



Memorandum

(ENV 392)

Date July 17, 1992

From Assistant Director for Codes & Practice
Retail Food Protection Branch, HFF-342

Subject Butter Blend - A Potentially Hazardous Food

To George J. Gerstenberg, Director
Los Angeles district, HFR-PA200

In your memorandum of May 22, 1992 to Heinz Wilms, Director, Division of Federal-State Relations and Janice F. Oliver, Director, Division of Regulatory Guidance you requested that FDA consider placing Butter Blends in the category of potentially hazardous foods.

Information obtained relating to the recent butter blend Staphylococcus intermedius outbreak indicates that the product may contain two to 33 per cent butter. Butter may be a component of butter blends that renders such products potentially hazardous.

The Retail Food Protection Branch regards butter as a potentially hazardous food. The decision, as to whether or not a product is potentially hazardous, is based on the Retail Food Protection Program Information Manual interpretation dated May 9, 1986. This interpretation on the subject: DEFINITIONS - POTENTIALLY HAZARDOUS FOOD is enclosed for your information.

The interpretation addresses several factors to be considered in determining if a food product is in a potentially hazardous form. Among these are hydrogen ion concentration (pH), water activity (a_w), and antimicrobial constituents.

Of particular importance with respect to butter are the factors of pH and a_w . The literature indicates that the pH of butter may range between 6.1 and 6.4 and the a_w value is well above 0.90.

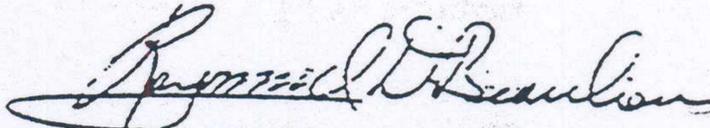
The salt content of butter may be assumed to act as an antimicrobial constituent. However, the antimicrobial property of the salt content usually found in butter does not appear to be significant in controlling microbial growth.

Enclosed is an article entitled "Effects of Time and Temperature on Salmonellae in Inoculated Butter" that appeared in the Journal of Milk and Food Technology, Vol. 32, No. 12, 1969. This article concludes, through experimentation and with varying salt content, that butter will readily support Salmonella growth at room temperature.

Other ingredients that may be used in butter blends include whey powder, dried buttermilk powder or non-fat dry milk. Any of these in reconstituted form are considered potentially hazardous.

It is our opinion that butter blends are potentially hazardous foods that are subject to time and temperature control. An exception is made to the refrigeration requirements in products having a pH level of 4.6 or less, an a_w of 0.85 or less, or laboratory results of inoculation studies showing that combinations of factors preclude growth of inoculated organisms.

Please advise if further information is needed.


Raymond D. Beaulieu

Attachments

cc:
HFC-150, Wilms (w/o attachment) ✓
HFC-152, Tucker (w/o attachment)
HFF-300 (w/o attachment)
HFF-310, Oliver (w/o attachment)
HFF-314, Gardine (w/o attachment)
HFF-340, Kvenberg (w/o attachment)
HFF-342, Banks (w/o attachment)
HFF-342, Beaulieu, r/f

HFF-342:RDBeaulieu:rdb:07/17/92:205-8140