



Canadian Food Inspection Agency

Agence canadienne RECEIVED d'inspection des aliments DOCKET ROOM

59 Camelot Drive Nepean, Ontario K1A 0Y9

04 MAY -7 PM 4: 26

lode

May 7, 2004

FSIS Docket Clerk, Room 102, Cotton Annex 300 C Street SW Washington, DC 20250-3700

Subject:

Docket No. 03-0251F - Comments on Interim Final Rule
"Prohibition of the Use of Specified Risk Materials for Human
Food and Requirements for the Disposition of Non-Ambulatory
Disabled Cattle"

Docket No. 03-0381F - Comments on Interim Final Rule "Meat Produced by Advanced Meat/Bone Separation Machinery and Méat Recovery (AMR) Systems"

Docket No. 01-03311F - Comments on Interim Final Rule "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter"

The Government of Canada welcomes the opportunity to comment on the Interim Final Rules listed above, as published in the Federal Register on January 12, 2004 (Volume 69, Number 7). Our comments on each Interim Final Rule are provided in the three annexes accompanying this letter.

The case of BSE diagnosed in Washington State and the international reaction, both in May of last year and under the current circumstances, underlines our mutual interest in cooperating to the maximum extent possible in the further development and implementation of measures to manage BSE risk within a North American context.

The United States and Canada strongly advocate the importance of basing public and animal health measures on scientific principles. Simply put, this is the most effective means of protecting our citizens and our resource base.

The Government of Canada is committed to working in close collaboration with its United States counterparts to fully respect the public interest through the highest achievable



credibility both in North American management of BSE risk and in re-establishing, to the fullest level of integration possible, the North American market.

If you require any clarification, please feel free to contact me.

Sincerely yours,

Dr. Brian R. Evans

Chief, Veterinary Officer for Canada

Enclosure

GOVERNMENT OF CANADA

Comments on Interim Final Rule - Docket No. 03-025IF "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle"

Specified Risk Materials (SRM)

Canada concurs with the list of tissues designated in this Interim Final Rule as SRM, namely the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle. These SRM are almost identical to those designated by Canada in July 2003, which will facilitate the harmonization of SRM measures in the two countries.

With regard to the small intestine, Canada also requires that the entire organ be removed in order to ensure effective removal of the distal ileum. This requirement could be modified if a clear anatomical definition of the distal ileum were developed, along with verifiable procedures to ensure effective removal. Before doing so, however, it would be prudent to investigate as-yet unpublished reports from the United Kingdom that BSE infectivity has been found in other parts of the small intestine, and to determine whether the amount found would constitute a risk to consumers of casings or other products derived from the small intestine.

Procedures for Removal of SRM

Canada notes the FSIS decision to not prescribe any specific procedures for the removal of SRM. Implicit in this decision, and exemplified by supplementary information published on its Website, particularly FSIS Notice 9-04, is the assumption that routine cleaning and sanitizing procedures are sufficient to prevent transfer of material from SRM that may contain BSE infectivity to edible tissue by tools used in the removal process. Under the SRM removal policy implemented in Canada in July 2003, establishments were required to use separate, dedicated visually-coded tools for the severing and removal of the spinal cord. In the absence of published work showing that SRM tissue can be effectively removed from such tools, this requirement was adopted after considering the procedures being applied in the United Kingdom. Canada recommends that a similar requirement be adopted in the United States until it can be shown that routine cleaning and sanitation, or other procedures can effectively remove potentially infective material from the tools.

-2-

Verification of the Age of Cattle

Canada concurs with the procedures prescribed in this Rule for verification of the age of cattle. The Canadian SRM removal policy currently differs somewhat in that it relies solely on examination of dentition to identify animals from which the full range of SRM must be removed. The same criteria as prescribed in this Rule are used for age verification, that is, an animal with an erupted third permanent incisor is deemed to be aged 30 months or older, and a tooth is considered to be erupted when it protrudes through the gumline or gingiva. As noted in FSIS Notice 5-04, the dentition procedure will be the most protective of public health because of the age at which the third permanent incisor generally erupts.

Canada recognizes the potential for certain documentation to provide accurate verification of the age of cattle presented for slaughter. We would stress, however, the importance of the documentory evidence being verifiable by inspection personnel.

Hand Deboning

The Canadian Food Inspection Agency (CFIA) has noted that hand deboning of parts of the bovine vertebral column can result in DRG tissue being excised, particularly in the lumbar area, and has carried out some preliminary work toward determining the extent to which this could occur. The CFIA and Health Canada would welcome the opportunity to compare data with FSIS and to collaborate in an assessment of the risk associated with this practice and identification of appropriate risk management measures.

Mechanically Separated Beef

As noted in the Interim Final Rule, mechanically separated (MS) beef that may contain central nervous system (CNS) tissue has the potential to be a "high-risk product" in a country in which bovine spongiform encephalopathy (BSE) has occurred. Canada acknowledges that banning the use of the product in human food would be an effective method to reduce the risk. However, given the extremely low probability of BSE occurring in cattle under 30 months of age, it would seem that exclusion of SRM, specifically the skull and vertebral column of cattle aged 30 months or older, would be an equally effective method to reduce the risk.

If FSIS deems it necessary to limit the presence of CNS tissue in product derived from the younger animals as well, as a precautionary measure or for some non-health related reason, there are alternatives to a ban that could be considered. For example, FSIS could modify its regulations to prohibit the use of skull and vertebral column from cattle of any

- 3 -

age as raw material for the production of MS beef. In addition or alternatively, FSIS could include absence of CNS tissue in the specifications for product identified as MS beef and control it in the same manner as for product from advanced meat recovery systems.

Non-Ambulatory Disabled Cattle

Canada recognizes the likelihood that diagnosing BSE is greatest in adult cattle that are exhibiting neurological signs. Cattle that are non-ambulatory comprise a portion of the higher BSE risk category. In order to further protect public health, increased scrutiny and control of this category is warranted given the recent diagnoses of BSE in Canada and the United States.

Canada agrees in principle with the need to exclude cattle with a higher likelihood of being infected with BSE from the food supply. In particular, these should include cattle with clinical signs of CNS disease, and cattle aged 30 months or older that are ill or disabled where BSE cannot be ruled out as a cause or contributing factor. Where Canada differs with the FSIS position is in the belief that the definition prescribed for non-ambulatory disabled animals is too broad. The policy encompasses animals where the possibility of BSE infection is remote to non-existent.

With regard to the definition of non-ambulatory disabled animals, Canada recommends that some provision be added for judgement to be exercised by FSIS veterinarians at slaughter plants. Criteria could be provided to guide decision-making by the veterinarians. Examples of types of animals that should be considered in this regard could include the following:

- Animals that are injured after having passed ante mortem inspection
- Animals under 30 months of age where the reason for the state of the animal is clearly evident, e.g. an animal with a fractured limb
- Veal animals affected by extreme fatigue

Note: While the above categories of animals are very unlikely to have BSE it should be noted that public health is being further protected through the required removal and disposal of all applicable SRM.

Canada recognizes that the broad scope of the definition may have been motivated to some degree by animal welfare objectives, in that automatic condemnation of animals that meet the non-ambulatory disabled definition would deter people from attempting to ship animals in that state, and perhaps persuade truckers to do more to prevent injury during transport. If this is the case, Canada hopes that FSIS will acknowledge that other

-4-

countries, Canada included, have more direct means to regulate humane transport which would achieve the same non-ambulatory policy objectives by preventing these animals from leaving the farm, and thereby their entry to slaughter establishments. Such alternative measures should be given due consideration by FSIS in equivalence determinations.

Injured cattle slaughtered at unusual hours:

Canada agrees with the amendments to 9 CFR 311.27 to prohibit the carcasses and parts of carcasses from cattle slaughtered on an emergency basis without ante-mortem inspection from being used for human food. In Canada, under the legislative authority of the Meat Inspection Act and Regulations, no carcass or part of a carcass of any food animal slaughtered in a registered establishment can be identified as edible unless the animal was subjected to ante-mortem inspection by a CFIA inspector and was approved for slaughter. No exemption is provided for animals arriving at the slaughter establishment at hours when an inspector is not available. If an injured or diseased animal requires immediate slaughter and an inspector cannot be present to perform the ante-mortem inspection, the animal must be euthanized for humane reasons and the carcass treated as condemned material. Exempting injured or diseased food animals from the requirements for ante-mortem inspection would not be consistent with internationally recognized meat hygiene principles.

Testing Cattle for BSE

Canada agrees that a negative test is not a reliable means to detect all animals infected with BSE, and therefore could not provide the same level of protection as, for example, prohibiting the use of SRM in human food.

GOVERNMENT OF CANADA Comments on Interim Final Rule - Docket No. 03-0381F "Meat Produced by Advanced Meat/ Bone Separation Machinery and Meat Recovery (AMR) Systems

Canada agrees in general with the preventive approach described in the Interim Final Rule with respect to the production of beef using AMR systems. In Canada, bones from the vertebral column of cattle under 30 months of age are also permitted for use as a source material in meat recovery systems that use pressure to separate beef muscle tissue from bones. However, the spinal cord of any red meat species (i.e. livestock species) must be removed from the vertebral columns before they are used as source material in meat recovery systems. The presence of red meat species' spinal cord tissue in either mechanically separated "meat" (red meat species) or "meat" (red meat species) from AMR systems is considered to be adulterated. Furthermore, federally-inspected establishments that slaughter cattle or that process the carcasses or parts of cattle are required to remove the spinal cord of cattle of any age before derived bone-in meat cuts enter into commerce. The only exception to this requirement would be for unsplit carcasses of veal or parts of unsplit veal carcasses sold as such.

To address the concern regarding the possibility that DRG from beef vertebral columns (i.e. derived from cattle under 30 months of age) could become dislodged and incorporated into the final product, Canadian manufacturers are either not using beef vertebral columns as a source material in meat recovery systems, or are testing the final product for the presence of spinal cord and DRG. In addition, the CFIA conducts a monitoring program to verify the absence of spinal cord and DRG tissue from AMR product.

In Canada, skulls from any food animal species are prohibited from use as a source material in meat recovery systems that use pressure to separate muscle tissue from bones, whether or not CNS tissue has been removed from the skull.

GOVERNMENT OF CANADA Comments on Interim Final Rule - Docket No. 01-0331F "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter"

Canada fully supports prohibition of the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle.

The Canadian Food Inspection Agency (CFIA) has banned the use of air-injection stunning equipment for any red meat species processed in federally registered establishments since May 2000 (Ref. Meat Hygiene Directive MHD 2000-16).

Furthermore, the destruction of brain matter using a rod (i.e. pithing) is also prohibited by the CFIA on the grounds that this procedure can result in the dislocation of portions of brain and release emboli into the circulatory system of stunned cattle.





Canadian Food Inspection Agency

Agence canadienne RECEIVED d'inspection des aliments DOCKET ROOM

59 Camelot Drive Nepean, Ontario K1A 0Y9

04 MAY -7 PM 4: 26

6 de

May 7, 2004

FSIS Docket Clerk, Room 102, Cotton Annex 300 C Street SW Washington, DC 20250-3700

Subject:

Docket No. 03-0251F - Comments on Interim Final Rule
"Prohibition of the Use of Specified Risk Materials for Human
Food and Requirements for the Disposition of Non-Ambulatory
Disabled Cattle"

Docket No. 03-0381F - Comments on Interim Final Rule "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems"

Docket No. 01-03311F - Comments on Interim Final Rule "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter"

The Government of Canada welcomes the opportunity to comment on the Interim Final Rules listed above, as published in the Federal Register on January 12, 2004 (Volume 69, Number 7). Our comments on each Interim Final Rule are provided in the three annexes accompanying this letter.

The case of BSE diagnosed in Washington State and the international reaction, both in May of last year and under the current circumstances, underlines our mutual interest in cooperating to the maximum extent possible in the further development and implementation of measures to manage BSE risk within a North American context.

The United States and Canada strongly advocate the importance of basing public and animal health measures on scientific principles. Simply put, this is the most effective means of protecting our citizens and our resource base.

The Government of Canada is committed to working in close collaboration with its United States counterparts to fully respect the public interest through the highest achievable



credibility both in North American management of BSE risk and in re-establishing, to the fullest level of integration possible, the North American market.

If you require any clarification, please feel free to contact me.

Sincerely yours

Dr. Brian R. Evans

Chief, Veterinary Officer for Canada

Enclosure

GOVERNMENT OF CANADA

Comments on Interim Final Rule - Docket No. 03-025IF "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle"

Specified Risk Materials (SRM)

Canada concurs with the list of tissues designated in this Interim Final Rule as SRM, namely the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle. These SRM are almost identical to those designated by Canada in July 2003, which will facilitate the harmonization of SRM measures in the two countries.

With regard to the small intestine, Canada also requires that the entire organ be removed in order to ensure effective removal of the distal ileum. This requirement could be modified if a clear anatomical definition of the distal ileum were developed, along with verifiable procedures to ensure effective removal. Before doing so, however, it would be prudent to investigate as-yet unpublished reports from the United Kingdom that BSE infectivity has been found in other parts of the small intestine, and to determine whether the amount found would constitute a risk to consumers of casings or other products derived from the small intestine.

Procedures for Removal of SRM

Canada notes the FSIS decision to not prescribe any specific procedures for the removal of SRM. Implicit in this decision, and exemplified by supplementary information published on its Website, particularly FSIS Notice 9-04, is the assumption that routine cleaning and sanitizing procedures are sufficient to prevent transfer of material from SRM that may contain BSE infectivity to edible tissue by tools used in the removal process. Under the SRM removal policy implemented in Canada in July 2003, establishments were required to use separate, dedicated visually-coded tools for the severing and removal of the spinal cord. In the absence of published work showing that SRM tissue can be effectively removed from such tools, this requirement was adopted after considering the procedures being applied in the United Kingdom. Canada recommends that a similar requirement be adopted in the United States until it can be shown that routine cleaning and sanitation, or other procedures can effectively remove potentially infective material from the tools.

-2-

Verification of the Age of Cattle

Canada concurs with the procedures prescribed in this Rule for verification of the age of cattle. The Canadian SRM removal policy currently differs somewhat in that it relies solely on examination of dentition to identify animals from which the full range of SRM must be removed. The same criteria as prescribed in this Rule are used for age verification, that is, an animal with an erupted third permanent incisor is deemed to be aged 30 months or older, and a tooth is considered to be erupted when it protrudes through the gumline or gingiva. As noted in FSIS Notice 5-04, the dentition procedure will be the most protective of public health because of the age at which the third permanent incisor generally erupts.

Canada recognizes the potential for certain documentation to provide accurate verification of the age of cattle presented for slaughter. We would stress, however, the importance of the documentory evidence being verifiable by inspection personnel.

Hand Deboning

The Canadian Food Inspection Agency (CFIA) has noted that hand deboning of parts of the bovine vertebral column can result in DRG tissue being excised, particularly in the lumbar area, and has carried out some preliminary work toward determining the extent to which this could occur. The CFIA and Health Canada would welcome the opportunity to compare data with FSIS and to collaborate in an assessment of the risk associated with this practice and identification of appropriate risk management measures.

Mechanically Separated Beef

As noted in the Interim Final Rule, mechanically separated (MS) beef that may contain central nervous system (CNS) tissue has the potential to be a "high-risk product" in a country in which bovine spongiform encephalopathy (BSE) has occurred. Canada acknowledges that banning the use of the product in human food would be an effective method to reduce the risk. However, given the extremely low probability of BSE occurring in cattle under 30 months of age, it would seem that exclusion of SRM, specifically the skull and vertebral column of cattle aged 30 months or older, would be an equally effective method to reduce the risk.

If FSIS deems it necessary to limit the presence of CNS tissue in product derived from the younger animals as well, as a precautionary measure or for some non-health related reason, there are alternatives to a ban that could be considered. For example, FSIS could modify its regulations to prohibit the use of skull and vertebral column from cattle of any

- 3 -

age as raw material for the production of MS beef. In addition or alternatively, FSIS could include absence of CNS tissue in the specifications for product identified as MS beef and control it in the same manner as for product from advanced meat recovery systems.

Non-Ambulatory Disabled Cattle

Canada recognizes the likelihood that diagnosing BSE is greatest in adult cattle that are exhibiting neurological signs. Cattle that are non-ambulatory comprise a portion of the higher BSE risk category. In order to further protect public health, increased scrutiny and control of this category is warranted given the recent diagnoses of BSE in Canada and the United States.

Canada agrees in principle with the need to exclude cattle with a higher likelihood of being infected with BSE from the food supply. In particular, these should include cattle with clinical signs of CNS disease, and cattle aged 30 months or older that are ill or disabled where BSE cannot be ruled out as a cause or contributing factor. Where Canada differs with the FSIS position is in the belief that the definition prescribed for non-ambulatory disabled animals is too broad. The policy encompasses animals where the possibility of BSE infection is remote to non-existent.

With regard to the definition of non-ambulatory disabled animals, Canada recommends that some provision be added for judgement to be exercised by FSIS veterinarians at slaughter plants. Criteria could be provided to guide decision-making by the veterinarians. Examples of types of animals that should be considered in this regard could include the following:

- Animals that are injured after having passed ante mortem inspection
- Animals under 30 months of age where the reason for the state of the animal is clearly evident, e.g. an animal with a fractured limb
- Veal animals affected by extreme fatigue

Note: While the above categories of animals are very unlikely to have BSE it should be noted that public health is being further protected through the required removal and disposal of all applicable SRM.

Canada recognizes that the broad scope of the definition may have been motivated to some degree by animal welfare objectives, in that automatic condemnation of animals that meet the non-ambulatory disabled definition would deter people from attempting to ship animals in that state, and perhaps persuade truckers to do more to prevent injury during transport. If this is the case, Canada hopes that FSIS will acknowledge that other

- 4 -

countries, Canada included, have more direct means to regulate humane transport which would achieve the same non-ambulatory policy objectives by preventing these animals from leaving the farm, and thereby their entry to slaughter establishments. Such alternative measures should be given due consideration by FSIS in equivalence determinations.

Injured cattle slaughtered at unusual hours:

Canada agrees with the amendments to 9 CFR 311.27 to prohibit the carcasses and parts of carcasses from cattle slaughtered on an emergency basis without ante-mortem inspection from being used for human food. In Canada, under the legislative authority of the Meat Inspection Act and Regulations, no carcass or part of a carcass of any food animal slaughtered in a registered establishment can be identified as edible unless the animal was subjected to ante-mortem inspection by a CFIA inspector and was approved for slaughter. No exemption is provided for animals arriving at the slaughter establishment at hours when an inspector is not available. If an injured or diseased animal requires immediate slaughter and an inspector cannot be present to perform the ante-mortem inspection, the animal must be euthanized for humane reasons and the carcass treated as condemned material. Exempting injured or diseased food animals from the requirements for ante-mortem inspection would not be consistent with internationally recognized meat hygiene principles.

Testing Cattle for BSE

Canada agrees that a negative test is not a reliable means to detect all animals infected with BSE, and therefore could not provide the same level of protection as, for example, prohibiting the use of SRM in human food.

GOVERNMENT OF CANADA Comments on Interim Final Rule - Docket No. 03-0381F "Meat Produced by Advanced Meat/ Bone Separation Machinery and Meat Recovery (AMR) Systems

Canada agrees in general with the preventive approach described in the Interim Final Rule with respect to the production of beef using AMR systems. In Canada, bones from the vertebral column of cattle under 30 months of age are also permitted for use as a source material in meat recovery systems that use pressure to separate beef muscle tissue from bones. However, the spinal cord of any red meat species (i.e. livestock species) must be removed from the vertebral columns before they are used as source material in meat recovery systems. The presence of red meat species' spinal cord tissue in either mechanically separated "meat" (red meat species) or "meat" (red meat species) from AMR systems is considered to be adulterated. Furthermore, federally-inspected establishments that slaughter cattle or that process the carcasses or parts of cattle are required to remove the spinal cord of cattle of any age before derived bone-in meat cuts enter into commerce. The only exception to this requirement would be for unsplit carcasses of veal or parts of unsplit veal carcasses sold as such.

To address the concern regarding the possibility that DRG from beef vertebral columns (i.e. derived from cattle under 30 months of age) could become dislodged and incorporated into the final product, Canadian manufacturers are either not using beef vertebral columns as a source material in meat recovery systems, or are testing the final product for the presence of spinal cord and DRG. In addition, the CFIA conducts a monitoring program to verify the absence of spinal cord and DRG tissue from AMR product.

In Canada, skulls from any food animal species are prohibited from use as a source material in meat recovery systems that use pressure to separate muscle tissue from bones, whether or not CNS tissue has been removed from the skull.

GOVERNMENT OF CANADA Comments on Interim Final Rule - Docket No. 01-0331F "Prohibition of the Use of Certain Stunning Devices

Prohibition of the Use of Certain Stunning Devices
Used to Immobilize Cattle During Slaughter"

Canada fully supports prohibition of the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle.

The Canadian Food Inspection Agency (CFIA) has banned the use of air-injection stunning equipment for any red meat species processed in federally registered establishments since May 2000 (Ref. Meat Hygiene Directive MHD 2000-16).

Furthermore, the destruction of brain matter using a rod (i.e. pithing) is also prohibited by the CFIA on the grounds that this procedure can result in the dislocation of portions of brain and release emboli into the circulatory system of stunned cattle.