

Petition for Rulemaking Re:
Amendment to 9 CFR 381.91 to
Allow On-Line Reprocessing of
Poultry Carcasses

September 18, 1998



Phosphates, Hydrocolloids and Food Ingredients

September 18, 1998

Mr. Thomas J. Billy, Administrator
Food, Safety and Inspection Service
c/o Policy, Evaluation and Planning Staff
Docket Room, Room 102 ANNEXBG
300 12th Street SW
U.S. Department of Agriculture
Washington, D.C. 20250-3700

**RE: Petition for Rulemaking Re: Amendment to 9 CFR 381.91
to Allow On-Line Reprocessing of Poultry Carcasses**

Dear Mr. Billy,

This document is submitted as a public petition for the express purpose of requesting that the Food, Safety and Inspection Service (FSIS) amend its existing rules, promulgated pursuant to the Poultry Products Inspection Act, as amended (21 USC 451 et seq.), to provide for the on-line reprocessing of poultry carcasses under conditions as specified herein, namely utilization of an on-line reprocessing system that will achieve prechill incidence rates of less than 0.5% for Salmonella and prechill incidence rates of less than 1.0% for E. coli.

I. REGULATORY PROVISION TO BE AMENDED

Specifically, it is requested that FSIS institute rulemaking to amend 9 CFR 381.91 by adding a new subsection which would allow poultry carcasses accidentally contaminated, but not grossly contaminated, with digestive tract contents during slaughter to remain on the main processing line for reprocessing on-line through the application of a substance or processing system, where such substance or system has demonstrated exceptional pathogen reduction characteristics under in-plant commercial operation by reducing prechill



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incidence rates of Salmonella to less than 0.5% and by reducing prechill incidence rates for E. Coli to less than 1.0%. The proposed amendment to 9 CFR 381.91 as requested herein is attached hereto as Exhibit 1 and is made a part of the public petition by this reference.

As will be substantiated herein, justification for requesting this exception to the normal FSIS rule authorizing reprocessing of poultry carcasses off-line is to allow poultry processors to benefit from the advantages offered by on-line reprocessing of accidentally contaminated carcasses when the processor achieves substantial pathogen reduction for all poultry on-line. Clearly, complying with the proposed performance standards for pathogens for on-line reprocessed poultry carcasses, as well as all normal carcasses which similarly benefit by remaining on-line and being subjected to the same reprocessing system, will provide a substantial public health benefit by greatly reducing the risk of foodborne illness to the consumer. Data clearly substantiates that the technology to achieve such reductions in pathogens common to poultry can be readily obtained through the use of existing technology. Consequently, the proposed amendment should be subjected to rulemaking as expeditiously as possible to allow poultry processors the benefit of on-line poultry reprocessing, while at the same time reducing the risk of foodborne illness to the vast poultry consuming public of this country. Validation for this request, as set out in further detail herein, exists from the substantial data generated by Rhodia Inc. in FSIS approved commercial poultry plant trials which have consistently shown that an on-line reprocessing system utilizing trisodium phosphate (TSP) can achieve pathogen reduction at levels substantially less than the requested performance standards.

II. BACKGROUND

As mentioned above, the substantiation for this requested rulemaking has its basis in an overwhelming amount of data generated by trials conducted during commercial operations in poultry slaughter plants utilizing on-line reprocessing with the application of a trisodium phosphate carcass rinse system. By way of background and understanding, TSP is a safe substance, listed by the Food and Drug Administration (FDA) as a multiple purpose generally recognized as safe (GRAS) food substance at 21 CFR 182.1778. See Exhibit 2 attached hereto and made a part of the petition by this reference. TSP has also been specifically approved by FSIS for use as an antimicrobial agent on raw chilled poultry



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carcasses, on raw unchilled poultry carcasses, on unchilled poultry giblets, and on raw beef carcasses.

Since 1987, Rhodia Inc., its parent company, Rhône-Poulenc Inc., and its predecessor company, Stauffer Chemical Company, have conducted tests on the efficacy of various processes utilizing solutions of TSP on raw poultry and raw meat carcasses for the purpose of reducing the numbers and incidence of various pathogenic bacteria commonly found on such carcasses. As a part of this research, numerous laboratory, plant, and commercial trials have been conducted, nearly all in consultation and cooperation with FSIS.

In 1992, Rhône-Poulenc petitioned (HC007) for, and FSIS granted interim approval of, the use of TSP on raw chilled poultry carcasses for its antimicrobial effect. Subsequently, the use of TSP on raw chilled poultry carcasses was added to the list of approved substances at 7 CFR 381.147 under a new class of substances entitled "Antimicrobial agents". Also, in 1994 Rhône-Poulenc petitioned and FSIS approved, both the use of TSP as an antimicrobial agent on raw unchilled poultry carcasses (HC015), and on unchilled poultry giblets (MT023). In 1995, Rhône-Poulenc petitioned (95-46) and FSIS approved the use of TSP as an antimicrobial agent on raw beef carcasses.

With specific reference to poultry, the efficacy of TSP rinses in reducing the incidence rates and levels of pathogenic bacteria during slaughter operations is well documented. Salmonella incidence rates can be reduced to below 1%, Enterobacteriaceae and E. coli can be reduced to below the level of detection, Campylobacter CFU's/ml can be reduced more than four logs while incidence rates can be reduced by greater than 40%, and Aerobic Plate Counts can be reduced up to 1.5 logs. For the general purpose of validating the efficacy of TSP as an antimicrobial agent for various pathogens on both poultry and beef, we request that the petitions and all supporting data contained in petitions HC007, HC015, MT023 and 95-46, filed with the FSIS Hearing Clerk, be incorporated by this reference to the extent pertinent herein.

III. ON-LINE REPROCESSING TRIALS AND EFFICACY DATA

A. PROTOCOL FOR COMMERCIAL PLANT TRIALS



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In light of positive laboratory studies and the antimicrobial efficacy demonstrated by TSP in commercial poultry slaughter operations, Rhodia Inc. approached FSIS for authorization to conduct in-plant trials of the use of TSP for on-line reprocessing of carcasses. Consequently, a protocol was developed and approved by FSIS to conduct validating trials of the use of TSP for on-line poultry reprocessing. Under the protocol, a TSP treatment system utilizes inside/outside birdwashers (IOBW) for the on-line reprocessing of poultry carcasses. Briefly, the protocol provides that poultry carcasses accidentally contaminated with digestive tract contents, but not grossly contaminated, which would normally be reprocessed off-line are allowed to proceed on-line and be reprocessed utilizing the TSP treatment system. The on-line reprocessing is accomplished in two stages. In the first stage, carcasses are subjected to removal of particulate contamination by passing through one or more IOBWs utilizing a water spray containing 20 ppm chlorine. In the second stage, carcasses pass through another IOBW where a TSP antimicrobial rinse is applied. It should be noted that a clear advantage to this on-line reprocessing system is the fact that by allowing the contaminated carcasses to remain on-line, all carcasses, including "normal" carcasses, are subjected to this further rinsing and antimicrobial treatment.

The TSP on-line reprocessing trials have proceeded utilizing several critical operating parameters under which data is obtained. They are as follows:

1. TSP Concentration of 8% - 12%. (Critical limit is not less than 8%)
2. Temperature – not more than carcass temperature at the time of treatment.
3. Grossly contaminated carcasses (cannot make disposition) are reprocessed off-line in the normal manner.
4. Zero fecal tolerance and FPS tolerance for ingesta prechill inspection station. (No change – must meet FSIS policy and existing FPS limits)



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B. TRIAL SAMPLING

Each TSP on-line reprocessing trial has an initial 12 week operating duration for the purpose of data collection. During that time period, the data must demonstrate satisfactory pathogen reduction and successful process control. Each trial results in obtaining 960 samples from carcasses which are tested by an independent, certified laboratory. All data from each trial is submitted to FSIS as the data becomes available from the testing laboratory.

The 960 samples generated in the initial operating duration at each plant are equally divided among three sampling points. "A" samples are taken randomly from "normal" on-line fully eviscerated carcasses obtained immediately prior to the first IOBW rinse. Consequently, the "A" samples, obtained from visibly noncontaminated carcasses, can be thought of as controls and they represent the actual bacterial load on carcasses proceeding on-line during days the sampling is conducted. "B" samples, from visibly contaminated carcasses that would normally have been off-line reprocessed, but which were marked and allowed to be reprocessed on-line, are obtained from those carcasses following application of the TSP treatment system and prior to entering the chiller. "C" samples are obtained from carcasses following a plant's current off-line reprocessing procedure. All samples taken are shipped to independent, certified laboratories for analysis of Aerobic Plate Count (APC), Enterobacteriaceae counts, E. coli counts and Salmonella incidence by "AOAC/BAM" methods of analysis.

C. PLANT TRIAL RESULTS

Results of the sampling for the initial 12 week operating duration of TSP on-line reprocessing for the first five plants participating in the trial have been made available by the independent, certified laboratories. A cumulative summary of the sampling results taken at these five plants is attached and made a part hereof by this reference as Exhibit 3. Results of sampling at each of the five plants are individually attached hereto and made a part hereof by this reference as Exhibits 4, 5, 6, 7 and 8. (These data also submitted to FSIS on computer disk.)



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The cumulative results obtained from all five plants as summarized in Exhibit 3 clearly demonstrate the efficacy of the TSP application system for on-line reprocessing of poultry carcasses. Perhaps most importantly, based on the results of the reprocessed on-line carcasses, one can infer that all poultry carcasses on-line, the "normal" carcasses and the carcasses that would previously have been subjected to off-line reprocessing, experience substantial pathogen reductions as a result of the on-line TSP reprocessing which would not have otherwise occurred. Specifically, on-line reprocessing utilizing the TSP system results in significant reductions in incidence rates and/or the average numbers of each organism tested.

The cumulative results of the five plants summarized in Exhibit 3 are based on the results from more than 1500 samples each of the normal on-line "A" carcasses, the TSP on-line reprocessed "B" carcasses, and the off-line reprocessed "C" carcasses. The results indicate that on-line TSP reprocessing achieves a one log greater reduction in average numbers of Aerobic Plate Counts than normally processed on-line carcasses and a one half log greater reduction in average APC numbers than off-line reprocessing. For Enterobacteriaceae, TSP on-line reprocessing reduced incidence rates to 1% while the average incidence rate for normal on-line carcasses was 98%, and the average incidence rate was 81% for off-line reprocessed carcasses. On-line TSP reprocessing resulted in less than a 1% incidence rate for E. coli, while normal on-line carcasses had an average incidence rate of 97%, and off-line reprocessed carcasses averaged an incidence rate of 72%. Salmonella incidence rates for TSP on-line reprocessed carcasses were less than 0.1% while normally processed on-line carcasses averaged an incidence rate of 30%, and off-line reprocessed carcasses averaged a 22% incidence rate. The testing also shows that the TSP on-line reprocessing system results in a greater than 40% reduction in Campylobacter incidence rates.

The importance of the requested on-line reprocessing rulemaking from a public health standpoint is further evident from a review of individual plant data regarding Salmonella. For example, the data indicate that "normal" carcasses proceeding on-line had average incidence rates of as high as 72% for Salmonella. In all cases, results of sampling of carcasses in the plants following the TSP on-line reprocessing treatment on those days showed a zero incidence rate for Salmonella. Sampling of



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off-line reprocessed carcasses on those days indicated some reduction in Salmonella incidence rates due to traditional off-line reprocessing, but the average incidence rate was still as high as 45%. These data demonstrate the urgent need for FSIS to authorize on-line reprocessing of poultry carcasses, both to improve pathogen reduction for traditionally reprocessed carcasses and for the normal carcasses that remain on-line, especially for those days where high levels of pathogenic bacteria occur due to a variety of reasons including seasonality, flock variation, and other common factors.

D. PRODUCT, WORKER, AND ENVIRONMENTAL SAFETY CONSIDERATIONS

The trisodium phosphate used in on-line reprocessing of poultry is all food grade and complies with all requirements of the Food Chemicals Codex, as supplemented. As mentioned earlier herein, the TSP used is a generally recognized as safe (GRAS) listed substance by the Food and Drug Administration for use as a multiple purpose food substance. Also, TSP has been specifically authorized by FSIS for use as a substance in meat and poultry processing for a number of different functions, specifically including use as an antimicrobial agent.

As with all general TSP use and application, the on-line reprocessing trials complied with all FSIS worker safety requirements, the Rhodia material safety data sheet for TSP use, and applicable ANSI standards to minimize any possible exposures. Rhodia also conducted TSP environmental air sampling to validate worker safety during each trial's operation. No significant phosphate exposures or worker safety incidents were reported during the course of the trials.

The use of TSP for on-line poultry reprocessing poses little, if any, environmentally related concerns. Several methods of TSP effluent disposal may be utilized. Normally, TSP effluent will be treated as other plant effluent subjected to an individual plant's water treatment system and disposed of as a flocculent. Regardless of the method utilized, all TSP is disposed of in compliance with all local, state, and federal requirements applicable to each plant.



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IV. NEED FOR CHANGE

The on-line reprocessing trial results outlined herein, and as validated by the data contained in the exhibits attached hereto, clearly substantiate the need for FSIS to adopt the requested rulemaking. Given the dramatic reductions in pathogenic bacteria common to poultry which can be achieved through on-line reprocessing utilizing a commercially validated and scientifically recognized technology such as the TSP reprocessing system, the widespread use of on-line reprocessing in poultry slaughter plants will provide a significant public health benefit by substantially reducing the risk of foodborne illnesses posed by common poultry pathogens.

It is recognized that FSIS' current rule places strict limitations on the circumstances when a contaminated poultry carcass may be reprocessed and subsequently be found fit for human consumption. While it has been demonstrated that on-line poultry reprocessing will provide significant public health benefits to the consumer and significant benefits to poultry processors, the proposed rulemaking does, however, take into consideration the need to justify making an exception to the current strict reprocessing requirements by establishing pathogen reduction standards which a qualified on-line reprocessing system must achieve under commercial operating conditions. Requiring a poultry processor's system to comply with the proposed pathogen standards as a condition precedent to taking advantage of the multiple benefits of on-line reprocessing insures that public health benefits and reductions in the risk of foodborne illness to consumers from poultry will occur.

FSIS is to be commended for its efforts to address the issue of pathogen reduction in meat and poultry products and for requiring Hazard Analysis and Critical Control Point (HACCP) systems for meat and poultry operations. We believe the proposed rulemaking is clearly consistent with FSIS' efforts and the concept of HACCP. The on-line reprocessing system will very likely be a critical control point and be incorporated into a plant's overall plan. Requiring on-line reprocessing systems to meet the proposed pathogen reduction standards is consistent with HACCP principles. Further, the development of the TSP on-line reprocessing system is a very good example of the type of technology which FSIS has encouraged the private sector to develop, validate, and commercially adopt. In this way FSIS and the poultry industry will move toward the shared goal of safer poultry products.



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Additionally, adopting the proposed rule will provide the industry with access to another important tool for complying with HACCP requirements. The standards which must be achieved in order to utilize on-line poultry reprocessing will ensure a plant's compliance with the HACCP performance standard for Salmonella and the performance criteria for generic E. coli. In either case, the use of on-line reprocessing will allow a poultry plant to achieve greater pathogen reduction levels than those otherwise required by the FSIS performance standard and the performance criteria, very significant additional benefits for the consumer. Lastly, FSIS has taken a very prominent role in identifying the cost associated with foodborne illnesses to the consuming public, both in terms of human and financial costs. FSIS has stated that nearly five million cases of foodborne illness are annually related to meat and poultry products contaminated with pathogenic organisms, that about 4,000 deaths may be associated with those foodborne illnesses, and that the total annual dollar cost to the public from such illnesses is nearly \$5 billion. In light of these sobering statistics, the ability to effectuate the tremendous pathogen reductions validated in the data attached hereto presents a compelling justification for the expeditious adoption of the proposed rule allowing on-line reprocessing of poultry.

V. ECONOMIC IMPACT

The cost for a poultry plant to adopt an acceptable on-line reprocessing system will vary from plant to plant and be contingent upon the type of reprocessing system being implemented and the location, physical structure, and age of the plant and its existing equipment. While we cannot estimate what such cost may be for any type of reprocessing system other than the TSP application system utilized by Rhodia, the TSP on-line reprocessing system can be commercially adopted in poultry plants at a reasonably modest overall cost amortized over the life of the equipment. For example, it is estimated that the cost for equipment for a single line will approximate \$30,000, and that the TSP application cost will be about 0.2 cents per pound for an average chicken slaughter plant. Again, equipment and application costs will vary from plant to plant based on a number of factors including plant size, species slaughtered, number of lines, daily processing capacity, plant configuration, and adaptability of existing equipment.

As this representative estimate shows, the cost of a TSP on-line reprocessing system represents an insignificant portion of the retail price per pound of poultry. Certainly, it represents a small cost in comparison to the benefit to be derived from expected reductions in foodborne illness outbreaks. In fact, plants should



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be able to achieve substantial cost savings from on-line reprocessing due to the increased operating efficiencies and the decreased amount of off-line reprocessing it affords. Consequently, we believe that only a modest retail increase in the price of poultry, if any, may result from the adoption of on-line reprocessing treatment systems, but that any increase would be favorably accepted by consumers in exchange for the reduced risk of foodborne illness associated with this important pathogen reduction system.

VI. CONCLUSION

In recent past years USDA has taken bold steps, as stated by Secretary Glickman in announcing the HACCP/Pathogen Reduction final rule, to "improve the safety of American meat and poultry by directly targeting the reduction of the pathogens that cause foodborne illness." Secretary Glickman went on to state that by taking steps aimed at "preventing and reducing contamination of meat and poultry with harmful bacteria such as E. coli 0157:H7 and Salmonella", the new FSIS approach will save lives and reduce foodborne illness. In light of the Secretary's stated goals, which we believe are fully shared by the poultry industry and the consuming public, the data submitted herewith make the strongest possible case for FSIS to expeditiously take steps to finalize the requested rulemaking by formally authorizing the use of on-line poultry reprocessing when the reprocessing system meets the requested pathogen levels for Salmonella and E. coli. The data clearly indicate that technology exists, through the use of the tested TSP reprocessing system, to consistently reduce prechill generic E. coli levels to below levels of detection and to reduce Salmonella incidence rates to well below 0.5%. The significance of the results of on-line reprocessing are even more important from a public health standpoint as the data indicates that such results can be achieved even where the E. coli and Salmonella incidence rates prior to such on-line reprocessing treatment are as high as 100%. Because of the tremendous pathogen reduction potential of this technology, which is completely in keeping with FSIS' stated HACCP and pathogen reduction objectives, FSIS should quickly approve poultry on-line reprocessing so that it can be rapidly adopted by the industry and so that the public health benefit can be made available to the consuming public as soon as possible. Therefore, we request your expeditious consideration and action to



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finalize the requested rulemaking authorizing poultry on-line reprocessing in instances where such reprocessing achieves the required pathogen standards.

We look forward to your early response to this petition to finalize a rule approving and establishing the parameters for the on-line reprocessing of poultry. In the interim, we request your continuing authorization to initiate on-line reprocessing, under the critical operating parameters outlined herein, at plants requesting such trials, and to continue operations and the collection of additional data at all plants where the initial twelve week operating duration has concluded. All data generated from current ongoing trials, new trials, and those plants operating after the initial twelve week operating duration will be promptly submitted to FSIS for the agency's review and to further support and supplement this petition.

Should you have questions regarding any aspect of this requested rulemaking, please promptly contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "James T. Elfstrum". The signature is fluid and cursive, with a large initial "J" and "E".

James T. Elfstrum
Manager, Regulatory Affairs
JTEjn:98-170

cc: Margaret O'K. Glavin
Patricia Stolfa

EXHIBIT 1

REGULATORY CHANGE TO ALLOW ON-LINE POULTRY REPROCESSING

Amendment to 9 C.F.R. 381.91--adding a new subsection, as follows:

"(c) Notwithstanding the provisions of subsection (b) of this section, any carcass of poultry accidentally contaminated during slaughter, but determined to not be grossly contaminated, with digestive tract contents may remain on the main processing/slaughter line and be promptly reprocessed while on-line through the application of a substance or a processing system that has demonstrated, with statistically significant validating data generated under conditions of in-plant commercial operation, the ability to reduce prechill incidence rates of Salmonella to less than 0.5% and to reduce prechill incidence rates for Escherichia coli Biotype I to less than 1%."

EXHIBIT 2

§ 182.1778 Sodium Phosphate.

(a) Product. Sodium phosphate (mono-, di-, and tribasic).

(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

EXHIBIT 3

OLR Cumulative Plant Trials

August 30, 1998

The Rhodia logo features a stylized white 'C' shape on the left, followed by the word 'Rhodia' in a white, italicized serif font.

SUMMARY OF CUMULATIVE RESULTS - "OLR" STUDY AT ALL PLANTS

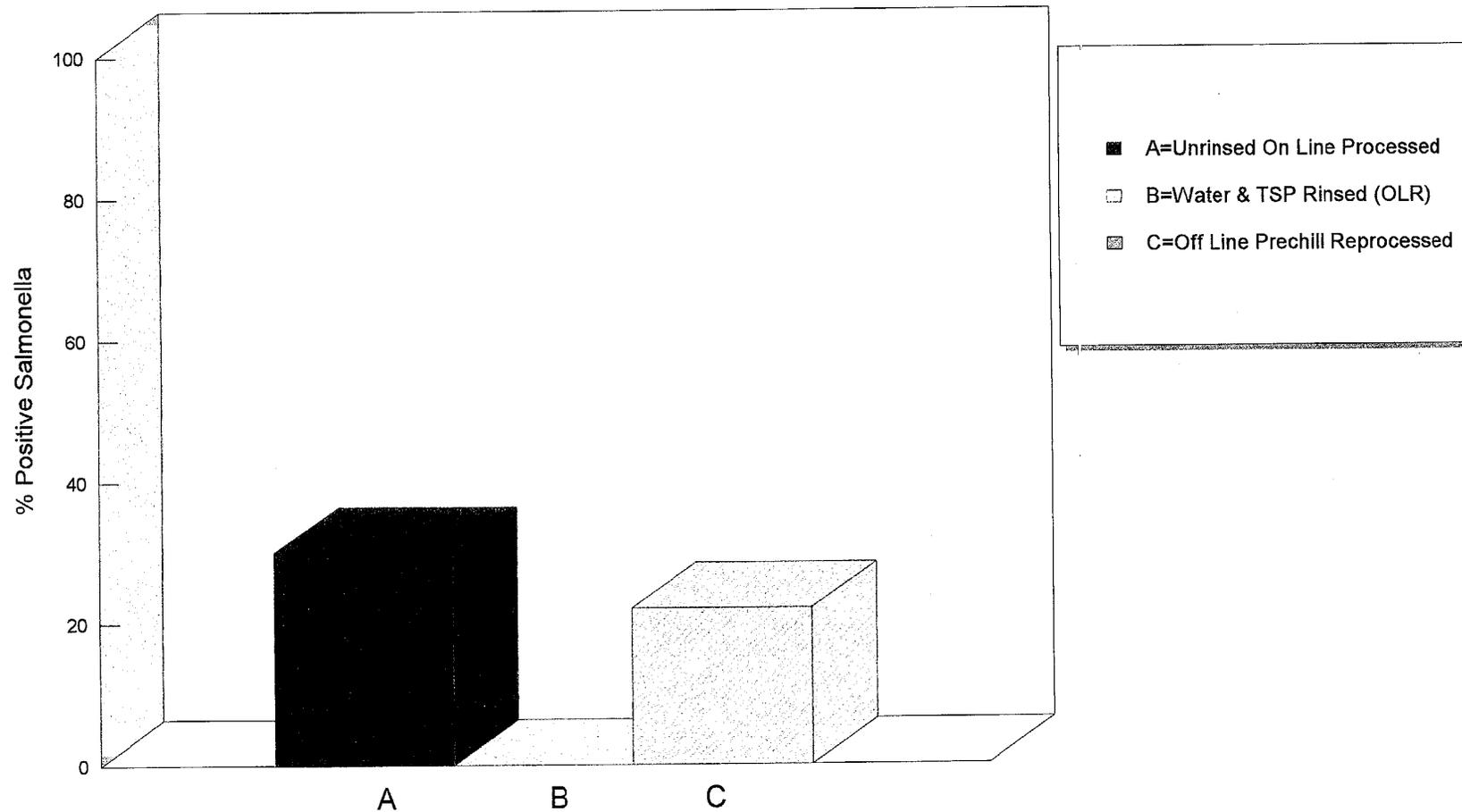
As of: Aug. 30 , 1998

	APC	Entero	E. coli	Salmonella	Campylo- bacter **
Normal Birds					
Site "A"					
Average	< 25,961	< 727	< 530	----	----
Incidence Rate	100%	98%	97%	30%	78%
# of Samples	1,530	1,530	1,530	1578	547
On-Line Reprocessed Birds					
Site "B"					
Average	< 2,581	< 18	< 11	----	----
Incidence Rate	94%	1%	0%	0%	46%
# of Samples	1,526	1,526	1,526	1572	547
Off-Line Reprocessed Birds					
Site "C"					
Average	< 12,175	< 312	< 162	----	----
Incidence Rate	100%	81%	72%	22%	80%
# of Samples	1,529	1,529	1,529	1579	548

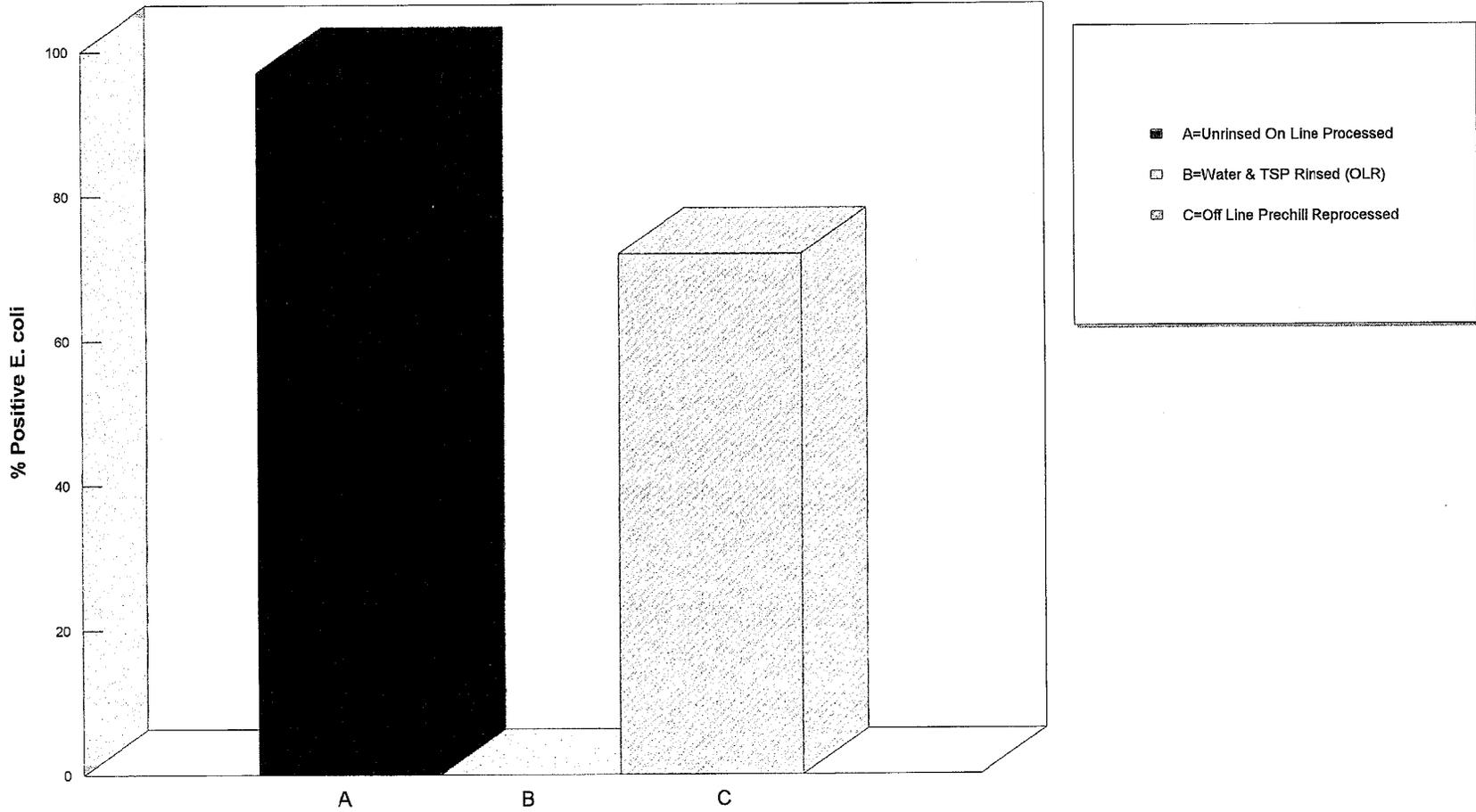
* Note: Actual number of samples may differ for individual assays because of lost or damaged samples.

**There were no campylobacter samples tested for phase 2.

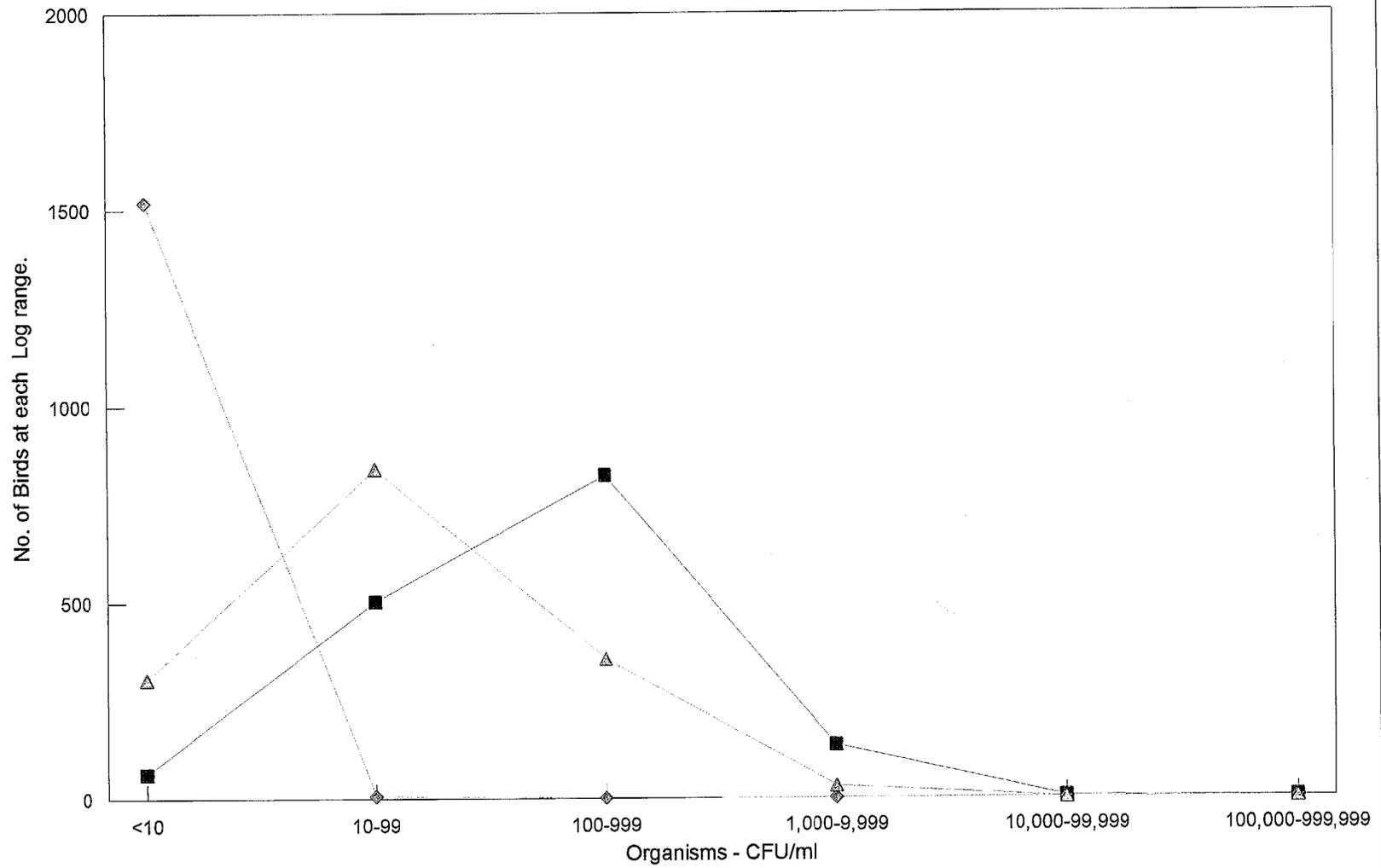
OLR TSP CUMULATIVE TRIALS AT ALL PLANTS
Salmonella Incidence rate as of Aug. 30, 1998



OLR TSP CUMULATIVE TRIALS AT ALL PLANTS
E. coli Incidence rate as of Aug. 30, 1998

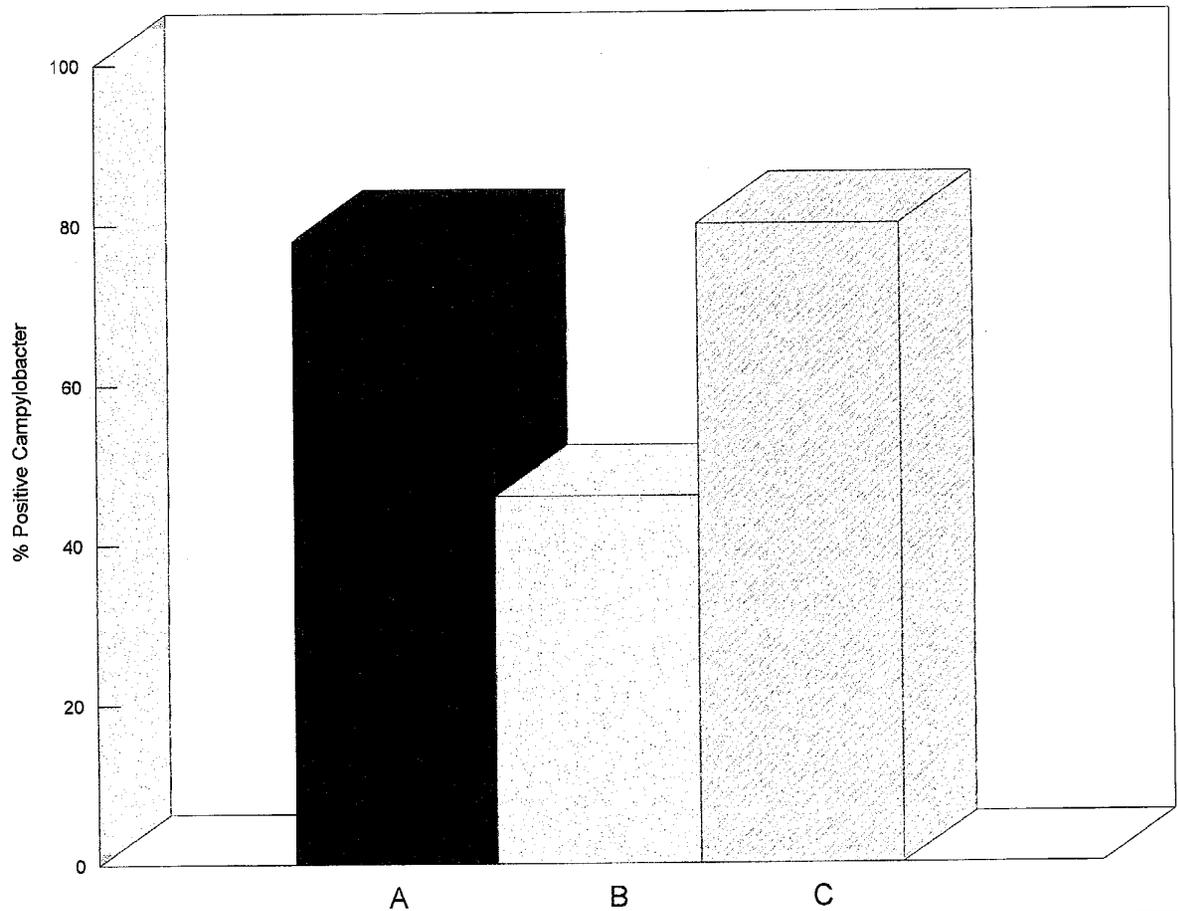


OLR TSP Trial at All Plants E. coli Data Distribution



■ A = Pre-IOBW ◆ B = On Line Repro. (TSP) ▲ C = Off Line Repro.

OLR TSP CUMULATIVE TRIALS AT ALL PLANTS
Campylobacter Incidence rate as of Aug. 30, 1998



- A=Unrinsed On Line Processed
- ▨ B=Water & TSP Rinsed (OLR)
- ▩ C=Off Line Prechill Reprocessed