**Application of (Current) Good Manufacturing Practices (GMPs)
& Sanitation Standard Operating Procedures (SSOPs)**

Prerequisites

So-called prerequisites are adjuncts to a HACCP plan. They are not part of the HACCP plan and can stand alone, but they should be firmly in place before a HACCP plan is made. Items and actions that can go into a prerequisite program should go there, rather than in the HACCP plan, as the consequences of deviation from, say, an SSOP may be less devastating.

GMPs

GMPs (CGMPs) are federal law. As discussed previously, they tell what a processing establishment **shall** do in terms of buildings, facilities, equipment, production and process controls, warehousing, and distribution. For FDA, they are published in 21 Code of Federal Regulations (CFR), whereas comparable information for USDA is in 9 CFR. The most pertinent portion of the FDA CGMP regulations follows; note that these specify what must be done, but not how to do it.

110.35 **Sanitary Operations**.

(a) General maintenance. *Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against 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 cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. 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 cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against 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 should be followed

(c) Pest control. *No pests shall be allowed in any area of the food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the 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 surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.*

(2) *In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. When equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.*

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

(4) *Single-service articles (such as utensils intended or one-time use, paper cups, and paper towels) should be stored in appropriate containers and disposed of in a manner that protects against contamination of food or food-contact surfaces.*

(5) *Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.*

(e) Storage and handling of cleaned portable equipment and utensils. *Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.*

Other subparts deal with management responsibilities and the cleanliness, health, dress, education, and training of workers. A competent supervisory person must be responsible for

compliance by all plant personnel.

SSOPs

Increasingly, plants are required to develop their own, individual Sanitation Standard Operating Procedures. Even if not required, these will be quite useful in conjunction with HACCP programs that may also be voluntary. SSOPs are to describe every cleaning and sanitation procedure used in a plant, in detail. The approximate time of the day or time in a shift when each operation is to be performed is specified. Water analyses and temperatures are likely to be included, as well as specific cleaning and sanitizing agents, how they are used, and on what. The person responsible for each step is to be specified, usually by job title, rather than by name. Provision is made for documenting every operation — the performance of each required task is recorded by the person who does it, subject to periodic verification by a supervisor. As we will see, unit operations that can be covered in the SSOP should be, rather than in the HACCP plan, if any.

A USDA example

The USDA has recently launched a new "Plant Sanitation and Good Manufacturing Practices Program" in conjunction with its egg grading operation that is intended to reward egg packers for maintaining enhanced sanitation programs. It focuses on SSOPs and GMPs and does not call itself a HACCP program. It is voluntary, and may or may not entail extra cost to the processor.

Plants that join are audited monthly, for compliance to program requirements, by the full-time resident egg grader. A very detailed audit form is used to address the following:

- Pre-operational sanitation inspection of premises, facilities, and processing equipment
- During processing — review of washing, packing, cooling, storage, and shipping practices
- Audit results recorded on audit worksheet
- Each audit control point is rated either critical, major, or minor

Plants that join the program and are in good standing get to print a special USDA "shield" on their egg cartons, next to the grade designation. It says: **United States Department of Agriculture** Sanitation and Good Manufacturing Practices Program – **USDA Verified** (in a circle-and-ribbon format). The perception is that consumers will prefer eggs so labeled, and may even pay more for them.

Part 2: Starting a HACCP plan

1. Form a HACCP team that represents all of the different segments of the operation: engineering, microbiology, quality assurance, housekeeping, (especially) hands-on workers.

2. Define the product (each product gets its own HACCP plan).

3. Identify the target clientele.

4. Develop a flow diagram that shows every step that takes place in generating the product.

5. Verify the flow diagram "on the floor," by walking through every step of what is actually done with the food, from beginning to end.

6. Plan to review and revise the HACCP plan at least annually and to do whatever is necessary to sustain the commitment of the entire work force.

Part 3: Human resources and responsibilities

1. Management must

- understand HACCP concepts
- be committed to HACCP
- provide funds for education and implementation
- accept changing roles in organization
- keep HACCP team enthusiastic

2. HACCP team must

- understand the seven principles of HACCP
- include people involved in daily processing
- include people with different backgrounds
- be able to identify hazards and preventive actions
- develop and implement HACCP plan
- train for 2 – 3 weeks
- develop plan in 2 – 3 months

3. Supervisors are responsible for HACCP verification — ensuring full implementation, all of the time

4. Outside experts may

- assist in evaluation of hazards and risks
- help in setting critical limits
- help defining deviation responses
- advise on equipment maintenance

5. Customers (wholesale) may do auditing

6. Governmental agencies' role should be limited to

- auditing
- validation

7. Consumers should follow instructions on labels