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December 23, 2005

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Re: Docket No. 2000P-1491; Petition to Amend Standards for Parmesan and Reggiano Cheese; 70 Fed. Reg. 56409 (Sept. 27, 2005)

Dear Sir or Madam:

Kraft Foods Global, Inc. (Kraft) is a U.S. based \$32 billion global company, the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells. Today, Kraft brands are found in more than 99% of all U.S. households and over 155 countries around the world.

As the largest U.S. producer of parmesan cheese, Kraft has a substantial interest in ensuring that the standard for parmesan cheese is modern and promotes honesty and fair dealing in the interest of consumers. Kraft also has considerable experience with this standard: we actively participated in the process to establish this definition and standard of identity in the 1940's, participated again in the 1970's when the standard was amended to reduce the minimum curing time from 14 to 10 months, and most recently, petitioned the agency to amend the standards to accommodate additional advances in curing technologies. Kraft's petition specifically seeks to amend the standard to reduce the minimum curing time from 10 months to 6 months. As FDA found when the agency last amended the standard to reduce the minimum cure time, a shorter curing period can provide many benefits, including improved use of plant resources, reduced production costs, and greater product consistency.

The proposed amendment is a straightforward but necessary change. In 1997, Kraft determined that modern enzyme technologies allow parmesan cheese to be produced with a curing period of 6 months, rather than the 10 months specified in the standard. We asked FDA for a temporary permit to market test (TMP) cheese cured for 6 months; in support of this request, we submitted compositional, nutritional, consumer acceptance, and performance data. FDA granted the TMP in January 1999. Based on the positive consumer response, in 2000, we asked FDA to amend the parmesan cheese standard to allow the shorter curing period on a permanent basis. FDA subsequently extended the TMP indefinitely and invited other cheese companies to participate. Since that invitation, the 6-month aging period has been tested

thoroughly—the agency docket log identifies at least five companies in addition to Kraft who have notified FDA of their desire to participate in the market test.

FDA now requests public comment concerning a 6-month curing period, including data and information addressing whether the proposed change will promote honesty and fair dealing in the interest of consumers; is necessary and appropriate; or will affect the basic nature, physical properties, organoleptic qualities or safety of parmesan cheese. In addition to the data Kraft submitted in the 1997 TMP application, as well as the clear agency precedent establishing the benefits of improvements of this type, we now have more than six years of experience with the shorter cure time. The broad consumer acceptance of cheese produced under the TMP shows that an amendment is both appropriate and necessary to bring the standard in line with the cheese currently found in the marketplace.

Marketing Experience – Consumer Acceptance. Since June 1999, when the TMP first took effect, Kraft has sold about 300 million pounds of parmesan cheese cured for 6 months with new enzyme technology. Based on our regular monitoring of consumer comments, we have found excellent consumer acceptance of the new product, and have observed no trend suggesting consumer dissatisfaction with product quality.

Our experience confirms that a minimum 6-month aging period results in a cheese with the same basic nature and essential characteristics as parmesan cheese aged for longer periods. In light of the total volume sold by Kraft and others, as well as the length of time the “new” product has been marketed, it is apparent that a 10-month aging period is not an “essential characteristic” of parmesan cheese. Indeed, products lawfully classified as parmesan cheese represent a range of flavor profiles and other characteristics. The revised curing period is simply a minimum standard that adds flexibility, not a mandate. Thus, any producer who wishes to use longer aging periods or other methods to create a parmesan cheese with unique attributes (e.g., particular flavor characteristics) may do so and market the product on that basis. Consumers are well-qualified to choose the cheese products they prefer from among the range of products properly marketed as parmesan cheese.

Kraft is aware of a point of view held by some in the cheese industry that the amendment should be allowed for grated parmesan cheese only. Grated parmesan cheese is necessarily a product of ungrated parmesan cheese, so the rationale for such a position is unclear to us. Our experience shows that wheels and blocks produced with a 6-month cure time have the traditional characteristics of parmesan cheese.

Marketing Experience – Safety. As we stated in our TMP application, parmesan cheese cured for 6 months is just as safe and wholesome as cheese cured for a longer time. Length of curing time is not an important safety factor for parmesan cheese: our expert microbiologists know that within the first two to three weeks of the aging process, undesirable organisms—assuming that any are present—become unable to compete with the starter culture. In addition, the low moisture and relatively high salt content of parmesan cheese contribute to

its good safety profile. Testing described in our TMP application showed parmesan cheese cured for 6 months to be within the ranges of moisture, salt levels, and pH (among other properties) found for 11 other products sold at that time. Our conclusions and data on the safety of parmesan cheese cured for 6 months are now supported by the past 6 years of extensive marketing experience, with over 300 million pounds sold by Kraft and others.

Need for Standards Reform. The proposed revision to the parmesan cheese standard is part of a broader effort to modernize food standards. An updated approach for parmesan cheese is consistent with the general principle that standards should permit maximum flexibility in the technology used to prepare a standardized food, so long as the technology doesn't affect the food's basic nature, essential characteristics, nutritional quality, or safety.

Although Kraft supports FDA action as soon as possible, we acknowledge that FDA may prefer to make a final decision in the context of the agency's broader effort to modernize food standards generally. As described in our August 2005 comments on modernizing food standards, we agree with the prevailing industry position that a "horizontal approach" can make the best use of limited agency resources. A horizontal approach could be used to increase flexibility for parmesan and other cheeses by establishing an across-the-board authorization for shorter cure times made possible by advances in technology, such as enzyme technologies that allow for faster ripening. Alternatively, FDA might consider amending the parmesan cheese standard to provide for any aging period resulting in a cheese with the basic nature and essential characteristics of parmesan, as determined through appropriate testing and other data.

At the same time, we appreciate that adoption of broader standards reform may require several years and substantial agency resources. The amendment under consideration provides a simple and efficient way to immediately update an important aspect of the parmesan cheese standards.

In summary, the action requested by Kraft is a straightforward but necessary change to an important standard of identity. We urge FDA to bring the existing parmesan cheese standard in line with the marketplace by adopting the proposed amendment.

Respectfully submitted,



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