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January 13, 2004

Ms. Ann M. Veneman
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250-1300

Dear Secretary Veneman:

I am writing on behalf of the Center for Progressive Regulation to request that you correct the public record with respect to misleading statements contained in USDA's December 30 press release on Bovine Spongiform Encephalopathy (mad cow disease) and to ask you to take more effective action to protect U.S. consumers from the risk of contracting variant Creutzfeldt-Jacob Disease (vCJD).

The Center for Progressive Regulation is a nonprofit research and educational organization of university-affiliated academics with expertise in the legal, economic, and scientific issues related to regulation of health, safety, and the environment.

Your December 30, 2003 press release dramatically announced that USDA would be implementing "additional safeguards to bolster the U.S. protection systems against" mad cow disease and "further protect public health." The reassuring tone of your remarks at the December 30 press conference was, however, belied by the text of the actual regulations that were finally made public on January 8, 2004. On December 30 you assured the American public that USDA would protect the meat supply, but the package that came out on December 8 delivered very little in the way of effective governmental protections.

The fine print of the January 8 regulations reveals that the rules with the greatest potential to enhance meat safety have no substantive content and merely allow individual companies to come up with their own procedures for preventing dangerous materials entering the food supply. It will be years before the verifiable system of national animal identification that you promised will be in place, despite your misleading suggestion that USDA would "begin immediate implementation" of the program. Other promises of forceful government action made on December 30 turn out on closer inspection to be irrelevant because the industry practices they address ended long ago.

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Instead of writing meaningless regulations, promising undeliverable programs and announcing unenforceable "performance-based" aspirations that allow the meat industry to fill in the details, USDA should simply require that all cattle be tested for mad cow disease prior to using them in human food. At this point, only a tiny sliver of the beef produced in the U.S. is tested for mad cow disease, even though testing is the best way to ensure that infected meat does not enter the food supply. Only when universal testing is required will the confidence of the American consumer in the U.S. meat supply be restored.

The failure to specify safety requirements.

The greatest failing in the regulations as written is that they *do not specify* the procedures and techniques that establishments must use to ensure that Special Risk Material (SRM) does not enter the food supply. Establishments are only required to come up with "written procedures" for the "removal, segregation, and disposition of SRMs." The same is true for the rule governing Advanced Meat Recovery Systems (AMRS). USDA promises to "ensure the adequacy and effectiveness" of each establishment's procedures, but it does not say how it will do that. And the rules provide no legally enforceable way for USDA to fulfill its promise, in any event.

In short, there are no requirements for how establishments must go about removing SRM from food. There is only a general prohibition on the use of SRM for human food and the aspiration that companies will at some point in the future come up with adequate individual plans to remove SRM from food. USDA does not specify any criteria for the plans that establishments must draft. The regulations do not even specify how companies should go about determining whether meat at the end of the production process contains SRMs. The establishments are free to do whatever they want. There is not even deadline for preparing the plan.

The rule does not say that the violation of a plan is a violation of law. It isn't. A company can only be prosecuted if USDA can prove that a company did use SRMs in human food. The burden of proof is entirely upon USDA. Consumers will no doubt take little comfort in the requirement that an establishment must take corrective action if it or USDA discovers that its plan failed and SRM did get into the food supply.

Rather than promulgate specific legally enforceable requirements for removing SRMs from human food, USDA has decided to trust private enterprise "to implement the most appropriate procedures that will best achieve" the general ban on using SRMs in human food. Consumers must therefore depend upon the good intentions of meat production establishments for assurance that the meat products they eat are free of the brain, skull, eyes, spinal cord and tonsils of cattle.

The 30-month loophole.

The loophole for cattle less than 30 months old is not well supported. BSE has been found in animals that were younger than 30 months old. The Preamble to the rule tries to explain away these instances, but the explanation is not persuasive. While it may be true that younger cattle

pose fewer risks, they are by no means risk-free. USDA does not explain why U.S. consumers should be intentionally subjected to such a high-consequence risk, even if the probability is low.

Germany, Italy and France all test for BSE in cattle older than 24 months prior to slaughter. This suggests that these countries have concluded that there is a significant risk that cattle between 24 months and 30 months may transmit risky material to humans.

The only plausible explanation for the loophole is an implicit cost-benefit analysis. The statute, however, does not allow the Department to rely upon a cost-benefit analysis. It requires that all adulterated meat be removed from the market, whether or not the costs to the industry of removing the meat are exceeded by the benefits to human health.

The bone marrow loophole.

Bone marrow is not included in the definition of "specified risk material." The loophole for bone marrow is not well justified. USDA acknowledges that bone marrow was determined to be infective in one experiment, but it has elected not to include it as a Specified Risk Material. The only rationale provided is that the "findings were not conclusive." SRM Rule at 18. USDA should not await a "conclusive" study before taking action to prevent exposing the U.S. population to a risk of BSE. The statute mandates a precautionary approach that does not require "conclusive" demonstration that a meat food product will cause adverse health effects. It requires only that the meat contain a deleterious substance that "may render it injurious to health." 21 U.S.C. § 601(m)(1). Meat is also adulterated under 21 U.S.C. § 601(m)(3) if it is "unhealthful, unwholesome or unfit for human food." Meat that may be contaminated with BSE prions may be "unhealthful, unwholesome or unfit," even if it has not been shown conclusively to be infective. Given even a small risk of contracting BSE from bone marrow, there is no plausible rationale for this failure to include bone marrow other than impermissible cost-benefit considerations.

The Optimistically Anticipated Animal Identification Program

The Department's December 30, 2003 press release announced that USDA would "begin immediate implementation of a verifiable system of national animal identification." Veneman Announces Additional Protection Measures To Guard Against BSE, USDA Press Release No. 0449.03, December 30, 2003. This statement is accurate only if one reads the word "implementation" very broadly to mean "move forward with a currently moribund program that may not be in place for years."

At the time USDA issued the press release, the Department was undoubtedly aware of the fact that it was not prepared to put a system of national animal identification into place in the near future. There is currently no infrastructure in place to support a national animal identification system. The cattle industry has fiercely resisted such a program, arguing that it will cost hundreds of millions of dollars to get such a system up and running. Under the current USDA plan, it will be at least another 18 months until a system is in place, and it is entirely unclear

where the money will come from to pay for the program, even if it could be put into place in that time frame. Realistically, it could be years before such a system is in place.

I am sure that you will agree that the American public has a right to know the truth about the steps that USDA has taken and has not taken to protect consumers from mad cow disease. The Department's statement of December 30 was at best misleading, and at worst deceptive. USDA should issue a press release providing a reasonable estimate of when a national animal identification program may in fact be operational.

Meaningless Public Relations Measures

It seems clear that two of the actions that you announced on December 30 were included solely for their public relations value and not as part of a sincere effort to protect U.S. consumers. Both the ban on air injection stunning and the ban on mechanically separated meat imposed no burden whatsoever on the cattle industry and will not enhance the safety of meat, because neither technology is currently used in the U.S. It seems disingenuous at best for USDA to claim credit for taking action that will have no impact one way or the other.

The rest of the actions that you announced on December 30 have been under consideration since Canada reported the presence of a mad cow in May, 2003. It is clear that they were rushed out in an effort to calm the public. Had a BSE-positive cow not been discovered in Washington State in early December, 2003, the rules would no doubt have germinated in USDA for years and may never have emerged. USDA proposed the Advanced Meat Recovery rule in 1998, and the comment period closed on June 12, 1998. Apparently, the regulation was not important enough to find its way onto USDA's agenda until a mad cow was discovered five-and-one-half years later. The fact that USDA was able to promulgate an interim final rule containing entirely new requirements in less than a week suggests that USDA can proceed expeditiously when it wants to. The public may legitimately wonder why it took an outbreak of mad cow disease to induce the Department to act.

USDA should do more

Finally, CPR would urge USDA to do more to ensure the safety of meat generated in the United States. The most effective step that USDA could take to protect U.S. consumers from the risk of contracting vCJD is to require testing of all cattle prior to slaughter. Japan already does this. Quick and inexpensive tests are readily available for this purpose, and CPR is confident that a universal testing requirement would stimulate additional research aimed at identifying even faster and cheaper testing procedures.

It appears that Japan will require universal testing of all cattle exported to Japan as a minimum precondition to lifting its current ban on U.S. beef imports. Beef consumers in the United States deserve no less protection than Japanese consumers.

Furthermore, it has recently been reported that almost one thousand cattle have been imported from Alberta, Canada into the State of Wisconsin alone during the last five years. Given the absence of a nationwide tracking system, it will be virtually impossible to track down those cattle and their offspring at this late date. How can we be certain that none of those animals was infected with BSE in the absence of a universal testing requirement?

The cattle industry will no doubt complain that the enhanced assurance that a universal testing requirement will provide does not justify its added expense. This, however, is another appeal to cost-benefit balancing, an approach that is not allowed by the law.

The American public has a right to expect that the federal government will take effective steps to prevent a future outbreak of mad cow disease and, more importantly, to prevent even a single U.S. consumer from contracting vCJD as a result of consuming meat products produced in the United States. Some of the steps that USDA has taken thus far are steps in the right direction. On close inspection, however, it appears that the bulk of the actions announced on December 30 are designed to reinforce the meat industry's public relations efforts. The actual regulations by no means ensure that U.S. consumers will not be consuming meat that is contaminated with mad cow disease.

CPR urges USDA to correct the misleading statements made in its December 30 press release and level with the American people about the effectiveness of the steps USDA is in fact taking. The Department should immediately close the 30-month and bone marrow loopholes and promulgate regulations containing specific requirements for how slaughterhouses should go about removing SRM from meat to be used as human food. Finally, CPR urges USDA to promulgate a rule requiring that all cattle be tested for BSE prior to slaughter for human consumption and expand its recently promulgated product holding guideline to include all BSE-tested cattle.

Sincerely,

Thomas O. McGarity
President
Center for Progressive Regulation