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05-013N 05-013N-13 Ken Kelly Caroline Smith DeWaal

U.S. Department of Agriculture Food Safety and Inspection Service Docket Clerk 300 12th Street, S.W. Room 102 Cotton Annex Washington, DC 20250

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RE: Request for comments on the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry. (Docket No. 05-013N)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) request for comments on the regulatory jurisdiction of certain food products containing meat and poultry. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

I. Summary

CSPI supports the need for a more unified food safety system. Currently the safety and quality of the nation's food is governed by a complex overlapping system that consist of over 30 laws governed by 12 agencies and over 50 interagency agreements. The existing framework has resulted in fragmented jurisdictions between the two principle food regulatory agencies, USDA and FDA. CSPI believes that a clearer approach for determining jurisdiction of these two agencies with respect to food products

¹ Government Accounting Office, Federal Food Safety and Security System: Fundamental Restructuring Is Needed to Address Fragmentation and Overlap Pg. 2.

containing meat and poultry is a small step towards reducing the confusion generated by the current system.

II. USDA and FDA Needs a Clearer Approach to Determining Jurisdiction

Both USDA and the FDA have regulatory authority over the vast majority of the food supply. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, USDA is responsible for regulating meat, poultry, and processed egg products. FDA, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act regulates all other food, including seafood, fruit, vegetables, and raw egg products. Although FDA-regulated food products are linked to two thirds of the outbreaks associated with known causes, the FDA's budget is just a third of the total budget for food-safety inspections. While USDA inspects meat-processing plants daily, plants processing FDA-regulated food are inspected on average just once every five years. Further, as a result of limited funding, the FDA inspects less than two percent of the estimated five million shipments of food imported into the country each year.

In the past, the Agencies determined jurisdiction for food products containing meat and poultry on a case-by-case approach, which has led to inconsistencies in product decisions and gaps in the underlying rational for determining jurisdiction. This case-by-case approach also causes confusion among the agencies, manufacturers of food products, and ultimately consumers who look to the government to ensure the safety of the food. A new method for determining jurisdiction is essential to integrating the complex patchwork of food safety laws and regulations that govern our food supply.

CSPI believes that a process that better delineates agency jurisdiction over food products will improve organizational efficiency, allow for the better allocation of

² General Accounting Office, Food Safety: Overview of Federal and State Expenditures 2-3 (2001) [hereinafter GAO Food Safety Expenditures]; U.S. Department of Agriculture, Office of Budget Program and Analysis, USDA FY 2004 Budget Summary.

³ GAO Food Safety Expenditures, at 12, 16.

⁴ This estimate is based on the new resources the FDA received in the FY 2002 bioterrorism supplemental appropriations. Hearings on FY 2003 Food and Drug Administration Appropriations Before the

resources, and set an example for state and local food safety programs. However, the method for determining jurisdiction must not compromise existing food safety protections. Consumers expect and deserve to know that the food they consume is safe to eat.

The USDA-FDA working group convened to consider the issue has suggested a new approach for determining jurisdiction. This approach looks at the contribution of the meat or poultry ingredients to the identity of the food taking into account whether it significantly contributes to the foods basic nature. CSPI believes this is a reasonable starting point. As the USDA/FDA working group noted, this method may lead to changes in jurisdiction for certain foods and categories of food.

CSPI believes that any new standard for determining jurisdiction should take into account a number of factors. First, any new standard for determining jurisdiction of a food product must be clearly articulated. It should be understandable to not only USDA and FDA, but also the average consumer buying the product. Second, the standard should be flexible enough to take into account the development of new products and variations in the original formula. New food products and variations are constantly being introduced to the market by companies seeking to increase market share and revenue. Third, the standard should not lessen the food safety protections afforded the food product if the regulating agency changes. Fourth, if the standard for determining jurisdiction relies heavily on the level of "contribution" of a meat or poultry product, as suggested by the USDA-FDA working group, then the threshold amount should be clearly defined, perhaps as the amount of overall weight or percentage of composition of meat or poultry in the food product.

III. Conclusion

USDA and FDA needs to improve the system by which it determines jurisdiction of food products containing meat and poultry. The current system is inadequate and contributes to an already confusing regulatory framework. However, any new method for

determining jurisdiction between the agencies must also take into account its impact on public health.

Respectfully submitted,

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