

OLSSON, FRANK AND WEEDA, P.C.
ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036-2220
SENDER'S PHONE: (202) 518-6311
FACSIMILE: (202) 234-1560
E-MAIL: djohnson@ofwlaw.com

June 5, 2007

Via Electronic Mail

Ms. Mary Ann Riley, FSIS Docket Clerk
U.S Department of Agriculture
Food Safety and Inspection Service
300 12th Street, S.W.
Room 112, Cotton Annex
Washington, DC 20250-3700

Re: Docket No. 03-038IF Interim Rule on Advanced Meat Recovery Systems

Dear Ms. Riley:

On behalf of our clients, we respectfully submit these comments on the above rulemaking. Specifically, we request that the Food Safety and Inspection Service (FSIS) clarify in the final regulation or the preamble to the rule that the current regulation of meat derived from Advanced Meat Recovery (AMR) systems, 9 CFR § 318.24, does not apply to meat derived from soft separation equipment.

Background – Hard and Soft Separators

Meat from certain livestock bones simply cannot be harvested economically by hand deboning. This will include meat attached to the vertebrae/neck bones and will also include meat on certain flat bones, such as feather bones and loin bones.

To enable establishments to harvest this meat, equipment manufacturers developed machines in the 1960's that could mechanically separate meat from bone. These systems worked by placing the bones with meat attached into the equipment where it was subjected to hydraulic pressure. This pressure crushed the bones and forced the less dense components, primarily meat (and some bone constituents) through a screen. The resultant meat product emerged as a paste. This process has been known as a "hard separation" process (and the equipment referred to as "hard separators").

In 1976, the FSIS amended its regulations implicitly to permit the use of this type of equipment for poultry by establishing a bone limitation of 1%. *See* 9 CFR § 381.118(d). At that time, the poultry product was known in the trade as mechanically deboned chicken or turkey, but could be labeled as chicken or turkey on any product in which it was used. When red meat establishments sought to use the equipment on livestock, FSIS rejected such use until a final rule was adopted. There were two consecutive regulations, the last, adopted in 1982, required the products resulting from the hard separators to be labeled as mechanically separated beef or pork and, to ensure process control, established a maximum calcium content (as a measurement of bone solids). *See* 9 CFR § 319.5.

In late 1980's, in contrast to the hard bone separation technology, certain equipment suppliers began manufacturing a totally different system to remove non-meat components from meat. These systems operate by using belt pressure against a rotating perforated steel drum (as opposed to hydraulic pressure) to separate meat from connective tissue, sinews, cartilage, bone chips, and other non-meat components in a "soft separation" process. These systems are known as "desinewers." In addition to developing the process to act as a desinewer, the equipment companies began experimenting with the separation of meat from bone by passing flat bones through the system. For bones such as feather bones, rib bones, button bones, loin bones, loin fingers, and strip bones, it was possible to remove the meat without damaging, let alone crushing the bones.¹ Indeed, the bones would emerge essentially intact from the system. Moreover, rather than emerging with a paste-like appearance, the meat from these systems would have a hand derived appearance. These systems have been known both as a desinewer and, when used for meat recovery, as a "soft separator."

Given the existing MS(S) regulation, these equipment manufacturers were concerned that, since their process technically could be deemed to mechanically remove meat from point, the meat derived from the soft separation systems would be covered by the MS(S) regulation. Accordingly, these manufacturers contacted the Equipment Approval Branch of FSIS (which has since been disestablished following adoption of the HACCP regulations). The Equipment Branch, in consultation with the Labeling Branch, reviewed the equipment, paying particular attention to how the bones emerged from the system and the appearance of the end product. Several pieces of equipment were approved, including the Baader and SEPAmatic soft separators, subject to the condition that the bones emerged essentially intact and the finished product had a meat, not paste-like appearance. If these conditions were met, the resultant product could be labeled as meat and could be used without any limitation.²

¹ Later developments in the "soft separation" equipment permitted a pork establishment to pass an entire vertebrae column through the soft separator and not only would the bones emerge intact, the entire column could be picked up and would remain together after passing through the system. This equipment has not been perfected for beef.

² This paste-like appearance criteria is still in use to distinguish ground turkey from mechanically separated (kind), even though both products are derived from a mechanical separation process. Admittedly, the poultry MS(K) regulations expressly include a paste-like appearance in the definition, but the absence of such criteria in the MS(S) regulation did not foreclose FSIS recognition that in the late 1980's that the meat product resulting from the soft separation process was meat, not MS(S).

The AMR Regulation 1994-2004

In 1994, FSIS published the initial regulation permitting meat derived from Advanced Meat Recovery systems to be labeled simply as “meat.” *See* 9 CFR § 318.24. The regulation initially used the same standard as the Equipment Branch approvals for the soft separators, the “bones emerge essentially intact.”³ However, it became immediately clear that this regulation was not being interpreted by the agency or the industry to apply to soft separators – rather it addressed the developments made in the hard separation process.

As discussed above, the earlier hard separators needed to use a force sufficient to harvest the meat and the required degree of pressure inevitably crushed the bones. While equipment manufacturers were developing the soft separation process, these companies and others were also improving the design of the hard separators. Through improved hard separation design, the newer equipment was able to remove meat from bone without the excessive pressure of the older MS(S) equipment. Instead of crushing the bones, the bones exited the system in a “cake” form. Consequently, the amount of bone constituents in the resulting product was greatly reduced as compared to the older MS(S) hard separation equipment. Although the product resulting from the advanced hard separators can be labeled as meat, it has acquired a name in the trade as “finely textured beef trimmings or finely textured beef,” a name which FSIS has recognized in its label pre-approval process as appropriate for product derived from the advanced hard separators.

In support of our contention that even from the beginning FSIS approached the AMR rule as if it only applied to hard separators, we respectfully direct you attention to the following:

First, in response to consumer group concerns as to the AMR regulation, FSIS surveyed “establishments mechanically separating muscle from beef neck bones“ in 1996. *See* 63 Fed. Reg. 17960 (April 13, 1998). Since neck bones cannot be used in the soft separation process for beef, the survey could only apply to the new hard separation technology.

Second, in its 1998 proposed revision of the AMR rule, the agency proposed dropping the requirement that the bones emerging from the AMR equipment “essentially intact.” *See* 63 Fed. Reg. 17961. According to the preamble, this was due to the difficulties of inspectors making such determinations on the “cake” from the bone cannons. *Id.* In lieu of the visual examination, FSIS would begin the use of laboratory analyses for calcium, iron and central nervous tissue. We respectfully submit that these tests would be unnecessary in whole or in part if applied to the limited raw materials and process capabilities of the soft separators.

Third, the FSIS AMR survey in 2002 kept a focus on the hard separators. Not only was the survey focused on the processing of the vertebral column of cattle (only being harvested through the hard separation process), the only two AMR units specified were the Protocon (P) and Hydrosep (H); both are hard separators.

³ The regulation also contained a maximum calcium limitation.

Fourth, FSIS has not applied the in-plant testing or naming requirements for hard separation AMR to the soft separation process:⁴

- There are at least nine beef establishments currently using hard separator AMR. These nine also have a soft separator at the establishment. Although the hard separation AMR product has been sampled, the product of the soft separators has never been sampled by FSIS for calcium or iron and only one case has it been sampled for spinal cord or DRG since 2004. (Under the revised regulatory sampling program, FSIS inspection program personnel take samples of beef AMR product on a routine basis to verify that spinal cord tissue is not present in such product (FSIS Directive 7160.03, Revision 1, August 25, 2003).
- In the vast majority of situations, the soft separation product is labeled as beef, beef trimmings and boneless beef.
- Additionally, at least eight pork plants are using a soft separator. Only once has FSIS sampled product from this equipment for calcium and iron and only twice has this product been sampled for spinal cord or DRG since 2004.

By 2004 and continuing on to today, it became unquestionably clear that the AMR regulation only applied to hard separation technology.⁵

2004 Interim AMR Rule

FSIS did not finalize its 1998 proposal on AMR, but did adopt a modified AMR regulation as part of the interim final rules resulting from the positive BSE bovine slaughtered in the United States in late 2003. In supporting its decision to ban the use of AMR for cattle over 30 months of age, FSIS relied on the Harvard Risk Assessment on BSE:

[T]he most important means by which low-risk tissue can become contaminated is through the use of AMR systems that can leave spinal cord and DRG in the recovered meat product. See 69 Fed Reg 1875 (January 12, 2004).

The agency's description of the AMR process both explains the decision and conclusively proves that the AMR regulation did not and indeed could not apply to meat derived from the soft separation process. According to FSIS:

AMR systems are newer models of systems that have been used since the 1960s. The new systems emulate the physical action of hand-held high-speed knives for the removal of

⁴ Please see Olsson, Frank and Weeda, PC, Survey of Large Slaughter Establishments – Beef and Pork (2007) (Attachment 1).

⁵ We do acknowledge that the soft separation process does technically “mechanically remove meat from bone,” which is part of the AMR definition. However, we respectfully note that the definition of MS(S) also speaks of the “mechanical removal of most of the bone from meat “9 CFR 319.5(a). Yet, as footnoted above, this virtually identical language did not foreclose FSIS in the 1980's from recognizing that product derived from soft separators was meat, not MS(S).

skeletal muscle tissue from bone through the use of hydraulic pressure. AMR systems apply pressure to detach the meat (skeletal muscle) tissue from the bones in a “hard separation” process. Desinewers that typically use belt pressure against a rotating perforated steel drum then separate meat from connective tissue, sinews, and other non-meat components in a “soft separation” process. In addition to vertebrae, typical bones processed by piston-driven AMR systems are brisket bones (breast or lower chest), rib bones, flat bones (scapulas), and hip bones (pelvis). *Id.* at 1876.

Once again, it is clear that the agency’s definition of AMR is limited to hard separators:

- The soft separators are not a newer model of the system in use since the 1960s – all systems in use until the 1980s were hard separators;
- The soft separators do not use hydraulic pressure for the separation
- Soft separators are distinguished from AMR (they are referenced as desinewers)
- Soft separators do not work on the bones listed, such as the vertebrae (at least for beef)
- In the vast majority of cases, product from the soft separation process is labeled as beef or trim, not finely textured beef, the current name for product from the hard separation process.

Moreover, it is undeniable that the meat from soft separators, regardless of the age of the raw materials, does not raise any of the concerns expressed in the Harvard Risk Assessment regarding AMR. First, soft separators do not damage the bones nor remove any internal bone components so that there cannot be any suspect materials being incorporated. Second, for beef harvesting, the soft separators can only be used on certain flat bones: feather bones, rib bones, button bones, loin bones, loin fingers, and strip bones. Given such bones do not contain spinal cord or DRGs, no safety risk is posed.

Suggested Clarification

In the final analysis, we are left with three distinctive classes of product and only two regulatory slots. The classes are: traditional hard separation, advanced hard separation and soft separation. There are only two regulatory slots: MS(S) and AMR.

There is no question but that the traditional hard separation process is appropriately classified as MS(S). The applicability of this regulation to the bone crushing hydraulic system has never been disputed.

We respectfully submit that, based on agency preambles, other public statement and in-field and labeling implementation, the advanced hard separators fall within the AMR regulation.

However that still leaves the soft separators without a clear regulatory slot. Ironically, this brings us back to the very same issue raised in the 1980’s when soft separators were first introduced. Although technically, the soft separators “mechanically separate meat from bone,” neither the soft separation process nor the resultant product (both in terms of appearance and composition) bears any resemblance to either of the hard separation processes.⁶

⁶ We have attached a comparison page showing the difference between the product and the bones exiting both the soft and hard separator (Attachment 2). As you can see, there is a significant difference.

Letter to Ms. Mary Ann Riley
June 5, 2007
Page 6

OLSSON, FRANK AND WEEDA, P.C.

In the 1980's FSIS decided that, given the differences, soft separation should not be treated as a mechanical separation process, but the product from such processes would be deemed to be "meat." We respectfully submit that the exact same decision should be made here – that soft separators are not AMR and have never been covered by the AMR regulations. Thus, the resultant product can be called meat and the process is not subject to the AMR restriction as to age of cattle found in the BSE interim regulation. To interpret the regulations differently would not only be a policy change, for which no prior notice was given, but would also arbitrarily treat dissimilar products in a similar matter without any legal or factual basis

We appreciate the opportunity to express our views on this matter. If you have any questions or desire additional information, please do not hesitate to contact us.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D.R. Johnson', with a long horizontal flourish extending to the right.

Dennis R. Johnson

DRJ:kes
Attachments

cc: Dr. Daniel L. Engeljohn, OPPED, FSIS

**2007 Survey of Large Slaughter Establishments – Beef and Pork
Summary Data**

1. Do you use a “soft separator system”, (e.g., sepomatic, Baader) for beef? **Yes= 9, No = 2**
2. If you use these systems for beef, do you have a letter from the old equipment branch for the system? **Yes = 1**
3. Do you use a “soft separator system”, (e.g., sepomatic, Baader) for pork? **Yes = 8, No = 0**
4. If you use these systems for pork, do you have a letter from the old equipment branch for the system? **Yes = 1**
5. Has FSIS ever tested the resultant product (beef or pork) for Iron? **Yes = 1 (pork)**
6. Has FSIS ever tested the resultant product (beef or pork) for Calcium? **Yes = 1 (pork)**
7. Has FSIS ever tested the resultant product (beef or pork) for spinal cord or DRG? **Yes = 1 beef and 2 pork**
8. What raw materials do you put through the equipment, e.g., trim, flat or feather bones, etc.?

| Pork | Beef |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trim, flat bones, feather bones, spare ribs, chine bones, aitch bones, backbones, sirloin bones, and product discharged thru the protocon system | Cartilage, featherbones, flat bones, back strip, rib bones, scapula chips, finger bones, button bones, gooseneck cartilage, and poss on the hind shank |

9. Do you test the resultant product for anything?

| Pork | Beef |
|----------------------------------------------------------------------------|----------------------------------------------------|
| Fe, Fe and Ca, Fe, Ca, and fat, Fe, Ca, and micro, and Fe, Ca, and CNS/DRG | Fe and Ca, Fe, Ca and protein, and Fe, Ca and GFAP |

10. How do you label the resultant product?

| Pork | Beef |
|-----------------------------------------------------|----------------------------------------------------------------------------------|
| Pork trimmings, meat, trim, or finely textured pork | Beef trimmings, boneless beef, beef trimmings, or beef trimmings finely textured |

11. Do you also have “advanced meat recovery equipment” (e.g. protocon or hydrosep) in use at your facility? **Yes = 10 beef and 9 pork**

Soft Separation Equipment

The process of using belt pressure against a rotating perforated steel drum to separate meat from bone, cartilage, bone chips, sinews and connective tissue.

Advanced Meat Recovery
(Bone Cannon/Protecon)
Bones are then processed under pressure in a HARD Separation step (hydraulic pressure)

*www.bfdcorp.com



Soft Tissue Separation
(SEPAmatic/Baader) Product is separated from the bones, and cartilage by a rotating flexible belt against a rotating sieve/screen. *

No HARD Separation step (hydraulic pressure)

The bones remain essentially intact

*www.bfdcorp.com



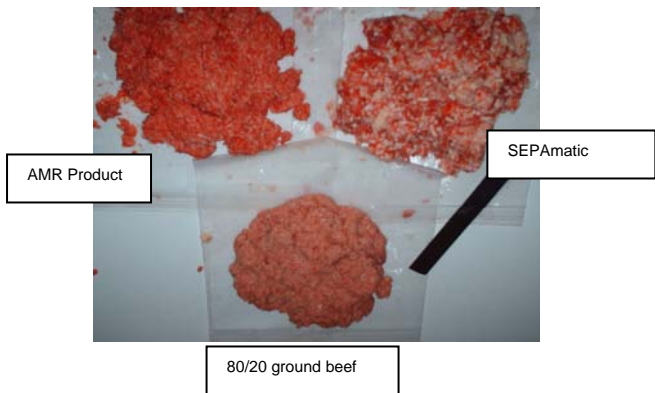
Flat bones prior to processing in a soft tissue separator (Sepamatic/Baader)



SEPAmatic 4000 Soft Tissue Separator



Flat bones after they have been processed through a soft tissue separator



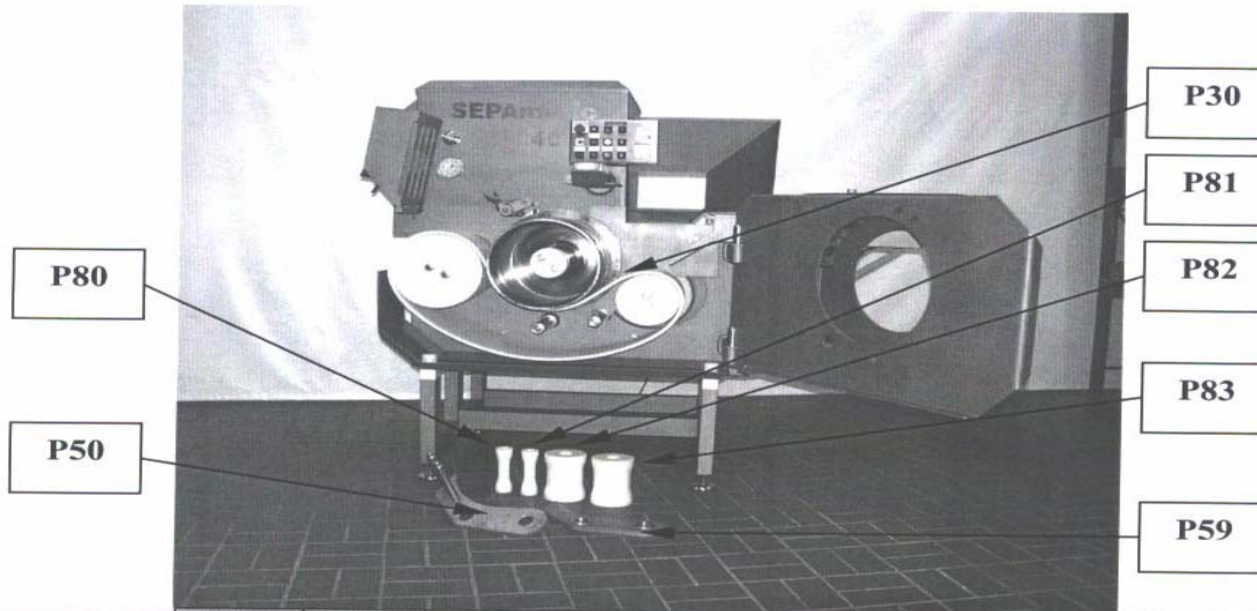
AMR Product

SEPAmatic

80/20 ground beef

Soft Separation Equipment

The process of using belt pressure against a rotating perforated steel drum to separate meat from bone, cartilage, bone chips, sinews and connective tissue.



Position Number

Part Name

| | |
|-----|--------------------------|
| P30 | Pressing Belt |
| P50 | Rear Roller Track Guide |
| P59 | Front Roller Track Guide |
| P80 | Press Roller |
| P81 | Press Roller |
| P82 | Press Roller |
| P83 | Press Roller |