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DRAFT GUIDANCE FOR INDUSTRY

SMALL ENTITIES COMPLIANCE GUIDE FOR RENDERERS—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

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Submit comments on this draft guidance by the date provided in the Federal Register notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments may also be submitted electronically on the Internet at <http://www.regulations.gov>. All written comments should be identified with Docket No. FDA-2008-D-0597.

For questions regarding this draft guidance document, contact Shannon Jordre, Division of Compliance (HFV-230), U.S. Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Place, MPN-4, Rockville, MD 20855, (240) 276-9229.

Additional copies of this draft guidance document may be requested from the Communications Staff, HFV-12, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/cvm>.

U.S. Department of Health and Human Services
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Center for Veterinary Medicine
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SMALL ENTITIES COMPLIANCE GUIDE FOR RENDERERS—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Background

On April 25, 2008, FDA published a final rule in the **Federal Register**, entitled "Substances Prohibited From Use in Animal Food or Feed" (73 FR 22719). This final rule established a new regulation at 21 CFR 589.2001 entitled, "Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy" and, amended the previously existing ruminant feed regulation at 21 CFR 589.2000 entitled, "Animal proteins prohibited in animal feed." FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121). This document is intended to provide guidance on the requirements of Title 21, Code of Federal Regulations, new Section 589.2001, and amended Section 589.2000, Effective Date: April 27, 2009.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

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II. Purpose

WHAT IS THE PURPOSE OF REGULATION 589.2001?

This regulation is designed to further strengthen existing safeguards against the establishment and amplification of Bovine Spongiform Encephalopathy (BSE), sometimes referred to as “Mad Cow Disease,” through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals.

The following materials are prohibited in all animal feed by the new rule:

- The entire carcass of BSE-positive cattle;
- The brains and spinal cords from cattle 30 months of age and older;
- The entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not removed;
- Tallow that is derived from other materials prohibited by this rule that contain more than 0.15 percent insoluble impurities; and
- Mechanically separated beef that is derived from the materials prohibited by this rule.

Throughout the regulation, these materials are referred to as “cattle materials prohibited in animal feed” or CMPAF. If you (i.e., renderers) receive, manufacture, blend, process, or distribute any of these materials, you must comply with the provisions of this regulation (21 CFR 589.2001(c)(2)).

ARE THERE ANY CATTLE MATERIALS SPECIFICALLY EXEMPTED FROM THIS REGULATION?

Yes. The following materials do not fall under the definition of CMPAF:

- Tallow derivatives (as defined in the regulation (See 21 CFR 589.2001(b)(6))).
- Tallow that is derived from material containing the brains and spinal cords of cattle 30 months of age and older if such tallow contains no more than 0.15 percent insoluble impurities.
- Cattle materials (as defined in the regulation (See 21 CFR 589.2001(b)(vi)(C))) from a foreign country that has received designation by FDA as not being subject to the new regulation.

IS MY FIRM AFFECTED BY THIS REGULATION?

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Under this regulation, no animal feed or feed ingredient can be manufactured from, processed with, or contain CMPAF. As a result, FDA imposes requirements on renderers of specifically defined cattle materials. For purposes of the regulation, FDA defines a renderer as any firm or individual that processes slaughter byproducts, animals unfit for human consumption, which would include carcasses of dead cattle, or meat scraps. The definition of renderer includes:

- Persons or firms that collect the materials set forth above and subjects them to minimal processing;
- Persons or firms that distribute the materials to firms other than renderers whose intended use for the products may include animal feed, industrial use, or other uses; and
- Persons or firms that also blend animal protein products. 21 CFR 589.2001(b)(4)

I AM A RENDERER WHO PICKS UP CATTLE MORTALITIES FOR RENDERING. WHAT DO I NEED TO KNOW IF THE RENDERED MATERIALS FROM THOSE CATTLE ARE INTENDED FOR NON-RUMINANT FEED?

The regulation requires you to remove the brain and spinal cord from dead cattle (cattle not inspected and passed for human consumption) if the cattle are to be processed for use in non-ruminant animal feed. 21 CFR 589.2001(c)(2)(i) However, this is not required if the animal can be shown to be less than 30 months of age. You can decide how best to determine the age of an animal, but you must have adequate written procedures explaining how you do the aging and make these written procedures available for FDA inspection. 21 CFR 589.2001(c)(2)(ii), (vi)

III. AGING CATTLE

WHAT IS THE BEST WAY TO DETERMINE THE AGE OF AN ANIMAL?

The best evidence of age is written documentation that includes the name and address of the current owner, and identifies the date and location where the animal was born. Types of documents that might contain this information are breed association registrations, production records, or animal identification systems. The documentation should relate identifying devices on the animal (such as official calf hood or other ear tags, electronic implants, or brands) with information about the age of the animal.

CAN I ACCEPT AN OWNER'S STATEMENT THAT AN ANIMAL IS LESS THAN 30 MONTHS OF AGE?

Yes. You may choose to accept certification from the owner of the animal that he or she is in possession of appropriate written documentation showing that the animal is less than 30 months of age. If you accept certification from producers, you may want to specify in

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your written procedures how producers will identify to drivers of collection trucks that an animal is certified to be less than 30 months of age. For example, you may have a pre-arranged agreement with producers that animals under 30 months of age will be identified by a certain color or type of leg band.

CAN DENTITION (EXAMINATION OF AN ANIMAL'S TEETH) BE USED TO AGE CATTLE?

Yes, dentition can be used to determine if cattle are less than 30 months of age. Veterinary medical textbooks and academic articles indicate that the second set of permanent incisors (i.e. third and fourth permanent incisors) come through the gum line when cattle are between 24 and 30 months of age. Therefore, cattle would be considered to be less than 30 months of age if the third permanent incisor has not yet come through and grown above the gum line. Please refer to Appendix A at the end of this draft guidance document, which provides diagrams from USDA's Food Safety and Inspection Notice (FSIS) Notice 5-04 (1/12/04), illustrating how dentition can be used to identify animals under 30 months of age. The diagrams, as well as photographs, are also available on the FSIS Web site.¹

WHAT ABOUT CALVES THAT ARE OBVIOUSLY LESS THAN 30 MONTHS OF AGE?

Body weight, size, and appearance can be reliable indications of age in very young animals. These characteristics could obviate the need for documentation or other means of determining the animal's age.

AREN'T CATTLE FROM FEEDLOTS GENERALLY LESS THAN 30 MONTHS OF AGE?

Yes. Cattle in concentrated feeding programs are often sent to slaughter well before 30 months of age. As a renderer, your written procedures for aging cattle might include a description of arrangements made with a feedlot to ensure that dead cattle you receive from that feedlot are less than 30 months of age.

WHAT CAN I EXPECT WHEN AN FDA INSPECTOR REVIEWS MY PROCEDURES FOR AGING CATTLE?

FDA inspection personnel, including state inspectors working on FDA's behalf, will verify that you have adequate written procedures in place, evaluate the adequacy of aging procedures, and verify that the procedures are being followed. If an inspector determines there is no basis to question the accuracy and reliability of your aging procedures, the inspector is expected to accept those procedures as verification of the age of the cattle.

Conversely, inspectors are expected to investigate further if they believe that your aging procedures are incorrectly identifying animals as less than 30 months of age.

¹http://www.fsis.usda.gov/OFO/TSC/bse_information.htm

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Investigators may conduct hands-on dentition examinations of animals that they believe to be 30 months of age or older. In resolving discrepancies, written documentation that the inspector believes to be valid should be accepted as the final determinant of age.

IV. BRAIN AND SPINAL CORD REMOVAL

WHAT DO I HAVE TO DO IF I WANT TO REMOVE THE BRAIN AND SPINAL CORD FROM DEAD CATTLE 30 MONTHS OF AGE OR OLDER SO THAT I CAN RENDER THE REMAINDER OF THE CARCASS FOR USE IN NON-RUMINANT FEED?

You are required to have adequate written procedures for the removal, segregation, and disposition of the brain and spinal cord (or material containing the brain and spinal cord) and make these written procedures available for FDA inspection. 21 CFR 589.2001(c)(2)(ii), (vi).

WHAT IS THE BEST METHOD FOR REMOVING THE BRAIN AND SPINAL CORD?

There is no single best method for brain and spinal cord removal. The choice of methods could depend on the layout of the plant, cost of equipment, skill level of employees, availability of alternative means of disposing of tissues that surround the brain and spinal cord, and a number of other considerations. Some options for removing the brain are:

- the use of suction equipment or other tools to remove the brain through the *foramen magnum* (large hole at the base of the skull through which the spinal cord passes);
- opening the skull to expose the brain cavity; and
- leaving the brain in place and treating the entire head as CMPAF.

Some options for removing the spinal cord are:

- removing the hide, eviscerating the carcass (removing the contents of the abdominal cavity), and using a saw to split the carcass down the midline to expose the spinal canal;
- using cutting equipment to remove the spinal cord with surrounding vertebral column, with or without hide removal or evisceration; and
- removing skeletal muscle or other parts and leaving the spinal cord in place, treating the remainder of the carcass as CMPAF.

WHAT CAN I EXPECT WHEN AN FDA INSPECTOR REVIEWS MY PROCEDURES FOR REMOVING BRAIN AND SPINAL CORD?

FDA inspection personnel, including state inspectors working on FDA's behalf, will verify that you have adequate written procedures in place and that the procedures are designed to ensure complete removal of the brain and spinal cord. Inspection personnel will verify proper execution of procedures by reviewing production records and observing plant employees performing the procedures. Inspectors may also conduct inspections to verify that brain and spinal cord have been completely removed.

V. Recordkeeping

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WHAT DO I NEED TO KNOW ABOUT THE NEW RECORDKEEPING REQUIREMENTS?

The new regulations set forth recordkeeping requirements applicable to all renderers of cattle materials. There are slight differences between the requirements for renderers who handle CMPAF, and those who do not:

- If you are a renderer that receives, manufactures, processes, blends, or distributes CMPAF, you are required to establish and maintain records sufficient to track the CMPAF to ensure that they are not introduced into animal feed. 21 CFR 589.2001(c)(2)(vi).
- If you are a renderer that receives, manufactures, processes, blends, or distributes any cattle materials, you must meet the recordkeeping requirement as follows:
 - You must establish and maintain records that sufficiently demonstrate that materials rendered for use in animal feed were not made from CMPAF.
 - If these materials were obtained from an establishment that segregates CMPAF from other materials, your records must demonstrate that the supplier has adequate procedures in place to exclude CMPAF from any materials supplied to you. 21 CFR 589.2001(c)(3)(i) Your records will meet this requirement if they include either:
 - Certification or other documentation from the supplier that materials supplied are free of CMPAF. These records must include a description of the segregation procedures used, documentation that the supplier confirms that such segregation procedures were in place prior to supplying the materials, and records of the your periodic review of the supplier's paperwork, i.e., certification or other documentation. 21 CFR 589.2001(c)(3)(i)(A).

OR

- Documentation of another method acceptable to FDA, such as third-party certification, for verifying that the supplier has effectively excluded CMPAF from any materials shipped to the renderer (see additional discussion below). 21 CFR 589.2001(c)(3)(i)(B).
- * Normal and customary business records maintained by you and/or your company might already contain much of the information required by the rule. Electronic records are acceptable when in compliance with 21 Code of Federal Regulations Part 11.
- * The required records could include invoices, receiving tickets, receiving logs, disbursement and distribution records, scale tickets, purchase orders, signed affidavits or other written statements from slaughter and processing establishments, or other business records or documents.

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- * Copies of all records must be made available for inspection and copying. 21 CFR 589.2001(c)(2)(vi); (c)(3)(i). Records should be readily retrievable and legible.
- * Records must be maintained for 1 year. 21 CFR 589.2001(e). That should be 1 year from the date the records were created. Because renderers handling any cattle materials will be relying on certification or other documentation from suppliers, renderers are urged to notify their suppliers of the renderers' 1-year record retention requirement.
- * All records (including certificates or other documentation) provided by any party for demonstrating compliance with this rule should be accurate and truthful. The knowing and willful making of any false, fictitious or fraudulent statements or representations in any manner within the jurisdiction of any department or agency of the United States is a matter subject to the provisions of Title 18 of the U.S. Code, Section 1001.

FOR PURPOSES OF THE SUPPLIER'S DOCUMENTATION DISCUSSED ABOVE, HOW WOULD THIRD-PARTY CERTIFICATION WORK?

Third-party certification to verify compliance with regulatory requirements is being used widely in both the private and public sectors. FDA recognizes the usefulness of such services and in July 2008 published its *Draft Guidance for Industry: Voluntary Third-Party Certification Programs for Foods and Feeds*.² Third-party certification is characterized as fee-based, voluntary product certification and production/processing verification services. Such certification provides independent assurance that regulatory requirements are met. Written production and manufacturing processes and recordkeeping requirements are typically confirmed through third-party audits that follow strict guidelines covering specific areas.

There are several third-party certifiers that provide independent auditing services to help ensure compliance with requirements for manufacturing, food safety, and documents and records.

If you choose to use third-party certification to verify that suppliers have excluded CMPAF from any materials supplied to you, copies of the audits and similar reports produced by the third-party certification firm should satisfy the recordkeeping requirement.

VI. MARKING REQUIREMENTS

WHAT ARE THE MARKING REQUIREMENTS IN THE NEW RULE?

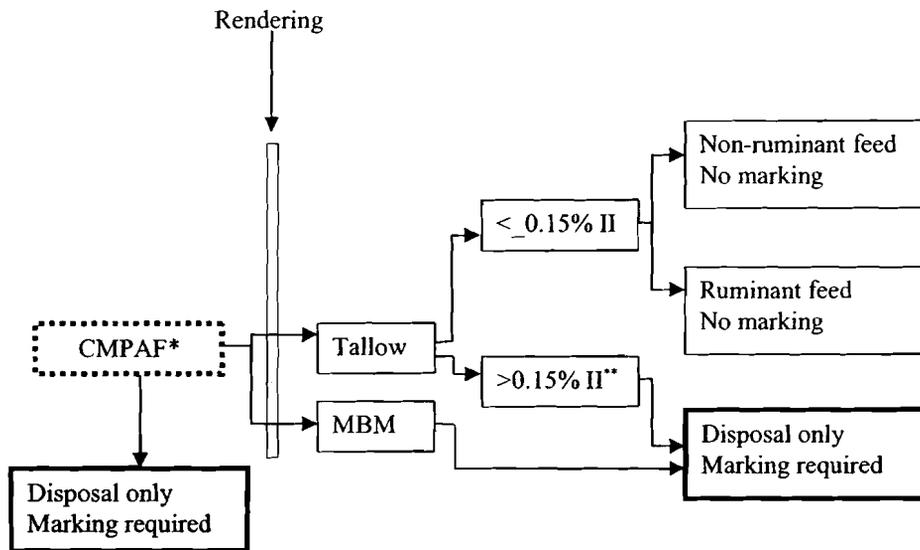
Once CMPAF has been separated from other cattle materials, renderers are required to mark the CMPAF with an agent that can be readily detected on visual inspection. 21 CFR 589.2001(c)(2)(v). The marking agent is intended to indicate to all parties in the feed chain that the material may not be used in animal feed. However, if material containing CMPAF is

² <http://www.fda.gov/oc/guidance/thirdpartycert.html>

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to be rendered to salvage tallow, the marking agent may be applied after the rendering process (see diagram below). In this way, tallow containing no more than 0.15% insoluble impurities (II) would not have to be marked because it could be used in animal feed. The marking agent would have to be applied only to the solids portion, i.e., the resulting meat and bone meal (MBM), and to tallow containing more than 0.15% insoluble impurities. The rule does not require carcasses of animals disposed of on the farm (e.g., by burial or composting) to be marked.



*materials that contain CMPAF such as entire carcasses of animals 30 months of age or older, brain and spinal cord or animals 30 months of age or older and other materials that contain or may contain CMPAF, are required to be marked at this point only if not intended for rendering

**contains or may contain CMPAF

WHAT ARE THE ACCEPTABLE MARKING AGENTS AND HOW DO I APPLY THEM?

Acceptable marking agents would include Patent Blue V (E131), approved in Europe for this purpose, or the list of agents approved for this purpose by the Canadian Food Inspection Agency.³ A marking agent should be applied by spraying, dipping, or some other manner so that the agent is visible on all surfaces of such marked CMPAF. FSIS regulations require that slaughter plants mark inedible material to indicate that it is not fit for human consumption. Renderers may want to suggest that their slaughter plant suppliers, as part of their segregation procedures, mark material containing CMPAF with a different agent, so that it can be readily distinguished from the inedible material that is to be rendered for animal feed use.

VII. Wastewater from Rendering

³ <http://www.inspection.gc.ca/english/anima/heasan/djsemala/bseesb/enhren/stacole.shtml>

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AS A RENDERER OR PROCESSOR, HOW SHOULD I HANDLE DISLODGED CMPAF and Non-CMPAF TISSUES RECOVERED FROM WASTEWATER?

Operations that remove CMPAF or render CMPAF should take reasonable precautions and employ reasonable methods to contain and collect dislodged CMPAF tissues, including such tissues recovered from wastewater. For example, removing CMPAF from the carcass in a designated area, collecting the dislodged CMPAF into a container designated for CMPAF, and screening CMPAF from the wastewater collection system. Inspection personnel will assess the adequacy of the methods described in your written procedures for removal of CMPAF. In addition, when removing CMPAF from the carcasses of cattle 30 months of age and older, renderers must consider non-CMPAF tissues that are dislodged and comingled with CMPAF in wastewater during the removal process to also be CMPAF. In this situation, all strained solids are CMPAF and should be marked as CMPAF as explained in the diagram above.

VIII. Tallow

WHAT DO I NEED TO KNOW ABOUT THE NEW REQUIREMENTS FOR TALLOW?

The new 21 CFR 589.2001 describes the requirements for tallow intended for use in feed for non-ruminant animals. The 1997 ruminant feed regulation (21 CFR 589.2000) has also been revised to add requirements for tallow intended for use in feed for ruminant animals. The overall effect of these two regulations on the use of tallow in animal feed is as follows: If your tallow meets the impurity standard of no more than 0.15% insoluble impurities, then it may be used in feed intended for all animals, regardless of its origin. Tallow that does not meet the 0.15% insoluble impurities standard is prohibited from use in ruminant feed but may be used in feed for non-ruminant animals if the tallow is derived from documented CMPAF-free sources.

Since 21 CFR 589.2000 now requires that tallow used in feed for ruminant animals contain no more than 0.15% insoluble impurities, the tallow you distribute should either meet the impurity standard or be labeled with the caution statement: *“Do not feed to cattle or other ruminants”*. If your intent is to meet the impurity standard, you should have a written description of your procedures for accomplishing this. For example, this may include a written tank management plan; procedures for load-out of tallow from storage tanks; procedures for sampling tanks, containers, or finished loads; and analytical results from a laboratory that uses AOCS Official Method Ca 3a-46, or an equivalent method.

Insoluble impurities, by definition, are not soluble in tallow or other fats. They are particles that may be suspended in tallow that has been or is being heated, agitated, or moved. Over time, impurities will migrate toward the bottom of a tank that has not been disturbed. The rate at which impurities will settle is affected by the size and weight of the particles, viscosity of the tallow, and time. Therefore, when sampling tallow to measure insoluble impurity levels, the length of time allowed for impurities to settle and the location in the tank where the sample is drawn from will affect the results. For this reason, your sampling procedures should be developed so that test results accurately reflect the insoluble impurity level in

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tallow that you intend to offer into commerce as meeting the impurity standard established in 21 CFR 589.2001. Similarly, if an inspector visits your facility to collect a tallow sample, we suggest that you explain your sampling procedures to the inspector so the sample they collect is representative of the tallow product you offer for distribution.

ARE ALL FATS CONSIDERED TO BE TALLOW?

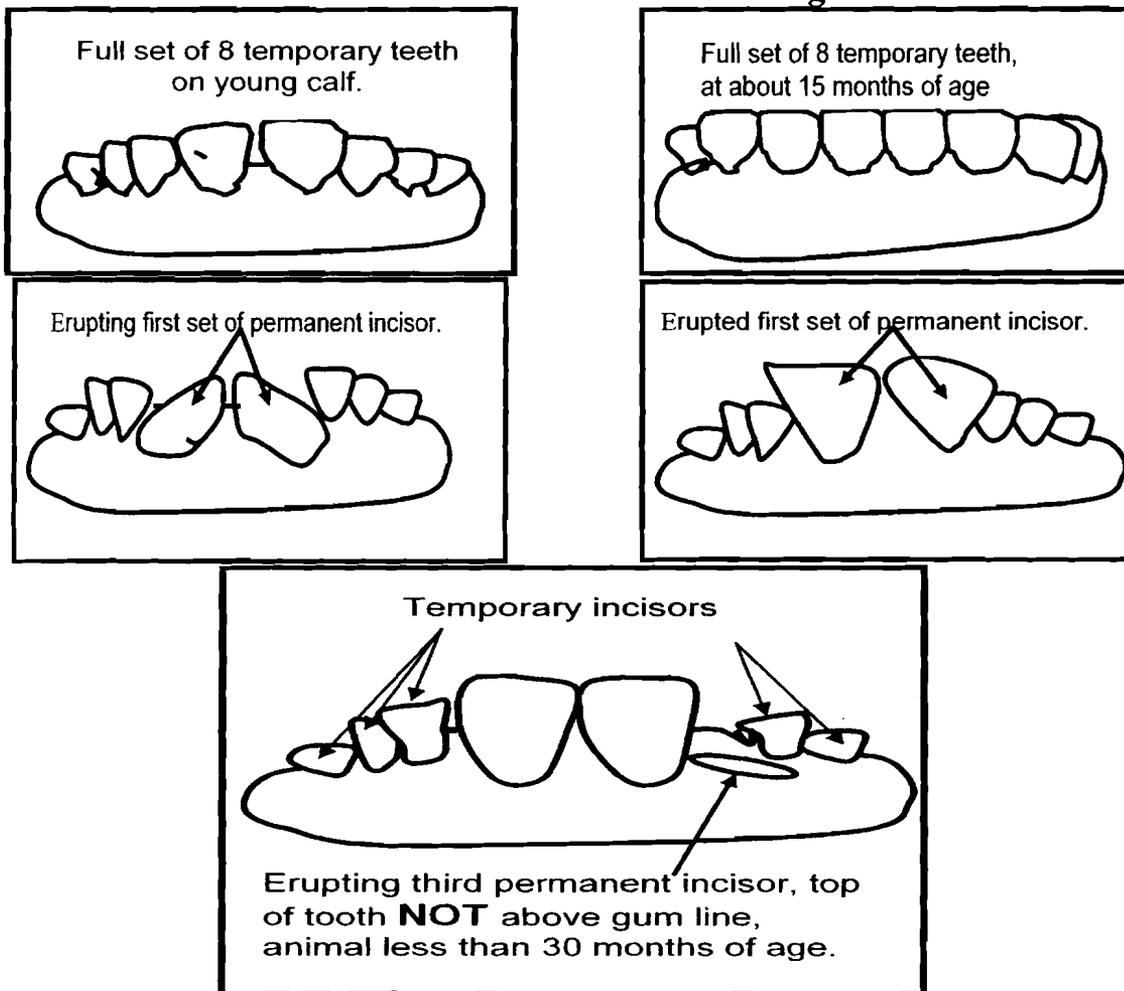
For purposes of 21 CFR part 589, tallow means the rendered fat of cattle. All other fats and oils not derived from cattle are not subject to this rule. For example, these would include, but not be limited to, fats and oils derived from poultry, pork, sheep, goats, equine, fish, and vegetable-based sources. In addition, recovered cooking oils from restaurants and food processors are exempt, because any tallow present in them is from edible sources from which CMPAF has already been removed under USDA inspection.

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APPENDIX A

FSIS Notice 5-04

The dentition depicted below represents
animals less than 30 months of age



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The dentition depicted below represents animals 30 months of age or older

