FOOD QUALITY ISSUES: understanding HACCP and other quality management techniques

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This is part of a series of straightforward and practical (rather than an academic) papers by leading experts and presented in a specially designed format as brief and basic teaching tools with resources for more in-depth expertise. They address topics relevant to the design, monitoring, and assessment of projects and interventions for the promotion of agricultural enterprises and markets in developing countries. Original publication year: 2000

***Keywords**: food quality, food safety, Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Points (HACCP), international trade, ISO*

***Abstract:** This teaching tool provides a basic understanding of food quality issues in developing countries and introduces the reader to HACCP and other dominant methodologies for improving food quality.*

I. Introduction

Quality has long been a factor in the success of food trade transactions; however, recent food safety issues have propelled quality control to the forefront of international trade concerns. Now with the increasing globalization of trade, food quality is also becoming a factor in domestic markets as quality and variety compete for a buyer's attention and regulatory bodies seek to better control potential threats.

The 1990s have been a decade of revised views and altered perspectives for food scientists, health officials, epidemiologists as well as produce growers and shippers. Food items historically not viewed as vectors for human diseases are now being considered potentially significant contributors to the occurrence of disease throughout the world. The global food chain is searching for possible mitigation measures as a growing body of literature is raising issue with the various practices that have provided consumers with unparalleled access to the widest selection of affordable fruits and vegetables ever known.

Various quality management systems are being applied to help ensure food safety. Currently, perishable commodities have limited access to post-harvest food safety remedies. Of the limited

[1]James Simon, PhD; and Primus Labs have made substantial contributions and Dr. Kerri Harris has kindly reviewed this document. See Resources section V for details.

number of post harvest treatments available, many are perceived to have negative consumer appeal (i.e. irradiation, fumigation, etc.). The best approach is to focus more on limiting potential contamination during the growing, harvesting and processing of food. Such process management is used to address food safety hazards that can be introduced at different points in the food chain or are difficult and costly to measure[2]. There are several preventive methods applied, to different extents, by most enterprises that export food in order to reduce the risk of microbial, chemical and physical contamination. Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) are the most widely used of these methods and part of a strong trend in the more developed markets that are increasingly requiring their rigorous application[3].

What is Food Quality

Despite its common use, the term "quality" is not easy to define. Unless it makes reference to particular criteria or standards, the general term “quality” is subjective. In the most generic sense, quality refers to the combination of characteristics that establish a product’s acceptability. In the food industry, this is usually an integrated measure of purity, flavor, texture, color, appearance and workmanship. In a highly competitive market, another criteria of quality can be ‘value’ or perception of the product's worth.

Quality control systems typically vary based on the particular requirements of buyers and regulatory agencies but one of their vital characteristics is the ability both to identify and to address such requirements. They can also vary in response to the different exigencies of the production or supply chain. For example, tomatoes grown in greenhouses will have a different quality control than those grown in an open field.

There are two distinct aspects of food quality management for agro-enterprises yet they are both are interrelated. The first approaches quality in terms of conforming to certain market requirements such as a perceptible superiority of desirable traits or characteristics like size, coloration, or organoleptic properties. The second approaches quality as a synonym for food safety, which can be also used as a marketing tool to move product in countries with high food safety standards.

Accessing New Markets

Product quality is a prime criterion in gaining access to competitive markets that demand a stable supply and a consistent quality. Standards for quality and reliability have already been established for most raw materials and value-added commodities by the international agro-industry markets. Any products which cannot reach equivalent levels of quality, functionality or reliability will not survive in competitive global markets except perhaps certain niche or ethnic markets.

Globalization Risks Associated with Poor Quality

The tenfold increase in food exports over the last thirty years has brought new concerns fueled by high-profile incidents such as Alar in apples and Mad Cow disease. Certain consequences of the increased movement of goods and services must now be more carefully considered.

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[2] Unnevehr, L. J., Jensen, H.H., 1999. The Economic Implications of Using HACCP as a Food Safety Regulatory Standard. *Food Policy*, 24:625-635.

[3] Government regulation for HACCP now exist in significant parts of the food systems in the EU, U.S.A., Australia, New Zealand, and Canada. National laws for certain industries also exist in countries as poor as Bangladesh (shrimp processing).

Emerging Foodborne Infectious Diseases[4]

The popular demand for foreign imported products has increased our exposure to goods from around the world. The loosening of restrictions on the movement of goods is symptomatic of globalization and contributes to emerging disease proliferation. Moving together with the free trade of goods and services, infectious diseases recognize no national boundaries. These diseases can journey with finished food products or raw agricultural commodities.

Several new or emerging infectious diseases have begun to appear which harbor the threat of significantly increased mortality. *Vibrio vulnificus*, *Escherichia coli* (O157:H7), and *Cyclospora cayetanensis* are examples of newly described pathogens that often are foodborne. *V. vulnificus* was identified in the bloodstream of persons who had infections after eating shellfish. *E. coli* (O157:H7) was first identified as a pathogen in 1982 in an outbreak traced to contaminated ground meat; it was subsequently shown to have a reservoir in healthy cattle. *Cyclospora*, emerged as a foodborne pathogen in outbreaks traced to Guatemalan raspberries in 1996.

Ordinarily, pathogenic organisms come to some type of ecological balance with other forms of life in their native environment. However, when these organisms are transferred to a new environment, they will often demonstrate much greater virulence simply because natural immunity or appropriate social or medical management practices have not been established. Even though the process of globalization may be beneficial for international economic development, from the standpoint of public health it can be very costly. Therefore the implementation of food safety mechanisms not only facilitates trade but also contributes to preventing outbreaks of disease.

Prevention can be "built in" to the food industry by identifying and controlling the key points—from field, farm, or fishing ground to the dinner table—at which contamination can either occur or be eliminated. The general strategy known as Hazard Analysis and Critical Control Points (HACCP) is displacing, though not eliminating the necessary strategy of final product inspection.

II. Key Principles of Quality Control

Delivering safe, high quality food to international markets requires process and procedural controls throughout the supply chain and also adequate mechanisms to certify to buyers and government regulators that such controls are effective.

IIa. Quality management

The public sector has played a significant role in the development, implementation and enforcement of agricultural safety standards and regulations, coordination with international organizations on harmonization of standards and regulations, surveillance of foodborne diseases, consumer education, training, extension, and research.[5] The responsibility for food quality management, in practice, usually falls to the private sector at the level of trade associations or agro-enterprises where these assess and manage risk in response to market and regulatory requirements. On a broader scale, the costs, logistics,

[4] This section draws considerably from Tauxe R V. Emerging Foodborne Diseases: An Evolving Public Health Challenge. *Emerging Infectious Diseases*. 1997; Vol 3 No 4

[5] World Bank. 1999. Animal and Plant Health and Food Safety (Agricultural Safety). Unpublished Issues Paper

and technical expertise required to effectively control quality even within a specific commodity subsector are usually not within the range of most governments. Nevertheless developing countries governments can fulfill some critical roles:

- help design and deliver an educational component
- promote a sound regulatory policy, licensing and certification
- developed mechanisms for effective response to food safety crises
- support testing facilities and reasonable access to them
- control single source contaminations i.e. pests in imported products

For quality management to be successful it typically requires simultaneous attention to several areas: education, grades and standards, and management practices. Although certain quality controls can be imposed as regulations, achieving quality is more successful when the impetus to do so comes from the stakeholders themselves.

Many quality requirements are dictated by buyers while government institutions provide regulatory support. Although, the private sector has a primary role in food quality management, joint ventures with governments can facilitate and help standardize quality control systems.

The burden on developing countries
International standards and the ever-increasing quality demands of developed markets require developing countries to take a hard look at their approaches to quality management if they want to participate in those markets. While it may be difficult for many agricultural enterprises in developing countries to apply HACCP methods with any sort of rigor, Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) are a practical step toward significantly improved quality and safety.

It is worth noting several trends, led by more developed countries but which are catching on quickly in other countries:

- the growing technical sophistication and cost of certification arrangements particularly involving laboratory testing
- quality registration that requires suppliers to be accredited, often after undergoing a conformity assessment to demonstrate that products and processes meet prescribed technical requirements
- vendor rating schemes that involve monitoring suppliers' performance on the basis of quality control systems, logistical capability, contract compliance, etc.

IIb. Quality Standards

Legal standards
Legal standards are commonly established by national governments and generally relate to safety. These standards are often mandatory and represent minimum standards of quality and safety. The major purpose of these is to ensure that products are not adulterated or do not harbor dangerous contamination. These might involve undesirable microorganisms, insects/filth, pesticides or potentially toxic additives; these can also include labeling standards or acid levels in canned foods. They may even consider processing conditions to ensure that foods are not contaminated or unduly damaged.

Few would argue the importance of standards genuinely related to food product safety. Problems arise when there is disagreement on what is actually required to ensure safety.
See Annex 3

Consumer standards
Another important area of standardization relates to the information presented to the consumer. In this case it is not the product itself, but rather its description that must conform to a particular standard. Much effort has been devoted to harmonizing labeling information and very large market segments do have common requirements. There may be some disputes arising out of a culturally based philosophy regarding the role of food in the diet. Some societies traditionally confer great health benefits to certain foods while others may not. This may lead to health claims that are allowed in one country and not another.

There are even standards which are established to make buying decisions easier for the consumer. Extra lean, lean and medium ground beef standards allow the consumer to make decisions based on particular requirements of taste, health and available income. The same goes for the various choice grades of products. These standards are not based on health or safety issues, but rather than on content or perceptions of overall appearance and taste.

Industry standards
These are sometimes set by an organized industry association in order to establish a reliable identity for a particular product. Normally such standards become effective because the majority of producers agree to them. They are seldom related to safety, but more to a characteristic quality which the industry feels is useful to establish credibility for the market. Products such as wheat, peanut butter, and corn starch all conform to a set minimum standard established by the industry. These standards are commonly referred to as commodity standards or standards of identity.

International standards
With over 180 national members, the Codex Alimentarius Commission is the most widely recognized international body that sets food standards.[6] Others include the Office International des Epizooties (OIE), and the International Plant Protection Convention (IPPC). The dual purpose of Codex is to protect the health of consumers and to ensure fair international trade in food. Codex elaborates numerical standards, codes of practice, and other guidelines through its committees and promotes acceptance and implementation of its standards by national Governments. Particularly where domestic capacity is limited, adoption of Codex standards ensures international acceptance.

Since 1962, Codex has produced numerous standards, guidelines, codes of practice, and recommendations and has evaluated the safety of over 500 food additives and contaminants and set maximum residue limits for approximately 2,500 pesticide/commodity combinations.

International Organization for Standardization (ISO)
ISO is a non-governmental organization established in 1947 as a worldwide federation of national standards bodies from some 130 countries, one from each country. The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of

[6] Ref. 1, Codex Procedural Manual, Ninth ed., FAO/WHO Rome, 1995

intellectual, scientific, technological and economic activity. These standards identify the 'what' rather than the 'how'. The most popular is the general series on quality management known as ISO 9000.

With the growth in international trade, standardization pervades every aspect of the agribusiness and agriculture supply chains. The internationally standardized freight container, for example enables all components of a transport system - air and seaport facilities, railways, highways, and even packages - to interface efficiently. This, combined with standardized documents to identify sensitive or dangerous cargoes makes international trade cheaper, faster and safer[7].

International standardization is market-driven and therefore based on voluntary involvement of all interests in the market-place. Countries individually decide whether to mandate adoption of ISO's or other standards for agricultural food products. Most but not all of these standards are specified in the work of Technical Committee number 34. Each national governing body is usually also a member body of ISO (see Resources section V for link).

International Agreements
The WTO agreement on the technical barriers to trade (TBT) is relevant to aspects of agribusiness quality management. It is intended to promote use by countries of standards, technical regulations, and conformity assessment procedures that are based on work done by international standard-setting bodies. In the TBT agreement, the term "standard" is defined as follows: "A document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory." Although it is open to some interpretation, it is designed to cover of the terminology, packaging, marking or labeling requirements for products, processes or production methods.

The 1994 SPS agreement of the WTO provides a framework for harmonizing and resolving sanitary and phytosanitary (SPS) issues. The SPS agreement covers, among other things, measures intended: to protect human or animal health arising from diseases carried by animals, plants, or products thereof and from the risks of unsafe additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs.

The SPS agreement encourages members to consider international standards, guidelines, and recommendations when establishing their own domestic SPS measures. A country is not required to use an international standard, but must have scientific justification to establish or maintain a more stringent measure to meet the country's chosen level of protection if that measure will unfairly hinder trade. Standards established by Codex regarding food and substances in food have status under the SPS agreement.

Hotlink Multilateral Trade Agreements

III. The Basic Road Map

[7] Achievements of ISO. www.iso.ch

Quality control programs
Quality control ensures that raw materials and finished products are handled, stored, processed, or packaged to the required standards. The fundamental purpose of a quality control program is to have timely and dependable information on all the attributes of a product which affect its quality. The basic functions of a Quality Control program include:

- Physical and chemical evaluation of raw materials and processed products
- In-process control of
  a) Raw materials, ingredients and packaging supplies
  b) Processing parameters
  c) Finished products
- Microbiological analysis and control of raw materials and finished products
- Control of storage and handling conditions
- Sanitation and waste products control
- Assurance that final products are within the established legal and marketing standards.

At the enterprise level the assurance of quality depends to a large extent on how the program is organized and how committed enterprise management is. Top management must not only want but also actively support quality control. Consistent and regular training, at both management and non-management levels, is required to ensure the effective monitoring and execution of such program.

The most effective control strategies are sometimes the most simple. For example:

- When shipping broccoli, one should ensure that the iced used is made from water that has been purified and tested for pathogens. If the ice is bought from another company, their quality control procedures must be confirmed and microbial results should be periodically requested from the supplier.
- Temperature in cool-rooms and refrigerated transportation should be checked at least once every two hours.
- Oyster harvesters should only use toilets with holding tanks on their oyster boats as an obvious way to reduce fecal contamination of shallow oyster beds.
- Simple pasteurization provides the necessary barrier that will prevent E. coli O157:H7 and other pathogens from contaminating a large batch of freshly squeezed juice.

Even such straightforward strategies may not be adhered to in localized situations where enterprises have "done it the same way for 20 years". In such cases an educational component is critical if improvements to food quality or access to distant markets is a priority.

Good Agricultural Practices (GAP)
Good Agricultural Practices (GAP) are basic food safety principles associated with minimizing biological, chemical and physical hazards from field through distribution of fresh fruits and vegetables. These principles are covered under the following categories: site selection, adjacent land use, water, fertilizers (including manure and municipal bio-solids), pesticides, worker hygiene, field and facility sanitation, cooling and transportation. ***Hotlink Annex Good Agricultural Practices***

In the United States the guidelines are based on applicable state and federal laws as well as the Guide to Minimize Microbial Food Safety Hazards in Fruits and Vegetables published by the Food and Drug Administration. Other countries, such as Mexico have developed their own Food Safety Guide, sometimes based on the FDA's and in some cases even exceeding the FDA's requirements.

In Europe, GAP guidance is provided by the Euro-Retailer Produce Working Group (EUREP) in the "EUREP GAP Protocol 2000" (see Resources); it varies from the U.S. guidelines by including consideration for issues such as wildlife and habitat protection, genetically modified organisms (GMO), and integrated crop management (ICM). Although these are only guidelines, importers are asking their developing countries suppliers questions about these issues and this could be the first stage of potential changes in the operational standards for developing countries.

(See Annex 1 for GAP Table details.)

Good Manufacturing Practices (GMP)
Good Manufacturing Practices (GMP) direct all persons working in direct contact with food, surfaces that food might contact, and food packaging materials, to conform to sanitation and hygiene practices to the extent necessary to protect against contamination of food from direct or indirect sources. One benchmarks standard for these hygiene practices is the U.S. Federal Government's Food and Drug Administration (FDA) Current Good Manufacturing Practices, CFR 21 Part 110 which is summarized in Annex 2.

In many developed countries, the expectation that processors will apply Good Manufacturing Practices is widely accepted but there are also more specific rules for exporters wanting to enter more developed markets such as those for the high-risk processes of uncooked meats and low-acid canned foods (to avoid botulism in canned asparagus, for example).

Hazard Analysis Critical Control Point Systems (HACCP)
In the 1960's, NASA wanted to guarantee that the food for astronauts on space flights was totally safe. The task of producing "Zero Defect" food was contracted to the Pillsbury Corporation who developed the first system of Hazard Analysis - Critical Control Points or HACCP (pronounced Hassep).

HACCP is a risk management tool that provides a more structured and arguably more effective approach to the control of processing or manufacturing hazards than that achievable by traditional inspection and quality control procedures. Rather than testing the end product for failure it functions to prevent failure by systematically controlling the process. It requires systematic analysis for potential risks and then identification of appropriate control and monitoring systems, particularly those deemed critical to the safety of the product. HACCP significantly reduces the risk of food contamination in two ways: First, it anticipates potential problems or failures and does not depend only on a final inspection. Second, because it identifies problems during the process rather than at the end of the process or once the product moves into the supply or marketing chain there is a greater likelihood of resolving the problem at hand as opposed to pursuing a product recall. Not surprisingly, HACCP can thereby also yield potential cost savings in product wastage, reprocessing, or recalls should problems occur.

HACCP has been incorporated into The Codex Alimentarius and is now required of many food processing or manufacturing businesses in the EU and the US. Its use in export manufacturing processes conveys a level of professionalism and safety that often facilitates foreign trade transactions. Since HACCP has the potential to identify areas of concern where failure has not yet been experienced it is particularly useful for new operations.

Many people, particularly those from industry, feel that the use of the HACCP system will significantly reduce the need for traditional government inspection. However, the ability of the HACCP system to deal with emerging pathogens has still to be determined. In fact, HACCP is far from perfect; one weakness is related to the pre-existing presence of microorganisms, chemical, and physical hazards in foods and the receiving of such contaminated foods into the processing plant. Once contaminated raw materials have been allowed to come into a plant, an incredible amount of remedial work has to be carried out in order to ensure that these microorganisms are killed during processing and that cross-contamination does not take place. Since many products exposed to cross-contamination do not have a definitive killing-step for microorganisms in their processing, the end result can be contaminated products. Although it is a significant improvement in overall process control, HACCP is definitely not a panacea for the problems of microbial contamination in foods.

In the U.S. HACCP has become a legal requirement for the fish, poultry and meat industries, and will soon apply to juices as well. It has not been accepted in fresh produce because of the variation in production and handling practices across commodities and source areas. There has been discussion of introducing HACCP for all processed food, but it is not yet legally required. However, it has become a de facto requirement for most supermarkets. The fresh cut produce segment, for example went far beyond HACCP from the very start, because of the significant risks of micro-bacteriological contamination.

The Seven HACCP Principles

HACCP can best be defined by describing its seven basic principles. Familiarity with technological processes may make the principles of HACCP appear simplistic. Yet, its simplicity belies an intrinsic thoroughness of process that can be rather complex when properly applied.

Principle 1. Conduct a hazard analysis. Prepare a flow diagram of the steps in the process. Identify and list the hazards and specify the control measures in use.

Step i) Clearly define the terms of reference.
Step ii) Select the HACCP team. Certification required?
Step iii) Describe the product or product cluster.
Step iv) Identify the intended use of the product, e.g. vulnerable target consumers.
Step v) Construct a flow diagram.
Step vi) On-site verification of flow diagram.
Step vii) List all the hazards associated with each process step and list all the measures to control these hazards.

Principle 2. Identify the Critical Control Points (CCP) in the process using a decision tree.

Principle 3. Establish critical limits or target levels and tolerances which must be met to ensure each CCP is under control.

Principle 4. Establish a monitoring system to ensure control of the CCP by scheduled testing or observations.

Principle 5. Establish the corrective actions to be taken when monitoring indicates that a particular CCP is moving out of control

Principle 6. Establish documentation concerning all procedures and records appropriate to these principles and their application.

Principle 7. Establish verification procedures that include appropriate supplementary tests, together with a review that confirms that HACCP is working effectively.

There are typically 3 ways to adopt a HACCP program:

1. External trainers or facilitators can help to prepare a HACCP system and train on-site staff in its use. This method can be particularly effective in gaining acceptance from the work-force and can better encompass workplace realities, rather than depending on management to implement a system which they may not have an active part in maintaining.
2. An on-site team can be trained by one external expert on the principles, preparation, and implementation of the system and this team can then train and monitor the enterprise's staff. This method can generate more buy-in in because of its participatory methodology, may be more adaptable in the long run given that the designers are always on-site, and is usually less expensive. It also takes longer and may not be of the same quality as one implemented by seasoned experts.
3. For certain businesses computer software and template documents applicable to similar industries is available to guide an enterprise through the basic steps of the process.

Verification ensures the HACCP plan is adequate, that is, working as intended. Verification procedures may include such activities as review of HACCP plans, CCP records, critical limits and microbial sampling and analysis. In the U.S. the Food Safety & Inspection Service (FSIS) requires that the HACCP plan include verification tasks to be performed both by plant personnel and FSIS inspectors.

How Is Quality Measured?

The measurement and evaluation of quality can be a complicated affair. Most organizations employ professional technicians to carry out this task, but this has not always been the case. In the past, many companies assumed that the quality of their raw materials could be guaranteed simply by paying the highest prices. However, this did not prove to be very reliable and almost all firms now use various analytical methods for quality determinations.

The methods used to measure quality can be subjective, as in taste tests or they can be objective, such as physical, chemical or microscopic analysis. Subjective methods are based on the opinions of the examiners and are often called sensory analysis. Training personnel to accurately describe their responses to product quality can be difficult and costly although computerized sensory evaluation systems are now available to facilitate the accurate reporting and statistical interpretation sensory responses.

The physical, chemical and microscopic analytical methods are considered to be objective because they are designed to exclude any subjective opinions of the examiner. These methods are usually standard scientific tests which should be able to be reproduced with the same result by any trained technician. Physical measurements include product attributes such as size, weight, color, texture, headspace, and even impurities such as filth and insects. Sometimes these analyses are carried out with

the help of instrumentation and at other times with little more than a pair of good eyes and a paper and pencil.

Chemical methods are usually more complex and often require instrumentation that can be rather sophisticated. Precise tests for moisture, protein, carbohydrates (total and specific), ash and fiber have become standard practice in the food industry along with a myriad of others pertaining to specific components of ingredients or products. Microscopic methods are used to determine the presence of mold, insect fragments or foreign materials as well as for any spoilage or disease microorganisms the product may harbor.

IV. Information and Resources

The people and organizations listed here are only intended to illustrate the sorts of resources available. Please note that neither The World Bank nor the authors of this document suggest or imply any endorsement of them, their products or services, nor is there any guarantee, implied or otherwise regarding their quality or usefulness.

Related teaching tools on this site
Hotlink Designing Effective Food Safety Interventions in Developing Countries
Hotlink Understanding Grades and Standards
Hotlink Multilateral Trade Agreements and Organizations
Hotlink Export Competitiveness

Organizations and experts
Search for standards for any product around the globe**:** www.nssn.org

Quality Links (http://www.foodfront.com/linklibrary/mainlinkspages/quality_links_main.htm)
Extensive links from private commercial site: the Internet Foodfront, a division of Foodfront Consulting, Inc.

Food Safety Virtual University's College of Pathogen Reduction and HACCP programs
[Training and educational materials used by FSIS in training related to HACCP, available in this electronic format for anyone seeking additional information on the regulatory components of HACCP programs]

International HACCP Alliance Tex A&M University http://www.haccpalliance.org

HACCP is a U.S. government food safety Website

National Seafood HACCP Alliance sponsored by UC Davis

USDA, Food Safety & Inspection Service (FSIS)
FSIS Food Safety Education Staff
Room 2932-South Building; 1400 Independence Ave. S.W.
Washington, D.C. 20250
Phone: (202) 720-7943
Fax: (202) 720-1843
Home Page @ www.fsis.usda.com and then go to "HACCP Implementation"

HACCP/Pathogen Reduction (meat and poultry) run by the USDA
Seafood, Land Foods, Retail run by the USDA
USDA/ FDA HACCP Training Programs and Resources Database

FSIS Food Safety Education and Communications Staff
Public Outreach and Communications
Phone: (202) 720-9352
Fax: (202) 720-9063

U.S. Food and Drug Administration (FDA)
Current Good Manufacturing Practices
www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199921)
Current good manufacturing practice in manufacturing, packing, or holding human food
Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
Exporting to the United States
Meat and poultry

http://vm.cfsan.fda.gov~dms/prodguid.html

USDA APHIS
Dan J. Sheesley, Associate Deputy Administrator, International Services (SPS resource)
Dan.J.Sheesley@usda.gov 202/720-7593, fax 202/690-1484,
www.aphis.usda.gov

Food and Agricultural Organization (FAO) Viale Terme di Caracalla 00100 Rome, Italy

FOOD AND NUTRITION DIVISION (ESN)
(http://www.fao.org/waicent/faoinfo/economic/dept/es960003.htm) The FAO Food Quality and Standards Service is concerned with the maintenance and improvement of the quality and safety of foods at the international, regional, and national levels. email to: Food-Quality@fao.org

Euro-Retailer Produce Working Group (EUREP) in the "EUREP GAP Protocol 2000"
(www.ehi.org/gb-index.html)

Spenser Henson, University of Reading s.j.henson@rdg.ac.uk

IICA P.O.Box 55-2200; San José, Costa Rica; Phone: (506) 216-0184/0185 Fax: (506) 216 0164
www.iica.ac.cr/sanidad
Kevin Walker, kwalker@iica.ac.cr Director, Agricultural Health and Food Safety
Benjamin Jara, bjara@iica.ac.cr Deputy Dir., Agricultural Health and Food Safety

WTO (http://www.wto.org/)

Codex Alimentarius
Codex Alimentarius Commission
Maximum Residue Limits for Pesticides and Veterinary Drugs in Foods
Food Hygiene - Basic Texts
Food labeling

Food Import and Export Inspection and Certification Systems - Combined Texts
Food Irradiation
http://vm.cfsan.fda.gov/~lrd/fr970707.html
U.S. Codex Activities

Food Manufacturing Forum (http://www.mts.net/~ccooke/food/) Provides a dialogue and a resource file for entrepreneur or manufacturer on how to build a small food manufacturing company.

National Food Processors Association (NFPA) (http://www.nfpa-food.org/) is the principal scientific and technical trade association for the U.S. food industry.

OIRSA - Food Safety links in Spanish (http://www.oirsa.org.sv/Castellano/Sitios/Direcciones.htm) OIRSA: Regional Organization for Agricultural Health (Mexico, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama, Dominican Republic)

Some HACCP consultants
Primus labs – provides food safety related services and free food safety manuals on the net.
HACCP International Ltd.
HACCP Consulting Group
Goodtimes, Inc
HACCP - Perry Johnson, Inc.

International Organization for Standardization (ISO)
Home page
Member bodies of ISO
Fruits, Vegetables and Specialty Crops
Gateway to US Government food safety information
National Food Safety Initiative page of the FDA

U.S. Agency for International Development Information Center
Ronald Reagan Building ; Washington, D.C. 20523-0016
Telephone: 202-712-4810 FAX: 202-216-3524 www.infousaid.gov
Carol Wilson, Agricultural Trade and Development Manager; 202-712-0506

Food Safety Websites

http://ace.orst.edu/info/extoxnet/faqs/foodmain.htm
http://www.who.int/fsf/link.htm
http://headlines.yahoo.com/Full_Coverage/Health/Food_Safety/
http://www.fao.org/WAICENT/FAOINFO/ECONOMIC/ESN/codex/default.htm
http://europa.eu.int/comm/dg24/

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Annex 1.

Table of Good Agricultural Practices

Production Step	Hazard To Be Controlled Biological "B" Chemical "C" Physical "P"	Control Procedures		Actions to be Taken if Deviation Occurs	Documentation
		Procedure	Frequency		
Site Selection	Contaminated Soils "C & B"	***Research site history and conduct a visual review*** -Restrict growing to land with well documented history	Each Land Purchase or Lease	Parcel is not purchased or leased Extensive chemical and/or microbial analyses should be conducted to confirm suitability	Record site history or laboratory results
Adjacent or nearby property uses should be compatible with intended use.	Contamination from runoff or wind "B & C".	Site selection and/or physical barrier (i.e. trenches, etc.)	Continuously	Select an alternative site or develop adequate barriers (i.e. wind break, etc.)	Grower certification of no recent non-crop use of land.
Alternative uses and Sustainable Agricultural Practices	Grazing or movement of livestock. Use of the field for disposal of waste (i.e. incinerator ash, sludge etc.) "B"	Site selection and/or physical barrier (i.e. fences, etc.)	Continuously	Prohibit the disposal of waste and restrict movement of livestock.	Grower certification of no recent non-crop use of land.
Fertilization	Microbiological or chemical contamination "B" & "C"	Limit the use of manure on all fields and limit manure and mineral fertilizers to approved suppliers	Each purchase	Limit supplier base to approved vendors. Base approval on State approved guidelines	Record fertilizer purchases, including lot # Record all applications.
Irrigation	Presence of E. coli, etc. in irrigation water "B"	Test water supply for presence of E.coli & Coliform	Underground wells-yearly, reservoirs & canals-quarterly	Stop use of contaminated water, use furrow or drip irrigation until contamination is corrected or access alternative source. Determine and address source of contamination.	Record test results & corrective action

Production Step	Hazard To Be Controlled Biological "B" Chemical "C" Physical "P"	Control Procedures		Actions to be Taken if Deviation Occurs	Documentation
		Procedure	Frequency		
Pest Control	Inappropriate pesticide use "B & C"	Restrict all pest materials to those registered by the USEPA and use as instructed by the label. Pesticide recommendations made by licensed PCA or equivalent.	Each application	Delay harvest. Sample the affected crop. Analyze the sample for inappropriate pesticide residues. Evaluate, release or reject the crop.	Record application date, pesticide used and application rate.
Selection of carrier waters used for application of pesticides	Presence of E. coli, etc. in irrigation water "B"	Test water supply for presence of E.coli & Coliform	Underground wells-yearly, reservoirs & canals-quarterly	Stop use of contaminated water; access alternative source. Determine source of contamination and address cause of contamination.	Record test results & corrective action
Carton Storage	Microbiological and chemical contamination of harvested commodities "B & C"	Proper storage of all cartons & containers used to hold and transport produce	Continuously	Do not use contaminated cartons, etc.	Maintain inventory records and storage sanitation program.
Harvesting: Site Sanitation and Personnel Hygiene	Microbiological contamination of harvested commodities "B"	Employee hygiene education Enforce State & Federal field sanitation regulations	Provide educational sessions on a regular basis Continuously	Alter personnel manuals and service provider contracts to reflect compliance as a requirement of continued employment or business	Document employee non-compliance. Record educational sessions; date, topic, personnel in attendance at meetings

		If rubber gloves worn Supervisor(s) provide adequate supply of clean gloves.	Rubber gloves cleaned daily using a high alcohol soap, replaced at least weekly as necessary. Knives should be cleaned in chlorinated (100-150 ppm total Cl) water.	Issue new gloves; educate personnel on hygiene requirements. Clearly define disciplinary action and procedure for termination	

Production Step	**Hazard To Be Controlled Biological "B" Chemical "C" Physical "P"**	**Control Procedures**		**Actions to be Taken if Deviation Occurs**	**Documentation**
		Procedure	**Frequency**		
Harvesting	Foreign material contamination of harvested commodities "P"	Prohibit smoking and eating on harvesting equipment and actively harvested field areas	Continuously	Inspect employee harvested commodity for contaminants; release or destroy; re-educate personnel on foreign material control; consider disciplining employees or subcontractors who display a disregard for foreign material control	Document employee non-compliance. Record date, topic, and personnel in attendance at the educational meetings.
		Examine each carton prior to packing	Each carton		
		Supply harvesters with wash or dip stations for cutting equipment	All harvest sites		
Transportation to Cooler	Temperature of harvested crop "B"	Expeditious transport to the cooling facility using vehicles dedicated to crop transport.	As necessary	Identify pallets with heat stress on arrival at cooler; inform sales; hold product at cooler for evaluation of raw product condition; release or destroy.	QC receipt report

Source: Adapted from Primus Laboratories (see Resources section IV)

Annex 2.

GOOD MANUFACTURING PRACTICES

Summary of GMP Requirements: FDA 21 CFR Part 110

The U.S. Federal Food, Drug and Cosmetic Act deems a food to be adulterated, among other things, "If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. 342(a)(4).

Good Manufacturing Practices (GMP's) remain the regulatory standard for all processed foods. GMP's are relevant to and supplement any additional pathogen reduction and HACCP requirements for the Meat, Poultry, and Seafood industries. GMP's regulations impose obligations on a manufacturer to control the risk of filth, chemical, microbiological, and other contaminants in food. If a manufacturer does not comply with any of the established GMP's, an FDA investigator may determine that the food has been produced under conditions which have rendered the food unfit or contaminated and may deem the food to be adulterated.

The quality and safety of finished food products is dependent on many factors. From the condition of the raw product throughout the manufacturing and distribution process contamination may occur to render the products alliterated. A review of these adulterated conditions is as follows.

Adulterated Foods

- Poisonous or Deleterious Substances
- Avoidable Poisonous or Deleterious Substances
- Tolerance
- Regulatory Limits
- Action Levels

Personnel

The plant management shall take all reasonable measures and precautions to ensure the following:

Disease Control

Any person who, by medical examination is shown to have or appears to have, an illness, open lesion, including boils, sores, or infected wound, or any other abnormal source of microbial contamination by which there is reasonable possibility of food, food-contact surfaces, or food packaging materials being contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such conditions to their supervisors.

Cleanliness

All persons working in direct contact with food, food-contact surfaces, and food packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include but are not limited to:

1. Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food packaging materials.
2. Maintaining adequate personal cleanliness.
3. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable organisms) in an adequate hand washing facility before beginning work, after each absence from the work station, and at **ANY** other time when the hands may have become soiled or contaminated.

4. Removing all unsecured jewelry and other objects that might fall into the food, equipment and containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, then gloves made of an impermeable material (such as rubber) shall be worn.
5. Maintaining gloves in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
6. Wearing, where appropriate and in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.
7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
8. Confining eating food, chewing gum, drinking beverages, or using tobacco to areas other than where food may be exposed or where equipment or utensils are washed.
9. Taking any other necessary precautions to protect against contamination of food, food contact surfaces, or food packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals and medications applied to the skin.

Education and Training

Food handlers and supervisors should receive appropriate training in proper food handling techniques and food protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

Buildings and Facilities

Plant and Grounds

The areas leading and adjacent to the building shall be kept clean and free of debris that may cause contamination of food products. Weeds and grasses shall not be allowed to grow against the building. A 36" "clear zone" shall be maintained around the perimeter. Dust shall be controlled so that airborne contamination is minimized. Areas that collect standing water shall be corrected so that the threat of microbial growth is minimized. All waste products, solids and liquids, shall be disposed of in a appropriate manor.

Sanitary Operations

Buildings and equipment shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated. Facilities, equipment, and utensils shall be cleaned and sanitized in a manor to minimize the risks of contaminating food products.

All materials and chemicals used for cleaning and sanitation shall be stored in a safe manor, which prevents contamination of food products. No toxic materials may be stored on site unless that material is necessary to the production or operation of the facility and/or equipment. All relevant regulations on the storage of toxic materials shall be implemented and followed.

Effective Pest, Rodent, and Bird control measures shall be implemented to minimize the risk of food product contamination. No Pests, Rodents, nor Birds are allowed within any area of the food plant. The use of pesticides and rodenticides are allowed only when use of these materials will not contaminant any food neither materials nor products.
Sanitation of all food contact surfaces, including utensils and equipment, shall be cleaned as frequently as necessary to prevent food contamination. In wet processing, all food contact surfaces shall be cleaned and sanitized prior to use. If any operation results in the contamination of any clean food contact surface, that surface must again be cleaned and sanitized prior to use. Non food contact surfaces must be cleaned as frequently as necessary to prevent food contamination. Single-service articles shall be stored, handled, used, and disposed of in an appropriate manor that prevents food contamination. Sanitizing agents shall be adequate and safe under conditions of use.

Sanitary Facilities and Controls

Each plant shall be equipped with adequate sanitary facilities and accommodations. An adequate water supply from an appropriate source shall be available. Plumbing to distribute that water in reasonable quantities, remove liquid wastes as to not create a health hazard, adequate floor drains, provide that there is not a back-flow from, or cross connection between systems carrying waste and piping systems carry water to food processing. Sewage disposal shall be adequate.

Employee toilet facilities shall be adequate, readily accessible, and maintained in a sanitary condition. Toilet room doors shall be self-closing and not open into any food processing area unless alternate methods ensure safety between rooms. Hand washing facilities shall be adequate, convenient, and furnished with suitable temperature water. Suitable sanitary towels or drying services, water control valves to prevent recontamination, understandable signage directing employees to sanitize their hands, refuse receptacles, and rubbish and offal disposal are required as well.

Equipment and Utensils

All plant equipment and utensils shall be so designed and made of such materials and workmanship, as to be adequately cleanable, and shall be properly maintained. The design and use of the equipment shall preclude their adulteration of food products. All equipment must be installed as to allow its cleaning and cleaning of the surrounding area. Equipment shall be made of non-toxic materials and food-contact surfaces shall be corrosion resistant. Seams on food contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter to minimize the opportunity for microbial growth.

Coolers shall be fitted with an appropriate temperature device that shows the temperature within the compartment. All instruments and controls used to measure, regulate, or record temperatures, pH, acidity, water activity, or other conditions shall be accurate, adequately maintained, and adequate in number to perform their designated use.

Compressed air or other gasses mechanically introduced into food or used to clean or operate equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Production and Process Controls

All operations in the receiving, inspecting, transportation, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source.

Chemical, microbial, and extraneous material testing procedures shall be used where necessary.

All raw materials and other ingredients shall be inspected and stored under conditions that will protect against contamination. Materials shall be washed to remove soils or other contaminates. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that they have not contributed to the contamination of the food.

Raw materials and other ingredients shall not contain levels of microorganisms that may produce food poisoning or other disease in human, or shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

Warehousing and Distribution
Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Defect Action Levels

The GMP regulation recognizes that some foods contain natural or unavoidable defects that are not hazardous to human health at low levels. The FDA has established "defect action levels" for many naturally occurring contaminants. These defect levels specify the level of contamination that may trigger an enforcement action. Uncontaminated food may not be mixed or blended with a batch that exceeds the current defect action level.

Record Keeping Requirements

The Umbrella GMP's does not require Record Keeping. It is however necessary to document and prove the correct application of GMP principles within manufacturing and distribution. Daily production logs, receiver logs, process control observations, and other written reports should be maintained to support the companies' compliance with the intent of the GMPs.

Pallets, Bins & Totes

Pallets, Bins, and Totes (PBT) should be cleaned and free of soils and other debris at the time of receipt. If soils or debris is evident, those PBT should be set aside and cleaned of all extraneous matter as is practical. If a particular PBT is suspect of contamination it should be replaced and then disposed of.

Bins and Totes shall be cleaned after each use and before any reuse. Minimum cleaning will remove all extraneous matter and debris. Additionally a sanitation step should be applied.

Used pallets must be clean and free of any extraneous mater, filth, and debris. No molds or other microbial growths shall be allowed on any pallets. Used pallets should be used only for product that will not be cooled by a cooling process that involves spraying or spreading of water over the product and pallet. This includes Hydro Vacuum, Hydro Cooling, and Ice Injection.

A plastic or cardboard slip-sheet may be inserted between the pallet and the first layer of cartons to separate the finished product from the used pallet.

Pallets shall be stored on a hard dust free surface and protected from airborne contaminants as possible. Pallet storage areas require proper Rodent prevention programs for control. Nails shall not be exposed nor shall nails be permitted to neither damage food product case nor package.

Annex 3.
Contraventions Cited for U.S. Food and Drug Administration Import Detentions.
Examples July 1996 to June 1997.

Reason for contravention	Total	Africa	Latin America Caribbean	Europe	Asia
Food Additives	**554 (5.0 %)**	2 (0.7 %)	57 (1.5 %)	69 (5.8 %)	426 (7.4 %)
Pesticide residues	**864 (7.7 %)**	0 (0.0)	821 (21.1 %)	20 (1.7 %)	23 (0.4 %)
Heavy Metals	**537 (4.8 %)**	1 (0.3)	426(10.9 %)	26 (2.2 %)	84 (1.5 %)
Mould	**570 (5.1 %)**	19 (6.3 %)	475 (12.2 %)	27 (2.3%)	49 (0.8 %)
Microbiological contamination	**1425 (12.8%)**	125 (41.3%)	246 (6.3 %)	159 (13.4%)	895 (15.5%)
Decomposition	**890 (8.0 %)**	9 (3.0 %)	206 (5.3 %)	7 (0.6 %)	668 (11.5 %)
Filth	**3519 (31.5%)**	54 (17.8 %)	1253 (32.2 %)	175 (14.8%)	2037 (35.2%)
Low Acid Canned Food	**1400 (12.5%)**	4 (1.3 %)	142 (3.6 %)	425 (35.9%)	829 (14.3 %)
Labeling	**1098 (9.8%)**	38 (12.5%)	201 (5.2%)	237 (20.0%)	622 (10.8%)
Other	**309 (2.8 %)**	51 (16.8 %)	68 (1.7 %)	39 (3.3 %)	151 (2.6 %)
Totals	**11166 (100%)**	**303 (100%)**	**3895 (100%)**	**1184 (100%)**	**5784 (100%)**

Source: FAO, "The Importance of Food Quality and Safety for Developing Countries", Committee on World Food Security, 25th Session, Rome, May 31-June3, 1999, at http://www.fao.org/docrep/meeting/x1845e.htm
Adapted from citing in Table 3 of Unnevehr, L.J. 2000. Food Safety Issues and Fresh Food Product Exports from LDCs. *Journal of Agricultural Economics,* Forthcoming.