

In re:

Respondents

This administrative action was instituted by the delivery of a Notice of Ineligibility for Custom Exempt Status on March 16, 2015, to Manuel's Ranch and Mr. Manuel Coto, 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 Poultry Products Inspection Act (PPIA) (21 U.S.C. §451 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 Title 9, Code of Federal Regulations (9 C.F.R. §303.1 *et seq.*), Section 15(c) of the PPIA (21 U.S.C. §464(a)), Part 381.10 of the Poultry Products Inspection Regulations, and Part 416 of the Sanitation Regulations (9 C.F.R. §416 *et seq.*).

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

2. This Stipulation and Consent 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. Respondent Manuel's Ranch is now, and at all times material herein, located at 13202 NW 182nd Street, Hialeah, FL 33018.

2. Respondent Manuel's Ranch is now, and was at all times material herein, a custom exempt operation under Section 23(a) of the FMIA, Section 15(c) of the PPIA at its place of business in Hialeah, Florida.

3. Respondent Manuel Coto is now, and was at all times material herein, the owner of Manuel's Ranch and is responsibly connected to Manuel's Ranch.

4. Manuel's Ranch and Mr. Manuel Coto operated under the custom exemption eligibility, pursuant to Section 23(a) of the FMIA, Section 15(c) of the PPIA, and applicable federal meat inspection (9 C.F.R. Part 303.1), poultry inspection (9 C.F.R. Part 381.10), and sanitation (9 C.F.R. Part 416) regulations.

5. In a Notice of Ineligibility letter delivered on March 16, 2015, Respondents were notified that they were no longer eligible to operate under the custom exempt provisions of the FMIA and PPIA because of violations of sanitation, facility, recordkeeping, and other requirements , as required by 9 C.F.R. Parts 303.1, 381.10, and Part 416.

CONCLUSION

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 and poultry slaughter and meat and poultry processing privileges under 9 C.F.R. Part 303.1 and 9 C.F.R. Part 381.10 are terminated from Respondents, 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. This Agreement shall remain in effect for a period of two (2) years after the date of the "Exempt Establishment Review Report," FSIS Form 5930-1, with findings of "acceptable" in every category.

CONDITIONS

1. Prior to the reinstatement 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 facility review by FSIS and examination of (a) Respondents' written operational procedures and other programs, and (b) of the physical and sanitary conditions of Respondents' facility.

2. Prior to the reinstatement 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.

Sanitation Performance Standards (SPS)

3. Prior to reinstatement of custom exemption privileges, and subject to verification by FSIS, Respondents shall:

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

(b) comply with the Sanitation Performance Standards (SPS) regulatory requirements specified in 9 C.F.R. Parts 416.1 through 416.5, except those addressing water reuse (416.2(g)(2) through (6)), prior to resuming custom exempt operations.

4. Upon reinstatement 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. Parts 416.1 to 416.5);

(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 poultry and meat and poultry food products are stored, prepared, and packaged so as not to become 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 are of 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)

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

(a) develop a written SSOP to describe the monitoring activities, recordkeeping , 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;

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

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

Planned Improvement Plan (PIP)

6. Prior to the reinstatement of custom exemption privileges, and subject to verification by FSIS, Respondents shall develop a PIP designed to identify and correct noncompliance 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.

7. Upon the reinstatement 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 mechanical repairs and improvements to their facility and make these records available to FSIS for review and copying upon request.

Pest Management Program

8. Prior to the reinstatement of custom exemption privileges, and subject to verification by FSIS, Respondents shall develop a written pest management program to prevent the harborage and breeding of pests within the facility and on its grounds consistent with 9 C.F.R. Parts 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.

9. Upon the reinstatement 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 and poultry products are stored, prepared, and packaged so as not to become contaminated or adulterated.

Humane Handling and Slaughter

10. Respondents shall ensure that any cattle, sheep, swine, or goats slaughtered or handled in connection with slaughter at their facility complies with the Humane Methods of Slaughter Act (HMSA) of August 27, 1958 (7 U.S.C. §§1901-1906), 21 U.S.C. 610(b), 9 C.F.R. Part 313, and any Federal, state, or local laws regarding the humane treatment of animals.

Specified Risk Materials

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

12. Upon the reinstatement 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.

Sewage and Waste Disposal

13. Prior to the reinstatement of custom exempt privileges, and subject to verification by FSIS, Respondents shall have a sewage waste disposal system in place that properly removes sewage and waste materials to prevent the adulteration of food products consistent with 9 C.F.R. Parts 303.1(a)(2)(i), 381.10(a)(3) and (4) , and 416.2(e) and (f).

14. Upon reinstatement of custom exempt privileges, and subject to verification by FSIS, Respondents shall maintain the sewage and waste disposal systems to prevent the adulteration of food products. When the sewage disposal system is a private system requiring approval by a State or local health authority, Respondent must furnish FSIS with a letter of approval from that authority upon request as required 9 C.F.R. Parts 416.2 (e) and (f).

Recordkeeping and Labeling Provisions

15. Respondents shall properly label and maintain full, complete, and accurate written records of all business activities applicable to the FMIA and PPIA, as specified in 9 C.F.R. Parts 303.1(b)(3), 309.3, 310.22, 320, and 381.175. Respondents shall make all such records available for review and copying upon request of any authorized representative of the Secretary of Agriculture. Respondents shall maintain such records for a period of two years after December 31 of the year in which the record was made, in accordance with 9 C.F.R. Parts 320.3 and 381.177.

Management and Training

16. Prior to reinstatement of custom exemption privileges, and subject to verification by FSIS, Respondents shall designate one person and an alternate who shall have overall responsibility for (a) implementing, and maintaining the sanitation and other requirements of 9 C.F.R. Parts 303, 381.10, and 416, and (b) compliance with the conditions of this Agreement. Respondents may name a new designee or alternate only upon written request to, and subject to the written concurrence of, the Director, ELD.

17. Prior to the reinstatement of custom exemption privileges, with prior concurrence and subject to verification by FSIS, all of Respondents' management and employees shall complete training in

sanitation and sanitary dressing procedures.

18. Prior to the reinstatement of custom exemption privileges, and subject to verification by FSIS, Respondents shall train all employees in all programs, procedures, and requirements of this Agreement.

19. Upon reinstatement of custom exemption privileges, and subject to verification by FSIS, Respondents shall conduct training for new employees, consistent with the requirements of paragraph 17.

20. Respondents shall maintain for the duration of the Agreement records documenting the completion of all training as described in paragraphs 17-19 and shall make those records available upon any request to any authorized representative of the Secretary.

Custom Exemption Requirements

21. Respondents shall (a) ensure that product does not become adulterated during processing, handling, storage, loading and unloading, or during transportation; (b) ensure that all slaughtered and processed animal carcasses and further processed meat or poultry or meat or poultry food products are properly marked, labeled, and packaged, (c) ensure that custom prepared products are plainly marked "Not for Sale", and (d) maintain records as required by 9 C.F.R. Part 303.

Poultry Exemption Requirements

22. Respondent shall ensure that the following poultry exemption requirements in 9 C.F.R. Part 381.10 are met:

(a) Respondents may not engage in the buying and 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

23. 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; (c) willfully make or cause to be made any false entry into any accounts records or memoranda kept by Respondents in compliance with Federal or State statutes or regulations; fail to make true and correct entries in such accounts, records, or memoranda; or fail to keep such accounts that fully disclose all transactions in Respondent's business; (d) assault, intimidate, impede, or interfere with, or threaten and assault, intimidate, impede or interfere with any representative or designee of the Secretary of Agriculture.

24. Respondents 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.

25. 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.

26. The Administrator, FSIS, shall have the right to summarily terminate custom exempt privileges from Respondents upon a determination by the Director, Enforcement and Litigation Division, Office of Investigation, Enforcement and Audit, FSIS, or his or her designee, 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, 9 C.F.R. Parts 1.130 – 1.151, concerning any violation alleged as the basis for a summary termination of custom exemption privileges.

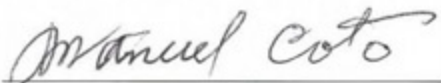
27. The provisions of this Agreement shall be applicable for two (2) years, beginning the

effective date of this Agreement.

28. This Agreement shall be considered issued on the date that is signed by the Administrator, FSIS, but shall become effective on the date that an FSIS exempt establishment review documents findings of "acceptable" in every category, on the "Exempt Establishment Review Report," FSIS Form 5930-1, a copy of which will be provided to the Respondent. The exempt establishment review will be conducted only after FSIS has verified that all of the above provisions stipulating completion "prior to reinstatement of custom exemption privileges" have been completed.

29. Nothing in this Agreement shall preclude any regulatory or administrative actions or the referral of any matter to any agency for possible criminal or civil proceedings, or preclude the Administrator, FSIS, from taking other appropriate administrative action under the FMIA, PPIA, or the regulations promulgated thereunder.

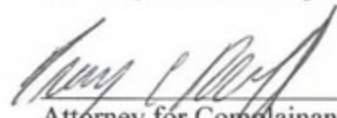
If any provision of this Agreement is declared invalid, such declaration shall not affect the validity of any other provision herein.



Manuel Coto, Owner
on behalf of himself and for Manuel's Ranch



Scott C. Safian, Director
Enforcement and Litigation Division
Food Safety and Inspection Service
U.S. Department of Agriculture



Attorney for Complainant
U.S. Department of Agriculture
Office of the General Counsel

Issued this 1st day of October 2015



Alfred V. Almanza, Administrator
Food Safety and Inspection Service