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From the Farm to the Factory: An Overview of the American and European Approaches to Regulation of the Beef Industry

by

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FROM THE FARM TO THE FACTORY: AN OVERVIEW OF THE AMERICAN AND EUROPEAN APPROACHES TO REGULATION OF THE BEEF INDUSTRY

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I. INTRODUCTION

Over 180,000 cases of bovine spongiform encephalopathy (BSE), or mad cow disease, have been detected since the first diagnosis of the disease in 1986 in the United Kingdom.[1] Outbreaks of mad cow disease have drawn considerable attention to the issue of livestock and meat regulation. Consumers are becoming more health conscious and increasingly concerned about food safety and quality. Both the United States and the European Union (E.U.) have created substantial bodies of regulations to ensure the safety and quality of the beef supply for their citizens.

In the United States, the bulk of the regulations pertaining to the beef industry are implemented by the United States Department of Agriculture (USDA), with additional regulations promulgated by the Food and Drug Administration (FDA). In many respects, state and local municipalities also contribute to the meat regulatory framework, especially in the area of health and safety inspection of meat production and processing facilities. Nevertheless, the scope of this article is limited to federal regulatory measures.

In Europe, the Council of the European Union addresses Directives to its Member States, and the Member States are given specific deadlines for the adoption of implementing legislation to incorporate

1. Food Safety and Inspection Service (FSIS), *Current Thinking on Measures That Could Be Implemented to Minimize Human Exposure to Materials That Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, *at* http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm (last visited Dec. 30, 2005) [hereinafter FSIS Measures].

the laws, regulations, and administrative provisions necessary to comply with the Directives into their national legal frameworks. Lists of the implementation deadlines for various Directives are routinely updated and published subsequent to the adoption of new Directives.[2]

Interestingly, USDA, FDA, and their predecessors have been implementing laws to regulate the meat industry since 1906;[3] whereas, E.U. and its predecessor, the European Economic Community (EEC), began implementing such laws more recently because EEC was more recently formed in 1957.[4] Considering that both the United States and E.U. face the Herculean task of regulating cattle and beef production in each of their many states and countries, respectively, many factors must be covered in their regulatory schemes. First, this article briefly describes the existing regulatory requirements under both systems. Second, it compares the two approaches. In comparing the two systems, attention is concentrated on the quality of legislative drafting, the likelihood of implementation, the adequacy of consumer protection, the voluntary or compulsory nature of the measures, and the requirement of records retention.

II. ANIMAL DRUG REGULATION

The United States and E.U. have different regulatory approaches regarding the rearing of livestock such as cattle. The difference is highlighted by the current World Trade Organization (WTO) dispute between the United States and Canada and E.U., involving trade in beef treated with growth promoting hormones.[5] The United States and Canada, two countries that have approved the administration of growth hormones to livestock, brought an action against the E.U. to determine, among other things, whether the E.U.'s ban on beef containing growth hormones is grounded on scientific evidence that the use of hormones poses a danger to human health.[6] This section of the paper outlines several major facets of animal drug regulation for both the United States and E.U.

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2. Council of the European Union, *Calendar for Transposition of Directives*, *at* http://europa.eu.int/comm/secretariat_general/sgb/droit_com/index_en.htm#calendar.

3. PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 4 (2d ed. 1991).

4. Europa, *The EU at a Glance: The History of the European Union* (2005), *at* http://www.europa.eu.int/abc/history/index_en.htm (last visited Dec. 27, 2005) [hereinafter Europa History].

5. *See*, *e.g.*, Press Release, Dispute Settlement Body, WTO, WTO Dispute Body Establishes Panels on US and Canada Sanctions in 'Hormones' Dispute (Feb. 17, 2005), *at* http://www.wto.org/english/news_e/news05_e/dsb_17feb05_e.htm (last visited Dec. 27, 2005) [hereinafter WTO Dispute].

6. *See* Press Release, USDA, Glickman and Barshefsky Announce WTO Panel to Review EU Hormone Ban (May 20, 1996), *at* http://www.usda.gov/news/releases/ 1996/05/0265 (last visited Dec. 27, 2005).

A. United States Regulation of Animal Drugs Used in Meat Production

The Federal Food, Drug, and Cosmetic Act (FDCA) was enacted in 1938 and revised completely by the enactment of the Animal Drug Amendments in 1968.[7] FDCA, which has been amended periodically since 1968, governs the regulation of new animal drugs. The Act establishes the requirements for a new animal drug application to obtain FDA approval of the use of an animal drug. Applications for new animal drugs must include the name and address of the applicant; the trade name and chemical name; the chemical structural formula; a description of the dosage and quantitative composition; the scientific and clinical purpose of the drug; the particularly significant pharmacological or toxicological findings of laboratory studies; a conclusion explaining the new drug's major points of effectiveness and safety; copies of each piece of labeling; usage directions as they appear on the label; a statement of the ingredients used in the production of the new animal drug; and a description of the manufacturing, processing, and packing methods.[8]

Along with information on other animal drugs, the relevant portions of FDCA provide details about permissible growth promotion hormones and their approved usage. Several specific hormones are examined in order to explore the approved quantities, methods of administration, and uses for such drugs.[9]

One of the hormones prohibited by E.U. is estradiol which can be administered in the United States in the form of silicone implants in either 25.7 or 43.9 milligram doses.[10] Estradiol implantation is allowed in steers and heifers only.[11] One 25.7 milligram implant may be used every 200 days, or one 43.9 milligram implant every 400 days.[12] The estradiol implant is used to increase weight gain in suckling and pastured growing steers, to improve feed efficiency, and to increase the rate of weight gain in confined steers and heifers.[13] A second implant was expressly permitted until November 2004 when the language authorizing such use was removed from the regulation.[14]

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7. *See* HUTT & MERRILL, *supra* note 3, at 13, 637.

8. *See* 21 C.F.R. § 514.1(b) (2005).

9. For detailed information regarding new animal drugs see 21 C.F.R. pt. 510 (2005).

10. 21 C.F.R. § 522.840(a) (2005).

11. *See* 21 C.F.R. § 522.840(d)(3) (2005).

12. 21 C.F.R. § 522.840(d)(1) (2005).

13. *See* 21 C.F.R. § 522.840(d)(2) (2005).

14. *See* 21 C.F.R. § 522.840(c)(3) (2005); 69 Fed. Reg. 67,818–67,819 (Nov. 22, 2004).

Section 522.841 permits the use of estradiol benzoate in stock-farming.[15] It may be administered for growth enhancement purposes via subcutaneous injection, but only in the ear.[16] Ten milligrams of estradiol benzoate may be administered to suckling beef calves,[17] and twenty milligrams for steers and heifers fed in confinement for slaughter.[18] Use of estradiol benzoate on calves intended for reproduction or calves less than thirty days old is prohibited.[19]

Section 522.850 authorizes the utilization of estradiol valerate and norgestomet in combination for synchronization of estrus or ovulation in cycling beef cattle and non-lactating dairy heifers.[20] Pursuant to section 522.850, the implant must be removed on day ten.[21] As implants are removed they must be collected and burned.[22] This combination is not to be used in cows producing milk for human consumption.[23]

Other hormones, such as testosterone propionate,[24] progesterone,[25] and trenbolone acetate,[26] can be used alone or in combination with other hormones.[27] Although the approved hormones are

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15. *See* 21 C.F.R. § 522.841 (2005).

16. 21 C.F.R. § 522.841(d)(1)(iii) (2005).

17. *Id.* § 522.841(d)(1)(i) (2005).

18. *Id.* § 522.841(d)(2)(i) and (d)(3)(i) (2005).

19. *Id.* § 522.841(d)(2)(iii) and (d)(3)(iii) (2005).

20. *Id.* § 522.850(c)(2) (2005).

21. 21 C.F.R. § 522.850(c)(3) (2005).

22. *Id.*

23. *Id.*

24. Testosterone treated beef has been banned in the E.U. *See generally* Council Directive 2003/74, 2003 O.J. (L 262) 17 (EC).

25. Progesterone is one of the six growth hormones that is prohibited in the E.U. *See generally* Directive 2003/74, at 17.

26. Trenbolone acetate is also one of the hormones prohibited by the E.U. *See generally* Directive 2003/74, at 17.

27. *See* 21 C.F.R. § 522.842 (2005); 21 C.F.R. § 522.1940 (2005); and 21 C.F.R. § 522.2476 (2005).

administered in different ways, they have several growth promotion and production functions, including increasing weight gain, improving feed efficiency, and synchronization of estrus and ovulation.[28]

B. E.U.'s Prohibition on the Use of Hormonal Drugs

In the 1970s, concerns over the use of growth-promoting hormones in livestock production and their impact on consumer health escalated in Europe.[29] Specifically in the 1970s, exposure to diethylstilboestrol (DES), due to its illegal use in veal production in France, was linked to hormonal irregularities in adolescent consumers in Italy and to congenital birth defects in infants born in other European countries.[30] In response to increasing concern surrounding the use of hormones in the production of livestock generally, on July 31, 1981, the European Council of Ministers European adopted Directive 81/602/EEC, the first directive of its kind, banning the domestic use of five growth hormones in livestock farming.[31] Subsequent directives were adopted leading to the E.U.'s ban of imported meat from animals treated with hormones.[32]

On April 29, 1996, Directive 96/22/EC was established in order to prohibit the employment of hormonal, thyrostatic, and beta-agonist substances in stock-farming.[33] This directive is applicable to beef and meat products.[34] The directive gives details on the growth hormones that have been banned by the E.U. since 1988.[35] It authorizes use of hormones for therapeutic, but not weight or growth promotion, purposes.[36]

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28. *See* 21 C.F.R. § 522.842 (2005); 21 C.F.R. § 522.1940 (2005); and 21 C.F.R. § 522.2476 (2005).

29. Tim Josling, Donna Roberts & Ayesha Hassan, *The Beef-Hormone Dispute and Its Implications for Trade Policy*, 3-4, *at* http://iis-db.stanford.edu/pubs/11379/ HORMrev.pdf (last visited Dec. 29, 2005).

30. *Id*.

31. *Id*. at 5.

32. *See*, *e.g.*, Council Directive 2003/74, 2003 O.J. (L 262) 17 (EC).

33. The full title of the Directive is Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock-farming of certain substances having hormonal or thyrostatic action on beta-agonists.

34. Council Directive 96/22, art. 4, 1996 O.J. (L 125) 3, 5 (EC).

35. *See generally* Directive 96/22, at 5.

36. *See* Directive 96/22, art. 4, at 5.

Article 4 provides that Member States may authorize the therapeutic administration to livestock of testosterone, progesterone, and their derivatives that readily yield the parent compound on hydrolysis after absorption.[37] Importantly, veterinary medicinal products must be administered by a veterinarian.[38] They cannot be administered by implant, but must be administered by injection or for the treatment of ovarian dysfunction in the form of vaginal spirals.[39] Farm animals undergoing such treatment must be clearly identified, and such treatment must be registered by the veterinarian responsible.[40] The veterinarian must record at least the following details in a register: the type of treatment, the type of products authorized, the date of treatment, and the identity of the animal treated.[41]

Member States may authorize, for therapeutic purposes, the administration of veterinary medicinal products containing beta-agonists to induce tocolysis in cows.[42] The above-mentioned registration measures must be followed for the administration of beta-agonists as well. Farmers are prohibited from holding veterinary medicinal products containing beta-agonists.[43]

Article 5 also allows veterinarians or their auxiliaries to administer hormonal substances for the synchronization of oestrus and for the preparation of donors and recipients.[44] However, under Article 6, the authorization of the following is prohibited: (1) hormonal products acting as a deposit, (2) products with a withdrawal period of more than fifteen days after the end of treatment, (3) products for which there are no reagents or equipment for detecting the presence of residues in excess of the permitted levels, and (4) veterinary medicinal products containing beta-agonists which have a withdrawal period of more than twenty-eight days after the end of treatment.[45]

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37. *See* Directive 96/22, art. 4(1), at 5.

38. *See* Directive 96/22, art. 4, at 5.

39. *See* Council Directive 96/22, art. 4(1), 1996 O.J. (L 125) at 5.

40. *See* Directive 96/22, art. 4(1), at 5.

41. Directive 96/22, arts. 4(1) & 5, at 5.

42. *See* Directive 96/22, art. 4(2)(ii), at 5.

43. Council Directive 96/22, art. 4, at 5.

44. Directive 96/22, art. 5, 1996 O.J. (L 125) at 6.

45. Directive 96/22, art. 6, at 6.

Article 8 requires that Member States restrict the possession of permissible substances to persons authorized by national legislation.[46] This article also provides that official checks by the competent national authorities must occur without prior notice, with a view toward ascertaining: (1) the presence of prohibited substances intended to be administered for the purpose of increasing weight gain, (2) the illegal treatment of animals, and (3) failure to observe the withdrawal periods and restrictions on the use of certain substances.[47] Article 8 requires tests for the presence of the substances and residues in the drinking water of animals, in all places where animals are kept and bred, and in their excrement, body fluids, animal tissues, and products.[48] Article 11 prohibits the inclusion of countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, hormonal, thyrostatic, and beta-agonist substances to livestock on the lists of countries authorized to import farm animals, meat or meat products.[49]

In 2003, the European Council and the European Commission amended Council Directive 96/22/EC with Council Directive 2003/74/EC in order to revise its prohibitions on the use of hormonal, thyrostatic, and beta-agonist substances in livestock farming.[50] This amendment was made in light of the Hormones Case, which is pending in the WTO, and the recommendations made by the WTO Dispute Settlement Body on February 13, 1998.[51] In this case, the United States and Canada challenged the E.U.'s ban on imported beef from cattle treated with growth hormones on the grounds that there is no evidence of adverse effects on human health.[52] The WTO found that the ban was not justified by a risk assessment, that there was there was no rational relationship between the directive and the scientific evidence submitted on the five hormones, and that there was no risk assessment at all for melengestrol acetate.[53]

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46. *See* Directive 96/22, art. 8(1), at 6.

47. *See* Directive 96/22, art. 8(2)(a)-(d), at 6.

48. Directive 96/22, art. 8(3), at 6.

49. Council Directive 96/22, art. 11, 1996 O.J. (L 125) at 7

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50. *See* Council Directive 2003/74, 2003 O.J. (L 262) 17 (EC).

51. The Hormones Case involves a dispute settlement proceeding between the United States and Canada and the E.U., regarding the E.U.'s ban on beef treated with growth promoting hormones. *See* WTO Dispute, *supra* note 5. There are six hormonal substances in question (estradiol 17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate) whose administration for animal growth promotion purposes is prohibited by Directive 96/22/EC. *See* Council Directive 2003/74, 2003 O.J. (L 262) 17 (EC).

52. World Trade Organization, SPS Agreement Training Module (2004), *at* http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s1p1_e.htm.

53. *Id*.

Article 2 of Directive 96/22/EC was amended to prohibit the placing on the market of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters for administering to animals of all species and the placing on the market of estradiol 17β, its ester-like derivatives, and beta-agonists for administering to animals whose flesh and products are intended for human consumption.[54] Article 3 was amended to prohibit thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, and provisionally prohibits estradiol 17β, its ester-like derivatives, and beta-agonists.[55]

Article 5a was added to allow Member States to authorize the administration to farm animals of veterinary medicinal products containing estradiol 17β or its ester-like derivatives for estrus induction in cattle until October 14, 2006.[56] The treatment must be carried out by the veterinarian on farm animals that have been clearly identified, and the veterinarian must record the details of treatment in a register.[57] However, stockfarmers are prohibited from holding on their farms veterinary medicinal products containing estradiol 17β or its ester-like derivatives.[58]

Consistent with the E.U.'s position that growth stimulating hormones pose dangerous risks to humans, the E.U.'s Scientific Committee on Veterinary Measures relating to Public Health re-evaluated the perceived risks from residues in beef meat and meat products treated with growth hormones.[59] In 1999, this independent advisory body concluded that no acceptable daily intake of hormones could be established.[60] Based on this opinion, the European Commission has maintained its ban on the importation of beef treated with the six growth hormones.[61]

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54. *See* Council Directive 2003/74, 2003 O.J. (L 262) 17 (EC).

55. These substances are prohibited under the following circumstances: (1) the administration of those substances to farm animals; (2) the holding, except under official control, of animals who have been administered the prohibited substance on a farm, and the placing on the market or the slaughter of such animals for human consumption; and (3) the placing on the market of meat from animals that have been administered prohibited substances. Directive 2003/74, art. 3, at 17-21.

56. Directive 2003/74, art. 1(4), at 19.

57. Directive 2003/74, art. 1(4)(3), at 19.

58. Directive 2003/74, art. 1(4)(3), at 19.

59. *See* Europa, *Summary Report of the Meeting of the Scientific Committee on Veterinary Measures Relating to Public Health*, *at* http://europa.eu.int/comm/food/ fs/sc/scv/out23_en.html (last visited Dec. 30, 2005).

60. Europa, Food and Feed Safety, *Hormones in Meat-Introduction*, *at* http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/hormones/index_en.htm (last visited Dec. 30, 2005) [hereinafter Europa Hormones].

61. *Id.*

III. ORGANIC LIVESTOCK PRODUCTION

One alternative to purchasing beef treated with growth hormones is the purchase of organically produced beef. In recent years, consumer demand for organic products has risen greatly.[62] While all agricultural products are covered by safety and quality guarantees, organically produced beef must fulfill additional production criteria. The next section describes the American and the E.U.'s approach to regulating organic livestock production.

A. United States Rules on Organic Livestock Farming

The Organic Foods Production Act (OFPA) of 1990 was enacted in order to establish national standards governing the marketing of agricultural goods as organically produced products.[63] OFPA seeks to assure consumers that organically produced products meet a consistent standard.[64]

OFPA enables USDA to establish a national certification program for producers and handlers of agricultural products that have been produced using organic methods.[65] USDA can also permit each state to implement its own organic certification program for producers and handlers of agricultural products that have been produced using organic methods.[66] The program must be implemented through certifying agents, who may certify a farm or handling operation as organically certified.[67] To be sold or labeled as an organically produced agricultural product, an agricultural product must have been produced and handled without the use of synthetic chemicals.[68]

A label may be affixed to organically certified domestic agricultural products for the purpose of indicating that they comply with USDA standards for organic production.[69] Such labels may

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62. *See* Organic Trade Association, Organic Food Facts, *at* http://www.ota.com/organic/mt/food.html (stating that some trends show that organically produced products such as milk, cheese, and meats are growing in popularity) (last visited Dec. 30, 2005).

63. OFPA of 1990, 7 U.S.C. § 6501(1) (2000).

64. *Id*. § 6501(2).

65. *Id.* § 6503(a).

66. *Id.* § 6503(b).

67. *Id.* § 6503(d).

68. OFPA of 1990, 7 U.S.C. § 6504 (2000).

69. *Id.* § 6505(a)(2).

incorporate the Department of Agriculture seal.[70] Imported agricultural products may be sold or labeled as organically produced if USDA determines that such products have been produced and handled under an organic certification program that is equivalent to the requirements laid down for products in the United States.[71]

An organic certification program is required to ensure that an agricultural product sold or labeled as organically produced is produced only on certified organic farms and handling operations.[72] To be certified, the producers and handlers must establish an organic plan.[73] The farm must certify to USDA, the state official, and the certifying agent on an annual basis that all agricultural products have been produced organically.[74] The farm must be inspected annually, there must be periodic residue testing by certifying agents of the agricultural products to determine whether they contain any pesticide or other nonorganic residue, and there must be public access to certifying documents and laboratory analyses that pertain to certification.[75]

Any livestock that is to be slaughtered and sold or labeled as organically produced must be raised in accordance with the requirements as established in Section 6509.[76] Livestock farms must feed the livestock organically produced feed.[77] The farms are prohibited from using growth promoters and hormones on livestock, including antibiotics and synthetic trace elements used to stimulate growth or production.[78]

Livestock produced by organic farm producers must not use subtherapeutic doses of antibiotics, synthetic internal parasiticides on a routine basis, or administer medicine other than vaccines, in the absence of illness.[79] In order to facilitate livestock identification, organic livestock producers are

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70. *Id.*

71. *Id.* § 6505(b).

72. *Id.* § 6506(a)(1)(A).

73. OFPA, 7 U.S.C. § 6506(a)(2) (2003).

74. *Id.* § 6506(a)(4).

75. *Id.* § 6506(a)(6).

76. *Id.* § 6509.

77. *Id.* § 6509(c)(1).

78. OFPA, 7 U.S.C. § 6509(c)(3)(2000).

79. *Id.* § 6509(d)(1)(4-6).

required to keep adequate records and maintain verifiable audit trails so that each animal can be traced back to the farm.[80] The records must specifically contain details on the amounts and sources of medications administered and all feeds fed to the livestock.[81] Producers must maintain records for five years concerning the production or handling of organically produced agricultural products.[82]

B. E.U. Regulation of Organically Produced Livestock

On July 19, 1999, the European Council drafted Regulation No. 1804/1999,[83] which is a supplement to Regulation No. 209/91, in order to prescribe rules for the organic production of livestock.[84] This supplemental regulation pertains to livestock and livestock products from bovine animals that are intended for human consumption.[85]

Under section B.1.3 of this Regulation, organic production requires stock-farming methods that use renewable natural resources, such as livestock manure, legumes, and fodder crops.[86] Organic stock-farming to maintain the soil fertility utilizes the cropping/stock-farming system and the pasturage system.[87] Section B.1.4 stipulates that organic stock-farming requires that animals have access to a free-range area and the number of animals per unit must be limited to ensure integrated management of livestock and crop production on the production unit.[88]

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80. *Id.* § 6509(f)(1).

81. *Id.* § 6509.

82. *Id*. § 6511.

83. The full title of this Regulation is Council Regulation (EC) No. 1804/1999 of 19 July 1999 supplementing Regulation (EEC) No. 209/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production. Council Regulation 1804/1999, 1999 O.J. (L 222) 1.

84. Regulation 1804/1999, at 1-28.

85. The Regulation does not apply exclusively to bovines. It also applies to swine, poultry, and other livestock. Regulation 1804/1999, at 8.

86. Regulation 1804/1999, ann. I.B.1.3, at 8.

87. *See* Regulation 1804/1999, art 3(5)(22), at 4.

88. Council Regulation 1804/1999, ann. I.B.1.4, 1999 O.J. (L 222) at 8.

Although section 3.2 provides that organic production systems must be applied throughout the life of the livestock, section 3.3 establishes that livestock not complying with organic rules of production can be converted in the specified time periods.[89] Conversion of livestock associated with organic livestock production is allowed under section 2.[90] In order to convert them, livestock from which organic products are derived must be reared as such for at least twelve months in the case of bovines for meat production.[91] Similarly, conversion occurs if livestock marketed as organically produced are reared as such for six months in the case of animals for milk production.[92]

In connection with the organic production of livestock for human consumption, feed is intended to ensure quality rather than maximize production.[93] However, fattening processes are authorized if they are reversible at any stage of the rearing process.[94] Livestock must be fed organically produced feed, and young bovine animals must be fed natural milk, preferably maternal milk, for a period of three months.[95] Rearing systems for herbivores are to be based on pasturage.[96] At least sixty percent of the dry matter in daily rations must consist of roughage, fresh or dried fodder, or silage.[97]

Vitamins and minerals can be fed to animals, but antibiotics, coccidiostatics, medicinal substances, growth promoters, or any other substance intended to stimulate growth or production can not be used in animal feeding.[98] Animal feed must not have been produced with genetically modified organisms or products derived from such organisms.[99]

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89. Regulation 1804/1999, ann. I.B.3.3, at 10.

90. Regulation 1804/1999, ann. I.B.2, at 9.

91. Regulation 1804/1999, ann. I.B.2.2.1, at 9.

92. Regulation 1804/1999, ann. I.B.2.2.2, at 9.

93. Council Regulation 1804/1999, ann. I.B.4.1, 1999 O.J. (L 222) at 11.

94. Regulation 1804/1999, ann. I.B.4.1, at 11.

95. Regulation 1804/1999, ann. I.B.4.2 & B.4.5, at 11.

96. Regulation 1804/1999, ann. I.B.4.7, at 11.

97. Regulation 1804/1999, ann. I.B.4.7, at 11.

98. *See* Council Regulation 1804/1999, ann. I.B.4.17, 1999 O.J. (L 222) at 12.

99. Regulation 1804/1999, ann. I.B.4.18, at 12.

In connection with organic production, disease prevention and veterinary treatment of organic animals should be performed under specific guidelines. Disease prevention in organic livestock production must adhere to the following principles: (1) selection of appropriate breeds or strains of animals; (2) the application of animal husbandry practices appropriate to encourage strong resistance to disease and infections; (3) the use of high quality feed, regular exercise, and access to pasturage to encourage natural immunological defenses; and (4) avoidance of livestock overstocking.[100]

These principles are intended to limit animal health problems so they can be controlled primarily through prevention.[101] Nevertheless, sick or injured animals must be treated immediately.[102] Naturalistic veterinary medicinal products are regarded as preferable for use in organic farming. For example, phytotherapeutic, homeopathic, and trace elements are to be used in preference to chemically synthesized allopathic medicinal products or antibiotics.[103] The latter may be administered by a veterinarian if necessary to combat illness or treat injury.[104] The use of substances to promote growth or production, such as antibiotics, coccidiostatics, and other growth enhancers and the use of hormones or similar substances to induce or synchronize estrus is prohibited.[105] Hormones may be administered to an individual animal for therapeutic treatment.[106]

Whenever veterinary products are used, the product type and details of the diagnosis and treatment must be recorded.[107] The legal withdrawal period must also be recorded. This information is to be declared to the inspection authority before the livestock or livestock products are marketed as organically produced.[108] Livestock that has been treated must be clearly identified.[109]

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100. Regulation 1804/1999, ann. I.B.5.1(a)-(d), at 12.

101. Regulation 1804/1999, ann. I.B.5.2, at 12.

102. Council Regulation 1804/1999, ann. I.B.5.3, 1999 O.J. (L 222) at 12.

103. Regulation 1804/1999, ann. I.B.5.4(a), at 12.

104. Regulation 1804-1999, ann. I.B.5.4(b), at 12.

105. Regulation 1804/1999, ann. I.B.5.5.(a), at 13.

106. Regulation 1804/1999, ann. I.B.5.5.(a), at 13.

107. Council Regulation 1804/1999, ann. I.B.5.6, 1999 O.J. (L 222) at 13.

108. Regulation 1804/1999, ann. I.B.5.6, at 13.

109. Regulation 1804/1999, ann. I.B.5.6, at 13.

With the exception of vaccinations, treatments for parasites, and any compulsory eradication schemes, livestock and livestock products that have received more than three courses of treatments with chemically synthesized allopathic medicinal products or antibiotics within one year may not be sold as organic products.[110] The livestock must undergo conversion periods subject to the agreement of the inspection authority.[111]

Additional rules for organic livestock exist. For instance, the reproduction of organic livestock should be natural as a matter of principle, but artificial insemination is permitted.[112] Keeping livestock tethered is forbidden unless it is for limited time periods as authorized by the inspection authority for health or safety reasons.[113] Insulation, heating, and ventilation of the livestock housing facilities must ensure that air circulation, dust level, temperature, and relative humidity are kept within safe limits.[114] Furthermore, free-range and open air exercise areas must provide sufficient protection from rain, wind, sun, and extreme temperatures.[115]

The E.U.'s rules encourage rearing practices that safeguard the health and welfare of the animals[116] as well as the consumer.[117] Beef bearing the E.U. logo for organic farming is produced under strict guidelines.[118] Member States are free to impose more rigid standards on organic beef produced in their territory.[119]

IV. HUMANE METHODS OF SLAUGHTER

Both the United States and E.U. have enacted legislative provisions on the humane slaughtering of livestock. The regulations prevent needless suffering of animals. Special provisions for religious or

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110. Regulation 1804/1999, ann. I.B.5.8, at 13.

111. Regulation 1804/1999, ann. I.B.5.8, at 13.

112. Council Regulation 1804/1999, ann. I.B.6.1.1, 1999 O.J. (L 222) at 13.

113. Regulation 1804/1999, ann. I.B.6.1.4, at 13.

114. Regulation 1804/1999, ann. I.B.8.1.1, at 15.

115. Regulation 1804/1999, ann. I.B.8.1.2, at 15.

116. *See* Council Regulation 1804/1999, whereas 20, 1999 O.J. (L 222) 1.

117. *See* Regulation 1804/1999, whereas 4, at 2.

118. *See* Regulation 1804/1999, whereas 11, at 1.

119. *See* Regulation 1804/1999, art. 12, at 6.

ritual slaughter are made in both instruments. Important provisions from both legislative frameworks are outlined below.

A. The United States Humane Slaughter Act

Inhumane slaughtering conditions became an issue of public concern in the United States following the publication of *The Jungle* by Upton Sinclair in 1905.[120] In this landmark novel, Sinclair vividly described the deplorable conditions of a Chicago meatpacking house and the threat such abominable conditions posed to consumers.[121] In 1906, the Federal Meat Inspection Act (FMIA) and the Food and Drug Act were passed to address these problems.[122] Section 603(b) of FMIA, the progeny of the Meat Inspection Act of 1906 as amended, provides that USDA is authorized to appoint inspectors to examine slaughtering methods in slaughtering establishments as a means of preventing the inhumane slaughter of livestock.[123] The United States Congress has explicitly declared that slaughtering and handling of livestock in connection with slaughter is to be carried out only by humane methods.[124] Humane methods of slaughter prevent needless suffering, result in safer and better working conditions for the persons employed in the slaughter industry, and improve products and economies in slaughtering operations.[125]

In furtherance of its policy for humane slaughtering of livestock, Congress enacted the Humane Slaughter Act of 1958.[126] In Section 1902, Congress has enumerated the methods of slaughter found to be humane.[127] In the case of cattle and calves, animals are rendered insensible to pain by a single blow, gunshot, electrical, or chemical means that is rapid and effective.[128] This stunning must occur

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120. FSIS, Agency History (2005), *at* http://www.fsis.usda.gov/About_FSIS/Agency _History/ index.asp (last visited Dec. 30, 2005).

121. *Id*.

122. *Id*.

123. 21 U.S.C. § 603(b) (2000).

124. 7 U.S.C. § 1901 (2000).

125. *Id.*

126. *Id.* §§ 1901-1907.

127. *Id.* § 1902.

128. The Humane Slaughter Act also applies to horses, mules, sheep, swine, and other livestock. *Id.* § 1902(a).

before the livestock is shackled, hoisted, thrown, cast, or cut.[129] In addition, this Act authorizes slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter in which the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries.[130]

Under Section 1904, USDA is authorized and directed to conduct research and experimentation using current methods and scientific knowledge to develop methods of slaughter and handling of livestock in connection with slaughter that are practicable in speed and scope of operations and are also humane.[131] Section 1906 contains the caveat that nothing in the Humane Slaughter Act is intended to be construed to prohibit or hinder the religious freedom of any person or group.[132] In order to protect religious freedom, ritual slaughter and the handling and preparation of livestock for ritual slaughter are exempted from the terms.[133] Similar provisions are found in the E.U. instrument on humane methods of livestock slaughter.

B. E.U. Rules on Humane Methods of Slaughter

Council Directive 93/119/EC was established in 1993 to set forth a framework of rules on the humane slaughter of animals.[134] Annex A of this Directive clearly details the rules to be implemented by Member States.[135] These rules apply to cattle, among other animals.[136]

With the aim of avoiding unnecessary pain and suffering, Annex A provides that animals in slaughterhouses must be protected from extreme weather, and the condition of the animals must be

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129. 7 U.S.C. § 1902(a).

130. *Id.*

131. *Id.* § 1904(a).

132. *Id.* § 1906.

133. *Id.* § 1906.

134. Council Directive 93/119, 1993 O.J. (L 340) 21-34 (EC).

135. Directive 93/119, ann. A, at 25-34.

136. Directive 93/119, at 21.

inspected at least every morning and evening.[137] In addition, non-ambulatory animals must not be dragged to slaughter.[138] Instead, such animals must be killed where they lie or transported on a trolley to a place of emergency slaughter.[139] Unloading equipment must have non-slip flooring and railings to prevent animals from falling, and animals must not be lifted by the head, horns, ears, feet, or tail.[140] Blows and kicks to animals are prohibited.[141]

Annex A goes on to establish that drinking water must always be available to animals that are not slaughtered immediately upon arrival in the slaughtering facility.[142] Animals that have not been slaughtered within twelve hours of their arrival must be fed at appropriate intervals, and animals kept more than twelve hours at a slaughterhouse must be lairaged.[143]

Annex B lays out rules for restraint of animals before stunning and slaughter. Animals must be restrained such that unnecessary pain, suffering or injury is avoided.[144] Particularly, animals' legs must not be tied, and animals must not be suspended before stunning or killing.[145] In the case of ritual slaughter, restraint of livestock before slaughter using a mechanical method intended to avoid pain, suffering, or injuries to the animals is obligatory.[146]

Under Annex C, the following methods of stunning are permitted: (i) captive bolt pistol fired into cerebral cortex; (ii) concussion using a mechanically-operated instrument that strikes the skull without fracturing it; and (iii) electronarcosis in which currents pass through the brain.[147] Stunning must not

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137. Directive 93/119, ann. A.I.4-5, at 21.

138. Directive 93/119, ann. A.I.6, at 21.

139. Council Directive 93/119, ann. A.I.6, 1993 O.J. (L 340) 21 (EC).

140. Directive 93/119, ann. A.II.1, at 21.

141. Directive 93/119, ann. A.II.4, at 21.

142. Directive 93/119, ann. A.II.9, at 21.

143. Directive 93/119, ann. A.II.9-10, at 21.

144. Council Directive 93/119, ann. B.1, 1993 O.J. (L 340) 21 (EC).

145. Directive 93/119, ann. B.2, at 21.

146. Directive 93/119, ann. B.1, at 21.

147. Directive 93/119, ann. C.II.1-3, at 21.

be carried out unless it is possible to bleed the animals immediately afterwards.[148] Annex C also establishes that cattle may be slaughtered with the use of a free bullet pistol or rifle, electrocution, and carbon dioxide gas.[149]

V. REGULATIONS ON BSE AND OTHER CONTAGIOUS DISEASES

Those familiar with the cattle industry can attest that infectious diseases, which have decimated entire herds and spread to other livestock and humans as well, have presented the industry with formidable challenges for many years prior to the advent of Bovine Spongiform Encephalopathy (BSE).[150] Strict measures have been implemented in the United States and E.U. for the purpose of curtailing the spread of communicable livestock diseases and the contamination of the human food supply. This portion of the article details the regulations on the spread of diseases that affect the beef industry.

A. United States Regulation of Contagious Livestock Diseases

Before BSE, other diseases infected cattle and threatened the wholesomeness of beef and beef products.[151] In response to this problem, the Cattle Contagious Diseases Act (CCDA) was enacted in 1903. The purpose of CCDA was to curtail the spread of livestock diseases and to protect the meat supply.[152]

Section 113 of CCDA authorizes USDA to adopt measures to prevent the exportation from any port in the United States to any port in a foreign country of livestock infected with any communicable disease. Transportation from one state to another state of any livestock infected with a contagious, infectious, or communicable disease is prohibited, unless such transportation is for the purpose of slaughtering the diseased animals.[153] Section 114 (a) is an example of the mandates created to

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148. Directive 93/119, ann. C.II, at 21.

149. Council Directive 93/119, ann. C.I.1-4, 1993 O.J. (L 340) 21 (EC).

150. *See* Marc Lappé & Britt Bailey, *Mad About Beef*, *available at* http://www.cetos.org/articles/madcow.html ("BSE is not the first disease that has jumped species lines from bovines to humans. Brucellosis, a serious systemic infection; E. coli 0157:H7 and salmonella, both cause potential fatal intestinal diarrheas; bovine tuberculosis; and possibly lymphoma have all been documented to transfer from beef or dairy cattle to humans.").

151. *See id.*

152. 21 U.S.C. §§ 112-122 (2000).

153. 21 U.S.C. § 115 (2000).

prevent the spread of contagious livestock diseases from one state to another state.[154] With respect to tuberculosis and brucellosis, domestic animals that have reacted positively to a test for paratuberculosis or brucellosis may be shipped from one state to any other state only for immediate slaughter.[155] Similar provisions exist in CCDA for other contagious diseases. The animals must be tested for the commonly known diseases according to established testing methods. Livestock that test positive for infectious diseases and diseases harmful to humans must be slaughtered immediately.[156]

In addition to the requirements in CCDA, regulations have been promulgated to ensure the identification of animals destroyed because of tuberculosis for indemnification purposes. Cattle are classified as infected with tuberculosis on the basis of an intradermal tuberculin test applied by a Federal, state, or otherwise accredited veterinarian.[157] In 2002, USDA, aiming to encourage destruction of animals that are infected with, or at risk of being infected with tuberculosis, amended the regulations on payment of indemnity for livestock destroyed because of tuberculosis with an interim rule.[158] This rule provides that the Animal Plant and Health Inspection Service (APHIS) of USDA will pay owners of the animals an indemnity equal to the difference between the net salvage received and the appraised value of the animals destroyed.[159] USDA will not pay more than $3,000 per animal destroyed.[160]

Pursuant to section 50.6(a) of USDA regulations, livestock destroyed because of tuberculosis must be identified as follows: (1) livestock[161] classified as reactors for tuberculosis must be identified within fifteen days after being classified as reactors; (2) reactor cattle must be identified by branding the letter “T” on the left hip and by attaching to the left ear an approved metal ear tag bearing a serial

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154. *Id.* § 114(a).

155. *See id.*

156. *Id.*

157. 9 C.F.R. § 50.4(a) (2005).

158. 9 C.F.R. §§ 50 & 77 (2005).

159. 9 C.F.R. §§ 50 & 77.

160. 9 C.F.R. §§ 50 & 77.

161. This title refers to cattle, bison, captive cervids, and other animals.

number and the inscription “U.S. Reactor;” (3) exposed cattle must be identified by branding the letter “S” on the left hip and by attaching to either ear a metal ear tag bearing a serial number.[162]

Under section 50.7, livestock to be destroyed because of tuberculosis must be given a permit to be shipped directly to slaughter at a Federal or State inspected slaughtering establishment or be disposed of by rendering, burial, or incineration.[163] Livestock for which federal indemnity may be paid because of tuberculosis must be destroyed and disposed of within fifteen days after the date of appraisal, unless the veterinarian in charge extends the time limit for slaughter to thirty days.[164]

Animals infected with or exposed to a communicable disease must be slaughtered promptly after appraisal and disposed of by burial or burning, unless otherwise provided in the Administrator’s discretion.[165] An APHIS employee must supervise the slaughter and disposal.[166] An APHIS Administrator is authorized to agree, on behalf of USDA, to pay fifty-percent of the expense of purchase, destruction, and disposition of animals that must be destroyed because of a communicable disease.[167]

Under the Animal Health Protection Act, USDA may hold, seize, quarantine, treat, destroy, or dispose of any animal that USDA has reason to believe may carry, may have carried, or may have been affected with or exposed to any pest or disease of livestock at the time of movement.[168] Similarly, if USDA determines that an extraordinary emergency exists due to the presence in the United States of a pest or disease of livestock and that the presence of such threatens the livestock of the United States, USDA may hold, seize, treat, destroy, or dispose of any animal or article.[169] USDA may also prohibit or restrict the movement within the United States of any animal or article in order to prevent the dissemination of the pest or disease.[170]

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162. 9 C.F.R. § 50.6 (2005).

163. *Id.* § 50.7(a) (2005).

164. *Id.* § 50.7(b).

165. *Id.* § 53.2.

166. *Id.*

167. 9 C.F.R. § 53.2(b) (2004).

168. 7 U.S.C. § 8306(a) (2000).

169. *Id.*

170. *Id.*

B. Measures for the Detection and Eradication of Bovine Spongiform Encephalopathy

Since the initial detection of BSE in 1986, the United States government has implemented various measures to prevent BSE from entering the Unites States and to prevent the spread of the disease in the event of its introduction into the Unites States.[171] For example, since 1989, APHIS has banned the importation of live cattle and cattle products, such as rendered protein products, from countries where BSE exists.[172] Specifically, in 1989, APHIS banned the importation of live ruminants and ruminant products from the United Kingdom.[173] In 1997, APHIS extended the application of these import restrictions to all European countries because of concerns about widespread risk factors and what APHIS believes to be inadequate surveillance for BSE in many European countries.[174]

Beginning in December 7, 2000, APHIS implemented a prohibition on imports of rendered animal protein products, irrespective of species, from BSE-restricted countries.[175] This ban resulted from apprehension that feed intended for cattle may have been cross-contaminated with the BSE agent.[176] Previously, in 1997, FDA prohibited the use of certain mammalian protein in the manufacture of ruminant animal feed.[177] Under this prohibition, firms must do the following: (1) keep specified records on the manufacture of their feed; (2) prohibit co-mingling between ruminant feed and non-ruminant feed containing materials prohibited in ruminant feed; and (3) assure that non-ruminant feed containing materials prohibited in ruminant feed is labeled conspicuously with the statement "Do not feed to cattle and other ruminants."[178] The purpose of these regulations is to prevent the introduction and spread of BSE to American cattle through contaminated feed.[179]

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171. These measures were set forth by USDA and FDA.

172. *See* APHIS, USDA, Bovine Spongiform Encephalopathy, *at* http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/fs_ahbse.html (last visited Dec. 30, 2005).

173. *See id.*

174. *See id.*

175. *See id.*

176. *See id.*

177. FSIS Measures, *supra* note 1.

178. *See id.*

179. *Id*.

Thus far, only two animals in the United States have tested positive for BSE. In June 2005, APHIS notified FDA that a twelve-year-old cow from a Texas ranch, which was dead upon arrival at the packing plant in November 2004, tested positive for BSE.[180] Its carcass was destroyed in November 2004.[181] When the BSE positive cow was discovered in 2005, APHIS, FDA, and other groups conducted an extensive investigation.[182] They learned that the infected animal was born prior to the implementation of the 1997 feed ban instituted by FDA, and that the ruminant feed ban was being followed.[183] During this investigation, APHIS attempted to trace the adult cattle that left the Texas ranch after 1990 and any offspring that will be born within two years of the BSE positive cow's death.[184]

APHIS also operates an interagency surveillance system for BSE in the United States.[185] In conjunction with the FSIS, APHIS has constructed an emergency response plan for use in the event of BSE detection in the United States.[186] Other Federal agencies have created contingency plans that work alongside the USDA plan.[187] In particular, the Centers for Disease Control and Prevention (CDC) runs a surveillance system for variant Creutzfeldt-Jakob Disease (vCJD), a fatal neurodegenerative disease that affects humans and is linked to the consumption of BSE-contaminated beef products.[188]

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180. *See* FDA, REPORT ON FOOD & DRUG ADMINISTRATION DALLAS DISTRICT INVESTIGATION OF BOVINE SPONGIFORM ENCEPHALOPATHY EVENT IN TEXAS 2005, *available at* http://www.fda.gov/cvm/texasfeedrpt.htm.

181. *Id.*

182. *See id.*

183. *See id.*

184. *See id.*

185. *See* APHIS & USDA, APHIS' BSE Surveillance Program, *available at* http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_ahbsesurv.pdf.

186. *See* APHIS, Bovine Spongiform Encephalopathy, *available at* http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html (stating that APHIS has prepared an emergency response plan in the event of the introduction of BSE into the United States).

187. *See* FSIS Measures, *supra* note 1.

188. *Id.*

Since the detection of BSE in Canada in May 2003, USDA has initiated additional measures, consistent with those taken by Canada, to improve protections against BSE.[189] USDA has undertaken the immediate implementation of a verifiable system of national animal identification to accomplish across the board uniformity and efficiency in the current national systems.[190] USDA has banned the use of all "downer"[191] cattle as human food.[192] Surveillance data from European countries where BSE has been found indicate that cattle with clinical signs of a central nervous system disorder, dead cattle, and "downer" cattle have a greater incidence of BSE.[193]

FSIS inspectors must wait to mark cattle tested for BSE as "Inspected and passed" until receipt of confirmation that the animals have tested negative for BSE.[194] USDA has designated as "specified risk" materials, the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over thirty months of age and the small intestine of cattle of all ages.[195] Use of special risk material in food for human consumption will be prohibited.[196] Tonsils from all cattle are already considered inedible and, therefore, do not enter the food supply.[197]

FSIS will require federally inspected establishments that slaughter cattle to develop, implement, and maintain procedures to remove, segregate, and dispose of these specified risk materials to preclude their entrance into the human food supply.[198] Meat production establishments must make records of this information available for review by FSIS inspection personnel.[199] FSIS has also

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189. News Release, USDA, Veneman Announces Additional Protection Measures to Guard Against BSE (Dec. 30, 2003), *at* http://www.usda.gov/documents/News Releases/ 2003/12/0449.doc (last visited Dec. 30, 2005) [hereinafter USDA News Release].

190. *Id.*

191. "Downer" cattle are unable to walk or rise from a recumbent position. *See* FSIS Measures, *supra* note 1.

192. *See* USDA News Release, *supra* note 189.

193. See FSIS Measures, supra note 1.

194. *See* USDA News Release, *supra* note 189.

195. *Id.*

196. *Id.*

197. *Id*.

198. *See* FSIS Measures, *supra* note 1.

199. *See id.*

developed methods for verifying the age of cattle that are slaughtered in official establishments, and they require state inspected plants to establish equivalent procedures.[200] These measures have been implemented because most of the cattle that have tested positive for BSE have been at least thirty months of age.[201]

FSIS has regulated the advanced meat recovery (AMR) process in order to protect the meat supply from disease contamination.[202] AMR is a technological method that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material.[203] FSIS has expanded the regulation prohibiting the inclusion of the spinal cord in AMR products labeled as "meat."[204] This prohibition will ban the inclusion of dorsal root ganglia and nerve clusters connected to the spinal cord. Like the spinal cord, the dorsal root ganglia may also contain BSE agents.[205] The vertebral column and the skull in cattle thirty months and older is inedible and can not be used for AMR.[206]

C. E.U. Rules on Transmissible Spongiform Encephalopathy

The E.U.'s provisions for the control of contagious diseases are often folded into legislation that encompasses a wider range of topics. However, E.U. has enacted specific rules in at least one case. On May 22, 2001, the European Parliament and the European Council passed Regulation No. 999/2001, an amendment to prior regulations, to address the transmissible spongiform encephalopathies (TSEs), including BSE.[207] This regulation applies to the production, placing on the market, and exportation of live animals and products of animal origin.[208] Where cases of TSEs are

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200. *Id.*

201. *See id.*

202. *See* USDA News Release, *supra* note 189.

203. *Id.*

204. *See id.*

205. *Id.*

206. *Id.*

207. Council Regulation 999/2001, 2001 O.J. (L 147) 1 (amending Council Directive 96/23, 1996 O.J. (L 125) 10-32).

208. Regulation 999/2001, art. 1(1), at 3.

confirmed, Member States are required to draft guidelines specifying the national measures to be implemented and indicating responsibilities in accordance with the Community rules.[209]

Annex II of this Regulation lays down the criteria for the determination of BSE status of a Member State, third country, or their regions.[210] BSE status is to be determined based on multiple factors. One factor is the outcome of a risk analysis that considers the following factors: (1) whether bovine animals consume meat and bone meal or greaves derived from ruminants; (2) whether meat and bone meal or greaves are potentially contaminated by a transmissible spongiform encephalopathy (TSE) or animal feed containing meat and bone meal or greaves is imported; (3) whether animals or ova/embryos potentially infected by a TSE are imported; (4) the epidemiological status of a country or region in regard to animal TSEs; (5) the extent of knowledge about the structure of the bovine population in the country or region; and (6) the source of animal waste, the processes for treating such waste, and the methods of producing animal feed.[211]

A second factor of consideration is whether the Member State, third country, or regions operate an education program that encourages veterinarians, breeders, and those who transport, trade, and slaughter bovine animals to report all cases of neurological manifestations in adult bovine animals.[212] A third important factor in determining BSE status is whether the compulsory reporting and examination of all bovine animals showing clinical signs of BSE is mandated.[213] Another factor is whether a system of continuous surveillance and monitoring of BSE with an obligation to retain the results for seven years is implemented.[214] The final factor is whether the Member State, third country, or region requires examination of encephala or other tissues collected under the surveillance system in an approved laboratory.[215]

The BSE status of countries or regions is to be determined by classification into the following five categories: (1) Category 1: Country or Region free of BSE; (2) Category 2: BSE provisionally free country or region where no indigenous case has been reported; (3) Category 3: BSE provisionally

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209. Regulation 999/2001, art. 14(1), at 8.

210. Regulation 999/2001, ann. II, at 13-15.

211. Regulation 999/2001, ann. II, ch. B, at 13.

212. Council Regulation 999/2001, ann. II, ch. A(b), 2001 O.J. (L 147) at 13.

213. Regulation 999/2001, ann. II, ch. A(c), at 13.

214. Regulation 999/2001, ann. II, ch. A(d), at 13.

215. *See* Regulation 999/2001, ann. II, ch. A(e), at 13.

free country where at least one case of BSE has been reported; (4) Category 4: Country or Region with low incidence of BSE; and (5) Category 5: Country or Region with high incidence of BSE.[216]

Annex 3 establishes a system with minimum requirements for monitoring BSE in bovines.[217] Under this scheme, each Member State carries out an annual program for monitoring BSE, which includes rapid post-mortem screening. Such screening must be performed on: (1) all bovine animals subject to "special emergency slaughtering" or showing signs of any form of disease at the time of ante-mortem inspection at the slaughterhouse; (2) all bovine animals over thirty months of age slaughtered normally for human consumption; (3) dead bovine animals that are not slaughtered for human consumption and that are found dead on the farm or during transport; and (4) bovine animals displaying a neurological disorder.[218]

Member States may voluntarily carry out targeted surveillance for TSE in higher risk animals.[219] Higher risk animals include those animals originating from countries with indigenous TSE, animals that have consumed potentially contaminated foodstuffs, and animals born or derived from TSE-infected cattle.[220] Member States must ensure that no parts of the body of animals being screened for TSE are used for human food, animal feed, or fertilizers until the laboratory examination has been concluded with negative results.[221]

Member States must submit reports on all detected cases of TSE to the European Commission.[222] The information reported must entail the number, age distribution, geographical distribution of positive cases of BSE, as well as the year and month of birth should be given for BSE cases born after the introduction of a ban on using ruminant protein in animal feed.[223]

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216. Regulation 999/2001, ann. II., ch. C, at 13-15.

217. Council Regulation 999/2001, ann. III, ch. A, 2001 O.J. (L 147) 16-19. The system also monitors for scrapie in other animals. Regulation 999/2001, ann. III, ch. B, at 17.

218. Regulation 999/2001, ann. III, ch. A.I.1.1, at 16.

219. Regulation 999/2001, ann. III, ch. A.III, at 18.

220. Regulation 999/2001, ann. III, ch. A.III, at 18.

221. Council Regulation 999/2001, ann. III, ch. A.IV, 2001 O.J. (L 147) at 18.

222. Regulation 999/2001, ann. III, ch. B.I.7, at 18.

223. Regulation 999/2001, ann. III, ch. B.I.6, at 18.

Annex 4 provides that Member States or regions grouped into Category 5 are prohibited from feeding ruminant animals protein derived from mammals.[224] Under this prohibition, farm animals must not be fed protein derived from mammals.[225] Member States and regions are also prohibited from feeding ruminants the fat rendered from ruminants.[226]

Depending on the category of the country or region, Annex 5 has designated the following tissues as specified risk material. As regards Categories 3 and 4, the skull, brain, eyes, tonsils, spinal cord of animals over twelve months old, and the intestines of bovines of all ages are deemed specified risk material.[227] With respect to Category 5, the entire head, tongue, brain, eyes, trigeminal ganglia, tonsils, thymus, spleen, and spinal cord of bovine animals over six months old, and the intestines of animals of all ages are classified as specified risk material.[228] All specified risk material must be removed at slaughterhouses, cutting plants, or similar premises under the supervision of an agent appointed by the competent authority.[229] All specified risk material must also be marked upon removal for identification purposes and immediately destroyed by incineration or burial in an approved landfill.[230]

Article 13 provides for the eradication of TSEs.[231] When the presence of a TSE has been officially confirmed, the following measures must be taken: (1) all of the animal's body parts must be completely destroyed; (2) an inquiry must be carried out to identify all animals at risk; (3) an inquiry must be performed to identify all embryos, ova, and the last progeny of a female animal in which the disease has been confirmed and the embryos or progeny collected or born up two years prior to or after the clinical onset of the disease; and (4) all animals and products of animal origin that have been identified as specified risk materials must be destroyed.[232] Owners must be compensated for the loss

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224. Regulation 999/2001, ann. IV.1(b), at 20.

225. Regulation 999/2001, ann. IV.1(a), at 20.

226. Council Regulation 999/2001, ann. IV.1(c), 2001 O.J. (L 147) at 20.

227. Regulation 999/2001, ann. V.1, at 21.

228. Regulation 999/2001, ann. V.1, at 21.

229. Regulation 999/2001, ann. V.2, at 21.

230. *See* Regulation 999/2001, ann. V.3, at 21.

231. Council Regulation 999/2001, art. 13, 2001 O.J. (L 147) at 7-8.

232. Regulation 999/2001, art. 13(1)(a)-(c), at 7-8.

of animals that have been killed or products of animal origin that have been destroyed pursuant to this Directive.[233]

In connection with the eradication of TSEs, Annex 7 lays out additional terms. It requires the performance of an inquiry to identify the possible origin of the disease and other farms and holdings on which there are animals, embryos, or ova that may have become infected by TSE or exposed to the same feed or contamination source.[234] The inquiry must also endeavor to pinpoint the movement of potentially contaminated foodstuffs or any other contamination sources.[235]

Annex 8 established provisions for the intra-Community trade of live animals, embryos, and ova.[236] It provides that bovine embryos and ova must be derived from females that are not suspected of TSE infection at the time of collection.[237] This condition applies to the movement of bovine embryos and ova irrespective of the category of the Member State, third country, or region.[238]

The following conditions apply to movements of bovine animals coming from Member States, depending on the category of the State. Regarding Categories 3 and 4, animals must have been born and raised in herds with no case of confirmed BSE for at least seven years, or have been born after the date from which the prohibition on the feeding of ruminants with protein derived from mammals has been effectively enforced.[239] With respect to Category 5, the animals must have been born after the date from which the ban on the feeding of ruminants with protein derived from mammals has been effectively enforced and have been born and raised in herds with no case of confirmed BSE for at least seven years.[240]

Healthy live animals, their semen, embryos, and ova may be placed on the market, provided that such articles are accompanied by animal health certificates.[241] Products of animal origin derived from

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233. Regulation 999/2001, art. 13(4), at 8.

234. Regulation 999/2001, ann. VII, at 24.

235. Regulation 999/2001, ann. VII.1(a), at 24.

236. Council Regulation 999/2001, ann. VIII, ch. A, 2001 O.J. (L 147) at 25.

237. Regulation 999/2001, ann. VII. ch. A.I.1(2), at 25.

238. Regulation 999/2001, ann. VIII, at 25.

239. Regulation 999/2001, ann. VIII, ch. A.II.3, at 26.

240. Regulation 999/2001, ann. VIII, ch. A.II.3, at 26.

241. Regulation 999/2001, art. 16(3), at 9.

healthy animals may also be placed on the market.[242] Annex 9 contains similar provisions in the context of exportation outside the European Community.[243]

Annex 10 establishes the guidelines for national reference laboratories, which are designated in order to ensure the uniformity of scientific analysis and reliable results.[244] The national reference laboratories must be able to confirm the results of regional laboratories, to identify the type and strain of TSE when the disease is diagnosed, to verify diagnostic methods used in regional laboratories, and to refer unidentifiable strains of TSE to the Community reference laboratory.[245] The Community reference laboratory for TSE, or the Veterinary Laboratories Agency, is responsible for coordinating the methods employed in the Member States for diagnosing BSE and facilitating the training of diagnostic experts in order to harmonize diagnostic techniques throughout the Community.[246]

VI. INSPECTION OF LIVE CATTLE, BEEF, BEEF FOOD PRODUCTS, AND BEEF PRODUCTION ESTABLISHMENTS

Much importance is placed on the inspection of livestock because inspection is the best way to ensure that unsafe and unwholesome beef and beef products do not enter the human food chain. Conscientious maintenance of quality and safety standards must be monitored under reliable and trustworthy conditions. Both the United States and E.U. require official inspectors to perform on-site checks of farms and meat production plants. A summary of the inspection regulations follows.

A. United States Federal Meat Inspection Act

As previously mentioned, in the interest of protecting the health and welfare of consumers and preserving the market for meat, Congress passed FMIA to ensure that wholesome, unadulterated,[247] properly packaged and labeled meat and meat food products enter interstate and foreign

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242. Council Regulation 999/2001, ann. VIII, 2001 O.J. (L 147) 1, 26.

243. *See* Regulation 999/2001, ann. IX, at 30-33.

244. *See* Regulation 999/2001, ann. X, at 34-37.

245. Regulation 999/2001, ann. X. ch. A.1(b), at 34.

246. Regulation 999/2001, ann. X. ch. A.2(a), (c), at 34.

247. The term “adulterated” refers to the condition of a carcass, meat, or meat food product that contains a poisonous or deleterious substance in a quantity that may render it injurious to health. 21 U.S.C. § 601(m)(1) (2000).

commerce.[248] This segment will summarize the requirements set forth by FMIA as they pertain to cattle.[249]

In order to prevent the use in commerce of adulterated meat and meat food products, Section 603(a) empowers USDA to authorize the appointment of inspectors to examine and inspect cattle before they are allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment.[250] Upon inspection, all cattle found to show symptoms of disease are to be slaughtered separately from healthy cattle.[251]

USDA must authorize the appointment of inspectors to conduct post-mortem inspections of carcasses and parts of carcasses to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any state, territory, or the District of Columbia as articles of commerce to be used as human food.[252] The carcasses and parts found not to be adulterated must be stamped as "Inspected and passed."[253] Carcasses and parts found to be adulterated are to be stamped as "Inspected and condemned."[254] Section 604 necessitates the destruction of all condemned carcasses intended to be used as human food.[255]

Carcasses and parts of carcasses, the meat, or meat products of such carcasses must be inspected and examined before they are allowed to enter any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in which they will be prepared for meat food products.[256] Any such products, which after leaving any slaughtering, meat-canning, salting, packing, rendering, or similar establishment are returned to the same establishment, must also be inspected.[257]

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248. *Id.* § 602.

249. FMIA regulates the inspection of meats derived from cattle, sheep, swine, goats, horses, mules, and other equines. *Id.* § 603.

250. *Id.* § 603(a).

251. *Id.*

252. 21 U.S.C. § 604 (2000).

253. *Id*. § 604.

254. *Id.*

255. *Id.*

256. *Id.* § 605.

257. 21 U.S.C. § 605 (2000).

Pursuant to Section 606 of FMIA, USDA appoints inspectors to examine and inspect all meat food products prepared for commerce and export in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment.[258] In order to carry out their inspection duties as mandated by this law, inspectors must be granted access at all times to every part of the establishment.[259] Inspectors must mark all unadulterated meat food products "Inspected and passed" and all adulterated food products "Inspected and condemned."[260] Furthermore, false or misleading marking or labeling on meat food intended for sale is prohibited under Section 607.[261]

Competent inspectors must perform continuous sanitation inspections of all slaughterhouses, meat-canning, salting, packing, rendering, or similar establishments where cattle are slaughtered and the meat and meat food products are prepared for commerce.[262] The inspections must be carried out with the aim of prescribing appropriate rules and regulations for the abovementioned establishments.[263]

When slaughter and preparation occurs at night, the examination and inspection of cattle and beef food products must be undertaken during that time.[264] Careful inspection of all cattle offered for export to foreign countries is required by Section 615 in order to ascertain whether such cattle are free from disease.[265] Thorough inspection of carcasses, parts of carcasses and fresh, canned, salted, corned, packed, cured, or otherwise prepared meat intended and offered for export to any foreign country is mandatory.[266] In addition, inspectors must prepare an official certificate clearly stating the condition of the inspected cattle.[267]

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258. *Id.* § 606.

259. *Id.*

260. *Id.*

261. *Id.* § 607.

262. 21 U.S.C. § 608 (2000).

263. *Id.* § 608.

264. *Id.* § 609.

265. *Id.* § 615.

266. *Id.*

267. 21 U.S.C. § 616 (2000).

Unless and until the owner procures a certificate from an inspector certifying that the cattle are healthy at the time of inspection and that their meat is wholesome, no clearance will be granted to any vessel carrying fresh, salted, canned, corned, or packed beef meat for export to and sale in a foreign country from any port in the United States.[268] However, USDA has discretion to waive this requirement.[269]

To avoid adulteration or contamination, animals, carcasses, animal parts, meat and meat food products must not be prepared in the same establishment in which cattle are slaughtered.[270] Under Section 620, no carcasses, meat or meat food products of cattle to be used as human food, can be imported in the United States if such articles are adulterated or misbranded.[271] The carcasses and meat or meat food products must comply with inspection standards and the Humane Slaughter Act of 1958, as well as all other provisions of this statute.[272]

Once carcasses, meat or meat food products are imported into the United States, these articles will be deemed and treated as domestic articles subject to the other provisions of this chapter and FDCA.[273] These articles must be properly marked and labeled according to FDCA and the regulations promulgated by FDA.[274]

Section 620(b)(1) gives USDA authority to prescribe the terms and conditions for destruction of all cattle carcasses, meat, and meat food products that are imported contrary to this section.[275] Section 620(b)(2) stipulates that articles found to be non-compliant with this chapter solely as a result of misbranding can be brought into compliance under the supervision of representatives of USDA.[276] Non-compliance can be cured in order to avoid the destruction of the articles.[277]

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268. *Id.* § 617.

269. *See id*

270. *Id.* § 619.

271. *See id.* § 620(a). The term "misbranded" refers to any carcass, meat, or meat food product with false or misleading labeling, or that omits labeling information required by law. 21 U.S.C. § 601(n)(1) (2000).

272. *Id.* § 620(a).

273. *Id.*

274. *Id.*

275. *Id.* § 620(b)(1).

276. 21 U.S.C. § 620(b)(2) (2000).

Section 620 also provides that the same inspection, sanitary, quality, species verification, and residue standards applied to products produced for human food in the United States applies to carcasses, meat and meat food products of cattle imported into the United States.[278] Random inspections for species verifications and residues, and random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country, may be conducted to facilitate enforcement of this provision.[279]

Each foreign country that imports carcasses, meat and meat articles into the United States is required to obtain certification from USDA stating that the country uses reliable analytical methods to maintain compliance with United States standards for residues in meat articles.[280] USDA must periodically review these certifications.[281] The consideration of any application for a certification and the review of certifications must include the inspection of individual establishments to ensure that the inspection program of the foreign country is satisfying United States standards.[282]

Section 620(g) permits USDA to prescribe terms and conditions under which cattle that have been administered an animal drug or antibiotic banned for use in the United States may be imported for slaughter and human consumption.[283]

Section 620(h)(2) governs reciprocal meat inspection.[284] At the behest of the Committee on Agriculture, the Committee on Ways and Means of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry, or the Committee on Finance of the Senate, or an USDA

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277. *Id.* § 620(b)(2).

278. *Id.* § 620(f).

279. *Id.*

280. *Id.*

281. 21 U.S.C. § 620(f) (2000).

282. *Id.*

283. *Id.* § 620(g).

284. *Id.* § 620(h)(2).

initiative, USDA may act to determine whether a particular foreign country applies standards[285] for the importation of meat from the United States "that are not related to public health concerns about end-product quality that can be substantiated by reliable analytical methods."[286] Upon determination that a foreign country applies such standards, USDA can begin consultation with the United States Senate and within thirty days after the determination, USDA and the United States Trade Representative are free to recommend to the President whether action should be taken to prohibit the country's importation into the United States of its carcasses, meat and meat food products.[287]

Section 644 prohibits the buying, selling, transporting, or importing of dead, dying, disabled, or diseased animals, or any part of the carcasses of any animals that died otherwise than by slaughter.[288] While it also provides that USDA may authorize regulations to allow such transactions, transportation, or importation of the animals or their unwholesome parts are not to be used as human food.[289]

FSIS is responsible for ensuring that meat is safe, wholesome, and correctly labeled and packaged.[290] Section 309 of the USDA regulations contains several inspection provisions that govern FSIS functions. Section 309.1 provides that all livestock offered for slaughter in an official pen must be inspected on the day of or before slaughter unless the FSIS Administrator has previously arranged for inspection to occur on a different day before slaughter.[291] Before livestock awaiting slaughter are permitted to enter into any department of the official slaughtering establishment or any department where edible products are handled, ante-mortem inspections must be performed in pens of the establishment.[292]

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285. The term "standards" means inspection, sanitation, quality, species verification, residue, and other standards that are applicable to carcasses, meat and meat food products of cattle that are capable of use as human food. *Id.* § 620(h)(1)(B).

286. 21 U.S.C. § 620(h)(2) (2000).

287. *Id.* § 620(h)(3).

288. *Id.* § 644.

289. *Id.*

290. *See generally* FSIS, *at* http://www.fsis.usda.gov/About_FSIS/index.asp (last visited Jan. 1, 2006).

291. 9 C.F.R. § 309.1(a) (2005).

292. *Id.* § 309.1(b).

Pursuant to Section 309.2, livestock suspected to be diseased as a result of ante-mortem inspection may be condemned after the carcass undergoes a post-mortem inspection.[293] When an ante-mortem inspection of livestock reveals a disease that would cause only part of the carcass to be condemned after post-mortem inspection, the livestock must be identified as a suspect until the final post-mortem inspection is performed.[294] If the post-mortem inspection reveals disease, the carcass must be marked for identification and disposed of accordingly.[295]

Seriously crippled or non-ambulatory disabled livestock must be identified as "U.S. Suspects" and disposed of, unless they are required to be classed as condemned.[296] Livestock that are diseased with leptospirosis, anaplasmosis, tuberculosis, epithelioma of the eye, or anasarca are to be identified as "U.S. Suspects" and destroyed.[297]

Livestock suspected of anasarca infection can be set apart and held for treatment under official supervision.[298] If upon completion of treatment the livestock is found to be disease-free, it may be released for any purpose.[299] If the livestock has diseases that the inspecting official believes are curable, such diseases may be treated under supervision, and if the livestock is found to be disease-free after treatment, it may be released for slaughter or any other purpose.[300]

Each animal required to be treated as a U.S. Suspect is to be identified as such by an FSIS employee with an official device that can not be removed by anyone other than an FSIS employee.[301] Animals identified as U.S. Suspect on ante-mortem inspection must be isolated and slaughtered separately from other livestock kept at that establishment.[302]

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293. *Id.* § 309.2(a).

294. *Id.*

295. *Id.*

296. 9 C.F.R. § 309.2(b) (2005).

297. *See id.* § 309.2(c)-(f).

298. *Id.* § 309.2(g).

299. *Id.*

300. *Id.*

301. *See* 9 C.F.R. § 309.2(m) (2005).

302. *See id.* § 309.2(n).

Animals identified as U.S. Suspect on ante-mortem inspection, must be sent to slaughter with a form MP 402-2 on which the inspector is required to record the U.S. Suspect identification number, a description of the animal, and the disease for which the animal was categorized as suspect.[303]

When any animal identified as U.S. Suspect is released for any purpose, the official suspect identification device must be removed by an FSIS employee, who must report the removal to the area supervisor.[304] When a suspect is to be released, the operator of the official establishment must first obtain permission for the removal of the animal from the local, state, or federal livestock sanitary official.[305]

Livestock found in a dead or dying condition at an official establishment must be identified as "U.S. Condemned" and disposed of as soon as possible.[306] If the ante-mortem inspection of the livestock reveals any disease that would cause condemnation of their carcasses on post-mortem inspection, the livestock must be identified as "U.S. Condemned" and disposed of without delay.[307] Cattle with a temperature of 105°F or higher must be identified as U.S. Condemned.[308] If there is doubt about the cause of the temperature, the livestock may be held for further observation before final disposition of the livestock is determined.[309] A retained animal must be re-inspected on the day of slaughter and must be condemned and disposed of if its temperature is 105° F or higher.[310]

Livestock identified as U.S. Condemned, if not already dead, must be killed.[311] Such animals can not be taken into the official establishment to be slaughtered or dressed, nor can they be taken into any department of the establishment used for edible products.[312] The tags must not be removed, and

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303. *See id.* § 309.2(o).

304. *Id.* § 309.2(p).

305. *Id.* § 309.2(p).

306. *See* 9 C.F.R. § 309.3(a) (2005).

307. *See id.* § 309.3(b).

308. *See id.* § 309.3(c).

309. *Id.*

310. *Id.*

311. *See* 9 C.F.R. § 309.13(a) (2005).

312. *Id*.

the tag number must be reported to the veterinarian in charge by the inspector who affixed the tag and also by the inspector who supervised the disposal of the carcass.[313] However, any livestock condemned because of a treatable disease, such as ketosis, vesicular diseases, anasarca, anaplasmosis, or pneumonia, may be isolated and held for treatment.[314] The "U.S. Condemned" tag will be removed following treatment if the animal is found to be free of disease, and the animal can be used for any purpose.[315]

During the slaughtering and preparation process, certain parts of the carcass are detached or removed from it. The head, tongue, tail, thymus gland, viscera, blood, and other parts severed from each slaughtered animal to be used in the preparation of meat food products or medical products must be identified with the rest of the carcass, until the post-mortem inspection of the carcass and its parts has been completed.[316] The retention of ear tags, back tags, implants, and other identification devices affixed to the animal is required.[317]

Testing procedures have been established to detect contamination with microorganisms. For example, official slaughtering establishments must test livestock for *Escherichia coli* (*E. coli*).[318] The establishments must collect samples from all chilled livestock carcasses, and the sampling frequency for cattle is 1 test per 300 carcasses, with a minimum requirement of one sample during each week of operation.[319] Exceptions are made for low volume establishments with an annual slaughter of no more than 6,000 cattle.[320] *Salmonella* testing is also performed on raw meat in slaughtering and processing establishments.[321] In order to enforce the provisions for microorganism detection, FSIS is authorized to sample raw meat products in an individual establishment on an unannounced basis.[322]

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313. *See id.*

314. *Id.* § 309.13(b).

315. *Id*.

316. 9 C.F.R. § 310.2(a) (2005).

317. *Id*.

318. *Id.* § 310.25(a)(1).

319. *Id.* § 310.25(a)(2)(iii)(A)
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320. *Id*. § 310.25(a)(2)(v).

321. 9 C.F.R. § 310.25(b)(1) (2005).

322. *Id.* § 310.25(b)(2).

B. E.U. Directives on Inspection of Various Beef Production and Processing Facilities

Desiring to unite their countries politically and economically, six European countries—Belgium, West Germany, Luxembourg, France, Italy, and the Netherlands—formed the European Coal and Steel Community (ECSC) in 1951.[323] ECSC integrated the coal and steel industries of Western Europe.[324] In 1957, the six countries further integrated additional sectors of their economies by signing the Treaties of Rome which created the European Atomic Energy Community (EURATOM) and the EEC in order to remove trade barriers and form a "common market."[325] In 1967, the three communities were merged into a single Commission, a single Council of Ministers, and the European Parliament.[326] The 1992 Treaty of Maastricht introduced inter-governmental cooperation to the existing community system and thus created E.U.[327]

Directive 64/433/EEC, one of the earliest EEC directives, was adopted in 1964. The Directive standardized health requirements for meat in slaughterhouses and cutting rooms and during storage and transportation.[328] In order to standardize the health requirements and improve intra-Community trade in fresh meat, it is necessary to eliminate differences between health requirements of Member states, i.e. to create a common agricultural policy.[329]

Article 1 establishes the health rules for the production and placing on the market of fresh meat derived from domestic animals and intended for human consumption.[330] Article 3 requires each Member State to ensure that carcasses, half carcasses, and quarter cuts: (1) come from a slaughter animal inspected ante-mortem by an official veterinarian, (2) have been slaughtered under satisfactory hygiene conditions, (3) have been inspected post-mortem by an official veterinarian, and

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323. *See* Europa History, *supra* note 4.

324. *Id*.

325. *Id*.

326. *Id*.

327. *Id*.

328. The full title of this Directive is Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-community trade in fresh meat. Council Directive 64/433, 1964 J.O. (121) 2012-2032 (EC).

329. *See* Directive 64/433, whereas 3, at 2012.

330. *See* Directive 64/433, art. 1, at 2013. Furthermore, Directive 64/433 applies to bovine, swine, sheep, goats, and solipeds. *See* Directive 64/433, art. 1(1), at 2013.

(4) do not show any changes that would render the carcass unfit for human consumption or dangerous to human health, and (5) bear a health mark.[331] Offal from carcasses must also comply with these requirements, and any other requirements for carcasses and smaller cuts of meat.[332]

With respect to transportation of carcasses, half carcasses, and quarter cuts, Article 3 provides that these items must be accompanied during transportation by an accompanying commercial document.[333] The document must be provided by the dispatching establishment, bear the veterinary approval number of the approved establishment and the month and year of freezing for frozen meat, and be retained by the consignee so that it can be furnished upon the request of the competent authority.[334] A health certificate is required for meat from a slaughterhouse in a restricted region or meat to be sent to another Member State.[335]

Cold storage fresh meat must be accompanied during transportation to its destination point by the accompanying commercial document or health certificate.[336] The certificate must be completed by the official veterinarian. In the case of importation, the certificate is to state the origin of the fresh meat and the veterinarian approval number of the cold store.[337]

Pursuant to Article 4, the official veterinarian or an auxiliary must carry out post-mortem inspection of meat. When the meat has lesions or appears to have deteriorated, the post-mortem inspection must be carried out by the official veterinarian.[338] Once inspected, meat from the approved slaughterhouses and cutting rooms that has been judged fit for human consumption must be marked

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331. *See* Directive 64/433, art. 3(c), at 2013-14.

332. *See* Council Directive 64/433, art. 3, 1964 J.O. (121) at 2013-14.

333. Directive 64/433, art. 3(1)(g), at 2014.

334. *See* Directive 64/433, ann. I, ch. VIII, at 2024.

335. Directive 64/433, art. 3(1)(g), at 2014.

336. *See* Directive 64/433, ann. I, ch. VIII, at 2024.

337. Council Directive 64/433, ann. I, ch. VIII, 1964 J.O. (121) at 2024.

338. Council Directive 91/497, art. 4, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, art 4, 1964 J.O (121)).

with a national stamp not to be confused with the Community Stamp and not ovular in shape.[339] The national stamp is not required for unpackaged cuts.[340]

Article 5 requires the official veterinarian to declare the following meat from animals unfit for human consumption: (1) meat from animals in which actinobacillosis, blackleg, tuberculosis, rabies, tetanus, acute salmonellosis, acute brucellosis, or botulism has been diagnosed; (2) meat showing acute lesions of broncho-pneumonia, pleurisy, peritonitis, arthritis, pericarditis, enteritis, or meningo-encephalo-myelitis and confirmed by a detailed inspection and bacteriological examination and a search for residues with a pharmacological effect;[341] (3) meat infected by sarcocystosis, cysticercosis; (4) meat producing a positive reaction to tuberculin;[342] and (5) and meat producing a positive reaction to brucellosis.[343]

Article 5 establishes that the official veterinarian must declare meat unfit for consumption that is derived from animals that are: (1) dead, stillborn or unborn; (2) slaughtered too young with edematous meat; (3) showing signs of emaciation or advanced anemia; and (4) showing multiple tumors, abscesses or serious injuries in different areas of the carcass or in different viscera.[344] The following must be declared unfit for human consumption: (1) parts of the carcass showing signs of major serious hemorrhaging, localized abscesses or localized contamination; (2) offal and viscera with pathological lesions of infectious, parasitic, or traumatic origin; (3) meat that is feverish, or shows serious abnormalities in color, smell, consistency, or taste; (4) offal that has not undergone post-mortem inspection; and (5) blood derived from any animal meat declared unfit for human consumption or blood contaminated by stomach contents.[345] Article 5 further provides that the following must also be declared unfit for human consumption by the official veterinarian: (1) meat from animals that have

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339. *See* Directive 91/497, at 69.

340. *See* Directive 91/497, art. 4, at 69.

341. Alternatively, where the special inspections and examinations are favorable, the carcasses may be declared fit for human consumption after parts unfit for consumption have been removed. Directive 91/497, art. 5, at 69.

342. Directive 91/497, art. 5, at 69. However, where tuberculous lesion has been found in the lymph nodes of the same organ or part of the carcass only the affected organ or part and the associated lymph nodes must be declared unfit for human consumption. Council Directive 91/497, art. 5, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, 1964 J.O. (121) 2012 (EC).

343. Directive 91/497, art. 5, at 69.

344. Directive 91/497, art. 5, at 69.

345. Directive 91/497, art. 5, at 69.

been administered any prohibited substances; (2) meat containing residues of unauthorized substances, or residues of medicinal products, antibiotics, pesticides, or other substances that are harmful to human health; (3) the liver and kidneys of animals more then two years old from regions where there is a generalized presence of heavy metals in the environment; and (4) meat that has been treated with ionizing or ultraviolet radiation.[346]

The official veterinarian must subject cattle and meat food products to examination for residues of substances with a pharmacological action, the conversion products of such substances, and for other substances harmful to human health.[347] If the examination reveals traces of residues in quantities which exceed permitted levels, the meat must be declared unfit for human consumption.[348] At least one reference laboratory must be designated per Member State to carry out the examination for residues.[349]

Article 9 requires that each Member State ensures the presence of at least one official veterinarian in a slaughterhouse throughout the ante-mortem and post-mortem inspections.[350] An official veterinarian must be present at least once a day in a cutting plant to inspect the hygiene conditions and to record the fresh meat entering and leaving the plant.[351] Article 9 also necessitates the regular presence of an official veterinarian in a cold store and in an approved packaging center.[352]

Under Article 10, each slaughtering, cutting, cold store, and packaging establishment must obtain approval from the competent national authority of the Member State.[353] Where hygiene is found to be inadequate despite attempts to remedy the situation, the competent national authority may be authorized by the Member State to suspend approval.[354] Following suspension of approval, if the

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346. Directive 91/497, art. 5, at 69.

347. Council Directive 91/497, art. 5, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, 1964 J.O. (121) 2012 (EC)).

348. Directive 91/497, art. 5, at 69.

349. Directive 91/497, art. 8, at 69.

350. Directive 91/497, art. 9, at 69.

351. Directive 91/497, art. 9, at 69.

352. Council Directive 91/497, art. 9, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, 1964 J.O. (121) 2012 (EC)).

353. *See* Directive 91/497, art. 10, at 69.

354. Directive 91/497, art. 10, at 69.

operator of the establishment does not remedy the situation within the period specified, the competent national authority may withdraw approval of the establishment.[355] The other Member States and the Commission are to be informed of the suspension or withdrawal of approval of any establishment.[356]

Article 11 provides that Member States must delegate the task of collecting the results of the official veterinarian's ante-mortem and post-mortem inspections for diagnosis of diseases transmissible to humans to a central agency.[357] Where such a disease is diagnosed, this diagnosis must be communicated as soon as possible to the competent veterinary authorities responsible for supervision of the herd from which the animal originated.[358] Member States must submit to the Commission information on certain diseases, particularly in cases where diseases transmissible to man have been diagnosed.[359] In order to secure their access to establishments, Article 12 enables veterinary experts to conduct on-site visits of slaughtering, cutting, cold store, and packaging facilities to ensure uniform application of the rules and regulations set forth in this Directive.[360] Where there is suspicion of non-compliance, Article 14 authorizes the official veterinarian to undertake any veterinary inspection deemed appropriate to investigate the matter.[361]

Clear rules have been laid out for ante-mortem health inspections under Annex I, Chapter VI of Council Directive 64/433.[362] Pursuant to Chapter VI animals must undergo ante-mortem inspection less than twenty four hours after their arrival in the slaughterhouse or less then twenty four hours before slaughter.[363] Each animal intended for slaughter must bear a mark identifying its origin.[364]

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355. Directive 91/497, art. 10, at 69.

356. Directive 91/497, art. 10, at 69.

357. Council Directive 91/497, art. 11, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, 1964 J.O. (121) 2012 (EC)).

358. Directive 91/497, art. 11, at 69.

359. Directive 91/497, art. 11, at 69.

360. Directive 91/497, art. 12, at 69.

361. Directive 91/497, art. 14, at 69.

362. Council Directive 91/497, ann. I, ch. VI, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, 1964 J.O. (121) 2012 (EC)).

363. Directive 91/497, ann. I, ch. VI, at 69.

364. Directive 91/497, ann. I, ch. VI, at 69.

The ante-mortem inspection must determine whether the animals have contracted or show symptoms of a communicable disease and whether they show symptoms of a disease likely to render their meat unfit for human consumption.[365] If an animal is suspected of having a disease that will render its meat unfit for human consumption, slaughter of the animal must be delayed until the animal undergoes an in-depth examination and diagnosis.[366] In the event that a post-mortem inspection is needed to conclusively diagnosis the animals, the official veterinarian can request that the animals are slaughtered separately.[367]

Chapter VII mandates that slaughter animals brought into slaughter premises must be slaughtered immediately and bleeding, flaying, dressing and evisceration must be carried out in a way that avoids any contamination of meat.[368] The chapter also provides that blood intended for human consumption must be collected in clean containers, and must be stirred with hygienic instruments.[369] Uninspected carcasses and offal must not come in contact with carcasses already inspected, and the blood or offal of several animals collected in the same container before the completion of the post-mortem inspection must be declared unfit for human consumption if the carcass of one of the animals is declared unfit for human consumption.[370]

Chapter VIII provides that all animals, animal parts and blood of animals must undergo a post-mortem inspection immediately following slaughter to determine its fitness for human consumption.[371] The following procedures must be performed during the post-mortem inspection: (1) visceral inspection of the slaughtered animal and its organs; (2) palpation of the organs; (3) incision in the slaughter room of organs, which have lesions that may contaminate the carcass; and (4) investigation

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365. Directive 91/497, ann. I, ch. VI, at 69.

366. Directive 91/497, ann. I, ch. VI, at 69.

367. Council Directive 91/497, ann. I, ch. VI, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, 1964 J.O. (121) 2012 (EC)).

368. Directive 91/497, ann. I, ch. VII, at 69.

369. Directive 91/497, ann. I, ch. VI, at 69.

370. Directive 91/497, ann. I, ch. VI, at 69.

371. Directive 91/497, ann. I, ch. VIII, at 69.

of abnormal consistency, odor, color, and smell. The official veterinarian must conduct a visual inspection of head, throat, and internal organs.[372]

Chapter XI lays out the requirements for health marking.[373] Health marking is done under the supervision of the official veterinarian.[374] The health mark must be an oval mark at 6.5 centimeters wide by 4.5 centimeters high bearing the initials of the consigning country in capital letters and the veterinary approval number of the establishment.[375]

Council Directive 72/462 was adopted on December 12, 1972 in order to specify the rules on importation of bovines, swine, and fresh meat from countries that are not part of E.U., or third countries as they are referenced in this Directive.[376]

Chapter 1, Article 4 of Directive 72/462 declares that E.U. will, from time to time, amend lists of countries approved for importation of bovine animals and fresh meat.[377] In order to determine whether a slaughterhouse, cutting plant, or cold store may appear an approved list, consideration should include: (1) the third country's guarantees to comply with this Directive; (2) the third country's regulations pertaining to animals for slaughter and substances which may affect the wholesomeness of the meat; and (3) the organization of the meat inspection services of the third country.[378]

Article 5 authorizes on-the-spot inspections by veterinarians of Member States and the European Commission to verify whether the provisions of the Directive are being observed, and provides that these inspection costs are to be paid by the European Community.[379]

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372. Council Directive 91/497, ann. I, ch. VIII, 1991 O.J. (L 268) 69 (EC) (amending Council Directive 64/433, 1964 J.O. (121) 2012 (EC)).

373. Directive 91/497, ann. I, ch. XI, at 69.

374. Directive 91/497, ann. I, ch. XI, at 69.

375. Directive 91/497, ann. I, ch. XI, at 69.

376. The full name of the Directive is Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries. Council Directive 72/462, 1972 O.J. (L 302) 28-54 (EEC).

377. Directive 72/462, ch. 1, art. 4, at 28-54.

378. Directive 72/462, ch. 1, art. 4, at 28-54.

379. Directive 72/462, ch. 1, art. 5, at 28-54.

Chapter 2, Article 6 states that Member States must typically authorize the importation of animals from non-Member States only under the condition that the animals are free from any disease to which animals are susceptible and the animals have been vaccinated during the preceding twelve months against diseases that are transmissible to other animals.[380] Article 11 provides that Member States can authorize the importation of bovine animals and swine only on the production of a certificate drawn up by an official veterinarian of the exporting non-Member State.[381] Pursuant to Article 12, Member States must ensure that bovines and swine are inspected by the official veterinarian when they arrive in the territory of the Community.[382]

Article 12 prohibits animals from entering the Community if during the inspection it is found that: (1) the animals do not originate from the territory of a third country contained in the list; (2) the animals are infected with or are suspected of being infected with a contagious disease; or (3) the conditions established in this Directive have not been complied with by the exporting non-Member State.[383] The Member State that inspected the animals denied entry in the Community is allowed to take measures such as slaughter, sending back animals, or quarantining animals to ensure the health and safety of the animals within its borders.[384] In the event that animals are denied entry and measures previously mentioned are taken, the exporter or importer is liable for all expenses incurred and will not be compensated from the State.[385]

Article 13 stipulates that imported animals must be slaughtered not later than three working days after their entry into the slaughterhouse.[386] Chapter 3, Article 17 requires Member States to authorize imports of fresh meat cut in halves or quarters only if the parts can be reconstructed as the entire carcass of each animal.[387] This provision ensures that diseased parts have not been removed. All fresh meat must have undergone a post-mortem health inspection carried out by an official veterinarian to determine that it is suitable for slaughter and exportation to the European

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380. Directive 72/462, ch. 2, art. 6, at 28-54.

381. Council Directive 72/462, ch. 2, art. 11, 1972 O.J. (L 302) 28-54 (EEC).

382. Directive 72/462, ch. 2, art. 12, at 28-54.

383. Directive 72/462, ch. 2, art. 12, at 28-54.

384. Directive 72/462, ch. 2, art. 12, at 28-54.

385. Directive 72/462, ch. 2, art. 12, at 28-54.

386. Council Directive 72/462, ch. 2, art. 13, 1972 O.J. (L 302) 28-54 (EEC).

387. Directive 72/462, ch. 3, art. 17, at 28-54.

Community.[388] Such meat must be accompanied by a public health certificate and stored and transported under satisfactory hygiene conditions.[389] The meat must also be inspected upon arrival into the territory of the European Community.[390]

Article 20 requires that Member States prohibit the importation of the following: (1) fresh meat containing residues of estrogenous or thyrostatic substances, antibiotics, antimony, arsenic, pesticides or other substances likely to render the meat harmful to human health;[391] (2) fresh meat treated with ionizing or ultraviolet rays; (3) fresh meat with any form of tuberculosis; and (4) fresh meat from animals found to have tuberculosis or cysticerci.[392] Article 22 provides that Member States must authorize fresh meat to be imported only on presentation of an animal health certificate and a public health certificate furnished by an official veterinarian of the exporting country.[393]

Chapter 4, Article 28 provides that if a contagious animal disease that could possibly endanger the health of the livestock of one of the Member States, erupts in a non-Member country, the Member State concerned is authorized to prohibit the importation of animals whether imported directly or indirectly through another Member.[394] An identical rule applies to a contagious animal disease which can be carried by fresh meat and endanger the public health or the health of the livestock in one of the Member States.[395]

On December 14, 1994, Council Directive 94/65 was established to create a framework for European Community regulation of minced meat and meat preparations.[396] Conditions for inspection, production, marking, labeling, and packaging are laid out in this directive.

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388. Directive 72/462, ch. 3, art. 17, at 28-54.

389. Directive 72/462, ch. 3, art. 17, at 28-54.

390. Directive 72/462, ch. 3, art. 17, at 28-54.

391. Council Directive 72/462, ch. 3, art. 20, 1972 O.J. (L 302) 28-54 (EEC). These substances must exceed permitted levels in order to be prohibited.

392. Directive 72/462, ch. 3, art. 20, at 28-54.

393. Directive 72/462, ch. 3, art. 22, at 28-54.

394. *See* Directive 72/462, ch. 4, art. 28, at 28-54.

395. *See* Directive 72/462, ch. 4, art. 28, at 28-54.

396. Council Directive 94/65, 1994 O.J. (L 368) 10-31 (EC). The full title of the Directive is Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations.

Article 3 requires that fresh minced meat obtained from bovine animals must satisfy these requirements to be traded: (1) it must have been inspected; (2) it must have been marked and labeled; (3) it must be transported by an accompanying commercial document from the dispatching establishment, and (4) frozen meat must bear the veterinary approval number of the production plant and the month and year of freezing.[397]

Minced meat that is frozen or deep frozen must meet these requirements: (1) it must come from fresh boned meat that has been stored no longer than eighteen months;[398] (2) the fresh meat source of minced meat that has been chilled must be used within no more than six days after slaughter of the animals;[399] (3) it must have undergone cold treatment within a period of not more than one hour after wrapping; and (4) it must be packaged properly.[400] Fresh minced meat must be chilled and cooled to an internal temperature below +2°C in the shortest time possible, and deep frozen minced meat must be deep frozen and cooled to an internal temperature below -18°C in the shortest time possible.[401]

Chapter I of Annex 1 contains special conditions of approval for establishments processing minced meat. In order to receive approval, production plants must have a room for mincing and wrapping that is separate from the cutting room.[402] The room for mincing and wrapping meat must be equipped with a thermometer or recording telethermometer.[403] However, only the competent authority may authorize the approval of an establishment in which meat is minced in the cutting room, provided that the mincing is carried out in a clearly separate area of the cutting room.[404] The room for mincing and wrapping meat must contain refrigeration equipment capable of reaching the cooling temperatures stated above.[405]

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397. Directive 94/65, ch. II, art. 3, at 10-31.

398. Directive 94/65, ch. II, art. 3, at 10-31. This rule applies to veal and beef. Directive 94/65, art. 3, at 10-31.

399. Directive 94/65, ch. II, art. 3, at 10-31. With respect to boned, vacuum-packed beef and veal, the time period extends to no more than fifteen days after slaughter of the animals. Council Directive 94/65, 1994 O.J. (L 368), ch. II, art. 3, 10-31 (EC).

400. *See* Directive 94/65, ch. II, art. 3, at 10-31.

401. Directive 94/65, ch. II, art. 3, at 10-31.

402. Directive 94/65, ann. I, ch. I, 1(a), at 10-31.

403. Directive 94/65, ann. I, ch. I, 1(a), at 10-31.

404. Council Directive 94/65, ann. 1, ch. I, 1(a), 1994 O.J. (L 368) 10-31 (EC).

405. *See* Directive 94/65, ann. I, ch. I, 1(a), at 10-31. The fresh minced meat must be chilled and cooled to an internal temperature below +2°C in the shortest time possible, and deep frozen minced meat must be deep

Chapter II of Annex 1 requires examination of meat before mincing occurs, and removal and condemnation of all soiled parts before mincing.[406] It further establishes that minced meat may not be obtained from scrap cuttings, so as to ensure the quality and wholesomeness of the meat produced.[407] In particular, minced meat may not be prepared from muscles of the head, the non-muscular part of the linea alba, the carpus and tarsus region, and bone scrapings.[408] The muscles of the diaphragm and of the masseter may be used only after an investigation for cysticercosis.[409]

Chapter IV of Annex 1 provides specific guidelines for the production of meat preparations. The preparation of meat must occur under temperature control, and meat preparations must be wrapped in such a way as to obviate any risk of contamination.[410] Further, meat preparations may be deep-frozen only once, and they are to be traded within an eighteen month time span.[411]

Pursuant to Chapter V, meat production plants in the business of mincing meat and meat preparations must be inspected by the competent authority to monitor the following: (1) the hygiene of the premises and its staff; (2) sample collection of the products that meet the aforementioned requirements; (3) the microbial condition of the minced meat and meat preparations, (4) the appropriate health markings; and (5) hygienic storage and transport conditions.[412] In addition, Chapter 6 provides that minced meat and meat preparations must have a health mark on the wrapping or packaging certifying that the items meet the requirements of this Directive.[413] Chapter 7 establishes that minced meat and meat preparation wrapping and packaging must be impenetrable in order to prevent the entrance of substances that are harmful to human health.[414]

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frozen and cooled to an internal temperature below -18°C in the shortest time possible. Directive 94/65, art. 5, at 10-31.

406. Directive 94/65, ann. I, ch. II, 1, at 10-31.

407. Directive 94/65, ann. I, ch. II, 2, at 10-31.

408. Council Directive 94/65, ann. 1, ch. II, 1994 O.J. (L 368) 10-31 (EC).

409. Directive 94/65, ann. I, ch. II, at 10-31.

410. *See* Directive 94/65, ann. I, ch. IV(a), at 10-31.

411. *See* Directive 94/65, ann. I, ch. IV(c), at 10-31.

412. *See* Directive 94/65, ann. I, ch. V(1)(a)(i)-(v), at 10-31.

413. Council Directive 94/65, ann. 1, ch. VI(1), 1994 O.J. (L 368) 10-31 (EC).

414. *See* Directive 94/65, ann. I, ch. VII, at 10-31.

C. United States Provisions for Residue Testing

In addition to inspection, residue testing is also vital to the production of safe, wholesome beef. Under FMIA, FSIS is responsible for inspecting meat products to ensure consumer safety.[415] An essential part of the inspection program is the FSIS Residue Program, which has been designed to detect and monitor residues of animal drugs and other chemical contaminants in the meat products.[416] The FSIS Residue Program collects samples of meat products at domestic slaughterhouses and analyzes them for unacceptable residue levels. The residue analysis is conducted either by one of the three field FSIS laboratories, by an accredited laboratory, or by a laboratory under contract with FSIS.[417]

Section 138a(a) of 7 U.S.C. authorizes USDA to administer a National Laboratory Accreditation Program that determines the minimum quality and reliability standards for laboratories conducting residue testing of agricultural products or making claims to the public concerning chemical residue levels on agricultural products.[418] Further, the Secretary of Health and Human Services is responsible for approving state agencies or private nonprofit entities as accrediting bodies to implement certification and quality assurance programs.[419] To gain accreditation, a laboratory is required to submit an application to the Secretary of Health and Human Services.[420]

D. E.U. Rules for Monitoring Residues in Meat

Council Directive 96/23 was adopted on April 29, 1996 to establish measures for monitoring substances and residues in live animals and animal products.[421] Article 3 prescribes monitoring plans for the detection of residues or substances.[422]

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415. FSIS Directive 10530.3, *Contamination Response System* (1993), *at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10530-3.pdf (last visited Jan. 2, 2006).

416. *Id*.

417. *Id*.

418. 7 U.S.C. § 138a(a) (2000).

419. *Id.* § 138a(c).

420. *Id.* § 138a(d).

421. Council Directive 96/23, 1996 O.J. (L 125) 10-32 (EC). The full title of the Directive is Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products.

422. Directive 96/23, ch. II, art. 3, at 10-32.

The production process of animals and the production of primary products of animal origin must be monitored for the purpose of detecting the presence of residues and substances categorized by "Group A" and "Group B" of this Directive in live animals, their excrement, body fluids, tissue, animal products, animal feed, and drinking water.[423] Group A substances have an anabolic effect.[424] The unauthorized substances include stilbenes, stilbene derivatives, stilbene salts and esters, antithyroid agents, steroids, resorcylic acid lactones, zeranol, and beta-agonists.[425]

Group B substances are divided into three categories of veterinary drugs and contaminants.[426] The first category includes antibacterial substances such as sulphonomides and quinolones; the second class comprises other veterinary drugs, such as antihelmintics, anticoccidials such as nitroimidazoles, carbamates, pyrethoids, sedatives, non-steroidal anti-inflammatory drugs, and other pharmacologically active substances; and the third category consists of other substances and environmental contaminants, including organochlorine compounds, organophosphorus compounds, chemical elements, mycotoxins, and dyes.[427]

Article 4 requires Member States to designate the inspection duties to a central public department, so that fraudulent use of substances on stock farms may be discovered.[428] According to Article 5 and Annex III, the inspection agency must adopt a residue control plan aimed at revealing the reasons for residue hazards in food of animal origin on farms and in slaughterhouses.[429] Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week, so as to maintain the element of surprise.[430] With respect to Group A substances, inspections should be carried out with an eye toward detecting illegal administration of prohibited substances and the abusive administration of approved substances.[431]

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423. Directive 96/23, ch. II, art. 3, at 10-32.

424. Directive 96/23, ann. I, at 10-32.

425. Directive 96/23, ann. I, at 10-32.

426. Council Directive 96/23, ann. I, 1996 O.J. (L 125) 10-32 (EC).

427. Directive 96/23, ann. I, at 10-32.

428. Directive 96/23, art. 4(1), at 10-32.

429. Directive 96/23, art. 5(1), (2)(c) & ann. III, at 10-32.

430. Directive 96/23, ann. III(1), at 10-32.

431. Council Directive 96/23, ann. III(2), 1996 O.J. (L 125) 10-32 (EC).

The samples must be identified in consideration of these minimum criteria: age, sex, species, fattening system, available background information, and all evidence of misuse and abuse of Group A substances.[432] For Group B substances, inspections should be carried out with the specific aim of controlling the compliance with maximum residue limits for residues of veterinary medicinal products and other contaminants.[433]

An E.U. guideline for monitoring residues in meat and meat products was adopted on February 23, 1998. Commission Decision 98/179 prescribes the procedures for official sampling of residues and substances that are illegally administered to cattle intended for human consumption and for controlling compliance with the maximum residue limits for residues of veterinary drugs and maximum levels of pesticides.[434] The Annex to the Decision lays out the precise rules for monitoring residue and substance sampling as follows. The competent authority is tasked with the duty of designating an agency to take and organize the transport of the official control samples.[435] The analysis of the samples is to be conducted in laboratories approved for official residue control, and regular proficiency testing schemes must be implemented to routinely check the competence of the laboratories.[436]

Section 2.1 of the Annex states that samples must be random and unforeseen. All Member States must ensure the element of surprise in the checks. Random sampling should be carried out at varying intervals throughout the whole year, because a number of substances are only administered in a particular season.[437]

E. United States' Science-Based Production Control System

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432. Directive 96/23, ann. III(2), at 10-32.

433. Directive 96/23, ann. III(3), at 10-32.

434. Commission Decision 98/179, 1998 O.J. (L 65) 31-34 (EC).

435. Decision 98/179, ann. I, 1.2, at 32.

436. Decision 98/179, ann. I, 2.1, at 32.

437. Council Directive 98/179, 1988 O.J. (L 65) 32 (EC).

In 1998, USDA established the Hazard Analysis and Critical Control Point (HACCP) program for meat processing plants to prevent microbiological, chemical, and physical hazards.[438] HACCP is a science-based process used by both FDA and USDA to determine the potential danger points in food production and to define a strict monitoring system.[439] HACCP began in 1959 when the Pillsbury Corporation cooperated with the Unites States Army and the National Aeronautics Space Association (NASA) to create the "Modes of Failure" program for the astronauts.[440] The program was designed to prevent hazards that could cause food-borne illnesses by applying science-based controls from raw materials to finished products.[441] The HACCP Final Rule went into effect for medium and large slaughterhouses and meat production plants in 1998, for small facilities in January 1999, and for very small facilities in January 2000; they are now required by FSIS to systematically target and reduce harmful bacteria.[442]

Meat processing plants must develop a HACCP plan for each product.[443] The seven principles of HACCP are: (1) analyze hazards, which requires the identification of potential hazards associated with a food and measures to control those hazards; (2) identify critical control points, which requires the identification of points in a food's production process at which potential hazards can be controlled or eliminated; (3) establish preventive measures with critical limits for each control point; (4) establish procedures to monitor the critical control points; (5) establish corrective actions to be taken when monitoring shows that a critical limit has not been met; (6) establish procedures to verify that the system is working properly; and (7) establish effective recordkeeping to document the HACCP system.[444] The HACCP Final Rule requires all slaughter and processing plants to adopt a system of HACCP process controls to prevent food safety hazards, to conduct microbial testing for generic *E. coli* to verify that their control systems are working as intended to prevent fecal contamination, to meet

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438. Food Safety Research Information Office (FSRIO), *A Focus on Hazard Analysis and Critical Control Points* (2003), *at* http://fsrio.nal.usda.gov/document_fsheet.php?product_id=155 (last visited Jan. 3, 2006) [hereinafter FSRIO].

439. *Id*.

440. *Id.*

441. *Id.* FDA Backgrounder, *HACCP: A State-of-the-Art Approach to Food Safety* (2001), *at* http://www.cfsan.fda.gov/~lrd/bghaccp.html (last visited Jan. 6, 2006).

442. *See* FSRIO, *supra* note 438.

443. 9 C.F.R. § 417.2(b) (2005).

444. *Id.* § 417.2(c)(1)-(7).

pathogen reduction performance standards set by FSIS for raw meat products, and to adopt and implement a written sanitation standard operating procedure.[445]

F. E.U.'s Science-Based Quality Assurance System

After facing several food scares in the 1990s, such as BSE, E.U. established the European Food Safety Authority (EFSA) in 2002.[446] EFSA provides independent scientific advice and risk assessments on food and food safety matters.[447]

EFSA has five chief objectives: (1) to provide scientific opinions and advice on food safety issues formerly addressed to EFSA by the European Commission, the European Parliament, the Member States, or EFSA itself; (2) to assess the risk factors for specific foods; (3) to monitor specific risk factors and diseases in order to provide scientific opinions on tests and methods of controlling these risk factors and diseases; (4) to prepare guidelines for the future evaluation of food-related health claims; and (5) to apply and promote new, harmonized scientific approaches for hazard and risk assessment of food and feed.[448]

VII. COMPARISON OF THE UNITED STATES' AND THE E.U.'S APPROACHES TO BEEF REGULATION

An examination of the United States and E.U. regulation of cattle farming and beef production and processing reveals some notable similarities and differences. This section entails a brief comparison of the two systems. The analysis will explore the quality of the legislative drafting, the likelihood of implementation, the adequacy of consumer protections, the voluntary or compulsory nature of the measures, and the requirement of record retention.

A. Animal Drug Regulatory Schemes

The first area of review is animal drug regulatory schemes. One marked difference in the pertinent American and E.U. rules is that the United States permits the administration of growth

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445. *See* FSRIO, *supra* note 438.

446. EFSA, *Moving Towards Full Strength* (2005), *at* http://www.efsa.eu.int/about_ efsa/catindex_en.html (last visited Jan. 3, 2006).

447. *Id.*

448. *See generally id*.

hormones to cattle intended for use as human food,[449] whereas the E.U. has banned such practices.[450] In this area of regulation, both the United States and the E.U. have drafted well-written, clearly articulated, and easy to comprehend rules.

FDA regulations list the hormones and growth promoters that are federally approved, and specify the permissible uses and dosages of the approved drugs. For example, estradiol valerate and norgestomet can be implanted in combination to synchronize estrus or ovulation.[451] The laws are specific in many other respects as well. They indicate whether the drugs are to be administered as injections or implants. Express details provide that certain drugs are only to be administered to certain types of cattle. For instance, 10 milligrams of estradiol benzoate may be administered to suckling beef calves, and 20 milligrams to steers and heifers fed in confinement for slaughter.[452]

E.U. also expressly states its proscriptions of the use of growth hormones, and the specific methods of administration where the utilization of hormones is permitted for therapeutic purposes. For example, Member States may authorize the therapeutic administration to livestock of testosterone, progesterone, and their derivatives that readily yield the parent compound on hydrolysis after absorption.[453] The directives also clarify that hormonal, thyrostatic, and beta-agonists are all prohibited for use as growth enhancing drugs.[454]

With respect to the likelihood of implementation, both the United States and the E.U.'s regulations contain loopholes that may allow for abuse of the prohibitions and half-hearted implementation of the rules. However, the E.U.'s laws are more likely to achieve the desired prohibitions, because farmers are not authorized to possess or administer hormonal drugs that are only allowed for therapeutic use.[455] Only official veterinarians, their supervisees, and other authorized persons are allowed to administer such drugs for therapeutic purposes, and farmers are prohibited from processing them.[456]

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449. *See supra* Section II.A.

450. *See supra* Section II.B.

451. 12 U.S.C. § 522.850 (2000).

452. *Id.* § 522.841.

453. *See* Council Directive 96/22, art. 4, 1996 O.J. (L 125) 3, 5 (EC).

454. Directive 96/23, art. 4, at 3-5.

455. Council Directive 2003/74, 2003 O.J. (L 262) 17-21 (EC).

456. Council Directive 96/23, art. 4, 1996 O.J. (L 125) 10-32 (EC).

Growth enhancing drugs have permissible uses in both the United States and E.U., hence they are available on the market and can be purchased legally in some circumstances. Thus, the possibility of them being used illegally in incorrect dosages, for unintended uses, and by unauthorized persons exists in both places. However, the E.U. enactments contain more detailed monitoring provisions that mandate surprise inspections of animals, their excrements, bodily fluids, drinking water, and stables in order to test for residues of prohibited drugs and substances.[457] This provides more incentive for livestock producers to obey the rules.

The laws can also be compared according to their effectiveness in consumer protection. The law in the United States prohibits the administration of growth hormones in unsafe ways. For instance, administration of estradiol valerate and norgestomet combinations are prohibited in cows that produce milk for human consumption. This provision is included in order to preserve the quality and wholesomeness of the milk supply.[458] These implants must be removed on the tenth day and collected and burned in order to avoid exceeding the approved dosages for animals intended for human consumption.[459]

E.U. operates under the premise that growth promoting hormones are dangerous to human health, and thus there are no tolerable daily intakes for any of them.[460] In order to prevent treatment of cattle intended for human consumption, Council Directive 96/23 enumerates the hormones and their derivatives that are banned, and prohibits the importation of beef and beef food products treated with such drugs.[461] The European Council has drawn up such provisions with the aim of ensuring that the beef supply of Member States is safe for human food.[462]

In the United States and E.U. the laws on animal drugs are compulsory, and penalties apply to violators.[463] Additionally, E.U. has provisions for recordkeeping.[464] Specifically, the official

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457. Directive 96/23, art. 8, at 10-32.

458. 12 U.S.C. § 522.850 (2000).

459. *Id*.

460. *See* Europa Hormones, *supra* note 60.

461. Council Directive 96/23, 1996 O.J. (L 125) 3-9 (EC).

462. Directive 96/23, at 3-9.

463. Directive 96/23, art. 4, at 3-9.

464. Directive 96/23, art. 4, at 3-9.

veterinarian is required to maintain records of animals treated by hormonal substances for therapeutic purposes.[465] Farm animals undergoing such treatment must be clearly identified, and such treatment must be registered by the veterinarian responsible.[466] The United States' rules do not contain such provisions.

B. Organic Livestock Production Regulations

The second area of comparison is the organic livestock production regulations. With respect to the quality of legislative drafting, the two systems are similarly adequate; but, the E.U. regulations governing the actual livestock rearing process surpass the United States regulations in terms of depth and detail. For example, the United States' OFPA lacks provisions on free range and open air exercise, prohibitions on overstocking of cattle in pastures, and advisory statements on the use of husbandry practices that encourage resistance to diseases and infections.[467]

The likelihood of implementation of these rules is fair, because both the United States and E.U. have implemented sufficient monitoring mechanisms in order to increase the certainty of implementation and to detect residues of prohibited substances and drugs. OFPA is slightly more clear, comprehensive, and explicit with respect to monitoring provisions than its European counterpart, because the provisions are included in OFPA itself; whereas, E.U. rules are contained in separate pieces of legislation, apart from Regulation 1804/1999, that provide for inspection of production and handling establishments and substance residue testing.[468]

For example, in the United States producers and handlers of organic livestock must create an organic plan.[469] OFPA establishes a built-in check on the monitoring system because organic farmers must not only certify to USDA, but also to the state official, and to the certifying agent on an annual basis that all agricultural products have been produced organically.[470] OFPA provides for annual on-site inspections by the certifying agent of each farm and handling operation, and the rules require periodic residue testing by certifying agents of agricultural products produced on certified organic

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465. Directive 96/23, art. 4, at 3-9.

466. Council Directive 2003/74, 2003 O.J. (L 262) 19 (EC).

467. The United States federal legislation may be less detailed, because the regulatory functions are shared by state and local governments such that areas that are unaddressed in federal laws may be covered in state or local laws. *See* 7 U.S.C. § 450 (2000).

468. *See*, *e.g.*, Council Regulation 1804/1999, 1999 O.J. (L 222) 1.

469. OFPA of 1990, 7 U.S.C. § 6506(a)(2) (2000).

470. *Id.* § 6506(a)(4).

farms and in handling operations to determine whether they contain pesticides or other nonorganic residues.[471] OFPA requires public access to certifying documents.[472] Collectively, all of these procedures increase the likelihood that the regulation will be followed by organic livestock producers.

Concerning the adequacy of consumer protection, it is important to note that E.U. Regulation 1804/1999 on organic livestock production is less airtight than the American OFPA, because it allows conversion of nonorganically produced cattle to organically produced cattle.[473] Plainly stated, livestock that was not initially raised pursuant to the organic production regulation can undergo a specified conversion process. Once that process is completed, the cattle can be classified and sold as organically produced. Regulation 1804/1999 opens the door to abuse and consumers may suffer, because there is a possibility that producers will market cattle as organically produced that have not been held in conversion for the required twelve month period.

Another shortcoming of the regulation is that it does not require organic farmers to inform consumers that converted beef was once subjected to nonorganic rearing methods before it underwent the conversion process. If Regulation 1804/1999 contained such a provision, this may improve the adequacy of consumer awareness. Granted, in some ways providing consumers with relevant information needed to make informed purchasing decisions is a separate matter from protecting consumers from unsafe or unhealthy products by regulating and monitoring the beef production process. However, adequate consumer protection requirements may include a provision on supplying consumers seeking organically produced food with full information on converted organic beef. Otherwise, there are significant measures in place to bolster the likelihood of implementation of the organic requirements.

Organic production is not compulsory in either system in the sense that producers may elect nonorganic production. Once they seek organic certification, however, the rules become compulsory. Both systems require record retention that is subject to inspection by the certifying agent. In E.U., records must be kept on all animals that are treated with veterinary medicinal products.[474] In the United States, organic cattle farmers must keep records on all animals treated with medicines, on all feeds fed to the livestock, and on all animals so that they can be traced back to a specific farm.[475]

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471. *Id*. § 6506(a)(6).

472. *Id.* § 6506(a)(2).

473. Council Regulation 1804/1999, 1999 O.J. (L 222) 1, 9-10 (EC).

474. Regulation 1804/1999, ann. III (4), at 25.

475. 7 U.S.C. § 6506(b)(1)(B) (2000).

C. Humane Methods of Slaughter

The regulations on the humane methods of slaughter in the United States and E.U. are very brief and substantially similar.[476] The quality of the legislative drafting in both is sufficient, because they each succinctly and clearly state the approved methods of slaughter allowing very little room for variance in interpretation.

The legislation in the United States and E.U. are both wanting with regard to measures that increase the likelihood of implementation. Express provisions requiring random inspections of slaughterhouses would improve upon this inadequacy. The rules in both systems are compulsory, but they do not contain recordkeeping provisions. From an economic efficiency standpoint, the United States and E.U. may have more incentive to allocate governmental resources to ensure safe and wholesome beef and beef products than to tightly monitor humane slaughtering practices. After all, the slaughtering practices in either system do not impact the quality and integrity of the beef food supply.

D. Regulation of BSE and Other Contagious Diseases

The next topic of comparison is the regulation of BSE and other contagious diseases. Both the United States and E.U. have skillfully-drafted, easy-to-interpret legislation in this area. In the case of the United States legislation, wide discretion is given to USDA to protect the meat supply in the United States. CCDA and the BSE control measures clearly state that cattle produced for human consumption must be tested for the presence of communicable diseases,[477] and they provide for the seizure, treatment, and destruction of cattle found to be diseased and unfit for human consumption.[478] The measures authorize USDA to prohibit the importation and exportation of diseased livestock. The United States policies on BSE signifycantly differ from those of E.U. in notable ways.

As regards the E.U. regulation of BSE, detailed rules are established for the determination of a Member State, third country, or region's BSE status, with a five category system of country classification ranging from BSE-free to high incidence of BSE.[479] The regulation gives precise information on the measures that must be taken to ensure that BSE is timely detected and eradicated.[480] Each Member State must carry out a yearly program for monitoring BSE that involves

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476. *See*, *e.g.*, Humane Methods of Slaughter Act of 1958, 7 U.S.C. §§ 1901-1906 (2000); European Convention for the Protection of Animals for Slaughter, 1998 O.J. (L 137) 27-38.

477. 21 U.S.C. § 114(a) (2000).

478. 7 U.S.C. § 8306(a) (2000).

479. Council Regulation 999/2001, 2001 O.J. (L 147) at 13-15.

480. Regulation 999/2001, at 1.

rapid post-mortem screening.[481] The screening is to be performed on cattle showing signs of any form of disease or neurological disorder, cattle over thirty months of age, cattle that are found dead on the farm or during transport, and all animals slaughtered for human consumption.[482] Specified risk materials have been designated under both systems to prevent these animal parts from introducing BSE into the human food supply.[483] These examples illustrate the comprehensiveness of the regulations. The United States has not detected nearly as many positive cases of BSE as has the E.U., which may explain the reason that there is no extensive categorization system in the United States.

The likelihood of effective implementation is fairly great in the United States and in the E.U. because regulations have become more stringent in order to address the seriousness of the communicable diseases, such as BSE, that are currently threatening the cattle population and the beef supply. In the United States and Europe, the regulations provide official inspectors and veterinarians with extensive authority to access production plants and slaughterhouses at all times of the day and night for random unannounced checks.[484] Specific rules governing sampling and testing during the ante-mortem and post-mortem stages increase the likelihood of effective implementation of the procedures. Surveillance systems for the detection of BSE exist in America and Europe, and these systems have been created to aid implementation of detection and eradication measures.[485]

Increased incentive to implement measures to detect and destroy cattle and beef food products infected with BSE or other diseases that render the meat dangerous to human health is provided through government indemnity programs in the United States and E.U. If farmers, handlers, and producers are indemnified for their losses, they are more likely to destroy cattle and beef that are found to be infected with diseases that cause them to be unfit for human consumption. E.U. provides for compulsory reporting and examination of all cattle that exhibit clinical signs of BSE and all cattle that test positive for the disease.[486]

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481. Regulation 999/2001, art. 6, at 5.

482. Regulation 999/2001, at 16.

483. Regulation 999/2001, at 21; *see also* FSIS Measures, *supra* note 1, at 6.

484. *See* FSIS Measures, *supra* note 1, at 6; Council Regulation 999/2001, 2001 O.J. (L 147) at 3.

485. *See* FSIS Measures, *supra* note 1, at 1, 3-4; Council Regulation 999/2001, 2001 O.J. (L 147) at 1.

486. Council Regulation 999/2001, 2001 O.J. (L 147) at 1.

The adequacy of consumer protection against BSE and other diseases is fairly decent in both the Unites States and E.U. Strict detection and eradication standards have been implemented in both countries. It is important to note that none of the measures provide absolute guarantees that no infected beef will enter the food supply. Samples are taken since it is economically infeasible to individually test all livestock that are placed on the market. Therefore, not all beef is tested for BSE and other diseases. However, as a general matter, the safety and quality of the beef supply is amply protected by the regulations in both systems.

In the United States and E.U., the law requires immediate destruction of livestock that test positively for diseases that render meat unfit for human consumption.[487] In E.U., Member States must ensure that no parts of the body of animals being screened for TSE are used for human food, animal feed, or fertilizers until the laboratory examination has been concluded with negative results.[488] Similar provisions have been implemented in the United States to protect consumers.

Since 1989, APHIS has banned the importation of live cattle and cattle products, such as rendered protein products, from countries where BSE exists with the intention of protecting American consumers from BSE exposure. In 2000, APHIS banned imports of rendered animal protein products from BSE-restricted countries.[489] In 1997, FDA prohibited the use of certain mammalian protein in the manufacture of ruminant animal feed in order to prevent the spread of BSE to cattle in the United States.[490] APHIS has formulated an emergency response plan for utilization if BSE is detected in the United States.[491] These measures represent several of the numerous steps that the United States has taken to ensure consumer safety with respect to BSE.

In addition to the above-mentioned classification scheme, monitoring and screening system, and indemnification programs, E.U. has also instituted unique provisions to protect its citizens from BSE. National Reference Laboratories and a Community Laboratory have been designated with the aim of ensuring uniformity and reliability of scientific analysis.[492]

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487. 9 C.F.R. § 53.4 (2005); Council Regulation 999/2001, 2001 O.J. (L 147) at 24.

488. Council Regulation 999/2001, 2001 O.J. (L 147) at 18.

489. *See* APHIS, USDA, Bovine Spongiform Encephalopathy, *at* http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/fs_ahbse.htm (last visited Dec. 30, 2005) [hereinafter APHIS BSE].

490. *See* FSIS Measures, *supra* note 1.

491. See APHIS BSE, *supra* note 489.

492. Council Regulation 999/2001, ann. X, 2001 O.J. (L 147) 34.

The regulations regarding BSE and other infectious diseases are compulsory in the United States and E.U. Regulations in E.U. allow Member States to undertake voluntary surveillance of TSE in higher risk animals, such as those originating from countries with indigenous TSE.[493] This is an exception, because the relevant BSE and infectious disease regulations are all compulsory in nature.

The requirements for record retention are equally stringent under the United States and the E.U. regulations. In particular, all detected cases of BSE must be recorded and reported to USDA,[494] in the case of the United States, and to the European Commission,[495] in the case of the E.U. E.U. has defined rules for the reports of TSE. For instance, the information reported must entail the number, age distribution, geographical distribution of positive cases of BSE, as well as the year and month of birth for BSE cases born after the introduction of a ban on using ruminant protein in animal feed.[496] Records of all positive cases in the E.U. must be retained for seven years.[497]

E. Inspection Regulations in the United States and E.U.

The final subject is inspection regulations in the United States and E.U. Regarding the quality of legislative drafting, the regulations in both systems are well written. The rules clearly articulate inspection requirements and permit very little, if any, room for differing interpretations. In the United States and E.U., the laws are fairly comprehensive in that they mandate inspections at various stages of the slaughtering and meat production process.

For example, in the United States FMIA requires the following: (1) ante-mortem inspections, (2) post-mortem inspections, and (3) pre-packaging inspections.[498] Subsequent inspections are required before beef and beef products are offered for marketing, and sanitation inspections are required for all slaughtering, canning, packing, and similar establishments.[499] FMIA expressly states that inspections

493. Regulation 999/2001, ann. III, at 16.

494. *See* FSIS Measures, *supra* note 1.

495. Council Regulation 999/2001, ann. IV, 2001 O.J. (L 147) 20.

496. Council Regulation 999/2001, ann. IV, at 20.

497. Council Regulation 999/2001, ann. II, ch. A(d), at 13.

498. *See supra* Section VI.A.

499. 21 U.S.C. § 604 (2000).

may be carried out randomly and without prior notice.[500] Similar provisions exists in the E.U. inspection regulations.[501]

Concerning the comprehensiveness of the E.U.'s inspection regulations, Directive 64/433/EEC clearly states the requirements for inspection at different stages of the meat production process. For instance, Directive 64/433/EEC mandates ante-mortem and post-mortem inspections by the official veterinarian.[502] The drafting of this Directive is slightly more specific than its American counterpart.

Directive 64/433/EEC explicitly mandates that meat affected with certain conditions or derived from certain sources must be declared unfit for human consumption.[503] Specifically, it provides that meat from animals with such diseases as actinobacillosis, blackleg, rabies, tetanus, acute lesions of broncho-pneumonia, pleurisy, peritonitis, arthritis, pericarditis, enteritis, meningo-encephalo-myelitis must be declared unfit for human consumption.[504] Directive 64/433/EEC also provides that meat must be declared unfit for consumption that is derived from animals that are stillborn, unborn, slaughtered too young, and emaciated, to name a few of the enumerated conditions.[505]

The likelihood of implementation of the inspection regulations is fair in both systems. Mainly due to economic constraints that hinder thorough inspection of each slaughterhouse and meat-processing plant, derogations occur. However, the inspection regulations of the United States and E.U. have built-in checks to increase the likelihood of implementation.

For example, there is continuous inspection of slaughterhouses and meat-processing plants in the United States in order to ensure compliance with federal regulations.[506] In the United States, several provisions of FMIA are intended to monitor implementation of the inspection regulations. For instance, the requirements for inspecttions at various stages of the meat production process are built-in checks, which seek to ensure the safety and wholesomeness of the beef supply through repeat inspections before the meat reaches supermarkets. In addition, inspectors must prepare official

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500. *Id.* § 620(f).

501. Commission Decision 98/179, ann. I, 2.1, 1998 O.J. (L 65) at 32 (EC).

502. Council Directive 64/433, 1964 J.O. (121) 2012-2032 (EEC).

503. Directive 64/433, at 2012-2032.

504. Directive 64/433, at 2012-2032.

505. Directive 64/433, at 2012-2032.

506. 21 U.S.C. § 608 (2000).

certificates clearly stating the condition of inspected cattle.[507] Owners must obtain health certificates in order to gain clearance for vessels carrying beef for export from the United States ports to foreign countries.[508]

Additional measures are contained in FMIA to verify implementtation of the inspection provisions. USDA must grant certification to all countries that import carcasses and beef products into the United States so as to verify that the country employs reliable analytical methods and comparable standards for detecting residues in meat. The review of certification applications necessarily entails the inspection of individual establishments to confirm that inspection programs in foreign countries comply with United States standards.[509]

Only designated employees are authorized to remove the official suspect identification device of animals identified as "U.S. Suspect" when the animals are released, and the removal must be reported to the area supervisor.[510] This provision is included in FMIA as another built-in check intended to prevent the release of animals suspected of harboring diseases that may render them unfit for human consumption from entering the food supply.

When an animal identified as "U.S. Suspect" is released for any purpose, the official suspect identification device may be removed only by a Program employee, who must report the removal to the area supervisor.[511] When a suspect is to be released, the operator of the official establishment must first obtain permission for the removal of the animal from the local, state, or federal livestock sanitary official.[512] Similarly, the tags for livestock identified as "U.S. Condemned" must not be removed, and the tag number must be reported to the veterinarian in charge by the inspector who affixed the tag and also by the inspector who supervised the disposal of the carcass.[513] All of these provisions are included to increase the likelihood of implementation.

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507. *Id.* § 617.

508. *Id.*

509. *Id.* § 620(f).

510. 9 C.F.R. § 309.2(n) (2005).

511. *Id*. § 309.2(o).

512. *Id.* § 309.2(p).

513. *Id.* § 309.13.

In E.U., Directive 64/433/EEC has built-in checks to improve the likelihood of implementation by Member States. For example, carcasses and beef items must be accompanied during transport by accompanying commercial documents.[514] These documents are provided by the dispatching establishment and they must bear the veterinary approval number of slaughtering or processing plant.[515] A health certificate is required for meat from a slaughterhouse in a restricted region and meat that is sent from one Member State to another Member State.[516]

Directive 64/433/EEC requires the presence of an official veterinarian at least once a day in slaughterhouses, cutting plants, and cold stores.[517] In each Member State, a central agency must collect the results of the official veterinarian's ante-mortem and post-mortem inspections for diseases transmissible to humans.[518] In addition, Directive 72/462/EEC authorizes on-the-spot inspections by veterinarians of Member States and the European Commission to verify whether the third countries that import fresh meat into the E.U. meet specified standards, and provides that these inspection costs are to be paid by the European Community.[519]

Directive 94/65/EC requires that fresh minced meat that is to be traded must be transported by an accompanying commercial document from the dispatching establishment, and frozen meat must bear the veterinary approval number of the production facility.[520] Commission Decision 98/179/EC requires that all Member States conduct surprise checks to sample for residues and substances that are illegally administered to cattle.[521] These checks must be random and unforeseen, and they must be performed at intervals throughout the year to test for substances that are only administered seasonally.[522] These provisions are included to increase the likelihood of implementation of the inspection regulations.

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514. Council Directive 64/433, 1964 J.O. (121) 2012-2032 (EEC).

515. Directive 64/433, at 2012-2032.

516. Directive 64/433, at 2012-2032.

517. Directive 64/433, at 2012-2032.

518. Directive 64/433, at 2012-2032.

519. Council Directive 72/462, art. 5, 1972 O.J. (L 302) 28 (EEC).

520. Council Directive 94/65, 1994 O.J. (L 368) 10-31 (EC).

521. Commission Decision 98/179, 1998 O.J. (L 65) 31-34 (EEC).

522. Decision 98/179, at 31-34 (EC).

In the United States and E.U. the inspection regulations are equally adequate with respect to consumer protection provisions. In both systems, the requirements for inspection at various phases in the meat production process are included in order to ensure that safe and wholesome beef enters the food supply. Moreover, immediate destruction and disposal of animals, carcasses, and meat that is found to be unfit for human consumption is required in the United States and E.U.[523] Animals that have been condemned must be isolated and slaughtered separately in order to avoid contamination of healthy animals intended to be slaughtered for human consumption.[524]

Both the United States and E.U. inspection regulations include science-based quality control programs that strengthen consumer protection measures. Particularly, the United States' Final provide that all slaughter and processing plants must adopt a system of HACCP process controls to prevent food safety hazards, conduct microbial tests for *E. Coli* to ensure that factory control systems are effectively preventing fecal contamination, meet pathogen reduction performance standards established by FSIS for raw meats, and adopt and implement a written sanitation standard operating procedure.[525] Similarly, the E.U.'s EFSA evaluates the risk factors for specific foods, monitors specific risk factors and diseases for specific foods to provide scientific opinions on measures for controlling these risk factors and diseases, composes guidelines for future assessment of food-related health claims, and apply and promote harmonized scientific approaches for hazard and risk assessment of food and feed.[526]

Considering the large volume of cattle and beef products that enter and exit meat processing plants in the United States and the E.U., it is impossible for each animal or product to be tested before it is declared fit for consumption. For instance, in the United States the sampling frequency requirement for official slaughtering establishments testing cattle for *E. coli* is one test per 300 carcasses, with a minimum requirement of one sample each week.[527] Clearly, economic limitations prevent the United States and E.U. from testing each cattle or beef article that is produced. Despite reasonable economic justifications, there is still a small risk that contaminated meat will not be detected under these rules.

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523. 9 C.F.R. § 53.2 (2004); Council Regulation 999/2001, art. 13(1)(a)-(c), 2001 O.J. (L 147) 1, 7-8.

524. 21 U.S.C. § 604 (2000); Council Regulation 999/2001, art. 13(1)(a)-(c), at 7-8.

525. *See* FSRIO, *supra* note 438.

526. EFSA, *Moving Towards Full Strength* (2005), *at* http://www.efsa.eu.int/about_ efsa/catindex_en.html (last visited Jan. 3, 2006).

527. 9 C.F.R. § 310.25 (2005).

The E.U. regulations that aim to ensure consumer safety in Directive 94/65/EEC require freezing and chilling meat in order to avoid contamination with pathogens and microbes that would render the meat dangerous to human health. For example, fresh minced meat must be chilled and cooled to an internal temperature below +2°C in the shortest time possible, and deep frozen minced meat must be deep frozen and cooled to an internal temperature below -18°C in the shortest time possible.[528] Similar provisions are likely to be present in the state and local inspection regulations in the United States.

The inspection regulations in the United States and E.U. are of a compulsory nature. For live cattle, beef, and beef food products to be placed on the market, they must be inspected in order to ensure that they are safe and disease-free. Therefore, mandatory implementation of the rules is needed to protect American and European consumers.

Both the United States and E.U. have recordkeeping requirements that allow them to trace cattle, from which beef food products are derived, back to the herd in case contagious diseases or other conditions are found upon inspection.

VIII. CONCLUSION

Even though their approaches to regulation of the beef industry differ in several ways, both the United States and E.U. have established legislation and implementing regulations that are generally effective in this area. This article has sketched an overview of the requirements for animal drugs, organic livestock, humane slaughter methods, BSE and other contagious diseases, and inspection of beef production facilities in both legal systems. A brief comparison of the American and E.U. regulatory systems examined the quality of legislative drafting, the probability of implementation, the adequacy of consumer protections, the voluntary or compulsory nature, and the requirement of recordkeeping. The analysis revealed that the regulations in each system seek to achieve fairly similar ends, though sometimes through different means.

528. Council Directive 94/65, art. 3, 1994 O.J. (L 368) 10-31 (EC).