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<http://www.fda.dockets@oc.fda.gov>
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Re: Recordkeeping Requirements for Human Food and Cosmetics
Manufactured From, Processed With, or Otherwise Containing, Material From
Cattle (Docket No. 2004N-0257)

Dear Sir or Madam:

With net revenues for 2003 exceeding \$31 billion, Kraft Foods Global, Inc. is the largest food manufacturer in North America and the second largest worldwide. Our well-known brands are found in 99% of U.S. households and sold in 150 countries around the world. The consumer trust we have built over the last 100 years is priceless and critical to our company's continued success. That trust, of course, depends upon the safety of our products, which is of paramount importance to us. Thus, we support the efforts of the Food and Drug Administration (FDA) to enhance current safeguards against the agent that causes bovine spongiform encephalopathy (BSE).

The FDA interim final rule limiting the use of specified cattle derived ingredients complements appropriately the aggressive steps taken by the U.S. Department of Agriculture (USDA) and many programs implemented by industry, all of which are designed to minimize the risk of a BSE outbreak in this country. Kraft is concerned, however, that the type of recordkeeping requirements contemplated by the proposed rule may not actually further this effort as the agency intends. Therefore, Kraft urges FDA to consider the options suggested below in developing a final regulation.

The proposal would require development of new recordkeeping systems that would not enhance food safety.

The recordkeeping proposal appears to require the creation of new documents of questionable utility. The rules USDA has implemented to address the risk of BSE in cattle destined for slaughter and in meat products produced under USDA supervision do not include recordkeeping requirements for manufacturers that use inspected materials in further processing operations. If the current risk management strategy adopted by

USDA is sufficient to address the risk of BSE in meat products, that strategy also should be sufficient to address risks potentially associated with ingredients derived from these products and used at the very low levels present in the meat containing food products FDA regulates. Yet the proposal appears to require creation of a new document for each lot of food ingredient containing material derived from cattle stating that the ingredient does not contain prohibited materials.

As outlined in these comments, Kraft has developed a beef-sourcing policy and detailed control program that includes recordkeeping requirements. In our opinion, the system we have in place effectively controls BSE risk without requiring unnecessary paperwork. In these comments, therefore, we share our efforts with FDA to encourage the agency to recognize alternatives to the pending recordkeeping proposal.

The continuing guarantee requirements in Kraft Foods Control Program are effective.

Kraft recognizes that food safety and processing technologies have little or no impact on inactivating the BSE agent in beef-based food products. Kraft, therefore, has developed BSE control policies that principally focus on the sourcing and harvesting of raw beef materials to exclude the BSE agent. As a result, our beef sourcing policy and detailed control program are based on a series of science-based requirements, or hurdles, that minimize the risk of BSE agents entering our raw beef material supply.

The control program is founded on the use of multiple hurdles to minimize the risk of sourcing any raw materials that may contain the BSE causative agent. These hurdles include:

- Sourcing healthy animals produced in compliance with the ruminant feed ban,
- Prohibiting specific risk materials (SRM) where the BSE agent is known to accumulate, including brain and spinal cord tissue,
- Purchasing meat recognizable as skeletal muscle trim or products directly derived from these materials, and
- Specifically excluding purchase of all beef materials that have been removed from bone by a mechanical process, including beef from advanced meat recovery (AMR) systems.

Additionally, Kraft requires its suppliers to comply with the following specific requirements to minimize the risk of cross-contamination during harvesting:¹

¹/ These requirements are consistent with the policies and rules announced by USDA in January. These include: 1) the interim final rule declaring that Specified Risk Materials (skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle 30 months of age or older and the small intestine of all cattle) are

- Maintaining an aggressive inspection system,
- Refusing to accept beef from diseased animals,
- Excluding cattle showing any clinical signs suggestive of BSE from the human food supply (unless individually tested for BSE with negative results),
- Stunning animals using methods other than air injection, and
- Verifying that they are in full compliance with federal regulations regarding the ruminant feed ban and requiring similar verification from stockyards or public auctions from which they acquire livestock.

Moreover, Kraft's vendors must adhere to a certification program that requires documentation of each BSE control measure. To that end, we require a Continuing Letter of Guarantee from our suppliers to demonstrate compliance with the requirements of our procurement policy. We also conduct on-site audits of our suppliers to verify that they are in compliance with our guidelines and specifications.

This same approach is followed for the products we manufacture and supply to customers as either finished products or ingredients. Compliance with the requirements of the Continuing Letter of Guarantee is enforced by USDA at the slaughter plant, complied with by our suppliers, and verified by random audits conducted by Kraft staff. Our customers also maintain an audit program, visiting our manufacturing sites to evaluate compliance with the Continuing Letter of Guarantee we provide. Kraft believes that maintaining a Continuing Letter of Guarantee from our raw material suppliers adequately demonstrates compliance with the requirements of FDA's recordkeeping proposal.

Further, Kraft believes these records can be effectively maintained electronically, and we do not believe each individual lot of raw materials or finished product needs to be accompanied by the Continuing Letter of Guarantee. Such a requirement would add no value to our food safety efforts. The requirement would add unnecessary costs without any added public health benefit or protection for consumers that is not already addressed by USDA's rules.

prohibited in the food supply, 2) the interim final rule expanding on the prohibition of central nervous system tissues in advanced meat recovery products, 3) the final rule to prohibit air injection stunning, and 4) the notice announcing that FSIS inspectors will not mark ambulatory cattle that have been targeted for BSE surveillance testing as "inspected and passed" until negative test results are obtained.

KRAFT RECOMMENDS THAT FDA CONSIDER FOUR ADDITIONAL BSE CONTROL PROGRAM COMPONENTS.

Kraft recommends that four additional BSE control program components receive high priority from industry groups and government regulatory agencies. These components are: 1) strict enforcement of import restrictions designed to keep the BSE agent out of the country, 2) complete compliance with the ruminant feed ban to prevent recycling of the BSE agent, 3) continued support for active BSE surveillance to benchmark the BSE status of the country, and 4) education of members of the meat supply chain. Given the possibility that a BSE-positive animal may be identified even in countries currently considered BSE-free, these measures are reasonable additional steps that in our opinion should be taken to tighten existing controls.

Kraft actively endorses and promotes continued vigilance and commitment to BSE prevention, including funding of research efforts through trade groups to develop BSE control practices and continued educational programs for animal producers, processors, retailers, food service operators, and consumers. Adherence to these four control program components, current USDA regulations, and a documentation program such as that suggested by Kraft, will enable industry and FDA to adequately protect the consuming public from the risks of BSE.

Conclusion

In summary, with the current regulatory and recommended safeguards in place, food manufacturers can successfully meet the goals of the agency's recordkeeping proposal by maintaining electronic copies of Continuing Letters of Guarantee from raw material suppliers or by collecting the same documentation with each shipment of all ingredients containing materials derived from cattle.

Kraft always stands ready to work with the government to protect the safety of the food supply. Please do not hesitate to contact me if we can provide additional information that might be helpful. Thank you for your consideration.

Sincerely,



John Ruff
Sr. VP Global Quality, Scientific Affairs & Nutrition
Kraft Foods Global, Inc.