

The Value of Countries Working Together to Regulate Pesticides and Food Safety

Achieving Public Health and
Environmental Protection
through International
Collaboration



Improved Protection and:

Access to Safer Pesticides in All
Markets

Cost-Effective Pesticide Regulation
Among Countries

Elimination of Trade
Barriers and Issues

TRADE FACTS AND FIGURES

The Numbers

FOOD IMPORTS

\$80.5 Billion (2008 data)¹

The United States imports food from over **150 countries**¹

44 percent of fresh fruit is imported²

16 percent of fresh vegetables is imported (2003 -2005)²

55 percent of agricultural imports is from the European Union, Canada, and Mexico (FY 2008)³

FOOD EXPORTS

\$115 Billion¹

One-third of U.S.-harvested acreage is exported (wheat, corn, cotton, and soybeans), according to USDA estimates³

\$28 billion was forecasted in FY 2008 for total U.S. agricultural exports to Canada and Mexico, the first- and second-largest markets for U.S. agricultural exports³

PESTICIDE IMPORTS

\$2.2 billion in 2008⁴

PESTICIDE EXPORTS

\$2.5 billion in 2008⁴

PESTICIDE USE

5.0 billion pounds

Estimated world pesticide use (2000-2001)⁴

1.2 billion pounds

Estimated U.S. pesticide use (2000-2001)⁴

Three-quarters of pesticide use occurs in developed countries, mostly in North America, Western Europe, and Japan³

Data Sources:

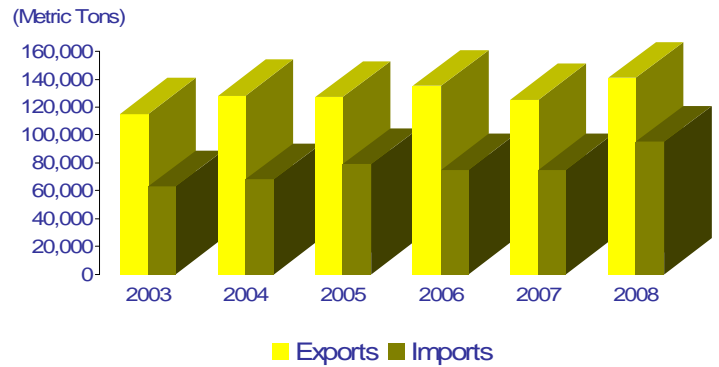
¹<http://www.fas.usda.gov/ustrade/USTExFatus.asp?QI>

²<http://www.ers.usda.gov/Publications/fts/2007/08Aug/fts32801/fts32801.pdf>

³<http://www.ers.usda.gov/Data/FATUS/DATA/XMScy1935.xls>

⁴<http://www.epa.gov/oppbead1/pestsales/>

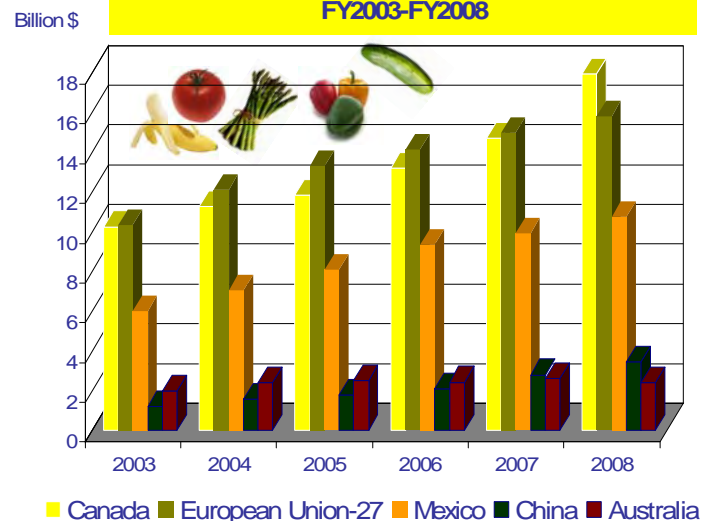
U.S. PESTICIDE EXPORTS AND IMPORTS BY VOLUME (2003-2008)



TOP 15 SOURCES OF U.S. FOOD IMPORTS

- Canada
- European Union (27 Countries)
- Mexico
- China
- Australia
- Brazil
- Indonesia
- Chile
- New Zealand
- Colombia
- Thailand
- Costa Rica
- Argentina
- India
- Malaysia

TOP 5 SOURCES OF U.S. AGRICULTURAL IMPORTS FY2003-FY2008



The top fresh fruit and vegetable imports include bananas, pineapples, citrus, avocados, apples, grapes, melons, tomatoes, cucumbers, peppers, asparagus, and onions.



Rice imports at port (Daylife image)

International Collaboration is Key to Achieving U.S. Goals

In the 21st century, food production and distribution are global. Pesticides are developed and marketed globally for use in controlling agricultural and other pests, and pesticide residues often remain in the food we eat. Scientific research and advances in risk assessment and management are also global. Decisions on pest control and pesticide management made in one country can have global repercussions. Increasingly, the agricultural labor force crosses national boundaries. Therefore, to achieve public health and environmental protection goals and fulfill our statutory and treaty mandates, our national pesticide program must actively engage with international partners.

Since 2001, U.S. agricultural trade has more than doubled, from \$91 billion to about \$195 billion. Food imports have increased from \$39 billion to \$80.5 billion. While this expanding international trade in food helps ensure a varied, abundant, and affordable food supply, it also underlines the critical importance of ensuring that foods that may contain pesticide residues meet high safety standards. Working with source countries is a critical component of our multifaceted safety scheme.

Many pesticide ingredients and pesticide products used in the United States are manufactured abroad. Since the 1960s, those pesticide imports have increased dramatically. It is in America's interest to help ensure those foreign products are safe and effective.

International regulatory, scientific, and risk communication work on pesticide issues advances public health and environmental protection in the United States and worldwide. It improves the effectiveness and efficiency of regulation, builds capacity that enhances sound management of pesticides, and encourages the development and deployment of effective pest control technologies in the United States and globally.

International Program Strategic Goals

The Office of Pesticide Programs (OPP) has identified four strategic goals for international work, all of which support the Environmental Protection Agency's core mission of strengthening public health and environmental protection:

- Goal 1: Strengthen Protection And Work With Partners To Reduce Pesticide Risks
- Goal 2: Enhance Scientific Basis of Regulatory Decision-Making
- Goal 3: Improve Efficiency And Save Resources
- Goal 4: Minimize Unnecessary Technical Barriers To Trade



Worker unloading bananas (Getty image)

Most industrialized countries have programs for pesticide review, so there are tremendous opportunities for collaboration to enhance the scientific basis of decision-making and harmonize approaches to pesticide evaluation and management. Developing countries are seeking assistance to improve food safety, public health, and environmental standards for their own people, and to promote economic development through agricultural exports. To safeguard the food supply and achieve development goals, it is key that these countries have information on how to comply with the pesticide residue standards that are in place in the United States and other potential markets.

OPP's international work is fundamental to helping OPP achieve key domestic program objectives:

- **Safer Food:** Reducing the possibility of illegal products (pesticides and foods containing excessive pesticide residues) entering the United States. Ensuring that food to be imported is protected at the source is fundamental to the web of activities necessary to promote a safe food supply.
- **Collaboration with Enforcement Agencies:** Improving compliance with U.S. food safety standards by collaborating with enforcement agencies. The Food and Drug Administration is responsible for enforcing EPA's pesticide residue requirements for most foods, and the Food Safety and Inspection Service of the U.S. Department of Agriculture is responsible for enforcement for meat, poultry, and some egg products. This includes sampling and enforcement for imported foods at the borders, as well as domestically produced food. While preventing problems at the source is our goal, enforcement remains an important tool and deterrent.
- **Lower-risk Pesticides:** Promoting use of safer means of pest control in the United States through greater international harmonization. Without international collaboration, the health and environmental benefits of safer means of pest control will not be realized. U.S. agricultural producers/exporters will not use newer, often safer, pesticide products approved by EPA unless residue standards that reflect U.S. agricultural practices are in place for those products in key export markets.
- **Better Science:** Improving the scientific basis of decisions by utilizing a broader range of scientific expertise and sharing reviews of scientific studies submitted in support of pesticide registration. Better, more protective, and defensible regulatory decisions result. Quicker actions can be facilitated through the international exchange of ideas and priorities.
- **Control of Trans-Boundary Pollution:** Providing expertise on the assessment and management of pesticides that affect the global commons (e.g., most of the Persistent Organic Pollutants (POPs) that are the focus of international attention are pesticides, as are most chemicals identified under the Rotterdam Convention relating to Prior Informed Consent/PIC for hazardous chemicals in trade).

Statutory Mandates

"The Administrator shall ... participate and cooperate in any international efforts to develop improved pesticide research and regulation."

-- Federal Insecticide, Fungicide, and Rodenticide Act, Section 17(d)

"The Administrator shall... determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission."

-- Federal Food, Drug, and Cosmetic Act, Section (b)(4)

About Some of Our International Partners

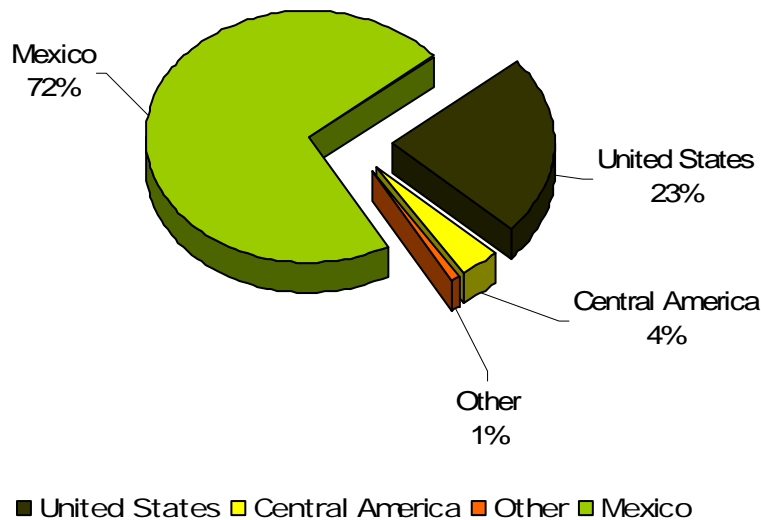
OECD - The Organisation for Economic Co-operation and Development, an intergovernmental organization consisting of 30 industrialized countries in Europe, North America, Asia, and the Pacific.

NAFTA TWG - The North American Free Trade Agreement Technical Working Group on Pesticides, a collaboration among the government agencies responsible for pesticide regulation in the United States, Canada, and Mexico, initiated in 1997.

Codex Alimentarius – The joint food standards program of the World Health Organization and the U.N. Food and Agriculture Organization. Over 160 countries are members of Codex, and many other international organizations and consumer, environmental, and industry non-governmental groups participate as observers

- **Protection of Agricultural Workers:** Addressing the needs of a common agricultural labor force in the Americas through more effective training programs for worker protection, which also reduces the cost to employers of meeting their training obligations. Findings from the 2003-2004 National Agricultural Worker Survey (over 6,000 workers surveyed) show that:
 - 72 percent of the workers were born in Mexico.
 - The agricultural workforce has a high turnover rate, with foreign-born newcomers comprising 14 percent of the hired crop labor force.

Agricultural Workers by Country of Origin



- **Saved Resources:** Reducing the burden on regulatory agencies and the private sector (which has to invest resources in developing data and submissions for OPP review and approval before new pesticide products can be marketed).

Representative Benefits of International Collaboration

Goal 1: Strengthen Protection and Work with Partners to Reduce Pesticide Risks.

Examples of recent accomplishments include:

- Supporting the work of the World Health Organization/U.N. Food and Agriculture Organization joint food standards program (known as the Codex Alimentarius) to ensure that the internationally recognized Codex maximum residue limits (MRLs) meet high safety standards. Many countries rely on Codex MRLs as their national standards, and under U.S. law, EPA must harmonize with Codex or publish a *Federal Register* notice explaining the deviation.
- Accelerating the availability of pesticides that do not pose dietary risk concerns and revoking MRLs that do not meet current safety standards and/or are not supported by up-to-date scientific data. At the most recent meeting of the Codex Committee on Pesticide Residues, over 260 MRLs for 18 pesticides were advanced for approval, 92 MRLs for 13 pesticides were recommended for revocation, and over 110 MRLs were either withdrawn or returned to an international panel of experts for further review.
- Encouraging a new global focus on “minor uses,” specialty crops that, individually, might not be attractive enough to pesticide producers for them to shoulder the costs of studies that are necessary for EPA approval. Minor uses include most fruits and vegetables and are important to a healthy diet, so it is critical that adequate means of pest control are available. The issues are similar for specialty crop producers in all countries. EPA has undertaken work in Codex to focus on the issues of minor uses from a global perspective and develop a crop grouping system that can serve the needs of global producers by including all traded crops in the crop grouping scheme. Such a scheme would allow for maximum residue limits to be established for a larger group of related crops based on data developed for a few representative crops, without requiring studies for all of the individual crops in the group.



Worker sorting tomatoes (Associated Press Photo)

- Reaching global consensus on one international standard for evaluating the safety of foods derived from biotechnology (including those food crops producing their own pesticides) through our participation in Codex Alimentarius activities. A harmonized standard helps ensure that foods coming to the United States meet our safety standards and prevents trade restrictions on U.S. commodities being exported.
- Working with Mexico, Central American countries, and other countries on training programs to reduce direct and indirect pesticide exposure to migrant agricultural workers and their families. For example, such work in Mexico, through a network of trainers across 20 Mexican states, has resulted in 1,300 new trainers and over 22,000 trainees, including health workers, field technicians, traders, and pesticide applicators, as well as agricultural workers and their families.
- Briefing over 100 international visitors each year, advising them on the U.S. regulatory system and the stringent standards we enforce for food safety, health, and environmental protection.



This worker safety training session in El Salvador included a demonstration on how to properly use personal protective equipment and a presentation/video about pesticide safety.

- Developing a two-year comprehensive program of bilateral cooperation with China to enhance pesticide management. We believe this program will not only benefit the United States and China, but also strengthen protection more broadly, given the importance of both countries in agricultural and chemical production and trade.



OPP Director and USDA officials meet with the Director of the Institute for Control of Agrochemicals, Ministry of Agriculture, People's Republic of China, to discuss a cooperative work program between the U.S. and China

Agricultural Trade with China

The United States is a net exporter of bulk commodities (primarily soybeans) to China, and a net importer of fish, forest products, vegetables, and various processed foods from China.

Chinese pesticide exports to the United States in recent years have increased more than ten fold, from \$12 million in 1999 to \$162 million in 2005.

Based in part on the U.S. evaluation and cancellation of fipronil, China proceeded with cancellation of fipronil use on rice.

Goal 2: Enhance the scientific basis of decision-making by leveraging scientific/regulatory resources with the international community.

We are increasing the pace and credibility of regulatory decisions and actions by building common/compatible international regulatory systems (e.g., harmonized data requirements and formats, work sharing, standard classification criteria and label elements). Compatible formats enhance efficiency and permit use of modern information technology, such as electronic data submission, to multiple regulatory authorities. Rather than operate in isolation, regulatory authorities can work together to improve the scientific basis and transparency of pesticide risk assessments while increasing efficiency.

OPP has taken a leadership role in this work, for example, working with Canada to develop an "MRL calculator," a standardized statistical approach to setting MRLs aimed at ensuring greater harmony when regulators review the same residue data. This is now the common approach in North America and is increasingly favored at a broader international level (notably, it has been recommended by the Codex Committee on Pesticide Residues).

Other work to advance the scientific basis of pesticide regulation includes:

- Development of harmonized testing protocols and guidance on data interpretation through the Organisation for Economic Co-operation and Development (OECD), including work to develop smarter testing strategies and address emerging concerns, e.g., with respect to screening pesticides for potential endocrine disrupting effects.

As an OECD member, the United States is bound by treaty obligations to accept data developed in accordance with OECD guidelines, so it is important that EPA contribute scientific expertise to these international efforts and work to ensure that our domestic policies are consistent with international scientific consensus to the degree possible. Harmonized, updated guidelines can also reduce the need for animal testing.

- Through the Codex Alimentarius, collaboration to reach global consensus on guidance documents related to the appropriate safety evaluation of foods derived from modern biotechnology. (Many of the most commonly grown biotech crops are regulated by EPA under U.S. pesticide laws because they have been genetically modified to express pesticidal properties.)
- The establishment of an international group of regulators who are comfortable working together provides the ability to cooperate with other authorities on controversial pesticide issues. Some current examples include:
 - Understanding and addressing bee colony collapse disorder.
 - Continuing concerns such as methods for screening pesticides for potential endocrine disrupting effects and the appropriate safety evaluations for foods derived with the use of biotechnology.

Smarter Testing

EPA has been working with regulatory and research agencies in other countries through existing international fora (e.g., NAFTA TWG, OECD, the World Health Organization) to move from a paradigm that involves requiring *in vivo* testing for “every possible adverse outcome” to a hypothesis-driven paradigm where existing data, *in silico* (computer simulated) models (e.g., structure activity relationships or SARs), and *in vitro* data, combined with estimates of exposure, are used to determine what specific *in vivo* tests are required.

Such a paradigm shift would significantly improve EPA’s ability to carry out its mission of protecting public health and the environment.

It would focus on the most likely hazards of concern and determine what specific effects data for each chemical and exposure situation are essential to assess and manage risks appropriately.

It would also reduce the use of animals in testing.

Additionally, it would lower the costs for the government and tax payers because the Agency could avoid reviewing unnecessary tests.

Goal 3: Conserve resources of EPA, consumers, growers, and industry stakeholders through more efficient regulatory processes.

Resource savings can be significant as a result of streamlining and sharing the work of regulatory reviews at the international level and promoting more timely development of international standards and common test methods.

- In 2007, a study presented to the OECD Working Group on Pesticides estimated resource savings of 33-40 percent as a result of joint review by three to five countries, compared to each country working alone. The study noted that the savings from reducing duplicative expert evaluation work significantly outweighed the marginal increase for project management, coordination, and travel. To date, OPP has achieved **savings of \$1.4 million** in extramural resources from seven multilateral joint reviews. These savings enable us to complete more, and more timely, decisions and avoid backlogs. Sharing reviews also provides a built-in additional element of scientific peer review.

EPA and other countries working together through OECD and the NAFTA TWG have completed 26 joint pesticide reviews and worksharing projects, and 14 joint reviews and worksharing projects are planned and/or ongoing.

- Development and implementation of common regulatory tools and approaches advance both scientific collaboration and regulatory efficiency goals. For example, we have worked to develop standardized templates, study review formats, harmonized test guidelines and "zone" maps (maps developed by the NAFTA TWG to permit field trials conducted in similar geographical circumstances in one NAFTA country to be used to support new product registration in the other countries).

These tools and approaches reduce compliance costs for stakeholders, facilitate work sharing for regulators, and help avoid costly, duplicative testing by ensuring that the data developed and submitted in one country can be used by other countries in reaching their regulatory decisions.

Estimated resource savings of 33-40% when three to five countries review pesticides jointly, compared to each country working alone. Estimated U.S. savings from seven multilateral joint reviews: \$1.4 million

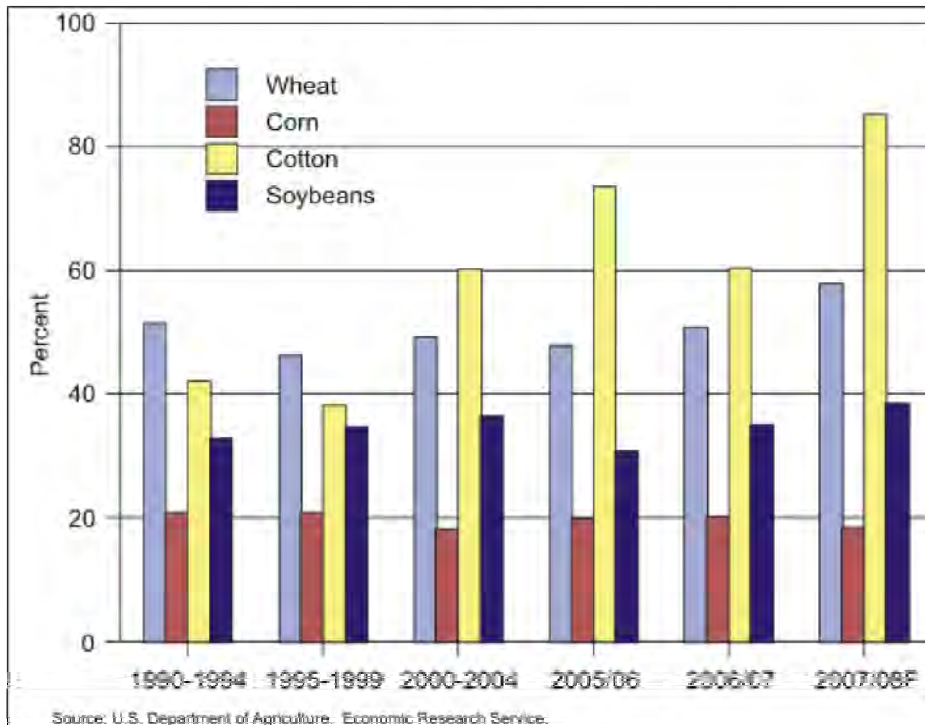
The first NAFTA Pesticide Product Label was for a conventional agricultural pesticide that was registered in January 2007, based on a joint review by U.S. EPA and Canada's Pest Management Regulatory Agency. Six additional NAFTA labels have been registered since then.

Goal 4: Minimize international trade issues related to pesticide regulatory requirements and facilitate fair trade that is consistent with high health and environmental standards.

OPP collaborates with domestic and international governmental agencies, trading partners, agricultural producers, the pesticide industry, and others to minimize trade irritants without lowering the level of protection afforded by our high regulatory standards.

- We provided extensive comments and shared data to Japanese authorities as they began implementing major changes to their food safety system, enabling the two countries to avoid major disruptions in agricultural trade. We also advise other countries on U.S. regulatory requirements so that they do not risk seizure and destruction of crops they export to the United States due to illegal pesticide residues.
- When OPP reached the conclusion that use of the pesticide azinphos-methyl (AZM) should be phased out in the United States due to unacceptable risks, we worked closely with U.S. growers and engaged our regulatory counterparts in other countries in ongoing work to make effective, reduced-risk alternatives available. To ensure a smooth transition to safer means of pest control, it is important that the required regulatory clearances be in place in other countries for crops that the United States exports. Many major markets have yet to adopt MRLs for AZM alternatives, but through Codex and the NAFTA TWG, we are continuing to work to resolve the remaining issues.
- Capacity building of regulatory bodies, especially in developing countries, improves the opportunities for unrestricted trade in U.S. commodities such as corn and soybeans that typically are genetically engineered crops in the United States. Information exchanges with Japan over the last several years have improved our ability to resolve issues more rapidly regarding questions on the safety of biotechnology products and have eased tensions over U.S. exports.

Figure 2. U.S. Agricultural Exports: Share of U.S. Production Exported, 1990/91-2007/08F



F = Forecast for 2008.

- We have also addressed stakeholder concerns about inconsistencies in residue standards by undertaking several commodity pilot projects to reduce trade irritants through the NAFTA TWG.

Summary

International work directly advances OPP's ability to achieve its core mission of public health and environmental protection. Greater collaboration also means increased transparency, stronger science, and improved regulatory credibility and efficiency. It provides opportunities to do things better, cheaper, and faster.

The range of OPP's international projects and partners is broad, deep, and increasingly integral to all aspects of the pesticide program. We have scores of projects and, while we have had to set priorities based on limited resources, we are continuing to reap real benefits from the international work we undertake. We expect those benefits to accelerate in the future as work proceeds.

Background/Source Materials

- CRS Report for Congress: U.S. Agricultural Trade: Trends, Composition, Direction, and Policy, Updated January 29, 2008
- Value of U.S. agricultural trade by fiscal year at Foreign Agricultural Trade of the United States (FATUS) - <http://www.ers.usda.gov/Data/FATUS/DATA/XMS1935fy.xls>
- Increased U.S. Imports of Fresh Fruit and Vegetables, Sophia Huang and Kuo Huang, September 2007 - <http://www.ers.usda.gov/Publications/fts/2007/08Aug/fts32801/fts32801.pdf>
- NAFTA 5-Year Strategy 2008-2013 and the NAFTA 2003-2008 Accomplishments Report at <http://www.epa.gov/oppfead1/international/naftatwg/index.html>
- THE "BUSINESS CASE" FOR THE JOINT EVALUATION OF DOSSIERS (DATA SUBMISSIONS) USING WORK-SHARING ARRANGEMENTS, Mark Lynch; Ireland 21st Meeting of the Working Group on Pesticides, 12-13 June 2007; Paris, France
- Findings from the Agricultural Worker Survey (NAWS) 2003-2004: A Demographic and Employment Profile of United States FarmWorkers, 2003-2004.
- Import Safety Agency Roles Web page: <http://www.importsafety.gov/members/agencies/roles.html>
- Other Web pages:
 - <http://www.fas.usda.gov/ustrade/USTExFatus.asp?QI>
 - <http://www.ers.usda.gov/Publications/fts/2007/08Aug/fts32801/fts32801.pdf>
 - <http://www.ers.usda.gov/Data/FATUS/DATA/XMScy1935.xls>
 - <http://www.epa.gov/oppbead1/pestsales/>