

UNITED STATES DEPARTMENT OF AGRICULTURE  
BEFORE THE ADMINISTRATOR  
FOOD SAFETY AND INSPECTION SERVICE

In re:	)	
	)	
Gary Welk, and	)	
Welk's Custom Butchering,	)	STIPULATION AND
	)	CONSENT AGREEMENT
Respondents	)	

This administrative action was instituted by the delivery of a Notice of Ineligibility for Custom Exempt Status on or about August 2, 2011, to Mr. Gary Welk and Welk's Custom Butchering, hereafter "Respondents," notifying them that they were no longer eligible for custom exemption under the Federal Meat Inspection Act (FMIA) (21 U.S.C. § 601 et seq.), and the regulations promulgated thereunder. The Notice of Ineligibility that was hand delivered by FSIS personnel was effective upon receipt, and was issued due to Respondents' alleged failure to maintain their facility in a sanitary manner.

The aforementioned action was instituted by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), hereafter "Complainant," in accordance with Section 23(a) of the FMIA (21 U.S.C. § 623(a)), Part 303 of the Federal Meat Inspection Regulations (9 C.F.R. § 303.1 et seq.), and Part 416 of the Sanitation Regulations (9 C.F.R. § 416).

The Parties have agreed that this administrative proceeding should be terminated by the execution of this Stipulation and Consent Agreement, hereafter "Agreement," set forth below and have agreed to the following stipulations:

1. For the purpose of this Stipulation and the provisions of this Agreement only, Respondents admit the jurisdictional allegations of the above-mentioned Notice of Ineligibility

and both parties waive:

- (a) any further procedural steps in this proceeding;
- (b) any requirement that this Agreement in this proceeding contains findings and conclusions with respect to fact or law, as well as to reason or basis thereof; and
- (c) all rights to seek further judicial review or to otherwise challenge or contest the validity of this Agreement.

2. This Agreement is for settlement purposes in this proceeding only, and does not otherwise constitute an admission or denial by Respondents that they have violated any Federal regulation or statute.

3. Respondents waive any action against USDA under the Equal Access to Justice Act of 1980 (5 U.S.C. 504 *et seq.*) for fees or other expenses incurred in connection with this proceeding, and any other action against the USDA and its employees in connection with this proceeding and the facts and events that gave rise to this proceeding.

#### FINDINGS OF FACT

1. Welk's Custom Butchering, is now and at all times material herein was, an unincorporated business operating as a custom exempt meat slaughter and processing facility at 636 Solanco Road, Quarryville, Pennsylvania 17566.

2. Mr. Gary Welk is now and at all times material, was the owner and operator of Welk's Custom Butchering.

3. Welk's Custom Butchering, and Mr. Gary Welk operate under the custom exemption eligibility, pursuant to section 23(a) of the FMIA and applicable federal meat inspection and sanitation regulations (9 C.F.R. §§ 303.1 and 416).

4. In a Notice of Ineligibility letter delivered on or about August 2, 2011, Respondents

were notified that they were no longer eligible to operate under the custom exempt provisions of the FMIA because of violations of sanitation, facility, and other requirements, as required by 9 C.F.R. 303 and 416.

### CONCLUSION

In as much as the parties have agreed to the provisions set forth in the following Agreement in disposition of this proceeding, the following Agreement will be issued.

### AGREEMENT

Custom exempt livestock slaughter and meat processing privileges under 9 C.F.R. Part 303.1, promulgated under the FMIA (21 U.S.C. §623), and 9 C.F.R. Part 381.10, promulgated under the Poultry Products Inspection Act (PPIA) (21 U.S.C. § 464), are terminated from Gary Welk and Welk's Custom Butchering, and its owners, officers, directors, partners, successors, affiliates, or assigns, directly or through any corporate device, for a period of two (2) years. This termination of exemption privileges shall be held in abeyance and custom exemption privileges shall be provided to Respondents, pursuant to Section 23 (a) of the FMIA, Section 15 (c) of the PPIA, and 9 C.F.R. Parts 303.1, 381.10, and 416, provided all statutory and regulatory requirements and the additional conditions set forth in this Agreement are met.

### CONDITIONS

1. Prior to the to the resumption of custom exemption privileges, and subject to verification and a satisfactory determination by FSIS, Respondents shall demonstrate compliance with the FSIS statutory and regulatory requirements including, but not limited to, 9 C.F.R. Parts 303.1, 381.10, and 416, upon a review and examination of: (a) Respondents' written operational procedures and other programs and (b) of the physical and sanitary conditions of Respondent's facility.

2. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall address and repair any premises, facility and or equipment issues identified by FSIS at the time of the facility review conducted pursuant to paragraph 1 of this Agreement.

3. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents' facility shall receive an "acceptable" rating in every category of FSIS' "Exempt Establishment Review Report," FSIS Form 5930-1.

**Sanitation Performance Standards (SPS)**

4. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall:

(a) develop written procedures for monitoring and identifying non-compliance, corrective and preventive actions, and recordkeeping that Respondents will conduct, and implement, to operate and maintain its premises, facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices;

(b) comply with the requirements of the Sanitation Performance Standards (SPS) regulations (9 C.F.R. Parts 416.1 to 416.6);

(c) ensure that meat and meat food products stored, prepared, and packed are not contaminated or adulterated; and

(d) address and repair the premises, facility, and/or equipment noncompliance issues previously identified by FSIS.

5. Upon the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall:

(a) comply with the requirements of the SPS regulations (9 C.F.R. 416.1 to 416.6);

(b) operate and maintain, at all times, the facility, including its premises, facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices;

(c) ensure that meat and meat products, are not contaminated or adulterated; and

(d) assess their written SPS procedures to evaluate their effectiveness, and make necessary improvements, corrective actions, and repairs to the facility buildings, structures, rooms, and compartments to ensure that they are kept in good repair, and sufficient size to allow for processing, handling, and storage of product in a manner to ensure and maintain sanitary conditions.

**Sanitation Standard Operating Procedures (SSOP)**

6. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall:

(a) develop a written SSOP to describe the monitoring activities, record keeping, and other procedures that Respondents will conduct, implement and maintain on a daily and on-going basis, before, during and after operations, in accordance with 9 C.F.R. Parts 416.11 to 416.16, to ensure sanitary conditions and prevent product adulteration.

7. Upon the resumption of custom exemption privileges, and subject to verification of FSIS, Respondents shall:

(a) implement and maintain on a daily and on-going basis their SSOP system as required by 9 C.F.R. § 416 to ensure sanitary conditions and prevent product adulteration; and

(b) implement corrective and preventative actions, as required by 9 C.F.R. § 416.15.

### **Planned Improvement Program (PIP)**

8. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall develop a PIP designed to identify and correct non-compliance and to ensure that the entire structure of the facility, to include its rooms and compartments, is of sound construction and that all equipment is maintained in proper working order and kept in good repair.

9. Upon the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall implement and maintain their PIP as required in this Agreement, and document any findings and corrective actions to address structural and/or mechanical repairs and/or improvements to their facility and make these records available to FSIS for review and/or copying upon request.

### **Pest Management Program**

10. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall develop a written pest management program, to be implemented and maintained by Welk's Custom Butchering, to prevent the harborage and breeding of pests within the facility and on its grounds consistent with 9 C.F.R. 416.2 (a) and (b) to ensure that:

(a) Respondents review and service the facility and grounds on at least a daily frequency for any signs of rodent and insect presence and activity; and

(b) Respondents provide written reports detailing their findings, corrective actions and recommendations based on their review and service of the facility and grounds for any signs of rodent and insect presence and activity.

11. Upon the resumption of custom exemption privileges, and subject to verification of FSIS, Respondents shall implement and maintain their pest control program in a manner sufficient to prevent the creation of insanitary conditions and practices, to prevent the harborage

and breeding of pests, and to ensure that meat products stored, prepared, and packed are not contaminated or adulterated.

### **Specified Risk Materials (SRM)**

12. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall develop a written specified risk material (SRM) control program, to include daily records sufficient to document procedures for the removal, segregation, and disposition of SRM, to ensure the control of SRM, and regulatory compliance with 9 C.F.R. Parts 309, 310, 311. This program shall include procedures indicating the handling and removal of non-ambulatory disabled cattle (downer) at their facility.

13. Upon the resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall implement and maintain, on a daily and on-going basis, their written SRM control program.

### **Humane Handling and Slaughter**

14. Respondents shall ensure that any cattle, sheep, swine, or goats slaughtered or handled in connection with slaughter at their facility comply with the Humane Methods of Slaughter Act (HMSA) of August 27, 1958 (7 U.S.C. 1901-1906), 9 C.F.R. Part 313, and any Federal, state, or local laws regarding the humane treatment of animals.

### **Personnel and Training**

15. Prior to the resumption of custom exemption privileges, and subject to verification by FSIS, all of Respondents' management and any other personnel shall complete training in sanitation and sanitary dressing procedures and all programs required to be maintained under this Agreement.

16. Upon resumption of custom exemption privileges, and subject to verification by FSIS, Respondents shall conduct annual training for all employees, current and new, consistent with the requirements of paragraph 15.

**Custom Exemption Requirements**

17. Respondents shall ensure that:

(a) product does not become adulterated during processing, handling, storage, loading and unloading, or during transportation;

(b) all slaughtered and processed animal carcasses and further processed meat or meat food products are properly marked, labeled and packaged;

(c) custom prepared products are plainly marked “Not for Sale” and kept separate and apart from any meat or poultry products held for sale, and

(d) records are maintained as required by 9 C.F.R. Part 303.

**Poultry Exemption Requirements**

18. If conducting poultry slaughter operations, Respondent shall ensure that the following poultry exemption requirements in 9 C.F.R. §381.10 are met:

(a) Respondents may not engage in the buying or selling of any poultry products capable of use for human food;

(b) ensure that the slaughtered poultry is for the personal use of the owner of the poultry and may not be sold or donated;

(c) ensure that the shipping containers of custom slaughtered poultry products bear the owner’s name, address, and the statement “Exempted-P.L. 90-492”; and

(d) ensure that only one poultry exemption is claimed during a calendar year.

## **General Provisions**

19. Respondents shall not:

(a) commit any felony or fraudulent act;

(b) 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; or

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

20. Respondent shall make all records required to be maintained by the FMIA, PPIA, or regulations issued thereunder or this Agreement available to FSIS personnel for review and/or copying immediately upon request.

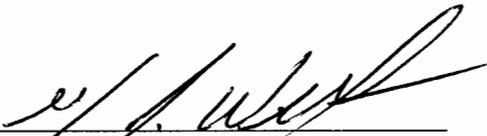
21. Respondents shall fully and completely cooperate with any USDA or FSIS investigation, inquiry, review or examination of Respondents' (a) facility, products, inventory or records, (b) compliance with the FMIA, PPIA, or the regulations issued thereunder, or (c) compliance with this Agreement.

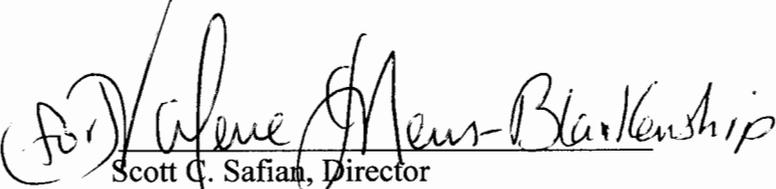
22. The Administrator, FSIS, may summarily terminate custom exemption privileges from Respondents upon a determination by the Director, Evaluation and Enforcement Division, Office of Program Evaluation, Enforcement and Review, FSIS, that Respondents have failed to comply with 9 C.F.R. Parts 303.1, 381.10, and/or 416 or any requirement of this Agreement. It is acknowledged that Respondents retain the right to request an expedited hearing pursuant to the Adopted Rules of Practice concerning any violation alleged as the basis for a summary termination of custom exemption privileges.

23. The provisions of this Agreement shall be applicable for two (2) years and become effective when signed by all parties and upon the reinstatement of custom exemption privileges.

24. Nothing in this Agreement shall preclude any regulatory or administrative actions or the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

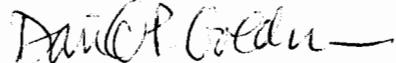
If any provision of this Agreement is declared invalid, such declaration shall not affect the validity of any other provision herein.

  
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Gary Welk on behalf of  
himself and as owner for  
Welk's Custom Butchering

  
\_\_\_\_\_  
Scott C. Safian, Director  
Evaluation and Enforcement Division  
OPEER, FSIS, USDA

  
\_\_\_\_\_  
Krishna Ramaraju  
Office of the General Counsel  
Attorney for Complainant

Issued this 29<sup>th</sup> day of August 2012

  
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 Alfred V. Almanza, Administrator  
Food Safety and Inspection Service