

MEMORANDUM OF UNDERSTANDING
Between The
DEPARTMENT OF PRIMARY INDUSTRY, AUSTRALIA
And the
U.S. DEPARTMENT OF HEALTH, EDUCATION & WELFARE FOOD AND DRUG ADMINISTRATION

ATTACHMENT A

Analytical Methods

The subsamples of dry milk products will be aseptically reconstituted. The 25 gram portions taken from each of the 30 subsamples collected from a lot of dry milk product may be composited up to an amount of 400 grams in each composite. The composites or individual 25 gram portions shall be reconstituted in an amount of diluent at least eight and no more than ten times the weight of the product.

A. Penicillin

Reconstituted dry milk products will be tested for penicillin residues by either of the following methods:

1. The *S. lutea* cylinder method as described in Methods of Analysis - AOAC, Twelfth Edition, Section 42.252 et. seq., p. 812-813; changes in Official Methods of Analysis made by the Nineteenth Annual Meeting, Oct. 18-21, 1976/Third Supplement to 12th Edition, Journal of AOAC, Volume 60, March 77, pp. 484-485, Section 42(4).
2. The *B. stearothermophilus*, variety *calidolactis*, disk assay method described in the Australian Standard Method of Microbiological Examination of Dairy Products and for Dairy Purposes, AS 1095.1.3, clause 3.3.2.

While the Department of Primary Industry may choose to use either of these methods for certification of lots, FDA will continue to use the *S. lutea* cylinder method in its regulatory enforcement to assure that imported dry milk products are free of detectable penicillin residues.

B. Phosphatase

Reconstituted dry milk products will be tested for phosphatase activity by either of the following methods:

1. Scharer Rapid Method for Phosphatase Analysis, described in Standard Methods for the Examination of Dairy Products, Fourteenth Edition, 17-8, Section 18.4; or,
2. Aschaffenberg and Mullen Method, described in the Australian Standard Method of Microbiological Examination of Dairy Products and for Dairy Purposes. AS 1095.1.3, clause 3.2.6.

C. Salmonella

Reconstituted dry milk products will be analyzed for presence of Salmonella according to either of the methods contained in:

1. Bacteriological Analytical Manual, Fifth Edition, 1978, Chapter VI Isolation and Identification of Salmonella.
And
2. Methods of Analysis - AOAC, Twelfth Edition, 1975, Chapter 46, Microbiological Methods, Section 46.013, et. seq. (Note: Both (A) and (B) give methods based upon 100 gram samples. For this MOU, 30/25 gram samples will be used.); or,
3. Standards Association of Australia viz AS 1095.3.8 (1976) Methods of Microbiological Examination of Dairy Products and for Dairy Purposes.