codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FAC 00/5**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-second Session
Beijing, People's Republic of China, 20-24 March 2000

ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES IN CODEX STANDARDS

BACKGROUND

1. In accordance with the section concerning Relations Between Commodity Committees and General Committees in the *Codex Alimentarius Commission Procedural Manual* (Tenth Edition, pages 76-78), "All provisions in respect of food additives (including processing aids) …. Contained in Codex commodity standards should be referred …. and will require to be endorsed by the Codex Committee on Food Additives and Contaminants".

2. No maximum levels for food additives have been submitted for endorsement since the 31st Session of the Codex Committee on Food Additives and Contaminants.

TECHNOLOGICAL JUSTIFICATION PROVIDED BY CANADA FOR THE USE OF PIMARICIN (NATAMYCIN) IN SLICED, CUT, SHREDDED OR GRATED CHEESE

3. The 3rd Session of the Codex Committee on Milk and Milk Products requested (ALINORM 99/11, para. 70) Canada to provide written technological justification to the Codex Committee on Food Additives and Contaminants for the extended use of pimaricin (International Numbering System No. 235) in sliced, cut, shredded and grated cheese in the Codex Standard for Cheese (CX-STAN A-6).

4. The 31st Session of the Codex Committee on Food Additives and Contaminants noted that pimaricin was currently only permitted for use on the surface of cheese. As some delegations expressed the view that pimaricin should only be used as a surface treatment and was not intended to be consumed, the Committee decided that this provision should not be endorsed pending written technological justification provided by Canada (ALINORM 99/12A, para. 25).

5. The 23rd Session of the Codex Alimentarius Commission adopted (ALINORM 99/37, paras. 93-94 and Appendix VII) the Codex General Standard for Cheese (ALINORM 99/11, Appendix IX) as a final Codex text (CX-STAN A-6, Rev. 1-1999), except for those food additives not endorsed (including the extended use pimaricin in sliced, cut, shredded or grated cheese)[1] by the Codex Committee on Food Additives and Contaminants.

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1 The Codex Standard for Cheese (CX-STAN A-6, Rev. 1-1999) recently adopted by the Codex Alimentarius Commission includes the use of pimaricin (natamycin) for surface/rind treatment in ripened cheeses, including mould ripened cheeses, at a maximum level of 2mg/dm of surface and a maximum depth of 5mm. The proposed use for pimaricin (natamycin) in sliced, cut, shredded or grated cheese at a maximum level of 10mg/kg, for surface treatment, calculated on the weight of the cheese, was not adopted by the Commission.

6. The following written technological justification for the use of pimaricin (natamycin) as a preservative in the provisions for sliced, cut, shredded or grated cheese of the Codex Standard for Cheese have been submitted by Canada in response to the request of the 31st CCFAC.

Natamycin

7. Natamycin is a polyene macrolide antimycotic which is fungicidal. It is equally effective against yeast and mold, but has no effect on bacteria. Several countries have approved its use on various foods. Natamycin has been used for over 30 years in providing extended shelf life to a variety of foods through the elimination of yeasts and molds, and the inhibition of mycotoxin development.

8. Natamycin kills yeast and mold on contact, and is effective at very low levels (3- 10 ppm). Because it is only slightly soluble in aqueous systems, natamycin tends to stay on the surface of foods where it is applied, and is thus very effective in preventing growth of yeast and mold on food surfaces. On the other hand, potassium sorbate, another approved antimycotic, is water soluble and can be absorbed into food, thus reducing the concentration at the surface, where mold grows. Additionally, sorbate is only fungistatic, so as the concentration is reduced on the surface, any mold present will begin to grow.

9. On cheese, natamycin can be applied to surfaces by spraying or dipping with an aqueous suspension, or applied as part of an emulsion cheese coating. Natamycin does not affect sensory qualities of food, and does not inhibit starter cultures in fermented foods. The effectiveness of natamycin on food surfaces is three months or more, depending on storage conditions. It is only minimally affected by heat, but is degraded over time with exposure to UV light. Additionally, bacteria present in food can degrade the natamycin molecule over time.

10. Other examples of antimicrobials of natural origin that have been approved and have found certain uses include egg-white lysozyme, hydrogen peroxide, ethanol and the bacteriocin nisin. Naturally occurring antimicrobials are abundant in the environment. The desire for expanded use is obvious, especially in light of consumer demands for minimally processed, safe foods of adequate shelf-life and convenience (resealable shredded cheeses or cheeses with pinholes), and the global need for increasing the supply of food.

11. JECFA evaluated the toxicology of natamycin in 1976 and recommended an acceptable daily intake of 0-0.3 mg/kg bw. "T'he Committee agreed that data demonstrated that problems related to the development of clinically significant microbial resistance or cross-resistance were unlikely to occur with pimaricin." [2]

12. The Codex Committee on Food Additives and Contaminants has included this substance in Table 2 of the General Standard for Food Additives, Food Category No. 01.6.2.2 at a maximum level of 20 mg/kg of cheese.[3] The ADI does not specify a depth restriction concerning the use of natamycin.

13. This additive should also be included in Food Categories 01.6.2 (Ripened Cheese) and 01.6.2.1 (Total ripened cheese, includes rind). Subsequent amendments should also be made to Codex Commodity Standards such as A-6 (Cheese) under the Codex Committee on Milk and Milk Products and any relevant C-standard.

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2 Twentieth Report of the Joint FAO/W'HO Expert Committee on Food Additives, Geneva, 1976, WHO Technical Report Series No. 599.

3 The current proposed provision for the use of pimaricin in Food Category 1.6 (Cheese) is 40mg/kg (surface treatment). See Table 1 of CL 1999/15-FAC.

Antibiotic Resistance Issues Related to Pimaricin in Grated and Shredded Cheese

14. According to the Bureau of Microbial Hazards, Food Directorate, Health Canada, the following are the key elements to be considered regarding the use of pimaricin in grated and shredded cheese:

(a) Currently in Canada, pimaricin is approved for use as an antimycotic on whole cheese as well as on grated cheese. Treatment of whole cheese results in minimum ingestion of pimaricin since the rind is normally discarded. However, when pimaricin is added to grated cheese, ingestion of pimaricin residues is unavoidable.

(b) Pimaricin belongs to a group of polyene antibiotics which are fungicidal drugs that bind to ergosterol in the fungal cytoplasmic membrane, altering its structure and function and results in cell lysis.

(c) There are no known reports of problems with pimaricin resistance. Little is known about any possible mechanism(s) of resistance to this antimycotic agent.

(d) Pimaricin is the active ingredient found in an ophthalmic antifungal drug. From information obtained via the Internet, it is not a commonly used drug and has limited availability (must be ordered directly from the manufacturer).

(e) Current growing concerns with the contribution of agricultural, aquacultural and medical uses of antibiotics towards the emergence of antibiotic resistance are mainly focussed on bacteria. Particularly the use of antibiotics, involved in human therapy against bacterial infection, as feed additives in agricultural animals has been placed under heavy scrutiny. The target site for pimaricin, ergosterol in fungal cytoplasmic membrane, is absent in bacteria. Therefore, ingestion of pimaricin will not induce resistance in normal flora bacteria.

(f) Compared with bacteria, the number of fungi found as normal flora in the human gut is extremely low. Therefore, the likelihood of fungi in the human gut being exposed to pimaricin due to cheese consumption is also extremely low. Furthermore, the probability of a series of events occurring, in which a fungus in the gut is exposed to pimaricin, developing resistance and subsequently is capable of causing an eye irritation/infection which is to be treated with pimaricin eye drop, would be infinitely small.

15. Based on the above factors, particularly the lack of evidence suggesting resistance to pimaricin is a problem, the low exposure risk of fungi to pimaricin in the human gut as well as the limited use of pimaricin as a therapeutic agent, it can be concluded that the use of pimaricin in grated cheese poses minimal risk to the selection of drug resistant fungal mutants.