market, and aggressively correct any problems that are found. This system is under stress because of new technologies, new distribution patterns, new consumption patterns, emerging pathogens, the size and diversity of the food industry, increasing imports, high public expectations, and the lack of resources at FDA.

FDA has issued an Advance Notice of Proposed Rule Making with regard to HACCP and is seeking comments on its desirable breadth and scope, the focus of a HACCP program, how it should be implemented and evaluated; roles of FDA, state governments and the food industry; an approach to harmonizing standards, potential costs and benefits; and environmental impacts.

FDA is conducting a pilot program to decide whether development and implementation of a proposed regulatory system based on HACCP principles is feasible. It is an opportunity for the food industry to work and engage in scientific dialogue with the FDA and contribute to the development of regulations. It will allow the FDA to obtain insights from the food industry and focus its monitoring of food safety on public health needs.

The FDA regulatory procedure is to publish an Advance Notice of Proposed Rule Making, review the comments, publish a proposed regulation, evaluate comments and then publish a final rule with an implementation period and effective date.

U.S. importers must meet the same requirements as domestic producers. Seafood is a big export industry for many countries, but most developing economies are not yet using HACCP for seafood; nor are they HACCP ready. The burden will be on the importer, but who will certify that an exporting country's programs are up to speed? How will importers verify that exporters in country X have viable programs?

The importer can perhaps use a third party certifier, but this is a big issue. There is no service within FDA to certify foreign producers. What assurance will there be if there is no confidence in a country's program. A template for a Memorandum of Understanding (MOU) is being prepared, but it will take a lot of confidence building prior to certification to recognize the entire program of another country. The agency will be very thorough in its selection of reliable countries.

Small and medium sized firms may find compliance difficult. Importers and brokers will put the issue of compliance on the producer. Perhaps trade associations can help by doing training on HACCP, etc. FAO may also help; it has a major educational effort in HACCP.

Companies need commitment to food safety. ***Perhaps USAID can increase level of commitment by helping companies understand the potential trade issues*** and move forward with training and other programs needed to avoid trade problems that may occur.

ISO 9000 Session - Audrey Talley-Carter, USDA/FAS and Mark Bradley, USDA/AMS

Audrey Talley-Carter:

The International Organization for Standardization, known as ISO, is a worldwide Geneva-based federation made up of the national standard bodies of 91 countries. It was founded in 1946 to facilitate trade in goods and services by setting standards and assessing conformity with them.

Early ISO standards focused on international manufacturing and communications. In 1987, ISO published the 9000 series and a guidance document, ISO Standard 8402.

In the U.S., the American National Standards Institute (ANSI) has delegated authority to the American Society for Quality Control (ASQC), to certify ISO 9000 registrars. The Registrar Accreditation Board (RAB) will ensure that companies in this field have the necessary skills and competence to do the work.

A registrar is an independent auditing firm, such as Underwriters Laboratories, that reviews the practices and standards of a given company and determines compliance with ISO 9000. For a list of registrars, contact the RAB.

ISO 9000 is a set of generic standards related to the quality management system in a company, not a judgement of the quality of a product. It covers all processes that apply to a company's quality system including activities to ensure customer satisfaction. In 1994, the average cost of ISO 9000 certification, including inspections and registration, was approximately ***$245,200.***

ISO 9000 is needed to respond to a growing concern worldwide over increasing confusion caused by different national and sub-national quality systems. It also seeks to address increasing customer demands for more stringent quality standards and is an outgrowth of new multinational trading blocs such as the European Union, NAFTA, and WTO.

The European Union is the leader with regard to ISO 9000. Approval of a supplier's quality system is mandatory to import appliances, construction products, some medical devices, recreational craft, terminal equipment, etc. to EU member states. EU requirements are the motivation for some US firms to seek quality system registration.

Quality system registration involves assessment and periodic audit of a supplier's quality system by a registrar/3rd party). When a supplier's quality system conforms to ISO 9000, the registrar issues the supplier a "Certificate of Registration." ***This means that the supplier's quality system is registered, not the product which is produced.*** There is often a conformity assessment component, which requires a more comprehensive evaluation.

Firms in more than 80 countries have adopted ISO 9000 standards, and more than 5,000 ISO 9000 certificates were issued in the U.S. in 1994.

Some problems with ISO 9000 are the following:

- The doctrine of reciprocity suggests that the U.S. should accept lower standards where its trading partners do so and should allow trading partners to follow standards as high as ours.

- The international community must decide how far to go in regulating quality of products and services. Governments traditionally regulate health and safety, not quality.

- When is the requirement to meet a specific quality standard a technical trade barrier?

- How will U.S. firms provide guarantees for their ISO 9000 quality system certification in foreign markets for products that are not regulated in the U.S.?

- How will nations ensure compliance and provide the uniform enforcement necessary to guarantee the integrity of an ISO Conformity Assessment program.

- Trade barriers, which could result from nations not recognizing other countries' test reports, quality certificates and the like, could conceivably be prevented through "Mutual Recognition" agreements.

In summary, ISO 9000 is an international language for quality management, a standardized approach for supplier capability assessment, a single standard for quality management, and a standardized format for documentation that permits comparison of quality management systems.

Mark Bradley:

ISO 9000 is really a contract issue, not a regulatory issue. HACCP issues can be included in the ISO system and they often they operate together.

The ISO 9000 Standards are the following:

ISO 9000- 9001	Guidelines for selection and use, design, development, production, installation and servicing
ISO 9002	Production, installation and servicing
ISO 9003	Final inspection and testing
ISO 9004	Guidelines for quality management and quality systems.

There are 20 ISO 9000 elements as follows:

1. Management responsibility; 2. quality system; 3. contract review; 4. design control; 5. document and data control; 6. purchasing; 7. control of quality records; 8. control of customer supplied product; 9. product identification and traceability; 10. process control; 11. inspection and testing; 12. control of inspection, measuring and test equipment; 13. inspection and test status; 14. control of nonconforming product; 15. corrective and preventive action; 16. handling/storage/packaging/preservation and delivery; 17. internal quality audits; 18. training; 19. servicing; and 20. statistical techniques.

CODEX is WTO approved standards and HACCP is regulatory, while ISO 9000 systems are voluntary. Is there conflict or redundancy? This is being discussed on an ongoing basis. HACCP is for safety, not quality, and ISO 9000 is a method of evaluating quality systems.

To effectively adopt an ISO system there must be commitment by top management to document the quality management process, conduct internal audits, identify non-conformance, implement corrective or preventative action, keep records, do a pre-assessment audit (optional) and an adequacy audit (desk audit), have a compliance assessment, register and obtain a registration certificate, and allow surveillance audits.

Registrars employ auditors to conduct assessments. They also maintain and publish lists of registered suppliers. A registrar may be accredited by an outside organization, like RAB. Lloyds Quality Assurance is one of the big commercial registrars.

RAB accredits U.S. quality system registrars. It is affiliated with the American Society for Quality Control (ASQC). It is not a government agency but is sometimes loosely sanctioned for certification because the EU requires certification for many products.

ISO 9000 certification can lead to increased participation in international markets and increased structure of quality management systems. It is a possible format for supplier development programs and a good game plan for organizing a quality system. Firms that do not have it may be excluded from markets.

In the future, ISO will play a larger role in U.S. domestic and international trade and perhaps in trade agreements, although some may consider it a technical trade barrier. It may be used in government management programs. There may be a linking of contractual (ISO 9000) and regulatory (HACCP) quality management systems. Also we may see development of a USDA or FDA registration or accreditation system.

The Agricultural Marketing Service of USDA is testing ISO 9000 for internal implementation, licensee management, commodity procurement, and a quality system certification program (QSCP). The QSCP would combine ISO 9000 with industry specific requirements provided by the AMS livestock and Seed Division. Certificates would be receivable as *prima facie* evidence of compliance, and fees would be established on a cost-recovery basis.

ISO 9000 registration is expensive for the small guy. There are not yet registrars in processes dealing with livestock. The QSCP would be very important for biological products, which cannot be corrected if they are not made correctly. Thus, USDA/AMS is expanding from quality of products to quality of processes.

Disposition and Capabilities of Small LAC Farmers and Agroenterprises to Absorb the New Systems - - John Bowman, DAI

The challenge is getting people or groups to gear up for a new level of quality and a different set of standards. How will they react?

At a basic level, CIAT in Colombia has a bean program in Costa Rica. Web blight of the bean plants was affecting quality of the seed and lowering yields. CIAT joined a local Costa Rican research station to study the problem. IPM methodology was used to establish a more tolerant variety with different planting densities and row spacing. Cultural practices of using mulch prevented spread of disease, and raised ridges lowered its impact. Fungicides were used as well. When an integrated package was put together and marketed through agricultural extension services, farmers readily accepted it. The result was a simple technology package communicated via small workshops to small farmers.

At a larger level, multinationals may look to foreign markets to get products. Pepsico purchases many products abroad. In 1990 they purchased about $157 million worth of potatoes outside the U.S. for Frito Lay products Doritos, Ruffles and Cheetos. If a potato from Thailand makes it into the bag, it has met a kind of high standard. There was great variability of contract growers' cultural practices from Canada to Turkey to Korea.

In Brazil, Pepsico had to find an appropriate counterpart, and this was more a human than a technology issue. We used local potato varieties and worked with local producers known for quality. Different varieties were tested, the best seeds were propagated, and local growers responded with increased production. A new premium Ruffles brand was then introduced in Brazil.

A bacterial problem with the seed appeared as production increased. Traditionally the farmers cut seed potatoes by hand into 4 pieces. Between cuts the knife was disinfected. With an automated cutting system the disinfectant did not work as well, and commercial growers got seed potatoes infested with a harmful bacteria.

In Turkey, cropping practices were more primitive and plots were larger. The potatoes were too big, too high in sugar, and mostly water. Farmers were always over-irrigating, wasting water and causing fungal disease. Potatoes were stored in the hills during the cold winters.

There was a prohibition on bringing potatoes from North America, so we worked with the Dutch and tested European varieties. Storage in the caves did not work well, so we built a huge storage facility. A quality control inspection team was set up at the storage facility with power to accept or reject potatoes, which was unheard of in Turkey. Not all growers understood what this meant when they signed on? Many potatoes with fungal rot were rejected, causing hard feelings. Also there was a cultural problem persuading farmers to grow for quality rather than yield because, historically, yield was the important factor; but quality was the new ideal and low quality potatoes were rejected. After 3 years, new Ruffles were introduced in Istanbul.

Tomatoes for processing are a main product and central focus of IPM programs. Many U.S. soups use Mexican tomatoes, which historically were over-sprayed with pesticides in Mexico. Campbell Soup invested in natural enemies which preyed on larval pests and in the pheromme technique which interrupt the mating ritual, so the pest population dropped. Campbell was able to reduce pesticide use by 90%, which saved about $800,000 per year for the growers. It worked mainly with large, sophisticated growers and was so successful in Mexico that the process was later adopted in California and Ohio.

In the Philippines a new tomato processing plant was set up about two years ago, without foreign participation. It uses sustainable production practices including IPM, has a biological control facility to rear natural enemies and does its own genetic research for disease resistance. The new techniques are being used with very small growers! It shows that one can transfer environmentally sensitive, esoteric concepts to people who farm on even one half a hectare.

Discussion of Likely Effects of Preceding Topics - - Ron Stryker, USAID

USAID's Global Bureau, Office of Agricultural Enterprise and Market Development, has been examining agriculture and these issues for some time. This subject is one that has been growing in global importance over the last several years and USAID needs to take a strong interest in it, but this is not a unanimous view in the Agency. Traditionally we have not looked at these kinds of issues. There's a need for more education of agency leadership on the importance of these concepts and their implications. They are very important issues.

Let me return to John Becker's questions of this morning:

1. Will Quality assurance procedures evolve to be important in global trade?

2. Will small and medium-sized enterprises (including growers, producers, etc.) be disadvantaged competitively?

3. If so, what steps should USAID take regarding these new evolving institutional mechanisms?

Contract growing and U.S. agribusiness firms have roles to play in working with foreign participants. Without multi-national participation, these new systems will have differing impacts on the small farmer or producer.

We should not just look at USAID in Latin America, but expand to other donors and other geographic regions including the former Soviet Union, Africa, Asia, etc.

Bailey: CODEX presents problems. Some countries are just now pulling together CODEX committees. Many countries just adopt CODEX as law. Maybe we should strengthen the CODEX committees. Also, USAID should be an observer at regional CODEX meetings. Finally, few countries have any idea how to do risk assessment. There needs to be a great deal more training in this area.

Stryker: Standards are one thing, but enforcement and application is quite another issue in the developing world. Budgetary issues will cause a major problem in this area. Maybe an answer lies in regional institutions to reduce costs?

Veek: Product detentions are very costly. We can make an importer responsible in a single case, but the larger regulatory infrastructure problem requires a level of sophistication by foreign governments.

Stathacos: Business buyers in the spice area have put lots of pressure on suppliers to get standards up. This is reflected now in the prices. In Madagascar USAID helped with resources but is not willing to pay recurring costs to maintain the system. We need to look at trade associations for cost recovery. USAID could work with trade associations to help develop local associations in producing countries.

Bailey: Associations could sell training in areas like HACCP. Also, local exporters have no confidence in local governments. We tend to focus on government to government programs.

Wehr: HACCP may be more esoteric than what is needed to resolve the problem. We should focus more on HACCP prerequisite programs and look at what is being stopped at ports of entry, and why.

The ISO 14,000 Series - Purpose, Description, Status, Possible Effects - - Ted Harris, The Delta Group

ISO 14,000 is not yet in effect. It is supposed to be finalized by early 1996, with auditing guidelines by January, 1997 and other guidelines by the year 2000. When it comes into existence, it will mirror somewhat ISO 9000. How is ISO 9000 relevant to the small farmer? ISO 14,000 will probably not be relevant in the next 5 years; but in 20 years, it may well be.

ISO 14,000 standards have been drafted and are being reviewed by technical committees. ANSI is in this process along with industry participants. ISO began by creating technical standards for weights and measures and then expanded to manufacturing and management standards. Original standards can be drafted by ISO staff or the corporate/private sector, except for ISO 14,000. The EU adopted ISO 9000 early on and will probably adopt ISO 14,000 very soon.

ISO 14,000 is a series of Environmental Management Systems (EMS) standards currently being developed by the ISO. It shares management system principles with the ISO 9000 series of quality system standards. Procedures for compliance audits will be normalized across countries and product lines. On the down side, third party auditors may have to be used.

There are many common elements of 9000 and 14,000. Such elements are a continuous improvement process, documentation of implementation programs including measurement of natural resources, reviews of problems, root cause analysis, and corrective action. ISO 14,000 systems will require information and analysis, performance criteria, good communications, and emergency response planning.

ANSI is developing its own set of environmental standards in concert with the ISO standards. As of this date, 15 standards are being developed in the following general areas:

14000	Overview Guidance Document
14001	Environment Management Systems Standard
14010-12	Environmental Auditing Guidelines
14020-24	Environmental Labeling Guidelines
1403X	Environmental Performance Guidelines
14030-43	Life Cycle Assessment Guidelines
14060	Environmental aspects of product standards guidelines

One principle involved is re-engineering of production processes that may make them better, faster, and cheaper. Manufacturers may learn how to take pollutants out early in a process so that they don't have to worry about them at the end.

The standards address systems and continuous improvement. Performance levels such as emission limits are specifically excluded. The standards will be considered a floor rather than a ceiling.

The purpose of ISO 14,000 standards is to reduce environmental damage. They are expected to provide a credible alternative to government regulation and control. They may, however, be barriers to trade when applied by importing countries.

The ISO Process works in many ways similar to a treaty. First standards are developed and then member nations write their own legislation. In theory the standards are voluntary, but the EU is likely to make them obligatory. Companies will have to conform to standards to conduct business in Europe or when customers insist. Also, they may wish to demonstrate environmental leadership or use conformance as a tool to meet previous voluntary commitments such as "Responsible Care."

Firms that can meet the international standards (ISO 14,000) will probably meet comparable EPA standards as well. Enforcement of environmental regulations is not very important now in most LAC countries, but this is changing. The IDB has a series of institutional loans in the pipeline (Argentina, Peru, etc.) for analysis of existing legislation and development of institutional frameworks to make it work. These loans are on order of 30 to 50 million dollars.

Firms will demonstrate conformity with ISO 14,001 by using independent certifiers, and each nation will have its own standards for accreditation. There will probably be environmental management companies certified to do audits. There are already hundreds of small companies that do this.

The cost of registration will depend on size and complexity and go into six figures for mid-sized and larger facilities. The cost in Argentina may be the same as in the U.S. If enforcement has no teeth, firms might be better off to violate and pay the fine rather than pay for compliance. However, an ISO 14,000 evaluation might pay for itself by showing ways to make a manufacturing process cheaper in the long run.