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Mr. James C. Sartori
President
Sartori Food Corporation
107 Pleasant View Road
Post Office Box 258
Plymouth, Wisconsin 53073

Re: Docket No. 00P-1687/CP1

Dear Mr. Sartori:

This letter is in response to your citizen petition, dated December 20, 2000, requesting that the Food and Drug Administration (FDA) amend the Standard of Identity for Parmesan Cheese (21 CFR § 133.165) to reduce the curing time from "not less than 10 months" to "not less than 6 months." Please disregard the letter of June 8, 2001. The docket number was incorrect. This letter replaces the letter of June 8, 2001.

In accordance with 21 CFR § 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other Agency priorities and the limited availability of resources. Additionally, FDA will not likely take any action on your petition until ongoing related standards modernization activities that would impact your petition progress further.

FDA recognizes the importance of reinventing food standards in a manner that both protects the interest of consumers and provides manufacturers reasonable flexibility in using innovative techniques to produce foods governed by a standard of identity. Consequently, the Agency is currently working with the Food Safety and Inspection Service of the United States Department of Agriculture to propose a set of guiding principles by which existing federal food standards of identity may be revised or eliminated, or new ones established. We encourage you and the food manufacturers you represent to provide comments on these

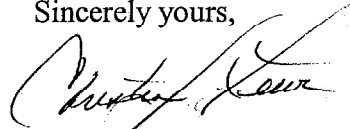
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guiding principles when the proposed rule is published in the Federal Register. As we continue to develop our policy on the modernization of food standards, we will consider how to most appropriately address your petition within FDA's overall strategy to reinvent food standards.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Christine J. Lewis".

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

SARTORI FOODS

The Flavor and Performance Specialists

December 20, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room I-23
12420 Parklawn Drive
Rockville, MD 20857

Subject: Citizen Petition to Amend the Definition and Standard of Identity for Parmesan Cheese as currently established in 21 CFR §133.165.

The undersigned, Sartori Food Corporation, a manufacturer and converter of aged Italian cheeses, located in Plymouth, Wisconsin submits this petition to the Commissioner of the Food and Drug Administration under sections 401 and 701 of the Food, Drug and Cosmetic Act (21 U.S.C. 341, 371) to amend the standard of identity for Parmesan cheese. Our purpose in doing so is to promote honesty and fair dealing in the interest of consumers--by proving economic value to both cheese manufacturers and consumers. Our petition also recognizes the advances in cheese making science in the manufacture of Parmesan cheese over the years.

1. Action Requested

Sartori Food Corporation (the petitioner) proposes that 21 CFR § 133.165, the standard of identity for Parmesan and reggiano cheese, be amended as follows:

Section § 133.165 (a), last sentence in paragraph, presently contains the provision that (Parmesan) "It is cured for not less than 10 months."

The petitioner proposes that this sentence now be revised to read:

"It is cured for not less than 6 months."

2. Statement Of Grounds

The petitioner, Sartori Food Corporation, manufactures, converts and markets large quantities of Parmesan cheese in the United States--selling this product to food service and industrial customers. Petitioner, formerly as the S&R Cheese Corporation, was an active participant in the development of the original Parmesan cheese standard in the late 1940's, and also actively participated in amending the Parmesan age standard from 14 months to the current 10 months in 1973.

A. Product Equivalency

The petitioner's make procedure involves the use of an improved enzyme technology, but is otherwise the same as the make procedure used in making Parmesan over the past

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several decades. No novel make procedures or manufacturing processes are used. And, the improved enzyme technology used is commonly used in cheese making with an ongoing history of safe and suitable use. This enzyme technology and manufacturing procedures and processes are commercially available to any knowledgeable Parmesan cheese maker. Using adequate scientific research and experimentation, other cheese makers can produce in this shorter 6-month time period Parmesan cheese that has the full functional and taste properties of Parmesan cheese aged for 10 months. As evidence of this, we reference the fact that another major manufacturer of Parmesan cheese is currently marketing Parmesan cheese aged for 6 months. (Volume 64 Federal Register, April 6, 1999 /Notices)

The petitioner has determined through internal sensory analysis utilizing trained panelists, and through a respected, independent nutritional analysis that Parmesan cheese aged for 6 months has the same organoleptic taste, texture and nutritional characteristics as Parmesan cheese aged for 10 months.

B. Economic and Consumer Advantages

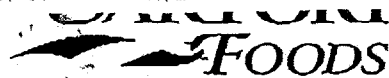
The reduction in aging time from the current 10 months to the proposed 6 months provides a substantial benefit to the cheese manufacturer and ultimately the user/consumer. The reduction in aging cycle of four months takes considerable costs out of the manufacturing and curing process. Resources are freed-up to produce more and other cheeses--maximizing the use of plant resources. With lower aging and inventory costs, an environment is created where total product costs will be lower--thereby allowing an opportunity for cheese manufacturers to better hold the line on costs to the ultimate consumer. Additionally, with lesser amounts of money being tied-up in inventory costs, 'barriers to entry' relative to the production of Parmesan cheese will also be lowered--allowing for the entry of new Parmesan cheese manufacturers--thereby creating new and additional competition in the marketplace. This directly benefits the ultimate consumer.

C. Historical Perspective

Back in 1973, the FDA Commissioner found that the reduction in Parmesan cheese curing time from the then standard of identity of 'not less than 14 months' to a new standard of 'not less than 10 months' still yielded an organoleptically and functionally equivalent Parmesan cheese--one that delivered advantages to cheese manufacturers and consumers with no drawbacks. Based upon these findings, the Commissioner concluded that 'it would promote honesty and fair dealing in the interest of consumers' to amend the then current 14 month curing standard to a curing time of not less than 10 months.

In the past four decades, advances in technology and cheese making science ~~once again~~ allow us to amend the Parmesan cheese standard for the benefit of both consumers and cheese manufacturers. We are now able to produce Parmesan cheese aged for not less than 6 months that has the properties of Parmesan cheese aged for 10 months. In the

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spirit of the earlier 1973 petition, this petitioner asks the Commissioner to again conclude, for the same practical reasons, that a change in the Parmesan cheese standard of identity from the current 'not less than 10 months' to a revised standard of 'not less than 6 months' curing time be made.

3. Environmental Assessment Exclusion

This petition is subject to a categorical exclusion from an environmental impact assessment under 21CFR §25.32 (a) (Promulgation, amendment, or repeal of a food standard).

4. Economic Impact

Information will be provided to the extent requested by the Commissioner.

5. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

James Sartori
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