UNITED STATES DEPARTMENT OF AGRICULTURE BEFORE THE ADMINISTRATOR

FOOD SAFETY AND INSPECTION SERVICE

In re:)	474	Signed - sol
Harvard Locker and)	اسر	Signed 2006
)		
Douglas Worman, Sharon Worman,)		
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Responder	nts) CONSENT AGREEME	ENT	

This proceeding was instituted under the Federal Meat Inspection Act (FMIA), as amended (21 U.S.C. §§ 601 et seq.) and the Poultry Products Inspection Act (PPIA), as amended (21 U.S.C. §§ 451 et seq.) and the applicable federal regulations (9 C.F.R. 303.1 and 9 C.F.R. 381.10), to terminate custom exempt privileges provided to respondents under section 23(a) of the FMIA (21 U.S.C. § 623(a)) and section 15(c) of the PPIA (21 U.S.C. § 464(c)). This proceeding was commenced by a Notice of Ineligibility for Custom Exempt Status letter (Notice) delivered to respondents on November 7, 2005 by the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA). This agreement is entered pursuant to the consent agreement provisions of the adopted rules of practice applicable to the proceeding. (Attachment).

The respondents admit the allegations in the Notice and specifically admit that the Secretary has jurisdiction in this matter. The respondents waive oral hearing and further procedure, and waive any claim against complainant under the Equal Access to Justice

Act of 1980 (5 U.S.C. § 504 et seq.). Respondents consent and agree, for purposes of settling this proceeding and for such purpose only, to the entry of this agreement.

The complainant agrees to the entry of this agreement.

Findings of Fact

- Respondent Harvard Locker, is, and at all times material herein was a business operating a custom exempt meat and poultry slaughtering and processing facility at 324 N. Clay Avenue, Harvard, Nebraska 68944.
- Respondents Douglas Worman and Sharon Worman are now, and at all times material were, owners and operators of Harvard Locker.
- 3. On or about May 2, 2005, May 6, 2005, August 9, 2005 and other dates, respondents failed to maintain the facility in a sanitary condition and comply with sanitation requirements in violation of the FMIA, PPIA and applicable federal regulations.
- 4. On November 7, 2005, FSIS delivered the Notice to respondents that they were no longer eligible for custom exemption privileges under the FMIA and PPIA.

Conclusion

The respondents having admitted the jurisdictional facts and the parties having agreed to the entry of this Agreement, this Agreement will be issued.

AGREEMENT

Custom exemption privileges granted under the FMIA and PPIA are terminated from respondents and its owners, officers, directors, partners, successors, and assigns for a period of two (2) years beginning on the effective date of this Agreement; <u>Provided</u>, however, the termination of custom exemption privileges shall be held in abeyance, and custom exemption privileges shall continue to be provided to respondents for so long as the conditions set forth below, in addition to all other requirements for custom exempt operations, are met.

1. Prior to Reinstatement

Prior to the reinstatement of custom exemption privileges, respondents shall demonstrate their ability to operate the custom exempt facility in compliance with the Sanitation Performance Standards (SPS) in 9 C.F.R. §§ 416.1 to 416.6, Standard Sanitation Operating Procedures (SSOP) in 9 C.F.R. §§ 416.11-416.16, 9 C.F.R. § 303.1 and 9 C.F.R. § 381.10, and the physical and sanitary conditions of the facility. Additionally, respondent's facility shall receive an "acceptable" rating in every category of FSIS' "Exempt Establishment Review Report," FSIS Form 5930-1.2. Future reviews will be conducted at the discretion and frequency specified by FSIS officials.

2. Sanitation Performance Standards (SPS)

a. Prior to the reinstatement of custom exemption privileges, Respondents shall make facility repairs and/or improvements necessary to ensure sanitary conditions, as required by 9 C.F.R. §§ 416.1 to 416.6 and 9 C.F.R. § 303.1 are met, including but not limited to: (i) repairing or replacing walls, floors, ceilings, doors, windows, or other outside openings to prevent the entrance of vermin, such as flies and rodents; (ii)

maintaining a ventilation system adequate to control vapors and condensation to prevent product adulteration and insanitary conditions; and (iii) maintaining overhead structures, including ceilings, and rails, in a manner to prevent the presence of algae, mold, flaking paint or rust.

- b. Respondents shall comply with the requirements in 9 C.F.R. §§ 416.1-416.6 and develop written SPS procedures to describe the monitoring activities respondents will implement and maintain on a daily basis to prevent insanitary conditions and ensure that meat and poultry will not become contaminated or adulterated. Respondents shall also comply with and incorporate into the SPS written procedures the sanitation requirements in 9 C.F.R. §§ 303.1 and 381.10. Such written procedures shall include how respondents will operate and maintain their premises, facilities, equipment and outside premises.
- c. Respondents shall monitor the soundness and structure of the facility in compliance with 9 C.F.R. §§ 416.1 to 416.6. Respondents shall document findings and corrective actions to address structural and/or mechanical repairs and/or improvements to their facility under a "Planned Improvement Program" (PIP) to ensure the entire structure of the facility is of sound construction and kept in good repair.
- d. Respondents shall develop written pest control procedures consistent with the requirements of 9 C.F.R. §§ 416.2(a) and (b), and shall implement and maintain the procedures for both in-plant and outside the premises to prevent the harborage and breeding of pests on the grounds and within the establishment. Respondents shall document findings and take appropriate corrective and preventive actions.

- e. Respondents shall establish a pest management program, implemented and maintained by an independent pest control service, to prevent the harborage and breeding of pests on the grounds and within the facility consistent with 9 C.F.R. §§ 416.2(a) and (b). Respondents shall assure that: (i) the pest control service reviews and services respondents' facility and grounds on at least a monthly frequency; (ii) written reports are provided by the pest control service to respondents detailing its findings and recommendations of its review; (iii) report recommendations are implemented by respondents in a timely fashion; and (iv) their pest management program and servicing firm's written findings, recommendations.
- f. Respondents shall implement and maintain the SPS written procedures for the duration of this Agreement.

3. Sanitation Standard Operating Procedures (SSOP)

- a. Respondents shall develop a written SSOP in compliance with 9 C.F.R. §§
 416.11 to 416.16 to describe the procedures and monitoring activities respondents will conduct, implement and maintain on a daily and on-going basis, during and after operations, sufficient to prevent direct contamination or adulteration of products.
- b. Respondents shall implement and maintain said written procedures for the duration of this Agreement and shall make all applicable records available to FSIS for review and/or copying immediately upon request.

4. Specified Risk Materials (SRM)/Non-Ambulatory Cattle

a. Respondents shall take action to ensure that all cattle slaughtered or processed at the facility are eligible for slaughter or processing and are not adulterated, and that Specified Risk Materials (SRM) are removed from any cattle slaughtered or processed at their facility.

b. Respondents shall develop, implement and maintain the written procedures to prevent the custom slaughtering or processing of non-ambulatory disabled cattle (downers). Respondents shall train and educate their employees in these procedures, post the procedures in an appropriate, visible area, and make the procedures and any records thereof available to FSIS for review and/or copying immediately upon request.

5. Custom Exempt Requirements

Respondents shall comply with custom exemption requirements in 9 C.F.R. §§ 303.1 and 381.10 to ensure that (i) meat and poultry does not become adulterated during processing, handling, storage, loading and unloading, and during transportation; (ii) all slaughtered livestock and poultry and further processed meat or meat food products or poultry or poultry food products are properly marked, labeled and packaged; (iii) custom prepared meat products are plainly marked "Not for Sale" and kept separate and apart from any meat and poultry products held for sale; and (iv) document and maintain complete and accurate written records of the numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products, in accordance with 9 C.F.R. § 303.1.

6. Poultry Exemption Requirements

Prior to the start of poultry custom slaughter operations, respondents shall ensure that the following poultry custom exemption requirements in 9 C.F.R. § 381.10 are met:

- Respondents may not engage in the buying or selling of any poultry products capable of use as human food;
- (ii) Ensure that the custom slaughtered poultry is for the personal use of the owner of the poultry and may not be sold or donated;
- (iii) Ensure that the shipping containers of custom slaughtered poultry products bear the owner's name and address and the statement "Exempted-P.L. 90-492.
- (iv) Ensure that only one poultry exemption is claimed during a calendar year.

7. Canning Requirements

Prior to the start of canning operations, Respondents shall ensure that the processing of canned meat and /or poultry products are in compliance with the requirements of 9 C.F.R. 318.300 through 318.311, including but not limited to:

- (i) a written process schedule (as defined in 9 C.F.R. 318.300(n)) for each canned meat product to be packed by the firm;
- (ii) developing and maintaining processing and production records in accordance with 9 C.F.R. 318.306;
- (iii) identifying critical factors and the application of the process schedule;
- (iv) posting process schedule in a conspicuous place near the thermal processing equipment;
- (v) equipping each retort with at least (1) indicating temperature device that measures the actual temperature within the retort;
- (vi) identifying charts from temperature/time recording devices by production date, container code, processing vessel number or other designation or

- other data as necessary to enable correlation with the records required in 9 C.F.R. 318.306;
- (vii) ensuring that all operators of thermal processing systems specified in 9
 C.F.R. 318.305 and container closure technicians be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations; and
- (viii) preparing and maintaining a current procedure for the recall of all canned product covered by 9 C.F.R. 318.300 through 318.311 and make these procedures available to FSIS employees for review and/or copying upon request.

8. Recordkeeping

Respondents shall maintain full, complete and accurate written records of all business activities involved in their operations under the FMIA and PPIA, including the SPS and SSOP record requirements. Respondents shall also maintain records of their PIP, Pest Control Programs, SRM or other records required by this Agreement. Respondents shall make all such records available to FSIS personnel for review and/or copying immediately upon request.

9. Establishment Management and Personnel

Prior to the reinstatement of custom exempt privileges, Respondents shall designate in writing one full-time person and one alternate who shall be responsible for the overall implementation, coordination, monitoring, recordkeeping, review and maintenance of the facility's SPS, PIP, Pest Control Programs, SSOP, SRM and compliance with 9 C.F.R. §§

303.1 and 381.10, and the requirements of this Agreement. Said designee(s) shall be present whenever respondent's establishment conducts any custom exempt or processing exempt operations, and respondents shall not conduct any custom meat or poultry exempt slaughtering or processing operations in the absence of said designee(s). Respondents may name a new designated official(s) upon written notification to the Des Moines District Manager.

10. Training and Education

Respondents shall, within thirty (30) days from the effective date of this Agreement, develop, implement, and maintain written training programs for managers and all employees including newly hired employees, in food safety regulatory requirements and the programs and written procedures included in this Agreement. Respondents shall maintain the training and educational program records and make them available to FSIS personnel for review and/or copying immediately upon request.

11. Access and Examination

Respondents shall fully and completely cooperate with any USDA or FSIS investigation, inquiry, review or examination of respondent's (a) facility, product, inventory or business records, (i) compliance with the FMIA, PPIA and the regulations issued under these Acts, or (ii) compliance with the requirements in this Agreement.

General Provisions

12. Respondents shall not (i) commit any felony or criminal act under the FMIA or PPIA; or (ii) violate any section of the FMIA, PPIA, Federal, State, or local statute or regulation involving the preparation, sale, transportation, distribution or attempted distribution of any adulterated or misbranded meat or poultry product; (iii) assault,

intimidate, impede, or interfere with, or threaten to assault, intimidate, impede, or interfere with any representative or designee of the Secretary of Agriculture.

- 13. The Administrator, FSIS, may summarily terminate Respondents' custom exempt meat and/or poultry exemption privileges upon a determination by the Director, Evaluation and Enforcement Division, Office of Program Evaluation, Enforcement and Review, FSIS, that respondents have failed to comply with any requirement of this Agreement and/or statutory and regulatory exemption requirements. Respondents retain the right to request an expedited hearing pursuant to the adopted rules of practice concerning any violation alleged as the basis of a summary withdrawal of exemption privileges.
- 14. Nothing in this Agreement shall preclude (i) any regulatory or administrative action authorized by law, regulation or otherwise, including, but not limited to the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.
- 15. The provisions of this Agreement shall become effective when (i) signed by the Administrator, FSIS, and (ii) upon completion of an official review of the facility in which each category is found acceptable.

HARVARD LOCKER

Respondent

BY: Soughas Wor

DOUGLAS WORMAN

Owner

SHARON WORMAN

Owner

SCOTT SAFIAN, Director

Evaluation and Enforcement

Division,

Office of Program Evaluation

Enforcement and Review

Food Safety and Inspection Service

TRACEY MANOFF

Attorney for Complainant

DOUGLAS WORMAN
Respondent

Shawn Worman
SHARON WORMAN
Respondent

Issued this 9th day of January, 2006

Barbara J. Masters, D.V.M.
Administrator
Food Safety and Inspection Service