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Peter Coppelman

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Chief, Standardization Branch
Livestock and Seed Program
AMS, USDA
Room 2603-S, Stop 0254
1400 Independence Avenue, SW
Washington, DC 20250-0254

Re: Docket No. LS-02-02

Dear Standardization Branch Chief:

Keep Antibiotics Working: The Campaign to End Antibiotic Overuse (KAW) is pleased to submit comments on United States Standards for Livestock and Meat Marketing Claims, Docket No. LS-02-02 (Fed. Reg. 67:79552-79556). This notice requests comments on a number of proposed marketing claims and standards applicable to cattle, sheep, swine, their carcasses and meat products. If adopted, the claims could be used in conjunction with voluntary USDA Certified or USDA Verified programs for the livestock and meat industries. USDA verification is intended to increase the credibility of the claims and assist segments of the meat and livestock industry seeking to distinguish their products from competing products.

KAW is a coalition of health, environmental, consumer, humane, and other advocacy groups that together have over nine million members. The KAW coalition was formed to address the loss in efficacy of the miracle drugs we know as antibiotics due to bacterial resistance. Antibiotic-resistant bacteria are on the rise as a result of the overuse of antibiotics in both human medicine and animal agriculture. KAW's focus is primarily on aspects of the issue related to animal agriculture. An estimated seventy percent of antibiotics used in the United States are given to farm animals that are not sick, to promote growth and to compensate for overcrowded conditions in industrial-scale livestock and poultry facilities.

KAW believes that meat labels giving consumers choices of products produced with reduced antibiotics could help accomplish the public health goal of reducing the use of antibiotics in animal agriculture. To work to that end, however, claims and standards must be clear and relevant to consumer interests. In addition, the claims must serve to distinguish "alternative" animal production practices from "conventional" practices that involve heavy or routine use of antibiotics. Label claims that obscure important differences between conventional and alternative production systems will deny consumers the freedom they want and label clarity they have a right to expect – the freedom to discern and choose between the

products from these different kinds of systems. In addition, unclear label claims undercut the ability of alternative producers to fairly compete for customers by making it harder for these producers to differentiate their products. By so doing, such claims put at risk the livelihoods of farmers who have staked their financial future on raising animals without the use of antibiotics.

In a separate letter cosigned by a number of producers, producer organizations, and consumer and other organizations, KAW strongly urges USDA to withdraw the proposed notice and begin a new, interactive process reaching out to a broader set of consumers and producers. After completing that process, the Agency should reissue the notice with a new set of proposed claims and standards.

In case the Agency refuses that request, the comments below set forth our recommendations and concerns about the substance of four proposed claims and standards relevant to the issue of antibiotic resistance.

I. KAW strongly recommends that USDA adopt the claim “No antibiotics used, or Raised without antibiotics.”

KAW strongly supports the first proposed claim (“No antibiotics used, or Raised without antibiotics”) and the accompanying standard (“Livestock have *never* received antibiotics from birth to harvest”) [italics in original]. Both the claim and standard are clear and unambiguous. They leave no room for equivocation or subterfuge by producers and accurately convey to consumers meaningful information on antibiotic use.

2. KAW recommends that the USDA abandon the claims for “No subtherapeutic antibiotics added, or Not fed antibiotics” and replace them with a new claim for “ No antibiotics used except for disease treatment.”

KAW strongly objects to both alternative formulations for proposed claim “No subtherapeutic antibiotics added, or Not fed antibiotics.” The term “not fed antibiotics” is confusing. Most consumers don’t understand the significance of animals being fed antibiotics as opposed to receiving them by other means such as injection. Many consumers could easily assume the proposed claim is equivalent to the claim of “No antibiotics used, or Raised without antibiotics.” Moreover, strictly speaking, the “not fed antibiotics” language does not discriminate among antibiotics administered to animals for different purposes. FDA has approved antibiotics for use in livestock feed for a variety of purposes ranging from feed efficiency and weight gain to treatment of bacterial disease.

The alternative formulation, “no subtherapeutic antibiotics added” is also confusing and, moreover, subject to enormous abuse. The word “subtherapeutic” is meaningless to most consumers. The term is not defined in the notice and is, in fact, notoriously difficult to define. Lack of an agreed upon definition leaves the claim open to interpretation by producers, including some who may well be doing little to reduce antibiotic use. As proposed, this claim creates a gigantic loophole in the existing standards, and thereby will sow greater confusion and inefficiencies in the consumer marketplace.

KAW recommends abandoning both alternative formulations of this claim.

KAW strongly recommends, however, that USDA offer a new claim “*No antibiotics used except for disease treatment.*” Many consumers concerned about the health implications of antibiotic overuse are interested in purchasing animal products from animals that were *only* given antibiotics if they were sick – in other words, animals treated with antibiotics in a familiar and restrictive manner akin to veterinary care for pets. The claim “No antibiotics used except for disease treatment” would fully meet consumer expectations that livestock were administered antibiotics only when clearly justified by clinical indications of illness. It would also allow consumers to choose products produced with reduced antibiotic use, since most antibiotic use in animals by far is for growth promotion and disease prevention.

We suggest that the standard for this claim would require that livestock only be administered antibiotics approved by FDA for disease treatment uses and that use of these or other antibiotics approved for feed efficiency, weight gain, disease prevention, and disease control would not be permitted. Such a standard would be consistent with FDA terminology in drug approvals and thus relatively easy for producers to interpret.

3. KAW also strongly recommends that USDA abandon the claim for “No detectable antibiotic residue (analyzed by ‘method x’).”

KAW also strongly opposes the claim “No detectable antibiotic residue (analyzed by ‘method x’).” This claim raises complex issues concerning the effects of antibiotic use, and will likely create considerable consumer confusion. If USDA decides to go ahead with the claim, it should amend and clarify the disclaimer accompanying the claim as detailed below.

Without additional information, consumers are likely to confuse a claim for “no detectable residues” with other claims, such as “no antibiotics used.” Moreover, in our experience, many consumers believe that antibiotic residues are the principle problem associated with agricultural antibiotics and cause antibiotic resistant infections in people, even though the available science suggests that the role of residues is relatively minor. By contrast, the causal role of the administration of antibiotics to livestock is well established and far more important. See, e.g., Barza, M. and S.L. Gorbach, eds., *The need to improve antimicrobial use in agriculture*, *Clinical Infectious Diseases* 34 (Supp. 3):S71-S144 (2002). Thus the proposed “no detectable antibiotic residue” claim may lead some consumers to mistakenly believe that they are purchasing meat from producers whose practices do not contribute to antibiotic resistance – even though these producers are still using antibiotics for growth promotion and routine disease prevention.

If used, the proposed requirement that the label clearly inform the consumer/purchaser that the animal may have been treated with antibiotics would need to be amended and clarified. First, the disclaimer should be presented in at least as large a font size and as prominent a place on the package label as the claim. Second, USDA should prescribe specific wording that includes language noting that production of the animal product may contribute to antibiotic resistance. We suggest the following language: “*This product may be derived from animals to which antibiotics were administered. The administration of antibiotics to animals, and not the presence of detectable antibiotic residues in food products, is believed to be the major cause of antibiotic resistance due to agriculture.*”

4. KAW recommends that USDA consult with a diverse group of stakeholders and develop a new standard for the grass-fed animal claim.

The standard for the grass-fed animal claim is unclear, but appears to be too weak to distinguish grass-fed livestock from conventional grain-fed animals.

The standard, “Grass, green or range pasture or forage shall be 80% or more of the primary energy source throughout the animal’s life cycle” is confusing and unclear. What is a “primary” as opposed to secondary energy source? How would the 80% be calculated? Where did the 80% figure come from in the first place?

Because the standard is confusing, it appears it may cover conventional operations that enclose animals and feed them grain in the final stage of their lives. To the extent that is the case, the standard will mislead consumers drawn to the label because they believe it indicates an alternative to that style of animal production.

A grass-fed claim that distinguishes alternative from conventional feedlot systems is important to KAW because it also differentiates products produced with reduced antibiotics. Ruminant animals fed grass or pastured throughout their lives are typically given few if any antibiotics. By contrast, feedlot cattle are routinely fed antibiotics, often to reduce diseases caused by their grain-rich diet.

KAW recommends that USDA convene a diverse group of stakeholder to formulate a new standard for the grass-fed claim that will distinguish alternative from conventional feedlot animals.

In summary, KAW believes label claims are an important route to protecting the public’s health by reducing the use of antibiotics in animal agriculture. We applaud USDA’s attempt to establish claims that are relevant to the antibiotic issue. Unfortunately, with the exception of the “No antibiotics used, or Raised without Antibiotics” claim, the proposed claims relevant to antibiotic resistance are confusing, misleading, and subject to abuse in the marketplace. We urge USDA to rethink and clarify the claims and standards relevant to antibiotic resistance in line with our recommendations above.

Sincerely,

Peter Coppelman
Director
Keep Antibiotics Working