DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. 2004N-0230]

21 CFR Part 110

Food; Current Good Manufacturing Practice Regulations; Public Meetings

Additional Comments from the Association of Food and Drug Officials

The Association of Food and Drug Officials (referred to henceforth as "AFDO") is pleased to provide the following additional comments to the U.S. Food and Drug Administration regarding 21 CFR Part 110 – "Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food."

AFDO recognizes the importance of modernizing Part 110 and wishes to provide more specific recommendations than those which were previously provided to FDA both verbally and in written form.

Many states have adopted 21 CFR Part 110 in whole or in part and it is generally recognized that this regulation serves as a foundation to other regulations which have been promulgated at the state level. A number of states will also apply Part 110 to retail processing establishments along with their own version of the FDA Model Food Code. Clearly, there is widespread application of Part 110 at the state level. For this reason, AFDO believes these regulations must be comprehensive, science based and have a clear food safety focus.

As states conduct more than 80 percent of all food safety inspections of food processors and distributors and as the number of contract inspections to the states are increasing, AFDO again wishes to recommend that FDA seek "buy in" from the states on what proposed new changes or philosophy the new GMP's may encompass.

Our specific Section by Section recommendations are as follows:

Part 110.3 Definitions

We believe the following definitions should be removed from the regulation:

1) "Batter"

2) "Blanching"

3) "Microorganisms"

4) "Quality Control Operation"

5) "Should"

We believe the following definitions should be added to this Section:

1) **"Adulterated"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, §402.

2) **"Approved"** means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

3) **"Critical control point"** means a point or procedure in a specific food system where loss of control may result in an unacceptable consumer health risk. (Note: Modification of current definition).

4) **"Food employee"** means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

5) **"HACCP plan"** means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods to prevent food from becoming adulterated within the meaning of the Act.

6) **"Hazard"** means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

7) **"Person in Charge"** means the individual present at a food establishment who is responsible for the operation at the time of inspection.

8) **"pH"** means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

9) **"Potentially Hazardous Food"**

   a) means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

      (i) The rapid and progressive growth of infectious or toxigenic microorganisms.

      (ii) The growth and toxin production of ***Clostridium botulinum***; or

      (iii) In raw shell eggs, the growth of ***Salmonella*** **enteritidis**.

   b) **"Potentially hazardous food"** includes any food of animal origin that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

c) **"Potentially hazardous food"** does not include:

(i) An air-cooled hard-boiled egg with shell intact, or a shell egg that is not hard-boiled, but has been treated to destroy all viable **Salmonellae**;

(ii) A food with an a_W value of 0.85 or less;

(iii) A food with a pH level of 4.6 or below when measured at 24^0C (75^0F);

(iv) A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

(v) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of S. enteritidis in eggs or C. botulinum can not occur, such as a food that has an a_W and a pH that are above the levels specified under Subparagraphs (C)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or

(vi) A food that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

10) **"Ready-to-Eat Food"** means food that is in an edible form without the need for additional preparation.

11) **"Regulatory authority"** means the local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

12) **"Risk"** means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

13) **"Sanitize"** means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

14) **"Scheduled process"** means the process selected by a processor as adequate for use under the conditions of manufacture for a food to achieve and maintain a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

15) **"Standard Sanitation Operating Procedures (SSOPs)"** – means all daily sanitation procedures conducted by a food plant to prevent direct contamination or adulteration of product(s). SSOPs shall describe the activity and how to properly complete the task, as well as specify the frequency with which each procedure is conducted and identify the employee(s) responsible for the implementation and maintenance of the SSOP.

<u>Part 110.10 Personnel</u>

1) Section (a) name should change from Disease Control to Employee Health. This Section should be more in tune with the 2001 FDA Model Food Code as it relates to food employees including listing the big 4 (Hepatitis a virus, Salmonella typhi, Shigella, and Shiga toxin

producing e-coli). The section should also include a list of symptoms associated with foodborne illness, (Diarrhea, Fever, Vomiting, Jaundice, or Sore Throat with fever in addition to the lesions and open wounds already addressed by this section. This section should also apply to current employees as well as applicants to whom a conditional offer of employment is offered. Some thought should be given to including high-risk activities that might lead to secondary infection. Exclusion and restriction needs to be defined along with specific steps necessary for a restricted/excluded employee to resume duties. An employee must be required to report symptoms or illness to the Person in Charge immediately and the Person in Charge must be required to notify the regulatory authority that a food employee is diagnosed with one of the four mentioned illnesses.

2) Section (b) (1) should indicate that no street clothing would be allowed unless protective outer garments are worn.

3) Add the following to (b) (4):

"While preparing food, food employees shall not wear jewelry on their arms and hands. This does not apply to jewelry on the hand which is covered and protected."

4) Add the following to (b) (5):

"The gloves shall be of an impermeable material unless covered by a durable tight fitting disposable glove made of impermeable materials." This Section should also include a statement related to minimizing bare hand contact with Ready to Eat foods. Fingernails should also be addressed in this section.

5) Part (c) must be mandated. Remove "should" and replace with "shall" in 2 areas for education and training.

6) Section (d) supervision should include some or all of the following related to demonstration of knowledge by the person in charge:

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the regulatory authority knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of this regulation. The person in charge shall demonstrate this knowledge by:

a) Complying with this Code by having no critical violations during the current inspection;

b) Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; or

c) Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:

1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;

2) Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;

3) Describing the symptoms associated with the diseases that are transmissible through food;

4) Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food and the prevention of foodborne illness;

5) Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs and fish;

6) Stating the required food temperatures and times for safe cooking of potentially hazardous food including meat, poultry, eggs, and fish;

7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food;

8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

   a) Cross contamination,

   b) Hand contact with ready-to-eat foods,

   c) Handwashing, and

   d) Maintaining the food establishment in a clean condition and in good repair;

9) Explaining the relationship between food safety and providing equipment that is:

   a) Sufficient in number and capacity, and

   b) Properly designed, constructed, located, installed, operated, maintained, and cleaned;

10) Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;

11) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;

12) Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;

13) Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this regulation;

14) Explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law or an agreement between the regulatory authority and the establishment;

Section 110.20 Plant and Grounds

This section is written in fairly general terms, which we believe is good. We also think it's good

to address outdoor operations because so many wineries have outdoor fermentation tanks. The language should be expanded so that it is not limited to fermentation tanks. Many operations have their first step (receiving) outside and a slightly broader term could address these other outdoor activities.

The language in 110.20 (3) should be rewritten as follows:

"The plant and facilities shall take the proper precautions to protect food in outdoor storage or processes such as receiving, initial product washing or bulk fermentation tanks."

Section 110.35 Sanitary Operations

We would propose a rewrite of this Section as follows:

A. General Maintenance. Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition to prevent food from becoming adulterated/contaminated within the meaning of the act. Washing, rinsing, and sanitizing of utensils and equipment shall be conducted in a manner that prevents adulteration/contamination of food, food-contact surfaces, or food-packaging materials.

B. Substances used in cleaning and sanitizing; storage of toxic materials.

1. Cleaning compounds and sanitizing agents used in washing, rinsing, and sanitizing procedures shall be free from undesirable physical, chemical and microbial contaminants and shall be safe and adequate under the conditions of use as specified in 21 CFR, Section 178.1010. Compliance with this requirement shall be verified by food establishment management by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Documentation of compliance shall be retained on filed for a period of 2 years. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

I. Those required to maintain clean and sanitary conditions;
II. Those necessary for use in laboratory testing procedures;
III. Those necessary for plant and equipment maintenance and operation; and
IV. Those necessary for use in the plant's operations;

2. Toxic and/or potentially toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified by a complete label, held, and stored in a manner that prevents adulteration/contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products shall be followed. In the event of an apparent conflict among those rules and regulations the order or priority for compliance, in descending order, is Federal, State, and then local government rule/regulation.

C. Pest Control. No pests shall be allowed in any area of a food plant. Service animals shall be allowed only in those areas of a plant where the presence of the animals will not result in contamination of food, food-contact surfaces, or food-packaging materials. An effective preventive and treatment program shall be in place to exclude pests from the processing and holding areas and to protect against the contamination of food, food equipment, and utensils on the premises by pests. The use of insecticides, pesticides, or rodenticides approved for use in a food establishment is permitted only under

precautions and restrictions indicated on the insecticide, pesticide, and/or rodenticide manufacturer's label that will protect against the adulteration/contamination of food, food-contact surfaces, and food-packaging materials.

D. Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

1. Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the food-contact surfaces are wet-cleaned, they shall be washed, rinsed, sanitized, and thoroughly air dried before subsequent use.

2. In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be washed, rinsed, sanitized, and air dried before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be washed, rinsed, sanitized, and air dried as necessary but in no event less frequently than once each 24 hour production day.

3. Non-food contact surfaces of equipment used in the operation of food plants shall be cleaned as frequently as necessary to protect against contamination of food.

4. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, food wrappers, food boxes, and food containers) shall be stored in appropriate, closed containers and shall be handled, dispensed, used, and disposed of in a manner that prevents adulteration/contamination of food or food-contact surfaces.

5. Sanitizing agents shall be effective for the intended use and safe under conditions of use as specified in 21 CFR, Section 178.1010. Any facility, procedure, or machine is acceptable for washing, rinsing, and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and properly sanitized.

E. Storage and handling of cleaned portable equipment and utensils. Clean and sanitized portable equipment with food-contact surfaces and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination.

<u>Section 110.37 Sanitary Facilities and Controls</u>

We believe requirements for a standard sanitation operating procedure should be required and language added as follows:

Each food plant shall implement and maintain written standard operating procedures for sanitation (SSOPs) in accordance with the following requirements:

?? The SSOP shall describe all procedures the food plant will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

?? The SSOP shall be signed and dated by the person with overall authority on site. This signature shall signify that the establishment will implement the SSOP as specified and will maintain the SSOP in accordance with the requirements of this part. The SSOP shall be

signed and dated upon initially implementing the SSOP and upon any modifications to the SSOP.

?? Procedures in the SSOP that are to be conducted prior to operations shall be identified as such and shall address, at a minimum, the daily cleaning of food contact surfaces of facilities, equipment and utensils.

?? The SSOP shall specify the frequency with which each procedure in the SSOP is to be conducted by the food plant and identify the employee(s) responsible for the implementation and maintenance of such procedure(s).

?? Each food plant shall conduct the pre-operational procedures in the SOP before the start of operations and shall conduct all other procedures as specified in the SSOP.

?? The person in charge of the food plant shall monitor the daily implementation of the SSOP.

?? The operator of the food plant shall evaluate the procedures contained in the SSOP to prevent direct contamination of adulteration of product(s) and shall revise the SSOP as necessary to keep the procedures effective and current with respect to changes in facilities, equipment, utensils, operations or personnel.

?? The operator of the food plant shall take appropriate corrective action(s) when either the establishment or department representative determines that the establishment's SSOP failed to prevent direct contamination or adulteration of product(s). Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the SSOP.

?? Each food plant shall maintain daily records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employee(s) specified in the SSOP shall authenticate the record with his or her initials and the date. These records shall be maintained for at least six months and made available to a department representative upon request. All such records shall be maintained at the food plant.

Part 110.80 Processes and Controls

The flexibility in this Section is an overall strength of the regulation. We believe this strength could be enhanced by requiring the application of a scheduled process for the manufacture of certain "potentially hazardous foods." The determination of what foods would require a scheduled process would be determined by the regulatory authority and based on illnesses associated with the products, how the products are packaged (reduced oxygen packaging), or other recognized concern. With reference to Parts 110.80(b)(3)(I) and (ii) – We believe the temperature requirements for refrigerated foods and foods held hot should be harmonized with the FDA Retail Food Code (i.e., refrigerated @ 41 degrees F and held hot @ 135 degrees F).

We further believe a requirement for food facilities to establish a written recall procedure should be included in this Section.

Part 110.93 Warehousing and Distribution

We recommend this Section be re-written as follows:

All storage and transportation of foods shall be under conditions that will protect food against chemical, physical, and microbiological contamination, or accelerated deterioration that would

render the food unfit for consumption [Section 402(a)(3) situation – "…..decomposed substance, or …..otherwise unfit for human consumption"].

A. Food Storage.

1) Facilities and grounds.

a) Food storage facilities shall be kept free of rodents, insects, birds, and other pests which may contaminate food.

b) Food storage facilities shall be properly constructed and maintained. All walls, ceilings, and floors shall be intact to preclude entry of vermin and environmental contaminants.

c) Doors and loading docks shall be tight-fitting and kept closed at all times when not in use, or adequately screened during normal operating hours to prevent entry of rodents, birds, insects, or other pests.

d) Outer premises, including trash receptacles, shall be kept clean and free of odors, debris, high weeds, or standing water which could harbor or attract vermin. All trash receptacles shall either be tightly covered or inverted if not in use.

e) Adequate protected lighting shall be provided to facilitate cleaning and inspection of stored foods and to prevent the unintentional contamination of foods or food ingredients.

f) Refrigeration units for storage of potentially hazardous foods (or whatever new name FDA comes up with) shall be adequate for properly cooling and maintaining all product at an internal temperature of 41 degrees Fahrenheit within safe time frames. Refrigeration units for storage of shell eggs (only) shall be adequate to maintain at an ambient air temperature of 45 degrees Fahrenheit.

g) Freezer units shall be adequate to maintain all frozen foods in a frozen state at all times.

h) All chemicals shall be properly labeled, stored, and physically separated from food storage at all times to preclude contamination.

i) Hand-washing and toilet facilities shall be provided and adequately maintained, including hot and cold running water, hand soap or approved hand sanitizer, and single-service towels as deemed appropriate (by the regulatory authority) for the types of foods handled.

j) Wastewater shall be disposed of in a sanitary and legal manner (as deemed by the regulatory authority).

k) Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food warehouse and/or food processing facility may be used. Pesticides shall be used only according to label directions. Rodenticides shall be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted use pesticides.

2) Food Safety Operations.

a) All potentially hazardous foods shall be maintained at an internal temperature of 41 degrees Fahrenheit or less at all times except as permitted in 2 c) below.

b) All frozen foods (that are either potentially hazardous or that are subject to decomposition that would render them unfit for human consumption) shall be kept frozen at all times.

c) After initial packing, shell eggs must be stored under refrigeration at an ambient temperature of 45 degrees Fahrenheit or less at all times. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine that a lower temperature must be maintained, the lower temperature shall prevail.

d) The temperature of molluscan shellstock from the harvester through the original shellfish dealer shall be maintained in accordance with the requirements of the National Shellfish Sanitation Program Model Ordinance. Raw molluscan shellstock shall be adequately iced or refrigerated to maintain an ambient air temperature of 45 degrees Fahrenheit or less during storage and distribution. Post-harvest treated shellstock shall be maintained at an internal temperature of 41 degrees Fahrenheit.

e) All foods, including refrigerated and frozen foods, shall be stored off the floor and away from the walls to help prevent contamination by vermin (rodents and insects for example) and moisture, and to facilitate cleaning, inspection, and proper application of pesticides and insecticides.

f) All damaged, distressed, and infested foods including swollen, leaking, and severely dented canned foods shall be segregated and stored in a "morgue area" adequately separated from undamaged food storage areas. Such foods shall be disposed of in a timely manner to preclude further contamination including by vermin.

g) All incoming foods and raw materials shall be inspected for insect or rodent contamination, temperature abuse, or other evidence of adulteration, prior to being placed in storage.

h) Foods and ingredients shall be rotated on a "first in, first out" basis or by the oldest date of pack.

i) Distressed foods salvaged in-house shall be reconditioned (we say "according to [our food salvage rules]" prior to sale except as indicated in (A)(2)(j) of this Subsection.

j) If the State in which the facility resides requires licensing and inspection of food salvage establishments, distressed foods may be distributed only to an establishment in compliance with State Law. (I don't know that FDA has ever included such information before, but it would be ground-breaking if FDA were to ensure that applicable State laws, that do not conflict with federal laws, were mandated by FDA…such as in the area of food salvaging).

B. Transportation of Foods.

1) Transportation vehicles shall be kept clean and free of rodents, insects, birds, and other pests which may contaminate food.

2) Vehicles used to transport foods may not be engaged in the back-hauling of any materials that could cause physical, chemical, or microbiological contamination of foods. Such activity is expressly forbidden unless the vehicle can be and is adequately cleaned and sanitized to prevent such contamination between uses.

3) Vehicles used to transport frozen or refrigerated potentially hazardous foods, including shell eggs and molluscan shellfish, must maintain the proper

temperature of such foods at all times according to the temperatures listed in (A)(2)(a-d) of Subsection (A) above.

4) Vehicles used for transporting potentially hazardous foods or frozen foods must be equipped with a continuous recording thermometer or an equivalent means to document and ensure that proper food temperatures are maintained at all times. Such temperature recording equipment must be calibrated according to the manufacturer's specifications, including the frequency of re-calibration, but not to exceed six months. Written records of all transportation temperatures and re-calibration must be kept for a period of one year and are subject to review by the [regulatory authority] upon request.

5) In lieu of compliance with (4) above, a Hazard Analysis Critical Control Point (HACCP) system may be used to ensure that potentially hazardous foods remain safe during transportation, including the identification, monitoring, verification, and validation of all critical control points.

6) Food transportation vehicles must be equipped with locking and/or tagging devices to ensure foods are not subject to intentional contamination (tampering) during transport.

7) If non-food items capable of causing contamination of food, such as cleaners or pesticides, are carried at the same time as food on the same vehicle, adequate precautions must be made to ensure that the food remains safe from cross-contamination.

8) Vehicles used to transport food shall be kept clean and free of excessive dust, dirt, spillage, and other debris, including excess moisture.

9) Staging of potentially hazardous foods shall be done in a manner that does not cause the food to become adulterated, either from filth or from being out of proper temperature for an extended period of time that could permit pathogen growth or toxin formation. The amount of time such foods may be staged must encompass such factors as the temperature of the food when staged, the time out of refrigeration, and the time it takes to bring the food temperature back to a safe range. Frozen foods must remain frozen.

We appreciate the opportunity to provide these additional comments.