December 6, 2006

Jack Kane
Deputy Administrator
Business and Standards Division
Department of Labor and Industry
P.O. Box 200517
Helena, MT 59620-0517

Re: MAR Notice No. 24-351-212, Proposed Rules regarding Country of Origin Placarding Act, M.C.A. 30-12-7.

Dear Mr. Kane:

The American Meat Institute (AMI) and the Food Marketing Institute (FMI) (collectively the Institutes) submit the following comments pertaining to MAR Notice No. 24-351-212, proposed rules pertaining to the Country of Origin Placarding Act, Montana Code Annotated Title 30, chapter 12, part 7. For the reasons set forth below, we believe that the provisions within H.B. 406, and its attendant proposed regulations, that mandate country of origin labeling through placarding represent an unconstitutional exercise of power in violation of multiple provisions of the United States Constitution, including the Supremacy Clause of Article VI, Section 2; the Commerce Clause of Article I, Section 8; the Free Speech Clause of the First Amendment; and the Eighth and Fourteenth Amendments.

Accordingly, we respectfully request that the Montana Department of Labor and Industry withdraw the proposed regulation. If the Department decides to proceed in this matter, we hereby request that the Department fully state its reasons for overruling the grounds urged herein against adoption.

I. Montana Country of Origin Law Violates Supremacy Clause of the U.S. Constitution

Article VI, Section 2 of the U.S. Constitution provides that, "the Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[1] Under the Supremacy Clause, laws or regulations that conflict with federal law are without effect.[2] As discussed more fully below, Montana's proposed country of origin labeling regulations and the underlying statute are preempted by federal law, both expressly and by implication.

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1 U.S. Const. art. VI, § 2.

2 Maryland v. Louisiana, 451 U.S. 725 (1981).

A. Preemption of The Federal Meat Inspection Act and Poultry Products Inspection Act

1. Express Preemption

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) (collectively the Acts) expressly provide, with respect to meat and poultry products prepared at any establishment under inspection pursuant to title I of the FMIA or the provisions of the PPIA, that, "marking, *labeling*, packaging, or ingredient requirements ... *in addition to, or different than*, those made under this chapter may not be imposed by any State...." (Emphasis added).[3] "Labeling" is defined under the FMIA as "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article;" the PPIA includes a comparable provision.[4] Accordingly, although the Acts enable states to exercise concurrent jurisdiction over products not in federally inspected establishments, the Acts do not permit the states to impose different or additional labeling requirements, including state requirements that are intended to be effectuated through store level placards.

2. Implied Preemption

In addition to the expressly preemptive language of the Acts, Congress and USDA have occupied the field concerning labeling of meat and poultry products through the Acts and the comprehensive regulatory scheme promulgated thereunder. Therefore, courts have found state labeling requirements to be preempted not only when they directly conflict with the federal labeling requirements, making it impossible to comply with both, but also in circumstances in which a state attempts to enact a requirement that has no counterpart under federal law.[5]

In the case of imported products, the Food Safety and Inspection Service (FSIS), the agency within USDA that administers the Acts, does not require such products that have been subsequently processed, either through further grinding, cutting, or other processing in the U.S., to bear country of origin labeling. Indeed, to require such labeling on, for example, beef that has been further processed at a retail store would be inconsistent with the provision in the FMIA that imported product must be treated the same as domestic product.[6]

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3 21 U.S.C. §§ 678, 467e.

4 21 U.S.C. § 601(p); 453(s).

5 *Anthony J. Pizza Food Products Corp. v. Wisconsin Dep't of Agriculture*, 676 F.2d 701 (7th Cir. 1982) (unpublished opinion adopting district court opinion); *National Broiler Council v. Voss*, 44 F. 3d 740 (9th Cir. 1994); *Armour & Co. v. Ball*, 468 F. 2d 76 (6th Cir. 1972), *cert. den'd*, 411 U.S. 981 (1973); *Grocery Manufacturers of America v. Gerace*, 581 F. Supp. 658 (S.D.N.Y. 1984), *aff'd in part and rev'd in part on other grounds*, 755 F.2d 993 (2d Cir. 1985).

6 21 U.S.C. § 620.

3. Judicial and Administrative Confirmation of Preemptive Effect

The federal courts repeatedly have confirmed the broad scope of the preemption authority provided by the Acts concerning labeling requirements. See *Jones v. Rath Packing Co.*, 430 U.S. 519, 532 (1976) (California law regarding net weight labeling that made no allowance for loss of weight resulting from moisture loss preempted by FMIA); *National Broiler Council v. Voss*, 44 F.3d 740 (9th Cir. 1994) (Poultry Products Inspection Act (PPIA) preempts California law prohibiting use of word "fresh" on labels of poultry products unless poultry has been stored at temperatures at or above 26 degrees); *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972) (Michigan law establishing standard of identity for sausage different than federal standard is preempted), *cert. denied*, 411 U.S. 981 (1973); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corporation*, 626 F. Supp. 278, 282-85 (D. Mass.) ("Meat ingredient standards, labeling and packaging have been preempted by the FMIA"), *aff'd*, 802 F.2d 440 (1986); *Grocery Manufacturers of America v. Gerace*, 581 F. Supp. 658, 666 (S.D. N.Y. 1984) (New York law regarding labeling of meat food products containing "imitation" cheese preempted by FMIA), *aff'd in part and rev'd in part on other grounds*, 755 F.2d 993 (2d Cir. 1985).

In addition to the judicial precedent, USDA has not hesitated to advise states of the Acts' broad preemptive effect concerning state-imposed labeling requirements for meat and poultry. In that regard, FSIS examined the labeling issue presented by HB 406.[7] In a letter, FSIS Administrator Dr. Barbara Masters states that the preemption provisions of the Acts are "an integral part of the comprehensive regulatory scheme created by the FMIA and PPIA for certain livestock and poultry products."[8] The FMIA defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its container or wrappers, or (2) accompanying such article."[9] Dr. Masters confirmed that labeling "clearly includes point-of-sale materials," citing U.S. Supreme Court precedent and FSIS policy memorandum 114, derived from those judicial decisions, which provides that "informational material such as pamphlets, brochures, and posters accompany meat and poultry products at the point-of-sale are labeling and are subject to the provision of the FMIA and PPIA."[10]

Dr. Masters' letter reiterates a perspective on the scope of labeling and the preemptive effect of the Acts long held by USDA.[11] Indeed, also relatively recently former USDA General Counsel Nancy Bryson in a letter to the officials in the State of California discussed the Acts' "comprehensive statutory framework," which is designed to ensure, among other things, that the labeling and packaging of meat and poultry products is not false or misleading. Ms. Bryson's letter is consistent with Dr. Masters' view regarding the breadth of the term "labeling" under the Acts, explaining that USDA interprets that

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7 See letter from FSIS Administrator Dr. Barbara Masters to Brad Griffin, Montana Retail Association, June 14, 2006.

8 *Id.*

9 21 U.S.C. sec. 601(p).

10 See Masters letter, p. 2.

11 See letters from former Secretaries of Agriculture Richard Lyng, Edward Madigan, and Mike Espy, and Anne Veneman, former USDA General Counsel Nancy Bryson, and former FSIS Administrator Dr. Lester Crawford to various states regarding labeling requirements those states sought to impose on meat and poultry products.

term to include point of sale materials attendant to a meat or poultry product.[12] She concluded that state requirements affecting meat and poultry labeling that are "in addition to, or different than, the federal requirements" are preempted.[13]

B. Montana Law and Proposed Rules Are Preempted by the Acts

HB 406 provides that, "Muscle cuts and ground beef, pork, poultry, or lamb, including any package that contains any blending of foreign and domestic product, that is produced in any country other than the United States and offered for retail sale in Montana must be labeled with a placard in a manner that indicates to an ultimate purchaser the country of origin." Similarly, the proposed rule provides as follows:

> "(1) A placard stating the country of origin for all products covered by this subchapter is required when a product is offered for retail sale as follows:
> (a) A product that was born, fed, and processed entirely in a foreign country must be placarded with a statement declaring the country where the product was born, fed, and processed.
> (b) A product that was born, fed, and processed in more than one country must be placarded with statements declaring which country each stage of production took place for each stage or production that was not within the United States.
> (c) A product that blends together foreign and domestic product must be placarded as required by (1)(a) or (1)(b) as if produced entirely in the foreign country.
> (d) A product lacking any documentation indicating where the product was born, fed, and processed must be placarded with a statement declaring the country of origin unknown. However, if any stage of production of a product is documented and is not within the United States, that product must be placarded with a statement indicating the country of origin for each known stage of production not within the United States and a statement indicating the country of origin unknown for the unknown stages of production."[14]

As the discussion below demonstrates, these provisions of HB 406 and the proposed rule are preempted by federal law because they are in addition to or different than the Acts' labeling provisions.

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12 See also FSIS, Food Labeling Division, Policy Memorandum 114A, "Point of Purchase Materials," August 18, 1994.

13 Letter from Nancy Bryson, USDA General Counsel, to the Honorable Bill Lockyer, Attorney General, State of California, February 10, 2005, at 3.

14 Proposed New Rule II, MAR Notice No. 24-351-212.

1. Express Preemption

The Acts require imported products that are not further processed to bear a declaration of their country of origin. The Acts do not require, nor does FSIS interpret them to require meat or poultry products that are imported but subsequently processed at a federally inspected establishment to bear a country of origin declaration. Indeed, those products bear the USDA mark of inspection. Thus, for example, a meat product derived from blending or processing imported meat with domestically produced meat, bears the mark of inspection provided by FSIS and is deemed to be a product of the U.S. FSIS does not require such a product to declare its country of origin and does not require that any such product "offered for retail sale" be "labeled with a placard that indicates ...the country of origin."

In contrast, the above-cited language of HB 406 would require a placard for such a product that declares the product's "country of origin." As placards fit squarely within the Acts' definitions of "labeling," the placarding requirements that would be imposed by Montana are in addition to or different than those established under federal law and are, therefore, undeniably preempted.[15]

The several subsections of proposed new rule II are equally constitutionally infirm because they too require labeling that is in addition to or different than that required by the Acts. Specifically, subsection 1(a) would require placarding when "a product ... was born, fed, and processed entirely in a foreign country." Although an imported product offered for direct sale with no other processing must declare on its label the country of origin, USDA does not require placarding, as does the proposed rule. Thus, the rule imposes a requirement that is in addition to federal law.[16]

Subsection1(b) provides that, "A product that was born, fed, and processed in more than one country must be placarded with statements declaring which country each stage of production took place for each stage or production that was not within the United States." This subsection, too, goes beyond that which FSIS requires for products that may have originated in whole or in part outside the United States.

Subsection 1(c) provides that, "A product that blends together foreign and domestic product must be placarded as required by (1)(a) or (1)(b) as if produced entirely in the foreign country." This provision conflicts directly with the language in the Acts that requires that imported product be treated the same as domestic product if processed in the U.S.

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15 21 U.S.C. §§ 678, 467e.

16 The definitions in the proposed rule create some ambiguity as to the rule's applicability. Specifically, the term "product" is defined as "(a) fresh, raw, uncured muscle cuts produced from beef, pork, poultry, or lamb; and (b) fresh, raw, uncured, single species, ground beef, ground pork, ground poultry, or ground lamb;" and excludes certain prepared foods for immediate sale or ready to eat. See new rule I(11). Subsections 1(a) and 1(b) would apply to products, e.g., a muscle cut of beef or ground beef that was "born, fed, and processed." In this case, although the animal from which cuts of meat is born and fed, the muscle cuts or the ground beef, which are the "products" subject to the rule, are neither born nor fed – calling in to question the applicability of the rule to those products.

Finally, subsection 1(d) provides that, "A product lacking any documentation indicating where the product was born, fed, and processed must be placarded with a statement declaring the country of origin unknown. However, if any stage of production of a product is documented and is not within the United States, that product must be placarded with a statement indicating the country of origin for each known stage of production not within the United States and a statement indicating the country of origin unknown for the unknown stages of production." This provision, as do the others that precede it, conflicts with federal law because it too imposes regulatory requirements that are different than and in addition to those established pursuant to the Acts.

2. Implied Preemption

The Montana country of origin meat labeling law is also preempted by implication because the Montana law conflicts with the Acts in other respects. Specifically, the FMIA and PPIA both prohibit the sale, transport, offer for sale or transportation, or receipt for transportation in commerce of any meat or poultry products that are misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation.[17] A product will be considered "misbranded" if its labeling is false or misleading in any particular.[18]

The country of origin labeling that is required under Montana law implies that the imported meat or poultry products are of lesser quality or present some health risk. One court noted that country of origin labeling can be designed to make a consumer "feel that the product was something to be shunned, as a matter either of stimulated reaction against it from its labeling, or of uncertainty as to what might be the implications thereof."[19] This would be particularly true under the instant law where products will be required to be labeled "Origin Unknown," if the actual country of origin cannot be documented.

However, as imported meat and poultry products are required to meet the same standards as domestically produced products,[20] the inherent implication of country of origin labeling that imported meat or poultry may be adulterated or unsafe is false and misleading. To require false and misleading labeling clearly conflicts with the federal laws' prohibition against misbranded products and, therefore, the Montana country of origin meat labeling law is preempted by the federal laws by implication.

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17 21 U.S.C. § 610(c).

18 21 U.S.C. § 601(n)(1).

19 *Armour*, 270 F. Supp. at 945-46.

20 See 21 U.S.C. § 620(a).

II. Montana Country of Origin Meat Labeling Regulation Violates Commerce Clause of U.S. Constitution

Article I, Section 8 of the U.S. Constitution enumerates the powers expressly delegated to Congress. In relevant part, the Commerce Clause of Section 8 provides that "the Congress shall have Power . . . [t]o regulate Commerce with foreign Nations, and among the several States . . ."[21] In addition to the direct grant of authority to Congress, the Commerce Clause has long been recognized to limit the power of states to erect barriers to trade.[22] Thus, under the so-called "dormant Commerce Clause," states are prohibited from imposing regulatory measures that are designed to benefit in-state economic interests by burdening foreign or out-of-state competitors.[23] In this regard, the courts have also confirmed that states may not enact labeling and other requirements that impose undue burdens on interstate commerce. See, e.g., *American Meat Institute v. Ball*, 550 F. Supp. 285 (W.D. Mich. 1982), *aff'd sub nom. on other grounds*, *American Meat Institute v. Pridgeon*, 724 F.2d 45 (6th Cir. 1984) (finding a Michigan requirement to identify federally inspected meat products as not meeting "Michigan's high meat ingredient standards" to place an unlawful burden on interstate commerce).

The Supreme Court has adopted what amounts to a two-tiered approach to analyzing state economic regulation under the Commerce Clause.[24] When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, the Court has generally struck down the statute without further inquiry.[25] When, however, a statute has only indirect effects on interstate commerce and regulates evenhandedly, the Court has examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.[26] There is, however, "no clear line" separating the categories of state regulation that are virtually *per se* invalid under the Commerce Clause and those that are subject to the balancing approach set forth in *Pike v. Bruce Church*; rather the critical consideration is the overall effect of the statute on both local and interstate activity.[27] In this case, regardless of the test that is applied, the Montana law does not pass constitutional muster.

A. Montana Law Discriminates Against Non-Domestically Produced Meat and Poultry Products

As discussed more fully above, the proposed rules treat meat and poultry products differently, depending on whether they are of foreign origin in some manner or whether they are derived from livestock or poultry from Montana only or solely within the United States. Specifically, in the case of the latter, the statute allows (but does not require) retailers to identify the product as Product of Montana or Product of USA, as appropriate. In contrast, products from animals produced entirely in a foreign country or in multiple countries must be identified with the country or countries in which they were produced.

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21 U.S. Const., art. I, § 8.

22 *Hughes v. Oklahoma*, 441 U.S. 332, 326 (1979); *H.P. Hood & Sons, Inc. v. DuMond*, 336 U.S. 525 (1949); *Welton v. Missouri*, 91 U.S. 275 (1873).

23 *See, e.g., Bacchus Imports, Ltd., v. Dias*, 468 U.S. 263 (1984).

24 *Brown-Forman Distillers v. NY Liquor Auth.*, 476 U.S. 573 (1986).

25 Id. at 579.

26 Id. at 579, citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

27 *Brown-Forman*, 476 US at 579.

To the extent that the origin of the products cannot be documented, retailers are required to identify products as "Origin Unknown."

The differential treatment between domestically produced products and those of foreign or multiple or unknown origin that is required or permitted under the Montana law places an undue burden on the latter products, as well as on interstate commerce. Specifically, non-US products must be placarded, whereas no comparable requirement is imposed for domestic products. Placarding imposes burdens in terms of the information that must be gathered and maintained over the lifetime of the food-producing animal, as well as the store level implementation costs for the placards, attendant recordkeeping, and labor, not to mention the opportunity costs of using valuable retail space to provide consumers with unnecessary information. The regulations, therefore, not only burden imported products but effectively favor domestic products by providing retailers with a regulatory incentive not to offer imported meats to customers.

B. Montana Lacks Legitimate Interest in Country of Origin Labeling Regulations

For a state law or regulation that impacts interstate or foreign commerce to withstand Constitutional scrutiny, the state must have and must have articulated a legitimate interest in enacting the restriction. For example, a state generally has the authority to implement non-discriminatory legislation to protect the health, safety, or welfare of its citizens, provided that the burden on interstate or foreign commerce does not clearly exceed the local benefits.[28]

In this case, the underlying rationale that we were able to locate was minimal. The preamble to the proposed rules provides:

> ...[T]he Legislature intended the act to supply consumers with more information so that consumers could make more informed decisions based on their individual concerns. These concerns include, among others, health concerns regarding various meat-borne illnesses, including bovine spongiform encephalopathy, more commonly referred to as "mad cow" disease, hoof and mouth disease (sheep) and bird influenza (poultry).

The State does not articulate why these concerns are sufficient to satisfy the Constitutional tests required, nor does the State indicate how the country of origin placarding required will enable consumers to meet their concerns.

Indeed, there is no reason to believe that they will satisfy any needs but base economic protectionism. Specifically, none of the diseases identified are human diseases. Although they may have significant impact on animal populations, they do not directly impact human health.

Furthermore, the food safety laws and accompanying regulatory systems provide substantial assurance that imported meat will not present any greater health or safety risk

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28 *Brown-Forman Distillers v. NY Liquor Authority*, 476 US 573, 579 (1986).

than domestically produced meat or poultry products. Specifically, a comprehensive federal regulatory oversight system is in place to ensure that imported meat is safe, wholesome, and nutritious at the time of import.[29] Once the imported meat has passed inspection and gained entry into the U.S., it is treated as a domestic product and is, therefore, subject to all provisions of the Acts and their implementing regulations. Accordingly, imported products must meet the same standards of quality, wholesomeness, nutrient content, and labeling that apply to domestically produced meats and the safety and security of those products is established well before they reach retail shelves.

Additionally, we note that the Department has exempted frozen products and "prepared foods for immediate sale or ready to eat" from the labeling requirements. The Department provides no rationale to justify the difference in treatment for frozen and prepared foods. Indeed, if the true rationale for the labeling was to provide information necessary to help consumers address legitimate health, safety or well-being needs, one would expect the Department to include all such products, rather than to limit the scope of products covered to "fresh, raw, uncured" products and to exempt frozen and ready-to-eat food products.

Moreover, although highly unlikely, it is not entirely inconceivable that a food-producing animal that was produced partly or entirely within the United States could be infected with one of the afore-mentioned animal diseases. If the purpose of the statute and accompanying regulations is truly to give consumers information to make informed choices, they should be told which products originated in whole or in part in the United States. Indeed, the proposed rules effectively hide the fact that a stage of production may have occurred in the United States if the animal was produced in multiple countries including the U.S.[30]

Therefore, the requirement to provide country of origin information for imported products does not in any way enhance the health, safety, or well-being of the State's citizens and the rationale proffered is not constitutionally sufficient to support the required labeling.

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29 Meat from foreign countries is eligible for entry to the United States only if the inspection system in the foreign country has been evaluated and found acceptable by the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS). 9 C.F.R. § 327.2(a)(2). The system must have a program administered by the foreign national government and provide standards equivalent to those required in the United States. Only a small number of countries have been deemed by FSIS to have adequate inspection systems. Plants in eligible countries must be certified annually by officials of the foreign country's meat inspection system. Upon arrival in the United States, all imported meat and poultry must be reinspected by FSIS within 72 hours of arrival by an FSIS inspector at a designated official import inspection establishment.

30 See proposed New Rule II(b).

C. Montana Country of Origin Meat Labeling Regulation Unduly Burdens Interstate Commerce

In addition to the foregoing, courts generally consider the impact of the state restriction on interstate or foreign commerce when conducting an inquiry under the Commerce Clause. In this case, the Montana statute and accompanying regulations would place significant costs and administrative burdens on all levels of the meat and poultry production system from producers and processors to wholesalers and retailers that would, in turn, place an undue burden on interstate and foreign commerce.

Specifically, once meat and poultry from abroad enters the United States, it enters the same distribution channels as domestic products. Separating fresh cuts of meat based on their country of origin will be difficult to do and will impose substantial recordkeeping and other administrative costs on retailers and wholesalers. Retailers and wholesalers will incur further costs to achieve compliance with the regulations, including the costs of training personnel in the necessary compliance measures; the costs of labels, signs, placards and the labor necessary to apply them; segregating meat and poultry products by country of origin; and, especially, costs of determining product country of origin from suppliers.

The burden will be felt in foreign commerce as well, as foreign suppliers will be required to utilize resources and adopt measures that will serve no other purpose but to satisfy the discriminatory Montana law. Accordingly, the regulations are intended to and will burden foreign commerce.[31]

D. Less Restrictive Measures are Available

In reviewing state action to determine whether it is permissible under the Commerce Clause, a reviewing court looks to see whether the state government used the least restrictive means possible to achieve a legitimate interest. In this case, because no legitimate interest was articulated, it is unnecessary to consider whether any less restrictive measures are available.

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31 We note that one of the most burdensome provisions concerns recordkeeping. Specifically, proposed New Rule V requires retail vendors to maintain documentation to justify statements made "on each country of origin placard." The documentation – from birth to slaughter – that would be necessary to support the required recordkeeping would be extremely costly. As it stands now, the requirement only applies to statements made on placarding. However, this creates an anomalous situation since retailers will inherently be making a country of origin declaration by *not* placarding any products; that is, they will inherently be declaring the unplacarded products as products of the U.S. If those retailers are not required to maintain records, and, presumably, there is an economic incentive to sell U.S. product, then the Department has effectively created a situation that will encourage less than scrupulous behavior that the Department will have no way to regulate or check. If, on the other hand, the Department amends the proposed requirement to include all products, then U.S. ranchers, producers, and processors will likewise be required to bear the costly burden of the proposed recordkeeping requirement.

III. Country of Origin Meat Labeling Regulation Violates Free Speech Clause of U.S. Constitution

The First Amendment of the U.S. Constitution provides that, "Congress shall make no law . . . abridging the freedom of speech . . .."[32] The First Amendment limits the government's ability to compel speech, as well as the government's ability to restrict speech.[33] The Montana law and accompanying regulations attempt to compel speech in an unlawful violation of the First Amendment.

The appropriate standard for determining whether a governmental compulsion of speech is unlawful is set forth in *Central Hudson Gas & Electric Corporation v. Public Service Commission.*[34] In order for compelled speech to meet the test set forth in *Central Hudson*, the government must assert a substantial interest in support of the compelled speech and the required speech must be narrowly tailored to advance the asserted substantial interest directly.

As discussed more fully above, Montana has not articulated a legitimate interest in requiring country of origin labeling; therefore, the state lacks a compelling interest in country of origin labeling regulations. Moreover, Montana has not demonstrated that the speech that would be compelled under the regulation would advance the government's interest. As states must supply empirical evidence of direct advancement of the interest by the compelled speech, Montana has not met its burden in this regard, either.

IV. Jail Term for Labeling Violation is Disproportionate and Violates the Eighth Amendment Prohibition on Cruel and Unusual Punishment

The Eighth Amendment to the U.S. Constitution states that, "Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." The Supreme Court has stated unequivocally and on numerous occasions that the "cruel and unusual punishments" clause prohibits not only barbaric punishments, but those that are disproportionate to the crime.[35] In this case, the Montana statute would subject a person who "knowingly removes any labels or identifying marks from beef, pork, poultry or lamb that is labeled as to the country of origin" to a fine of up to $500 or imprisonment in the county jail for a term not to exceed 6 months or both.

First, the statutory penalty provision is overly broad. Although the purpose of the statute is to require country of origin labeling, the provision would criminalize the removal of *any* labels or identifying marks from the covered meat and poultry products. In the course of ordinary business, retailers remove some information that may have accompanied the product as it was originally delivered to the retailer that is not relevant to the consumer.

Second, judicial precedent requires proportionality between the offense and the punishment. Loss of liberty for a relatively minor labeling offense is clearly disproportionate and, therefore, renders the Montana statute constitutionally infirm on yet another basis.

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32 U.S. Const. amend. I, cl. 2.

33 *International Dairy Foods Association v. Amestoy*, 92 F.3d 67 (2d Cir. 1996); *Wooley v. Maynard*, 430 U.S. 705 (1977).

34 *Central Hudson Gas & Elec. Corp. v. Public Serv. Commission*, 447 U.S. 557 (1980).

35 See, e.g., *Solem v. Helm*, 463 U.S. 277 (1983).

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AMI and FMI appreciate the opportunity to provide comments on the proposed rule. We would be pleased to discuss any of the information provided above at your convenience.

Sincerely,

Mark Dopp
Senior Vice President
& General Counsel
American Meat Institute

Deborah White
Vice President &
Associate General Counsel
Food Marketing Institute

CC: USDA
Montana Governor Brian Schweitzer
Attorney General Mike McGrath

ATTACHMENTS

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

JUN 14 2006

Mr. Brad Griffin
Executive Vice President
Montana Retail Association
1645 Parkhill Drive, Suite 6
Billings, Montana 59102

Dear Mr. Griffin:

Thank you for your February 3, 2006, letter to the Food Safety and Inspection Service (FSIS) regarding the Montana Country of Origin Placarding Act.

We agree that both the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) contain explicit preemption clauses. The FMIA preemption clause states that "marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this Act may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under title I of this Act" (21 U.S.C. 678). The PPIA has very similar language in 21 U.S.C. 467(e). In addition, a State may only, consistent with requirements under the FMIA or PPIA, exercise concurrent jurisdiction over articles required to be inspected thereunder for the purpose of preventing the distribution of such articles that are adulterated or misbranded, as certified therein, and also are outside of such establishments.

USDA views these provisions as an integral part of the comprehensive regulatory scheme created by the FMIA and PPIA for certain livestock and poultry products, respectively. In the legislative findings for both the FMIA and the PPIA, it is declared that all meat and poultry products that are regulated under these Acts "...are either in interstate or foreign commerce or substantially affect such commerce." It is also declared that "...regulation by the Secretary and cooperation by the States are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers" (U.S.C. 602 and 451).

The FMIA also states that "the term 'label' means a display of written, printed, or graphic matter upon the immediate container (not including package liners) or any article" and that "the term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article" (21 U.S.C. 601 (o) and (p)). The PPIA has similar language in 21 U.S.C. 453(s).

We agree that "labeling" clearly includes point-of-sale materials. In *V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1957), *cert. denied*, 354 U.S. 923 (1957), the court ruled that the term "labeling" must be given broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped in interstate commerce along with the article. Based on this and other Federal court decisions, on August 18, 1994, FSIS issued Policy Memo 114, which states that informational materials such as pamphlets, brochures, and posters accompanying meat and poultry products at the point-of-sale are labeling and are subject to the provisions of the FMIA and the PPIA.

It is not, however, FSIS' practice to write to the States each time one contemplates or takes an action that is preempted under the Acts. I hope this information is useful if you choose to pursue this with State authorities.

Thank you again for writing to me.

Sincerely,

Barbara Masters

Barbara J. Masters, D.V.M.
Administrator

United States Department of Agriculture
Office of the General Counsel
Washington, D.C. 20250-1400

FEB 10 2005

The Honorable Bill Lockyer
Attorney General
State of California Department of Justice
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, California 94612-0550

SUBJECT: California Proposition 65

Dear Mr. Lockyer:

In view of recent developments, we would like to advise you of our legal position concerning the application of the provisions of California Proposition 65 with respect to the distribution of meat and poultry products inspected at federal establishments under the Federal Meat Inspection Act and the Poultry Products Inspection Act..

As you know, California Proposition 65, enacted as the Safe Drinking Water and Toxic Enforcement Act of 1986, provides that no person in the course of doing business may "knowingly and intentionally expose any individual to a chemical known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." Such warning "may be provided by general methods such as labels on consumer products, posting of notices, and the like, provided that the warning accomplished is clear and reasonable."

In 1987, then Secretary of Agriculture Richard E. Lyng sent a letter to the then California Governor George Deukmejian concerning the implementation of Proposition 65. In that letter, USDA set forth the statutory authorities and precedent cases supporting the position that the provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act concerning labeling requirements preempted the application of the provisions of Proposition 65 to meat and poultry products.

In November 2004, an individual in California filed a 60-day Notice of Violation against several USDA inspected meat and poultry establishments, alleging that these establishments violate Proposition 65 because they cause consumer exposure to certain chemicals in violation of Proposition 65. That individual is requesting that the firms provide point-of-sale labeling on their products to include a warning that the products contain polychlorinated dibenzo-p-dioxins and polychlorinated biphenyls.

In December 2004, then Secretary Ann M. Veneman sent a letter to Governor Arnold Schwarzenegger concerning the application of provisions of Proposition 65 to meat and poultry products regulated by USDA. In that letter, USDA reaffirmed the position taken in the 1987 letter regarding federal preemption.

On January 14, 2005, USDA attorneys had conversations with Edward G. Weil, Senior Deputy Attorney General, with respect to enforcement of Proposition 65. In that conversation, Mr. Weil advised that he did not believe that USDA had preemptive authority with respect to California's point-of-sale warning requirements. In support of his position, he cited the 9th Circuit Court of Appeals decision issued in 1992 concerning California warning requirements applicable to fungicides, insecticides, and the like. (Chemical Specialties Manufacturers Association v. Allenby, 958 F.2d 941 (1992)). The USDA attorneys disagreed with Mr. Weil as to USDA's preemptive authority with respect to point-of-sale labeling. They noted that USDA's preemptive authority under the Federal Meat Inspection Act and the Poultry Products Inspection Act has consistently been interpreted very broadly based on the uniquely comprehensive regulatory and inspection provisions of those statutes.

Both the Federal Meat Inspection Act and the Poultry Products Inspection Act provide a comprehensive statutory framework to ensure that meat, meat food products, poultry and poultry food products prepared for commerce are wholesome, not adulterated, and are properly labeled and packaged. The Federal Meat Inspection Act mandates that inspectors in federal establishments (slaughtering, packing, meat-canning, rendering or similar establishments) perform ante-mortem inspection and examination of animals for disease prior to slaughter. 21 U.S.C. § 603. The inspectors also must perform post-mortem examination and inspection of all the animal carcasses and parts, and all meat food products prepared for commerce. Those found not to be adulterated are marked, stamped, tagged or labeled as "Inspected and Passed", while all carcasses and parts and meat food products found to be adulterated are marked, stamped, tagged or labeled as "inspected and condemned" and are destroyed. 21 U.S.C. §§ 604, 605 and 606. The Act also mandates that inspectors examine the sanitary conditions of all federal establishments in which the animals are slaughtered and the meat and meat food products are prepared for commerce. Where sanitary conditions of any establishment are such that the meat or meat food products are rendered adulterated, the inspector shall refuse to allow the meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed". 21 U.S.C. § 608.

The Act also sets out stringent requirements for the labeling of meat or meat food products prepared for commerce. The container or receptacle of the meat or meat food products inspected and passed for commerce shall be labeled as "inspected and passed". 21 U.S.C. § 607(a). The carcasses, parts of carcasses, meat and meat food products inspected at any establishment and found not to be adulterated shall bear, either directly or on their containers, information as required under the misbranding provisions of 21 U.S.C. § 601(n). 21 U.S.C. § 607(b). Additionally, only meat food products which have marking, labeling, and containers which are not false or misleading and which are approved by the Secretary may be distributed in commerce. 21 U.S.C. § 607(d).

The Poultry Products Inspection Act has similar inspection, labeling and sanitation provisions for poultry and poultry products. 21 U.S.C. §§ 455, 456 and 457.

The Federal Meat Inspection Act and the Poultry Products Inspection Act have explicit preemption clauses which provide that marking, labeling, packaging or ingredient requirements which are in addition to, or different than, those made under the Federal Meat Inspection Act and the Poultry Products Inspection Act may not be imposed by a State with respect to articles prepared at any establishment under inspection in accordance with the requirements under those Acts. The Federal Meat Inspection Act preemption clause states that "[m]arking, labeling, packaging or ingredient requirements in addition to, or different than, those made under this Act may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with requirements under title I of this Act..." 21 U.S.C. § 678. Likewise, the Poultry Products Inspection Act preemption clause states that "[m]arking, labeling, packaging or ingredient requirements (or storage or handling requirements found by the Secretary to unduly interfere with the free flow of poultry products in commerce) in addition to, or different than, those made under this Act may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any official establishment in accordance with the requirements under this Act ..." 21 U.S.C. § 467(e).

In the legislative findings for both the Federal Meat Inspection Act and the Poultry Products Inspection Act, it is declared that all meat and poultry products which are regulated under those Acts "...are either in interstate or foreign commerce or substantially affect such commerce." It is further declared that "...regulation by the Secretary and cooperation by the States are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers." 21 U.S.C. § 451 and 21 U.S.C. § 602.

In addition, the Federal Meat Inspection Act and the Poultry Products Inspection Act have specific definitions for the terms "label" and "labeling". The Federal Meat Inspection Act states that "the term 'label' means a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article"; and "the term 'labeling' means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 601(o) and (p). Likewise, the Poultry Products Inspection Act states that "the term 'label' means a display of written, printed or graphic matter upon any article or immediate container (not including packaged liners) of any article; and the term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 453(s).

It is our view that the term 'labeling' clearly includes point-of-sale warning materials required pursuant to the provisions of Proposition 65. See V.E. Irons, Inc. v. United States, 244 F.2d 34 (1957), *cert. denied*, 354 U.S. 923 (1957) (The term "labeling" must be given broad meaning to include all literature used in sale of food and drugs, whether or not it is shipped into interstate commerce along with the article). Thus, to the extent that Proposition 65 would require a warning statement on point of purchase materials for meat or poultry products, it would be imposing a requirement in addition to, or different than, the federal labeling requirements.

Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, California is preempted from doing so. With such warning, the point-of-sale materials would only confuse the public as to the wholesomeness of the meat and poultry products.

We believe that our position is supported by other precedent federal cases. In 1977, the United States Supreme Court confirmed the preemptive authority of the Federal Meat Inspection Act concerning labeling requirements. *See* Jones v. Rath Packing Co., 430 U.S. 519 (1977) (California law regarding net weight labeling that made no allowance for moisture loss was preempted by the Federal Meat Inspection Act). *See also* Armour & Co. v. Ball, 468 F.2d 76 (6th Cir. 1972), *cert. denied,* 411 U.S. 981 (1973). Since that time, federal courts have consistently ruled that the Federal Meat Inspection Act and the Poultry Products Inspection Act clearly and explicitly preempt labeling, marking and ingredient requirements being imposed by a State that are in addition to, or different than, the federal labeling, marking and ingredient requirements. *See* Grocery Manufacturer's of America v. Gerace, 581 F. Supp. 658 (S.D. N.Y. 1984), *aff'd in part and rev'd in part on other grounds,* 755 F.2d 993 (2d Cir. 1985); Animal Legal Defense Fund v. Provini Veal Corporation, 626 F. Supp. 278 (D. Mass., 1986), *aff'd,* 802 F.2d 440 (1986); National Broiler Council v. Voss, 44 F.3d 740 (9th Cir. 1994) (Poultry Products Inspection Act preempts California law prohibiting use of the word "fresh" on poultry products unless poultry is stored under certain conditions).

The Food Safety and Inspection Service of this Department has implemented a policy consistent with the legal arguments specified above. In August 18, 1994, the agency issued a policy memorandum affirming that informational materials such as pamphlets, brochures, and posters, accompanying meat and poultry products at the point-of-sale are deemed labeling and are subject to provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act. FSIS, Food Labeling Division, Policy Memo 114A, "Point of Purchase Materials". Additionally, the agency has issued regulations on nutrition information provided at the point of purchase. 9 C.F.R. § 317.345. The agency has consistently taken enforcement actions to implement this policy. We are enclosing copies of letters reflecting the agency's enforcement actions in the past with respect to point-of-sale labeling.

We hope that the foregoing clarifies our position in this matter, and hope you will agree that Proposition 65 may not be effected in a manner requiring point-of-sale labeling of meat, poultry, or products thereof regulated under the Federal Meat Inspection Act or the Poultry Products Inspection Act. Please let me know if you believe there is any need to discuss this issue further.

Sincerely,

Nancy S. Bryson

Nancy S. Bryson
General Counsel

Enclosures

cc: Edward G. Weil, Senior Deputy Attorney General

To: Branch Chiefs

Policy Memo *114A*

August 18, 1994

From: Cheryl Wade, Director
Food Labeling Division
Regulatory Programs

Subject: Point of Purchase Materials

ISSUE: To establish guidelines for use of point of purchase promotional materials for meat and poultry products.

POLICY: This Policy Memo supersedes Policy Memo 114. Point of purchase materials which refer to specific meat or poultry products are considered labeling under certain circumstances. When printed and/or graphic informational materials (e.g., pamphlets, brochures, posters, etc.) accompany or are applied to products or any of their containers or wrappers at the point of purchase, such materials and the claims that they bear are deemed labeling and they are subject to the provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act.

Although the Food Labeling Division (FLD) does not exercise its authority to subject point of purchase materials to specific prior approval (materials shipped with the products from the federally inspected establishment are an exception), we do expect point of purchase materials to be in accordance with the Federal regulations and all current labeling policies. Upon request, FLD will review and comment on the point of purchase materials submitted to our office. During the review process, promotional materials will be scrutinized for special claims, particularly those related to nutrition, diet, and animal husbandry practices.

Claims related to nutrition and diet must be made in accordance with all current nutrition labeling regulations. Continuing compliance with stated claims will be assured through periodic sampling, as necessary. claims are expected to be within the compliance parameters identified in the nutrition labeling regulations.

Animal husbandry claims (e.g., the nonuse of antibiotics or growth stimulants) may be made only for products shipped in containers or wrappers labeled with the same animal production claims.

RATIONALE: Historically, point of purchase materials generally consisted of printed and/or graphic literature located in close proximity to a product at the retail counter. However, the nature of promotional materials which bear claims about specific products has broadened and presently includes materials which adhere directly to a package, are inserted into a package, or enclose an entire product as it is sold to the consumer.

Since such point of purchase materials are deemed labeling and subject to the provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act but have not been reviewed for prior label approval, a process is still needed by which the accuracy of the information presented to the consumer can be substantiated. In the case of animal husbandry claims, accuracy is best assured if labeling bearing the same claims has been granted prior approval and is subject to the monitoring procedures available through the authority of prior label approval. Without review for prior label approval, virtually no practical methods exist to assure accuracy.

The nutrition - labeling regulations, effective July 6, 1994, differ dramatically and, in many cases, are far more restrictive than previously published nutrition labeling policies. It is important that nutrition-related information included in point of purchase materials comply with the new nutrition labeling regulations. As before, analytical sampling offers a means of assuring the accuracy of the stated nutritional claims.

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

Jeff Farrar
Section Chief
Food Safety Section
California Department of Health Service
Food and Drug Branch
1500 Capitol Avenue, MS 7602
Sacramento, California 95899-7413

OCT 5 2006

Dear Mr. Farrar:

California Proposition 65, enacted as the Safe Drinking Water and Toxic Enforcement Act of 1986, provides that no person in the course of doing business may "knowingly and intentionally expose any individual to a chemical known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." Such warning "may be provided by general methods such as labels on consumer products, posting of notices, and the like, provided that the warning accomplished is clear and reasonable."

A private, non-profit organization in California has filed a complaint against several restaurant business establishments that sell cooked poultry products to consumers, alleging these establishments violate Proposition 65 because they cause consumer exposure to certain chemicals in cooked poultry products in violation of Proposition 65. The organization is requesting that the business establishments warn consumers that the cooked poultry products contain the chemical "PhIP" (2-amino-1-methyl-6-phenylimidazo[4,5-*b*] pyridine).

This letter serves to reaffirm our position that Proposition 65 is preempted by federal law and thus may not be effected in a manner requiring point-of-sale labeling of meat, poultry, or products thereof regulated under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). In summary, USDA's Food Safety and Inspection Service (FSIS) has determined that Proposition 65 warnings concerning PhIP in cooked poultry are preempted by federal law because: 1) they obstruct the carefully developed policies implemented by FSIS to prevent foodborne illness associated with the consumption of meat and poultry products and 2) they cause poultry products to be misbranded under the PPIA. Moreover, by implying that cooked poultry is somehow unsafe or unwholesome, Proposition 65 warnings provide a disincentive for consumers to thoroughly cook raw poultry products. Thus, in addition to the preemption issues, to attempt to enforce Proposition 65 in restaurant establishments that serve cooked chicken would also have the paradoxical, and rather unfortunate, effect of jeopardizing the health of consumers.

The FMIA and PPIA give the Secretary of Agriculture (and FSIS by delegation) the authority to require that meat and poultry products bear labeling that informs the public of the manner of handling that is necessary to maintain these products in a safe and wholesome condition.[1] Under this authority, FSIS has adopted regulations that require that the labeling of all raw and partially cooked meat and poultry products bear safe handling instructions. These safe-handling instructions must include a rationale statement that informs consumers that some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly and must address four parameters of food safety.[2] One of the required safe handling instructions is to cook raw meat and poultry thoroughly. The safe handling instructions are among the measures implemented by FSIS to protect consumers from potential exposure to pathogenic bacteria that may be found in or on raw meat and poultry products. The Agency adopted the safe handing instructions regulations as part of its efforts to reduce foodborne illnesses associated with the consumption of meat and poultry products.

In addition to requiring that the labeling of raw and partially cooked meat and poultry products bear safe handling instructions, FSIS develops and implements food safety education programs to instruct consumers on how to properly handle and prepare meat and poultry products to reduce the risks associated with foodborne illness. While these food safety programs provide information on all parameters of safe food handling, educating consumers on how to properly cook meat and poultry products for safety is an essential component. The Agency's consumer education programs emphasize the need to cook meat and poultry products until they reach a sufficient internal temperature to eliminate the bacteria that are known to cause foodborne illness.[3]

In developing its policy to require that all raw and partially cooked meat and poultry products bear safe handling instructions, FSIS studied data on consumer knowledge and practices with regard to food handling and preparation. Based on the data that were available at that time, the Agency concluded that many consumers in the United States have limited experience in preparing food and limited knowledge on how to handle and prepare food to prevent the risk of foodborne illness. FSIS also reviewed the available data on foodborne illness outbreaks and found that undercooking was a factor in several outbreaks associated with foods prepared both in and outside of the home.[4]

FSIS studies data related to consumers' knowledge and practices with regard to food handling and preparation on an ongoing basis to ensure that the Agency's consumer education programs are effective in providing consumers with the information that they need to safely handle and prepare meat and poultry products. The Agency also follows surveillance and epidemiological

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[1] The FMIA and PPIA provide that the term "misbranded" applies to any product that "... fails to bear on its containers ... or directly thereon, as the Secretary may by regulations prescribe, the official inspection legend and official establishment number of the establishment where the article was processed, and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition." (21 U.S.C. 601(n)(12) and 21 U.S.C. 453(h)(12).

[2] See 9 CFR 317.2 and 9 CFR 381.125(b).

[3] For example, the "Thermy™" and "Is It Done Yet" campaigns encourage consumers to use food thermometers to determine whether meat, poultry, and other foods have been cooked to a safe internal temperature.

[4] A more complete description of these data can be found in the preamble to the final rule "Mandatory Safe Handling Statement on Labeling of Raw Meat and Poultry Products" (*59 Federal Register* 14528, March 28, 1994).

data on reported foodborne illnesses to identify areas where consumers may need additional education on how to handle and prepare food to ensure that it is microbiologically safe. Based on its ongoing analysis of these data, FSIS has determined that educating consumers on how to properly handle and prepare meat and poultry products continues to be an essential component of the Agency's efforts to reduce foodborne illness associated with meat and poultry products.

If a warning were required under Proposition 65 that stated that cooked poultry products contain PhIP, a chemical known by the State of California to cause cancer, the warning would conflict with federal labeling policy and obstruct FSIS' efforts to prevent foodborne illness because the warning would imply that cooking poultry somehow renders the poultry unsafe or unwholesome. As discussed above, safe handling instructions required on the labeling of all federally-inspected raw and partially cooked meat and poultry product recommend that consumers cook these products thoroughly. In addition, food safety education campaigns developed by FSIS stress the need to cook meat and poultry products to a proper internal temperature. Thus, a Proposition 65 warning that raise issues with regard to the safety of cooked poultry would contradict the food safety information that FSIS communicates to the public through product labeling and consumer education campaigns. Because the warning would stand as an obstacle to policies implemented by FSIS under the authority of the PPIA, the Agency has determined that Proposition 65 is preempted by federal law.

In addition, FSIS has evaluated the available studies on PhIP in cooked meat and poultry and has determined that Proposition 65 warnings with regard to PhIP would be misleading because they fail to provide information that accurately characterizes the level and the carcinogenicity of this compound in cooked poultry. For example, Proposition 65 warnings do not explain that the concentration of PhIP in cooked poultry varies, which in turn affects the level of human exposure to this compound. According to the available studies, the development and level of PhIP in cooked poultry is influenced by multiple factors, including the cooking method, the cooking temperature, the cooking time, the place of preparation (e.g., home, restaurant, fast-food restaurant), as well as the degree of doneness and surface browning on the meat. Furthermore, studies indicate that there is substantial variability in the formation of PhIP even within high temperature cooking methods.

In addition, Proposition 65 warnings do not explain that while PhIP has been shown to cause cancer in laboratory animals, the carcinogenicity of PhIP in humans has yet to be fully characterized. This information is relevant because cancer is induced in laboratory animals by exposing them to doses of a substance that are several orders of magnitude higher per unit of body weight than is ingested in the typical human diet. Thus, raising the issue of cancer with regard to PhIP in cooked chicken is speculative at best, whereas the adverse effects of eating chicken that is not thoroughly cooked are real and predictable.

Therefore, because Proposition 65 warnings omit information that is needed for consumers to put statements with regard to PhIP in cooked chicken in their proper context, FSIS has concluded that these warnings are misleading and render cooked poultry products misbranded under 21 U.S.C. 453 (h)(1) of the PPIA[5]. Consequently, federal law preempts Proposition 65 because

[5] A poultry product is misbranded "if its labeling is false of misleading in any particular" 21 U.S.C 453(h)(1).

restaurant establishments that serve cooked poultry cannot comply with Proposition 65 without violating the PPIA.

USDA's position that federal law preempts Proposition 65 is longstanding. In 1987, then Secretary of Agriculture Richard E. Lyng sent a letter to the then California Governor George Deukmejian concerning the implementation of Proposition 65. In that letter, USDA set forth the statutory authorities[6] and precedent cases supporting the position that the provisions of the FMIA and the PPIA concerning labeling requirements preempted the application of the provisions of Proposition 65 to meat and poultry products. In December 2004, then Secretary Ann M. Veneman sent a letter to Governor Arnold Schwarzenegger concerning the application of provisions of Proposition 65 to meat and poultry products regulated by USDA. In that letter, USDA reaffirmed the position taken in the 1987 letter regarding federal preemption. In May 2005, Secretary of Agriculture Mike Johanns sent a letter to Governor Schwarzenegger, stating that the USDA remains of the view that the application of Proposition 65 to meat and poultry products is preempted by specific provisions of federal law, and that Proposition 65 should not be construed to require point-of-sale labeling of meat and poultry products that have been inspected and passed by federal inspectors and bear labels that have been reviewed and approved in advance under the FMIA and PPIA.

In February and May 2005, the Office of the General Counsel for USDA also sent letters to the California Attorney General, advising him of USDA's position on the federal preemption of Proposition 65 with respect to labeling requirements on meat and poultry products. The letters reviewed both federal and state court decisions relevant to federal preemption and Proposition 65, the express labeling provisions of the FMIA and PPIA, and the comprehensive regulatory framework in place for these Acts. In addition to reviewing the express labeling requirements of the FMIA and PPIA, the correspondence also articulated the position of USDA that the term 'labeling' clearly includes point-of-sale warning materials required pursuant to the provisions of Proposition 65, and that Proposition 65 may not be effected in a manner requiring point-of-sale labeling of meat, poultry, or products thereof regulated under the FMIA or PPIA. Also, FSIS has implemented a policy consistent with these legal arguments.

In our May 2005 letter to the California Attorney General, we discussed the application of the California Supreme Court case Dowhal v. SmithKline Beecham Consumer Healthcare, 32 Cal. 4th 910 (Cal. Supr. Ct. 2004) on federal preemption resulting from a conflict between federal and state law. In Dowhal, the issue was whether the requirement of Proposition 65 that health warnings be placed on stop-smoking products containing nicotine sold over the counter were preempted by the labeling requirements of the Federal Food, Drug and Cosmetic Act (FFDCA). 21 U.S.C. § 310 *et seq.* The Dowhal court ruled that the August 2001 letter issued by the Food

[6] Section 23 of the PPIA provides that "[m]arking, labeling, packaging, or ingredient requirements...in addition to, or different than, those made under this Act may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any official establishment in accordance with the requirements under this Act, but any State or Territory or the District of Columbia may, consistent with the requirements under this Act, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under this Act, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States." 21 U.S.C. 467e.

and Drug Administration (FDA) on these products established federal policy prohibiting defendants from giving consumers any warning other than the one approved by FDA in that letter and that the Proposition 65 warning would conflict with that policy. Dowhal at 929. The Dowhal court also rejected the plaintiff's argument that Proposition 65 warnings through point-of-sale notices or public advertising were not preempted:

> Warnings through point-of-sale posters or public advertising could have the same effect of frustrating the purpose of federal policy. Conflict preemption does not require a direct contradiction between state and federal law; the state law is preempted if state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (English v. General Electric Co., *supra*, 496 U.S. at p. 79.)

Recently, a California Superior Court applied the tenets of the Dowhal decision in the case People v. Tri-Union Seafoods, LLC, et al., S.F. County Sup. Ct. consolidated case nos. CGC-01-402975 and CGC04-432394. In June 2004, the California Attorney General filed suit against tuna canners to enforce Proposition 65 labeling requirements for canned tuna products for the chemical methylmercury. Defendants argued that the Proposition 65 requirement would conflict with the federal 2004 joint advisory issued by the FDA and EPA (FDA/EPA 2004 Advisory) to inform consumers on the benefits and risks of eating canned tuna. After a trial on the merits, the court applied Dowhal and found that conflict preemption existed in this case, stating that Proposition 65 stood as an obstacle to the accomplishment and execution of the full purposes of Congress as bestowed on the FDA according to the FDCA, and that it was impossible for the Tuna Canners to comply with the joint FDA/EPA 2004 Advisory as well as Proposition 65's warning requirement. (Tri-Union, Findings of Fact and Conclusions of Law Re: Preemption, MADL and Naturally Occurring, May 11, 2006, p. 89).

The court also gave deference to FDA's views on labeling, as articulated in a May 2005 letter from Dr. Lester M. Crawford, Commissioner of Food and Drugs, FDA to California Attorney General Bill Lockyer. The court found that FDA made clear in this letter that Proposition 65 warnings on tuna products were preempted for three reasons: "(1) Proposition 65 warnings frustrate FDA's carefully considered approach to advising the public concerning the benefits and risks of consuming canned tuna; (2) point of purchase warnings conflict with FDA's longstanding opposition to warning signs in connection with the sale of food; and (3) Proposition 65 warnings conflict with federal law because such warnings on canned tuna would be misleading under section 403 of the FDCA. Tri-Union at 92. The court agreed with FDA's views and concluded "A federal agency's own views respecting whether a state law conflicts with federal law it administers are to be accorded *substantial* deference." Tri-Union at 91.

Thus, it is clear that even if express preemption language were not present in the FMIA and PPIA, Proposition 65 requirements would be preempted by conflict because the requirements would thwart the purposes and objectives of the FMIA and PPIA.

Sincerely,

Richard A. Raymond, M.D.
Under Secretary
Office of Food Safety

Marc L. Kesselman, Esq.
General Counsel

cc: Forest A. Hainline III
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