

Sanova[®] Food Quality System
Protocol for Validation Studies to be conducted by Alcide Corporation
for Poultry Plant Startups

Experiment No./Project No:

(The calendar date of the planned start plus two letters identifying the location e.g. 050199PF).

Location:

(The complete plant address and contact details).

Dates:

(The planned start and completion dates).

Study Coordinators:

(Alcide and plant personnel that will be primarily responsible in oversight the testing process).

Objective: Generally to validate the impact of acidified sodium chlorite (ASC - Sanova[®]) treatment on the surface microbial populations of processed poultry. Also, to validate the performance of the Sanova[®] Continuous On-line Processing (COP) system in comparison to a plant's standard off-line reprocessing system. The populations of *Escherichia coli*, total *Coliform* the incidence of *Salmonella* spp. will be measured and/or monitored.

Experimental Design:

Table 1: Sample Site Designations and Sample Numbers

SAMPLE SITE	NUMBER	PROCEDURE	VALIDATION PROCESS	
			PERFORMANCE	COP
SS1. Post Evisceration	10	Whole carcass rinse	No	Yes
SS2. Post IOBW	10	Whole carcass rinse	Yes	Yes
SS2. Post IOBW	10	Zero Fecal check	No	Yes
SS3. Post Sanova	10	Whole carcass rinse	Yes	Yes
SS4. Off line Reprocessed	10	Whole carcass rinse	No	Yes
SS5. Post Chill	10	Whole carcass rinse	Optional	Optional

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Sampling Plan:

If the facility is installing the Sanova[®] system for COP benefits then the following sampling schedule should be followed:

Validation for COP: In addition to the sampling schedule designated for the "Validation of Performance," the following additional procedures will be applied at each of the designated sample sites on each sample day for a total of four days over the first month of operation. At least one sample day for COP validation must be completed during the first week of full operation:¹

SS1. Ten marked carcasses will be randomly collected from one line, Post evisceration and subjected to a whole carcass rinse procedure.

SS2. Ten marked carcasses will be randomly collected from the same line, Post IOBW and subjected to a whole carcass rinse procedure.

SS2. Ten marked carcasses will be randomly collected from the same line, Post IOBW and examined for Zero fecal tolerance.

SS3. Ten marked carcasses will be randomly collected from the same line, Post Sanova and subjected to a whole carcass rinse procedure.

SS4. Ten marked carcasses will be randomly collected from the same line post-evisceration then re-routed to the off-line reprocessing area.

Following off-line reprocessing, these ten carcasses will be subjected to a whole carcass rinse procedure.

SS5. Optionally, ten carcasses will be randomly collected from the same line Post Chill and subjected to whole carcass rinse procedure.

Plant Operation: The Inside/Outside Bird Washers (IOBW's) on all lines will be configured to run as normal but preferably with chlorinated water at an incoming feed line level between 20 to 30 ppm free chlorine. Pre-chiller and post-chiller waters will be chlorinated at normal plant levels.

Microbial Methods: Samples may be processed by the plant's own microbiological facilities or may be processed by an independent laboratory. The standard plating methods for *Escherichia coli* and coliform enumeration and for the determination of incidence of *Salmonella spp.* will be applied.

¹ Note that testing for Performance Validation can be combined with testing for COP Validation. Hence, at any COP site startup, sampling during week one would only be required on three days, one of which would be for both COP and Performance Validation purposes. The total No. of sample days required for a typical COP site startup would therefore be six.

Table 4: Total Microbiological Sample Numbers for COP Validation.

Sample Site ID	Organism		
	<i>Escherichia coli</i>	<i>Salmonella spp.</i>	<i>Campylobacter spp.</i>
Post Evisceration	40	40	40
Post IOBW	40	40	40
Post Sanova	40	40	40
Post OLR	40	40	40
Post Chill (optional)	(40)	(40)	(40)
Total	160 (200)	160 (200)	160 (200)

Sampling Schedules:

1. Validation for COP

Sampling should be initiated during the first week after startup of the plant's system (in combination with the sampling for Validation of Performance). Samples will be collected once a week for a total of four weeks. Sample days will be every Tuesday. On each sample day, samples should always be collected from the same line. The line to be sampled may be changed between sample weeks.

WEEK	TUESDAY
Week 1	Sample
Week 2	Sample
Week 3	Sample
Week 4	Sample

General Procedures:

Comment: The sampling will begin approximately one hour following determination of an acceptable Sanova[®] Food Quality System startup (Mixed product pH at 2.5, chlorite at 1100 ppm). Prior to startup, all of the nozzles in the Sanova[®] cabinets should be checked to ensure that they are not blocked. Standard practices for the maintenance of aseptic techniques will be applied at all times for the collection of carcass samples throughout the duration of the study.

Carcass Marking: On each sample day, the USDA inspector on the specific line to be sampled will be asked to identify fecal or food contaminated carcasses to his/her helper. This will only be required during the period of sampling. The inspector's helper will then mark the carcasses by a method suitable for the plant and that will not be confused with marking methods used for other requirements. Examples of possible marking methods are; a single knife cut below the tail; a split tail; tail removal.

Sampling supplies:

- 400 ml volume carcass rise solutions of sterile Butterfield's phosphate diluent containing 0.1% sodium thiosulfate.
- Sterile Stomacher Bags
- 70 % Isopropyl alcohol as Disinfectant
- Sterile Gloves
- Scissors
- Cooler
- Blue ice bags
- Gallon size Ziplac bags
- Labeled taps (Date/site/ID)

Buffer Storage: The sterile sampling Buffer can be stored at room temperature. However, to obtain the most accurate results, upon receipt check solutions for cloudiness then place the number of bottles of sampling buffer that you will need for the next day's sampling in the refrigerator at least one day prior to sample collection.

Before sample collection, ensure all sampling supplies are present and have been properly labeled.

Carcass Collection Procedure: On the day of sampling, gather together all of the required supplies. When ready, put on sterile gloves and open a stomacher bag without touching the sterile interior of the bag. (Rubbing the top edges between the thumb and forefinger will cause the top to gape for easier opening).

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With one hand, push up through the bottom of the sampling bag to form a “glove” over the hand and use this “glove” to grab the bird, while using your other hand to pull the bag back over the hand that will grab the bird. This should be done aseptically without touching the exposed interior of the bag.

Using the hand with the bag reversed over it, pick up the bird by the legs through the stomacher bag and place the bird vent up into the sampling bag. Do not touch the exposed interior of the bag.

Rest the bag on a flat surface. 6 While holding the top of the bag slightly open, add the 400-ml of sterile buffer to the plastic bag, attempting to pour the solution into the vent of the carcass and over the body.

Close the bag and rinse the bird inside and outside using a rocking motion for a total of 30 shakes or approximately one minute.

Open the buffer container and rest the cap upside down on a flat table. Spray your scissors with disinfectant (70% Alcohol) as well as the corner of the stomacher bag that is to be clipped. Cut the corner of the stomacher bag with the scissors and aseptically pour the rinse sample from the carcass rinse bag back into the buffer container.

Close the top of the container and place it in the cooler.

Sample Shipment: If the samples are to be shipped to a remote laboratory for assay, place the collection bottles into a plastic cooler containing a bed of chipped ice on the bottom as soon as possible after collection. When all samples have been collected, remove the chipped ice then add frozen blue ice packs and double bagged, chipped ice to the cooler to fill the remaining space. (It is very important that you ensure the bag of chipped ice is sealed properly with twist ties to prevent any leakage. Using double bags will ensure that there will be absolutely no spillage into the shipping container). Place a corrugated cardboard pad on top of samples to prevent the direct contact of frozen gel packs with samples. Seal the cooler with packing tape and label with the appropriate shipping documents. Mark your packages for next day delivery and store in a refrigerated area until as close as possible to the time of collection for shipment.

If the samples are to be processed by the plant, follow the same procedures as above but exclude the use of frozen blue ice and do not seal the container for shipment. The sample bottles may be nestled in a bed of chipped ice until processed. If the samples are to be held for any period of time prior to assay by the laboratory, they should be kept in a refrigerated area but for no longer than 24 hours.

USDA Notices of Sanova Approval



**United States
Department of
Agriculture**

**Food Safety
and Inspection
Service**

**Washington, D.C.
20250-3759**

Dr. G. Kere Kemp
Executive Vice President
Alcide Corporation
8561 154th Avenue NE
Redmond, WA 98052

JAN - 7 1999

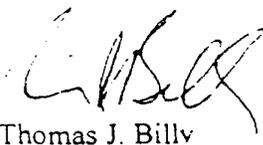
Dear Dr. Kemp:

This letter is in response to your request for approval of the Sanova system as an antimicrobial treatment. We have considered your request as a petition to amend 9 CFR 381.147(f)(4) to permit the use of acidified sodium chlorite as an antimicrobial agent. The Food Safety and Inspection Service (FSIS) has completed the technical review of your application and supporting data, including data from FSIS approved inplant testing. FSIS has determined that the acidified sodium chlorite in a system using Sanova International equipment is effective in reducing microbial levels on raw poultry carcasses when applied as a spray or dip solution.

The Food and Drug Administration (FDA) concluded (Federal Register Vol. 61, pages 17828-17829) that an acidified sodium chlorite solution is safe and will have the intended effect of reducing microbial contamination on poultry. FDA consulted with FSIS scientists when making this determination.

Based on these determinations, FSIS is proceeding with rulemaking proposing to add acidified sodium chlorite solution to the poultry product inspection regulations, 9 CFR 381.147(f)(4) as an antimicrobial agent to reduce microbial levels on raw poultry carcasses. FSIS also grants interim approval for use of acidified sodium chlorite solution as a processing aid for the purpose of reducing microbial levels on raw poultry carcasses when used as a spray or dip in accordance with the conditions prescribed in § 173.325 (21 CFR Part 173).

Sincerely,


Thomas J. Billy
Administrator

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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JAN 14 1999

Dr. G. Kere Kemp
Executive Vice President
Chief Scientific Officer
Alcide Corporation
8561 154th Ave., NE
Redmond, WA 98052

Dear Dr. Kemp:

This is in response to your letter dated January 8, 1999, requesting a continuation of in-plant trials evaluating the Sanova acidified sodium chlorite anti-microbial system according to a protocol, revised September 24, 1998. The trial being conducted at Establishment P-2178, Perdue Farms, Inc., Georgetown, Delaware may be re-initiated with Phase II, involving expansion of the system to all four evisceration lines at the facility. Testing may be expanded to other facilities and concurrent multiple plant trials are permitted. Please notify us at least one week before each start date to allow for notification of inspection personnel.

Agency inspection personnel will allow carcasses that are normally subject to off-line reprocessing to be processed on-line using the Sanova System. Carcasses determined by the inspector to be grossly contaminated will not be processed on-line.

During testing of the Sanova System, on-line processed carcasses will continue to comply with the regulatory requirement in 9 CFR 381.65(e) that carcasses contaminated with visible fecal material not enter the chilling tank and with the finished product standards in 9 CFR 381.76(b)(3). Also, carcasses must comply with the criteria for verifying process control (*Escherichia coli* testing) and the pathogen reduction performance standards for *Salmonella* as prescribed in Section 381.94 of the poultry regulations. The data collection and analysis will include pre-and post-treatment samples tested for the presence of *Campylobacter* spp.

The in-plant trial will have an initial 90-day duration for data collection in accordance with the protocol. Daily sampling will consist of 40 carcasses per day.

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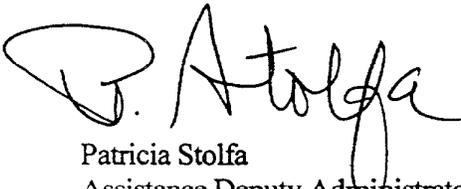
Dr. G. Kere Kemp

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Alcide Corporation will conduct an information session before the start of each trial for Agency inspection personnel and company employees. A briefing packet will be available for reference and technical guidance.

If you have any questions, please contact Patrick Burke at (202) 205-0005.

Sincerely,

A handwritten signature in black ink, appearing to read "P. Stolfa". The signature is written in a cursive style with a large, looped initial "P".

Patricia Stolfa
Assistance Deputy Administrator
Office of Policy, Program Development
and Evaluation

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Plants Involved in Sanova[®] COP Testing

Plant Name	Address	P #
Gold Kist, Inc.	1 Gold Kist Street, Boaz, Alabama 35957	P413
Perdue Farms, Inc.	200 Savannah Road, Georgetown, Delaware 19947	P2178
Perdue Farms, Inc.	255 N. Rehoboth Blvd., Millford, Delaware 19963	P1318
Townsend's, Inc.	Route 24 East, Millsboro, Delaware 19966	P3
Tyson Foods, Inc.	100 East Cassady, Nashville, Arkansas 71852	P7100

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