

Guidelines for a
Cooperative Program in Food Hygiene
Between the
American Institute in Taiwan and the
Coordination Council for North American Affairs
January 28, 1985

1. Background

Cooperation between U.S. and Taiwan scientists is furthered pursuant to an agreement signed on September 4, 1980, between the American Institute in Taiwan (AIT) and the Coordination Council for North American Affairs (CCNAA). The "Taiwan Relations Act" (Public Law 96-8, April 10, 1979) authorizes the continuation of commercial, cultural and other relations between the people of the U.S. and the people on Taiwan. Such relations are conducted by or through AIT, a non-profit corporation, incorporated under the laws of the District of Columbia. CCNAA is the unofficial instrumentality which has been established to provide assurances and take actions on behalf of the people on Taiwan in accordance with Public Law 96-8. The Center for Food Safety and Applied Nutrition, Food and Drug Administration, functions as the focal point for cooperative activities on the U.S. side, while the Bureau of Commodity Inspection and Quarantine and the Department of Health in Taipei perform a similar function in Taiwan.

2. Scope of Cooperation

The cooperation envisaged in these Guidelines pertains generally to frozen fishery products and low-acid canned foods, but it does not exclude other food items which are involved in international commerce and which are regulated in the United States by the Food and Drug Administration.

3. Implementation

a. AIT and CCNAA shall exchange and provide information relative to the following:

- (1) Inspectional procedures
- (2) Sampling procedures
- (3) Analytical procedures
- (4) Laws and regulations

- (5) Action levels and tolerances
- (6) Food additive safety
- (7) Microbiological safety
- (8) Food labeling

b. Both sides agree to inform each other on a timely basis of the following:

- (1) Proposed and final modifications of existing regulations.
- (2) Proposed and final new regulations.
- (3) Proposed and final new legislations.

c. Whenever one side considers the above proposals (b.1, 2 or 3) to adversely affect its interests, the affected side upon request will be given an opportunity for a full discussions and may file objections and comments through the other side.

d. When products are detained by either side due to non-compliance with the respective laws or regulations, the exporting side should be provided by the enforcing side the following information:

- (1) Commodity and its quantity.
- (2) Name and address of the shipper.
- (3) Reason for detention.
- (4) Other records if necessary.

The exporting side shall also provide to the enforcing side the following information if available:

- (1) Name and address of manufacturer.
- (2) Date of production.
- (3) Other records if necessary.

Notice of refusal of admission should be provided to the exporting side by the enforcing side.

e. AIT and CCNAA will provide upon request available assistance, so that both sides may jointly work toward resolving problems resulting from detentions of products.

f. AIT and CCNAA will arrange, upon request, on-site training, as appropriate, for technical and scientific personnel in the following categories:

- (1) Methods of analysis or inspection, and confirmation.
- (2) Procedures for check analysis or inspection.
- (3) Inspection and sampling procedures.
- (4) Import procedures.
- (5) Techniques of checking facilities, operational procedures, and quality control of food factories.

g. Procedures will be established by both sides to deal with emergency situations such as detentions indicating serious problems or concerns of major health significance. Prompt communications channels will be utilized to bring these problems to the attention of appropriate personnel.

h. In the case of products originating in countries other than those of the signatory side which have been rejected because they are a hazard to health significance, both sides agree that the side which has rejected the products will as soon as possible inform the other side of the complete identification and if possible the final destination of the shipment.

i. The certificates of Analysis or Inspection issued by CCNAA or laboratories authorized by CCNAA will be considered by AIT. The contents of the certificate will be examined and worked out jointly by both sides.

j. AIT and CCNAA will establish interlaboratory Quality Assurance Programs (QAP's). The QAP's will be designed to promote laboratory proficiency. QAP's shall be developed and mutually agreed upon by both sides prior to participation in a certification program. By mutual agreement, areas to be covered in QAP's may include:

- (1) Protocols to obtain standards of known purity and potency.
- (2) Specifications for reagents and materials.
- (3) Methods and validation procedures.
- (4) Guidelines for instrument and equipment performance.
- (5) A program for analyzing split samples by participating laboratories, interchange of data and critiques.

- (6) Plans for periodic technical conference to review and evaluate QAP's.
- (7) Other areas as deemed necessary.

k. Scientific research investigations conducted by either of the two sides, and whose data demonstrate existing procedures or methodology to be erroneous or inadequate, are to be topics for discussion by scientific personnel of both sides. Prior to such discussions, the investigating side must provide the other with all pertinent data.

4. Funding

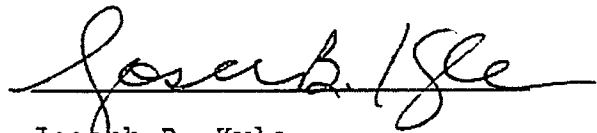
Funding of cooperative activities under these guidelines shall be carried out on the basis of mutuality, reciprocity, and flexibility. In general, each side will fund the cost of its participation in cooperative activities and may, if it chooses, provide full or partial support for participation in these activities by scientists of the other side. Decisions on funding for joint activities will be made by mutual agreement.

5. AIT and CCNAA will hold periodic conferences, alternating at cities in each side. In addition, other meetings may be arranged when necessary and by mutual agreement.

6. Amendments to these Guidelines may be proposed by either side at any time and shall be discussed during the periodic conferences. Upon mutual consent, the amendment agreed upon shall be incorporated into these Guidelines.



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Joseph B. Kyle
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January 28, 1985

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