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Jean Hofve

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To Whom It May Concern:

On behalf of the Animal Protection Institute, a national non-profit animal advocacy organization and its 85,000 members, I am pleased to submit comments on the Draft Risk Assessment of the Relative Risk to Public Health from Foodborne *L. Monocytogenes* among Selected Categories of Ready-to-eat Foods, and the draft Risk Management Plan (Action Plan).

The goal of this program is to reduce foodborne *Listeria monocytogenes* (LM) associated illnesses by 50% by the year 2005, to comply with the President's May 5, 2000, directive. We commend the ongoing efforts of HHS and USDA and their various departments in this regard.

General Comments on Draft Risk Assessment document

The principal reservoir of LM is in forage crops, mud, water, and silage. Wild and domestic animals comprise another reservoir. Inapparent infections are common. While fruits and vegetables can be contaminated by soil or manure used as fertilizer, most human outbreaks have been traced to consumption of animal products such as smoked seafood, fresh soft cheese, and other meat and dairy products. In one outbreak, pasteurized milk was determined to be the source. In this instance, post-pasteurization contamination was considered highly unlikely, and the pasteurization process was done properly, leading to speculation as to the ability of LM to survive pasteurization (possibly sequestered within leukocytes).<sup>1</sup> Because LM is resistant and can grow at refrigeration temperatures and under adverse conditions, it is an extremely difficult organism to control.

The Draft Risk Assessment document states: "Many healthy people carry *L. monocytogenes* in their intestinal tract at some time in their lives. This suggests that people are routinely exposed to *L. monocytogenes*. This also suggests that exposure rarely leads to serious illness, given the low number of reported cases . . . In humans, both food contamination data and fecal Carriage studies suggest that exposure to *L. monocytogenes* is relatively common among humans." This is a vast understatement. In fact, one survey found that an average adult consumes LM-

contaminated food about **100** times a year – that’s once every 3 or **4 days**, or about once per **10** meals. It appears that the main thing saving the population from being totally devastated by this organism is the relative resistance of most adults to LM. The bacterial numbers found in samples ranged **from** only a few cells to greater than 25,000 CFUs (colony-forming units) per **25** grams of food in about **5%** of samples, in spite of the U.S.’s “zero-tolerance” policy. The researchers estimated that of 100 average (annual) exposures to LM, **10** will contain more than **100,000** CFUs, **5** will contain **1,000,000** CFUs, and **2** will contain about **100,000,000**. (This study was done in the U.K., but incorporated international data, and the author emphasized that the conclusions are equally applicable to the U.S.).<sup>2</sup> This is astounding data that serves to highlight the urgent need for corrective action.

### General Comments on Draft Action Plan

The draft Action Plan notes that HHS and USDA have been working to prevent illness and control LM “[f]or more than **15** years. It **also** states that LM “causes an estimated 2,500 illnesses and 500 deaths in the United States each year.” The Draft Assessment of Risk states that the incidence of LM **was** reduced by approximately **50%** during the **1990’s** due to “[m]ajor efforts by industry and regulatory agencies.” However, a review of the literature shows that in **1980-1982**, there were about 3.6 cases per million population (**800** cases),<sup>3</sup> in **1986** the rate was about 7 per million (an estimated **1,700** cases),<sup>4</sup> and as of **1988-90** there were **7.4** cases per million.<sup>5</sup> While there was a decline to about **5** cases per million by **1996**,<sup>6</sup> according to one study this rate tripled to **15** cases per million in **1997**<sup>7</sup> (although CDC’s estimate remained at 5 cases per million<sup>8</sup>). If there are now 2,500 cases annually, this is about **9** cases per million. We are somewhat at a loss to understand what HHS and USDA have been doing for the last **15** years, and how they have calculated this 50% reduction, given that there are 30% more cases annually now than in **1986**, and **300%** more cases now than in **1980**, while the population has increased only about **17%** in that time. The claim of a 20% mortality rate (**500/2500**) also seems optimistic, considering that mortality has consistently hovered around **25%** throughout the **1990s**.

The Action Plan has identified eight primary objectives dealing with consumer and health care provider education, guidance for producers, training for industry, enhanced enforcement, regulatory, and surveillance activities, and further research. Specific comments on the Action Plan Objectives follow.

#### Objective 1: Enhance consumer and health care provider information and education efforts.

There **are** seven specific actions outlined within **this** Objective, including two specifically directed toward consumers, particularly high-risk groups such as pregnant women and immunocompromised individuals. The “messages” the Action Plan proposes will address safely selecting, storing, handling, and preparing foods.

Because LM is ubiquitous in the environment and a common contaminant of many kinds of food, at least **part** of the responsibility for preventing problems does appropriately lie with the consumer. Therefore the actions outlined in this objective are necessary and appropriate. However, there seems to be a trend for FDA and USDA to **pass** along a disproportionate amount of the food safety burden to the consumer, **as** with the Egg Safety Action Plan. We believe that the *primary* responsibility belongs to the agencies who oversee food safety, FDA and **USDA**, and that the majority of LM reduction should be accomplished *pre-consumer*.

Listeriosis appears to be associated with higher fat foods (skim milk is said to be “protective”), and most animal products contain a significant amount of fat. For instance, so-called ‘**98% lean**’ sliced turkey actually derives 20% of its calories **from** fat. There also appears to be a correlation between **high** risk, outbreaks, and individual instances of foodborne listeriosis with consumption **of** animal products. Therefore, we strongly urge **HHS** and **USDA** to include in these “messages” a recommendation that consumers limit consumption of (or completely avoid) meat, **poultry**, fish, and dairy products in favor of the most low risk products such **as** fruits and vegetables, as well as beans, nuts, and grains. Clearly, HHS and FDA recognize this association, because Objectives **4** and **5** focus primarily on meat, dairy and **poultry** products.

Health care professionals should emphasize the risks of animal product consumption to their patients. These include not **only** potential exposure **to** foodborne pathogens (LM and others such as Salmonella, *Campylobacter*, E. coli, Clostridium *perfringens* and C. botulinum, Aeromonas, *spp.*, Bacillus cereus, Staphylococcus *aureus*, Vibrio *spp.*, and *Yersinia enterocolitica* – an estimated **5** million cases annually, resulting in 4,000 deaths<sup>9</sup>), but also chronic diseases associated with meat and **dairy** consumption, such as cardiovascular disease, **high** blood pressure, **ulcers**, colitis, Crohn’s disease (which may be caused by drinking milk from cattle infected with Johne’s disease), obesity, diabetes, hormone imbalances, and breast, colon and prostate cancers.

We commend the plan to utilize information technologies such **as** the internet and satellite video conferences. However, we hope that more conventional media, such **as** public service announcements and educational broadcasting on television and **radio**, will not be neglected. These have the **potential** to reach huge numbers of consumers who might not otherwise be exposed to this information.

Objective 2: Develop and revise guidance for processors, retailers, and food service establishments / institutions that manufacture or prepare ready-to-eat **foods**.

We are concerned that mere “guidance” is inadequate, and **are** pleased to see that appropriate, supportive rulemaking is also planned under Objective **5**. Clearly, post-processing contamination is a significant contributor to LM occurrences, and prevention must be emphasized.

Objective 3: Develop and deliver training / technical assistance for industry and food safety regulatory employees.

Effective regulation and inspection is essential to reduce LM contamination. The goals outlined in **this** Objective **are** reasonable and comprehensive when considered **as** part of the whole program.

Objective 4: Review and redirect enforcement and regulatory strategies including microbial product sampling.

Adequate and appropriate sampling/testing is the only way to ascertain whether the objectives relating to production and pre-consumer handling are effective. Insofar as these processes affect LM contamination, we concur with the planned increases in inspection and sampling **as** well **as** instructional labeling designed to improve handling of ready-to-eat meat and **poultry** products prior to consumption.

The implementation of HACCP beginning in 1996 has shifted the burden of food hazard control toward **industry** and away **from** government regulators. **This** **has** resulted in the potential loss of control over some hazards by regulatory officials. **An** example of this is the situation with Supreme **Beef** that occurred in Texas in late 1999, when USDA inspectors were withdrawn after ground beef made in the meat processing plant tested positive for Salmonella three times in a row. A federal judge ruled that USDA had no authority to withdraw its inspectors, and cast doubt on the ability of HACCP to accurately identify contamination **sources**, and an appeals court upheld this judgment. A subsequent USDA audit report concluded that, with HACCP, the agency had “reduced its oversight beyond what was prudent and necessary for the protection of the **consumer**.”<sup>10</sup> **API** is therefore concerned that this Objective relies to **a** significant extent on HACCP, which may itself be unreliable. Even assuming that HACCP implementation is valid, ensuring/enforcing compliance by producers **has** not been adequately addressed. None of the proposed measures will be effective without strict compliance, and compliance cannot be assured without strict enforcement.

Objective 5: Propose new regulations and revisions to existing regulations. **as** needed.

The first item is to expedite the review of food additive petitions for LM control interventions. We believe that prevention should come before control, and that efforts directed toward prevention **are** the best and most effective actions that can be taken.

Many consumers and consumer health groups are concerned about the current levels of antibiotics, pesticides, and other additives in foods that may pose long-term or cumulative health **risks**, or risks to persons who are chemically sensitive. There may also be **risks from** combinations of additives that have not been assessed for possible interactions. Additionally, **there are** significant concerns about environmental contamination through sewage, accidental spills, runoff, and other sources. **The** addition of more chemicals **and** treatments to **the** existing arsenal may not be in the ultimate best interests of people, animals, or the environment. FDA’s role in reviewing additives and treatments is to **assure** relative, not absolute, safety. That is, there

should be minimal risks associated with these additives, not zero risks. We believe that any additional **risks** associated with food additives or treatments are unjustifiable.

Similarly, Good Manufacturing Practice regulations are intended to reduce, not eliminate, food safety risks. Perhaps elimination *should* be the goal. We realize that 100% risk elimination is unattainable, but aiming for perfection will produce better results than aiming for something less.

The major flaw in promoting more and “better” intra- or post-processing treatments is that they may tend to discourage crucial efforts toward preventing contamination in the first place. **Why** should a producer bother with all those expensive, labor-intensive, time-consuming sanitation procedures when they can “**fix**” the product later by adding more chemicals or irradiating? We are very concerned about a long-term attitude shift away from prevention and more toward the quick **fix**.

#### Objective 6: Enhance disease surveillance and outbreak response

**This** objective delineates the responsibilities of the CDC. While the increase in laboratories and diagnostic capabilities is commendable, it is not clear how this will “more effectively limit the spread of illness.” Because of the variable and often lengthy latent **period** before symptoms occur (3 to **70 days**<sup>11</sup>), a single source of contamination, **as in most** outbreaks, is often long gone by the **time** CDC knows – or will know, even with fulfillment of **this** objective – that there **is an** outbreak. Because exposure has already occurred, it does not seem likely that even rapid detection would significantly “limit the spread of illness,” although quickly identifying the source and persons who have been exposed may enhance prompt diagnosis and treatment.

Information is an important tool, and we support the ongoing research outlined in this objective.

#### Objective 7: Initiate projects with retail operations such as delicatessens and salad bars to pilot LM control measures including employee practices.

Given the **high** potential for LM contamination and **growth** in these situations, this objective will close a significant gap in LM containment. We are concerned about disseminating these procedures to “all” such operations, since there **are** probably hundreds of thousands of them around the **country**, from tiny mom-and-pop stores to huge restaurant chains. We would like to see more specific plans for promoting successful control measures.

#### Objective 8: Coordinate research activities to refine the **risk** assessment. enhance preventive controls and **support** regulatory, enforcement. and educational activities.

A comprehensive plan **that** minimizes duplication and **maximizes results** is extremely important. However, we see a lot of research in **this** objective, but no application. Knowledge alone is

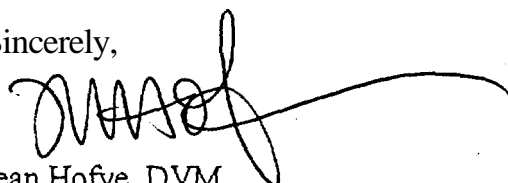
impotent; we would like to see plans for effective utilization of the information that will be gained from **this** research, **as well as** options for enforcement.

**Objectives 2 - 8** are essentially “closing the barn door **after** the horse is gone.” None of these objectives address the primary source of contamination of meat and **dairy** products – the animals themselves. The slaughterhouse is the source of carcass contamination, **commonly** from organisms in dirt or feces on the hide, hooves, or tail, or from the gastrointestinal tract of the **animal**, but also from infected body **fluids**, excised abscesses, mastitic mammary glands, or lymph nodes. Contamination may occur **from** spattering of body fluids onto walls, floors, **fixtures** or equipment, which can then be transmitted to the carcass. Specific problem points include the kill box, bleeding knives, hide puller, and areas where carcasses are eviscerated and split.<sup>12</sup> Similar contamination can occur during the slaughter of swine, sheep, and **poultry**.

However, a significant share of the bacterial contamination problem may occur even earlier. Animals raised in battery, confinement or “factory farming” **operations** are prone to **stress**-associated disease. Animals may be shipped, fattened at feedlots, or held **at** the auction barn or slaughter-house for various periods of time. Sick, pregnant, stressed, and non-ambulatory animals may have increased pathogen loads. Poor husbandry techniques, contaminated feed, and inadequate sanitation **on** the farm, in trucks and holding pens, and at the slaughterhouse may all add to the problem. We strongly urge HHS and **USDA** to examine common animal husbandry, **transport** and slaughter practices to see where the LM problem can be prevented at its most basic source.

**Thank** you for your consideration of these comments.

Sincerely,



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Program Coordinator  
Animal Protection Institute

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