

PETITIONS

**NEW USES FOR HIGH PRESSURE PROCESSING
(HPP), AN USDA-FSIS APPROVED
TECHNOLOGY**

**Submitted by
Professional Research Organization, Inc
On behalf of
Santa Maria Foods, ULC**

BACKGROUND

The use of HPP by the meat industry has been well established. In 2003 the first letter of no objection (Log # 03-NT004-N-A) was issued for use of HPP as a post-lethality intervention for *Listeria monocytogenes* (*Lm*) contamination in RTE packaged foods. Since then, numerous RTE products have been treated with HPP to produce safer foods. Both Gram-negative and Gram-positive pathogenic microorganisms are killed by HPP using various pressures and times of treatment. Substantiating references are numerous, and several are listed in the attached peer-reviewed manuscript [Porto-Fett, A. C. S., J. E. Call, B. Shoyer, D. E. Hill, C. Pshebniski, G. J. Cocoma, and J. B. Porto-Fett. 2010. Effectiveness of freezing, fermentation/drying, and post-process pressurization on viability of *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* O157:H7, and *Trichinella spiralis* in raw pork and/or Genoa salami. Int. J. Food Microbiol. (Accepted 02-08-10)] by USDA-ARS scientists that serves as the basis for this petition.

The application of 87,000 PSI for three minutes has been accepted by USDA-FSIS as effective for elimination of *Lm*. As for other Gram-positive bacteria, *Lm* is generally more resistant to the effects of HPP than are Gram-negative bacteria and, therefore, since treating foods with 87,000 PSI for three minutes eliminates *Lm*, it would also eliminate more pressure sensitive microbes such as Gram-negative bacteria and more complex organisms such as *Trichinella spiralis* (*Ts*).

PETITION

It is requested that the following new uses of HPP be established and that letters of no objection be issued for:

- 1.) The use of HPP at 87,000 PSI for three minutes as a post processing and packaging intervention to eliminate *Ts* in RTE meats, specifically in non-thermal processed, dry-cured, whole-muscle and ground sausage products.
- 2.) The use of HPP at 87,000 PSI for three minutes as a post processing and packaging intervention for eliminating *E. coli* O157:H7 and *Salmonella* spp. in RTE meats, specifically in non-thermal processed, dry-cured, whole-muscle and ground sausage products.
- 3.) Affirm the use of HPP at 87,000 PSI for three minutes as a post processing and packaging intervention for *Lm* in RTE meats (lethality

plus inhibition), specifically in non-thermal processed, dry-cured, whole-muscle and ground sausage products.

PRODUCTS

The following classes of products are those for which a letter of no objection is requested:

Non-thermal processed, dry-cured, ground sausage products:
Genoa, Salami w/Prosciutto, Sopressata, Calabrese, Casalingo, Cacciatore, Abruzzese.

These ground products are made with the same all pork meat formula and only vary in the types of spices added and/or casing sizes. Products are whole or sliced and packaged.

Non-thermal processed, whole-muscle products:
Prosciutto, Speck, Pancetta, Capocollo, Prosciuttino

These whole muscle products are made from the ham, shoulder and belly of the hog. Products are whole or sliced and packaged.

We are requesting that the application of HPP at 87,000 PSI for three minutes be established as an alternate to the following USDA-FSIS regulations and or requirements:

- 1.) For *Ts*, 9CFR Ch. 111 section 318.10 and other related sections of this CFR and its regulatory requirements that would also be obviated by this new food safety procedure.
- 2.) For *E. coli* O157:H7, establish post processing application of HPP as an allowed “option #4” to achieve a 5-D reduction of this pathogen in fermented dry-cured products as detailed in the Executive Summary of the Blue Ribbon Task force of the National Cattlemen’s Beef Association (Nickelson, R., II, J. Porto-Fett, C. Kaspar, and E. Johnson. 1996. Update on dry fermented sausage *Escherichia coli* O157:H7 validation research. An executive summary prepared by The Blue Ribbon Task Force of the National Cattlemen’s Beef Association. Research Report No. 11-316.).
- 3.) For *Salmonella*, establish post processing application of HPP as an acceptable method to achieve the required 6.5 log reduction of this

pathogen in non-thermally processed, fermented/dry-cured RTE products [i) United States Department of Agriculture-Food Safety and Inspection Service (USDA-FSIS). 2001. Performance Standards for the Production of Processed Meat and Poultry Products. 9CFR parts 301, 303. Federal Register, Washington, DC, and ii) United States Department of Agriculture-Food Safety and Inspection Service (USDA-FSIS). 2004. Compliance guidelines for meat and poultry jerky. USDA-FSIS, Washington, DC. <http://www.fsis.usda.gov/OOPDE/nis/outreach/models/Jerkyguidelines.htm>.]

Data supporting these recommendations are found in the attached peer-reviewed publication conducted by USDA-ARS that is being submitted with this petition (Porto-Fett et al., 2010).

WAIVER REQUEST

This petition does not obviate the above noted USDA-FSIS regulations or requirements, it only requests the establishment of HPP as an alternative to the involved regulations and requirements. When a company operates under the requested alternative, it will establish the appropriate operating and HACCP procedures with documented records for the application of the HPP treatment.

If a waiver is needed to operate under this alternate method of achieving the end result of established regulations and its requirements, it is hereby requested. It is obvious and can be scientifically established that the alternative, namely HPP, is effective for the requisite purposes (see attached manuscript by Porto-Fett et al., 2010).

If a period of plant operations is needed, it should be concerned only with the operation and documentation of the HPP equipment under an established HACCP plan. The attached manuscript by Porto-Fett et al. (2010) establishes the adequacy of the stated requirements of 87,000 PSI for three minutes. The achievement of these requirements in operation is verification that the expected results will be achieved. Absence of the pathogens in the treated product will be demonstrated periodically after treatment at an appropriated time (see HACCP plan).

In addition, the following concerns raised by USDA-FSIS in previous communications are addressed herein:

- 1.) Product safety: the treated products will have improved safety. This is fully documented in the ongoing production of HPP-treated products presently under USDA-FSIS oversight and inspection.

2.) Jeopardizes the safety of Federal inspection program personnel: HPP has been employed in USDA-FSIS inspected plants for a number of years without any adverse health or safety concerns involving either Federal inspection personnel or plant employees. A complete list of the safety measures employed is attached.

3.) Interferes with inspection procedures: the inspection procedures remain the same. The HACCP program with its documentation of attendant CCP's is available for USDA-FSIS review and regulatory action if necessary.

4.) No change in the existing regulations or requirements is requested, only that the HPP treatment is allowed as an alternative to achieving the end results of established regulations and its requirements.

TRICHINAE WORST CASE SCENARIO:

As previously stated, the literature establishes that when present, numbers of trichinae are quite low, that being negligible in most cases to only a couple hundred larvae per gram under the worst conditions. The research by Porto-Fett et al. (2010) validated that HPP was sufficient to eliminate about 1600 larvae per gram in naturally-infected pig masseter tissue in as little as 1 minute using 483 MPa and in as little as 0.5 minute using 600 MPa and, as such, would be sufficient to eliminate even the highest number of larvae that may on rare occasion be found in pork. Good Agricultural Practices in As previously stated, the literature establishes that when present, numbers of trichinae are quite low, that being negligible in most cases to only a couple hundred larvae per gram under the worst conditions. The research by Porto-Fett et al. (2010) validated swine production have dramatically decreased the prevalence of trichinae in conventionally raised swine to virtually non-detectable levels in the United States over the past 60 years (Gamble et al., 1998; Gamble et al., 1999; Pyburn et al., 2005). Moreover, when present, levels of this parasite in pork are quite low. For example, Gamble et al. (1983) surveyed 37 pigs and reported levels of trichinae ranging from 0.01 to 2.30 larvae/g. In related studies, Gamble et al. (1999) reported levels ranging from 0.003 to 0.021 larvae/g in four infected pigs, whereas Murrell et al. (1986) reported levels ranging from <5 to 73 larvae/g from five infected pigs. In another study, Schad et al. (1985) found that 0.73% (39 of 5315) of hogs surveyed from five New England states were infected with trichinae at an average level of 4.7 larvae/g. Schad et al. (1987) also conducted an on-farm survey and reported that 88% (56 of 63 pigs) of the original stock was infected with trichinae at an average level of 260 larvae/g. In a recent study by Hill et al. (2009), naturally-infected pigs harbored levels of trichinae ranging from 0.1 to 467 larvae/g. These

findings confirm that pigs continue to harbor this parasite, albeit at reduced prevalence and levels than in the previous six decades.

UNIVERSAL APPLICATION POSITION:

The design of the research with its standardized meat type and content, effective fermentation, reduction of pH to pH 4.6-4.9, and defined casing size does not present a public health concern. Likewise, from a food safety perspective, the reduction in drying time or the establishment of an endpoint water activity of a_w 0.94 present no concerns. Thus, application of 87,000 PSI for 3 minutes is an effective food safety treatment for all non-thermally treated, dry-cured, whole-muscle and ground meat products.

The destruction of trichinae in whole, raw muscle products validates the use of HPP for eliminating *Ts* in whole-muscle, dry-cured meats. Since HPP eliminated *Ts* even at elevated levels in raw (masseter) pork muscle (see Porto-Fett et al., 2010), the addition of salt in combination with fermentation/drying of non-thermally treated, cured, whole-muscle products will serve to exacerbate the collective and integrated lethality of HPP towards this nematode in meats targeted for human consumption.

The efficacy of HPP for eliminating *Lm*, *E. coli* O157:H7, *Salmonella*, and *Ts* in meats has been demonstrated over a wide range of processing conditions, namely for varying ranges/levels of pH, a_w , and casing sizes, as well as for pressurization levels, temperatures, and times. The aforementioned conditions do not lessen the ability of HPP to eliminate pathogenic organisms in non-thermally processed, whole-muscle and ground dry-cured products. Thus, the use of HPP as an alternative method to heating, freezing/refrigerating (certification), and/or curing is practicable and readily achievable, as well as equally effective and comparable to the established regulations and requirements related to the elimination of the targeted microbial pathogens and nematode in such products. Lastly, for facile access and inspection, the data supporting these conclusions are reported pathogen-by-pathogen in separate tables in the manuscript by Porto-Fett et al. (2010).

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