



Kraft Foods

CONFIDENTIAL

Paul J. Petruccelli
Senior Food and Drug Counsel

6097 '99 APR 15 19:18

BY OVERNIGHT DELIVERY

December 15, 1997

Felicia Satchell, Chief
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Grated Parmesan Cheese With A Curing Period of Six Months

Dear Ms. Satchell:

I enclose on behalf of Kraft Foods, Inc., a petition for a temporary permit to test market grated parmesan cheese manufactured from parmesan cheese which, through the use of a safe and suitable enzyme, is fully cured and suitable for grating in six (6) months.

Based on the evidence described more fully in the enclosed correspondence, Kraft submits that grated parmesan cheese produced as we describe could be deemed to be in compliance with the existing standards of identity applicable to this product. Admittedly, the product we describe will be cured for 6 months, rather than for the 10 months noted in 21 C.F.R. Section 133.165(a). It has long been our view, however, that at least in connection with a product like parmesan cheese, for which the curing period relates to quality rather than safety, the required curing period should be viewed as something that could be modified pursuant to the "alternate make" authorization of the standard of identity. We do not think that the historical accident of the placement of this curing requirement in subsection (a) of the regulation should prevent the Agency from accepting under the standard shorter-cured products that have been proven to be chemically, nutritionally, and organoleptically equivalent to products cured for the more customary 10 months.

As a result, we believe that the grated parmesan cheese described in our enclosed correspondence could and should be treated by the Agency as acceptable for sale under the existing standards of identity. Nevertheless, we

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Felicia Satchell, Chief
Food Standards Branch
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are mindful of the possibility that the Agency may reach a contrary conclusion. If that were to occur, we would find both our reputation and, indeed, our grated parmesan business itself in very substantial jeopardy, since we could not compete effectively with a product the Agency did not regard as grated parmesan cheese and we could not -- overnight -- manufacture grated parmesan cured for 10 months. Accordingly, we have submitted the enclosed temporary marketing permit request. However, if the Agency concludes, as we believe it should, that the product we describe can be sold as grated parmesan cheese under the existing standards, then we request that our correspondence be treated as a request for an Agency opinion to that effect, and that the request for a temporary marketing permit be deemed withdrawn.

Please feel free to contact me directly at 847-646-2796 if you require additional information or assistance of any kind.

Respectfully submitted,



Paul J. Petruccelli
Senior Food & Drug Counsel

Enclosures

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Felicia Satchell, Chief
Food Standards Branch
December 15, 1997
Page 2

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Please feel free to contact me directly at 847-646-2796 if you require additional information or assistance of any kind.

Respectfully submitted,



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Paul J. Petrucci
Senior Food and Drug Counsel

BY OVERNIGHT DELIVERY

December 15, 1997

Felicia Satchell, Chief
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

**Re: Request for Approval of Temporary Marketing Permit
Under 21 C.F.R. Section 130.17**

Dear Ms. Satchell:

I am writing on behalf of Kraft Foods, Inc., pursuant to the provisions of 21 C.F.R. Section 130.17, to request a temporary permit to test market grated parmesan cheese, manufactured from parmesan cheese produced by the make procedure described in the parmesan standard, in which, through the use of a safe and suitable curing enzyme, fully-cured parmesan cheese suitable for grating is produced in six (6) months.

Grated cheeses of all types are produced in conformity with the standard of identity for grated cheese at 21 C.F.R. Section 133.146. This standard requires, among other things, that the grated cheese be produced by grating one or more varieties of natural cheese for which there are standards of identity. In the case of grated parmesan cheese, the underlying cheese standard is that for parmesan cheese at 21 C.F.R. Section 133.165.

Like many of the cheese standards, the parmesan cheese standard describes a typical make procedure and specifies a curing time. In the case of parmesan cheese, the curing time is currently ten (10) months.¹ However,

¹ The current curing period of 10 months was established in 1973. Prior to that time, the standard mandated a curing time of 14 months. However, in response to a petition filed by Tolibia Cheese in 1971, the Agency conducted rulemaking and concluded that advances in the production of parmesan cheese had made it possible to produce in 10 months a cheese that was as fully cured as, and equivalent to, the parmesan cheese

D OUBT # 488-1121



Kraft Foods

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Paul J. Petruccelli
Senior Food and Drug Counsel

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December 15, 1997

Felicia Satchell, Chief
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Grated Parmesan Cheese With A Curing Period of Six Months

Dear Ms. Satchell:

I enclose on behalf of Kraft Foods, Inc., a petition for a temporary permit to test market grated parmesan cheese manufactured from parmesan cheese which, through the use of a safe and suitable enzyme, is fully cured and suitable for grating in six (6) months.

Based on the evidence described more fully in the enclosed correspondence, Kraft submits that grated parmesan cheese produced as we describe could be deemed to be in compliance with the existing standards of identity applicable to this product. Admittedly, the product we describe will be cured for 6 months, rather than for the 10 months noted in 21 C.F.R. Section 133.165(a). It has long been our view, however, that at least in connection with a product like parmesan cheese, for which the curing period relates to quality rather than safety, the required curing period should be viewed as something that could be modified pursuant to the "alternate make" authorization of the standard of identity. We do not think that the historical accident of the placement of this curing requirement in subsection (a) of the regulation should prevent the Agency from accepting under the standard shorter-cured products that have been proven to be chemically, nutritionally, and organoleptically equivalent to products cured for the more customary 10 months.

As a result, we believe that the grated parmesan cheese described in our enclosed correspondence could and should be treated by the Agency as acceptable for sale under the existing standards of identity. Nevertheless, we

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Section 133.165(a) also recites that parmesan cheese in compliance with the standard may be produced by any other procedure "which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used." Last year, Kraft Foods began examining whether it was possible to produce parmesan cheese suitable for grating under a make procedure which involved more rapid curing. Our ability to manufacture that product is the basis for this submission.

Kraft's make procedure is fully described in Exhibit 1. It involves the use of a different enzyme technology, but is otherwise identical to the make procedure Kraft has followed for many years. Using this enzyme and make procedure, it is possible to produce parmesan cheese suitable for grating in 6 months, rather than in the customary 10 months.

In developing this product, Kraft conducted a variety of tests designed to ensure the equivalency of the product to our popular Kraft Grated Parmesan Cheese. These tests, which are described in greater detail below, included tests of both chemical and nutritional equivalency to other grated parmesan cheeses. In addition, we have conducted substantial consumer taste testing for the purpose of satisfying ourselves that the 6-month cured product is considered by consumers to be equivalent -- in taste, in texture, and in cooking properties -- to grated parmesan cheeses currently available to consumers. Our test results are included with this submission and are discussed more specifically below.

In light of this evidence, and given the benefits to be derived from a shorter curing time for grated parmesan cheese, Kraft determined to explore the production and sale of this product. The 6-month curing process provides a substantial economic benefit to a manufacturer, by reducing both the cost of inventory and losses from damage during the required holding period. The lower costs will benefit consumers by helping to hold down or reduce the cost of grated parmesan cheese. Moreover, a shorter curing time may make it possible for manufacturers to devote some of their production resources to the manufacture of other cheese products, thereby maximizing the use of plant resources and increasing production efficiencies.

previously produced in 14 months. On the basis of this finding, the Agency amended the standard. See 38 Fed. Reg. 4710 (Feb. 21, 1973).

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Food Standards Branch
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2. Statement whether applicant is regularly engaged in production:

Kraft is regularly engaged in the production of grated parmesan cheese at several facilities throughout the United States.

3. Applicable standard of identity:

The applicable standard of identity for grated cheese is 21 C.F.R. Section 133.146. The standard of identity for parmesan cheese is at 21 C.F.R. Section 133.165.

4. Description of proposed variation from the standard of identity:

The product we propose to market is grated parmesan cheese produced from parmesan cheese which has been cured for 6 months, rather than for 10 months. Prior to grating, the product has a minimum milkfat content of 32 percent by weight of the finished food, and a maximum moisture content of 32 percent by weight, as determined by the methods described in 21 C.F.R. Section 133.5. Except for the fact that it has been cured for 6 months, the product meets all requirements of the standards applicable to parmesan cheese. The make procedure for the product is set forth in detail in Exhibit 1.

5. Basis for belief that the food is wholesome and nondeleterious:

The grated parmesan cheese that is the subject of this application is just as wholesome and nondeleterious as other such cheeses available to consumers. No novel ingredients or processes are involved in its manufacture.

We produced the grated parmesan cheese described in this request pursuant to the make procedure described in Exhibit 1. Chemical analysis of the product shows that, prior to grating and drying, it meets the requirements of Section 133.165. Specifically, as Exhibit 2 shows, chemical analysis of the product shows that moisture, lactose, pH, protein, sorbic acid and salt levels to be consistent with the standard of identity and within the ranges found for eleven other products currently available for sale to consumers. Similarly, nutritional analysis, included at Exhibit 3, shows that our

Felicia Satchell, Chief
Food Standards Branch
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samples meet expected nutritional targets for grated parmesan cheese and compare favorably with other such cheeses being sold to consumers.

We have also examined the organoleptic acceptability of this product. Exhibit 4 contains a report of sensory testing conducted by Kraft to determine whether the taste profile and textural attributes of this grated parmesan product are equivalent to those of other such cheeses, including Kraft's own brand. We compared several test products cured for 6 months versus eleven different products currently available to consumers. Each product was evaluated (on a blind basis) on 45 different attributes by a panel of 5 trained judges, using a 15-point scale. For example, we compared the 6-month product to others on such attributes as nutty/woody taste, moistness, saltiness, sourness, and so on. On all 45 attributes tested, no significant differences were found between our 6-month cured and grated product and the scores found for other grated parmesan cheeses available to consumers.

We also assessed our 6-month cured product via in-home testing with 300 consumers. These consumers compared our current grated parmesan product, used for one week, versus a sample of 6-month cured and grated product, also used for one week.⁴ Again, in blind testing, consumers rated the products as equivalent to our current grated parmesan product. A summary of this test data is included at Exhibit 5.

We further examined our 6-month cured product to assess its acceptability in recipe usages. Exhibit 6 contains a report of testing conducted by the Kraft Creative Kitchens to compare the performance of this product in a variety of cooking applications with that of Kraft's current grated parmesan product. Again, in each of these tests, Kraft's 6-month cured and grated cheese was judged to be equivalent to our current grated parmesan.

⁴ In the test we included two different samples of 6-month cured product -- one with a fat level identical to that in our current product, and one with a slightly higher fat level. There were no significant differences between these products.

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6. Amount of any new ingredient and deviations from standard:

As stated above, manufacture of this product involves no novel ingredients nor any material deviations from processes long used to produce grated parmesan cheese. The only deviation is the use of a specialized enzyme with a history of safe and suitable use in cheeses and the shorter curing period.

7. Purpose of the variation from the standard:

The purpose of the variation is to facilitate the test marketing of a shorter-cured product under the statement of identity that most accurately describes the product and that is most familiar to consumers in the United States -- namely, "grated parmesan cheese." In addition, the temporary permit will facilitate the collection of data on consumer acceptance of the product, in support of a later petition to amend the standard of identity to permit the production of shorter-cured grated parmesan cheese on a permanent basis.

8. Statement of the variation's advantage to consumers:

The variation from the standard will permit Kraft or other producers to manufacture grated parmesan cheese more efficiently, thus holding down the cost of cheese to consumers.

9. Proposed label:

The proposed label for the product is enclosed as Exhibit 7.

10. Time period covered by the temporary marketing permit:

The time period requested for the temporary permit is a period commencing 6 months after FDA's approval of the request, and extending for 15 months thereafter. This period of time is needed for a complete evaluation not only of the acceptability of the product to consumers in a wide variety of grated parmesan cheese usage applications, but also of the acceptability of the product to Kraft as a replacement for its current 10-month cured cheese.

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11. Probable amount to be distributed:

During the 15-month period covered by the permit, we expect to distribute approximately 86 million pounds of our product in retail containers of various sizes, to foodservice customers, and as an ingredient. This is the amount of grated parmesan cheese that would be produced by our facilities during the time period in question. For reasons of production efficiency and capital cost, it is necessary to convert a plant completely to this formula. Moreover, this is the amount produced during a long enough production cycle to support an assessment of manufacturing feasibility and consistency.

12. Area of distribution:

The product will be distributed nationally.

13. Manufacturing address:

The product will be grated at and distributed from Kraft Foods, Inc., 1007 Town Line Road, Wausau, WI 54401.

14. Statement regarding distribution within State of manufacture:

Grated parmesan cheese manufactured under this procedure will be distributed by Kraft in the State of manufacture.

15. Statement of reasons regarding item 13:

Not applicable.

16. Statement of reasons for distribution in multiple States:

Given current production and distribution methods in the food industry, it is not generally possible for a large producer to limit the distribution of a product to a single state. Moreover, a test market limited to one or two states would not provide sufficiently broad-based information about the acceptability of the product to permit an informed decision whether or not to market it on a continuous basis. Ultimately, the only truly effective test of a nationally-

Felicia Satchell, Chief
Food Standards Branch
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distributed product like Kraft Grated Parmesan Cheese is a national test.

* * *

In light of the evidence described above and enclosed with this petition, we ask the Agency to approve a temporary marketing permit authorizing an appropriate test market of our 6-month cured product, as a precursor to a petition to amend the standard of identity. We would be happy to provide any additional information that would assist the Agency in its evaluation of this issue.

Please feel free to contact me directly at 847-646-2796 if you require additional information or assistance of any kind.

Respectfully submitted,



Paul J. Petruccelli
Senior Food & Drug Counsel

Enclosures



Kraft Foods

Paul J. Petruccelli
Senior Food and Drug Counsel

JUN 15 09:18

BY OVERNIGHT DELIVERY

June 2, 1998

Ms. Loretta Carey
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Grated Parmesan Cheese Temporary Marketing Permit

Dear Ms. Carey:

This responds to your request for additional labels we would be using while marketing under the temporary marketing permit we have requested, and for clarification of our volume during the period of the permit.

As our request indicated, we would expect to market approximately 86 million pounds of product during the 15-month period covered by the request. Of that amount, approximately 70.5 million pounds would be retail product, while the remainder would be used in foodservice (7.75 million pounds) and ingredient (7.75 million pounds) applications of various types.

I have enclosed for your information copies of labels for 11 products that would be sold at retail during the marketing period in question.

Please do not hesitate to contact me directly at 847-646-2796 if you require additional information or assistance of any kind.

Respectfully submitted,

Paul J. Petruccelli
Senior Food & Drug Counsel

Enclosures



Kraft Foods

Paul J. Petruccelli
Senior Food and Drug Counsel

6099 '99 APR 15 19:18
BY OVERNIGHT DELIVERY

June 8, 1998

Ms. Loretta Carey
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Grated Parmesan Cheese Temporary Marketing Permit

Dear Ms. Carey:

I have enclosed for your information copies of labels for products that would be sold by our foodservice and food ingredients businesses during the period of the temporary marketing permit we have requested. I inadvertently omitted these labels from my most recent submission.

Please do not hesitate to contact me directly at 847-646-2796 if you require additional information or assistance of any kind.

Respectfully submitted,

Paul J. Petruccelli
Senior Food & Drug Counsel

Enclosures



Kraft Foods

Paul J. Petruccelli
Senior Food and Drug Counsel

BY OVERNIGHT DELIVERY 5:18

July 9, 1998

Ms. Loretta Carey
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Grated Parmesan Cheese Temporary Marketing Permit

Dear Ms. Carey:

Per your request, I am enclosing revised labels for products that would be sold at retail during the period of the temporary marketing permit we have requested. Our foodservice labels will arrive under separate cover.

These labels reflect the changes you requested, with one exception. You suggested in our conversation that the serving size on the label for our *Parm Plus* product should be revised. The serving size currently reads: "2 Tsp (4.5g)." You suggested that the parenthetical amount should be 5 grams, consistent with our other labels. I have followed up with our Nutrition Department, which develops these figures, and confirmed that the 4.5 gram figure is accurate. The density of our *Parm Plus* product is slightly different from that for our other products. Since the gram equivalent of the 2 teaspoon serving size is less than 5 grams, the regulations require that we round the gram equivalent to the nearest half-gram increment. See Section 101.9(b)(7)(ii).

I trust this clarification will be helpful. Please do not hesitate to contact me directly at 847-646-2796 if you require additional information.

Respectfully submitted,

Paul J. Petruccelli
Senior Food & Drug Counsel

Enclosures



Kraft Foods

Paul J. Petruccelli
Senior Food and Drug Counsel

BY OVERNIGHT DELIVERY 5 A9:18

August 3, 1998

Ms. Loretta Carey
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Grated Parmesan Cheese Temporary Marketing Permit

Dear Ms. Carey:

Per your request, I am enclosing revised labels for the three foodservice products we have previously discussed, as well as for one additional item that recently came to my attention. With respect to the bulk items (i.e., 5-pound and 25-pound), I am enclosing one overall view of the label, as well as copies of each of the individual panels. This will make your review of these labels a bit easier. Of course, all of the labels reflect the changes you requested.

Please do not hesitate to contact me directly at 847-646-2796 if you require additional information.

Respectfully submitted,

Paul J. Petruccelli
Senior Food & Drug Counsel

Enclosures



Kraft Foods

Paul J. Petruccelli
Senior Food and Drug Counsel

BY OVERNIGHT DELIVERY

October 22, 1998 6102 '99 APR 15 A9:18

Ms. Loretta Carey
Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Grated Parmesan Cheese Temporary Marketing Permit

Dear Ms. Carey:

I am enclosing labels for the other grated parmesan products produced by Kraft Foods, as we discussed in our last conversation. These include a few more labels used by our food ingredient and foodservice businesses, as well as those for private label brands which are produced by Kraft for various retailers. As you know, we had inadvertently omitted these labels from our prior submissions, and I apologize for the oversight. Of course, all of the labels reflect the removal of any reference to a 10-month aging period.

As I mentioned in our last conversation, I also want to confirm that the submission of these additional labels does not change our previously-supplied estimate that we would expect to market about 86 million pounds of grated parmesan cheese during the 15-month time period covered by our request.

With this submission, I believe we have now provided all materials necessary for you to complete your review of our request. Please do not hesitate to contact me at 847-646-2796 if you require additional information. I look forward to hearing from you.

Respectfully submitted,

Paul J. Petruccelli
Senior Food & Drug Counsel

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