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FSIS Docket Clerk
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USDA /FSIS
Room 102, Cotton Annex
300 12th St SW
Washington, DC 20250-3700
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97-013F
97-013F2
Robert Hanson

To whom it may concern:

I request that FSIS remove all commercial names – including names of specific equipment manufacturers and any trade marks – from Attachment 4 of the FSIS "Compliance Guidelines to Control *Listeria monocytogenes* in Post-lethality Exposed RTE Meat and Poultry Products." If this change is not possible, then because the post-lethality treatments listed in the guidelines are not specific to any equipment manufacturer, I request that a complete list of *all* equipment manufacturers that sell in the U.S. be listed in the appropriate category

The three categories listed in Attachment 4, Section A of the FSIS Compliance Guidelines are – (I) Steam and hot water pasteurization, (II) Pre- and post-package surface pasteurization, and (III) High hydrostatic pressure. By inclusion, these methods are FSIS-suggested means of post-lethality treatments or interventions to treat RTE meat and poultry products. However, these post-lethality treatments are not exclusive to any specific equipment manufacturer, and in fact all can be run on many different manufacturer's equipment. Therefore, any mention of a commercial name is an implied endorsement by FSIS of that specific equipment manufacturer.

As a government agency, I know that the USDA FSIS must avoid endorsing any specific brand of equipment or ingredients. As a policy, I believe that the USDA typically adds the disclaimer, "Mention of trademarks or commercial names does not constitute endorsement by USDA" to any documents that list commercial names – as noted on Attachment 4. However, notwithstanding this disclaimer, the mention of specific commercial names in the *Lm* Compliance Guidelines still implies endorsement, and thus should be avoided. If it is believed that commercial trade names must be used, then to be fair the FSIS should list *all* manufacturers that sell equipment in the U.S. for each category. However, to avoid any inadvertent omissions or implied endorsements, I believe that the simplest solution is to remove all references to commercial names.

Example of implied FSIS endorsement

One example of implied endorsement of a specific manufacturer is listed in Section A.II. "Pre- and Post-package Surface Pasteurization". The second paragraph of this section reads as follows:

> "Muriana et al. (2002) used a stainless steel water bath (similar to the Unitherm commercial Aquaflow food processor) to submerge cooked RTE deli-style whole or formed turkey, ham and roast beef, removed from their package, inoculated with *L. monocytogenes* and vacuum packaged.

Results show a 2-4 log decrease in the levels of *L. monocytogenes* in inoculated products post-cooked at 195-205°F for 2-10 min."

This paragraph gives an implied endorsement of the Unitherm pasteurizer by stating that the hot-water bath used in the cited study was "similar to the Unitherm commercial Aquaflow food processor." In the cited paper, however, the authors did not write that the lab-scale water bath they used was "similar to the Unitherm commercial AquaFlow food processor." The authors actually wrote, "the method of heating and control is similar to Unitherm's commercial Aquaflow™ food processor" (Exhibit 1; Muriana et al., 2002). Furthermore, the researchers used a lab-scale water bath that was not manufactured by Unitherm and was not at all "similar" to a commercial continuous Unitherm Aquaflow™ pasteurizer. As stated in the paper's materials and methods (Exhibit 1), the researchers used a small lab-scale water bath that was designed for manual dipping of one or two pieces of product (5-12 lb each). After heating, the products were manually removed from the hot water bath and submersed in ice water for cooling. In contrast, a commercial Unitherm AquaFlow system is a continuous belt submersion system designed to automatically surface pasteurize and chill over 100,000 lb of product per day (Exhibit 2). The commercial Unitherm system is continuous, not batch – it automatically feeds packages into a hot water tank and conveys them through the machine. Belt pasteurizers would typically be 20-22 ft long and hold over 1,000 gallons of hot water – in contrast to a 3' x 3' lab-scale water bath that might hold 20 gallons. After pasteurization, the Unitherm continuous system automatically conveys packages into an ammonia-based vertical chiller that circulates high velocity air at –30°F to cool the product (Exhibit 2) – in contrast to the cited study where one or two pieces are manually dipped into ice water. In reality, the hot-water bath in the cited study and a Unitherm AquaFlow commercial pasteurizer are not at all similar – nor did the authors say that they were. The only significant similarity between the researcher's lab-scale hot-water bath and a Unitherm AquaFlow continuous pasteurizer is that both use hot water for pasteurization – a trait shared not only with Unitherm but also with Alkar and many other manufacturers of hot-water submersion pasteurizers (Exhibit 3). Post-packaging pasteurization using hot water immersion is a common method of surface pasteurization and is independent of any piece of equipment.

Several potential problems may arise if commercial names are listed in the FSIS Compliance Guidelines. First, any FSIS reference to commercial names may be mis-interpreted as unfairly endorsing or recognizing one manufacturer over other competitive manufacturers. Second, the use of commercial names in the paraphrased excerpts from the studies may inadvertently bias the guidelines in favor of one manufacturer over others. Third, equipment manufacturers, FSIS inspectors, and others may incorrectly refer to the commercial names listed in the Compliance Guidelines as "approved" or "recognized" manufacturers – even though the FSIS no longer approves equipment.

To avoid any misinterpretation of FSIS approval, recognition, or endorsement of specific manufacturers, I recommend that FSIS remove all references to commercial names from Attachment 4 of the *Lm* Compliance Guidelines. If this change is not possible, then I request that a complete list of *all* equipment manufacturers that sell in the U.S. be listed in the appropriate category in the USDA Compliance Guidelines.

Best regards,

Robert Hanson
Vice President of Research & Technology

Exhibit 1

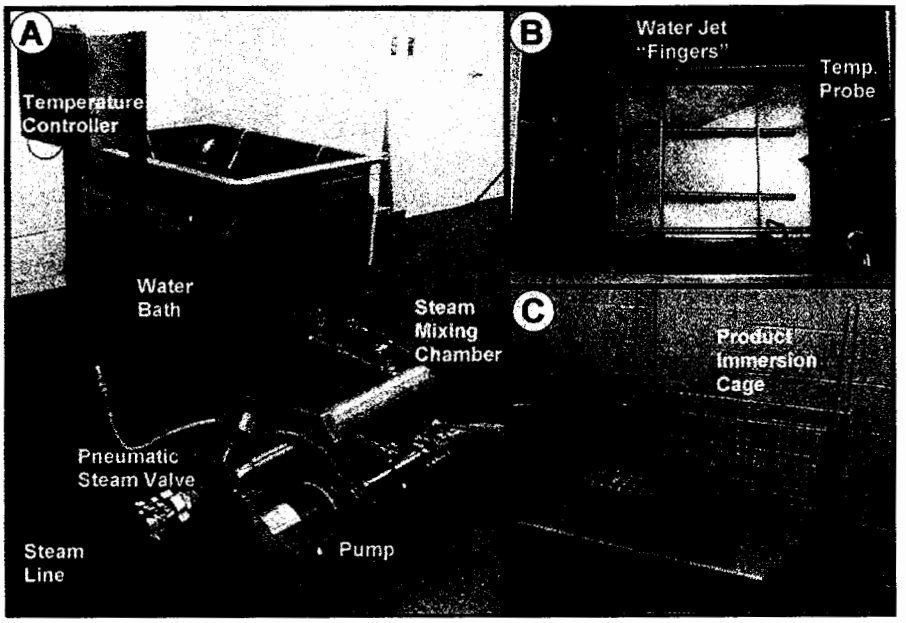


FIGURE 1. *(A) Water bath with digital temperature control, pneumatic valve controlling steam entry, and stainless steel steam injection tube. (B) Inside of water bath showing four sets of directional water jets and the tank temperature probe. (C) Stainless steel cage used to submerge products in the water bath.*

mer sausage inoculated with *L. monocytogenes* and sealed in vacuum packages, achieving as high as 3-log reductions at 210°F. However, little or no published literature is available that adequately addresses submerged water pasteurization of large-sized RTE deli meats (5 to 12 lb) as used herein. In this article, we have examined postpackage submersion heating as an effective means for reduction of *L. monocytogenes* surface contamination in RTE deli meats.

MATERIALS AND METHODS

Cultures. A four-strain cocktail of *L. monocytogenes* (Scott A-2, V7–2, PMM39–2, PMM383–2) was used in decimal reduction assays and postpackage pasteurization experiments. Strains Scott A and V7 are well-known strains; strains PMM383 and PMM39 were isolated from raw and RTE meat products, respectively. The strains have been made constitutively resistant to streptomycin (100 μg/ml) and rifamycin (10 μg/ml) (Sigma Chemical Co., St. Louis, Mo.) by passage on these antibiotics, thereby allowing recovery of viable and heat-injured cells on all-purpose plating media containing these antibiotics (e.g., tryptic soy agar) or recovery from mixtures containing other background microflora. Individual strains of *L. monocytogenes* were cultured overnight in brain heart infusion broth at 30°C (86°F) for use the next morning in inoculation trials.

Decimal reduction assays. Thermal death time curves were performed in thin-walled glass capillary tubes (100 mm, 1.1- to 1.2-mm inside diameter, 0.25-mm wall; VWR Scientific Products, South Plainfield, N.J.). Cultures were grown in brain heart infusion broth at 30°C (86°F), mixed in equal amounts, centrifuged, and resuspended in filter-sterilized purge obtained from smoked turkey, roast beef, or smoked ham RTE deli products. A temperature-controlled water bath was used to maintain specific temperatures of 145°F (62.8°C), 150°F (65.6°C), 155°F (68.3°C), or 160°F (71.1°C). Purge-suspended cells (50 μl) were introduced into glass capillary tubes with a gas-tight, 100-μl Hamilton syringe (Fisher Scientific Co., Pittsburgh, Pa.). Capillary tubes were sealed by flame and kept on ice before and after retrieval from the heated water bath. After cooling, capillary tubes were completely broken in sterile 50-ml Oak Ridge tubes containing 5 ml of sterile diluent. Appropriate dilutions were made, plated on tryptic soy agar, and then incubated at 30°C (86°F) for enumeration after 48 h. All assays were run in triplicate replications.

Products and inoculation procedures. RTE deli-style whole or formed turkey (cured, smoked, pastrami-style, sodium lactate-injected versus noninjected formed turkey), ham (cured, smoked, roasted, peppered), and roast beef products were provided by commercial processors. The products were received in commercial vacuum packages in either their original cook-in bag or retail-ready packages. Products were removed and placed into new shrink-wrap vacuum-packaging bags (Cryovac 12 by 17 in., no. 02398–10203 or Viskase equivalent). The product-specific purge was recovered and saved as diluent for resuspending the *Listeria* inoculum. The *Listeria* cultures were equally mixed and diluted 1:10 with purge obtained from specific products (i.e., 5 ml of mixed culture + 45 ml of purge), and then 50 ml of this purge-cell suspension was pipetted over the surface of each product in the packaging bags. The purpose of resuspending the inoculum in product purge was to provide the same liquid suspension chemistry as would be found by contaminating cells in actual product (i.e., as opposed to buffer or media). The products were then vacuum-sealed, massaged to distribute the cell inoculum, and maintained at 4.4°C (40°F) for 30 to 60 min before heat processing.

Submersion heating process. A stainless steel water bath (2 ft 6 in. length by 2 ft wide by 2 ft 6 in. deep) was modified by Unitherm Food Systems, Inc. (Bristow, Okla.) for use in our postpackage heating trials (the method of heating and control is similar to Unitherm's commercial Aquaflow food processor). The water bath included continuous pumping of water from the bottom of the bath through a pump and into a mixing chamber. Steam is injected into the chamber and continues to be pumped into the water bath through four "fingers" with exit holes directed toward the geometric center of the water bath. Injection of steam is controlled by a digital controller connected to a temperature sensor probe that activates a pneumatic valve to inject steam into the external chamber if the temperature is below the set point (Fig. 1). A stainless steel cage was used to manually dip two products (i.e., 5 to 12 lb each) per heating regimen (2 to 10 min). After heating, the products were quickly removed from the water bath and submersed completely in ice water to mimic a brine chill cooling procedure. Products were jostled in the ice water to hasten

Winning the war on listeria

Exhibit 2

THROUGH ITS USE OF SURFACE PASTEURIZATION TECHNOLOGY, COOPER FARMS HAS GAINED THE UPPER HAND IN ITS BATTLE AGAINST LISTERIA

By Joshua Lipsky, senior editor

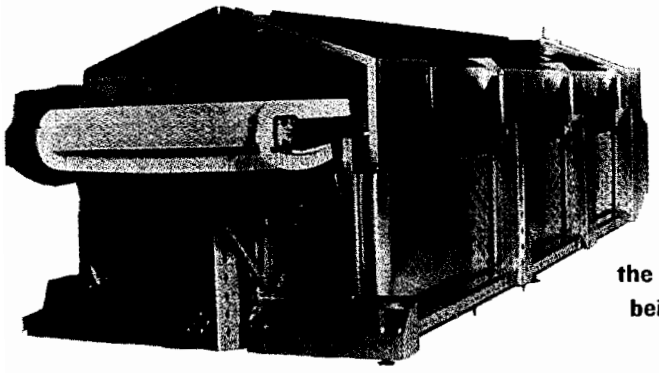
Nestled in the heartland of Ohio is Cooper Farms, which has been producing turkey since the 1940s.

Today, Cooper offers a full line of cooked turkey products, ready-to-cook turkey products and turkeys for further processing. While Cooper's product line has grown over time, one thing that has remained a constant for the company is fear of pathogen contamination.

Until recently, Cooper had been battling pathogens, mainly *Listeria monocytogenes*, by re-cooking its products post-packaging in the oven. While this practice had been in place for quite some time, Cooper wanted to switch to a method that would provide greater assurances that all pathogens were being eliminated.

"There had been too many large and small-scale processors suffering from listeria recalls," says Eric Ludwig, Cooper's plant manager. "We wanted to make sure that we were using the best possible method to make sure that all our products would be pathogen free."

Surface pasteurization (killing pathogens using high temperatures) is an attractive option for turkey processors because only the surface of the product is pasteurized. This makes it safe from being contaminated from the stripping of the cooking bag to the re-bagging in the final deli bag.



Turkeys are automatically fed into a hot water tank and are conveyed through the machine while being submerged under water.

In early 2001, Cooper Farms implemented an AquaFlow Surface Pasteurization system manufactured by Unitherm.

Unitherm's in-line pasteurization method consists of a hot water bath that is maintained at a constant temperature of 205 degrees F by means of steam injection. Cooper's turkeys are automatically fed into the tank and are conveyed through the machine while being submerged underwater. By having water continuously flowing over the product, there are no hot or cold spots in the process, ensuring more even pasteurization.

After the product has been pasteurized, it is chilled to maximize the lethality rate and to minimize purge within the bag. For this, the AquaFlow employs an ammonia-based vertical chiller that circulates high velocity air at a temperature of –30 degrees F. The vertical chiller brings the surface of the product to a temperature below 30 degrees F within 10 minutes.

The primary advantage of an ammonia-based chill system is cost savings. Ammonia chill systems cost about $10 per 30,000 pounds of product, versus nitrogen-based chill systems that cost about 10 cents per pound.

"There are substantial savings involved in using ammonia as opposed to using nitrogen," Ludwig says. "Performance isn't compromised and there is increased value. That's what you're really looking for when deciding on which type of machine to use."

KEY findings

- **Surface pasteurization protects product from being contaminated from the stripping of the cooking bag to the re-bagging in the final deli bag.**
- **Steam pasteurization results in a 3-log (99 percent) reduction of bacteria and increases shelf-life.**
- **Ammonia-chill systems cost $10 per 30,000 pounds of product versus 10 cents per pound for nitrogen-based chill systems.**

Today more than 100,000 pounds of product each day are pasteurized at Cooper Farms with solid results.

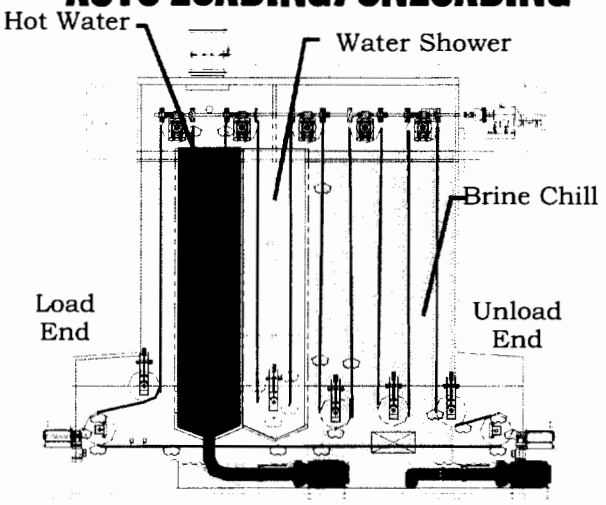
The AquaFlow system has resulted in a 3-log reduction of bacteria, reflecting a 99.9 percent bacteria lethality rate.

"The process does exactly what we have wanted it to do," Ludwig says. "Our line speed has been unaffected, which is very important, and not only have we had a 3-log reduction of bacteria, but through surface pasteurization, we are able to increase the shelf-life of our products." Poultry

Exhibit 3

SURFACE PASTEURIZATION OF DELI PRODUCTS

AUTO LOADING/UNLOADING



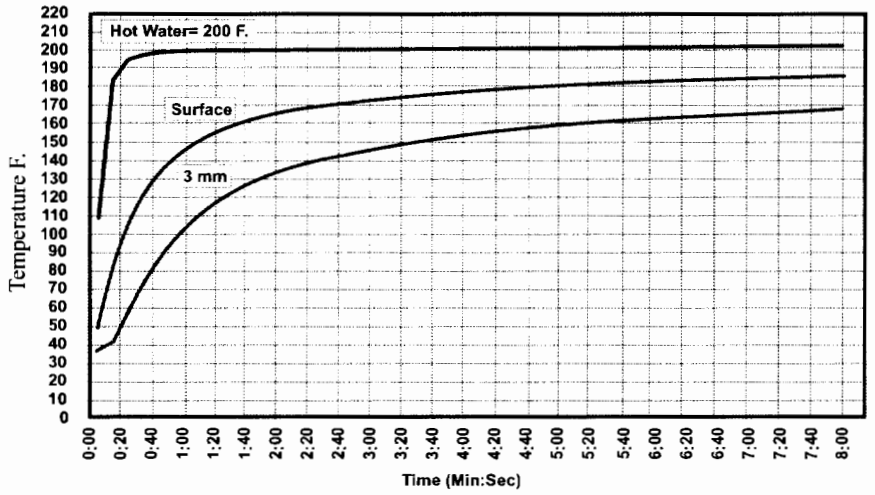
PROVEN PROCESSES

Heat	3 -5 minutes
200+F. Hot water or Glycol	
Surface Temperature	170 - 180 F.
Log Kill	2 - 3
Chill	25 - 40 minutes
15 - 20 F. Brine or Glycol	

HIGH CAPACITY, LESS FLOORSPACE

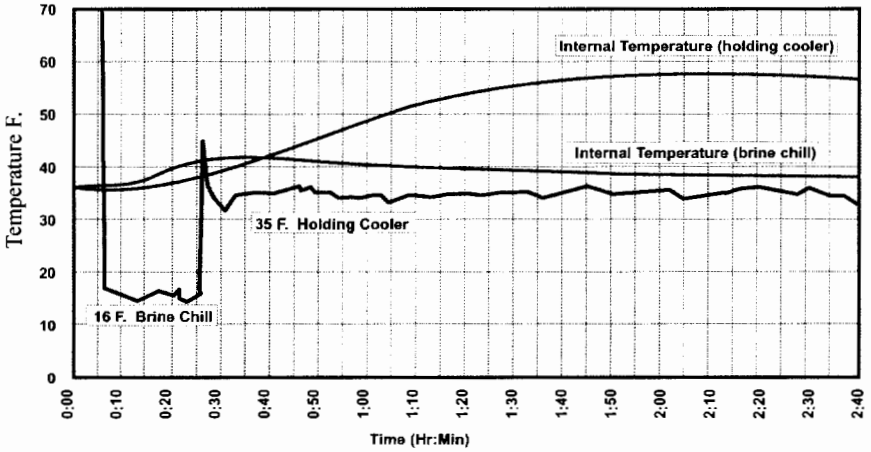
Turkey Breast or Ham
9 - 10 lb weight per piece
60 pieces per minute
Unit Size: 11'-9" wide
21'-0" long
19'-10" high

Pasteurization Process



- Analyze your product and determine risks from knife cuts or variable surface conditions
- Heat penetration beyond surface will lengthen process
- Deli ham pasteurization process utilizing 200 F. water.
  Surface temperature vs 3 mm penetration

Post-Pasteurization Chilling



- Rapid chilling with brine or water is required to minimize core temperature rise
- Deli ham chilling process utilizing 16 F. Brine vs 35 F. holding cooler

ALKAR

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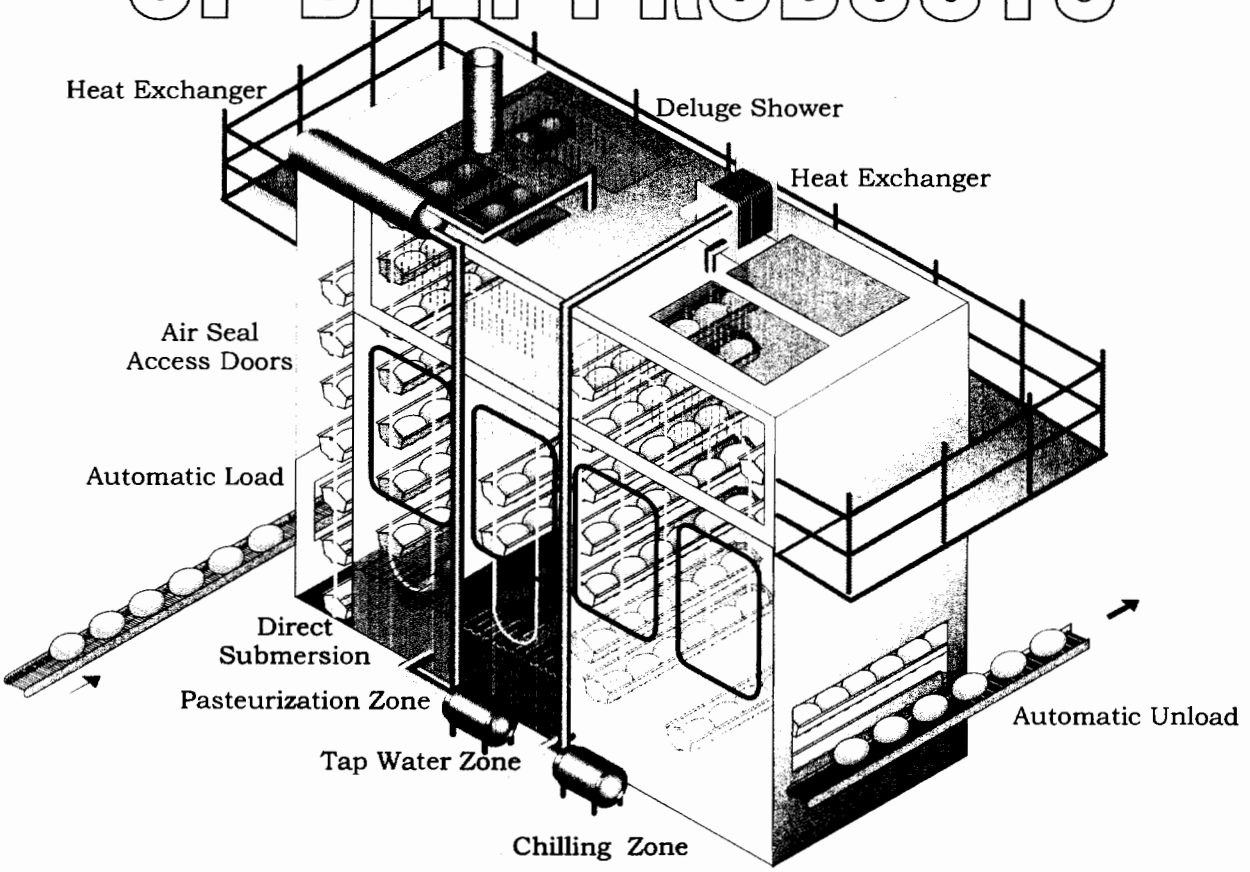
SURFACE PASTEURIZATION OF DELI PRODUCTS



IMPROVE FOOD SAFETY

- Destroy pathogens effectively

EXTEND REFRIGERATED SHELF LIFE

- Increase capacity to handle peak seasons

MINIMIZE FLOORSPACE

- Utilize vertical height
- Flexible to design for alternate layouts

FULLY AUTOMATED

- No additional labor required
- Integrated into your process and packaging line

EFFECTIVE COOK/CHILL TREATMENT

- Precise control over each package
- Custom designed to your specified process
- Isolated designed to your specified process
- Immediate chilling after pasteurization

PROVEN CARRIER DESIGN

- Ensures effective treatment on all areas of the product
- Tested on your product in our development lab

ALKAR

www.alkar.com