United States General Accounting Office

GAO

Report to Congressional Requesters

August 1991

# INTERNATIONAL FOOD SAFETY

# Comparison of U.S. and Codex Pesticide Standards

144927

RELEASED

RESTRICTED——Not to be released outside the General Accounting Office unless specifically approved by the Office of Congressional Relations.

GAO/PEMD-91-22

GAO United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-243921

August 22, 1991

The Honorable Patrick J. Leahy
Chairman, Committee on Agriculture,
Nutrition, and Forestry
United States Senate

The Honorable Richard G. Lugar
Ranking Minority Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

In response to your request, we are submitting this report, which compares pesticide standards established in the United States with those of the Codex Alimentarius Commission. The report also identifies and describes the potential implications of differences in standards for U.S. trade and food safety. The purpose for conducting this study was to provide information to assist the members of the Committee in evaluating international efforts to improve the long-term harmonization of health-related regulations that have an impact on agricultural trade.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date of issue. At that time, we will send copies to interested congressional committees and government agencies and make copies available to others upon request.

If you have questions or would like additional information, please call me at (202) 275-1854 or Kwai-Cheung Chan, Director of Program Evaluation in Physical Systems Areas, at (202) 275-3092. Other major contributors to this report are listed in appendix III.

Eleanor Chelimsky
Assistant Comptroller General

# Executive Summary

## Purpose

International disputes involving differences in health and safety measures have disrupted agricultural trade between countries. Efforts to improve international rules concerning health-related regulations that affect agricultural trade have been underway in the Uruguay Round of the General Agreement on Tariffs and Trade negotiations since 1986. The draft agreement under discussion emphasizes that countries should base their regulations on sound science and, to the extent possible, on existing international standards, particularly those of the Codex Alimentarius Commission (Codex). The Senate Committee on Agriculture, Nutrition, and Forestry is concerned about the possible implications of increased emphasis on international standards and asked us to (1) compare Codex's standards for pesticide residues and its process for setting standards with that of the United States, and (2) examine the implications of different standards for both U.S. trade and food safety.

## Background

In the United States, the Environmental Protection Agency (EPA) has chief responsibility for establishing legal tolerances for pesticide residues on food commodities. Codex, created in 1962 under the auspices of the United Nations, has established international standards, codes of practice, and guidelines for different foods and for food quality and safety concerns, including pesticide uses. Codex standards are voluntary and only enforceable if adopted and used as national regulations.

The principal pesticide standards used by EPA and Codex are: (1) an acceptable daily intake (ADI) measure, which represents the total amount of a pesticide compound that can be ingested daily over a lifetime without any appreciable health risk, and (2) a maximum residue limit (MRL), or tolerance, which represents the maximum concentration of residue allowed on a food or feed commodity according to accepted uses of a pesticide. MRLs pertain to the maximum residue levels permitted on a commodity at the time of harvest; actual residue levels in foods identified at the point when they are consumed are usually much lower than MRLs. However, since MRLs are official standards, they could be used by countries to bar trade in certain food commodities.

## Results in Brief

Important differences distinguish U.S. and Codex ADI and MRL standards. These differences reflect several technical factors pertaining to pesticide and agricultural practices and to the procedures for evaluating and establishing standards. (See chapter 3.) Our analysis of U.S. and Codex pesticide standards indicates that, overall, almost two-thirds of them cannot be compared because of the absence of U.S. tolerances for corresponding Codex MRLs or differences in the way pesticide residues are defined. Of the one-third that can be compared, we found less than half to be numerically the same. As long as differences persist, the potential for restrictions on exports and imports and greater consumer exposure to pesticide residues will remain. Opportunities may exist to reconcile differences, but in order to determine this, a systematic review and assessment of the scientific basis for existing differences between standards will be necessary.

# Principal Findings

## Different Procedures for Establishing Standards

The basic processes the United States and Codex use to evaluate potential health effects and estimate residue limits on commodities are similar; however, several areas reveal key differences that affect the setting of pesticide standards.

- Types of pesticides: Under the Codex system, only pesticides considered important to international trade and those likely to result in residues on food commodities are included. In the United States, all pesticide products must be registered and have tolerances established before they can be legally used on food products.
- Good agricultural practices: Pesticide residue levels are closely associated with different characteristics of accepted good agricultural practices, which include crop-growing conditions (climate, soil, pest problems), uses of pesticides (types, quantities applied, and frequency of application), and production practices (planting, cultivation, and harvesting).
- Definitions: When Codex evaluates pesticide residues, it places greater emphasis on identifying and using an indicator compound (often the parent compound) as an indicator of the total residue. EPA tends more often to examine the total residue of a pesticide, including the parent compound as well as significant chemical breakdown components (metabolites) of the pesticide.
- Pesticide data: EPA has formal requirements for pesticide data submissions, but Codex lacks the authority to require data. Thus, standards can be based on different data packages. Even when the same data are used, their interpretation may result in different scientific opinions about an appropriate standard. Differences of opinion can exist, for

instance, in the way outliers (extreme values) are treated or the level of safety factors applied in estimating ADIs.

- Carcinogenic pesticides: EPA assumes a risk exists at any level of exposure to a carcinogenic pesticide and focuses its quantitative assessment on whether the risk is acceptable at given exposure levels. The Codex process emphasizes calculating a threshold level (no observed effects level), which then serves as a basis for establishing an ADI.
- Dietary risk exposure: EPA conducts a dietary risk exposure assessment for proposed pesticide tolerance standards by comparing the acceptable daily intake level of a pesticide against a theoretical or anticipated intake of pesticide residues. Codex has recently conducted some regional dietary risk exposure assessments, but as a practical matter, it advocates that individual countries should determine if pesticide residues pose unreasonable health risks.

## Numerical Differences Between Standards

The Codex system includes about 170 pesticides and, when commodity groupings are converted to individual commodities, over 3,300 pesticide-by-commodity MRLs as compared to over 400 pesticides and 8,500 pesticide-by-commodity tolerances (MRLs) in the U.S. system. GAO compared, where possible, U.S. pesticide MRLs and ADIs against the smaller set of Codex standards.

In 62 percent of the Codex cases (2,069), MRLs cannot be directly compared because the United States either has no standard or standards are defined differently. In the remaining 1,267 pesticide-by-commodity combinations that are comparable, the United States has lower MRLs for 19 percent of the cases; the Codex for 34 percent. A comparison of the ADIs GAO examined (78 pesticides) reveals a different pattern: the United States has set lower levels for 66 percent of the pesticides; the Codex, for only 16 percent.

Among the pesticides studied that EPA has rated as probable carcinogens, the United States has lower MRLs in 55 percent of the cases; the Codex, in only 27 percent. A study of the magnitude of the differences between U.S. and Codex MRLs for major U.S. agricultural exports and imports revealed that the United States has lower MRLs for about 20 percent of the pesticide-by-commodity combinations; the Codex, for 37 percent.

## Implications for Trade and Food Safety

Differences in pesticide standards can have important economic and health consequences. In cases where one nation has no standard established for a pesticide, or a standard does exist but it is more stringent than another nation's, trade can be restricted, as recently occurred with the United States' detaining European wine treated with the fungicide procymidone. Large differences between standards can also affect consumer exposure to residues. For example, the estimated theoretical dietary intake of the pesticide diquat increases for U.S. consumers from 31 percent of the ADI when U.S. MRLS are used (assuming that the food in an average diet contains residues at maximum allowed concentrations) to 94 percent of the ADI when Codex MRLS are substituted. Conversely, for other pesticides such as malathion, the theoretical dietary intake of residues decreases when Codex MRLS are considered.

## Recommendation

If countries move to base their national standards more firmly on scientific evidence, possible agricultural trade disputes may be avoided and harmonization should improve in the long term. GAO recommends that the Administrator of EPA, in cooperation with the Secretary of Agriculture, conduct further analyses to (1) determine the likely effects that differences in standards would have on U.S. health and trade interests and (2) set priorities for determining the extent of the scientific basis for differences in pesticide standards.

## Agency Comments

As agreed upon with the Committee, Department of Agriculture (USDA), EPA, and Food and Drug Administration (FDA) officials reviewed a draft of this report and provided GAO with oral comments on it. Generally, they all agreed with the major findings and conclusions of the study. The officials we spoke with noted that both the Codex and U.S. systems are appropriate scientific approaches for establishing standards and protecting health. Their main concern was that some readers might misinterpret our findings about the differences between U.S. and Codex standards and procedures to mean that one system is necessarily more protective than the other with respect to health and safety. As a result, we modified language in the report to help avoid the potential for misinterpretation of our findings. They also provided suggestions for clarifying certain technical aspects of the report, and these have been incorporated throughout where appropriate.

# Contents

# Glossary



# Tables



# Figures



## Abbreviations

| | |
|---|---|
| ADI | Acceptable daily intake |
| Codex | Codex Alimentarius Commission |
| EPA | Environmental Protection Agency |
| FAO | Food and Agriculture Organization |
| FDA | Food and Drug Administration |
| GATT | General Agreement on Tariffs and Trade |
| JMPR | Joint Meeting on Pesticide Residues |
| MRL | Maximum residue limit |
| TMRC | Theoretical maximum residue contribution |
| USDA | U.S. Department of Agriculture |
| WHO | World Health Organization |

# Introduction

## Background

### Importance of International Trade

The United States is the world's largest exporter of agricultural goods, which amounted to about $40 billion in 1990. Although U.S. farmers continue to be highly productive, they are facing a modest decline in their share of world markets as competition from other producing nations, particularly the European Community, has increased in recent years. The dollar value of U.S. agricultural exports as a percent of the world's total declined from about 20 percent in 1970 to 18 percent in 1980 and 15 percent in 1988. At the same time, U.S. agricultural imports have steadily grown from $17 billion in 1980 to about $23 billion in 1988, leading to a narrowing of the overall U.S. agricultural trade surplus.

If agriculture in the United States is to remain as economically strong as it has been, then expansion of international trade will be important. Concern about the large U.S. trade and budget deficits highlights the need for ensuring that ample opportunities exist for U.S. farmers to sell commodities overseas and that such commodities can be sold with reduced levels of government support.

### Role of Food Safety Standards

At the same time, health and food safety measures have become increasingly important in international agriculture. This is reflected in rising consumer concerns and scientific debate both in the United States and abroad about the possible health risks associated with pesticide residues and other chemical additives in foods. Recent highly-publicized incidents have involved Alar-treated apples in the U.S. and the planned use of bovine somatatropin, a growth hormone developed to increase milk production in dairy cows.

Agricultural trade has been disrupted by international disputes involving food safety measures, often because standards for safety are different in different countries. For example, in 1989, the European Community banned imported meat products containing certain synthetic hormones. In the United States, however, regulatory standards permit the use of synthetic hormones to promote livestock growth. The European Community action, according to a Department of Agriculture (USDA) report, may have cost U.S. producers over $100 million in lost export sales in 1989.[1] In 1990, the United States seized imports of European wine containing residues of the fungicide procymidone. The United States took this action because there was no legal tolerance established for procymidone. European exporters and U.S. importers claimed that the ban would result in up to $300 million in lost market sales. In April 1991, the Environmental Protection Agency (EPA) issued an interim tolerance for procymidone, which allows for the distribution of the imported wine.

## GATT Negotiations on Food Safety

Efforts are underway to improve international rules concerning health-related regulations that impact on agricultural trade in the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations.[2] Virtually all of the countries participating in the GATT Working Group on Sanitary and Phytosanitary Regulations and Barriers have agreed to the requirement that countries base food safety and plant and animal health measures on sound science and not on artificial trade-related barriers. The draft agreement under discussion also emphasizes that countries should, to the extent possible, base their measures on existing international standards and guidelines, particularly those of the Codex Alimentarius Commission, International Office of Epizootics, and International Plant Protection Convention.

The draft agreement does not propose that national and international standards be uniform. Rather, it recognizes that countries would maintain the right to apply standards that differ from existing international standards if there is reasonable scientific evidence to support them. In addition, the U.S. position in the negotiations has been that any agreement should state the right of each GATT member to set stricter standards when a country demands a higher level of health protection, so long as there is demonstrated consistency to such actions. However, harmonization is viewed as a long-term approach where national standards would become more similar as countries move to base their standards on scientific evidence.

[1] Kelch, David, and Terri Raney, "Europe 1992, GATT, and Food Safety: How Will U.S. Agriculture Fare?" Agricultural Outlook, Dec. 1989, pp. 33-36.

[2] The Uruguay Round of the GATT negotiations was scheduled to conclude the week of December 3, 1990. Participating countries, however, were unable to reach agreement on the issue of agricultural reform, resulting in a suspension of the negotiations. Since then, some discussions pertaining to agricultural reform have taken place, but no significant progress has been achieved to date.

## Objectives, Scope, and Methodology

The Senate Committee on Agriculture, Nutrition, and Forestry is concerned about the possible impacts that harmonization of international food safety standards could have on the safety of foods Americans consume and on the ability of U.S. farmers to export commodities overseas. In view of the importance the Uruguay Round GATT negotiators placed on the work of the Codex Alimentarius Commission, the Committee asked us to undertake a study that would compare current U.S. and Codex food safety standards and the processes used for establishing such standards.

In discussions with the Committee's staff, we agreed to limit the scope of our study to the subject of Codex and U.S. pesticide residue standards for food commodities. We formulated the following general evaluation questions to guide our work:

1. What are existing Codex and U.S. pesticide standards for food commodities? (See chapter 2.)

2. How are they established? (See chapter 2.)

3. Are there differences between the processes used to establish the standards? (See chapter 3.)

4. How do the two sets of standards compare? (See chapter 4.)

5. What are the potential implications of different standards for food safety and agricultural trade? (See chapter 5.)

Our study includes several evaluation components. To learn more about the characteristics of pesticide standards and the processes used to establish them, we reviewed available research studies and other relevant literature. We also interviewed key U.S. agency officials from the EPA, USDA, and Food and Drug Administration (FDA); officials of the two main U.N. agencies associated with the Codex—the Food and Agriculture Organization (FAO) and the World Health Organization (WHO); and other experts. We also examined various U.S. agency and Codex documents and other material.

To identify numerical similarities and differences between the two sets of standards, we developed and analyzed a data base containing the U.S. and Codex pesticide standards. The data for these comparisons come from a list of U.S. acceptance positions on Codex pesticide standards prepared in 1988 by the EPA as well as more recent information on current standards obtained from the Codex and the U.S. Code of Federal Regulations.

Our final evaluation component involved examining potential trade and consumer health-related impacts associated with different standards. Using available information, we identified potential implications that can occur with U.S. exports and imports and consumer dietary exposure under different sets of conditions—where the United States has a pesticide standard but the Codex does not, where the Codex has a standard but the United States does not, and where both systems have a standard but one is higher or lower than the other.

Our work was performed in accordance with generally accepted government auditing standards from July 1990 through March 1991.

# Codex and U.S. Pesticide Standards

Regulatory programs to promote the safe and effective use of pesticides exist in most industrialized countries. Because they need to protect consumers' health and the environment, national governments have established standards pertaining to what pesticides can be used and how they can be used with different food commodities. In this chapter, we provide an overview of the Codex and U.S. roles and responsibilities for pesticides and then discuss the standards that have been established.

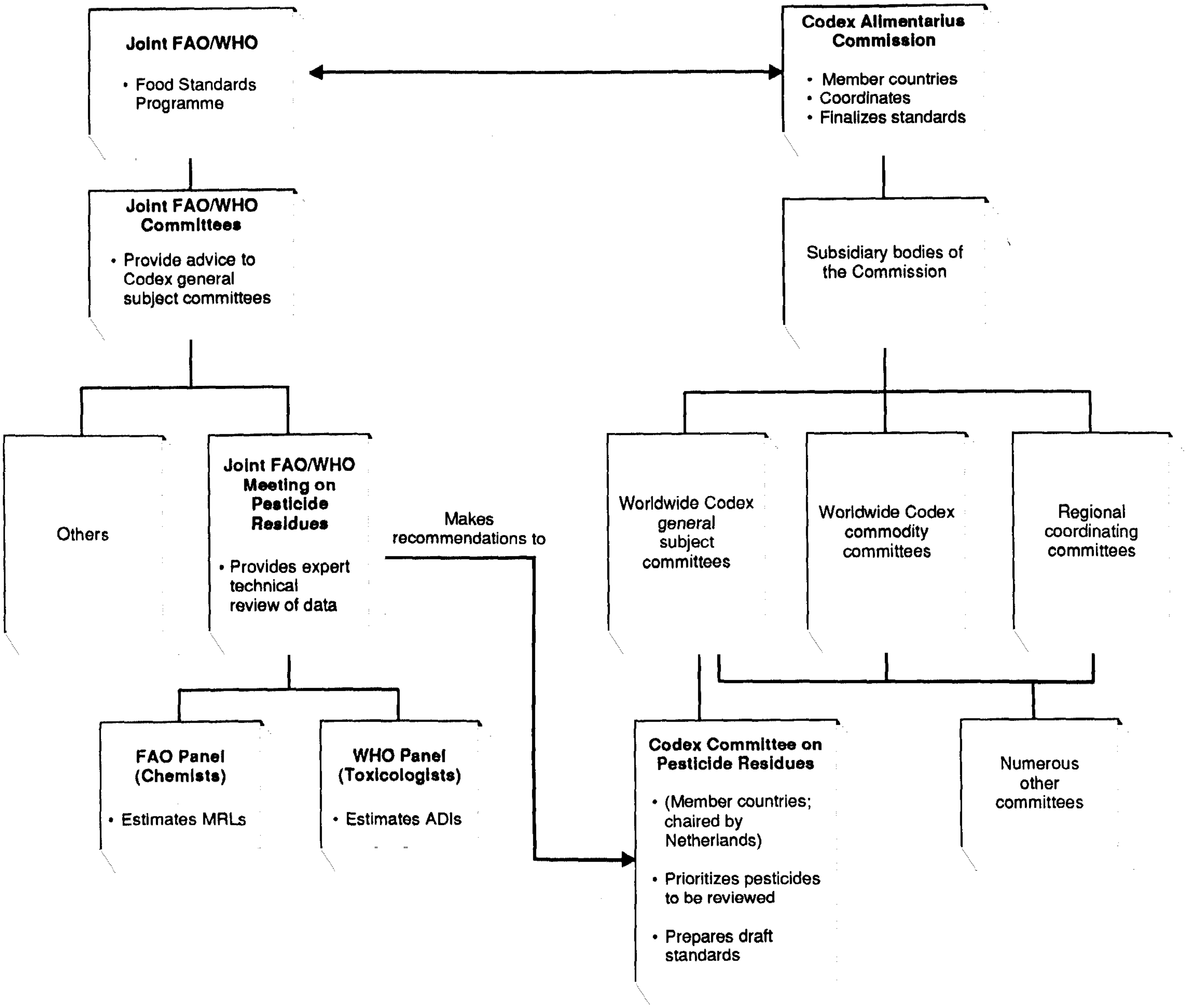
## Roles and Responsibilities for Pesticide Standards

### Codex System for Coordinating Standards

The Codex Alimentarius Commission (Codex) was established in 1962 under the auspices of the United Nations to facilitate fair trade in food, protect the health of consumers, and promote the coordination of international food standards. It was organized to implement the work of the Joint FAO/WHO Food Standards Programme. Codex is a multinational organization, open to all member nations of the FAO and WHO. Currently, 137 nations participate in the Codex. Funding for its operation was $3.7 million in 1989, provided jointly by FAO (75 percent) and WHO (25 percent).

The Codex has established standards, codes of practice, and guidelines for various foods and for food quality and safety concerns. These are developed through several different subsidiary regional, commodity, and general subject committees. (See figure 2.1.) Standards are adopted by the Commission at formal meetings that occur every 2 years. More information on the formal procedures followed by the Codex in adopting pesticide standards is provided in appendix I.

**Figure 2.1: Codex Organization Chart**




Source: This chart has been abstracted from a U.N. organization chart.

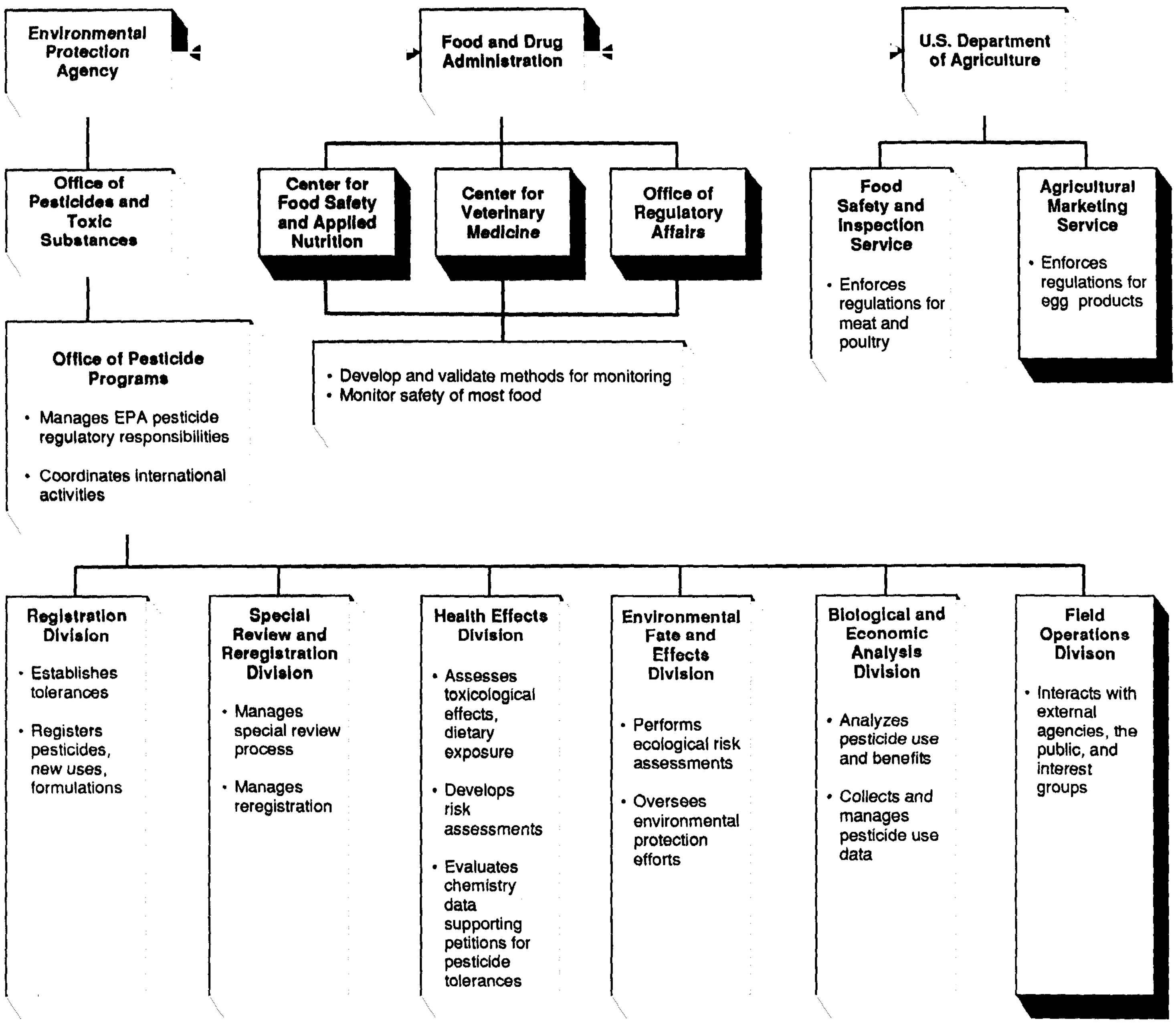
The U.S. delegation to the Codex is currently headed by the Administrator of USDA's Food Safety and Inspection Service. Delegation members to the various Codex committees include officials from USDA, EPA, FDA, and other agencies with food-related responsibilities. Industry representatives also participate in various committee delegations as technical observers or advisers.

The main Codex work on pesticide matters is conducted by the Codex Committee on Pesticide Residues, which consists of about 40 countries and is chaired by a representative of the Netherlands, which hosts the meeting annually. The Committee is responsible for prioritizing the pesticides for which standards will be established and for deliberating draft pesticide standards. It relies on an independent body of experts to conduct scientific evaluations of pesticides and to make recommendations on draft standards. This group of experts, the Joint Meeting on Pesticide Residues (JMPR), is selected and organized by the FAO and WHO. Members are appointed because of their expertise in pesticide chemistry or toxicology; they serve as independent experts and not as representatives of their respective governments or agencies.

## U.S. Regulatory System

Three federal agencies—the Environmental Protection Agency, Food and Drug Administration, and U.S. Department of Agriculture--share responsibilities for regulating pesticides in the United States. (See figure 2.2.) Of these, the EPA has by far the largest role in setting standards. The Federal Insecticide, Fungicide, and Rodenticide Act and several sections of the Federal Food, Drug, and Cosmetic Act give the EPA the chief responsibility for regulating the sale, distribution, and use of pesticides in the United States and for establishing legal tolerances for pesticide residues on food and feed commodities. The EPA is responsible for ensuring that when properly used, a pesticide does not pose an unreasonable risk to human health or the environment. When considering risk, the EPA can take into account possible economic, social, and environmental benefits associated with the use of a pesticide. The Office of Pesticide Programs, located within EPA's Office of Pesticides and Toxic Substances, is in charge of carrying out EPA's regulatory work. Its staffing totaled 724 and funding was approximately $77 million in fiscal year 1990.

**Figure 2.2: U.S. Pesticide Regulatory System**




The FDA and USDA are responsible for monitoring the food supply and enforcing pesticide tolerances established by the EPA on both domestic and imported foods. The FDA covers all foods other than meat, poultry, and egg products, which are USDA's responsibility. The FDA and USDA have established programs to assess the frequency and levels of pesticide residues in the food supply.

## Existing Standards

Two types of pesticide standards are used by the EPA and by the Codex:

1. An acceptable daily intake (ADI), which represents the total amount of a pesticide that can be ingested daily over a lifetime without any appreciable health risk. ADIs are reported in milligrams of the pesticide per kilogram of body weight.

2. A maximum residue limit (MRL), which represents the maximum concentration of residue allowed in a food commodity according to accepted pesticide uses. MRLs are reported in milligrams of pesticide residue per kilogram of commodity (parts per million).[1]

Currently, the Codex system includes about 170 pesticides and 2,300 pesticide-by-commodity MRLs as compared to over 400 pesticides and 8,500 pesticide-by-commodity tolerances (MRLs) in the U.S. system. We compared, where possible, U.S. pesticide standards to those of the Codex system. When Codex MRLs that are listed by commodity group or subgroup are converted to the individual commodities that are listed in the U.S. system, the number of Codex MRLs increases from 2,300 to about 3,300. There are no corresponding Codex pesticide MRLs on about 6,200 of the U.S. MRLs; conversely, there are no U.S. MRLs established on about 1,000 of the 3,300 Codex pesticide MRLs. There are corresponding U.S. and Codex MRLs on about 2,300 pesticide-by-commodity cases. These cases are the focus of further analysis in chapter 4.

## Scientific Approach to Setting Pesticide Standards

The scientific approach used to establish pesticide standards is divided into two main evaluation components dealing with potential health effects and the occurrence of residues in food commodities. The following provides a general overview of the conventional processes that the Codex and the United States have in common for establishing standards. Important differences in procedures do exist and are addressed in chapter 3.

[1]In the United States, MRLs are usually referred to as tolerances; the two terms, however, are similar in meaning.

## Health Effects

The evaluation of potential health effects results in the establishment of an estimated ADI level. Assessments of both acute and chronic health effects associated with a pesticide are typically conducted. A variety of animal test data, covering different animal species and testing methods, provide the basic information for identifying such effects.

The basis for proposing an ADI is the identification of a threshold point at which no observed adverse health effects are evident. This point represents an amount of pesticide fed to test animals which produced no health effects. The "no observable effects level" is usually then divided by a safety factor of 10 to 1,000, to account for the uncertainty involved in extrapolating animal test data to humans and to account for differences across the human population. The use of safety factors provides an extra margin of safety in setting the ADI. The size of the safety factor used is a qualitative judgment. A safety factor of 100 is frequently used. In cases where human test data are available, or when available evidence indicates a low health risk, a safety factor of 10 has been used. Larger safety factors of 1,000 or more have been used for pesticides that have an incomplete data base or where higher health risks are apparent.

## Residues on Commodities

An evaluation of pesticide residues is conducted to determine the maximum acceptable level of residues occurring on commodities from existing or proposed uses. Establishing maximum residue limits is contingent upon the setting of an ADI level, which demonstrates that there is an accepted pesticide level where no appreciable health risk exists. MRLs represent the maximum concentration of residue that might occur from the use of a pesticide according to recognized and accepted agricultural practices. MRLs are set high enough to cover a broad range of "good agricultural practices," including different pesticide uses, application rates, and crop-growing conditions.

MRLs are based largely on data covering good agricultural practices, residue chemistry, plant and animal metabolism, environmental fate, and analytical methods for detecting residues. Much of the residue data are derived from supervised field trials. MRLs apply at the "farm gate"; that is, they represent the maximum levels that can be found on a crop at the time of harvest. Actual residue levels found in food commodities at the point of consumption are usually below the MRL.[2] Actual residues are

[2]Some pesticides, however, have been found to concentrate in foods, particularly some processed foods.

lower in part because tolerances are set high enough to account for maximum use rates and extreme residue conditions. In practice, pesticide use is not uniform; an entire crop is not necessarily treated with a particular pesticide nor is it necessarily treated at maximum amounts or application rates. In addition, residue levels for many pesticides decline from the "farm gate" to the point of consumption. These pesticide residues can dissipate during storage and processing. Also, some portion of the residue may be reduced on certain crops when inedible parts or outer layers are removed.

# Differences in the Standard-Setting Processes

In this chapter, we describe differences that exist between the Codex and U.S. processes for establishing pesticide standards. Some of the key technical areas where differences are apparent include: the mix of pesticides included in each system, the use of good agricultural practices, pesticide and commodity definitions, data availability and interpretation, treatment of carcinogenic pesticides, and the use of dietary risk exposure assessments.

## Pesticides Included in Codex and U.S. Sets of Standards

Under the Codex system, the Codex Committee on Pesticide Residues selects pesticides for the FAO/WHO Joint Meeting on Pesticide Residues to evaluate. The Committee bases its selections on the following criteria:

1. The pesticide is used on food or feed commodities important in international trade.

2. It is used commercially somewhere.

3. A member country has nominated the pesticide.

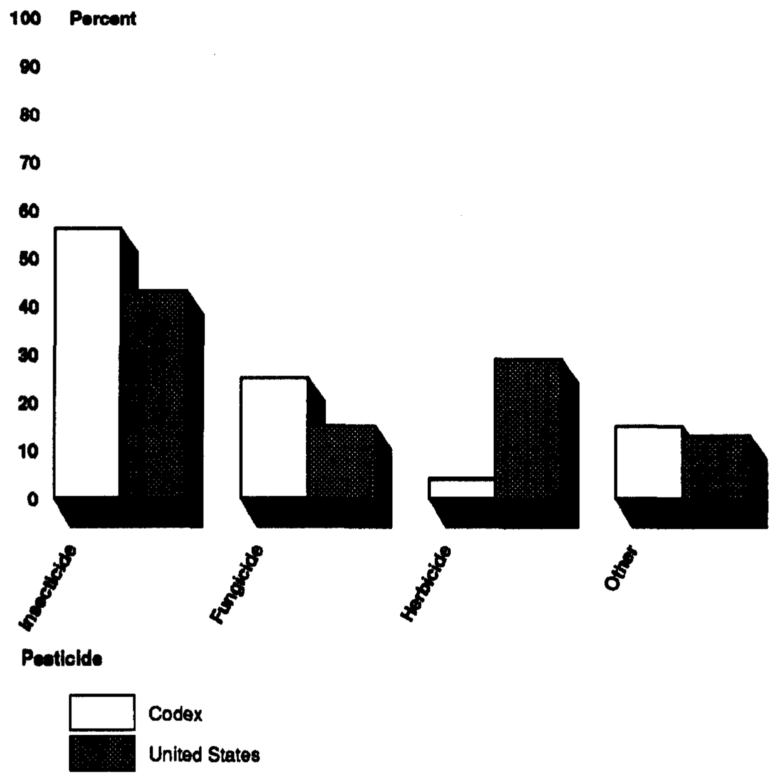
Codex standards also include those pesticides where residues on food and feed commodities are considered likely to occur. As shown in figure 3.1, more fungicides and insecticides are addressed in the Codex system than herbicides (only 4 percent). Fungicides and insecticides are often used late in the growing season or postharvest, when crops are mature and therefore likely to retain residues. In contrast, herbicides are frequently used during the preplanting period, which often results in lower levels of residue on crop plants.[1] In the United States, 29 percent of the established tolerances are for herbicides.

Some pesticides important to international trade or used commercially in other countries that are included in the Codex system are not registered in the United States. There are no U.S. pesticide tolerances, for example, on about 30 percent of the Codex MRLs. Conversely, some pesticides used in the United States for domestic production are not in the Codex system.[2]

[1]Some herbicides, however, are systemic and may be absorbed by a plant rather than dissipating before the plant grows.

[2]Pesticide manufacturers must register a product and have a tolerance granted before it can legally be sold or used in the United States. Thus, all pesticides used for domestic crop production have standards established. In addition, federal tolerances apply to pesticides that leave residues on food commodities that are imported into the United States.

Figure 3.1: Types of Codex and U.S. Pesticides




Note: The Codex system includes about 170 pesticides; the U.S. system includes just over 400 pesticides.
Source: U.S. percentages from National Research Council, Regulating Pesticides in Food (National Academy Press, 1987); Codex percentages from Codex Alimentarius Commission, Guide to Codex Maximum Limits for Pesticide Residues (Sept. 1990).

## Good Agricultural Practices

Pesticide residue levels are directly linked to good agriculture practices, which pertain to the authorized or recognized uses of pesticides. Differences in agricultural practices affect the setting of maximum residue limits. Some differences include:

1. Crop growing conditions such as climate, soil, and pest problems. A crop grown in a hot and humid climate, for example, is likely to require different pest control practices than the same crop grown in a more temperate climate.

2. Allowable uses of pesticides including the types, quantities applied, and frequency of application. Differences can exist with respect to

restrictions on pesticide uses. Under one regulatory system, for example, farmers may be allowed to apply a pesticide more frequently than under another country's system, or farmers may be limited to using a pesticide only during a particular stage of crop production rather than throughout the entire cycle. The pesticide permethrin, for example, can be applied six-to-eight times a season to lettuce in California, while in parts of Europe, it is reported that the pesticide can only be applied one-to-two times a season.

The interval between the time a pesticide is applied to a crop and the point when residue data are collected at the time of harvest can also affect the amount of residue found on the crop. Preharvest intervals in one country, for example, may be 3 days for certain pesticides, whereas in some other countries, the accepted interval may be as high as 21 days for the same pesticides.

3. Production practices such as planting, cultivation, and harvesting. The mix of crops grown and the methods of production can also have some influence on pesticide residue levels. Aerial spraying methods may result in different residue levels on a crop as compared to the application of pesticides more directly to a crop in banded rows.

## Different Definitions of Pesticides and Commodities

### Defining Pesticides

Codex and U.S. standards include different components in their definitions of pesticide residues. Total pesticide residues on commodities can include the parent compound of the pesticide chemical plus components of the pesticide, which may be metabolized or degrade into other chemicals. Some metabolites or degraded materials are considered toxic and may be found in residues in significant amounts.

In the Codex process of evaluating pesticide residues, emphasis is placed on an indicator compound concept. That is, a single compound, such as the parent compound or in some cases a major metabolite, is often considered to be an indicator of the significant residue of concern. The United States, does not use the indicator compound concept as frequently; rather, the EPA tends to base tolerances on the total residues of the parent compound plus significant metabolites. Consideration of the total residue can result in the setting of a numerically higher limit than would be the case if the indicator approach was used.

Differences in the definition of pesticides make it difficult to compare MRLS. In our analysis of Codex and U.S. pesticide standards, we found that about one-third of the pesticide-by-commodity MRLS were not directly comparable because of these differences. According to EPA officials, about 50 percent of the pesticide-by-commodity MRLS set by Codex in recent years have different pesticide residue definitions than those used in the United States.

### Defining Commodities

The definitions of commodities that residue limits apply to can differ as well, which in turn result in different MRLS being established. An MRL may be set on only a portion of a commodity such as the edible part (shelled peanuts) or on the entire commodity (peanuts including the shell). We encountered only a small number of these cases in analyzing Codex and U.S. pesticide MRLS.

## Pesticide Data

### Availability of Data

Pesticide standards are also established using different data packages. The EPA has formal data requirements for manufacturers registering pesticides. The Joint Meeting on Pesticide Residues and the Codex do not have regulatory authority to require specific data for their pesticide reviews and, in some cases, may recommend standards judged by some national authorities to be based on incomplete data. JMPR policy is not to recommend an MRL or ADI if there are major gaps in the data provided by pesticide manufacturers. As Codex member countries review proposed draft standards, they may be able to provide additional data. However, data on residues from a large number of countries representing a variety of agricultural practices—different climates, growing conditions—are not always available under the Codex system for some pesticides. This appears to be the case particularly with obtaining data from some developing countries, which often lack the resources to conduct residue field trials. Data gaps also exist with many of the older tolerances set by the United States and Codex. Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act require the EPA to reevaluate pesticides under current data requirements. In addition, the Codex established a process to reevaluate its older pesticide standards.

## Interpretation of Data

Even when the same data package is used, data may be interpreted differently, resulting in different scientific opinions on where to set MRLs or ADIs. Such differences may be legitimate, because data used to establish an ADI or MRL are often based on test results that provide estimates or ranges of effects. Different levels within a certain range may, in fact, be similar but they are translated into a proposed standard that is defined as a point estimate, the maximum in the case of an MRL.

The JMPR has adopted the approach of "rounding up" to one significant figure when recommending MRLs. Residue levels that fall between 0.01 and 10 parts per million are set at intervals (0.05, 0.1, 0.2, 0.5, and so on) rather than at specific numbers between intervals. The rationale for this approach is to avoid the "appearance of greater analytical accuracy than is possible in practice" and "to minimize debate and proliferation of MRLs".[3] Although the EPA does "round up" in some cases, they tend to use a more precise arithmetic approach to setting tolerances and have not supported the JMPR approach as applied.

Another difference in data interpretation is the consideration of outliers or extreme values from residue test data. Differences of opinion exist about whether or not outliers should be incorporated into the setting of MRLs or excluded because of the small likelihood they would occur as a result of pesticide uses. The EPA tends to include outliers to a greater extent than the JMPR.

Also, there can be differences of opinion concerning the level of the safety factor to use in setting ADIs. Even when Codex and U.S. reviewers arrive at the same threshold value specifying the no observed effects level, a different ADI level can result because different safety factors are employed.

[3]Report of the Twenty-Second Session of the Codex Committee on Pesticide Residues, ALINORM 91/24, appendixes VII and VIII, (Sept. 1990), p. 5.

## Treatment of Carcinogenic Pesticides

The EPA employs a quantitative risk procedure for evaluating pesticides that may be carcinogenic. With noncarcinogenic pesticides, a threshold level (no observed effects level) is identified, which then serves as the basis for establishing an ADI. With carcinogenic pesticides, the EPA assumes that there is no threshold level but rather, a probability of risk exists at any level of exposure.

The focus of the EPA's assessment is to determine if an acceptable level of risk exists for the pesticide. This is accomplished by applying multistage mathematical models to available dose/response test data and taking into account the weight of evidence concerning carcinogenicity. The result is the calculation of human risk probabilities. A risk of one in a million is considered acceptable under certain conditions.[4]

The JMPR uses basically the same procedures for interpreting carcinogenic data as in evaluating other toxic effects of pesticides. It may use a larger safety factor when recommending an ADI level for pesticides where carcinogenic risk is apparent. In cases where a no observed effects level cannot be clearly established and the carcinogenic risk is high, there would be cause for not recommending an ADI.

## Use of Dietary Risk Exposure Assessment

Pesticide tolerances by themselves are not a measure of exposure or health risk. One approach for determining whether a pesticide MRL is safe and reasonable is to evaluate the extent to which consumers may be exposed to pesticide residues. This is done by comparing the established ADI level for a pesticide (which is considered to be the level of residue that can be ingested without any adverse health risk) to an estimate of the amount of residues that are consumed by the general population through their diets. An estimated intake of residues exceeding the ADI is considered questionable.

The EPA conducts theoretical dietary risk exposure assessments as part of its current process for setting tolerances. These assessments of the U.S. population and numerous population subgroups use national dietary food consumption survey data. If the estimated theoretical exposure to pesticide residues exceeds the ADI level, then often the exposure

[4]The United States also has a different safety standard for certain cancer-causing pesticides found in processed food. The Delaney clause (section 409 of the Federal Food, Drug, and Cosmetic Act) prohibits the establishment of food tolerances on a pesticide shown to induce cancer when residues of the pesticide are also found to concentrate in processed food at a level higher than that permitted on a raw commodity. The problems associated with applying different regulatory standards to residues in processed foods versus raw commodities have been the subject of extensive review by the National Academy of Sciences, GAO, and Congress.

is reassessed using more realistic estimates, when they are available, of actual residues found in foods that are consumed. Otherwise, tolerances are modified or denied.[5]

The Codex position, however, is that national authorities should determine the extent to which the consumption of pesticide residues poses an unreasonable risk to the public. The Codex has discussed the feasibility of assessing dietary risk exposure when recommending MRLs. Given the large number of and variability in international diets and potential exposure to residues that exist, coupled with a general lack of accurate food consumption data, it is difficult to conduct such assessments. In recent years, the World Health Organization, using regional types of diets, has conducted exposure assessments for some pesticides.

[5]In practice, a number of older U.S. pesticide tolerances remain in place that would apparently exceed ADI levels using this dietary risk exposure approach.

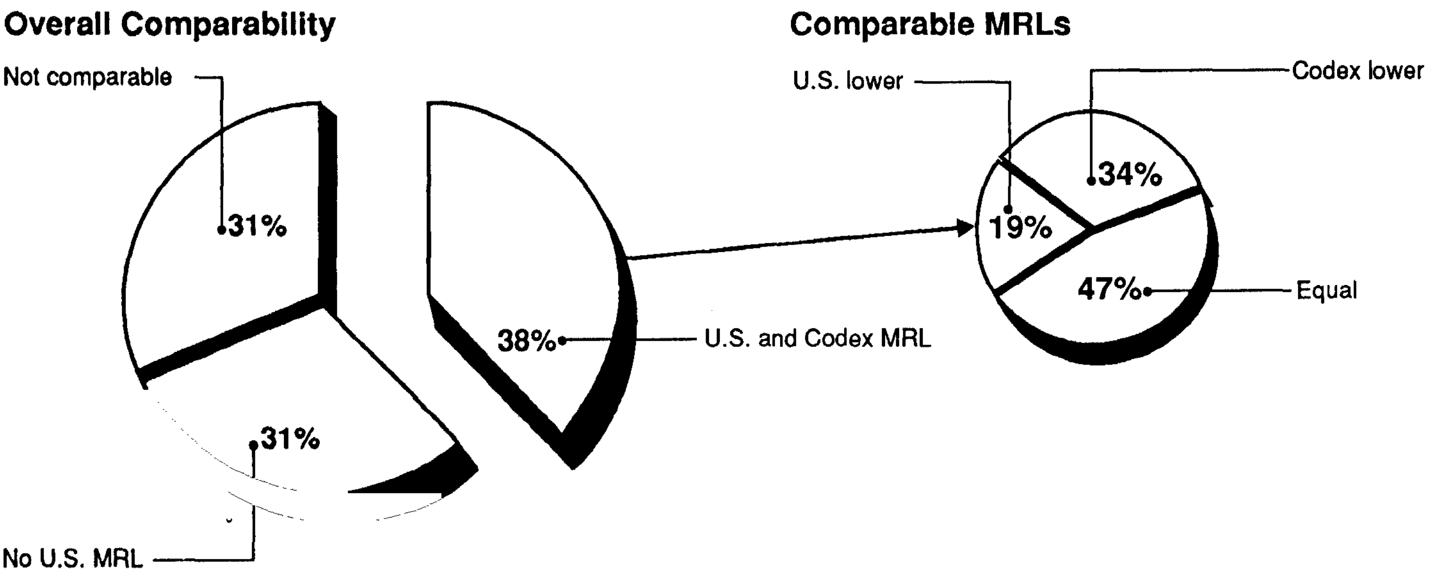
# Comparison of Codex and U.S. Pesticide Standards

In this chapter, we analyze the numerical similarities and differences between Codex and U.S. pesticide standards. We constructed our data base of pesticide standards from the list of 168 pesticides included in the Codex system, although only 119 pesticides had commodities with fully adopted maximum residue limits. U.S. pesticide standards were matched to the Codex list by pesticide and pesticide-by-commodity combinations. Thus, the only standards from the U.S. system included in our analysis are those that correspond to a standard in the Codex system. In a number of cases, the Codex reports an MRL for a commodity group or subgroup as a whole; whereas, the United States reports MRLs for the individual commodities within a group. In these cases, we converted the Codex commodity group MRLs into MRLs for the equivalent individual commodities. This resulted in a total of 3,336 pesticide-by-commodity MRL cases in our data base. The following figures highlight the comparisons between Codex and U.S. pesticide MRLs and acceptable daily intake levels.

## Pesticide MRLs

As shown in figure 4.1, MRLs in the data base could not be compared across the U.S. and Codex systems in 62 percent of the cases. This is because either no MRL was assigned by the United States (31 percent) or

**Figure 4.1: Comparability of U.S. and Codex MRLs**

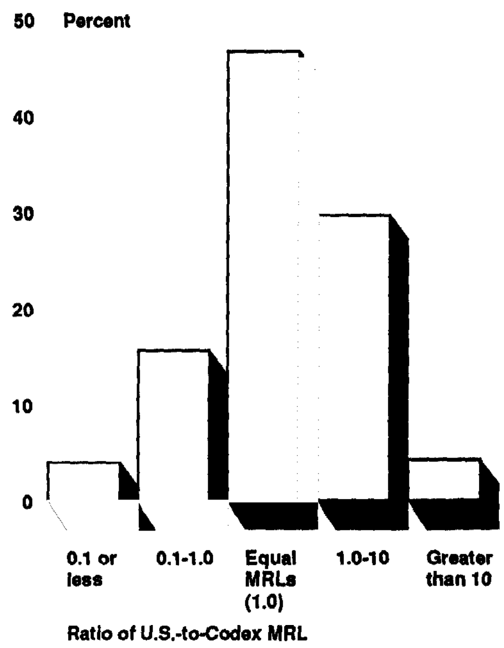



Note: The data base contains 3,336 cases.

different definitions were applied to the pesticide or commodity tested (31 percent). In 38 percent of the cases, U.S. and Codex MRLs can be compared. Of these 1,267 cases, nearly half (47 percent) of the MRLs are the same across the two systems. The United States has a lower MRL for 19 percent of the commodities, while the Codex MRLs are lower for 34 percent of the cases.

Figure 4.2 portrays the magnitude of the differences between the Codex and U.S. systems for the 1,267 cases in which U.S. and Codex MRLs are comparable. The comparison is based on the ratio of the U.S. MRL to the Codex MRL for each commodity. In about 8 percent of the cases, either the Codex or the U.S. MRL differs from the other by more than a factor of 10. The Codex tolerance exceeds the U.S. tolerance (4 percent) about as often as the U.S. tolerance exceeds that specified by the Codex (4 percent). Smaller differences between the two systems (less than a factor of 10) are found in 45 percent of the cases, with the Codex tolerance being lower than the U.S. tolerance a larger proportion of the time. Across this sample, the Codex tolerance is lower for 29 percent of the cases, while the U.S. tolerance is lower for 16 percent of them.

**Figure 4.2: Comparison of U.S.-to-Codex Maximum Residue Limits**

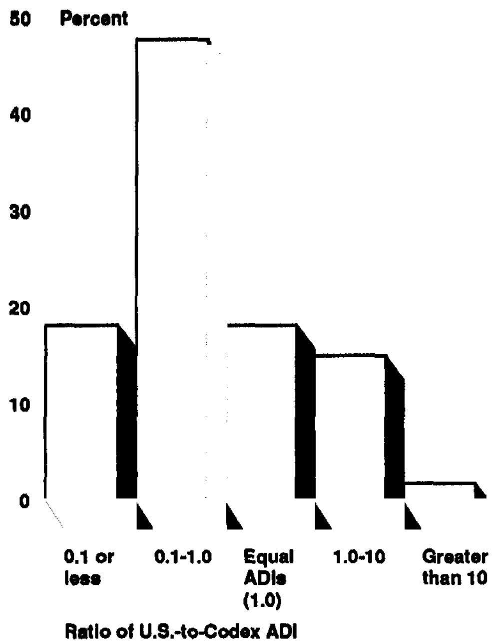



Note: These 1,267 cases represent those pesticides with U.S. and Codex MRLs. When less than 1.0, U.S. MRL is lower; when greater than 1.0, U.S. MRL is higher.

## Pesticide ADIs

In contrast to the pattern observed with the MRLs, U.S. standards tend to be numerically lower, as shown in figure 4.3, than Codex standards when acceptable daily intake levels are compared. A comparison of the ADI levels for the pesticides reveals that the United States has specified lower ADI levels for the majority of cases (66 percent). For 18 percent of the pesticides, the U.S. ADI is at least 10 times lower than the Codex ADI. The United States has specified a higher ADI for 16 percent of the cases; only 2 percent are at least 10 times greater than the Codex ADI.

**Figure 4.3: Comparison of U.S.-to-Codex Acceptable Daily Intake Levels**

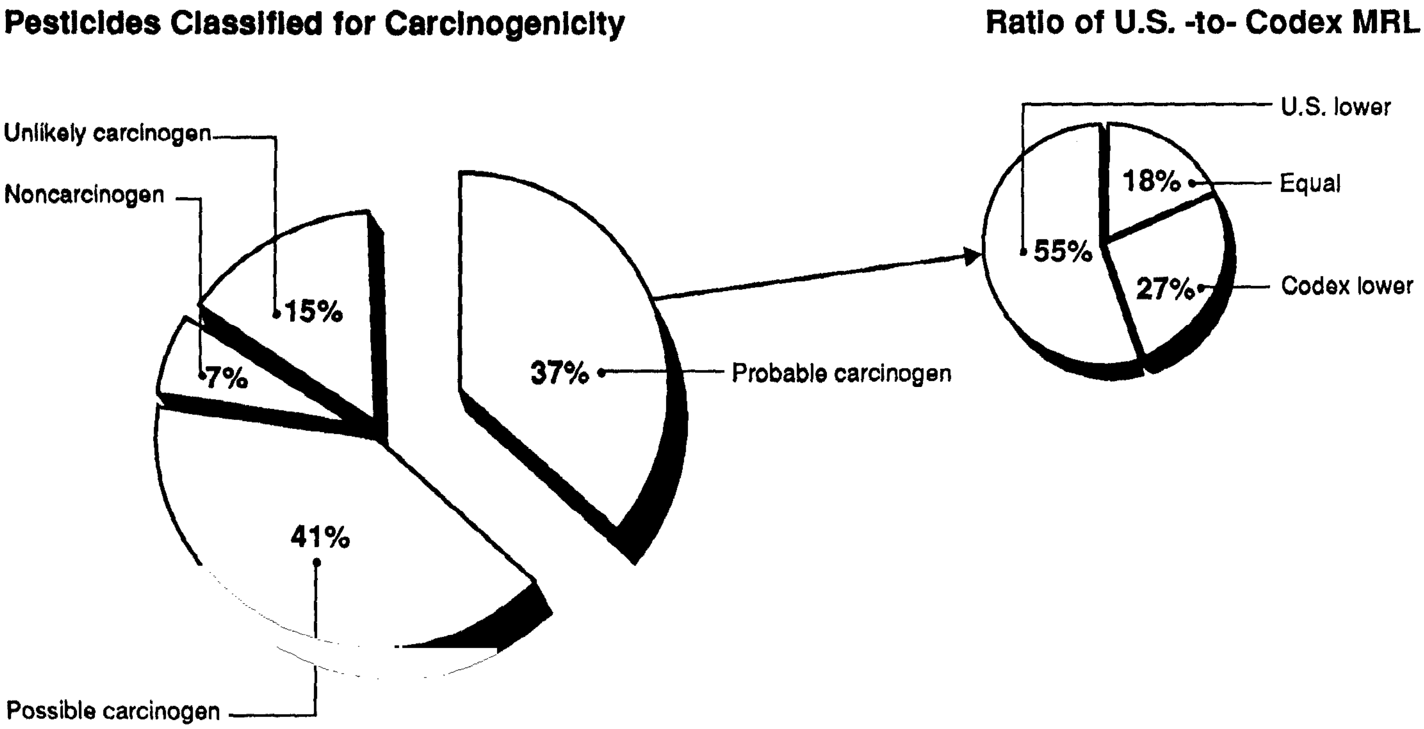



Note: The sample consists of 78 pesticides having both U.S. and Codex ADIs. When less than 1.0, U.S. ADI is lower; when greater than 1.0, U.S. ADI is higher.

## Pesticides Evaluated for Carcinogenicity

Among the pesticides included in our study, the EPA has classified 41 on the basis of some evidence of carcinogenicity. While none is considered a definite human carcinogen, 15 (37 percent) are viewed as probable carcinogens and another 17 (41 percent) are considered possible carcinogens.[1] Among those rated as probable carcinogens, the United States has a lower tolerance than the Codex in 55 percent of the cases.[2] (See figure 4.4.) This compares with 19 percent for the total set of MRLs that can be compared, which was shown in figure 4.1. Also, there is considerably less agreement between the U.S. and Codex systems on the appropriate tolerance level for these pesticides. This is indicated by the fact that

**Figure 4.4: Comparison of U.S. and Codex MRLs on Probable Carcinogens**




Note: Of the 41 pesticides evaluated in our data base, none is considered a human carcinogen; 139 pesticide-by-commodity cases are included in this comparison of Codex and U.S. MRLs.

[1] Pesticides evaluated for carcinogenicity are classified, based on the weight of the evidence, in accordance with EPA's Cancer Assessment Guidelines. A human carcinogen (Group A) demonstrates sufficient evidence of cancer causality from human epidemiologic studies. A probable human carcinogen (Group B) demonstrates either limited evidence of carcinogenicity from human epidemiologic studies or sufficient evidence of carcinogenicity from animal studies. A possible human carcinogen (Group C) demonstrates limited evidence of carcinogenicity in animals when human data are absent and under various other circumstances. A pesticide is classified as an unknown carcinogen (Group D) when it cannot be classified because of inadequate evidence of carcinogenicity or the absence of data. A pesticide is classified as a noncarcinogen (Group E) when there is no evidence of carcinogenicity in at least two adequate animal tests in different species or when there is no evidence occurring in both epidemiologic and animal studies.

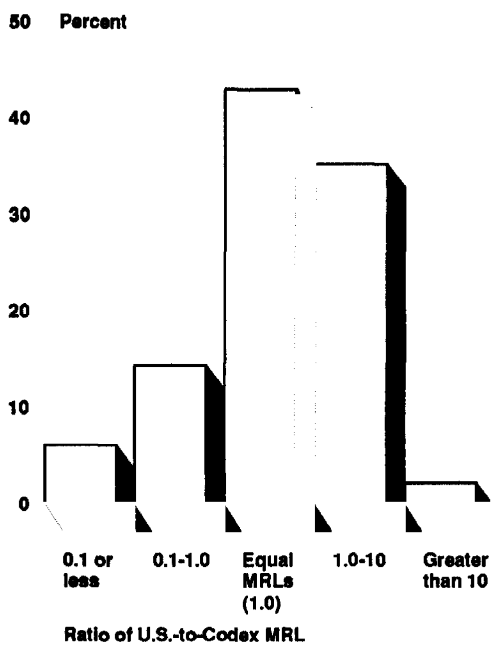
[2] There are 139 pesticide-by-commodity combinations included in the comparison of Codex and U.S. MRLs for the 15 pesticides considered probable carcinogens.

only 18 percent of the MRLs are equal, while for the total number of MRL cases, 47 percent of the tolerances are equal.

## Pesticides Used on Major U.S. Commodities

Figure 4.5 portrays the magnitude of the differences between U.S. and Codex MRLs for major U.S. exports and imports.[3] The results for this group of cases are similar to those found for the entire set of MRLs shown in figure 4.2. Somewhat less than half of the MRLs are equal between the two systems. In only about 8 percent of the cases does either the U.S. or Codex MRL exceed the other by at least a factor of 10. And among those cases in which the differences between the two systems are smaller, there is a tendency for the United States to assign a higher tolerance.

**Figure 4.5: Comparison of U.S. and Codex MRLs for Major U.S. Exports and Imports**




Note: Our sample consists of 353 MRLs. Comparison is the ratio of U.S.-to-Codex MRL. When less than 1.0, U.S. is lower; when greater than 1.0, U.S. is higher.

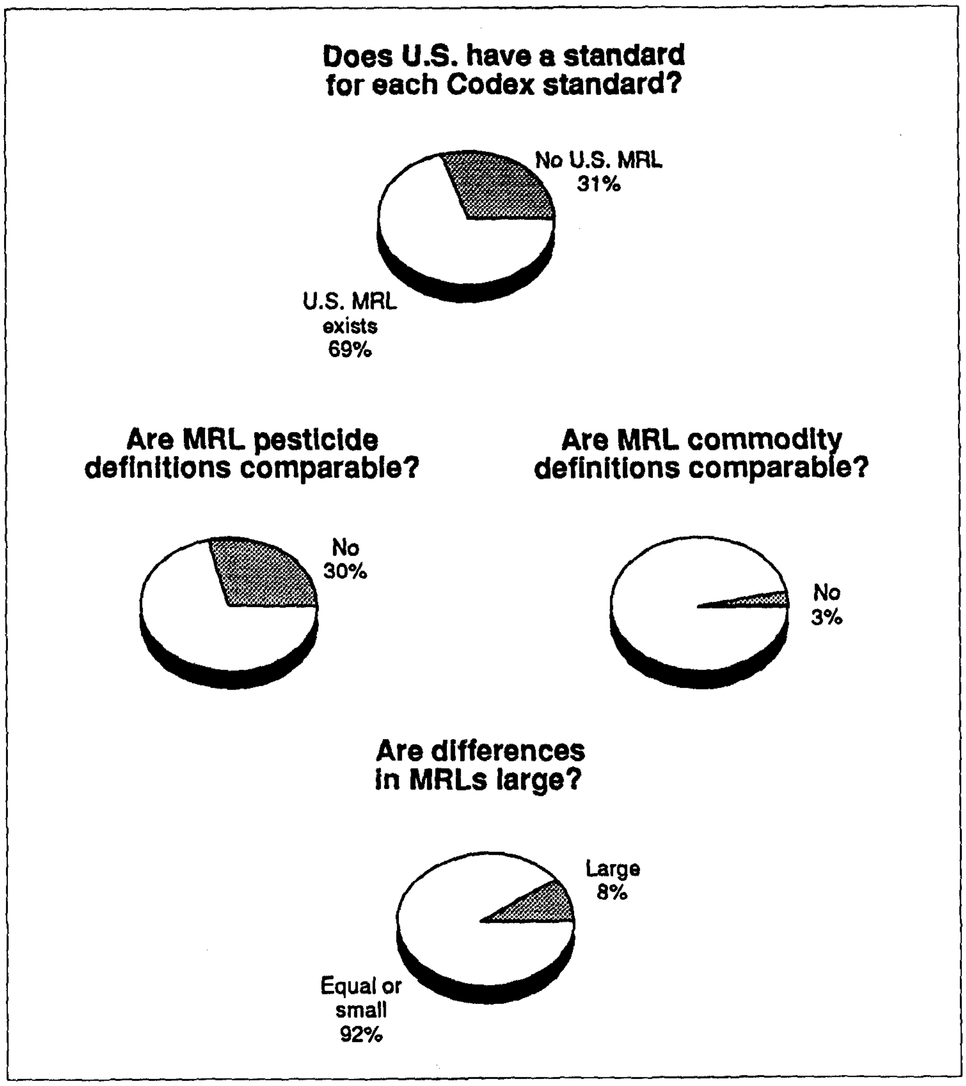
## Summary of Differences

As figure 4.6 shows, major differences distinguish U.S. and Codex MRLs. The absence of a U.S. MRL (portrayed by the upper chart) and technical differences owing to the use of incompatible definitions of pesticides and commodities (indicated by the two charts in the middle) account for over 60 percent of the cases. Another important difference, which is not

[3]Using available USDA trade data, we selected 20 fruits, vegetables, and grain crops that account for the largest U.S. agricultural exports and imports.

reflected in our data base comparisons but should be highlighted, is the significant number of other cases where the United States has established tolerances for pesticides and commodities that are not covered in the Codex system. Where cases can be compared, however, large numerical differences (by more than a factor of 10) in the level of U.S. and Codex MRLs occur infrequently (see the lower chart).

**Figure 4.6: Summary of Differences Between U.S. and Codex Pesticide Standards**




Note: A total of 3,336 pesticide-by-commodity combinations were compared in all but the lower chart, which includes 1,267 cases.

# Implications of Differences in Standards

As shown in the previous chapter, numerical differences are apparent between Codex and U.S. standards. Whether these differences are, in fact, significant is difficult to determine. Specific criteria are not available for evaluating what constitutes a large difference. Some experts note that, overall, differences tend to be small and probably not significant, while others consider significant any standards that differ by a factor of 5 to 10. To understand better what these differences in standards can mean, it is useful to examine them within the context of agricultural trade and food safety issues.

In this chapter, we characterize the potential trade and food safety implications of different Codex and U.S. pesticide standards under three general cases, where (1) the Codex has an MRL, but the U.S. does not; (2) the United States has an MRL, but the Codex does not; and (3) the Codex and the United States each have a different MRL. Since Codex standards are currently voluntary and have not been fully adopted by most national authorities, these comparisons are essentially hypothetical. However, they are important because they help to illustrate the type of problems that can arise between countries with differences in standards. Otherwise, little empirical research exists to provide insight into the likely economic or health effects associated with different food safety standards.

## Trade Implications

Pesticide monitoring studies have shown that actual residue levels found on commodities are usually well below maximum residue limits. Pesticide MRLs, however, have the potential to be viewed as official standards and subsequently used as trade barriers by countries wanting to protect domestic market interests. Generally though, trade problems occur between countries not only because differences exist in the standards themselves, but also because residues on imported commodities are discovered and found to be in violation of a country's standard.

### Codex Has an MRL but U.S. Does Not

As shown in figure 4.6, the United States has no pesticide MRLs for 31 percent of the Codex MRLs. Two basic conditions exist to explain why there is no U.S. MRL. Either (1) a pesticide has never been used in the United States, and therefore, no tolerance was ever established through the U.S. regulatory system, or in the case of imports, no import tolerance was ever sought; or (2) a pesticide may have been used previously in the United States, but tolerances were revoked based on health or environmental concerns.

Trade problems, in this case, can occur with imports. Under current U.S. law, imported commodities found to contain residues of pesticides for which there are no existing tolerances, as well as those which exceed established tolerance limits, are considered "adulterated" and are subject to impoundment under federal regulations. The economic consequence of this condition would be a loss of market sales to both foreign exporters and U.S. importers.

The recent U.S. detention of wine imported from Europe that was found to contain residues of the fungicide procymidone could, according to EPA estimates, have resulted in trade losses of up to $300 million for European producers and exporters as well as for U.S. distributors. Although procymidone is used in a large number of wine-producing countries of Europe to control the grape disease botrytis, it is not registered for use in the United States nor were there any U.S. tolerances established for it in 1990 when it was detected in European wine imports.[1] The manufacturer of procymidone, Sumitomo Corporation of Japan, petitioned the EPA to establish a tolerance in 1990 after the detention of wine occurred. The EPA conducted a preliminary risk assessment on procymidone. Even though the petitioner did not meet all data requirements, the EPA concluded that enough data were available to indicate that there would be no significant public health risk from exposure to identified residue levels in wine. In April 1991, the EPA established an interim pesticide tolerance for procymidone residues on wine grapes. The interim tolerance will remain in effect for 4 years and only allows those wines made from grapes treated with procymidone prior to 1990 to be imported into the United States.

If the United States were to allow imports treated with pesticides that do not have legal tolerances, then under certain situations, this might give foreign producers a competitive advantage over domestic producers who grow the same crop. That is, foreign producers could have the advantage of using a pesticide that may be cheaper and more effective than those the U.S. producers are currently allowed to use. However, a restriction on foreign food imports that are treated with unaccepted pesticides could benefit domestic producers because there would be less market competition from foreign producers.[2]

[1] Under the Codex system, draft maximum residue limits for procymidone have been recommended by the JMPR and the Codex Committee on Pesticide Residues.

[2] If substitutes—other pesticides or technologies—are available that are similar in cost and effectiveness, then no economic impact would be likely to result because of restrictions.

Access to foreign markets should not be a problem for U.S. exports under this condition. If a pesticide is not used domestically in the United States, then there should be no problem in terms of U.S. exports meeting established international standards.

### U.S. Has an MRL but Codex Does Not

In this case, trade problems are possible for U.S. food exports but not likely for imports. The inverse of the trade considerations discussed above could pertain to U.S. exports under this condition. Foreign governments could restrict the import of U.S. products treated with pesticides not officially recognized by their own national regulatory systems. With respect to foreign exports to the United States, there would be no restrictions on foreign-grown commodities that do not contain pesticide residues that may be regulated in the United States.

### Codex and U.S. Each Have a Different MRL

Where a Codex MRL is higher than a U.S. MRL, U.S. exports should not be restricted. However, U.S. imports of foreign foods that have been produced with higher levels of pesticides could be restricted unless foreign producers varied their pesticide use to comply with the lower U.S. standards. Restrictions on U.S. imports might benefit U.S. producers by limiting foreign competition.

Where a Codex MRL is lower than a U.S. MRL, the potential for restrictions on U.S. exports would exist. Economic consequences for the United States would depend on the size of the particular agricultural sector and the extent to which U.S. producers could meet the more stringent international standards. This would involve the possible revision of existing pesticide use, effects of reduced use on crop yield or quality, and the availability of cost-effective alternatives. A process might have to be developed to assure foreign governments that U.S. products comply with the international standard if export problems develop. There should be no problem with imports into the United States in this case because the commodities would have been grown under conditions permitting lower residue limits.

## Food Safety Implications

An equally important concern involving pesticide use is the extent to which the public may be exposed to harmful pesticide residues on food products. Differences in pesticide residue limits can lead to an increase or decrease in exposure depending on the particular pesticide, its use on food crops, and the type and amounts of foods consumed by the general population. The potential food safety implications of different Codex and U.S. pesticide standards can be characterized under three general cases.

## Codex Has an MRL but U.S. Does Not

Foods that are treated with pesticides for which the United States has not established tolerances run the risk of creating possible health concerns. Foods might either be treated with pesticides that were previously banned in the United States for health or environmental reasons, or they may be treated with pesticides that have not previously been evaluated by the United States for health and safety risks.

## U.S. Has an MRL but Codex Does Not

This condition should not increase health concerns because it pertains only to those pesticides that have been evaluated by U.S. regulatory procedures.

## Codex and U.S. Each Have a Different MRL

Acceptance of a higher international standard could raise health concerns because of possible increased exposure. A lower international standard should not produce any possible health concerns.

# Dietary Risk Exposure Assessment

We conducted a dietary risk exposure assessment of selected pesticides to demonstrate the correspondence between differences in maximum residue limits and established acceptable daily intake levels. As discussed previously, the EPA makes such comparisons when evaluating proposed tolerances in order to determine if further refined residue estimates are necessary. The analysis is theoretical in that it assumes the maximum allowable residue limits without attempting to estimate anticipated or actual residue levels that are likely to occur on foods.

We selected three pesticides—diquat, triforine, and malathion—which showed large numerical differences between Codex and U.S. MRLS and which also illustrated conditions where Codex MRLS are both higher (diquat) and lower (triforine and malathion). The results of this assessment are provided in table 5.1.[3] As shown, the theoretical maximum residue contribution as a percentage of the U.S. ADI for diquat increases

[3]The analysis was conducted using USDA's 1977-78 dietary food consumption data for the U.S. population average. Each Codex and U.S. pesticide-by-commodity MRL was multiplied by the average daily consumption of the corresponding food item to derive a theoretical maximum residue contribution. These values were then summed and compared to the established U.S. acceptable daily intake for that pesticide. The ADI is the estimated daily intake of a pesticide over a lifetime that is determined to have no appreciable health risk. In the analysis, no attempt was made to estimate the percent of each crop that is consumed from imports or from domestic production.

from 31 percent for the U.S. MRLs to 94 percent for the Codex MRLs. The theoretical intake of triforine residue is reduced slightly when the Codex MRLs are substituted for U.S. MRLs. And for malathion, residue consumption is reduced from 493 percent of the ADI to 267 percent when considering the Codex MRLs.[4]

**Table 5.1: Theoretical Dietary Risk Exposure Assessment: Codex and U.S. Standards**

| Pesticide | Theoretical maximum residue contribution[a] | Acceptable daily intake[a] | TMRC as a percent of U.S. ADI | Change in U.S. dietary exposure using Codex MRLs |
|---|---|---|---|---|
| Diquat | | | | |
| U.S. | .00069 | .0022 | 31 | |
| Codex | .00208 | .0080 | 94 | Increase |
| Triforine | | | | |
| U.S. | .00351 | .0250 | 14 | |
| Codex | .00277 | .0200 | 11 | No change |
| Malathion | | | | |
| U.S. | .09870 | .0200 | 493 | |
| Codex | .05360 | .0200 | 268 | Decrease |

[a]The theoretical maximum residue contribution (TMRC) and acceptable daily intake (ADI) are stated in mg/kg body weight per day.

## Conclusions: Implications of Different Standards

Many differences exist between U.S. and Codex pesticide standards. These differences are a reflection of both technical factors pertaining to pesticide uses and agricultural practices and factors related to the procedures used to evaluate and establish standards. As long as such differences persist, the potential for international trade problems will remain. Yet reducing potential trade problems by harmonizing general standards could affect food safety.

A greater degree of harmonization may be possible for pesticide standards in particular, but in order to determine if and where such improvements can occur, the United States needs to systematically review and assess existing pesticide-by-commodity standards on a case-by-case basis. Small differences could be adjusted as long as it is clear that unreasonable health risks would not result. Conversely, larger differences may involve consideration of more systemic changes in the way

[4]Malathion was initially registered in the United States in 1956, and many of the tolerances set on food commodities were established years ago when federal registration requirements were less stringent than current regulations. Many of the older tolerances are not considered by the EPA to be adequately supported by current scientific data requirements, and malathion will be reviewed as part of the reregistration effort mandated by the Federal Insecticide, Fungicide, and Rodenticide Act.

pesticide tolerances have been set, including: risk assessment approaches for carcinogenic pesticides, appropriate definitions for pesticides and commodities, consideration of issues pertaining to good agricultural practices, and methods for recognizing international standards in cases where national standards do not exist.

## Recommendation

Avoiding possible agricultural trade disputes in the future will require a better understanding of the scientific basis for the differences between U.S. and international food safety standards. Our study provides an important first step at assessing the correspondence of pesticide standards and evaluating the implications of differences in standards for trade and food safety. Harmonization will be difficult to achieve because there are significant differences between U.S. and Codex standards; however, opportunities exist to reconcile some standards, particularly those that have only small numerical differences and are likely to have no associated trade or health impacts. Reconciling others, though, which may be more difficult because (1) pesticide definitions are different, (2) either the United States or the Codex has no standard established, or (3) numerical differences between standards are large, may nonetheless be critical because of health, safety, or international trade consequences. Therefore, we recommend that the Administrator of EPA, in cooperation with the Secretary of Agriculture, conduct further analyses to (1) determine the likely effects that differences in standards would have on health and trade interests of the United States and (2) set priorities for determining the extent of the scientific basis for differences in pesticide standards.

# Codex Process for Adopting Pesticide Standards

The Codex establishes standards through a lengthy stepwise procedure that takes several years to complete. Draft standards are first recommended by the Joint Meeting on Pesticide Residues and then reviewed at different stages by members of the Codex Committee on Pesticide Residues and the Codex Alimentarius Commission. Decisions for approval or referral to the JMPR for further evaluation are made at formal meetings. In principle, the chairmen of the Committee and the Codex synthesize a majority of opinion among members and if no major opposition is voiced, a standard is approved and adopted.

## Codex Stepwise Procedure

The following describes the action taken at each step of the Codex procedure for establishing standards.

1. The selection of a pesticide is made by the Codex Committee on Pesticide Residues based on recommendations of a Committee priorities working group.

2. Arrangements are made for the FAO/WHO Joint Meeting on Pesticide Residues to conduct the pesticide evaluation.

3. JMPR recommendations (MRLs and ADIs) are sent out to member countries for comment.[1]

4. Proposed draft standards and member country comments are discussed by the Committee. A decision is made either to forward the draft standards to the Codex for consideration or to refer them back to the JMPR for further evaluation.

5. Proposed draft standards are submitted to the Codex for review. The Committee may recommend that the Codex skip steps 6 and 7 and consider draft standards directly for adoption.[2]

6. A draft standard is sent to member countries for comment.

[1]Draft MRLs are also available to international organizations for comments. Representatives from the following international organizations have attended Committee meetings in recent years: International Group of National Associations of Manufacturers of Agrochemical Products, European Economic Community, Confederation Europeenne du Commerce de Detail, International Organization for Standardization, Association of Official Analytical Chemists, International Organization of Consumers' Unions, and International Union of Pure and Applied Chemistry.

[2]A recommendation to omit steps 6 and 7 is made in cases where the general view of the Committee is that the proposed standards are not controversial and, therefore, a second round of comments from member countries is not needed. The option of eliminating these two steps is offered as a means of streamlining the process.

7. The Committee reviews the comments and considers amending the draft standard.[3]

8. The draft standard is submitted to the Codex for its approval to adopt it as a standard.

## Formal Acceptance of Codex Standards by Member Countries

Once a standard is adopted by the Codex, it is published and distributed to member countries, who are asked to indicate whether or not they will accept it. The Codex provides the following categories of acceptance:

1. Full acceptance: country ensures that it will comply with the maximum residue limit on both domestically produced and imported foods.

2. Free distribution: food products conforming to the Codex maximum limit will be distributed freely.

3. Nonacceptance.[4]

A majority of the member countries have not provided formal acceptance responses. Codex officials have indicated that pesticide standards have not been widely accepted by many member countries. A Codex survey is currently underway asking member countries to provide acceptance responses in a new computerized format.

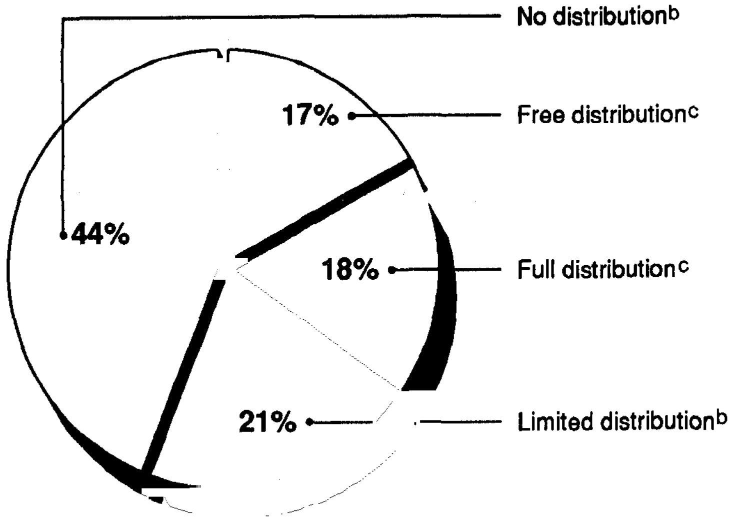
The U.S. position on Codex pesticide standards has been to review individual standards and determine how they compare to U.S. standards. U.S. acceptance positions for Codex pesticide MRLs as of 1988 are provided in figure I.1.[5]

[3]Draft standards can be held at step 7 in cases where: (1) an ADI is only temporary, (2) further consideration by the JMPR is underway, or (3) further action by the Committee may be forthcoming.

[4]Codex previously used four categories of acceptance: (1) full acceptance; (2) nonacceptance, but products complying with the Codex limits can be distributed freely; (3) nonacceptance, but products complying with Codex limits can be distributed under certain conditions; and (4) nonacceptance, with no distribution allowed.

[5]Includes those MRLs for which there were no corresponding U.S. MRLs as well as MRLs with different definitions of pesticides.

**Figure I.1: U.S. Acceptance of Codex MRLs[a]**




[a]The number of MRLs is 2,784 as of 1988.

[b]Nonacceptance by current Codex definition of terms.

[c]Acceptance by current Codex definition of terms.
Source: EPA.

# Comparability of Pesticide Residue Limits

Table II.1 provides a comparison of U.S. and Codex maximum residue limits for each pesticide in the Codex list. A ratio of the U.S.-to-Codex MRLS is used to show numerical differences. Also listed is the number of commodities for each pesticide in which there is no U.S. MRL or in which Codex and U.S. MRLS are not comparable because of different residue definitions.

**Table II-1: Comparability of Pesticide Residue Limits**

| Codex number | Pesticide | Number of commodities in which ratio of U.S.-to-Codex MRL is: 0.01 or less | 0.01-1 | 1 (equal) | 1-10 | 10 or more | Not comparable[a] | Total |
|---|---|---|---|---|---|---|---|---|
| 023 | 1,2-Dibromoethane[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 024 | 1,2-Dichloroethane[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 020 | 2,4-D | 0 | 0 | 9 | 10 | 3 | 4 | 26 |
| 121 | 2,4,5-T | 0 | 0 | 0 | 0 | 0 | 13 | 13 |
| 095 | Acephate | 0 | 0 | 9 | 2 | 0 | 5 | 16 |
| 117 | Aldicarb | 0 | 2 | 15 | 1 | 0 | 5 | 23 |
| 001 | Aldrin and dieldrin | 0 | 22 | 17 | 5 | 1 | 7 | 52 |
| 134 | Aminocarb[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 122 | Amitraz | 1 | 1 | 4 | 5 | 0 | 7 | 18 |
| 079 | Amitrole[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 163 | Anilazine[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 068 | Azinphis-ethyl[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 002 | Azinphos-methyl | 4 | 5 | 6 | 28 | 1 | 7 | 51 |
| 129 | Azocyclotin[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 155 | Benalaxyl | 0 | 0 | 0 | 0 | 0 | 3 | 3 |
| 137 | Bendiocarb | 0 | 0 | 0 | 0 | 0 | 25 | 25 |
| 069 | Benomyl[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 003 | Binapacryl[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 093 | Bioresmethrin[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 144 | Bitertanol | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 004 | Bromophos | 0 | 0 | 0 | 0 | 0 | 46 | 46 |
| 005 | Bromophos-ethyl | 0 | 0 | 0 | 0 | 0 | 28 | 28 |
| 070 | Bromopropylate | 0 | 0 | 0 | 0 | 0 | 14 | 14 |
| 139 | Butocarboxim[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 071 | Camphechlor[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 006 | Captafol[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 007 | Captan | 0 | 0 | 2 | 12 | 2 | 6 | 22 |
| 008 | Carbaryl | 0 | 6 | 38 | 46 | 3 | 14 | 107 |
| 072 | Carbendazim[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 096 | Carbofuran | 0 | 0 | 17 | 11 | 4 | 14 | 46 |

(continued)

| Codex number | Pesticide | Number of commodities in which ratio of U.S.-to-Codex MRL is: 0.01 or less | 0.01-1 | 1 (equal) | 1-10 | 10 or more | Not comparable[a] | Total |
|---|---|---|---|---|---|---|---|---|
| 009 | Carbon disulphide[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 010 | Carbon tetrachloride[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 011 | Carbophenothion | 2 | 7 | 5 | 4 | 1 | 10 | 29 |
| 145 | Carbosulfan[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 097 | Cartap | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 080 | Chinomethionat | 0 | 1 | 7 | 1 | 0 | 15 | 24 |
| 012 | Chlordane | 0 | 0 | 0 | 40 | 0 | 31 | 71 |
| 013 | Chlordimeform[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 014 | Chlorfenvinphos | 3 | 0 | 2 | 0 | 1 | 25 | 31 |
| 015 | Chlormequat | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 016 | Chlorobenzilate | 0 | 0 | 0 | 1 | 0 | 9 | 10 |
| 081 | Chlorothalonil | 3 | 1 | 17 | 1 | 0 | 13 | 35 |
| 017 | Chlorpyrifos | 1 | 4 | 6 | 10 | 7 | 10 | 38 |
| 090 | Chlorpyrifos-methyl | 0 | 2 | 0 | 5 | 8 | 13 | 28 |
| 156 | Clofentezine | 0 | 1 | 3 | 4 | 0 | 6 | 14 |
| 018 | Coumaphos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 019 | Crufomate | 0 | 0 | 3 | 0 | 0 | 2 | 5 |
| 091 | Cyanofenphos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 157 | Cyfluthrin[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 146 | Cyhalothrin | 0 | 0 | 0 | 0 | 0 | 6 | 6 |
| 067 | Cyhexatin | 0 | 0 | 10 | 0 | 0 | 8 | 18 |
| 118 | Cypermethrin | 0 | 1 | 0 | 2 | 0 | 37 | 40 |
| 104 | Daminozide[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 021 | DDT | 11 | 22 | 9 | 9 | 1 | 19 | 71 |
| 135 | Deltamethrin | 0 | 0 | 0 | 0 | 0 | 29 | 29 |
| 092 | Demeton[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 073 | Demeton-s-methyl[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 164 | Demeton-s-methylsulphon[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 098 | Dialifos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 022 | Diazinon | 0 | 9 | 39 | 21 | 0 | 10 | 79 |
| 082 | Dichlofluanid | 0 | 0 | 0 | 0 | 0 | 23 | 23 |
| 025 | Dichlorvos | 0 | 3 | 9 | 2 | 0 | 8 | 22 |
| 083 | Dicloran | 0 | 0 | 3 | 7 | 2 | 5 | 17 |
| 026 | Dicofol | 0 | 0 | 25 | 13 | 0 | 4 | 42 |
| 130 | Diflubenzuron | 0 | 1 | 14 | 1 | 0 | 9 | 25 |
| 151 | Dimethipin | 0 | 0 | 11 | 0 | 0 | 14 | 25 |
| 027 | Dimethoate | 0 | 0 | 5 | 6 | 0 | 12 | 23 |
| 087 | Dinocap[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 028 | Dioxathion | 0 | 0 | 15 | 0 | 0 | 2 | 17 |

(continued)

| Codex number | Pesticide | Number of commodities in which ratio of U.S.-to-Codex MRL is 0.01 or less | 0.01-1 | 1 (equal) | 1-10 | 10 or more | Not comparable[a] | Total |
|---|---|---|---|---|---|---|---|---|
| 029 | Diphenyl | 0 | 0 | 1 | 0 | 0 | 1 | 2 |
| 030 | Diphenylamine | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| 031 | Diquat | 6 | 18 | 0 | 1 | 0 | 14 | 39 |
| 074 | Disulfoton | 1 | 4 | 13 | 26 | 0 | 4 | 48 |
| 105 | Dithiocarbamates | 0 | 4 | 0 | 13 | 2 | 4 | 23 |
| 084 | Dodine | 0 | 0 | 4 | 1 | 0 | 1 | 6 |
| 099 | Edifenphos | 0 | 0 | 0 | 0 | 0 | 9 | 9 |
| 032 | Endosulfan | 4 | 1 | 38 | 1 | 0 | 4 | 48 |
| 033 | Endrin | 0 | 2 | 0 | 8 | 2 | 8 | 20 |
| 106 | Ethephon[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 107 | Ethiofencarb | 0 | 0 | 0 | 0 | 0 | 32 | 32 |
| 034 | Ethion | 0 | 0 | 44 | 2 | 1 | 4 | 51 |
| 149 | Ethoprophos | 0 | 0 | 18 | 0 | 0 | 11 | 29 |
| 035 | Ethoxyquin | 0 | 0 | 2 | 0 | 0 | 0 | 2 |
| 108 | Ethylenethiourea (ETU)[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 123 | Etrimfos | 0 | 0 | 0 | 0 | 0 | 29 | 29 |
| 085 | Fenamiphos | 0 | 1 | 4 | 4 | 0 | 11 | 20 |
| 109 | Fenbutatin oxide | 0 | 0 | 2 | 16 | 5 | 7 | 30 |
| 036 | Fenchlorphos | 0 | 4 | 5 | 1 | 1 | 0 | 11 |
| 037 | Fenitrothion | 0 | 0 | 0 | 0 | 0 | 32 | 32 |
| 038 | Fensulfothion | 0 | 1 | 15 | 0 | 0 | 0 | 16 |
| 039 | Fenthion | 4 | 1 | 1 | 0 | 0 | 25 | 31 |
| 040 | Fentin | 0 | 3 | 2 | 0 | 0 | 5 | 10 |
| 119 | Fenvalerate | 1 | 3 | 11 | 30 | 5 | 22 | 72 |
| 152 | Flucythrinate | 1 | 0 | 4 | 1 | 0 | 23 | 29 |
| 165 | Flusilazole[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 041 | Folpet | 0 | 1 | 2 | 11 | 0 | 1 | 15 |
| 042 | Formothion | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| 158 | Glyphosate | 6 | 3 | 4 | 1 | 1 | 7 | 22 |
| 114 | Guazatine | 0 | 0 | 0 | 0 | 0 | 6 | 6 |
| 043 | Heptachlor | 1 | 38 | 7 | 1 | 1 | 8 | 56 |
| 044 | Hexachlorobenzene[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 045 | Hydrogen cyanide | 0 | 0 | 8 | 0 | 1 | 1 | 10 |
| 046 | Hydrogen phosphide | 0 | 0 | 11 | 9 | 0 | 2 | 22 |
| 110 | Imazalil | 0 | 0 | 0 | 3 | 1 | 8 | 12 |
| 047 | Inorganic bromide | 0 | 3 | 28 | 9 | 0 | 4 | 44 |
| 111 | Iprodione | 0 | 0 | 1 | 9 | 1 | 8 | 19 |
| 131 | Isofenphos | 0 | 0 | 0 | 23 | 0 | 13 | 36 |
| 088 | Leptophos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

(continued)

| Codex number | Pesticide | Number of commodities in which ratio of U.S.-to-Codex MRL is | | | | | Not comparable[a] | Total |
|---|---|---|---|---|---|---|---|---|
| | | 0.01 or less | 0.01-1 | 1 (equal) | 1-10 | 10 or more | | |
| 048 | Lindane | 0 | 13 | 2 | 17 | 2 | 10 | 44 |
| 049 | Malathion | 0 | 5 | 21 | 23 | 16 | 7 | 72 |
| 102 | Maleic hydrazide | 0 | 0 | 2 | 0 | 0 | 0 | 2 |
| 050 | Mancozeb[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 124 | Mecarbam | 0 | 0 | 0 | 0 | 0 | 4 | 4 |
| 138 | Matalaxyl | 0 | 1 | 0 | 12 | 4 | 6 | 23 |
| 125 | Methacrifos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 100 | Methamidophos | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 051 | Methidathion | 2 | 6 | 4 | 15 | 2 | 10 | 39 |
| 132 | Methiocarb | 0 | 2 | 0 | 0 | 0 | 15 | 17 |
| 094 | Methomyl[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 147 | Methoprene | 0 | 0 | 1 | 8 | 0 | 4 | 13 |
| 052 | Methyl bromide[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 053 | Mevinphos | 0 | 0 | 13 | 9 | 3 | 5 | 30 |
| 054 | Monocrotophos | 0 | 1 | 1 | 2 | 0 | 25 | 29 |
| 140 | Nitrofen[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 055 | Omethoate | 0 | 0 | 0 | 0 | 0 | 23 | 23 |
| 056 | Ortho-phenylphenol | 0 | 0 | 17 | 3 | 0 | 4 | 24 |
| 126 | Oxamyl | 0 | 2 | 11 | 4 | 0 | 9 | 26 |
| 166 | Oxydemeton-methyl[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 161 | Paclobutrazol[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 057 | Paraquat | 2 | 5 | 30 | 2 | 8 | 3 | 50 |
| 058 | Parathion | 0 | 4 | 3 | 63 | 0 | 3 | 73 |
| 059 | Parathion-methyl | 0 | 0 | 0 | 36 | 3 | 4 | 43 |
| 120 | Permethrin | 2 | 10 | 9 | 16 | 7 | 38 | 82 |
| 127 | Phenothrin[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 128 | Phenthoate | 0 | 0 | 0 | 0 | 0 | 5 | 5 |
| 112 | Phorate | 0 | 0 | 11 | 3 | 1 | 2 | 17 |
| 060 | Phosalone | 0 | 1 | 3 | 9 | 0 | 12 | 25 |
| 103 | Phosmet | 0 | 2 | 16 | 5 | 2 | 5 | 30 |
| 061 | Phosphamidon | 0 | 0 | 1 | 10 | 0 | 16 | 27 |
| 141 | Phoxim | 0 | 0 | 0 | 0 | 0 | 13 | 13 |
| 062 | Piperonyl butoxide | 2 | 3 | 36 | 2 | 0 | 5 | 48 |
| 101 | Pirimicarb | 0 | 0 | 0 | 0 | 0 | 48 | 48 |
| 086 | Pirimiphos-methyl | 0 | 2 | 0 | 7 | 2 | 40 | 51 |
| 142 | Prochloraz | 0 | 0 | 0 | 0 | 0 | 13 | 13 |
| 136 | Procymidone[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 148 | Propamocarb | 0 | 0 | 0 | 0 | 0 | 11 | 11 |
| 113 | Propargite | 0 | 3 | 42 | 4 | 1 | 11 | 61 |

(continued)

| Codex number | Pesticide | Number of commodities in which ratio of U.S.-to-Codex MRL is | | | | | Not comparable[a] | Total |
|---|---|---|---|---|---|---|---|---|
| | | 0.01 or less | 0.01-1 | 1 (equal) | 1-10 | 10 or more | | |
| 160 | Propiconazole[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 075 | Propoxur | 0 | 0 | 0 | 0 | 0 | 15 | 15 |
| 150 | Propylenethiourea (PTU)[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 153 | Pyrazophos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 063 | Pyrethrins | 2 | 3 | 38 | 0 | 0 | 5 | 48 |
| 064 | Quintozene | 1 | 3 | 1 | 5 | 0 | 3 | 13 |
| 089 | Sec-butylamine[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 115 | Tecnazene | 0 | 0 | 0 | 0 | 1 | 2 | 3 |
| 167 | Terbufos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 065 | Thiabendazole | 1 | 0 | 11 | 4 | 1 | 6 | 23 |
| 154 | Thiodicarb | 0 | 1 | 2 | 3 | 0 | 3 | 9 |
| 076 | Thiometon | 0 | 0 | 0 | 0 | 0 | 34 | 34 |
| 077 | Thiophanate-methyl | 0 | 2 | 5 | 8 | 2 | 14 | 31 |
| 162 | Tolyfluanid[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 133 | Triadimefon | 0 | 4 | 2 | 5 | 4 | 14 | 29 |
| 168 | Triadimenol[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 143 | Triazophos[b] | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 066 | Trichlorfon | 1 | 8 | 17 | 2 | 1 | 23 | 52 |
| 116 | Triforine | 2 | 0 | 1 | 6 | 0 | 8 | 17 |
| 078 | Vamidothion | 0 | 0 | 0 | 0 | 0 | 2 | 2 |
| 159 | Vinclozolin | 0 | 0 | 3 | 5 | 0 | 20 | 28 |

[a]No U.S. MRL or MRLs are not comparable because of differences in pesticide or commodity definitions.

[b]There are no Codex MRLs for commodities under this pesticide.

# Major Contributors to This Report

## Program Evaluation and Methodology Division

Richard T. Barnes, Assistant Director
John E. Oppenheim, Project Manager
Nila Garces-Osorio, Social Science Analyst
Cathy D. Kassab, Social Science Analyst

# Glossary

| | |
|---|---|
| Acceptable Daily Intake | This term refers to the total estimated amount of a pesticide that can be ingested daily over a lifetime without any appreciable health risk. ADIs are reported in milligrams of the pesticide per kilogram of body weight per day. |
| Good Agricultural Practice | This term refers to the nationally authorized and recognized use of a pesticide, which is presumed to be a safe as well as an effective and reliable means of pest control. |
| Metabolite | A pesticide metabolite is a chemical derivative of a pesticide formed by plant or animal metabolism. |
| Maximum Residue Limit | This is the maximum concentration of a pesticide residue allowed on a food commodity according to recognized and accepted agricultural practices. MRLs are reported in milligrams of pesticide residue per kilogram of commodity (parts per million). In the United States, MRLs are referred to as tolerances. |
| No Observable Effects Level | This is the highest dose of a pesticide fed to test animals that produces no acute or chronic health effects. It is used to determine the acceptable daily intake for a pesticide. |
| Safety Factor | The safety factor is a numerical value used to provide a margin of safety in establishing an ADI. It accounts for the uncertainty involved in extrapolating animal test data to humans and for differences in the human population. |
| Theoretical Maximum Residue Contribution | This is an estimate of the maximum amount of a pesticide residue theoretically consumed per day by a person on an average diet. |
| Tolerance | The term is used by the EPA to indicate the maximum amount of pesticide residue allowed to remain in food or animal feed. The Codex Alimentarius Commission refers to a pesticide tolerance as a maximum residue limit (MRL). |

## Ordering Information

The first five copies of each GAO report are free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20877

Orders may also be placed by calling (202) 275-6241.

United States
General Accounting Office
Washington, D.C. 20548

Official Business
Penalty for Private Use $300

First-Class Mail
Postage & Fees Paid
GAO
Permit No. G100