia petitioned, and FSIS's Administrator granted interim approval, for the use of TSP as an antimicrobial agent on raw, unchilled giblets;
- Raw Beef Carcasses--Based on commercial plant trials conducted in accordance with FSIS approved protocols that showed significant reductions in a number of organisms following **TSP** treatment, in **1995** Rhodia petitioned, and FSIS granted interim approval, for the use of TSP on raw beef carcasses as an antimicrobial agent.

The FSIS interim approvals for pre-chill poultry carcasses, pre-chill poultry giblets, and raw beef carcasses for use of TSP as an antimicrobial agent are noted, since the proposed rule neglects to recite these previous TSP approvals.



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All supporting data for the above-referenced four petitions were submitted to **FSIS** and are publicly available through the agency. Therefore, due to the voluminous nature of the data, it is not attached to these comments, although copies of each petition, which contain a *summary* of multi-plant trial data, and each interim approval letter are attached hereto as Attachment 1.

## **B. On-Line Reprocessing Plant Data and Approval**

Based on continued efficacy shown in laboratory experimentation and its promise for commercial poultry plant operations, Rhodia worked closely with **FSIS** to develop a system acceptable to the agency for the purpose of conducting on-line reprocessing trials on less than grossly contaminated pre-chill carcasses in poultry slaughter plants. In 1997, **FSIS** granted Rhodia approval to conduct such an on-line reprocessing trial pursuant to an FSIS mandated protocol. Briefly stated, the trial allowed carcasses visibly contaminated, but not grossly contaminated with digestive tract contents, that would otherwise be required to be removed ~~from~~ the line and reprocessed off-line, to remain on-line and be reprocessed using a TSP antimicrobial treatment. During the trial, three sets of samples were to be taken: one set of samples of non-visibly contaminated "normal" carcasses randomly selected from the line, but without being subjected to the on-line TSP antimicrobial reprocessing treatment; one set of samples of previously identified visibly contaminated carcasses, which were allowed to remain on-line and to be subjected to the TSP on-line antimicrobial reprocessing treatment; and one set of samples of carcasses obtained following traditional off-line reprocessing methods. In accordance with the FSIS mandated protocol, all samples were maintained with dry ice for shipment and until analysis at an independent laboratory, utilizing AOAC/BAM analytical methods.

Since FSIS's on-line reprocessing rule describes the Rhodia trial requirements and operating parameters in detail, and since attachments to these comments and other documents on file and available for public inspection at **FSIS** provide full and complete information, Rhodia will not describe in detail the trial processes and procedures, but will concentrate on the trial results in these comments.

Data from the five plant trials submitted by Rhodia in support of its petition clearly demonstrated that an on-line reprocessing system could meet and exceed the rigorous pathogen reduction measurement requested in the petition to allow a plant to voluntarily implement on-line reprocessing. The five plant trial data submitted in support of Rhodia's petition summarized results of more than 1500 samples from each sampling site of "normal" on-line carcasses, of TSP on-line reprocessed carcasses, and ~~of~~ traditional off-line reprocessed carcasses. Rhodia's independent analytical laboratory results of cumulative average *Salmonella* incidence rates for carcasses following TSP on-line



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reprocessing were less than 0.1%, while “normal” on-line processed carcasses averaged an incidence rate of **30%** and traditional off-line reprocessed carcasses averaged a 22% incidence rate. Sampling showed that visibly contaminated carcasses allowed to be reprocessed on-line by TSP resulted in less than a **1%** cumulative average incidence rate for *E. coli*, while “normal” on-line processed carcasses had an average incidence rate of 97%, and traditional on-line reprocessed carcasses had an average incidence rate of **72%**. TSP on-line reprocessing reduced cumulative average *Enterobacteriaceae* incidence rates to 1% while average incidence for “normal” on-line carcasses was 98%, and the average incidence rates was 81% for traditional off-line reprocessed carcasses. Average number of Aerobic Plate Counts showed a greater than 1 log reduction following TSP on-line reprocessing than “normal” processed on-line carcasses, and a greater than 0.5 log reduction in average **APC** numbers than traditional off-line reprocessed carcasses. Further, although only minimal *Campylobacter* testing was conducted during the trials, results did show that TSP on-line reprocessing results in a statistically significant reduction of greater than 40% in *Campylobacter* incidence rates.

Following the completion of trials in five commercial poultry slaughter plants which developed consistent data showing that the TSP on-line reprocessing treatment system results in significant pathogen reductions on pre-chill poultry slaughter carcasses, on September 18, 1998, Rhodia petitioned FSIS to amend 9 CFR 381.91 of the poultry products regulations to allow on-line reprocessing of poultry carcasses under certain conditions. Specifically, the petition requested FSIS to allow on-line reprocessing through the application of a substance or processing system to accidentally contaminated, but not grossly contaminated, carcasses, “where such substance or system has demonstrated exceptional pathogen reduction characteristics under in-plant commercial operations by reducing pre-chill incidence rates of *Salmonella* to less than **0.5%** and by reducing pre-chill incidence rates for *E. coli* to less than 1%.”

Following its review of the petition and the above-referenced data from Rhodia’s five plant trials, on March 27, 1999, FSIS granted Rhodia’s petition, but withheld pending rulemaking the determination of appropriate performance standards to be required with the use of on-line reprocessing. A copy of Rhodia’s petition requesting FSIS to amend its regulations to allow poultry on-line reprocessing, along with all data generated during the five commercial plant trials supporting the petition request, is enclosed as Attachment 2 hereto.

Based on results from the initial plant trial demonstrating dramatic reductions in a number of pathogens due to TSP on-line reprocessing treatment, FSIS granted Rhodia’s request to conduct TSP on-line reprocessing trials at additional slaughter plants to develop further data under commercial operating conditions.



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### C. On-Line Reprocessing Data From More Than 80 Continuing Plant Operations

Based on the tremendous efficacy shown in reducing the incidence of pathogens on pre-chill poultry carcasses through the use of **TSP** on-line reprocessing, pending petition review and rulemaking, Rhodia requested and received permission from FSIS to continue on-line reprocessing and the collection of data at the initial five plants, and to initiate further trials at other interested plants. Due to tremendous industry interest, Rhodia subsequently implemented plant trials, followed by continuing operation and data collection of the TSP on-line reprocessing system, in more than 80 slaughter plants **with** such operations continuing through the date of submission of these comments. Each of these plant trials and continuing on-line reprocessing operations have been, and are being, conducted in accordance with the original **FSIS** mandated on-line reprocessing protocol, including TSP operating parameters and sampling methodology as directed by the protocol and FSIS in separate documents. A cumulative *summary* of all data generated from TSP pre-chill on-line reprocessing operations at each of the more than 80 poultry slaughter plants is enclosed as Attachment **3**.

More than 15,000 individual samples were obtained in the ongoing TSP on-line reprocessing operations at more than 80 commercial poultry slaughter plants. The samples were taken in conformity with **FSIS's** mandated sampling protocol, which required maintaining them on *dry* ice, and analyzing them in accordance with AOAC/BAM analytical methods. **An** independent laboratory analyzed all samples. A collective, cumulative analysis and average of the total plant data generated from TSP on-line pre-chill reprocessing as of the date of these comments can be summarized **as** follows:

- **Salmonella** average incidence rates of visibly contaminated carcasses are reduced to 0.5% after TSP on-line reprocessing, versus 19% average incidence rates for "normal" untreated on-line not visibly contaminated carcasses;
- **E. coli** average incidence rates (equal to or greater than 10 cfu/ml) are reduced to **2%** on visibly contaminated carcasses following TSP on-line reprocessing, while average incidence rates for untreated not visibly contaminated "normal" on-line carcasses are 88%.

It should be noted that **Campylobacter** testing was not included as a part **of** these trials, primarily due to the tremendous cost associated with sampling for that organism. As mentioned earlier, Rhodia has conducted some smaller scale efficacy testing of TSP on-line reprocessing on **Campylobacter** which shows a statistically significant incidence rate



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reduction in the organism due to TSP on-line reprocessing. Rhodia agrees that further *Campylobacter* testing is warranted prior to the establishment of an on-line reprocessing performance standard for *Cumpylobacter*, and pledges to work with FSIS to develop such data.

#### **D. Action Warranted By Multi-Plant Trial Results**

The amount of data generated by Rhodia from TSP on-line reprocessing operations in more than 80 poultry slaughter plants set out in attachment 3 and summarized above is overwhelming. These data clearly and convincingly show that on-line reprocessing is a tremendous tool for dramatically reducing the incidence of pathogens during pre-chill poultry slaughter operations, which should also greatly reduce the risk of foodborne illness to the consuming public. It is important to note that the pathogen reduction results achieved by Rhodia have been consistent at all plants from plant start-up through the initial plant trial phase and during continuing plant operations, which have been ongoing for years in many of the plants. The results clearly indicate that on-line reprocessing, using the best available technology, can achieve reductions in the incidence of pathogens which are much less than the present FSIS required post-chill pathogen reduction performance standard and process control verification criteria for *Salmonella* and *E. coli*, respectively. These data demonstrate, not only the value of on-line reprocessing to significantly improve the microbiological profile of carcasses requiring reprocessing, but also the significant added pathogen reduction which occurs by subjecting all "normal" carcasses to an on-line antimicrobial treatment.

During the past several years, USDA has made improvements in food safety one of its top priorities. Emphasis has been placed on pathogen reduction to reduce the risk of foodborne illness to the meat and poultry consuming public. Implementation of HACCP systems, containing inherent food safety safeguards, has been mandated for meat and poultry plants. In keeping with these efforts, FSIS's objectives and the aforementioned pathogen reductions achievable through the use of on-line reprocessing justify FSIS allowing the process in the poultry products regulations.

Since on-line reprocessing is consistent with FSIS's goals and objectives, the larger question is what conditions or standards should be adopted in allowing on-line reprocessing in poultry slaughter plants. Based on the data generated in its numerous and continuing TSP on-line operations, Rhodia strongly urges FSIS to adopt pre-chill numerical quantitative performance standards for specified pathogens with which plants must demonstrate compliance when utilizing on-line reprocessing. Extensive data from Rhodia's on-line reprocessing trials using frozen samples, as per the FSIS mandated protocol, indicates that available technology can achieve average incidence rates that justify FSIS establishing pre-chill performance standards of an incidence rate of no more



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than 2 percent for *Salmonella* and not more than 3 percent for *E. coli* (equal to or greater than 10 cfidml) for poultry plants voluntarily operating on-line reprocessing systems. These performance standards are based on utilizing the sampling methodology mandated by FSIS in Rhodia's on-line reprocessing trials, i.e., maintaining samples on dry ice following sampling until the time of analysis. Rhodia's on-line reprocessing trial data has authoritatively demonstrated that such performance standards can be met by available technology that is safe, cost effective, and readily adaptable to modern poultry slaughter plant operations.

In the alternative, FSIS requested comments on performance standards using a sampling methodology different than that mandated for Rhodia's on-line reprocessing trial protocol, i.e., maintaining samples utilizing water ice rather than dry ice prior to laboratory analysis. As will be explained in greater detail later in these comments, as requested by FSIS, Rhodia conducted additional on-line reprocessing sampling utilizing water ice chilling of samples which indicate that some adjustment in the performance standard above suggested for the use of frozen (dry ice) sampling would be in order. Consequently, utilizing the testing methodology presently specified by FSIS for post-chill HACCP compliance would indicate a slight upward adjustment in on-line reprocessing pre-chill performance standards for *Salmonella* incidence to 5% and to 5% for *E. coli* (equal to or greater than 10 cfidml) incidence rate.

Again, Rhodia urges FSIS to adopt the lowest achievable quantitative numerical performance standards, regardless of the sampling methodology mandated. Such standards are consistent with FSIS's pathogen reduction efforts, and will insure that individual plant averages and the national baseline averages for specific pathogens will continue to decline. Should FSIS, however, establish pre-chill reprocessing performance standards on some basis other than the lowest achievable numerical quantitative standards, such as a minimum percentage decrease in incidence of particular pathogens as some have suggested, progress on further pathogen reduction would likely be inhibited at worst, or stalled at best. Such weak and nebulous performance standards would eliminate incentives to develop better and more effective antimicrobial technologies, and could actually provide incentives to some companies to use less effective pathogen reduction systems, thereby reversing the impressive nationwide reduction in average plant pathogen incidence rates that FSIS recently reported. But, perhaps the strongest rationale for adopting numerical quantitative pre-chill reprocessing performance standards is to fulfill FSIS's responsibilities to the consuming public to ensure the maximum reasonably achievable safety of meat and poultry products, and to minimize as much as possible the risk of foodborne illness. This sacred responsibility will be achieved by adopting the strongest possible performance standards demonstrated to be achievable under commercial poultry plant operating conditions by practical, usable and economical





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technology. We believe the above recommended pre-chill performance standards meet this test.

In summary, data is clear and overwhelming to support FSIS amending its poultry processing regulation to allow the on-line reprocessing of carcasses visibly contaminated, but not grossly contaminated, with digestive tract contents. Rhodia agrees with FSIS's indication that pre-chill pathogen performance standards should be established and complied with by plants choosing to voluntarily employ on-line poultry reprocessing. Rhodia further strongly recommends that such pre-chill performance standards be established at levels significantly lower than the present post-chill HACCP pathogen reduction performance standard and process control verification criteria. The standards should be numerical, quantitative standards set at least at the pathogen control levels we have recommended above, levels which have been demonstrated to be achievable by the best available current technology that is practically and economically adaptable by the industry. The balance of these comments will address specific questions raised by the proposed rule, respond to FSIS's requests for comment, and provide further details regarding Rhodia's position in reference to the proposed rule.

## **II. Establishing Pathogen Reduction Standards for On-Line Reprocessing**

On page 75190 of the *Federal Register* the proposed rule discusses FSIS's intention to adopt pre-chill microbial performance standards that on-line reprocessing establishments would be required to meet. FSIS specifically requests comments, supported by data, on the topic.

Again, Rhodia wholeheartedly endorses allowing on-line reprocessing of visibly, but not grossly, contaminated poultry carcasses to be reprocessed on-line. The numerous data developed by Rhodia in extensive on-line reprocessing plant trials and subsequent continuing operations clearly indicate that allowing such carcasses to remain on-line does not create a health **risk**, but, rather allows a properly controlled antimicrobial reprocessing treatment system, such as that utilizing TSP, to greatly reduce the incidence of pathogens common to such carcasses. In fact, Rhodia's data clearly demonstrate that on-line antimicrobial reprocessing provides significantly greater pathogen reductions than traditional off-line reprocessing accomplishes on contaminated carcasses. **An** important, if not an even greater, benefit obtained through on-line antimicrobial reprocessing is the fact that all carcasses whether visibly contaminated or not, remain on-line and are subjected to the same antimicrobial treatment. Consequently, on-line antimicrobial reprocessing provides substantial pathogen reduction for all carcasses processed on the line.



### **A. Mandating On-Line Antimicrobial Agent Treatment**

Although it may be inferred as an assumed requirement of FSIS in proposing to allow on-line reprocessing, Rhodia would be remiss if it did not emphasize one critical required aspect of any authorized on-line reprocessing system, *i.e.* the application of an **FSIS** approved antimicrobial agent during reprocessing. Although the proposed rule is vague on this point, we believe that it is very important for FSIS to make such a requirement clear in its final regulation, and in any related guidelines and/or directives issued regarding on-line reprocessing. A major stated objective of FSIS in proposing to allow the poultry processing industry to realize substantial economic and other benefits from voluntary on-line reprocessing is to achieve a corresponding dramatic reduction in the presence of pathogens on pre-chill poultry carcasses. It has been suggested in some quarters that on-line reprocessing can be accomplished through less rigorous means, such as adding an additional water wash or another lesser process not utilizing an FSIS approved antimicrobial treatment. Application of **an** antimicrobial treatment is key to effective on-line reprocessing, and to achieving pathogen reduction as anticipated by FSIS. Therefore, we strongly urge that the final rule makes clear the requirement for use of an FSIS approved antimicrobial treatment **as** a part of any on-line reprocessing system.

### **B. Organisms Covered By Performance Standards**

Rhodia concurs with FSIS's stated intention to establish one or more pre-chill performance standards which plants would have to meet when using voluntary on-line antimicrobial reprocessing. Rhodia also concurs with FSIS that *E. coli* is the best indicator organism for fecal contamination, and that the common presence of *Salmonella* on raw poultry carcasses also makes it an appropriate organism for a pre-chill on-line reprocessing performance standard. Further, plants are knowledgeable of, and understand testing for, such organisms due to the current **HACCP** post-chill performance standard and process verification testing procedures. Consequently, Rhodia supports FSIS's proposal to adopt pre-chill on-line reprocessing performance standards for *E. coli* and *Salmonella*.

With regard to FSIS's request for comments on *Campylobacter*, while it may be appropriate at some point in the future to establish a pre-chill on-line reprocessing performance standard for *Campylobacter*, Rhodia agrees with FSIS's stated assessment that insufficient data presently exists to establish a *Campylobacter* performance standard. As stated earlier in these comments, Rhodia has conducted limited *Campylobacter* on-line reprocessing sampling, which shows that **TSP** on-line reprocessing can result in statistically significant reductions in pre-chill *Campylobacter* incidence rates of **more**



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than 40 percent. Extensive testing for *Campylobacter* has not been undertaken, however, due to the extremely high cost associated with current methods of *Campylobacter* testing. Incidence rates and actual numbers of *Campylobacter* on raw pre-chill poultry carcasses are common and relatively high. Given the need, therefore, for most probable number sampling to provide meaningful efficacy data, costs associated with *Campylobacter* enumeration are extremely high when compared to testing for other organisms, such as *Salmonella* or *E. coli*. Consequently, Rhodia is not able to submit further data beyond that which we previously submitted to FSIS as a part of the data submission in support of our on-line reprocessing petition. Rhodia is, however, interested in developing more TSP on-line reprocessing efficacy data for *Campylobacter* and pledges to work with FSIS in developing protocols for trials which will achieve the most cost-effective and statistically significant *Campylobacter* on-line reprocessing efficacy data. In that manner, a database can be developed from which FSIS can determine the appropriateness of establishing a future *Campylobacter* on-line reprocessing performance standard.

### C. Establishing Standards at Lowest Achievable Numerical Level

As mentioned at the outset of our comments, Rhodia feels strongly that pre-chill on-line reprocessing performance standards for pathogens should be established at the lowest numerical quantitative level demonstrated to be achievable by cost-effective, industry adaptable, available technology. Such standards will provide national uniformity, be understandable and concise, and allow for comparative ease in industry compliance and verification procedures. They will provide continuing incentives for research and development of new and better technologies that will meet or exceed the **known** performance standards. They will discourage industry use of minimally effective technologies which contribute little, if anything, to further pathogen reductions. In fact, performance standards based on something other than a quantifiable numerical value, such as achieving a minimum percentage pathogen reduction which could change daily based on variations from season to season, plant to plant, flock to flock, etc., could actually cause the national average incidence rate for pathogens covered by the performance standards to increase, rather than achieving the **FSIS** goal of a continuing reduction in the nationwide industry incidence rates for those pathogens.

Further, the adopted numerical quantitative performance standards must be meaningful and significant, reflecting the lowest achievable pathogen reduction levels reasonably achievable by best available current commercial technology. To not establish the performance standard at the lowest achievable level would frustrate FSIS's success in pathogen reduction, and could stifle achieving further reductions. For example, some on-line reprocessing technologies have provided FSIS with data indicating that the systems utilized can only achieve an on-line reprocessing pre-chill pathogen level for *Salmonella*



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which is equivalent to **FSIS's** recently reported overall national average for HACCP poultry plants for *Salmonella*, i.e., **9.9%** incidence.

Obviously, if FSIS were to adopt pre-chill performance standards which are not greater than levels achievable by marginally effective systems, it would be difficult to envision widespread industry use of such systems resulting in further pathogen reduction nationwide. Indeed, such standards would not compel the industry to adopt the best available on-line reprocessing technologies, especially if the more efficacious systems result in any increased cost, regardless of how modest. Further, inferior systems may offer plants financial or other inducements to adopt such systems, or even to abandon more efficacious systems to achieve cost savings, however slight. The net result being that the national average for pathogens could actually increase rather than decrease due to lax pre-chill on-line reprocessing performance standards. Such **as** scenario is realistic in the normal competitive commercial environment, and is another compelling reason for FSIS to adopt meaningful, significant numerical quantitative performance standards. But, perhaps the paramount reason for adopting such standards is the obligation FSIS bears to the consuming public to ensure that all reasonable and practical steps are taken to achieve the maximum pathogen reduction possible so that the risk of foodborne illness from eating meat and poultry products is reduced to the lowest practicable level.

#### **D. Recommended Frozen Sample Performance Standards**

As stated earlier, Rhodia's petition requested that on-line reprocessing be allowed to operate in plants by systems that had demonstrated the ability to achieve **0.5 % *Salmonella*** and **1.0% *E. coli*** average incidence rates during commercial plant trials. The five plant trial data, submitted in support of the petition and contained as a part of Attachment 2 of these comments, clearly demonstrate that TSP on-line reprocessing met the requested standards outlined in the petition in plant trials conducted under continuous commercial operating conditions utilizing the mandated sampling procedure, i.e., maintaining samples on dry ice (frozen) until laboratory analysis. Rhodia has also generated extensive data from more than 80 commercial plant trials as summarized in Attachment 3. Those data show that for frozen samples average pre-chill *Salmonella* incidence rates can be reduced from 19% for "normal" carcasses to 0.5% after TSP treatment, a greater than 95% reduction in *Salmonella* incidence rates. Similarly, average pre-chill *E. coli* incidence rates (equal to or greater than 10 cfu/ml) can be reduced **from** 88% for "normal" carcasses to **2%** after TSP treatment, a greater than 95% reduction in *E. coli* incidence rates. These data represent reasonable average pathogen levels demonstrated to be achievable by current practical and economical technology that has demonstrated it can be readily integrated into poultry slaughter plant operations. Therefore, we urge FSIS to adopt pre-chill on-line reprocessing performance standards of incidence rate levels of **2%** for *Salmonella* and **3%** for *E. coli* (equal to or greater than 10



cfu/ ml), which adjusts the average data to reflect incidence rates currently being met by greater than 85% of the plants utilizing TSP on-line reprocessing. These requested standards are based on utilization of frozen sampling methodology as required by **FSIS** in the Rhodia on-line reprocessing protocol, i.e., maintaining samples on dry ice prior to laboratory analysis.

**E. Correlating Frozen and Chilled Sample Performance Standards**

In the alternative, the proposed rule suggests that **FSIS** now believes that the proper methodology for pre-chill carcasses sampling for on-line reprocessing should be consistent with other required HACCP sampling methods, i.e., generally maintaining samples with water ice prior to laboratory analysis. Utilization of the sampling methodology suggested by FSIS necessitates some revision in the pre-chill reprocessing performance standards recommended above and in Rhodia’s on-line petition. Rhodia has conducted tests utilizing the two sampling methodologies, i.e., maintaining samples on dry ice prior to laboratory analysis (frozen) and maintaining samples on water ice prior to laboratory analysis (chilled). The chilled sampling analysis was conducted in 12 slaughter plants, representing 13 sets of data generated from 1190 samples collected over 23 days since December 2000. Results of the frozen sample analysis are summarized in Attachment 3 and results of the chilled sample analysis are contained in Attachment 4. These data, summarized below as Table I, show that differences in results are achieved by the different sampling methodologies, with chilled samples generally resulting in slightly higher incidence rates.

TABLE 1.

**TSP SALMONELLA AND E. COLI INCIDENCE RATES**

*FROZEN SAMPLES*

	<i>Salmonella</i>			<i>E. coli</i> >10 cfu/ml	
	Average	(n)	Incidence Rate (%)	(n)	Incidence Rate (%)
Normal Carcasses Prior to Final Water Wash		(7563)	19%	(7540)	88%
TSP Treated OLR Carcasses		(7563)	0.5%	(7539)	2%



TSP *SALMONELLA* AND *E. COLI* INCIDENCE RATES

CHILLED SAMPLES

	<i>Salmonella</i>			<i>E. coli</i> $\geq 10$ cfu/ml	
	Average	(n)	Incidence Rate (%)	(n)	Incidence Rate (%)
Normal Carcasses Prior to Final Water Wash		339	70%	339	98%
TSP Treated OLR Carcasses		1,190	3%	1,190	3%

These data show that the *Salmonella* incidence rate from TSP treated frozen samples averaged 0.5%, while the *Salmonella* incidence from TSP treated chilled samples averaged 3%. Similarly, the *E. coli* equal to or greater than 10 cfu/ml incidence rate for frozen samples averaged 2%, while the *E. coli* incidence rate for chilled samples averaged 3%.

These data clearly show for chilled samples that *Salmonella* incidence rates can be reduced from 70% for normal carcasses prior to TSP treatment to an average of 3% after TSP treatment, a greater than 95% reduction in *Salmonella* incidence rates. Similarly, *E. coli* incidence rates equal to or greater than 10 cfu/ml can be reduced from 98% for normal carcasses prior to TSP treatment to an average of 3% after TSP treatment, a greater than 95% reduction in *E. coli* incidence rates.

Rhodia believes these data provide a solid basis upon which to correlate chilled sampling results with frozen sampling results, and upon which to arrive at proper adjustments in proposed performance standards to reflect the type of sampling methodology FSIS may direct plants to utilize.

**F. Recommended Chilled Sample Performance Standards**

Given the ability to correlate data obtained from different sampling methodologies as explained above, should FSIS determine that chilled sampling methodology is to be utilized in determining compliance and verification with pre-chill on-line reprocessing standards for *Salmonella* and *E. coli*, Rhodia recommends that incidence rates for the *Salmonella* on-line pre-chill performance standard be established at 5%, and for the *E.*



*coli* (greater than or equal to 10 cfdml) performance standard be established at **5%**. These recommended performance standards reflect the slight, but proper, adjustment of Rhodia frozen pre-chill on-line reprocessing sampling data from the 80 plant trials, correlated and adjusted to reflect results achievable utilizing chilled sampling methodology. Again, these requested performance standards are fully supported by sampling data, as correlated. They reflect the lowest pathogen standards that are readily achievable by existing economical and commercially operable technology and are standards currently being met by greater than **85%** of the plants utilizing TSP on-line reprocessing. The suggested performance standards will provide the greatest practical pathogen reduction, and the greatest reduced risk of foodborne illness to the consuming public in allowing the poultry industry to utilize on-line reprocessing,

Further, with respect to **TSP** on-line reprocessing plant operations, it is noted that publicly available year 2000 **FSIS** post-chill data reflect 21% of these plants **as** having no reported *Salmonella* presence, i.e. **0%**. Also, these same data indicate that **57%** of TSP on-line reprocessing plants exhibit less than 5% *Salmonella* incidence, post-chill. Lastly, these same data indicate that **79%** of plants using TSP on-line reprocessing are operating at less than 10% *Salmonella* incidence, post-chill. These **FSIS** data further substantiate the efficacy of TSP in on-line reprocessing plant operations. Clearly, to continue to make improvements in reducing the presence of *Salmonella*, post-chill, **FSIS** needs to require significant on-line reprocessing standards, pre-chill.

It should be noted here that the post-chill levels of *Salmonella* and *E. coli* may be higher than pre-chill levels when any antimicrobial treatment is used. This is because it is not unusual for some microbial cells to only be injured, rather than killed. Such cells may be hardier or may be merely protected in the environment during the antimicrobial treatment. The chilling or refrigeration period can allow such cells to resuscitate and repair. This is normal and even occurs when product is cooked. It is clear, however, that the lower the levels pre-chill, the lower the levels that can be expected post-chill.

### **III. Review of Alcide Petition and Trial Data**

On page 75191 of the proposed rule published in the *Federal Register*, **FSIS** discusses a petition submitted by the Alcide Corporation requesting approval of the use of acidified sodium chlorite as an antimicrobial treatment for on-line reprocessing of contaminated poultry. The proposed rule generally describes data submitted by Alcide in support of its petition, but notes that its system only documents degrees of reduction in pathogens, rather than providing quantitative, absolute levels of pathogen reduction as Rhodia provided regarding commercial plant operations of the TSP on-line reprocessing system. In the proposed rule, **FSIS** requests comments on the acidified sodium chlorite data and whether it is possible to compare that data with the TSP data developed by Rhodia. **As**



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explained herein, Rhodia believes that the acidified sodium chlorite and TSP data sets can be compared, but in so doing, it is clear that the results achieved from the acidified sodium chlorite treatment provide minimal efficacy and, therefore, fall far short of providing meaningful pathogen reduction for the indicated organisms sampled. Consequently, pre-chill on-line reprocessing performance standards based on criteria as requested by Alcide would achieve little, if anything, in the way of enhanced pathogen reduction. In fact, if performance standards are adopted by FSIS to accommodate the minimal antimicrobial efficacy demonstrated by such systems, leading to widespread adoption of such systems for on-line reprocessing, the likely result would be an increase, rather than a decrease, in the present national industry pathogen averages. We believe such a result would not be in keeping with **FSIS's** mission as the primary food safety agency for the meat and poultry consuming public.

#### **A. Acidified Sodium Chlorite Submission**

Specifically, Rhodia conducted a review of the petition and data submitted to FSIS on November 17, 1999 by Alcide relating to the use of acidified sodium chlorite as an antimicrobial intervention for continuous on-line processing of fecally contaminated carcasses in poultry slaughter operations. Following is an analysis of this data, and a discussion of how it can be compared to Rhodia's TSP on-line reprocessing data.

The acidified sodium chlorite (ASC) data contained in the submission discloses that following ASC treatment using the frozen sampling technique, *E. coli* levels (greater than or equal to 10 cfu/ml) can be reduced from 74%, on average, to 3%, and *Salmonella* can be reduced from 18%, on average, to 3%. Using a chilled sampling technique, the combined data indicate that *E. coli* (equal to or greater than 10 cfu/ml) can be reduced from 99% to 25% after ASC treatment, and that *Salmonella* can be reduced from 34% to 12%, on average, after ASC treatment. In particular, the *Salmonella* limit of 12% provided by ASC treatment is four times higher than that provided by TSP under the same conditions, i.e. 3%. Similarly, the average *E. coli* (equal to or greater than 10 cfu/ml) limit of 25% provided by ASC treatment is greater than eight fold higher than that provided by TSP, i.e. 3%.

It should be noted that the minimal efficacy associated with ASC treatment of on-line reprocessed carcasses is very similar to that which is observed in the literature for carcasses treated with other chlorinated solutions. In fact, the demonstrated efficacy is only in the same order of magnitude as would be expected to obtain from freezing carcasses as opposed to chilling carcasses, i.e. 70% reduction is achieved by freezing carcasses, even without an antimicrobial agent treatment.





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Also, a review of the data contained on Page 22 of Alcide's petition indicates great variation in the post ASC treatment results as it relates to **various** phases of plant trials. In fact, in one trial carcasses having averages of 69.17% *Salmonella* incidence were reduced to 21.67% after ASC treatment. In this particular case, the data indicate that there was no significant reduction as a result of ASC treatment.

In addition, another plant trial also showed no significant reduction, even at lower levels, i.e. 72799TP. Phase 2, showed a post water wash average incidence of *Salmonella* of 7.50% reduced to post ASC treatment of 6.25%, only a 17% overall average reduction. This was not a significant reduction, even at this low level **of** *Salmonella* presence.

In sum, critical scientific analysis of the *Salmonella* data submitted by Alcide to **USDA** shows that the data lack consistency and sufficient efficacy and therefore do not rise to the level of significance that would justify use as an on-line reprocessing agent in poultry plants. This is particularly true in those plants where the level of incoming contamination is significantly greater for on-line reprocessed carcasses than it is for normal carcasses. We believe the option of on-line reprocessing should be reserved for technologies that provide a significant reduction in pathogens under actual operating conditions. The *Salmonella* data presented by acidified sodium chlorite and other chlorine disinfectants do not meet this standard.

Similarly, with respect to *E. coli* (equal to or greater than 10 cfdml), reductions from **99%** pre ASC treatment to 25% post ASC treatment are barely significant. As mentioned above, the TSP process produces *E. coli* levels well under 3% when evaluated under the same conditions. Again, as stated previously, simply freezing the samples achieves a 70% reduction in *E. coli* and by that analogy, simply freezing these samples will achieve the same reduction as ASC treatment provides as shown by the ASC plant data. The voluntary use of on-line reprocessing in poultry slaughter operations should be reserved for the most efficacious systems, ones able to achieve at least a 90% reduction in *Salmonella* and *E. coli* incidence on carcasses.

## **B. Comparing ASC and TSP Data**

The *E. coli* data in the ASC petition provides sufficient information for conversion and comparison to the TSP trial data since distribution data are indicated therein. For example, on Page 35 of the ASC petition, the *E. coli* levels for post ASC treated product clearly indicate that **24.3%** of samples, when chilled on water ice, contain *E. coli* equal to or greater than 10 cfdml. Rhodia's independent laboratory established a standard *E. coli* detection limit of 10 cfdml for all on-line reprocessing analysis, including the above mentioned analysis of chilled samples. As such, the data provided in ASC trials can be compared to the data provided by Rhodia in TSP trials. Consequently, equating the data

shows that ASC on-line reprocessing reduces average *E. coli* incidence to **24.3%**, while TSP on-line reprocessing reduces average *E. coli* incidence to **3%**. These data express a very significant difference in efficacies provided by the two treatments under equivalent conditions.

The ASC data itself presents a strong argument for the necessity of FSIS establishing significant numerical quantitative pre-chill on-line performance standards for *Salmonella* and *E. coli* that represent the lowest level reasonably achievable by available technology for these organisms. Providing an accommodation for technologies whose own data indicate efficacies that barely equate to essentially freezing samples should not be the basis for establishing regulatory performance standards. In light of the Alcide data it is even more important for **FSIS** to set numerical quantitative performance standards at levels for *Salmonella* incidence at not greater than **5%** and for *E. coli* (equal to or greater than 10 cfu/ml) incidence of not greater than **5%**. This will assure continued reductions in post-chill *Salmonella* and *E. coli* levels equivalent to those currently being experienced with TSP on-line reprocessing plant operations. To fail to provide a strict numerical quantitative performance standard for on-line reprocessing operations will likely result in increased *Salmonella* and *E. coli* levels on carcasses.

### C. Tabular Presentation of ASC Data

The following tables have been constructed to show average results of the ASC trial data, using frozen and chilled sampling methods.

#### ASC SALMONELLA AND *E. COLI* INCIDENCE RATES

##### FROZEN SAMPLES

	<i>Salmonella</i>			<i>E. coli</i> >10 cfu/ml	
	Average	(n)	Incidence Rate (%)	(n)	Incidence Rate (%)
Normal Carcasses Post Final Wash		(347)	18%	(350)	74%
ASC Treated OLR Carcasses		(347)	3%	(349)	3%



ASC SALMONELLA AND E. COLI INCIDENCE RATES

CHILLED SAMPLES

Normal Carcasses Post Final Wash	Salmonella			E. coli >10 cfu/ml	
	Average	(n)	Incidence Rate (%)	(n)	Incidence Rate (%)
		(1419)	34%	(1068)	99%
ASC Treated OLR Carcasses		(1420)	12%	(1070)	25%

IV. Review of National Chicken Council Data

The preamble to the proposed rule on page 75191 of the *Federal Register* briefly discusses data submitted to FSIS by the National Chicken Council (NCC) relating to results of trials NCC conducted of TSP on-line reprocessing systems in nine commercial poultry slaughter plants. NCC claims to have achieved different results than those experienced by Rhodia in its TSP on-line reprocessing operations. FSIS has requested comments on the NCC data, on the general question of criteria for pre-chill performance standards in balancing public health benefits and industry participation, on the effect of freezing versus chilled sampling, and on whether the agency should require as a condition of permitting on-line reprocessing that all carcasses entering the chiller, including off-line reprocessed carcasses, be treated with an antimicrobial agent. As the following analysis explains, Rhodia believes, that when properly evaluated and compared, the NCC data is very supportive of, and consistent with, the data developed by Rhodia in its plant trials and in continuing plant operations. Consequently, we believe that the NCC data should be considered as additional support for the quantitative numerical pre-chill performance standards requested by Rhodia, adjusted as previously described to account for use of chilled sampling methodology. Further, Rhodia strongly supports FSIS mandating that all reprocessed carcasses, whether on-line or off-line, be treated by an approved antimicrobial agent prior to entering the chiller so that a potential major source of cross-contamination can be minimized.

A. National Chicken Council Submission

Data and information submitted to FSIS by the National Chicken Council, dated September 18, 2000, relates to a series of trials conducted by NCC in various poultry slaughter plants utilizing TSP as an on-line pre-chill reprocessing agent. Generally speaking, while these data appear to be voluminous and comprehensive in their scope,



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several deficiencies in the data are noted in our analysis of the results of these studies. First of all, the *Salmonella* results reported in these data appear to differ appreciably from the data we have generated over the last several years, particularly with respect to frozen samples, and the presence of *Salmonella* in TSP treated product. Unfortunately, the NCC data is incomplete.

Upon close scrutiny of the NCC data, it is clear, with respect to *Salmonella*, that absolute numbers for incidence rate, post **TSP** treatment, are not determinable by the data submitted since appropriate footnotes indicate that the incidence rates are overstated since *Salmonella* negative plants were eliminated from the database. Also, relatively few plants actually participated in the study. Rhodia's data was developed in more than 80 plants, comprised of greater than 15,000 samples over a three year period. Because of these deficiencies, the NCC *Salmonella* data has little value. It is noted, however, that even with these discrepancies, the selected data reported by NCC showed that TSP on-line reprocessing reduced average *Salmonella* incidence to 8%, a substantial reduction. Moreover, one can only conclude that had all favorable data from *Salmonella* negative plants been included in the NCC calculations, the average incidence rates would likely have been consistent with, or even lower than, the results obtained by Rhodia.

The data, also, indicate that chill sample analysis is more sensitive with respect to *Salmonella* incidence rates than frozen sampling techniques. We certainly agree with this finding reported by the NCC and feel that this is an important point for the NCC to have raised. We would, however, again note that the frozen sampling technique utilized by Rhodia for the last several years was mandated by **FSIS's** protocol requiring frozen sampling techniques. In fact, these frozen sampling techniques well preceded the onset of the post-chill pathogen reduction standard published in 1998. We agree with **FSIS's** finding reported in the February 27, 2001 Federal Register relating to a proposed rule on performance standards for ready-to-eat processed meat and poultry products, which states on Page 12596 that *Salmonella* recovery from frozen samples is about 30% of that for chilled samples.

With respect to *E. coli* determinations in the NCC submission, there is a more definitive conclusion one can draw from the data, and that is that the post **TSP** treated chilled samples achieve a greater than 99% reduction in *E. coli* cfu/ml when compared with pre TSP chilled samples. This is equivalent to a 2 log<sub>10</sub> reduction for the presence of *E. coli* corresponding to the numbers of *E. coli* present in TSP treated samples. Therefore, the NCC data are consistent with Rhodia's data showing an *E. coli* incidence rate of well less than 5% when *E. coli* is expressed on a equal to or greater than 10 cfu/ml basis, as used by Rhodia, rather than the equal to or greater than 1 cfu/ml basis used by the NCC. The lower level of detection used by the NCC is unnecessary as an indicator of process



control in this usage as the marginal level of concern as expressed in the post-chill *E. coli* performance standard is greater than 100cfu/ml. In fact, Rhodia's data show that *E. coli* incidence rates are reduced greater than **95%** by TSP treatment when expressed on a chilled sample basis.

Lastly, it is noted that the NCC data confirm the efficacy of Rhodia's methodology for the analysis of *E. coli* and *Salmonella* by our independent laboratory, Ralston Analytical Laboratories. To address the concerns of NCC, Rhodia recently conducted a study to evaluate two different AOAC approved methodologies for the recovery and enumeration of *E. coli*. The results of these two studies are summarized in Attachment 5, showing the methods to be essentially equivalent. We believe, therefore, that the NCC data totally supports all of the data collected by Rhodia with respect to the efficacy of TSP treatment, both as to frozen samples and most appropriately with respect to the data currently submitted relating to chill sample analysis, pre and post TSP. In fact, Rhodia would support FSIS adopting strict performance standards for *Salmonella* and *E. coli* based on chilled sample analysis to assure the greatest accuracy in these data and to minimize sampling confusion in view of the chilled sample analysis required for post-chill HACCP performance standard and process verification compliance.

Rhodia, therefore, appreciates the NCC's submission of data on behalf of the efficacy of TSP with respect to its use as an on-line reprocessing antimicrobial agent. *E. coli* data from the NCC TSP plant trials is summarized below.

*NCC 9 PLANT TSP TRIALS  
E. COLI (CHILLED SAMPLES)  
cfu/ml*

Pre TSP	(n)	Post TSP	(n)
Average <b>84.42</b> cfu/ml	(710)	0.77 cfu/ml	<b>(644)</b>

99.1% reduction in *E. coli* cfu/ml



***NCC 5 PLANT TSP TRIALS  
E. COLI (CHILLED SAMPLES)  
cfu/ml***

Pre TSP	(n)	Post TSP	(n)
Average 128.83 cfidml	(339)	1.48 cfu/ml	(340)

98.9% Reduction in *E. coli* cfidml

Average NCC 14 plant trial *E. coli* cfidml TSP induced reduction is 99%

**V. Environmental Impact of On-Line Reprocessing Operations**

The preamble to the proposed rule on page 75192 of the *Federal Register* requests comments regarding environmental impacts associated with on-line reprocessing operations. In its discussion, **FSIS** mentions that the more than 80 poultry plants utilizing TSP on-line reprocessing are handling reprocessing waste water through routine operations of the plants' existing water treatment systems, or through recycling the by-products without requiring discharge of such waste water. While the TSP on-line reprocessing system does contain a phosphorus component, the more than 80 slaughter plants presently utilizing the system are doing so in conformity with requirements of all local, state and federal environmental regulations. Such plants have typically not had to undergo extensive modifications in their existing waste water treatment systems, nor have they incurred major additional costs as a result of implementing TSP on-line reprocessing. Consequently, Rhodia does not believe that major additional costs, if any, would be required to operate TSP on-line reprocessing in states that may have restrictive environmental laws and regulations. In fact, Rhodia is not aware of any state that has environmental laws or regulations which would presently restrict or prohibit the use of TSP on-line reprocessing systems.

Further, given the nature of the phosphorus contained in TSP, its ability to form attractive compounds which can be utilized for a number of commercial uses provides several disposal use alternatives to plants which may be located in states having the most restrictive environmental law and regulations. In fact, Rhodia remains fully prepared to work closely with any plant to develop practical and workable waste water disposal and/or by-product utilization systems to appropriately meet all environmental requirements and the plant's operating needs. This latter point is perhaps best demonstrated by reiterating the fact there are presently more than 80 poultry plants



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operating TSP on-line reprocessing system in **full** compliance with all local, state, and federal environmental laws and regulations.

## **VI. FSIS General Requests for Comments**

In the preamble to the proposed rule on page **75192** of the *Federal Register*, **FSIS** makes general statements regarding its goals and policies. **FSIS** then requests further comments on a number of topics which Rhodia will address in this part.

### **A. Need to Establish Performance Standards**

As stated throughout these comments, Rhodia strongly supports the **FSIS** stated intention to establish pre-chill pathogen performance standards that an establishment must meet in voluntarily utilizing on-line reprocessing. Rhodia also agrees with **FSIS** that it is appropriate in allowing on-line reprocessing that more rigid pre-chill pathogen reduction performance standards for carcasses should apply than are now required by HACCP for post-chill carcasses. This is due to the fact that on-line reprocessing allows visibly contaminated carcasses to proceed on-line with uncontaminated carcasses where, otherwise, a large cross-contamination potential would exist. Further, allowing on-line antimicrobial reprocessing provides significant economic and operational benefits to poultry plants, for which it is not unreasonable to expect meaningful, significant pathogen reductions to accrue to the consuming public in return for such industry benefits. However, as demonstrated earlier in these comments, to be able to achieve these corresponding pathogen reduction levels, **FSIS** must adopt meaningful numerical pre-chill performance standards in allowing on-line poultry reprocessing.

### **B. Recommended On-Line Reprocessing Performance Standards**

**FSIS** has asked for specific comments on what the on-line pathogen performance standards should be. Again, Rhodia strongly believes that the performance standards should be established at levels which are reasonably achievable by the best available technology(s) that can be utilized at a reasonable cost in modern poultry plant operations. Adjusting Rhodia's extensive TSP on-line reprocessing commercial plant data to reflect the utilization of a chilled sampling methodology, which the proposed rule indicates to be **FSIS's** preference, Rhodia believes that the clear scientific data for commercially available and cost effective technology indicates that the pre-chill on-line reprocessing performance standard for *Salmonella* incidence should be set at **5% and** the pre-chill on-line performance standard for *E. coli* (equal to or greater than 10cfidml) incidence should be set at **5%**. Rhodia's data generated from more than 80 plants utilizing the **FSIS's** mandated frozen sampling trial methodology when adjusted to reflect chilled sampling results, and Rhodia's separate data generated utilizing chilled sampling methodology,



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indicates that these recommended *Salmonella* and *E. coli* performance standards can be consistently met by existing available on-line antimicrobial reprocessing systems in modern commercial plant operations that continually monitor and control their operations to ensure minimal contamination of carcasses.

### **C. Accommodating Systems and Furthering Pathogen Reduction**

Although Rhodia recognizes FSIS's stated concern to accommodate alternative systems, adoption of the performance standards recommended by Rhodia would not preclude the use of technologies other than TSP for on-line reprocessing operations. For example, radiation technologies should be able to easily meet the recommended performance standards. Although data from the acidified sodium chlorite system indicates it is much less effective as an antimicrobial agent in comparison to results achieved through the use of TSP, operation of such a system appears possible in plants with initial low pathogen levels for *E. coli* and *Salmonella*, even though use of such a system would not ensure that those plants would achieve the lowest possible pathogen reduction. Rhodia feels that it is very important that FSIS not compromise the meat and poultry consuming public's expectation of, and right to, the maximum possible achievable safety for the meat and poultry products it consumes because of a misplaced desire by FSIS to accommodate systems that have demonstrated only an ability to achieve the present national average pathogen levels of plants. Further, if FSIS does not establish performance standards equating to the maximum achievable pathogen reduction demonstrated by current technologies, there will be little, if any, incentive for research and development of new technologies that will meet and exceed the established performance standards.

Perhaps, an example will best demonstrate the risk to achieving further national industry reductions in poultry pathogens should FSIS not require meaningful numerical quantitative performance standards, but rather allow standards to be based on other vague measurements, such as the suggested percentage reduction in pathogen incidence rates. One system has generated data which indicates it can achieve about a 65% reduction in *Salmonella* incidence rates. If FSIS would establish a *Salmonella* performance standard for the purpose of "accommodating" that technology, it is conceivable that the national *Salmonella* incidence rates could actually rise as a result of such a standard. This could occur in poultry plants that are experiencing extremely high *Salmonella* incidence rates, some which Rhodia has documented to be as high as 100 percent. In those plants, a percentage reduction performance standard accommodating systems only able to achieve a 65% pathogen reduction would only require a reduction in the pre-chill *Salmonella* incidence rate for such a plant to less than 35%, an unacceptable level.





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Use of the best available technology, an antimicrobial treatment such as **TSP** or similarly effective technologies, to achieve compliance with a meaningful numerical quantitative performance standard would, however, ensure that plants realize significant reductions in *Salmonella* and other pathogens. Otherwise, it will be extremely difficult for FSIS to further improve on the impressive nationwide pathogen reduction which has occurred in poultry plants over the past several years. Consequently, Rhodia believes that there is every reason for FSIS to adopt the meaningful numerical quantitative pre-chill performance standards we recommend herein to continue improvements in pathogen reduction and in protecting the meat and poultry consuming public from unnecessary added risk of foodborne illness.

#### **D. Mandating Antimicrobial Treatment Of All Reprocessed Carcasses**

Responding to the preamble request for comments regarding the necessity of requiring an antimicrobial treatment of all reprocessed carcasses, Rhodia strongly believes that FSIS should mandate such treatment by an antimicrobial agent approved by FSIS and listed for that purpose in the table at 9 CFR 424.21(c). The extensive data submitted in 11. above from Rhodia's sampling in more than 80 plants clearly show that traditional off-line reprocessed carcasses frequently contain unacceptably high levels of pathogens, even after being subjected to the chlorine treatment required by the current reprocessing regulation. When such off-line reprocessed carcasses are allowed to enter the chiller without being subjected to an effective antimicrobial treatment, such as **TSP**, the likelihood of those carcasses contaminating the chiller and cross-contamination occurring to otherwise clean on-line reprocessed carcasses is high. Indeed, the increased pathogen rates experienced in post-chill sampling at some plants, versus pathogen results achieved in pre-chill sampling following on-line reprocessing, can be attributed to a lack of treating traditional off-line reprocessed carcasses with an antimicrobial agent prior to allowing those carcasses to enter the chiller.

Great potential exists for defeating much of the pathogen reduction achieved through pre-chill antimicrobial on-line reprocessing in the absence of requiring traditional on-line reprocessed carcasses to be subjected to an effective antimicrobial agent prior to entering the chiller. Therefore, we strongly urge FSIS to make application of an effective antimicrobial agent on all reprocessed carcasses, both on-line carcasses and off-line carcasses, a requirement of any allowed carcass reprocessing. The antimicrobial agent should be specifically approved for such use by FSIS and be listed in the poultry products regulations at 9 CFR 424.21(c).



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## VII. The Proposed Rule

In its discussion of its proposed rule commencing on page **75** 192 of the *Federal Register*, Rhodia notes FSIS's emphasis on the voluntary nature of an establishment choosing to adopt on-line reprocessing and the type of on-line reprocessing system utilized. While Rhodia concurs with **FSIS's** initial decision to make on-line reprocessing voluntary, we want to reiterate our beliefs that meaningful numerical quantitative performance standards must be established by FSIS for the operation of such voluntary systems, and that such systems must include the application of an **FSIS** approved antimicrobial treatment as a part of the allowed on-line reprocessing.

### A. Maintaining Existing Standards With On-line Reprocessing

Rhodia also concurs with **FSIS's** stated intention to maintain the existing requirements that no carcasses visibly contaminated with fecal material be allowed to enter the chill tank, and to maintain the present finished product standards. Rhodia believes that there is no reason to change either requirement in allowing on-line reprocessing. In fact, on-line reprocessing, operated in conformity with meaningful pre-chill pathogen performance standards and application of an approved antimicrobial treatment, will markedly improve compliance with both requirements.

There is an error on page 75 189 of the proposed rule in which it **is** stated that under the **FSIS** approved protocol for TSP on-line reprocessing, the zero tolerance verification station is located prior to TSP treatment. In fact, under the **FSIS** approved protocol, and in use currently and throughout the entire study in over 80 plants, the zero tolerance verification station is located after TSP treatment. This location was chosen, and approved, to permit full utilization of the surface cleaning properties of TSP in addition to its antimicrobial properties. There have been no adverse consequences noted to visual cleanliness of the birds or antimicrobial effectiveness.

Rhodia would ask, however that **FSIS** clarify in the final rule that TSP and other similarly applied antimicrobial agents are considered the final rinse prior to entering the chiller for prechill inspection purposes. Clarity on this point is needed to insure uniform national application in plants and to avoid inspector uncertainty which has been experienced in some plants.

On page **75** 192 of the proposed rule, it is stated that **FSIS** expects visibly contaminated carcasses to be identified before proceeding down the processing line. The voluminous microbial data collected to date relative to TSP treated birds indicates that this is not necessary. The physical marking of these carcasses causes whole carcasses to be downgraded, thus reducing the economic incentives to use antimicrobial treatments.



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Rather than continually marking all such birds, it is recommended that birds be marked only during the testing period, such as is done for moisture testing.

## **B. Antimicrobial Agent Use Listings for TSP**

In this section, FSIS also requests comments on amending the chart in 9 CFR 424.21 (c) to extend the use of trisodium phosphate to pre-chill poultry carcasses. As mentioned in II. above, based on extensive commercial plant trial efficacy data submitted in support of its petition, in 1994, FSIS granted interim approval for the use of TSP as an antimicrobial agent on pre-chill poultry carcasses. Not only was the data submitted in support of the petition sufficient to gain interim approval, since that time Rhodia has developed overwhelming data from its on-line reprocessing trials to substantiate the efficacy of TSP as a pre-chill carcass antimicrobial treatment. The supporting efficacy data was summarized in II. above and is contained in the more than 80 plant trial data in Attachment 2.

Clearly the trial data supports addition of the pre-chill use of TSP to the list of antimicrobial agents under section 424.21(c). Additionally, Rhodia requests that specific changes be made under the "Amount" column as proposed by FSIS. The "Amount" column basically reflects established good manufacturing practices (GMP) in connection with the stated use. In a letter from the Administrator dated March 29, 1994, FSIS determined that the appropriate application time for TSP spraying or dipping pre-chill carcasses was a time up to 30 seconds. Further, continuous inplant operation of TSP pre-chill systems has indicated that the GMP for temperature of the solution should be equated to no more than the temperature of the carcasses at the time of application. In fact, FSIS recognizes this GMP in written guidance prepared for TSP plant operation. A copy of this FSIS document, entitled "TSP Orientation Packet for On-Line Reprocessing", is enclosed as Attachment 6. Therefore, we request that the column "Amount" be modified as follows:

"8 to 12%; in connection with a solution dip, or a water spray containing 20 ppm chlorine; solution to be maintained at no more than the temperature of the carcass to be applied to for pre-chill application, or between 45-55°F after chilling, and to be applied by dipping or spraying chilled or pre-chill carcasses for up to 30 seconds in accordance with 21 CFR 182.1778."

Additionally, as discussed in I. of these comments, pursuant to petitions accompanied with supporting commercial plant trial data filed by Rhodia, FSIS granted interim approval for the use of TSP as an antimicrobial agent on raw unchilled poultry giblets in 1994, and granted interim approval for the use of TSP on raw beef carcasses as an



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antimicrobial agent in 1995. The efficacy of these uses of TSP as an antimicrobial agent are clear from the data submitted. The operating parameters for each use also fall within the operating parameters recommended above to be added to the final rule under the column "Amount." Therefore, we would urge **FSIS** to take this opportunity to add these additional uses of TSP as an antimicrobial agent to the final rule when published. This can be accomplished simply by deleting the period after "carcasses" and adding ", pre-chilled poultry giblets, and raw beef carcasses" to the "Products" column of "Antimicrobial agents" in 9 **CFR** 424.21(c). In the interest of administrative efficiency, we would urge **FSIS** to make this addition to the final rule.

#### **VIII. Cost and Economic Impact of On-Line Reprocessing**

On page **75193** of the proposed rule, **FSIS** outlines its cost estimate to the industry and individual plants from voluntarily adopting on-line reprocessing and analyzes its view of the economical impact thereof. While Rhodia can only comment upon its experience with implementation costs for the use of TSP on-line reprocessing systems, it agrees with **FSIS**'s observation that the economic impact of on-line reprocessing will be minimal due to its voluntary nature. Several factors will enter into a plant's determination as to whether to voluntarily implement on-line reprocessing. Cost of implementation and operation of on-line reprocessing systems will be weighed against factors such as economic benefit derived from the use of such systems, their effectiveness in reducing common poultry pathogens, and their contribution to meeting finished products standards and other regulatory requirements.

With regard to the cost associated with implementation and operation of TSP on-line reprocessing systems, the average equipment cost and on-going operational cost described by **FSIS** in the proposed rule's preamble appear to accurately reflect those costs. Other costs and assumptions made by **FSIS** appear to be accurate **or** reasonable estimations. Rhodia does agree with **FSIS** that the per pound poultry cost of implementing TSP on-line reprocessing systems is an insignificant portion of retail prices, and that any resulting retail price increases should be modest, but are offset by the reduced risk of foodborne illness provided by on-line reprocessing.

As noted earlier, while Rhodia cannot comment on actual cost savings to plants from the utilization of on-line reprocessing, it is noted that significant economic benefits accrue due to the substantial reduction in remaining off-line reprocessing costs. Perhaps, the best example of positive economic benefits and increased pathogen reduction is provided by the fact that more than 80 poultry slaughter plants, representing more than half of the national annual poultry slaughter volume, have voluntarily implemented TSP on-line reprocessing since **FSIS** authorize such trials and continuing operations.



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FSIS also asks to receive comments on whether it should be considered deleting provisions for off-line reprocessing should on-line reprocessing be implemented. Rhodia believes that it is appropriate to limit on-line reprocessing to visibly contaminated, but less than grossly contaminated, carcasses. Off-line reprocessing for carcasses and parts containing defects, requiring trimming, or other conditions presently requiring off-line reprocessing remain even when on-line reprocessing is utilized. Consequently, Rhodia would encourage FSIS to maintain its off-line reprocessing regulations, but as described in detail above, would urge FSIS to require the use of an effective approved antimicrobial treatment prior to the chiller for all off-line reprocessed poultry.

## IX. Industrial Hygiene Surveys

On page 75193 of the preamble to the proposed rule, FSIS discusses various industrial hygiene questions and refers to such studies performed by Rhodia. **As** with other processing aids and substances, TSP poses no safety or other hazards to plant inspectors or employees when used in conformity with required safe operating procedures and equipment. As the preamble to the proposed rule outlines, Rhodia has conducted studies that confirm the safe and proper use in plants of TSP for on-line reprocessing.

Prior to each plant start up of TSP on-line reprocessing, Rhodia provides an orientation session on the safe handling of TSP and recommended safety features and equipment regarding operations of the TSP on-line reprocessing system for plant employees and inspectors. Copies of the manufacturer's safety data sheet (MSDS) are also provided to the plant personnel and inspectors. Copies of the **MSDS** and Rhodia's industrial hygiene studies are attached hereto in Attachment 7.

According to this data, there were no detectable TSP exposures determined at the USDA inspection station in 80 plants comprising 279 samples. Even at the USDA finished product inspection station, only 5% of air samples were positive at an average level of 0.01 mg/m<sup>3</sup>. Since the American Industrial Health Council's (**AIHC**) recommended limit is 5 mg/m<sup>3</sup>, this is 50 fold less than the AIHC limit. The TSP application area exhibited a 12% incidence rate at the limit of detection with an average TSP concentration of **0.02** mg/m<sup>3</sup>, which is 30 fold less than the recommended limit. Lastly, the air sampling exposure at the TSP hopper (TSP make-up area) were positive in 50% of the samples at an average level of 0.30 mg/m<sup>3</sup>, an average level 17 fold less than the AIHC recommended limit. What this means is that there are no TSP exposures that come close to the recommended **AIHC** limit from its use in poultry plant on-line reprocessing operations.



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## **X. FSIS Alternatives Considered**

With regard to the alternatives considered by FSIS and discussed on page 75194 of the proposed rule, the overwhelming degree of pathogen reduction on-line reprocessing provides is so well documented by the plant trial data submitted by Rhodia that it requires FSIS to reject the first alternative posed of not allowing on-line reprocessing to proceed. FSIS also states its decision to reject another alternative, mandating that establishments utilize on-line reprocessing and establishing numerical performance standards that must be met while using a mandated antimicrobial treatment. While it may not be appropriate at this time for FSIS to mandate that poultry establishments utilize on-line reprocessing as a required part of plant operations, Rhodia feels strongly that FSIS must adopt numerical quantitative pre-chill pathogen performance standards for *Salmonella* and *E. coli* that must be met by the plant in voluntarily choosing to implement on-line reprocessing. For reasons stated earlier in these comments, to not mandate numerical performance standards, as well as the use of an FSIS approved antimicrobial agent, risks losing much of the pathogen reduction gains that FSIS has accomplished in policies it has implemented during the past several years.

Rhodia strongly believes that if pathogen reduction is to remain central to the FSIS food safety strategy, which Rhodia firmly believes to be a primary obligation of FSIS as the nation's safekeeper of the meat and poultry products consumed in this country, FSIS must mandate meaningful numerical on-line reprocessing pre-chill performance standards and the use of an antimicrobial treatment therewith. Rhodia would reject any contention that such requirements are either prescriptive or a type of command and control regulation for a voluntary process such as on-line reprocessing. Such requirements only represent reasonable operational criteria which are entirely appropriate for FSIS as a regulatory agency to impose as the quid pro quo food safety benefit obtained for the economic and operational benefits accruing to the poultry industry by allowing voluntary on-line reprocessing.

## **XI. Conclusion**

It is important to remember that, as proposed, on-line reprocessing would be voluntary. Therefore, requiring a pre-chill performance standard does not impact on any plant that does not choose to reprocess on line. All plants could still continue to reprocess off-line and not be subject to a pre-chill performance standard. Plants choosing to on-line reprocess would also be choosing to meet a pre-chill performance standard. Moreover, the adoption of a stringent pre-chill performance standard will encourage plants choosing to on-line reprocess to use the best available technology and to closely monitor their entire processing operation including their reprocessing operation. Rhodia's experience in the over 80 plants currently employing TSP on-line reprocessing has shown that plants



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not closely monitoring their entire processing operation will not be able to continually meet a stringent pre-chill standard. **This** does not argue against a stringent standard; it argues for more closely monitoring and controlling the entire processing operation.

That said, a stringent pre-chill performance standard also protects a plant from investing time and money in a technology that is unable to provide the degree of treatment necessary to provide the basis for meeting the standard. In fact, the original technology standard proposed by Rhodia in its petition was designed, in part, to shield plants from ineffective technologies. A stringent pre-chill standard compels technology companies to develop effective technology and to provide reasonable support to plants to assure compliance, or risk losing their customer base. Every plant is different and reprocessing equipment needs to be designed and optimized to achieve the desired results. Given that, however, a performance standard should not be based, as some have suggested, on an average of technologies to "accommodate" systems that may not be efficacious. Rather a pre-chill on-line performance standard should be based on the level achievable by the best presently available technology to meet both the needs of public health and national uniformity of product.

Rhodia believes the food safety benefits of on-line reprocessing are obvious and sufficiently compelling to require **FSIS** to act to allow poultry slaughter plants to utilize this process. Results of the sampling of off-line reprocessed carcasses using present off-line reprocessing procedures indicate that such carcasses receive little pathogen reduction, and in many cases actually contain higher levels of pathogens following off-line reprocessing because of the extensive handling. Also, the on-line reprocessing procedure subjects not only the visibly Contaminated carcasses to the process, but also ensures that "normal" on-line carcasses are also subjected to an **FSIS** antimicrobial treatment during on-line reprocessing. This latter fact is a very important food safety consideration since sampling indicates that "normal" carcasses frequently contain high levels of pathogens which would otherwise go untreated. On-line reprocessing has the benefit of allowing all carcasses on-line to be treated with an approved **FSIS** antimicrobial agent--at least that is Rhodia's strong recommendation for the final rule.

In the interests of food safety and pathogen reduction, and fully supported by the overwhelming efficacy demonstrated by its commercial plant data, Rhodia requests **FSIS** to allow the reprocessing of visibly contaminated, but not grossly contaminated, pre-chill poultry carcasses on-line, utilizing an **FSIS** approved and listed antimicrobial agent and complying with pre-chill performance standards of 5% for *Salmonella* incidence and 5% for *E. coli* (equal to or greater than 10 cfu/ml) incidence, based on chilled sampling methodology. Consequently, we urge **FSIS** to modify the proposed regulation to indicate that on-line reprocessing will be allowed through the use of an approved and listed antimicrobial agent, rather than mere use of an antimicrobial technique **as** proposed which



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could be interpreted to be **as** minimal as allowing reprocessing using only a common water wash. The final rule should be further amended to include the pre-chill performance standards for *Salmonella* and *E.Coli* above stated. **Also**, Rhodia requests that part 424.21(c) be further amended to include poultry giblets and raw beef carcasses under the "Products" column, and that the "Amount" column **of** that section be revised **as** recommended in section VII. herein to specify conditions for both spray and dip applications for up to **30** seconds, and by adding that the solution be maintained for pre-chill applications at the temperature of the carcass to be treated.

Rhodia appreciates the **opportunity** to provide these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "James T. Elfstrum".

James T. Elfstrum  
Manager, Regulatory Affairs  
JTE/jn:01-053  
Enclosures