



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

NOV 6 2013

Mr. George Cocoma
Professional Research Organization Inc.
1405 Irvine Drive
Edmond, OK 73025

Dear Mr. Cocoma:

This is in response to your petition dated October 20, 2011, requesting that the Food Safety and Inspection Service (FSIS) amend 9 CFR 318.10(c) to list High Pressure Processing (HPP) as an alternative treatment of pork products. Specifically, the petition requests that the Agency establish the use of HPP at 87,000 psi (600 MPa) for three minutes as an alternative treatment of pork to destroy *Trichina*.

The petition also requests that the Agency: (1) approve 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 ready-to-eat (RTE) meats, specifically in non-thermal processed, dry-cured, whole-muscle and ground sausage products; and (2) affirm the use of HPP at 87,000 psi for three minutes as a post processing and packaging intervention for *Listeria monocytogenes* (*Lm*) in RTE meats (lethality plus inhibition), specifically in non-thermal-processed, dry-cured, whole-muscle and ground sausage products. This portion of your petition does not require a regulatory change. Establishments may use HPP without prior approval from FSIS to reduce or eliminate these pathogens if they address such use in their Hazard Analysis and Critical Control Points (HACCP) system, i.e., in their HACCP plan or sanitation SOP or other prerequisite program. FSIS Directive 6120.2, *High Pressure Processing and Inspection Program Personnel (IPP) Verification Responsibilities*, provides instructions to IPP on how to verify an establishment's use of HPP as an antimicrobial treatment (available on the FSIS Website at: <http://www.fsis.usda.gov/wps/wcm/connect/a64961fa-ed6f-44d1-b637-62232a18f998/6120.2.pdf?MOD=AJPERES>).

On November 2, 2011, FSIS issued a waiver of 9 CFR 318.10(c) to allow your company, Professional Research Organization, Inc., to conduct in-plant trials to obtain additional data to be used in support of its petition. The waiver allows the use of HPP as a post processing and packaging intervention to eliminate *Trichinella spiralis* in RTE products.

In 2001, we issued a proposed rule titled "*Performance Standards for the Production of Processed Meat and Poultry Products*" (66 FR 12589; February 27, 2001), to modify and extend the lethality performance standards to cover additional classes of RTE meat products, including RTE pork products. As part of the proposed rule, we also proposed to amend 9 CFR 318.10 to remove the prescriptive provisions that require certain treatments for pork and pork products to destroy *Trichina* because the requirements are inconsistent with HACCP.

Under the proposed rule, establishments would have greater flexibility to choose validated treatments and to support their use as part of their HACCP system to control *Trichina* in pork and pork products. FSIS will consider issues raised in your petition as we proceed with this rulemaking process.

Because we already have a related rulemaking and for purposes of Agency economy, we do not intend to initiate a separate rulemaking in response to your petition. Your company may continue to use HPP as provided in the waiver pending the issuance of any final rule that may result from the 2001 proposal.

Sincerely,

A handwritten signature in blue ink that reads "Rachel A. Edelstein". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Rachel A. Edelstein
Assistant Administrator
Office of Policy and Program Development