Good Manufacturing Practice (GMP)

Every aspect of food manufacture should be controlled according to defined managerial and technical standards. Good Manufacturing Practice (GMP) standards document management responsibility for the production of foods which meet quality and safety requirements. GMP integrates with Hazard Analysis Critical Control Point (HACCP) systems and provides a framework for the development and implementation of Quality Management Systems, with subsequent registration to ISO 9000. GMP standards define requirements for the management and control of activities and operations involved in the manufacture, storage and distribution of foods. Elements of activities and operations are identified as determinants of product quality and food safety. Standards are established for each element and it is the responsibility of management to ensure they are upheld. Broadly, GMP standards should express requirements which cover:

Premises

- suitability of the manufacturing environment, buildings, roadways, paths, surface drainage, effluent treatment, etc.

Facilities

- provision of manufacturing space, storage space, refrigeration space, freezer space
- provision of ventilation, water supplies, drainage, effluent removal, lighting
- suitability of personnel facilities etc.

Manufacturing, storage and distribution operations

- purchased products identification and storage
- suitability and use of plant and equipment, ingredients, packaging materials, additives, processing aids
- handling, storing and packing of product, labelling and product presentation
- product warehousing, transport and distribution
- reworking of product
- product specifications, product inspection and testing, Good Laboratory Practice, etc.

Hygiene and food safety

- specific preservation requirements-heat treatment, refrigeration, freezing, dehydration, chemical preservation
- cleaning schedules, cleaning practices, waste management, pest control
- personnel hygiene and practices
- foreign body control, metal detection, glass control, chemical control, etc.

Management responsibility

- provision of resources, management and supervision, quality assurance and technical personnel
- personnel training
- provision of production and hygiene procedures
- complaints procedure, product recall.

The embodiment of a GMP standard will not automatically ensure achievement of the given criteria. Audits should be carried out against the GMP standard to assess compliance and to identify non-compliances which should be rectified by appropriate corrective action.

Good Hygiene Practices (GHP)

The General Principles of GHPs should be used in conjunction with each specific code of hygienic practice and the guidelines on microbiological criteria. The document follows the food chain from primary production to final consumption, highlighting the key hygiene controls at each stage.

It recommends a HACCP-based possible to enhance food safety as described in the Hazard Analysis and Critical Control (HACCP) System.

The General Principles are internationally recognized and commended to Governments, industry (from individual primary producers, manufacturers, processors, food service operators and retailer s) and consumers alike.

The CODEX of GHP includes specific aims and objectives:

- to identify the essential principles of food hygiene, applicable throughout the food chain (including primary production through to the final consumer), to achieve the safety of food and suitability for human consumption
- to recommend a HACCP-based approach as a means to enhance food safety
- to indicate how to implement its principles
- to provide a guidance for specific codes which may be needed (for all sectors of the food chain) and to amplify the hygiene requirements specific to those areas.

Governments can consider the contents of GHPs and decide how best they should encourage the implementation of these general principles to:

- provide assurance that food is suitable for human consumption
- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population
- maintain confidence in internationally traded food

- provide health education programmes which effectively communicate the principles of food hygiene to industry and consumers.

Industry should apply the hygienic practices set out in this document to:

- provide food which is safe and suitable for consumption
- ensure that consumers have clear and easily-understood information, by way of labelling and other means, to enable them to protect their food from contamination and food borne pathogens by correct storing, handling and preparing.

Consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

Good Laboratory Practices (GLP)

The OECD (Organization for Economic Co-operation and Development) member countries have realized that there is a strong need for international harmonisation of test methods and Good Laboratory Practices to avoid different schemes of implementation, which would have an impeding impact on international trade in chemicals.

The document concerning the "Principles of Good Laboratory Practices" was developed by an international group of experts in 1979-80, published in 1981, under the Special Programme on the Control of Chemicals. The purpose of this document is to support the generation of high quality and reliable test data, which results in the harmonising of testing procedures for the Mutual Acceptance of Data (MAD), and hence duplicative testing and the creation of technical barriers to trade can be avoided, furthermore, human health and environment protection can be improved.

Good Laboratory Practices (GLPs) define the rules and criteria for a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded and reported.

So far 30 countries (the member states of the OECD) have signed agreements that make the OECD GLP Principles binding on them. This effectively makes the OECD Principles an international text.

The 1981 Council Decision on the Mutual Assessment of Data in the Assessment of Chemicals (revised 1997) integrates the OECD Principles of GLP. MAD is also concerned with the harmonisation procedures of GLP compliance monitoring, and it ensures that pre-clinical safety studies are performed according to the Principles of GLP.

Since 1997 non-OECD member countries can adhere to the MAD system through a procedure which has been embodied in a Council Decision (Council Decision on the Adherence of Non-Member Countries to the Council Acts Related to the Mutual Acceptance of Data in the Assessment of Chemicals C(97)114/FINAL).

An outline of the principles of the good laboratory practices

The organisation of the test facility and personnel:

Management's Responsibilities

Most of the responsibilities of test facility management are of a general nature, such as the requirements that test facility management has to ensure the availability of qualified personnel and of appropriate facilities and equipment for the timely and proper conduct of the study.

Furthermore, it has to ensure that health and safety precautions are applied according to national and/or international regulations; appropriate Standard Operating Procedures are established and followed, etc.

Study Director's Responsibilities

The study director continues to be the single point of study control and has the responsibility for the overall conduct and reporting of the study. He/she should agree to the study plan and ensure that the procedures specified in the study plan are followed.

Personnel Responsibilities

Personnel should exercise safe working practice and health precautions; the chemicals should be handled with suitable caution until their hazard(s) has been established. Personnel known to have a health or medicinal condition that is likely to have an adverse effect on the study should be excluded from operations that may affect the study.

Quality Assurance Programme

The documented Quality Assurance (QA) Programme should ensure that the performed studies are in compliance with the Principles of GLP. The QA activities should be carried out by someone who is directly responsible for management and familiar with the test procedures.

Facilities

The GLP Principles mandate in general that test facilities should be of suitable size, construction and location to meet the requirements of the studies performed therein, and an adequate degree of separation should be provided between the different activities to ensure the proper conduct of each study. Specific regulations are valid on test system facilities, on facilities for handling test and reference substances, on archive facilities and on waste disposal according to the Principles of GLP.

Apparatus, material, and reagents

Apparatus should be suitably located, be of appropriate design and adequate capacity, and should be periodically inspected, cleaned, maintained and calibrated according to SOPs. Apparatus and materials should not interfere with the test systems, and reagents should be properly labelled.

Test Systems

Distinction has to be drawn between the physical/chemical and the biological test systems:

- Regarding physical/chemical test systems, the used apparatus should be properly located and have appropriate design and capacity. Reference substances should be used to ensure the integrity of the test systems.
- Considering biological test systems the housing, handling and care of animals, plants, microbial as well as other cellular and sub-cellular systems should be carried out under proper conditions to ensure the quality of the data. The isolation of newly received animal and plant test systems is highly important until their health status has been evaluated. A number of recommendations are given in the Principles considering the acclimatisation of the test systems, the pieces of information that should be recorded, indicated.
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Test and Reference Substances

All the records referring to test and reference substances should be maintained; handling, sampling, and storage procedures as well as the test and reference substances should be identified. The stability of test and reference substances under storage and test condition should be known for all studies.

Standard Operating Procedures

Standard Operating Procedures (SOPs) should be elaborated for test facilities, and there should be immediately available SOPs for each separate laboratory unit.

Performance of the Study

Prior to initiation of a study, a study plan should exist. It should be retained as raw data, and the study should be conducted according to it. The proper form and content of a study plan is specified in the Principles of GLP.

Reporting of Study Results

For each study a final report should be prepared by using the International System of Units (SI). It is the task of the Study Director and perhaps of principal scientists from co-operating disciplines to sign and date the final report.

Storage and Retention of Records and Material

This final chapter specifies the proper way of storing and retention of any records and material (e.g. study plans, raw data, final reports, samples and specimens, etc.).

Good Agricultural Practice (GAP)

Within the European Union – upon the initiative of FAO (UN Food and Agriculture Organisation) – Good Agricultural Practice (GAP) forms the basis of food safety. GAP sets regulations for all players in the food chain. This logic is based on the realization of the principle: "from food to table". GAP approach is an initiative that aims at environmental, economic and social compliance on the farm and through the stages of post-treatment and processing, one which thus guarantees safety and a healthy production of food and other agricultural products.

GAP is based on the dual principle of:

- methods used in agriculture shall be economically in harmony with the food industry regulations and shall conserve the own natural resources
- declared and latent consumer demands, on the other hand, emphasize the importance of safe, high quality food production, and products.

At the same time, GAP does not entail new standards; it provides a tool to help the harmonisation of present standards by integrating environmental and social indicators into the production process.

The principle, "from farm to table", is very well-reflected within the integrated production system; this process starts with open-field plant cultivation, continues with feed process, and finishes with animal husbandry and animal process. The implementation of GAP in this process provides the following:

- apply GAP guidelines for open-field plant cultivation
- introduce Good Hygienic Practice (GHP) into all links of the chain
- introduce certified HACCP system (verified upon the relevant regulations on manufactured goods) operating in an integrated way into all links of the chain
- introduce quality and environmental management systems into all links of the chain in harmony with integrated ISO 9001:2000 and ISO 14001 standards
- introduce computer-assisted identification, tracing and controlling systems from manufactured goods to seeds
- integrated system-audit – auditing performed once on an annual basis; this procedure is an integrated assessment of all elements in the management system (MIR, KIR, HACCP, FSYS etc.)
- register trademark for strategic products upon product certification
- apply Total Quality Management (TQM) based system in the entire verticum.

Hazard Analysis and Critical Control Points (HACCP)

HACCP is an industry-wide effort approved by the scientific, as well as by the regulatory and industry communities, designed to focus on food safety, including food safety in retail establishments. A major focus of the HACCP program is "from farm to table." In this context HACCP is a concept as well as a method of operation, applied to all phases of food production, including agricultural production, food handling, food processing, food services, food distribution, and consumer use. In short, everyone is responsible for safe food products. When it comes to pathogens, "sight, smell, and taste" is not enough. It is necessary to have control over the process, the raw materials, the environment, and the people, beginning as early in the food production system as possible.

In the beginning there was great interest in this new method of food safety. The Food and Drug Administration (FDA) began to train its inspectors on the elements of HACCP and instituted special inspections of HACCP in food processing plants. There were a great number of conferences and meetings about HACCP, including a symposium during the 1974 Annual Meeting of the Institute of Food Technologists. During the 1970s, the FDA promulgated the regulations for thermally processed low-acid canned foods1 and acidified foods.2 Although these regulations did not mention HACCP, they were based on HACCP concepts.3 Over the years, HACCP has been slowly accepted by the food industry and it has become a preventive system that guarantees the safety of food products. In practice, the HACCP program considers all types of hazards or potential hazard factors — biological, chemical, or physical — that could affect food safety and that occur naturally in the food or in the environment, or that are generated due to an error during food processing.

Although the description of the HACCP principles and concepts is relatively simple, the fact is that the development of an HACCP program is not. It takes time, expertise, common sense, and ability to develop an HACCP program.

HACCP was a program originally developed as a microbiological system in the 1960s, to ensure the safety of food for astronauts. The Pillsbury Company was asked to develop the first space foods as well as to design a system for controlling the safety of space foods used first for the Mercury flights and later for the Gemini and Apollo flights. Working in collaboration with the National Aeronautic and Space Administration (NASA), the U.S. Army Natick Laboratories and the U.S. Air Force Space Laboratory Project Group, Pillsbury pioneered its development, based on the "Failure, Mode and Effect Analysis" (FMEA) engineering system. This system looks at what could potentially go wrong at each stage in an operation, together with possible causes and the likely effects. But HACCP is more than a failure-mode-effect analysis for food. Essentially, HACCP is a product safety management system that identifies and monitors specific food-borne hazards— biological, chemical, or physical properties — that can adversely affect the safety of the food product, allowing food processors to take a proactive approach to prevent food-borne diseases.10 This hazard analysis serves as the basis for establishing critical control points (CCPs) or steps in the process that must be controlled to ensure the safety of the food.

Critical limits are then established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system to ensure that potential risks are controlled. The hazard analysis, CCPs, critical limits, and monitoring and verification steps are documented in an HACCP plan. A properly implemented and functioning HACCP program minimizes the need for extensive product sampling and testing, since preventive measures are built into the production controls.

During the original development of HACCP, assurances of safety necessary for the space program required nearly totally destructive sampling with little product remaining for consumption. This was unacceptable for obvious reasons. In the Pillsbury-Natick program, a food processing operation was treated as an interlocking total system. Each facet was broken down and analyzed for its contribution to the overall level of risk associated with consumption of the product. Effective control mechanisms were then put in place to ensure that potential failures were prevented from occurring, focusing on preventing — rather than correcting — hazards that could cause food-borne illnesses, by applying science-based controls from raw material to finished products. The program allowed the identification, prediction, and prevention of potential safety problems throughout the food-manufacturing process, setting up methods to control each possible hazard. A manufacturer then could keep records to make sure that the controls worked. With this program in place, testing the foods for safety was unnecessary.

It is important to always remember that the establishment of effective HACCP programs involves primarily the application of good common sense and preventive considerations to address situations before they become problems. The emphasis is on prediction rather than reaction, on getting the process right initially rather than correcting it after problems have occurred. Many food companies operated in this manner long before 1971 because it made sense and it was cost-effective to do so. Only more recently have programs been formalized and honed to the point that they are effective tools, acceptable to both industry and regulators.

Professionals seeking additional information on HACCP programs and their implementation are directed to the publication of the HACCP working group of the National Advisory Committee on Microbiological Criteria for Foods. This document provides a detailed explanation of HACCP principles and includes a decision tree, which may be of assistance in identifying CCPs.

By using HACCP, the manufacturer will no longer need to rely solely on routine inspections to spot potential food safety hazards. An HACCP program makes inspections more useful by concentrating only on potential problems and on critical areas and thus saves time. Once problems are identified, they can easily be corrected. Records produced for the HACCP system also have benefits. Tracking food temperatures and other data allows workers to become interested in food safety, leading to better food handling, improved food quality, and increased pride in their work.

An HACCP program should cover all foods. For most foods, this requires knowledge of basic food-manufacturing practices and common sense. For multi-ingredient foods, technical

assistance is recommended. The HACCP program for each food product being manufactured in a plant make up the HACCP program of that plant.

Advantages

HACCP offers a number of advantages. Most important, the program:

1. Focuses on identifying and preventing hazards from contaminating food, based on sound science.
2. Permits more efficient and effective government oversight, primarily because record keeping allows investigators to see how well a firm is complying with food safety laws over a period, rather than how well it is doing on any given day.
3. Places responsibility for ensuring food safety on the food manufacturer or distributor.
4. Helps food companies to compete more effectively in the world market.
5. Reduces barriers to international trade.

In the application of HACCP, the use of microbiological testing is seldom an effective means of monitoring CCPs, because of the time required to obtain results. In most instances, monitoring of CCPs can best be accomplished through the use of physical and chemical tests, and through visual observations. Microbiological criteria do, however, play a role in verifying that the overall HACCP system is working.

For a successful HACCP program to be properly implemented, management must be committed; this indicates an awareness of the benefits and costs of HACCP, and will include education and training of all employees. Benefits, in addition to enhanced assurance of food safety, are better use of resources and timely response to problems.

The HACCP Program

Guidelines for Application of the HACCP Principles

HACCP has become a technical management program in which food safety is addressed through the control of biological, chemical, and physical hazards in all segments of the food industry from growing, harvesting, processing, manufacturing, and distributing to preparing food for consumption. For the successful implementation of an HACCP program, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

Prerequisite programs such as current Good Manufacturing Practices (cGMPs) are essential for the development and implementation of successful HACCP programs. Food safety systems based on the seven principles of HACCP have been universally accepted by government agencies, trade associations, and the food industry and are being successfully applied in food processing plants, retail food stores, and food service operations around the world. The development of effective HACCP programs should be appropriately implemented in each manufacturing stage of the food industry under consideration.

HACCP Program Prerequisites

The production of safe food products requires that an HACCP program be built upon important prerequisites. The following are examples of common prerequisites.

- **Facilities.** The establishment should be located, constructed, and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw to cooked materials.

- **Supplier Control.** Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.

- **Specifications.** There should be written specifications for all ingredients, products, and packaging materials.

- **Production Equipment.** All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.

- **Cleaning and Sanitation.** All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.

- **Personal Hygiene.** All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.

- **Training.** All employees should receive documented training in personal hygiene, GMPs, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.

- **Chemical Control.** Documented procedures must be in place to assure the segregation and proper use of nonfood chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.

- **Receiving, Storage, and Shipping.** All raw materials and products should be stored under sanitary conditions and the proper environmental conditions, such as temperature and humidity, to assure their safety and wholesomeness.

- **Traceability and Recall.** All raw materials and products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.

- **Pest Control.** Effective pest control programs should be in place.

Other prerequisite programs include:

- Quality assurance procedures
- Standard operating procedures for sanitation, processing, product formulations and recipes
- Glass control
- Procedures for receiving, storage, and shipping
- Labeling
- Employee food and ingredient handling practices

Each stage of the manufacturing process must provide the conditions necessary to protect food while it is within that stage. This has traditionally been accomplished through the application of cGMPs, now considered to be prerequisite to the development and implementation of effective HACCP programs.

Prerequisites provide the environment and conditions necessary for the production of safe, wholesome food. Many of the conditions and practices are specified in federal, state, and local regulations and guidelines (e.g., cGMPs and Food Code). At the international level, the Codex Alimentarius General Principles of Food Hygiene describes the basic conditions and practices expected for foods intended for international trade. In addition to regulatory requirements, industry often adopts policies and procedures specific to their operations.

The existence and effectiveness of prerequisites should be assessed during the design and implementation of an HACCP program. All prerequisites should be established, documented, regularly audited, and managed separately from the HACCP program. Certain aspects, however, may be incorporated into the program. For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production. During the development of an HACCP program, the team may decide that the routine maintenance and calibration of an oven should be included in the plan as a verification activity. This would further ensure that all the food in the oven is cooked to the minimum internal temperature necessary for food safety.

Education and Training

The success of an HACCP program depends upon educating and training management and employees in the importance of their role in producing safe foods. Employees and operators must understand what HACCP is and learn the skills necessary to make it function properly. This should include information about the control of foodborne hazards in all stages of food manufacturing. Specific training should include working instructions and procedures outlining the tasks of those employees monitoring CCPs. Personnel must be given the materials and

equipment necessary to perform their required tasks; management must provide the time for a thorough education and training of their personnel.

The seven HACCP principles

The HACCP system is based on a universally recognized set of seven principles that are used for the development of an HACCP plan for a food. These principles reflect a framework that was developed on the basis of a combination of recognized, science-based, food safety considerations and quality systems characteristics. This integration of basic food safety principles with the quality systems approach has been an important factor in the widespread recognition of the HACCP principles by food quality professionals.

The universally recognized Seven Principles of HACCP are:

- Principle 1: Conduct hazard analysis
- Principle 2: Determine critical control points
- Principle 3: Establish critical limits
- Principle 4: Establish monitoring procedures
- Principle 5: Establish corrective action procedures
- Principle 6: Establish verification procedures
- Principle 7: Establish record-keeping and documentation procedures