FOOD SAFETY MANAGEMENT SYSTEM

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BOOKS ARCADE

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Website: www.booksarcade.co.in

Year of Publication 2023

International Standard Book Number-13: 978-81-19199-92-1

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CHAPTER 1

BASICS OF FOOD ANALYSIS

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Chemicals must be examined in a wide range of materials. The presence of chemicals in food is no different. Analyzing ingredients in foods whether they are chemical additions, nutrients, or other substances is essential because humans consume them. Therefore, foods are examined to determine what ingredients are included in the product that is distributed to the general public in order to verify that they are suitable for human consumption. This also applies to some food items that may be fake or otherwise not be what things claim to be

Importance of Food Analysis

Any product intended for human consumption must undergo thorough testing, and since food is consumed, the testing is frequently much more important to prevent health problems. Consumers who ingest tainted food may not only become ill, but the corporation may also suffer reputational damage and financial losses. Therefore, it is essential to ensure that meals contain the nutrients they are supposed to in the quantities they are supposed to, and this may be done either internally or at a contractual evaluation facility

Companies desire to study meals for a variety of reasons, and there are numerous main categories of food analysis. A broad variety of analytical characterization equipment that are present in practically all quality control facilities are the first options when it comes to procedures. For food analyses, a variety of equipment are utilized, including greater liquid chromatography (HPLC), gas chromatography, atomic absorption (AAS), nuclear magnets resonance (NMR) spectroscopy, and others. Titrations and slim chromatography (TLC), both of which are more "wet chemical" in nature, can also be employed. Depending on the food being analyzed, what is being examined inside the meal, and the purpose of the study, several techniques are used.

Analysis of Nutritional Content

Numerous outcomes can be obtained through food analysis. It is also a method that may be used for different quality control purposes, mainly to determine whether the proper ratios are within the food. It can be used to see that there are any elements that shouldn't be there (typically the presence of extra metals).One large area is examining the nutritional value of a food sample. An effective food analysis technique in these operations can allow the operator to assess the foodstuff's fibre, protein, carbohydrate, carbohydrate, fat, vitamins, and mineral composition.By doing so, the business may ensure that the products it sells are accurate both internally and with regard to any applicable external food rules, such as those established by that of the Food and

Drug Administration (FDA) in the USA. Despite focusing on distinct ingredients, these standards also apply to drinks. In the case of alcohol, the alcohol level of something like the product can also be evaluated to guarantee that it is at the stated/correct proof. Organic foods can also be examined to make sure they comply with food laws that the item being marketed as organic is, in fact, organic.

Food Forgery

Another significant factor in food analysis is food fraud. Honey is a significant area of food fraud. Honey can be filtered so thoroughly that its origins cannot be determined without the use of sophisticated analytical techniques. In addition, honey may include additional sugar syrups that increase processing beyond what is necessary and degrade the product's value and quality.These are frequently carried out since all honey need to have a source, and the honey is mega so that it may be passed off as honey from another nation in order to avoid some of the tariffs in place for particular nations. In addition, by adding sugar syrup to the honey, counterfeiters may generate greater quantities of inferior honey and increase their earnings. Therefore, to stop these fakes from reaching the market, modern food analysis techniques are also in place at federal buildings.

Food Analysis Methods

Meat products represent another area of food fraud where food analysis techniques are crucial. A significant incident involving burgers that were partially composed of horse meat but claimed to include beef occurred in the UK a few years ago. To avoid this, food analysis procedures are in place (although the odd one gets through before being noticed). Food analysis techniques may be used to verify the authenticity of the meats and stop cheaper cuts or varieties of beef from being mislabeled as a different, frequently more costly type of meat.

The types of meat that may be studied range from those you would typically see and purchase at the grocery store, such chicken, hog, lamb, as beef, to those that are more likely to be fake meats, like dog and dog meat.Determining the content and properties of food is frequently necessary for investigations in food technology, whether they are conducted by the food business, governmental organizations, or academic institutions. As they labor to monitor food composition and assure the quality or safety of the food supply, food scientists face challenges from consumer trends and desires, the food business, and national and global legislation. All food items must undergo analysis is part of a quality management programmer at all stages of development (including raw materials, manufacture, and distribution. Additionally, competitive items and tissue samples are analyzed.

Finding details about the composition of food items or a sample of food raw materials is the goal of food product analysis. This information gathering can be done on several levels. The elemental, molecular, and structure levels can all be included in this hierarchy. What (qualitative research) and what (quantitative analysis) may be discovered in the given sample depends on the quantity of the chemical components (elementals). Although the answer to what chemicals and crystalline forms make up the sample from of the building blocks may be determined at the molecular level. The level of complexity for the analytical work varies. Any method used for

food analysis relies on what research is trying to find, and there are many different food qualities to pick from. As customers' concerns about the ingredients in their food and the security of the foods people eat have risen, so too have the development and implementation of analytical methodologies and techniques in the field of food science.

Definition of Food Safety

To different audiences, the word "safe food" conveys different ideas. Consumers, special interest groups, governments, industry, and academics will all have their own definitions depending on their points of view. Most of the information concerning food safety that the general public receives originates from the media. As a result, media perceptions on food supply safety can impact those of the general population.

Customers are the final link in the food supply chain, from production through processing and distribution to retail and food service establishments. Customers are diverse and multidimensional. Age, life experiences, health, knowledge, culture, sex, political views, dietary demands, purchasing power, media inputs, family status, employment, and education all differ amongst populations. The influence of these parameters' interrelationships on an individual's description of "safe food" has not been demonstrated.

When the author asked knowledgeable consumers to describe safe food, their responses contained certain crucial aspects. Safe food is food that has been handled correctly, including thorough washing of cooked fish and poultry, as well as anything consumed raw. Food cooked on clean and sterilised surfaces with clean and sanitised utensils and plates is considered safe.

These customers emphasise the necessity of hand cleaning by employees involved in food preparation, as well as avoiding recycling filthy rags or sponges. For the educated and informed consumer, common sense is a guiding concept.Some customers desire healthy food that is high in vitamins and minerals yet low in pesticides. They define safe food as food that is still edible and has been kept and delivered at the right temperature.Some customers are familiar with the term "contamination," and they define safe food as food that is not contaminated.

Food Safety

Some customers' definitions of safe food are more practical, such as food that does not make them sick. For these customers, safe food means buying fresh chicken and not having the packaging leak or drop juice, making them question the initial seal's integrity. Consumers describe safe food using their senses, and they believe that food that looks or smells terrible should not be consumed. Interestingly, few consumers consider labelling to be an important component of food safety. Customers believe they know what to do with food once it has been purchased, and they feel that food safety is mostly decided before it enters their hands. Data from the public domain imply otherwise.

McDowell (1998) revealed the findings of professional auditors' on-site examinations of 106 families in 81 U.S. locales. 73% of the participants have a college degree. In 96 percent of the families, at least one serious violation was found in food preparation, cleaning, temperatures, sanitation, the environment, and personal hygiene. Cross-contamination (76'% of homes with

this violation), missed hand washing, incorrect leftover chilling (29'%1), poor chemical storage (28%), insufficient cooking (240/;1), and refrigeration over 40°F were the most prevalent critical violations.

Similarly, Jay *et al.* (1999) employed video recording to evaluate food handling procedures in 40 Melbourne household kitchens. Several sorts of households were video watched for up to two weeks in 1997 and 1998. In terms of food safety in the home, there was a substantial difference between what individuals stated they would do and what they really did. Infrequent and poor hand washing, inadequate cleaning of food contact surfaces, the presence of dogs in the kitchen, and cross-contamination between dirty and clean surfaces and food were the most prevalent unsanitary behaviours.

Historical Significance and Background

Special interest organizations give a narrow perspective on food safety. These organizations do research on the topics they feel are most important to food safety and then communicate their findings to consumers, regulatory agencies, industry, and academia. They often define safe food by hazard levels that are more detailed than those employed in the food supply chain. Special interest groups define safe foods as having stricter control limits for microbiological infections and chemical risks. On concerns about harmful health impacts, they demand a better degree of food safety through mandates for greater interventions to limit dangers and the removal of chemicals used in food production.

Special interest groups frequently criticise governmental agency approvals of agricultural and animal husbandry procedures aimed to promote production and efficiency, such as the use of antibiotics and hormones. Additionally, several special interest groups' definitions of safe food would ban foods developed with advanced technology, such as genetic engineering. They would again be sceptical of the research that demonstrated the safety of these new foods for the regulatory agencies in charge of their approval.Special interest groups, such as the Center for Science in the Public Interest (CSPI) in the United States, offer consumer advice and government recommendations. CSPI and the Safe Food Coalition have outlined their recipe for safe food by calling for funding for the proposed 1997 US National Food Safety Initiative, more authority for the USDA to enforce food safety laws, more power for the FDA to keep contaminated products off the market, and a single agency responsible for food safety.

The CSPI has said that consumers must be aware of the expanded range of items that can be used to transmit foodborne diseases. According to the CSPI, the government has enhanced the safety of the nation's food supply through law and regulation, despite the fact that the endeavour is underfunded and poorly organised.

Background and Historical Significance

E.M. Foster has offered a unique viewpoint on the history of safe food throughout his remarkable career. He described how, for many people, food production and consumption were inextricably linked to agricultural life. Because refrigeration was still not available to many people, time management became the mechanism through which safe food was assured via experience.

According to Foster, botulism, salmonellosis, and Clostvidium perfringens food poisoning from novel food vehicles have demonstrated how our perceptions and understanding of safe food evolve as we learn more about microbial diseases' abilities to adapt and multiply in specific circumstances.

Scientific Basis and Implications

Because academicians are some of the most educated consumers, they typically have the best grasp of food safety, blending science with practical application in the food supply chain.Academicians are often the best aware about the scientific research that is utilised to define safe food. Nonetheless, the intricacies of study, as well as the countless issues raised by research, unavoidably lead to differing perspectives on science. Academic problems about food safety are frequently multifaceted, including scientific fields such as biochemistry, microbiology, genetics, medicine, plant and animal physiology, and food science, to mention a few. Academicians' definitions include information surrounded by limitations and assumptions since they are often exclusively concentrated in certain study subjects.

The amount of diseases connected with food is a standard scientific metric used to identify safe food. The Foodborne Diseases Active Surveillance Network, the National Notifiable Disease Surveillance System, the Public Health Laboratory Information System, the Foodborne Disease Outbreak Surveillance System, and the Gulf Coast States Vibvio Surveillance System are all data sources for this measure in the United States. Some nations utilise similar surveillance programmes to collect data on foodborne diseases.

Regulatory, Industrial, and International Implications

Because regulatory authorities are also consumers, they have many of the same prejudices and views as the general public. Regulatory agencies, on the other hand, often have a greater level of training in food safety. They differ in scope:

Whether at the local, state, federal, or global levels, they are aware of their obligations and impact. Individuals also have different eating experiences as they move up the food chain, from agricultural and animal production through manufacture, distribution, and testing, and finally retail and food service. These encounters will shape their perceptions of safe food.

Regulatory agencies in charge of food production are increasingly aware of the influence of agricultural pesticides, animal hormones, feed pollutants, and antibiotics, and would incorporate information about these aspects in their definition of safe food. Regulators would be more likely to characterise safe food in terms of the microbiological, chemical, and physical dangers involved with manufacture in processing facilities.

Regulatory agencies characterise safe food in accordance with regulations established by authorities such as the World Health Organization (WHO), the European Commission, and the United States Food and Drug Administration (FDA). The international trade norms and rules become part of the regulatory definitions of safe food. For example, the food safety standards established by the Joint Food Agriculture Organization/World Health Organization Codex Alimentarius Committee (CAC) have become the international norm for resolving international

trade disputes. Several regulatory agencies use quantitative risk assessment to assist define food safety and establish the best intervention options. With the World Trade Organization's (WTO) release of the Sanitary and Phytosanitary Agreement, scientific risk assessments are said to have been the cornerstone for food safety globally.

Government officials frequently use words like "safe food" to appeal to public fears about food safety. On July 2, 1998, for example, the United States Vice President encouraged the United States Congress to support a Food Safety Program in order to "offer Citizens peace of mind when they reach for a piece of food." The Vice President emphasised the need for "additional authorities to seize potentially tainted meat in order to protect America's families." Experts, on the other hand, know that more recall authority does not enhance food safety. The vision and scope of the United States Food Safety Initiative are vast. A fundamental component of the Initiative is educating consumers about the food safety responsibilities of everyone involved in the food supply chain.

The constituency of the industry sector is diverse. Farmers and ranchers constitute the foundation of the majority of the food supply chain. At this level, food safety is determined by farmer and rancher practises, such as chemical soil treatment or the use of hormones in animal production. These plant and animal producers define safe food based on the actual application of production principles, balancing production economic pressures with requests for hazard management. At this level, safe food means doing what is feasible to assure safety and focusing on the most efficient use of government-approved chemicals to optimise output. Thus far, there hasn't been much emphasis on managing microbial dangers at this level of the food chain; nevertheless, there is growing acknowledgement of farmers' and ranchers' roles in defining safe food through their practises.

The food business defines safe food by its raw material and end product criteria. Chemical dangers such as pesticides and hormones, physical hazards such as bone and metal fragments, and microbiological hazards such as Listeviu monocytogenes and Sdmonella are also defined in these requirements. The food business defines safe food in terms of pathogen reduction related with processing technologies, whether long-established such as pasteurisation or newer such as pulsed, high-energy light.Distribution, retail, and restaurant businesses are also included in the industrial sector. Definition of food safety nesses, as well as adjacent businesses supporting plant and animal development and the utilisation of byproducts for nonfood purposes such as health care and apparel. The expectations of their consumers and regulatory bodies define safe food for distributors, retailers, and restaurants.

Current and Future Consequences

Consumers, special interest groups, academics, regulatory agencies, and business all have different perspectives on what constitutes safe food. Because safe food is a complicated, nuanced issue, almost any single definition will be unduly simplified. The following is how scientific experts at the 1998 American Academy of Microbiology Colloquium on Food Safety (AAM, 1999) defined safe food: Safe food is dependably unlikely (i.e., the chance is low and the

variability is modest) to cause disease or harm if handled appropriately at all stages of manufacture through consumption.

Everyone desires a secure food supply. When additional actions are made to improve food safety, the criteria used to define safe food will become more thorough and comprehensive. Expectations will grow as capabilities improve. The hardest decisions are those involving perceived risks, which cause the waste of public and private resources. If a meal is considered or reported to be harmful, the narrative can be magnified in the press and then verified in the public eye by politicians and regulators' participation. All of this is possible in the absence of scientific evidence that accurately characterises the danger.Consumers have a responsibility to play in maintaining the safety of food. Kids must be able to make educated decisions about their food and how it is handled and prepared.

Consumer education regarding food safety, according to Lopez (1 999), is required. Without a generally acknowledged definition of safe food, the general public will have unreasonable expectations about the level of safety that can be achieved. Lopez stated that food safety standards have both economic and scientific elements, and that customers are unlikely to pay the high expenses of perfectly safe food. To that aim, business and government must work together to improve safety while also educating consumers on the practical elements of safe food? It is necessary to do research to identify what influences consumers' food safety behaviours.

The use of Sulmonellu and Eschevichiu coli performance criteria in the United States food supply shows regulators' inclination towards employing microbial counts and prevalence data to determine safe food. Yet, food safety experts generally agree that food sampling and testing are not the only ways to ensure safe food. Routine sample data reveal the limitations of testing to determine safe food. *E. coli* 0157:H7 in ground beef and Listeviu monocytogenes in cooked meals, for example, are found at low quantities, often less than 0.1"/0. Even after analysing 60 samples each lot, there is a higher than 90% probability that the pathogen will not be detected. Businesses often test fewer samples (3-5 each lot) to validate that their Hazard Analysis and Critical Control Point (HACCP) system is operational; hence, the possibility that testing will demonstrate food safety is considerably reduced. Additionally, pathogens will not be spread uniformly in many contaminated foods, which may impair the use of sampling and testing to assess safety.Worldwide variations in food safety judgements are likely to persist, as seen by the ongoing conflicts between the United States and the European Union over the safety of cattle hormone treatments and genetically modified foods. Notwithstanding systems such as the WTO's dispute settlement system, these discrepancies persist. In general, the European perspective on safe food differs significantly from that of the United States, with culture and history being as important as science in some decision-making processes.

Characterization of Food Hazards

Food hazard categorization developed as a way to assist prioritise risks and identify hazards. The number and range of the criteria used to analyse dangers has expanded throughout time, so has the scope of hazard classification. In creating food safety control procedures today, hazard characterisation is more crucial than ever. The use of classification becomes less important as the

population's vulnerability to dangers increases. According to the World Health Organization (1995), hazard characterisation is the qualitative and quantitative assessment of the nature of the adverse effects associated with biological, chemical, and physical agents that may be present in foods.Van Schothorst proposed renaming hazard characterization "impact characterization." The severity of the effect can range from modest (simple acute diarrhoea) to severe (chronic disease or death), and is mostly determined by the sensitivity of the individual exposed. To account for the numerous assumptions connected with impact characterizations, a worst-case scenario is frequently employed to quantify the risk posed by a given disease in a specific meal. According to Van Schothorst, assumptions and uncertainties in hazard categorization might eventually lead to an incorrect risk assessment, as well as credibility and liability issues.

A hazard is defined as a "biological, chemical, or physical substance that is reasonably likely to cause disease or harm in the absence of its control" by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (1997). Microbial pathogens are the most prevalent biological hazards, producing infections (the development of the disease-causing microorganism) and intoxications (sickness caused by a prepared toxin generated by a microFood

Pesticides, antibiotics, and growth hormones are examples of agricultural chemicals; industrial chemicals such as cleansers and sanitizers; and equipment-related compounds such as oils, fuel, and lubricants.Natural poisons such as mycotoxins, environmental pollutants such as lead and mercury, and chemical preservatives and allergies are all examples of chemical risks.Glass, wood, plastic, stones, metal, and bones are all potential threats. Inadvertent contamination from growing, harvesting, processing, and handling; purposeful sabotage or tampering; and chance contamination during distribution and storage have all been identified as sources of physical risks.

Historical Significance and Background

The phrase "hazard characterization" has been used to refer to both the food items themselves and the risks that may be present in the food. Hazard characterization has been utilised in the creation of HACCP programmes and regulatory rules, as well as risk assessments. The National Academy of Sciences published a paper on the Sulnionellu problem in 1969. This research indicated three food and Sublzonellu hazard characteristics:

1. Items containing components identified as important potential contributors.
2. Industrial operations lacking a control step.
3. Significant possibility of microbiological growth in salmonellosis if mistreated or misused in salmonellosis, destroy Scdwwnellae, and in distribution or consumer usage.

Five categories were constructed using various combinations of these three hazard criteria to indicate the possible danger to the customer. Food goods in Category I were meant for use by infants, the elderly, and the infirm, i.e. the high-risk group. Processed foods in Category 1 were subject to all three danger characteristics (ABC) described above. Products in Category 111 had two of the three general danger criteria. Products such as custard-filled baked items (AC), cake mixes and chocolate confectionery (AB), and sauce mixes that do not contain a sensitive

ingredient would fall into this category (BC). Products in Category IV posed just a modest microbiological health threat and were subject to only one of the danger Criteria. Retail baked cakes (A) and various frosting mixes are examples (B). Foods in Category V have none of the BACKGROUND AND

Historical Significance

Microbiological danger characteristics and so have a low hazard potential, such as canned goods sterilised after packaging in the final container.The Pillsbury Corporation is credited with being the first to design HACCP programmes. The Pillsbury approach to HACCP systems classified food products based on three danger criteria. The hazard features were generalised in this case to encompass all potential microbiological, physical, and chemical threats, not just Sulmonellu (Sperber, 1991). The permutations of the danger characteristics, as in the NAS study, resulted in five product hazard classifications.

The three hazard characteristics were widely used to analyse hazards in the 1970s (Bauman, 1974). In 1989, the NACMCF released a HACCP paper that ranked microbiological dangers based on six hazard factors for risk evaluations (NACMCF, 1989). Chemical and physical risks were later included (Corlett and Stier, 1991). At the time, hazard classification was based on characteristics such as:

1. Consumers' risks are related to characteristics such as age and health.
2. The danger posed by the components used to manufacture the food product.
3. The manufacturing process and its effect on the hazard.
4. The possibility of recontamination following processing.
5. The possibility of misuse throughout distribution and customer handling.
6. The consumer's capacity to discover, eliminate, or eradicate the hazard during the last preparing procedures.

The 1989 NACMCF document's hazard categorization scheme was modified in 1992 and again in 1997. These improvements brought HACCP ideas in the United States in line with those established by the globally recognised Codex Alimentarius Commission (CAC). As part of the hazard analysis, the most recent HACCP documents define dangers.

When the dangers have been identified, the hazard characterization, or evaluation, takes place. The intensity of the danger, including the seriousness of the effects of exposure, or the quantity and duration of the disease or damage, are among the factors for describing the hazard.

The danger characteristics were dropped in favour of an open-ended hazard analysis in which an endless number of relevant questions may be asked regarding the product and the method by which it is created," according to William H. Sperber (personal communication).

The product danger categories went out of favour as we realised that a sizable proportion of consumers are immunocompromised. All goods must be safe for all customers to eat. The advent of novel foodborne pathogens in very small niches, such as Listeria inonocytogenes in some perishable ready-to-eat foods, has rendered the idea of product risks categories obsolete.

Technical Base and Implications

Hazard characterization has been highlighted as the second phase of the risk assessment process, in addition to its involvement in the formulation of HACCP plans. Characterization include identifying risk factors, characterising the location and mechanism of action, and determining the dose-response relationship (proportion responding or severity of response). Despite significant uncertainty, dose-response models are widely employed to predict human health impacts and even to develop regulatory regulations.A dose-response evaluation should be undertaken for chemical risks, according to the WHO. If data on biological or physical agents are available, a dose-response evaluation should be done. Although potentially harmful substances may be present in foods at low concentrations, such as parts per million or fewer, animal toxicological studies are often conducted at greater concentrations to produce a quantifiable impact. The importance of the adverse effects associated with high-dose animal studies for low-dose human exposure is a prominent point of contention in chemical hazard evaluation.

Extrapolating animal exposure data to human exposure levels is both qualitative and statistically imprecise. The hazard's nature may alter with dosage. Not only is estimating the equivalent dose in animals and humans hard in comparative pharmacokinetics, but the chemical's metabolism may alter as the dose varies. High dosages can overburden detoxification mechanisms, although the effects may be unrelated to those reported at low concentrations.The intraspecies variation in dose response at different dosage levels is a major contribution to the ambiguity in hazard categorization. Large exposures are frequently employed to boost the power of a study, although they may be misleading for low-dose exposure. Variation is also caused by a variety of different characteristics between particular animals and people.

Toxicologists frequently utilise thresholds to measure the negative consequences of chemical exposures, with the exception of carcinogenic effects, where beginning events might occur as persistent somatic mutations that eventually evolve into cancer. Certain carcinogens, such as the "No Observed Effect Level (NOEL)-safety factor," may be regulated using a threshold approach. Using safety factors, a safe amount of a chemical is frequently calculated from an experimental NOEL or No Observed Adverse Effect Level (NOAEL). When considering data from long-term animal studies, a safety factor of 100 was used, however this may be changed if data are insufficient or if the impact is more severe or permanent. Because of the unpredictability of these systems, it has been advised that conservative models with large safety factors be employed for food systems possibly contaminated with biological risks. Unfortunately, the safety factor method is fraught with uncertainty and cannot provide 100% safety for everybody.

The NOEL safety factor technique is typically not employed for carcinogens that produce genetic modifications in target cells due to the assumption that danger occurs at all doses, even the lowest. Using quantitative risk assessment, risk management choices include banning the chemical or establishing a minimal, inconsequential, or socially acceptable level of risk. Another method has been to utilise a lower effective dosage, or a benchmark dose, which is based on data closer to the observed dose-response range. This might lead to more precise projections of low-dose dangers.

The purpose of characterising biological risks is to offer a qualitative or quantitative assessment of the severity and duration of adverse effects caused by the presence of a pathogen in a meal. For microbial pathogens, dose-response data are useful yet limited. Furthermore, data inaccuracies may occur due to the following factors: host susceptibility to pathogenic bacteria varies; attack rates from specific pathogens vary; pathogenicity is subject to genetic mutation; antagonism from other microbes may affect pathogenicity; and foods will modulate microbial-host interactions.

CHAPTER 2

REGULATORY, INDUSTRIAL, AND INTERNATIONAL CONSEQUENCES

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As Kaferstein *et al.* point out, trade globalisation necessitates cooperation across international regulatory and health protection bodies.WTO-recognized food safety standards entail a higher reliance and focus on scientific risk evaluations. Hazard characterisation will continue to be an important component of risk assessment (NACMCF, 199%).The International Commission on Microbiological Standards for Foods (ICMSF) has advocated that the Food Safety Objective (FSO) be used as a management tool to reduce the risk of foodborne disease. The FSO indicates the frequency or maximum concentration of a microbiological hazard in a food that is acceptable for consumer protection. FSOs are more general than microbiological criteria in that they connect risk assessment and risk management procedures and develop control mechanisms (ICMSF, 1998). The hazard characterisation procedure will provide data to help establish the FSO.

Current and Future Consequences

According to the Institute of Food Technologists (IFT), a scientific organisation for food science and technology with over 28,000 members, food safety measures must be risk-based. The IFT concurred with the WHO (1995) that advances in risk assessment need more specific categorization of hazards and measurements of exposure. Improved data on pathogen exposure, pathogen behaviour in foods, and dose-response relationships for population subgroups are required.

Future research requirements indicated by scientific experts at the AAM Colloquium on Food Safety include a cross-discipline description of dose-response relationships and clearer characterization of risks producing chronic illness syndromes such as reactive arthritis and ulcers. The hazard categorization technique will be updated and enhanced as new scientific evidence is generated. The allowable levels for risks fluctuate with time, as does the spectrum of hazards addressed in a specific food safety control programme.

Harmonization of hazard characterisation methodologies will benefit global commerce by providing a uniform foundation for establishing product standards and defining safe food. The SPS Agreement and FAO/ WHO CAC standards and recommendations were used to take the first steps. Although hazard characterization is important in the establishment of food safety management strategies, it does not define safe food. The concept of safe food will evolve as we learn how to better combine danger characterization, demographic preferences, cultural biases, and a variety of other factors into safe food judgments:

Risk Analysis Frameworks for chemical and Microbial Hazards

1. Consumers' risks are connected with aspects such as age and health.
2. The danger connected with the substances used to manufacture the food product,
3. The manufacturing process and its influence on the danger,
4. The possibility of recontamination following processing,
5. The possibility of misuse during distribution and customer handling, and
6. The capacity of the customer to discover, eliminate, or eradicate the hazard during the final preparing procedures.

The hazard categorization scheme established in the 1989 NACMCF publication was modified in 1992 (NACMCF, 1992) and again in 1997. These adjustments brought HACCP ideas in the United States in line with those established by the internationally renowned Codex Alimentarius Committee (CAC). The most recent HACCP documents define dangers as part of the hazard analysis. When the dangers have been identified, the hazard characterization, or evaluation, is performed. The following factors are used to characterise the danger: the severity of the hazard, which includes the seriousness of the effects of exposure, or the quantity and duration of the disease or damage,

In addition to its significance in the formulation of HACCP plans, hazard characterization has been highlighted as the second phase in the risk assessment process (Smith et al., 1999). Characterization comprises determining risk factors, characterising the location and mechanism of action, and quantifying the dose-response relationship (proportion responding or severity of response). Despite considerable uncertainties, dose-response models are routinely employed to predict human health impacts and even to develop regulatory rules.

For chemical risks, the WHO recommends performing a dose-response analysis. If data on biological or physical agents are available, a dose-response analysis should be done. Although potentially harmful substances may be present in foods at low quantities, such as parts per million or fewer, animal toxicological studies are often conducted at greater levels to produce a quantifiable impact. The importance of the adverse effects associated with high-dose animal studies for low-dose human exposure is a key matter of controversy in chemical hazard classification.

The extrapolation of animal exposure data to human’s exposure levels is both qualitative and statistically imprecise. The nature of the danger may alter with dosage. Not only is estimating the comparable dose in animals and humans difficult in comparative pharmacokinetics, but the chemical's metabolism may alter as the dose varies. While large dosages can overload detoxification mechanisms, the effects may be unrelated to those reported at low concentrations. The intraspecies variation in dose response at different dosage levels is a major contribution to the uncertainty of the hazard categorization. Massive exposures are frequently employed to boost the power of a study, although they may be erroneous for low-dose exposure. Several other distinctions between individual animals and people contribute to variation.

Toxicologists frequently utilise thresholds to measure deleterious consequences from chemical exposures, especially in the case of carcinogenic effects, where beginning events might occur as

persistent somatic mutations that eventually evolve into cancer. Certain carcinogens may be regulated using a threshold method, such as the "No Observed Effect Level (NOEL)-safety factor" approach. Using safety factors, a chemical's safe level is frequently calculated from an experimental NOEL or No Observed Adverse Effect Level (NOAEL). When considering data from long-term animal studies, a safety factor of 100 was used, although it may be changed if data are insufficient or the impact is more severe or permanent. Because of the unpredictability of these systems, it has been advised that conservative models and substantial safety factors be employed for food systems that may be contaminated with biological dangers. Unfortunately, the safety factor technique is fraught with uncertainty and cannot ensure total safety for everyone.

The NOEL safety factor technique is typically not employed for carcinogens that produce genetic modifications in target cells since it assumes danger occurs at all doses, even the lowest. Risk management strategies include banning the chemical or establishing a minimal, inconsequential, or socially acceptable level of risk through quantitative risk assessment. An alternate method has been to utilise a lower effective dosage, or a benchmark dose, which is based on data closer to the observed dose-response range. This might lead to more accurate forecasts of low-dose dangers.

Characterization of biological hazards is done to offer a qualitative or quantitative estimation of the severity and duration of adverse effects caused by the presence of a pathogen in a meal. Dose-response data are valuable but limited for microbial pathogens. Furthermore, data inaccuracies may occur for the following reasons: host susceptibility to pathogenic bacteria varies; attack rates from specific pathogens vary; pathogenicity is subject to genetic mutation; antagonism from other microbes may affect pathogenicity; and foods will modulate microbial-host interactions.

Regulatory, industrial, and transnational implications

Trade globalisation necessitates cooperation among international regulatory and health protection bodies.Food safety standards recognised by the WTO place a higher reliance and focus on scientific risk evaluations. Hazard characterisation will continue to be an important part of risk assessment (NACMCF, 199%).The International Commission on Microbiological Standards for Foods (ICMSF) has advocated using the Food Safety Objective (FSO) as a management tool to reduce the risk of foodborne disease. The FSO represents the frequency or maximum concentration of a microbiological hazard in a food that is regarded acceptable for consumer protection. FSOs have a larger reach than microbiological criteria; they connect risk assessment and risk management procedures and provide control mechanisms. The hazard characterization procedure will help to develop the FSO.

Current and Future Implications

The Institute of Food Technologists (IFT), a scientific organisation for food science and technology with over 28,000 members, has emphasised that food safety rules must be risk-based. IFT concurred with WHO that advancements in risk assessment need more accurate categorization of hazards and measurements of exposure. Improved data on pathogen exposure, pathogen behaviour in foods, and dose-response correlations for population subgroups are

critical. Future research requirements indicated by scientific experts attending the AAM Colloquium on Food Safety include a cross-discipline description of dose-response relationships and clearer characterization of risks producing chronic illness syndromes such as reactive arthritis and ulcers. When new scientific evidence becomes available, the hazard categorization procedure will be updated and enhanced. The allowable levels for risks will fluctuate, as will the spectrum of dangers addressed in a specific food safety control programme.

Harmonization of hazard characterization methodologies will benefit global commerce by providing a uniform foundation for creating product standards and defining safe food. The SPS Agreement and FAO/WHO CAC standards and recommendations were used as a starting point. Hazard characterisation, while important in the establishment of food safety management systems, will not define safe food on its own. The concept of safe food will improve as we learn how to better combine danger characterisation, demographic preferences, cultural biases, and a variety of other factors into safe food judgements.

Communication of Risk

The practise of engaging stakeholders (all interested parties, including consumers, producers, scientists in academics, business, and government, as well as numerous professional or advocacy groups) in discussions regarding risk, its assessment, and management is known as risk communication. The risk assessor may be responsible for communicating the risk assessment's data, models, and conclusions in nontechnical words. Based on the risk assessment, the risk manager is responsible for articulating the rationales for several possible risk management techniques. Stakeholders must also convey their concerns while also reviewing and comprehending the risk assessment as well as risk management choices. Some risk communication standards for agencies to follow. Decisions are made based on available data. These assumptions and inferences based on inadequate evidence may be highly subjective assessments that cause disagreement and debate among other risk analysts and stakeholders.

The risk manager and stakeholders must comprehend the risk assessment in order for it to be used successfully to assist decision making on risk management methods. Understanding risk assessment entails being familiar with: 1) the simplifying assumptions used in model construction; 2) whether or not the specific models used are based on scientific community consensus; 3) the magnitude of the uncertainty associated with the data and the models; and 4) the procedures for estimating the likelihood of the occurrence of adverse events for given scenarios. The risk assessment is deemed "transparent" if clear, detailed explanations of the assumptions and methods are supplied so that the study may be replicated.

Yet, transparency may be defined as being in the eye of the beholder, because risk assessors must adapt varying degrees of technical detail for transparency to distinct audiences of stakeholders and risk analysis specialists.Other from measuring the degree of the risk and the uncertainty of the risk estimations in a transparent manner, generality is another important feature of a risk assessment methodology. The models must explain processes in a way that allows them to be applied to a broad number of scenarios, such as showing a variety of contemporary farm-to-fork food production processes. A model, on the other hand, may be excessively comprehensive,

requiring many unsubstantiated assumptions or inappropriate conclusions and resulting in erroneous risk estimations. In contrast, the facts and supporting scientific theory may allow for useful risk estimations for just a limited range of possibilities.

At the preliminary phase of risk assessment, the underlying conflict between these two poles of generality and specificity should be addressed. By doing sensitivity analysis, this tension may also be addressed in the risk assessment.The influence of changes in model parameters on risk estimations is shown via sensitivity analysis. If the values of a parameter have a large influence on the risk estimate (high sensitivity), and the real value of the parameter is unknown, the risk assessment findings will be very uncertain. A detailed examination of the uncertainty of estimates and the impact of alternative models generated from various assumptions would allow for the evaluation of more broad situations while protecting against unjustified conclusions.

Each risk assessment is distinct from the others. As a result, the risk assessor must create a one-of-a-kind set of processes tailored to particular risk assessment. For example, several engineering-appropriate approaches, such as fault tree analysis, lack the flexibility to account for dynamic development, which is required for predicting the likelihood of severe outcomes from numerous microbiological risks. Since risk evaluations are unique, the Codex Committee on Food Hygiene (CCFH) does not provide procedures for microbiological risks in its principles and recommendations document. The NRC framework addressed later in this chapter, for example, is relevant to microbiological dangers, albeit approaches to account for dynamic proliferation of infections in exposure models were probably not envisioned during the formation of the framework for carcinogenic risk assessment.

The purpose of risk assessment for a society is to model realistically the probability of consequences, including uncertainties, for specific scenarios, rather than to generate "conservative" estimations of the probabilities of outcomes. For the risk management and stakeholders, a model should distinguish "real" variability (irreducible variation across hosts, pathogens, or environmental matrices) from uncertainty (ignorance reducible by fresh research data) imposed by the data and model assumptions. Imposing conservatism across a risk assessment model is not a good practise since it imposes bias on the risk estimate that may be difficult to evaluate. Conservatism should be the risk management processes or society's judgement, informed by a risk assessment that presents a range of possibilities rather than a worst-case scenario.

Management of risk and society the history of laws passed by elected and appointed representatives and enforced by governmental regulators can reveal a society's concerns and effect on risk management. Delaney Clause of 1958 which mandated a zero-risk cancer criterion aimed to prevent carcinogenic food additives, including pesticides, from concentrating in processed foods. A zero-risk standard does not need a quantitative risk assessment, but rather a simple statistical test at a predetermined threshold for the existence of a carcinogen danger in processed food.

Two recent pieces of legislation that suggest or expressly demand risk assessments for food safety under particular situations demonstrate the evolving atmosphere of risk analysis over the

last 40 years. The Office of Risk Assessment and Cost-Benefit Analysis was established by the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 to review risk assessments and cost-benefit analyses used in support of major regulations in the United States Department of Agriculture (USDA). The Food Quality Protection Act of 1996, as amended in 1998, revised the language in the Delaney Clause pertaining to pesticides from "zero risk" to "reasonable assurance that no damage would arise from maximum external to pesticide residue." Hence, the absence of statistically significant evidence for the presence of a carcinogenic halard does not imply "safe" food in terms of pesticides. Rather, estimations of "acceptable" dietary risk and consideration of vulnerable subpopulations imply "safe" food.

Risk communication and society prior to communicating with the risk manager, risk assessors may not have regarded risk communication to be their role at all. Public meetings may have been held to announce the results of the risk assessment or to explain policy choices based on the study. More recent studies by the NRC (1996) and the President's Commission on Risk Management hint to opening up risk analysis to more participatory debate throughout the process. As a result, U.S. government agencies (EPA, USDA, and FDA) are increasingly frequently conducting public hearings to present risk assessment teams and gather data at the beginning of significant risk assessments rather than at the conclusion.

Risk Management Structures

As previously stated, the NRC's original framework for risk assessment and risk management suggested in 1983 was the first U.S. publication that systematically connected foodborne human health, risk assessment, and risk management. The NRC's study was the first significant attempt in the United States to establish terminology for, and critical procedures in, public health risk assessment. The Committee convened to discuss chemical dangers as well as carcinogenic effects or end points. The effort, dubbed the "Red Book," has, however, been extended beyond its basic area of risk evaluation for carcinogens.

Management Methods for Risk Assessment

These connections support the idea that risk assessment is an organized process that connects research and policy. The first unidirectional arrow on the left suggests that research data and information are used to estimate risk. In other words, research initiatives are not created expressly to suit the demands of risk assessments. The President's Committee on Risk Management, which acknowledged the issue, said that risk assessments should inspire research. Risk assessment model uncertainty and sensitivity analysis can uncover critical research needed to improve risk assessments.

The second and third unidirectional arrows indicate the science's impartiality and risk assessment's independence from other elements that impact the risk manager's decision-making process. Preliminary assessments for the scope of the risk assessment necessitate some early discussion between risk assessors and risk managers. Throughout the evaluation, a risk manager should clearly avoid from having any influence on the process that may skew the outcomes. As a result, risk managers are often excluded from the phases of risk assessment that deal with scientific data. When a risk assessment nears completion, risk assessors and risk managers may

collaborate to generate policy choices for risk mitigation or risk reduction, as well as economic assessments such as cost-benefit analysis for potential mitigation, legislation, or guidelines. This perspective on risk analysis necessitates some interaction between risk assessors and risk managers, but only at the conclusion of the process, at the decision point.

The risk assessment results are fed into the risk manager's decision-making process. One unintended effect of these unidirectional interactions is that open and honest communication with risk managers and other stakeholders regarding the scientific data, assumptions, and methodology utilised in risk assessment is hampered. With this approach, risk assessment has the potential to become a "black box" for both the risk manager and the stakeholders.

The bidirectional arrow on the left suggests that research should be inspired and led by the demands of risk assessors while performing risk assessments. This reflects a growing focus on risk assessors' ability to detect important data gaps and actively participate in shaping the direction of research to enhance risk assessment models. The right bidirectional arrow emphasizes that not only is decision making a collaborative effort between risk assessors and risk managers, but that the risk assessors' assumptions and conclusions must be conveyed explicitly to the risk managers.

The bidirectional arrow on the right is not meant to suggest that the influence of risk managers reduces the independence of risk assessment, but that independence may be reduced as a result. The risk communication with stakeholders appears to be missing from the NRC 1983 framework. One incentive for reform or framework extension is to include stakeholders who wish to understand risk and select how they respond to risk as people and society (NRC, 1996). Several risk analysts and stakeholders agree that the utility of unidirectional risk analysis methods warrants additional investigation.

Researchers, risk assessors, and managers must communicate at several levels. For example, conversation is required between risk assessors and managers to define the scope of the risk assessment, prepare and test models for alternative risk management solutions, engage in discussions about the risk assessment results and interpretations, and influence the direction of the study. Communication between risk analysis professionals and stakeholders, on the other hand, is more difficult. One of the numerous causes of difficulties, for example, is the degree of technical expertise necessary to grasp the risk assessment. Numerous technical assumptions are made, which raises concerns regarding the conclusions' validity. Another issue is that risk assessments sometimes do not address the problem in its totality, but rather a fraction of it, neglecting other linked dangers that might become community issues (NRC, 1996). Stakeholders must understand the risk assessment process in full in order to build a deeper grasp of the nature of the problem and evaluate potential solutions. The following section discusses the nature and limitations of the risk assessment process.

Structure of Risk Assessment

The initial responsibility for risk assessors who have been assigned to do a risk assessment by their risk managers is to gather data and organise it in some acceptable fashion in accordance with a logical framework, such as the four-step process (Figure 1.1).

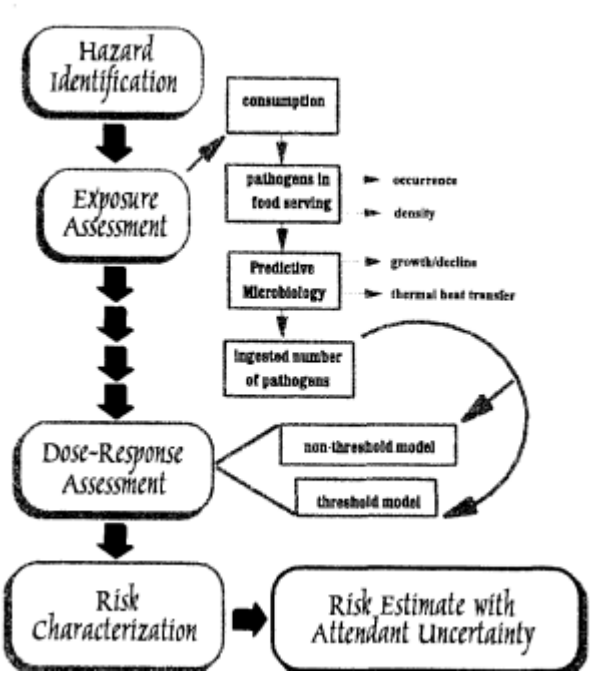

Figure 1.1 represents the Structure of model for microbial risk

Kaplan's risk definition has been modified.

The first aspect of the 1983 NRC framework is Hazard ZdentiJication (HI), which specifies the nature of the problem and the agents that induce unfavourable consequences in a specific situation. Numerous different forms of negative consequences or "end points" might be discussed. Toxicological or epidemiological investigations are used to show a link between a hazard in food or water and a risk to human health.

Nevertheless, identifying a hazard may be contentious, particularly for chemical risk assessments that rely on extrapolation from animal research and may only examine a single chronic "end point."

The second component is E.xposure Assessment (EA), which focuses on modelling the incidence and amount of hazards, as well as the possible ingestion of the hazards in the food, which cause or contribute to bad consequences. An EA would normally involve an evaluation of a hazard in a specific food for certain scenarios describing the food's manufacturing, processing, distribution, and preparation. Also, the EA must evaluate the dietary patterns of the target demographics. This is frequently achieved by reviewing consumption surveys or huge survey datasets, such as the USDA Ongoing

Persons' Food Consumption. Yet, it is frequently difficult to categorise the foods that are surveyed in such a way that they correlate to the categories of foods that carry the dangers.Chemical risk assessment must consider the fact that chemicals in food might alter throughout processing and preparation. To effectively predict exposure, an understanding of the dangerous chemical's food chemistry is required. The worry in microbiological risk assessment is the possibility of ongoing development and reduction of infections in food. Risk assessors are

currently developing methodologies to properly represent chemical changes and microbial growth and decrease. Several technological assumptions for EA are based on extremely little evidence, which stakeholders should be aware of. When a considerable quantity of information is unknown with certainty, simplifying assumptions are frequently used, which may lead to an overestimation of the results' confidence. For example, predictive microbiology, which accounts for the dynamics of microbial development and decrease, is a key differentiating trait for microbial pathogens.

Unfortunately, as of this writing, EA models for microbial pathogens in foods did not explicitly identify strain variability, which can be significant for some bacterial pathogens. Typically, data are only accessible for a few strains or a cocktail or mixture of multiple strains that may differ taxonomically and physiologically from the hazard of interest. Inferences for all strains are drawn from the behaviour of a few strains, with little respect for population heterogeneity.Predictive microbiological models, for example, are supposed to be "conservative" rather than impartial. The utilisation of high quantities of pure cultures of a cocktail or mixture of pathogen strains cultivated under optimum circumstances in complete nutrition broth in the utter absence of competing microflora of foods is one source of bias. In actuality, several factors impact pathogen development that are not explicitly accounted for in the models. Another growing aspect of EA that makes simplifying assumptions is predicting the possibility for person-to-person transmission as well as dietary exposure for specific foodborne illness pathogens.

The third component of the NRC framework is Dosc-Resxmse Assessnwrzt (DRA), which entails modelling the link between the ingested dosage of the hazard and the likelihood and severity of the adverse impact. Dose-response modellers in chemical risk assessment spend a lot of time analysing data from animal studies. Animal studies are rarely employed for microbial risk assessment, but the DRA is mostly based on data from a restricted group of controlled clinical studies in which human volunteers were administered the hazard, generally at high doses. Mechanistic or genetic factors may be used in chemical risk assessment, which may contradict the findings of animal research.

When extending data from clinical or animal research to the low-dose zone, the model form can have a significant impact on the outcome. Another challenge that dose-response modellers must grapple with, particularly in the microbiological field, is the construction of surrogate dose-response models in the lack of data for the hazard of interest. Chemical risk assessors draw conclusions about compounds for which no dose-response information is available based on chemical structures that are comparable to substances for which some information is available. Yet, expertise or information for forming such conclusions appears to be lacking in the microbiological domain. To identify realistic surrogates, questions concerning the structural features of host-pathogen interactions must be addressed. Selection of surrogate dose-response models will continue to be of interest to microbial risk assessors as long as novel pathogenic strains arise and are discovered. The incidence and severity of human foodborne disease at a given exposure or ingested dosage are the dose-response model's outputs.

CHAPTER 3

RISK ASSESSORS

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Risk assessors must underline the difficulty of forecasting the incidence, likelihood, and severity of sickness. Sickness is a complicated function of variability in all parts of the epidemiological illness triangle of host, pathogen, and environment (matrix) impacts, as well as their interactions. Epidemiological monitoring and outbreak studies have revealed a clear relationship between the age of human hosts and the incidence of disease for microbiological risks. Nevertheless, because ingested dosages are unknown, these data are not an acceptable proxy for age dependency in dose-response relationships. Pathogen strains are likely to differ in a variety of ways, including growth, physiology, and the presence and expression of virulence genes. An example of an environmental impact is the fact that fat in meals appears to create a protective habitat for infections, allowing them to live in hostile environments. DRA is surrounded by a great deal of debate.

The fourth component of the NRC architecture, Rkk Charucterizution (RC), begins by integrating the output of the EA models with the DRA models to estimate the frequency and severity of human sickness (the consequence) for certain scenarios. RC frequently use techniques such as Monte Carlo simulation. To assist risk assessors in constructing reliable risk assessment models, principles of good practise for Monte Carlo simulation have been established (Burmaster and Anderson, 1994). The main result of RC is a set of distributions of the frequency and severity of sickness for the relevant subpopulations.

Risk assessors frequently predict sickness for specific subpopulations based on a baseline (as-is) scenario and with interventions or potential system breakdowns. This method connects risk assessment and risk management operations, and it may include defining the notion of comparative risk, comparing simulation results for the baseline (as-is) and many alternative mitigation scenarios most important to policymakers. This sort of study provides policymakers with information about the relative impact of various measures to risk reduction.

The execution of sensitivity and uncertainty studies to establish which variables most significantly impact the uncertainty of the risk assessment is an important analytical part of RC. Another part of RC is validating the model or verifying its prediction abilities. Conventional statistical processes, such as goodness of fit testing and confidence interval creation for predictions, can be applied. Nevertheless, because risk assessment models are frequently complicated, nonparametric validation approaches are utilised. The most effective method of verifying the model is to compare the model's estimations against data from an independent source. The issue is that there are frequently doubts about the reliability of the independent source of data. For example, active monitoring data from the FoodNet programme (USDA,

1998) give some insight into the potential scale of foodborne pathogen disease rates within and across sentinel sites. Yet, interpreting this data presents a number of challenges.

The principles of suitable analysis utilised in the RC, and more broadly in risk assessment, are laid out on pages 100-101 in an excellent book titled Understcinding Risk: Znfumzing Choices in a Democratic Society. The principles are often simple to grasp and comprise the following concepts: Analysis must be consistent with the state of the art; it must be reviewed for correctness; assumptions must be clearly stated; and extraneous assumptions must be rejected. Nevertheless, one standard or concept, "Calculations are published in such a way that they may be examined by those interested in validating the findings," causes some difficulties. There are two significant issues with this principle. The first is that the mathematical and statistical processes utilised are frequently so sophisticated that the findings cannot be confirmed unless the computer code is independently replicated. In practise, most interested parties will be unable to verify the analysis.

A second potential problem with this principle is that managers and risk assessors, in an attempt to adhere to this principle, may simplify procedures and adopt less than state-of-the-art methodologies, contradicting the first principle. Our preferred statement of the principle is that methodologies, including mathematical derivations and justification of statistical procedures, should be presented in a clear and coinplete fashion and in accordance with standard practices of the mathematical and statistical professions. Computer programmes, as well as reported findings, should be made available to everyone who is interested.

Developing Risk Communication

Risk assessment is a highly complex and contentious subject. It is difficult to communicate the conclusions, and actions taken as a consequence of a risk assessment may be contentious. As previously stated, the 1983 NRC portrayal lacked a risk communication component. Because of the intricacies of a risk assessment, the ambiguity of the outcomes, and the high stakes involved in the decisions, distrust among stakeholders and risk analysis specialists may grow. These and other issues are addressed by the National Research Council.

The idea of risk characterisation is broadened beyond the description of mathematical models and statistical studies connected with risk assessment as described by the NRC "red book" (1983). By 1996, NRC personnel saw risk categorization as a decision-driven effort "to improve practical understanding and enlighten practical decisions." As a result, stakeholders should be included in the risk assessment from the start, either directly or through surrogate representations.As a result, the enlarged risk categorization process can encompass social, behavioural, economic, and ethical risk factors. To make risk characterisation relevant to all stakeholders, the NRC includes not only an analytical component of risk characterization, but also a "deliberation" component. Hence, risk characterisation is a "deliberative-analytical" process.

"RC is a synthesis and summary of information regarding a potentially hazardous situation that satisfies the requirements and interests of decision makers and affected parties," according to the new enlarged definition.RC is a step before reaching a choice and is based on an iterative

analyticaldeliberative process." Consequently, risk characterisation is no longer in the realm of risk assessment or in the hands of risk assessment sponsors or managers. RC, on the other hand, becomes a public or political process. The NRC introduces the word "iterative" in addition to "analytical-deliberative." This word is intended to convey that risk characterisation is a two-way street between participants, and that it may include an update to the risk assessment. The above definition depicts an all-inclusive process that appears to be ongoing.

The deliberative process as part of risk categorization is of special importance to us in this chapter. Deliberation entails the interchange of ideas, opinions, comments on the viewpoints of others, and so on. The NRC (1996) defines deliberation officially as "any formal or informal procedure for communicating and raising and collaboratively considering concerns." According to the NRC, "deliberation frames analysis, and analysis informs deliberation". There are two distinct stages of the discussion. Secondly, scenarios must be developed at the start of the risk assessment process, as our concept of risk is conditional on well-defined scenarios. The scenarios should be created with the participation of all parties. The second step involves making decisions based on the evaluation results. A lengthy discussion identifies and discusses the deliberative process's principles and problems.

A deliberative process is rife with disagreement and controversy. The NRC advises enterprises not to shorten the analytical-deliberative process, but also not to postpone necessary decisions under the excuse of needing additional study. In reality, the latter scenario offers a challenge that must be addressed from the start. The NRC provides instances of continuous risk assessments, where continual monitoring may guarantee that the risk assessment's assumptions and theories are true. The initial rulings remain in effect. Yet, risk assessments are frequently well-defined time-limited initiatives. The decision-driven approaches advocated by the NRC would need the use of decision-matrix tables prior to the analysis. Yet, the decision-matrix tables would not limit feasible decisions based on the results. In practice, there must be a clear demarcation point for decision making in the risk assessment. It's not over till it's over, but once it's done, it's over, to quote Yogi Berra. There will be decisions, and the risk assessment may be modified or repeated years later.

This extended idea of RC alters risk analysis managerial frameworks. We've labelled risk characterization with the starting letters "RC," which are also used for risk communication. This dual acronym was not by accident, but was meant to emphasise that risk communication is the heart of risk characterization.

Revised Management Framework

As previously stated, the motive for change tends to be centred on stakeholders who want to understand risk and participate in the risk assessment process. As a result of the broadened idea of RC, the structure of risk analysis has changed to incorporate stakeholders from the start.The picture created by the United States President's Commission on Risk Management. The stakeholders are at the heart of this diagram, with risk management activities around them. This is designed to convey that there is a stake (Figure 3.1).

Figure 3.1: represents the Framework for risk management.

Holders are involved in all phases of the risk assessment. Such a notion lays a significant responsibility on stakeholders to comprehend the risk assessment process and procedures. At the first level, "issue context," the graphic illustrates stakeholder input. In recent years, U.S. agencies have frequently conducted public meetings to explain risk assessment projects and gather data at the commencement of significant risk assessments to achieve this goal. Other stages are depicted in the graphic ("risks," "options," "decisions," "actions," and "assessment"). Because of the highly technical nature of these domains, integrating stakeholders into these activities, particularly the "risks" and "options" activities, provides a problem. Some stakeholder groups may lack the skills and financial resources to engage risk analysis professionals to offer input to these procedures. The onus is on US authorities to encourage a fair and balanced process, especially for stakeholders who cannot afford to retain professional experts to represent their interests. This technique would impose a duty on regulators to offer a fully impartial and transparent risk assessment open to feedback as a result of another source of tension or possible conflict.

Risk Analysis Expansion

The notion of risk analysis has been expanded to encompass debates, improving knowledge, and adopting real solutions. As a result of broadening RC, risk analysis grows to encompass non-risk assessment processes that lead to a better knowledge of dangers and effective strategies for dealing with them. The conditions for doing a full risk assessment are not always completed, yet solutions to concerns are still required. Time, resources, experience, and data available to enable risk assessment modelling constraints may preclude a thorough quantitative risk assessment. The data gaps might be so large that the veracity of a complete quantitative risk assessment is called into doubt.Several typical ways to analysing risks, while not comprehensive risk assessments,

involve risk assessment tools. These techniques, dubbed "quasi-risk assessments," provide managers with practical answers to issues and hence fall under the broader definition of risk analysis. Several of these "quasi-risk assessment" approaches are discussed in more detail below.

"Qualitative Risk Evaluation"

The phrase "qualitative risk assessment" refers to a method of rating or categorising hazards and risks that does not include quantifying risks and associated uncertainties. This word contradicts the definition of risk provided here. A "qualitative" risk assessment is inadequate since it does not account for the possibility of negative effects. Maybe a new word, such as "qualitative risk accounting," would be more appropriate to express a legitimate technique of rating or classifying hazards that does not include risk estimation.

With accompanying ambiguity, utility in problem solving and decisionmaking. An HI would be completed, and portions of an EA and DRA would be addressed, but no quantitative data would be provided (USDA, 1998). For a "qualitative risk accounting," a comprehensive RC as outlined by the NRC (1996) would be impossible.A quantitative risk assessment may have the advantage of identifying the sensitive variables that most strongly impact risk and using them to prioritise a research agenda that may cover critical data gaps.

Although a qualitative risk accounting would not involve such a sensitivity analysis, a systematic discussion and ranking of hazards and risks might give helpful insight as well as plausible "guesstimates" of factors that may be relevant for further research."Worst-case Scenarios" and "Safety Assessment" Another approach, known as "safety assessment" (Wilson, 1999), is estimating "safe levels" of dangers for the entire population. Rather than explicitly assessing "risk with attendant uncertainty," the emphasis is frequently on simplifying default assumptions, epitomised by the application of a series of I0-fold "safety factors," such as for inter- and intraspecies extrapolations and high-to-low-dose extrapolations. For regulating some chemical dangers, government authorities in the United States and overseas have adopted the safety factor method. On the basis of these estimated "safe values," tolerances for chemical levels in food are defined.Another method is to use information from surveys or epidemiological research to determine the "worst-case" level of a danger for a certain amount of product. Standards are created to guarantee that the danger associated with the worst-case scenario is likely to be eliminated from the product. This method implies some knowledge about the "lowest" dose that would have negative implications if consumed. Both of these techniques, although meeting an immediate regulatory requirement, lack the risk quantification that would be included in a risk assessment.

Additional NRC Risk Assessment Framework Changes

The NRC framework can be used to analyse quantitative risk.Nevertheless, as previously noted, the choice to do a "quasi-risk assessment" rather than a quantitative risk assessment may be prompted by a lack of appropriate data for either exposure or dose-response evaluations. The Codex Committee on Food Hygiene proposed replacing "dose-response assessment" with "hazard characterization," a more broad phrase that stresses the significance of qualitative techniques when dose-response data for the pathogen and food of interest do not available for the

populations at risk. Covello and Merkhofer propose replacing "dose-response assessment" with "consequence assessment."

More significant improvements have been proposed that reflect the need for greater interaction between research and policy sectors. Covello and Merkhofer advocated that "hazard identification" be seen as a preparatory step before conducting a risk assessment rather than the initial step. To improve stakeholder knowledge and identify scenarios, hazards must be recognised prior to risk calculations. This technique is compatible with our risk definition and the enlarged risk characterization notion outlined above.

Another variation from the NRC's four-element risk assessment approach from 1983 actually precedes it. An extra step of modelling exposure known as "Release Assessment" was developed in the mid-1970s by the Nuclear Regulatory Commission to mimic unexpected radiation emissions by the nuclear power sector. A corpus of work in probabilistic risk assessment has built detailing unintentional releases of many additional sorts of dangers. The term "release assessment" might apply to chemical spills in animal feeds or bacterial contamination in foods.

The use of a managerial framework to structure the risk assessment process neither validates nor invalidates the approach. Most importantly, the analysis should be based on the best available knowledge and follow essential concepts and criteria. The Codex Committee on Food Hygiene elected not to give a methodological formula for performing a risk assessment, instead providing recommendations that does not limit methodological methods, encouraging the use of the best available knowledge.

Regulatory, Industrial, and International Consequences

As stated in the introduction, risk assessment is a structured, methodical process that connects strong scientific research with policy. The outcomes of a risk assessment, which are projections for certain scenarios of the risk of an unfavourable occurrence with associated uncertainty, would advise the risk manager, who is in charge of developing risk management strategies. Imposing laws that require particular criteria or standards to be satisfied is one viable technique for government risk managers. Nevertheless, in addition to the risk assessment results, the risk manager would examine other considerations such as a cost-benefit analysis when deciding on the right level of standards to safeguard public health. Setting regulatory standards is, in fact, a risk management activity that engages stakeholders in organised discourse through regulatory rulemaking. As a result, the broader idea of risk characterisation is quite similar to regulatory actions. As previously noted, there is a trend towards requiring regulatory requirements to be backed by risk assessments. Assessments can be used to support regulations by comparing a "baseline" risk that occurs when no regulatory requirements are in place to the predicted risk when the regulatory requirements are met.

As previously stated, the information and data required to conduct a thorough risk assessment are frequently unavailable. Nonetheless, there is a compelling urge to intervene for a number of social, ethical, and political reasons. As a result, agencies have developed regulatory standards using a variety of techniques, including the ones outlined above, qualitative analysis, safety evaluation, worst-case scenarios, and other practises, such as grandfathering earlier procedures

that were "safe" based on long-term experience. The application of these relatively ad hoc approaches may result in the implementation of exposure standards that are not directly connected to documented reductions in public health risk. Risk assessments will replace these ad hoc but potentially beneficial techniques as food safety choices become more risk-based. As a result, the facts, assumptions, and technique underlying a risk assessment will be reviewed more closely. As our society shifts away from food systems created just to decrease exposure to risks and towards more risk-based systems developed explicitly to safeguard public health, risk assessment technique will become increasingly important.

Food Safety Regulations

Food safety standards are established by regulatory authorities as part of their regulatory duties. A food safety standard is a description of a certain amount of product that relates, in theoretical probabilistic terms, the distribution of levels of dangerous elements that would offer reasonable assurance that consumers would not be harmed. In the field of food microbiology, for example, a food safety standard would establish, in theoretical probabilistic terms, the distribution of the number of viruses in a completed food product coming from a hypothetical "worstcase" product (USDA, 1999). In the chemical field, a food safety standard may require that the process-average level of a hazard be less than a certain value.

To establish "safety" criteria based on research, one must first understand the dose-response relationships or the maximum quantity of hazardous substance that may be consumed by different human subpopulations in a certain food matrix without causing harm. Knowledge on the minimal "apparent infective dosage" could be extrapolated from food microbiology data produced in outbreak regulatory, industrial, and international implicationsinvestigations of foodborne illness. Real "infective dosage" is affected by several factors, is impossible to test directly in people, and is difficult to quantify. There is no such thing as a single actual "infective dosage" for the whole human population. Infective dosages, on the other hand, are dependent on people existing in specific conditions.

In this way, the infective dosage is determined by the specific circumstance under consideration. Infective dosages for healthy adult consumers, for example, are likely to differ from infective doses for the subgroup of consumers with immunological dysfunction or recent antibiotic administration (which diminishes the protective impact of indigenous GI tract bacteria). Another illustration is that dose-response relationships may alter depending on the dietary matrix. Since bacteria have a greater capacity to thrive in fatty matrices, the same dosages in fatty meals may result in a higher risk of sickness than those in nonfatty foods. Nonetheless, in the lack of understanding concerning dose-response relationships for specific circumstances, some government agencies set food safety guidelines that represent cautious estimates of "infective dosage" for the supposedly most vulnerable individual based solely on expert judgement.

Hazard Analysis and Critical Control Point (HACCP) programmes are emerging as a risk management method in food production, processing, distribution, and preparation systems across the world. H ACCP programmes require the identification of a process's critical control points (CCPs). The Code of Federal Regulations defines a CCP as "a point, phase, or method in the

food process at which control can be applied, resulting in a food safety hazard being averted, eliminated, or decreased to acceptable levels." The risk manager establishes the acceptable degree of safety such that product usage is connected with a reasonable assurance of no damage (safe or unadulterated). The USDA is using HACCP as a regulatory instrument in order to correctly assign tasks and give flexibility in production methods. As a result, under HACCP rules, enterprises must identify CCPs and set process "control limits" for them. These "control limits" are used to assess the processing's efficacy, or if the process is under control enough for the result to be "safe." HACCP appears to be a merger of risk management and task control in this sense. The inputs for the initial aspects of risk assessment (hazard identification) and HACCP have some commonalities (hazard analysis). For example, hazard identification and hazard analysis may both take into account data from epidemiological studies that show risk factors, food vehicles, and connections.The hazard analysis produces a description of the harmful substances, their amounts, and how they may enter the product. The purpose of processing would be to control the danger for the end product so that it meets a food safety standard set by government regulation. After this is completed, the establishments would identify the CCPs of the process that, if managed, would control the danger and result in a product that fulfils the food safety standard. To identify what it means to "be in control," the institution must create processing objectives or criteria for the CCP, as well as process control mechanisms for determining whether or not the processing objectives are reached. As previously indicated, risk assessment might be utilised to define the food safety standard that would serve as an aim for developing a HACCP plan.

Therefore, the HACCP "safe" standard may not be risk-based. Conversely, identifying a "safe" product is sometimes a subjective decision based on previous traditions, such as excellent agricultural or industrial methods. As a result, these techniques may become acceptable for excellent manufacturing and be implemented into the HACCP plan. Instead, the "safe" conclusion might be based on the use of a "quasi-risk assessment" approach, such as one of those outlined above. A frequent approach in process design would be to believe that merely decreasing exposure is enough to produce a "safe" product. This method may lead one to believe that infrequent samples exhibiting detectable quantities of a danger do not always imply that the product is harmful. As a result of this somewhat erroneous logic, production procedures that minimise exposure but do not deliver the lowest-risk product possible may become acceptable.

After a food safety standard is created, enterprises must select their own processing techniques to meet the food safety standard, according to the HACCP regulatory concept. In practise, businesses may be unable to create processing techniques that ensure a "safe" product.As a result, in addition to requiring a HACCP plan, US agencies are setting acceptable "process performance" targets for chosen control stages (USDA, 1999). The regulatory process performance objectives assume just the most basic procedural limitations. A process performance goal for a thermal treatment control step, for example, would require the process to achieve a theoretical s - log,, relative reduction of certain pathogens on raw product that has not been temperature abused or handled according to some acceptable handling procedures prior to the control step. In this example, the government is detecting hazards and determining the control step and processing goals for the control phase. The establishment is still responsible for

the process control processes and control limits that ensure the process achieves the process performance target. Furthermore, the authorities give compliance recommendations to help the industry meet the process performance target.

Risk assessment can provide light on potential dangers associated with certain manufacturing processes. Risk assessments or other quasi-risk assessment techniques undertaken by government agencies, on the other hand, frequently estimate probable risk that represents the output of the sector as a whole. We underline here that the risk assessment in this application is dependent on the processing scenario, which specifies the handling or processing of the product before it enters the control step and after it leaves the control phase. Based on this evaluation, a food safety standard and associated process performance objective for the control step are defined. The process performance objective is established in such a way that, in a given situation, the product generated at the control phase of a process that meets the process performance goal would meet the food safety standard and so be regarded "safe." To meet the process performance target, establishments must design their processes for the stated control step, taking into account product handling before and after.

Nonetheless, an establishment may be able to regulate its process by the use of incoming material certifications or other means to create a product that meets the food safety standard, even if their process does not reach the regulatory process performance objective at the stated control step.That is, an institution may be able to regulate the process preceding and following the control step more effectively than the level of control expected by the government when defining the process performance target. Furthermore, an institution can build specific knowledge about its product in order to create procedures that ensure the end product meets food safety standards even if the process performance target is not met. As a result, producers may be able to create alternate process performance targets that ensure the end product meets the needed food safety standard.

A risk assessment that properly simulates the processes, including storage, heating, and cooling processes, would give establishments with information that would assist them in defining CCPs and processing goals for the CCPs. In general, a good risk assessment model would enable businesses to develop procedures based on food safety requirements more efficiently. In reality, a comprehensive risk assessment would yield risk estimations and associated uncertainty for several processing scenarios, from which CCPs and control limits might be constructed (Zwietering and Hasting, 1997). The progress of risk assessment and HACCP will be critical in the establishment of risk-based standards that minimise not just exposure but also risk.

International Initiatives

Considerable emphasis has been placed in the United States and internationally on risk assessment definitions, concepts, and standards. The World Health Organization (WHO) and the Food and Agricultural Organization (FAO) are two main international agencies in global food safety (FAO).

CHAPTER 4

FRAMEWORKS FOR RISK ANALYSIS OF CHEMICAL AND MICROBIAL HAZARDS

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Both organisations take part in the Codex Alimentarius Commission's debates (CAC). The CAC's 163 member nations participate to the work of different committees that generate worldwide consensus documents for assessing and managing risk, such as the Codex Committee on Food Additives and Contaminants (CCFAC) or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Since 1956, JECFA experts have produced Acceptable Daily Intakes (ADIs), Provisional Tolerable Weekly Intakes (PTWIs), and other end points for over 700 chemical risks in foods. JECFA advises the CCFAC on the appropriate numerical standard level for various chemical risks. This suggestion may lead to the CAC's adoption of Maximum Residue Limits (MRLs) or Maximum Limits (MLs) as globally recognised standards for public health protection. In addition, the CAC has issued standards regarding radioactive dangers in foods. The FAOIWHO is also creating an advisory group, similar to JECFA, to address scientific concerns associated in establishing guidelines for microbial dangers in foods for international commerce.

The United States or any other country may choose to establish criteria for foods consumed by its citizens that are more or less protective than those recommended by Codex (WHO, 1998). Disputes may emerge between nations that trade in a food item but impose differing standards or degrees of protection for their populations, particularly where Codex restrictions do not exist for specific dangers. The World Trade Organization (WTO) is the organisation that settles international trade disputes. Article 5 of the Sanitary and Phytosanitary Measures Agreement (SPS) stipulates that sanitary measures to safeguard public health must be accompanied by a risk assessment that takes "into consideration risk assessment procedures developed by the relevant international organisations." Hence, on a global scale, the establishment of standardised procedures and risk assessment tools remains critical.

The Codex Committee on Food Hygiene (CCFH) is working on essential texts concerning international food safety and microbiological dangers.Documents have been created to cover various risk assessment and risk management frameworks. The first risk assessment document, "Principles and Guidelines for the Conduct of Microbiological Risk Assessment" (CCFH, 1998), was completed in less than three years after the first discussion paper was developed. A draught document based on the FAOIWHO Consultation on Microbiological Risk Management (1996) is currently in the Codex process. Although these texts recognised the importance of risk communication as a component of risk management, they do not go into detail about the

interactive parts of risk analysis (assessment, management, and communication) articulated by the NRC and explored in this chapter. Presumably, future Codex Committee debates will address the tensions and interconnections associated with risk analysis for both microbiological and chemical dangers.

Another recent development reflected in the Codex discussion paper on risk management is the concept of "Food Safety Objective" (FSO), defined as "a statement based on a risk analysis process that expresses the level of hazard in a food that is tolerable in relation to an appropriate level of protection." However, at the time of publication, this FSO definition did not represent a consensus stance. Additional refinement of the meaning of words in this definition, as well as techniques for determining FSOs, are required. As stated in this chapter, the use of risk analysis to design rules and food safety goals is in its early stages. The openness of the analytical-deliberative risk analysis process, as explained in this chapter, is required to discover solutions to global food safety challenges.

Current and Future Consequences

There are several management frameworks available to help with risk analysis methods for chemical, biological, and physical risks in food and water. The choice of any particular framework may be less significant than a commitment to the application of sound science in risk assessment and adherence to risk analysis principles and standards. Transparency in both the risk assessment and risk management processes, for example, is critical for boosting the chance of a viable risk management plan and securing public approval of the approach. Thorough documentation is essential for identifying the points in the risk assessment where policy decisions, assumptions, and extrapolations beyond scientific evidence became inputs or limitations to the risk assessment model.Nonetheless, an engaged and active public is required to achieve successful risk assessments. Risk assessment is essentially a political process; the ultimate responsibility for a society's quality of life rests with a well-informed citizenry. As a result, this chapter has gone full circle, with the duty for providing safe food resting on individual dedication. The opening speech, which quoted Deuteronomy, obligated everyone to take responsibility for removing risks. If dangers were disregarded, regardless of whether anybody was wounded, the individual was guilty of allowing a danger to exist. Every member of society is required to become aware of and participate in discussions regarding risk and risk management. The rest of this book is a modest start for this quest.

Dose-Response Modeling For Microbial Risk

The Dose-Response Relationship's Role

The dose-response relationship is the function that relates the predicted pattern of exposure to the expected amount of adverse effect in microbial risk assessment. In general, the estimated proportion of a population that would experience a risk of a certain result (p) is expressed as a function of the average dose (d) supplied to that population, i.e. As a result, the pattern of exposure must be defined as an input, and the specific consequenceor outcomes to be estimated must be specified.Although human 'trials (volunteer participants fed controlled doses of organisms) provide dose-response information for some infections, only animal data are

available for others. Even if human feeding research data are available, the residual level of risk needed for public health protection is significantly below the lowest dosage administered, necessitating the adoption of a dose-response model to give this extrapolation.

Multiple Exposure vs. Single Exposure

All currently known human or animal feeding experiments have employed single (bolus) doses and have been monitored for adverse consequences. Several exposures may occur in actual exposure circumstances, for example, at separate meals or by different channels (food, water, touch, etc.). To use dose-response models based on bolus doses to these later cases, an assumption about how many exposures and doses may interact to generate is required**.**

Historical Significance and Background Information

Outcome Selection vs. Disease Progression

Individuals in a community exposed to an infectious agent will demonstrate a succession of effects. Those who are infected may be symptomatic or asymptomatic; a part of the symptomatic (sick) persons may subsequently display a range of severities, with a tiny percentage of the results being fatal. It is critical to focus on the result(s) of interest when employing a dose-response model, or to combine a model for infection as an outcome with additional data on illness progression probabilities as a function of dosage.

Haas, Rose, and colleagues provide a full discussion. In many microbial dose-response analyses, infection is employed as the end point because it provides a common point from which other outcomes emerge. Furthermore, it has been suggested that public health protection based on infection as a result provides some conservatism for the protection of more vulnerable subpopulations. As a result, the next discussion will concentrate on dose-response modelling using infection as an end point.

Scientific Background and Implications

Infection Onset Processes

If a dose-response model is to be mechanistic, it must account for various aspects of the infection process. Secondly, there is variation in the number of organisms absorbed by individual individuals, particularly at low averuge dosages provided to a population. In other words, not all members receive the same dosages.

After ingesting one or more organisms, a birth-death process occurs in which organisms may survive to colonise and multiply or may be destroyed from the host before proliferation. These two processes can be coupled to provide physiologically grounded dose-response correlations.

Scientific Background and Implications

A dose-response model's fundamental properties, as seen above, can be expressed in a simple relationship. A variety of particular dose-response models may be generated from this overall connection.

Models based on empirical data

A dose-response model has the same basic mathematical structure as a cumulative probability distribution function (cdf) computed over the positive real line. As a result, any cdf can be investigated as a dose-response function; nevertheless, such

Problem of Low-Dose Extrapolation

A same data set may suit many dose-response models. Most data sets, particularly when human subjects are involved, test a small number of participants per dosage, and the average doses employed are very high (usually to achieve an expected proportion of responses greater than 10%). Many alternative dose-response models may produce adequate fits and look relatively comparable within the range of observation under these conditions; nevertheless, when these models are used to extrapolate to lower doses, they may provide significantly different estimates of risk for the infectivity of different nontyphoid strains of Sulrnonellu fit to the beta-Poisson and three empirical dose-response models. The original data may be found in the report by Haas, Rose, and colleagues (1999). The fit adequacy of the four models is almost equal (the beta-Poisson model produced the highest match and is the only mechanistically coherent model investigated). The experimental data has a high degree of dispersion (due to the limited number of people at most dosages); yet, the fit of the data to all of the models is quite comparable throughout the dose range studiedYet, when the best-fit parameters for the models are applied to compute the dose-response predicts the lowest risk (at low dosage), whereas the Weibull model calculates the highest risk—however, the relative ranking of models will vary depending on the data set.

Implications Regulatory, Industrial, Or International

Model Validation

Validating a dose-response model entails gathering information on real human exposure during an outbreak (e.g., average number of organisms swallowed) as well as attack rate. The exposure data is then utilised to calculate a predicted attack rate based on the dose-response curve (derived from feeding studies), and the coherence with the measured attack rate is investigated. According to Fontaine *et al.* (1978), the likely inoculum size, following a 1- to 2-log reduction after freezing, would still place the infecting concentration between 60 to 2,300 organisms per 100 g.

Microbial Risk Dose Response Modeling

This is about four orders of magnitude lower than the lowest provided dosage in the human feeding experiments.Using this dosage estimate and the best-fit parameters for the dose-response relationship, the predicted daily risk is calculated to be 2.5. lop4. This is around one-third of the reported assault rate. Considering the uncertainties in epidemiological measurement (case underreporting, period of exposure) and exposure assessment, the predicted and observed attack rates are in agreement.Dose-Response Parameters That Are AvailableMany dose-response parameters for bacteria, viruses, and protozoa transmitted via the fecal-oral route have been determined to date. Haas has listed a few of these.

Current and Future Consequences

The subject of microbial dose-response modelling is still active and promising for future research. There are several areas where progress is being done and will be made.

Pathogens with no human dose-response information are likely to arise and may never become available. In these circumstances, animal models may be required. In the cases of E. roli 0157:H7 and Listeria monorytogenes, the use of animal data to estimate human potency is plausible.Further research with different organisms is required to obtain expertise with transspecies extrapolation for microbial risk assessment.As previously stated, the assumptions for handling multiple exposures are based on independent behaviour. This must be rigorously explored, most likely utilising animal models for specific drugs. Animal model studies to evaluate changes in infectivity.

Introduction and Definition of Issues

Bacteria may live for only a few hours or for lengthy periods of time in foods where growth is not permitted due to acidity or salt (months). Population fluctuations of this scale impact the chance of sickness when the meal is ingested. Because of the possibility of periodic population expansions or declines, exposure evaluation is an important component of bacterial risk assessment.Microbial risks are currently thought to be acute and the result of a single exposure. Although there is growing interest in the consequences of many foodborne bacteria, there is currently inadequate data to simulate these illnesses. Similarly, regular exposure to low numbers of Sulnionellue or Listerill monocjtogerzes may influence their infective dosage, although there is yet no solid proof

Modeling

Microorganisms have predictable behaviour, which may be explained mathematically. This approach underpins microbiological modelling and risk assessment. Although qualitative predictability was previously acknowledged, and microbiological procedures, models, and statistics were available prior to the mid-1980s, the introduction of personal computers enabled quantitative treatment of microbiological data. Models enable the measurement of interactions between various environmental elements as well as the interpolation of combinations of parameters that have not been explicitly evaluated. Microbial modelling has gained popularity as a result of the inability to conduct inoculated pack studies for every food and situation of interest, the need to provide quantitative scientific support for HACCP programmes, the farm-to-table concept for food safety, the desire to allow industry more flexibility in designing food processes, and increased international trade in foods.

Microbial models for foods are often descriptive rather than based on biological principles (mechanistic models) due to the complexity of biological processes and the requirement to include easily observable factors into the models. In contrast to fermentation models, which simulate growth or metabolite synthesis in response to substrate levels, models typically contain environmental conditions like as temperature, pH, and salt level as variables.There are three stages to the modelling process. The first (primary) level is a mathematical equation that

represents the change in microbial populations over time in a single, constant environment. Parameters from this level include the linear drop in the logarithm of the population with increasing heating periods (the D value) and the exponential growth rate, p.

These D or p values are temperature, heating menstruum, organism strain, and other environmental and physiological parameters particular. The second level of modelling (secondary) depicts how the first level's parameter values vary when the environment changes. For example, the z value connects the change in the D value (time for inactivation) to the heating temperature.Because these equations are difficult to solve, the third (tertiary) modelling level consists of computer programmes that store the equations, receive desired input values, and calculate and show predicted microbial behaviour.

This level might include basic spreadsheets with an equation, sophisticated software programmes like the USDA Pathogen Modeling Program or the UK Food Micromodel, expert systems, and risk assessment-simulation models.Microorganisms in food can multiply, live, or die. A unit operations technique is used to simulate a whole food process, preferably from raw materials to a consumer's table. Each stage is examined individually, and a suitable growth, survival, or inactivation model is used to that phase.Shifting circumstances can be divided into small times that can be deemed unchanging. The outputs of one phase are used as inputs for the next.

Scientific Background and Implications

1. Models of Development
2. Microbial development is divided into three stages: lag, exponential growth, and stationary growth.

Another model for describing microbial development is the linear model. It features a lag phase that represents the time when the cells adjust to their new surroundings. A distribution with mean and variance describes the times for individual cells to adapt. Once a cell has completed the lag phase, it reproduces exponentially.Where /I is the duration of the lag phase and,u is the exponential growth rate (log units/h).The curvature observed between the lag and growth phases is a cultural feature resulting from the cumulative amount of daughter cells as the inoculum cells exit their lag phases, not from individual cells speeding their growth rate.The majority of cells in a developing culture are the daughters of the first cells to shift from the lag to growth phase.

At this time, no comparisons have been conducted between these three methods to secondary level modelling.Tertiary level modelling is demonstrated by the USDA Pathogen Modeling Program. The Gompertz and regression equations are used in the growth models. This spreadsheet-based software allows users to choose the organism of interest, input environmental data, and calculate expected lag times and generation times, as well as view a growth graph.

Cells in the exponential growth phase adapt to their new environment the fastest, but stagnant and starving cells take longer, and desiccated cells take the longest. Cells that were transferred with little temperature change, or transported to warm temperatures, have shorter lag periods than cells that were cultivated at warm temperatures and transplanted to cool temperatures. The bulk of the food and the insulating effect of the packaging slow the pace of temperature change

in many food processing conditions, and the bacteria constantly respond to the changing temperatures without entering a lag phase.

Models of Inactivation

Thermal death models are the most often used inactivation models, however other microbial killing processes are also studied. Modeling is possible for irradiation, pulsed electrical fields, and ultrahigh pressure. The basic thermal death model was created for retorted foods in the 1920s and has been successfully adapted to various pasteurised and nonthermal processes, including calculating inactivation durations for Clostridiurn hotulinuni spores. It is expected that the decrease in the log number of surviving organisms is linear with treatment time. The D number is the time required for one log unit of inactivation at a certain temperature and other circumstances and Nt are the cell populations at time zero and time t. The slope of the linear change in the logarithm of the D value with heating temperature is the z value. Thermal inactivity, on the other hand, has been found to be nonlinear in some instances, notably at pasteurization temperatures. Curvature is possible using an exponentially damped model.Where iL is the damping coefficient, the value of which is affected by the microorganism, environment, and temperature.

Another possible reason for this pattern is that the culture comprises cells with varying D values. The rising slope indicates the more resistant (higher D value) cells as the more easily destroyed cells (lower D values) are eliminated from the culture by heating. A population dynamics theory combines first-order (linear) mechanisms for quick inactivation of less heat-resistant spores, activation of survivors to a heat-sensitive condition, and subsequent inactivation. The combination of these steps' rate parameters leads in nonlinear survival curves.While constructing thermal and other deadly processing methods, linearity in thermal inactivation has been assumed. The targeted inactivation of microbes in food extends below population levels detectable via experiments, necessitating extrapolation from inactivation results at high inocula.Should research definitively show instances of nonlinear inactive? Inactivation calculations (modelling) will grow increasingly sophisticated as time goes on. Cells that have acclimated to high growth temperatures, low pH, or high-salt conditions will also need to be accounted for in future models. Thermal survival in these cells is usually seen to be higher than in unadapted cells.

Models of Survivability

Survival models are used to study microorganisms in conditions that do not allow them to develop but allow them to survive for periods ranging from hours to months. Refrigerated and semi-preserved foods with low water activity, high acidity, or high salt levels, for example, refrigerated fresh orange juice (low temperature and pH), yoghurt (low temperature and pH, lactate ion), and salami (low pH and water activity, lactate, salt) are examples. Survival modelling and inactivation are comparable; inactivation is a more active rather than passive process, and the time duration is often seconds and minutes rather than days to months. Primary level data graphs may exhibit a linear drop similar to thermal inactivation plots. They may also exhibit lag or shoulder

Nevertheless, if a diet has another component that inhibits microbial development, such as high lactate concentrations or low water activities from other humectants, the model may be ineffective in generating predictions for that food. Models estimate values within the ranges of the components employed in the model's creation. Extrapolating outside the data range may result in inaccurate estimations. Particularly for empirical models. Before completely accepting a model's predictions for usage in a specific food of interest, it is necessary to compare the behaviour of a pathogen in that food under a few situations.

Cocktails with three to six bacterial strains are often used to create models. According to research, various strains of the same virus have vastly varying survival and heat inactivation durations, as well as growth properties..Lactic acid-producing flora can lower pH levels, and many microbial species create bacteriocins, which impede the development of other organisms. The extent to which the comparatively low levels of natural flora on high-quality foods influence the low quantities of pathogens that often appear in contaminated food is unknown.

Models that are deterministic versus models that are probabilistic

The preceding models are determinative or point estimate models. They compute the predicted mean number of microorganisms under specific conditions. Yet, when growth circumstances deteriorate, the growth rate falls and the variance around the mean rate rises. Also, the possibility of growth reduces at the extremes of adverse circumstances. If a sequence of identical tubes are incubated at progressively lower temperatures, the tubes at the higher temperatures will all grow. Certain tubes will not develop at lower temperatures, even after extended incubation durations. When the temperature drops approaching the minimal growth temperature, just a few tubes in a set will develop. To define predicted growth in the low-temperature range or other severe conditions, fLilly requires both a growth rate and a probability of growth model. In addition to environmental influences, the likelihood of growth is highly reliant on depending on the amount of cells present. An aliquot having a large number of spores is more likely to proliferate than an aliquot containing only a few spores. This scenario was investigated in C. botulinum time-to-turbidity models and growth-no growth boundary models.

The model depicts the projected microbial population at the conclusion of the procedure and highlights which phases permit growth. With this data, the food technologist may alter processing factors such as spice microbiological quality or temperature, and evaluate the change in microbial counts at the conclusion of the process. The procedure can be structured to provide an acceptable product with information on the occurrence of a pathogen in the raw ingredients and the determination of the food safety objective (the frequency and amount of pathogen found to be acceptable in the product). A similar model predicts the growth of Bacillus cereus cells during the vacuum-packing of cooked potatoes.

Using solitary input parameter values, the deterministic beef patty and cooked potatoes process models compute single values for each stage in the process.This method ignores the inherent variability and uncertainty in both process inputs and model outputs. Variation refers to true differences in a metric, such as distinct strains of a microorganism having varied growth rates and D values. Each strain might be defined, but because it is uncertain which strain will be

present in a diet at any particular moment, a single growth rate or D value cannot adequately represent what will happen in the future. Similarly, when heat processes decrease the number of pathogens in a package to a handful or less, their recurrence in that package is often determined by binomial and Poisson distributions.

The variance in thermal inactivation of microorganisms in food can be minimised by redesigning the process or equipment; greater control of the oven temperature would lessen the variation.

Our lack of information is referred to as uncertainty. This uncertainty can be reduced by more exact or broad measurement and monitoring. Estimates for the amount of time an egg spends in a retail store or the degree of Sulmonellu inactivation during home cooking of an egg are two instances of considerable uncertainty.In actuality, most parameters in microbiological models contain both variance and uncertainty.

Due of variance and uncertainty, each parameter has a range of values that it may attain in any given situation. This distribution can be characterized by a number of functions, such as normal, log normal, exponential, beta, or triangular, as well as the relevant parameter values, such as mean and standard deviation. Distributions are typically skewed, having more occurrences at one extreme than the other. A frequency graph that merely presents experimental data may also be used to illustrate distributions.

Each parameter input value in each unit action has a distribution, such as temperature, time, food pH, and microbial growth rate. Monte Carlo simulation is a method of computing a model using many distributions. The simulation will select a value for each distribution, calculate each model, and walk through the full process operation step by step.

The simulation model iteratively calculates the procedure. Each iteration will select a value from the distributions of input values. These distributions will tend to cluster around the mean value, but they will also represent the range of possible outcomes based on the shapes and ranges of the individual input

In conjunction with risk management, the risk assessment will examine the whole process from raw materials to consumption and design a set of process steps that fulfil the food safety aim. The risk managers will next choose the specific procedure to be employed, taking quality, cost, and feasibility into account. The chosen process risk assessment outlines what each step will accomplish, such as 7 log, units of inactivation or less than 1 log, unit growth. They are referred to as performance criteria. Similarly to the overall process, there may be several ways to meet a given performance requirement. Several time-temperature combinations, for example, can result in inactivation of 7 loglo units. The particular mix will be chosen depending on quality, cost, engineering, and other factors. The precise combination chosen is referred to as the process criteria, and it serves as the essential control points.

The modern process of food chemical risk assessment is highly sophisticated and frequently contentious. Many assumptions are typically necessary in both determining exposure and determining safe levels of exposure. These assumptions are usually based on legislative mandates and/or regulatory agency policies, and they frequently lack a sufficient scientific

foundation. Using different sets of assumptions on exposure or acceptable levels might result in substantially disparate risk estimations that are often conveyed in the public sphere. Substantial changes are required to increase the accuracy of food chemical risk assessments, and this chapter discusses many of the current trends to improve the process.

CHAPTER 5

EXPOSURE AND DOSE-RESPONSE MODELING FOR FOOD CHEMICAL RISK ASSESSMENT

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Despite the fact that some kind of risk assessment has been used to aid regulatory authorities in making choices concerning chemicals in food since the early 1900s, the discipline of chemical risk assessment is still in its infancy and is expanding fast. In the United States, the first complete standards for undertaking chemical risk evaluations were released in 1983. The risk assessment procedure was divided into four components, according to these guidelines:

1) Hazard identification,

2) Dosage response evaluation,

3) Exposure assessment, and

4) Risk characterization.

Several improvements to the risk assessment process have been made since the publication of this report, but it continues to serve as the foundation for modern risk assessment approaches for food chemicals such as pesticide residues, food additives, naturally occurring toxins, hormones, antibiotics, environmental contaminants, and even novel products derived from food biotechnology applications.

Pesticide residues in foods have regularly been implicated in advances in food chemical safety risk assessment. A National Research Council study proposed several revisions to the risk assessment policies used by the United States Environmental Protection Agency (EPA) to establish the acceptability of pesticide residues in the food supply. This study recommended, among other things, that the EPA investigate the possible sensitivity of newborns and children to pesticide residues, as well as the population's exposure to pesticides through water and residential sources, in addition to food sources. The study also suggested that risk evaluations be conducted for families of toxicologically related pesticides whose effects are caused by a similar mechanism of action rather than on a chemical-by-chemical basis.

When President Clinton signed the Food Quality Protection Act (FQPA) in 1996, several of these suggestions became law. The EPA was required by law to employ certain risk assessment methodologies. The "lox factor," which requires the EPA to consider applying up to a 10-fold additional uncertainty factor to provide greater protection for infants and children, the "aggregate exposure" provision, which requires exposure to be calculated from food, water, and residential exposure, and the "cumulative exposure" provision, which determines risks for families of

chemicals whose members share a common mode of toxicological action.Ironically, the FQPA arose not from documented cases of excessive pesticide residue exposure, but rather as a legislative "fix" to the anachronistic 1958 Delaney Clause, which, based on recent legal decisions, called for the elimination of many pesticide uses on statutory grounds rather than health risks.

The FQPA rules bring substantial new challenges to the scientific community and will assist influence the methods for determining the dangers from all sorts of chemicals in food, including pesticide residues.Estimating exposure to food chemicals necessitates knowledge of both the amount of chemical in food and the volume of food ingested. The fundamental algorithm for food chemical exposure is as follows:

Food Consumption x Residue Level = Exposure

In the instance of a chemical that is present on many food commodities, the estimated exposure would be the total of all individual commodity exposures.

Simulation of Deterministic Exposure

Previously, exposures were typically calculated using a "deterministic" technique, which assigns finite values to both food consumption and residue levels in order to obtain a "point" estimate of exposure. A detenninistic exposure estimate for pesticide on commodity X, for example, would need knowledge about pesticide A residue levels and commodity X food intake. Often, the amount of pesticide A may be set to reflect a maximum legal or maximum detectable level rather than a more normal value when using a cautious approach that is unlikely to underestimate exposure. Commodity X food consumption might be chosen to reflect the per capita mean consumption or a higher level, such as the upper 95th percentile of consumption. The residue and food intake levels used are typically, but not always, exaggerations of average values, leading to computations of worst-case or unrealistic exposures (Archibald and Winter, 1989). Such deterministic techniques are useful when the worst-case exposure estimations are still regarded to be well within acceptable ranges, because adjustments to increase exposure assessment accuracy are not required. Deterministic techniques also allow for modifications such as replacing "expected" residues for maximum legal residues; this approach may frequently push exposure estimates below thresholds of concern. Regrettably, worst-case exposure scenarios are frequently given without regard for the potential degree of exaggeration, which can lead to an inflated impression of danger (Winter, 1994).

In practise, deterministic approaches for predicting long-term (chronic) pesticide exposure in food use more realistic estimates (i.e., average residue, median per capita daily consumption) than approaches for predicting short-term (acute) exposure (i.e., maximum legal or detected residue, upper 95^{th}or upper 99^{th}percentile consumption).

Modeling Exposure and Dose-Response for Food Chemical Risk Assessment

A deterministic methodology is still the best way for determining chronic exposure. Nevertheless, for estimating acute exposures, deterministic procedures are frequently being

superseded by "probabilistic" approaches that take use of advances in processing capabilities and are significantly more data expensive than deterministic methods.

In the actual world, neither residue level nor food consumption statistics exist as single numbers, but rather as distributions (Petersen, 2000).

Testing pesticide X on commodity A, for example, would most likely show that the majority of samples had little or no detectable pesticide X residue, while a smaller percentage has intermediate levels and an even smaller percentage has high residue levels. A similarly shaped distribution curve may be imagined for commodity A's daily consumption level; on most days, the commodity may not even be consumed, and moderate use of the commodity is more likely than high consumption.

Probabilistic techniques make use of our present computing skills to merge all of the data in the residue distribution with the food consumption dala to create a daily exposure distribution. This strategy is commonly referred to as a Monte Carlo simulation model, while probabilistic approaches can be carried out in a variety of ways using various types of data, algorithms, and assumptions.In the simplest scenario, a Monte Carlo study would randomly choose a residue to estimate acute exposure from a single pesticide on a single product.

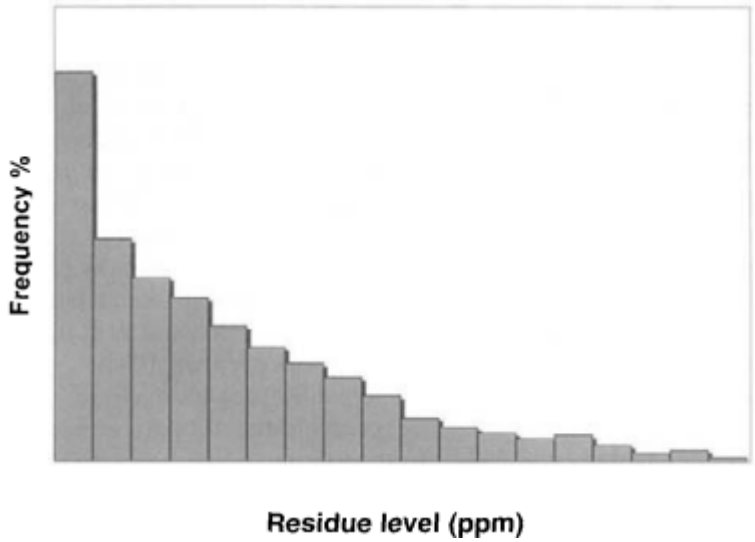

Figure 5.1 Food residue distribution

Issues Introduction and Definition

Chemicals in food may provide possible health concerns to consumers if consumer exposure to that same chemicals exceeds levels judged to be health-threatening. The key components underlying food chemical risk assessment are the determination of permissible exposure limits and the calculation of possible exposure to chemicals in food. The results of risk assessments strongly impact regulatory decisions about the current or future use of substances that may reach the food chain. Risk evaluations are also used to inform conversations among food and agricultural sectors, as well as consumer and environmental organizations, about the sufficiency of existing food chemical laws.

The modern process of food chemical risk assessment is highly sophisticated and frequently contentious. Many assumptions are typically necessary in both determining exposure and Pesticide residues in foods have regularly been implicated in advances in food chemical safety risk assessment. A National Research Council study (NRC, 1993) proposed several revisions to the risk assessment policies used by the United States Environmental Protection Agency (EPA) to establish the acceptability of pesticide residues in the food supply. This study recommended, among other things, that the EPA investigate the possible sensitivity of newborns and children to pesticide residues, as well as the population's exposure to pesticides through water and residential sources, in addition to food sources. The study also suggested that risk evaluations be conducted for families of toxicologically related pesticides whose effects are caused by a similar mechanism of action rather than on a chemical-by-chemical basis.

When President Clinton signed the Food Quality Protection Act in 1996, several of these suggestions became law. The EPA was required by law to employ certain risk assessment methodologies. The "lox factor," which requires the EPA to consider applying up to a 10-fold additional uncertainty factor to provide greater protection for infants and children, the "aggregate exposure" provision, which requires exposure to be calculated from meals, water, and residential exposure, and the "cumulative exposure" provision, which determines risks for families of chemicals whose members share a common mode of toxicological action.Ironically, the FQPA arose not from documented cases of excessive pesticide residue exposure, but rather as a legislative "fix" to the anachronistic 1958 Delaney Clause, which, based on recent legal decisions, called for the elimination of many pesticide uses on statutory grounds rather than health risks. The FQPA rules bring substantial new challenges to the scientific community and will assist influence the methods for determining the dangers from all sorts of chemicals in food, including pesticide residues.

Modeling of Probabilistic Exposure

In the actual world, neither residue level nor food consumption statistics exist as single numbers, but rather as distributions. Testing pesticide X on commodity A, for example, would most likely show that the majority of samples had little or no detectable pesticide X residue, while a smaller percentage has intermediate levels and an even smaller percentage has high residue levels. In the simplest scenario, a Monte Carlo study would randomly choose a residue to estimate acute exposure from a single pesticide on a single product.

The FQPA mandates that risk evaluations for pesticide residues be based on "existing evidence about the cumulative effects of such residues and other chemicals that have a shared mechanism of toxicity on babies and children." This FQPA clause is based on the NRC study, which found that children may be exposed to various pesticide residues that have a cumulative harmful impact.As an example, the reference chemical for a toxicologically related family of pesticides (probably the one that has received the most attention) would be picked. The TEF would be determined by comparing the potency of other family members to that of the reference chemical. If the chemical in issue is two times more potent than the reference chemical, the TEF is two; if the chemical in question is one-half as potent as the reference chemical, the TEF is 0.5.

Cumulative pesticide exposure might be calculated by multiplying the actual amount of each pesticide residue by its TEF and then adding the findings for each pesticide.

The NRC report presented a concrete illustration of this strategy. This example investigated five organophosphate pesticides, all of which are thought to have a similar mechanism of harm via cholinesterase enzyme inhibition, and their existence on eight foods and three juices often found in babies' and children's diets. TEFs were determined relative to the pesticide chlorpyrifos in this case using NOAEL values for cholinesterase enzyme action.

As previously stated, the value determined for the NOAEL is dependent on experimental design decisions such as dosage levels, test species, and routes of exposure. As a result, comparing such numbers to develop TEFs is fraught with risk. The NRC example included NOAELs generated from animal studies as well as NOAELs derived from people. Comparing RfDs for various chemicals to derive TEFs introduces additional uncertainty since this RfDs are based on both the NOAELs and the uncertainty factors utilised. Curiously, the EPA has ruled that the extra lox factor should be preserved for methyl parathion, although its near chemical cousin, ethyl parathion, which is structurally identical with the exception of 2 additional methylene groups, does not. In circumstances when there are considerable disparities between the NOAEL and the LOAEL, the experimentally measured NOAEL may not be a good approximation of the "real" NOAEL; such errors are amplified when NOAELs of various compounds are compared to determine TEFs.

The EPA defines a "point of departure" as a dosage or exposure level estimate that is used to depart from the observed range of empirical response (or incidence) data in order to extrapolate risk to the human population (EPA, 2000b). Because the NOAEL is a single arbitrary dosage, the EPA prefers to utilise a "effective dose," which is basically equivalent to a benchmark dose and is linked with some specified amount or percentage of reaction compared to the control or baseline level of response. The EPA recommends using a 10% effect level (ED,") as the usual point of departure

Economic Consequences of Foodborne Hazards

Because of information issues and transaction costs, the private economy does not always deliver the best degree of food safety for society when it comes to microbiological and chemical dangers. As a result, at the start of the twentieth century, American consumers entrusted this supervisory job to the federal government. This chapter presents a summary of the economic expenses of foodborne disease incurred by people, business, and government. Microbial and chemical dangers are addressed in separate sections. The cost of disease method is given special importance in the microbiological portion. Five microbiological foodborne dangers cost society an estimated $6.9 billion in medical bills, productivity losses, and the value of early death each year. The chemical part underlines the modest human health concerns and the limited customer willingness to pay for pesticide residues decreased below existing regulatory tolerance levels in food.The last portion focuses on economic research subjects that might assist enhance regulatory effectiveness in this area. The relative benefits of regulation focused at microbiological and chemical dangers are discussed, as well as the implications for government-wide food safety

regulatory priority setting. There are efforts underway to increase the economic assessment of foodborne hazards.A strategy for explicitly accounting for uncertainty in regulatory effect studies for foodborne hazard control is described. Moreover, methods for leveraging economic incentives to increase the efficacy of public and private pathogen control measures are reviewed.

The Economic Impact of Foodborne Illness

Foodborne sickness is both a "experience positive" and a "credibility good," according to economists. People are oblivious to the dangers of food safety. Hundhook, Ronald H. Schmidt and Gary E. Rodrick edited the piece.

Disease surveillance, outbreak investigation, and research to develop novel pathogen management strategies from farm to table are all funded by government funding.Reducing the overall societal cost of foodborne disease involves equalising the marginal costs of all involved parties, such as the marginal cost of foodborne illness to consumers, the marginal cost of boosting safety to industry, and the marginal cost of enforcing rules to government. While examining a single rule, additional costs must be compared.

In general, economic considerations recommend that a law should be implemented if it decreases the consumer costs of foodborne disease by more than enough to offset increases in business compliance costs and government oversight expenses. And, according to economic principles, the law should not be implemented if it decreases the cost of disease but not sufficiently to pay the additional costs.WTP studies can, in principle and maybe in reality, determine ex ante values for all of the foodborne disease costs. While performing a benefit-cost analysis, the ex post measurements of actual expenses incurred are frequently assessed using the cost of illness (COI) technique. WTP and COI measurements are covered in further depth in the sections on microbiological and chemical risks.

Chronic sequelae are issues that can arise in any region of the body, including the joints, neurological system, kidneys, or heart, and can affect people for the rest of their lives or end in early death. Cmzpylohacter infections, for example, are thought to account for 20-40%1 of all Guillain-Barre syndrome (GBS) cases in the United States (a major cause of paralysis unrelated to trauma). Hemolytic uremic syndrome (HUS) affects around I.5% of E. cdi 01 57:H7 illness patients, and it often involves red blood cell destruction, renal failure, and neurological problems such as seizures and strokes.According to the medical literature, the severity of the infection and its consequences varies depending on the individual's age and health state. In an ERS COI investigation of campylobacteriosis GBS patients, for example, the analysis was confounded by demographic variations as well as the wide range of probable GBS symptoms, following medical expenses, and ultimate outcomes. ERS classified GBS patients into two age and therapy groups using data from Sunderrajan and Davenport.

Mechanically ventilated patients aged 47 on averageIndividuals who are not on mechanical ventilation and have an average age of 30.Individuals who are mechanically ventilated have more significant problems and prognoses than those who are not, including a lower chance of returning to work (for a more thorough example of this COI analysis,the COI approach has traditionally been used to evaluate the societal costs of human sickness caused by

microbiological foodborne pathogens. Traditionally, COI assessments have only calculated the individual's (or household's) medical expenditures, lost productivity, and the value/.

Hospital Association's Annual Survey of Hospitals, and the National Center for Health Statistics' National Hospital Discharge Survey (NHDS) and National Mortality FollowBack Survey.

The incidence statistics, together with severity information, were also utilised to calculate the costs of lost production. Most persons who have food poisoning limit their normal activity for only one or two days. Some patients, however, die, while others acquire chronic difficulties so severe that they never return to work, regain just a percentage of their pre-illness productivity, or transition to less challenging and lower-paying employment. The total cost of missed productivity is the sum of all expenditures incurred by all persons impacted, principally the patient or, in the case of sick children, their parents or hired carers. When work is momentarily interrupted, we calculate productivity loss as the product of time lost from work multiplied by the relevant wage rate given by the Bureau of Labor Statistics. In economic research, an individual's daily salary is commonly employed as a proxy for the value of production generated in a day's labour. When statistics on time missed from work due to sickness are unavailable, this lost time is calculated by assuming a typical ratio of average time spent in the hospital to time lost from work.

The human capital model included in projections of lost wages, which were adjusted for a "risk The market approach, the second method for estimating the value of a statistical life, infers the worth of a statistical life from market activity and serves as the foundation for ERS VOSL estimations for foodborne disease mortality. The essential premise of this strategy is that people make compromises in their daily lives between safety and other consumer goods. Volvos, for example, are offered at a higher price because certain people are ready to pay a higher price for things that are safer to use, in this case, automobiles that give better crash protection. The price increase related to safety features demonstrates customers' willingness to pay at the margin for (implicit price of) safety. Another example of customers' readiness to exchange safety for other products and services is the debate over the sweetener saccharin. Weight-conscious customers demonstrate a readiness to utilise items associated with a possible higher risk of cancer in exchange for the ability to eat sweet meals having less calories by utilising saccharin. The bulk of studies that estimate the worth of life in this way use labour market data. Employers must often pay workers more to entice them to pursue jobs with a higher risk of occupational fatalities than those with a lower risk.

The most popular style is the discrete choice format, in which respondents are given a choice between two commodities (e.g., meals) that differ in just two ways: a quality feature such as danger of disease or death and price. Instead, respondents might be asked to state the most they would be prepared to pay for the less risky product. CVM has been used in several studies to evaluate customers' willingness to pay for decreases in sickness symptoms such as shortness of breath, nausea, and migraines. Foodborne infections since the analysis only includes five foodborne pathogens suspected of causing human sickness. Foodborne diseases are caused by about 250 different species. Because many different organisms cause similar symptoms (particularly diarrhoea, abdominal cramps, and nausea), determining which microbe is causing a

given illness is difficult unless laboratory tests are performed to identify the microbe or the illness is part of a recognised outbreak. Expected expenses would rise further if all chronic problems associated with foodborne infections, such as arthritis and meningitis, were included. Medical expenditures, lost productivity, and the value of premature deaths are all factored into these calculations.

Overall costs would rise if other societal expenditures like as pain and suffering, travel to medical treatment, and lost leisure time were included in general, COI estimations for foodborne pathogen sickness may be utilised in three ways: To assess the economic effect of foodborne infections on the US economy,pathogen reduction efforts should be directed towards the most expensive illnesses, and The benefits and costs of control measures should be compared to find the most cost-beneficial treatments.

The avoidance of foodborne disease among people results in societal advantages from food safety regulations. Economic advantages include, at a minimum, savings in illness prevention and mitigation expenses, gains in worker productivity, pain and suffering reductions, and decreases in worry about foodborne health risk begin five years after the HACCP requirements were implemented. Costs for industry compliance are expected to begin in the first year. According to the findings, the advantages of applying HACCP outweighed the expenses as long as four pathogens were decreased by 17% or more.

CO1 estimations were also employed in the Food and Drug Administration's (FDA) seafood rule and proposed egg regulations, and the ERS COI approach for Listrriu was integrated in the USDA's 2001 proposed regulation for ready-to-eat beef and poultry products (e.g., hot dogs and luncheon meats). As a measure of process control, this rule includes provisions for mandatory in-plant testing for Listeriu and stricter performance limits for certain pathogens.The USDA's Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) examines USDA regulations that affect human health and safety or the environment and have an anticipated yearly economic effect of at least $100 million dollars The USDA performs a detailed study for these rules that explains the nature of the risk, possible methods of decreasing it, the logic that justifies the proposed rule, and a comparison of the expected costs and benefits of lowering the risk The FDA has a similar review procedure; visit the FDA website for FDA food regulation and its review process as well as the US government-wide web site

Chemicals in foods are classified into two types: (I) compounds added to avoid spoiling, enhance product quality, or modify colour, and (II) pesticide residues used to grow crops and to prevent spoilage or damage during postharvest processing and storage. It is difficult to determine the incidence of sickness and early mortality caused by such substances in meals. To the best of our knowledge, they are exceedingly rare, at least in industrialised nations with robust regulatory systems, such as the United States. It appears to be so low that it is almost undetected in surveillance data and epidemiological research.

Acute adverse effects are relatively uncommon. Levine's review of pesticide literature from 1930 to the late 1980s discovered 42 cases of pesticide poisonings caused by ingesting contaminated food and water. Approximately one-third of the instances included peasants in developing

nations facing poverty who intentionally ate pesticide-treated seed labelled unfit for food. The bulk of the remaining cases were likewise from impoverished nations and involved unintended pesticide eating while thinking it was flour or sugar, consumption of cooking oil stored in pesticide containers, and other similar occurrences involving inadequate sanitation.

Eating of meat from animals fed illegally with treated seed was responsible for numerous instances, but intake of fish from contaminated waters was responsible for only one. The sole recent occurrence in the United States happened in 1986, when the pesticide aldicarb was illegally applied to watermelons, despite a restriction on its use on food crops. Recent occurrences of severe sickness in other industrialised nations have also included unlawful usage, such as meat fed on feed containing high amounts of dioxin in Belgium and fungicide-contaminated soft drink cans in Western Europe.

Acute illnesses caused by food additives have mostly been allergic responses, such as the sweetener aspartame producing severe reactions in people who are unable to digest the enzyme phenylalanine.

Doll and Peto (1981), Henderson *et al.* (1991), Lutz and Schlatter (1992), and Ames *et al.* (1995) sought to quantify the contributions of controlled drugs to known long-term health impacts, particularly cancer. These research integrated data from animal bioassays with epidemiological data to estimate the number of cancer deaths owing to various sources each year. Tobacco, fat, and potentially overnutrition are the primary causes of cancer connected with food. Because epidemiological evidence showed no significant correlation between ingestion of these substances and elevated rates of any cancers for which laboratory studies and physiological analyses suggested a possible causal connection, all food additives were assigned a token amount of less than 1% of annual cancer deaths.

The low frequency of disease and mortality associated with chemicals in foods attests to the FDA's and the EPA's stringent control of food additives and pesticides (EPA). Before licencing food additives for use, the FDA is obligated by law to ensure their safety. Food additives that have been demonstrated to cause cancer in animals cannot be approved.

Similarly, the EPA is obligated to establish tolerances (maximum permissible limits) for pesticide residues on foods that provide a reasonable certainty of no damage. Surveillance data collected by the FDA as part of its enforcement effort show that the majority of domestic fruits, vegetables, cereals, meat, eggs, and dairy products sold in the United States have no detectable pesticide residues and that only about l'% have residues that exceed tolerances (Food and Drug Administration Pesticide Program, 1987-1998).

Chemical Hazards

As previously stated, the value of a marginal increase in food safety is often calculated as the product of two components. The first component is a change in risk, which is a change in the chance of sickness or death or, more accurately, the frequency of illness or death in the population. The average cost of saving a life or averting disease is the second element. The estimation of both components has proven contentious.

Chemical Risk Assessment in Foods

The danger of sickness or death from chemicals in foods cannot be determined directly from human data in most cases. Previous experience may not be a reliable predictor of the dangers of new substances. Because regulation is future and attempts to minimise negative repercussions, human data for novel substances may simply be unavailable. To measure toxicity, regulatory assessments of the hazards associated with chemical exposure in foods often depend on animal research. These toxicity data are corrected to account for physiological variations between people and test animals before being paired with exposure estimates to produce an overall quantitative risk categorization.

In general, the outcomes of these processes are not properly defined as risk assessments. The EPA makes a variety of assumptions in order to achieve "conservative" results. Its underlying logic is a desire to prevent type I1 mistake, which is designating a substance safe when it actually poses a risk, perhaps to a particularly vulnerable group. Rather than utilising the average toxicity from animal tests, the EPA utilises the upper limit of a 95% confidence interval of a substance's toxicity to the most susceptible test species. To translate the dosage from the test animal to a human counterpart, the greatest medically justifiable value is employed. Similarly, the highest feasible values are utilised to assess exposure.

These techniques have a number of negative outcomes. First, they overestimate the advantages of regulation while underestimating the costs, both overall and at the margin. As a result, they suggest that excessively high levels of control are desirable. Second, they make comparing quantitative risk characterizations across compounds difficult, making it hard to assess whether substances are controlled with equal degrees of stringency. Any quantitative risk characterisation may be described as an upper limit of a confidence interval, but the kind of confidence interval varies in an unpredictable way due to the arbitrary nature of the assumptions enforced. Finally, they have a tendency to exaggerate the net advantages of ex ante regulatory acts.

The EPA refers to its quantitative risk characterizations as risk estimates, and they are discussed in policy as such. As a result of the EPA's risk assessment methodology, chemicals in foods offer far bigger dangers than the facts show. Moreover, cognitive psychology studies has demonstrated that people continuously overestimate infrequent occurrences such as cancer caused by chemicals in food. This distortion in risk perception gives credence to the EPA's overstated danger estimations. Concerns about chemicals in foods are significantly more prevalent in food safety policy discussions than the prevalence of food safety concerns related to them would appear to suggest.

Yet, after growing in previous decades, concern over chemicals in food has waned in the last decade. A series of polls done in the United States between 1984 and 1990 found that most Americans were concerned about pesticide residues on foods. When Sachs *et al.* (1987) compared the results of their study of Pennsylvania homes to those of a survey conducted 20 years previously, they discovered that there was substantially more worry about pesticides in 1985 than in 1965. Yet, according to a nationwide poll conducted in 1994, a minority of Americans (35-38%) considered pesticides were extremely hazardous to themselves or the

environment, nearly half the percentages voicing similar worries only a few years before (National Opinion Research Center, 1994). According to Food Marketing Institute public opinion polls conducted in the mid- to late 1980s, the majority of Americans ranked chemicals in foods as their top food safety worry. By 1995, only approximately 14% of respondents cited chemicals as their primary food safety concern.

CHAPTER 6

CHEMICAL-FREE MEALS

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The value of preventing sickness or death due to chemical exposure in meals may differ from the value of avoiding illness or death in general. It is possible, for example, that people have specific concerns about the forms of sickness or death that might come from chemical exposure. Many sources of evidence indicate that this is not the case, implying that life-saving values determined from the general literature are relevant to situations involving chemicals in meals. Overall, most customers sought confirmation that their food was safe, but they were ready to pay a little premium for tiny increases in safety over the regulatory threshold.

One recent research explicitly addressed this topic by comparing the implicit value of saving lives from pesticide residues on foods and auto-scientific basis and implications: accidents. It discovered no statistically significant difference between them.A number of previous studies have looked at customers' willingness to pay for reduced levels of pesticide residues on foods, particularly total removal. CVM was employed in all of these experiments.

Eom and Buzby *et al.* utilised a discrete choice format to ask survey participants which of two varieties of product they would buy at a given price difference. Eom (1994) discovered that participants' willingness to pay was indifferent to the degree of danger they were told they faced. Buzby *et al.* discovered no statistically significant difference between respondents' willingness to pay for produce that fulfilled government pesticide residue regulations on foods and products certified to be residue-free. The remaining trials asked participants to identify the largest premium they would be prepared to pay for residue-free vegetables. This latter style produces abnormally high responses of willingness to pay. Furthermore, none of the surveys were designed to imitate genuine decision circumstances; that is, respondents were aware that the questions were hypothetical and that their answers had no immediate financial ramifications, such as paying extra.

This type of hypothetical survey style tends to produce exaggerated claims of willingness to pay. As a result, one would anticipate these studies to give exorbitant estimates of customers' willingness to pay to erase pesticide residues on vegetables. Yet, few customers indicated a willingness to spend more than 5% extra for pesticide residue-free vegetables. Between 20 and 40% of those polled were prepared to pay nothing more, while another 25-60% were willing to pay no more than 5% more. Most surveys found that just approximately 10% of respondents were ready to pay 10% or more.

Even fewer said they would buy certified residue-free fruit with inferior aesthetic quality or more surface flaws. Baker and Crosbie (1993) used conjoint analysis on a small sample of vegetable customers at two San Jose, California supermarkets in 1992 to investigate their relative preferences for price, cosmetic quality, and pesticide residues. According to cluster analysis, these shoppers may be split into three groupings. Approximately 30% were concerned with price and quality but not with pesticide residues. The majority (55%) were concerned about pricing, quality, and if the food fulfilled federal residue regulations. The remaining (about 15%) desired stronger government control of pesticide usage on farms.

Demand studies for organic food provide more confirming data. Others claim that the rise in organic food sales reflects the public's willingness to pay to prevent pesticide residues on foods. Organic produce costs are 25- 35% more than equivalent conventional produce, and have been seen to be twice or triple the pricing of conventional produce in local retailers. These price premiums reflect consumer desire for chemical reductions in foods to the extent that demand for organic foods is driven by concerns about chemicals in foods. Yet, it appears that pesticide worries do not account for the majority of the rationale for purchasing organic foods. Most organic food consumers feel that organic foods are more nutritious and tasty than conventionally cultivated foods (Hammitt, 1986; Jolly et al., 1989), however some purchase organic foods for worker safety and/or environmental concerns. Over the years 1985-1989, certification as pesticide residue-free had no effect on demand for organic broccoli, carrots, or lettuce.

To summarise, it appears that the vast majority of the US populace wants assurance that produce is safe but has little or no desire for greater chemical reductions in meals. As a result, the average willingness to pay for chemical reductions in meals should be viewed as comparable to the desire to pay for other reductions in sickness or mortality. There certainly appear to be a tiny part of the public prepared to pay a substantial price premium for organic food.This sector appreciates the entire cultivation of food rather than the lack of pesticides per se. The absence of chemicals appears to be a minor motivator for purchasing organic food. The price elasticity of demand for organic food appears to be exceptionally low, implying that organic product customers do not regard conventional produce as a viable option. Demand for organic food has a high income elasticity, implying that organic produce is a luxury item. As a result, there appears to be no need to regard this portion of the population differently from the entire population when assessing the benefits (costs avoided) of chemical reductions in meals.

Chemical Risks

The Federal Food, Drug, and Cosmetic Act regulates food additives and pesticide residues on foods (FFDCA). In both circumstances, regulation is purely motivated by health concerns. Food additives can generally be used lawfully only if the FDA has decided that they are safe. Yet, the FDA has the authority to permit the use of potentially harmful additives if they are found to be safe at sufficiently low amounts. In such circumstances, it sets a tolerance stating the maximum permitted concentration, which is usually one-hundredth of the maximum concentration at which detrimental health consequences are found. The FFDCA also expressly prohibits the use of chemicals that have been shown to cause cancer in people or animals.

The EPA regulates pesticide residues on foods under the FFDCA, as revised by the Food Quality Protection Act of 1996. This legislation instructs the EPA to set pesticide residue limits on foods at levels that give a reasonable assurance of no damage from aggregate exposure, encompassing all dietary exposures as well as additional exposures for which credible evidence exists. It also requires the EPA to make a particular judgement of safety for babies and children, as well as an additional 10-fold margin of safety for any compounds having threshold effects that pose some danger to infants and children. In assessing exposure and health consequences, the EPA must consider the sensitivity of particular subpopulations (including babies and children) and utilise safety factors recognised by competent experts as appropriate. Data on real pesticide usage on crops and actual residue levels can only be utilised for this purpose if the EPA considers that the data is trustworthy and does not underestimate exposure for major subpopulations. Tolerances are valid for five years before being revisited.

The Act provides allow for the limited use of economic criteria in assessing suitable levels of pesticide residues on food by enabling tolerances to be established at levels that "prevent major disruption in domestic production of a sufficient, healthy, and inexpensive food supply." Nevertheless, economic factors may be utilised to analyse the validity of regulatory choices ranging from tolerance approval to monitoring and enforcement measures. Nevertheless, economic concerns typically enter regulatory decision making indirectly, even when legislation do not explicitly mention them. Buzby *et al.* present an example of an economic study of food safety adjustments in a pesticide regulatory instance, particularly, postharvest treatment of fresh market grapefruit with sodium orthophenylphenate.

Grower surveys were utilised to identify possible alternative grapefruit postharvest treatment procedures, estimate packinghouse level changes in treatment cost, and predict spoilage losses. These predicted increases in treatment costs and spoiling losses were then utilised to calculate a shift in grapefruit supply to the fresh market. A grapefruit supply and demand model was used to estimate changes in grapefruit consumption and price, as well as income changes for grapefruit consumers and producers. Price changes function as a method for moving some of the costs of the prohibition from producers to consumers. Customers will respond to price fluctuations in part by substituting other goods for grapefruit consumption. Because of these substitute options, the overall cost of the regulation, as measured by changes in consumer and producer revenue, will typically be less than the increased cost of treating the preregulation grapefruit crop.

CVM was used to determine consumers' willingness to pay for the EPA-estimated risk reductions caused by the rule. The incremental benefit of the rule determined from willingness to pay estimates was then contrasted against the losses in consumer and producer incomes, which represented the regulation's incremental cost. The overall impact was positive, implying that prohibiting SOPP would improve society net income. This outcome should be regarded as illustrative: Because the EPA's risk assessment methodology exaggerated the risk reductions achieved by the proposed regulation, the net benefits were likely smaller than those projected.

Since food safety is both an experience and a credibility good, the private market supplies less than the socially ideal degree of food safety. From the turn of the century, the United States government has utilised its regulatory authorities to address market failures related to food

safety. Yet, it is still necessary to examine existing rules in order to enhance their efficiency in light of experience and new information regarding the nature and scope of food safety issues. Economic analysis may be beneficial in a variety of situations. Four are highlighted here.

Ideally, the federal government's limited funding for food safety should be used on the most cost-effective means of mitigating severe hazards. In other words, food safety regulatory spending should be directed to produce the highest possible degree of safety from any given level of total investment across dangers and agencies. In this setting, a comparison of microbiological and chemical dietary dangers becomes important. The literature clearly shows that the dangers of foodborne microbiological hazards outweigh the risks of chemical hazards.

According to the ERS, foodborne disease caused by five bacteria costs the US society $6.9 billion (in August 2000 dollars) in medical costs, lost productivity, and the value of premature mortality each year. The economic consequences of foodborne chemical hazards have not been evaluated since the risks are so minimal. These discrepancies in present societal costs imply that too much chemical safety and too enough microbiological safety may be supplied now. Rating pathogen risks has begun in Tables 7.2 and 7.3, but it must be expanded to include the other pathogens found by CAST.

WTP Approaches Enhance Economic Appraisal of Microbial Hazards

A second field of economic study is concerned with customer concerns about food safety hazards. As previously stated, the acceptable degree of safety equates the marginal benefit of decreasing foodborne risk with the marginal cost of risk reduction. 11 1 tion. The value of risk reduction, that is, what customers are ready to pay for reduced food safety hazards, is thus a crucial component of appraising legislation. The USDA's ERS and the DHHS's CDC have both contributed funds to the Food Safety Initiative to generate new valuation estimates for lowering risks from microbial diseases.The CDC funded a cooperative partnership to research public demand for food safety in 1998. The project, which might last up to five years, aims to quantify the value that consumers place on lowering the risk of particular microbiological foodborne diseases for which therapies currently exist. The impact of diverse combinations of private and communal risk reduction techniques on consumer value is also being examined.

The study offers chances to increase risk communication, conceptual and empirical economic modelling, and value estimation methodologies in the public health environment. Another significant contribution of the research is consumer education on the danger of foodborne disease and existing governmental and private measures to mitigate risk. The agreement pave the door for further CDC-led collaborations with the economic research community.Under cooperation agreements awarded in fiscal year 1999, the ERS is also studying approaches for developing ex ante values for the willingness to pay to avoid risks connected with foodborne diseases. Various valuation strategies can be used: The contingent valuation method is a stated-preference methodology in which surveys disclose the consumer's WTP for non-market items.

An artificial choice situation with actual alternatives is used in experimental auction marketplaces. In one staged experiment, for example, participants bid real money to purchase an irradiated chicken sandwich with decreased food safety hazards.Buzby *et al.* and Golan *et al.*

provide technique comparisons (2001). The ERS program's other three goals are as follows: 1) to assess the validity and effectiveness of various methods that model the process by which consumers assess changes in probability and risk, 2) to see if different pathogen-specific and symptom-specific scenarios result in different consumer valuations, and 3) to see how different combinations of private and collective risk reduction strategies affect consumer valuation of safer food.

These research' findings will be utilised to enhance valuation methodologies in regulatory bodies. Many valuation issues were discussed at a conference cosponsored by the Risk Assessment Consortium, Federal agencies, the NE-165 regional research group of economists and others in September 2000 at the University of Maryland. Include Uncertainty in Regulation Impact Assessments for Food Safety

The handling of ambiguity in regulatory decision making is a third area. The quantitative evaluation of the hazards of foodborne disease from bacteria and chemicals is fraught with ambiguity. Individual susceptibility to infections and chemicals varies across the population. Part of the variation is tied to observable characteristics, allowing policymakers to target certain subpopulations. Some of such variability is difficult to see and must be viewed as random when studying regulatory implications. Moreover, limitations in scientific understanding of the processes by which chemicals (and, in some cases, microorganisms) generate harmful health consequences imply that predicted cause-effect correlations are fraught with uncertainty. Because of gaps in scientific understanding of correspondences between animal and human reactions to chemicals and diseases, the use of animal models introduces additional uncertainty.

As previously said, authorities are sensitive to these uncertainties, particularly the possibility of pronouncing a substance safe when it actually poses a considerable danger. At the moment, they change quantitative risk characterizations by using arbitrary "conservative" assumptions, which has a variety of detrimental consequences as stated above. An alternate option is to employ probabilistic risk assessment methodologies that overtly and officially include uncertainty. Based on such probabilistic risk evaluations, Lichtenberg and Zilberman provide a technique for evaluating uncertaintyadjusted regulatory costs. This Lichtenberg-Zilberman strategy entails lowering the expense of achieving a nominal risk criteria while limiting violations to a predetermined (low) likelihood.

Cost-cutting techniques are made up of a variety of approaches, some of which are more successful in lowering risk on average, while others are more effective in decreasing risk uncertainty. Monte Carlo techniques may therefore be used to produce regulatory costs as a function of the nominal standard and likelihood of violation, as well as to investigate changes in efficient risk-reduction measures combinations. The cost of reducing the risk of cancer from pesticide contamination of drinking water, the cost of mitigating the risk of gastroenteritis from consumption of shellfish contaminated by dairy wastes, the cost of reducing farm workers' cancer risk from insecticide exposure, and the cost of meeting nitrate standards in drinking water are examples of empirical applications of this approach.

There are two main avenues for expanding this technique in the context of food safety. Secondly, the generic method may be utilised to account for uncertainties while developing HACCP procedures. Risk factors differ in terms of uncertainty about (or unobservable variability in) their influence on risk.The Lichtenberg-Zilberman technique allows for the inclusion of uncertainty into the creation of cost-minimizing HACCP solutions. Second, using the method indicates that demand for uncertainty reduction must be considered as part of the value of life saving. Consumers and regulators are likely to value the degree of dependability with which safety is achieved. Techniques for including willingness to pay for increased dependability (lower uncertainty) would allow for a comparison of benefit and cost with uncertainty.

Economic incentives are an essential component of any regulation plan. In many cases, economic theory argues that relying on incentives permits regulatory aims to be met at a cheap cost. Moreover, laws may generate incentives that result in unexpected effects that impair regulation's efficacy. For example, both nominal food safety requirements and how they are implemented modify the economic incentives faced by food processing enterprises, sometimes increasing foodborne hazards. In theory, better regulatory design can improve economic incentives for enterprises to create safer food in the short term and, through technical progress, in the long run. Gill discovered substantial variation in cattle slaughter facility methods and the levels of generic *E. coli* on carcasses and trim destined for hamburgers. Modest changes in worker habits during the skinning process resulted in a large reduction in generic *E. coli* levels on the corpse, indicating that slight improvements in economic incentives may considerably reduce contamination in slaughter facilities.

One strategy is to transition from process standards to performance standards. Process standards establish the precise safety-enhancing processes that businesses must apply, whereas performance standards enable enterprises to select the combination of safety-enhancing procedures that produces the specified level of safety at the lowest cost. Moreover, performance requirements promote innovation since enterprises may keep any cost savings created by technological advancements. The EPA's sulphur dioxide trading programme, for example, owes much of its effectiveness to the substitution of performance criteria for process standards. The widespread use of low-sulfur coal, as well as a number of technological advances, accounts for a large portion of the cheap cost of achieving higher sulphur dioxide emissions limits. These improvements would have been difficult to implement under the EPA's previous process requirements, which required the use of scrubbers to satisfy emissions objectives. Such a move would not be altogether novel in terms of food safety, given HACCP-mandated testing for Sulmonellu and generic *E. coli* is a performance standard. The economic incentives contained in other HACCP methodologies, on the other hand, merit more investigation.

Another possible application of incentives would be to develop differentiated markets for safer foods through the use of certification and labelling. Certification is now being utilised to address issues related to experience and credibility products in a variety of marketplaces. For example, Underwriters Laboratories is a commercial group that certifies the safety of household electrical equipment, while the USDA's Agricultural Marketing Service is a government agency that certifies the quality of fruits and vegetables. In the context of food safety, the parallel would be

to mark items that have been verified as having a very low risk of microbiological infections. One fundamental to the viability of this strategy is the dependability of testing procedures (and consequently certification itself). If testing accurately identifies danger from foodborne pathogens, then a certification programme provides enterprises with incentives to deliver higher levels of safety—as long as the testing is performed by a third party that is not tied to the industry that uses its services.

Yet, if testing is flawed to the point that certification is not a credible signal of improved safety, then product differentiation is likely to be impossible. In this instance, the advantages of certification are unlikely to outweigh the expenses. It is also possible that the greater safety provided by certification will be undermined by the "lulling effect," which occurs when customers take fewer measures due to a heightened sense of safety, as has been shown in the case of safety caps on toxic items. Enforcement is essential to verify that industry meets certification criteria.

It is necessary to do research to evaluate whether testing is sufficiently trustworthy to make certification a viable policy instrument. There is also a need for research to establish the possibility for certification in providing incentives for improved food safety, i.e. demand for "safer" food items. Consumer reaction to the perceived danger of sickness from foodborne pathogens, as well as confusion regarding that risk, is likely to be of great relevance. If customer behaviour is highly influenced by perceived risk, certification is likely to have a significant impact on demand, producing strong incentives for improved safety.

CHAPTER 7

PREVALENCE OF FOODBORNE PATHOGENS

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Despite the fact that the United States' food supply ranks as the safest in the world, we confront ever-changing difficulties. Food processing and packaging technologies have undergone significant advances. Most foods were created and supplied locally forty to fifty years ago. We now have significant production facilities that deliver meals both domestically and globally. Because of the globalisation of the food supply, food can get contaminated in one nation and trigger foodborne disease epidemics in another. Foodborne pathogens have an increased chance of causing sickness in a significant proportion of consumers as a result of the centralization of the food supply. Foodborne pathogens have evolved resistance to traditional preservation procedures, and when new processing and preservation technologies become available, foodborne pathogens will adapt to them, becoming resistant to them as well.The United States today has a higher number of immune compromised or elderly people. This population group is more vulnerable to foodborne disease. With more people living in and around big cities, the demographics of the American population have shifted. Consumers' eating habits have also altered. People are consuming more fresh fruits and vegetables now than they were five to 10 years ago. Considering all of these changes, one would anticipate the prevalence of foodborne pathogens to change.

Foodborne transmission of pathogenic microbes has been recognised as a risk for decades. The most common foodborne pathogens were identified in the Food Safety) Manual. Ronald H. Schmidt Pathogens of bacterial, viral, and parasitic origin have joined, *Clostridium hotulinum, Clostridiurn perfringens,* and *Stuphylococcus uuretis*. Pathogens that were previously solely connected with animals have now been identified as illness-causing agents in humans.Most meals were traditionally purchased and cooked on the same day, or they were taken from the cellar or pantry as home-canned items. Furthermore, most items were consumed on the same day they were produced, discarded if there were any leftovers, or fed to farm animals. Because it was all that was available, grocery stores used to stock solely locally grown vegetables.

Yet, the food supply is now genuinely global in character, with an abundance of varied crop products as well as a range of ethnic meals accessible in your supermarket at practically any time of year. Furthermore, individuals used to exclusively purchase meat from a local butcher or slaughter their own farm animals. The meat you buy at the store may now originate from thousands of kilometres distant.

According to the Centers for Disease Control and Prevention (CDC), foodborne disease causes 76 million illnesses, 325,000 hospitalisations, and 5,000 fatalities in the United States each year.

These figures show that foodborne disease is far more common than previously considered. Bacterial-related foodborne sickness is most commonly caused by *Cumpylohucter spp.* And *Sulmonellu spp*. The most commonly reported foodborne parasite is *Giurdiu lumhliu.* Yet, viruses are responsible for the great majority of foodborne infections. *Sulrnonellu spp.*, *Listeria monoqytogenes, Toxoplusnza gondii,* and norwalk-like viruses are the foodborne pathogens with the largest estimated number of deaths.

Foodborne Illnesses

The food supply in the United States is largely regulated by two federal agencies: the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) and the United States Department of Health and Human Services/Food and Drug Administration (USHHS/FDA). The FSIS is responsible for regulating meat and poultry as defined by the Meat Inspection Act and the Poultry Inspection Act, as well as egg products as defined by the Egg Products Inspection Act. All other food items, as well as exotic animals, are regulated by the FDA under the Food, Drug, and Cosmetic Act. Monocytogenes serotype 4b infections were documented. This epidemic was responsible for 21 fatalities (15 adults and 6 miscarriages/stillbirths). The producer voluntarily recalled certain manufacturing batches of potentially contaminated hot dogs and deli meats. The outbreak strain of L. monocytogenes was recovered from both opened and unopened hot dog packages. The pollution was thought to have come from dust generated during facility building.

Listeria monocytogenes in turkey deli meat Following May of 2000, 29 infections caused by L. monocytogenes were discovered in ten states. Pulsed-field gel electrophoresis revealed that the patient isolates were indistinguishable (PFGE). A case-control research determined that deli turkey meat was the most likely cause of illness. In December 2000, the involved producer recalled the implicated product.Escherichia coli 0157:H7 contamination in fermented sausage in 1994, commercially marketed dry-cured salami was linked to an *E. coli* 0157:H7 epidemic in California and Washington. This is the first epidemic of *E. coli* 0157:H7 linked to dry-cured salami. There were 23 laboratory-confirmed cases recorded. All salami related with sickness was purchased from a deli counter at a local supermarket chain. Using inoculated salami batter, researchers discovered that E. coZi 0157:H7 could survive the fermentation, drying, and storing processes.Infections with Escherichia coli 0157:H7 linked to frozen ground beef The Colorado Department of Public Health and Environment discovered an epidemic of *E. coli* 0157:H7 illnesses in 1997 linked to the eating of a nationally distributed commercial brand of frozen ground beef patties and burgers. PFGE revealed that *E. coli* 0157:H7 isolates from patients and the implicated batch of product were identical. Hudson Foods recalled a total of 25,000,000 pounds of ground beef.

Commodities controlled by the Food and Drug Administration (FDA)

Unpasteurized orange juice contains Salmonella Muenchen. In 1999, a commercially manufactured unpasteurized orange juice was blamed for a salmonellosis epidemic. In 21 states and three Canadian provinces, 423 confirmed cases and one fatality were recorded. The death involved an older man who lived in an assisted-living facility. The unpasteurized orange juice

was produced in Arizona and marketed under many brand names throughout multiple states and Canada provinces. S. Muenchen was discovered after analysing juice from an unopened bottle, as well as a blender and some juice-dispensing equipment from various retail outlets. The PFGE pattern of S. Muenchen isolates from juice, retail equipment, and patients was identical. The outbreak investigation was unable to identify the source of the Sulrnonelln contamination.

Apple juice contaminated with *E. coli* 0757:H7 A cluster of *E. coli* 0 157:H7 illnesses was epidemiologically related to the consumption of brand a unpasteurized apple juice in the fall of 1996. The study resulted in the identification of 70 persons with *E. coli* 0157:H7 illnesses. Twenty-five of the 70 people were hospitalised, 14 had hemolytic uremic syndrome, and one died.

E. coli 0157:H7 was isolated from a brand-new, unopened jar. Apple juice that has not been pasteurised. Subsequent inspection at the production plant revealed no source of contamination; nonetheless, contamination was assumed to have entered the manufacturing facility on inbound apples because no other juices were connected with sickness.*Salmonella agona* contamination in toasted oat cereal in 1998, a salmonellosis epidemic was linked to a commercially made widely disseminated cereal. His was the first Srihnonrllu outbreak linked to ready-to-eat cereal. In 23 states, 409 confirmed cases and one fatality occurred. *Srlriioizrllu agona* was isolated from unopened cereal boxes.

A sample study of consumer and unopened cereal boxes indicated an apparent infective dosage ranging from 1 to 45 cells per 30 g serving size (RosasMarty and Tatini, 1999). According to an inspection of the production plant, the contamination may have been caused by the spraying of a vitamin mix over the dry cereal.Deer jerky contains Escherichia coli 0157:H7. In 1995, jerky produced from deer meat was linked to an epidemic of *E. coli* 01 57:H7 illness (Keene et al., 1997). Six verified cases and five suspected cases were discovered. A deer was shot one day, eviscerated in the field, hauled to the shooters' truck, and left outside for five days at room temperature. The corpse was disassembled and trimmed by hand after it had been skinned. A part of the beef was sliced into strips and marinated overnight in the fridge. Following marinating, the beef was dried for 12 to 14 hours in a home food dehydrator set at 51.7 ^{0}Cto 57.2^{0}C.

E. coli 0157:H7 was found in environmental samples of the equipment used to dismember the deer and deer skin remains. Pulsed Field Gel Electrophoresis revealed that all *E. coli* 01 57:H7 isolates from jerky, raw venison, equipment, deer skin, and human patient isolates were identical (PFGE). *E. coli* 0157:H7 may be recovered from experimentally infected and dried deer meat, according to recovery trials.

Shell eggs contaminated with Salmonella Enteritidis In humans, the incidence of S. Enteritidis (SE) infections has increased dramatically during the last 15 years. Throughout the 1980s and 1990s, SE emerged as a significant source of human sickness in the United States. According to CDC data, from 1985 toimprove the safety of sprouted seeds, the FDA issued advice to the sprout business. The guidelines included instructions for disinfecting seeds with 20,000 ppm calcium hypochlorite as well as protocols for testing wasted irrigation water for Salmonella spp. and *E. coli* 0157:H7 (FDA, 1999).

Parsley Shigella sonnei Prior to 1998, there was no link between parsley and foodborne disease. Around 400 cases of shigellosis were recorded in three states and two Canadian provinces in 1998 (CDC, 1998). Fresh chopped parsley was sprinkled on platters or blended with the meal item in each occurrence. A traceback examination indicated that the tainted parsley might have come from a farm in Mexico or four farms in California. Because humans and other primates are the sole reservoirs for *S. sonnei*, transmission occurs via the fecal-oral route.*Cyclospora cayetanensis* may be found in raspberries, lettuce, and basil. A novel foodborne pathogen and food vehicle were linked to foodborne disease beginning in 1996. *C. cayetanensis* is a coccidian parasite first identified by Ortega *et al.* in 1993. This parasite's oocysts are thought to be exceptionally robust and capable of withstanding severe environmental conditions. *Cyclospora oocyts* in newly voided faeces are noninfectious and are thought to require days to weeks outside the host under ideal environmental conditions (heat and humidity) before sporulating and becoming infectious. A multistate epidemic affecting 1,465 persons in the United States and Canada in 1996 was linked to *Guatemalan raspberries*.

This clearly established that food may be used to transport this disease. Foods other than raspberries were linked to sickness in 1997. Five outbreaks of cyclosporiasis were linked to mesclun lettuce, basil, and raspberries in the United States and Canada (Herwaldt, 2000). Cyclospora had never been found in an epidemiologically linked food item prior to 1999. In the summer of 1999, an epidemic of cyclosporiasis was linked to the eating of chicken pasta salad and tomato basil salad in Missouri. Basil was a prevalent ingredient in both meals. A Cyclospora oocyst was discovered in a leftover sample of chicken pasta salad.Listeria monocytogenes in fresh Lafin-style soft cheese in the fall of 2000, 12 cases of listeriosis were discovered among Latinos in North Carolina who had eaten handmade Latin-style fresh soft cheese obtained from local markets or door-to-door sellers (CDC, 2001). One of the 12 instances was a 70-year-old immunocompromised guy.

Ten of the women were pregnant, and the Listeria monocytogenes infections caused five stillbirths, three preterm births, and two sick neonates. The cheese was prepared using raw milk obtained illegally from a nearby dairy farm. Fourteen isolates were acquired from patients, cheese samples, and raw milk samples, totaling, all fourteen isolates were indistinguishable, confirming a shared connection.

As microbes adapt to changing environmental circumstances, business and government must decide whether to adopt new control methods. Prior to 1991, it was never assumed that the high acid content of unpasteurized juice would allow foodborne bacteria to survive or thrive. The FDA imposed additional requirements to avoid future outbreaks in response to many illnesses related with unpasteurized juice products. These new rules required the use of warning labels as well as Hazard Analysis Critical Control Point (HACCP) systems (see Part IV). The sector has also created innovative methods for processing and manufacturing food goods. Several of these ways make use of technology that increase the shelf-life of food while keeping it fresh.

Foreign travel has grown dramatically in recent years. It was predicted that by the year 2000, the number of travellers will be around 660 million. It is also projected that, depending on the destination, 20 to 50% of global travellers may contract a foodborne infection. This suggests that

between 130 and 330 million people per year may become infected with foodborne pathogens in nations other than their own country.

Consumer Education The need of continuing to educate consumers cannot be overstated. The public's food handling behaviours will begin to alter when simple food safety messages are reinforced. Furthermore, informing the customer when a problem develops, such as a foodborne epidemic or a product recall, may cause them to adjust their eating or purchasing habits. Those in the "at-risk" group are particularly prone to foodborne disease and should be informed on foods to avoid.

Surveillance

Most nations have procedures in place to record notifiable diseases, but there are few few that have foodborne illness monitoring programmes. Foodborne illness is poorly understood on a global scale. Foodborne illness monitoring is carried out in the United States by local, state, and federal public health authorities. By immediately identifying outbreaks and defining the source or cause of the epidemic, monitoring enables for the development of early intervention methods that may be used to prevent future disease.

Emergence/Reemergence

There are two forms of emergence related with harmful bacteria found in food. The first is a real emergence, which is the appearance of a microbe that has not previously been linked to human sickness. The second, reemergence, is far more prevalent. A microbe that is normally connected with a specific type of food, environmental state, or geographic area will develop a novel method of causing disease. Microorganisms will continue to evolve in order to live as food processing changes.

Research

We must continue to encourage and perform research in order to stay up with the evolving microbial world. We must perform research to understand and manage emerging infections as they adapt, evolve, and find new habitats. The following broad study categories are available: detection methods, growth and survival characteristics, microbial ecology, pathogenicity, and control.

Physiology and Survival of Foodborne Pathogens

Pathogens in raw or inadequately treated and handled foods can exist. The presence of pathogenic microorganisms in sufficient quantities to cause sickness or create poisons is determined by the growth and survival properties of specific organisms as well as the environment to which the foods are exposed. Infectious microorganisms in food items have varying metabolic rates and growth characteristics, which are influenced by nutritional content and storage circumstances, among other things. Many bacteria can grow and/or survive in extreme food processing and storage settings (e.g., low or high temperature, high salt, low pH), however toxigenic bacteria require extremely particular growth conditions to produce toxin.Pathogenic bacteria have varying degrees of heat tolerance, and some create spores, which

boosts their heat resistance and capacity to live in harsh environments. While viruses and parasites cannot develop on food, they can survive in large enough quantities to cause illness.

Scientifically upgraded food processing and food safety surveillance technologies have resulted in efficient food safety and sanitation systems. Shifting lifestyles have also led to an increase in the demand for more convenient, shelf-stable, and ready-to-eat meals. The microbial flora of food items comprises microorganisms linked with raw ingredients as well as those acquired during food processing.

Since organisms are very adaptable, technological developments, although reducing the overall level of microbial contamination in food, may also select or modify the microbial flora, causing new concerns. Improved refrigeration, modified environment packaging, vacuum sealing, and microwave cooking are examples of such advancements. Agricultural operations, such as increased centralization, increased crowding of animals in feedlots and in transit to slaughter, changing feeding methods, and subtherapeutic antibiotic and medication usage, may also modify the microbial flora. Medical antibiotic and medication use may potentially contribute to the emergence of resistant disease strains.

Scientific Background and Implications

The majority of pathogens found in food are naturally occurring in the environment, such as soil, plants, and animals. Its survival and development in foods are influenced by a variety of variables classified as intrinsic and extrinsic. Barrier or "hurdle" technology is based on the use of the combined or synergistic effects of these inherent and external elements in food preservation. Pathogen development and survival are also influenced by the interactions between the various types of microorganisms that comprise the complex microbial flora. Depending on the environment, these bacteria may thrive competitively or cooperatively.

Factors Influencing Growth and Survival

A variety of food-related variables influence microbial growth and survivalpH, moisture content, oxidation-reduction potential, nutritional content, antimicrobial components, and biological structure are examples of these. The intrinsic factors are assumed to have developed as defence mechanisms against alien germs that can penetrate and grow in plant or animal tissues, and they reflect nature's approach of safeguarding and conserving the tissues collectively. Tnost fruits, for example, whose biological role is to shield the crucial reproductive body or seed, have pH levels that are lower than those allowed by many spoilage species. Although the pH of live animals promotes microbe development, various intrinsic features of animal tissue may regulate microbial growth and survival. By evaluating the many intrinsic variables in specific meals, it is possible to forecast what broad types of microorganisms may be present and alter handling and processing techniques to ensure a high-quality, safe product.

Acidity It is generally known that most bacteria can survive and develop in a pH range of 6.5-7.0. The pH range for microbes thriving on food, on the other hand, is fairly broad (pH 4.0-9.5). Although few microorganisms (mainly yeast and moulds) can thrive below pH 4.0, several can survive. The kind of microbe and other parameters such as temperature, acid type, salt level,

dietary composition, and the presence of preservatives (e.g., potassium sorbate or sodium benzoate) all influence growth and survival at low pH levels. Microorganisms are more sensitive to pH changes during the early or logarithmic growth phases, when fast growth occurs, than during the stationary or resting growth phases.

As a result, microorganism growth and survival differ between food systems. Less acidic goods, such as meats, seafood, and vegetables, are more prone to bacterial deterioration and pathogenic development. Fruits, fruit juices, soft drinks, vinegar, and wines have pH values that are lower than those at which bacteria normally thrive. As a result, yeast and mould spoiling are more prevalent than bacterial deterioration (one exception being the rotting of certain fruit juices by lactic acid bacteria and other acid-tolerant bacteria).

Certain foods have an intrinsic pH, whereas others may be changed by the action of particular microbes. This impact is shown in lactic acid-fermented goods such as cheese, cultured dairy products, sauerkraut, and pickles. Certain foods are buffered because they withstand pH changes produced by microbial development. The different proteins included in meat and milk products act as buffers. Vegetables, on the other hand, are poor in protein and cannot withstand pH fluctuations.

Acid has two major impacts on respiring microbial cells: it makes the food less suitable as a setting for essential enzyme processes, and it alters nutrient delivery into the cell. A neutral pH is required for metabolic processes such as the creation and usage of deoxyribonucleic acid (DNA) and adenosine triphosphate (ATP). When microorganisms are cultured below or above their ideal pH, the duration of the lag time (the period immediately following inoculation or contamination when cells have not yet begun to develop exponentially) increases. If the substrate on which the cells are growing is buffered at a low pH, the lag period may be extended even more.

The pH of the environment can influence metabolite transfer into bacterial cells. Bacterial cells often retain a negative charge. Nonionized (uncharged) chemicals can therefore enter the cell, whereas ionised (charged) compounds cannot. Organic acids in their ionised state, in particular, (at higher, i.e., neutral or alkaline, pH) do not penetrate microbial cells, but nonionized acids (at low pH) may.The interaction between Hi and enzymes in the cytoplasmic membrane is another impact of low pH on bacteria. Several microorganisms' morphology changes as a result of acidity: Pcriicilliuni chrysogenuni, for example, has shorter hyphae when cultivated on media with a pH greater than 6.0.

Other environmental elements, such as temperature and salt, may interact with pH in a synergistic manner. For example, when temperature rises, the pH of the substrate becomes more acidic. As a result, many microbes may be more acid tolerant at lower temperatures. As salt concentrations reach the ideal limit for most microbes, the pH range that allows them to flourish narrows. Microorganisms are also more vulnerable to a wide range of hazardous substances when the pH is low.Since enteric infections must survive the acidity of the stomach before they can cause sickness in the intestinal system, their acid survival abilities are critical to their pathogenicity. Some strains of Yersinia enterocoliticu have been found to exhibit low pH stability and survival in tartar sauce, cheese, and yoghurt. Listeriu mwzocjItogrrws has

demonstrated the capacity to survive fermentation in the production of fermented goods such as sauerkraut, cheese products, and sausages. Plesiomonus shigelloides, a waterborne pathogen commonly associated with seafood, has been demonstrated to be acid- and salt-tolerant, with some strains growing at pH 4.0 (Miller and Koburger, 1986). Some strains of Eschrrichiu cdi 0157:H7 have been demonstrated to exhibit high acid pH tolerance, living for 14--21 days at 4°C in apple cider (pH 3.7-4.1). (Miller and Kaspar, 1994). Also, these *E. coli* 01 57:H7 strains survived better at 4°C than at 25°C in acidic trypticase soy broth (pH 2, 3, and 4).

Cells with increased acid survival characteristics can develop from relatively low pH exposure. This behaviour, known as acid adaptation, has been reported in *E. coli* as well as Sahnonellu species (Leyer and Johnson, 1993).Streptococcus, Lirtcvu (Kroll and Patchett, 1992), and Enterococcus (Belli and Marquis, 1991). The acid tolerance response (ATR) of Snlnionrllri tyldiimiiriimi is the most thoroughly studied acid adaptation (Foster, 1993). Native antimicrobial agents some naturally occurring chemicals present in certain foods improve their stability by killing or suppressing microorganisms. Essential oils such as eugenol in cloves, allicin in garlic, cinnamic aldehyde and eugenol in cinnamon are examples of such chemicals in plants. Lactoferrin, conglutinin, and the lactoperoxidase system are all antibacterial compounds found in cow's milk. The best-known of these agents, the lactoperoxidase system, is made up of three components: lactoperoxidase, thiocyanate, and peroxide, all of which are necessary for antibacterial action.

Gram-negative bacteria, such as pseudomonads, are very sensitive to extremely low concentrations (1.0 ppm) of these chemicals. In poor nations where refrigeration is scarce, this approach has been used to preserve milk. The system's ability to change the thermal characteristics of bacteria in milk is an intriguing aspect. Thermal D values (decimal reduction: the time required at constant temperature to reduce the bacterial population by one log) of L. nzonocytogenrs and Staphylococcus uureuJ, for example, may be reduced by more than 80%. (Kamau et al., 1990). The fundamental process is yet unknown. Fatty acids and casein, among other milk components, have been found to exhibit antibacterial action under specific circumstances. Pasteurization destroys the rotovirus inhibitor that is present in raw milk.

Lysozyme is found in eggs, milk, clams, and oysters and can operate as an antibacterial agent. Fruits, vegetables, tea, molasses, and a variety of plants have antibacterial and antifungal properties that are hypothesised to be derived from hydroxycinnamic acid derivatives such ferulic, caffeic, and chlorogenic acids. Glucosiiiolates are found in the cell vacuoles of cruciferous vegetables such as cabbage, brussels sprouts, broccoli, and turnips. When these molecules break down, isothiocyanates are released, which have antifungal and antibacterial properties.

Potential for oxidation-reduction it is widely known that different microorganisms are sensitive to the oxidation-reduction (O/R) potential of their growth medium. The ease with which a substrate loses or obtains electrons is defined as its O/R potential. When an atom or molecule loses electrons, it is oxidised; when it acquires electrons, it is reduced; hence, a substrate that rapidly gives up electrons is a good reducing agent, and one that readily accepts electrons is a good oxidising agent. When electrons move from one chemical to another, they generate a

potential difference (E) that may be detected with a potentiometer. E can be positive (oxidation), negative (reduction), or zero when represented in millivolts (mV).

The oxygen tension of the environment, the availability of the food system to that environment, the intrinsic O/R features of the system, and the poising capacity all influence the O/R potential of food systems or complex growth mediums (represented as &,). Reducing conditions are maintained in food items by reducing components such as sulfhydryl (SH) groups in proteins and amino acids, ascorbic acid moieties, and/or reducing sugars. Oxidizing circumstances are controlled by the presence of oxygen, oxidising catalysts (such as iron and copper), and specific oxidation processes (for example, lipid oxidation). Because Eh measurement is heavily impacted by pH, published measurements should include the system's pH. Food's & vary greatly. Plant meals and juices often have Eh values ranging from 300 to 400 mV. Protein-rich diets typically have negative Eh values.Aerobic bacteria require positive Eh values for growth, while anaerobes require negative Eh values. The Eh requirements for severe anaerobe development (such as Clostuidium) are around -200 mV. Very low Eh levels would be toxic to stringent aerobes like Bucillus. Some bacteria are classed as either microaerophilic (aerobes that grow better at lower (lowering) Eh values) or facultatively anaerobic (those that may thrive anaerobiotically or aerobically).

Moisture level Drying or dehydration is one of the oldest ways of food preservation, performed by eliminating water and/or binding the water in the food so that germs cannot thrive. Microorganisms' water needs are characterised in terms of water activity (a,) in their environment. This number is defined as the ratio of a food's water vapour pressure to pure water's vapour pressure at the same temperature (pure water has a, of 1.00). For example, of a saturated sodium chloride solution in water is 0.75. Water activity is proportional to relative humidity (RH; see below): RH = 100 x a,because all biochemical reactions require an aqueous environment, decreasing water availability has a negative impact on enzyme activity and hence on biological processes. In general, decreasing LI lengthens the lag phase of development of microorganisms, decreases their growth rate, and decreases the ultimate population size.

Yeast and moulds may thrive in a broader range of temperatures than bacteria, which often require a greater level of water activity. Most spoilage bacteria, for example, will not grow below a, of 0.91, whereas moulds can thrive as low as 0.81 a, 5'. aureus, a bacterial pathogen, may grow as low as 0.84 a, however its toxin production may be limited. Clostvidiurn botulinum cannot develop at temperatures below 0.94 a.

Several foodborne germs can develop in response to relationships between a, temperature, pH, Eh, and nutritional variables. Lowering a, for example, at any given temperature limits the capacity of microorganisms to grow.The, range that permits a certain bacterium to grow can be stretched 146. The presence of particular nutrients or growth factors affects the physiology and survival of foodborne pathogens. The minimal a, values for various foodborne bacteria.

Although bacteria cannot multiply in dried food products, they can usually survive in them. Salnzonellu's long-term survival at low. Salnzonellu has showed species heterogeneity in survival properties after long-term (19 month) storage of chocolate and cocoa products and

nonfat dry milk (Tamminga et al., 1977). L. rnonocytogenes has also been demonstrated to withstand nonfat dry milk manufacturing and long-term storage.

To combat osmotic stress, microorganisms growing at suboptimal an accumulate suitable osmoprotective solutes such as K+, glutamine, glutamate, proline, sucrose, trehalose, and polyols (i.e., glucosylglycerol). These solutes accumulate as a result of cellular production or enhanced transport. Although enteric pathogens such as *E. coli* and S. typhimurium do not synthesise proline as a protective measure, they accumulate proline through enhanced transport into the cells. When grown under unfavourable osmotic conditions, L. monocytogenes can accumulate several osmoprotectants (primarily carnitine). Several researchers suggest that L. monocytogenes grows at 4°C due to the buildup of glycine betaine. Saln~onella oranienhur-g grown at suboptimal water activity levels has demonstrated an elevation in respiratory activity in the presence of proline. Overall, the effect of reduced water activity on the feeding of microorganisms appears to be of a general character, because cell metabolism depends on reactions in an aqueous environment. Microorganisms that can grow under extreme water activity conditions do so by virtue of their ability to concentrate salts, polyols, and amino acids to internal levels sufficient not only to prevent water loss but to allow the microorganism to extract water from its environment.

Nutrient content To grow, microorganisms require, besides water, (I) an energy source, (2) a nitrogen source, (3) vitamins (especially B vitamins) and related cofactors, and (4) minerals. Energy sources for microorganisms include simple sugars, alcohols, and amino acids. Very few microorganisms are able to metabolize polysaccharides such as starch, cellulose, and glycogen (which must first be degraded to simple sugars), and few can utilise fats. The primary nitrogen source for food microorganisms is amino acids; some species can also hydrolyze and use more complex nitrogen sources such as peptides and proteins.B vitamins are found in most foods at levels adequate to support the growth of microorganisms (such as gram-positive bacteria) that cannot synthesise these vitamins. Gram-negative bacteria and yeast can synthesize B vitamins and as a result can grow in and on foods low in B vitamins. Fruits tend to fall into this category, which (along with their usually low pH and positive Ell) may help explain why fruits are generally spoiled by moulds rather than bacteria.

The coverings of many foods help prevent the entry of microorganisms and subsequent food damage and spoilage. For instance, the skin of fish and meats tends to dry out faster than the flesh it covers, retarding spoilage. Fruits and vegetables are also usually covered by skins and spoil faster when these are damaged or broken than when they are intact.

Extrinsic Factors Affecting Growth and Survival

Extrinsic factors are those factors associated with the storage environment that can affect both a food and the associated microorganisms. These include heat treatment, storage temperature, relative humidity of the environment, presence and concentration of gases, and presence and activity of other microorganisms.Heat treatment Food products may be subjected to a variety of treatments that eliminate or reduce the potential for pathogenic microorganisms. The most common approach is heat treatment, including pasteurisation, sterilisation, and cooking.

Microorganisms vary in their heat resistance, with the most heat stable being termed therinodurics. With exception of the spore formers (e.g., Clostvidium and Bacillus), most microbial pathogens can be destroyed by hightemperature heating. However, certain bacterial toxins (e.g., the s. aureus enterotoxin) as well as some viruses (e.g., hepatitis A) are relatively heat stable. Selection of appropriate process parameters of temperature and heating time for a particular food is based on the properties of the most heat-resistant pathogen associated with the product, heat penetration and transfer characteristics, and compositional parameters. In commercial sterilisation, appropriate heat treatment is applied to achieve a 12-log reduction of test spores of higher heat resistance than C. hotulinum. Pasteurization is a milder heat treatment applied to destroy pathogens likely to be associated with a specified food system. For example, the heat treatment involved with milk pasteurisation is based on the destruction of Coxirllu huvnetii (the causative agent of Q fever), and the pasteurisation requirements for egg products are designed to destroy Sulmonellu.

Storage temperature because microorganisms grow over a wide temperature range, it is important to select proper food storage temperatures to help control their growth. The general effect of temperature on microbial activity is shown in Figure 7.1. The lowest temperriture at which microorganisms are known to grow is -34°C (-29"F), and the highest is slightly over 100°C (212°F). Microorganisms are generally categorised into three groups based on their growth temperature requirements. The largest category are the mesophiles, which grow well between 20°C (68°F) and 45°C (1 13°F). Those that grow well between 55°C (131°F) and 65°C (149°F) are called thermophiles.

The foodborne thermophilic bacteria of most importance belong to the genera Bocillus and Clostridizm. Finally, some mesophiles, termed psychrotrophs, arecapable of growing at or below 7°C (45"F)-in contrast to other bacteria that can survive but not develop in food stored at refrigeration temperatures. Psychrotrophs thrive at cold temperatures and cause spoiling of meats, fish, milk, poultry, and eggs. AIcciligenes, Sheu.rmellu, Brochotlzrix, Corynehacterium, Fluvohacterium, Ltrctohacilhs, Micrococcus, Pseudomonus, Psvchrohacter, and Eiiterococcus are all psychrotrophic species.

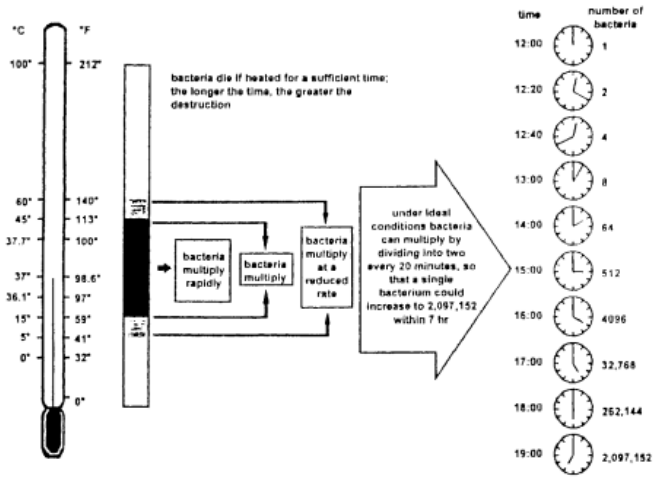

Figure 7.1 represents the General effect of temperature on bacteria.

lists psychrotrophic foodborne microorganisms that have been found to flourish at refrigerator temperatures. Some pathogens, although not growing at low temperatures, are capable of surviving (CAST, 1994). Temperature abuse and variation during storage should thus be avoided to prevent these organisms from multiplying to the point where they might cause sickness.Molds may grow in a variety of pH, osmotic pressure, nutritional content, and temperature conditions. Several moulds, including Aspergillus, Clidosporium, and Tlzu171iiiidium, may grow on eggs, meats, and fruits when refrigerated. Yeast may grow in both psychrotrophic and mesophilic environments.

The most crucial factor influencing the deterioration and safety of extremely perishable, ready-to-eat meals may be storage temperature. Inadequate temperature management has been a major contributor to foodborne illness outbreaks. Freezing is not an efficient way to destroy germs. In fact, inappropriate thawing temperatures can promote microbe development, and a frozen and improperly thawed food product may be an even better substrate for microbial growth than fresh food provided the freeze-thaw process has caused enough cellular damage for nutrient release.

Humidity relative the relative humidity (RH) of the storage or packaging environment is critical for maintaining an optimum an in the food and regulating microbial development on the food's surface. If a food u has been established, it is critical that the food does not absorb moisture from its surroundings, increasing its LI and allowing microbial development. Foods placed in low-RH situations will lose water and re-acclimate to their surroundings. Foods with low a, on the other hand, will absorb moisture (raise a,) when kept in a high-RH environment.While keeping foods, keep in mind the link between temperature and RH value—in general, the higher the temperature, the lower the RH. Molds, yeast, and bacteria on the surface of foods should be preserved under low-RH settings. Foods such as meats, entire chickens, and fish that are inadequately wrapped and stored in a refrigerator likely to suffer surface spoiling before deep deterioration begins due to the high RH of the refrigerator and the fact that surface spoilage bacteria on meats tend to be aerobic. As a result, while selecting optimal storage conditions, the possibility for surface growth as well as the necessity to retain desired attributes in the food must be considered. Changing the food's gaseous environment (as explained in the following section) might delay surface rotting without lowering the relative humidity.

The makeup of the atmosphere The modification of the environment during food storage, known as controlled-atmosphere (CA) or modified-atmosphere (MA) storage, has been generally recognised in some parts of the food business as a method of improving shelf life. Atmospheric alteration can be accomplished by using various gas mixes high in car-bon either in the storage chamber or in the packing, or via vacuum packaging. In recent years, the use of 03 as a preservative during storage has also been considered. 03 is a powerful broad-spectrum bacteriocide. Nevertheless, because to its high oxidative qualities, it is only useful in situations where lipid oxidation and equipment corrosion are not a problem.Increased CO2 levels during fruit storage have been found to delay fungal decay. CO? also works as a competitive ethylene inhibitor, delaying fruit ripening. In addition to vacuum packaging, COz or N2 enrichment is employed in meat preservation.

Other microbes are present. The microflora of food items is made up of a diverse range of microorganisms, including rotting bacteria, pathogens, benign microorganisms, and desirable microbes that help in food preservation. Lactic acid bacteria are the most well-known of these beneficial microorganisms. They are required for the creation of a wide range of fermented foods, such as cheese and cultured dairy products, pickles, sauerkraut, and sausages. Additionally, their activity and development extend the shelf life of packed beef products. In addition to the direct effect of the lactic acid's lower pH, lactate itself is inhibitory to other microorganisms. The lactoperoxidase system is found in many lactic acid bacteria, which results in the formation of hydrogen peroxide, which inhibits other bacteria. Bacteriocins are another family of antibacterial chemicals produced by some lactic acid bacteria.

Certain spoilage bacteria prevent pathogenic microorganism growth through competition; others, on the other hand, might increase pathogen growth. Pseudomonus species, for example, have been found to accelerate L. 1iioi7oc.ytogevzes (Marshall and Schmidt, 1988) and S. oureus (Seminiano and Frazier, 1966) growth by increasing available substrates via proteolysis and lipolysis.While not as thoroughly investigated as bacterial impacts, the presence of yeast and moulds and their metabolites can change bacterial growth and activity. Several spoilage and dangerous bacteria are inhibited by yeast metabolites (such as carbon dioxide and ethanol) in alcoholic drinks and bread products, for example. The naturally existing yeast has an antilisterial action during the ripening of Camembert and comparable cheese products. L. monocytogenes growth, on the other hand, may be encouraged by the mould Penicillium cumemberti, which is connected with Camembert production.

The fundamental variables listed above, with the exception of how they may be influenced by incorrect production procedures or inadequate sanitation standards, are not normally subject to regulatory inspection. Several of the extrinsic elements, particularly heat treatment and food storage temperature standards, are governed by federal, state, and international laws.

CHAPTER 8

THERMAL THERAPY

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The Food and Drug Administration (FDA; 19984) regulates commercial sterilisation of hermetically sealed food items made in the United States or imported into the country. These requirements apply to low-acid canned foods (LACF) with a pH greater than 4.6 and a (I,+ of 20.85, as well as acidified foods (AF) with a pH greater than 24.6. Although the FDA does not authorise, licence, or issue permits for finished food products in interstate commerce, all commercial processors and importers of LACF and AF are required to register with the FDA and provide processing information. According to the Grade A Pasteurized Milk Ordinance (USPHS/FDA, 1995), it is necessary to ensure that every particle of milk is heated to the appropriate temperature for the appropriate time and that the equipment used meets strict regulatory testing and controls to avoid any risk of cross-contamination with raw product or risk of postpasteurization contamination. Guidelines for pasteurisation temperature and time limits for juice and other liquid food items are less detailed. The FDA Food Code (USPHS/FDA, 1997) describes recommended cooking processes for meats, seafood, and other goods prepared in retail food systems.

Food Storage and Transportation Temperature Requirements Maximum regulatory storage temperature limits for a variety of commercial food goods, including milk, meat, and marine products, have typically been set at 7°C (45°F) by state and federal laws. The FDA-recommended temperature for food storage in retail businesses has been dropped from 7°C (45°F) to 5°C (41°F) or below due to concerns about psychrotrophic development of some infections (USPHS/FDA, 1997). The Food Safety and Inspection Service (FSLS) and the FDA has announced a draught regulation aimed at minimising the possibility of Sulmonellu enteritidis contamination in eggs (FDA, 1998b). FSIS would change its regulations in the proposed rule to require that shell eggs packed for consumer consumption be kept and transported at 57°C (45°F), and that these eggs be labelled to indicate that refrigeration is necessary. Although some jurisdictions now mandate a temperature of 7°C (45°F) for egg storage, others have maintained the 15.5"C (60°F) formerly needed by USDA grading systems.

Adaptation and Acid Tolerance

In recent years, acidic foods such as mayonnaise, apple cider and other fruit juices, and yoghurt have been linked to foodborne illness outbreaks including *E. coli* 0 157:H7 or Salmoiiellu (USDA, 1998). As previously stated, the acid survival qualities of these bacteria are influenced by a number of circumstances. Acid survival is often higher during low-temperature storage.

Current research is largely focused on gaining a better knowledge of acid adaption and its significance in food safety. Acid adaptation by previous pH 5.0 incubation has recently been found to considerably improve acid survival features [particularly at 5°C (41"F)I of strains of *E. coli* 0157:H7 and Sulmonellrr in different acidic condiments] (Tsai and Ingham, 1997). In general, acid-adapted *E. coli* 0157:H7 bacteria outlived Sulwmnellu or nonpathogenic *E. coli* strains. The presence of acid-adapted *E. coli* 0157:H7 in feedlot cattle faeces has been linked to feed type and may be lower in animals on grass-based diets vs grain-based diets (Stanton, 1997).

Resistance to Heat

Foodborne disease outbreaks linked to commercial hamburger products, as well as the identification of *E. coli* 0157:H7 from ground beef, have raised concerns about optimal cooking temperatures in retail and home cooking applications for the eradication of this pathogen. This worry has resulted in the revision of cooking instructions and retail preparation regulations (USPHS/FDA, 1997).

The potential pathogen link with unpasteurized juice products noted above has sparked debate about the need to mandate pasteurisation of fruit and vegetable juices. current and future implications Instead of requiring pasteurisation, the FDA is proposing that all juice manufacturers develop a Hazard Analysis Critical Control Point (HACCP) system that includes validation that the processing/handling system used is capable of a 5-log reduction in a relevant pathogen (defined as *E. coli* 0157:H7 or L. monocytogenes; USDA, 1998).

Milk pasteurisation rules in the United States and throughout the world are now under investigation because to worries about the purported heat resistance of Mycohacterium paratuberculosis in milk. This microbe, which causes Johne disease in cattle and may be linked to Crohn's disease in humans, was discovered from raw and pasteurised milk samples in the United Kingdom (Streeter et al., 1995).

The experimental findings on this organism's survivability after pasteurisation treatment have been contradictory and unsatisfactory. This microorganism's heat resistance is related to both its original population and its physical condition (clumped vs. nonclumped). At initial inoculation levels of >lo2, M. parutuberculosis may withstand normal pasteurisation procedures in test tube heating studies (Stabe1 et al., 1997; Sung and Collins, 1998) or utilising laboratory scale high temperature short time (HTST) pasteurisation equipment (Grant et al., 1996; Grant et al., 1998). Additional studies employing laboratory grade HTST pasteurisation equipment found that an initial inoculation of lo4 and 10' cfu/ml resulted in full inactivation (Stabel et al., 1997).

For several bacteria, heat-inducible thermal tolerance, a feature acquired following sublethal heat treatment or "heat shock," has been identified. For example, it has recently been demonstrated that "heat stunning" vegetative cells at 55°C (1 3 1°F) for 30 minutes can result in Clostridium perjringens strains with acquired thermal tolerance—capable of surviving standard cooking procedures (Heredia et al., 1997). Exposure to low heat has also been proven to improve *E. coli* 0157:H7 heat resistance. In studies where beef gravy infected with 0157:H7 was warmed to 46°C (1143°F) for 15-30 minutes, the microorganism's heat resistance at 60°C (140°F) rose by

1.5-fold (Murano and Pierson, 1993). Heat-induced thermal tolerance might have ramifications for makers of refrigerated, cook-in-the-bag goods including filled pastas, gravies, and beef stews.

Antimicrobial Drug Resistance

Subtherapeutic antimicrobial medication usage in animal husbandry, as well as their use in medicine, may provide selective pressures that favour the establishment of resistant strains of enteric infections. Because of the selection and transmission of transferable multiple resistance factors (R factors; D'Aoust et al., 1992), poultry has been proposed as a major reservoir of antibiotic-resistant Sulnionrllrr bacteria. Recently, the antibiotic resistance profiles and R factors of Salmonella and *E. coli* isolates from 104 broiler carcasses were studied.While predominantly studied in the United Kingdom, zoonotic infection with S. fyphinzurium [definitive type (DT) or phage type] 104 has become a well-known concern worldwide (Dargatz et al., 1998). Multidrug-154 S. fyplzinzurium (mrDT104) has been shown to be resistant to five antibiotics (ampicillin, chloramphenicol, streptomycin, sulfonamides, and tetracycline) and may have gained resistance to more medicines. Although the presence of S. typhimurium mrDT104 and associated phage types 104b and U302 in the United States has not been thoroughly documented, it may have been prevalent since the early 1990s. In addition, a multiresistant 5' Enterica serotype has recently evolved in the United States (1998).

Characteristics of Biological Hazards in Foods

Foodborne biological risks are recognised and explored in this chapter based on their inclusion in three broad but separate categories: bacterial, parasitic, and viral. These dangers are referred to jointly in the United States.Result in millions of diseases and thousands of deaths per year, with an estimated economic effect of $8.4 billion per year. Evidently, the majority of foodborne infections go unreported and untreated, because unknown agents cause an estimated 62 million illnesses and 3200 deaths in the United States each year, whereas established etiologies cause just 14 million illnesses and 1800 fatalities.Undercooked meat, poultry, shellfish, and unpasteurized milk have all been linked to illness outbreaks in the past. Other foods, such as internally infected eggs, juices, fruits, sprouts, and other plants, have lately emerged potential vehicles of transmission. Foodborne infections may originate as a result of societal, economic, and/or biological reasons. The globe currently sustains an all-time high human population, including individuals with a wide spectrum of disease susceptibility.

Variance in susceptibility has occurred from a rise in the number of people with impaired immune systems, an increase in the use of immunosuppressive medications, an increase in the average population age, and a global increase in malnutrition. Furthermore, increased global travel, particularly in developing countries, and expanding international trade contribute to the introduction and spread of foodborne diseases, while urbanization causes increased human crowding, resulting in more contact and, as a result, increased opportunities for pathogen transmission.

Food production and processing processes, as well as food preparation procedures, have been influenced by industrial innovations and changes in consumer lifestyles and demand. The increased number of single-parent homes and working women has reduced the amount of time

available for dinner preparation. In response to customer demand, the food industry is progressively manufacturing foods that are fresher in flavour and appearance, little processed, and "natural" or additive-free, while also needing minimal preparation prior to consumption.The sections that follow identify and discuss biological risks that are now a public health issue in food and water. A brief background discussion is followed by a review of general features and foodborne disease characteristics, as well as a section on mechanisms of pathogenesis for each infection. Foodborne/waterborne diseases are discussed in terms of regulatory, industrial, and international consequences, as well as existing and future implications.

Despite the fact that food microbiology is a relatively new scientific area, foodborne and waterborne pathogens have been known for almost 200 years. Vibrio cholcrm is made up of various serogroups, with V. clzolvw 01 being the causative agent of cholera, which has been reported as far back as 1817, when the first known pandemic occurred. The bacterium was initially characterised in 1854, and a link between cholera and drinking water was proposed. Robert Koch recovered the bacillus from suspicious pond water in 1883, proving the theory (Murray et al., 1999). During an outbreak in India in 1992, the serogroup V. clzulcrNe 0 139 Bengal was discovered. Several non-0 1 /O 139 V. cholcruc. serogroups, in addition to these, have been found and are known to collectively as nonagglutinating vibrios (NAGS) (Jay, 2000). Toxigenic V. cholerae is thought to be responsible for 49 cases of foodborne sickness in the United States per year, with a case fatality rate of 0.006.

Eberth discovered Scrlnzonrllu Typhi, the etiologic agent of typhoid illness, in f880. Gamy identified the organism that Lignieres named after Dr. Salmon in 1900, based on his work with the isolation of S. Cliolerae-suis from hog cholera-infected pigs. The first antigenic variation-based approach for Srilrnonella categorization was established in 1926, and it was extended into the Kauffmann-White scheme in 1941. Snlnzonellrr was linked in 69'2 recorded bacterial foodborne illness outbreaks in the United States between 1988 and 1992; 60'2 of those outbreaks featured S. Enteritidis. Scllnionellu is the second most prevalent bacteria implicated in foodborne illness outbreaks in the United States, with nontyphoidal strains responsible for an estimated 1.3 million cases per year and a case fatality rate of 0.0078. Ercherichia coli, formerly known as Bacterium coli, was identified by Theodor Escherich over a century ago and was implicated as a cause of gastroenteritis and considerable newborn mortality by the mid-1940s (ICMSF, 1996). Two findings in 1982 led to the identification of Shiga toxin-producing *E. coli* (STEC) as a distinct type of diarrheagenic E. coli.

The first was the identification of specific symptoms in patients from two outbreaks involving a fast-food chain's restaurants in two states, where the etiologic agent was a hitherto seldom identified serotype, 01 57:H7. The second finding concerned occasional incidences of hemolytic uremic syndrome (HUS) in people who had faeces containing cytotoxin-producing *E. coli* (Blaser et al., 1995). Today, diarrheagenic *E. coli* is thought to be responsible for about 170,000 instances of foodborne illness in the United States each year; the case fatality rate for 0157:H7 and non-O157:H7 STEC is 0.0083. The word "staphylococcus" derives from the Greek root staphyle, which refers to grapes, and was first used in 1882 to describe pathogenic, cluster-forming cocci. In 1884, the link between staphylococci and foodborne disease was proposed. In

1914, Barber observed sickness symptoms in people who had consumed milk contaminated with Staphylococcus aureus. Toxins had a part in staphylococcal food poisoning (intoxication) in 1930, when consumption of s. azirezis cell-free filtrates resulted in the development of clinical symptoms (Jay, 2000; Lund et al., 2000). It is estimated that S. aurezis causes 185,000 cases of foodborne sickness in the United States per year, with a case fatality rate of 0.0002.

Despite the previously documented association between aerobic, endosporeforming bacteria and foodborne sickness, it was not until the early 1950s that Bacillus cereus was identified as an etiologic agent of foodborne disease. Presently, B. cereus is expected to cause roughly 27,000 instances of foodborne disease in the United States each year, while the number of deaths related to this agent is exceedingly low.Yersin discovered the etiologic agent of plague in 1894, and Van Loghem described the genus Yersinia in 1944, suggesting the inclusion of Pasteurella pe- tis and P. pseudotuherculosis; in 1964, Pasteurella X, or Bacterium enterocoliticum, was added to the genus Yersinia. Although being discovered and identified as a human pathogen in the 1930s and as a cause of gastroenteritis in 1965, the transmission of Y. enterocolitrca to humans through food has only been recognised in the United States since 1976. It is estimated that Y enterocolitica is implicated in about 87,000 cases of foodborne sickness in the United States each year, with a case fatality rate of 0.0005. Clostridium perjringens has been linked to gastroenteritis since 1895, but it wasn't recognised as a major source of foodborne illness until the 1940s (Jay, 2000). It is responsible for two forms of human disease: C. perfringens type A food poisoning and necrotic enteritis, with the latter being the less common of the two. C. perjiringens is now expected to cause roughly 250,000 instances of foodborne disease in the United States each year, with a case fatality rate of 0.0005.

Although a botulism-like disease had been connected with the intake of sausage in the early 1800s, the bacteria Clostridiium botulinum was first identified from food and implicated as the causative agent in a foodborne epidemic in 1897. Baby botulism was first identified in 1976 and has since become the most prevalent type of the disease in the United States.

C. botulinum is now responsible for 58 foodborne illness cases in the United States per year, with a case fatality rate of 0.0769. Since 1898, when Shiga characterised it during a Japanese epidemic, the genus Sliigellu has been identified as a cause of bacillary dysentery (Murray et al., 1999). Flexiier hypothesised the presence of a toxin related with Slzrgella infection in 1900, which Conradi validated in 1903. Shigellu infections are more prevalent than waterborne infections, and it is estimated that Shigella spp. are implicated in almost 90,000 cases of foodborne sickness in the United States each year, with a case fatality rate of 0.0016. (ICMSF, 1996; Mead et al., 1999).

Cmnpylobacter was isolated in culture for the first time in 1909, and King initially identified the group as "related vibrios" in 1957, so termed because of their appearance and relationship with acute enteritis in humans. Species of Cunzp,vlobacter have been recognised as agents of foodborne gastroenteritis, known as campylobacteriosis or Cunipj3/obucter enteritis, since the late 1970s, and in the past 10 years Cumpylobucter jejzini has become well established as the most common cause of bacterial foodborne illness in the United States, resulting in 2.0 to 2.5 million cases annually and having a case fatality rate of 0.001.

ListerLC1 nionocytogens were initially characterised in the 1910s and 1920s, and the first recorded human case in 1924 was a soldier suffering from meningitis during World War I. (Ryser and Marth, 1999). Foodborne outbreaks were not recognised until 1981, when the first verified epidemic occurred in Nova Scotia, Canada. Due to the high case fatality rate. Listeriosis has arisen as a major source of worry for the food sector, as well as health and regulatory bodies. According to current estimates, L. n?onoc.ytogenes is responsible for around 2500 cases of foodborne illness in the United States each year, with a case fatality rate in excess of 0.2. Vihrio parulzurmoljticzu was originally detected in the United States in Maryland in 1971 as the causative agent in a gastroenteritis outbreak in Japan in 1950. (Janda et al., 1988). It has become one of the most prevalent causes of Vibrio-induced diarrhoea in the United States, with more than 20 outbreaks recorded between 1973 and 1987. V. parahuemolyticus was responsible for 88 hospitalisations and 8 fatalities in Florida between 1981 and 1993. V. vulnificus, also known as Beneckiu vulnlficu or the "lactose-positive Vibrio," was first investigated in depth by researchers in 1976. (Janda et al., 1988). It was called V vulnificus, which means "wound inflicting," as a new species, and a second biotype (biotype 2) was found in 1982. It is now estimated that it causes 47 cases of foodborne illness in the United States per year, with a case fatality rate of 0.39.

A disease can be categorised into two groups based on the function that the pathogen plays during the illness-causing process. An infection occurs when a host is directly invaded by a microbe that, once established, multiplies in the host. Intoxication, on the other hand, occurs after the entry of a particular, prepared toxin into the body of a host, resulting in sickness in the presence or absence of the toxin producer.A food supply can act as a vehicle for the biological danger (infection) and/or its metabolic products, including different poisons (intoxication). The majority of foodborne infections include clinical symptoms that include acute diarrhoea, vomiting, and/or some other gastrointestinal manifestation. Nevertheless, in addition to other chronic sequelae, disorders involving the central nervous system or numerous organs may be the direct or indirect outcome of foodborne pathogenic bacteria.

Bacteria

Bacterial agents are thought to be responsible for around 30% of all foodborne diseases with known aetiology, resulting in more than four million cases in the United States each year. While accounting for just 30% of all foodborne disease, bacterial agents in foods cause roughly 1300 fatalities each year, accounting for 72% of all deaths related to contaminated foods.The following is a summary of foodborne and waterborne bacterial pathogens. Gram-negative pathogenic bacteria investigated include Cumpjilobacter, Salmoizellu, Escherichiu, Shigrlla, Yersiniu, and Vibrio species.Listeria, Stuphylococcus, Clostridium, and Bacillus were among the pathogenic gram-positive bacteria studied. Other bacterial infections that are transmitted less commonly in foods are also listed to a lesser extent.

Campylobacter

Characteristics in general Cumpylobucter and Arcohacter are members of the Campylobacteraceae family, which comprises 18 species and subspecies in the genus

Campylobucter and 4 species in the genus Arcobcrcter. Campyluhuctrr are ecologically linked to poultry and migratory birds, rodents, natural water sources, and insects that may transport the organism on their exoskeleton and have been recognised as key reservoirs in the poultry environment (Altekruse et al., 1999).

Cunipylohucter are thin, curved, gram-negative non-spore-forming rods (0.2-0.5 pm width and 1.5-5.0 pm long) that move through a single polar unsheathed flagellum situated at one or both ends and exhibit a distinctive "corkscrew-type" motility. They are microaerophilic in general, growing best in environments containing 2.0-5.0'% oxygen and 5.0-10.0'%1 carbon dioxide, because growth is impeded in the presence of 21% oxygen. The optimal temperature range for Curiipjdohucter growth is 37-42°C; however, growth occurs between 30 and 45°C under appropriate nutritional, climatic, and environmental circumstances (ICMSF, 1996). Additionally, they can grow in culture medium with pH ranging from 4.9 to 8.0, but prefer pH 6.5 to 7.5. (Doyle, 1989). Cuinpylohacter are drying sensitive and require a water activity (u,) greater than 0.912. They are also very sensitive to sodium chloride, since variation from the optimum (i.e., 0.5%) results in lower growth rates or increased rates of mortality depending on temperature, while greater sodium chloride concentrations are tolerated better at higher temperatures (Lund et al., 2000).

Foodborne disease characteristics the most prevalent Cunipylohucter species involved with foodborne diarrheal disease are Cmpylohucter jejuni and C. coli. Cainpylobacteriosis or Cumpylohucter enteritis can be caused by as few as 500 viable cells, but because not all people are equally susceptible to infection and virulence factors differ between Cunipylobactel- isolates, there are likely to be significant infectious dose differences. Clinical symptoms may last up to 10 days after a 2-5 day incubation period before the start of gastroenteritis. The development of acute colitis is commonly accompanied with fever, malaise, stomach discomfort, headache, watery or sticky diarrhoea with tiny evidence of blood, inflammation of the lamina propria, and crypt abscesses. Infection can cause acute cholecystitis, urinary tract infections, reactive arthritis, bursitis, meningitis, hemolytic uremic syndrome (HUS), endocarditis, peritonitis, pancreatitis, abortion, and neonatal sepsis, in addition to gastrointestinal symptoms (Murray et al., 1999). Additionally, C. jejuni is the most often recognised cause of Guillain-Barre syndrome, an acute paralytic disorder of the peripheral nerve system; particular serotypes, notably 0:19, have been implicated more frequently than others.

In outbreaks, milk, eggs, red meats, water, and, most notably, chicken foods have been identified as vehicles of transmission. Unpasteurized raw milk was used as a vehicle of transmission in the greatest Cunzpylohuctcr enteritis outbreak, which sickened 2,500 schoolchildren. For the purposes of this chapter, foodborne biological risks are recognised and described in three broad but separate categories: bacterial, parasitic, and viral. In the United States, these dangers are referred to as result in millions of diseases and thousands of fatalities per year, with an estimated yearly economic effect of $8.4 billion. Evidently, the majority of foodborne infections go unreported and untreated, because unknown agents cause an estimated 62 million illnesses and 3200 deaths in the United States each year, whereas only an estimated 14 million illnesses and 1800 fatalities include established aetiology.

Undercooked meat, poultry, shellfish, and unpasteurized milk have long been linked to illness outbreaks. Other items that have lately surfaced potential vehicles of transmission include internally infected eggs, juices, fruits, sprouts, and other vegetables. The rise of foodborne infections may be caused by societal, economic, and/or biological causes. The globe currently sustains an all-time high human population, including individuals with a wide range of sensitivity to diseases.Variance in susceptibility among the general population has come from a rise in the number of people with weaker immune systems, an increase in the use of immunosuppressive medications, an increase in the average population age, and a global increase in malnutrition. Furthermore, increased global travel, particularly in developing countries, and expanding international trade contribute to the introduction and spread of foodborne diseases, and urbanisation leads to increased human crowding, resulting in more contact and, as a result, increased opportunities for pathogen transmission.Food production and processing processes, as well as food preparation procedures, have been altered by industrial innovations and changes in consumer lifestyles and demand. The growing number of single-parent homes and working women has reduced the amount of time available for dinner preparation. In response to customer demand, the food industry is progressively manufacturing foods that are fresher in flavour and appearance, little processed, and "natural" or devoid of additives, while also needing minimal preparation before consumption.

The sections that follow identify and discuss biological risks that are now a public health issue in food and water. In addition to a brief background discussion, each pathogen is given an overview of general features and foodborne disease characteristics, as well as a section on mechanisms of pathogenesis. Foodborne/waterborne diseases are discussed in terms of their regulatory, industrial, and international consequences, as well as their current and future implications.Although food microbiology is a relatively new scientific area, foodborne and waterborne pathogens have been identified for about 200 years. Vibrio cholcrm is composed of various serogroups, with V. clzolvw 01 being the causative agent of the illness cholera, which has been reported as far back as 1817, the period of the first known pandemic. The bacterium was initially characterised in 1854, and the link between cholera and drinking water was proposed. The notion was eventually confirmed correct when Robert Koch recovered the bacillus from questionable pond water in 1883. (Murray et al., 1999). During an outbreak in India in 1992, the serogroup V. clzulcrNe 0 139 Bengal was discovered. In addition to these serogroups, several non-0 1 /O 139 V. cholcruc. nonagglutinating vibrios (NAGS) have been found. Toxigenic V. cholerae are thought to be responsible for 49 cases of foodborne sickness in the United States per year, with a case fatality rate of 0.006.

Eberth discovered Scrlnzonrllu Typhi, the causative agent of typhoid sickness, in 880. Gamy identified the organism that Lignieres named after Dr. Salmon in 1900, based on his work with the isolation of S. Cliolerae-suis from pigs suffering from hog cholera (ICMSF, 1996). The first strategy for Srilrnonella categorization, based on antigenic variation, was established in 1926 and expanded into the Kauffmann-White scheme in 1941. Between 1988 and 1992, Snlnzonellrr was linked to 69'2 recorded bacterial foodborne illness outbreaks in the United States, 60'2 of which contained S. Enteritidis. Scllnionellu is now the second most prevalent bacteria linked in

foodborne illness outbreaks in the United States, with nontyphoidal strains producing an estimated 1.3 million cases per year and a case fatality rate of 0.0078.

Formerly known as Bacterium coli, Ercherichia coli was identified by Theodor Escherich over a century ago and was implicated as a cause of gastroenteritis and considerable newborn mortality by the mid-1940s. Two findings in 1982 led to the discovery of Shiga toxin-producing *E. coli* (STEC) as a distinct class of diarrheagenic E. coli.

The first was the identification of specific symptoms in patients from two outbreaks involving fast-food outlets in two states, where the etiologic agent was a hitherto seldom identified serotype, 01 57:H7. The second finding concerned occasional occurrences of hemolytic uremic syndrome (HUS) in patients who generated stools containing cytotoxin-producing *E. coli* (Blaser et al., 1995). Today, diarrheagenic *E. coli* is thought to be responsible for around 170,000 cases of foodborne illness in the United States each year; the case fatality rate for 0157:H7 and non-O157:H7 STEC is 0.0083. The word "staphylococcus" derives from the Greek root staphyle, which refers to grapes, and was first used for taxonomic categorization of pathogenic, cluster-forming cocci in 1882. The link between staphylococci and foodborne disease was proposed in 1884. In 1914, Barber observed sickness symptoms in people who had consumed milk with Staphylococcus aureus. The function of toxins in staphylococcal food poisoning (intoxication) was proven in 1930, when consumption of s. azirezis cell-free filtrates resulted in the development of clinical symptoms. It is estimated that S. aurezis is responsible for 185,000 cases of foodborne sickness in the United States per year, with a case fatality rate of 0.0002. Despite the previously documented association between aerobic, endosporeforming bacteria and foodborne sickness, Bacillus cereus was not identified as an etiologic agent of foodborne disease until the early 1950s. B. cereus is now estimated to cause roughly 27,000 instances of foodborne disease in the United States each year, while the number of deaths related to this agent is exceedingly low.

Yersin identified the etiologic agent of plague in 1894, and Van Loghem described the genus Yersinia in 1944, suggesting the inclusion of Pasteurella pe- tis and P. pseudotuherculosis; Pasteurella X, or Bacterium enterocoliticum, was placed in the genus Yersinia in 1964. (Murray et al., 1999). Although being discovered and identified as a human pathogen in the 1930s and a cause of gastroenteritis in 1965, the transmission of Y. enterocolitrca to humans through food has only been recognised in the United States since 1976. Y enterocolitica is thought to be implicated in about 87,000 cases of foodborne sickness in the United States each year, with a case fatality rate of 0.0005. Clostridium perjringens has been linked to gastroenteritis since 1895, but it was only in the 1940s that it was recognised as a major source of foodborne illness (Jay, 2000). It is responsible for two forms of human disease: C. perfringens type A food poisoning and necrotic enteritis, the latter being the less common of the two. Presently, C. perjiringens is expected to cause roughly 250,000 instances of foodborne disease in the United States each year, with a case fatality rate of 0.0005.

Although a botulism-type disease had been connected with the intake of sausage in the early 1800s, the bacteria Clostridiium botulinum was first identified from food and implicated as the causative agent in a foodborne epidemic in 1897. Baby botulism was first identified in 1976 and

has since become the most frequent type of the disease in the United States.C. botulinum is now estimated to be responsible for 58 foodborne illness cases in the United States per year, with a case fatality rate of 0.0769. Since 1898, when Shiga first characterized it during a Japanese epidemic, the genus Sliigellu has been identified as a cause of bacillary dysentery (Murray et al., 1999). Flexiier hypothesised the presence of a toxin related with Slzrgella infection in 1900, which Conradi subsequently validated in 1903. Foodborne Shigellu infections are more prevalent than waterborne infections, and it is estimated that Shigella spp. are implicated in almost 90,000 cases of foodborne illness in the United States each year, with a case fatality rate of 0.0016.

Cmnpylobacter (previously known as Vibrio foetus) was originally isolated in culture in 1909, and King first identified the group as "related vibrios" in 1957, so termed because of their appearance and relationship with acute enteritis in humans. Species of Cunzp,vlobacter have been recognised as agents of foodborne gastroenteritis, known as campylobacteriosis or Cunipj3/obucter enteritis, since the late 1970s, and in the past 10 years Cumpylobucter jejzini has become well established as the most common cause of bacterial foodborne illness in the United States, resulting in 2.0 to 2.5 million cases annually and having a case fatality rate of 0.001.

ListerLC1 nionocytogens were initially characterised in the 1910s and 1920s, and the first recorded human case occurred in 1924, involving a soldier suffering from meningitis during World War I. (Ryser and Marth, 1999). Foodborne transmission was not detected until 1981, when the first verified foodborne epidemic occurred in Nova Scotia, Canada. Due of the high case fatality rate. Listeriosis has arisen as a serious foodborne illness of concern to the food sector, as well as health and regulatory bodies. Vihrio parulzurmoljticzu was originally detected in the United States in Maryland in 1971 as the causative agent in an episode of gastroenteritis in Japan in 1950. (Janda et al., 1988). It has become one of the most prevalent causes of Vibrio-induced diarrhoea in the United States, with over 20 outbreaks documented between 1973 and 1987 (Doyle et al., 1997). V. parahuemolyticus was responsible for 88 hospitalisations and 8 fatalities in the state of Florida between 1981 and 1993. Another *Vibrio species, V. vulnificus*, commonly known as *Beneckiu vulnlficu* or the "lactose-positive Vibrio," was first researched in depth by researchers in 1976. It was called *V. vulnificus*, which means wound inflicting, as a new species, and a second biotype was found in 1982. It is now expected to cause 47 cases of foodborne illness in the United States per year, with a case fatality rate of 0.39.

A disease can be categorized into two groups based on the function that the pathogen plays in the illness-causing process. An infection occurs when a host is directly invaded by a microbe, which, once established, multiplies in the host. Intoxication, on the other hand, occurs after the entry of a particular, prepared toxin into the body of a host, causing sickness in the presence or absence of the toxin producer.A food supply may act as a vehicle of transmission for the biological hazard (infection) and its metabolic products, including numerous poisons (intoxication). The majority of foodborne infections are characterised by acute diarrhoea, vomiting, and/or other gastrointestinal manifestations. Yet, disorders involving the central nervous system or numerous organs, in addition to other chronic sequelae, may be the direct or indirect effect of foodborne pathogenic bacteria.

Bacterial agents are thought to be responsible for over 30% of all foodborne diseases with known aetiology, resulting in more than four million cases in the United States each year. While accounting for just 30% of all foodborne illnesses, bacterial agents in foods cause roughly 1300 fatalities each year, accounting for 72% of all deaths attributable to contaminated foods.The following is a basic summary of foodborne/waterborne bacterial pathogens. Gram-negative pathogenic bacteria investigated include species from the genera Cumpjilobacter, Salmoizellu, Escherichiu, Shigrlla, Yersiniu, and Vibrio.Pathogenic gram-positive bacteria investigated include those from the genera Listeria, Stuphylococcus, Clostridium, and Bacillus. Also, additional bacterial infections that are transmitted less commonly in meals are listed to a lesser extent.

Campylobacter

General qualities Cumpylobucter and Arcohacter are members of the Campylobacteraceae family, which include 18 species and subspecies in the genus Campylobucter and 4 species in the genus Arcobcrcter. Campyluhuctrr are ecologically related with poultry and migratory birds, rodents, natural water sources, and insects that may transport the organism on their exoskeleton and have been recognised as key reservoirs within the poultry environment.Cunipylohucter are thin, curved, gram-negative non-spore-forming rods (0.2-0.5 pm width and 1.5-5.0 pm long) that are motile by a single polar unsheathed flagellum situated at one or both ends and exhibit a distinctive "corkscrew-type" motility (Lund et al., 2000). In general, they are microaerophilic, growing best in environments containing 2.0-5.0'% oxygen and 5.0-10.0'%1 carbon dioxide, because growth is impeded in the presence of 21% oxygen. The ideal temperature range for Curiipjdohucter growth is 37-42°C; however, growth occurs between 30 and 45°C under appropriate nutritional, climatic, and environmental circumstances (ICMSF, 1996). Additionally, they can grow in pH 4.9 to 8.0 culture medium but prefer pH 6.5 to 7.5. (Doyle, 1989). Cuinpylohacter are susceptible to drying and require a water activity (u,) greater than 0.912. They are also highly sensitive to sodium chloride since variation from the optimum (i.e., 0.5%) results in lower growth rates or increased rates of mortality depending on temperature, while greater sodium chloride concentrations are tolerated better at higher temperatures.

Foodborne disease symptoms Cmpylohucter jejuni and C. coli are the most prevalent Cunipylohucter species involved with foodborne diarrheal disease. Cainpylobacteriosis or Cumpylohucter enteritis can be caused by as few as 500 viable cells, but because not all people are equally susceptible to infection and there are differences in virulence factors among Cunipylobactel- isolates, there are likely to be significant infectious dose differences (Lund et al., 2000). Clinical symptoms might last up to 10 days after a 2--5 day incubation period before the start of gastroenteritis. Infection typically manifests as acute colitis with fever, malaise, stomach discomfort, headache, watery or sticky diarrhoea with tiny evidence of (occult) blood, inflammation of the lamina propria, and crypt abscesses (ICMSF, 1996; Lund et al., 2000). In addition to gastrointestinal symptoms, infection can cause acute cholecystitis, urinary tract infections, reactive arthritis, bursitis, meningitis, hemolytic uremic syndrome (HUS), endocarditis, peritonitis, pancreatitis, abortion, and newborn sepsis. Additionally, C. jejuni is the most widely documented cause of Guillain-Barre syndrome, an acute paralytic disorder of the

peripheral nerve system; particular serotypes, notably 0:19, have been implicated more frequently than others. Milk, eggs, red meats, water, and, most notably, chicken products have been identified as vehicles of transmission in epidemics. Unpasteurized raw milk was used as a vehicle of transmission in the greatest outbreak of Cunzpylohuctcr enteritis, which affected 2,500 schoolchildren. Pets (e.g., puppies and kittens) have also been linked to human instances of canipylobacteriosis.

The pathogenesis of EIEC involves the penetration of the cellular epithelium in the colonic mucosa and entry into the cell via endocytosis, which is dependent on the creation of numerous outer membrane polypeptides mediated by both plasmid and chromosomal genes. After lysis of the surrounding endocytic vacuole, one or more secretory enterotoxins are produced in combination with intracellular replication. Eventually, EIEC travel across the cytoplasm and expand into neighbouring epithelial cells.

Shigella

Characteristics in general the genus Slzigellu belongs to the Enterobacteriaceae family and has four serogroups that have historically been considered as species: serogroup A as S. dysenteviue, serogroup B as S. jlexneri, serogroup C as S. boydii, and serogroup D as S. sonnei. Serogroup D has only one serotype, whereas serogroups A, B, and C have 38. Shigellu are gram-negative rods that are nonmotile, do not produce spores, and are facultatively anaerobic. They can thrive at temperatures ranging from 6 to 48 degrees Celsius, but prefer 37 degrees Celsius, and S. soniiei appears to tolerate lower temperatures better than the other serogroups. Growth is best between pH 6.0 and 8.0, however growth has also been documented between pH 4.8 and 9.3.

Foodborne disease characteristics Sliigellu is genetically related to *E. coli* and shares some biochemical characteristics as well as antibody reactivity, but despite these similarities, their differentiation should be considered clinically significant based, at least in part, on differences in symptoms expressed by infected individuals. Slzigellu are most commonly found in places with poor sanitation and hygiene, and while person-to-person contact is the predominant mode of infection, shigellosis can develop after consuming fecally contaminated water or food. Foods associated with outbreaks of shigellosis have included milk, salads, chicken, shellfish, and other fresh produce served at a variety of establishments including restaurants, homes, schools, sorority houses, commercial airlines, cruise ships, and military mess halls (Doyle et al., 1997; ICMSF. 1996). International travel is responsible for around 20% of all shigellosis cases in the United States, with S. soiinei being the most common and S. fhxnerz being the second most frequent in industrialised nations. S. Jexneri and S. dysenteriue type 1 are the most prevalent serogroups in underdeveloped nations, with S. dysenteriue type 1 being implicated in a protracted pandemic in southern Africa and large outbreaks in other regions of Africa, Asia, and Central America. These outbreaks have led in severe morbidity and fatality rates, particularly among malnourished children, immunocompromised people, and the elderly.

S. sonnei, and S. dysenteriue, while some people have fallen ill after ingestion of doses as low as 10-200 organisms. During an incubation period of 12--50 hours, all Shigellu serogroups can cause gastrointestinal infections, resulting in watery diarrhoea, fever, lethargy, malaise, and

abdominal pains, potentially developing to typical dysentery with sparse stools containing blood, mucus, and pus. Despite its severity, shigellosis is self-limiting, with clinical symptoms lasting 1-2 weeks on average, however they can last up to a month. Although all four Shigellu serogroups can cause dysentery, S. dysenteriue type 1 is the most common cause of epidemic dysentery and is linked with a particularly severe form of the illness that may be followed by additional problems such as HUS. In addition to the link between S. dysenteriae and HUS, S. Jexneri infection has been linked to other consequences such as Reiter chronic arthritic syndrome.

Pathogenicity Mechanisms Classic dysentery is caused by widespread colonisation and invasion of the intestinal mucosa, which culminates in phagocytosis and an immediate inflammatory reaction. Shigellu escape the vacuole and proliferate while spreading across neighbouring epithelial cells without ever leaving the intracellular milieu after cellular entrance.Shigella colonise the lamina propria and form abscesses and mucosal ulcers, resulting in the appearance of blood, pus, and mucus in stools after the sloughing of dead mucosal surface cells.

Shigella virulence is temperature-dependent, and after sensing host ambient temperature (37°C in humans), gene expression of numerous chromosomal and plasmid-encoded genes is activated, and virulent strains may enter mammalian epithelial cells. S. jlexneri type 2a has been identified as releasing two enterotoxins in addition to the Shiga toxins generated by S. dysenteriae type 1, explaining the watery diarrhoea noticed prior to the commencement of dysentery (Vargas et al., 1999). Slzigellu also produces the endotoxin lipopolysaccharide (LPS), which aids in host immune system protection.

Enterocolitica Yersinia

Characteristics in general the genus Yersinia belongs to the family Enterobacteriaceae and has ten recognised species, only three of which are harmful to humans or animals. Yersinia pestis causes plague, Yersinia pseudotuberculosis is primarily an animal pathogen but can infect humans after consuming contaminated food or water, and Yersinia enterocoliticu has been identified as a cause of foodborne gastroenteritis in humans. Yersinia is a gram-negative or gram-variable, non-spore-forming rod that grows in both aerobic and anaerobic environments but is classified as a facultative anaerobe. Except for Yersinia pestis, all Yersinia species have peritrichous flagella and are motile at 22-30°C but not at 37°C.

Ymmia enterocolitica is extensively spread in the environment and has been isolated from raw milk, sewage-contaminated water, soil, seafood, people, and numerous warm-blooded animals, most notably pigs. As a psychrotroph, *Y. enterocoliticu* may offer a health risk in contaminated chilled foods, however the pathogen is generally outgrown by other competing psychrotrophs at refrigeration conditions.Yersinia enterocolitica grows at temperatures ranging from 0 to 45°C, with a preferred temperature range of 25 to 30°C. This psychrotroph can live in alkaline settings just like any other gram-negative bacteria, but not in acidic surroundings since growth occurs between pH 4.0 to 10.0, with pH 7.6 being optimal. Moreover, *Y. enterocolitica* may grow at concentrations as high as 5% sodium chloride).

Foodborne disease characteristics not all *Y. enterocolitica* serotypes are enteropathogenic, and the specific serotypes of *Y. enterocolitica* associated with hunian yersiniosis are predominantly found in pigs. Ingestion of infected water or food, notably raw or undercooked pork, is a cause of foodborne illness in humans, with symptoms showing after a few days to a week of incubation. Intestinal yersiniosis can last 1-2 weeks in adults and up to 4 weeks in children, and symptoms include watery, often bloody, stools or bloody diarrhoea, fever, vomiting, and stomach discomfort that can resemble appendicitis and mesenteric lymphadenitis (Lund et al., 2000; Murray et al., 1999). Immunocompromised people and children under the age of 15 are the most usually affected, and yersiniosis-related extraintestinal illnesses include septicemia, meningitis, Reiter syndrome, myocarditis, glomerulonephritis, thyroiditis, and erythema nodosum.

Pathogenicity Mechanisms Y. eviterocolitica pathogenic serotypes, notably 0:3, 0:5, 0:8, and 0:9, create an enterotoxin and move via the circulation to target lymphatic tissues, where they enter lymph nodes and flourish. Yersinia enterocolitica toxin is heat stable, resists enzymatic degradation, remains stable over time, and has similar pH stability to ETEC's thermostable enterotoxin (ST). Nonetheless, there is evidence that this toxin has a minor role in pathogenesis (ICMSF, 1996).

Although some *Y. enterocoliticu* pathogenicity genes are found on the chromosome, the vast majority are found on virulence plasmids, which produce 171 adhesinlinvasin proteins, antiphagocytic proteins, processing- and excretion-related proteins, and regulatory proteins. The lack of virulence plasmids or plasmid activity leads to diminished pathogenicity and, as a result, the inability to cause illness.

CHAPTER 9

PARAHAEMOLYTICUS VIBRIO

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Characteristics in general the genus Vibrio, which belongs to the family Vibrionaceae, has around 35 species, nearly half of which have been reported in the previous 20 years and more than one-third of which are harmful to humans. Non-spore-forming, predominantly motile, facultatively anaerobic, gram-negative straight or curved rods comprise this genus. For optimal development, all pathogenic Vibrio species, including V. cholerae, V. parahuemolyticus, and V. vulnificus, require salt. They are typically found in brackish or marine habitats in tropical or temperate locations, since their frequency reduces dramatically as water temperature falls below 20°C. Crabs, prawns, scallops, seaweed, oysters, and clams have all been implicated as possible carriers of V. parahaemolyticus ", with optimal growth temperatures and pH levels between 30 and 37°C and 7.6 and 8.6, respectively. The organism will thrive in settings with pH 4.8-11.0, sodium chloride concentrations of 0.5-10.0Y0, and a minimum uw of 0.94; however, it prefers a sodium chloride concentration of 2 to 4%.

Foodborne disease characteristics Vibrio parahuemolyticus is the most common Vibrio species isolated from clinical samples acquired in the United States. Gastroenteritis is usually caused by eating raw, undercooked, or cooked yet recontaminated seafood. Following a 4- to 96-hour incubation period, symptoms of V. paralzamnolyticus-induced gastroenteritis include nausea, vomiting, headache, abdominal cramps, mild fever, chills, and bloody diarrhoea. Other signs of polluted water exposure include infected wounds, eyes, and ears.Although symptoms are normally self-limiting and last only a few days, severe instances can lead to fulminant dysentery, primary septicemia, or cholera-like sickness, with the chance of death.

A preexisting condition (e.g., liver illness, alcoholism, diabetes mellitus, antacid medication, peptic ulcer disease, immunological issue, etc.) considerably increases the risk of acquiring a clinical syndrome such as gastroenteritis, wound infection, or septicemia.Pathogenicity Mechanisms Vibrio pcrrahaeniol.yticus has four hemolytic components, including a thermostable direct hemolysin (TDH), a thermolabile direct hemolysin, phospholipase A, and lysophospholipase.

The majority of strains are TDH-negative, however pathogenicity is linked to the presence of the TDH gene and subsequent generation of the enterotoxin. TDH produces intestinal lumen fluid accumulation after interacting with cellular receptors in the intestinal mucosa via the usage of Ca2+ as an intracellular messenger. Vihrio parahuemolyticus is an invasive pathogen that may penetrate the lamina propria and enter circulation, as evidenced by its presence in the heart, spleen, pancreas, and liver.

Vibrio vulnificus is a kind of bacteria

Characteristics in general Vihrio vulrzijicus, a member of the Vibrionaceae family, moves through a single polar-sheathed flagellum. Vihrio vzi(ficus is found in the same environments as the other pathogenic Vihrio species, and is typically found in temperate or tropical, marine or brackish water sources, particularly near estuaries. It has been cut off from the Gulf of Mexico, the east and west coasts of the United States, and the rest of the globe (Lund et al., 2000). V. vulnijicus has also been isolated from crabs, clams, saltwater samples, and the digestive tracts of bottom-feeding fish (Doyle, 1989).The optimal temperature for V. vulnzjicus growth is 37°C "The organism may thrive at temperatures ranging from 8 to 43 degrees Celsius. Vibvio vulnijiciis can grow in pH ranges 5.0-10.0 with a minimum an of 0.96, but prefers pH 7.8 and an an of 0.98. Moreover, while a sodium chloride concentration of 2.5% is ideal, growth can occur at concentrations ranging from 0.5 to 5.0%. Foodborne disease characteristics Infections caused by Vihrio vu1nficus are significantly connected with water temperature, since most occurrences occur between April and October, and are linked to the eating of infected raw oysters. As compared to other pathogenic Vilio species, Vihrio vulnijicus produces the most severe illness, with wound infections, diarrhoea, and septicemia happening swiftly and usually ending in death.

Vibvio vulnificus is responsible for 95% of seafood-related deaths in the United States and is the primary cause of foodborne illness-related mortality in Florida. Virtually majority V. vulnrjiicus systemic infections following oyster eating occur in people who already have a liver or blood-related illness, such as cirrhosis of the liver; the subsequent increase in accessible iron induced by liver impairment is regarded as a high risk factor for infection. Heinatopoietic diseases are another pre-existing risk factor. Chronic renal illness, gastrointestinal disease, immunosuppressive drug usage, and diabetes; in susceptible individuals, the infective dosage may be as little as 100 cells.

The incubation period for Vihr-io sulnificus ranges from 7 hours to several days, after which symptoms may include fever, chills, nausea, hypotension, stomach discomfort, vomiting, diarrhoea, and the development of secondary lesionson the periphery. Primary septicemia caused by infection has a 60% mortality rate, the highest of any foodborne illness agent in the United States, and death generally occurs within a few days. Wound infections caused by exposure to polluted water have a 20-25% death rate, and in those who survive, surgical debridement of the infected tissue or amputation is frequently necessary.

Pathogenicity Mechanisms Certain V. vulnzjicus strains, particularly pathogenic strains, develop a polysaccharide capsule that is required for infection initiation because it shields the pathogen from phagocytosis. A serum resistance factor, in addition to capsule protection, aids in the reduction of complement-mediated cell lysis. Vibrio vulnijicus is very invasive and produces a heatlabile cytolysin, which is thought to be responsible for the severe tissue damage associated with infection. As previously stated, increased serum iron levels promote host proliferation since they cannot grow in normal human serum due to their inability to compete for iron with serum transferrin. Several extracellular chemicals are produced by Vihrio vulnlficus, including hemolysin, protease, elastase, collagenase, DNase, lipase, phospholipase, mucinase, chondroitin

sulfatase, hyaluronidase, and fibrinolysin. While some of these variables may play a role in pathogenesis, they may not all be required for V. vuln$cus pathogenicity.

The pathogen Vibrio cholerae

Characteristics in general Vibrio choferae is another species in the Vibrionaceae family that is motile with a single polar-sheathed flagellum.Being part of the microflora prevalent in estuaries, these bent rods survive in their environmental reservoir. V. cholerae has been isolated from places other than those associated with a marine or brackish water supply, such as freshwater lakes and rivers, as well as from birds and herbivores. Vihrio cholerae 01 is made up of the traditional biogroup that has been isolated during previous pandemics and El Tor, the current pandemic's leading biogroup. It has been proposed that the introduction of V. cholerae 0139 Bengal may mark the beginning of the next pandemic.The optimal temperature for V. cholerae growth is between 30 and 37°C, however growth can occur between 10 and 43°C. Vibrio cholerae grows at pH levels ranging from 5.0 to 9.6, but prefers 7.6. They grow at a minimum of 0.97 but prefer 0.984. V. cholerae grows best in environments with a sodium chloride concentration of 0.5%, although it may thrive in values ranging from 0.1% to 4.0%. Lusks (raw oysters) or crustaceans consumed raw, undercooked, or even contaminated after cooking, or exposure of an open wound to a polluted water source. Symptoms caused by V. cholerae 01 infection range from asymptomatic to the most severe type known as "cholera gravis," and are influenced in part by the biogroup involved, with 75% of the El Tor biogroup and 60% of the classic biogroup causing asymptomatic infections. Moreover, the El Tor biogroup causes severe disease in 2% of infected people and mild or moderate disease in 23%, whereas the traditional biogroup causes severe disease in 1% of people and mild or moderate disease in 30%.Following an incubation period ranging from several hours to five days, depending on the size of the inoculum and the amount of food consumed, typical symptoms include muscle cramping caused by severe dehydration (fluid loss of up to 500-1000 ml/h) caused by vomiting, increased peristalsis followed by loose stools progressing to watery stools, and mucus-flecked diarrhoea that is characteristic of cholera. Further consequences, in addition to dehydration, may include hypovolemic shock, hypoglycemia, and metabolic acidosis.

The symptoms of V. cholcvur 0139 Bengal illness are clinically comparable to those of V. cholcuae 01-infected people. In addition to V. cholera serogroups 01 and 0139 Bengal, other V. cholera serogroups are known as nonO1, nonagglutinating vibrios, or noncholera vibrios, and are not known to produce epidemic sickness. Noncholera vibrios, on the other hand, are known to induce self-limiting gastroenteritis and may also cause wound infections, bacteremia, and septicemia when combined with a preexisting liver problem. V. chokerrre has an infectious dose of around IO", but when food is consumed, the infectious dosage is lowered to about 10', depending on the buffering capacity of the meal.

Pathogenicity Mechanisms Cholera symptoms are caused by the production and action of cholera toxin, which binds to receptors on the membranes of intestinal epithelial cells and then, through the activation of adenylate cyclase, produces elevated CAMP levels, resulting in the accumulation of water and electrolytes in the intestinal lumen. Cholera toxin is a heat-labile, chromoornally mediated enterotoxin that is similar to plasmid mediated enterotoxin. Enterotoxin

generated by E. co/i that is heat-labile.Noii-01 strains generate no cholera toxin. Instead, they make two forms of hemolysins, a heat-stable enterotoxin, and a capsule that causes bactereinia. Listeria rnonocytogenes, most likely through inhibiting serum's bactericidal action (Kaper et al., 1995).

Characteristics in general the genus Listoriu has six species with two lines of ancestry. The first line comprises the species innoctiu, L. ivanovii, and L. monocytogenes, among others. The other line of lineage includes L. gruyi and, until recently, L. niurrayi, which is now classified as L. gvuyi. Listeria nzonocytogenes are gram-positive, non-sporeforming, psychrotrophic, aerobic, microaerophilic, or facultatively anaerobic rods that move at 28°C by up to five peritrichous flagella.

This hardy organism is widely distributed throughout various environments and has become a major concern in the food industry, where it is frequently found growing in conditions of high humidity and limited nutrient levels, such as in floor drains, condensed and stagnant water, floors, and food residues on processing equipment (Ryser and Marth, 1999). Carriers range from 11-52% of animals, with 45% of pigs and 24% of cattle harbouring L. monocytogenes in their tonsils and retropharyngeal nodes, respectively. Listeria monocytogenes has also been found in 2-5% of raw milk bulk tanks, 2-10% of soft cheeses, 0.3-2.0'1/0 of ice cream, 1-700/0 of whole and processed red meats, up to 60% of ready-to-eat poultry, 80-90% of raw or processed poultry, and up to 25% of raw and ready-to-eat fish and seafood products.Listeria nzonocytogeneJ may grow at temperatures ranging from -0.4°C to 45°C, with an optimum of 30-37°C. Growth occurs in pH ranges of 4.39-9.4, with a preference towards pH 7.0. Listeriu nzonocytogenes development needs an a greater than 0.92, and the organism can live at up to 30% salt chloride levels and presently permitted nitrite levels in foods (ICMSF, 1996; Murray et al., 1999).

Foodborne disease characteristics Listeriosis is a rare foodborne illness that causes a range of severe symptoms. The illness is nonenteric in nature, with infections of the central nervous system (meningitis and meningoencephalitis) being the most common in persons without an underlying condition; individuals with an underlying condition commonly have bacteremia (Doyle et al., 1997). Pregnant women may have a flu-like sickness in addition to a fever, myalgia, or a headache, whereas foetal symptoms may include meningitis, neonatal septicemia, stillbirth, foetal death, or spontaneous abortion.

Listeriosis is frequently associated with a long incubation period, ranging from a few days to 2-3 months, and a preference for infecting the immunocompromised, resulting in a high case fatality rate of 20-30%1 for both epidemic and sporadic cases, and 38-40%1 among immunocompromised individuals and those with an underlying condition. Further listeriosis problems have been observed in up to 30% of those who survive a central nervous system illness (Ryser and Marth, 1999). Statistics from epidemic and sporadic foodborne cases show infectious dosages more than 100 CFU/g, however it has been proposed that the likelihood of infection from smaller doses should not be discounted due to variability in enumeration methodologies.

Pathogenicity Mechanisms Listeria monocytogenes has 13 serovars and is the only species in the genus Listeria that poses a public health risk.1/2a, 1/2b, and 4b account for 95% of human

isolates collected, with serovar 4b strains implicated in 33-50% of sporadic human infections globally and in the majority of big outbreaks (Lund et al., 2000). There are significant variances in virulence potential across strains, and no association has yet been discovered between virulence and origin (human, animal, food, etc.) or strain features (serovar, etc.). Yet, all strains of L. nzonocytogenes are now thought to be capable of producing listeriosis.

Upon consumption of contaminated goods, the organism passes the intestinal barrier and is internalised by macrophages before being transferred to lymph nodes via the circulation and finally to the liver, the major site of infection.

Characteristics in general Clostridium perfringen, formerly known as Clostridium welchii, is a member of the Bacillaceae family and a leading cause of foodborne illness. These are nonmotile, encased rod-shaped cells that manufacture protein poisons and develop spores that are resistant to radiation, desiccation, and heat. Vegetative cells develop at temperatures ranging from 6 to 50°C, with the ideal temperature falling between 43 and 47°C. A minimum an of 0.93 is required for growth, as is a sodium chloride content of less than 5--8'% depending on the strain, and a pH of 5.0-9.0, while 6.0-7.2 is recommended.Foodborne disease characteristics Clostridium perjiringens is the most prevalent Clostridiuni species found in human clinical specimens, excluding feces, and has been implicated in simple wound infections to myonecrosis, clostridial cellulitis, intra-abdominal sepsis, gangrenous cholecystitis, postabortion infection, intravascular hemolysis, bacteremia, pneumonia, thoracic and subdural empyema, and brain abscesses. As a result of its ubiquity throughout the environment, the organism's spores and cells are commonly connected with dust contamination on numerous surfaces, including foods such as meat and shellfish.

Clostridiliurn perfringens can cause Darmbrand or Pig-Bel food poisoning, as well as type A food poisoning. Since many cells are damaged by contact to the stomach's acidic environment, Type A food poisoning usually necessitates the consumption of a highly infected meal (>106-107). (Doyle et al., 1997). Temperature abuse almost always causes foodborne illness, and in many cases, the food vehicle has been improperly cooked meat or meat product that has been left to cook and/or cool too slowly or has undergone insufficient reheating, allowing surviving spores to germinate and lead to vegetative cell proliferation. Following consumption and a 7-30-hour incubation period, symptoms generally include cramping and stomach discomfort, however nausea and vomiting may also occur and last for 24-48 hours.

Pathogenicity Mechanisms C. perj'bingens toxin-producing varieties (A through E) have been discovered, and all generate an alpha-toxin (phospholipase) that plays a role in myonecrosis (Lund et al., 2000). Type B strains create beta- and epsilon-toxins, while type D strains produce epsilon-toxin and type E strains produce iota-toxin. Virtually all documented instances of C prrfbingerz.s foodborne gastroenteritis in the United States are the consequence of type A infection following the intake of highly con- There were 181 contaminated items with more than 106-107 live vegetative cells, which sporulate in the small intestine and create enterotoxin. After cell lysis, the enterotoxin created during sporulation is released along with the spores. Upon release, the enterotoxin attaches to epithelial cells, producing cytotoxic cell membrane damage and subsequent permeability changes, resulting in diarrhoea and stomach cramps. Severe

histopathologic damage, including necrosis of villus cells, has been documented following C. perfringens enterotoxin exposure in animal models.

Bacillus cereus (Bacillus cereus)

Characteristics in general Bacillus cereus is a gram-positive, motile rod that belongs to the Bacillaceae family. Although vegetative cells may develop anaerobically, the most distinguishing feature is the capacity to sporulate freely, creating subterminal, central, or paracentral endospores in the presence of oxygen. The majority of Bacillus species are found in soils as well as fresh and salt water habitats.

Endospores are frequently found in dried foods such as spices and farinaceous items, where they survive and are redistributed from the environment (Murray et al., 1999). B. cereus spores have appendages and pili and are more hydrophobic than any other Bacillus spore. These qualities allow the spores to attach to a wide range of surfaces and to withstand removal during washing and sanitation. B. cereus vegetative cells thrive at temperatures ranging from 4-15 to 35-55°C, with a preference for 30-40°C depending on the strain (ICMSF, 1996). The organism thrives at pH levels ranging from 4.9 to 9.3, however the inhibitory impact of pH in meals is diminished, as indicated by poor growth on meat at pH 4.35. (Jay, 2000). The minimum u, for growth has been set at 0.93, although it has been proposed that 0.912 be used as the minimum requirement for growth since fried rice has a, values ranging from 0.912 to 0.961 and readily supports B. cereus growth (ICMSF, 1996). When maintained in cooked rice and trypticase soy broth, B. cereus spores normally germinate at temperatures ranging from 5 to 50°C; however, under laboratory settings, spore germination has occurred between - 1 and 59"C, with optimal germination happening at 30°C.

Foodborne disease characteristics B. cereus is the most important animal and human pathogen in the genus, with the exception of B. anthrucis, and it is a substantial source of foodborne disease, accounting for 1-23'541 of documented outbreaks of known bacterial aetiology (Doyle, 1989). Ingestion of infected food might result in one of two clinical types of gastroenteritis (diarrheal or emetic). Both symptoms (diarrheal and emetic) are caused by B. cereus endospores surviving the cooking process, following which germination and subsequent vegetative cell multiplication occurs at some time during storage. The diarrheal condition is caused by ingesting a wide variety of contaminants. It is caused by tainted foods such as meats, vegetables, pastas, and soups and is characterised by stomach discomfort, nausea, and diarrhoea after an incubation period of 8- 16 hours. Diarrheal syndrome symptoms usually last no more than 12-24 hours. The emetic sickness is most commonly related with the consumption of infected rice-containing meals, while milk, potatoes, and vegetable sprouts have also been implicated. During a 1- to 5-hour incubation period, emetic syndrome symptoms include nausea and vomiting that last 6-24 hours. Moreover, it has been shown that emetic toxin is linked to fulminant liver failure.

Pathogenicity Mechanisms the diarrheal syndrome type of food poisoning is caused by a thermolabile enterotoxic complex, whereas the emetic syndrome type is caused by a thermostable toxin. The diarrheal enterotoxin is a protein that is most active at temperatures between 32 and 37°C and is rendered inactive after 5 minutes of exposure to 56°C. The

enterotoxin is sensitive to protease activity (i.e., trypsin and pepsin) and is unstable outside of the pH range of 4.0-11.0. (Doyle, 1989). The emetic toxin is most active at temperatures between 25 and 30°C, but it may be active at 126°C for 90 minutes, is stable between pH 2.0 to 11.O, and is resistant to trypsin and pepsin.Ingestion of B. cwus populations ranging from 200 to lo9 cells/g, with predicted infective dosages in the range of 5 x 104-10" cells/g, has been linked to sickness in studies utilising outbreak-associated foods.The variation in infective dosage (10'-lo8 viable cells or spores/g) can be linked to strain variances in enterotoxin generation, and so food containing B. cereus cells at a level of lo4 cells/g should not be regarded safe for human consumption (Lund et al., 2000).

Additional bacterial dangers several pathogenic species, in addition to the bacteria mentioned above, may be related with foodborne disease, albeit their participation has not been thoroughly established.Aeromonas Aeronionus members are gram-negative, facultatively anaerobic, predominantly motile rodshaped organisms that belong to the family Vibrionaceae. Aeromoncrs are commonly found in aquatic settings and have been linked to incidences of foodborne disease using raw meats, poultry, fish, milk, and vegetables (ICMSF, 1996). The presence of Arronionac spp. in a person can cause an intestine infection, similar to dysentery, with diarrhoea, abdominal discomfort, nausea, chills, and headache, or an extraintestinal infection, such as septicemia, meningitis, endocarditis, peritonitis, endophthalmitis, or wound infection (ICMSF, 1996). They can grow at temperatures ranging from 0 to 45T, pH 4.5-9.0, a minimum of 0.95, and a sodium chloride content of 0.0-4.5'%.

Brucella Brucellu members are gram-negative, aerobic, nonmotile cocci or short rods (B. ahortus, B. ranis, B. melitensis, B. neotomae, B. ovis, B. suis, and maybe B. niuris) (Murray et al., 1999). Human brucellosis is primarily transmitted by the handling of an infected animal, although it has also been linked to food transmission. Brucellosis is seldom deadly and is characterised by a variety of symptoms such as fever, chills, weakness, body pains, headaches, sweating, and weight loss (Murray et al., 1999). Although certain strains grow best in 5-10% COz, growth occurs at temperatures ranging from 6 to 42"C, at pH 4.5-8.8, and in conditions with salt chloride concentrations less than 4.0%).

Helicobacter Helicohacter are gram-negative spiral or curved bacilli that are motile and microaerophilic, growing best in conditions with low oxygen levels (5-10%) and high carbon dioxide levels (5-12%), with the exception of H. westnzeudii, which is totally anaerobic (Murray et al., 1999). They have been isolated from numerous animals' gastrointestinal tracts and are classed as gastric or enteric Helicohacter, depending on where the organism predominantly colonises within the host. Gastric Helicobacter seldom enter the circulation and instead grow inside or under the mucous gel layer adjacent to the stomach epithelium. Enteric Helicobacter, on the other hand, has been isolated from blood, colonises the lower gastrointestinal tract, and is linked to gastroenteritis.

H. pylori, a particular stomach helicobacter, is the principal cause of peptic ulcer disease and is thought to infect 50% of the world's population (Dunn et al., 1997). The majority of people who have chronic infections develop chronic active gastritis, which causes a variety of abdominal symptoms such as nonulcer dyspepsia, duodenitis, duodenal ulcers, gastric ulcers, and even

chronic atrophic gastritis and subsequent gastric ulcer disease and gastric adenocarcinoma, one of the most common human cancers worldwide. Moreover, H. pylori infection has been linked to Menetrier disease, a rare gastrointestinal condition.

Mycobacterium the Mycobacteriaceae family has only one genus, Myrobacterium, with species classified into two groups based on growth rates. The "rapidly developing" species establish colonies in less than 7 days, but the "slow-growing" species might take 6 weeks or more under ideal conditions. Slow-growing species, such as M. leprue, A. TB, and M. paratuherculosis, have the capacity to cause disease in animals and people, but faster-growing species do not, however there are exceptions. MJxobacterium are aerobic or microaerophilic bacilli that are gram-positive, nonmotile, straight or slightly curved, and grow best between 30 and 45°C.

Mycobacteria may infect humans in a variety of ways, including through the drinking of contaminated water, which has been identified as a mode of transmission in multiple epidemics. Concerns have recently surfaced about the transmission of M. purafuherculosis, the causative agent of a chronic infectious ileitis in ruminants known as Johne's disease or bovine paratuberculosis, in milk-containing foods, and there has been much speculation about the relationship between M. paratuberculosis and Crohn's disease, a debilitating inflammatory bowel disease in humans.

Plesiomonas shigelloides is a kind of Plesiomonas. Plesioinonus shigelloides are gram-negative, facultatively anaerobic rods that are largely motile and can grow at pH 4.0-8.0, in environments with sodium chloride concentrations ranging from 0.0 to 5.0'%, and at temperatures ranging from 8 to 45°C. They are mostly connected with fresh and estuary water in more tropical and temperate regions, where fish, mollusks, and crabs are most commonly found, while the organism has been isolated from pigs, poultry, and cattle (Doyle, 1989). Plesiornonas shigelloides usually infects humans if they consume polluted water or raw seafood.During a 24-48-hour incubation period, symptoms such as severe stomach pain, cramping, nausea, vomiting, fever, headaches, and dehydration may remain for 2-14 days, and maybe longer.Pseudomonas Pseudomonads are gram-negative, motile, rod-shaped aerobes that may develop under anaerobic circumstances. These organisms can be found in a variety of wet settings, including water, soil, fruits and vegetables, and the human digestive tract.

P. aeruginosu is the most important species in terms of human sickness. Infected people may develop skin infections, ear infections, nosocomial respiratory and urinary tract infections, and bacteremia, among other symptoms. Pseudonioiias aeruginosa grows at temperatures ranging from 0 to 42"C, with pH levels ranging from 5.6 to 9.0, and in an environment with a minimum (I, of 0.94).Streptococcus Streptococci are gram-positive, facultatively anaerobic cocci that inhabit human and animal mucous membranes and are classified based on their hemolytic characteristics, colony size, and responses to Lancefield serological tests (Doyle, 1989). S. pyogenes strains that produce large colonies, are beta-hemolytic, and react with Lancefield's group A antibodies are included in the species, which after infection can cause fever, pharyngitis, respiratory, skin, and soft tissue infections (necrotizing fasciitis), endocarditis, meningitis, puerperal sepsis, and arthritis; severe infections can. S. ugalactiae is a type of bacteria that reacts with Lancefield's group B antibodies and is beta-hemolytic. It is a common cause of mastitis and

can be transmitted to humans through raw milk intake, resulting in sepsis, meningitis, newborn pneumonia, and postpartum infections.

Strains that develop large colonies and are positive for the C and G antigens are comparable to group A, S. pyogenes, and have virulence characteristics that can contribute to infection resulting in bacteremia, endocarditis, meningitis, septic arthritis, respiratory tract and skin infections. Smallcolony-forming strains with antigen to Lancefield group A, C, F, or G antibodies are commonly classified as S. milleri, and are less virulent than the aforementioned species.Streptococcus can thrive at temperatures ranging from 10 to 44°C, pH levels ranging from 4.8 to 9.2, a minimum of 0.92, and salt chloride concentrations of less than 6.4%. (ICMSF, 1996; Banwart, 1989). Streptococcus is currently expected to cause roughly 5 1,000 instances of foodborne disease in the United States per year.

Parasites

Foodborne illness parasites are classified into three types: intestinal protozoa, tissue protozoa, and tissue helminths. Foodborne disease-causing parasites (obligate parasites) require a host to complete their life cycle. The parasite's environmental stage can be consumed by the fecal-oral pathway, or the tissue stage (helminths) can be ingested through contaminated food (e.g., undercooked meat) or water.

Controlling parasites in foods requires adequate cleanliness, hygiene, appropriate cooking, and freezing storage, salt, and radiation treatments. It is estimated that parasite agents cause around 2.6% of all foodborne diseases with known origin, resulting in more than 350,000 cases in the United States each year. Although being implicated in just 2.6% of foodborne disease cases, parasite agents in foods are responsible for an estimated 383 fatalities every year, or nearly 21% of total deaths related to contaminated foods (Mead et al., 1999).

Cryptosporidium parvum is a kind of parasite. Cryptosporidiuin parvum is a protozoan parasite that has been isolated from a variety of warm-blooded species including chickens, rodents, pigs, horses, calves, sheep, dogs, cats, nonhuman primates, and humans (Jay, 2000; Doyle et al., 1997). C. purvum's life cycle occurs in just one host, and human cryptosporidiosis can be acquired by zoonotic, person-to-person, nosocomial, or contaminated food or water pathways (Jay, 2000). Cryptosporidiunz parvum can infect both immunocompromised and immunocompetent people, infecting the intestinal mucosa and causing diarrhoea. The organism spends its asexual life cycle stages at the brush border of the intestinal epithelium, where it develops "intracellularly but extracytoplasmically" due to the existence of a parasite-containing vacuole with an external feeding organelle. C. parvum oocysts vary from those generated by other parasites in that they directly contain sporozoites without the presence of sporocysts. Moreover, two kinds of oocysts are produced: 80% are thick-walled cysts that shed with environmental protection and 20% are thin-walled cysts that shed and excyst promptly, resulting in autoinfection (Doyle et al., 1997; Murray et al., 1999). This recycling of thin-walled oocysts appears to have a role in the severe sickness found in immunocompromised people, when thickwalled oocysts are no longer present.

C. purvum produces a self-limiting infection in the immunocompetent after a 6-14 day incubation phase, which can last up to 23 days and is followed by watery diarrhoea, epigastric cramps, nausea, and anorexia. In the immunocompromised, however, a life-threatening illness can cause copious diarrhoea that can linger for weeks, months, or even years. C. parvum can also infect other epithelial cells, such as those in the respiratory system and biliary tree.

Milwaukee saw the greatest waterborne epidemic to date in 1993, resulting in 403,000 cases of cryptosporidiosis and numerous deaths C. pmum is now expected to cause around 30,000 instances of foodborne disease in the United States each year, with a case fatality rate of 0.005.

Cyclospora cayetanensis is a species of Cyclospora. Cyclosporr c'rryetaticnsis are Eimeriidae protozoan parasites that inhabit the small intestine, where they spend the intermediary life cycle stages in the cytoplasm of enterocytes and then generate oocysts containing two sporocysts encapsulating four sporozoites. When the oocysts are discharged, it takes 7 to 15 days for sporulation to occur. Cyclospora cqvtmcnsis can cause long-term sickness (6 weeks or more) in both immunocompromised and immunocompetent people, with symptoms including nonbloody diarrhoea, nausea, vomiting, anorexia, bloating, abdominal cramps, malaise, fever, and exhaustion.

C. cayetanensis was identified as the causative agent in various outbreaks including raspberries, baby lettuce, and basil in the United States and Canada between 1996 and 1998. (Murray et al., 1999). C. cuyetanensis is now predicted to cause around 15,000 cases of foodborne disease in the United States each year, with a case fatality rate of 0.0005. Giardia lamblia is a parasitic worm. The flagellate Giurdia lurnbliu, a member of the Hexamitidae family, is presently the most prevalent cause of human intestinal parasitosis worldwide (Jay, 2000). The cyst form of the flagellate enters the human or animal body via fecal-oral transmission, which is often linked with the ingestion of contaminated water or food. The organism excysts, releasing trophozoites that cling to the intestine's mucosal epithelium.

The trophozoite is attached via a suction disc positioned ventrally that maintains flagellate adhesion but does not pierce the mucosa. The flagellates encyst after binary fission, giving two identical daughter flagellates, and the life cycle is completed when the new cysts are re-released into the environment through faecal excretion by the host (Garcia and Bruckner, 1997). Children at day care facilities, the immunocompromised, and hikers and campers are the most typically affected, owing to their ingestion of unclean water. Although the majority of infections are asymptomatic, individuals can develop subacute or chronic infections with symptoms such as nausea, chills, low-grade fever, watery diarrhoea, abdominal discomfort and distention, heartburn, malabsorption, and reduced pancreatic function after an incubation period of 12-20 days (Murray et al., 1999). G. Iamhlia was linked to 34 outbreaks that resulted in 3994 cases of giardiasis in the United States between 1984 and 1994. G. lumhliu is now predicted to cause around 200,000 instances of foodborne disease in the United States each year.

Suihominis/Sarcocystis hominis six genera of cyst-forming coccidia comprise the Sarcocystidae family. Two Sarcocystis species are known to cause sarcocystosis in people, out of the 13 currently identified. Humans are the major hosts for both species; however, cattle and pigs are

the secondary hosts for S. horninis and S. suilzontinis, respectively (Jay, 2000). Ingestion of sarcocysts causes the release of bradyzoites, which target and enter the small intestine's mucosal epithelium, penetrating into the lamina propria, where sexual reproduction occurs and new sarcocysts are generated and excreted by the host. In the main host, ingestion of sporocysts (the infective stage) leads in the release of sporozoites that move throughout the body, reproducing asexually and forming sarcocysts as large as 1 cm in diameter in both skeletal and cardiac muscle (Doyle et al., 1997). During an incubation period of 3-6 and 6-48 hours, respectively, for S. hominis and S. suihomiizis, symptoms such as nausea, stomachache, and diarrhoea may occur (Jay, 2000). Moreover, symptoms in animals may include miscarriage, weight loss, reduced milk supply, wool breaking, lameness, and even death.

Toxoplasma gondii is a parasite. To.xoplusnlu gondii are obligate intracellular protozoan parasites that live in cats and any other warm-blooded mammal as intermediate hosts (Doyle et al., 1997). The protozoan may be found in three phases of its life cycle: tachyzoites, bradyzoites, and sporozoites. Tachyzoites and bradyzoites live in bodily tissues, where tachyzoites multiply and kill infected host cells while bradyzoites multiply within tissue cysts. Sporozoites are shed as oocysts in cat faeces, where they sporulate after 1-5 days and can live for months by resisting disinfectants, freezing, and drying.

T gondii infection in humans can occur through a variety of routes, including consumption of contaminated food or water containing the oocyst, contaminated blood transfusion or organ donation, transplacental transmission, or accidental tachyzoite inoculation. Toxoplusiizu gondii infections are generally caused by eating cysts in raw or undercooked meat, with fresh pork and beef proving to be the most common causes (Murray et al., 1999). Toxoplasmosis can be caused by ingesting as few as 100 tissue cysts or oocysts, at which point the cyst walls break, allowing sporozoites or bradyzoites to migrate past the intestinal epithelium and circulate throughout the body. Sporozoites and bradyzoites mutate into tachyzoites and begin quickly multiplying intracellularly; once the host cell dies, the tachyzoites infiltrate nearby cells and continue the reproduction process. The host immunological reaction forces these tachyzoites to change back into bradyzoites and form cysts in the local tissue, where they can persist throughout the host organism's life.Toxoplasmosis symptoms include fever, rash, headache, muscular aches and soreness, and lymph node enlargement, which can last for more than a month (Jay, 2000). Toxopkusmu oocysts can be inactivated by heating to 61°C for 3.6 minutes or freezing to -13°C. T. gondii is now expected to cause around 113,000 instances of foodborne disease in the United States each year.

Spirillum spiralis the prevalent roundworm implicated in human trichinosis is Trichinellu spirulis, a member of the Trichinellidae family. It is often associated with the consumption of undercooked pork or pork products contaminated with the encysted larvae. Adult nematodes reside in the mucosal epithelium of the duodenum and jejunum for up to 8 weeks before being discharged. Adult female nematodes may release roughly 1500 larvae into the bloodstream during this transitory time, when they move around the body and eventually penetrate muscle tissue, where they can survive for several years (Jay, 2000). Larvae grow, mature, and are encapsulated in a calcified wall in skeletal muscle 6-18 months later. The larval and adult stages

are both handed down from the same host. Symptoms include nonspecific gastroenteritis, nausea, vomiting, headaches, fever, vision impairments, trouble breathing, chills, nocturnal sweating, eosinophilia, myalgia, and circumorbital edoema following a 3-14 day incubation period (Murray et al., 1999). Because the nematode may be thermally inactivated, the USDA advises cooking pig products to an internal temperature of 76.7"C. T. spiralis is now predicted to produce 52 instances of foodborne disease in the United States per year, with a case fatality rate of 0.003.

Viruses Viruses have joined bacteria and parasites as species that cause gastroenteritis and are engaged in medically significant diarrheal illness in recent decades. Viruses in foods are managed by good sanitation, hygiene, cooking, and cross-contamination prevention prior to consumption.

CHAPTER 10

FOODBORNE PATHOGENIC VIRUSES

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Foodborne pathogenic viruses are thought to be responsible for around 67% of foodborne infections with known origin in the United States, resulting in more than 9 million cases per year. Despite the fact that viruses are linked in 67% of foodborne disease cases, their presence in foods leads in just 129 fatalities, or around 7% of total deaths related to contaminated foods (Mead et al., 1999). Hepatitis A, Norwalk and Norwalk-like viruses, rotavirus, astroviruses, and enteroviruses are among the viruses that cause foodborne disease. The sections that follow highlight some of these medically significant bacteria' features and probable implications in foodborne illness.

Acute Hepatitis Hepatitis A, a member of the Picornaviridae family, is an icosahedral, nonenveloped virion that is heat and pH resistant. Hepatitis A infection is spread by the fecal-oral route and is particularly common in developing communities with inadequate sanitation. It is responsible for 20-25Y of all hepatitis infections globally and can be spread by contaminated food or water or through direct contact with contaminated blood. Shellfish taken raw or partially cooked from contaminated waters have been identified as vehicles of transmission in many outbreaks, with symptoms ranging from moderate sickness to severe hepatitis infection with jaundice.

The commencement of a preicteric phase may be characterised with fever, lethargy, malaise, myalgia, anorexia, nausea, and vomiting after a dose-dependent incubation period ranging from 10 to 50 days. Symptoms of the icteric phase include a yellowish colouring of the mucous membranes, conjunctivae, sclera, and skin, as well as the discharge of dark, golden brown urine and pale faeces. Skin rash, Guillain-Barre syndrome, renal failure, meningoencephalitis, cryoglobulinemia, arthritis, and hematologic and cardiovascular issues are some of the other consequences linked with hepatitis A infection. Clinical symptoms associated with the preicteric and icteric stages of hepatitis A infection normally last 4-8 weeks; however, hepatitis A faecal shedding can continue for months after symptoms have subsided. Currently residing in the United States. Hepatitis A is thought to produce around 4000 instances of foodborne disease each year, with a case fatality rate of 0.003 percent.

Norwalk Norwalk and Norwalk-like viruses, often known as small, round structural viruses (SRSV), are members of the Caliciviridae family. The Norwalk virus group, the White Mountain agent group, and the Sapporo virus group are the three groups of human caliciviruses. In addition to contaminated water, raw or slightly cooked shellfish and other items not cooked after infection have been suggested as vehicles of transmission in outbreaks happening in institutions,

restaurants, and households, as well as aboard cruise ships. After consumption of contaminated food and an incubation period of 18 to 48 hours, symptoms may include nausea, vomiting, diarrhoea, and other gastroenteritis-related symptoms. While symptoms last for 24-72 hours, the virus is shed for nearly a week. The agent attacks mucosal epithelial cells, causing lesions in the small intestine where offspring are formed and then excreted by the host. These creatures are resistant to acid, ether, and heat, and they can tolerate cold temperatures (ICMSF. 1996). They are more chlorine resistant than any other enteric virus and have been found to be active in drinking water with a chlorine concentration of 5-6 ppni. Presently, Norwalk and Norwalklike viruses are expected to cause 9.2 billion episodes of foodborne disease in the United States each year.

Rotaviruses Rotaviruses, which are members of the Reoviridae family and have a double-stranded ribonucleic acid genome (dsRNA), are classified into six groups (A through E), albeit only three (A, B, and C) infect humans. Group A is most commonly connected with babies and children across the world, and it is a leading cause of infant mortality in underdeveloped nations. Group B typically causes diarrhoea in adults, but Group C primarily affects older children. Children are especially vulnerable during the winter months, and rotaviruses account for around one-third of all diarrheal hospitalisations in children under the age of five.

The fecal-oral route is the predominant form of transmission, which can occur directly, through contact with an infected individual, or indirectly, through contaminated water or food. Rotaviruses infect the absorptive villous epithelium associated with the top two-thirds of the small intestine, where they target enterocytes following a 1-3 day incubation period. After entering the target cell, the virus is carried to the lysosomes and then uncoated. Vomiting and watery diarrhoea may occur as a result of a nonstructural protein (NSP-4) with enterotoxin-like action.

Symptoms, which normally last 3-8 days, may also include stomach discomfort, fever, or any other gastroenteritis-related symptom. Rotavirus is now expected to cause around 39,000 instances of foodborne disease in the United States each year (Mead et al., 1999). Nonetheless, rotavirus infection is the most prevalent cause of diarrhoea in children globally, accounting for roughly 800,000 fatalities each year.Understanding the features and attributes of foodborne biological hazards associated with certain food sources has significant regulatory, industrial, and international ramifications. The consideration of internal and extrinsic variables, and how they impact microorganism growth and/or survival, is critical in the development of appropriate required or recommended performance standards.

Establishing a microbiological criteria necessitates knowledge of the organism's qualities, such as microbial ecology (prevalence among food and other environmental sources), mode(s) of transmission, virulence factors (e.g., preformed toxin production), and metabolic characteristics, among others. Additionally, this knowledge is crucial for developing an appropriate sample strategy and analysis technique.Although it is certainly preferable to err on the side of caution when making public health choices, mistake can be costly in and of itself. For example, greater understanding of the pathogenicity characteristics of specific strains of L. inonocyfogrnes could result in an amendment to the general assumption that all strains are capable of causing

listeriosis, potentially reducing the likelihood of recalling and/or destroying otherwise biologically safe foods. Furthermore, the development and/or application of various techniques or technologies to preserve or improve the microbiological quality of foods by effectively and efficiently eliminating, reducing, or inhibiting individual or groups of microorganisms, to meet performance criteria, or otherwise, necessitates an understanding of the target organism(s), as well as preservation/decontamination methods and antimicrobial properties or mode(s) of action (Jay, 2000).

These concerns have a broad range of applications, including, for example, the HACCP system, which supports proactive, recurrent evaluations and strategy implementations during the food production process. Microbiologically safe foods are manufactured and marketed not merely on the basis of end product testing, but also by closely monitoring production procedures that contribute to acceptable product cleanliness. This technique identifies critical control points (CCPs), which are places in the food production process.

Critical limitations, or operational parameters (e.g., time and temperature), are linked with CCPs to ensure that implemented procedures connected with CCPs effectively manage the intended danger. HACCP depicts one method of establishing uniform product manufacture on a global scale, in an attempt to "harmonise" the global supply of safe food.Regardless of the debate over the use of performance criteria or microbiological limits as indicators of food safety or process control/hygiene, their development and implementation have undoubtedly influenced, and will undoubtedly continue to influence, the methods by which foods are produced, harvested, processed, and marketed.

Microorganisms continue to develop, as they did in the past, and their high genetic variety and short generation periods boost their chances of survival in less-than-ideal environmental settings (Hall, 1997).

Because of the prevalence of environmental antimicrobials, the rise of antibiotic-resistant bacteria has raised public health concerns about increasing morbidity and death linked with failed antimicrobial treatment regimes. For example, the United States saw its first pentadrug-resistant epidemic in 1997, involving a strain of S. Typhimurium phage type 104 (DT104), previously observed in the United Kingdom, that was resistant to ampicillin, chloramphenicol, streptomycin, sulfonamides, and tetracycline (Centers for Disease Control and Prevention, 1997). In addition to pentadrug-resistant S. Typhimurium, quinolone-resistant nontyphoidal Sulrnonellu has emerged.

During 1979-1980, when 16% of Sulnzonelb isolates were resistant, through 1989-1990, when 29% were resistant, and to 1996, when 37% of isolates were resistant to at least one drug. Antimicrobial resistance in the genera Sliigellu and Stuplzylococcus is another example, in addition to Sulnzonellu. Shigellu have evolved resistance to sulfonamides, ampicillin, trimethoprim-sulfamethoxazole, tetracycline, chloramphenicol, and streptomycin, while S. dysenteriae type 1 serotypes have been found to be resistant to all locally available treatments in parts of Africa and Asia. Similarly, methicillin-resistant S. aureus, which emerged in the 1980s and early 1990s, has had an impact on human health, particularly in hospital settings.

In addition to the rise of antibiotic resistance, common foodborne pathogenic bacteria have showed resistance, cross-protective capacities, and enhanced virulence to food preservation conditions. A foodborne pathogen must endure a wide variety of stressors associated with both the vehicle of transmission and host immune responses in order to cause illness. Foodborne infection demonstrates a pathogen's capacity to adapt to and withstand environmental stress. Bacterial resistance to environmental stressors such as temperature and pH extremes is induced by the creation of "protective" shock proteins, some of which have cross-protective properties, or the capacity to defend against more than one form of stress. For example, heat shocking increases the capacity of acid-induced *E. coli* 0157:H7 to withstand the antimicrobial actions of acid. L.

Monocytogenes has enhanced tolerance to ethanol and NaCl in addition to higher heat tolerance after shocks. With adaption to ethanol, Listeriu monocytogenes exhibit enhanced tolerance to low pH and H202 (Sheridan and McDowell, 1998). Stress-hardened microorganisms may emerge from sublethal stress exposure during the food processing process. These infections may be able to withstand further antimicrobial treatment applications targeted at enhancing microbiological food quality, perhaps leading to persistent microbiological populations with enhanced virulence factor expression. The ability of an organism to withstand environmental stresses, either individually or in combination, and with or without prior exposure, is an important consideration when developing future systems aimed at improving microbiological quality within a specific food, and it also merits consideration during predictive microbiology and modelling efforts to ensure food safety.

Contemporary Monitoring Methods

Modern technologies for quick, effective, and accurate monitoring of environmental hygiene, detection of biological threats, and product quality are required to assure the safety of the global food supply. These techniques include ATP bioluminescence, polymerase chain reaction (PCR), and enzyme-linked immunosorbent test.ATP is a nucleotide made up of adenine, ribose, and triphosphate units. Because of the phosphanhydride bonds in the triphosphate unit, ATP is a high-energy molecule. ATP is hydrolyzed to adenosine diphosphate (ADP) and adenosine monophosphate (AMP) in water, releasing energy.Bioluminescence, as measured by a luminometer, is one method for determining ATP levels. The light generated by living creatures with the ability to synthesise luciferase enzymes is referred to as bioluminescence. Photinus pyralis, a common firefly in North America, is the most thoroughly researched luciferase. The molecular weight of firefly luciferase is 62,000. It catalyses an oxidative reaction of luciferin, leaving one of the end products in an unstable state that decomposes to produce light.

Firefly bioluminescence has a peak emission wavelength of 560 nm, with emission wavelengths ranging from 560 to 630 nm.PCR is a method for amplifying DNA in vitro. The test is performed in a DNA thermocycler, which was created by Perkin Elmer, Inc. (Norwalk, CT). The thermocycler produces temperature change cycles that are repeated. During these cycles, modest quantities of DNA taken from a pathogen are rapidly amplified into millions of copies. ELlSA is an immunological test that detects target microorganisms using polyclonal or monoclonal antibodies. To develop specific antibodies against pathogenic germs, distinctive surface features

or poisonous compounds are employed as antigens. In the ELISA, these antibodies recognise their matching antigens, the presence of which indicates pathogen contamination of a tested sample. Heat- or chemical-killed entire cells are occasionally utilised to generate antibodies against pathogens with uncertain pathogenicity.

When an antibody comes into contact with its antigen, an antigenantibody complex is created. This response may not be apparent if the antigen molecules are too tiny or too diluted. As a result, for the creation of a detectable signal, a secondary antibody, that is, an antibody against the main antibody coupled with an enzyme, is required.

Responses to Bioluminescence

Because ATP is a rapid supply of free energy, an ATP molecule is spent shortly after creation and the energy associated with the molecule cannot be preserved. As a result, ATP is only found in live cells and vanishes quickly (approximately 2 hours) following cell death. As a result, the presence of ATP may be utilised to determine cell viability.The bioluminescence response of fireflies is an energy-intensive process. ATP, as in many other biological events, is the energy provider. Firefly luciferase requires luciferin, molecular oxygen, and magnesium as substrates in addition to ATP. An adenyl moiety is transferred from ATP to the carboxyl group of luciferin to generate luciferyl adenylate in the first phase of the firefly bioluniinescence test, with the removal of inorganic pyrophosphate.

In the firefly bioluminescence experiment, the amount of ATP consumed is proportional to the amount of light created. Because the quantity of ATP in certain microbial cells is pretty stable (to lop" mol/bacterial cell), light genotoxicity is reduced. The ATP bioluminescence test was created in the 1960s to search for life in space (Chappelle and Levin, 1968). Years later, the technology was developed for the detection of bacteria in foods (Sharpe et al., 1970). ATP bioluminescence is now commonly employed for quick monitoring of food processing conditions and microbiological contamination. It has also been utilised for critical control point (CCP) monitoring during Hazard Analysis and Critical Control Point (HACCP) management. Unlike previous monitoring methods, the ATP bioluminescence assay is quick, with test results available in minutes. Because luminometers, which measure emitted light, have become portable, the test may be performed on-site.

Unlike traditional swabbing approaches for hygiene monitoring, the ATP test assesses not only the quantity of microbiological contamination but also the cleanliness of food processing surfaces and equipment.Polymerase Chain Reaction (PCR) PCR was initially described in 1971 (Kleppe et al., 1971), but gained popularity as a diagnostic tool in the 1980s and 1990s. The approach is more popular than ever after two decades and has been employed in many fields of life science. PCR is largely utilised in the field of food microbiology for the quick detection or identification of bacteria in food. Microorganisms' genetic features, like those of larger plants and animals, are determined by the information contained in their deoxyribonucleic acid (DNA).

This data comprises genetic determinants that encode for enzymes and proteins involved in metabolic processes, as well as microbial cell shapes and virulence factors. PCR uses distinctive sections of DNA, known as templates, to identify a target bacterium. Positive PCR amplification

of these areas indicates microbial contamination of the tested material. As a modern detection technology, PCR is more sensitive and specific, as well as less intense and time-consuming, than classic microbiological procedures.Tq DNA polymerase, an enzyme identified from the themophilic bacteria Thevnzus aquaticus, synthesises new DNA based on the template in PCR. The Tag DNA polymerase is stable and active even at high temperatures used for DNA denaturation.

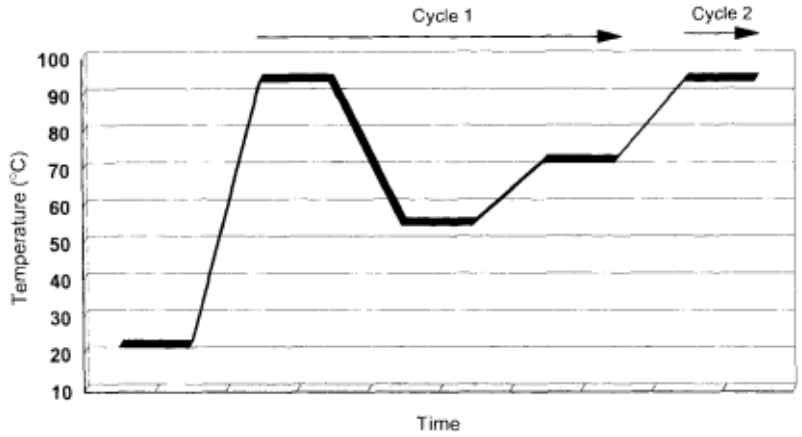

Figure 10.1 Process of PCR.

The test requires the participation of many other components, in addition to the DNA template and enzyme: 5' and 3' specific primers, deoxynucleotide triphosphdtes (dNTPs), and salts. The nucleotide sequences of the two primers are homologous to the template's 3' and 5' locations, respectively. The stretch of DNA between the two primers is amplified in PCR. The salts create an ideal environment for the process to continue, while the dNTPs function as substrates for Taq DNA polymerase. The PCR process. A PCR cycle involves three temperatures: 95°C for DNA denaturation, which causes a double-stranded DNA template to separate and become single-stranded; 55°C for primer annealing, during which the two primers selectively bind to the single-stranded template; and 72°C for primer extension, which synthesises the area of DNA between the two primers. The fluorescent colouring of amplified products separated by electrophoresis on an agarose gel is used to assess the PCR results (Figure 11.1).

CHAPTER 11

ENZYME-LINKED IMMUNOSORBENTS

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ELISA was developed in the 1960s and has been in use for quite some time. Nevertheless, the recent availability of more precise dyes and substrates has increased the value of ELISA. Unlike PCR, ELISA identifies phenotypic traits of harmful bacteria. The test is semiautomatic and can handle up to 96 samples per assay when utilising a commercial ELISA reader.ELISA comes in a variety of forms. As a solid phase, the most common kind use a polystyrene microtiter plate. Overnight incubation in a coating buffer coats the microtiter plate wells with antigen. In ELISA, two antibodies are used the main antibody, which is typically generated in rabbits or mice, binds precisely to the antigen and establishes the assay's specificity. Depending on the origin of the main antibody, a secondary antibody is enzyme-labeled goat antirabbit or goat anti-mouse IgG. Enzyme-conjugated secondary antibody is utilised for detection and may be used to identify various diseases as long as the primary antibody is present.

The microbiological quality of raw milk and meats has been assessed using ATP bioluminescence. Milk was filtrated or centrifuged after treatment with the milk-clarifying solution Enliten to collect bacterial cells, which were then lysed and tested for ATP activity. To gather microbiological cells, poultry and beef samples required to be washed or swabbed. Microbial cells were separated from meat using repeated centrifugation at varying speeds, first at medium speeds to recover meat particles and then at high speeds to sediment bacterial cells. Two-step filtering was an option.

Samples were filtered through a coarse filter to remove meat tissues, then a fine membrane to capture bacterial cells. Following that, ATP was taken from the bacterial cells and measured using a commercial firefly luciferase and luciferin combination. Monitoring and record keeping are critical aspects in HACCP management, since they give information on whether possible hazards are under control and whether remedial measures are required. The microbiological quality of poultry processing fluids as shown by ATP bioluminescence was employed in CCP monitoring in poultry processing facilities. Swabbing chicken carcasses was used to gather samples from various CCPs discovered in poultry processing plants. A 2-minute bioluminescence experiment was used to measure ATP extracted from chicken rinse fluids. ATP levels in chicken corpses increased following evisceration but fell to low levels following prechill and chill treatments.

Yeasts and lactobacilli are frequently responsible for beverage and juice deterioration (Griffiths, 1996). Because carbonated beverages contain modest quantities of nonmicrobial ATP, the ATP bioluminescence test can properly determine their quality. Nevertheless, the natural components

of beers contain a lot of ATP and quenching compounds, which might skew the findings if the tests aren't done properly to separate the microbial cells. The findings of an ATP detection technique used to evaluate bacteria in fruit juice were unsatisfactory; the assay's poor performance was ascribed to the product's low pH and the presence of nonmicrobial ATP (Griftiths, 1996).

Methods for Monitoring PCR

More than 200 PCR techniques for the detection of foodborne bacteria, moulds, yeasts, viruses, and parasites have been published since the early 1990s. BAXTM is a Qualicon-marketed commercial PCR system used to test for major foodborne bacterial infections such as *Sulmorzrllu, Esclericliiu coli* 0157:H7, *Listeriu monocytogenes*, and *Curiipjdohurtev jrjuni*.

Pathogen identification through PCR can be problematic since dietary components such as proteins and lipids frequently limit the activity of Taq DNA.During DNA amplification, polymerase is used. To eliminate food inhibitors prior to PCR, ether extraction or column purification might be utilised.To circumvent the inhibition, bovine serum albumin, protease inhibitor, or Tween 20 are occasionally added to the PCR mix. Microbial cells may be effectively isolated from food using differential centrifugation or filtering. If the cells are thoroughly cleaned, the DNA in the supernatants of heat-killed cells is sufficient for PCR amplification.

Because DNA survives cell death for a reasonably long time. When DNA from dead cells is amplified during PCR, it might provide false positive findings. However, if microbial messenger RNA (mRNA) is employed as the initial template during amplification, this problem can be overcome. The reverse transcription PCR (RT-PCR) technology incorporates a reverse transcription step, the conversion of mRNA to copy DNA (cDNA), into a standard PCR experiment. Microbial mRNA is relatively fragile; mRNA breakdown begins several minutes after cell death as a result of intracellular RNase activity (Sheridan et al., 1998). Reverse transcriptase catalyses the production of cDNA during RT-PCR, which then acts as the final template for DNA amplification. Since mRNA is a strong predictor of cellular vitality, RTPCR prevents the false positive findings that traditional PCR occasionally produces owing to dead cells. RNA extraction and RT-PCR are slightly more difficult than DNA isolation and standard PCR. Commercially accessible kits, on the other hand, make the assay less difficult.

Pathogen counts in food are often lower than in clinical samples

Immunomagnetic separation (IMS) is frequently used to concentrate cells prior to PCR to increase test sensitivity. Paramagnetic particles coated with pathogen-specific antibodies trap pathogens. Following that, microbial DNA is isolated and analysed using PCR. IMS has been shown to be successful, and commercially accessible immunomagnetic particles for collecting key foodborne pathogens.Boehringer Mannheim sells PCR-ELISA as a commercially accessible method (Indianapolis, IN). To avoid post-PCR gel electrophoresis and enhance sensitivity, the test combines PCR and hybridization. During PCR, a dig-dUTP-labeled dNTP mix is used to incorporate digoxigenin (dig), a steroid hapten, into PCR products. Amplified PCR products are linked to a microtiter plate by hybridization using an internal DNA probe, the biotin label of

which binds to streptavidin coated on the microtiter plate wells. A chemiluminescent signal is produced when dig interacts with an alkaline phosphatase-labeled anti-dig antibody in the presence of a suitable substrate.

Another way to improve PCR sensitivity is to employ nested or seminested primers in a PCR test (Wegmuller et al., 1993). The second-round PCR amplification includes a primer or a set of primers that are internal to an initial PCR result. The approach is frequently used to identify low amounts of target DNA sequences.

When it was initially reported, PCR appeared to be more promise for detection than enumeration of pathogens in food. Yet, recent advancements have made it feasible to quantify infections. PE Applied Biosystems' (Foster City, CA) 5' nuclease PCR test incorporates an internal TaqMan probe tagged with a fluorescent reporter dye and a quencher dye at the 5' and 3' ends, respectively. Due of its close proximity on the probe, the quencher dye reduces the reporter dye's fluorescence emission prior to PCR amplification. During PCR, Tuq DNA polymerase exploits its 5' exonuclease activity to hydrolyze the probe that anneals to the amplified products, triggering quencher dye cleavage and fluorescent reporter emission. Because the fluorescence signal is only emitted during positive PCR amplification, detecting the fluorescence in the PCR reaction may be used to detect a specific DNA sequence. Without the need for DNA gel electrophoresis, a positive or negative result can be obtained around 15 minutes after PCR amplification.

Methods for ELISA Monitoring

ELISA has been used to identify a variety of foodborne infections by focusing on their surface features, toxins, or whole cells. Aflatoxin, Clostvidium difficile toxin A, Staphylococcus enterotoxins, and *E. coli* verotoxins are among the microbial toxins that may be detected with some of the tests. Other kits are designed to target microbes such as Sulinotellu, *E. coli* 01 57:H7, L. monocytogmes, C.,jtjuni, and C. hotulinuni.

Since ATP bioluminescence is an enzymatic process, it is temperature and pH sensitive (Griffiths, 1996). Laundry detergents are similarly toxic to firefly luciferase. Cleaners and sanitizers either increase or decrease bioluminescence signals, resulting in Fdse findings (Velazqaez and Feirtag, 1997). Nonmicrobial ATP is frequently found in food residue. Different extractants can be used in a two-step lysis technique to selectively lyse prokaryotic or eukaryotic cells to separate microbial from nonmicrobial ATP.

The firefly luciferase enzyme can detect ATP produced by 10'-104 CFU/ml. A modified ATP bioluminescence test can be utilised to increase sensitivity.The test is designed to detect adenylate kinase, an enzyme that transforms ATP and AMP into two molecules of ADP. By include ADP in the test, the reaction is pushed in the other direction, producing ATP that may subsequently be detected using firefly bioluminescence.

Hazards from Natural Origins

Numerous natural risks may be present in most basic foods of the human diet. The magnitude of the hazards to human health associated with consuming naturally hazardous chemicals is still

being debated academically. All human diet is a complex chemical matrix that includes carbs, amino acids, lipids, oils, colours, enzymes, minerals, and vitamins, some of which are poisonous if ingested in high quantities. Plants, in example, contain a number of compounds that are harmful to both animals and humans. Plants evolved some of these compounds to defend themselves from insects, plant diseases, and other creatures. A few of these compounds, such as the hydrazines present in some mushrooms, are extremely carcinogenic. The debate on this topic has been hampered by a lack of systematic techniques to defining and, particularly, measuring human dangers.Toxic compounds in plants, on the other hand, have a negative impact on nutritional availability, metabolic processes, detoxifying systems, and allergy reactions in animals and humans. This chapter goes over a few of them. Although data on the chemical and functional characteristics of the majority of these substances has been amassed, the long-term hazards to public health have not been proven. Moreover, the National Research Council has found that present evidence on human food intake is inadequate and has advocated for further research with bigger sample numbers and improved testing methods (NAS, 1996). Above all, it is critical to underline that there is currently no strong evidence linking long-term absorption of natural poisons in regularly consumed foods to any sort of chronic human illness (NAS, 1989; NAS, 1996).

Plants do contain several compounds that are very hazardous to animals and humans, such as hydrazines and mycotoxins. Although these substances may have an impact on the incidence of some forms of human cancer, the exact percentage of cancers caused by "natural" vs manmade carcinogens is unknown. Nonetheless, there is considerable evidence that synthetic chemicals in food may enhance cancer risk beyond that presented by the presence of natural poisons alone. Laboratory rodent diets, for example, include many of the same naturally occurring poisons seen in human diets. Nevertheless, chemicals such as aflatoxin, 2,3,7,8-Tetrachlorobenzo-p-dioxin (TCDD), and 1,2-dibromo-3- chloropropane (DBCP) greatly increase tumour incidence when given to the diets of mice and rats, even at extremely low levels. This shows that in certain circumstances, the danger of cancer from specific synthetic food pollutants outweighs any risk posed by the background level of "natural pesticides" in the animal (Weinstein, 1991). No research has explicitly proved that applying dietary adjustments in a specific individual prevented the onset of cancer or prevented the spread of an existing malignancy. In the absence of contrary data, there is no reason to believe that humans vary. Several cautions should be acknowledged when taking findings from risk evaluations of food toxin exposure. Short-term screenings, such as the "Ames test," which look for genetic damage or enhanced cell proliferation, are far from reliable in predicting carcinogenicity and should not be used in place of long-term bioassays (Cohen and Ellwein, 1991). Furthermore, no matter how conclusive epidemiological or experimental research are, they cannot give definitive proof that a certain diet increases the risk of cancer.

Controlling heredity and environmental influences is quite challenging. Data from laboratory animal experiments and epidemiological research involving people must be used to drive food safety assessments. As a result, predicting human sensitivity to a target compound's tumor-promoting, mutagenic, or cytotoxic potential in the absence of other knowledge is exceedingly challenging. Hence, risk extrapolation in situations in which individuals are exposed to various

causes and in diverse groups (as occurs in the actual world) is far more complicated and perplexing than some writers imagine.

Mycotoxins are the most potent natural poisons that pose a threat to human health. They are not exactly plant chemicals, but harmful metabolites generated by fungus infesting foods, particularly grains and nuts that have been kept at high temperatures and humidity (NAS, 1989). The most notorious historical illness induced by these mycotoxins is ergotism, sometimes known as "St. Anthony's fire," which affected humans centuries ago.

The ergot alkaloids generated by Claviceps purpureus growing on wheat grains were responsible for this (NAS, 1973).Fungi that infest foods such as cereals and nuts that have been kept at high temperatures and humidity create mycotoxins. Mycotoxin aflatoxin is present in peanut butter and maize. It can induce liver cancer and cirrhosis, as well as reduced immunological function. Aflatoxin poisoning can be avoided by avoiding peanut butter and cornmeal from suspect suppliers.

G1ycoside that is Cyanogenic

Y is found in numerous food plants, including cassava, lima beans, and the seeds of several fruits, such as peaches. Due of their cyanide concentration, excessive amounts of cassava and, to a lesser extent, lima beans can be lethal if consumed raw or improperly cooked. Peeling, washing in running water to remove the cyanogens, and then heating and/or fermenting to inactivate the enzymes and volatilize the cyanide reduces cassava toxicity significantly. Cassava is prepared with care for human consumption in countries such as Africa, where it is a staple diet.

Several regularly ingested plants contain goitrogens, which limit iodine absorption by the thyroid. They are believed to contribute around 4% of the global incidence of goitres in humans (Liener, 1986). Cabbage, cauliflower, brussels sprouts, broccoli, kale, kohlrabi, turnip, radish, mustard, rutabaga, and rape and turnip oil seed meals all have some goitrogenic action (Coon, 1975). The effects of thyroid inhibition are not mitigated by dietary iodine ingestion. The mechanism and degree of glucosinolate toxicity are currently being debated. While glucosinolates have produced few, if any, acute human disorders, chronic and subchronic consequences remain a potential.

Luthyrogens are amino acid derivatives found in legumes such as chickpeas and vetch that function as metabolic antagonists of glutamic acid, a neurotransmitter in the brain. When these compounds are consumed in significant quantities by humans or other animals, they induce debilitating paralysis of the lower limbs and may end in death. Lathyrism is largely an issue in some parts of India.Lpctin proteins (phytohemugglzitunirzs) are found in different concentrations in legumes and grains, but not in tomatoes, fresh vegetables, fruits, or nuts. Ricin, a very poisonous lectin that may be lethal to humans, was once employed as a pesticide. When untreated lectins are consumed, they agglutinate red blood cells and attach to intestinal epithelial cells, limiting nutritional absorption. Thankfully, heat removes lectin toxicity. Protease inhibitors are found across the plant world, most notably in the Leguminosae family and, to a lesser extent, in cereal grains and tubers.

Food Safety Management System (FSMS)

In conversations regarding diet, food, health, regional economic development, and agriculture, the phrase "food system" is commonly used. In order to feed a population, a variety of infrastructure and procedures must be in place. These processes include planting, harvesting, processing, packing, transporting, selling, consuming, and disposing of food and food-related things. Inputs required and outputs produced for each of these processes are also included. The social, political, economic, and environmental settings in which a food system functions have an impact on it. Additionally, it needs people resources for work, research, and education. According to their conception of the food life cycle from origin to plate, food systems can either be conventional or alternative.

In order to guarantee that all food produced meets quality requirements and is safe to eat, food safety is managed through a regulated process known as a food safety management system (FSMS). This takes into consideration each and every stage, from receiving supplies to delivering out the final items, therefore every activity and job must have a clear method. Additionally, an FSMS should adhere to the HACCP principles, and it is the duty of each organization to create policies based on these principles. To abide by legal requirements for food safety, an FSMS is necessary.

FSMS Plan

A set of guidelines called the FSMS Plan or Food Safety Management System (FSMS) plan was created to guide and regulate several elements of food safety. International FSMS include the HACCP system, ISO 22000, FSSC 22000, and numerous others. The Food Safety and Standards Act, 2006 defines the FSMS as the implementation of good manufacturing practices, good hygienic practises, hazards analysis and crucial control points, and other activities that may be mandated by legislation. These certifications, however, are voluntary. When obtaining a new FSSAI License or renewing an existing FSSAI License, an FSMS plan is necessary.

CHAPTER 12

HAZARD ANALYSIS CRITICAL CONTROL POINT

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A set of guidelines known as Hazard Analysis Critical Control Point (HACCP) calls for analysing all potential hazards to food safety and putting measures in place to reduce those risks. It ought to serve as the cornerstone of any food safety management system. There are seven guidelines should take into account:

1. Determine all possible risks, such as those associated with handling raw materials.
2. Find the key control points (CCPs) for each possible hazard; an example of one of these controls would be to ensure that all fresh components are up to date.
3. Set important boundaries, such as the minimal and maximum refrigerator temperatures for items that need to be refrigerated.
4. Create processes for keeping an eye on CCPs. One of them might include a daily check list to make sure the times of these components have been verified.

Importance of Food Safety Management System

Manufacturers who work with food are required to have an FSMS so they can demonstrate they are in compliance with food safety laws and creating goods that are safe for consumption. It is necessary to comply with the following rules and laws:

1. BRC Global Standard ISO 22000
2. The 1990 Food Safety Act (UK)

Additionally, it gives food makers the peace of mind that everything, including employees and suppliers, is handled properly and safely and that all potential risks have been considered and prepared for. So, come back to the example of marketing your chocolate chip cookies, it provides with a central location to oversee all aspects of their production

Six Sigma of Food Safety Management System

Six Sigma is a collection of tools and methods that businesses use to enhance the caliber of process outputs and reduce variability in business operations. It aims to reduce variability in commercial and industrial processes and increase the quality of the output of either a process by locating and eliminating the sources of flaws.

It employs a variety of quality management techniques, including empirical and statistical techniques, and builds a specialized team of internal specialists in these techniques. Each Six Sigma implementation is carried out inside a company adheres to a predetermined set of

procedures and has specified value objectives, such as: reducing process cycle time, reducing pollution, lowering costs, raising customer satisfaction, and raising profits.

A manufacturing process's maturity may be determined by the sigma rating of its yield, or the proportion of items it produces that are free of defects.

The Six Sigma technique guarantees:

1. The success of a firm depends critically on ongoing efforts to provide predictable and stable process outputs (e.g., by decreasing process variances).
2. The features of business and manufacturing processes may be examined, studied, managed, and improved.
3. The entire organisation must be committed to achieving persistent quality improvement, but top-level management in particular.

Features of Six Sigma Methodology

1. Any Six Sigma project must have a clear focus on generating measurable and verifiable financial rewards.
2. A stronger focus on managerial leadership and support that is passionate and powerful.
3. A firm commitment to basing judgements not on conjecture and assumptions but on verified facts and statistical methodologies.

Introduction to Sampling

Monitoring the crucial traits of raw materials, components, and processed meals is crucial for keeping food quality or acceptance within acceptable bounds. If the analytical approach is quick and non-destructive, this might be accomplished by testing all the meals or components from a certain lot. In most cases, it is more feasible to choose a percentage of the entire product volume and presume that the quality of the chosen piece is representative of the entire lot.Sampling is the process of obtaining a fraction that is typical of the population; the population is the entire amount from which the sample was taken. A good sampling procedure makes sure that sample quality measures provide a precise and accurate approximation of the population's size. A quality estimate can be generated more rapidly, for less money, and with fewer resources than if the entire population were sampled and assessed. Although the sample merely provides an estimate of the population's value, a good sampling procedure can produce a highly precise estimate.

Sample Collection

It is crucial to specify the population that will be sampled. A factory lot, a day's worth of manufacturing, or a warehouse's worth of goods may all be considered as populations. It is possible to reliably extrapolate data from a manufacturing lot sample to the overall population of the lot, but conclusions cannot be reached from data characterizing bigger populations, such as the entire warehouse.Populations can either be limitless or finite, like the size of a lot or the number of temperature readings taken of a lot through time. Sampling offers an indication of lot integrity for limited populations. In contrast, drawing samples from an unlimited population yields data about a process. The data collected via sampling are matched to a range of

permissible values regardless of the group type, such as finite or infinite, to make sure the public sampled is within requirements.

Importance of Sample Collection

The dependability of the analytical data so collected is influenced by a number of variables, with sampling playing a significant role. Using current analytical techniques, a food sample of only a few grammes may be analysed. A sample must thus be as representative of the overall population as is reasonably practicable.

1. Analysis of food items involves three fundamental processes.
2. Obtaining a representative sample.
3. Preparing the sample.
4. Analysis utilizing the right tools and methodologies.

Despite being autonomous in nature, these activities can have a significant impact on one another. Additionally, each of these operations has prospective sources of variation on its own, which raises the amount of uncertainty surrounding any analytical outcome. Therefore, caution must be used to recognize the causes of variance and reduce or prevent them when carrying out any task. Therefore, it is essential for the laboratories to create a strategy for the appropriate execution of each operation, as well as to set quality standards and documented processes that adhere to those requirements. The act of sampling frequently falls outside the scope of a laboratory's mandate or oversight.

This is particularly true in professional testing labs where the delivery of samples is the "initial touch." A laboratory must make every effort to receive acceptable, applicable, and defendable samples if it hopes to improve the overall quality of both the analytical process.

Understanding the issues raised by each action will be necessary for the creation of acceptable plans, which will then rely on the use of reasonable judgements to find answers. It should be highlighted that the language and methods used for sampling might differ between businesses and between different applications.

However, the ideas presented in this Unit are meant to serve as a foundation for comprehending, creating, and assessing sampling strategies and sample handling techniques for particular applications that may be encountered.

Risks Associated with Sampling

Two different dangers are connected to sampling. A sampling strategy should take into account both. The possibility of adopting a population of low quality is referred to as the consumer risk. This should only occur in a small percentage of lots (5%), but the real acceptable likelihood of a client risk relies on the repercussions of selecting a subpar lot. These might range from significant health risks and resulting deaths to a lot being of somewhat worse quality than typical lots.The second might happen more frequently whereas the former requires little to no chance of happening. Vendor risk, or the possibility of rejecting any acceptable product, is the second risk.

The repercussions of an error define the permissible probability of the risk, much like with consumer risk. Typically, 5–10% of partner risk is considered acceptable.

Sampling Standards

The results of an analytical technique's step-by-step process, which includes sampling, sample preparation, laboratory tests, data processing, and data interpretation, are the data. Every phase has the potential for mistake, and the dependability or uncertainty of the outcome relies on the total number of faults throughout all stages. Variance serves as a measure of uncertainty. The accuracy of the process is shown by the overall variance of the total testing method, which is equal to the sum of variances associated with each phase of the sampling operation.A measure of data repeatability is precision. Contrarily, accuracy measures how closely the data reflect the actual value. The most effective strategy to increase accuracy is to increase the Food Analysis step's level of dependability. This is frequently the first sampling step. More so than population size, sample size affects how reliable a sample is. The sampling is more trustworthy the greater the sample size. The time, money, sampling procedures, sample management, analysis, and computational logistics all have an impact on the sample size.It should be emphasized that the language and methods used for sampling might differ between businesses and between different applications. The methods and means to analyze a certain lot are provided by a number of standards and guidelines.Aflatoxins can be found in varying concentrations, with a small number of peanuts making up the majority of the contamination. Similar to this, when grapes were sampled from the field, it's possible that various grape bunches had despite widespread of pesticide residues present, which led to variable findings when each bunch was examined independently. These examples serve to highlight how sampling error can contribute substantially to the total error in the analytical model.

CHAPTER 13

SAMPLING PLAN

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Amplifying typically has a goal, and the type of any sample scheme may be suggested or determined by the objective. A sampling plan is "a defined strategy for the selection, withdraw, preservation, transportation, the preparation of the sections to be extracted from a lot as samples," according to the International Union of Pure and Applied Chemistry (IUPAC). A sample plan should be well-structured document that outlines the steps necessary to carry out the goals of the programmed. The questions of who, what, why, where, and how should all be covered. Subject to size restrictions, the main goal of is to gather a sample that satisfies the requirements of the sampling plan.The sampling aim, the research population, that statistical unit, the sample selection standards, and the analysis techniques should all be taken into consideration when choosing a sampling strategy. Factors influencing the selection of a sampling strategy estimating the average value of a characteristic and determining if the average value complies with the requirements outlined in the sample strategy are frequently the two main goals of sampling. A well-designed plan is essential because it gives personnel executing the sampling activity a consistent model to follow and acts as a reminder of the crucial components in this section of the average sample analysis programmed.

Types of Sampling

Bulk Sampling

Bulk sampling is the process of selecting a representative sample from a large quantity of data that does not contain discrete, recognizable, or constant components. Sampling can be done in either static or dynamic circumstances. The number of intervals to be taken, their size, where in the huge stack or stream they should be drawn from, the sampling device that can be used, and how to lessen the advancements taken to a plausible size sample for shipment to the laboratory are all decisions that must be made when conducting large volume sampling.

Acceptance Sampling

In contrast to the preceding categories, acceptance sampling uses a planned strategy to determine if a large number of items match predetermined acceptance criteria. The hazards associated with accepting "poor" lots or rejecting "excellent" lots are listed together with one or so more characteristics, such as the plan's quality indices. The probability of rejecting excellent lots or adopting bad lots can be controlled with statistical planning. Acceptance sampling falls into two basic categories: sampling by qualities and sample by variables.

Sampling by attributes

In characteristics sampling, the product unit is categorised as either faulty or implementation in order, or the amount of defects in such a unit of the product is tallied in relation to a certain criteria. Alternately, sampling may be done to assess a population's acceptability depending on whether the sample demonstrates a certain trait, such as C. perfringens contamination in canned products. The distinctions between the two groups may be clarified using an illustration of net weight calculation. Any unit weighing 1 pound upwards of is accepted in attribute sampling, while each unit weighing less than 1 pound is discarded. The lots is rejected if there are more rejections than a specific number.

Sampling by variables

In a variable sampling procedure, a sample is taken in order to calculate the quantity of a material (such as salt) or a feature (such as color) on a scale that measures. The estimate derived from the samples is contrasted with a previously established 20 acceptable value, and the deviation is then calculated. This kind of sampling typically yields data with a normal distribution, such as the total solids in a food sample and the percentage of a container that is filled. In general, variable sampling calls for a lower sample size then attribute sampling, and wherever feasible, separate samples should be taken for each feature.

Problems in Sampling

The sampling method is never a more dependable source of analytical data. Reliability may be harmed by sampling bias brought on by convenience that is not statistically feasible. Choosing the wrong sampling strategy after failing to comprehend the population distribution can also result in errors.

Non-statistical issues, such as poor sample storage that causes sample deterioration, can also provide unreliable results. Samples need to be kept in a container that shields them from water and other elements that might harm them. Samples should be kept in an airtight container to prevent changes in moisture content. Light-sensitive samples should be kept in opaque glass containers or containers that have been covered with aluminum foil.

Nitrogen or another inert gas should be used to hold samples that are sensitive to oxygen. For the protection of samples that are chemically unstable, chilling or freezing may be required. When keeping unstable emulsions, freezing ought to be avoided. Certain food items can be stabilized during storage using antioxidants, such as ccl4, potassium dichromate, and chloroform. Mislabeled samples result in incorrect sample identification. In order to ensure that the marks on the sample container are not removed or destroyed during storage and transit, samples should be properly identifiable.

For instance, ice water storage plastic bags should be labelled with water-insoluble ink.The container must be sealed to prevent tampering if the sample is such an official or legal sample, and the seal mark must be visible. Along with the title and signature of the sampling agent, the date of sample must also be included in official samples. Such samples must clearly show who has possession of them in the chain of custody.

Requirements of Good Sampling Methods

When samples are gathered in a way compatible with commonly acknowledged excellent sampling procedures and good sampling practices, they are valuable for the purpose for which they were intended. What is need for this is:

a. Lot inspection prior to sampling
b. Using the proper sampling equipment for the specific product and intended sample type.
c. Use of appropriate holding containers for the sample.
d. Upkeep of the sample's integrity and any related documents.
e. Taking the necessary safety procedures to preserve, pack, and transport the sample towards the lab on time.

Food Safety

Food safety is the practice of handling, preparing, and storing food in a way that reduces the risk of food-borne illness and harm. Food items may come into contact with a variety of health risks as they travel along the supply chain from farm to manufacturing to fork. In order to reduce these hazards and safeguard customers, safe food handling methods and procedures are followed across the whole food production life cycle.

A large spectrum of academic disciplines, such as chemistry, microbiology, and engineering, are relevant to food safety. Everywhere food items are obtained, produced, processed, stored, or marketed, these many schools of thinking come together to assure food processing safety. Food safety, in this sense, refers to a comprehensive system of cleanliness and accountability that affects every facet of the global food sector. The relevance of food hygiene for such global supply chain is discussed in the following article, which defines food security in manufacturing. The article covers the fundamental ideas behind efficient food safety regulation after giving a quick summary of the many regulatory organizations charged with assessing food safety globally.

The history of food safety

Health threats from foodborne disease have existed since the beginning of mankind. In reality, a lot of the food preparation techniques just use today, such heating, canning, smoking, and fermentation, may be seen as early attempts to ensure food safety. These techniques were created to prevent people from becoming sick. The profusion of safe food and drink items that are available today is a result of decades of scientific and technical advancement that most of us take for granted. However, the idea of food security as we understand it today and the strictness in which it is upheld are relatively recent developments in history of mankind that are closely related to changes in how we live and what we consume.

Physical Hazards

Physical risks are founded on the chemical's inherent characteristics. Physical hazards can be divided into five categories: explosive, flame, oxidizing, gases under pressure, and corrosive to

metals. Depending on the level of risk, these are then classified into several categories and given unique hazard statements to identify them.Anything that has that potential to cause injury or other negative outcomes is a danger. While businesses may lose property or equipment, people may incur health repercussions. Environmental damage might also potentially result from hazards.The negative consequences that dangers might cause are referred to as "harm." Imagine a dangerous substance seeping from a container that is sitting on a pallet at a warehouse. The material that is leaking is a danger, but harm doesn't happen until the material has harmed someone's health, damaged something, or damaged the environment.

Types of Hazards

The six primary categories of occupational risks are as follows:

Biological Entities

Among other sectors, research centers and hospitals create wastes classified as biological hazards that might include pathogenic organisms. These provide a threat of illness to site workers, and they may spread quickly and contaminate other areas if they are dispersed into the environment by wind and water. Animals, plants, birds, insects, bacteria, and viruses are examples of biological entities.

Chemical

When exposed to a various chemicals at work, employees are exposed to chemical dangers. This substance can exist as a gas, liquid, or solid. All materials provide a danger to workers, even though some are safer than others. The substance's toxicity, chemical composition, and physical characteristics

Ergonomics

When working environments, body postures, and the nature of the task exert stress on the body, ergonomic hazards occur. Since the strain placed on the body sometimes takes time to manifest itself, ergonomic dangers can be challenging to spot. After being harmed by ergonomic risks, workers may feel mild symptoms like aching muscles. Attitude, workflow, workstations design, subpar equipment design, unsuitable workstation arrangement, difficult or heavy lifting, repeated actions, etc. are all examples of ergonomics.

Physical

Workers are exposed to environmental physical elements that can injure their bodies even if they do not physically come into touch with the danger. Disturbing sounds, high pressure, electric flux, radiation, fire, dim illumination, dangerous machinery, machinery utilized improperly, obstacles in the path, slick surfaces, etc.

Psychological Factors

Psychological risks can hurt like tiredness or stress, causing workers to become disengaged and perhaps make mistakes. Managers and supervisors may develop a healthy workplace culture that prioritizes safety, equality, and sustainable working practices to counteract the causes of

psychological trauma. Violence, stress, persistent low-level noise, hazard threats, discrimination, harassment, media affairs, heavy workloads, shift work, etc. are examples of psychological factors.

Safety Issues

The most frequent kind of workplace danger is a safety hazard. They speak about dangerous situations that can cause disease, harm, or even death. It include equipment breakdowns, malfunctions, improper machine guarding, trip and slip hazards, etc.

\Factors Affecting food safety

Around the world, reports of foodborne disease have significantly increased. Are there any reasons why food is now less secure than it .While certain hazards to food security have been there since the dawn of time, others include more recent changes in lifestyles, manufacturing techniques, and even the evolution of microbes?

Food quality control

The requirement to obtain and handle extremely delicate items for the food sector is a major factor in ensuring that high quality criteria are reached. Food goods from the same brand are frequently purchased, and even a little occurrence in which the quality of the products is damaged might significantly damage the reputation of the entire brand and the repeat business of a firm. Therefore, when brands handle food products, having suitable quality control methods in place is quite essential. This requires quality inspections, and hiring a third-party quality organization may facilitate, accelerate, and improve the process.

Quality Assurance in the Food Industry

A collection of procedures known as quality assurance (QA) is used to guarantee that goods are created using high-quality procedures. It's a proactive procedure that focuses on the production process of the product in order to prevent flaws. To prevent faults from appearing while the product is being created, quality assurance (QA) aims to enhance the development and testing processes. Establishing an efficient quality system and determining its suitability can help you accomplish QA. Furthermore, quality assurance is the responsibility of the whole product development team.

In any sector, quality control is essential. It is crucial to the operation of businesses because it enables them to continually offer to customer’s items that are safe and consistent. A dedication to quality is a crucial area of attention for something like the food and beverages industry in particular, as its end-users eat the products and items they make and package on a daily basis. Of addition, there are tiers of the value chain in between, and ignoring quality at any of these levels might harm a company's reputation as a brand and its connections with customers. This best practices manual for quality assurance gives food makers a foundation for determining which best practices are crucial for food quality. Quality assurance includes a wide range of proactive fault prevention procedures. It requires daily practice in order to consistently produce the intended results since it is a continuous endeavor rather than a one-time event.

1. Ascertain the standards for quality
2. Operate contrary to expectations
3. Realize Continuous Data-Driven Improvement

Setting reasonable expectations is essential to a quality assurance program's success. With the capabilities the facility possesses, both internal and external product standards from the client should be feasible. A company's chances of running into quality-related problems are significantly decreased when they are confident in their capacity to supply goods or materials in accordance with their customers' requirements from the outset.

Quality Control in the Food Industry

By locating flaws in the actual items that are created, quality control (QC) is a set of procedures for guaranteeing product quality. It's a reactive procedure that seeks to find (and fix) flaws in completed goods. To ensuring that the needs of the client are consistently satisfied, quality control may be done by locating and removing the sources of quality issues. It incorporates the quality management inspection component and is often the duty of a dedicated team tasked with inspecting goods for flaws.

Importance of food quality control

Controlling food quality is crucial for ensuring that people handle and eat safe food. Customers can be shielded from threats like tainted food while also receiving the quantity and calibre of food they having paid for. Quality management in the food sector may also assist a corporation avoid unreliable suppliers, equipment damage, and unfounded quality claims from clients or vendors. Finally, it may make sure that rules and laws governing food are followed.

In order to regulate the quality of corn syrup, test the quality, and locate a buyer for that run of food, quality control is utilized. Therefore, the providers or sellers should agree to write down their quality criteria, and any control concerns must be found throughout the inspection process people make sure that business has security and integrity of all your products starting at the source and continuing all throughout entire food supply and production chains, regardless of whether grow vegetables, are a packer, processor, distributor, or buyer of bulk food, supplements, or any other food stuffs that are for human consumption. A specialist third-party organization should constantly monitor and test the growing, processing, purchasing, and shipping procedures. This should be done at each and every level of the supply chain as well as the manufacturing processes.

Unsafe food consumption is bad for the consumer. When a food includes hazardous germs (like Listeria or Salmonella), poisonous chemicals (such pesticides or herbicides), or foreign objects, it may be deemed unsafe (e.g., glass, wood, metal, insect matter). As a result, food producers should take all necessary precautions to remove these dangerous ingredients from food. Analytical methods are used by government laboratories to examine food, identify harmful ingredients, and verify that the food is safe to consume.

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Good Manufacturing Practices

Good Manufactured Practices, or GMP, is a system made up of steps, instructions, and paperwork that guarantees manufacturing commodities like food, cosmetics, and pharmaceuticals are regularly produced and monitored in accordance with predetermined quality standards. GMP implementation may reduce losses and waste while preventing recalls, seizures, penalties, and prison time. Overall, it guards against bad food safety incidents for both the business and the customer. Every step of the manufacturing process is examined and covered by GMPs to prevent hazards that might have disastrous effects on the goods, such as cross-contamination, fake products, and mislabeling. The following are some areas that GMP guidelines and regulations might affect in terms of product quality and safety

1. Quality management
2. Sanitation and hygiene
3. Building and facilities
4. Equipment
5. Raw materials
6. Personnel
7. Validation and qualification
8. Complaints
9. Documentation and recordkeeping
10. Inspections & quality audits

Current Good Manufacturing Practice (CGMP) Regulations

FDA regularly monitors medication manufacturers' comply with its Present Good Manufacturing Practice (CGMP) requirements to assure the quality of medicinal products. The minimal standards for the processes, settings, and controls utilized in the creation, processing, and packaging of a drug product are laid forth in the CGMP laws for pharmaceuticals. The rules ensure that such a product is harmless to use, that it has the components and strength it purports to have, and that it is labelled accurately. An examination of the manufacturer's adherence to the CGMPs is part of the approval procedure for new and old drug different applications. Assessors and investigators from the FDA decide if the company has the facilities, tools, and capacity to produce the medication it proposes to sell.

Difference between GMP and CGMP

By closely observing medication manufacturers' adherence to its Current Good Manufacturing Practice (CGMP) requirements, the FDA maintains the quality of medicinal products. For the

procedures, settings, and controls used in the production, processing, and packaging of a drug product, the CGMP laws for medicines provide minimum standards. The rules ensure that an item is safe to use, contains the ingredients and power it claims to have, and is manufactured in a manner consistent with those claims.

The examination of the manufacturer's adherence with the CGMPs is a step in the review process for marketing applications for new or generic drugs. When evaluating a company's capacity to produce the medication it seeks to sell, FDA assessors & investigators look at whether it has the requisite infrastructure, tools, and capabilities.

Main Components of Good Manufacturing Practice

To guarantee constant product quality and safety, the manufacturing sector must strictly enforce GMP in the workplace. Following these 5 GMP Ps will help you adhere to high standards throughout the whole production process.

People

Every employee must follow precisely to the rules and procedures for manufacture. To properly comprehend their duties and responsibilities, all workers must complete a current GMP training. Enhancing their performance helps they become more competent, productive, and effective.

Products

Before being distributed to customers, all items must go through ongoing testing, comparison, then quality assurance. At every stage of manufacturing, manufacturers should make sure that raw resources, such as goods, have precise requirements. For the purposes of testing, assigning, and packing sample products, the standard procedure must be followed.

Processes

All staff should have access to adequately written, concise, consistent processes. To make sure everyone is following the established procedures and upholding the necessary organizational standards, regular evaluations should be undertaken.

Procedures

A collection of instructions for carrying out a crucial activity or step in a process to get a consistent outcome is called a procedure. It needs to be explained to every employee and applied consistently. Any variation from the established method has to be reported right once and looked into.

Premises

To prevent inter, accidents, or even fatalities, premises should always encourage cleanliness. To reduce the risk of equipment breakdown, all apparatus should be put or maintained appropriately and calibrated on a regular basis to guarantee they are appropriate for the goal of delivering consistent results.Producers are required to follow GMP laws to control the manufacturing, verification, and validation of produced goods and guarantee their efficacy and safety for market

distribution control the production, verification, and validation of produced goods and guarantee their efficacy and safety for market distribution, producers are required to follow GMP laws. For instance, the US FDA enforces GMP in the country through Current Good Manufacturing Procedures (CGMP), which apply to a wider variety of businesses, including those producing food, medical devices, cosmetics, and prescription medications. To determine if a manufacturing business complies with CGMP rules, the FDA performs facility inspections. FDA recalls all items if any severe breaches are discovered during the inspection, which is troublesome for producers in terms of both revenue and operational efficiency.

Total Quality Management

Total quality management (TQM) is a common management technique in which every employee continuously evaluates the organization's production procedures in order to raise the manufacturing caliber of goods and services and raise customer satisfaction. It entails adopting analytical techniques and providing management training to find and fix operational issues. It is challenging for a company to control the market in the ever-evolving and cutthroat global market. Additionally, the availability of similar items from several manufacturers gives clients a variety of choices. Buyers base their choice of goods on a number of factors, such as price, brand recognition, after-sales support, etc. Quality will always be the decisive element among these. In a nutshell, a high-quality product means consumer attraction and retention. Every firm now has a customer-focused strategy, making quality assurance crucial to providing the finest good or service.TQM assists businesses to better the general effectiveness of their outputs by enabling their employees to be in sync with the production processes. The top management, managerial level, and executives do this to evaluate the finished goods from every angle and create excellent production plans in accordance. They employ a variety of strategies, such as:

- Find the problem and stop it before it starts.
- Send it to the price chain for additional quality control.
- If the mistakes continue at any point in the production, stop it.
- Use the technology to your advantage.

History of Total Quality Management

The origins of TQM may be traced to Walter A. Shewhart's introduction of contemporary quality control in the early 1900s. In 1931, Shewhart published Economic Control over the Quality of Manufactured Product, a seminal industrial book. One of the foundational and fundamental tenets of industrial quality control is this explanation. Later improvements on Shewhart's work resulted in the introduction of new quality management standards.

Primary Principles of Total Quality Management

TQM is regarded as a method that is customer-centered and concentrates on continuously enhancing company operations management. It makes an effort to make sure that all involved personnel are working toward the same objectives of raising the calibre of the delivered goods or services and enhancing the production processes. TQM is defined by a number of guiding concepts.

Focus on Customers

Customers determine if your items are of a high caliber under TQM. Customer feedback is highly valued since it enables a business to more fully comprehend the demands and specifications for the production process. For instance, customer surveys may point to inadequate product durability. To improve raw material procurement, production processes, and quality assurance procedures, this feedback is then pushed back into TQM systems.

Commitment by Employees

Employee buy-in to the procedures and system is essential for the success of TQM. This involves clearly outlining the objectives, standards, requirements, and limitations across departments and among leaders. When a corporation applies TQM concepts, it must be prepared to invest in training personnel and provide them with the tools they need to finish projects effectively and on schedule. TQM also aims to keep skilled personnel and lower attrition rates.

Improve Continuously

A business should gradually change and aim for tiny, incremental gains as it learns about its clients, operations, and rivals. This idea of continual development enables more flexibility to various goods, markets, consumers, or geographies and aids a corporation in adjusting to shifting market expectations. The economic benefit a firm has developed over similar companies is likewise fueled by and grows as a result of continuous development.

Adherence to Processes

Process flowcharts, TQM drawings, visual strategic plan, and documented processes are frequently utilised in TQM's methodical approach. To guarantee that the necessary procedures are performed at the appropriate period of production, everyone participant in the method must be aware of and knowledgeable about their portion of it. Then, these procedures are regularly examined to identify any process flaws.

A Systematic and Strategic Approach

A company's policies and practices have to be an exact representation of its goals, objectives, and long-term strategy. To implement TQM, a firm must commit to making quality its central component and make the necessary financial investments. TQM advocates for a systems perspective to decision-making.

Data Utilization

TQM's systematic methodology can only be effective if input and feedback are provided to assess how the overall process is progressing. Output, turnover, efficiency, etc. employee indicators must be consistently relied upon by management to compare expected outcomes to actual outcomes.

TQM strongly relies on planning and documentation, and management can only determine whether those strategies are being met by using and analysing data.

Integrate Systems

Integrating systems is one approach to use data. According to TQM plans, systems should communicate with one another, share pertinent data across departments, and make informed choices. Another area should have rapid access to the ERP data when items or inventories are utilised in one area. TQM aims to make it possible for everyone to be aware of the same information at the same time by connecting data sources and exchanging information across systems.

CHAPTER 14

MANAGEMENT INFORMATION SYSTEMS

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A management information system (MIS) is a component of a company's total internal controls that addresses how management accountants apply people, documents, technology, and processes to solve business challenges like estimating the cost of a good or service or a corporate strategy. Because they are used to assess other information systems that are employed in operational activities inside the company, management information systems differ from normal information systems. In academia, the phrase is frequently used to describe a collection of information management techniques linked to the automation or assistance of human decision making, such as Executive information systems, Knowledge - based systems, and Decision Support Systems

Objectives of Management Information Systems (MIS)

1. The decision-making process along by providing information in a timely manner. This aids the decision-maker in deciding which course of action is best.
2. Give each managerial level the information they need to do their duties.
3. Aid in emphasizing the important elements that must be closely monitored for the company to operate well.
4. In both organized and unstructured issue situations, support decision-making.
5. Give users access to a system that combines people, computers, processes, interactive query tools, and documents for gathering, sorting, retrieving, and transferring information.

Characteristics of Management Information Systems

Management Oriented

The system is constructed from the top down. It does not imply that the system has been created to give information to senior management directly. Information that is pertinent is also given to higher levels of management. For instance, processing sales orders, shipping items to clients, and charging for the things are all examples of operational control tasks in the company or an organization. If the system has been configured properly, a salesperson may additionally track this information to learn about the sales region, order quantity, geographic location, and product line. If the system is established with the top management in mind, information on external competition, the market, and pricing may be generated to determine the market dominance of the company's product and to serve as the foundation for the launch of a new item or market niche.

Management Directed

Management must actively oversee the system development activities due to the management emphasis of MIS. Management should regularly assess the system it has built to guarantee its efficacy

Integrated

The term "integration" refers to the requirement that a system cover all functional areas of an organization in order to create more insightful management information and advance organizational goals.

It must take into account different subsystems, their goals and information requirements, and acknowledge the interconnectedness that these subsystems have with one another in order to identify and process shared information without duplication or overlapping.

Common Data Flows

While MIS is integrated, common data flow idea prevents repetition and overlap in storage and collection of information by integrating related processes and, if feasible, simplifying activities.

Heavy Planning Element:

Establishing a management data system takes time. It takes nearly two to four years to properly develop it in an organization. Therefore, long-term planning is necessary for MIS growth in order to meet the organization's future goals and demands. Therefore, before an information system is put into use, the designer needs to make sure it won't become outdated.

Flexibility and Ease of Use

An MIS system is made adaptable by include all forms of potential future ways when it is being built. The simplicity of use is a characteristic that frequently goes with flexibility. The MIS must be equipped to include every element that makes it easily usable and accessible to a wide variety of users.

Food Traceability and Recall

All food business owners are required to guarantee the safety of the food they produce and that their operations comply with all applicable laws and regulations. The Abu Dhabi Food Control Authority's (ADFCA) Codes of Practice outline best practices for adhering to UAE food laws and regulations. And guarantee a high level of conformity to Gulf Standards. Recent food incidents have shown how crucial it is to know where food comes from if you want to safeguard your customers. In instance, traceability makes it easier to recall and remove goods from stores and gives customers accurate information about products that may be at fault.

Operators of food businesses need to refer to this Code of Practice frequently. It attempts to make processes for identifying and removing dangerous food first from market clearer and more uniform. The cornerstones of every company's management system for food safety are traceability and recall procedures. It is crucial that owners of food businesses are aware that

problems with food safety might occur with their goods and that a strategy must be made in advance. It is important to regularly evaluate these programmers and systems to make sure they are working properly.

Objective of a Traceability System

In order to track food forward through the food web to the immediate consumer and backward through the food system to the immediate supplier, a traceability system must be able to clearly identify a sample of food and the food supplement batches used in its manufacturing.

World Trade Organization

An international organization with its main office in Geneva, Switzerland, is the World Trade Organization (WTO). It was established as the General Agreement upon Tariffs and Trade's replacement on January 1, 1995. (GATT). The company serves as a hub for facilitating international trade. The WTO offers a single forum for member states to promote international cooperation and settle any trade disputes. About 300 regional and 60 international trade agreements are managed by it. It has been decided to treat the 60 agreements as international treaties. 164 countries make up the WTO. Additionally, several countries partake in free trade as observers but do not ratify the WTO accords.

Structure of the World Trade Organization

Every two years, the WTO Ministerial Conference convenes to make crucial decisions about current trade agreements. All multilateral agreements concluded under the WTO are subject to final decision by the Ministerial Conference.

General Council

The General Council, which is made up of delegates from every member nation, serves as the Ministerial Conference's conduit for day-to-day business. Its responsibility is to carry out the WTO's implementation and monitoring duties. The General Government is further split into several committees and councils, each of which has a purpose. The Council of Goods, the Parliaments on Services, the Subcommittee on Textiles within the Committee on Goods, etc. are a few examples of these organizations.

Dispute Settlement Body

Trade disputes between member nations are resolved by the Dispute Settlement Body, which is a division of the General Council. Additionally, there is an Appellate Body where member nations can challenge any judgements rendered against them in a dispute.

Trade Policy Review Body

The General Council's Trade Policy Evaluation Body is tasked with making sure that member states' trade policies are in conformity with the WTO's objectives. The WTO requires member nations to notify it when their trade policies and regulations change. The organization evaluates the policies on a regular basis to make sure they adhere to WTO regulations. This aids the WTO in adapting to the shifting economic situation and is a component of its monitoring role.

Functions of the WTO

Trade Negotiations

By offering a framework to organise the agreements and dispute resolution procedures, the WTO promotes trade discussions between nations.

It establishes a global legal framework to facilitate seamless trade in products and services between the participating nations.

Implementation and Monitoring

The WTO's responsibility once the arrangements are finalized is to make sure the signatory nations uphold their obligations in reality. Additionally, it conducts research on how the accords affect the economics of the participating nations.

Dispute Settlement

When trade disputes arise amongst its members, the WTO also serves as a dispute resolution body. If a country's trade and economic practices conflict with its obligations under one of the WTO's agreements, members of the organization have the right to submit complaints against that nation.

Following the filing of the petition, there are official court-style hearings until a resolution is obtained.

Building Trade Capacity

By assisting them in acquiring the skills necessary to engage in trade agreements with more developed nations, the WTO operates specific initiatives to benefit emerging nations. Low-development nations are also granted benefits under specific accords to help them transition to free trade agreements with other countries.

Objectives of WTO

Establishing and Enforcing Rules for International Trade

The General Agreement on Trade in Services, the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the laws governing the international trade in goods are the three accords that make up the World Trade Organization (GATS). The WTO uses a united nations of dispute settlement to enforce its rules when one of its member nations violates a trade agreement. The methods and decisions must be respected and adhered to by the members in accordance with approved agreements.

Acting As a Global Apex Forum

The World Trade Organization serves as the international platform for regulating and negotiating more trade liberalization. The foundation of WTO trade liberalization initiatives is built on the advantages for members to make the most use of their comparative advantages as a result of a free and fair trading system.

Resolution of Trade Disputes

Trade disagreements before the WTO typically result from breaches of agreements between members. Such trade disputes are settled through aUN framework with predetermined rules and processes in front of the dispute resolution body, not unilaterally.

Codex Alimentarius

To reach acceptable living standards, one essential component is to have access to adequate, secure, and healthful food. Concern over food safety, as well as the health of plants and animals, is growing on a global scale. The fundamental guidelines for food safety and laws governing the health of animals and plants are laid forth in the Covered Agreements on Sanitary и Phytosanitary Measures. It applies to all of these policies that may have an impact on commerce internationally, either directly or indirectly. All nations are free to establish or enact the essential safeguards to safeguard human, animal, or plant life or health, provided that they do not apply in a way that would be an arbitrary or unreasonable method of discrimination between Members in situations where the same conditions exist.

The main goals of the Codex Alimentarius Commissions are to safeguard consumer health, ensure honest business practises in the food industry, and ease cross-border food commerce. To ensure that this goal is achieved, the National Codex Contact Point (NCCP) in the Ministry of Health and Family Welfare serves as the liaison office to coordinate with the other relevant government departments (at the central and state level), the food industry, consumers, traders, and research and development institutions.

Members must give information on the country's phytosanitary or sanitary requirements under Article 7 of the Agreement. Each Member is obligated to make sure that there is a single Enquiry Point that is tasked with responding to any reasonable inquiries from interested Members and disseminating pertinent materials on SPS Regulations that have been enacted or proposed, among other things.

Codex Alimentarius Commission [CAC]

In order to develop food standards, recommendations, and associated publications like codes of practise for the Joint FAO/WHO Food Standards Programmed, the Food and Agriculture Organization of the United Nations (FAO) and also the World Health Organization (WHO) established the Codex Alimentarius Commission in 1963. The major goals of this programmer are to safeguard consumer health, guarantee honest business practices in the food industry, and encourage coordination of all work on international food standards done by governmental and non-governmental groups.

The World Commerce Organization (WTO) accepts these norms as a means of resolving disagreements in global trade. A collection set standards, rules of conduct, directives, and other suggestions is called Codex Alimentarius. The primary food safety management system, Hazard Analysis and Critical Control Point (HACCP), is introduced in the Codex General Principles of Food Hygiene. Several important challenges that are essential to achieving the goals of Codex Alimentarius Commission,

Organic Food

Certain manufacturing criteria are followed when producing organic foods. Agriculture may be characterized as organic throughout a significant portion of human history; only after the 20th century was a significant amount of new manufactured chemicals added to the food system. The use of typical non-organic pesticides, insecticides, and herbicides is severely limited in organic cultivation and is only used as a last option. In contrast, organic food has had expansion rates of approximately 20% annually since the early 1990s, considerably outpacing the rest of the global food business in both rich and developing countries. As of April 2008, 1%–2% of all food sales globally are organic.

Meaning and Origin of Term

The term "organic food" refers to produce cultivated on a farm without the use of genetically modified organisms, synthetic pesticides, or fertilizers. Contrarily, "conventional" agriculture refers to the style of farming practiced by the majority of farmers, which does make use of synthetic fertilizers and pesticides. Food that is organically grown and produced without additives. Products containing exclusively organic ingredients be labelled 100% organic, while food whose contents are at least 95percentage - point organic by volume can bear the "USDA ORGANIC" label. Compost, organic fertilizers, natural root stimulators, and biological pest management are all used in organic farming.

Dried Food

The freeze-drying method was commercialized during World War II when blood plasma & penicillin were preserved using it. A specific device called a freeze-dryer is required for freeze-drying; it contains a sizable freezing chamber and a vacuum pump to remove moisture. Since the 1960s, more than 400 new kinds of freeze-dried food stuffs have been created for the market. Due to their excessive water content and poor freeze-drying properties, lettuce and watermelon make for two poor freeze-drying options. The most popular freeze-dried product is coffee.

Freeze drying

The method of "freeze drying" involves dehydrating frozen meals in a vacuum such that the moisture content transforms straight from a solid to a liquid state without going through the intermediate liquid stage through sublimation. With little cell breakage during this procedure, the result retains its original structure and form.

Food irradiation

Ionizing radiation is used to irradiate food in order to eliminate and prevent the reproduction of any bacteria, virus, or insects that may be present. Additional uses include the prevention of sprouts, postponement of ripening, and enhancement of rehydration. Ionizing radiation processing of food really damages DNA, the building block of life's genetic code. Microorganisms are unable to reproduce and carry out their harmful or cancerous functions. Microorganisms that cause spoilage cannot function further. Insects either die out or lose their ability to reproduce. Irradiation slows down the process of a plant maturing or ageing.

World Health Organization

The World Health Organization (WHO), a division of the UN specializing in health, was founded in 1948. Headquarters for the organization are in Geneva, Switzerland. The Organization consists of 100 Nations, 150 Country Office, and Regional Offices. It is an international organization that works with its members, mostly through their ministries of health. By setting the future research, creating norms and standards, outlining evidence-based policy choices, providing countries with technical support, and tracking and analyzing health trends, the WHO takes the lead on matters relating to global health. The day it started operating, April 7, 1948, is now annually recognized as World Health Day.

Goals of WHO

The main goal of WHO is to guarantee that everyone has access to the greatest medical services. The organization performs a wide range of duties to help it achieve its main objective. These consist of

1. Take on the position of ultimate authority in global healthcare.
2. To promote technology cooperation in the healthcare industry.
3. To support various countries in their efforts to improve healthcare.
4. Provide suitable technical help for crisis relief and on the petition or acceptance of governments.
5. To start and maintain initiatives for the prevention and control of epidemic, regional, and other diseases.
6. In coordination with other specialized organizations both inside and outside the United Nations, to promote, as necessary, the improvement of nutritional, housing amenities, sanitation, entertainment, economic or working conditions, and other areas affecting environmental hygiene.
7. To promote international research in biomedicine and health services.
8. To promote improved standards for instruction and training in the medical, allied health, and other related fields.
9. Establishing global standards for bio, pharmaceutical, and related products.

Structure of WHO

World Health Organization Assembly

The Health Assembly is composed of representatives of members. A maximal of three delegates may represent each member, with the member designating one of them as the head delegate. These representatives, who preferably represent the Member's national health administration, are chosen from among individuals with the best technical experience in health. Regular yearly sessions as well as occasionally special sessions are held by the Health Assembly.

International Consultative Group on Food Irradiation:

The World Health Organization (WHO), the International Atomic Energy Agency (IAEA), and the Food and Agriculture Organization of the United Nations (FAO) encouraged member states

to consider joining a consultative group in 1982 to focus on international cooperation on food irradiation. It was intended to be a free-standing group of professionals chosen by the government. The three UN agencies met in 1983 to prepare a Declaration creating the International Consultative Group on Food Irradiation after receiving favorable responses from 44 of the 45 Member States who responded to the invitation (ICGFI).

Irradiation of food refers to the application of a particular form of energy to food. The procedure, which will be explained later in the book, entails subjecting the food, whether packed or in bulk, to precisely regulated doses of ionising radiation for a predetermined period of time. No matter how long the meal is exposed to radiation for or how much energy is absorbed, the method cannot raise the meal's typical level of radioactivity. By altering their molecular structure, it can stop the reproduction of bacteria and mould, two types of microbes that cause food rotting. By changing or altering the physiological functions of the plant tissues, it can also delay the ripening or maturation of several fruits and vegetables.The proclamation was approved by the 19 Member States' representatives present at the conference. The Consultative Group was founded in May 1984 for an initial tenure of 5 years and is made up of delegates chosen by each administration. The Joint FAO/IAEA Division, Vienna, which is a joint venture between the FAO, IAEA, and WHO, acts as the ICGFI's secretariat. 22 nations participated in the Consultative Group's inaugural meeting, which took place in Vienna in December 1984.

Consultative Group functions

According to the Declaration, the ICGFI has the following responsibilities:

1. Assessing international developments in the field of food irradiation; serving as a focal point for Member States and the three organizations for advice on the use of food irradiation.
2. Providing information to the Joint Of who Expert Committee upon that Wholesomeness of Irradiated Food.
3. The Codex Aliment Arius Review board as needed through the organizations.
4. The ICGFI handles issues including ensuring the process's safety, law, public awareness, technical/economic viability, training, and global trade.

Decontamination

Decontamination is the process of removing or destroying contamination so that bacterial pathogens or other pollutants can't get close enough to a vulnerable place to cause an infection or other negative reaction. For their unique tastes, colours, and scents, spices, herbs, and vegetable condiments are prized. However, because to the production environment and processing circumstances, they are frequently highly contaminated with bacteria. Therefore, the microbial burden needs to be decreased before they may be safely added to other food items. A "cold technique," like irradiation, is best since heat treatment can significantly reduce flavour and fragrance.
