PROCEEDINGS

Workshop on Food Safety in the Republic of China

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CONTENTS

FOREWORD i

PREFACE iii

INTRODUCTION 1

RECOMMENDATIONS OF TASK GROUPS 3

Task Group 1: Food Safety and the Law 5
Task Group 2: Information Systems and Consumer Awareness 16
Task Group 3: Food Safety from Harvesting Through Processing 19
Task Group 4: Contamination and Food Poisoning Follow-up 22

U.S. PRESENTATIONS TO TASK GROUPS 25

The Development of U.S. Food Laws 27
Peter B. Hutt

Enforcement of Food Laws Through Regulation 33
Taylor M. Quinn

Information Systems 41
C. Jelleff Carr

Industry's Response to Consumer Concerns 45
Channing H. Lushbough

Government's Response to Consumer Concerns 52
John J. Slavics

Cosmetics and the Concerns of Consumers 55
John A. Wenniger

Postharvest Transportation of Food 58
Mahlon A. Burnette

Good Manufacturing Practices 61
Richard V. Lechowich

Low-acid and Acidified Foods 65
Robert M. Schaffner

Activities of the National Food Processors Association 67
Allen W. Matthys

Environmental Contaminants 69
Edwin Johnson

The Role of Epidemiology and Risk Assessment 71
Frank Cordle

Chemical Contamination--PCBs 76
Ronald E. Engel

Microbiological Contamination (Shrimp) 81
John M. Taylor

BACKGROUND PAPERS 85

Food Safety, the Law, and the Government 87
Chen Shan Lin

Agricultural Science and Technology Information Resources in the Republic of China 100
Wan Jiun Wu

Current Status of a Preventive Program for Food Safety in Taiwan 110
Jean May Taiang

Safety Factors to be Built in at Food Processing Plants: Manufacturing Technology and Quality Control System 117
Yung Sing Chang

Safety Aspects of Food Additives and Food Contaminants — 136
Jen Kun Lin

Official Testing and Analysis of Food Hygiene in Taiwan, Republic of China — 160
Chi Byi Horng and Shin Shon Chou

Edible Oil Production in Taiwan and its Food Hygiene Implications — 185
Shin-Chan Chang

APPENDIXES — 195

A Opening Address — 197
Sanford Miller
Director Bureau of Foods
U.S. Food and Drug Administration

B Unraveling the Confusion Over Food Safety: How Successful Are We? — 206
Paul C. Ma
Director
Food Industry Research and Development Institute Republic of China

C Workshop Participants — 211

FOREWORD

Food safety has long been a focus of concern by the Republic of China and many other countries in the world as well. With rapid progress in industrialization and urbanization in the past decade, the people of the Republic of China on Taiwan are able to enjoy foods of various kind, fresh and processed, while safety becomes more important a factor of choosing. Food safety is not only a subject of intense study by welltrained scientists, but also a regulatory issue to the government and a topic of educating public, both producer and consumer. As a result, a joint Sino-American Workshop on Food Safety in Taiwan, sponsored by the National Academy of Science of the United States and the Academia Sinica of the Republic of China, was in held Washington,, D. C. on February 16-20, 1981.

There has been a long history of science cooperation programs between these two academies. Activities such as meetings and workshops regarding science policy, graduate education and research, marine biology and oceanography, industrial research, scientific and technical information, industrial innovation and product development, science based industrial park, regional land use planning, and industrial energy con ervation have been taken place successfully since 1964. These topics are of urgent concern during the rapid development of Taiwan. The American expertise and experience can assist Taiwan to solve the many problems we face and the road that the Republic of China marched could well serve as an international model.

In this workshop, topics such as food safety and the law, information systems and consumer awareness, food safety from harvesting through processing, and contamination problems and food poisoning follow-up were thoroughly discussed by the representatives from government, university, industry, research center and lawyer's office of both sides. A great deal of constructive suggestions were obtained in their conclusion, which I believe, will be carefully considered in the nation's decision-making agenda on the food safety issue.

As the chairman of the ROC Committee for Scientific and Scholarly Cooperation with USA, I wish to express my sincere gratitude to the co-chairmen of the workshop, Drs. Sanford A. Miller and Paul C. Ma. Without their devotion, this workshop wouldn't have been so successful I also deeply appreciate the US participants for their contributing invaluable information to the workshop. Special thanks are due to Mr. John G. Hurley and Ms. Tresa A Bass for their cordial correspondence and arrangement.

K.T. Li
Chairman
ROC Committee for
Scientific and Scholarly
Cooperation with USA,
Academia Sinica

PREFACE

The National Research Council of the United States and the Academia Sinica of the Republic of China (ROC) jointly sponsored a Workshop on Food Safety in Washington D.C., U.S.A., held in February 1981.

In early 1980, Frederick Seitz, co-chairman of the Sino-American Science Cooperation Committee, and Victor Rabinowitch, director of the Board on Science and Technology for International Development (BOSTID), visited Taipei to discuss topics for future activities in BOSTID's ongoing cooperative program with the ROC. Concurrently, concern with food safety issues in the ROC peaked, precipitated by a number of instances of illness attributed to faulty food handling or processing methods. Thus it was decided that a workshop to examine safety problems of processed food would be an appropriate activity.

In September 1980, K.T. Li, Minister without Portfolio, ROC, met with Donald Kennedy, president of Stanford University and former commissioner of the U.S. Food and Drug Administration (FDA), and BOSTID staff to further develop plans for the workshop and suggest possible participants. Upon his return to the ROC, a steering committee was formed and ROC workshop participants selected. Paul C. Ma, director of the Food Industry Research and Development Institute (FIRDI), was selected to chair the ROC team. Dr. Ma visited Washington, D.C., in November 1980 to meet with BOSTID staff and with officials of FDA's Bureau of Foods, who had agreed to help organize the workshop.

The workshop was held February 16-20, 1981, in Washington, D.C., and ROC panelists visited a number of U.S. institutions dealing with

food safety before and after the workshop. They include: Andrew W. Briedenback Environmental Research Center, U.S. Environmental Protection Agency, Cincinnati, Ohio; FDA State Training Branch, U.S. Public Health Service, Food and Drug Administration, Cincinnati, Ohio; Department of Dining Services, University of Maryland, College Park; Maryland Variety; Seafoods, Inc., Tampa, Florida; local offices of the National Marine Fisheries Inspection Service and the FDA, Tampa, Florida; Centers for Disease Control, Atlanta, Georgia; National Center for Toxicological Research, FDA, Jefferson, Arkansas; Total Diet Survey Lab, FDA, Kansas City, Missouri.

This report contains summaries of presentations made by BOSTID panelists at the workshop, recommendations of the four task groups, and background papers prepared by the ROC participants. A workshop report was prepared in Chinese by the ROC workshop participants for submission to appropriate ROC agencies in April 1981.

Many individuals contributed to the success of this workshop. Workshop sponsors and participants are especially indebted to the organizations who hosted the ROC panelists. Special thanks are extended to Frank MacKeith, Industrial Program Branch, Bureau of Foods, FDA, for his assistance in developing the workshop agenda, identifying appropriate workshop participants, and arranging observation visits to FDA facilities.

Facilities and local staff support for the workshop were provided by the National Research Council (NRC). Participation of the NRC and its U.S. panel members, participants, and staff was made possible by financial support from the International Foundation, Texas Instruments Foundation, Ford Motor Company Fund, General Instrument Corporation, and Hewlett-Packard Company. The National Science Council of the ROC supported the participation of the Chinese panelists.

INTRODUCTION

The Republic of China has achieved a remarkable record in economic and social development. Per capita income is now more than US$2,000, and the economy is changing from an agricultural to an industrial base. Education has expanded rapidly at all levels. The growing population is becoming increasingly urbanized.

As these changes occur, the percentage of income spent on food remains high, and the consumption of processed foods has increased. Following several severe cases of food poisoning in 1980, government and consumer concern about the safety of processed foods increased.

This workshop on food safety was held in response to this concern. The purposes of the workshop were:

- To examine the current legal and administrative structure for food safety in the ROC and make recommendations for improved structure and enforcement
- To discuss information systems available for food safety topics
- To consider the consumer's role in questions of food safety and quality
- To examine safety factors in food processing from harvesting through processing, including environmental contaminants, transportation of food, good manufacturing practices, and appropriate materials and packaging

- To discuss appropriate mechanisms for rapid response when contamination problems and food poisoning occur.

At the workshop food safety issues were presented from a U.S. perspective to all participants in order to examine historical development and past and current problems. After workshop participants split into task groups, ROC participants presented the current situation on Taiwan. Recommendations were formulated by each group in four major areas:

- In the session on food safety and the law, participants considered what elements should make up a food law, how the law should be enforced, the types of regulations needed, and the structures and types of technical and scientific personnel required to implement the law.

- Available information systems and how to gain access to them were discussed in the session on information systems and consumer awareness. Food safety through consumer awareness was presented from both industry and government viewpoints. A special session on concerns about cosmetics was included.

- The task group on food safety from harvesting through processing considered diverse topics including environmental contaminants, postharvest transportation of food, good manufacturing practices, risk assessment, materials and packaging, and low-acid and acidified canned foods.

- Case studies of chemical and microbial contamination and the operations and responsibilities of an epidemiological control center were discussed by the task group on contamination problems and food poisoning follow-up.

The task group recommendations are found in the following section.

RECOMMENDATIONS OF TASK GROUPS

TASK GROUP 1: FOOD SAFETY AND THE LAW

Co-chairmen: Chau Ching Lin and Taylor M. Quinn

Task Group 1 set itself the following goals:

- Reorganize the current ROC administrative structure for consistent and efficient development, administration, and enforcement of food laws.
- Amend the January 28, 1975 Law Governing Management of Food Hygiene to include new provisions and to clarify ambiguous provisions.
- Identify other actions to be taken to aid in developing, administering, and enforcing food laws.

As the following recommendations address certain sections of the January 28, 1975 Law Governing Management of Food Hygiene, the law is reproduced below in its original English translation provided by the ROC delegation.

LAW GOVERNING MANAGEMENT

OF FOOD HYGIENE

Promulgated on Jan. 28, 1975

I. GENERAL

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Article 1

This Law is specially established for management of food hygiene to protect people's health. For matters not provided for in this Law, provisions of other relevant laws shall apply.

Article 2

The term "food" as used in this Law shall mean the items supplied for eating, drinking and chewing by people, and their raw materials.

Article 3

The term "food additive" as used in this Law shall mean material which is added to or brought into contact with food in the course of manufacturing, processing, compounding, packing, transporting, and storing of food, for the purpose of coloring, seasoning, preserving, bleaching, emulsifying, flavoring, stabilizing the quality, promoting the fermentation, increasing the viscosity, enhancing the nutrition, preventing its oxidation or others.

Article 4

The term "food utensil" as used in this Law shall mean instrument, tool, or container which is brought into direct contact with food or food additive.

Article 5

The term "food container" or "food package" as used in this Law shall mean container, packaging material which is brought into direct contact with food or food additive.

Article 6

The term "food trader" as used in this Law shall mean the one who is engaged in manufacturing, processing, compounding, storing, selling, importing or exporting food or food additive, or the one who is engaged in manufacturing, importing, exporting or selling food utensil, food container or food package.

Article 7

The term "label" as used in this Law shall mean the letters, pictures, or symbols affixed on the container or package of food or food additive for indicate its name or descriptions.

Article 8

The agency-in-charge referred to in this Law shall mean the National Health Administration in case of the central level, and provincial (or special municipal) government or county (city) government in case of local level.

II. MANAGEMENT OF FOOD HYGIENE

Article 9

The food and food additive for sale and their utensils, containers and packages should conform to hygienic standard; such standard shall be established by the central agency-in-charge.

Article 10

Food or food additive which has any of the following conditions should not be manufactured, compounded, processed, sold, stored, imported, exported, presented as gift or displayed publicly:

(1) Those which have changed in quality, spoiled or are still unripe and therefore, are harmful to human health;

(2) Those which are toxic or contain substance or heterogeneous material harmful to human health;

(3) Those which are contaminated by disease-causing bacteria;

(4) Those with Pesticide residue exceeding the permissible safety level set by the central agency-in-charge;

(5) Those which are contaminated by atomic fallout or radioactive pollutant with such harmful content exceeding the permissible safety level set by the central agency-in-charge;

(6) Those which have been adulterated or counterfeited;

(7) The carcasses of animals slaughtered for meat which have been disqualified in hygienic inspection.

Article 11

The food additive admixed in the course of food manufacturing and food processing and its name, specification, scope of use and the maximum quantity that may be used shall meet the regulation set by the central agency-in-charge.

Article 12

The livestock which will be slaughtered for meat and their carcasses should receive hygienic inspection. The rules for conducting such inspection shall be established by the central agency-in-charge.

Article 13

The following articles should not be manufactured, imported or exported unless inspected, tested, registered and permit issued by the central agency-in-charge:

(1) Food additive, and

(2) The foods and food utensils, containers and packages which have been designated and announced by the central agency-in-charge.

Article 14

The food utensil, container or package having any of the following conditions should not be manufactured, sold, imported, exported or used:

(1) That which is toxic,

(2) That which tends to produce bad chemical reactions, and

(3) Others which are harmful to health.

III. MANAGEMENT OF FOOD LABELLING & ADVERTISEMENT

Article 15

Food or food additive packed in a container, the following items shall be prominently labelled thereon:

(1) Name;

(2) The weight, quantity or volume of the contents; and if it is a mixture of two or more than two components, they shall be labelled separately;

(3) Food additives and their concentrations;

(4) The name of manufacturing firm and its address;

(3) The date manufactured or the shelflife;

(6) Other items required to be labelled by other laws or government orders.

The items mentioned in sub-paragraph (6) above shall be limited only to the foods designated and announced by the central agency-in-charge.

Article 16

The labelling of food or food additive shall not be false, exaggerated or misleading people into believing the contents to have certain medical efficacy.

Article 17

Mass media or names of other persons shall not be used for publicity or advertisement containing falsehood, exaggeration, distortion of food additive.

IV. MANAGEMENT OF HYGIENE IN FOOD TRADING

Article 18

The place and facilities used by a food trader for manufacturing, compounding, processing, selling or storing of food or food additive should conform to the hygiene standard set by the central agency-in-charge.

The aproval for a food trader to establish a factory shall be processed by the agency in charge of the type of enterprise in conjunction with the agency in charge of public health.

Article 19

The factory for manufacturing dairy products, food additives, special nutrient foods and other foods which are under the regulations established by the central agency-in-charge should have hygiene administrative officer(s).

The rules governing establishment of hygiene administrative officer(s) mentioned in the preceding paragraph shall be formulated by the central agency-in-charge.

Article 20

The regulations governing management of hygiene in public eating and drinking places shall be formulated by the provincial (special municipal) agency-in-charge.

V. INSPECTION, TESTING & CONTROL

Article 21

Provincial (special municipal) or county (city) health agency-in-charge may make spot check on hygienic situation of food, food additive, food utensil, food container or package which is manufactured, compounded, processed or displayed for sale or for being presented as gift, and the hygienic situation of the place used for its manufacture, compounding, processing, sale or storage; when necessary, the agency-in-charge may take random samples for inspection and for test and issue receipt therefore. The agency-in-charge may order temporary suspension of manufacture, compounding, processing or sale of such items which are suspected of violating Article 10 herein or the regulations established by the central agency-in-charge pursuant to the provision of Article 11 herein; and seal said items for a set period of time; to the trader for temporary keeping in return for a letter of safekeeping established by the trader. The trader shall not refuse the spot check and random sampling referred to in the preceding paragraph provided that the random sampling shall be limited to the quantity sufficient for test.

Article 22

Based on the results of the sample inspection and testing of food, food additive, food utensil, food container or package pursuant to the provision of the preceding Article, the local agency-in-charge shall make the following disposal:

(1) The articles which have any of the conditions listed in Article 10 shall be confiscated and destroyed;

(2) Those which do not conform to hygiene or to the regulations established by the central agency-in-charge pursuant to Article 11 shall be confiscated and destroyed. For the items which may still be used or re-manufactured for use after disinfection, or proper safety measure, the agency-in-charge shall notify the trader a time limit within which to make disinfection, re-manufacture or take safety measure. If such action is not taken within the prescribed time limit, the items in question shall be confiscated and destroyed.

(3) If an item which has been suspended of its manufacture, compounding, processing or selling and has been sealed by order of the agency-in-charge pursuant to the first paragraph of the preceding Article is found to be free from the situations set forth in the two preceding subparagraphs, the disposal shall be revoked and the item unsealed.

If the confiscable items mentioned in the preceding paragraphs of this Article have been sold, their manufacturers, importers or sellers shall be ordered to recall them; and the items so recalled shall be disposed according to the preceding paragraphs.

The provincial (municipal) health agency-in-charge shall announce in newspapers the name and address of the firm, the responsible person's name, the commodity name and details of violation of the food trader who has manufactured, compounded, processed, sold, imported or exported the items set forth in sub-paragraphs (1) or (2) of the first paragraph of this Article.

Article 23

If the food, food additive, food utensil, food container or package which has been approved to be manufactured, imported or exported, has been found to have the situation set forth in sub-paragraph (1) or (2) of the first paragraph of the preceding Article, the central agency-in-charge, besides disposing of the item pursuant to the provision of the preceding Article, may in conjunction with the Ministry of Economic Affairs publicly announce prohibition of its manufacture, import or export at any time.

Article 24

The regulations for the inspection and testing prescribed in this Law shall be established by the central agency-in-charge in conjunction with other related agencies.

The regulations for inspection and testing of the food to be exported shall be established by the central agency for commodity inspection and quarantine in conjunction with the central agency-in-charge.

Article 25

If any person reports or assists the government agencies which leads to discovery of the food, food additive, food utensil, food

container, package, labelling, publicity, advertisement or food trader which or who has violated provisions of this Law, his name shall be kept strictly confidential and in addition he shall be properly rewarded.

The regulations for rewarding the reporting mentioned in the preceding paragraph shall be established by provincial (municipal) agency-in-charge.

VI. PENALTY

Article 26

Anyone found to have violated any of the following is punishable with imprisonment for a term not exceeding three years or detention of imposed, or combined with imposition of, a fine of no less than five thousand Yuan, and no more than twenty thousand Yuan, and the business or factory license granted to him may be suspended:

(1) Violation of the provision of Article 10 or 14.

(2) Violation of the prohibition set forth in Article 25.

If the responsible person of a judicial person or the agent employee or other worker of a judicial or natural person commits any of the crimes set forth in the preceding paragraph while performing his duty, besides punishing the actor, the judicial person or natural person shall also be imposed of the fine set forth in the preceding paragraph.

Article 27

In case of any of the following situations, the responsible person shall be imposed a fine of no less than three thousand Yuan and no more than ten thousand Yuan; and if a case is serious or if a violation is the second time in less than one year, the business or factory license may also be revoked;

(1) Failure to improve as directed within a prescribed time limit after violation of Article 9;

(2) Violation of the reguletions established by the central agency-in-charge pursuant to Article 11

(3) Violation of Article 12, 13, 15, 16, 17 or 19;

(4) Failure to improve as directed within a prescribed time limit after violation of the standard set by the central agency-in-charge pursuant to Article 18;

(5) Violation of the regulations formulated pursuant to Article 20; or

(6) Failure to recall already sold commodities as ordered by the agency-in-charge pursuant to the second paragraph of Article 22 of this Law.

Article 28

For refusal, obstruction or evasion of the spot check and random sampling prescribed in Article 22 or disobedience to the order for temporary suspension of manufacture, compounding, processing or selling, the responsible person shall be imposed a fine of no more than five thousand Yuan. If the case is serious or the violation is the second time in less than one year, the business or factory license may be revoked.

Article 29

The fine prescribed in this Law shall be imposed by the government of special municipality or county (city). Failure to pay such a fine after the expiry of the time limit given in the notice demanding payment thereof, the case shall be referred to the court for compulsory execution.

VII. SUPPLEMENTARY PROVISIONS

Article 30

The provisions on food utensil and food container of this Law may apply mutatis mutandis to management of toys which are directly touched or are put into the mouth by children.

Article 31

The enforcement rules of this Law shall be established by the central agency-in-charge.

Article 32

This Law shall become effective on the date it is promulgated.

DESCRIPTION OF CURRENT ADMINISTRATIVE STRUCTURE

The Division of Food Sanitation, a subsidiary of the Bureau of Food and Drug Control of the National Health Administration, is responsible for drawing up, interpreting, and administering food sanitation laws and regulations and safety standards. This division presently has a staff of four, but recently, the National Health Administration decided to enlarge this division to a bureau and to increase the staff to 37 persons.

In 1978, the Drug and Food Inspection Bureau was established as a separate unit to perform official testing and safety analysis of finished food and drug products. This Bureau is under the direct supervision of the National Health Administration.

The Bureau of Commodity Inspection and Quarantine (BCIQ), under the Ministry of Economic Affairs, drafts and administers food laws and regulations concerning nonsanitation (such as adulteration and misbranding). The BCIQ's quality control inspectors deal primarily with products intended for export, which are usually produced in plants separate from those processing for domestic consumption.

Recommendations

We recommend that the Food and Drug Bureau of the National Health Administration be enlarged to include the newly inaugurated Bureau of Food Sanitation and the food section of the Bureau of Commodity Inspection and Quarantine, now under the Ministry of Economic Affairs.

The enlarged Food and Drug Bureau should be staffed adequately to:

- Draft and administer the food law (both sanitation and quality control)
- Regulate and inspect imported food and food produced for local consumption, with ultimate expansion to include inspection of food produced for export
- Take charge of all official analytical work and testing now performed by the Drug and Food Inspection Bureau.

The name of the enlarged bureau should be changed to Bureau of Food and Drug Control. There should be only one food law and only one agency in charge of establishing, interpreting, and administering the law.

RECOMMENDED AMENDMENTS TO THE 1975 LAW

Article 24 of the January 28, 1975 Law Governing Management of Food Hygiene should be expanded to give the central agency-in-charge (Bureau of Food and Drug Control) authority to establish regulations covering (1) food manufacturing practices; (2) food sanitation standards; (3) pesticide usage standards; (4) limits of filth, bacteria, pesticides, and environmental contamination in foods; and (5) testing procedures.

Article 15, Section 5, of the January 28, 1975 Law Governing Management of Food Hygiene should also be amended. This section currently requires that food or additives packed in a container be labeled with the date manufactured or the shelf life. This is ambiguous and should be changed to require merely the date of manufacture. Any other dates used will be at the discretion of the manufacturer with the approval of the Bureau of Food and Drug Control.

Control of food from unknown sources (primarily bulk materials) is a serious problem in the Republic of China. In order to trace the source of all food products, it is recommended that the 1975 Law Governing Management of Food Hygiene be amended to allow the central agency-in-charge to require a registration number for all domestic manufacturers of process foods. This registration number should appear on the container. The specific article in the 1975 law to be amended is to be determined by ROC legal experts.

The central agency-in-charge should be given authority to inspect any plant records relating to health in the manufacturing process.

OTHER RECOMMENDATIONS

Special funds should be set aside to employ lawyers to draw up a set of wholesome food laws and to collect reference materials from the United States, Japan, and other countries.

The National Health Administration lacks technical and scientific personnel such as bacteriologists, toxicologists, and public health workers. The task group recommends that the U.S. Food and Drug Administration (FDA) be asked to (1) send their experts to the ROC to conduct training classes; and (2) accept National Health Administration personnel in FDA training courses in the United States.

TASK GROUP 2: INFORMATION SYSTEMS AND CONSUMER AWARENESS

Co-chairmen: Tin Yin Liu and C. Jelleff Carr

Task Group 2 considered the types of information needed to deal with food safety problems and to provide sources for further study of toxicology and epidemiology. According to this task group, ROC officials responsible for food safety must be able to:

- Deal with food poisoning problems quickly and efficiently by having access to information about similar outbreaks occurring elsewhere and about how these outbreaks were handled, preferably assessed by a list of symptoms.

- Set safety standards for food additives and contaminants. Toxicity information (such as GRAS* lists) should be available so that safety evaluations can be made for acceptable levels of each additive or contaminant.

- Carry on further research on food safety. Access to established bibliographies such as those at the National Library of Medicine and the National Agriculture Library should be arranged. A Food and Cosmetics Safety Data Base should be set up in Taiwan.

To execute the following recommendations, it is suggested that the U.S. National Academy of Sciences (NAS) undertake the following short- and long-term projects. Short-term projects include:

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*Generally Recognized as Safe.

- Sponsor a workshop in the ROC to train information staff.

- Arrange on-the-job training for information staff.

- Hold a seminar that includes the following topics:

  — Detailed explanation of the currently available food safety data bases
  — How to set up a data base
  — How to construct a thesaurus of terms for accessing the system
  — Records management and retrieval techniques
  — An overview of the agricultural information system at present in use in the United States.

Longer-term projects include:

- Place the ROC Agricultural Science Information Center (ASIC) on the mailing lists at FDA, U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and relevant agricultural agencies to receive publications related to food safety, toxicology, epidemiology, and related fields of interest.

- Have the ASIC and the above-mentioned U.S. organizations exchange data.

- Through the NAS, arrange for exchange of information between ASIC and international organizations.

- Set up a nationwide information network in the Chinese language.

- Develop a software package for processing information into the Chinese language.

The task group also considered consumer awareness. At present, most consumer information is disseminated by consumer groups through television programs and newspaper columns. Other existing resources could be used including elementary schools, county health departments, and the mass media. However, money must be made available to publish the information to be distributed. In addition, to make long-term plans, the government needs better information about how people's eating habits are changing.

To provide correct information and education on food safety to consumers in order to protect their health, it is recommended that ROC food safety officials undertake the following:

- Establish a Consumer Office within the National Health Administration to respond to questions or expressions of concern from consumers.

- Have government scientists involved with food safety educate consumers. This can be accomplished through radio or television appearances, through articles in newspapers or magazines, through publications written for distribution by county health departments and schools, or through other means.

- Distribute food safety and nutrition information as part of hygiene courses in elementary schools, perhaps taught by the school nurse or by an additional, specially trained staff person.

- Establish some sort of outreach program for the growing urban population on the model of the extension program for the rural population.

- Keep a record of consumer questions or expressions of concern for use by government policy planners.

- Have professional societies help the government disseminate accurate information about food safety and nutrition and be willing to serve as a source for food editors or other interested reporters from the mass media.

- Establish an exchange between FDA and USDA consumer affairs offices and appropriate ROC officials to determine appropriate materials that might be used in the ROC.

TASK GROUP 3: FOOD SAFETY FROM HARVESTING THROUGH PROCESSING

Co-chairman: Yung Sing Chang and Robert M. Schaffner

Task Group 3 enumerated the following recommendations:

- Current ROC good manufacturing practices should be compared with the "umbrella" good manufacturing practices proposed by the U.S. Food and Drug Administration in June 1979 for safety aspects and upgraded where necessary. The ROC should maintain the practice of issuing a single good manufacturing practices regulation applicable to most types of food processing rather than issuing regulations by product type.

- The ROC Farmers' Association, Fisherman's Association, Vegetable and Fruit Marketing Cooperative, and other relevant organizations should work with consumer, industry, and government associations to develop a voluntary agreement or specific laws or regulations if necessary covering standards for transportation of food so that foods will not be contaminated by chemicals and/or industrial wastes that may be carried in the same vehicle.

- To maximize the benefits that can be derived from public health people at all governmental levels in the ROC, all these professionals should be organized by the National Health Administration to: (1) exchange information, and (2) develop model local regulations and inspection guidelines that could be used by provinces, counties, and municipalities.

- A suitable division of the central agency-in-charge of food safety should develop, collect, and disseminate food safety and food handling guidelines to small local food processors and small food service organizations.

- The National Health Administration (NHA) and the Food and Drug Bureau (FDB) should encourage establishment of independent food analytical service laboratories (perhaps affiliated with educational institutions) to provide services for small food manufacturers and food service establishments. The NHA and FDB should establish an accreditation program for such laboratories.

- A national food safety week should be sponsored by the central government each year to increase public awareness of food safety concerns.

- Programs for training and educating food workers and supervisors in manufacturing plants should be expanded.

- To encourage voluntary compliance with the 1975 Law Governing Management of Food Hygiene, the National Health Administration should apply its penalty clauses in selected well-documented, well-publicized cases representing frequent, typical food safety problems. The National Health Administration should employ food safety lawyers to advise and assist its technical bureaus on these enforcement actions.

- The National Health Administration should establish an emergency action plan and train personnel to take the necessary steps in case of acute food-borne threats to the public health. This should include an around-the-clock office to coordinate the response to such emergencies and to supply correct information to the proper authorities.

- A national nutrition survey and eating pattern study are urgently needed to provide base-line information for food safety, risk assessment, and national nutrition guidelines. Such studies should be updated periodically. Sufficient financial support from the central government is essential to make a complete and meaningful study of this type to improve the food safety, nutrition, and health of all people in the ROC. ROC scientists should determine whether the normal ROC diet includes larger quantities of foods containing dangerous additives than the standards set by international studies.

- Recently, considerable progress has been made in the proper use of food additives in Chinese food, but some foods on the

market contain prohibited additives. We recommend that the National Health Administration place further emphasis on enforcement of the existing law concerning inspection and regulation of food additives. We further recommend that the FDB and NHA receive increased funding to support related research on food safety methods of analysis and surveys.

- Programs must be developed to educate farmers, fishermen, transporters, as well as processors, servers, and sellers of food of their role in food safety and protecting public health. Joint meetings and conferences should be held between the Farmers' Association, the Fisherman's Association, FIRDI, NHA, FDB, transport associations, and industry groups to develop such programs.

TASK GROUP 4: CONTAMINATION AND FOOD POISONING FOLLOW-UP

Co-chairmen: Chi Syi Horng and Ronald E. Engel

According to Task Group 4, ROC officials responsible for food safety must be able to:

- Eliminate chance of food contamination by control of bulk imported products, particularly industrial oil which in the ROC is sometimes diverted to use as a food product.
- Control domestic food production through inspection by FDB personnel empowered to enter all food processing plants and sample products. Inspection personnel must have well-defined food safety standards and be trained in their application.
- Carry out fast, accurate laboratory tests, using well-trained personnel. These tests must be able to discover contamination in time to prevent contaminated food from being widely distributed to consumers.
- React quickly and effectively to recognize, diagnose, and contain food poisoning outbreaks.

This task group made the following recommendations:

- Industrial oil should be declared unacceptable for food use. All imported oil to be used for food should carry some certification from the country of origin stating that it is

edible. Oil that is not intended for food use should be traced in some way to prevent it from being diverted to food use.

- Edible oil that has been used, for example, for frying food, and is therefore no longer suitable for food use should be downgraded to inedible oil uses and research should be continued to find the most economically advantageous uses for this oil.

- NHA inspectors should have the power to enter and inspect all sources as well as to seize contaminated food. County inspectors should cooperate with the NHA in this work.

- Drug residues in food-producing animals should be regulated by the National Health Administration so that residues originating from medicated feeds and animal drugs can be better controlled.

- Action and/or tolerance levels should be established for pesticides, antibiotics, and other contaminants with particular consideration being given to susceptible populations. Coupled with the determination of these levels, a surveillance (monitoring) methodology for measuring contamination in foods must be developed to enforce the limits set up.

- Levels approved by the ROC National Bureau of Standards and methodologies for analytical procedures developed by FDB should be established and certified so that they can be followed consistently by county offices of FDB regional laboratories. Responsibility should be assigned to one authority such as the ROC National Bureau of Standards.

- The U.S. FDA Program Manager System should be investigated to judge whether this is a suitable method of coordinating multidisciplinary projects in the FDB.

- A protocol covering areas of mutual interest in the furtherance of food safety should be explored by the ROC and the United States.

- Since impure water can enter food from many sources, it is necessary to protect the safety of ROC water supplies.

- To keep chemical contaminants out of the food supply, environmental pollution must be monitored and controlled. NHA

should set up a budget for such a program of systematic environmental monitoring.

- Scientific personnel will be needed on a continuing basis for these monitoring and testing programs. Thus the Ministry of Education should consider encouraging education in environmental health in the country's schools and universities.

- The recommendation of Task Group 1 that FDA train ROC personnel both in the United States and in the ROC in order to provide personnel in the immediate future to staff these programs, is noted and endorsed.

- A central authority toxicology unit should be set up to function in risk assessment and evaluation in the food area.

U.S. PRESENTATIONS TO TASK GROUPS

THE DEVELOPMENT OF U.S. FOOD LAWS

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The content of a food law is far less important than the people who interpret, apply, and enforce the law. Enforcement officials must be well trained and exist in sufficient numbers to get the job done. Without enforcement, any law is useless.

The basic principles of hygiene and sanitation are most important for the ROC. Cleaning up U.S. water and milk supplies has been the most important contribution of the U.S. Food and Drug Administration (FDA) and its predecessor agencies to raising the standard of living in the United States. Some of the subtle and sophisticated concerns now expressed in U.S. laws and regulations are not immediate problems in the ROC.

The ROC must be careful not to emulate American food law exactly. The ROC is quite a different country from the United States, and adoption of U.S. laws and regulations wholesale would be inappropriate.

Below is a brief history of the development of U.S. food law, and a discussion of three of its essential elements: misbranding, adulteration, and most important, enforcement.

HISTORY OF FOOD AND DRUG REGULATION

Food and drug laws are among the oldest forms of government regulation; for example, the Magna Carta has provisions covering standard weights and measures.

English statutory and common laws regarding adulteration and misbranding were brought to the American colonies at the time of settlement. Early American food laws developed first at city level, and later at county, state, and federal levels as techniques for transportation and preservation of food were developed.

The 1883 Tea Act, the first basic federal food safety law, was passed to prohibit the admixture of chemicals or other deleterious substances with tea. An 1890 Federal Export/Import Act was important in the development of federal food law: it prohibited importation of food containing any ingredient "injurious to health."

Comprehensive Federal Food and Drug Statute

The food law passed in 1906 was primitive by present standards but contained all elements regarding adulteration and misbranding that remain the backbone of today's law. It prohibited false or misleading labeling and addition of deleterious substances. Enforcement included everything up to and including criminal prosecution. The same principle of criminal liability that exists today existed at that time, namely, liability without fault. There was no need to prove that the individual who violated the statute knew or intended to violate the law--all that needed to be proved was a violation.

That law worked very well for some 30 years. With a few minor changes that law would be quite sufficient today to regulate the entire U.S. food supply. And that law would be sufficient, in my judgement, for any nation concerned about sanitation and hygiene rather than the latest new information about esoteric food additives.

In 1938 the law was completely rewritten. The 1906 act was repealed and the 1938 Federal Food, Drug, and Cosmetic Act took its place. Changes that were made included recognition of two types of food constituents: natural or inherent food constituents, and constituents added to food. These two types were dealt with in different ways in the 1938 law. The 1938 act stated that natural components of food would be "adulterated and illegal" only if the government could prove that they "ordinarily rendered the food injurious to health." For added constituents, over which greater control can be exercised, a tougher standard of safety was established. Added ingredients are considered injurious if they "<u>may</u> render the food injurious to health." U.S. consumers are willing to accept a greater degree of risk from a natural constituent of the food supply than from an added constituent of the food supply.

One other major change in the 1938 law was the development of sophisticated labeling requirements. Under the 1906 law there was no

affirmative labeling requirement, that is, food could be put on the market without saying anything on the label. In 1913, the law was amended to require net quantity of contents. The 1938 law requires net quantity of contents, a statement of ingredients (it does not specify descending order of predominance--this is found in the FDA regulations), the name and address of the manufacturer, and the name of the food.

Negative labeling requirements were also instituted. The law prohibited false or misleading labeling, and introduced a requirement that material information needed by the consumer in using the product be included on the label. The failure to reveal material facts became a violation of the law.

In 1973, the FDA required nutrition information on the label. This requirement, not in the 1938 statute, was imposed by FDA on the theory that the failure to put nutrition information on the label was a violation of the provision of the law regarding material information for consumers.

Under the 1906 act, no food standards--general statement of what food should contain--existed. In 1930, Congress amended the 1906 act and permitted industry to use on a voluntary basis food standards developed by the U.S. Department of Agriculture's (USDA) Bureau of Chemistry. The 1938 law included authority for FDA to promulgate mandatory standards of identity for food.

Since 1938 there have been more than 40 separate changes in the Federal Food, Drug, and Cosmetic Act, not all related to food. The statutory provisions relating to food labeling have basically remained unchanged. All the new requirements have been added by regulation without any change in the statute. Similarly, the provisions in the law relating to natural constituents of food and their safety have not been changed since 1938. The regulations for added food constituents have changed four times. In 1954, the Miller pesticide amendment set up a specific procedure for setting tolerances for pesticide residues on raw agricultural commodities.

The 1958 Food Additives Amendment was designed to control ingredients added to foods. In 1960, the Color Additives Amendment dealt with the safety of all colors added to food. The 1968 Animal Drug Amendments dealt with ingredients given to food-producing animals and therefore found as a residue in human food.

FOOD MISBRANDING

There are two elements to food labeling--economics and safety. Today's food standards exist solely for economic reasons--to define

food in a way that meets the economic expectations of producers and consumers. Likewise, net contents and the name and address of the manufacturer are on the label for economic reasons. The rationale for a statement of ingredients on the label is partly economic--so the consumer will understand what he is getting--and partly safety--in the event the consumer has a known allergic reaction to an ingredient in that food product. Nutritional information is on the label partly for economic reasons--to show the value of the food--and partly for health reasons. Labeling can be used for important health messages. For example, American food products containing saccharin show a warning that saccharin causes cancer in test animals. Nevertheless, food labeling is not the major way to deal with food safety problems.

FOOD ADULTERATION

Food adulteration provisions of the 1938 law govern three types of adulteration: economic, esthetic, and hazardous.

Economic adulteration is the oldest form of consumer fraud--watered milk, for example, is not a health problem but it is a economic problem and is prohibited by law.

Esthetic adulteration involves more analysis. Under American law, food that contains any filthy or decomposed matter, or that is "otherwise unfit for food," is adulterated and therefore illegal. (This is true even if the food is absolutely sterile and presents no health problem.) These esthetic provisions in the law protect the consumer's sensitivity and his health. Consumers are more concerned about filth in food than they are about food additives that may produce cancer. To the extent that these requirements of the law merely protect human sensibilities, they must become increasingly suspect in our society and around the world. Soon we will not be able to afford to throw away good food merely because it contains a small amount of filth. However, in many areas of the world where hygiene is not adequate, filth may not only offend sensibilities, but may contain contaminants that present health problems. Esthetic adulteration provisions deal more directly with human health problems when applied in developing countries, and will be much more important there than in the United States today.

Any food held under insanitary conditions that may present a danger to health is adulterated and illegal. The FDA has taken most of its enforcement action under the "insanitary conditions" provision of the food law, which is the backbone of food and drug protection in the United States.

Regulation of added poisonous or deleterious substances has been a burning issue in U.S. food safety for the past 10 years. Developing countries, however, should probably devote 99 percent of their resources to dealing with insanitary conditions, with emphasis on basic sanitation and hygiene, and 1 percent to the subtle issues of potential harm at some unknown future date from food additives. Solution of insanitation problems will result in a higher quality food supply than experimentation with an emphasis on food additives.

Food additives include basic components of food and other items such as preservatives, emulsifiers, fillers, colors, etc. Indirect food additives include things that come in contact with food such as the container, processing machinery, pesticide residues, and animal drugs, etc. U.S. laws have treated these different substances on an ad hoc basis.

A food safety law should also include an escape hatch—a way to allow some ingredients in food that cannot be banned because of their importance to the food supply. Tolerances for these ingredients in food can be set. For example, if a tolerance of 0 percent for aflatoxin in peanuts were set, about 80 percent of the American peanut supply would be considered unsuitable for consumption. FDA uses the escape hatch to say that peanuts are a recognized part of the food supply and sets a tolerance for aflatoxin. A food law that does not provide for exemptions as well as rules will not be functional.

ENFORCEMENT

Enforcement is the key to making the law work. Four major enforcement methods exist under U.S. law.

Inspection of food plants and warehouses for insanitary conditions, good manufacturing practices, and generally recognized principles of hygiene and sanitation is the first method. In some countries (but not in the United States) authorities can also look at records kept by the food manufacturer.

Analysis of products, including checks for filth, microbial contamination, decomposition, toxic substances, etc., may be performed without access to records or inspection of the factory.

After violation has been found, formal legal action can be brought or informal enforcement methods used. Three methods of court enforcement action are possible: seizure of the product, issuance of an injunction against the illegal activity, and criminal prosecution by fine or jail sentence.

Informal enforcement action is often used instead of formal action because it is more efficient and less expensive. Letters to violating companies, recalls, and publicity, the most potent weapon of all, are informal enforcement tools.

CONCLUSION

One must not be misled by the complexity of American food safety laws, a very few provisions of the law would be quite sufficient to regulate the safety of all foods. One must also not worry about details of wording and proliferating provisions. Often a single sentence or phrase will represent most of the FDA's effort to protect the American food supply. Those who handle enforcement will make the law work.

ENFORCEMENT OF FOOD LAWS THROUGH REGULATIONS

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A good food law sets up the basic structure for protection of the public. A food law with a great wealth of detail can create more problems than it solves. It is difficult to change a law once it is put on the books, even when it becomes archaic. The law should be kept reasonably simple, and then enforced by a series of regulations.

Regulations should be written so that the regulated industry and law enforcement officials charged understand what is expected of each. Most often, industry will obey regulations if they understand what they are supposed to do; however, some regulations are so complex that no one understands them, and it is difficult to convince anyone to obey. The enforcement agency must be willing and able to enforce the regulations. If some producers in an industry obey voluntarily while their competitors do not, and the violators are not penalized for their practices, soon none will follow the regulations because they cannot compete economiclly. Everyone must understand that the regulations will be enforced. Often the promise of enforcement is enough.

Regulations in the United States are formalized, and they go through a rule-making procedure, either with or without public hearings. Regulations in the broader sense are anything put in writing to implement the law, and may take the form of regulations, guidelines, or statements of policy. Regulations are easier to amend than the law, guidelines easier to amend than regulations, and statements of policy

are probably easiest of all to amend. In establishing regulations, one must consider which form to use, how often the regulation might be revised, and the stage of development of the enforcement structure.

Procedural regulations will include methods for changing regulations when necessary, a mechanism for informing people when regulations are changed, and methods for informing industry how it will be regulated--how and when inspections will be made.

These regulations also detail the authority of law enforcement officials, methodology for inspections, sample collection including payment for samples, sample analysis methods, reconditioning of violative lots, appeals, and warranties. Imports and domestic goods are treated similarly in the United States but not necessarily in other countries; establishment of separate regulations for these two types of goods should be considered.

Additional types of regulations may be needed for food sanitation or hygiene, pesticides, food additives, environmental contaminants, food standards, and labeling and packaging. These overlap to some extent, and some can be used for more than one purpose.

Food sanitation or hygiene regulations are an important category. Manufacturers need guidelines for production of different kinds of goods. A reasonably detailed set of good manufacturing practices controlling avoidable problems is necessary for some products. Tolerances for unavoidable filth may be dealt with in regulations. Tolerances for pathogenic bacteria such as salmonella must be established. Control of bacteria that are not necessarily pathogens may assist in the control of pathogens. In establishing sanitation regulations, the amount of food a country is willing to throw away for esthetic reasons must be considered.

Pesticides are a mixed blessing--without them food production is lower, and food contains more filth. With pesticides, inherent safety problems such as long-term toxicity and danger to farm workers must be considered. Positive controls for pesticide use should be established, including labeling to ensure proper use.

In the United States, food additives are substances added deliberately to food either by direct or indirect methods. Other definitions of additives are used in other countries. After carefully defining what will be considered a food additive in a particular situation, mechanisms to control, but generally not to prohibit, them should be established. Control may be positive or negative; levels of decision must be established, along with the means of performing

toxicity tests; standards of evaluation of toxicity tests must be chosen. These questions invariably come up, and they are easier to deal with if guidelines have been set in advance.

Environmental contaminants are accidental contaminants. Aflatoxin, polychlorinated biphenyls (PCBs), mercury, cadmium, lead, etc., are showing up in the food supply. Each country must decide whether it will set limits for these contaminants, and at what level. The lower the guidelines are set the more food will be thrown away.

Food standards were originally designed to prevent adulteration of basic commodities. Over time, standards have become more sophisticated, and are now also used to protect industry from competitors who can produce foods that look, smell, and taste like the original food but cost less. Food standards can be used in lieu of food additive regulations to prevent addition of deleterious chemicals. They are also an easy way to add nutrients that certain populations lack, and, further, may be used for quality control.

Labeling and packaging regulations are primarily economic in nature rather than safety oriented. Storage and preparation instructions are important labeling requirements for safety.

Further details on much of this discussion can be found in Guidelines for an Effective National Food Control System, published by the Food and Agriculture Organization of the United Nations.

STRUCTURE AND TYPES OF TECHNICAL AND SCIENTIFIC PERSONNEL REQUIRED TO ENFORCE FOOD LAWS

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Without the proper number and types of enforcement officials, including inspectors, investigators, analysts, and other experts to enforce regulations, any regulations are meaningless.

When the first Food, Drug, and Cosmetic Act was passed in 1906, Dr. Harvey Wiley did not have the resources to carry out the law as he hoped. He and his professional staff of about 12 served as inspectors and analysts. They traveled the country making inspections and collecting samples for later laboratory analysis.

The present U.S. Food and Drug Administration (FDA) enforcement structure has come a long way from the days of Dr. Wiley. It now has three areas: administrative, inspectional, and laboratory. The FDA is responsible for six primary product areas: food, drugs, radiological products, biologics, veterinary medical products, and cosmetics. Each product area has a bureau that develops the agency's policy for regulations of the product. The bureau staff includes technical experts in its product areas. These scientists conduct toxicological studies and evaluations, clear food additive and new drug petitions, establish tolerances, develop regulations, and provide the field force with the needed guidance to carry out the law and regulations as the agency directs. They also evaluate the activities of the field force to determine whether its activities conform to agency policies, and they review all regulatory actions.

FDA's ORGANIZATIONAL STRUCTURE

Agencies responsible for carrying out food safety and sanitation laws could be organized in many other ways. FDA's organization is but one example of an organizational structure. The field support organization I direct is patterned after our field organization--each division and office has a specific responsibility. One responsibility is coordinating the activities of counterpart agencies at the state level to produce greater inspectional coverage. The office of resource planning and management is responsible for deploying field resources and for developing the agency's annual implementation plan.

When developing a food law one must determine how many food establishment exist, where they are, and what kinds of products they make--some type of registration requirement is helpful. The United States does not require its food firms to register. Whatever intelligence is gathered about new firms or firms going out of business results from inspectional activities.

Each of the divisions--field science and technology, field investigations, regulatory guidance--corresponds to the operating branches in the field district offices. They provide the field offices with guidance in their areas of expertise.

The FDA has established 10 regional offices to provide management control over activities in the field organization. Each regional office in FDA could contain one or more district offices, which are the operating arm of the agency. Resident posts may contain one or more investigators and inspectors. FDA attempts to put field inspectors and investigators as close as possible to the firms they will be responsible for inspecting to reduce travel time. FDA has a total of 10 regions, 21 district offices, 2 stations (which do not have laboratory capability), 18 district laboratories, 7 specialized laboratories, and 126 resident inspection stations.

The regional office oversees district offices, and is an administrative arm for each of the district and specialized laboratories' functions. The district director is the chief administrator responsible for carrying out district activities on a day-to-day basis. Planning for inspectional activities is conducted at headquarters, and execution is carried out at the local level.

STAFF LEVELS AND TRAINING

Inspectors and Investigators

The FDA's investigators are its eyes and ears--they are on the firing line, making inspections, detecting violations, determining

whether or nor procedures and process conform to good manufacturing practices. There have never been enough investigators and inspectors to carry out all the agency's duties and rasponsibilies. The annual plan must be a consensus, and agency management must be intimately involved in its development.

A career ladder exists for investigators and inspectors. Inspectors, who need not be college graduates, can progress up to the district director level through a series of educational, training, and experience opportunities. Investigators, called consumer safety officers, must be college graduates with a bachelor of science degree in one of the physical sciences, and a minimum of 30 semester hours of science. They start at mid-level grades. A new investigator spends a minimum of 6 months of intensive training in investigative techniques, including classroom instruction by experienced investigators from the local office, college and university courses; a series of demonstration exercises with an experienced investigator; and law lectures given by either his supervisor or an experienced investigator. For on-the-job experience, new investigators are sent out with experienced investigators to a proper inspection.

FDA investigators are responsible for inspecting food and drug firms, biologic firms, manufacturers of radiation-emitting products, cosmetics, etc. They do not begin to specialize until they reach the upper grades of the journeyman level, after several years of intensive experience in investigations.

It is assumed that an investigator can be trained to become an evidence developer. An individual with a keen mind and the ability to search, document his findings, and present them to his supervisor and the administration in an understandable and clear fashion is needed. In court, the investigator is responsible for testifying about his findings and convincing the court and jury that they are sound, based on his documentation.

A number of very technical courses have been developed for FDA staff. Courses in basic food technology, laboratory food technology, and demonstration food technology are provided, as well as a university-level bacteriological sanitation course and demonstration inspections. University-level courses in low-acid and canned foods cover process development, process evaluation, and can seaming technology, including tear down and seam evaluations.

"Hazard analysis and critical control point" (HACCP) is another technique used to train more sophisticated investigators. This technique identifies the points in a process where experience has shown that the process is not controlled and could go astray, producing

hazardous products. This procedure requires the identification of these critical control points and evaluation of the entire process.

These are examples of training provided in the food investigative area. Comparable courses are used in other product areas such as drugs and veterinary medicine.

Analysts

The laboratory or the analytical force is more diverse than the investigative force. Analysts must have a chemistry degree with at least 30 semester hours in chemistry, and must go through an intensive 6-month training program including steps and exercises to demonstrate certain analytical principles. On-the-job training requires him or her to use various methods from the U.S. pharmacopoeia or the association of official analytical chemists. The specialized training offered analysts includes sophisticated assay techniques, entomology sanitation, microbiology sanitation, pesticide analytical work and work associated with the detection of environmental contaminants. The 18 general laboratories now located throughout the United States can analyze an array of food and drug products. A number of specialized laboratories concentrate on such areas as microbiological analysis of food products and radiation-emitting products. Other research centers have recently been established to detect a whole array of environmental and elemental contaminants and drug residues.

FDA constantly needs new, updated equipment to detect and identify levels of contaminants found in food products. Some laboratories are equipped with nuclear magnetic resonance techniques and procedures; some with mass spectometry, gas chromatography, and liquid-liquid chromatography; and all have modern analytical tools.

Compliance Officers

In addition to conducting inspections and determining whether firms are in compliance with the rules and regulations, investigators are also responsible for collecting samples for laboratory analysis. The results of the sample analyses and investigational findings are reviewed at the local level to determine the agency's course of action to either enforce or correct the problem.

A total of 84 compliance officers are selected from the ranks of analysts and investigators to determine whether or not a violation exists and what course of action the agency should recommend. These officers participate in advanced law courses and annual seminars to keep them abreast of changing rules and regulations. After officers

examine the inspectional and analytical findings, their recommendation is sent to the bureau responsible for that product where it is reviewed by bureau compliance officers, and in some instances the bureau scientists if a specific issue is at question. They will either concur or reject the recommendation. If they concur, it proceeds to the next level of review, the office of the commissioner. If approved, it proceeds to the Department of Justice.

UNIFORMITY

In any enforcement structure there must be assurance that the law is carried out uniformly, that is, inspectors and investigators in San Francisco should conduct the same quality of inspection as those in New York and their findings should be treated the same way. Regulations and laws must be interpreted and applied using the same base and the same criteria.

There must also be general uniformity in the application of sanctions when problems that warrant agency action are found. The headquarters structure works hard at assuring this uniformity by providing field staff guidance and training. While over the years science and the law have become more complex, requiring a shift of resources from the field to headquarters, it is incumbent upon the enforcement authority to ensure that adequate resources exist to enforce the regulations.

INFORMATION SYSTEMS

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The increasing capability to analyze, detect, and identify small amounts of chemical substances in foods has led to questions about the safety of such substances.

Where does one obtain the information for addressing these questions? The scientific literature is the immediate source, but locating specific toxicologic information may require an intensive search. Some sources already exist for searches; toxicological literature contains information about hundreds of thousands of substances. However, much of it is not of a quality to permit a final judgment about the safety of certain food ingredients. One is always forced to make a judicious evaluation of the quality of the information--its extent, and when and how well the work was conducted. The quality of the material must be also evaluated for validity and methodology due to the rapid advances being made in analytical chemistry.

The National Library of Medicine has maintained a toxicology program for some years; it is a good way to assess information quickly. Computer printouts on a particular substance will list all publications in any given year relating to the toxicity and animal studies of the substance. The information is for recent years only; there are other ways of searching the older literature.

The U.S. National Technical Information Service, which also conducts information searches on request, compiles all information accumulated from government reports and study contracts. For example,

one of their recent announcements lists under "Food" patents related to the treatment of cured meat products and reviews of food processing techniques and safety factors in small canning factories.

The Chemical Abstracts search service of the American Chemical Society is also an excellent source. Food toxicity is one of their specialty areas, and for a modest fee, they will provide a printout of the references cited in Chemical Abstracts on a particular subject.

I would like to describe briefly a review by the Federation of American Societies for Experimental Biology of the "generally recognized as safe" (GRAS) substances. Substances that have been used traditionally in foods for many years were designated in the law as "generally recognized as safe." About 10 years ago the safety of these GRAS substances was questioned. Who says they are safe? Why are they generally recognized as safe? At the request of the U.S. Food and Drug Administration (FDA) the Federation assembled a Select Committee on GRAS substances that is just concluding its review of the evidence on several hundred food ingredients. To date, reports on 415 substances have been published. The committee had a difficult task because it was asked to give an opinion on the safety of each food ingredient based upon rather insufficient evidence--there have been relatively no modern toxicological investigations of these substances. The committee struggled with this problem and developed a satisfactory program. Five definitive conclusions were developed which may be useful as we consider the ROC food supply. The committee's report on each of the GRAS substances provided the FDA with an analysis of all relevant scientific data and an opinion leading to one of the following conclusions:

- There is no evidence in the available information on substance "X" that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at current levels or levels that might reasonably be expected in the future. (The FDA allowed such substances to continue in GRAS status with no limitations other than good manufacturing practice.)

- There is no evidence in the available information on the substance that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current and in the manner now practiced; however, it is not possible to determine without additional data whether a significant increase in consumption would constitute a dietary hazard. (The FDA allowed such substances to continue in GRAS status with limitations on the amount that can be added to foods.)

- While no evidence in the available information on the substance demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted. (The FDA issued an interim food additive regulation requiring a commitment that within a stated period of time the necessary testing be undertaken. The substance could be continued in GRAS status while the tests are being completed and evaluated.)

- The evidence on the substance is insufficient to determine that the adverse effects reported are not deleterious to the public health, when it is used at levels that are now current and in the manner now practiced. (The FDA could establish safe usage conditions or rescind its GRAS status. Interested parties may submit petitions establishing conditions for safe use.)

- There is insufficient information available to give any evaluation on the particular substance.

These five conclusions were worked out over a period of time and proved to be quite satisfactory to all parties.

The manufacturers of the products and consumers, both of whom have interests in the products, sought an opportunity to review the committee's opinions. Therefore as each draft report was made available, an open hearing was held so that all could make their views known. Additional information often surfaced at these hearings which led the committee to revise its tentative opinion. The final report to FDA reflected the input from the hearings.

One confounding factor in food safety regulations is the level of consumption of a given ingredient. In pharmacology, one deals with effects of drugs where the accurate dosage is usually known. However, with food substances, so little is known about who eats what and how much, the "dose" of any given food or food ingredient is difficult to ascertain. The level of consumption by the public as a whole and individually is a crucial issue in any toxicological survey. One cannot divide total amount consumed by 220 million people to determine individual consumption. Special groups, such as children, the aged, and pregnant women, must have special considerations; it is important to know what those individuals will consume. This question has not been adequately addressed in any recent review.

Following my work with GRAS review, I assisted the Food Safety Council in developing a protocol for food safety assessment. A committee composed of prominent scientists worked for 4 years to

produce a proposed system of food safety assessment which seeks to fill in the deficiencies of the GRAS review and specify the kind of toxicology information needed to make a fair and proper judgment of the safety of a good ingredient. This report addresses such issues as legal standards, quantity of a substance ingested, acute toxicity studies in animals, mutagenicity testing, chronic toxicity testing, and concludes with four mathematical models for assessing the potential hazard of a food substance based upon the model that best fits the toxicological data available. There are a number of difficult issues. One is the fact that our toxicity information is usually based on studies in animals which must then be extrapolated to man.

NOTE: Dr. Carr provided workshop participants with copies of the following Food and Safety Council reports: Proposed System for Food Safety & Assessment, Final Report of the Scientific Committee of the Food Safety Council, June 1980; and Principles and Processes for Making Food Safety Decisions, Report of the Social and Economic Committee of the Food Safety Council, December 1979.

INDUSTRY'S RESPONSE TO CONSUMER CONCERNS

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Industry feels voluntary compliance is very important in maintaining product standards. Although Kraft Co. has 10 full-time inspectors, 1,262 government inspection visits were made to Kraft plants and warehouses during 1980, or 10 times the number of in-house inspections made. In-house inspections are more detailed, however.

Three major issues are considered in this presentation: (1) consumer complaints, (2) out-of-specification materials, and (3) serious product quality defects.

CONSUMER COMPLAINTS

Kraft Co. is in business to serve its customers, and to satisfy consumers with the consistent quality of its products. When a food processing firm fails to satisfy individual consumers and serve its customers well, that business fails in its purposes. Should this occur frequently, permanent business failure will result.

Because consumer satisfaction and customer service are essential to continuing sales and profitability, every consumer complaint must receive thoughtful consideration and effective response. It must also be reviewed within the company for whatever product quality implications it may bear. A consumer complaint is a signal that something may be wrong. It is important to listen when consumers stop in at a office or plant, telephone, or complain in writing.

If it is clear that a food product or its package has exhibited a significant quality defect, it is essential that it be obtained for examination and laboratory evaluation if possible. Because some foods are perishable, the consumer may have discarded the remnants. If, however, the package is still available, the production lot code should be obtained and shelf samples of the lot evaluated. If there is enough of a sample left after an in-house examination, several nonexperts could be invited to try it too. Some flavors cannot be detected by all people. If the product bears such a flavor, and it is unattractive and unacceptable to those who can taste it, the future sales and profitability of this product are in jeopardy.

In short, consumer comments on the quality of products often provide the first inkling that the quality a company has worked so hard to provide is not being delivered for consumer use and satisfaction. Because they serve as an early warning, consumer complaints merit prompt evaluation. They may provide clues to significant product quality defects which are apparent in the home, but which a quality control program was not designed to detect in the production plant. Consumer complaints may thus lead to improved quality control procedures, such as more extensive evaluation of shelf life samples.

OUT-OF-SPECIFICATION MATERIALS

Specification limits and acceptable ranges define the quality of each ingredient used to prepare and process a food product. For purchased materials, a company may test every lot for every specification parameter when it is delivered and before it is used.

If a material has a long history of meeting all specifications, quality control tests could be run only on every tenth lot, while continuing to do one or two check tests for identity and for another fundamental characteristic or two on every lot. Eventually, however, your supplier could mistakenly ship a lot that is "out-of-spec"; or much worse, a shipment that is another material altogether and mislabeled.

Consider, for example, an ingredient—a free-flowing powder—that when mixed with water under controlled conditions is to disperse without lumps and remain suspended after 12 minutes at rest. What if this ingredient fails the dispersibility test? Since it came from an outside supplier and does not meet specifications, the following alternatives are available:

- Return the shipment to the supplier, freight collect; or

- "Blend off" this lot, mixing it in at a 5 percent or 10 percent level with other satisfactory lots, provided your quality control laboratory has evaluated this procedure in advance and found that it results in a finished product that meets all specifications. In this case, the supplier must be informed of his product quality defect and assurances should be obtained that this situation will not recur.

When out-of-spec, in-process goods and finished products are produced in one's own plant, they cannot be returned to the supplier. What steps must then be taken? First and most important, it must be ascertained that there is no health hazard associated with failure to meet specifications. One must be equally certain that its further use does not cheapen the finished product to the point it is deceptive or fraudulent.

When one is absolutely certain that there is no health hazard and no economic cheat, one could either (1) rework the product, if past experience shows the materials can be reworked successfully; (2) "blend off" the product, which may be less costly, even though logistically more complicated than rework; (3) downgrade the product to animal feed when neither rework nor blending off yields a finished product that meets your specifications; or (4) destroy the product, which is the most costly and wasteful alternative. These alternatives assume, of course, that specifications are drafted properly.

Whenever specifications cannot be met routinely and repeatedly, perhaps the specs are impracticably tight. Administrative review and internal controls on preparing and revising material specifications are exceedingly important parts of the whole process of establishing finished product standards and effective quality control. Specifications should not be revised lightly.

RECALLS, MARKET WITHDRAWALS, AND STOCK RECOVERIES

In an imperfect world, every food processor will occasionally produce a lot of a product with an undetected but serious quality defect. For whatever reasons, the sampling plan on which the quality control test schedule is based failed to identify a defective product.

The U.S. Food and Drug Administration (FDA) has categorized the increasingly serious levels of such defects as "stock recovery," "market withdrawal," and "recall." Stock recovery goes into effect when a defective product has never left the producer's control. For example, the packaging quality laboratory may discover that samples from production between 11 a.m. and noon show inadequate sealing of the

flexible film. Meanwhile, no shipments of this lot have been made and the stock is simply recovered from the warehouse for repackaging.

Market withdrawal is initiated when a defective product has left the producer's control and entered the marketplace, and when the product defect represents no significant hazard to the public health. A product is defective due to age, as for example bread or milk, the removal and return of such products from the store shelves fit the technical definition of market withdrawal. Stale bread or sour milk will not enhance a company's reputation with consumers, but they do not threaten health. To use FDA's terminology, the product defect that leads to a market withdrawal is not an "actionable defect" under the Federal Food, Drug, and Cosmetic Act; that is, FDA will not take legal action against the product, or its producer or distributor.

When a serious product defect occurs involving a significant health risk or some other "actionable defect," a recall begins immediately. If the risk is life-threatening, it must be announced to the general public, consumers must be urged to check their pantry shelves, freezers, and refrigerators for the particular lot(s) involved and return all that is found to their retailers for exchange or refund. If lesser degrees of risk to the public health are involved, a product may be recalled only from retail store shelves and back rooms or perhaps only from the warehouses operated by the company's customers.

Planning for a Stock Recovery

Few quality control systems are complete, 100 percent before-the-fact operations. In particular, evaluation of the integrity of final packing necessarily occurs after the product is packaged. Or for such products as cottage cheese and yogurt, bacteriology test results are available only two or three days after the product has been produced, at the earliest. The occurrence of an isolated defect in a small proportion of a production lot is also common but infrequent; such defects slip through between quality control samples.

Regardless of the seriousness of a product defect, stock recovery is rather simple, since none of it has left the producer's control. Planning an effective stock recovery requires:

- Good production lot identification: every shipping container that contains defective products should be identifiable by clear, legible lot codes.

- Good production records of how much of the defective product was produced and the identity of each ingredient used in its production.

- Good shipping records: if a company operates more than one warehouse, defective products may have been shipped from the production plant to other company locations. Shipping documents must show the lot code and quantity sent to each.

Planning for a Market Withdrawal

In a market withdrawal, there is a defective product in the marketplace, beyond a company's direct, immediate control. This product involves no health hazard, and, according to the FDA, the product defect is not legally "actionable."

In addition to the basic requirements for an effective stock recovery (i.e., good production lot identification, good production records, and good shipping records) plans for market withdrawals must also include systems for:

- Defective product pick-up and return. Depending on the product, market withdrawals may be routine and repetitious, as they are, for example, for fluid milk, bread, and baked goods. Other market withdrawals may be exceptional and infrequent, and product pick-up planning for these is more difficult and complex, because they are not routine.

- Segregation of the defective product to minimize repeated inspection and handling. Such a program must be designed to keep the defective product segregated in the truck pick-ups and in a storage area until disposed. Otherwise, the company will waste time and money reinspecting and resegregating the defective product, and some of it may be redelivered to customers.

- Disposition of the defective product. As with stock recoveries, final disposition will depend on the specifics in each case. "Day-old bread" may be sold to consumers at reduced prices; out-dated milk may be sold to farmers as animal feed. Other food products may be repackaged, reworked, or destroyed, depending on the defect and the basic economics.

Planning for a Recall

In planning for a recall, it is important that every executive understands that the entire future of the company depends on the outcome. When a good company inadvertently produces a product that poses a significant health hazard, the absolute first priority must be the prevention of further consumption by consumers. <u>THE IMPORTANCE OF SPEED CANNOT BE OVEREMPHASIZED</u>.

A prime rule seems to be that all recalls begin on Friday afternoon at 4:55 p.m., and continue through the weekend. Plans for coordination and communication must take this into full account, so precious days are not lost.

Plan for a recall should include these steps:

1. Gather, correlate, and evaluate all known information on the nature and extent of the reputed health risk.

2. If the details available are not yet definitive, decide whether to proceed with an immediate recall or continue the investigation.

3. When a company decides that a recall is essential to protect public health, notify all affected company officials and the government agency responsible for food safety.

4. Next, notify and issue operating instructions to all company staff who will help execute the recall.

5. Immediately embargo all further shipment and distribution of the product lot(s) involved.

6. Prepare and issue a news release that includes details needed for effective consumer response and for protection of the public health, and specify how inquiries will be handled and by whom.

7. Search shipping records and notify all customers by telephone, telegram, or personal visit that specified production lot(s) are being recalled.

8. If customers have sold the recalled product to their commercial customers, it must be tracked down!

9. Reverse the usual distribution system and return all products recalled from customers and consumers to specified warehouse(s).

10. Keep a detailed log of time and events throughout the recall.

11. Continue and complete ongoing investigations of the nature, extent, causes, and remedies, and of future precautions to preclude repetition of the circumstances that led to the recall.

12. Make periodic recall progress reports to company officials and the government agency responsible for food safety. All communications should flow between one individual in the company and one at the agency.

13. Initiate an "effectiveness check" to determine how well efforts have succeeded in removing the recalled product from the marketplace.

14. Finally, determine the ultimate disposition of the recalled product, so it does not reenter the channels of commerce and again cause a hazard to health.

These 14 steps to an effective recall depend on having in place effective plans for the six elements essential to a market withdrawal outlined earlier. Under the exceptional pressures of an emergency recall, not only do items 1-14 occur almost simultaneously, but the company's recall coordinator may quickly discover that many routine company procedures do not fit the advance planning for a recall. For example, production counts may not tally with distribution figures. Shipping cases, pallets, indeed, whole truckloads of the product may have "disappeared."

In developing recall plans, it may help to:

1. Run an unannounced trial recall at least once a year, especially if there has not been an actual recall recently. When the trial recall is over, evaluate what went wrong and revise plans accordingly.

2. Establish an ingredient tracking system so that in the event a supplier recalls his product, every lot of every product containing the product can be identified by production lot code.

3. Identify shipping containers not only with a product lot code, but also with product plant, line, and hour. Then, if a product must be recalled from a known, identifiable production period, the scope of the effort is minimized.

4. After every recall (and following every unannounced trial recall), review recall plans and revise them to fit the current facts of the company organization.

GOVERNMENT'S RESPONSE TO CONSUMER CONCERNS

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Two programs of the Food Safety and Quality Service (FSQS) of the U.S. Department of Agriculture (USDA) use consumer input: the Inquiry Response program and the Meatborne Hazard Control Center program.

USDA defines "consumer" as a purchaser of products in the marketplace, or recipient of government-supplied benefits. The latter includes members of the armed forces, patrons of school lunch programs and women's and children's nutrition programs, patients in hospitals operated by the Veterans Administration, and inmates of the federal prison system.

INQUIRY RESPONSE PROGRAM

The Inquiry Response Program is operated by the Policy Development and Public Participation Division (PDPPD) which has two broad program functions--policy development and improvement of public participation in the rulemaking process. For the first function, PDPPD advises the administrator of USDA through the development and recommendation of policy options relating to overall FSQS program activities. For its second activity, PDPPD uses the Inquiry Response System to obtain public participation. This system has been operating in the Washington Metropolitan area and in California since September 1980. The system's efficiency was reviewed in January 1981 and a decision to expand, terminate, or modify the system is now being made.

The FSQS Inquiry Response System was established in 1979 by Executive Order 12160, and provides "for the Enhancement and Coordination of Federal Consumer Programs." It was finalized in the USDA Consumer Affairs Plan, dated June 9, 1980.

The objectives of the system are to improve the ability of FSQS to respond to consumer inquiries; to establish procedures for recording and tracking inquiries received throughout the agency; to insure that consumer concerns are reflected in FSQS policy; and to educate consumers about how to obtain information from FSQS.

The system is not designed to answer inquiries made through the Freedom of Information Act or to satisfy requests from industry for copies of standards, specifications, or bulletins, etc.

Principles of Operation

Telephone and Mail Referral. The objective is to reduce the number of referrals consumers must go through when making inquiries of the department. A single telephone number has been established and publicized and will be manned by PDPPD staff. Further, each staff director has established a contact resource person whom PDPPD can consult for information. PDPPD staff should try to determine why the consumer called the government agency, which cannot provide any financial relief, instead of calling the manufacturer.

Consumer Reponse Procedures. All written inquiries should be answered with 10 days, and oral inquiries answered within 2 days. The priority order of response should be alleged health hazards, complaints, and requests for information. Responses answer questions directly and do not refer the consumer to another agency. Responses are also followed up when policy changes occur, when a matter is under continuing investigation, or when the inquiry must be referred to another agency that has jurisdiction. Careful records are kept of all responses.

Policy Development. Inquiries and concerns are tracked, classified, and analyzed for reporting to senior policy staff officials who prepare appropriate policy.

Evaluation. The efficiency of these procedures are measured by contacting consumers and interviewing them to determine that their inquiries or concerns were adequately addressed.

Consumer Education. A fact sheet and press release informing the public about the Consumer Response System has been prepared and distributed to the public, the press, and other federal agencies.

THE MEATBORNE HAZARD CONTROL CENTER (MHCC)

The Pathology and Epidemiology Division of the FSQS Science program has operated the MHCC since its establishment in 1976. It receives reports from USDA personnel, state health departments, other federal agencies (e.g., Food and Drug Administration, Centers for Disease Control), and the public, and accumulates data on the public health significance of illness resulting from meats. This computerized data system files and can sort episodes by type of contaminant, type of food, suspected disease, geographical area, type of illness, etc. Analyses are carried out on request.

The Inquiry Response Program of PDPPD receives input exclusively from consumer complaints. It sorts by type of complaint, geographical area, etc., but the material is not examined by epidemiologists as at MHCC. The two systems do not interact.

COSMETICS AND THE CONCERNS OF CONSUMERS

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Total consumer expenditures for cosmetics in 1979 are estimated at $10 billion. These retail sales accounted for more than 9 billion packages of cosmetic products which were produced in approximately 2,600 establishments. There are estimated to be more than 50,000 different cosmetic formulations currently on the market made up of 5,000 cosmetic raw materials and 5,000 fragrance components.

Cosmetics are regulated by the Food and Drug Administration (FDA) under the authority of the Food, Drug, and Cosmetic Act (FD&C Act), particularly the color additives regulations, and by the Fair Packaging and Labeling Act (FP&L Act) of 1966, which provides that "packages and their labels should enable consumers to obtain accurate information as to the quantity of contents and should facilitate value comparisons."

The FD&C Act defines cosmetics as articles applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Soap is exempted from the provisions of the act. Articles intended to affect the structure or any function of the human body, though often promoted as cosmetics, are drugs (and may also be cosmetics) and must therefore comply with the more stringent drug provisions. Toothpaste containing fluoride is considered a drug, as is an antiperspirant. A deodorant is a cosmetic. Drugs must be safe and efficacious; cosmetics need be neither.

The FD&C Act authorizes FDA to promulgate regulations, carry out examinations and investigations of products, and conduct factory inspections. Duly designated employees are authorized to enter and to inspect at reasonable times and within reasonable limits any factory, warehouse, or establishment in which cosmetics are manufactured, processed, packaged, or held for introduction into interstate commerce.

The FD&C Act prohibits the introduction into interstate commerce of any adulterated or misbranded cosmetic. The FP&L Act authorizes the agency to publish regulations for the proper and informative labeling of cosmetics.

Contrary to widespread belief, there is no statutory requirement, as in the case of food additives, color additives, and drugs, that a cosmetic product or ingredient be proved safe before it is introduced into interstate commerce. Furthermore, cosmetics manufacturers or distributors are not required by law to register with FDA their manufacturing establishments, product formulations, or consumer reports of adverse reactions, or make available any data or information on product safety. However, a large voluntary registration program exists. While manufacturers are not required to report consumer complaints, many do so voluntarily.

The burden of proof that a product is unsafe and therefore adulterated rests with FDA. With the exception of color additives, a cosmetic manufacturer may use essentially any ingredient or market any cosmetic until the Agency can demonstrate that an ingredient or cosmetic may be hazardous to consumers under customary conditions of use. If the FDA wishes to remove a cosmetic from the market for lack of safety, it can do so only based upon a showing that the product is harmful. If the FDA wishes to prohibit the further use of an ingredient, it must demonstrate that the ingredient may be poisonous or deleterious under the intended conditions of use. When such proof is available, the FDA may publish in the Federal Register a notice of rulemaking and propose the banning of the hazardous ingredient. The public is invited to comment on the proposal, and the comments are carefully evaluated before the final order is drafted. The regulation banning the ingredient is then published in the Federal Register, and it becomes part of the Code of Federal Regulations.

The FDA cosmetics program reviews consumer complaints; maintains the (voluntary) registries of manufacturing establishments, raw materials, and formulations; conducts surveillance of cosmetic products and manufacturing establishments; conducts scientific research; assists with promulgation of regulations; and educates consumers and industry.

Researchers are now looking at the long-term carcinogenic effects of cosmetics, particularly through skin penetration studies. Such studies are more expensive than ingestion studies used with other substances because more animals are required.

Cosmetic ingredients presently prohibited include bithionol, hexachlorophene, mercury compounds, vinyl chloride, halogenated salicylanilide, and chloroform.

Current interests of FDA cosmetics personnel include nitrosamines in cosmetics, microbial contamination of mascara, carcinogenicity of hair dyes, and injuries from nail preparations.

POSTHARVEST TRANSPORTATION OF FOOD

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The Republic of China is now assessing food safety and establishing regulations in a manner similar to a process undertaken in the United States over the past 15 years. In the late 1960s, two assessments of our food system were made from farm to consumer, and discrepancies were discovered. A number of landmark actions were taken by the Food and Drug Administration (FDA), the U.S. Department of Agriculture, and other agencies to improve the overall sanitation and safety of our food system. No new laws or regulations were written and no new agencies created, and some good manufacturing practices were promulgated. Basically, better organization and improved enforcement resulted. The FDA did a very good job of encouraging the food industry to take a more active role in developing food protection systems.

One of the first systems implemented to improve food safety and sanitation in the United States dealt with use of food manufacturing practices. U.S. laws also provide authority to regulate the way foods are held, in particular, sanitation for food distribution centers and warehouses.

The ROC currently has laws that cover food manufacturing and food holding. However, in both the ROC and the United States no matter how cleanly or safely food is manufactured or stored, if the transportation system is not safe, safe food will not be delivered to the consumers. ROC food law makes no direct mention of food transportation, and U.S.

food law does not make much mention of food transportation. Transportation was the last major issue to be treated by the Food and Drug Administration.

In 1974, a group of trade associations representing food manufacturers, shippers, distributors, and retailers was formed to consider food transportation safety. After much discussion, voluntary Transportation Guidelines were endorsed by the American Feed Manufacturers Association, Inc., the Association of American Railroads, the Association of Food and Drug Officials, the Association of Operative Millers, the Cooperative Food Distributors of America, the Grocery Manufacturers of America, the National-American Wholesale Grocers' Association, and the National Association of Food Chains, in cooperation with the Food and Drug Administration.

U.S. law gives some control over food transportation to various agencies including FDA, the Department of Agriculture, the Department of Transportation, and the Department of Defense; however, there are some areas in food transportation over which no government agency has any legal control.

Most food transportation regulations arise from the clause prohibiting food adulteration, including holding food in a manner where it might become contaminated. This section of the U.S. food law is strong because it does not require the agency to prove that food is contaminated. All that must be proven is that food was held in close proximity to microorganisms, rodents, insects, or other pests, and that they may have gotten into the food. The holder of the food can be held criminally liable and the FDA can seize the food. The FDA need not wait until after an accident has happened; it can seize the product and take action against the owners or storers before a problem occurs.

Another clause in the Food, Drug, and Cosmetic Act exempts common carriers from liability under the act when they are acting solely as a common carrier. This protects transportation companies who do not handle the food in other ways. This clause had been interpreted by lawyers of railroads and trucking companies to mean complete exemption from the Food, Drug, and Cosmetic Act. No common carrier had been held liable for contaminating food from the first law in 1906 until the Penn Central case in 1979. Thus there were provisions for dealing with food contaminated in storage or manufacturing, but while food was moving around the country, there was little that could be done. With a growing urban population, more food being shipped, and different types of vehicles and containers, control of the vehicles, as well as of the packages, is needed.

The 1979 Penn Central case involved using a railroad car reserved for transport of food as transport for a chemical. When the car was later returned to its regular status without cleaning, the chemical residue contaminated dog food ingredients. The Penn Central Railroad was held criminally liable because it caused the contamination of food. It is debatable whether they would have escaped liability had the Voluntary Transportation Guidelines developed by the groups listed above not existed.

The Cycle of Liability section compensated for the deficiency in U.S. laws and regulations by establishing a system under which someone must be held liable. The manufacturer has a responsibility to ask for the proper vehicle. The carrier is responsible for sending a car suitable for the load intended. It is the manufacturer's responsibility to examine the car to make sure it is clean and empty. (In the Penn Central case, however, liability was found to rest with the carrier.) Responsibility for loading and sealing carriers is assigned. The carrier must handle food properly in transit. It is illegal to ship caustic chemicals and poisonous metallic salt items in the same truck with food, but it is very hard to stop this practice.

As a result of this court case, U.S. carriers are now taking their liability seriously. The ROC should also consider methods to prevent contamination of food during transportation, in addition to considering food additives, processing, good manufacturing practices, quality control procedures, export licenses, and inspection procedures. As more processed food is used, consumers have less control over what they eat. Specialized processing with several companies making parts of a product and transporting ingredients between cities require transport regulations.

GOOD MANUFACTURING PRACTICES

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The United States does not yet have official approval for its proposed "umbrella" good manufacturing practices (GMPs) for the food industry.

GMPs address questions of safety, sanitation, and adulteration. In the United States, most concern is with microbial adulteration, whereas the ROC may be concerned primarily with other types of adulteration.

The 1938 U.S. Food, Drug, and Cosmetic Act gave the U.S. Food and Drug Administration (FDA) the authority to establish reasonable sanitation standards for the production of food, drugs, and cosmetics. These statutory provisions defined the conditions under which a food was considered adulterated. They were added to expand the agency's basis for initiating enforcement proceedings and to provide control mechanisms against insanitary and contaminated (adulterated) foods. The FDA has used its inspection authority to (1) prevent the introduction or delivery for introduction into interstate commerce of adulterated food, or (2) to prevent adulteration of food while it is being held for sale after shipment in interstate commerce.

Under section 402 A.3 of the act, food is deemed adulterated if it actually consists in whole or in part of any filthy, putrid, or decomposed substance or if it is otherwise unfit for food. Moreover, under section 402 A.4 of the act, food is adulterated if it has been

prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth. It does not have to be proved that the food is contaminated; only the chance or the probability must exist. On the basis of evidence gathered during inspections, FDA uses its legal authority to go to court to seize the adulterated food, to prevent its shipment or sale, or to have the persons adulterating the food criminally prosecuted.

The number of inspections and court actions instituted by the FDA has varied over the years, in part because of the vast number of products and parties regulated, but FDA now conducts approximately 20,000 food establishment inspections each year. In the late 1960s, FDA ceased relying exclusively on case-by-case litigation and adopted a combined policy of promulgating regulations, relying on self-regulation by the industry, and, within the limits of resources, enforcing regulations when the industry failed to comply.

In 1967, FDA proposed regulations to establish current good manufacturing practice criteria for the manufacturing, processing, packing, or holding of food to bring about compliance with Section 402 A.4 of the act. In 1971, because of comments and at the request of the General Accounting Office, FDA inspected 97 food manufacturing plants of all types selected at random from food manufacturing and processing plants located in various FDA districts. The United States has a fairly good food manufacturing and distribution system, but deficiencies exist and they were uncovered by this survey. The FDA then initiated a series of actions to improve conditions in the food industry. Meetings were held with representatives of various segments of the food industry to exchange ideas and gather information for developing improved good manufacturing practices.

Based on these discussions, the FDA proposed GMP regulations for cocoa products and confectionaries known as the "candy GMPs." Later it proposed regulations for bakery foods, tree nuts, and peanuts. FDA selected these foods because representatives of these industries were cooperative and represent a cross-section of the U.S. food industry.

The GMP regulations for specific segments of the food industry were proposed as complementary provisions to the "umbrella" GMP regulations for the overall industry. Industry-specific GMPs deal with personnel, plant construction, and sanitation. The FDA is now waiting for approval of the umbrella GMP regulations following industry comments. The umbrella GMP attempts to insure that food will be manufactured, processed, packed, and held under conditions that are sanitary, and that such food will be safe, clean, and wholesome. The GMPs revise and update the requirements for plant personnel, plant

design and construction, sanitary operations, facilities and controls, equipment and utensils, regulating and recording controls, processing operations, and coding and record keeping.

The FDA commissioner is authorized to issue and enforce regulations as necessary to prevent the introduction, transmission, or spread of food-borne communicative diseases from one state to another. This authority is designed to eliminate the introduction of diseases such as typoid and must be exercised upon a disease-causing substance within the state where the food is manufactured, processed, or stored. Because of the nationwide interrelated structure of the food industry, communicable diseases may, without proper interstate controls, spread, as indicated by annual U.S. Centers for Disease Control (CDC) reports.

The basic rules for sanitation and cleanliness of buildings, fixtures, and other physical facilities and equipment and utensils require general maintenance, control of animals and other pests, sanitation of equipment and utensils, and storage and handling of clean equipment and utensils. The proper use of cleaning compounds, sanitizing agents, and pesticide chemicals to protect raw packaging materials and finished food from contamination is described. The minimally acceptable adequate sanitary facilities and accommodations for all food processing operations are listed. These include, but are not limited to, the water supply, plumbing, sewerage disposal, toilet facilities, hand-washing facilities, and rubbish and offal disposal. There is a paragraph prohibiting the backflow or cross connection between plumbing systems that carry water for food processing use and the piping system that discharges waste water or sewerage to prevent spread of filth or disease-causing microorganisms throughout the sanitation facilities. These principles are applicable to all food handling operations.

The industry comments on the proposed umbrella GMPs were useful. Items criticized or thought too restrictive were blanching and the definitions of "corrosion free" and "lot." Some questioned the definition of "food processing plant," which was essentially "factory." Some thought that warehouses were included.

The definition of microorganisms of public health significance and what should be done to prevent the growth of microorganisms was also troublesome. A number of industry responses stated that it might be impossible to prevent the growth of microorganisms and perhaps the intent of the GMPs was to minimize the growth of food poisoning microorganisms.

Requirements for the use of separate rooms versus partitions for some types of processing must still be resolved. The frozen food

industry criticized the proposed requirement for minimum temperatures. Compliance with the requirement may be accomplished by any effective means including maintaining refrigerated foods at 45°F (roughly 7°C) or below, maintaining frozen foods at 0°F, and maintaining hot foods at 140°F (60°C) or more. Comments were also received on coding and record-keeping requirements and recall follow-up procedures.

It is hoped that the FDA will approve the proposed umbrella GMPs in 1981.

LOW-ACID AND ACIDIFIED FOODS

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From 1900 to 1970, 473 outbreaks of botulism in home canned low-acid food and 62 outbreaks involving commercially processed low-acid foods occurred in the United States. Although this is almost a 10 to 1 ratio, commercial food cases may involve many people. In 1971, two serious botulism cases received a great deal of publicity and had a substantial effect on sales. One case involved a small soup company, and the other the largest U.S. soup manufacturer. As a result of the death and recalls caused by these cases, the National Canners Association petitioned the Food and Drug Administration (FDA) to detail guidelines on production of canned low-acid foods.

FDA officials felt the best way to accomplish this was to issue a good manufacturing practice (GMP) regulation with the effect of law. In 1973 and 1974, proposals were made and regulations went into effect. FDA found that some parts of the regulation could be improved. In 1976, low-acid canned food regulations were separated from the acidified product regulations. Many acidified products were not safe because the pH of the products had not been lowered to 4.6. Two new regulations went into effect in 1979 covering the emergency permit control aspect of record keeping and making those records available upon request to the FDA. There are now 3,000 firms registered and 125,000 processors have filed with the FDA.

Low-acid canned food regulations require that the products be prepared and packed in containers in such a way that they can be

adequately processed, that the heating process be designed by persons with expert knowledge of thermal processing requirements, and that the heating process achieve commercial sterility. They also require proper design, controls, and instruments for all of the common retorting systems being used and operating practices that will provide the necessary safety. Records must be kept of all coding, processing, and container closure inspections so that management can review the records to assure commercial sterility prior to release for shipment.

If a processor finds from the records that a retort load is underprocessed, he must either reprocess the load or set it aside for evaluation. If it does not present a health problem he may ship it. If this cannot be done, he must destroy the product. Container closures must be inspected to assure that containers are properly sealed.

Supervisors of heat processing operators and the container inspectors must receive instruction in a school approved by FDA. FDA has collaborated with other countries and has included foreign food safety personnel in training courses.

The most frequently reported deviations from the GMP, based on several thousand FDA inspections since 1973, are (1) inadequate, incomplete records that are not properly signed or inspected; (2) registration and process filing forms that are incomplete and sometimes nonexistent; (3) process deviations that have not been adequately evaluated to determine whether a public health hazard exists; (4) faulty temperature recording devices; (5) adequacy not verified; (6) improper venting of the retort; (7) initial temperature not controlled; (8) inadequate retorts; (9) reference thermometers not in compliance; and (10) critical factors not controlled.

In order for their products to be accepted for importation into the United States, foreign low-acid canned food producers must register with the FDA. Registration requirements include the name of the product, the manufacturer's name and address, and even the can size. The processing method used must be on file. Products must not be under-processed or abnormal, nor should they contain more than the allowable amount of filth. In some cases, decomposition and contamination have been problems with imports.

ACTIVITIES OF THE NATIONAL FOOD PROCESSORS ASSOCIATION

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U.S. industry must meet numerous requirements to comply with federal regulations. One critical factor in compliance is supplying food processors--including top management on down to the retort operator--with current information on these requirements.

Regulations require that retort operators and supervisors attend a process control school. The National Food Processors Association (NFPA) (formerly the National Canners Association) or its subsidiary the Food Processors Institute publish a number of pamphlets. "Better Process Control Schools" lists NFPA schools providing instruction for operations supervisors. Instructors for these schools are drawn from the Food and Drug Administration, selected universities, the Food Processors Institute, the NFPA, and industry. This year, NFPA is organizing 10-12 such schools around the United States.

NFPA also issues booklets on federal regulatory developments. Schools are organized for middle to upper management which must keep up with government regulations. Other NFPA publications and courses cover statistical methods for statistical quality control systems, principles of thermo process control, and principles of food processing sanitation. NFPA works with industry on research projects and has laboratories in Washington, D.C., Berkeley, and Seattle. Each laboratory holds a "research highlights" meeting once a year to discuss research being conducted on behalf of industry.

NFPA training materials for low-level employees include text/slide presentations on can handling, quality control, evaluation of can double seams, retorting and glass containers, and good manufacturing practices. NFPA booklets also cover process certification and evaluation for low-acid canned foods in glass containers and for the basic commodity groups, such as peas, beans, and corn. A similar booklet deals with metal containers. These booklets are developed by NFPA with cooperation from industry and canning companies.

Plant personnel must be able to evaluate problems as they occur or have a place to go for quick information. The NFPA, as a trade association, partially provides this service for U.S. industry. Many large companies have their own labs and can handle their own evaluations; NFPA provides the service for smaller operators. A hotline for action, advice, evaluation, etc., is accessible 24 hours per day, 7 days per week.

ENVIRONMENTAL CONTAMINANTS

Edwin Johnson
Deputy Assistant Administrator, Pesticide Programs
Office of Toxic Substances
U.S. Environmental Protection Agency

The Environmental Protection Agency (EPA) regulates pesticides used on food, not food itself. EPA is concerned with preventing contamination of the raw food commodities.

Sources of contamination include permitted pesticides, illegal pesticides, environmental residues such as kepone, chemical contaminants such as polychlorinated biphenyls (PCBs), agricultural residues such as salts from irrigation, and fumigants used in transportation and storage. EPA uses a four-part control strategy outlined below.

PREVENTIVE CONTROL

Preventive control, the most effective part of the strategy, includes registration and premarket clearance of pesticides, establishment of tolerances, and risk/benefit considerations. EPA preventive regulations also include policies for rotation of crops, education of users and food processors, and establishment of standards for record keeping.

MONITORING OF COMMODITIES

EPA cooperates with other agencies including state governments, the Food and Drug Administration (FDA), and the U.S. Department of

Agriculture (USDA) to monitor food commodities for environmental contaminants. Surveys used include EPA/state monitoring of pesticide use and misuse, the FDA RAC and market basket surveys, and the USDA meat and poultry inspections. The CODEX system is used to define edible commodities and crop groupings for international standardization.

RESPONSE TO EPISODES

EPA response to contamination episodes is designed to minimize risks quickly. Clean-up of waste disposal sites and spills, and, when necessary, enforcement by destruction of contaminated crops are part of EPA's response to contamination episodes.

INTERNATIONAL COOPERATION

FDA surveys at ports and borders are used to monitor pesticide levels of imports. Exporting countries should also monitor levels in commodities being shipped abroad. CODEX tolerances are being used, and imported pesticides must be registered with EPA. Since 1978, pesticides exported from the United States have carried special labels and notification such as "not registered for use in the U.S."

Consumers can do better to control contamination of raw crops. However, they should bear in mind that not all pesticides are detrimental to health (dosage levels are often the most important determinant of potential harm) and that pesticides are used to improve the cosmetic qualities of food. This would not be necessary if consumers would accept wholesome food less than perfect in appearance.

THE ROLE OF EPIDEMIOLOGY AND RISK ASSESSMENT

Frank Cordle
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U.S. Food and Drug Administration

Epidemiologists form a distinct part of preventive medicine and are interested in the distribution of disease within populations and determinants of the differences in distribution—that is, who is sick and what made them ill. By studying the etiology of disease they hope to discover new ways of preventing it. The epidemiology unit of the U.S. Food and Drug Administration (FDA) works with other federal agencies, universities, and state health departments. Figure 1 shows the organization of this unit.

Information exchange with scientists all over the world is important for epidemiologists; the best way to obtain such information is not from written sources, but through personal relationships with scientists in other countries.

PCB CONTAMINATION CASE

A 1974 environmental accident involving polybrominated biphenyl (PBB) illustrates the human element in such events. This accident occurred in Michigan at a chemical company that manufactures Nutrimaster, a dairy feed supplement, and Firemaster, a flame retardant containing PBB. During the summer of 1973, the company packaged both products in 50-pound brown kraft bags, stenciling the name of the product on the top of the bag. After the top of the bag was pulled off

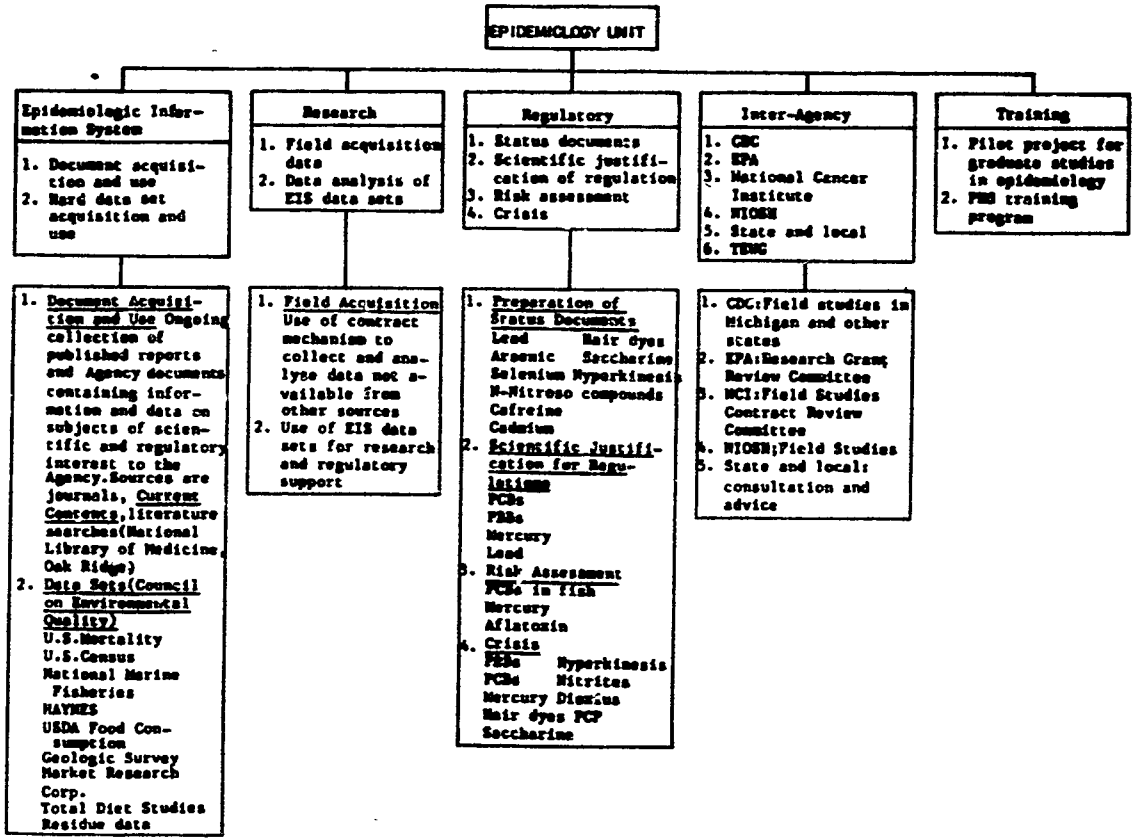

FIGURE 1 Organization of the FDA Epidemiology Unit.

there was no way to know what the contents were. Many people probably did not look at the name--they saw "master" and assumed they had the correct product. As a result, an unknown number of pounds of flame retardant were substituted for dairy feed supplement in the manufacture of dairy feed.

Early preventive action could have reduced the effort needed to clear up the problem. However, FDA did not hear about the contamination until 1974 because the farmers first tried to handle the problem themselves, then through the state department of agriculture. When identification of PBB was finally made, human exposure was limited to perhaps 10 counties in Michigan. Farmers who had the contaminated food may have blended it and sold it around the state. Probably 8 million people in Michigan have been exposed to the PBB in the flame retardant.

When FDA became involved in 1974, it initially tried to find out something about the toxicology of that class of compounds. Two animal studies had been conducted by the chemical companies that had hoped to produce PBB, but toxicity problems rapidly turned their interest away. Data from their studies were never published, but they were willing to share the data with FDA. FDA then tried to predict from PCB episodes what might happen to individuals exposed to polybrominated biphenyls.

The initial action taken by FDA was based on the "avoidable adulteration" section and products with detectable levels of PBB were seized. The FDA, the National Cancer Institute, the National Institute for Environmental Health Sciences, the Centers for Disease Control (CDC), the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), the U.S. Department of Agriculture (USDA), and others have spent large sums tracing people in Michigan. While there was evidence that some people on heavily contaminated farms may have consumed as much as 9 1/2 grams of flame retardant--a fairly substantial dose for an individual over a period of time--case control studies, cohort studies, prevalence studies, and descriptive studies have been unable to identify any adverse health effects from this exposure. Rodents are very susceptible to the toxic effects of halogenated biphenyls, both PCBs and PBBs--this case illustrates the problems of extrapolating animal studies to humans.

RISK ASSESSMENT

The decision-making process for regulatory activities dealing with safety issues is a difficult and often unappreciated effort. Scientific uncertainties often require that questions of safety be

answered without an adequate scientific data base. This is particularly true in the case of environmental contaminants where human exposure has never before occurred, and where animal toxicological data may be scarce if they exist at all.

Much of the information concerning the toxicology of various chemical substances has been obtained from animal experiments. Traditionally, regulatory agencies have used the information obtained in these experiments to evaluate hazard and predict safety in humans.

Recent efforts have been directed toward design of a combination of studies that will more reliably assess the risk of disease and mortality in human populations during prolonged exposure to a range of chemical residues. Animal studies fail to account for the wide social, behavioral, and biological variations that characterize human populations, which can be properly ascertained only by using epidemiologic techniques which permit direct measurement of responsiveness to toxic agents in humans. From this point of view, the consideration of epidemiologic information in both design and analysis of chronic toxicity studies is essential to the accurate evaluation of the long-term risk of toxicity in human populations.

Perhaps the most important use of epidemiologic data is in providing approaches to adjusting for differences between animals and humans in biological responsiveness and sensitivity to potentially toxic substances, and for assessing the effects of the many confounding variables that characterize human populations, which cannot be accounted for in controlled animal studies alone.

Steps have been outlined by which epidemiology and toxicology can interact to provide methods for estimating human risk from environmental chemicals during prolonged low-level exposure (i.e., toxicity in general, not just carcinogenicity). As a first step in this procedure, epidemiologic studies of highly exposed human populations may be used to estimate the incidence of disease associated with prolonged exposure to a toxic agent accidentally or in an occupational setting. The second step uses epidemiologic studies of highly exposed human populations in the design of chronic toxicity studies in animals. The purpose of these studies is to construct dose-response relationships for the disease or condition identified in step one over a range of concentrations including the levels to which highly exposed humans have been subjected. Such studies should normally comprise several species of animals, including, if possible, a non-rodent species. The third step involves making corrections for differences in species responsiveness to the chemical agent being investigated.

One of the most difficult problems in using animal dose-response data to estimate incidance of toxicity in human populations involves the fourth step of the assessment procedure: extrapolation of dose-response relationships from high- to low-dose levels. Once the animal model has been adjusted for species differences in biological responsiveness, and the dose-response relationship has been extrapolated to the low-dose region using an appropriate statistical technique, the fifth step on the risk assessment procedure can be performed. A modified animal model is used to estimate human incidence at community exposure levels. This procedure also requires an assessment of the size of the population at risk and the average concentration of toxic substances to which this population is continuously exposed. Such estimates are, in general, quite difficult to obtain accurately and must include ambient air measurements as well as determinations of the concentrations of the substance in food and water.

The final step in this procedure involves confirmation of risk predictions made from animal models using epidemiologic techniques.

CHEMICAL CONTAMINATION--PCBs

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Food Safety and Quality Service
U.S. Department of Agriculture

The U.S. Department of Agriculture (USDA) is responsible for meat and poultry inspection. The tolerances and action levels for various substances are set by either the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA). The Food Safety and Quality Service (FSQS) of the USDA actually conducts monitoring and surveillance, and reports its results to the respective agencies. USDA determines what action to take.

Polychlorinated biphenyls (PCBs) are part of a broad group of organic chemicals known as chlorinated hydrocarbons. Research into the effects of exposure to PCBs has yielded data indicating that these substances can cause health disorders including reproductive failure, gastric disorders, skin lesions, and tumors in laboratory animals. Studies of human exposure to PCBs at levels much higher than those encountered in the case to be described have indicated a high incidence of skin disorders, digestive disturbances, jaundice, throat and respiratory irritations, and severe headaches.

These chemicals were produced in the United States from 1929 to 1977, primarily by the Monsanto Corporation. They were for the most part used in closed systems in electrical transformers, capacitators, heat transfer systems, and hydraulic systems. When they were legally marketed, PCBs were commercially attractive due to their high degree of chemical stability, low solubility in water, low vapor pressure, low flammability, high heat capacity, and low electrical conductivity.

In a 1979 PCB contamination case, USDA found many weaknesses in its monitoring and surveillance program. It is very important to have a "preventive medicine" approach to contamination, and in the 1979 case USDA found that it had a very poor preventive medicine posture. A second case of contamination occurred after USDA had an improved interagency team in place.

USDA's National Residue Program was founded in 1967, but its origins can be found in two related historical trends that occurred in the period following World War II.

The first was the "toxics revolution" in American agriculture. The discovery following World War II that pesticides such as DDT could be used to destroy certain insect pests of plants kindled the interest of agriculturalists. Scientists and technologists responded to the problem with ingenuity, and developed a whole host of chemical solutions to farm problems. Not only DDT, but other hydrocarbons such as chlordane, heptachlor, dieldrin, and aldrin were introduced and used widely to combat pests. Drugs such as penicillin, streptomycin, tetracycline, and various sulfas were fed to animals to prevent disease and promote growth. As a result, American agriculture became dependent upon pesticides, drugs, and other chemicals to maintain high levels of production.

The second trend was the development of new analytical techniques capable of detecting low levels of chemical residuals in food. In the late 1940s, the techniques for detecting residues in food were quite rudimentary. Today very sophisticated instrumentation is used.

The National Residue Program now has a budget of $4.5 million, and a staff of 50. In 1978, approximately 25,000 samples of meat and poultry were tested for the presence of 40 chemical residues. Despite this growth, the program still does not provide the coverage it should to protect adequately the American people from potentially dangerous chemicals. It is impossible to test every carcass going through the slaughter plants. Therefore, a statistical sampling of meat and poultry products is used that gives 95 percent confidence that the violation rate is less than 1 percent.

The National Residue Program is relatively young and still developing. Its future development will depend upon continued public recognition of the critical nature of chemical residues in food, wise policy choices, and the imaginative application of new technology. The recent PCB incident in the western United States provides some important lessons that will help guide such development.

1979 PCB CONTAMINATION CASE

In June 1979, poultry samples were taken by a USDA inspector in the northeast United States and processed normally--frozen storage, shipment to a USDA laboratory, analysis, and confirmation. By the end of the process, the presence of PCB in the tissue had been confirmed. Some of the reasons for the delay were that inspectors were not aware the problem existed, and the laboratory technicians ran into some analytical problems--to identify this PCB 13 separate peaks had to be isolated, taking valuable time and adding to the problem. In September, after the PCB was identified, inspectors went back to the packing company and found that an unused electrical transformer stored in the holding area for inedible products had been damaged by a tractor. Its cooling system had ruptured, and 200 gallons of PCB cooling fluids leaked onto the floor and ran into a pool where fat was skimmed off. PCB eventually ended up in meal used in manufacturing feed.

One thousand four hundred companies were identified as having received the meal and were incorporating it into their feeds. Twenty states and two foreign countries were involved. The clean-up was lengthy and expensive and involved considerable effort by FDA, USDA, EPA, state governments, industry, and producers. Over 2,500 samples were checked for PCB. USDA resources were taxed to the limit.

In analyzing this case, USDA identified seven areas that needed improvement. Neither USDA employees nor the general public were sufficiently conscious of the potential health problems that can arise from environmental contaminants like PCB. USDA did not have authority to detain products to prevent consumption. There were no areas for quarantine and destruction. The sample collection and analysis were so large and intensive that laboratories were not able to handle it. There was no system for distribution of data to extension workers, state officials, FDA, EPA, and USDA regional officials. No certification program existed to allow movement of meat or poultry proven clean--it had to be held--necessitating development of a certification program on the spot. Federal/state relations thought good proved to be poor when it was difficult to find anyone with responsibility for emergency operations. Management of the problem was strictly on a crisis basis--hour to hour, day to day, and week to week.

If plant management had been aware that a leaking, broken transformer might contaminate feed the episode might have been prevented. It is very important that all plant personnel be aware that contamination by chemical residues can be easily prevented with reasonable care.

Follow-up

Since 1979, USDA has undertaken an education program--it has gone to the general public and explained the potential health problem of residues, the residue programs, what tolerances mean, and what action level means. USDA inspectors and extension personnel have worked with producers and farmers, particularly on record keeping. USDA has set up an office for emergency preparedness, which has eliminated lack of coordination among agencies. When an alert is received, USDA contacts EPA and FDA and their emergency groups work with USDA's. One person acts as a team leader for emergencies, with authority to call together a team from the agency--including microbiologists, chemists, epidemiologists, or field inspectors--and to set up a control point. Legislative problems regarding quarantine will take longer to solve, but if problems are caught early these measures are not so crucial.

This new Contamination Response System (1) establishes the conditions that will trigger a prescribed set of actions designed to determine the extent of the contamination; (2) lays out step by step the process by which USDA will proceed from the initial detection of an environmental contaminant to a full mobilization to control and eliminate it; and (3) lists the specific responsibilities of each FSOS component for each stage of the process.

1980 PCB CONTAMINATION CASE

In February 1980, another kind of PCB was discovered in swine tissue in the southeastern United States. The Contamination Response System was initiated the same day the contamination was discovered, and a press release went out almost immediately. A command center was set up within 100 miles of the area of contamination by the following day. The press release provided farmers with pertinent information and advised them to check with extension specialists or call the command center toll free for information about the contamination outbreak. County extension agents and swine specialists visited farmers. Animals suspected of having PCB were tested free of charge. Monitoring and surveillance around the area were increased to determine the extent of the problem and detect the source.

Some 30 years before, a large industrial company had sprayed an adhesive containing PCB on tar-like material and used it on a steel building. The building was later torn down and piled in a far corner. Parts of it were sold to local people, and parts of it given to workers. The material found its way into hog pens and chicken coops where pigs and the chickens gnawed and pecked on it. There were some very high levels of PCB in the animals and, once inside the body, PCBs very seldom disappear.

The discovery and clean-up process in this case took one month. No one was harmed financially, and none of the farmers eating the pigs were harmed. After animals were tested, farmers could decide whether or not to eat their home-slaughtered animals. A major crisis was avoided.

USDA has tried to implement a strong preventive program. Agencies with diverse interests can work together as a team if organized correctly. To prevent residue contamination disaster and reduce exposure, coordination and a team effort are necessary.

MICROBIOLOGICAL CONTAMINATION (SHRIMP)

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Bureau of Food
U.S. Food and Drug Administration

The Food and Drug Administration (FDA) continues to have problems with salmonella in shrimp. This presentation will discuss FDA's concern with probable health hazards of the problem, possible avenues of contamination of shrimp, and steps FDA has taken in conjunction with appropriate officials in other countries and with industry groups to solve the problem.

FDA has long considered food containing salmonella bacteria to be adulterated and subject to the enforcement provisions of the federal Food, Drug, and Cosmetic Act. Salmonella is a pathogen and a common cause of illness which can range from mild to severe. For this reason, FDA has carried out sampling programs to detect salmonella contamination. Upon finding this contamination, FDA has proceeded to protect the public health through detentions, product recalls, seizure actions, and injunctions. The federal courts have supported these actions.

Fish products do not normally contain salmonella bacteria—the organism becomes associated with fish products through poor handling and manufacturing practices which can be controlled to eliminate salmonella. Not all fish products are cooked, a process that normally eliminates salmonella. Even when consumers and commercial establishments cook fish products, the possibility of cross contamination of other uncooked products is still likely.

SALMONELLA CONTAMINATION CASE

Frozen shrimp was the primary source of salmonella contamination found during the period January 1977-July 1979. In 1977, an FDA district office found salmonella in a number of shrimp from one country. As a result, salmonella in shrimp was highlighted as a possible problem in FDA's work plan known as Compliance Program on Import Foods. By December 1978, three districts (Boston, Los Angeles, and Baltimore) had detained shrimp due to salmonella. Other districts were then asked to sample shrimp for salmonella analysis.

By February 1979 a request was received that shrimp from one country be blacklisted. At that time the violative rate for the fiscal year (October 1978-February 1979) was 28.3 percent with a total of 31 detentions due to salmonella contamination. Officials from the country at fault met with FDA and requested that blacklisting be delayed because they had instituted a new inspection and analytical program for their shrimp industry which they felt would correct the problem. FDA then implemented a plan under which it would:

- Automatically detain all shrimp intended for processing upon voluntary requests and application for reconditioning (an industry proposal).
- Sample all shrimp not intended for heat treatment at a 100 percent rate.
- Provide increased technical assistance to the country to improve control measures to deal with the problem.
- Negotiate a formal Memorandum of Understanding with the country when effective control measures are in place.

An FDA team traveled to the country to inspect its shrimp processing industry and reported that the freezing and packing plants were in satisfactory condition. However, they concluded, based on limited observations, that the shrimp was probably being contaminated during catching, landing, and peeling-deveining operations. The team was not allowed to observe the actual peeling-deveining operations. Some problems found were:

- Poor freezing facilities
- Lack of adequate fly proofing for processing plants
- Wooden work surfaces which were difficult to clean
- Poor personal hygiene for food handling personnel

- Potable water not being used in processing plants
- Poor drainage
- Product (shrimp) stored on contaminated floors (floor subject to heavy foot traffic)
- Chlorine solutions of the wrong concentrations
- Use of bamboo baskets which are very difficult to sanitize
- Insufficient ice to keep product chilled properly
- Lack of analytical examination for salmonella by a sufficiently sensitive procedure.

Recommendations were made to the proper officials that the above deficiencies be corrected. It was promised that steps would be taken to correct all of the deficiencies.

The situation did not improve. In July 1979, FDA learned that (detained and refused) shrimp were being purchased as salvage. This material was then shipped to Brownsville, Texas under Transportation and Export Entry (T&E) for shipment to Matamoras, Mexico, where it was improperly reprocessed or simply repacked and sent back to the United States.

In August, seizure actions were recommended against all of the imported shrimp instead of the usual detention and refusal action. This enforcement action was to stop the flow of refused shrimp to Mexico under T&E and the subsequent shipment back to the United States without proper reconditioning. FDA also made a mass seizure of shrimp in two warehouses in Brownsville, Texas.

The shrimp in question were labeled as originating, or otherwise determined to have originated, outside of the United States; shrimp examined and found adulterated by the FDA at the time of entry; and shrimp transported to those locations under T&E entry.

In September 1979, shrimp examination data for the six-month period of March to August 1979 revealed that six countries met the criteria for blacklisting. By October 1979, shrimp from all six countries were blacklisted.

Since that time, concerted efforts have been made by the blacklisted countries to remove those problems or conditions that could lead to contamination of the product with salmonella. Action has also

been taken to reduce the likelihood of the product being decomposed or containing filth. For example, in one country a certification program (government certifies product is free of filth and decomposition) was developed. Based upon this program, the automatic detention of shrimp with regard to filth and decomposition was discontinued, and the country has now approached FDA about a Certification Program for Salmonella. Some U.S. buyers visited the blacklisted countries and assisted the processors in establishing good manufacturing practices (GMPs) which would assure the production of an unadulterated product. In a number of countries, government laboratories are analyzing the product for salmonella decomposition and filth. Needed repairs and extra precautions are being performed daily. Therefore, the number of adulterated shrimp being offered for entry into the United States is steadily decreasing. The problem with salmonella in shrimp is being eliminated because of mutual understanding and cooperation with the countries and the private and government sectors.

BACKGROUND PAPERS

FOOD SAFETY, THE LAW, AND THE GOVERNMENT

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Bureau of Food and Drug Control
National Health Administration
Taipei, Taiwan
Republic of China

THE PRESENT SITUATION

Taiwan covers about 14,000 square miles, and has a population of 18 million and a population density of about 1,244 persons per square mile (see Figure 1). The population density is one of the highest in the world.

Taiwan has approximately 2,000 food factories, 3,000 rice mills, 20,000 food manufacturing and distribution firms, and 250,000 food services and vendors.

Governmental organizations concerned with the management of food safety are shown in Figure 2. These include the Executive Yuan of the central government, the Taiwan provincial government (which includes 16 counties and 3 provincial cities), and the Taipei and the Kaohsiung city governments (which are directly governed by the Executive Yuan).

The Law Governing Management of Food Hygiene, promulgated on January 28, 1975, is the first law that addresses food safety management in the Republic of China. It is limited to food hygiene, comprising food additives (including food colors), food utensils, food containers and packaging, food traders, food labelling, and food advertising. This law differs from the U.S. Food, Drug, and Cosmetics Act in that it cannot be applied to general food quality management, but only to the management of products hygiene.

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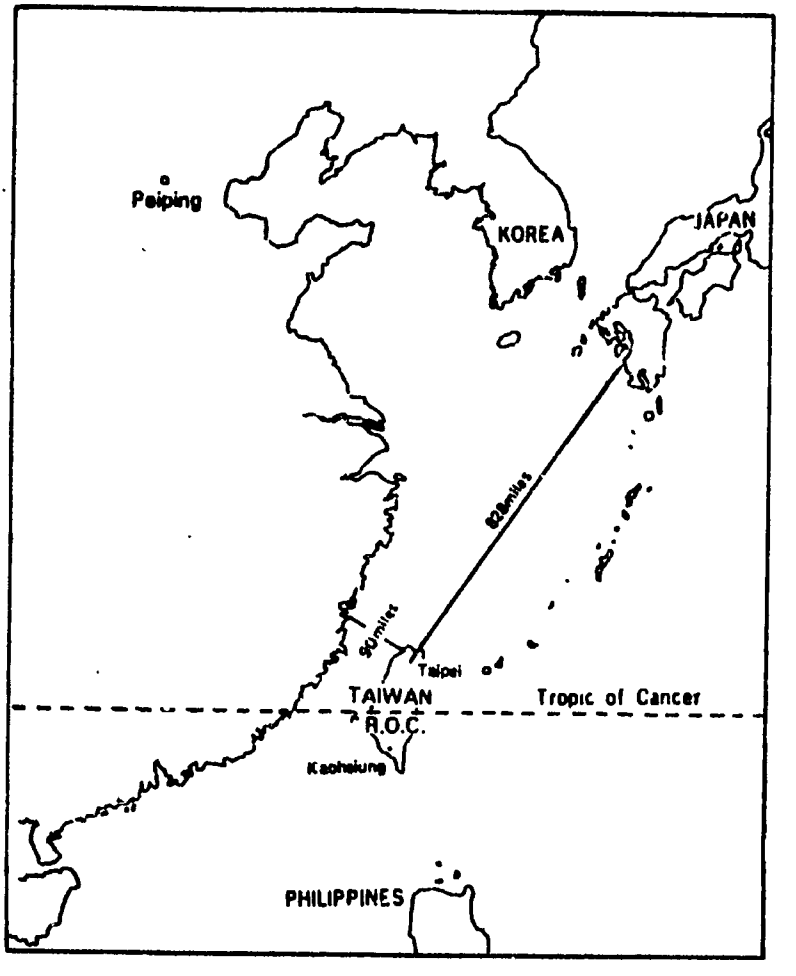

FIGURE 1 Location of Taiwan.

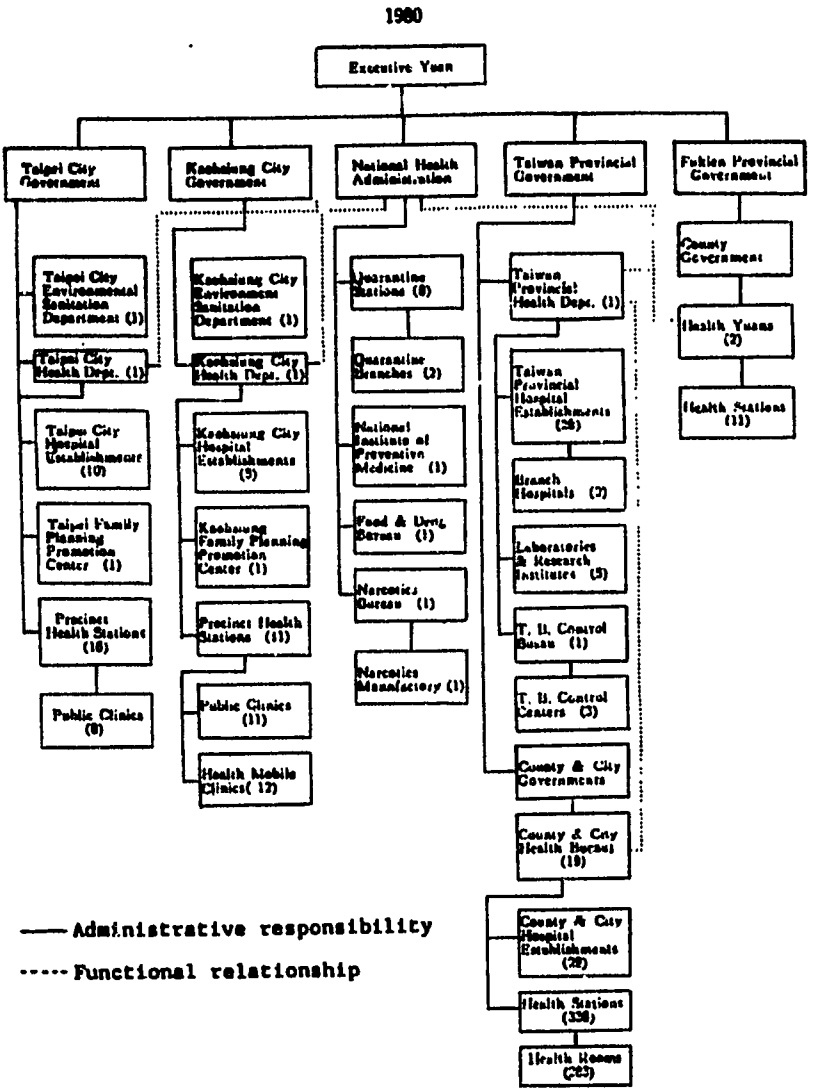

FIGURE 2 Health organizations in Taiwan, February 1981.

Specifically, this law covers:

- Regulation of food additive management
- Specifications and standards for food additives
- Limitations and tolarances for use of food additives
- Regulation of hygienic inspection of slaughtered livestock
- Hygienic standards for dairy products, eggs, fish and shellfish, canned foods, and edible oils and fats; tolerance of pesticide residues on or in foods, ices, beverages, infant foods, frozen foods, general foods (cooked), and raw foods for direct consumption; tolerance of aflatoxin in cereals, food utensils, containers, and packages, etc.

Regulations proclaimed by the Ministry of Economic Affairs that address: (1) standards for establishing food factories, (2) good manufacturing practices for food factories, (3) thermal processing of low-acid foods packaged in hermetically sealed containers, (4) regulations for dairy businesses, (5) Chinese national standards for foods, and (6) laws of commodity inspection and quarantine.

Food sanitation management is only part of the larger sphere of food management. Food management includes policy making, business management, balance of supply and demand, quality control, sanitation management, and other affairs concerning foods.

Government Agencies Dealing with Food Sanitation Management

A number of government authorities are concerned with food sanitation management. The National Health Administration and the provincial and city health authorities address sanitary management of foods, food additives, food containers and packaging, food utensils, food businesses, food labelling, food advertising, and training and supervision of food traders (see Figure 3).

Under the government's Ministry of Economic Affairs, the Bureau of Commodity Inspection and Quarantine inspects exported foods and imported agricultural products, (e.g., cereals) and supervises quality control of food factories. The Bureau of Industry addresses food management, food additives, food utensils, and container and package manufacturing. The National Bureau of Standards establishes food standards. The Board of Foreign Trade addresses management of food

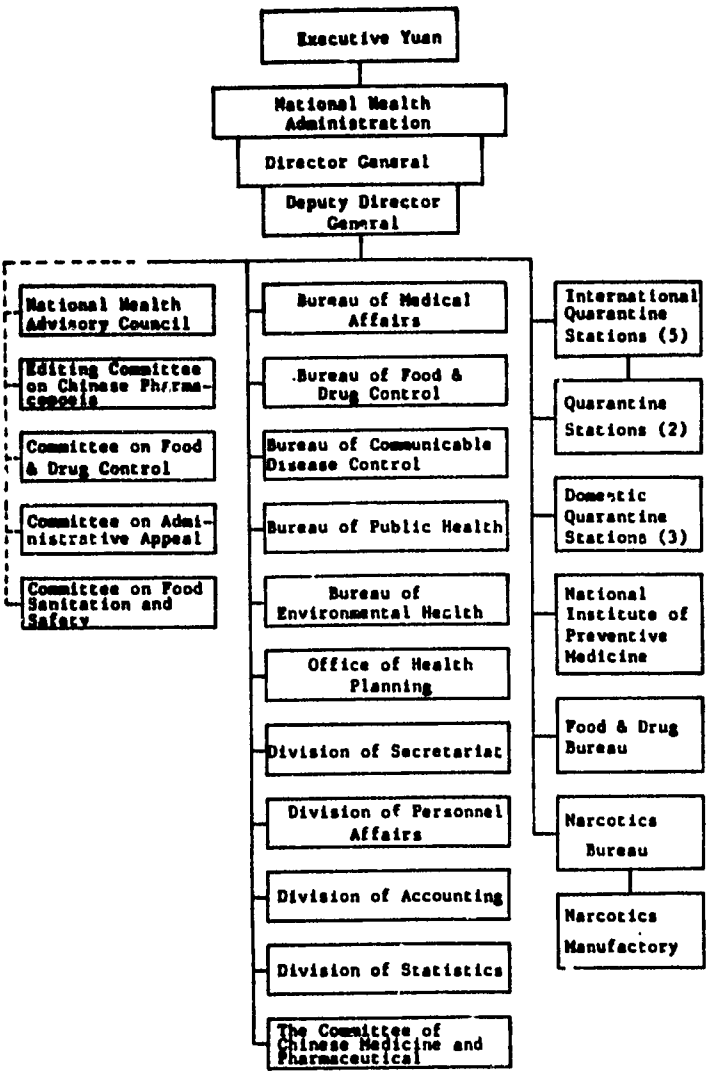

FIGURE 3 Organization of the National Health Administration, Taiwan, February 1981.

imports and exports, food additives, food utensils, and food containers and packaging. The Department of Commerce oversees registration of food businesses, and the Department of Agriculture and Forestry oversees prevention and control of disease of livestock and poultry, dairy and ranch management, and pesticides, animal drugs, and feed and feed additives.

Within the provincial and national city agencies (directly governed by the Executive Yuan), Provincial Department of Reconstruction oversees the registration and management of food, food additives, food utensils, container and package manufacturing, commercial registration and management of food businesses, and management of retail markets, etc. The purview of the Provincial Departments of Agriculture and Forestry extends to prevention and control of livestock and poultry diseases, ranch and dairy management, pesticides, animal drugs, and feed and feed additives. Provincial Department of Finance manages old-type slaughter houses, inspects slaughtered livestock in these houses, and manages alcoholic beverages. Provincial Food Bureaus manages staple foods (e.g., rice, cereals). Provincial Police Departments manages food vendors.

Provincial City Bureaus of Reconstruction are concerned with the management and registration of foods, food additives, food utensils, container and package manufacturing, commercial registration and management of food businesses, management of retail markets, prevention and control of livestock and poultry diseases, range and dairy management, pesticides, animal drugs, feed and feed additives, and new-type slaughter houses. Provincial City Police Bureaus are concerned with the same tasks as the Provincial Police Department.

Present Organization of Food Sanitation Management

At present, food sanitation management in the ROC is organized as follows (see Figure 4). Within the National Health Administration, the Bureau of Environmental Health trains and instructs food traders. The Bureau of Communicable Disease Control monitors food poisoning cases and food-borne diseases, while the Bureau of Public Health educates the public about food sanitation. The Bureau of Food and Drug Control interprets food sanitation laws and draws up and is concerned with regulations and standards, management of food, food additives, food utensils, food containers and packages, registration of imported and exported foods, execution of food sanitation management, management of food advertising, and related affairs. Fundamentally, the management of food sanitation should be executed by the Food Sanitation Division of the Bureau of Food and Drug Control. However, this Division

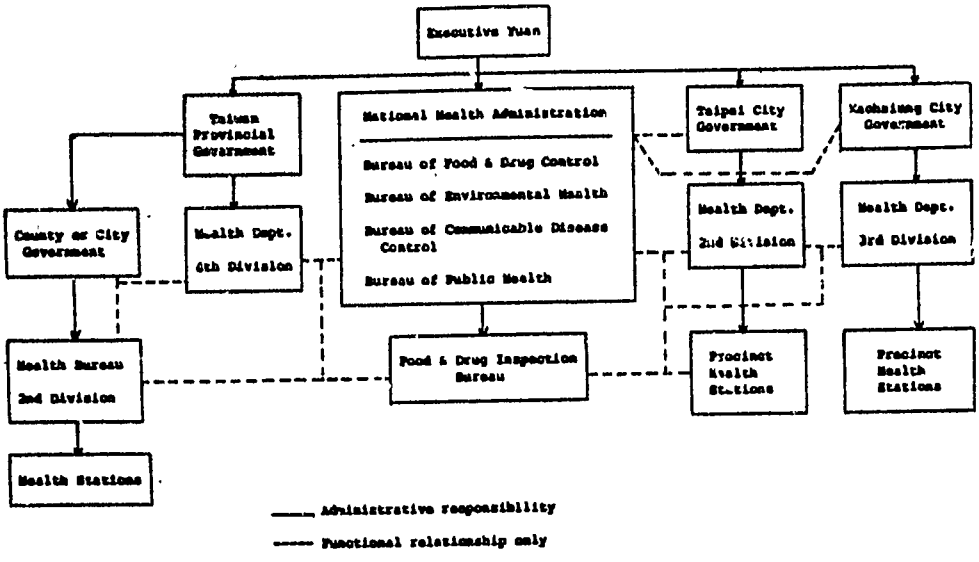

FIGURE 4 Taiwan's present system of food sanitation management.

currently only has four employees. Thus some items must be executed by other bureaus of the National Health Administration.*

At present, food sanitation management in Taiwan Province is carried out by the Food Sanitation Subdivision of the Division of Food and Drug Control, Provincial Department of Health. This subdivision now has three employees, an insufficient number to manage the food sanitation of Taiwan province.**

Food sanitation management in Taipei city is executed by the Food Sanitation Subdivision of the Division of the City Health Department that manages environmental health and food sanitation. At present, this subdivision has four employees. In addition, 16 precinct health stations carry out the food sanitation management in their own precincts. However, 10 of the 16 precinct health stations have only part-time employees (one person for each health station); the other 6 health stations have no employees. The total number of food inspectors is obviously insufficient for a city with a population of 2 million.

In Kaohsiung city, the Food Sanitation Subdivision of the Division of Food and Drug Control, City Health Bureau, has only two employees. Each of the 11 precinct health stations has a part-time food inspector. The total number of inspectors is insufficient for a city with a population over 1.2 million.

Food sanitation management within the county and provincial city health bureaus is carried out by their second divisions whose major functions are: general environmental sanitation, air pollution, potable water hygiene, business sanitation, elimination of dirt and disorder, vector control, sanitary construction, garbage and waste management, supervision of county and town cleaning teams, etc. Therefore, food sanitation management is only a minor task of the bureaus. Taiwan Province, which has 16 counties and 3 provincial cities and a total population of 15 million, has only 11 regular inspectors and 14 part-time inspectors, too few to carry out food sanitation management efficiently.

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*The National Health Administration is planning to expand the Food Sanitation Division into a Bureau of Food Sanitation this year.

**The Provincial Department of Health is going to or already has expanded the Food Sanitation Subdivision into the Division of Food Sanitation.

Present Status of Food Sanitary Inspection by the Health Authorities (see Figure 5)

The Food and Drug Inspection Bureau of the National Health Administration was expanded from the Taiwan Provincial Hygienic Laboratory on September 20, 1978. This bureau has now assumed the laboratory work for the Taiwan Provincial Health Bureau. The testing laboratories of the Taipei and Kaohsiung city health departments can test general items of food hygiene; only a few special items must be sent to the Food and Drug Bureau.

The county and provincial city health bureaus have laboratories that can perform simple food hygiene tests. However, as a result of insufficient equipment and personnel (only one county health bureau has a regular technician for food hygiene testing, while the other 18 county and city health bureaus have only part-time technicians), their functions are very limited. Therefore, most items for food hygiene testing must be sent to the Food and Drug Inspection Bureau (counties and city in the northern area). In short, the number of employees, equipment, and budgets of food sanitary inspection units are insufficient to carry out their responsibilities at the present time.

THE FUTURE OUTLOOK

To strengthen the administration and organization of food sanitation management in the ROC, the National Health Administration will expand its existing Food Sanitation Division into the Bureau of Food Sanitation, and will increase the number of employees from 4 to 37 (see Figure 6). The Taipei and Kaohsiung city health departments will expand the existing Food Sanitation Subdivision into the Division of Food Sanitation, increasing the number of employees to more than 10.

The Republic of China's 16 counties and 3 provincial cities are being divided into three classes, and the health bureaus for each will establish a Food Sanitation Division. The six counties and cities falling into Class 1 will have health bureaus of five employees each. Ten counties and cities fall into Class 2, with four employees for each health bureau, and three fall into Class 3, with three employees each. Thus the health bureaus will have a total of 79 employees. At the level of precincts, towns, and districts, inspectors will be placed at health stations if necessary.

To increase the number of employees, facilities, and resources available to food hygienic testing units, the Food and Drug Inspection Bureau will locate a number of offices at international airports, ports, and container distribution centers. This bureau will also increase its Middle Area Testing Station personnel from 8 to 21, and

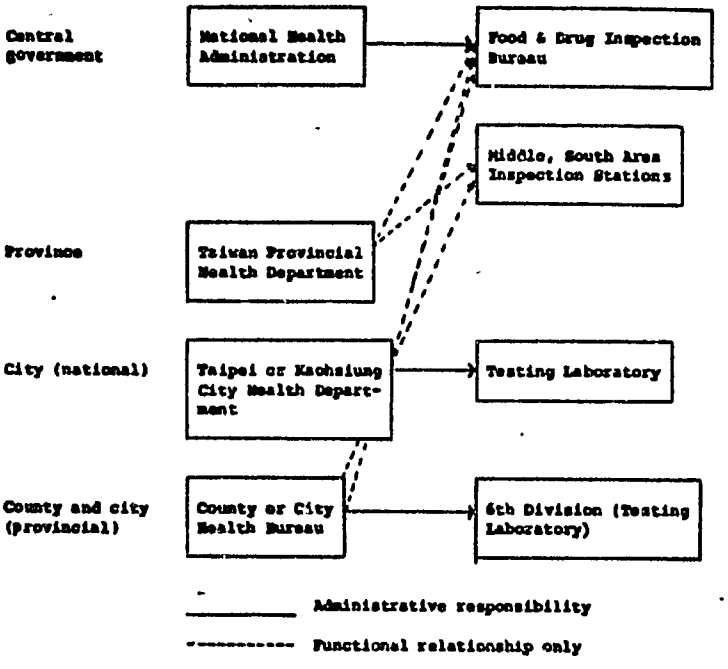

FIGURE 5 Taiwan's present system of food sanitary inpsection units.

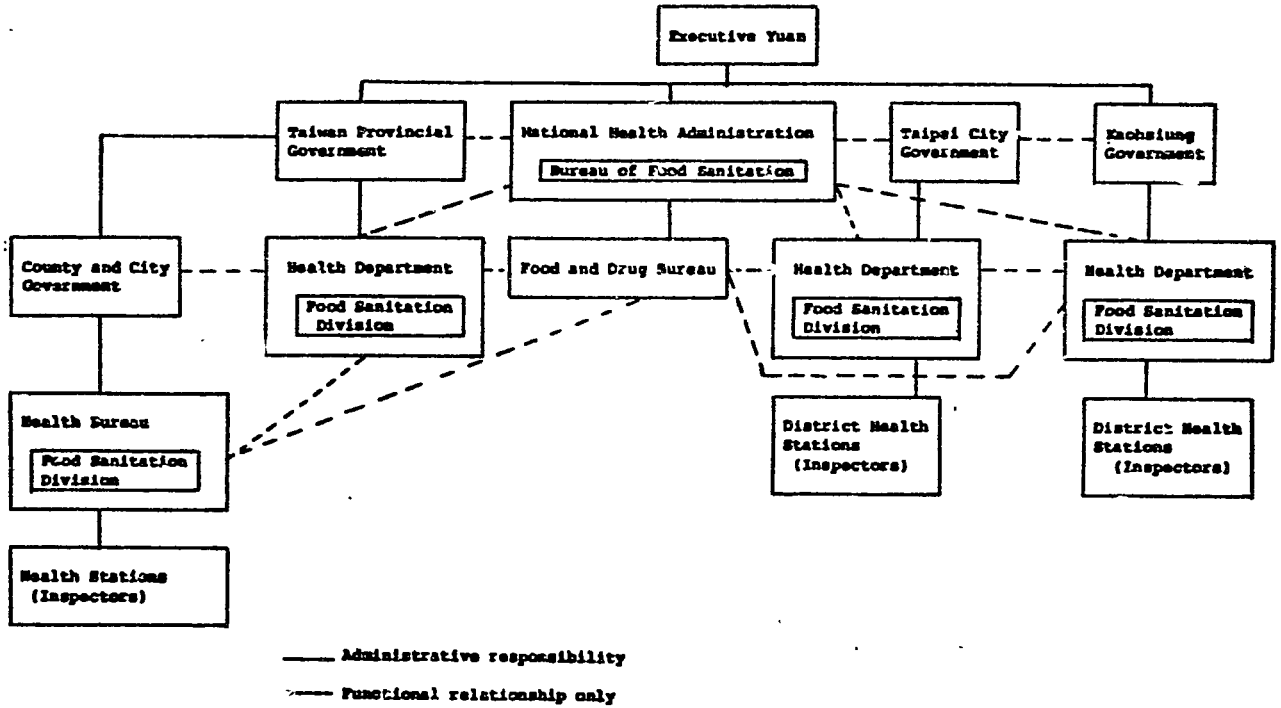

FIGURE 6 The future system of food sanitation management in Taiwan.

its South Area Testing Station personnel from 7 to 21. Further, it will establish an East Area Testing Station which it will staff with 12 persons. The laboratories of Taipei and Kaohsiung cities will each have staffing of 14.

The laboratories of the counties and provincial cities will be divided into three classes, broken down and staffed as shown above.

Steps that will be taken to strengthen laws and regulations include:

- Foods will be divided into two groups. Group A (food produced by factories) would anjoy free sales throughout the country. Group B (products of food businesses, excluding food factories) could only sell at the location of that business.
- More detailed regulations will be formulated for food labelling.
- Management of food vendors will be strengthened.
- More control will be exercised over food from unknown sources.
- Slaughtered livestock will be inspected more stringently.
- More regulations and hygienic standards related to food sanitation will be formulated.
- A good food inspection system will be established.
- Management of food advertising will be improved.

Other measures planned for the future to strengthen food safety in the ROC include:

- Promoting research and surveys on food safety and sanitation
- Promoting the training of food inspectors and sanitary personnel of food factories
- Strengthening cooperation among government agencies
- Establishing a Consulting Committee on Food Safety and Sanitation
- Promoting educational materials related to food safety and sanitation

- Making officials and technicians more aware of food sanitation
- Increasing the budget, facilities, and resources available to health agencies.

AGRICULTURAL SCIENCE AND TECHNOLOGY INFORMATION RESOURCES IN THE REPUBLIC OF CHINA

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At a time in world history when nearly 1 billion people are on the brink of starvation, the Republic of China on Taiwan has, over the past 30 years, been able to feed and clothe its people decently. This has resulted in large measure from development of an agriculture reinforced by scientific and technological innovation.

In the process of transforming its industrial infrastructure from a labor-intensive to a technology-intensive one, this country is faced with a fundamental challenge: how to continue technological modernization under the restrictions of limited agricultural and energy resources and with the aid of science and technology and a modern agricultural information system.

The success of agricultural development in modern societies depends upon an efficient system for collecting, processing, and disseminating agricultural science and technology information, as well as supplies of raw materials and energy resources. This report describes the status of an agricultural science and technology information system in Taiwan, the objectives of the system, and the prospects for cooperation with international information organizations.

THE AGRICULTURAL SCIENCE INFORMATION CENTER

I. Objectives

1. To support agricultural research programs

2. To ensure effective use of agricultural science and technology information
3. To promote cooperation between local and foreign agricultural science and technology information organizations
4. To establish a service network of agricultural science and technology information

II. Brief History

The organizational meeting for the Center was held in August 1976 under the sponsorship of the Council for Agricultural Planning and Development (CAPD). As a result of this meeting, the Center was formed, and in December 1976 the Agricultural Association of China Building, which houses the Center, was opened. On January 1, 1977, the staff of the Center began planning. In September 1978, the Committee for Fund Management was established. The Center itself was opened to the public in October 1978 and planning for a national agricultural science and technology information management system began in January 1979.

III. Service Guidelines

1. Right information provided to
2. Right users in the
3. Right forms at the
4. Right times

IV. Information Defined

1. Intelligence, news
2. Documents
3. Data
4. Service

V. Targets

1. Cooperation among the various organizations involved in agricultural science and technology development in the Republic of China
2. Circulation of information
3. Centralization of sources of specific information
4. Computerization of the overall information system

VI. Information Users

Those who wish to make use of the information provided by the Center, i.e., researchers, students, farmers, etc.

PRESENT STATUS OF THE SYSTEM

I. The Agricultural Science and Technology Information Management System (ASTIMS) Coverage

1. FASTEP--Files for Agricultural Science and Technology Personnel
2. FASTEJ--Files for Agricultural Science and Technology Research Projects
3. FASTER--Files for Agricultural Science and Technology Research Reports
4. FASTCL--Files for Agricultural Science and Technology Literature in Chinese
5. FASTEL--Files for Agricultural Science and Technology Literature in English
6. FASTES--Files for Agricultural Science and Technology Statistical Data
7. The others--still to be developed

II. System Targets

1. To establish a system for processing domestic agricultural science and technology information and to give priority to setting up data bases on researchers, research projects, research papers, and literatures in Chinese and English
2. To coordinate the efforts of domestic information organizations at building up core collections and various special data bases to form an integrated service network without needless duplication
3. To assist other information organizations in introducing from abroad standard information processing practices in order to unify all information processing procedures and methods to facilitate information exchange
4. To train information staff and introduce foreign processing techniques for the development of an automated Chinese-language information system
5. To join international information organizations and introduce selective data bases into the domestic information system
6. To develop an information classification system and terminology adaptable to domestic conditions

III. System Functions

1. Data input, correction, and updating
   a. Input of information in both Chinese and English
   b. On-line and off-line information input
   c. On-line and off-line correction and updating

2. Perusal
   a. Required information displayed on CRT
   b. Results of retrieval
   c. Operating and retrieval procedures
   d. Contents of data base

3. Retrieval
   a. Retrieval in Chinese
   b. Two retrieval operations

   (1) Relational operators
      (a) EQ (equal to)
      (b) NE (not equal to)
      (c) LE (less than or equal to)
      (d) LT (less than)
      (e) GE (greater than or equal to)
      (f) GT (greater than)
      (g) WL (within limit)
      (h) OL (outside limit)

   (2) Query operators
      (a) NOT
      (b) AND
      (c) OR

4. Printout
   a. Information perused
   b. Information retrieved
   c. Statistics
   d. Other inputs

5. Indices
   a. Classification index
   b. Key word index
   c. Institutions index
   d. Authors index

6. Statistical analysis
   a. Research funds
   b. Retrieval results
   c. Science and technology personnel (age, degree, specialty, etc.)

7. Editing and publication
   a. In formats required
   b. Who's who, abstracts of papers or projects, digests of related literatures

8. RS, SDI, and STD services

VI. Information Cooperation

Since its inception, the Center has joined the following international information organizations:

1. FID (International Federation for Documentation)
2. IFIS (International Food Information Service)
3. IFLA (International Federation of Library Associations and Institutions)
4. IAALD (International Association of Agricultural Librarians and Documentalists)
5. ASIS (American Society for Information Science)

A SELECTED LIST OF AGRICULTURAL SCIENCE AND TECHNOLOGY PUBLICATIONS/JOURNALS PRODUCED IN THE REPUBLIC OF CHINA

I. Food science and nutrition

1. Food and Nutrition
2. Food Industries
3. Food Sanitation Newsletter
4. Food Science
5. Food Science Digest
6. Food Today
7. Health and Nutrition
8. Journal of Chinese Food
9. Journal of Hwa-Gang Food Science and Nutrition
10. Journal of the Marine Food Processing
11. Journal of the Chinese Nutrition Society
12. Modern Food
13. Mycotoxin Digest
14. Report of Food Industry Research and Development Institute
15. Soybean and Oil Processing

II. Agriculture

1. Agriculture and Economics
2. Agriculture Extension
3. The Agriculture Finance Tribune
4. Agricultural Information
5. Agricultural Research
6. Agri-Week
7. Agrometerological Bulletin
8. Annual Report of International Seeds and Seedlings Exchange
9. Annual Report of Plant Protection Center, Taiwan
10. Annual Report of Rice Cultivation Improvement
11. Annual Report of Taiwan Agricultural Research Institute

12. Annual Report of Taiwan Sugar Research Institute
13. Annual Report of the Tobacco Research Institute, Taiwan Tobacco and Wine Monopoly Bureau
14. Biology
15. Botanical Bulletin of Academia Sinica
16. Bulletin of Agricultural Engineering
17. Bulletin of Agricultural Extension
18. Bulletin of Agricultural Research
19. Bulletin of Agronomy Society
20. Bulletin of Botany
21. Bulletin of Taiwan Agricultural Research Institute
22. Bulletin of Taiwan Provincial Pingtung Institute of Agriculture
23. Bulletin of the Department of Botany, College of Science, National Taiwan University
24. Bulletin of the Tobacco Research Institute, Taiwan Tobacco and Wine Monoply Bureau
25. China Agricultural Machinery
26. China Floriculture
27. Companionship of Orchid
28. Cooperative Bank Today
29. Environment Protection
30. Farmer's Friend Monthly
31. Food and Agricultural Economics Review
32. Food Production and Activities of Taiwan Provincial Food Bureau
33. Foreign Market Information on Agricultural Products
34. Fruit Growers' Cooperation
35. Fruit Research
36. The Grains and Livestock Monthly
37. 4-H Feed Monthly
38. Harvest Farm Magazine
39. Hwa-Gang Plant
40. Journal of Agricultural Research of China
41. Journal of Agriculture and Forestry
42. Journal of Agriculture Vocational Education
43. The Journal of Chinese Agricultural Chemical Society
44. Journal of Chinese Agricultural Engineering
45. Journal of Chinese Soil and Water Conservation
46. Journal of the Agricultural Association of China
47. Journal of the Chinese Agricultural Chemistry Society
48. Journal of the Chinese Biochemistry Society
49. Journal of the Chinese Microbiology Society
50. Journal of the Chinese Society for Horticultural Science
51. Journal of the Microbiology Society
52. Memoirs of the College of Agriculture, National Taiwan University

53. Mushroom Cultivation
54. NCHU Horticulture
55. NTU Phytopathologist and Entomologist
56. Pineapple Magazine
57. Pineapple Newsletter
58. Plant Protection Bulletin
59. Quarterly Journal of Agricultural Marketing
60. Quarterly Journal of Chinese Forestry
61. The Quarterly Journal of Taiwan Bank
62. The Quarterly Journal of Taiwan Land Credit
63. The Report of Agriculture Census of the Republic of China
64. Report of Farm Record-keeping Families in Taiwan
65. Report of the Taiwan Sugar Research Institute
66. Report on Agricultural Information
67. Rural Taiwan
68. Scientific Agriculture
69. Soil and Fertilizer Newsletter
70. Soils and Fertilizers in Taiwan
71. Sugarcane Bulletin
72. Sugarcane Research
73. Taiwan Agricultural Economics
74. Taiwan Agricultural Extension Newsletter
75. Taiwan Agricultural Yearbook
76. Taiwan Agriculture Quarterly
77. Taiwan Fertilizer Monthly
78. Taiwan Floriculture
79. Taiwan Fruits Magazine
80. Taiwan Horticulture
81. Taiwan Mushrooms
82. Taiwan Orchid
83. Taiwan Sugar
84. Taiwan Sugar Bulletin
85. Taiwan Sugar Industry Quarterly
86. Taiwan Sugar Statistics
87. Taiwan Tobacco
88. Tea in Taiwan
89. Tea Newsletter
90. Weed Science Bulletin

III. Forestry

1. Bulletin of Taiwan Agricultural and Forestry Survey Team
2. Bulletin of Taiwan Forestry Research Institute
3. Bulletin of the Chinese Forestry Association
4. Bulletin of the Experimental Forest of National Taiwan University
5. Companionship of Forestry

6. Forestry Product Monthly
7. Forestry Statistics of Taiwan
8. Lumber Marketing Monthly
9. NTU Forest
10. Quarterly Journal of Chinese Forestry
11. Silviculture Knowledge
12. Silviculture Today
13. Taiwan Forest
14. Taiwan Forestry Journal
15. Taiwan Forestry Quarterly
16. Taiwan Lumber

IV. Fishery

1. Acta Oceanographica Taiwanica
2. Annual Catch Statistics of Taiwan's Tuna Longline Fishery
3. Aquaculture
4. Bulletin of Taiwan Fisheries Research Institute
5. China Fisheries Monthly
6. Collected Reprints Tungkang Marine Laboratory
7. The Culture of Prawns and Shrimps
8. Fisheries Tribune
9. Fisheries Yearbook in Taiwan Area
10. Fisherman Magazine
11. Fish World
12. Journal of the Fisheries Society of Taiwan
13. Report of Taiwan Fisheries Research Institute
14. Yearly Journal of National Taiwan College of Marine Science and Technology

V. Animal Husbandry and Veterinary Medicine

1. Agriculture and Animal Husbandry Bulletin
2. Animal Husbandry of the Republic of China
3. Annual Report of Taiwan Livestock Research Institute
4. Annual Research Report of Animal Industry Research Institute, Taiwan Sugar Corporation
5. Biological Bulletin of National Taiwan Normal University
6. Bulletin of the Chinese Society of Animal Husbandry
7. Bulletin of the Institute of Zoology, Academia Sinica
8. Chinese Animal Husbandry Weekly
9. Chinese Apiculture
10. Chinese-Japanese Feedstuffs
11. Companionship of Pigeon
12. Experimental Report of Taiwan Provincial Research Institute for Animal Health
13. The Journal of Animal Husbandry and Veterinary Medicine

14. Journal of the Chinese Society of Animal Science
15. Journal of the Chinese Society of Veterinary Science
16. Journal of the Taiwan Livestock Research
17. Livestock Digest
18. Milk Industry
19. Modern Livestock
20. Poultry World
21. Racing Pigeon
22. Taiwan Feed Industry Magazine
23. Taiwan Feedstuffs
24. The Taiwan Journal of Veterinary Medicine and Animal Husbandry
25. Technical Bulletin of Taiwan Fertilizer Company

PROPOSAL FOR THE ESTABLISHMENT OF A SINO-AMERICAN AGRICULTURAL SCIENCE AND TECHNOLOGY INFORMATION SYSTEM COOPERATION PROJECT

I. Objectives

1. Exchange agricultural publications and related information
2. Exchange agricultural information data bases
3. With the assistance of American concerns, ASIC would obtain agricultural information from international organizations and their participation
4. Provide the Republic of China with necessary agricultural information processing training

II. Work Plan

1. Exchange of publications and related information will start July 1981
2. Exchange of data bases will start January 1, 1982
3. Depending on necessity, hold one or two training classes annually on information retrieval, data base management, and information system practice, etc.
4. Hold an agricultural information system seminar in 1981 that will include the following topics:
   a. An introduction to management information systems
   b. Information analysis
   c. Information system management
   d. Information system case study
   e. How to construct a thesaurus
   f. How to set up a data processing system

III. Organization

1. The Republic of China and the United States will each assign three to five specialists to the committee

2. Each side will designate a liaison officer for the planning and execution of programs
3. Members of the U.S. task committee should include:
   a. Information system management specialist
   b. Information processing specialist
   c. Agricultural research management specialist
   d. Management information system specialist

IV. Activities

1. Promote exchange of information
2. Assess the performance of information system operations
3. Study, through joint efforts, the technology of Chinese information processing

CURRENT STATUS OF A PREVENTIVE PROGRAM FOR FOOD SAFETY IN TAIWAN

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Taiwan's remarkable record in economic and social development has gained worldwide recognition. Taiwan's population increased from 14.3 million in 1969 to 17.5 million in 1979, with an annual growth rate of 2.4 percent in 1979. Per capita income in Taiwan is now more than US$2,000. Taiwan's prosperity has resulted both from a growing population rate and increased national income and from rapid extension of education at all levels. Since 1968, a 9-year education has been compulsory. All these dramatic changes have brought about demands for tastier, more nutritious food and concerns about food safety.

During the past decade, most research and regulation in the area of food safety have emphasized food exports, reflecting the stringent requirements of Taiwan's customers in foreign countries. But in the past few years, local food consumption has gradually increased, giving rise to government and consumer concern with food safety. The outbreak of several severe cases of food poisoning last year led to immediate instigation of a food safety prevention program. Taiwan wants to establish a more ideal and reliable system or program of professional training and consumer education to strengthen this preventive program.

PROFESSIONAL TRAINING

Many of those responsible at present for Taiwan's food sanitation and safety program do not have intensive training in this field (Table 1). They majored in food science and technology, food and

nutrition, public health, home economics, or other closely related fields. They were trained at senior vocational schools, junior colleges, and universities at the undergraduate or graduate levels. Table 2 shows estimated figures for 1980 of all graduates in fields closely related to food safety.

TABLE 1 Home economics major training courses related to food safety.

Level of training	Course credits						
	Microbiology	Food microbiology	Family health	Food sanitation	Food and nutrition	Food processing	Human nutrition
Senior vocational school	-	-	-	-	2	4*	-
Junior college	-	3*	2-4	3*	3-4	2-3	-
University (undergraduate)	3	-	-	-	3-	2	3

*Listed as elective courses.

The home economics extension program is one of the regular branches of agricultural extension education in Taiwan. In 1979, Taiwan's agricultural population numbered 5,638,810, or 32.2 percent of the total population. Thus the importance of the extension program to the rural community is obvious. At present, this program has 380 home economics extension agents (26 county or city supervisors and 354 township advisors, most of whom majored in home economics). There are also 5,213 local volunteer helpers.

In 1980, an on-the-job training program for these extension agents included:

- o A summer class for 40 home economics extension supervisors and advisors, conducted by the Home Economics Education Department of Taiwan Normal University.

TABLE 2 **Estimated number of 1980 graduates in fields closely related to food safety.**

Level of professional training	Department graduates							
	Food science and technology	Food and nutrition	Public health/ health education	Agricultural chemistry	Animal science	Environmental engineering/ environmental sanitation	Home economics	TOTAL
Senior vocational school	900	67	--	--	--	--	777	1,744
Junior college	100	150	--	--	--	--	200	450
University (undergraduate)	220	110	60	35	30	--	250	705
University (graudate)	25	--	--	5	5	16	7	58

- Technical training conducted at District Agricultural Improvement Stations with 32 classes and 700 participants.

- A panel discussion sponsored by the American Soybean Association and assisted by the Council for Agricultural Planning and Development on the topics of "Food Sanitation and Safety," "Food Nutrition," "Food Processing and Nutritional Value," "Processing of Salad Oil," and "The Right Way of Using Salad Oil." Thirty extension advisors and hospital dietitians participated.

The Food Industry Research and Development Institute (FIRDI) also offers a training program under its technical services group. FIRDI is a nonprofit organization that serves the food industry. Its areas of

interest include improving food processing technology and quality of food products, developing new products, solving problems, and training technical personnel. Training courses address can seamer operation and seam inspection, retort operation, thermal processing, food plant sanitation, quality control and examination, etc. As of 1980, FIRDI had trained more than 4,176 technical personnel from the food industry and food processing teachers from vocational schools (Table 3).

Training classes and workshops are also offered for health and sanitation inspectors and laboratory technicians and for sanitary quality control personnel from the food industry. Health departments or health bureaus offer periodic classes on management of food plant sanitation.

In 1980, the Drug and Food Inspection Bureau conducted three training classes for 75 food sanitation laboratory technicians, two training classes for 125 food sanitation inspectors, and a training class on "Handling of Food Poisoning cases and the Laboratory Examination Technique" for 43 laboratory technicians and 39 inspectors. Experts from research institutes and universities were asked to lecture in these classes.

CONSUMER EDUCATION

Home economics extension workers play a very important role in the consumer education program. The extension program mentioned earlier is implemented through a system of farmers associations, under government supervision. The number of extension agents assigned to each association depends upon its size--usually one agent is assigned to a 1,000-2,000 family association and one to two agents to a 2,000-3,000 family association. Extension agents emphasize improvement of rural sanitation and living conditions; family planning, child care, personal hygiene, and home environment beautification; and improvement of family diet.

In Taiwan, a number of magazines and journals related to food, health, sanitation, and safety are available, including an estimated 15 for the general public. Some of these are The Woman, Health World, Popular Medicine, and Consumer Time. The publisher of Consumer Time claims that it is the only consumer magazine on the market with information on commercial products.

A number of academic journals are published by academic societies and student associations in the related field for professionals. Eight other magazines (e.g., Food Industries, National Science Council Monthly, Food Friday, Agri-Week) are published by nonprofit organizations such as FIRDI and the National Science Council.

TABLE 3 On-the-job-training program sponsored by the Food Industry Research and Development Institute, 1977-1980.

Training subjects	1977		1978		1979		1980	
	No. of classes	Participants	No. of classes	Participants	No. of classes	Participants	No. of classes	Participants
Food processing for vocational school teachers	1	26	1	24	1	26	1	19
Quality control of food canning	6	166	6	137	5	89	5	79
Retort processing control	4	68	5	62	3	43	3	40
Retort operation	11	183	7	97	5	66	4	62
Quality control of frozen seafoods	3	66						
Management of canned foods production	2	52						
Quality control of pickled fruits and vegetables			3	81				

TABLE 3 Continued

Training subjects	1977		1978		1979		1980	
	No. of classes	Participants	No. of classes	Participants	No. of classes	Participants	No. of classes	Participants
Inspection of UHT* processed milk and fruit juice			1	10				
Sealing technique in canning			3	36	11	120		
Thermophilic spores counting in canned mushrooms					2	61		
Quality control of can seaming							5	74
TOTAL	27	561	26	447	27	405	18	274

Total number of classes: 98
Total participants: 1,687

*Ultra-high temperature.

The Monday issue of the China Daily News carries a Weekly Consumer Report, edited by the Consumer Association of Taipei. The Taipei Saturday News aims "to protect the benefit of the people's life." Newspapers also occasionally carry special articles on food.

Taiwan has three television networks broadcasting 163 hours per week. Food safety programs are telecast approximately 0.6 percent of this time which include the programs mentioned below. The Taipei City Health Department also sponsors 3-minute public service announcements concerning food sanitation, inspection, etc., which are between television programs.

A half-hour television program, "Health Classroom," has been sponsored by the Taipei City Health Department for 2 years. In 1981, the name of the program will change to "The Green Mountain Will Exist Forever," meaning our health is very important. The total budget for this program is US$156,000, or US$3,000 for each half-hour program. A book titled Concern about Your Health covers the content of "Health Classroom."

None of Taiwan's 20 broadcasting stations carry special programs related to food safety. The subject is covered occasionally on such programs as "Happy Farmers," "Our Family," and "The Early Morning in the Park."

Food exhibitions are sometimes sponsored by student associations, consumer organizations, or health departments and bureaus.

"Consumer Guide" is published by the China Daily News and is sponsored by the Consumer Association of Taipei. This book runs 720 pages, of which 92 pages is devoted to food and health.

To protect consumers against misleading statements by the mass media, an advertisement control law is provided in the "Law Governing Management of Food Hygiene," Article 17, which reads as follows: "Mass media or names of other persons shall not be used for publicity or advertisement containing falsehood, exaggeration, distortion of food additive."

CONSUMER ORGANIZATIONS

The Consumers Association of the Republic of China was the first consumer organization founded on the island, but it has never been active.

The Consumers Association of Taipei, founded in 1974 to protect the consumer, provides the following services:

- o Settles consumer complaints about merchandise
- o Conveys consumers' interests to the government
- o Acts as a bridge between the producer and the consumer
- o Compares product prices and quality to consumer opinions and responses
- o Educates the consumer by mass communication (e.g., panel discussions, publications).

The China Daily News is the sole sponsor of this association which receives US$1,000 annually from the Taipei Municipal Government. An individual member entrance fee is US$5 per year (students are free); group membership dues are US$50. At present, this organization has 2,000 individual members and eight group members. Obviously, its financial affairs are in a difficult condition.

The Consumer Foundation of the Republic of China was founded on November 1, 1980, and is promoted by Taipei Jaycees. The foundation held a panel discussion on "Food and the Consumer" on July 13, 1980, and has set up "Educating Consumer Classroom," a class especially designed to educate consumers on such subjects as "How should we eat?," "Cosmetics and your skin."

The National Matrons Association of the Republic of China was founded in 1961 by housewives.

The Center for Quality of Life, sponsored by the Ming-Teh Foundation, was founded in August 1980. The purpose of this center is to improve the quality of life of the people. The center conducts research in the fields of environmental pollution, health and nutrition, etc.; arranges seminars and panel discussions; and publishes books on quality of life, technical manuals, seminar proceedings and research reports, and journals.

SAFETY FACTORS TO BE BUILT IN AT FOOD PROCESSING PLANTS: MANUFACTURING TECHNOLOGY AND QUALITY CONTROL SYSTEM

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INTRODUCTION

Taiwan receives more rainfall than any other part of the Chinese mainland, and has a mean monthly temperature in winter of above 15°C, both favorable conditions for agriculture.

About 32.2 percent or 5.64 million of Taiwan's total population of 17.48 million (in 1979) derive their income from agriculture. Most farmers are landowners; tenant farmers comprise 8 percent of the total farming population. Approximately 915,393 hectares (ha) of land are cultivated and the average farm is 1.02 ha in area. Production figures (1978) for specific crops, vegetables, livestock, and fish are shown in Table 1.

TAIWAN'S FOOD PROCESSING INDUSTRY

Taiwan is intensively developing its industrial sector while leaning heavily on its agricultural sector, but there is close coordination between the two. The food processing industry has significantly influenced the availability of raw materials, and the export of processed agricultural products has played an important role in the development of Taiwan's economy since the early 1950s when sugar

and banana were Taiwan's two major exports. The share of exported processed agricultural products has gradually become less, but their export value has increased (see Tables 2 and 3).

TABLE 1 Crop, vegetable, livestock, and fish production in Taiwan, 1978.

	Harvest area (ha)	Number of head or pieces	Production (metric tons)
Crops			
Rice	749,415		2,439,018
Sweet potato	91,749		1,462,999
Sugarcane	5,037		336,302
Pineapple	11,556		249,627
Vegetables			
Water chestnut	198		3,711
Bamboo shoot	19,487		218,775
Asparagus	12,610		97,393
Tomato	8,781		220,719
Mushroom	1,170		119,460
Livestock			
Hog (slaughtered)		6,204,549	579,327
Chicken (dressed)		91,463,285	
Egg		2,260,839	
Fish			
Tuna			112,349
Grass shrimp	1,525		1,606

Source: Taiwan Agricultural Yearbook

TABLE 2 Composition of exports in Taiwan, 1978.

	Value (million US$)	Percent
Industrial products	11,233.4	88.7
Textile products	3,195.8	
Electrical machinery and apparatus	2,012.5	
Metal products and machinery	1,033.3	
Other	4,991.8	
Agricultural products	1,429.0	11.3
Sugar	73.3	
Canned foods	391.5	
Fresh fruit	31.4	
Salted foods	61.2	
Dehydrated foods	33.9	
Other	837.7	
TOTAL EXPORTS	12,662.4	100.0

Sources: Customs Statistics, Council for Agricultural Planning and Development, Taiwan Exports of Canned Food, Taiwan Regional Salted Vegetable and Fruit Exporters Association, and Taiwan Regional Dehydrated Vegetable Exporters Association

The food processing industry has an important influence on the production and price of farm products. At least 50 percent of the farm households producing agricultural, forest, fishery, and animal processing materials are related directly or indirectly to the food industry. Food factories employ tens of thousands of farm workers during their operating periods. Farm income from the production of sugar cane, mushrooms, asparagus, pineapples, oranges, and other vegetables and fruits, as well as marine and livestock products used as processing materials, has reached over NT $10 billion a year. Payments to farmers for harvesting, transporting, and processing these materials

TABLE 3 Share of processed agricultural product exports of Taiwan's total exports and agricultural exports value.

Year	(1) Total export (million US$)	(2) Total agricultural exports (million US$)	(2)/(1) (percent)	(3) Processed agricultural product exports (million US$)	(3)/(1) (percent)	(3)/(2) (percent)
1979	16,092	1,610	10.00	940	5.84	58.36
1978	12,662	1,429	11.29	809	6.39	56.62
1977	9,348	1,212	12.97	705	7.55	58.20
1976	8,155	1,071	13.13	668	8.19	62.41
1975	5,302	909	17.14	627	11.82	69.01
1965	488	264	58.20	159	32.58	55.99
1955	133	123	92.48	82	64.16	68.29

Sources: Statistics of Trade, Agricultural Trade Statistics of Taiwan

also total hundreds of millions NT dollers. Thus development of the food processing industry is not only closely related to the growth of agriculture and the rural economy, but also to other economic sectors.

Canned Food Industry

Canned foods are one of Taiwan's major food industries. At the end of 1979, 60 plants were producing canned asparagus; 53, canned mushrooms; and 16, canned pineapple. As these products are processed during different seasons, the same plant usually produces more than one kind of product. Pineapple canning, a traditional food industry, was established in 1901. Canned mushrooms and asparagus, developed by the government in 1959 and 1963, respectively, further enhanced the development of the food processing industry.

In 1978, the major canned items were bamboo shoots, 4,379,695 c/s (standard cases); asparagus, 4,344,340 c/s; and mushrooms, 3,729,748 c/s (see Table 4). More than 97 percent of Taiwan's canned foods were exported, chiefly to Europe, the United States, and Japan. Only pineapple, mushrooms, bamboo shoots, and asparagus canned products have a collective export company. Other products have been competing for international markets resulting in an uneven distribution of profits among canneries and very unstable production.

TABLE 4 Taiwan's exports of canned foods, 1976-78 (standard cases).

	1976	1977	1978
Pineapple	1,351,484	1,012,767	717,214
Mandarin orange	492,284	794,590	906,015
Other fruits	998,920	584,962	717,375
Mushroom	2,670,924	3,899,716	3,729,748
Asparagus	3,899,449	2,835,369	4,344,340
Bamboo shoots	3,034,375	3,543,541	4,379,695
Water chestnut	666,287	872,123	680,284
Tomato products	1,556,255	1,466,308	1,918,306
Other vegetables	950,013	1,560,288	1,616,587
Marine products	586,518	900,205	946,360
Others	2,179,770	1,555,021	2,419,602
TOTAL	18,386,279	19,024,890	22,375,526

Source: Taiwan Exports of Canned Food

As a result of this situation, a number of problems have arisen:

- Exports of canned products have been concentrated too much in one or two countries. For example, most mushrooms are shipped to the United States, asparagus to West Germany, and bamboo shoots to Japan and the United States, creating trade problems with importing countries. New international markets must be developed for exported canned goods.

- Exported canned goods are facing keen competition from other countries. For example, Thailand and the Philippines have been using cheaper raw materials and labor in pineapple production; Korea and the People's Republic of China have increased their mushroom production; Mexico, Spain, the People's Republic of China, and Brazil have been expending greater efforts on their production of asparagus.

- The high cost of tin cans has been a major problem, resulting in steps to reduce the thickness of tin plate and to increase the amount of tin coating.

- A labor shortage has been a major problem in the food processing industry. For many years, the export food trade took advantage of relatively cheap labor. Machines must be developed for peeling, grading, and filling.

Frozen Food Industry

The frozen food industry appeared in Taiwan about 15 years ago. At the end of 1977, 55 frozen food factories were producing vegetables and fruits; 82, marine products; 12, roast eel; 26, pork meats; and 7, prepared foods. Ninety-eight percent of frozen foods was exported to Japan, West Germany, the United States, Hong Kong, and Canada. The most important frozen vegetables were mushrooms, asparagus, soy beans, and beans. Among marine products, shrimp, eel, crab, and fish paste were the main items. Of frozen meat, pork was about the only item, and spring roll was the major item in frozen prepared foods.

Taiwan has four frozen dehydrated food factories, exporting 218 tons valued at US$3.57 million in 1978. The price of these products is high, yet the output is unstable. Frozen prepared foods have been produced for about 5 years, and consist mainly of Chinese-style snack foods. Exports in 1978 were 398 tons valued at US$1.12 million (see Tables 5 and 6).

Problems faced by the frozen food industry include:

- Heavy investment and high storage and transportation costs which have made this industry more difficult to manage than the canning industry.

- Insufficient raw materials for the 120 factories in operation. Total freezing capacity amounts to 2,200 metric tons per day or

TABLE 5 Export of frozen products from Taiwan, 1974-78 (metric tons).

	1974	1975	1976	1977	1978
Vegetables and fruits	28,337	14,823	28,272	38,740	48,679
Marine products	19,559	16,150	20,969	26,790	31,076
Prepared products	38	27	1,404	454	398
Pork	11,106	8,698	24,608	19,553	20,330
Freeze-dried products	314	51	583	176	218
TOTAL	59,404	39,749	132,032	85,721	100,701

Source: Taiwan Frozen Vegetable and Fruit Association

TABLE 6 Export of frozen products from Taiwan, 1974-78 (US$1,000).

	1974	1975	1976	1977	1978
Vegetables and fruits	15,465	8,007	25,068	34,235	39,816
Marine products	21,777	38,955	112,459	35,777	108,878
Prepared products	37	54	655	957	1,130
Pork	26,313	24,674	72,664	73,517	78,277
Freeze-dried products	4,089	542	2,872	2,463	3,570
TOTAL	67,681	72,232	203,718	146,949	231,671

Source: Taiwan Frozen Vegetable and Fruit Association

800,000 metric tons per year; but only 85,721 metric tons were produced in 1977 and 100,701 metric tons in 1978.

- Frozen foods are not popular in local markets, and exported frozen foods have been concentrated in one or two countries. This industry depends too much on foreign markets.

- A recent U.S. Food and Drug Administration blacklist of Taiwan's frozen seafood products which means that all shipments are automatically detained at the port of entry until declared free of contamination.

Edible Oils Industry

During the past 10 years, the edible oil industry has developed very quickly in Taiwan, particularly soybean oil processing. In 1977, 38 soybean oil refineries were in operation, all equipped with modern machinery. Annual demand for soybean oil is about 110,000 tons, and for lard and peanut oil, 50,000 tons (see Table 7). Margarine and shortening are used mainly for food processing, with an annual demand of 12,000 tons. Annual demand for edible oil is increasing at a rate of 6 percent annually. Further research should be conducted on frying oils to find a new source of vegetable oil material such as rice bran to use instead of soybean.

Salted Vegetables and Fruits Industry

The salted food industry is important to farmers who grow fruits and vegetables on sloping land. Since the government started issuing tax refunds on salt for processing, the export of salted foods has increased, reaching 108,000 tons worth US$61.2 million in 1978 (see Table 8 for a listing of the chief salted food items). Japan imports 80 percent of Taiwan's salted foods. Because most products are semi-finished, profits are limited. Most factories are family businesses with limited funds and competition is sharp. Thus this industry has had to depend heavily on the cooperation of the manufacturers, improvement of management, and export of finished products.

Juice and Soft Drink Industry

Presently in Taiwan 21 factories are producing carbonated drinks; 14 factories, juices (including fruit and vegetable); and 22 factories, juices and soft drinks. Most fruit or vegetable juices are consumed locally. The fruit juice industry has developed further since

TABLE 7 Per capita consumption of fats and oils in Taiwan, 1974-78 (kilograms).

	1974	1975	1976	1977	1978
Soybean oil	4.16	5.55	5.64	6.22	6.99
Peanut oil	0.55	0.52	0.49	0.41	0.52
Rapeseed oil	0.04	0.10	0.19	0.21	0.05
Sesame oil	0.18	0.14	0.19	0.07	0.20
TOTAL VEGETABLE OILS	4.92	6.31	6.41	6.91	7.76
Lard	3.26	2.73	3.54	2.69	2.76
Butter	0.06	0.05	0.07	0.11	0.15
TOTAL ANIMAL FATS	3.32	2.78	3.61	2.80	2.91
TOTAL FATS AND OIL	8.24	9.09	10.02	9.71	10.67

Source: Taiwan Food Balance Sheet

TABLE 8 Taiwan's export of salted foods, 1974-78 (tons).

	1974	1975	1976	1977	1978
Ginger	13,570	20,054	27,506	29,395	44,703
Prune	12,328	7,931	15,996	16,963	21,449
Eggplant	5,899	4,697	9,490	12,155	8,050
Mustard	2,042	4,048	3,817	3,199	5,139
Cucumber	1,340	6,408	4,025	2,525	3,807
Mushroom	68	29	285	2,235	5,460
Bulbous onion	1,436	1,679	2,399	1,326	3,198
Others	16,367	6,945	21,011	23,035	16,299
TOTAL	53,050	70,791	84,529	90,833	108,105

Source: Taiwan Regional Salted Vegetable and Fruits Exporters Association

1971 when the government started issuing tax exemptions for fruit or vegetable juices that met CNS (Chinese National Standard) standards. In 1978, fruit juice exports reached 2.17 million standard cases valued at US$21.4 million and were sent mainly to Middle Eastern countries. Chief exports were mango, orange, guava, pineapple, and tomato juices. Soft drinks are only consumed locally and in 1978, 74,396,000 dozen were sold (see Table 9). Storage of juices and maintenance of quality for off-season production are the two major problems in the juice industry.

TABLE 9 Soft drink and juice production in Taiwan, 1975-79 (1,000 dozen).

	1975	1976	1977	1978	1979
Soft drink	38,090	46,544	56,535	74,396	77,899
Juice	13,126	19,481	16,013	39,798	30,888
TOTAL	51,216	66,025	72,548	114,194	108,787

Source: Industry of Free China

GOVERNMENT AND RESEARCH INSTITUTE ASSISTANCE FOR THE PROCESSING INDUSTRY

National Bureau of Standards (NBS), Ministry of Economic Affairs

The NBS, under the supervision of the Ministry of Economic Affairs, is currently in charge of standards, measures, patents, and trademarks. NBS sets national standards for unit, name, definition, constant, quality, dimension, testing procedure, exchangeability, safety, and packing. Further, NBS promotes industrial standardization and administers the CNS Certification Mark. Currently, NBS has 22 technical committees composed of 1,557 committee members. The National Standard Council is composed of 40 leading figures from the industrial sector. The chairman of the National Standard Council is the director-general of NBS.

Normally, a CNS standard is drafted by industrial or academic associations at the request of NBS. Relevant international standards

and organizations are consulted. After the draft is prepared, copies are circulated to organizations and food factories concerned. Discussion meetings that include NBS technical committee experts, specification writers, and representatives of producers and users are then called to justify the draft according to the industrialization of the country. When the draft is passed, it is then voted on by the National Standards Council. Finally, this draft is promulgated by the Ministry of Economic Affairs as a National Standard. Recently, the efficiency of this Bureau has increased and about 500 standards per year are being drafted.

The Chinese National Standards are basically voluntary. As of May 1979, 4,940 standards were in existence (Table 10), of which 2,582 have been revised. NBS has cancelled 174 standards because they related to industrial products regarded as out of date.

TABLE 10 Breakdown of the Chinese National Standards.

	Number of standards
Chemical industry	1,418
Mechanical engineering	1,055
Electrical engineering	323
Processed food	356
Others	1,788
TOTAL	4,940

Source: National Bureau of Standards

Bureau of Commodity Inspection and Quarantine (BCIQ), Ministry of Economic Affairs

During the last decade, the export volume of the Republic of China has grown tremendously as a result of increased industrial development. To improve the image of Taiwan's products in the world market and to promote the export trade, the Ministry of Economic Affairs has subjected certain items to inspection by BCIQ or its designated institution before they are shipped. If carried out by the Bureau and its six branch offices, inspections of various commodities

involve more than 50 laboratories and about 500 trained inspectors. BCIQ has also designated six well-equipped private and public technical or academic institutions to help perform export inspections.

As stipulated by the Inspection Law, inspection of both imports and exports is to be according to CNS.

Industrial Development Bureau (IDB), Ministry of Economic Affairs

Established in February 1970, IDB comprises eight divisions and three offices. The third division is responsible for the food processing industry. Its responsibilities include:

- Formulating and evaluating existing factories
- Recommending approval of imported machinery, equipment, and raw materials
- Recommending approval of applications of qualified export factories and their products
- Assisting in improving product quality
- Assisting in solving production and sale problems
- Collecting engineering and technical data.

Other Organizations

The Board of Foreign Trade of the Ministry of Economic Affairs supervises and promotes exports and oversees imports. It also oversees the planned production of processed agricultural products for export.

The Council for Agricultural Planning and Development (CAPD), under the Executive Yuan, resulted from a 1979 reorganization of the Joint Commission on Rural Reconstruction (JCRR). The Food Processing Division of this organization assists in improving processing techniques and sanitation and developing new processed foods, and conducts research in the many areas of food science and technology.

The National Health Administration (NHA), under the Executive Yuan, consists of five departments: public health, medical affairs, communicable disease control, food and drug control, environmental health, and the Bureau of Food and Drug Inspection. Its major tasks are handling health affairs and food safety.

The Taiwan Supply Bureau, under the Taiwan Provincial Government, imports tin plate according to a production plan submitted by food processors which must be approved by the Ministry of Economic Affairs. Tin can manufacturers cannot individually import tin. The Bureau is responsible for supplying the food canneries with tin cans.

The Food Industry Research and Development Institute was established in 1967 by the food industries with financial assistance from government organizations. This institute helps solve the technical problems encountered by food processing plants, collects technical information, and conducts technical training. The services rendered by this institute have been greatly appreciated by the food industries.

TOTAL QUALITY CONTROL IN THE FOOD PROCESSING INDUSTRY

Before 1976, the export inspection system was solely responsible for the quality assurance of exports. Under this system, the BCIQ had to be notified when an exported commodity was ready for inspection. The BCIQ would then designate an inspector to carry out an on-the-spot check and pick up samples for quality assessment. Approved products would be given export approval.

This system was quite successful in the 1960s and into the early 1970s. However, due to the rapid growth of export trade in the 1970s, the BCIQ could not meet all the inspection demands. Occasional delays often caused complaints from manufacturers and trading firms. Thus the government decided that some measure must be taken to improve the inspection system.

It was believed that if all manufacturers had their own quality control system, export inspection by the BCIQ could be minimized or even eliminated. It was also believed that it would be much more constructive for the BCIQ to see that manufacturers had quality built into their products instead of waiting until the products were ready for export. Thus in 1976 the government decided to undertake a total quality control system.

The quality control program is carried out in five steps, namely, survey, surveillance, audit, performance analysis, and rating.

Survey

A survey is used to determine whether a plant has an "adequate" quality control system. In addition to general plant information, 34 items are examined and evaluated in each survey, including: 20 items directly related to product quality, 5 items to productivity, 5 items to safety and sanitation, and 4 items to management. Each of the 34 items are scored according to the extent of deficiency found during the survey. Definitions and scores for each category of deficiency are: (1) critical deficiencies that will cause total failure of the system (0.006); (2) major deficiencies that may significantly reduce the efficiency of the system (0.20); (3) minor deficiencies that may not significantly reduce the efficiency of the system (0.60); (4) incidental deficiencies that may not reduce the efficiency of the system, but are not desirable in quality control practice (0.85); and (5) no deficiency (0.95).

For example, a survey might produce the following results:

Deficiency	Number of items	Score
Critical	1	0.006
Major	5	0.20
Minor	11	0.60
Incidental	13	0.85
None	4	0.95
TOTAL	34	

$$R = \sqrt[34]{(0.006)\ (0.20)^5\ (0.60)^{11}\ (0.85)^{13}\ (0.95)^4}$$

$$= 0.54$$

This score would then receive a grade according to the following:

Score	Grade	
0.00 - 0.24	C	Unacceptable
0.24 - 0.31	B_2*	Poor temporary grades
0.32 - 0.36	B_1*	Poor temporary grades
0.37 - 0.75	B	Fair
0.75 - 1.00	A	Good

*Grades B_2 and B_1 were temporarily permitted to be exported until the end of 1978 and 1979, respectively.

Surveillance

Only if the final grade is above the minimum requirement for an approved export plant can the plant export its products. Once a plant's quality control system is approved it is put under surveillance to see whether the quality control system is functioning properly. Unannounced periodic visits are made by BCIQ representatives to monitor the quality control functions continuously. Frequency of visits is determined by the plant's quality control system rating--the higher the rating, the less frequent the visits. A plant with a B_2 rating is usually visited every 2 weeks; B_1, once a month; B, every 2 months; and A, every 4 months.

After each surveillance, any deficiencies are discussed with management, possibilities for corrective action are explored, and the progress of improvements is reviewed. The plant's quality control system is reevaluated and scored after each surveillance. The frequency of surveillance may be changed on the basis of the new rating.

Product Audit

Once a plant is under surveillance, periodic audits of finished product quality are made with the same frequency as surveillance. The purpose of the audit is to estimate the effectiveness of the plant's quality control system. No attempt is made to approve or disapprove for shipment any material sampled, except when an unsafe product is discovered. The results of the audits are evaluated and scored

according to the following: (1) critical—deficiencies cause a health hazard or seriously affect a product's reputation in international trade circles (0.06); (2) major--deficiencies cause the product to lose its function (0.2); (3) minor--deficiencies reduce the function of the product (0.60); (4) incidental—deficiencies may not affect the function of the product, but indicate a need for improvement (0.85); and (5) none (0.95). These scores are combined with the surveillance scores. The results are referred to the plant management for corrective action.

Audit results are judged against specifications--Chinese National Standards, the manufacturer's own specifications, the purchaser's specifications, or specifications issued by the BCIQ, whatever is appropriate.

Below is an example of a product audit rating:

Product characteristics	Score	
	Product A	Product B
Color	0.60	0.95
Flavor	0.20	0.85
Texture	0.20	0.60
Appearance		0.95

$$\text{Product A} = \sqrt[3]{(0.2)^2\ (0.60)} = 0.29$$

$$\text{Product B} = \sqrt[4]{(0.60)\ (0.85)\ (0.95)^2} = 0.82$$

$$\text{Factory Product Audit} = \sqrt{(0.29)\ (0.82)} = 0.49$$

Performance Analysis

Market reaction and customers' complaints are analyzed to help manufacturers correct defects, improve the design of the products, improve manufacturing processes, and strengthen their quality control system.

Final Quality Control System Rating

The product audit score is combined with the system survey score (adjusted after surveillance) to obtain a final factory quality control rating and grade.

$$R = \sqrt[4]{G^3_1 \times G_2}$$

$$= \sqrt[4]{(0.54)^3 \times (0.49)}$$

$$= 0.53 = \text{B grade}$$

G_1 = survey or surveillance

G_2 = product audit

Under the close supervision of government, as represented by the BCIQ, an overall quality control system has been set up in all manufacturing industries, including food industries. Manufacturers design their own systems according to their needs. However, it is the responsibility of the BCIQ to determine how appropriate the system is, and to ensure that the system is functioning at all times and that a well-organized system is reflected in their products.

Because of continuous efforts by the government, as well as keen competition in the international market, the ROC has a good start in setting up a quality control system. However, the success of the system still depends on many things:

- A factory quality control system must be set up according to the specific processing operations of the company, not to satisfy BCIQ inspectors. There were complaints from industries that too much paper work was required to meet the general BCIQ requirements. Cooperation between BCIQ inspectors and factory quality control personnel is needed to adjust the individual system so that it is tailored to specific cases and carried out effectively in each plant.

- Ongoing training of BCIQ inspectors as well as factory quality control personnel is of great importance. Because different products require different processes, BCIQ inspectors and quality control personnel should not only have a basic knowledge of quality control but also a thorough understanding of each processing procedure.

- Industry management should be well aware of the importance of product quality to further development of the industry. Setting up a good system, of course, requires some investment in equipment and personnel which management may hesitate to do. But in the long run, it is a sure way to cut production costs and consequently increase profits.

SAFETY ASPECTS OF FOOD ADDITIVES AND FOOD CONTAMINANTS

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INTRODUCTION

According to the Law Governing Management of Food Hygiene, promulgated on January 28, 1975 by the National Health Administration, a "food additive" is defined as a material that is added to or brought into contact with food in the course of manufacturing, processing, compounding, packing, transporting, and storing, for the purpose of coloring, seasoning, preserving, bleaching, emulsifying, flavoring, stabilizing quality, promoting fermentation, increasing viscosity, enhancing nutrition, or preventing oxidation.

A more concise definition is given by the U.S. National Academy of Sciences's Food Protection Committee (1959): "A food additive is a substance or mixture of substances, other than a basic foodstuff, which is present in food as a result of any aspect of production, processing, storage or packaging. The term does not include chance contaminants." The second sentence of this definition changes it from one primarily concerned with health to one more concerned with regulation, and it makes this statement a definition of intentional food additives and purposefully omits incidental, unintentional, or contaminating material. This ignores pesticides, packaging materials, fertilizers, promotants, and material that may inadvertently but consistently become a part of a food. Therefore, the broad meaning of the second sentence is a more acceptable definition. Fortunately, the Food Protection Committee (1961) accepted incidental additives within its domain.

Food additives are so much a part of eating today that most of us would find it difficult to assemble a meal that did not include them. In a typical lunch, for example--sandwich, instant soup, gelatin dessert, and a cola drink--the bread is fortified with vitamins and contains an additive to keep it fresh; the margarine is colored pale yellow; the luncheon meat contains nitrites; the soup contains an additive to keep it from becoming rancid; and the gelatin contains red coloring to making it pretty. Finally, without coloring, flavoring, sweeteners, or artificial carbonation, the cola beverage is nothing more than plain water.

The fact that additives are in foods does not please everyone. Many contend that some additives are often dangerous or are at least "unnecessary chemicals." The critics note that some additives can cause allergic reactions in some people.

In the March 1978 issue of Environment, Anita Johnson contends that "many hazardous chemicals in food and other products provide consumers with trivial or no benefits at all...." She cites a March 1976 Gallup Poll conducted for Redbook, which found that "59 percent of the women surveyed said they favored banning food additives used only to improve the appearance of food even if there was no positive evidence of harm." However, food processors apparently think otherwise and their sales figures seem to back their thinking. Moreover, the nation's laws on the subject are designed not to question use of additives but to assure that they are as safe as possible.

USE OF NITRITE AS A FOOD ADDITIVE IN CURED MEAT

The use of food additives in Taiwan has been complicated by the tremendous variety of Chinese foods. For example, Chinese sausages recipes have been formulated by individuals over several generations, and hundreds of different Chinese sausages are on the market. These sausages can be classified as factory-made or homemade; the composition of the former is more constant and homogeneous, while that of the latter is quite diverse and heterogeneous. When the nitrite contents of these sausages were estimated, it was found that the factory-made sausages had lower and more constant levels of nitrite than the homemade products which contain varying levels of nitrite (Lin 1978).

The nitrite contents of Chinese sausages were analyzed by Chen and Lin (1975) and Lin (1977, 1978), and the results of these two studies are presented in Table 1. At the time of this analysis, the maximum official allowance of nitrites in this kind of food was 70 parts per million (ppm); it is now revised to 50 ppm. During 1974-75, 100 percent of the sausage samples purchased from the Taipei area and

TABLE 1 Nitrite residue in sausage.

Nitrite ppm	1974 (Chen and Lin)		1977 (Lin)	
	Taipei 7 samples	Other area 30 samples	Taipei 62 samples	Other area 104 samples
> 14000	0	3	0	0
> 10000	0	8	0	0
> 5000	2	14	0	0
> 2000	4	17	0	3
> 1000	6	19	0	6
> 500	6	24	1	10
> 200	6	26	2	16
> 70	7 (100%)	26 (87%)	14 (23%)	33 (32%)

Source: L.T. Chen and K.M. Lin (1974) National Science Council Monthly (ROC) 3:21-29, and J.K. Lin (1977) Proceedings, Workshop on Food Safety (Taipei), pp. 53-63

87 percent from other areas were over 70 ppm. Approximately 10 percent and 46 percent of the collected samples were found to exceed 14,000 ppm and 5,000 ppm, respectively.

Educational efforts by the media have convinced many manufacturers that too much nitrite in processed food is unnecessary and harmful, and significant progress has been made in the proper use of this additive, as indicated by a survey performed in 1976-77. The results showed that only 23-32 percent of the sausage samples contained more than 70 ppm residual nitrite; none of the samples contained nitrite above 5,000 ppm (Lin 1977).

Data gathered by the Division of Food Sanitation, National Health Administration, and the Taipei Municipal Health Department Laboratory (Table 2) indicate that only 10 percent of recent sausage samples contained over 50 ppm nitrite. The data provided by the Taipei Municipal Health Department Laboratory were obtained from samples given by manufacturers. It is conceivable that the sampling methodology used has a profound effect on the data gathered. A nationwide inspection based on random samples would likely provide more reliable data.

TABLE 2 Nitrite residue in sausage and other foods (number over 50 ppm/number of samples).

	1977[a]		1978[a]		1980[b]	
Food	Number	Percent	Number	Percent	Number	Percent
Sausage	434/533	81	60/306	20	8/82	10
Ham	64/77	83	--	--	--	--
Dried meat	110/585	19	--	--	4/101	4
Pulverized meat	0/198	0	--	--	--	--

[a]Data from Annual Report (1977, 1978), Division of Food Sanitation, NHA.
[b]Data from Taipei Municipal Health Department Laboratory.

A number of studies have elucidated the toxicity of nitrite. Asahina, et al. (1971) reported that simultaneous oral administration of sodium nitrite and dimethylamine or methylbenzylamine to male mice produced acute synergistic toxicity, as evidenced by relative weight loss, mortality, and liver necrosis. Lijinsky, et al. (1973) demonstrated that tumors were induced in various organs of experimental animals fed amines and nitrite concurrently in diet and drinking water. The dimethylamine was shown to be the most abundant naturally occurring secondary amine in several fish and shrimp (Lin and Lai 1980). Recent studies have also demonstrated the presence of dimethylamine in wines and fermented soybean products (J. Lin, unpublished data). Fine, et al. (1977) demonstrated conclusively that N-nitrosamines could be formed in vivo in man after ingestion of conventional foodstuffs such as bacon, spinach, tomato, and beer.

In the United States, nitrites were first approved for direct use in meats in 1925 by the U.S. Department of Agriculture (USDA). Today, it is used primarily to prevent botulism, but also to create a desired

color and flavor in processed meats, poultry, pet foods, and home-cured products. However, nitrites may carry their own health hazards. Since 1962, scientists have known that nitrites can react with secondary or tertiary amines in food to form nitrosamines, compounds that cause cancer in laboratory animals. The U.S. Food and Drug Administration (FDA) and USDA have already acted to limit the nitrosamine risk, but the cancer risk apparently does not stop with nitrosamines. Other studies have shown that nitrites themselves cause cancer in test animals (Smith 1978).

Under the present law, nitrites are banned as a food additive; however, nothing in the law specifies what to do when the substance in question also protects against another very serious health risk. Fearing that an immediate ban of nitrites would result in many deaths from botulism, FDA and USDA have submitted legislation to Congress that would permit a gradual phase-out of nitrites as soon as safe, feasible alternatives for prevention of botulism become possible (Lehmann 1979).

COAL TAR DYES IN FOODS AND DRUGS

Coal tar dyes in 32 samples of foods and drugs were analyzed with polyacrylamide gel disc electrophoresis by Yeh and Yi (1976). They found that brillant blue, amaranth, sunset yellow, new coccine, and tartrazine were among the most popular dyes in foods and drugs (Table 3). They also reported that about one third of the samples analyzed contained amaranth (red dye No. 2) which was banned in Taiwan in 1975 and in several other countries, including the United States. Some other illegal dyes were found in a few samples.

The chronic toxicity of certain synthetic food dyes in rats has been investigated by Lin, et al. (1977). The food dyes amaranth, tartrazine, new coccine, and sunset yellow fed at a concentration of 8.01 millimoles per kilogram of the diet for 560 days increased mortality from 17 to 56 percent in male and female rats. Histopathological studies have unveiled the hepatotoxicities of amaranth, tartrazine, and sunset yellow as indicated by the presence of fatty liver and hepatic necrosis in the dye-treated rats (Table 4). The importance of employing a low-protein diet to demonstrate the hepatotoxicities of these dyes was discussed with special reference to a previous study by Hannell, et al. (1958) which used a high-protein diet and failed to demonstrate this toxicity.

TABLE 3 Coal tar dyes in foods and drugs.

Dye	Candies	Soft drinks	Jams	Drugs
Brilliant blue FCF	+	+	—	+
Amaranth	+	+	—	+
Sunset yellow FCF	+	+	+	+
New coccine	+	+	+	+
Tartrazine	+	+	+	+
Eosine	—	—	—	+
Indigotine	—	—	—	+

Source: D.B. Yeh and S.D. Yi (1976) Food Science (ROC) 3(2):38-45.

TABLE 4 Chronic toxicity of certain synthetic food dyes in rats.

General name	Chinese certified number	U.S. certified number	Conc. mmole/kg	Fatty liver	Liver necrosis
Amaranth	FD Red No. 2	FD and C Red No. 2	8.01	+++	+
Tartrazine	FD Yellow No. 4	FD and C Yellow No. 5	8.01	++	+
New coccine	FD Red No. 6	—	8.01	±	-
Sunset yellow	FD Yellow No. 5	FD and C Yellow No. 6	8.01	+	±

Source: J.K. Lin, et al. (1977) Proceedings, National Science Council (ROC), 1:46-52
Experiment period, 560 days. Low protein (10-12%) diet.

THE ILLEGAL USE OF DYES, SWEETENERS, AND PRESERVATIVES

Each year the Division of Food Sanitation of the National Health Administration has offered project grants to research institutes to support examination of the illegal use of dyes, sweeteners, and preservatives in certain foods. The results are given in Table 5. Twelve to 22 percent of candies (71/591) and cakes (97/439) were found to contain uncertified dyes. A high percentage of jams (582/816), including seasoned fruits,

TABLE 5 Illegal use of dyes, sweeteners, and preservatives (number of samples fail to pass/number of samples analyzed).

	1977			1978		
Food	Dye	Sweetener	Preservative	Dye	Sweetener	Preservative
Cakes	97/439	0/277	--	--	--	--
Candies	71/591	0/301	--	--	--	--
Jams	76/816	582/816	--	38/363	254/363	--
Fruit jels	--	--	--	8/159	29/159	18/159
Pickles	--	--	--	9/151	14/151	2/151
Bean cakes	26/207	--	51/207	0/151	--	0/151
Fruit juices	--	--	--	0/153	0/153	0/153
Cooked rice	--	--	0/518	--	--	--
Milk products	--	--	31/600	--	--	--

Source: Annual Report (1977, 1978) Division of Food Sanitation, NHA

contained artificial sweeteners such as cyclamate, saccharine, etc. No preservatives (0/518) were found in cooked rice sold in the market.

MARKETING THE DYED YELLOW CROAKER

The yellow croaker (yellow fish) is a highly regarded seafood in Taiwan. These fish are primarily caught off the east coast of mainland China in the spring.

Two kinds of yellow croakers exist, Pseudosciaena manchurica (Jordan and Thompson) and Pseudosciaena crocea (Richardson). Both the white flower fish (Nibea albiflora Richardson) and the spiked-head fish (Nibea acuta Tang) are similar morphologically to the Pseudosciaena manchurica. Occasionally, white flower fish or spiked-head fish stained with crocien or carotene are sold as yellow croaker. A survey carried out by Yu (1977) found that 36-86 percent of yellow fish sold in the marketplace were dyed (Table 6). The percentage of dyed fish varied with seasons. During the winter (December-February), more yellow croakers were caught; therefore fewer dyed yellow fish (36 percent) were found in the marketplace. In the autumn (September-November), fewer yellow croakers were available and more dyed fish (86 percent) were sold.

Fish were dyed to change a low-price fish into a high-price one, and to make an unfresh real yellow croaker look fresher in appearance. According to the ROC's Law Governing the Management of Food Hygiene (1975), no food dye is allowed in fresh fish. An appropriate action should be taken to enforce this law.

BORAX AS A FOOD PRESERVATIVE

Borax, toxic to both man and animal, is not permitted by law to be used as a preservative. However, this substance has been used in some traditional Chinese foods. A survey by Jeng and Huang (1976) of 915 food samples purchased from 46 markets all over the island found that borax was present in 96 samples from 20 kinds of foods. The foods that contained appreciable amounts of borax are summarized in Table 7. Chinese ham, oil noodle, and rice ball material often contained borax. The concentration of borax in the latter was as high as 4.5 percent, based on its wet weight. The rice ball material is made from wet rice grain by pulverizing, dehydrating, and finally packaging with a suitable preservative such as borax. To serve, the material is moistened with water, pressed evenly, and rice balls of about 1-2 centimeters in diameter are made by hand. They are cooked in boiling water with sugar or other flavoring agents.

The addition of borax to rice ball material and oil noodle results from the recipe used by the ancient Chinese. From daily experience, they found that borax inhibited the growth of microbes, induced a physico-chemical change in the texture of food, and made it more elastic, tasty, and enjoyable.

TABLE 6 Dyed yellow fish in markets.

District	September-November			December-February		
	Sample	Dyed	Percent	Sample	Dyed	Percent
Su-ou	--	--	--	11	3	27
Kee-lung	60	49	82	30	17	57
Taipei City	12	12	100	41	12	30
Taipei hsien	9	9	100	6	3	50
Taichung	--	--	--	5	1	20
Kaohsiung	--	--	--	14	3	21
TOTAL	81	71	86	107	38	36

Source: C.Y. Yu (1977) Journal of the Chinese Nutrition Society 2(2):13-19

TABLE 7 Borax used as a preservative in Taiwan (number of positive samples/number of samples analyzed, 1976).

Food		Number	Percent	Borax conc., percent (based on wet wt.)
Meat product:	Chinese ham	16/25	64	0.50-2.50
	Dried meat	7/35	20	0.05-0.25
	Meat ball	2/16	13	0-0.25
	Sausage	3/39	7.7	0.10-0.25
Fish product:	Shrimp ball	3/13	27	0-0.25
	Fish cake	1/5	20	0-0.10
	Fish ball	6/43	14	0-0.10
Wheat product:	Oil noodle	16/26	62	0-0.25
	Fried noodle	4/20	20	0-0.25
	Plain noodle	5/34	15	0.05-0.25
Rice product:	Rice ball material	5/7	71	1.25-4.50
	Rice cake	5/15	33	0.05-0.25

Source: S.S. Jeng and D.F. Huang (1976) Food Science (ROC):124-132
Turmeric paper method, AOAC (1970), 11th ed., p. 335.

Data provided by the Division of Food Sanitation indicates that less borax was used as a food preservative in 1978 than in 1977 (see Table 8).

TABLE 8 Borax used as a food preservative in Taiwan (number of positive samples/number of samples analyzed, 1977, 1978).

	1977		1978	
Food	Number	Percent	Number	Percent
Sausage	35/533	6.6	--	--
Ham	64/77	83.1	6/49	12.2
Cured meat	--	--	16/56	28.6
Dried meat	31/600	5.2	--	--
Pulverized meat	3/198	1.5	--	--
Fish ball	92/608	15.1	--	--
Shrimp	--	--	7/306	2.3

Source: Division of Food Sanitation, NHA, ROC (1977, 1978)

LEVELS OF HEAVY METALS IN GRAPE WINE AND BLESSED FISH

The heavy metals contents of red and white grape wines manufactured by the Taiwan Tobacco and Wine Monopoly Bureau were determined by using atomic absorption spectrophotometry with a flame system on samples that had been decomposed by the wet ashing method using nitric acid and perchloric acid (Lee 1976). The results are summarized in Table 9. The maximum allowance of heavy metals set by West Germany is listed for comparison. It is obvious that the levels of these metals in the grape wines are quite acceptable.

The heavy metals contents of blessed fish raised in the river have also been determined (Jeng 1978) and are shown in Table 10.

LEAD IN PIDAN

Pidan, a favorite dish of most Chinese people, is made by treating a duck's egg with an alkaline medium for a period of time. Traditionally, the alkaline gelation of the duck egg white required

TABLE 9 Heavy metals contents of grape wines.

Wine	Heavy metals, ppm (mean)					
	Fe	Cu	Mn	Zn	Pb	Hg
Red grape wine (n = 3)	4.38	0.59	3.36	0.72	0.31	0.0063
White grape wine (n = 3)	2.83	0.48	2.33	0.80	0.15	0.0056
Max. allowance (W. Germany)	15	5	--	6	0.4	0.01

Source: Chuan-Hui Lee (1976) Annual Report, Research Institute for Wines, Taiwan Tobacco and Wine Monopoly Bureau, pp. 101-114

TABLE 10 Heavy metals contents of released fish (Taiwan river).

Element	Content, ppm			
	Muscle		Viscera	
	Mean	Range	Mean	Range
Hg	0.08	0 - 0.17	0.08	0 - 0.09
Pb	0.1	0 - 0.4	0.5	0 - 2.0
Cd	0.02	0 - 0.10	0.07	0 - 0.15
Cu	1.4	0.5 - 1.6	5.9	1.4 - 15.0
Ni	0.3	0 - 0.18	2.4	0.1 - 7.2
Zn	25	6 - 92	46	16 - 64

Source: S.S. Jeng (1978) Proceedings, Workshop on Food Safety (Taipei) pp. 37-52

Official allowance Hg: 0.5 ppm.

several weeks to several months. However, recent research in food technology has developed a rapid (7-10 days) gelation by using lead salt in the alkaline medium, a procedure adopted by food industries for mass production of pidan.

This procedure raises the problem of lead contamination in the final product. The Division of Food Sanitation has set the allowable content of lead in pidan at 2 ppm. In 1977 and 1978, 87.8 percent and 64.2 percent, respectively, of pidan in the markets were found to contain more than 2 ppm lead (Table 11). Fortunately, recent data from the Taipei Municipal Health Department Laboratory (1980) indicate that only 4 percent of the samples analyzed contained over 2 ppm.

TABLE 11 Lead content of pidan (number of samples above 2 ppm/ number of samples analyzed).

Year	Number	Percent
1977[a]	165/188	87.8
1978[a]	217/338	64.2
1980[b]	—	4.0

[a]Data from Annual Report (1977, 1978), Division of Food Sanitation, NHA, ROC.
[b]Data from Taipei Municipal Health Department Laboratory.

The Department of Animal Husbandry at National Taiwan University has developed a new lead-free method for preparing pidan, which has been adopted by certain industries (C.W. Lin, personal communication).

FORMALDEHYDE ELUTED FROM PLASTIC BOWLS AND CHOPSTICKS

The extractable formaldehyde contained in some plastic dinnerware in Taiwan--such as melamine resin bowls, urea resin chopsticks, and bamboo chopsticks coated with urea resin--was studied by Kuo, et al. (1978). The formaldehyde concentrations found in this dinnerware were

25.2 ppm, melamine bowls; 42.0 ppm, urea resin chopsticks; and 20.2 ppm, bamboo chopsticks coated with urea resin (see Table 12). The maximum permissible concentration according to the Chinese National Standard is 3 ppm.

TABLE 12 Formaldehyde eluded from plastic bowls and chopsticks.

Material	No. of brands	HCHO conc., ppm (range)
Plastic bowls (Melamine ware)	10	25.2 (16.7 - 37.6)
Plastic chopsticks (Made of melamine or urea resin)	5	42.0 (31.8 - 50.4)
Bamboo chopsticks (Coated with urea-HCHO resin)	9	20.2 (13.2 - 27.9)

Source: T.L. Kuo, et al. (1978) Journal of the Formosan Medical Association 77:218-225

It has been reported that the ingestion of formaldehyde leads to a number of serious gastrointestinal problems (van Gaal 1931; Roy, et al. 1962). Kuo, et al. (1978) suggests that the safety of using these kinds of dinnerware should be carefully evaluated because of popular use of melamine and urea resin dinnerware by households, schools, and public restaurants in Taiwan.

One recent survey has shown that the concentration of extractable formaldehyde in melamine bowls is less than 1 ppm (T.L. Kuo, personal communication). The indicates that dinnerware made from pure melamine resin releases less formaldehyde than that made from urea resin or a mixture of urea and melamine resin. Thus, dinnerware made from pure melamine resin is possibly acceptable for daily use.

MYCOTOXIN CONTAMINANTS IN FOODS AND DOMESTIC FOODSTUFFS

Because of Taiwan's warm, humid climate, it is conceivable that foodstuffs can be spoiled by fungi and thus contaminated with various

mycotoxins. Tung, et al. (1967) surveyed foodstuffs in Taiwan for the aflatoxin-producing strains of Aspergillus flavus in 1966. They reported that 16 out of 106 fungi samples were capable of producing aflatoxins. Ling, et al. (1968) surveyed 37 samples of unrefined peanut oil, 12 samples of peanut cake, 8 samples of peanut kernel, and 12 samples of peanut butter, and found that 21 percent, 41.6 percent, 37.5 percent, and 59 percent, respectively, of these peanut products were contaminated with aflatoxins at levels ranging from 12 to 737 parts per billion (ppb). Recently, over 400 samples of locally consumed peanuts and peanut products including peanut butter, peanut cake, fried peanuts, roast peanuts, and peanut oil were analyzed for the presence of aflatoxins by the HPLC (Wei and Wei 1980). The incidence of aflatoxin contamination in the examined samples was 23.4 percent. Aflatoxin B_1 was found in all the positive samples ranging from 16 to 1,075 ppb.

Tang and Ling (1977) have surveyed 149 samples of soy sauce and 80 samples of fermented soybean paste for possible contamination with 13 mycotoxins. Among the samples of soy sauce, only one was identified as containing aflatoxin G_2, whereas other mycotoxins were not detected (Table 13). Among the fermented soybean samples, there were 1 aflatoxin B_1, 4 aflatoxin B_2, 1 aflatoxin G_1, and 8 aflatoxin G_2 positive samples, whereas other mycotoxins were not detected (Table 13).

Tsang and Yuan (1978) surveyed aflatoxin-contaminated domestic feedstuffs in 1977. A total of 239 feed samples, including swine, chicken, duck, fish, and cattle feedstuff, were collected from various districts of Taiwan. The results are summarized in Table 14. Swine and chicken feeds were more severely contaminated with aflatoxins than the other samples.

PESTICIDE RESIDUES IN FOODSTUFFS

Because of the continuing rapid increase in the use of pesticides in Taiwan, much attention has been focused on pesticide contamination of food and of the environment. Although the use of organochlorine insecticides, such as aldrin, dieldrin, BHC, heptachlor, and DDT for agricultural purposes has been banned in Taiwan during recent years, their residues remain in the environment. In an attempt to evaluate the possibility of contamination of food by these residues, a large-scale research program was carried out by the Plant Protection Center (PPC) to monitor their concentrations in river water and sediments, in soils of various types of crop land, and in biotic samples (Fu 1976). While most of these organochlorine residues have been found in the environment (Table 15), the levels were rather low, mostly within the ppb range. However, the relatively high residue

TABLE 13 Mycotoxins detected in soy sauce and soybean paste.

Mycotoxin	Sauce (194 samples)		Paste (80 samples)	
	Suspected	Positive	Suspected	Positive
Aflatoxin B_1	--	--	19	1
Aflatoxin B_2	--	--	33	4
Aflatoxin G_1	8	--	25	1
Aflatoxin G_2	11	1	53	8
Sterigmatocystin	13	--	--	--
Ochratoxin	40	--	44	--
Citrinin	9	--	24	--
Patulin	9	--	27	--
Aspertoxin	9	--	15	--
Luteoskyrin	2	--	--	--
Diacetoxyscirpenol	2	--	1	--
T-2 toxin	4	--	19	--
Zearalenone	--	--	26	--

Source: Tang and Lin (1977) Journal of the Formosan Medical Association 26:482-487 TLC: 2 ppb

TABLE 14 Aflatoxin B_1 contamination in domestic feedstuff.

Feedstuff	No. of specimens analyzed	Aflatoxin B_1		
		Positive	Above 100 ppb	Above 200 ppb
Swine	116	47 (40.5%)	14 (12.1%)	9 (7.8%)
Chicken	156	59 (37.5%)	18 (115%)	11 (7.1%)
Duck	9	3 (33%)	1 (11%)	1 (11%)
Cattle	4	1 (25%)	0	0
Fish	4	0	0	0

Source: T.C. Tseng and G.F. Yuan (1978) National Science Council Monthly (ROC) 6(8):756-769

TABLE 15 Residue samples of organochlorine insecticides in water samples collected from Tatu Chi (November 1973-December 1976).

Compound	Number of samples analyzed	Number of positive samples	Percent positive samples	Average residue levels (ppb)	Range of detected residues (ppb)
Aldrin	456	120	46.1	0.030	0.001-1.596
Dieldrin	456	186	40.8	0.022	0.001-0.277
Lindane	456	360	78.9	0.022	0.001-0.149
Heptachlor	456	78	19.2	0.016	0.001-0.247
Heptachor epoxide	456	86	18.9	0.009	0.001-0.127
DDT	456	74	35.1	0.077	0.002-0.568
DDE	456	136	29.8	0.007	0.001-0.066
TDE	456	60	13.2	0.020	0.001-0.227
DDTR	456	154	33.8	0.022	0.001-0.568

Source: T.Y. Ku (1976)

levels found in the eggs of ducks raised in river water (Table 16) show that contamination of food with these residues is possible. Fortunately, the overall residue levels in both the water and sediments of the major rivers have shown a tendency to decline over the 3-year period 1973-76 of monitoring (Li 1979).

Analyses of rice grain samples collected from 86 townships in Taiwan during 1975 revealed that about 95 percent of the samples contained detectable amounts of arsenic. The arsenic levels in the grains of second crop rice were higher than those from first crop rice (Table 17). The townships from which the rice grain samples with high arsenic levels (more than 0.76 ppm) were found, were widespread geographically (Li, et al. 1978).

An analysis of pork samples collected by the PPC from 60 retail markets all over the Island showed the presence of DDT and its metabolites in all samples. Residues of lindane, heptachlor, heptaclor epoxide, and dieldrin were also found in 6-33 percent of the samples (Table 18). Residues of aldrin, endrin, and methoxychlor were not detected (Li, et al. 1975). The concentrations of all pesticide residues found in the pork samples were much lower than the tolerances set by the U.S. Food and Drug Administration.

TABLE 16 Summary of organochlorine residue in duck eggs from duck-raising farms in Taiwan.

Compound	Number of samples analyzed	Number of positive samples	Percent positive samples	Average residue levels (ppb)	Range of detected residues (ppb)
Aldrin	81	39	48.15	6.2	1.3- 18.7
Dieldrin	81	78	96.30	39.2	6.3- 344.4
Lindane	81	5	6.17	9.4	5.8- 15.5
Heptachlor	81	24	29.63	5.1	2.6- 8.9
Heptachor expoxide	81	36	44.44	5.3	1.5- 18.9
DDT	81	78	96.30	128.2	3.3- 652.3
DDE	81	80	98.77	486.7	18.5-3268.2
TDE	81	31	38.27	20.5	0.5- 83.9
DDTR	81	80	98.77	635.4	29.1-3859.0

Source: T.Y. Ku (1976)

TABLE 17 Summary of arsenic levels in rice grains from different locations in Taiwan (1975).

	Ponlai rice		Native rice		Sen rice	
	First crop	Second crop	First crop	Second crop	First crop	Second crop
Number of samples analyzed	83	84	67	53	22	20
Number of positive samples	80	79	61	50	21	19
Average residual levels (ppm)	0.43	0.53	0.40	0.41	0.30	0.50
Maximum residual levels (ppm)	1.04	1.74	1.41	1.47	0.58	1.25

Source: G.C. Li, et al. (1978)

TABLE 18 Residual levels of chlorinated hydrocarbon insecticides in the pork samples of Taiwan.

Insecticide	Percentage of positive samples		Average residual levels (ppm)		Maximum residual levels (ppm)		Tolerance (ppm)*
	Muscular tissue	Adipose tissue	Muscular tissue	Adipose tissue	Muscular tissue	Adipose tissue	
Lindane	23	12	0.004	0.009	0.0078	0.0169	0.3
Heptachlor	22	22	0.004	0.006	0.0085	0.0116	
Heptachlor epoxide	0	6	--	0.017	--	0.0371	0.3
Aldrin	0	0	--	--	--	--	
Dieldrin	28	33	0.008	0.037	0.0126	0.0848	0.3
Endrin	0	0	--	--	--	--	0.3
DDT	58	95	0.061	1.294	0.2355	1.9928	7.0
DDD	8	22	0.014	0.033	0.0319	0.3208	7.0
DDE	98	100	0.036	0.290	0.1074	0.9463	7.0
Methoxychlor	0	0	--	--	--	--	

*Cited from U.S. Food and Drug Administration (1971).

Source: G.G. Li, et al. (1977, 1978)

A Pesticide Control Act promulgated and implemented in 1973 states that pesticides cannot be distributed on Taiwan without government approval, which is given only after all necessary data on their effectiveness, toxicology, and residue tolerance are established under local environmental conditions and found to be satisfactory. Supervised trials have been conducted by PPC in cooperation with various agricultural research institutes and stations for this purpose. Table 19 shows some of the results obtained by these trials on cabbage (Li, et al. 1978).

Twenty-two bioassay stations have been set up on Taiwan by the provincial Department of Agriculture and Forestry and the Taiwan

TABLE 19 Insecticide residues in cabbage resulting from supervised trials in Taiwan.

Pesticides	Rate (kg a.i./ha)	No.of treatment	Residue (mg/kg) Interval after last application (day)							
			3	6	9	12	15	18	21	24
10% Kestral E.C.	0.5	3	0.2800	-	0.1639	0.1115	0.0118	-	-	-
	0.25	3	0.2971	-	0.1784	0.1741	-	-	-	-
	0.16	3	0.1482	-	0.1077	0.0866	0.0307	-	-	-
28% Decis E.C.	0.28	5	0.3648	0.1368	0.1100	0.0434	0.0668	0.0034	0.0022	<0.0022
	0.56	5	0.4913	0.2343	0.1445	0.0397	0.0210	0.0144	0.0022	<0.0022
20% Sumicidin W.P.	0.13	4	0.6845	0.4658	0.1376	0.0564	-	-	-	-
	0.10	4	0.5599	0.2119	0.1523	-	-	-	-	-
	0.08	4	0.5261	0.1386	0.1375	0.0514	-	-	-	-
5% Ripcord E.C.	0.2	4	0.5711	0.5032	0.1891	0.1584	0.0442	-	0.0303	-
	0.1	4	0.1791	0.1584	0.1648	0.0628	0.0297	-	-	-
	0.06	4	0.1480	0.1101	0.0727	0.0269	0.0124	-	-	-
40.64% Furadan 4F	0.50	5	0.0683	0.0482	0.0194	0.0166	-	-	-	-
	0.76	5	0.0583	0.0516	0.0531	0.0450	0.0126	-	-	-
25% Orthene E.C.	0.75	4	3.3087	5.4453	-	2.4326	-	-	0.0359	-
	0.47	4	3.7668	-	1.5438	-	-	-	0.5389	-

Source: G. C. Li, et al. (1977, 1978)

Agriculture Research Institute to make quick assessments of the total toxicity of pesticide in fresh vegetables in the local market before they reach consumers. The number of vegetable samples found to have toxicity levels greater than the toxicity of 2.1 ppm parathion to houseflies has decreased sharply since 1966 (Table 20) (Li 1979).

GENERAL REMARKS ON FOOD SAFETY

Toxic Chemicals in Food

The food industry is not permitted to use chemicals known to be toxic. Each substance must be proven safe for use in the amount normally consumed. Occasionally, the more refined methods of assessment may demonstrate that a substance is not as benign as once believed. In this case, the substance is outlawed or the amounts permitted are restricted to an established level of safety.

Toxicity is the ability of a substance to produce injury; hazard is the probability that injury will result from the use of quantity of the substance in a given manner; and safety is the practical certainty that injury will not result. Therefore, a toxic compound at a very low concentration may still be safely tolerated; on the other hand, a rather nontoxic compound at an extremely high concentration may not be tolerated by certain organisms. It is important that the level of safety for all food components, including basic stuffs and additives, be systematically investigated and established.

Toxic Compounds from Heat Treatment of Foods

Many foods contain both proteins and carbohydrates, which when heated undergo a Maillard browning reaction to form a variety of materials (Lee 1978). These are often associated with the characteristic flavor and color of a cooked or processed food. Research over the past several years suggests that under some conditions the ingestion of heavily-browned foods results in marked physiological and toxicological change in rats. The toxic compounds that cause these changes have not yet been identified.

Toxic Compounds from the Interactions of Additives with Foods

Many of the compounds that come into contact with foods either by chance or as an intentional addition are chemically reactive. Chemical reactions between the components of the food and the foreign compound will take place and may produce some biohazard derivatives.

TABLE 20 Toxicity levels of vegetable samples.

Year	Number of samples analyzed	Toxicity higher than 2.1 ppm of parathion to houseflies	
		Number of samples	Percent
1966	2,513	121	5.62
1967	5,124	321	4.40
1973	24,281	20	0.08
1974	23,756	10	0.042
1975 (Jan. to June)	11,850	4	0.034
1977 (July) to 1978 (June)	15,942	2	0.013

Source: G. C. Li (1979)

Of the constituents of foods, proteins are particularly at risk because of the range of reactive groups they contain. The classical example of the interaction of an additive and a food constituent came to light during the search for a cause of some cases of canine hysteria. It was found that the hysteria only developed if the dogs were fed relatively large amounts of bread made from flour treated with nitrogen trichloride. The toxic compound in the bread was shown to be methionine sulphoximine formed by a reaction between nitrogen trichloride and the methionine of flour proteins.

When protein is exposed to severe treatment with alkali, lysine and cysteine residues can be eliminated with formation of lysinoalanine which may be toxic. Lysinoalanine is of importance not only as a mechanism by which lysine becomes unavailable but also because after absorption it becomes concentrated in the cortex of the kidney where it produces cell enlargement and multinucleation (Woodard and Short 1973). The toxicological implications of these changes in the kidney have not been resolved.

The interaction of nitrites with foods is being vigorously investigated because of the possibility that nitrosamines, which have been shown to be carcinogenic, are formed by the reaction of nitrite with secondary amines present in food. In Norway, an outbreak of liver

disease among ruminants was traced to the feeding of a fish meal that had been exposed to high concentrations of nitrite. The toxic meal was shown to contain dimethylnitrosamine.

In conclusion, the occurrence of methionine sulphoximine, lysinoalanine, and nitrosamines in processed foods represents a setback in food processing. More attention should be paid to the toxicological aspects of these unexpected by-products. Furthermore, when evaluating the safety aspects of food additives, the possible toxicity of any derivative that may arise from the interaction of food additives with food constituents should be considered.

REFERENCES

Asahina, S., M.A. Friedman, E. Arnold, G.N. Miller, M. Mishkin, Y. Bishop, and S.S. Epstein (1971) Acute synergistic toxicity and hepatic necrosis following oral administration of sodium nitrite and secondary amine to mice, Cancer Research 31:1201.

Chen, L.T. and K.H. Lin (1975) Correlation of added and residual nitrite in cured meat, National Science Council Monthly (ROC) 3(1):21-29.

Fine, D.H., R. Ross, D.P. Rounlehles, A. Silvergleid, and L. Song (1971) Formation in vivo of volatile N-nitrosamines in man after ingestion of cooked bacon and spinach, Nature 265:753-755.

Food Protection Committee, National Research Council (1959) Principles and Procedures for Evaluating the Safety of Food Additives. National Academy of Sciences Publication No. 750, Washington, D.C.

Food Protection Committee, National Research Council (1961) The Use of Chemicals in Food Production, Processing, Storage and Distribution. National Academy of Sciences Publication No. 887, Washington, D.C.

Gaal, Van (1931) Zur Kenntnis der Anatomischen Veranderungen bei der Formalinvergiftung. Zbl. Allg. Pathol. 51, 257-262.

Jeng, S.S. (1978) Proceedings, Workshop on Food Safety (Taipei). Sponsored by the Food Industry Research and Development Institute and the National Science Council.

Jeng, S.S. and D.F. Huang (1976) Survey on the use of borax as food preservatives in Taiwan, Food Science (ROC) 3(1):124-133.

Ku, T.Y. (1976) In: Chlorinated hydrocarbon insecticide residues in the agricultural environment of Taiwan. (A pamphlet).

Kuo, T.L., J.S. Lai, and W.S.J. Lin (1978) Formaldehyde content of some plastic dinnerwares in Taiwan, Journal of the Formosan Medical Association 77:218-225.

Lee, T.C. (1978) Nutritional and toxicological effects of Maillard browning of food products, Proceedings, Food Safety Conference (Taipei). Sponsored by the Food Industry Research and Development Institute and the National Science Council.

Lehmann, P. (1979) FDA Consumer. HEW Publication No. (FDA) 79-2118. May.

Li, G.C. (1979) Pp. 173-188 in: Sensible Use of Pesticides. FFTC Book Series No. 14.

Li, G.C., S.H. Chiang, P.Y. Kuo, and Y.S. Lee (1975) Preliminary Report No. 3. Pesticide Residue Division, Plant Protection Center, Taiwan, R.O.C.

Li, G.C., W.C. Fei, and Y.P. Yen (1978) Research Paper No. 17, Pesticide Residue Division, Plant Protection Center, Taiwan. R.O.C.

Lijinsky, W., H.W. Taylor, C. Synder, and P. Nettesheim (1973) Malignant tumors of liver and lung in rats fed aminopyrine or heptamethyleneimine together with nitrite, Nature 244:176-178.

Lin, J.K. (1977) The contaminstion of nitrite and nitrosamines in Chinese foods. Proceedings, Workshop on Food Safety (Taipei). Sponsored by the Food Industry Research and Development Institute and the National Science Council.

Lin, J.K. (1978) Studies on the chemical toxicants in Chinese Foods I. National Science Council Monthly (ROC) 6(2):155-162.

Lin, J.K., S.S. Sung, K.H. Ling, R.B. Lee, and S.S. Chang (1977) Studies on the chronic toxicity of certain synthetic food dyes in rats, Proceedings, National Science Council (ROC), 1(II):46-52.

Lin, J.K. and C.C. Lai (1980) High performance liquid chromatographic determination of naturally occurring primary and secondary amines with dabsyl chloride. Analytical Chemistry 52:630-635.

Ling, K.H., C.M. Tung, I.F. Sheh, and J.J. Wang (1968) Aflatoxin B_1 in unrefined peanut oil and peanut products in Taiwan, Journal of the Formosan Medical Asaociation 67:309-314.

Mannell, W.A., et al. (1958) Chronic studies on food colours, part IV. Observation on the toxicity of tartrazine, amaranth and sunset yellow in rats. Journal of Pharmacology 10:625-634.

Roy, M., Jr., et al. (1962) Corrosive gastritis after formaldehyde ingestion: report of a case. New England Journal of Medicine 66:1248-1250.

Smith, R.J. (1978) News and comment, Science 201:887-889.

Tang, S.Y. and K.H. Ling (1977) Mycotoxins in soy sauce and fermented soybean paste of Taiwan, Journal of the Formosan Medical Association 76:482-487.

Tseng, T.C. and G.F. Yuan (1978) Survey on aflatoxin contamination of domestic feedstuff, National Science Council Monthly (ROC) 6(8):756-759.

Tung, T.C., et al. (1967) Survey of foodstuffs in Taiwan for the aflatoxin producing strains of Aspergillus flavus, Journal of the Formosan Medical Association 66:339-342

Wei, D.L. and R.D. Wei (1980) HPLC determination of aflatoxins in peanut and peanut products of Taiwan, Proceedings, National Science Council (ROC) 4(2):152-155.

Woodard, J.C. and D.D. Short (1973) Toxicity of alkali-treated soyprotein in rats, Journal of Nutrition 103:569-574.

Yeh, D.B. and S.D. Yi (1976) Polyacrylamide gel disc electrophoresis of water soluble acid coal tar dyes II. Food Science (ROC) 3(2):38-45.

OFFICIAL TESTING AND ANALYSIS OF FOOD HYGIENE IN TAIWAN, REPUBLIC OF CHINA

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In Taiwan, food hygiene is controlled by the National Health Administration, while the quality of foods as a marketing commodity is governed by the Bureau of Commodity Inspection and Quarantine of the Ministry of Economic Affairs. Implementation of food hygiene laws and regulations, as well as enforcement of a compliance program, are performed within the National Health Administration, while official testing and analysis of food hygiene are conducted by the Food and Drug Bureau which operates under the direct supervision of the National Health Administration. In addition, 21 units of the local health bureaus carry out direct inspections and some limited laboratory examinations within their capabilities. This report is concerned with the testing and analysis of food hygiene within the Food and Drug Bureau.

ORGANIZATION, FACILITIES, AND TRAINING

The Food and Drug Bureau (FDB) was established on September 20, 1978, by reorganizing the Taiwan Provincial Hygienic Laboratories and improving facilities and personnel (see Figure 1). Of FDB's five divisions, Division IV is responsible for the laboratory chemical and microbiological examination of foods. Division V is responsible for training personnel at the district/local levels in food inspection and examination, as well as for information resources on food and drug

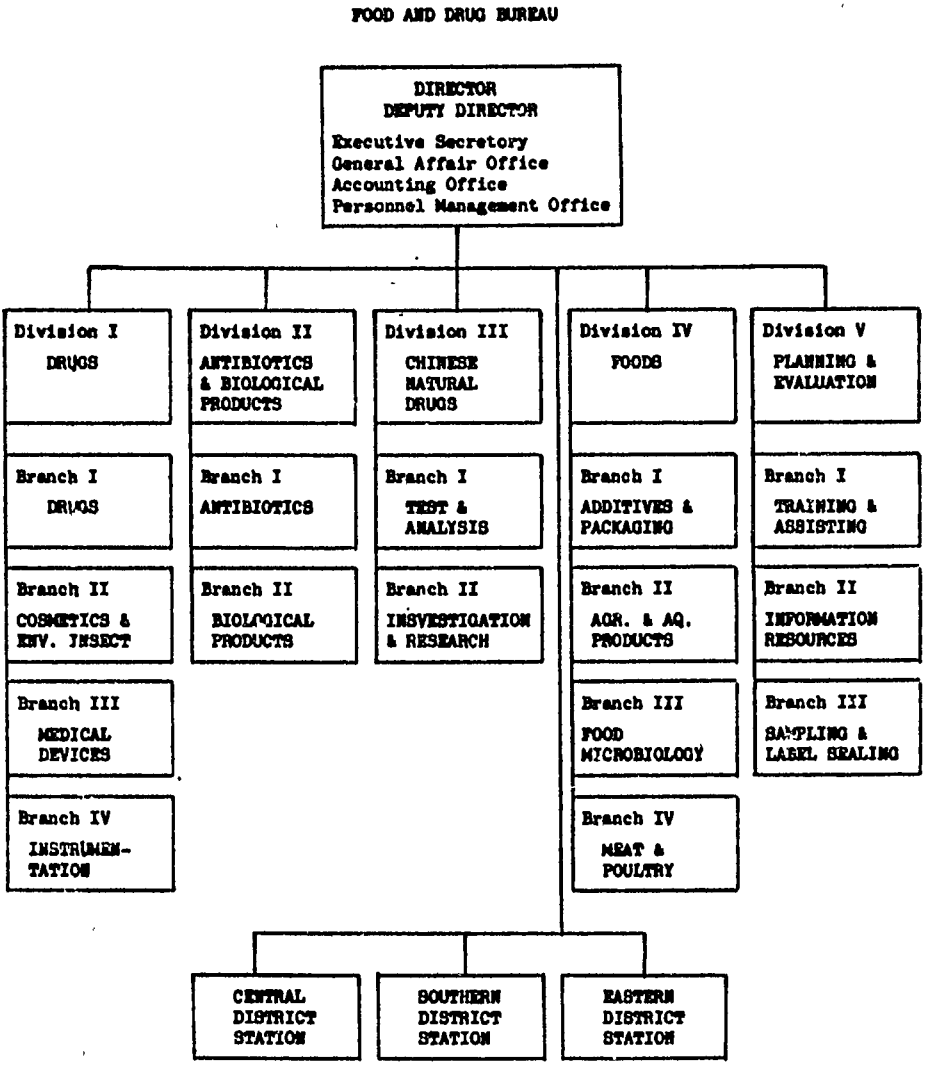


FIGURE 1 Organization chart of the Food and Drug Bureau.

safety. Division II investigates residual antibiotics in foods and sets up a biological toxicology unit for safety evaluation. The three district stations are devoted almost totally to the inspection and examination of foods in their district areas.

FDB inherited a laboratory and office floor space from Taiwan Provincial Hygienic Laboratories. A new building will be constructed to accommodate the expanding facilities and personnel. Over the 1979-1981 fiscal years, a total government budget of US$3.55 million has been granted for instruments and equipment. Efforts to establish information resources essential for safety evaluation have been made. Microfilm of drug safety information updated from 1965 will be acquired from IDIS of the University of Iowa within this fiscal year. Food safety information will be established next.

Although FDB is to have a maximum staff of 268, limited floor space has resulted in increasing the staff only to 198 from the previous 103 Taiwan Provincial Hygienic Laboratories employees. Eighty percent of the staff members are college graduates who majored in science and technology, including four at the Ph.D. level and 13 at the M.S. level; the other 20 percent are administrative workers. All new recruits have to attend a short orientation and are then trained individually for the work to be performed. Employees involved in inspection and laboratory work at district stations and local health bureaus take periodic training programs conducted by Division V of FDB.

RESEARCH ON ANTIBIOTIC RESIDUES

Antibiotics are used in the treatment and prophylaxis of animal diseases, as well as in animal feed supplements to promote growth. Thus antibiotic residues may be found in foods. As a result, such problems as increases in microbial resistance and toxicity of individual antibiotics have been implicated. Alertness to the residual antibiotics problem is reflected by the survey reports listed in Table 1. However, because different assay methods were used, inconsistent data were obtained. Moreover, most of the methods employed were based on antimicrobial reactions that were unable to differentiate antibiotics from the other antimicrobial substances.

In response to the methodological insufficiency, a systematic analysis of antibiotics by agar gel electrophoresis and antimicrobial spectrum (AGE/AS) was developed in the Division II laboratory of FDB. Essentially, this method takes into consideration both the physiochemical and biological characteristics of the chemically heterogeneous antibiotics to be analyzed. As shown in Figure 2, after

TABLE 1 Studies of residual antibiotics in foods previously reported in the Taiwan area.

Time	Area	Assay System				Food	% Positive	Ref.
		Sample Dilution	Test Organism	Implicated Antibiotic	Method			
1974	Taipei City	-	-	-	T.T.C.	Fresh Milk	17.12	(1)
1977	Southern Taiwan	-	B. subtilis ATCC 6633	-	Disk & Plate	Raw Milk	35.6	(2)
1975	Taipei City	1/5	S. lutea. ATCC 9341 B.cereus var. mycoides ATCC 11778	Penicillin Tetracycline	Cylinder & Plate	Hen Egg	1.81	(3)
1976	Taipei City	1/5	Same as the above	Same as the above	Cylinder & Plate	Duck Egg	1.16	(4)
1979	Central Taiwan	-	Same as the above	Same as the above	Cylinder & Plate	Pork Muscle Pork Liver Beef Muscle Chicken Muscle Chicken Liver Duck Muscle Duck Liver	12.1 17.2 10.8 51.8 85.6 52.4 86.8	(5)
1977	Taichung City	1/5	B.subtilis ATCC 6633 In addition to the above	Streptomycin In addition to the above	Cylinder & Plate	Duck Muscle Duck Liver	0 0.62	(6)

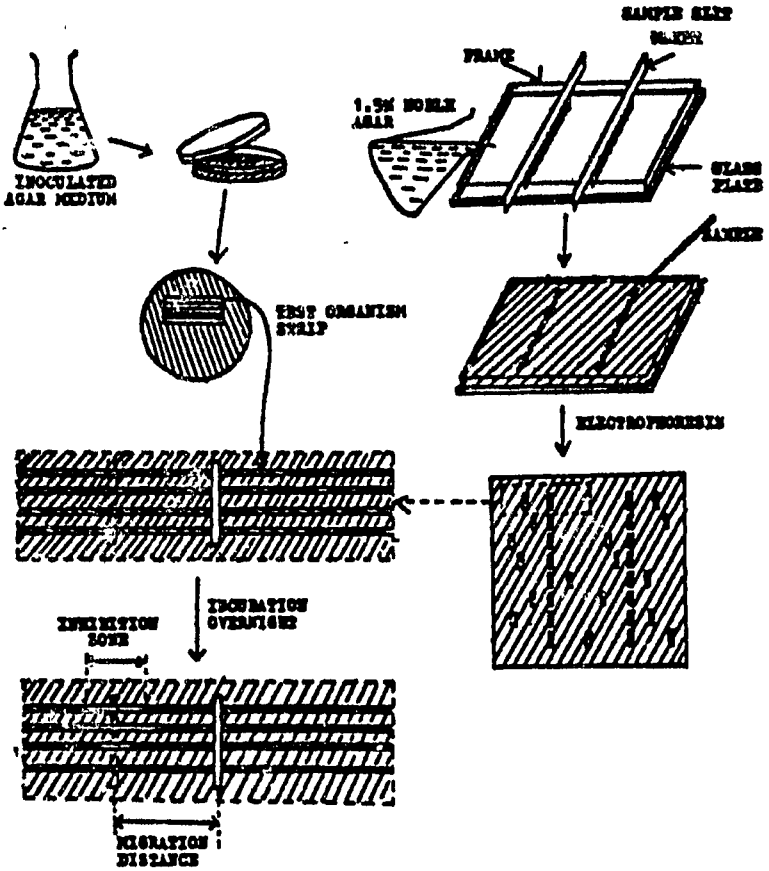


FIGURE 2 The AGE/AS method.[7]

electrophoretic separation of each sample as a band on agar gel, strips of different test organisms are placed on agar gel so that inhibition zones of different size and position characteristic of each antibiotic appear after incubation. From the electrophoresis mobility and antimicrobial spectrum, a residual antibiotic in an unknown sample can be compared with samples of standard antibiotics and thus possibly identified. This method was subsequently used to assess residual antibiotics in fresh foods. As presented in Table 2, although we were able to identify some antibiotics in foods, many antimicrobial substances still cannot be ascertained as antibiotics. Methodological improvements and refinement must be further pursued. Another effort was made to investigate the use of antimicrobial substances as veterinary medicines and feed supplements. The results, shown in Tables 3 and 4, indicate the heterogeneity of chemicals being used for raising domestic animals which may explain the difficulty in detecting residual antibiotics in foods. Overall, research on antibiotic residues has encountered the following difficulties.

- The methodological inefficiency in qualitatively and quantitatively detecting heterogeneous species and small amounts of residual antibiotics, especially when a routine laboratory examination of a large number of samples is to be carried out.

- Lack of a record system to trace a sample from market to farm.

- A gap between the health institutions that control the hygienic aspect of marketing foods and the agricultural institutions that administer the formulation and application of veterinary medicines and feed supplements.

SETTING UP A BIOLOGICAL TOXICOLOGY UNIT

Over the past 20 years, industrialization has resulted in the prevailing usage of chemicals in food production and processing, in increasing contamination of foods via environmental pollution, and in changing the pattern of food spending from natural products to processed foods. Moreover, an improved standard of living has resulted in increased per capita spending on foods.

To counter the increasing seriousness of the food safety problem, toxicology studies must be initiated. Because of its involvement in drug safety testing and the availability of an experimental animal colony as well as microbiological and tissue culture facilities, Division II of FDB was recently asked to set up a biological toxicology unit. The unit will screen toxic substances in foods and drugs and

TABLE 2 General assessment of residual antibiotics and antimicrobial substances in commercial foods.[8]

Foods	Total Sample	Antimicrobial subst.		Antibiotics*									
		Positive Sample	% Positive	Positive Sample									% Positive
				PN	TC	EM	SM	CM	BT	NB	FM	Total	
Milk	279	47	16.8	2	1							3	1.07
Pork	211	7	3.3			1						1	0.47
Pork Liver	151	58	38.4	2			1			1		4	2.65
Beef	143	71	49.7	5	2	3	1	1			1	12**	8.39
Chicken Meat	200	17	8.5		1				1			2	1.00
Hen Egg	444	2	0.5		2							2	0.45
Fish	342	55	16.1		2							2	0.58
Total	1,770	257	14.5	9	8	4	2	1	1	1	1	26	1.46

* PN: Panicillins, including Ampicillin; TC: Tetracyclines; EM: Erythromycin; SM: Streptomycins; CM: Chloramphenicol; BT: Bacitracin; NB: Novobiocin; FM: Polymyxin B.

** Counted one less because both Erythromycin and Streptomycin appeared in one sample.

Table 3. Antimicrobial substances being used as veternary medicines

Livestock**	PIG			CHICKEN			DAIRY COW		
Chemical	Freq.	%	Dose(g)	Freq.	%	Dose(mg)	Freq.	%	Dose(g)
Penicillin G	71	61.7	0.2-9*	5	11.4	N.A.	45	75.0	0.2-42*
Chloramphenicol	23	37.4	0.3-15	3	6.8	40-120	8	13.3	1.0
Kanamycin	40	34.8	0.5-4	2	4.5	60	1	1.7	N.A.
Streptomycin	25	20.0	0.3-11.3	11	25.0	60	12	20.0	0.5-2.4
Tylosin	17	14.8	1-4	15	34.1	60-1250	2	3.3	N.A.
Oxytetracycline	15	13.0	0.6-6	7	15.9	40-1250	30	50.0	0.6-1.275
Neomycin	11	9.6	0.2-4	3	6.8	N.A.	10	16.7	N.A.
Tetracycline	8	7.0	0.75-3						
Ampicillin	6	5.2	9.						
Spiramycin	6	5.2	0.5-3	4	9.1	N.A.	1	1.7	N.A.
Sulfamethoxypyrid.	6	5.2	0.6						
Sulfisoxazole	4	3.5	N.A.						
Sulfadimethoxine	4	3.5	3-9	2	4.5	N.A.	1	1.7	N.A.
Chlortetracycline	3	2.6	N.A.				4	6.7	1.0
Spectinomycin	3	2.6	N.A.						
Sulfamethazine	3	2.6	6-21.6				3	5.0	N.A.
Sulfamonomethoxine	2	1.7	N.A.	2	4.5	N.A.			
Erythromycin	2	1.7	0.4	12	27.3	0-400			
Dicloxacillin	1	0.9	9.4						
Sulfamerazine	1	0.9	N.A.						
Gentamycin	1	0.9	N.A.						
Sulfathiazole							10	16.7	0.45
Sulfaquinoxaline				4	9.1	N.A.			
Dynamycin				7	15.9	N.A.			
Lincomycin							1	1.7	N.A.
Total	115			44			60		

* : Million I.U.
** : Adult dosage
N.A. : Data Not Available

Table 4. Antimicrobial substances being used as feed supplements

Feed for	PIG			HEN			CHICKEN		
Chemical	Freq.	%	Conc.(ppm)	Freq.	%	Conc.(ppm)	Freq.	%	Conc.(ppm)
Carbadox	78	32.5	10-55						
Chlortetracycline	63	26.3	7-250	11	26.2	20-220	13	12.4	50-77
Tylosin	57	23.8	10-110				1	1.0	100
Sulfamethazine	45	18.8	50-250						
Oxytetracycline	44	18.3	1.25-300	5	11.9	50-55	8	7.6	30-100
Lincomycin	40	16.7	14-40	3	7.1	4-4.4	44	41.9	2-4.4
Neomycin	26	10.8	30-300	8	19.0	110	1	1.0	50
Spectinomycin	24	10.0	11-22						
Roxasone	23	9.6	25-400	28	66.6	50	25	23.8	25-50
Flavomycin	23	9.6	2.2				2	1.9	1
Virginiamycin	22	9.2	5-25				18	17.1	7-16
Halquinol	21	8.8	60-120						
Dimetridazole	12	5.0	100-150						
Colistin	10	4.2	2.52-5.0*						
Penicillin G	8	3.3	25-55				13	12.4	10
Tiamulin	3	1.3	10-13.4						
Destomycin A	2	0.8	10						
Spiramycin	2	0.8	100	1	2.4	5-10			
Furazolidone	2	0.8	100						
Sulfadimethylpyr	6	2.5	100-110				38	36.2	12-45
Bacitracin	1	0.4	50	12	28.6	10-12			
Furazoxyl	1	0.4	30				4	3.8	50
Hyamine	1	0.4	50						
Olaquindox	1	0.4	50						
Sulfamonomethox.				32	76.2	10-25	22	21.0	25
Zoalen				27	64.3	125			
Amprolium				10	23.8	100-125	4	3.8	125
Nicarbazine				4	9.5	125	40	38.1	125
Ethopabate				2	4.8	5	1	1.0	8
Sulfaquinoxaline				2	4.8	60			
Nitrovin				2	4.8	15	1	1.0	15
Monensin				1	2.4	100	34	32.4	90-100
Robenidine				1	2.4	33			
Clopidol							15	14.3	125
Sulfamethazine							2	1.9	25
Sulfadimethoxine							2	1.9	20
Total	240			42			105		

* IU/g

assess safety experimentally. The latter would embody the carcinogenic, teratogenic, and behavior toxicities, in addition to general toxicity. An array of methods exists, ranging from microbial system and in vitro cell culture systems to animal systems. However, it is not possible to extrapolate from these various systems to human ones (Table 5).

Thus a reasonable methodology must be selected. At this developmental stage, advice and help must be sought on the following:

- The priority of toxicology testing and research in comparison with other food safety problems
- The methodologies to be selected for screening purposes and for official judgment, respectively
- An exchange of information concerning toxicology data and publications
- Personnel training for toxicology studies.

SCOPE OF LABORATORY ACTIVITIES AND ROUTINE EXAMINATION OF FOODS

Hygienic analysis of foods in the Food and Drug Bureau are performed in Division IV. This division is responsible for testing foods and their additives, utensils, containers, packages, etc. Its activities include:

- Testing and analysis of food additives, utensils, containers, packages, and agricultural, aquatic, animal husbandry products, as well as pesticide residues, microorganisms, and parasites in or on foods, and improving methods for their testing and analysis
- Studying, surveying, and evaluating the hygienic quality and safety of food additives, utensils, containers, and packages, as well as of agricultural, aquatic, and animal husbandry products
- Identifying and investigating causes of food poisoning through detection of chemical and pathogenic microbes. Items routinely examined in connection with foods and food poisoning are shown in Tables 6 and 7.

TABLE 5 Short-term genetic test systems.[9]

BACTERIAL SYSTEMS

Salmonella typhimurium

arabinose resistance (forward mutation)

8-azoguanine resistance (forward mutation)

histidine reversion

DNA repair assay

Escherichia coli

WP_2-tryptophan reversion

343/113-arginine, nicotinic acid reversion

galactose utilization (forward mutation)

gal^+-lysine requirement (deletions)

rec^--DNA repair

$PolA^-$ -DNA repair

Bacillus subtilis

rec^--DNA repair

FUNGAL SYSTEMS

Saccharomyces cerevisiae

mitotic recombination

histidine, hanasarine reversion

canavanine resistance

Neurospora crassa

adenine reversion

PLANT SYSTEMS

Allium

Tradescantia

Barley

Maize

INSECT SYSTEMS

Drosophila melanogaster

sex-linked recessive lethals

MAMMALIAN CELLS IN CULTURE

Chinese hamster cells

HGPRT system-8-azoguanine resistance

sister-chromatid exchanges

Human leukocytes

sister-chromatid exchanges

Human Fibroblasts

Unscheduled DNA synthesis

TABLE 6 Items analyzed for foods.

Sample	Analysis items
Beverages	Bacteria, coloring agent, preservative, artificial sweetener, heavy metal
Agricultural, aquatic, and animal husbandry products	Bacteria, coloring agent, preservative, artificial sweetener, heavy metal, antioxident, bleaching agents, color fasting (developing) agents, aflatoxin, pesticide residues, foreign substances, and parasites
Spices	Bacteria, coloring agent, preservative, artificial sweetener, heavy metal, adulterant, free minera acid, ethanol, and aflatoxin
Food additives	Purity, appearance, specific gravity, refractive index, description, heavy metal, acid value
Utensils, containers, and packages	Residue on evaporation, consumption of potassium permanganate, formaldehyde, phenol, heavy metal, coloring agents, methanol, n-hexane extract substance, and xylene extract substance
Other foods	Consistent with labeling, analysis item depending on the food

TABLE 7 Items analyzed for food poisoning.

Class	Analysis items
Microorganisms	Bacteria, aflatoxin
Chemicals	Pesticide residues, heavy metals

RESEARCH ON PESTICIDE RESIDUES

Monitoring Pesticide Residues in Taiwan

Because of the continuing rapid increase in pesticide use in the ROC, much attention has been focused on pesticides contamination of food and of the environment.

A survey of organochlorine insecticides, such as aldrin, dieldrin, and DDT which have been banned from use, revealed that their residues still remain in various components of the environment but that levels were low and almost within the parts per billion (ppb) range. The overall residue levels in both the water and sediment (Tables 8a, 8b) of the major rivers declined from 1973 to 1976. A number of other studies have examined the residue levels of some chlorinated hydrocarbon insecticides in paddy soil (Table 9).

Studies of persistent pesticide residues in food carried out in early 1972 found that residues of aldrin and heptachlor were present in asparagus shortly after application of these pesticides to the soil (Tables 10 and 11). The government immediately banned their use on asparagus.

An analysis of pork samples (Table 12) collected from 60 retail markets on Taiwan showed the presence of DDT and its metabolites in all samples. Residues of lindane, heptachlor, heptachlor epoxide, and dieldrin were also found in 6-33 percent of the samples. Residues of aldrin, endrin, and methoxychlor were not detected.

Twenty-two bioassay stations have been set up on Taiwan by the provincial Department of Agriculture and Forestry, the Taiwan Agricultural Research Institute, and FDB to make quick assessments of the total toxicity of pesticides in fresh vegetables in local markets before they reach consumers. The number of vegetable samples found to have toxicity levels greater than the toxicity of 2.1 ppm parathion to house flies has decreased sharply since 1966 (Table 13).

Establishing Tolerances

Some countries that do not know enough yet about pesticide safety may feel inadequate to establish tolerances for pesticide residues. Some published tolerances indicate that levels set for the same pesticides in different countries may vary from a few times to as high as 50 times for lindane. Furthermore, some tolerances are so low that they are not practical for agricultural uses. To solve these problems,

Table 8a Residual levels of organochlorine insecticides in water samples collected from Tatu Chi (November 1973-December 1976).[10]

Compound	Number of samples analyzed	Number of positive samples	Percent positive samples	Average residue levels (ppb)	Range of detected residues (ppb)
Aldrin	456	120	46.1	0.030	0.001-1.596
Dieldrin	456	186	40.8	0.022	0.001-0.277
Lindane	456	360	78.9	0.022	0.001-0.149
Heptachlor	456	78	19.2	0.016	0.001-0.247
Heptachor epoxide	456	86	18.9	0.009	0.001-0.127
DDT	456	74	35.1	0.077	0.002-0.568
DDE	456	136	29.8	0.007	0.001-0.066
TDE	456	60	13.2	0.020	0.001-0.227
DDTR	456	154	33.8	0.022	0.001-0.568

TABLE 8b Residual levels of organochlorine insecticides in sediment samples from Tatu Chi.[10]

Compound	Number of samples analyzed	Number of positive samples	Percent positive samples	Average residue levels (ppb)	Range of detected residues (ppb)
Aldrin	304	158	51.8	3.4	0.1- 66.0
Dieldrin	304	134	44.1	3.7	0.1- 55.0
Lindane	304	244	80.2	2.8	0.1- 13.3
Heptachlor	304	89	29.3	1.4	0.1- 2.4
Heptachor epoxide	304	67	22.0	1.5	0.1- 13.9
DDT	304	112	36.8	2.4	0.4- 55.4
DDE	304	152	50.0	3.1	0.2- 27.2
TDE	304	101	33.2	7.0	0.3- 35.1
DDTR	304	148	48.7	4.9	0.1-103.0

TABLE 9 Residual levels (ppb) of several chlorinated hydrocarbon insecticides in the paddy soil of Taiwan.[11]

Location	Soil profile (depth in inches)	Lindane	Heptachlor	Heptachlor epoxide	Aldrin	Dieldrin	DDT	DDD	DDE
Peti, Taipei	0–5	[illegible]	1.041.5	0.211.2	7.1110.0	6.310.8	0	9.1112.9	9.216.9
	5–10	7.509.8	0.510.3	0.510.8	0	3.310.4	0	0	3.010.1
	10–15	1.710.8	0.510.4	1.110.8	0	0	0	0	0
Wulu, Taipei	0–5	107.7[illegible]143.3	5.815.7	0	87.0479.7	9.013.1	11.217.9	90.0117.3	19.119.6
	5–10	6.217.4	0.310.3	0.510.9	0	6.612.7	16.1123.7	15.2121.5	8.9110.0
	10–15	2.816.2	1.310.9	1.410.5	0	1.511.0	0	0	0.710.5
Taihan, Taipei	0–5	8.514.1	3.712.5	1.811.4	14.9121.1	7.321.5	0	25.5120.0	7.311.6
	5–10	0.810.7	0.510.6	1.110.8	0	0	0	0	0
	10–15	1.710.3	0.710.9	1.710.2	0.310.4	0	0	0	0
Chutung, Hsinchu	0–5	0.911.3	0	0	0	5.211.9	0	20.5114.0	13.313.7
	5–10	0.710.7	0	0	0	3.613.1	0	13.419.5	12.316.9
	10–15	1.810.4	0.710.1	1.210.5	0	3.012.1	0	0	1.411.9
Chanlin, Hsinchu	0–5	1.511.6	1.311.4	0	0	2.611.2	4.313.6	20.410.3	12.317.0
	5–10	0.710.5	0	1.311.9	0	2.910.9	2.914.1	6.419.1	6.013.8
	10–15	1.310.9	0.710.6	1.411.1	0	4.510.5	0	0	1.711.2
Chupei, Hsinchu	0–5	16.916.8	0	0	0	4.111.4	4.816.7	22.7116.5	14.316.5
	5–10	4.110.8	0.210.2	0.510.7	0	2.810.7	2.513.6	16.1122.7	6.016.2
	10–15	3.210.4	0.610.4	1.310.1	0	2.812.3	0	0	1.610.5
Taiping, Taichung	0–5	8.014.4	0	0	1.011.4	24.6119.6	30.0129.4	61.6113.7	34.8110.2
	5–10	5.111.2	0.916.2	1.910.6	3.510.1	15.5110.6	0	3.314.6	6.811.3
	10–15	4.110.5	0.210.3	0.310.6	0.410.5	8.011.1	0	3.214.6	5.811.6
Tali, Taichung	0–5	2.810.4	0	0	0.711.0	56.7120.2	64.6154.4	96.3134.6	30.7112.9
	5–10	3.912.6	0.310.8	0.410.6	2.711.9	20.216.3	0	18.116.2	10.612.6
	10–15	5.311.7	0.210.3	0	1.811.1	22.119.7	0	0	6.211.0
Chichew, Changhua	0–5	14.919.2	0.710.9	0	1.010.1	10.2114.5	7.6110.8	34.819.6	8.3111.7
	5–10	6.014.4	0.710.5	3.210.9	2.710.2	19.117.1	0	6.5112.6	9.114.7
	10–15	6.511.6	0.410.3	0	2.011.4	9.111.1	0	0	2.211.6
Pitou, Changhua	0–5	0	0	0	0	9.116.4	11.7116.5	27.617.2	14.4112.1
	5–10	0.312.1	1.711.2	0.711.0	2.910.8	12.413.8	6.117.2	9.2113.1	9.619.2
	10–15	5.513.5	0.610.0	0.510.7	1.311.9	15.116.8	0	0	3.212.3
Tapei, Yunlin	0–5	10.211.3	0.810.6	0	2.111.5	19.612.1	6.116.6	52.3116.5	19.614.7
	5–10	1.011.4	0	0.510.6	0.610.5	10.118.4	0	6.2111.6	6.014.6
	10–15	2.611.6	0.510.4	0.510.7	1.611.9	6.011.3	0	0	0
Tounan, Yunlin	0–5	5.816.6	1.511.5	0	2.216.2	16.111.3	19.614.5	64.113.6	31.612.7
	5–10	3.210.3	0	1.211.2	1.811.0	4.014.6	0	0	4.214.2
	10–15	4.110.3	0.310.3	0.610.6	0.510.5	9.410.1	0	0	3.910.6
Hsuwei, Yunlin	0–5	14.4	4.3	10.6	66.3	0	13.9	31.5	14.2
	5–10	0	0	1.9	0	6.9	0	0	7.8
	10–15	2.1	0	0	0	7.6	11.6	0	3.6
Minhsiung, Chiayi	0–5	8.813.4	0.510.7	16.3114.2	1.011.6	19.0111.2	26.6140.7	67.6158.2	23.8110.9
	5–10	3.712.9	0.310.6	1.210.6	2.310.2	10.815.1	17.6154.1	29.6141.9	7.210.9
	10–19	3.010.3	0.210.3	1.110.5	0.310.4	6.011.0	0	4.210.0	2.311.6
Tsiin, Chiayi	0–5	5.013.9	1.211.7	6.514.6	4.7119.6	23.912.4	0	73.4117.7	34.814.6
	5–10	3.812.7	0.310.4	0	1.911.4	13.112.3	4.516.4	37.1111.1	13.214.4
	10–15	5.016.5	0.510.3	1.110.6	2.712.0	6.710.6	0	6.117.2	3.112.9
Hsipu, Pingtung	0–5	3.012.1	3.914.4	0	0.811.0	10.113.4	9.3113.2	45.415.1	26.414.6
	5–10	7.414.7	0	0	1.611.2	5.213.7	0	0	3.412.5
	10–15	3.710.9	0	0	1.910.6	5.013.0	0	0	2.612.4
Wanlan, Pingtung	0–5	11.211.0	0	0	1.111.6	34.4123.3	36.5161.6	83.716.4	30.713.5
	5–10	5.211.6	0.410.6	0	2.810.7	9.912.2	0	0	3.510.8
	10–15	4.211.1	0	0	2.910.4	7.511.6	0	0	2.011.4
Chutien, Pingtung	0–5	5.616.8	0	0	9.9114.0	29.8116.6	34.1148.3	74.0120.1	37.9111.1
	5–10	4.110.9	0.310.4	0	7.817.7	11.465.6	0	4.916.9	6.111.6
	10–15	3.310.6	0	0	3.010.4	7.010.4	0	0	2.910.5
Linlo, Pingtung	0–5	1.211.6	0	0	26.811.9	16.213.6	30.6129.1	41.6127.2	26.6110.6
	5–10	4.212.1	0.610.5	0	0	4.713.4	0	10.6114.1	4.413.1
	10–15	4.111.3	0	2.111.3	7.711.6	0	0	0	1.611.3

Each figure in the table represents the average of three determinations in a township.

TABLE 10 Residual levels of heptachlor and heptachlor epoxide in asparagus after soil treatment with heptachlor.[12]

	Rate of application					
	3 kg/ha		6 kg/ha		9 kg/ha	
Days after soil treatment	Heptachlor	Heptachlor epoxide	Heptachlor	Heptachlor epoxide	Heptachlor	Heptachlor epoxide
7	9.05	42.6	16.25	61.15	30.1	111.3
14	3.95	28.6	3.95	30.15	10.7	52.1
31	0.86	11.4	0.07	16.00	ND	14.4
45	0.40	ND	ND	ND	ND	10.7
70	ND	ND	ND	ND	ND	9.1
100	ND	ND	ND	ND	ND	ND

TABLE 11 Residual levels of aldrin and dieldrin in asparagus after soil treatment with aldrin.[13]

	Rate of application					
	3 kg/ha		6 kg/ha		9 kg/ha	
Days after soil treatment	Aldrin	Dieldrin	Aldrin	Dieldrin	Aldrin	Dieldrin
7	11.75	106.75	5.00	37.65	10.00	117.3
14	3.10	36.15	ND	55.30	2.75	64.2
31	ND	25.00	2.50	23.95	ND	32.2
45	1.50	ND	ND	ND	1.90	ND
70	ND	ND	ND	ND	ND	ND
100	ND	ND	ND	ND	ND	ND

TABLE 12 Residual levels of chlorinated hydrocarbon insecticides in the pork samples of Taiwan.[14]

Insecticide	Percentage of positive samples (%)		Average residual levels (ppm)		Maximum residual levels (ppm)		Tolerance (ppm)*
	Muscular tissue	Adipose tissue	Muscular tissue	Adipose tissue	Muscular tissue	Adipose tissue	
Lindane	23	12	0.004	0.009	0.0078	0.0169	0.3
Heptachlor	22	22	0.004	0.006	0.0085	0.0116	
Heptachlor epoxide	0	6	--	0.017	--	0.0371	0.3
Aldrin	0	0	--	--	--	--	
Dieldrin	28	33	0.008	0.037	0.0126	0.0848	0.3
Endrin	0	0	--	--	--	--	0.3
DDT	58	95	0.061	1.294	0.2355	1.9928	7.0
DDD	8	22	0.014	0.033	0.0319	0.3208	7.0
DDE	98	100	0.036	0.290	0.1074	0.9463	7.0
Methoxychlor	0	0	--	--	--	--	

*Cited from U.S. Food and Drug Administration (1971).

TABLE 13 Results of bioassay on vegetable samples.[15,16]

Year	Number of samples analyzed	Toxicity higher than 2.1 ppm of parathion to houseflies	
		Number of samples	Percent
1966	2,513	121	5.62
1967	5,124	321	4.40
1973	24,281	20	0.08
1974	23,756	10	0.042
1975 (Jan. to June)	11,850	4	0.034
1977 (July) to 1978 (June)	15,942	2	0.013

the following equation was devised and accepted in Taiwan for establishing tolerances for nine pesticides applied to several vegetables:

$$\text{Tolerance} = \frac{I_d \times W_b}{W_f \times F_t \times P_t}$$

where I_d is ADI (acceptable daily intake) expressed in milligrams of residues per kilogram (kg) of body weight, and obtained from the correlation of U.S. tolerances and ADI values published by the Food and Agriculture Organization of the U.N./World Health Organization; W_b (kg) is the body weight; W_f (kg) is daily food consumption (Table 14); F_t is the percent of food treated; and P_t is the percent of a pesticide used on each group of crops. Taking into consideration of toxicological data, properties of pesticides, safety factors, and dissipation of residues on treated crops, temporary tolerances were established in Taiwan in 1976 (Table 15) for parathion (0.75 parts per million), methyl parathion (0.75 ppm), diazinon (0.5 ppm), dicofol (3 ppm), malathion (5 ppm), dichlorovos (0.5 ppm), naled (1 ppm), and mevinphos (0.75 ppm). Time intervals between the last application and harvest time were also set. Final tolerances were established in 1978 after further studies of residues in commercial fields, in food markets, and in prepared foods.

Effects of Trimming, Washing, and Cooking

To further evaluate the safety of treated crops for human consumption, cabbage was treated three times with high and low dosages of parathion, harvested 10 days after the first application, and then analyzed for parathion residues, following local practices of trimming, washing, and cooking (Figure 3). The results indicate that parathion residues were substantially reduced by a series of processes before serving it at the dinner table.

Establishing Methods for a Systematic Analysis

Chromatographies have recently developed into a simple, rapid analytical method which is useful for a residue analysis of pesticides. The modified paper and thin-layer chromatographies in reversed phase (Tables 16 and 17) and impregnated thin-layer in

polyamide adsorbent (Table 18) were established in the laboratory to assist in routine analyses of pesticides. The results were obtained with respect to the sensitivity and specificity of the color changes of the spots. Each method can be used conveniently to detect pesticides in fields and markets.

TABLE 14 Mean daily food consumption* of people in Taiwan.[17]

Food	Kg/person/day	Approx. percent
Rice	0.377	40
Wheat and other cereals	0.082	10
Fruits	0.098	10
Vegetables	0.296	30
Potato and sweet potato	0.101	10
TOTAL	0.954 (or ca 1 kg)	100

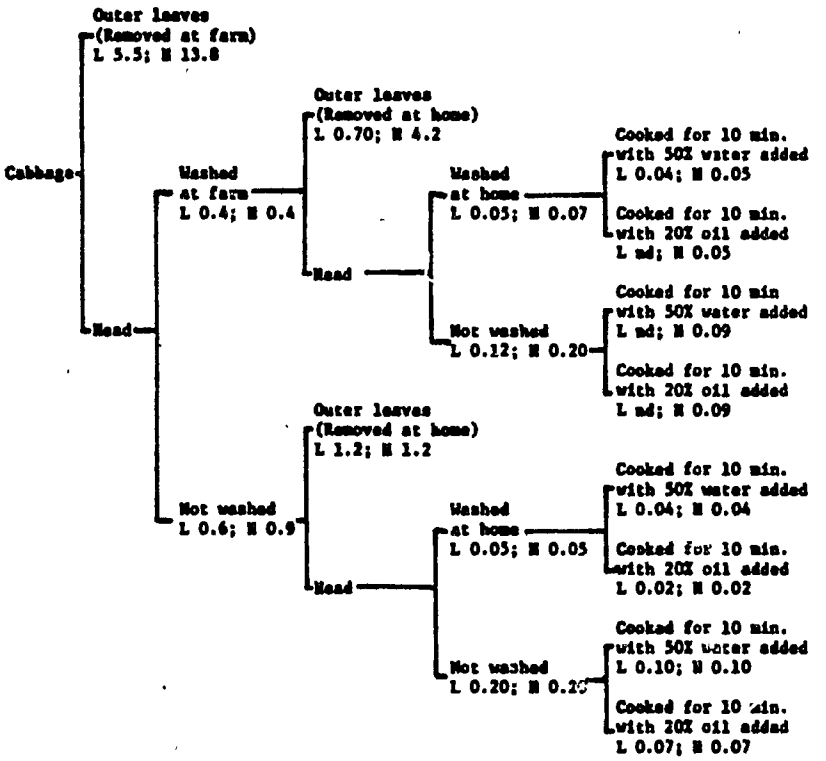
*Excluding meat and animal products (about 15 percent of total food consumption).

Pesticide	ADI, mg/kg FAO/WHO	Calc.[a] (ld)	Pt. % Min.	Pt. % Max.	Pt(%)	Calculated tolerance (ppm) High	Calculated tolerance (ppm) Low	Temporary[b] tolerance (ppm)	Harvest times (days after last application)
Parathion	0.005	0.0025	40	80	25	0.63	0.32	0.75	14(1,2,4,5,6,)[c]
Methyl parathion	0.001	0.0025	40	80	20	0.70	0.35	0.75	7(1)
Diazinon	0.002	0.0018	40	80	20	0.50	0.25	0.5	4(1,2,3,4)
Lindane	0.0125	0.028	40	80	20	7.8	3.9	5	3(1,2,3,4)
Dicofol	0.025	0.014	30	60	20	5.2	2.6	5	2(5)
Malathion	0.02	0.022	40	80	25	5.5	2.8	5	2(1,4,5,6)
Dichlorvos	0.004	0.0012	40	80	25	0.30	0.15	0.5	1(1,2,3)
Naled	-	0.0025	30	60	20	0.93	0.47	1	1(6)
Mevinphos	-	0.0025	40	80	25	0.63	0.32	0.75	1(1,2,3,4)

[a]From Figure 2 or calculated by equation 2.

[b]Same as proposed tolerance.

[c]Number in parentheses indicates the name of the following vegetables: 1=Chinese Pai-Tsai, 2=Chinese cabbage, 3=cabbage, 4=Chinese leek, 5=Kidney bean, and 6=Cucumber



L = Low dose, 3 applications each at 0.55 kg a.i./ha
H = High dose, 3 applications each at 1.10 kg a.i./ha
Figures after L or H = Parathion residue found in ppm
nd: Not detectable

FIGURE 3 Effects of trimming, washing, and cooking on Parathion-treated cabbage in relation to reduction of the residue.[17]

TABLE 16 Reversed phase paper chromatographic data on individual pesticides.[18]

Pesticide	Rf value[a] (I)	Rf value[a] (II)	Color of spot in each stage[b]: Spraying reagent: Bromine	Fluorescein	o-tolidine	UV exposure
Ethion	0.27	0.16	Y	Y	Y	Y
Ronnel	0.37	0.40	-[c]	-	-	Dg
Methyl parathion	0.44	0.35	W	Y	Y	Y
Ethyl parathion	0.57	0.40	W	Y	Y	Y
Diazinon	0.65	0.65	W	Y	Y	Y
Fenitrothion	0.70	0.70	W	Y	Y	Y
Malathion	0.75	0.63	W	GY	Y	Y
Dichlorvos	0.89	0.90	-	-	-	B
Trichlorfon	0.90	0.82	-	-	-	B
Azinphos-methyl	0.92	0.85	W	Y	Y	Y
Phosphamidone	0.94	0.89	-	-	-	O
Mevinphos	0.97	0.95	-	-	-	Y
Aldrin	0.04	0.05	-	-	-	G
DDT	0.13	0.15	-	-	-	GGr
Dieldrin	0.17	0.18	-	-	-	B
Endrin	0.20	0.20	-	-	-	B
Dicofol	0.24	0.20	-	-	-	GGr
Lindane	0.42	0.45	-	-	-	DGr
Zineb	0.00	0.00	-	Y	Dis	Y
Carbaryl	0.88	0.85	-	-	-	RB

[a]Solvent system.
[b]Dis, disappear; W, white; Y, yellow; GY, gray yellow; Dg, dark gray; B, brown; O, orange; G, gray; DGr, dark green; RB, red brown; WG, white gray; GGr, gray green.
[c]Negative (-) reaction to the detection reagent.

TABLE 17 Reversed phase thin-layer chromatographic data on individual pesticides.[19]

Pesticide	Rf value[a] (I)	Rf value[a] (II)	Color of spot in each stage[b] — Spraying reagent: Bromine	Fluorescein	o-tolidine	UV exposur
Ethion	0.10	0.60	W	Y	dis	LYBl
Ronnel	0.16	0.65	-[c]	-	-	DrG
Methyl parathion	0.30	0.70	W	Y	dis	LYBl
Ethyl parathion	0.25	0.67	W	Y	dis	LYBl
Diazinon	0.34	0.63	-	-	-	DrG
Fenitrothion	0.38	0.63	W	Y	dis	LYBl
Malathion	0.49	0.60	-	-	-	DrBl
Azinphos-methyl	0.53	0.84	W	Y	dis	DrBl
Dichlorvos	0.72	0.00	-	-	-	YG
Phosphamidone	0.80	0.30	-	-	-	GrB
Trichlorfon	0.81	0.19	-	-	-	YG
Mevinphos	0.85	0.35	-	-	-	BBl
Aldrin	0.04	0.60	-	-	-	DrB
DDT	0.05	0.65	-	-	-	DrB
Dieldrin	0.08	0.65	-	-	-	B
Dicofol	0.10	0.57	-	-	-	DrB
Endrin	0.14	0.68	-	-	-	DrB
Lindane	0.28	0.60	-	-	-	DrB
Zineb	0.16	0.06	W	Y	dis	DrG
Carbaryl	0.72	0.40	-	R	V	R

[a]Solvent system.
[b]W, white; Y, yellow; R, red; dis, disappear; V, violet; LYBl, blue ring light yellow spot; DrG, dark green; DrBl, dark blue; YG, yellow green; GrB, gray brown; BBl, brown blue; B, brown; DrB, dark brown.
[c]Negative (-) reaction to the detection reagent.

TABLE 18 Polyamide chromatographic data on individual pesticides.[20]

Pesticide	Rf value[a]		Color of spot in each stage[b]			
			Spraying reagent			
	(I)	(II)	Bromine	Fluorescein	o-tolidine	UV exposure
Dichlorvos	0.81	0.92	-[c]	-	-	B
Malathion	0.78	0.85	B	Y	D	DG
Diazinon	0.78	0.67	B	Y	D	DG
Ethyl parathion	0.65	0.46	B	Y	D	DG
Methyl parathion	0.64	0.48	B	Y	D	DG
Fenitrothion	0.64	0.56	B	Y	D	DG
Ethion	0.58	0.32	B	Y	D	DG
Lindane	0.45	0.26	-	-	-	DB
Endrin	0.40	0.21	-	-	-	B
Aldrin	0.36	0.20	-	-	-	B
DDT	0.31	0.07	-	-	-	B
Dicofol	0.21	0.31	-	-	-	B
Carbaryl	0.68	0.55	B	Y	D	Gr
Zineb	0.00	0.78	B	Y	D	DG

[a](I) acetone-ethanol-water (2:2:4); (II) ethanol-ammonia-water (5:2:4).
[b]Y, yellow; B, brown; DG, dark green; DB, dark brown; R, red; D, dark; Gr, gray.
[c]Negative (-) reaction to the detection reagent.

REFERENCES

1. H.C. Tseng and L.C. Chen (1974) Studies on the hygienic safety of animal products in Taiwan. II. Residues and changes of antibiotics in milk, Journal of the Agricultural Association of China 85:45-56.

2. C.C. Huang (1978) Studies on the residues and change of antibiotics in raw milk, Taiwan Livestock Research 11(2):87-100.

3. H.C. Tseng, L.C. Chen, and K.J. Lin (1975) Studies on the hygienic safety of animal products in Taiwan. III. Residues and changes of antibiotics in egg of laying hen, Journal of the Agricultural Association of China 89:36-47.

4. H.C. Tseng and L.C. Chen (1976) Studies on the hygienic safety of animal products in Taiwan. V. Residues and changes of antibiotics in egg of domestic duck, Journal of the Agricultural Association of China 95:47-48.

5. C.S. Shih, S.W. Luan, and L.T. Horng (1979) Studies on the antibiotic residues in animal products in the middle of Taiwan. Unpublished.

6. T.C. Chang (1977) Antibiotic residues and changes in duck tissues, Journal of the Chinese Veterinary Association 3:41-48.

7. C.B. Horng (1978) Systematic analysis of antibiotics via agar gel eletrophoresis and antimicrobial spectrum--a method developed for detecting residual antibiotics in food. In: Proceedings of Food Safety Conference, Taipei, Taiwan, September 12-15, 1978.

8. C.B. Horng, J.H. Li, J.T. Hsieh, F.L. Hsuh, R.H. Jan, K. Tseng, and H.C. Ko (1980) Analysis of Residual Antibiotics in Commercial Foods. Submitted to the National Science Council, January 31, 1980.

9. J.L. Epler, W. Winton, A.A. Hardigree, and F.W. Larimer (1980) The appropriate use of genetic toxicology in industry. In: The Scientific Basis of Toxicity Assessment, edited by H.R. Witschi. Elsevier-North Holland, Amsterdam, The Netherlands.

10. T.Y. Ku (1976) In: Chlorinated Hydrocarbon Insecticide Residues in the Agriculture Environment of Taiwan, pp. 45, 47. (A pamphlet).

11. G.C. Li and Y.S. Lee (1973) Plant Protection Bulletin (Taiwan) 15:170-174.

12. G.C. Li, P.Y. Kwo, and C.C. Tang (1976) Proceedings of 1st Symposium on Asparagus Research in Taiwan 2:125-130.

13. G.C. Li, S.H. Chiang, P.Y. Kwo, and Y.S. Lee (1975) Preliminary Report No. 3, Pesticide Residue Division, Plant Protection Center, Taiwan.

14. G.C. Li, W.C. Fei, and Y.P. Yen (1978) Research Paper No. 17, Pesticide Residue Division, Plant Protection Center, Taiwan.

15. Provincial Department of Agriculture and Forestry (1975) Report of Pesticide Management in Taiwan.

16. Provincial Department of Agriculture and Forestry (1978) Unpublished data.

17. Y.P. Sun, et al. (1977) Archives of Environmental Contamination and Toxicology 5:279-293.

13. R.T. Wang and S.S. Chou (1968) Journal of the Chinese Agricultural Chemistry Society. Vol. 6, Nos. 3 and 4.

19. R.T. Wang and S.S. Chou (1969) Chemistry 4:80.

20. R.T. Wang and S.S. Chou (1969) Journal of Chromatography 42:416.

EDIBLE OIL PRODUCTION IN TAIWAN AND ITS FOOD HYGIENE IMPLICATIONS

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The edible oil industry in Taiwan has been developing rapidly the past decade due to the fast expansion of the feed and livestock industry and a substantial improvement in living standards. In 1970, the Taiwan Vegetable Oil Manufacturing Association (TVOMA) had 137 members. It was estimated that members used more than 1,672 hydraulic presses and 202 expellers. However, in 1980 the number of the members decreased to 94, and more than 90 percent of this equipment was no longer in operation because of the rapid extension of solvent extraction plants.

There are currently in operation 12 continuous solvent extractors (Table 1) with a capacity of 200-400 metric tons of soybeans per day, 6 semicontinuous and continuous solvent extractors of 80-120 metric tons per day, and 18 batch extractors of 20-50 metric tons per day. The rest are of the hydraulic press and expeller type with rather small capacity. Most of these plants are designed to process soybeans, with the exception of 6 that process rice bran; 24, peanuts and rapeseed; and 2, corn. Sesame processors are rather small and are not associated with TVOMA.

The total capacity of the 94 members is about 1.5 million metric tons of soybeans per year, but only 1 million metric tons of raw materials were crushed in 1980. Soybeans accounted for 85 percent of the total oilseed used for this purpose, and rice bran, peanuts, rapeseed, and sesame made up the other 15 percent. It is expected that

the hydraulic press will be gradually phased out in a few more years, due to the low operation rate (less than 25 percent), high production cost, and poor quality of oil and cake. To further improve the production technology and quality of edible oil and fat products, an oil processing pilot plant was established at the Food Industry Research and Development Institute (FIRDI) in 1980.

TABLE 1 Major solvent extraction plants, Taiwan.

Plant	Extractor	Degumming/deacidification system	Deodorizer
1	Extraktion Technik (W.G.)	Alfalaval (Switzerland)	Extraction Technik (W.G.)
2	"	"	"
3	"	"	"
4	Crown (USA)	"	Krupp (W.G.)
5	Lurgi (W.G.)	Westfalia (W.G.)	Lurgi (W.G.)
6	"	De Smet (Belgium)	De Smet (Belgium)
7	De Smet (Belgium)	Westfalia (W.G.	"
8	Yoshino (Japan)	Alfalaval (Switzerland)	(Japan)
9	Rotocel (Taiwan)	"	EMI (USA)
10	Yoshino (Japan)	(Taiwan)	(Taiwan)
11	Rotocel (Taiwan)	(Taiwan)	(Japan)
12	Rotocel (Taiwan)	"	"

Source: Taiwan Soybean and Food Industry Directory (1980)

PATTERNS OF EDIBLE OIL PRODUCTION AND CONSUMPTION IN TAIWAN

Soybean Oil

Soybeans crushed by the large oil mills are extracted with solvent (n-hexane) into soybean meal and oil. The small oil mills press soybeans into soybean cake and oil. About 60 percent of Taiwan's soybeans was processed by hydraulic presses in 1970, decreasing to 12 percent in 1980.

Crude oil is generally refined, bleached, and deodorized for cooking purposes. The finished oils are usually marketed as first grade refined soybean oil, and are sold in 53-gallon drums or 16-kg tin cans. Soybean salad oil is sold in 2.7-kg. plastic or glass bottles or tin cans. The latter is made without partial hydrogenation and winterization. The quality of the finished oil depends on its free fatty acid content, color, and cold test, etc., according to the Chinese National Standard. The production of soybean oil was 63,231 metric tons in 1970, increasing 177 percent to 175,200 metric tons in 1979 (55 percent soybean salad oil and 45 percent first grade refined oil).

Rice Bran Oil

Rice bran oil is currently the most important domestic source of vegetable oil in Taiwan. The annual production of brown rice is about 2.5 million metric tons, about 10 percent of which can be converted to rice bran after milling. If all of these rice brans, which are 15-18 percent oil, were used for oil extraction, at least 40,000 metric tons of crude oil could be obtained. Since most of the rice mills are family-owned and are widely distributed, the rice bran is difficult to collect and therefore used mainly for feed preparation. Currently, only a few refineries which obtain raw materials from rice mills producing milled rice for export or for military supply, produce limited quantities of refined rice bran oil for edible purposes. All of these refineries use the conventional alkaline refining method except one larger rice bran refinery which employs "miscella refining", a process to neutralize the crude oil in a mixture of oil and inert solvent (hexane) with alkali solution, miscella refining. The recovery rate of these two methods is 44 percent and 65 percent, respectively. The relative low rate of recovery is due to the high free fatty acid content of up to 15 percent in the crude oil. It not only increases the production cost but also hinders the improvement of oil quality, and has become a bottleneck for the industrial development of domestic rice bran oil. Recently, FIRDI developed an extrusion cooking process to stabilize the lipase activity in fresh bran. Rice bran thus treated could keep its free fatty acid content at a level of less than 6 percent after being stored for a month. Improved

storageability of rice bran would greatly facilitate the development of the rice bran oil industry in this country.

Peanut Oil

Shelled peanuts are first toasted and then processed by an expeller into peanut oil and meal. In 1979, about 86,000 metric tons of shelled peanuts were produced, but only 24,000 metric tons were pressed to produce 10,000 metric tons of oil (Table 2). Peanut oil is not refined to preserve the typical peanut flavor traditionally preferred by local consumers. The crude peanut oil, deep brown in color, is usually mixed with the first grade refined soybean oil to a lighter yellowish color at a 20:80 ratio and sold to consumers as peanut cooking oil with peanut flavor. The price of natural peanut oil is about four times higher than that of refined soybean oil, and the mixed oil is also sold for three times higher than that of the first refined soybean oil.

TABLE 2 Oilseed production and imports, Taiwan (1,000 metric tons).

Year	Soybean		Peanut	Rapeseed	Sesame	
	(a)	(b)	(a)	(a)	(a)	(b)
1969	67	472	100.8	2.7	2.9	--
1974	67	529	94	1.4	1.6	7.4
1975	62	827	91	4.5	1.0	6.0
1976	53	800	89	4.6	1.0	8.8
1977	52	663	77	3.3	0.6	9.8
1978	41	959	92	3.1	1.2	9.5
1979	32	1104	90	2.4	1.0	9.9

(a) Taiwan Agricultural Yearbook (1979).
(b) Customs statistics (imports).

Sesame Oil

Sesame oil is made either by hydraulic press or expeller and is used unrefined as flavoring. Local production of sesame is only about 1,000 metric tons per year. Therefore, about 10,000 metric tons per year of sesame (Table 2) were imported to Taiwan over the last few years to supply domestic oil consumption of 3,000 metric tons per year.

Margarine and Shortening

Margarine and shortening production is estimated to be about 20,000 metric tons per year. These products are largely used by institutions and bakeries, and the number of small consumer packs of margarine and shortening is limited so far. The 12 oil mills producing margarine and shortening usually use imported inedible meat fats, after being refined or blended with hydrogenated palm oil, as a major source of oil.

Imports of Fats and Oils

Imports of fats, oils, and oilseed are shown in Table 3. For each of the past 5 years, 2,671 metric tons of palm oil and 4,000 metric tons of coconut oil were imported. In addition, substantial quantities of inedible industrial fats and oils were imported in 1978, including 33,558 metric tons of inedible hog grease, a lard steanin, etc., and 47,484 metric tons of inedible tallow. Some of these inedible oils and fats might have been used illegally by the food processing industry.

TABLE 3 Oil production and imports, Taiwan (1,000 metric tons).

Year	Soybean oil[a]	Peanut oil[a]	Palm oil[b]	Coconut oil[b]
1969	46.8	10.1	--	--
1974	90.1	16.3	2.6	1.6
1975	106.6	14.0	4.1	3.8
1976	127.0	12.6	3.6	3.8
1977	107.5	8.3	1.0	4.7
1978	147.9	7.9	2.6	4.3
1979	175.2	10.7	2.5	4.0

[a]Taiwan Agricultural Yearbook.
[b]Customs statistics (imports).

Consumption of Fats and Oils

The per capita consumption of total fats and oils in 1968 was only 6.56 kilograms (kg) of which 64 percent was vegetable oils, and 36 percent animal fats. In 1979, however, consumption increased to 10.07 kg, of which 66.6 percent was vegetable oils and 33.4 percent animal fats. Table 4 shows the recent consumption of edible oils and fats in Taiwan.

TABLE 4 Per capita consumption of fats and oils, Taiwan (kilograms).

	1968	1974	1975	1976	1977	1978	1979
Soybean oil	3.13	4.16	5.55	5.64	6.22	6.99	6.04
Peanut oil	0.93	0.55	0.52	0.49	0.41	0.52	0.46
Rapeseed oil	0.09	0.04	0.10	0.09	0.07	0.05	0.05
Sesame oil	0.08	0.18	0.14	0.19	0.21	0.20	0.13
Total vegetable oils	4.23	4.92	6.31	6.41	6.91	7.76	6.68
Lard	2.31	3.26	2.73	3.54	2.78	2.76	3.24
Butter	0.02	0.06	0.05	0.07	0.11	0.15	0.15
Total animal fats	2.33	3.32	2.78	3.61	2.89	2.91	3.39
TOTAL	6.56	8.24	9.09	10.02	9.80	10.67	10.07

Source: Taiwan Food Balance Sheet

HYGIENIC PROBLEMS OF EDIBLE OILS

Heavy Metals Contamination of Edible Oils

Heavy metals are detrimental to the quality of edible oils and thus to the consumer's health. It was reported in 1974 that edible oils in the local market contained an excessive amount of heavy metals which caused consumers great concern. Therefore, FIRDI undertook an assessment of heavy metals in edible oils, as well as a survey of edible oils produced in Taiwan including crude, refined, and finished products.

The change of heavy metals contents during the refining process by sodium hydroxide produced by either a flow mercury cell or a diaphragm cell was also studied (Tsai 1977). These studies found that only a trace of mercury and arsenic could be detected in the samples, mostly less than 0.005 ppm and 0.02 ppm, respectively. The average amount of lead, copper, manganese, and zinc in refined soybean oil were 0.04 parts per million (ppm), 0.03 ppm, 0.01 ppm, and 0.2 ppm, respectively. More heavy metals were found in oils consumed in the form of nonrefined crude oil such as peanut oil and sesame oil than in refined soybean oil or rice bran oil. The iron contained in refined soybean oil was 1.2 ppm, but that can be effectively removed by the proper refining process. Recontamination of iron, either during refining processes and/or during storage by packaging material, was suspected. In conclusion, all heavy metals, namely, mercury, lead, copper, manganese, zinc, iron, and arsenic in the refined oils under investigation were within the safety limits as specified in the regulations of the Chinese National Standard (CNS). Heavy metals such as mercury, lead, copper, manganese, zinc, and iron can be effectively removed through the refining process, especially by acidification. No mercury contamination could be detected in refined oils if sodium hydroxide produced by either a flow mercury cell or a diaphragm cell and used for deacidification did not contain an excessive amount (no more than 0.5 ppm) of mercury. However, regulations now state that only sodium hydroxide produced by a diaphragm cell can be used in the refining process. Tolerance limits of 0.1 ppm for arsenic, copper, and lead, and 0.05 ppm for mercury have also been established.

Polychlorinated Biphenyls (PCBs) Contamination in Rice Bran Oil

A food poisoning outbreak in which about 1,200 people in the middle area of Taiwan suffered from PCBs in rice bran cooking oil was first reported by the ROC Food and Drug Administration in October 1979. This outbreak was caused by PCBs which accidentally leaked from the heating coil used in the deodorization process of rice bran cooking oil. The concentration of PCBs in some samples of rice bran cooking oil and in the blood of some patients was as high as 100 ppm and 136 parts per billion (ppb), respectively. Actions for diagnosis and cure were taken immediately after symptoms were recognized by the ROC Food and Drug Administration, and import of PCBs and its usage in industries were banned by regulatory agencies in June 1980.

Possible Contamination of Aflatoxin in Unrefined Peanut Oil

Taiwan is situated in a temperate zone with high temperature and humidity, which presents the possibility of enough mold growth in

peanuts to cause aflatoxin contamination. This contamination in crude peanut oil can be removed by the refining process, but the typical peanut flavor is removed as well. As a result, peanut oil is usually consumed as crude oil in Taiwan.

Strong measures should be taken to improve quality control of raw materials as well as products, although a tolerance limit of less than 0.025 ppm aflatoxin in edible oils has been set in the Chinese National Standard.

Inedible Meat Fats Refined for Edible Purposes

In the United States, animal fats and oils derived from sheep, cattle, and hogs can be divided generally into two basic classes, namely greases and tallows. A fat with a titer below 40°C is considered a grease, and above 40°C a tallow. Historically, lard oil is manufactured from hog or pig grease. Edible lard oils can be derived only from hog back fat and must be segregated in storage, rendering, and processing. Fat derived from all other parts of the hog, including bone stock, skins, hooves, etc., is classified as inedible. The ROC customs service estimates that imported inedible meat fats are used at a rate of over 100,000 metric tons per year by soap or fatty acid manufacturers as well as by the animal feed industry. Of this amount, 14,000 metric tons were refined for deep frying purposes and for making margarines and shortenings. Although the fat or grease, either edible or inedible, must be produced from clean, fresh fat obtained from standing animals (i.e., animals in good health at the time of slaughter), sanitation of the container or barge during rendering or shipping of these inedible meat fats is very important. Good manufacturing practices may have been neglected completely in processing and handling if the fat was considered an inedible material. Thus the government is studying how to prevent inedible meat fats from being used for edible purposes.

CONCLUSION

The edible oil industry is considered one of the most important industries in Taiwan. With improvements in living standards, it is expected that this industry will continue to grow, improve, and modernize. Therefore, it is likely that the future will see a substantial decrease in the number of small oil mills. Meanwhile, the larger solvent extraction plants, with capacities from 500 to 1,000 metric tons per day will emerge in the future to improve production efficiency and quality control, as well as to reduce labor and production costs.

REFERENCES

American Soybean Association (1980) Taiwan Soybean and Food Industry Directory 1980.

Council for Agricultural Planning and Development, Executive Yuan, ROC (1979) Taiwan Food Balance Sheet 1979, 1974 -- 1979.

Department of Agriculture and Forestry, Taiwan Provincial Government (1979) Taiwan Agricultural Yearbook 1979.

Tsai, W.C., L.C. Shaw, C.B. Lin, S.D. Pan, S.C. Chang, and I. Yu (1977) Study on the Heavy Metal Contamination in Edible oils. Report No. 110, FIRDI.

APPENDIXES

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APPENDIX A

OPENING ADDRESS

Sanford Miller
Director, Bureau of Foods
U.S. Food and Drug Administration

I would like to describe some of the historical thrusts that have led to the development of contemporary U.S. law, and draw from that some general conclusions about the characteristics of a food law or at least what the characteristics of the food regulatory system ought to be.

However, first I would like to introduce Dr. Frank MacKeith who had the major burden of organizing the FDA's activities for this conference. Frank will follow up this conference on behalf of the FDA.

Second, although we appreciate the compliments concerning the role of the FDA in the organization of the conference, let me emphasize that for the FDA this is an exercise in enlightened self-interest. World food trade today is enormous, and international sources of food for the United States increase constantly. The FDA is responsible for insuring that all foods entering the United States meet the standards that we apply to domestic products and are of an acceptable quality. It is important to us, and will help our activities enormously, if each of our trading partners uses the same general set of rules and regulations. It is, of course, not possible for all laws to be identical, nor should it be. Each country has its own particular requirements and its own traditions of law which must be followed. But if we agree on the fundamental standards and the science underpinning the law, I believe that the current problems in food trade between our countries can be corrected. The FDA has successfully participated in

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similar activities with other countries, and it is our hope that this activity will achieve the same measure of success we have had with other colleagues throughout the world.

CREATION OF A FOOD LAW OR REGULATORY SYSTEM

The need to create a food law or food regulatory system is a function of the changing characteristics of the society in which that regulatory system is developed. The increasing urbanization and industrialization of a society almost always makes the need for such a regulatory system essential. As individuals are separated from the sources of their food supply, the need for their protection and for assuring the quality of their food supply increases. Thus the indication from the Republic of China that there is need to develop a more elaborate and more technically sophisticated food regulatory system is a function of the increasing urbanisation and industrialization of the ROC. With this increasing activity it becomes clear that sophistication is also an essential part of the process.

In the United States this was equally true. In 1906, following many years of hard work, the United States passed the first of what ultimately became several food laws. The 1906 law was preceded by several state laws which dealt with one or another of the separate issues on which food safety is based. Largely through the efforts of Harvey Wiley, who was then in the Department of Agriculture, the Congress of the United States, and before it the people of the United States, became concerned about the quality of their food supply. This concern was expressed in different ways in terms of the physical quality of the product and the capacity of the product to cause disease and harm to the people consuming it. But there was an economic concern as well. One of the major problems in 1906 was that people did not know that what they were buying was what they thought they were buying. The question of fraud in the food industry represented a major thrust for the development of the law.

It is interesting to note that Dr. Wiley, in his 12 years of efforts to get the first law passed, enlisted the aid of a great portion of the American food industry, particularly that part whose activities extended across state lines. In fact, over the 75 years of the Act, the role of American industry in applying of the law and in assuring the basic components of the law has been essential. This is one of the important tenents of developing an effective food regulatory system. Without the full cooperation of the industry, either entirely voluntarily or partially voluntarily and partially through the threat of further law, it is impossible to develop an effective food regulatory system. There is no way for any country, even the United

States, to develop a series of regulatory options and a regulatory structure strong enough to investigate the entire industry without the cooperation of the industry itself. The success of the U.S. food law is in large measure a reflection of the cooperation that it has received from the food industry.

In 1906, the government needed to address several kinds of questions in developing a law. It became clear that government needed control over what went into food in terms of the safety of the product itself. It needed control over the processing of food to ensure that the processing produced a product that did not cause illness or disease, and to ensure that the product met some minimum standards. It needed some way of controlling the quality of the food, and some means of allowing the consumer to know what was in the product. Over the last 75 years, a number of different regulatory options have develop. Irrespective of the nature of these regulatory options, the three control points that I mentioned represent the fundamental basis of food and drug regulatory activity.

Since 1906 there have been several changes in the law. These changes have usually come about because of some traumatic, dramatic event which has focused the attention of the American people on the capacity of the law to meet contemporary problems. I want to emphasize that the law itself must be a changing structure that allows the government the ability to meet the demands of the people.

Perhaps even more important than these revolutionary changes in law has been the evolution of the way the law has been interpreted and regulations written. Not only does the law have to be changed in order to meet changing needs, but the interpretation of the law, its application, the regulatory structure built upon the law, must change as well. One can argue that the only time one ought to force a change in the law itself is when interpretation of the law and the development of regulatory structure are no longer sufficient to meet the perceived goals of society.

At the time of passage of a law, it is almost always interpreted strictly; the Agency takes the most literal reading of the law. However, with time and increasing knowledge of changes in the industry which the law regulates, and the changing goals of society, the law almost always become more flexible. On occasion, it goes the other way, becoming less flexible. Changes depend on the circumstances.

Delaney Clause

The "Delaney clause" in the 1958 amendment to the U.S. food law was written to exclude absolutely, at least so it seemed in 1958, the

presence of any carcinogen in the food supply. For the last 22 years the Delaney clause has been interpreted in different ways and now the FDA recognizes that what we knew in 1958 is not necessarily what we know in 1981. In 1958, the number of known carcinogens was few. In 1981, we recognize that the individual is exposed to literally hundreds, perhaps thousands, of carcinogens. In 1958, we were primarily concerned about carcinogens that were purposely added to food. In 1981, we recognize that foods naturally contain compounds which in tests produce increases in rates of tumors. The result is that today the law that seemed so rational in 1958 does not seem so scientifically rational, or at least the way in which it was interpreted in 1958 does not seem so rational today. The result has been an evolution in the regulatory implementation of the 1958 law--but not necessarily a change in the law to effect a change in the way the law is applied.

Labeling

The use and importance of labeling in assuring the safety and quality of the food supply has changed considerably over the last 75 years. Originally the function of a label was to assure the consumer that what was inside the package was what he thought was inside the package. It is impossible to tell the contents of an opaque container if there is no label on it. Later the label was used to carry warnings: "Warning: This product is hazardous." "Warning: This product contains lye, which may prove hazardous to your health." Further needs due to the increasing sophistication of the food industry led to identifying on the label the various components of the product. In 1973, it became apparent that the label was needed to serve an educational function. Thus with the development of the provision of nutritional information on the label, interpretation of the law had come full turn from identifying the contents of a container to educating the consumer in making appropriate choices of food.

Even this has changed throughout the years. The question now arises as to how much information should be on that label. How much information does the consumer need? And is this information different from that required by a regulatory structure to enforce the quality of the product? It is important, for example, that certain basic nutritional qualities be maintained in a product. It is also important that the public receive certain basic nutritional information to assure good selection of food. Do these necessarily both have to be delivered and available in the same form? Can one interpret the law to permit different ways of providing each of these different kinds of information? The law must evolve in recognition of these different requirements.

Regulatory Emphasis

Regulatory tools have also changed throughout the years, and these will be discussed in some detail later. From a concept that was originally enforcement oriented (and necessarily so), we have evolved a whole series of other regulatory options, including information and education. One might argue that the development of good manufacturing practices (GMPs) not only provides a group of standards by which government can tell if foods are being processed and produced properly, but also represents a structure that can be used to educate the industry on how best to produce the needed product. A government agency, given responsibility for assuring the safety of the food supply, must use every tool at its command, and the law must be interpreted so that such educational activities can go on simultaneously with the enforcement activities that are explicit in the law.

The subjects of emphasis of the law also have to change with time. In 1906, Dr. Wiley's primary concern was the addition of harmful chemicals to food. Based on the kind of information he had at the time, Dr. Wiley was not concerned much about long-term exposure. He was concerned about acute exposure to various substances. His worries were about the addition of copper sulfate to green vegetables to keep them green, and the use of sodium borate, which he thought a very toxic substance for the short term. He also was concerned about economic fraud; that people were not selling what they said they were selling. He was not overly concerned about microbiological hazards, although this soon became one of the most important facets of FDA activities. Why did this happen? In the late 1800s and the early 1900s, it was not known that the spoilage of processed foods occurred as the result of microbiological action. It took the work of William C. Underwood and Sam Prescott to demonstrate this fact. But once this was recognized, the FDA began to emphasize its concern about microbiological hazards and the presence of other filth in food over its concern for chemical additives. During the 1930s, with the evolution of organic chemistry and the development of large numbers of new chemicals for food, concern again increased over the addition of chemicals to foods. The law, the interpretation of the law, and the agency's emphasis shifted, and while interest in microbiology and in filth reduction remained, the interest in chemical concerns increased. This probably reached its peak in 1958 with the passage of the Delaney clause of the 1958 amendment.

Since that time, our concerns have also shifted. While we are still concerned about chemicals in foods, we are becoming less worried about those chemicals that we add purposely to food and have become more concerned about those chemicals that get into food accidentally, either in the form of natural toxins, or in the form of manmade

contaminants such as PCBs. Our concern over microbiological hazards is also increasing as we begin to develop techniques that reduce the use of chemical persarvatives in our food supply.

The specific short-term goals of the agency also change with time. The overall goals remain the same--basically to help maintain public health and protect the public against the hazards associated with food. But the specific goals may change, as seen in the shift from concern about acute hazards to a concern with chronic hazards. Today the concerns of the agency--reflections of the concerns of the society--are not aimed solely toward those things that lead to death, but have begun to expand to include those things that might be included under "quality of life," such as effects on behavior, teratogenicity, and birth defects. The law, or at least the science of the law, must also change to meet the changing aspirations of the society for which it is structured.

Changes in Agency Structure

The structure of the agency has changed to meet the requirements of society. In 1906, a small bureau of the Department of Agriculture, the Bureau of Chemistry, was charged with implementation of the food and drug laws. The responsibilities began to increase with a food industry transporting an ever-increasing variety and complexity of products from one end of the country to another. It became clear that this structure would no longer be viable. The Food and Drug Administration was then formed, still under the Department of Agriculture. It soon became apparent that the Secretary of Agriculture could not be concerned with increasing food production and processing, and at the same time have the responsibility of ensuring that processors met legal standards. Ultimately the Food and Drug Administration was transferred to what is now the Department of Health and Human Services. The fox, as the old saying goes, should never be given the job of serving as watchdog over the chickens. In answer to Dr. Ma's question about where the food activities ought to be, I would argue they ought not to be in those agencies that are also responsible for the production of food.

I have not said much about contemporary law as it will be discussed later during these meetings. Today, food safety is regulated in several different agencies of the federal government. Meat products are regulated in the Department of Agriculture, and responsibility for setting tolerances for pesticides rests with the Environmental Protection Agency. Over the years a reasonably successful series of formal and informal cooperative activities have developed among FDA and these other agencies. In addition, successful relationships have been

made with the various states, which still maintain for themselves certain responsibilities for food safety, such as providing guidance and guidelines for the states. Only when products cross state lines in significant amounts does the FDA play a more active role. FDA has provided the states with technical expertise in many areas. An important component of any food regulatory structure must be the development of cooperative relationships between other governmental entities. These relationships must be addressed in any development of the structure for food laws.

General Components

I would like to indicate the kinds of general components that a structure must have to meet the needs of contemporary society. First, the structure must be based on knowledge--indeed, the ability to develop new knowledge and information must be an integral part of the structure of any food safety establishment. This cannot be only a side effect, it cannot be done separately from the regulatory structure itself; it must be an integral part of the structure. In the United States, those regulatory agencies that are most successful in application of the law are those that have a strong technical science base as part of the agency. Those regulatory agencies that depend on structures outside their own institution for this purpose simply are not effective. You cannot be a good food and drug regulator unless you have some idea of the science involved.

Second, you must have a clear definition of goals. What do you intend for the structure to accomplish? These goals will change with time, and you must be willing to accept those changes with time, but each step of the way you must continually reevaluate those goals and articulate them clearly so that the people working within the institution and those whom you regulate know precisely what you are attempting to accomplish.

The system must be run with integrity. Perhaps nothing is more important. The industry must recognize that the individuals in the regulatory agency are above reproach in their application of the law, and the public must have confidence in the honesty and in the competence of the food control institution. This is often difficult to achieve, but it is essential, for without it the system will never work.

Third, the system must have resources. It is often said that compared to institutions in other parts of the world the U.S. Food and Drug Administration is very big. But it regulates a very big industry. And even though the FDA staff often feels its resources are insufficient to meet the demands of contemporary American society, on

the whole, the resources of the agency have increased as the demands of society have increased and as the industry has become larger and more sophisticated. A government must make such a commitment if it wants to have an effective food control mechanism.

The agency needs a structure that meets all these demands, a structure that incorporates components that are basically technical and legal, and components to implement the decisions of other groups. Such a structure must be capable of change to meet new demands and needs. The law and the food regulatory structure must meet the needs of the particular society for which it is constructed and in which it is used. One cannot take the food control structure of one society and apply it to another. U.S. law may be useful and very efficient for the United States, but it simply cannot be transferred "whole hog" to the Republic of China. Yet the fundamental concepts on which the U.S. law is based can be transferred and then can be integrated within the structure of the ROC's governmental organization and societal structure. Fundamentally the science remains the same and fundamentally, I believe, the goals remain the same. In areas of providing the scientific underpinning, and in providing some idea of how goals are reached under the U.S. system, we can perhaps offer the most help and advice to our colleagues from the ROC. And I hope that this will be the goal of the conference. We will not write ROC law, nor develop an ROC structure, but provide the concepts and the scientific basis from which you can develop your own structure to meet the needs of your society.

INSTRUCTIONS TO TASK GROUPS

I leave to each task group the final say on the specific subjects it will cover. Nevertheless, there are several areas that each task group ought to consider. First, we ought to begin by defining what the ROC goals are in achieving food safety; that is, in each task area what are the specific goals to be attained. It is clear that we want to assure food safety for the people of Taiwan, but we need somewhat more specific goals. What exactly do you want to accomplish in the end? How far do you want to go? What degree of safety are we talking about? This seems to me an important concern. Second, each group needs to consider the continuing problems that will be attained in reaching these goals. Are there some fundamental problems inherent in either the legal system, in the industrial structure, or in the scientific resources which will make the attainment of these goals difficult? What are the resources available today, what will they be in the future, and what should they be to accomplish the goals? Recommendations might be developed on two levels: immediate recommendations--those that might be implemented reasonably quickly,

perhaps in the next year or two--and those that must be implemented over a much longer period of time, and that might require more important structural and legal changes. This might deal with such things as law, structure of food regulatory activity, the implementation of the food regulatory activity including inspectional services, the science base, technology, and the educational component of any regulatory activity. These kinds of general rules might apply to any discussions in any of the task groups.

APPENDIX B

UNRAVELING THE CONFUSION OVER FOOD SAFETY: HOW SUCCESSFUL ARE WE?

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A considerable amount of confusion could be dispelled if we first clarify the definition of the word "safety." Traditionally, it has meant "freedom from danger, injury, or damage." Is there an absolute safety? The answer is "No." Rather, safety is a judgment of acceptability of risk, and risk is a measure of the probability and severity of harm to human health. What is involved, in a practical sense, is the degree of risk and the degree of safety, which are matters of relativity. Judgment will also vary according to the eating habits, educational levels, living standards, and professions of the people making the judgment. Therefore, enough confusion already exists if we have to agree on the measures of safety, not to mention that there are at least four different groups of people interested in the problems--consumers, producers, scientists, and policymakers--who could display inconsistent and incoherent views on the very subject. Difference breeds difference. It will end only with endless disputes.

If we define food safety as "food hygiene," according to the Food Codex Committee of World Health Organization (WHO) and Food and Agriculture Organization (FAO), food hygiene means all measures necessary for ensuring the safety, wholesomeness, and soundness of food at all stages from its growth, production, or manufacture until its final consumption, i.e., from harvesting through processing until ultimately reaching its consumer. The scope of food sanitation could widely include food itself, food additives, contaminants, food-borne diseases, food poisoning, kinds of toxicants, food utensils,

containers, and packagings, the places and the processes of manufacture, processing, storage, transportation, display, sales, etc. It could also include food labeling and food sanitary education. Recently, waste from processing has been mentioned as a possible source of contamination. Any incidence of an uncontrollable factor could breed a risk. It could bring about endless disputes.

We recognize the confusion involved and therefore are most grateful to the National Academy of Sciences of the United States and the Academia Sinica of the ROC which are jointly sponsoring this conference on food safety at this appropriate time and at this proper place. We are also gratified to learn that many American institutes have sent their delegates to contribute either at the conference itself or during our tours before or after the conference.

As the ROC's per capita income reached more than US$2,202 in 1980, and as our government has enforced 9-year compulsory education since 1968, demands have arisen not only for tastier and more nutritious foods, but also for more variety of wholesome and safe foods. More housewives are now taking jobs outside the home and can afford no time for cooking; they demand instant and snack foods, prepared or semi-prepared foods--all wholesome and safe. In 1978, canned, salted, and dehydrated foods--only three items of processed foods--earned an export value of US$487 million for Taiwan; the future volume lies in maintaining their quality, especially a high standard of food safety that is acceptable abroad and able to withstand the challenge from other competing exporting countries. School lunch program and institutional food are developing. Whether or not they could be successfully expanded depends upon the quality and cost of the foods so distributed, which definitely involves the standard of food safety. Accelerating tourism attracts visitors to Taiwan and inspires them to eat Chinese dishes. The favorities displayed toward Chinese foods in every corner of the world encourages our delving into studies on commercial production of Chinese foods. However, we must endeavor to give our best--wholesome and safe foods. This explains why our meeting to tackle the problem together at this time is most opportune.

The United States, through its government agencies such as the Food and Drug Administration, the Department of Agriculture, and the Environmental Protection Agency, and nongovernment agencies such as the Food Safety Council, are tackling the food safety problem systematically and seriously. Nothing is more rewarding to us than to hold this meeting in Washington, D.C., which is the headquarters of the majority of these agencies.

Confusion exists within the ROC about a number of issues. I wish to mention only a few for your reference.

First, there is the question of the Food Law, on which one of our delegates, Mr. C.S. Lin from our National Health Administration (NHA), will present a paper entitled "Food Safety, the Law, and the Government." Then there is the question of which party in our government is to administer the law. The first Law Governing Management of Food Hygiene was promulgated in 1975, and its scope is limited to food hygiene. It imposes the sanitary standards of foods (including meat products), food additives, food containers, food utensils, food packages, and food businesses. It deals with food labeling and food advertisements bearing on food hygiene. However, it omits food quality control, such as adulterated and misbranded foods, and the enforcement of the law, which falls on the Bureau of Commodity Inspection and Quarantine (BCIQ), under the Ministry of Economic Affairs.

In 1978, the Food and Drug Bureau (FDB) was established as a separate unit, but still under the direct supervision of the National Health Administration. It takes charge of official testing and analysis of food from the viewpoint of safety evaluation. The function of the Bureau of Food and Drug Control (with a subsidiary Division of Food Sanitation) within the National Health Administration is to interpret and draw up food sanitation laws and regulations and safety standards and also their administration. Recently, definite action has been taken by the National Health Administration to enlarge the organization of this Food Sanitation Division into a Bureau (but still within the premises of the National Health Administration), to be staffed with 37 persons.

With the establishment of the FDB in 1978, the inspection of 347 food items, under five categories of canned foods, soy sauce, monosodium glutamate, instant noodles, and infant food was transferred from the BCIQ to the FDB. Recently, a shipment of milk powder was found to be of low vacuum and of low net weight by the FDB, and apparently did not meet the quality standard of that product. However, since the product did not carry any sanitation hazard, the National Health Authority thought that it was not their responsibility to make the decision on whether to accept or to reject the entry of this shipment to my country. The case was duly transferred to the BCIQ, but was turned down by the BCIQ as it was no longer in charge of inspection of products to be sold on the local market. The NHA again made the proposal that in the future for the inspection of imported foods they take care of the sanitation quality, while the BCIQ checks qualities other than food safety.

This conference could offer a platform for discussing the feasibility of one comprehensive food law that could safeguard the

consumers' welfare, and also of one organization to draw up and interpret the food law and regulations, for both sanitation and nonsanitation components, and administer them.

Second, there arose the confusion caused by the open dating of packaged food case. Recently, under the auspices of our Consumers' Association, a large amount of undated, improperly dated, or overdue products were found in the local market. This caused a great disturbance to supermarkets and food manufacturers. The problem is how should the date be properly marked on a food product?

Our current "Food Sanitation Control" law and "Standard for Labelling of Packaged Foods" (altogether 18 lines), simply states that the packaged foods should bear the "date of manufacture" or "date of validity." There are no further details as to what kind of food should bear the "date of manufacture," and what others must declare "valid date." How should they be shown on the package--open date or a code? Location and size?

Apparently the standard adopted is oversimplified. We solicit advice on:

1. What kind of food necessitates date of expiration?

2. How should the date be determined?

3. What should be done with products that are overdue in validity?

Third, there is the question of GMP (Good Manufacturing Practices). The Bureau of Industry, under the Ministry of Economic Affairs, promulgated a generalized "Good Manufacturing Practice for Food Factories." The only detailed supplement is the one on the "practice for thermal processing of low-acid food packaged in hermetically sealed containers." GMP serves as a guideline to the food processors on what is right to do in their food manufacturing process in order to produce safe and better food. Each process requires a specific guideline according to the processing techniques, equipment, and nature of food product. We wish to learn from our American delegates how wide an area their GMP covers in the United States and, taking a specific example, how to work out the details of the GMP. And, which organization is to be given the authority of working out the GMPs?

Fourth, with the rapid development of industry in the last decade in the ROC, activities in trade, business, and even tourism have become intense. Restaurants, food services, and institutional foods flourish. In 1980, at least two food poisoning outbreaks were reported

among the schools supplying lunch for students. Hundreds of students were involved in each case. Liver and intestinal disease are not uncommon among students in colleges and universities where food supply depends on the small restaurants around the campus. Sanitation of lunch boxes offered for sale in big cities is questionable. Examination of regulation controlling the sanitation status of these food services and reinforcement of such regulations are of primary importance. To prevent food poisoning outbreaks and improve the sanitation of food services, a complete food poisoning outbreak report system should be established, and the U.S. experience with such a reporting system would be most helpful. Its experience in food service sanitation training extended to food handlers and to persons in food management should also be considered.

Throughout this conference, we wish to carry on our conversation in a constructive, frank, open-minded, and sincere mode, so that our American counterparts fully realize our problems and give their good advice in return. They may have encountered many bitter experiences in reaching where they are now, and they could teach us not to repeat these mistakes. In listening to our problems, our American counterparts might also pick up some new experiences which could be helpful in solving their problems. Therefore, I hope this 5-day conference will be a most fruitful one, resulting in workable, pragmatic recommendations that we can study and put into action. In this respect, we hope that in the future we will have the privilege of calling on the services of our American scientists, lawyers, and food managers to visit the ROC and render their generous assistance.

APPENDIX C

WORKSHOP PARTICIPANTS

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