UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	23-04	4-5-04

FSIS VERIFICATION OF VEAL CALVES WITH IMPLANTS

NOTE: THIS NOTICE EXPIRES ON JUNE 6, 2004.

I. PURPOSE

This notice advises inspection program personnel that the Food and Drug Administration (FDA) has determined that veal calves with implants may be passed for food as outlined below and at www.fda.gov. This notice provides instructions for inspection program personnel to use when verifying that the food safety restrictions determined necessary by FDA have been met.

II. BACKGROUND

FDA has determined that a withdrawal time of 63 days for non-ruminating calves that have been implanted may be allowed, provided certain food safety provisions are met. FDA has determined that food from these veal calves will not pose a risk to human health. Additionally, FDA has determined that implanted calves that have a functioning rumen (see attachment: Photographs of Non-ruminating and Ruminating Calves) may be passed for food. FSIS veterinarians will have the responsibility to determine that the parameters determined necessary by FDA have been met. Each implanted non-ruminating calf presented for slaughter must be accompanied by a signed certificate from a licensed veterinarian.

The FDA requirements are:

Veal calves that have been implanted with growth-promoting hormones may be adulterated. However, they may be made acceptable for human consumption if special precautions are taken. The policy contained in the guidance from FDA only applies to veal calves presented for slaughter prior to June 06, 2004.

The special precautions are as follows:

1. The veal calf is not processed for food within 63 days of implantation.

2. The veal calf has been implanted in accordance with the labeled dose for beef, in accordance with the directions on the implant, and in the proper location (under the skin of the ear).

3. The veal calf is presented for slaughter prior to June 06, 2004.

4. The veal calf is presented for slaughter with appropriate certification as outlined in this notice being issued by FSIS.

The entire text can be found at:
http://www.fda.gov/oc/opacom/hottopics/veal_guidance.html

There are four circumstances in which calves will be presented for slaughter.

1. The calf is presented for slaughter with a written statement from the producer, in accordance with 9 CFR 309.16(d)(1)(ii), that the calf has not been implanted,

2. The calf is presented for slaughter with an implant with a functioning rumen,

3. The calf is presented for slaughter with an implant and veterinary certification;

4. The calf is presented for slaughter with an unknown implant status but without certification, and does not have a written statement from the establishment regarding functioning rumen.

Calves will be subject to rigorous test and hold provisions by FSIS. FSIS will collect liver samples from 10 percent of carcasses from lots where the calves had implants and were certified to have completed the 63-day post-implantation period. FSIS will not sample calves that have no implants, are certified as never having implants. Also, FSIS will not sample ruminating calves with implants.

When FSIS detects an implant in formula-fed non-ruminating calves that have not been certified as completing the 63-day post-implantation period, FSIS cannot determine that the carcass is fit for food. Consequently, FSIS cannot find that the carcass is not adulterated and thus cannot apply the mark of inspection to the carcass.

As means to prevent non-ruminating calves with implants that have not been certified from entering the establishment, an establishment may include procedures in its food safety systems to preclude the use of implants in calves entering their establishment. Such procedures could be included in the establishment's HACCP plan, Sanitation SOPs, or prerequisite programs.

NOTE*:* There is no requirement for all establishments to reassess their HACCP plans at this time—it is only required when meeting the requirements of 9 CFR 417.3(b).

III. INSPECTION FOR IMPLANTS

A. During antemortem inspection, inspection program personnel are to visually determine if implants are present (see attachment: Veal Implant). If the inspection is performed by a non-veterinarian, inspection program personnel are to hold the lot in the" U.S. Suspect" pen for veterinary disposition when:

1. the calves are presented without any certification regarding implant use or non-use, and without any written statement regarding rumen function, or

2. they observe the following:

a. missing ears
b. ears with incisions indicating recent surgery
c. mutilated ears
d. actual presence of implants or evidence of multiple implants.
e. atrophied testicles or unusually heavy muscle development.

B. During postmortem inspection, inspection program personnel will perform visual observation of the head and the ears, and where applicable palpation of ears, on each calf. If necessary, the establishment may remove ears prior to hide removal, place them in a plastic bag, and attach the bag to the carcass. The establishment can also remove the ears when skinning the head and present them for review with inedible offal. Inspection program personnel are to consult their supervisor should adjustments in linespeed be necessary to complete the inspection procedure. If an implant is present, when palpating the ear, inspection program personnel will feel a linear, firm swelling in the ear, right under skin. The implant may feel like "beads on a string". The individual pellets that make up the implant are of approximately 3mm size and about 2 mm apart. If inspection program personnel observe any of the indicators in III.A, or palpate implants at postmortem, each such affected carcass is to be U.S. retained.

NOTE: Public Health Veterinarians (PHVs) are to condemn animals or carcasses, with missing ears, ears with incisions indicating recent surgery, or mutilated ears in which they are unable to determine whether an implant was present. Also, if PHVs identify multiple implants, or implants in non-approved locations (such as the coronary band or tail) in an animal certified to be treated in accordance with FDA requirements, the PHVs are to retain the animal carcass, document his or her observations and findings, collect and preserve the implants (if slaughtered) , and immediately notify, through supervisory channels, the Office of Program Evaluation and Enforcement Review (OPEER), Regional Manager, through Office of Field Operations (OFO).

IV. PHV ANTEMORTEM VERIFICATION ACTIVITIES

A. If a calf is presented for slaughter with a written statement from the producer, in accordance with 9 CFR 309.16(d)(1)(ii), that the calf has not been implanted, the program employee will carry out routine antemortem inspections.

NOTE: Producers cannot certify conditions involving actual use of implants. If implants are found in calves, the PHV will condemn those calves. OPEER should be contacted as outlined in Section III. Any remaining calves in the lot may be "U.S. Suspect."

B. If a calf without veterinary certificate is presented for slaughter with an implant and a written statement from the establishment that each animal has a functioning rumen (see attachment: Photographs of Non-ruminating and Ruminating Calves) the program employee will carryout routine antemortem inspections. FDA has determined that implanted calves that have a functioning rumen may be passed for food. These calves proceed to postmortem inspection where determinations are made about rumen function (see attachment: Photographs of Non-ruminating and Ruminating Calves).

C. If calves have implants and certifications, the program employee will verify that proper signed certification accompanies implanted non-ruminating veal calves and includes the following:

1. The trade name of the hormone implant used,

2. the date each calf was implanted (to show that it meets the 63-day withdrawal time period),

3. a legible address, name and license number, and signature of the certifying veterinarian,

4. identifying information, such as ear tag numbers or other individual identification, on each calf in the lot,

5. information that verifies that the calf has been implanted in accordance with the labeled dose for beef, in accordance with the directions on the implant, that there has been a 63-day withdrawal period, and that implant was placed in the proper location (i.e., under the skin of the ear). Different manufacturers use different pellet sizes and numbers, therefore the certification should indicate if it is one single pellet or a string of multiple pellets.

NOTE: Also, a location other than the base of the ear (e.g., brisket, tail, head, coronary band around feet) is placement that is not consistent with the drug approval.

D. If the non-ruminating calf is presented for slaughter with an implant but without veterinary certification, the PHV is to condemn the calf on antemortem inspection (9 CFR 309.16(a)). Condemned animals can be shipped in accordance with 309.13(d). Calves condemned due to the presence of implants may be rendered following removal of the implant. Any remaining calves in the lot may be permitted for slaughter as "U.S. Suspect."

V. PHV RESPONSIBILITIES AT POSTMORTEM INSPECTION

A. At postmortem, calves without veterinary certificate and with a written statement from the producer indicating that the calves do not have implants (9 CFR 309.16(d)(1)(ii)) will be observed and the ears palpated for implants. If no implants are found, calves are passed for food. If implants are found, affected calves are condemned and other calves in the lot are condemned. OPEER is notified in accordance with section III above.

B. At postmortem, calves without veterinary certificate and with a written statement from the establishment that the calf is ruminating, will have their rumens observed and palpated to determine whether they are ruminating (see attachment: Photographs of Non-ruminating and Ruminating Calves). If calves are determined to be ruminating they are passed for food if not otherwise subject to condemnation under 9 CFR Part 311. For any calves found to NOT be ruminating, inspection program personnel will palpate ears and otherwise observe for implants. If implants are found these calves are condemned and OPEER is contacted as indicated in section III above. Other calves in the lot that are non-ruminating and with implants are subject to condemnation.

C. At postmortem, "U.S. Suspect" calves without veterinary certificate and **without** a written statement regarding rumination status will be observed and the ears palpated for the presence of implants. If no implants are found, the calves are passed for food. If implants are found in any animals in the lot (may require lotting until entire lot is inspected), then palpate those calves' rumens to determine whether they are ruminating. If ruminating they may be passed for food, if not, the calves are condemned.

VI. TESTING

A. At postmortem inspection, FSIS will test calves that have implants and certification as verified by the PHV for a variety of implant substances including Trenbalone. During this period, all lots will be sampled and all carcasses and parts in each lot will be "U.S. Retained" pending test results. FSIS will collect liver samples from 10 percent of the calves in each lot, or a minimum of 1 animal in lots smaller than 10 animals.

B. The PHV may bias his or her sample to include animals with palpable implants, atrophied testicles or heavy muscling.

C. The PHV is to collect samples as follows:

1. Collect a 1/3 pound sample from the liver collected in accordance with FSIS Directive 10,210.1.

2. Ship the sample(s) to Midwestern Laboratory by Federal Express. Write "IMPLANT" in box 10 and in the remarks section of FSIS Form 10,000-2.

NOTE: The PHV will be also collect liver samples that the establishment will be submitting to an independent laboratory certified to analyze for Trenbalone. The establishment is responsible for providing its own boxing and shipping supplies and costs.

D. The FSIS laboratory expects to report results four days after receipt. The PHV can not make final disposition until he or she obtains the FSIS and independent laboratory results.

E. If all FSIS and independent laboratory test results are negative, the PHV is to release the entire lot.

F. If some individually sampled carcass results are negative, and one or more are positive, then the PHV will only release the individually tested carcasses that are negative for all analyses. The PHV will condemn all other carcasses that tested positive and the remainder of the untested calves in the lot because FSIS is unable to determine that they are not adulterated. For the remaining calves in the lot, the establishment may present information, such as 100% testing results for Trenbalone on the remaining animals, as to why FSIS should not consider the entire unsampled portion of the lot to be adulterated.

G. Sample results from the independent laboratory must include individual animal results referenced to individual animal identification information contained in the signed certification. The establishment is to provide these laboratory results to FSIS. If Trenbalone is detected it is above the tolerance.

VII. DOCUMENTATION

If an implant or evidence of an implant (cut or missing ears, etc.) is found in calves; If the calf is presented for slaughter with an implant but without certification and does not have a functioning rumen; or if test results for hormones are positive, inspection program personnel are to document accordingly.

1. If the establishment **has not** included procedures to preclude the use of implants in animals entering the establishment in its HACCP plan, Sanitation SOPs, or prerequisite programs, then inspection program personnel will issue a noncompliance record (NR) for presence of implants or suspicion of biological residues using procedure code 03J01/02 for an unforeseen hazard. Inspection program personnel are to verify that the establishment complies the regulatory requirements of 9 CFR 417.3(b),

or

2. If the establishment **has** included procedures to preclude the use of implants in ruminating calves entering the establishment in their HACCP plan, Sanitation SOPs, or prerequisite programs, then inspection program personnel will issue a NR for presence of implants or suspicion of biological residues using procedure code

03J01/02. Inspection program personnel are to verify that the establishment complies the regulatory requirements of 9 CFR 417.3(a).

NOTE: For additional guidance see attachment: Veal Implant Decision Flowchart.

P. R. Santiago /s/
for Philip S. Derfler
Assistant Administrator
Office of Policy and Program Development