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

I. OBJECTIVES

The goals of the Food and Drug Administration (FDA) and the Australian Department of Primary Industry (DPI) in entering into this Memorandum of Understanding (MOU) are to:

A. Expedite the entry of Australian dry milk products at U.S. ports by minimizing the need for extensive FDA sampling of DPI certified dry milk products from Australia.
B. Give assurance that Australian dry milk products exported to the U.S. are free from contamination or under processing in accordance with the standards set out in this MOU.

II. DEFINITIONS

For purposes of this Memorandum, both parties accept the following definitions:

DRY MILK PRODUCTS: Dry milk products include dry whole milk, nonfat dry milk, low fat dry milk, dry cream, dry whey, dry buttermilk, casein; caseinates and co-precipitates. Products marked "FOR NON-EDIBLE USE ONLY" are excluded from this definition.

LOT: A lot is a quantity of dry milk product produced by one manufacturer during a discrete period of time, not exceeding one day, in one continuous process using a single processing line, packaged in identical containers which are identified by a code or mark traceable to the manufacturer.

PENICILLIN NEGATIVE: The lot of dry milk product is penicillin negative when the samples from that lot, taken in accordance with Section IV "SAMPLING" of this MOU, or units composited from those samples in accordance with that section, are reported as penicillin G not detectable, when tested by one of the methods described in Attachment A , "ANALYTICAL METHODS."

PHOSPHATASE NEGATIVE: The lot of dry milk product is phosphatase negative when the samples from that lot, taken in accordance with Section IV "SAMPLING" of this MOU, or units composited from those samples in accordance with that section, are reported as phosphatase not detectable when tested by one of the methods described in Attachment A, "ANALYTICAL METHODS".

SALMONELLA NEGATIVE: The lot of dry milk product is **Salmonella** negative when the samples from that lot taken in accordance with Section IV "Sampling" of this MOU, or units composited from those samples in accordance with that section, are reported as **Salmonella** not detectable, when tested by one of the methods described in Attachment A, “ANALYTICAL METHODS”.

III. OBLIGATIONS OF PARTICIPANTS

A.

A. **DEPARTMENT OF PRIMARY INDUSTRY, AUSTRALIA**
The Department of Primary Industry (DPI) is responsible to the Government of the Commonwealth of Australia for the administration of the Exports

{Dairy Produce} Regulations. In fulfilling its responsibilities under those Regulations, DPI directs its activities towards the reputation of the dairy exports from the Commonwealth of Australia by ensuring that dairy foods are safe and wholesome and that such products are honestly and informatively labeled. This is accomplished by inspecting the processed products before distribution and by collecting and examining samples to assure compliance with these Regulations. To carry out these responsibilities as they relate to exports of dry milk products and in fulfillment of commitments under this Memorandum of Understanding:

1. The Department of Primary Industry has furnished the Food and Drug Administration with copies of the current regulations and procedures used to assure that dry milk products are sanitary. The DPI will supply the FDA with copies of any future changes as they become effective.
2. The Department of Primary Industry has informed FDA of the sampling and testing procedures involved in the microbiological/chemical testing of dry milk products manufactured in export establishments in Australia registered under the Exports (Dairy Produce) Regulations as these procedures operated on and from January I, 1978. DPI will inform the FDA of any modifications initiated in the Australian analytical regime.
3. The department of Primary Industry will furnish to the Food and Drug Administration, on request, a full description of the manufacturing process and quality control used in respect to any particular lot to assure that the production of the dry milk product concerned is sanitary.
4. The Department of Primary Industry will inspect each lot of dry milk product produced in Australia and offered for certification and exportation to the United States of America to assure that the lot is penicillin negative, phosphatase negative, and Salmonella negative.
5. The Department of Primary Industry will issue a separate certificate for only those lots which meet the criteria in 4 above. Any lot offered for certification which fails to meet such criteria shall be denied export to the United States of America.
6. The Department of Primary Industry will require all packages in each lot exported to the United States of America to be identified by a lot number.
7. The Department of Primary Industry will include in the certificate for each lot exported to the United States of America the following information:
    a. Lot identification, including name and address of manufacturer;
    b. Name and size of containers in the lot;
    c. Information that the product described is negative for penicillin, phosphatase and Salmonella in accordance with the requirements of this MOU;
    d. Date of the certificate; and,
    e. Name and stamp, or seal of authorizing official.
    f. The validated certificate will accompany the shipping manifest.

B. **THE FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

The Food and Drug Administration (FDA) of the Department of Health, Education and Welfare is charged by the Government of the United States of America with the enforcement of the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. In fulfilling its responsibilities under the Acts, FDA directs its activities toward the protection of the public health of the United States of America by ensuring that foods are safe and wholesome and that products are honestly and informatively labeled. This is accomplished by inspecting the processing and distribution of foods and by collecting and examining samples to assure compliance with these Acts. To carry out these responsibilities as they relate to imported dry milk products and in fulfillment of its Memorandum of Understanding commitment:

1. The Food and Drug Administration acknowledges that the Department of Primary Industry has informed FDA of the sampling and testing procedures involved in the microbiological testing of dry milk products manufactured in export establishments in Australia registered under the Exports (Dairy Produce) Regulations as these procedures operate on and from January 1, 1978.
2. The Food and Drug Administration will sample dry milk products certified under this Memorandum of Understanding to assure that the exporting country and the exported products comply with specifications set forth in this Memorandum. On commencement of this MOU, the intensity of sampling of lots of DMP from Australia, will not exceed the highest rate of lot sampling applied to any other country entering into an MOU. The intensity of sampling may be reduced on gaining confidence in the compliance of the products to these specifications. The FDA may also check for other attributes to make sure the products also comply with the other requirements of the Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act.
3. The Food and Drug Administration will share any information obtained through its audit sampling with the Department of Primary industry through the Australian Embassy.
4. The Food and Drug Administration will promptly notify the Australian Embassy of any detention of dry milk products covered by the Memorandum and of any modifications in the Acts or the regulations which pertain to the dry milk products.
5. The Food and Drug Administration will share expertise and will provide consultative assistance to the exporting country when necessary to assure the safety of the dry milk products exported to the United States of America.

IV. SAMPLING

Subsamples will be collected as follows: Using aseptic sampling techniques, 30 subsamples, each containing approximately 100 grams, will be randomly collected from each lot. If the lot

contains packaged units weighing approximately 225 grams (about 8 ounces) or less, but more than 100 grams, 30 of these units will be randomly collected unopened, from the lot

V. ANALYTICAL METHODOLOGY

The methodology used in analyzing samples collected for the purpose of this MOU shall be acceptable to both the U.S. Food and Drug Administration and the Australian Department of Primary industry. The analytical methods currently in use are Listed in the Attachment A.

VI. Administrative Procedures

A. **Activation of MOU**
This Memorandum of Understanding will become effective 60 days after signature by the parties and will remain in effect pending revocation by either party.

B. **Modification of MOU**
Changes in this Memorandum of Understanding may be proposed by either of the parties. When the proposed changes are acceptable to both parties, they will be incorporated into the Memorandum.

C. **Termination of MOU**
This Memorandum of Understanding may be revoked by either party. The Memorandum of Understanding will cease to operate 60 days after Notice of Intent to Revoke has been given by one party to the other. The terms of the Memorandum of Understanding would continue to apply in respect to dry milk products manufactured prior to the date of the Notice of Intent to Revoke.

D. **Publication of MOU**
Upon its effective date, the Memorandum of Understanding will be published in the Federal Register. A copy will be available for public review at the Office of the Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, Maryland, 20857.

In witness whereof, the agencies have executed this Memorandum of Understanding covering dry milk products.

For the Department of Primary Industry

BY:---/s/---
TITLE: Minister (Commercial), Embassy of Australia
COUNTRY : Australia
DATE: November 28, 1979

For the Food and Drug Administration

BY: Joseph P. Hile --/s/--
TITLE: Associate Commissioner for Regulatory Affairs
COUNTRY: United States of America
DATE: November 23, 1979

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