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GLOBAL STANDARDS AND LEGISLATION: ENSURING FOOD SAFETY AND MITIGATING HAZARDS

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Abstract

Approximately 1 billion cases of infections, especially in the developing world, are spread by biological infectious agents annually. Some of these conditions comprise Botulism, Shgellaiosis, and Campylobacteriosis. In most instances, distress with the stomach, blotting, excessive perspiration, and recurrent fever are often recorded. Physical, chemical, and biological health consequences are few of the variables that threaten food safety. In developing countries, the major cause of contaminants and hazards is primarily linked to underground water sources. The negligence of proper sanitation and drainage system leads to mixing sewage waste into portable water leading to contamination and infestation of many microbes. The habitual practice of dumping the industrial waste into rivers, lakes and other sources of ground water is also responsible for contamination of physical and chemical origin leading to development of various symptoms which could be associated with disease or food poisoning. Another very common practices in developing countries is the habitual adulteration in developing countries, and the use of untreated water for the preparation of various products. These food laws and legislations are implemented to mitigate the hazards and prevent the plausible food born infections, by ensuring food safety and enhancing the quality of the products. In conclusion, using laws like FSMA, GMP, and HACCP to address biological, chemical, and physical risks is necessary to ensure food safety, while also mitigating the various possible hazards of biological, chemical and physical origin.

Key Words: Food Safety, HACCP, Hazard, International standards, Legislations, Microorganisms, Regulations, Risk,

INTRODUCTION

Food safety is the promise that, when made as well as consumed in conformity with its stated consumption, food will not cause damage to the person consuming it, based on the guidelines issued by the Codex Alimentarius Commission (Lelieveld and Motarjemi, 2013; Lubis *et al*., 2016). Although bloody diarrhea is the main reason for several of these cases in nations that are underdeveloped, advanced nations also have a high prevalence of food-borne diseases. The first of the 10 World Health Organization (WHO) Golden Rules for Safe Food Preparation advises the consumer to purchase food processed for safety (Lund, 2008; Odueke *et al.*, 2016). Chemical hazards are infrequent but can have long-term impacts; biological hazards, including bacteria, present immediate threats (Salehi *et al*., 2019). Physical risks are observable yet nonetheless dangerous, such as foreign items. Despite their advantages, technological breakthroughs like food irradiation cause issues.

The Food Safety Modernization Act (FSMA), which prioritizes partnerships, imports, inspection, prevention, and response, strengthens regulatory authority. With a focus on risk-informed prevention, it changes the FDA's strategy from reactive to proactive. All facets of food production, processing, and distribution are covered by FSMA

laws, except for USDA-regulated meat, poultry, and egg products. Food safety is guaranteed by Hazard Analysis and Critical Control Points (HACCP) and Good Manufacturing Practices (GMP). While HACCP systematically finds, evaluates, and controls hazards, GMP establishes minimum requirements for cleanliness. Benefits of HACCP include decreased consumer risk and increased production. The benefits of food safety rules are analyzed theoretically by considering variables such as susceptibilities, income, pricing, and perceptions of risk. Expressions for willingness to pay (WTP) for lower risks of sickness and death related to contaminated foods are derived using models (Lund, 2008).

Biological, chemical, and physical hazards that might harm consumers are considered as part of food safety. Food can become contaminated by biological dangers like bacteria and viruses, which can cause sickness. Toxins and pesticides are examples of chemical hazards that can be dangerous if they are present in excess. Physical dangers include extraneous materials that might unintentionally find their way into food products. Risk assessment determines the possible impact of these dangers and directs the application of risk management strategies. The USA follows the FSMA, which emphasizes preventive measures, the EU establishes fundamental food safety principles through legislation such as EC 178/2002. While HACCP systematically identifies and manages risks throughout production, Good Manufacturing Practices (GMPs) guarantee hygienic food manufacturing. Applying the regulations enhances consumer trust in foods and ensures a safe food supply chain (Chen *et al*., 2014).

The objectives of this study are to evaluate and contemplate the importance and impact of various international standards and legislations on food safety, hazards, risk mitigation and standardizing the quality of raw ingredients, while also mitigating the food borne infections. Secondly, the assessment and comparison of the different standards and evaluate the different legislations and their contribution in food safety.

HAZARDS:

Any factor that exists in food and has potential to lead to illness or injury for the consumer is considered a food safety hazard. Hazards can be anything ranging from a microorganism to a physical object which could lead to potential complication in either a food product or human such as lactic acid bacteria and a piece of metal in pasteurized milk (Harlia *et al*., 2018). The role of international standards and regulations is to prevent complications by actively regulating the hygienic practices, sterilization techniques and preparatory operations carried out in industries, thereby ensuring food safety and minimizing health complications (Lan *et al*., 2017). These hazards can be biological, like pathogenic bacteria, chemicals like a toxin produced while processing, or physical like a stone or piece of metal. In other words, hazards are the things that food safety practices try to protect against, contain, and eliminate from foods (Chen *et al*., 2014; Nardi *et al*., 2020).

Biological Hazards:

The biggest immediate threat to consumer food safety comes from biological risks. For example, most food firms are likely to have to deal with the threat posed by food-poisoning bacteria, which can quickly produce huge outbreaks of acute sickness. Very few foods are safe from biological dangers throughout the production, storage, or delivery

processes. In a technical sense, larger species like insects and rats could be considered biological risks. These, however, are not further discussed here because they rarely pose a direct risk to health. The risks mostly concerning food safety are microorganisms and certain foodborne parasites (Jayan *et al*., 2020; Zhang *et al*., 2021).

1. Bacteria

A variety of bacteria constitute food safety hazards. Since some of these species, like *Salmonella* as well as *Listeria monocytogenes*, are well-known and recognizable to consumers, other species are much less common and have less information accessible (Togan, 2024). Examples of these involve *Vibrio parahaemolyticus*, that is a very rare reason for food poisoning linked to aquatic life, and *Yersinia enterocolitica*, which is mainly to blame for gastroenteritis that usually impacts general population (Barzegar *et al*., 2023).

Another less well-known source of foodborne illness is campylobacter. While remaining comparatively unnoticed to consumers, this organism is currently responsible for more food poisoning incidents than any other possible agent, such as *Salmonella* (Shofia *et al*., 2023). The food sector is similarly less familiar with campylobacter, and its human transmission mechanism is still mostly unknown. This emphasizes how crucial it is to carry out more studies and scientific study to improve our comprehension of biological dangers. Based on how they cause illnesses, bacterial food safety concerns can be classified into two types (Lawley *et al*., 2012).

a. Infection

By consuming tainted food, most foodborne bacterial infections proliferate in the stomach, resulting in disease. Subsequently, they could cause signs by 2 a Guide breaking into the intestinal lining cells or, in certain situations, by breaking into other body areas and resulting in more serious disorders. Food poisoning caused by bacteria includes *Salmonella*, *Campylobacter*, and *E. coli* O157 (Almaary, 2023)

The typical characteristic of this kind of food poisoning is that the signs often take at least 8 to 12 hours (and occasionally much longer) to manifest. Some bacteria in this category also cause symptoms by growing in the stomach and secreting toxins, as opposed to penetrating the tissues. *Clostridium perfringens*, which is a food-poisoning bacterium typically associated with cooked meat items, is a prime instance of this class of virus (Kostoglou *et al*., 2023).

b. Intoxication

A small number of foodborne bacteria that are pathogenic generate disease by intoxication instead of by infection. Under appropriate circumstances, such bacteria can develop in specific foods and, as the outcome of their growth, create toxins. As a result, the toxin is already present in the meal when it comes into contact, and in rare circumstances, it may remain after heating has destroyed all the bacterial cells. While *Staphylococcus aureus* and *Bacillus cereus* are a couple examples of bacteria that may produce intoxication, *Clostridium botulinum* is a particularly significant and possibly dangerous source of intoxication. When poisons already exist in the meal, intoxications normally have much shorter periods of incubation than diseases (Jovanovic *et al*., 2021; Lv *et al*., 2021)

2. Viruses

Globally, gastroenteritis caused by viruses is highly prevalent. Foodborne illnesses can be caused by a variety of viruses, whereas additional methods of transmission are usually more prevalent. The most well-known are probably hepatitis A and noroviruses, which have been linked to several major reports of foodborne illness and are frequently the consequence of improper sanitation on the part of diseased workers who handle food.

The safety of food may potentially be threatened by "new" viruses. Extremely dangerous avian influenza viruses, for instance, usually infect birds, but they can also occasionally infect humans and cause life-threatening illnesses. Although there isn't any concrete proof that this distribution may be foodborne at this point, the poultry sector is quite concerned about such viruses and their potential consequences. Further research is needed to fully understand them (Lawley *et al*., 2012).

3. Parasites

Although contaminated foods can spread an extensive range of intestinal parasites to human beings, faecal-oral or aquatic transmission is more typical for most of them. Although such organisms are considerably more prevalent in underdeveloped nations with inadequate sanitation, their significance may grow in wealthier nations because of the growing global food supply chain. Although Phase 3 protozoan parasites were the most significant now, other kinds should also be considered as potential threats to food safety (Gabriël *et al*., 2022).

a. Protozoans

Human foodborne illnesses can be caused by several recognized protozoan parasite species, including *Cryptosporidium parvum* and *Entamoeba histolytica*, which are responsible for amoebic dysentery in humans. But recently, certain strange species have become a hazard to food safety, particularly when they contaminate imported goods. One such instance is *Cyclospora cayetanensis*, which has been linked to many gastroenteritis epidemics in the United States linked to imports fruit (Eslahi *et al*., 2024).

b. Other types of parasites

Different kinds of foodborne parasites include cestodes (tapeworms), such *Taenia solium*, and nematode worms, like *Trichinella spiralis* and the anisakid parasites prevalent in fish. Thanks to better sanitation, many diseases are now significantly less common in industrialized nations than they formerly were, however they remain major worldwide factors of disease (Lawley *et al*., 2012).

4. Prions

Although the full extent of prions' risk to food safety is still unknown, there has been plenty of worry due to their likely role in the foodborne transmission of the always fatal brain disease variant Creutzfeldt-Jakob disease (vCJD) (Awuchi, 2023).

Chemical Hazards

In contrast to bacteria and other biological concerns, chemical hazards in food are typically less noticeable at first glance. In industrialized nations, acute toxicity resulting from chemical pollutants found in food is now quite rare. Long-term exposure to low concentrations of hazardous substances in food poses a considerably more pernicious risk. There's a chance that certain toxins could cause cancer, and in certain situations, this could result in chronic sickness.

Any point along with the production process could allow an extensive range of chemical pollutants to find their way into the food supply. For instance, industrial chemicals like lubricants and detergents may seep into food during processing, fresh fruit may be contaminated by agricultural chemicals like insecticides and herbicides during initial production, and certain commodities may include "natural" biological toxins. Additionally, when food is being stored, chemical pollutants may seep into it from the container. Several major categories of chemical contaminants that are noteworthy for food safety include the following:

- Agricultural chemicals, pesticides, etc.
- veterinary drugs
- Naturally existing biological toxins
  - fungal toxins
  - plant toxins
  - fish toxins
- Contaminants of the environment (e.g. dioxins and heavy metals)
- contaminants produced during processing (e.g. acrylamide)
- Food-contact materials contaminants (e.g. plasticizers)
- cleaning and sanitizing chemicals
- Adulterants (e.g. illegal food dye)

There are a lot of potentially dangerous substances that could contaminate food in general. The United Kingdom's regulation, for instance, specifies maximum residue levels (MRLs) for more than 28,000 pesticide/commodity combinations. Therefore, discussing pesticides in any detail here would be impractical. Many nations have very tight regulations on the use of pesticides, and the presence of residues in imported food is frequently checked (Kamboj *et al*., 2020).

There is also a long list of possible adulterants. Under the definition, adulterants are substances that one would not anticipate finding in food, and if they are, little is known about the potential health risks. Synthetic Sudan dyes, which are present in imported spices as well as other goods in the EU, are a recent example. Although it is against the law to use them in food, there is currently some debate about the importance of these substances for food safety given their unclear health effects at low levels in food. It is impractical to discuss adulterants here for these reasons. Food safety experts and authorities have given certain contaminants substantial consideration to determine the degree of risk they provide, and these are the subject of the chemical risks section (Lawley *et al*., 2012; Togan, 2024).

Physical Hazards

Physical hazards are any foreign objects or superfluous objects in food that could make a consumer sick or hurt. Certain objects can lead to injuries such as broken teeth, choking hazards including jewelry, wood splinters, and gel capsules, and cuts from metal shavings, glass shards, and needles. Because they are easily identified, complaints about physical hazards exceed those about other problems. Even while they are not inherently dangerous, foreign bodies-insects, mice, or their parts-can occasionally cause psychological anguish. Optical and magnetic detectors, X-ray machines for solid object detection, vendor certification and words of guarantee, effective pest control within the facility, preventative maintenance of equipment, appropriate sanitation protocols, and education of employees are some examples of control methods. The potential for

food choking, especially in newborns and young children, is another danger. These don't usually get reported as foodborne disease incidents, but they happen frequently enough to be concerning. The size, shape, and consistency of food-such as jelly sweets made with Konjac flour-as well as the item itself-such as baby biscuits, tiny sausages, and candies-all increase the danger of choking. In conclusion, it is noted that nanoparticles represent a form of physio-chemical hazard as well due of the possible negative health effects resulting from their extremely small size and maybe shape (Motarjemi *et al*., 2009; Lawley *et al*., 2012). Physical hazards are:

- Injury causing sharp items
- Dental damage is causing hard items
- Choking and airways block causing items

Technological hazards

Food exposure to radiation and genetic manipulation are two examples of potential harmful effects of technical improvements in food products that are referred to as technological risks. When it comes to food safety and availability, technology has generally produced several advantages. However, the public expressing worry about emerging technologies is not unprecedented. According to researchers, technological innovations are typically contentious, and it is hard to forecast how customers will react to such (Yeung and Morris, 2001; Kamboj *et al*., 2020).

Allergens

As more people, especially children, have been experiencing the indications of food allergies, the issue of food allergies has become more significant for the food sector in recent years. Considering this development, food makers have been urged to react, especially about clearly labeling items. Accurate labeling of allergens is a responsibility that goes hand in hand with clearly labeled products. It is crucial that goods labeled as allergen-free don't get contaminated with certain allergens when they are being produced. This is crucial for allergens like peanuts, which Introductory 5 can trigger potentially fatal anaphylactic reactions in susceptible people. Unreported food allergies are becoming a more common reason for product recalls in North America, Europe, and other regions.

Food allergy control is currently a quickly evolving area of food safety that many manufacturers will need to be aware of. EU legislation now recognizes twelve major food allergens, although many more items are probably being able of triggering allergic reactions in susceptible people (Lawley *et al*., 2012).

These are common food allergens and can cause severe respiratory issues associated with redness and puffiness of face and neck i.e. Gluten from cereal sources, crustaceans, fish, eggs albumin, peanuts, soya beans, milk and dairy products, tree nuts, celery and asparagus, mustard, sesame seeds, SO_2 and Sulfites are included among the common allergens and cause complications in public. Food allergies are likely to become more and more significant in the years to come, and more allergens will likely be acknowledged by law (Reshma *et al*., 2023).

Case Studies:

The case study addresses the interaction among international trade and food safety, illustrating how distinct national standards impart problems for global food markets. Several safety laws, that include *Salmonella* or pesticide residues, can result in trade disputes. Global structures, including the World Trade Organization's (WTO) Sanitary and Phytosanitary

(SPS) Agreement, attempt to mitigate disputes by integrating standards through acceptance and science-based regulation. Influenced by the desire to protect brand image and market access, multiple nations establish private sector approaches, like third-party certifications and HACCP systems, to eliminate legislative flaws. Though food safety problems are real, standardized regulations could promote trade by increasing demand for safe, high-quality food. Aiming to merge consumer safety with the perks of trade, the report highlights the importance of regular investments in food safety science alongside the interaction between governments and business (Unnevehr, 2015).

Analysis of international legislations and standards to regulate aflatoxins (AFs) in food, the study illustrates the substantial health threats, especially cancer, that such pathogenic substances offer. To protect customers, bodies such as EU and WHO have set extremely precise regulation limits for aflatoxins, that can often be found in cereals, nuts, and milk. Although, exchange is influenced, and risk management has become much complicated by various national legislations and standards. Efficient legislation is relying on constant risk assessments that emphasize vulnerable people and high-risk places. In the long run, combined efforts, including ones from the commercial sector, support safer food systems and equal competition practices internationally by better monitoring and ensuring standard laws (Bhardwaj *et al*., 2023).

The case of etizolam intoxication, more so when transformed with cocaine, indicates the possibility of drug effects, which may arise serious health issues especially breathing problems and heart failure. The benzodiazepine analogue etizolam enhances the effects of other medications, constantly creating serious side effects. When trying to control the transport and labelling of substances, reduce unintended intake, and prevent misuse, this situation illustrates the crucial role of rigorous food and drug safety measures. Being able to get substances that may be hazardous without sufficient medical control can be minimized by stronger regulations and public awareness (Drevin *et al*., 2022).

RISK

As "the intersection of the likelihood, or rate, of occurrences of a described risk and the size of the effects of the occurrence," risk is defined technically in the setting of potentially dangerous events (Liguori *et al*., 2022). Among the most common types of risks are associated with contamination, spoilage, infestation and putrefaction of food products, which not only damage the quality and shelf life of the food products but also causes complications such as abdominal cramps, swelling, vomiting, nausea, diarrhea and excessive sweating in individuals upon accidental consumption (Keim, 2018). Food laws prevent such mishaps by standardizing and ensuring quality standard of the food product, as microorganisms are majorly responsible for risk associated with foods (Rana and Paul, 2020). “A measurement of the likelihood of a negative health consequence and the seriousness of such impact, far-reaching to a hazard(s) in food,” according to Codex Alimentarius Commission (CAC), is how hazard is expressed in the context of food safety.

Food safety risk analysis, which is composed of three separate but related aspects—risk examination, risk handling, and risk communication was developed under the direction of the Food and Agricultural Organizations of the United Nations and

the World Health Organization (FAO/WHO) and later adopted by the CAC as an outline for a based on science food safety system that can be utilized by countries in the face of food safety risks (Rustia *et al*., 2021).

In order to weigh policy options that might address the current situation, food safety risk prevention considers the specifics of a precisely completed risk evaluation, the interests of all major participants in the food system (manufacturers, distributors, buyers, etc.), and other relevant factors for the preservation of the general population, the economy, and other social issues that impact the food industry. Appropriate food safety risk communication, which is the interactive sharing of knowledge and viewpoints among risk analysts and risk managers, is essential throughout the whole risk analysis process as demonstrated in Figure 1.

Fig 1: Risk Analysis Process

A scientific foundation is necessary for a risk-based approach to food safety management in order to identify areas of highest risk and allocate national resources to appropriate risk reduction measures for the most urgent food safety issues. The Food and Agricultural Organization of the United Nations (FAO/WHO) highlights that one of the most important ways to enhance a nation's food safety control system is to have a solid foundation in risk analysis as explained in Table 1. This can be accomplished by using a standard risk management method that the FAO/WHO has developed to assist nations in developing national risk management systems. It begins with unreliable risk mitigation measures meant to clarify the food safety risks (Rustia *et al*., 2021; Momtaz *et al*., 2023).

Table 1. Risk identification in general commodities

Type of risks	***Interpretations***	***Source's***
Risk assessment	Comprises identifying hazards, effect of hazards and dose-effect relationships.	(Manning and Soon, 2013)
Risk management	Involve depriving and analyzing various groups upon exposure to risk and suggesting suitable legislation.	(Manning and Soon, 2013)

Risk communication	Information and discussion regarding the risk management choices.	(Manning and Soon, 2013)

Risk Profiling

To help risk managers in identifying gaps of scientific knowledge related to the risk, risk managers first establish a risk profile. This profile serves as a guide for work prioritization, identification of potential risk reduction options, and assessment of whether a structured risk assessment is required.

Through dialogue with additional interested parties or stakeholders, risk assessors and risk executives who specialize in risk profiling will ascertain whether a formal risk assessment is necessary and to what extent.

Information contained in a risk profile includes:

1. An overview of the issue of food safety
2. The product or commodity in question and the possible routes of customer exposure to the risk
3. Potential outcomes or repercussions of being exposed to society
4. Risk perception
5. Risk distribution across various demographic sublevels, additionally
6. Potential advantages of using the substance in meals

This will identify the questions under risk categorization that must be addressed to satisfy the demands of the risk manager. It will also include a summary of the data that is currently available, the data that is not, and the estimated time of completion for the assessment (Rustia *et al*., 2021).

LEGISLATIONS:

The law pertaining to food safety is an intricate topic and is not intended to be a comprehensive analysis of the law in relation to food safety issues. Moreover, published literature on food safety are practically guaranteed to be outdated by the time they are published because the body of regulations pertaining to the topic is continually expanding and changing.

1. European Legislation

Not national authorities, but the European Commission (EC) is primarily responsible for most food safety laws currently in effect in EU member states. The Commission may propose new food laws using two primary legislative mechanisms. One of those includes the Instructions, which set out a goal but leaves it up to national authorities to decide how to get there. It also cannot be enforced in a particular Member State until it is incorporated into national law. The Regulation is the second tool; once it is enacted, national laws do not need to be changed because it is "directly applicable" and becomes a law in every Member State (Lawley *et al*., 2012; Todua and Mghebrishvili, 2018).

The Food Hygiene Package

Three primary regulations comprised the Package were implemented immediately across the European Union. These are the following:

- On the hygiene of foodstuffs; Regulation (EC) 852/2004

- Setting out specific hygiene requirements for foods of animal origin; Regulation (EC) 853/2004
- Setting out specific requirements for organizing official controls on products of animal origin intended for human consumption; Regulation (EC) 854/2004

Regulation 852/2004 covers an extensive variety of subjects, including the general responsibilities of businesses regarding the cleanliness of food, the requirements for managing food safety procedures based on hazard analysis critical control points (HACCP) analysis, sanitation standards for assumptions and machinery, training for employees and personal sanitation, heat processes, and packaging. General hygiene requirements are contained in this regulation and apply to all food businesses. To produce meat, milk, fish, and eggs and for by-products such gelatine, Regulation 853/2004 adds certain hygienic criteria to 852/2004. Rules 854/2004 and 854/2004 exclusively address the formal controls that must be put in place for animal products being consumed by humans (Lawley *et al*., 2012; Todua and Mghebrishvili, 2018).

Other EU Legislation

The foundation of food safety laws in the EU is currently provided by the Food Hygiene Regulations in 2006, although they do not encompass all the regulations that food enterprises must be aware of. For instance, the Hygiene Regulations have undergone numerous revisions and a significant number of new "implementing regulations" have been developed to address issues.

The Microbiological Criteria Regulation

Microbiological criteria of foodstuffs (MRCR) Regulation (EC) 2073/2005, which went into effect on January 1, 2006, is one of the most significant implementation laws for all food industries. The microbiological requirements for foods that were previously dispersed over several vertical directives were gathered and presented in a uniform manner by this regulation.

Food Contaminants Regulations

Three new EU laws addressing various chemical pollutants found in food went into effect on March 1, 2007. From the perspective of the food sector, Regulation (EU) 1881/2006, which supersedes Regulation (EC) 466/2001 and establishes maximum allowable limits for specific pollutants in food products, is the most significant of these. Numerous contaminants are covered by this regulation, such as dioxins, heavy metals, mycotoxins, PCBs, PAH, and chloropropanols (Pettoello-Mantovani and Olivieri, 2022).

2. US Legislation

The US and the European Union have quite different legal systems when it comes to food safety. Despite this, safeguarding consumers against exposure to healthy and dangerous food-products remains primary goal. The system is founded on the fundamental duty of industry to create safe foods as well as flexible, scientifically based government and state rules. Precautionary, risk-based thinking is ingrained in the legal system (Lawley *et al*., 2012).

Federal Legislation

Congress sets the fundamental framework for US food safety laws in the form of enabling acts, which are intended to accomplish goals related to food safety and to define the degree of public protection.

They specify the boundaries of regulation while maintaining a broad reach. Some significant statutes are as follows:

- Federal Food, Drug and Cosmetic Act
- Federal Meat Inspection Act
- Poultry Products Inspection Act
- Egg Products Inspection Act
- Food Quality Protection Act
- Public Health Service Act

State Legislation

State-level regulations are an extra layer of oversight on top of the federal structure of food safety laws. State legislative assemblies have the authority to enact state laws, which local authorities may subsequently enforce as agricultural or health restrictions. State laws pertaining to food safety should, in general, comply with federal guidelines; nevertheless, specific variations may exist, and many states like California have enacted their own legislation. For instance, even though it goes against federal law, the California state government recently enacted a law mandating the labeling of meat derived from cloned animals. There are also numerous state-specific microbiological recommendations or standards for food (Lawley *et al*., 2012).

REGULATIONS:

A. FOOD SAFETY MODERNIZATION ACT

The President signed the bill known as the Food Safety Modernization Act on January 4, 2011, giving the FDA more regulatory power. Based on this expanded jurisdiction, the FDA created new regulations, which it is currently completing. The Food Safety Modernization Act (FSMA) imposed new standards on food producers, manufacturers, and distributors, including wholesalers and retailers. Regarding the evolving food industry, the FSMA seeks to address issues such as intricate new supply chains, global sourcing according to new consumer demand, growing risks to food safety, the impact of conventional and social media, or handling of legal challenges. The FSMA placed a strong emphasis on five main areas: imports, response, detection, verification and compliance, and improved collaborations. The FDA's regulatory strategy was historically reactionary, acting only after a foodborne illness outbreak had occurred. With the help of the FSMA, the FDA is now able to hear about taking a risk-aware and preventive strategy, create prevention-oriented standards, and use industry compliance through examinations and verification efforts thanks to the proactive approach that has been developed. The FDA regulates all items, except for poultry, meat, and egg-based goods, which are under USDA jurisdiction. These new rules apply to international suppliers as well as food producers, processors, distributors, and retailers (Barnes *et al*., 2022).

The seven categories that comprise the regulations imposed by FSMA, sometimes referred to as "rules, are as follows:

1. **Produce safety rule** focus on the main channels of contamination that have been identified, including agricultural-water, domestic and wild-animals, building and equipment sanitation, soil amendments derived from animals, and employee sanitation and health. This governs most produce farmers at the farm level.
2. **Preventive control rule for human food:** It mandates all domestically food processing

and production facilities, as well as some produce packing enterprises, be registered with the FDA and adhere to updated cGMPs. The regulation mandates that a written food safety strategy, known as a HARPC (Hazard Analysis and Risk-Based Preventive Controls) plan, be developed, implemented, monitored, and verified. Every facility that uses preventative control must have a recall strategy in addition to supply chain program documentation. Food companies that are registered with the FDA are required to provide all documentation pertaining to the preventive measures implemented with 24-hour notice or less.

3. **Preventive control rule for animal feed:** The regulation guarantees the safety of pet food, livestock feed, and human food by-products (donated or sold), much as the Prevention Controls for Human Food. Where heated by-products were produced in accordance with the Preventive Controls for Humans Food, they do not require additional preventative controls, even if they still need to adhere to cGMPs. Production facilities are required to have a written HARPC food security plan and recall plan. Businesses must have quick access to all documents pertaining to the preventative measures they've implemented.
4. **Foreign supplier verification program:** Ensuring that food and feed imported into the United States adhere to the FSMA is the aim of this regulation. In accordance with this regulation, food exporters must attest to FSMA compliance, take remedial action as needed, and implement a HACCP and mitigation plan by US importers, foreign owners, or consignee representatives at the time of arrival. Along with outlining the methods for onsite audits, testing, sampling, record-keeping, corrective action protocols, and any exemptions, this rule also outlines the criteria for verification of supplier. Noteworthy is the fact that importers can adhere to the FSMA by using third-party verification services. Any foreign facilities that refuse FDA accessibility to the facility or the nation in which it is located may have its products denied admission by the FDA.
5. **Third party certification program:** specifies the proper frameworks, processes, and specifications to fulfill the requirements for third-party auditors' accreditation and certification. When the FDA deems it necessary, traders can use certifications to: (1) accelerate the evaluation of goods entering the country; or (2) get a food certified by an authorized third-party auditor.
6. **Sanitary transport:** This law intends to avoid subpar transportation practices, such as insufficient washing of packaging between loads, inappropriate food refrigeration, and failure to secure food during transportation that could pose a danger to food safety. This rule establishes hygienic standards for food transportation apparatus, vehicles, training, records, and record keeping, as well as for underlying activities. It covers both the carriers and the recipients of food for humans and animals that are brought within the United States by rail and road. This law does not apply to food that is delivered by train or automobile over US borders and does not

reach the US food supply. Up until the consignment approaches the port or the US border, export businesses shipping food out of the nation are protected. This restriction does not apply to certain businesses, such as grocery stores and restaurants, if they have proper local jurisdictional permissions.

7. **Protection against intentional adulteration (food defense):** The goal of this regulation is to stop local and foreign food companies that are registered with the FDA from adulterating food in the supply chain. Food firms are required by law to have a documented food defense policy and identify and assess the vulnerabilities in each food that is produced, packaged, or kept in their facility. The FDA mandates that, in addition to confirming the efficacy of the protocols followed, plans for mitigating or eliminating any vulnerability that is found. The FDA has a mandate to hold products that are suspected of being tampered with or mislabeled for up to 30 days, preventing them from being moved or sent.

The FSMA contains several noteworthy exclusions. The FDA's HACCP regulations for seafood facilities, the FDA's HACCP regulations for juice production facilities, the FDA's Canned Food requirements for manufacturers and packers of low-acid canned foods, and the related regulations are some of the main exceptions to the FSMA regulations. It's interesting to note that materials in touch with food surface coatings, product washes, etc. are not subject to the foreign supplier verification program but are subject to the preventative control laws (Barnes *et al*., 2022).

Most safety, health, and environmental objectives can be achieved in a variety of other ways, and the security of food is no exception. The production and transportation of animals, the methods used for slaughter and processing, and the ways in which food is prepared can all be changed to lower the health risks associated with consuming food-borne viruses. Each of such adjustments can usually be attempted either through rules, or indirectly through information sharing and market participants' responses. The vast array of different strategies for achieving food safety is known to food safety policy makers, who are also typically cognizant of the potential issues that could arise if a specific strategy is mandated by law. The issue is that most alternatives' benefit and cost estimations are highly speculative (MacDonald and Crutchfield, 1996; Rustia *et al*., 2021).

When there are no alternative methods that are more effective and when they are projected to increase the level of consumer protection, mandatory criteria will be applied to such goods and/or places in the food chain. When applicable, these oughts to be product-specific and limited to the regulation's designated point of application at the food chain. When microbiological requirements are not met, regulatory control measures may include product rejection, destruction, sorting, or reprocessing. Additional research may also be necessary to ascertain the best course of action. The evaluation of the consumer's risk, the product's intended purpose, the product's position in the food supply chain, and other factors will determine the right course of action.

Food safety and hygiene are closely related, so it is important to create programs that support

sanitation to guarantee that food is both safe and fit for human consumption.

Following years of expansion of the national microbiological standards system, the following Technological Rules (TR) for Basic Food Items and Food items (Efimochkina, 2022) incorporate the system with the help of the countries that are members of the Custom Union (CU): Uniform Sanitary Epidemiological as well as Hygiene Conditions for the Items in addition to Sanitary and Epidemiology Supervision.

- On the Safety of Food Products (TR CU 021/2011)
- Technical Regulations on Fruit and Vegetable Juice Products (TR CU 023/2011)
- Technical Regulation on Safety of Oil and Fat products (TR CU 024/2011)
- Technical Regulation on Safety of Certain Types of Specialized Foodstuffs, Including for Dietary Therapy and Protective Diet (TR CU 027/2012)
- Technical Regulation on Safety Requirements for Food Additives, Flavoring Agents and Processing Supplements (TR CU 029/2012)
- Technical Regulation on Safety of Milk and Dairy Products (TR CU 033/2013)
- Technical Regulation on Safety of Meat and Meat Products (TR CU 034/2013)
- Technical Regulation on Safety of Fish and Fish Products (TR EAEU 040/2016)

Microbiological standards are only set by governments when they are seen necessary to guarantee the security of the foods under their regulatory purview. As risk managers, food control authorities may determine at one or more stages in the food chain that a food item requires a microbiological requirement by using a risk analysis procedure. A reasonable degree of danger and FSO associated with the relevant hazard should ideally serve as the foundation for the criteria. Industry and government alike can evaluate a lot or shipment of food by using microbiological criteria as the foundation. It is important to apply the same microbiological criteria to both imported and domestic commodities (ICMSF, 2018).

A proposed rule published on January 16, 2013, in the Federal Register is being corrected by the Food and Drug Administration (FDA or us). The Federal Food, Drug, and Cosmetic Act (FDandC Act) requires domestic and foreign facilities to register to establish and implement risk-based preventive controls and hazard analyses for human food. The proposed rule would modernize the current good manufacturing practices (CGMPs) in these areas. Additionally, the proposed rule would clarify the extent of the FDandC Act's exemption for "farms" from registration requirements by updating some definitions in our present regulation for the registration of food facilities. As part of our previously announced plan to update the CGMPs since their 1986 revision and to enact additional FDandC Act statutory requirements, we put forth these proposals (Rana *et al*., 2024).

Food manufacturers, processors, retailers, and regulators have long relied on microbiologically safe and stable food production using Good Manufacturing Practice (GMP), hygiene management, and end-product microbiological testing. The limitations of this conventional method have come to light as worries about microbiological safety and quality of food have grown. Thus, in recent years, the

adoption of quality assurance and quality management ideas, as well as the Hazard Analysis Critical Control Point (HACCP) system, have enhanced this approach. The fundamental prerequisites for a food's sanitary manufacturing are outlined and defined in GMP regulations, particularly in relation to the hygiene criteria they include. Typically, these will cover specifications for the following: hygienic facility design, construction, and operation; hygienic food processing equipment design and use; hygienic facility maintenance and cleaning schedules; and hygienic staff training. There is a global consensus that using HACCP principles is the best way to guarantee food safety.16. Through the identification of potential biological, chemical, or physical hazards connected to the manufacturing, distribution, and retailing of a specific food product and the implementation of controls to reduce those risks to acceptable levels, the HACCP system is an organized approach to risk management that attempts to prevent issues with product safety. A safety assurance strategy and system unique to a product, its manufacturing process, and the associated dangers are produced through the application of HACCP. It is limited to use in production operations that follow GMP guidelines; it cannot take the place of adopting GMP regulations (Lund, 2008; Rustia *et al*., 2021).

B. APPLICATION OF GOOD MANUFACTURING PRACTICE

1. General Concepts

GMP outlines and records the conditions (space, tools, and procedures) required to produce food that is of a quality that is acceptable. Regarding microbiological safety as well as quality standards for that kind of food, it outlines the fundamental hygienic practices that all facilities falling within the purview of a GMP must adhere to.

As previously stated, the use of HACCP is contingent upon these fundamental hygiene measures, which free up the process to concentrate on the essential actions, practices, or procedures necessary for the safe preparation or handling of food in a specific institution. Regulation-making bodies have created GMP papers in the form of guidelines. Some international organizations, including the Food Hygiene Committee of the Food and Agriculture Organization/World Health Organization (WHO) Codex Alimentarius Commission (Codex Alimentarius Commission, 1997a; Smigic *et al*., 2016), have created additional papers in the form of norms of sanitary practice. Additionally, a great deal of excellent manufacturing and hygiene rules have been released on a national or international level by the food manufacturing and processing businesses, frequently in collaboration with other organizations and regulatory agencies. These codes serve as a guide for producers and enforcement agencies, even though they are typically advisory in nature. Certain codes describe the specifications needed to produce a particular food, while other codes are broader and encompass the ideas that are used in the manufacturing of most foods. Supplementary codes for the manufacture of certain food categories may be used in addition to the latter. The European Union Directive 93/43/EEC on the cleanliness of Foodstuffs therefore establishes minimum standards of cleanliness for food production, distribution, and sale, but it leaves it up to the food sector to record any extra and mandatory standards in the form of guidelines. The following tasks are typically covered by GMP documents: choosing ingredients and manufacturing conditions, constructing and using food processing equipment in

a hygienic manner, cleaning and disinfecting food premises and equipment, personnel training and hygiene, and the necessary documentation (Lund, 2008).

2. Hygienic Design and Construction of Food Manufacturing Premises

Proper planning and building techniques are required to restrict the ability of microorganisms to enter, multiply, and spread inside the setting in which food is produced or processed. Most significantly, these measures are required to avoid or reduce product cross-contamination. Among the crucial elements to consider are:

Control of Conditions External to the Facility. Reducing the amount of contaminants that enter the plant, paved surfaces for foot and vehicle traffic, covered containers for trash, routine weed and trash removal, and the storage of undesirable equipment away from production areas are all recommended.

Rooms Should Be Arranged to Ensure Straight-Through Flow of Products from Raw Materials to Final Product. An appropriate barrier should be placed between areas used for handling potentially contaminated raw materials or other materials and areas used for handling finished goods. Separation should be applied to personnel working in "high-risk" regions as well as any stationery or mobile equipment employed, as preventing cross-contamination is critical.

Durability, Integrity, and clean ability of Surfaces of Structural Components of Buildings and Facilities (Floors, Walls, and Ceilings). The materials that are utilized should be strong, impermeable, non-porous, easy to clean (extra care should be taken to eliminate areas that are hard to clean, like corners where the floor and walls meet), and devoid of cracks and gaps.

Control of the Environment. Minimize the airborne transmission of microbiological pollutants by directing air flow from clean to filthy items. The correct cleaning, upkeep, and inspection of filters, ducts, and other air conditioning plant components are vital. Significant temperature changes between the product and the air can produce condensation and serve as a source of microbial contamination, thus it is important to regulate the temperature to prevent these kinds of problems.

Water Supply and Drainage Systems. Processing water needs to be drinkable and of high microbiological quality. There should be a plentiful supply in the right place at the right temperature for usage. Cross-connections between plumbing and non-potable water supplies should be removed, and back-flow prevention devices should be placed anywhere back-flow or back-siphon aging may occur, to prevent contamination. Effluent disposal systems should be designed with extra care to ensure that the flow is constantly directed away from the production areas, and that seepage or backflow is never an issue. These systems should also be built and maintained with this in mind.

Pest Control. Pathogenic germs or spoilage can be spread by rodents, insects, birds, and other animals. Among the steps in pest management are:

- Removing natural habitats and breeding grounds surrounding the plant, such as weeds, brush, tall grass, litter, waste, or discarded materials, and standing water.

- Installing extermination procedures (eliminating nesting sites, installing insect electrocution devices, and using chemicals or biological treatments).
- Actively excluding or restricting access to food storage and processing areas by using screens on windows, air curtains, or automatic closing devices on doors and sealing cracks, crevices, and holes. It is important to routinely check the facilities outside for any new openings that pests can use to enter.

Appropriate Design, Location, and Maintenance of Sanitary Facilities to Minimize Potential Sources of Contamination. These include sewage disposal, garbage storage and removal, handwashing stations, clothing changing places, and water supply and distribution systems (Kamboj *et al*., 2020).

3. Hygienic Design and Construction of Food Processing Equipment

When choosing food processing equipment, factors like cost, operator safety, compatibility with other equipment, simple operation and technical maintenance, size required for production rate, dependability, and suitability for the intended function are frequently the only ones considered. Too often, hygienic design elements of equipment are neglected; shoddy construction and design can cause microbial contamination of goods. Poor clean ability, which can be caused by inappropriate building materials, inadequate rounded corners, rolled edges, sharp angles, and poor welds, as well as the presence of dead legs and void spaces that are inaccessible to cleaning fluids (such as in clean-in-place [CIP] systems), is the primary factor that has been identified as causing unsatisfactory microbiological performance (Aytac and Taban, 2014).

Additional circumstances the incapacity to adequately drain equipment, inadequate access to the equipment itself or to portions or surfaces in direct contact with food, inadequate repair, maintenance, and incorrect equipment use can all lead to microbial build-up and product contamination (Lund, 2008).

4. Cleaning and Disinfection of Food Premises and Equipment

For plant and food hygiene, a routine cleaning and disinfection program is essential. This kind of program ought to be viewed as an essential component of the manufacturing process and "not regarded as an end-of-shift chore, liable to be hurried or superficial"; it ought to cover surfaces that come into touch with the product as well as related spaces: walls, floors, and ceilings. There are two goals for sanitary procedures in food processing. The first step is cleaning to get rid of food residues, which might impede equipment from operating properly and give microbiological development with the nutrients it needs. Along with eliminating most germs, washing and rinsing physically gets rid of them. The second step is disinfection, also known as sanitization, which aims to lower the number of bacteria that stick to surfaces after cleaning to a point where they won't significantly contribute to product contamination when the product encounters the equipment. Prior to usage, the regions need to be shielded from recontamination after washing and disinfection (Lund, 2008).

Wet cleaning involves:

1. Depending on the design of the equipment or area to be cleaned, the type of soil (tenacious

or water soluble), the soil level, the design features, the construction materials, the operational characteristics of the equipment, and the conditions within the facility, the best system should be chosen (high pressure low volume; low pressure high volume; CIP systems, manual, foam/gel).

2. The choice of chemicals (detergents and disinfectants) should consider factors like the range of antimicrobial activity (Gram-positive, Gram-negative, spores, and bacteriophages), corrosiveness, skin irritability, hard water performance, organic matter presence, incompatibility with equipment or other cleaning and disinfecting agents, stability of use solution, stability of hot solution, effectiveness at use pH, whether or not active residues are left behind, maximum amount allowed by law, and cost.
3. Choosing a cleaning cycle or technique that works, such as brushing, scraping, pre-rinsing, soaking in detergent, rinsing, disinfecting, drying, or a mix of these. These processes specifically try to manage four fundamental factors: temperature, contact time, chemical concentration employed, and mechanical force. Remember that most disinfectants are useless when there are food residues present, except for certain products like detergent sanitizers, which combination detergent-disinfectant products are. Because wet cleaning is typically not the equipment used in plants that process dry foods or ingredients

Dry cleaning creates unique challenges because moisture in the food might encourage microbial development and/or lead to the creation of deposits that are hard to remove.

Vacuum cleaners, mechanical action (scraping or brushing), and, if required, disinfection with 70% ethanol-which vaporizes fast and leaves the equipment's surface dry-are the typical cleaning techniques used in dry processes (Yousaf *et al*., 2016). Although it is usually too expensive for widespread usage, the use of carbon dioxide freezing and acoustic devices for dry cleaning is being considered (Lund, 2008; Aytac and Taban, 2014).

5. Selection of Raw Materials and Production Conditions

Hygienic practices should permeate every step of the process, from obtaining components and raw materials to processing and preparation to packaging, storing, shipping, and distribution. It is imperative to implement all feasible measures to guarantee that the production processes do not introduce microbiological hazards, along with other chemical or physical hazards, into the final product.

6. Training and Hygiene of Personnel

Microbiological issues are typically caused by ignorance, carelessness, or both rather than by purposefully unsafe actions. Thus, labor is an essential component. Establishing a favorable attitude toward microbiological quality, product safety, and wholesomeness is the most effective training strategy. Using an appropriate training program, knowledge and skills are developed as part of this method. Managers, supervisors, and operators are among the personnel categories that ought to be involved. National or worldwide organizations, manufacturers' associations, research groups, and consultants all provide a wealth of useful training materials. Workers' consultation

(through quality or hygiene circles, for example), knowledge transfer, task design (or redesign), information feedback, auto control, and personal commitment to implementing hygiene management are some of the ways that workers can be involved in hygiene and quality tasks at the production line. The employees will be encouraged by this to uphold or enhance their personal hygiene, which includes:

- General personal hygiene
- dressing appropriately, changing, and washing clothes; refraining from using tobacco products; and not chewing, smoking, or eating while working in an area where food is handled.
- Cleaning hands thoroughly and taking off any jewelry that can't be securely fastened or properly sterilized
- Using disposable gloves when necessary, or cleaning and disinfecting reusable gloves after each usage
- Wearing a suitable hair cover.

Management bears the obligation of ensuring that the necessary facilities and instructions are provided, as well as setting an example of compliance with these criteria. A specialized working group of the WHO concluded after reviewing health examinations of food handling personnel that routine examination of food handlers has severe limitations that significantly reduce its usefulness as a control measure. Pre-employment medical examinations and periodic re-examinations of food handlers for microorganisms are likely to be transmitted by food are established practices in some countries.

Therefore, these tests ought to be extremely low on the priority list and limited to certain targets (such as those directly handling chilled, ready-to-eat food before packaging). Providing food workers with training on sanitary food handling and implementing suitable controls for food hygiene, such as GMP and HACCP, is a more effective and widely applicable approach. (Lund, 2008; Kamboj *et al*., 2020).

7. Documentation

The significance of documentation has already been emphasized; all GMP practices, including hygiene, should be recorded, and relevant performance logs should be kept up to date. The management of the establishment has committed to continuously implementing the fundamental control procedures outlined in GMPs, as evidenced by the documentation. Effective documentation also shows outside parties that the establishment's managers are aware of and cognizant of how to run their business, particularly about upholding hygienic standards. The designation of the person in charge of monitoring and controlling the GMP, records of the steps taken to address deviations, and all fundamental procedures employed by the place of operations to avoid contamination or adulteration prior to and throughout production should be the minimum requirements for documentation in GMPs pertaining to hygiene (Kamboj *et al*., 2020).

8. Management Commitment

It is impossible to overstate how crucial management commitment is to uphold and, when required, improve hygienic standards. Every business, regardless of size, needs to have a well-thought-out policy for meeting the necessary hygienic standards and determining best to use its financial, technical, and human resources (Kamboj *et al*., 2020).

C. THE HACCP SYSTEM

1. General Considerations

A methodical approach to hazard detection, evaluation, and control is the HACCP system. The primary purpose of this is to enable food producers to fulfill their obligation to create nutritious and safe food products. It was initially created in the US to supply microbiologically safe food to astronauts during space flights (Wallace *et al*., 2012). Global trade and governmental organizations have supported its use since it was introduced at a food safety convention in 1971. HACCP can be applied in a prospective or retroactive manner. When applied to the development of a new product's design and manufacturing process, it is prospective. When used to confirm the effectiveness of an already-existing procedure or product, it is retroactive. In both situations, the goal is to enhance control over production processes and product qualities by means of a proactive, dynamic, and iterative process. Its application should result in increased productivity and lower consumer risk.

The breadth of applicability and consideration of any actions taken before or following the operation under investigation are essential components of every HACCP research. For a HACCP plan to be implemented successfully, senior staff members in charge of the food operations under investigation must demonstrate their dedication and support.

There might be little disorientation between the use of risk estimation in the hazards analysis process within HACCP and the application of hazard evaluation as part of risk evaluation by a health authority. It is critical to recognize that the scope and aims of the two kinds of assessments differ significantly. Therefore, a health authority's usage of the risk assessment process is a government-led method intended to evaluate health hazards to a community or subpopulation resulting, for example, from a foodborne pathogen contaminating a food item (Lund, 2008; Kamboj *et al*., 2020).

2. Use of the Codex Alimentarius Approach to HACCP

This approach's fundamental characteristics are that it outlines seven essential concepts or phases in creating a HACCP plan, gives an internationally recognized vocabulary of words, and establishes a framework for using HACCP that is accessible throughout the food chain.

These principles are:

1. Conduct a hazard analysis
2. Determine the CCPs
3. Establish critical limit(s)
4. Establish a system to monitor control of the CCP
5. Establish the corrective actions to be taken when monitoring indicates that a particular CCP is not under control
6. Establish procedures for verification to confirm that the HACCP system is working effectively
7. Establish documentation concerning all procedures and records appropriate to these principles and their application

Additionally, it offers instructions for putting these ideas into practice via a series of 12 tasks.

These are:

1. Assemble an HACCP team
2. Describe the product
3. Identify the intended use
4. Construct a flow diagram

5. Carry out onsite confirmation of the flow diagram
6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards
7. Determine CCPs
8. Establish critical limits for each CCP
9. Establish a monitoring system for each CCP
10. Establish corrective actions
11. Establish verification procedures
12. Establish recordkeeping and documentation.

This method bears a strong resemblance to the NACMCF46's recommendation and has been adopted as a standard format by the majority of other modern HACCP descriptions. Each of the 12 Codex-recommended activities for the application of HACCP will be covered in turn in the following sections (Codex Alimentarius Commission, 1997b; Manning *et al*., 2019).

Assembling HACCP Team

A team effort involving multiple disciplines is necessary for the creation of a system of HACCP for a specific product. The team's makeup depends on the study's scope. The team should have a variety of experience and internal (or external, if needed) expertise to effectively complete the tasks assigned. Depending on the specific study, the team may consist of a quality assurance/quality control specialist, an engineer (who understands the technical capabilities of any processing equipment and aspects of design that may affect product hygiene), a production specialist directly involved in the process under study, and other pertinent experts (e.g., a food microbiologist with specific knowledge of the microbiological consequences associated with the particular processing operations). Teams should designate a team leader to facilitate debates and a secretary to document decisions. In smaller organizations, it might be suitable for one person to perform multiple roles if the team can gather and analyze pertinent data to identify potential hazards associated with a given production operation, evaluate their importance, and identify control options. In larger organizations, this might be too challenging or impossible, and if the necessary level of in-house expertise is lacking, a third-party organization might have to be enlisted to provide it (Kamboj *et al*., 2020).

Describe Product

This kind of description ought to list both the finished product and the basic elements. Note the kind, supplier, purchase specifications, and percentage of each raw material utilized in the finished item (see below) for each one. It is also important to document any pre-receipt processes or treatments, storage conditions, and further information about the raw materials, such as pH or aw. The final product, or any intermediates that may be required, should be specified in terms of its composition, structure, processing circumstances (such as heat treatment), intrinsic stability-affecting factors (such as pH, aw, and preservatives), the packaging, distribution and storage conditions (especially temperature), expected shelf life, package labeling, and usage instructions. In this approach, information is gathered for every raw material utilized, including its type, percentage in the finished product, storage conditions, and other details like pH and aw that are pertinent to its microbiological stability. Data is gathered for every process operation, including the kind of execution, the machinery utilized, the product, the time and temperature of the environment, and further details about the equipment, including the building materials. The data in the boxes

can be connected to show the product flow(s) and create a thorough process diagram (Lund, 2008).

Identify Intended Use

The anticipated applications of the good by the final user, or consumer, should inform the intended use. Furthermore, it must be considered that the finished product may be subjected to improper temperature handling by the buyer and that it may be consumed by susceptible populations, such as young-children, pregnant-women, the elderly, or individuals with compromised health.

Construct Flow Diagram

The creation of a diagram showing the process is necessary for the process description. The process flow for the entire operation, including raw material selection, processing, packaging, distribution, and ultimate storage, should be depicted in the diagram, along with a breakdown of each individual phase. Specific technical data should be included with the flow diagram. These could include the layout of the factory, lines, and equipment; the flow conditions of the products, such as any delays in the middle of steps, reuse and recycle or rework looping structures, and steps-to-step transfers; the routes of the mobile supplies, machinery, and utensils; the flow of air and water; the routes of personnel; and the segregation of any areas that are low- or high-risk. Every process operation should also have data collected on its type and technological advance's function (e.g., effect on microbial populations and numbers), gadgets features (e.g., size, capability, and existence of void space), operation criteria, time and temperature conditions for the product and environment, cleaning and disinfection techniques, and the environment and personnel hygiene (Lund, 2008).

Carry Out Onsite Verification of Flow Diagram

The real processing action should be faithfully depicted in the flow diagram. When gathering data for an established product or process, production conditions must be met, and every step-including any night shifts or weekend operations-must be closely monitored. An adequate verification of the data collected will be provided by a final confirmation obtained on-site during business hours.

The departments participating in the development submit data describing the item's definition and their most likely processing alternatives when the creation of a novel item is being evaluated. These will need to be verified, and when the item is eventually put into production, they could need to be revised. Early in the product development process, a preliminary HACCP can be used to identify the primary possible CCPs and emphasize control requirements (Kamboj *et al*., 2020).

Perform a Hazard Analysis

Hazard analysis is a method of gathering and assessing data on health risks connected to a specific food (as well as any circumstances that may contribute to their existence at health risk levels) to determine which are important for the safety of food and, thus, need to be covered in a HACCP strategy. Thus, danger identification and risk evaluation are the two phases of hazard analysis. A methodical inquiry must be used to identify any potential chemical, chemical, or physical risks connected to any process step, point, or technique to establish a safety assurance plan. But for the purposes of this lecture, we'll just talk about microbiological risks, which also cover spoiling and health issues.

Hazard Identification. All relevant microbiological hazards for the product under consideration are listed, and the conditions (such as failure to control a specific starting point or processing step) leading to the presence of microbiological contaminants at dangerous levels (i.e., levels that are likely to cause illness or spoilage) are specified as part of the microbiological hazard identification process. A food product under investigation may be contaminated or decontaminated, or an organism or toxin may develop or survive in the food, depending on the circumstances. These situations might arise at any point in the food operation.

Listing of Types of Microorganisms and Microbial Toxins. While infections and toxins would be the only things considered in a specialized safety assurance plan, both food poisoning and rotting bacteria (and their metabolic products) are concerning. A hazard analysis naturally begins with an understanding of the hazards that are pertinent to the item and process under review. It is also the most challenging aspect of the evaluation because choices about product safety standards may be made later if this task is not completed carefully and by competent individuals who have a suitable grasp of the food-related operation under investigation. Therefore, this step requires microbiological knowledge of the physiology of potentially dangerous microorganisms in the food, and particularly the impact of relevant intrinsic, extrinsic, and implicit factors; processing; storage and use conditions; and their ability to form toxins and their resistant qualities. It also necessitates an understanding of the microbial ecology of the products, the factory setting, and the raw materials utilized (data that could only be discovered from a microbiological study conducted on the real facility). All this data is utilized to identify the microorganisms that the study must consider. Selecting pertinent microorganisms and toxins that are likely to be of concern is the exercise, which begins with a list of known diseases (and spoiling microorganisms when applicable). Based on shared physiology and survival traits, it might be able to classify related creatures of interest and use one organism as a representative of that group (Kamboj *et al*., 2020). The organism of choice ought to be one that is most likely to cause contamination, exhibit high resistance to the manufacturing conditions, and, if suitable, be able to proliferate in the finished product. When choosing microorganisms of concern, the following other factors should be considered:

- The type (and number) of microorganisms expected to be present in raw materials
- The type (and number) of microorganisms likely to be introduced during handling or processing
- The effect of processing or handling, including consumer practices such as preparation for consumption, on their growth, survival, or death
- The target group(s) of consumers.

It is crucial to identify all pertinent possible dangers, regardless of their severity or likelihood of occurrence. For example, a food producer should always add Clostridium botulinum as a possible risk for such sort of production when starting a HACCP study of a process that uses heat to generate low-acid canned foods, even though this technique effectively controls botulism. As the study continues, this will enable the HACCP team to determine if the production conditions and the state of the controls in place are enough or require improvement. For the same reason, HACCP investigations of ecologically significant

products must take new or emerging infections into account, such as strains of *Escherichia coli* that produce verocytotoxin.

In cases where food products have defined microbiological criteria (especially if they have been derived from a risk assessment), they can serve as a tool to help identify microorganisms of concern and the degree to which they need to be controlled. It is imperative that hazard identification consider not just the microorganisms that fall under the current criteria, but also any pertinent toxins, spoilage microorganisms, and food borne pathogens.

The specific microorganism or microbial toxins that could compromise the product(s) under consideration's safety or "keep ability" should be methodically examined by the HACCP team. This method generates a list of potential microbiological dangers based on available data (Lund, 2008; Kamboj *et al*., 2020).

Conditions Leading to the Presence of Microorganisms and/or Microbial Toxins. The study then moves on to finding circumstances in which the hazard or hazards indicated under the previous section could be introduced into the manufacturing process for each hazard that has been discovered. Using the process flow chart as a guide, the exercise is carried out step-by-step for each raw material, ingredient, and operation stage, such as packing, storage, and distribution. Consequently, the likelihood of the existence of any microorganisms and/or toxins that have been found to be concerning is assessed for every unprocessed substance or ingredient.

Hazard Assessment. The process of identifying hazards yields a list that includes the circumstances that contribute to the incidence of each microbiological hazard. It is necessary to determine which of the identified hazards will significantly affect the safety or wholesomeness of the final product to determine the degree to which resources should be applied to their control, even though it is obvious that all such hazards and the condition(s) under which they may occur should be appropriately controlled. The frequency or possibility of a situation or conditions that could lead to hazard(s) occurring, as well as the seriousness of those conditions in terms of potential health risks or spoiling concerns, should be included in such a hazard assessment. Therefore, a ranking of the major hazards, a list of the health issues that could cause them to occur, and the likelihood of frequency and severity of such an event, if it occurred, are predicted outcomes of such an assessment. This data should be used for control setup, action priority determination, and defining the necessary level of control rigor (Kamboj *et al*., 2020).

Determine Critical Control Points

Hazard-causing scenarios in the food operation can be identified, together with the level of worry associated with them, thanks to the hazard analysis process and conclusions. To decide how to handle such scenarios, it is now necessary to handle this knowledge. The HACCP team should first make sure that all GMP criteria are met before determining whether any further control measures are needed. One option that could come up is whether to modify the product or the process to completely remove a hazard or lessen the effects of a hazardous circumstance or condition. A step in the manufacturing process or it’s processing the parameters may need to be changed, as well as the conditions of packaging or distribution or the directions for preparing the product for consumption. It may also be necessary to change the

formulation of the product, such as by adding new microbiological barriers.

The application of the CCP idea serves as the foundation for controlling the remaining dangerous circumstances. This can be characterized as a stage where control is necessary to either prevent or eradicate a hazard to food safety (recognized by the hazard analysis procedure previously discussed) or to lower it to a level that is acceptable. The justification for designating a CCP is that if the procedure is flawed and/or monitoring is ineffective at this stage, there is a significant risk of a serious, direct health risk or a high degree of spoiling.

Effective CCPs need to have a few fundamental qualities. Initially, there must be precise locations where action is required to prevent the occurrence of any number of dangers. Second, they need to have affordable and easily accessible operating means. Using pasteurization, for example, one can kill pathogens that cause infectious diseases like *Salmonella* in milk and extend its shelf life. Alternatively, one can use these methods to prevent an unsafe situation from occurring or lessen its effects, such as by acidifying or refrigerating a product to slow down or avoid microbial growth. Lastly, they ought to be able to be easily and consistently observed. For instance, they could be seen visually, through physical means like measuring temperature or pH, or chemically, by keeping an eye on the amount of chlorine in the water used to chill canned food following heat processing (Lund, 2008).

CCPs are created specifically for each major hazard that has been recognized. They often correlate directly to an action, practice, or method that, if control is lost, may result in a dangerous condition. In certain cases, it is not possible to attain direct control over a hazardous state at the scene, or it is not practical to conduct adequate monitoring. In these situations, it is advisable to think about the prospect of creating CCPs later in the procedure. For example, proper temperature and timing management throughout the sterilizing process helps the canning sector prevent under-sterilization. It's important to make sure that recontamination-a dangerous situation-cannot happen after sterilization. Because the sterilized container has microscopic holes and because organisms are pulled into it when it cools, recontamination may happen. Although the sealing procedure, which is done to the container before sterilization because is a CCP, it is challenging to regulate such that there are no holes in the seams or sealing of the containers, and monitoring methods cannot ensure that there are no holes in any of the containers. To avoid contamination getting into the packaging and polluting the product, CCPs must be set up following sterilization. Chlorinating the water used to cool the containers and avoiding handling those by hand when they're hot are two control strategies (Lund, 2008).

Technical know-how, expert judgment, and a solid grasp of the food industry are necessary for the identification of CCPs. It could be helpful to utilize "decision trees" as a guide to help with this process. There are decision tree examples in the literature that are used to find CCPs. Figure 58-4 shows one example of such a decision tree that was created by a working group operating under the Codex Alimentarius Food Safety Committee's guidance. This decision tree considers and provides an answer sequentially for every phase in the process that has a recognized hazard (beginning with the initial supplies and working through the process step-by-step). Although the quantity of CCPs that can be recognized in a process has no maximum or lower bound, it is generally

advisable to reduce the quantity of CCPs to a minimum to maintain a "user friendly" system; never forget that general hygiene criteria are managed as part of GMP. Verify that the CCPs that were first identified are not redundant (that is, even though stopping a certain step seems to be important to avoid a potentially dangerous situation, like the possibility of a foodborne pathogen growing or surviving, and is thus a CCP, another step in the procedure may also offer effective control and is also a CCP, rendering the first CCP redundant). By making modifications to the good or process, it is possible to eliminate further CCPs and, in addition to doing so, reduce the quantity of CCPs while also improving product safety. When an analysis indicates that a potentially dangerous condition cannot be effectively controlled at a particular stage of the production process and that no additional CCP will provide control, this should lead to changes being made to the step (such as equipment or procedure) or to the product's formulation to incorporate a CCP (Kamboj *et al*., 2020).

It cannot be overstated that CCPs are extremely specific to a particular product and the circumstances surrounding its production; as such, they must be verified by a hazard analysis before being used for another food business. A fresh risk assessment and, if required, an update to the list of CCPs should be prompted by any modifications made to the product or process. CCPs listed in so-called generic HACCP models—HACCP models created to produce a specific commodity or food product and unrelated to a specific plant or specific manufacturing operation-may be completely misleading due to their extreme specificity, which also lessens the flexibility that comes with using HACCP correctly. Therefore, their use should be discouraged and avoided in general, except for their being used for illustrative purposes for general cleanliness codes. In such cases, their purpose must be made clear, and the reader is cautioned against applying them to a specific operation without first conducting a hazard analysis. The safety precautions that can be used for each hazard must be determined and recorded for each CCP. These are closely related to the idea of a CCP. They speak of the methods and actions that enable the CCP to prevent, remove, or reduce hazards to a level that is acceptable. The utility and efficacy of the controls in place at each CCP should be taken into consideration. The control procedures used to guarantee the pasteurized ham's microbiological acceptability can be used to demonstrate this idea. Here, sampling and testing for signs of under processing or post-processing recontamination are less successful and cost-effective than equipment design and maintenance and operational management (e.g., processing time and temperature and sanitary handling of cans post-processing) (Lund, 2008).

Third, a critical limit must be consistent with the microbiological standards (including microbiological specifications) established for the finished product to be considered important. Appropriate critical limits can only be determined at a single processing step, a collection of steps, or even for the entire process by taking these needs into account. There should always be established and supplied evidence of such a link. To do this, the HACCP team should be aware of or have consented to in advance the microbiological requirements for the product generated by the operation for which the HACCP plan is being developed. Numerous sources, including risk assessments, studies, scientific and technical literature, computer simulations, in-house experiments, supplier records and data, expert advice and consultation, international organization norms,

and legislation, can be used to determine critical limits.

Limits already in place for items that are already on the market should be evaluated and verified before being used in the comprehensive HACCP plan. When required, a modification to the characteristics and/or values may be made (Kamboj *et al*., 2020).

Establish a Monitoring System for Each CCP

Monitoring is a planned process that involves measuring or observing a CCP in relation to its critical boundaries or limits. Monitoring is necessary to demonstrate that important steps or processes, or CCPs, are maintained under control and that, if an out-of-control situation arises, it can be quickly discovered to enable prompt remedial action. It entails the planned measurement or observation of important elements or variables at CCPs to determine whether they have been brought under management.

Identifying an out-of-control scenario at a CCP prior to start-up or during production should be the goal of monitoring. Systems that continuously, online, and in real-time monitor control at CCPs should ideally be in place to allow for quick and automatic adjustments when needed. However, most of the time, only offline and/or discontinuous monitoring solutions are suitable. As a result, it is essential to guarantee that the sample and/or observation frequency are statistically valid. Statistical process control approaches should be applied whenever possible to make objective decisions that lead to corrective action.

Many reviews have been conducted on monitoring techniques. As previously mentioned, the most suitable methods for monitoring include visual observations, sensory evaluation, and physical or chemical measurements; microbiological approaches, except for extremely fast ones like ATP bioluminescence, are not suitable. Nonetheless, microbiological techniques are useful for examining a process and could be helpful for confirmation.

The monitoring processes should have comprehensive documentation that includes information about the CCPs they apply to, the feature(s) that need to be monitored, how often they should be monitored, the method(s) to be used, and the person in charge of approving the records and making decisions about corrective action. All monitoring data must be fully documented, and the individual in charge of data collection and record distribution must be identified (Lund, 2008).

Establish Corrective Actions

When monitoring findings show that CCP's operation is not meeting the critical limit, that is, when control is lost and a hazardous state arises-corrective measures are the steps that need to be implemented. A plan for corrective action must specify these kinds of remedial measures in advance.

When a CCP is beyond its critical limit, the main worry is that the created product might not fulfill the required safety standards. As a result, the plan for corrective action needs to include documentation of the suspect product's proof of identity, segregation, review, and proper disposal always. This presupposes a traceability system and, for products that are delivered immediately, a crisis or recall plan. For all such actions, ISO 9004 standard37 offers pertinent data and recommendations (Kamboj *et al*., 2020).

Preventing a recurrence of the departure that caused the critical limit to be exceeded is another equally important concern. This means that the

processing or other conditions must be changed right away to get the CCP back inside its critical limit(s). It also necessitates a correct identification of every aspect influencing the process's capacity to consistently satisfy the key constraints. The decisions that follow are mostly determined by how serious the possible departure is. In a scenario when there is a significant risk to food safety, it can be necessary to halt the process until the issue has been resolved. If not, specific extra surveillance or regular checks should be conducted to ensure that the process adjustment is successful in keeping control. In addition to immediate remedial action, the HACCP plan should be verified and reviewed if deviations happen frequently or if control becomes difficult to maintain. Corrective intervention to modify the process when the drift results in transgression of key limits must always be carried out for successful avoidance of issues caused by process drift. Records on incidents and actions should be maintained, and remedial efforts should be thoroughly recorded (Lund, 2008).

Establish Verification Procedures

The HACCP strategy and the ensuing HACCP system should undergo routine evaluations after they are put into place. The HACCP technique refers to this procedure as "verification." The operator should be the main source of verification to ensure that all the components of the HACCP plan are in place, the HACCP system that was developed from the plan is operational, and it offers the level of confidence that the plan specifies.

In commercial or regulatory contexts, the customer or a public body may also verify the HACCP-based safety plan to ascertain the food producer's capacity to comply with certain requirements. The topic of discussion today will be verification as it is applied internally by businesses. The verification process may involve multiple objectives. These include evaluating whether a plan is implemented correctly (i.e., the HACCP system complies with the HACCP plan; this prior implementation check may be called validation), confirming that a plan and system are operating efficiently, or examining the HACCP plan and system to determine what modifications are necessary.

The evidence that persuades the operator that the equipment is operating correctly will determine how frequently and how thoroughly verifications are conducted. Verification should therefore always be done upon plan implementation in cases when there is no proof of a system's correct operation. The frequency of inspection can be decreased when documented proof of the system's satisfactory operation is acquired. Reviewing the HACCP plan ought to be like this:

- Frequent occurrence of process deviations
- Receipt of information from the market indicating a health (or spoilage) problem
- When epidemiological or scientific information identifies new hazard(s) of concern
- When commercial information indicates changes in distribution systems or consumer's use or when anticipating such a change
- Prior to (rather than after) introducing changes in product/process conditions (e.g., new raw material/product to be used, formulation to be changed, new processing technology/equipment to be used).

Auditing the HACCP plan and system, or a portion of it, is the fundamental method for verification. The following are covered in full or in part by the procedures (Kamboj *et al*., 2020),

Pre-audit Documentation Review. This would entail going over records and documentation related to HACCP, GMPs (such as cleaning schedules, personnel hygiene and training, and implemented hygiene measures), and records.

Onsite Audit. The product description, facility layout, flow diagram, identified hazards, evaluation and confirmation of CCPs, review of control options and critical boundaries and their efficacy, and assurance of monitoring activities and their efficacy are all examples of what this would entail. Evaluation of the efficacy and suitability of corrective measures, Verification of the current verification protocols.

Additional Verification Procedures. This can entail gathering and microbiologically analyzing samples from CCPs or other suitable locations, as well as doing storage tests on goods (like those from a recently installed operation) or conducting more product testing. When considering the latter, particular attention should be paid to whether the microbiological procedures in question are practical and, more crucially, whether a workable sampling plan can reliably assess the microbiological quality level. Routine microbiological testing of end goods is not advised once a HACCP plan has been correctly created, implemented, and thoroughly verified due to the statistical limits of end-product sampling and testing.

Audit Follow-Up. This would entail the application of protocols to confirm that the suggested modifications have been successfully incorporated into the HACCP strategy and executed. The standard inquiries an auditor ought to make while confirming a HACCP system (Kamboj *et al*., 2020).

Establish Record Keeping and Documentation

To demonstrate that all concerns pertinent to the HACCP plan's scope have been addressed and that controls have been appropriately established, implemented, monitored, and verified, adequate documentation is required. Three components comprise the documentation system.

Documentation of the HACCP Plan. The scope of the plan, the makeup of the team and their assigned responsibilities, the specifications of the raw materials, intermediate, and final products, the facility layout and process flow diagram, the identification of hazards and their causes, the identification of CCPs, the management of each CCP, which includes measures for control, critical limits, tracking activities, and remedial plan(s), and verification procedures are all included in the documentation.

Documentation Necessary for the Implementation of the HACCP Plan. This covers work instructions and processes for monitoring, operating, and corrective actions that need to be completed at each CCP, as well as procedures for verification.

Records Obtained During the Operation of the HACCP System (Operation, Monitoring, Corrective Actions, Verification). The management of the documentation system needs to be done correctly. Appropriate criteria are provided by the ISO 9004 Standard. Like the system itself, the documentation must only be as thorough as is necessary and appropriate for the level of risk involved

for the system to be managed efficiently (Rosak-Szyrocka and Abbase, 2020).

BENEFITS OF FOOD SAFETY REGULATION

Reductions in the risks of illness and mortality from eating food that may be contaminated with micro-biological pathogens and other hazards are the advantages of food safety regulations. The economic methods that have been established to model and value minimize health risk serve as the foundation for theoretical analyses of the advantages of food safety rules (Radu *et al*., 2023). Theoretically, research indicates that a person's desire for risky foods is influenced by several factors, including income, costs, the perceived and objective risks of the food, the possibility that the person will be exposed to the risk, and their susceptibility to the risk (Rosak-Szyrocka and Abbase, 2020).

As a result, the factors that define individual traits, such risk perceptions and susceptibilities, are distributed in the consumer population, as well as income and price, influence market demand functions for items that represent a health risk. Demographics (age, education, etc.) and policies (product-labeling, availability of food-safety information, etc.) are probably among these determinants (Bevilacqua *et al*., 2023). Expressions for willingness-to-pay (WTP) for a lower risk of illness and death can also be derived from theoretical models. According to these models, WTP for lower morbidity risk can be broken down into four main categories: sickness-related expenses, lost wages from missed work, disease prevention expenses, and illness's disutility.

The statistical life value can be used to calculate the risk of death. Various techniques, including discounting lost income and utilizing wage disparities between occupations with differing hazards, have been used to infer the value that people place on the danger of dying. A statistical life can have values ranging from less than $1 million to tens of millions of dollars, depending on the approach used. The prevention of food-borne illness-related deaths has not been used in any of the research reported in the literature. Unresolved is the question of whether the values obtained in a situation unrelated to food inevitably translate to the food risk scenario (Schirone *et al*., 2017; Bevilacqua *et al*., 2023).

Conclusion:

Hazards or risk factors are associated with health complications and other degenerative factors responsible for destroying quality and damaging health standards. In the developing nations the hazards or risks associated with food products are exceptionally high as compared to developing nations one of the major causes for such high health complications is contaminated portable water. The microbes lack proper sanitation and sterilization synergized with adulteration can cause havoc on general population health. The role and objective of international laws and standards is to monitor the safety and quality standards of general food commodities to ensure safe, uncontaminated and nutritious food. The uncontrolled food borne infection and intoxication is minimized only by observing and regulating the standards set by these legislative bodies and are only fighting chance is to enhance awareness and further modification of these regulatory bodies. The review of the published literature has indicated the authority and influence these regulatory bodies have on food products. Therefore, further experimentation, novel advancements and enhanced standardization must be presented for better safety and quality control

and mitigation of possible hazards and risks associated with food commodities.

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AUTHOR'S CONTRIBUTION

All authors contributed equally.

Conflict of Interest:

Authors declare no conflict of interest.

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