

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

|                  |                    |
|------------------|--------------------|
| Display Date     | 3-7-01             |
| Publication Date | 3-8-01             |
| Certifier        | <i>[Signature]</i> |

21 CFR Part 172

[Docket No. 00F-0175]

**Food Additives Permitted for Direct Addition to Food for Human Consumption;  
Natamycin (Pimaricin)**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

---

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of natamycin on cheese. This action is in response to a petition filed by Cultor Food Science, Inc.; DSM Food Specialities; and Protein Technologies International.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*]. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 172.155(c), as of [*insert date of publication in the Federal Register*].

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-001, 202-418-3095.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of January 24, 2000 (65 FR 3719), FDA announced that a food additive petition (FAP 0A4704) had been filed

CF0083

NFL2

by Cultor Food Science, Inc., 430 Saw Mill River Rd., Ardsley, NY 10502; DSM Food Specialties, 700 American Ave., suite 300, King of Prussia, PA 19406; and Protein Technologies International, Checkerboard Square, St. Louis, MO 63164. The petitioners proposed that the food additive regulations in § 172.155 *Natamycin (pimaricin)* (21 CFR 172.155) be amended by listing only the use level of natamycin permitted in cheese and by eliminating the reference for the method of application.

Natamycin is currently approved in § 172.155 for use as an antimycotic agent on the surface of cuts and slices of cheese(s). Under the current regulation, natamycin may be applied to the surface of cuts and slices of cheese to inhibit mold spoilage with the following limitations: (1) The additive may be applied as a dry mix containing the additive and safe and suitable anticaking agents, resulting in no more than 20 parts per million (ppm) of the additive in the finished product, or by dipping or spraying, using an aqueous solution containing 200 to 300 ppm of the additive; (2) the additive may be applied to the surface of those cuts and slices of cheese(s) listed in part 133 (21 CFR part 133) only if the cheese standards provide for the use of “safe and suitable” mold-inhibiting ingredients.

The agency is revoking the limitations on the application of natamycin to the surface of cuts and slices of cheese in § 172.155(c)(1) and (c)(2), and is revising § 172.155(c) to set forth a limitation for the amount of natamycin on cheese that may remain in the finished product, regardless of the method of application.

The agency is setting forth a test method in revised § 172.155(c) that will ensure that natamycin does not exceed 20 milligrams per kilogram (20 ppm) in the finished product. This limitation will not restrict the process of application of natamycin to cheese nor the physical form (e.g., cuts, slices, or grated) of the cheese to which natamycin may be applied. The agency has concluded that the dietary exposure to natamycin will not change as a result of the use of the new test method for the application of natamycin to cheese and new physical forms of cheese to which natamycin may be applied. Further, because of the existing limitation in part 133 for

when “safe and suitable” mold inhibiting ingredients, such as natamycin, may be used in cheese, the agency has determined that repeating such limitations in § 172.155 is not necessary. Therefore, omitting the previous limitation in § 172.155(c)(2) from revised § 172.155(c) does not change the varieties of cheeses in which natamycin may be used. Consequently, because the dietary exposure to natamycin in cheese remains the same as considered in the previous safety assessment for § 177.155(c)(1) and (c)(2), no new safety issues are raised and no new safety evaluation is needed for this rule.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 0A4704. No new information or comments have been received that would affect the agency’s previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the **Federal Register***]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection

for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### **List of Subjects in 21 CFR Part 172**

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

### **PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION**

1. The authority citation for 21 CFR part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

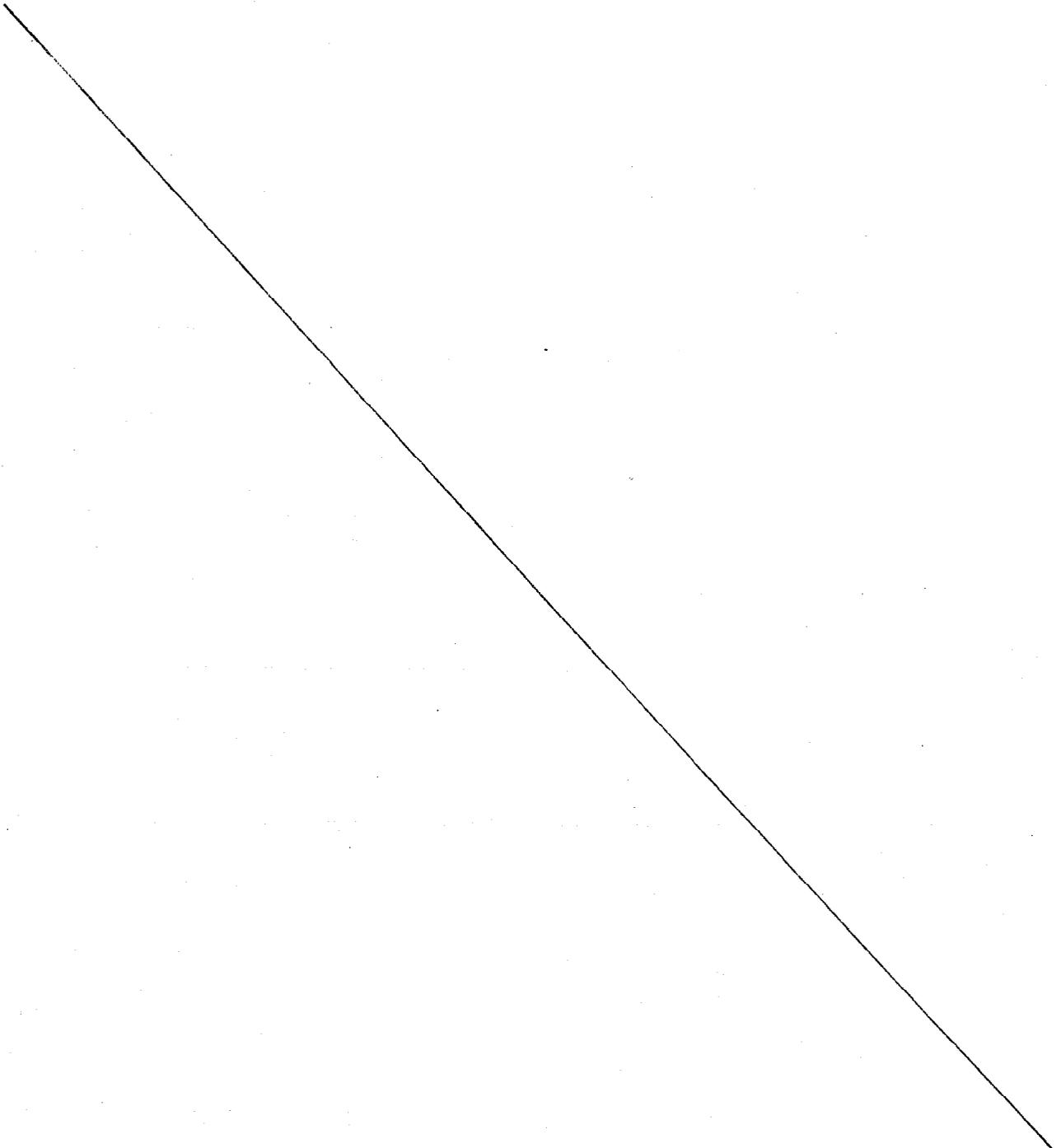
2. Section 172.155 is amended by revising paragraph (c) to read as follows:

#### **§ 172.155 Natamycin (pimaricin).**

\* \* \* \* \*

(c) The additive may be applied on cheese, as an antimycotic, in amounts not to exceed 20 milligrams per kilogram (20 parts per million) in the finished product as determined by International Dairy Federation (IDF) Standard 140A:1992, "Cheese and Cheese Rind—Determination of Natamycin Content—Method by Molecular Absorption Spectrometry and by High-Performance Liquid Chromatography," which is incorporated by reference. The Director of the Office of the

Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Product Policy (HFS-206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library,



200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Dated: 2/9/01  
February 9, 2001.

L. Robert Lake

L. Robert Lake,  
Director of Regulations and Policy,  
Center for Food Safety and Applied Nutrition.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Jan Waidson

[FR Doc: 01-???? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-F