No. 16233

UNITED STATES OF AMERICA
and
MEXICO

Memorandum of Understanding relating to the exchange of information on Food and Drug Administration regulated products. Signed at Mazatlán on 13 August 1974

Authentic texts: English and Spanish.

Registered by the United States of America on 27 January 1978.

ÉTATS-UNIS D'AMÉRIQUE
et
MEXIQUE

Mémorandum d'accord relatif à l'échange de renseignements concernant les produits réglementés par l'Office des produits alimentaires et des médicaments (FDA) des États-Unis. Signé à Mazatlán le 13 août 1974

Textes authentiques : anglais et espagnol.

Enregistré par les États-Unis d'Amérique le 27 janvier 1978.

MEMORANDUM OF UNDERSTANDING[1] FDA-CONACALPE

Mazatlán, Sinaloa
August 13, 1974

Memorandum of Understanding between the Food and Drug Administration (FDA) of the United States of America and the Secretariats of Agriculture and Livestock, of Industry and Commerce, and of Health and Welfare, and the Mexican Institute for Foreign Trade and the National Council for Science and Technology of the United States of Mexico which comprise the National Commission of Quality for Export Products (CONACALPE) of said country; Commission which will represent said Secretariats and Organizations and which will be the coordinator for the execution, on behalf of the United States of Mexico, of the items which are contained in this Memorandum.

The items in this Memorandum pertain only to those products which are involved in commerce between both countries and which are regulated on behalf of the United States of America by the Food and Drug Administration.

1. FDA and CONACALPE shall interchange and provide information relative to the following:

A. Methods and procedures for sampling
B. Methods of analysis
C. Methods of confirmation
D. Specifications and tolerances
E. Reference standards
F. Procedures for check analysis
G. Routine inspectional procedures
H. Laws
I. Regulations

2. Both parties agree to inform each other on a timely basis of the following:

A. Proposed modifications of existing Federal regulations
B. Proposed new Federal regulations
C. Proposed new legislation

3. Whenever one of the parties considers the above proposals (2, A, B, or C) to be of grave concern or adversely affect its interests, the affected party upon request will be given an opportunity for a full discussion and may file objections and comments through the proper channels that are legally and administratively provided for by their respective countries.

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

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[1] Came into force on 13 August 1974 by signature.

A. Commodity
B. Name and address of the shipper
C. Reason for the detention
D. Sampling procedure
E. Methods of analysis and confirmation
F. Defect action level (published)

The exporting country shall provide to the enforcing organization the following information if available:

A. Name and address of the manufacturer or grower
B. Date of production

5. The Food and Drug Administration and CONACALPE will provide upon request available technical assistance so that both organizations may jointly work toward resolving problems resulting from detentions of products.

6. FDA and CONACALPE will provide training upon request to technical personnel in any one of the following specialized categories:

A. Methods of analysis and confirmation
B. Procedures for check analysis
C. Inspection and sampling procedures
D. Import procedures

7. Procedures will be established in both organizations to deal with emergency situations such as detentions indicating serious problems or concerns of major health significance. Prompt communication channels will be utilized to bring these problems to the attention of appropriate officials, including immediate notification of the detentions to inspectors at the border, for bi-partisan sampling and verification by both parties.

In the case of products originating in countries other than those of the signators which have been rejected because they are a hazard to health, both parties agree that the authority which has rejected the products will immediately inform the other party of the complete identification and the possible final destination of the shipment.

8. The Certificates of Analysis issued by Mexican laboratories authorized by the Mexican Government will be accepted by the Food and Drug Administration according to the conditions agreed upon by both parties.

9. FDA and CONACALPE 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 by both parties prior to participation in a certification program. By mutual agreement, areas to be covered in QAP's may include:

A. Protocols to obtain standards of known purity and potency
B. Specifications for reagents and materials
C. Methods and validation procedures
D. Guidelines for instrument and equipment performance
E. A program for analyzing split samples by participating laboratories, interchange of analytical data and critique
F. Plans for an annual technical conference to review and evaluate QAP's

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

11. The Food and Drug Administration and CONACALPE will hold periodic conferences at least three times a year, alternating at cities in each country. In addition, other meetings between these organizations may be arranged when necessary and upon mutual agreement.

12. Amendments to this Memorandum of Understanding may be proposed by either organization at any time and shall be discussed during the tri-yearly conferences. Upon mutual consent, the amendment agreed upon shall be incorporated into this Memorandum of Understanding.

Approved: August 13, 1974

CONACALPE:

[*Signed*]
Ing. CÉSAR LARRAÑAGA ELIZONDO
Director General for Standards
Secretariat of Industry and Commerce

[*Signed*]
Dr. ARMANDO L. BEJARANO
Director General for Control of Foods,
Beverages and Medicines
Secretariat of Health and Welfare

[*Signed*]
Ing. BENJAMÍN ORTEGA CANTERO
Director General
for Vegetable Sanitation
Secretariat of Agriculture
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[*Signed*]
Dr. CARLOS ENRIQUE PEÑA
Director General for Coordination
National Council
for Science and Technology

[*Signed*]
Lic. RICARDO SAMANIEGO D.
Sub-Director General Technical
Mexican Institute for Foreign Trade

Food and Drug Administration:

[*Signed*]
SHERWIN GARDNER
Deputy Commissioner
Food and Drug Administration

Aprobado: Mazatlán, Sinaloa, agosto 13 de 1974

Food and Drug Administration:

[*Signed — Signé*]

SHERWIN GARDNER
Deputy Commissioner
Food and Drug Administration

Por CONACALPE:

[*Signed — Signé*]

Ing. CÉSAR LARRAÑAGA ELIZONDO
Director General de Normas
Presidente suplente de CONACALPE
Secretaría de Industria y Comercio

[*Signed — Signé*]

Ing. BENJAMÍN ORTEGA CANTERO
Director General de Sanidad Vegetal
Secretaría de Agricultura y Ganadería

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Dr. ARMANDO L. BEJARANO
Director General de Control
de Alimentos,
Bebidas y Medicamentos
Secretaría de Salubridad y Asistencia

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