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Food Safety Hazards

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Food Safety Hazards

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PREFACE

The agro-food sector is of major importance in many economies worldwide. In many countries the food and drink industry is a leading industrial sector. Food is a serious component of everybody daily life activities and it is recognized the contribution of safe food to a healthy life. For this reason, food safety and the protection of end consumer health is of increasing concern not only for the consumers but also for governments, professional associations and all organizations involved in the food chain from the primary production to retailers and other food businesses that put food products at the disposal of the population. Food safety is used as a scientific discipline describing the handling, preparation, and storage of food in ways that prevent food-borne illness. This includes a number of routines that should be followed to avoid potential hazards. Food safety considerations include among others, the origins of food, the practices related with food labeling, food hygiene, food additives, control of hazards and good manufacturing practices. The prevention of the multiple type of hazards with very distinctive origins requires a comprehensive and integrated approach to food safety in order to address food safety risks in every day more complex and globalized food chains. All actors in a food chain have a responsibility to ensure the safety of food products at the stages of intervention, irrespective of the nature of the activities they carry out. This book is one of a collection that aims to facilitate to the users the understanding of relevant issues related with food safety.

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DEDICATION

To,

Our beloved teams at MonoJo Biotech and the Jordan University of Science and Technology (JUST) and everyone who contributed towards the success of this series of e-books.

This series of e-books has been prepared for the FOODQA Project which was co-funded by EU through Erasmus+.

The series of e-books has been composed with passion and is available for public access to provide a high quality reference on the best practices in food quality and safety that can be used by the food industry, relevant governmental bodies, students, professors, and academics.

Our heartfelt gratitude goes towards our Jordanian and European partners who dedicated their precious time and effort towards the success of this entire project.

We dedicate this work to our beloved country, Jordan, and its people and to our European partner countries.

- ***Prof. Fahmi Abu Al-Rub, Dr. Penelope Shihab, and Dr. Safwan Abu Al-Rub***

Chapter 1

FOOD SAFETY: DEFINITIONS AND ASPECTS

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Chapter Objectives

- Overview the most relevant definitions used in Food Safety studies
- Explain the difference between FSOs and microbiological criteria
- List the conditions that may favour the emergence of foodbornepathogens

Introduction

Safety is an intrinsic quality attribute of foods and it is strictly related to their suitability for human consumption. It is recognised that a main role on food safety is played by microbial contamination and growth of pathogenic microorganisms as well as of presence of microbial/biological toxins that make raw materials and commodities as well as processed foods dangerous and may cause illnesses and infections with main impact on human health.

However, food safety is a concept with a wider meaning and do not deals only on the actions to reduce microbial contamination but has to take into account other hazards that during handling, storing and preparing food may determine loss of nutrients making foods of low importance in our diet or cause the formation of unhealthy compounds.

The purpose of this e-book is, thus, to give an overview of the main hazards in food manufacturing and processing that could affect the safety of foods as well as the health and wellbeing of consumers. Actions to prevent presence and formation of compounds or organisms that may impair the safety of a food will be described along with the legal and regulation framework.

In particular, the first two chapters deal with the definitions and main aspects of food safety and its hazards (**Chapter 1 and 2**). Then, a series of chapters that describe the hazards of food safety categorised by origin and in particular the microbiological and biological (**Chapter 3**), chemical (**Chapter 4**), physical and mechanical (**Chapter 5**).

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The nutritional hazards including the use of ingredients and products containing allergens as well as unbalanced diets are described and discussed in (**Chapter 6**).

Innovation in food processing and innovative foods and ingredients that may represent hazards for human consumption and thus, the risk on safety and human health has to be unravelled; specific assessment actions allocated in general within a legal framework are required (**Chapter 7**).

Chapter 8, eventually, gives a main overview of the European food safety regulations and describes their history and evolution taking into account also the consumers interests on food safety.

DEFINITIONS

The increasing amount of data and information on foodborne diseases has boosted public awareness on food safety. In this respect, television and Internet play a significant role, because food attracts attention and increases audience engagement.

Food safety can be described as "The strategies and activities aimed to protect foods from biological, chemical, physical, and allergenic hazards that may occur during all stages of production, distribution, and consumption".

In the last years, the overall increase in foodborne outbreaks is only partially explained by improvements in data collection and diagnosis. On one side, globalization and urbanization led to increased opportunities for pathogens transmission, on the other, food product development tends to focus on clean label products, where preservatives and safety hurdles have been removed.

To develop food safety strategies, the World Trade Organization and Codex Alimentarius have proposed the application of the Appropriate Level of Protection and the Food Safety Objective.

The Appropriate Level of Protection (ALOP, also known as ALR, Acceptable Level of Risk) is "the level of protection that is considered acceptable by each country in order to protect human, animal or plant health". Instead of ALR, Food Safety specialists often use the definition Tolerable Level of Risk (TLR) that is "the risk that can be tolerated by society, in comparison with the other significant risks of daily life". TLRs are established according to public health impact, technological feasibility, and economic implications. In particular, each society regards TLRs as reasonable in comparison with other risks in everyday life. Therefore, TLRs are closely connected to social and local factors, although they shall be established on scientific basis.

ALRs and TLRs can be indicated in relation to mortality or morbidity as the number of cases/year caused by a specific food hazard on 100 000 people. As a matter of fact, these values can be considered reasonable estimates based on available data, e.g. outbreak investigations, notifications, surveillance studies. However, the true incidence of a food disease is not known and can be very different according to population characteristics. For example, ICMSF (International Commission on Microbiological Specifications for foods) suggested a TLR of 10 cases/year on 100 000 people for HAV (Hepatitis A Virus) but this value might be underestimated in populations where raw shellfish are commonly consumed, e.g. Japan or Southern Italy.

Expressing Food Safety in terms of ALR or TLR does not provide any guidance for problem solving, which is of paramount importance for producers, distributors, and control authorities. To reduce the level of risk in manufacturing and distribution environments by establishing practical control measures, the Food Safety Objective (FSO) was proposed.

Although FSOs can be proposed for any food hazard (e.g. allergens, carcinogens, antibiotic residues, etc.), their application is particularly useful for microbiological hazards. A microbiological FSO can be defined as "the maximum

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frequency and/or concentration of a microbial hazard in a food at the moment of consumption that provides the appropriate level of health protection". Thus, an FSO converts a TLR into parameters that can be easily understood and controlled by manufacturers and distributors.

The specification of an objective that shall be guaranteed at the moment of consumption was the basis for important legal applications, e.g. the European Union Regulation on Microbiological Criteria for Foodstuffs 2073/2005/EC and its modifications.

Food Safety Agencies can play a major role in the proposal of FSOs. In the European Union, the European Food Safety Authority (EFSA) should play a strategic role, as well as the national Food Safety Authorities for criteria that have not been harmonized yet.

Hypothetical examples of FSOs are

- The count of *Listeria monocytogenes* in ready-to-eat foods must not exceed 100 cfu g^{-1} at the moment of consumption.
- The count of *Salmonella* spp. in raw chocolate must not exceed 1 cfu kg^{-1} at the moment of consumption.

Apparently, FSOs might seem similar to microbiological criteria. However, differently from microbiological criteria, FSOs cannot be applied to individual lots, do not contain a sampling plan, and cannot be used for legal purposes.

Although FSOs should be measurable, this does not necessarily mean that they should be checked by microbiological analyses. As an example, when we express an FSO for low-acid canned foods in terms of 12D value (probability of a viable spore of *Cl. botulinum* being less than 0.000000000001 per can), this does not involve counting *Cl. botulinum* in end products. In fact, this value shall be verified by heat penetration curves and process measures, aimed to assess the probability of non-sterile cans.

According to ICMSF (2002), FSOs need to be validated under the responsibility of regulatory authorities. If an FSO can be technically achieved, then it comes into force for all manufacturers. On the other hand, if an FSO cannot be technically met, the product or process should be modified or, if modification is not possible, the product should be banned.

In Research & Development (R&D) projects, if foods are designed and validated to fulfil all the relevant FSOs, they are very likely to be assessed as acceptable. Producers and distributors can find different solutions to meet FSOs, e.g. formulation changes, storage conditions, shelf-life decrease.

FSOs are undoubtedly useful for control authorities, as they can form the basis to evaluate if a process or product is in compliance. At the same time, in production and distribution they are practical to assess and communicate whether a food is manufactured and managed properly.

FOOD SAFETY ASPECTS

Specific aspects should be taken into account when microbiological hazards are evaluated. In this case, the level of risk also depends on prevalence and incidence.

Prevalence can be defined as "The total number of cases of a disease in a community at a certain time"

Incidence is "The rate at which new cases of a disease occur in a community in a given time period"

Changes in prevalence and incidence of a given disease may result in the emergence of food pathogens. In particular, the following conditions correspond to the definition of emerging pathogens.

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- Infectious diseases whose incidence has increased in the past two decades or threatens to increase in the short term.
- New infections resulting from changes or evolution of existing microorganisms.
- Known infections spreading to new geographic areas or populations.
- Old infections re-emerging due to new vehicles.
- Previously unrecognized foodborne infections.
- Suspected foodborne pathogens.

According to Woolhouse & Gowtage-Sequeria (2005), 73% of emerging pathogens are zoonotic agents. For this reasons, food safety authorities should always keep a watchful eye on data regarding animal diseases.

Besides emerging pathogens, other researchers have proposed the definition of re-emerging pathogens, defined as "known infectious diseases that had fallen to such low prevalence or incidence that they were no longer considered a public health problem, but that are currently increasing in prevalence or incidence".

Re-emerging infections include tuberculosis, which have increased worldwide since the early 1980s, dengue in tropical regions, and diphtheria in Eastern Europe.

Moreover, demerging pathogens (also known as vanishing pathogens) are "microorganisms that were once considered important for human health but whose importance is now considered inconclusive or not definitively proven".

Aeromonas spp. could be considered an example of demerging pathogens, because foodborne transmission has not been definitively proven, and a possible role as opportunistic pathogen is also questionable.

The following factors can be involved in the emergence of foodborne pathogens:

- Climate changes and weather, e.g. aflatoxin contamination in cheeses following hot weather conditions.
- Globalization, e.g. HAV outbreak in the European Union in 2013-2014, presumptively correlated to berries produced in different countries in Eastern Europe.
- Changing manufacturing technologies, as in recent cases of food botulism associated with ready-to-eat sauces or ready-to-heat soups.
- Human demographics and behaviour, e.g. the increase of the number of meals consumed away from home.
- Human susceptibility to infection, e.g. the emergence of *Cl. difficile* infections in nosocomial environments.
- Microbial adaptation and modification, as in the emergence of MRSA (methicillin-resistant *St. aureus*) in foods and food manufacturing environments.

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Chapter 2

DEFINITION OF FOOD SAFETY HAZARDS

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Chapter Objectives

- Overview the most relevant definitions used for food safety hazards
- Compare Hazard definitions with other hazard-related terms
- Describe the methods used for Hazard Characterization
- Analyse practical implications and future challenges

HAZARDS: DEFINITIONS IN THE EVOLUTION OF THE HACCP SYSTEM

The HACCP system evaluates and controls all significant hazards associated with a specific food throughout manufacturing and distribution.

In the evolution of the HACCP system, the definition of Hazard has changed. At the beginning, Hazard was defined as "any biological, chemical or physical property that may cause a food to be unsafe for human consumption" (USDA, 1997). Then, the definition was modified by including the conditions created by producers, distributors or consumers. As an example, vacuum packaging of fish carpaccio can be considered a special condition that favours the formation of *Cl. botulinum* toxins (BTXs). Thus, Hazard can also be defined as "a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect" (CAC, 1997).

Together with the development and application of voluntary standards on Food Safety, the definition of Hazard included allergens, which have become increasingly important for food in production and distribution, as they represent a significant health hazard. An updated definition of Hazard can be the following: "a biological, chemical or physical agent in food, including allergens, or a condition of food with the potential to cause an adverse health effect". Therefore, the HACCP system addresses three categories of food safety hazards (microbiological, physical, and chemical), plus an additional category represented by allergens.

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In the last decades, the emergence of outbreaks associated with new food vehicles has extended the profile of potentially hazardous foods, which now includes meat, poultry, fish, shellfish, dairy products, eggs, cooked foods, raw vegetables, also fresh-cut fruit and vegetables, and even low-a_w foods (Pittia & Paparella, 2016).

HAZARD-RELATED DEFINITIONS

In food companies and distribution chains, the HACCP system is part of the Quality Management System. Consequently, the definitions used in HACCP should be compared with other food safety related definitions.

Here is a list of the most common food safety definitions encountered in Quality Plans:

- **Failure (FMEA System):** Any malfunction, defect or error that results in a process not performing its intended function(s) or not meeting requirements satisfactorily.
- **Accident (HAZOP System):** An unexpected happening that causes loss or injury to people.
- **Nonconformity (Quality Management System):** Nonfulfillment or failure to meet a requirement.
- **Mishap:** An unfortunate accident.

UNITS OF MEASUREMENT

As for definitions, also the units of measurements for hazards have changed over time.

In 1969, the National Academy of Sciences (NAS) proposed to evaluate the hazard of *Salmonella* spp. in foods according to the following three parameters:

- Products containing ingredients that might be potential factors in salmonellosis.
- Manufacturing processes that do not include a control step that would inactivate salmonellae.
- Substantial likelihood of microbiological growth if mishandled or abused during distribution or consumer usage.

In 1989, the National Advisory Committee on Microbiological Specifications for Foods (NACMCF) proposed a hazard classification scheme, based on the following 6 Hazard Categories (A-F):

Hazard A: Non sterile product, intended for high-risk consumers.

Hazard B: Presence of ingredients that can contain the hazard.

Hazard C: No treatment eliminating the hazard.

Hazard D: Possible recontamination after processing.

Hazard E: Possible thermal abuse during distribution/consumption.

Hazard F: Eaten without heat treatment.

Following analysis of the 6 Hazard Categories, Risk Category 6 is assigned if Hazard A is present, whereas Risk Categories from 5 to 1 correspond to the presence of 5 to 1 general Hazard Categories (from B to F).

Risk Categories have been extensively used in regulations (e.g. German regulations on *L. monocytogenes* in foods, Ryser & Helliot, 2007), as well as in the classification of food processes according to food safety hazards (Paparella et al., 2009).

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Presently, the classification of food hazards in HACCP is performed on the basis of two units of measurement:

- Severity (Importance).
- Risk (Probability).

A specific hazard can show high severity and low risk, e.g. *Cl. botulinum* toxins in foods, or a low severity but a relatively high risk, e.g. hairs in restaurant dishes.

In many HACCP plans, Hazard Characterization is expressed as Severity x Risk. However, this operation has nothing to do with Risk Characterization performed in Quantitative Risk Analysis that shall be based on sound scientific basis, also including predictive microbiology studies.

CURRENT AND FUTURE IMPLICATIONS

In the HACCP system, the classification of hazards on the basis of Severity and Risk is subjective. In particular, in many HACCP plans, a scale 1-10 is used for both units of measurements but harmonization of assessment is very difficult.

Thus, differences in hazard ranking may cause a diverse impact on production costs. In fact, the management of food safety hazards has costs that can depend on the severity and/or risk of the hazard. This means that a company where hazard characterization was less severe could gain competitive advantage on the market.

In the future, it is very unlikely that all decisions on food safety hazards shall be based on Quantitative Risk Assessment that is very expensive and not easily suitable for small-scale manufacturers or distributors.

However, technological progress might be the key to provide economic and easy-to-use tools to predict and solve food safety issues. In particular, sensors, drones, smart packaging, nanotechnologies, and image recognition technologies could add useful information that might be essential for Hazard Characterization.

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Chapter 3

MICROBIOLOGICAL AND BIOLOGICAL HAZARDS

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Chapter Objectives

- Foodborne pathogens and conditions affecting their growth, survival and death in foods
- Methods used to prevent foodborne illness that can be taken during food processing, at food service and retail as well as in the home

Introduction

Biological hazards are microorganisms such as bacteria, viruses, yeasts, molds and parasites or they may produce toxin in the food chain that pose a threat to human health. Biological hazards are of great concern to food industry because they are responsible for most of foodborne illness outbreaks.

FOODBORNE BACTERIA

Salmonellosis

Importance of *Salmonella*

Salmonella infection is considered to be second major causes of worldwide foodborne outbreaks. The increase incidence of *Salmonella* infection may be due to better reporting and surveillance, rather than a real increase in disease. In addition, other factors may be involved such as:

a) Increase prevalence of antimicrobial-resistant *Salmonella* strains.

b) Increase in the number of immunocompromised individuals that become more susceptible to infection with *Salmonella*.

c) Increase consumption of egg-based products associated *Salmonella* Enteritidis.

d) Changing of eating behaviour that becomes more dependent on fast and ready to eat foods.

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More than 2,400 serotypes of *Salmonella* are recognized that has been grouped into the following subspecies

1. *Salmonella enterica* subsp.a *enterica.*
2. *Salmonella enterica* subsp. *salamae.*

3a. *Salmonella enterica* subsp. *arizonae.*

3b. *Salmonella enterica* subsp. *diarizonae.*

4. *Salmonella enterica* subsp. *houtenae.*
5. *Salmonella enterica* subsp. *bongori.*

Salmonella enterica, subsp. *enterica* are mainly associated with foodborne salmonellosis.

Characteristics of *Salmonella*

Salmonella cells are non-spore forming mesophilic bacteria that can grow over a wide range of temperatures (5 - 46°C). Furthermore, the cells are sensitive to pasteurization conditions and can-not multiply at pH < 4.5 and a_w < 0.94. *Salmonella* cells can survive for long times in dried and in frozen storage conditions. They can multiply in foods without affecting its organoleptic characteristics.

Source of *Salmonella*

The natural habitat of *Salmonella* is the gastrointestinal tract of humans and other primarily warm-blooded animals. In addition, plant derived foods also may act as vehicles of *Salmonella* following environmental contamination. Both animal and, to a lesser extent, plant-derived animal feed materials are important in the source of *Salmonella* to the food production environment. This explains the increase of the carriage rate of *Salmonella* by poultry. Water also represents a significant source of transmission, directly through consumption in countries where environmental sanitation is poor.

Toxins

Once *Salmonella* cells in the colon, they invade the mucosa cells of the small intestine as a result of thermostable cytotoxic factor production. After their multiplication inside the epithelial cells, an inflammatory reaction and fluid accumulation in the intestine occurs as a result of toxin production. The ability of the pathogens to invade and damage the cells once inside the epithelial cells, the pathogens multiply and produce a thermolabile enterotoxin that is directly related to the secretion of fluid and electrolytes.

Disease and Symptoms

Salmonellosis symptoms appear after ingestion of food contaminated with > 10^6 after 12-36 h. The main symptoms include watery diarrhea that leads to dehydration accompanied by abdominal pain, nausea and vomiting. However, typhoid and paratyphoid fever caused by Sal. typhi and Sal. paratyphi causes diarrhea, abdominal pain, headache in the first few days and prolong and spiking fever upon ingestion of as low as 5-25 cells.

Prevention

Since poultry is a major vehicle for the transmission of *Salmonella*, a range of management strategies have been developed or devised to control *Salmonella*. These strategies include the provision of *Salmonella*-free stock and feed, vaccination with attenuated *Salmonella* strains, and use of competitive exclusion.

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The most important control measure to minimize infection with *Salmonella* involves both worker and consumer education in the areas of personal and food hygiene, prevention of cross contamination, and proper handling of foods.

Pathogenic *Escherichia Coli*

Importance of *E. coli*

Escherichia coli (*E. coli*) is a bacterium that is considered as a normal inhabitant commonly found in the gut of humans and warm-blooded animals. Most strains of *E. coli* are generally harmless. *E. coli* is present at a very high level in feces, therefore it has been used as an index organism for possible fecal contamination and presence of enteric pathogens in food and water. However, some strains are considered pathogenic strains to human that can be transmitted via food. These strains are subdivided into specific groups based on virulence properties, mechanisms of pathogenicity, clinical syndromes and distinct O:H into the following groups:

1. Enteropathogenic (EPEC).
2. Enteroinvasive (EIEC).
3. Enterotoxigenic (ETEC).
4. Diffuse-adhering (DAEC).
5. Enteroaggregative (EAEC).
6. Enterohemorrraghic (EHEC).

Enteropathogenic *E. coli* (EPEC)

These strains cause infant diarrhea that is associated with poor sanitation practices as a result of ingestion of high numbers (10^{6-9} cfu/g or ml of food). They are transmitted directly or indirectly through human carriers. Several serotypes are implicated in waterborne and foodborne disease outbreaks in different countries. The major O serotypes associated with illness O55, O86, O111ab, O119, O125ab, O126, O127, O128ab and O142. The organism colonies the microvilli over the entire intestine to produce the characteristic "attaching and effacing" lesion in the brush border microvillus membrane. The predominant symptom are vomiting, fever and watery diarrhea with mucus.

Enteroinvasive *E. coli* (EIEC)

These strains cause non-bloody diarrhea and dysentery similar to that caused by *Shigella sp.* by invading and multiply in the epithelial cells. The organism colonies the colon and produces fever and diarrhea containing mucus and streaks of blood. To develop symptoms, an infected person should ingest as many as 10^6 cells.

Enterotoxigenic *E. coli* (ETEC)

It is considered as a major cause of infantile diarrhea in developing countries and the bacterium most frequently responsible for traveler's diarrhea upon consumption food and water contaminated with of large numbers of cells (10^{8-9}). ETEC colonize the small intestine and produces enterotoxins: heat-labile (LT) or heat stable (ST) or both toxins. The LT is similar to cholera toxin produced by Vibrio cholera; it causes fluid accumulation and watery diarrhea, rice watery diarrhea, and low grad fever.

Enteroaggregative *E. coli* (EAEC)

This group is also known as enteroadherent and can be distinguished from EPEC for the aggregative adherence

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displayed by these strains. EAEC produces an enterotoxin/cytotoxin that can cause a persistent diarrhea that lasts for more than 14 days, especially in children.

Diffuse-adhering *E. coli (DAEC)*

These strains are mainly associated with diarrhea in young children (1-5 years old) that cause diarrhea without blood.

Enterohemorrhagic *E. coli(EHEC)*

Importance of EHEC *E. coli*

The strains in this group (a principal serogroup is O157:H7) was first recognized as a foodborne pathogen in 1982. It is considered as a virulent bacterium since 10-100 cfu in food product sufficient to cause illness. Dairy and beef cattle had been identified as main reservoir that can be shed via feces and the illness are associated with undercooked meat or to post process contamination.

Characteristics EHEC *E. coli*

The principal serotype associated with enterohemorrhagic colitis is *E. Coli* O157:H7. However, other non O157:H7 serotypes have been involved in food outbreaks like O26:H11, O111:H8 and O157:NM. It grows rapidly at 30 to 42°C, but poorly at >44.5°C and does not grow < 10°C. The bacterium is killed by pasteurization process (64.3°C in 9.6 s). Even EHEC strains cannot multiply at pH < 4.5, they can survive in acidic foods like fresh apple cider, fermented foods or mayonnaise. Most of the strains do not ferment sorbitol or produce β glucuronidase.

Sources EHEC *E. coli*

The natural habitat for *E. coli* O157:H7 is the intestinal tract of the dairy cattle. Therefore, it is transferred to food like beef through contact with the intestines of slaughter animals. Apple used for juice from orchards where cattle grazed is also suspected. If employees who are carrier do not wash their hands properly after going to the toilet, they are considered as a source.

Toxins

E. coli O157:H7 is designated as Shiga-like toxin *E. coli* (SLTEC) or Verotoxin producing *E. coli* (VTEC) because they produce a shiga toxin (ST) or verotoxin (VTI), respectively.

Upon their growth of this strain in the human intestine, they produce a large quantity of toxins that cause severe damage to the lining of the intestine (cause bleeding) and other organs of the body. The toxin (cytotoxin) causes breakdown of red blood cells and clotting in small blood vessels of the kidney and brain.

Disease and Symptoms

E. coli O157:H7 causes non bloody diarrhea with severe abdominal cramps that last for 1-2 days upon its colonization of large intestine and appears after 4 days of incubation. About 6% of cases progress to hemorrhagic colitis (HC) that lasts for 4-10 days. Moreover, Hemolytic uremic syndrome (HUS) develops once the toxins reaches the kidney through blood stream causing breakdown of red blood cells, and clotting in small blood vessels of the kidney and occasional associated with kidney failure. Half of the victims require dialysis and or transfusions and it can be fatal (case fatality is about 1%), particularly in children. Finally, Thrombotic thrombocytopenic purpura (TTP) that resembles HUS but is accompanied by blood clots in the brain and seizures and often death can also develop.

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Prevention

The most important safeguard to minimize the outbreaks of E. coli O157:H7 is to cook ground beef and hamburger thoroughly at internal 68.3°C for 1 min. Proper sanitation is essential for the prevention of cross-contamination. The Food Safety Inspection Service (FSIS) in the U.S. has provided the following guidelines to control foodborne illness from this pathogen: use only pasteurized milk; quickly refrigerate or freeze perishable foods; never thaw a food at room temperature or keep a refrigerated food at room temperature over 2 h; wash hands, utensils, and work areas with hot soapy water after contact with raw meat and meat patties; cook meat or patties until the center is gray or brown; and prevent fecal–oral contamination through proper personal hygiene.

Shigellosis

Importance of *Shigella*

Shigellosis is caused by *Shigella* which contains four species: *S. sonnei*, *S. boydii S*, *flexneri*, and *S. dysenteriae*, *Shigella* is one of the most easily transmitted bacteria either directly through fecal–oral routes or indirectly through fecal-contaminated food and water. In general, the most predominant place associated with shigellosis is food service establishments as a result of poor personal hygiene.

Characteristics of *Shigella*

The optimum growth temperature for *Shigella spp.* is 37°C with a range between 10 and 48°C and can be killed by pasteurization temperatures. They can not growth at pH < 4.5 and 5% NaCl.

Source of *Shigella*

The primary reservoir of *Shigella* is the intestine of humans. It can be shed in the feces of infected person without showing any symptoms for several months after recovery period. This bacterium is spread by direct and indirect contact with infected individuals, water that is contaminated by fecal material and food and utensils handled by workers who are carrier of this bacterium (poor personal hygiene). This organism is common in ready to eat (RTE) salads, milk and dairy products, poultry, raw vegetables and any food contaminated by feces that contain the microbe.

Toxins

The shigella cells have the ability to invade epithelial mucosa of the small and large intestines. Once being engulfed by the epithelial cells, shigella cells can produce Shiga exotoxin (ST) with enterotoxigenic characteristics. The infected cells will die and shigella cells will be released and extend the infection to other epithelial cells causing ulcers and lesions.

Disease and Symptoms

Ingestion of contaminated food with 10 -1000 cells is sufficient amount to bloody diarrhea, abdominal pain, fever, chills craps and dehydration within 12 h to 7 days that last for 5 to 6 days.

Prevention

Since the illness is mainly associated with food handlers, proper education of those people about the significance of good personal hygiene is important. In addition, prevent cross-contamination of ready-to-eat food through adaptation of effective sanitary procedure and the use of chlorinated water to wash vegetables to be used for salads.

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Campylobacteriosis

Importance of *Campylobacter*

There are two major species of *Campylobacter* causing food poising; *C. jejuni* causes the majority of Campylobacteriosis (89-93%) where *C. coli* causes the rest. *C. jejuni*. Nowadays, Campylobacter spp. are responsible for human diarrheal disease in many countries and it may exceed the total of shigellosis and salmonellosis.

Characteristics of *Campylobacter*

Campylobacter is micro-aerophilic bacterium that requires 3-6% O_2 and about 10% CO_2 for good growth. It grows from 25-42°C and prefers relatively high temperature (42°C) and pH from 5.5-8. It cannot grow in the presence of 3.5% NaCl. It is heat sensitive; with internal heating of ground beef to 70°C, 10^7 cells/ g cannot be detected after about 10 min. However, they survive well under refrigeration and for months in the frozen state. It is considered as poor competitor.

Source of *Campylobacter*

Campylobacter species are widely distributed in most warm-blooded animals. They are prevalent in food animals such as poultry, cattle, pigs, sheep and ostriches; and in pets, including cats and dogs. *W*ater, sewage, vegetables, and foods of animal origin are easily contaminated with *C. jejuni* excreted through feces. *Campylobacter* is transmitted to humans from animals or animal products especially carcasses or meat are contaminated by *Campylobacter* from feces during slaughtering.

Toxins

The bacteria penetrate the intestinal epithelial of the small and large intestine, multiply within and beneath the cells and cause inflammatory reaction through production of a thermolabile enterotoxin.

Disease and Symptoms

Campylobacteriosis is developed after ingestion of considerably low numbers of cells (~500 cells). The symptoms including profuse diarrhea, abdominal pain, fever and nausea appear after 2 to 5 days.

Prevention

Proper sanitation and the use of chlorinated water during slaughtering can be used effectively for decreasing fecal contamination of carcasses and cross contamination from one carcass to another. In addition, consumers education about the importance of good personal hygiene, cooking food thoroughly and avoiding consumption of raw foods of animal origin are of great importance to decrease the prevalence of Campylobacteriosis.

Listeriosis

Importance of *Listeria monocytogenes*

Listeria species are widespread throughout the environment and can be found in many different food types. Listeria monocytogenes, the causative agent of listeriosis, is considered as emerging since it has been recognized as foodborne pathogen in the early 1980s. L. monocytogenes is of great importance to food industry because of its ability to survive under many stressful environmental conditions and its high mortality rate (30 to 40%) to immunocompromised individuals. L. monocytogenes species is represented by 13 serovars where the epidemiological important serotypes are 1/2a, 1/2b and 4b.

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Characteristics of *Listeria monocytogenes*

L. monocytogenes is psychrotrophic microorganism that grows at temperature between 0 to 45°C and grows best between 30-37°C. The organism can grow at pH values between 4.5- 9.0 and $a_w \geq 0.93$. Although *L. monocytogenes* cells are relatively resistant to high salt, drying, freezing, it is not particularly heat-tolerant and can be killed by pasteurization temperature.

Source of *L. monocytogenes*

L. monocytogenes is everywhere. It has been isolated from decaying vegetation, soil, animal feed, sewage and water. It is most common in raw meats, raw poultry, dairy products, raw vegetables and seafood. Many heat-processed foods such as ready-to-eat meat products and pasteurized milk as well as dairy products may contain *L. monocytogenes*. In addition, a 26% of healthy individuals carry *L. monocytogenes* without showing any symptoms.

Toxin

Hemolysin (listeriolysin O) is a specific virulence factor of *L. monocytogenes* that is produced during the exponential growth phases. *L.monocytogenes* has the ability to invade different body tissues where it can multiply inside and release its toxin. The toxin causes death of the cells.

Disease and Symptoms

Listeriosis is clinically defined when the *L. monocytogenes* is isolated from blood, cerebrospinal fluid or a sterile site such as placenta or fetus. Infection can be symptomless resulting in fecal excretors of infectious *L. monocytogenes.* Usually, symptoms including mild flu-like symptoms with slight fever, abdominal cramps, and diarrhea appear after 1 to 70 days of ingestion of 100 to 1000 cells. When immunocompromised people (Pregnant women, unborn fetuses, infants, elderly people with reduced immunity due to diseases, and people taking special medications, such as steroids and chemotherapeutic agents) become infected with the bacterium, the symptoms get more complicated. It starts with nausea, vomiting, abdominal cramps, and diarrhea, along with fever and headache. Then, the pathogens spread through the bloodstream and invade tissues in different vital organs, including the central nervous system. In pregnant women, the pathogen can invade organ tissues of the fetus through the placenta. Symptoms include bacteremia (septicemia), meningitis, encephalitis, and endocarditis. The fatality rate in fetuses, infected newborn infants, and immunocompromised individuals is very high.

Prevention

Prevention of cross contamination of foods through implementing an effective hazard analysis critical control point (HACCP) system along with a good manufacturing program (GMP) and cooking food thoroughly are considered as effective tools. Another important strategy that has been adopted by the regulatory agencies is the zero-tolerance policy in ready to eat food.

Staphylococcal food poisoning

Importance of *S. aureus*

Staphylococcus aureus is the causative agent of staphylococcal food poisoning and it is considered as one of the most frequently occurring foodborne diseases before 1980s. However, the number of staphylococcal food poisoning outbreaks has declined in the recent years. This is mainly due to improved sanitary practices that minimize contamination with *S. aureus* and better use of refrigerated storage that can control its growth.

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Characteristics of *S. aureus*

S. aureus is mesophilic bacterium with a rapid growth between 20 and 37°C and it can grow over wide range of temperature 7 to 48°C. It can multiply at relatively low a_w (0.86) like in foods containing high concentrations of sugar (60% sucrose) and salt 15%. Additionally, it can grow in low acid foods up to pH 4.2 and also in foods that contain nitrite (NO_2) like cured meats. *S. aureus* is a facultative aerobe that can grow in the absence of oxygen by fermentation or by using an alternative electron acceptor. On the other hand, S. aureus cells are heat sensitive and can be killed at 72°C in 15s or 66°C in 12 min.

Source of *S. aureus*

S. aureus are naturally present in the skin, hair, throat, nose, and skin of healthy humans, animals, and birds. *St. aureus* can be present in burns, infected cuts and wounds of humans.

Toxins and Toxin Production

There are seven different types of staphylococcal enterotoxins (SE) produced by enterotoxigenic strains of *S. aureus* (SEA, SEB, SEC1, SEC2, SEC3, SED, and SEE) where SEA and SED are the most common types involved in food poisoning.

These SE are heat-stable proteins where normal cooking temperature heat stable (80°C for 30 min; 100°C for 5 min) does not destroy toxin potency. Sufficient amount of toxin can be produced when *S. aureus* population reached over a few million cells per gram or milliliter of food within 4 hours. The amount of toxin required to initiate the illness is 1 ng toxin/g of food ingested.

Because of their poor ability to compete with other microorganisms present naturally in foods, most of outbreaks are mainly result from consumption of ready to eat foods.

Disease and Symptoms

Staphylococcal enterotoxins cause mainly gastroenteritis. Severe nausea and vomiting, abdominal pain and diarrhea are the main symptoms that appear within 1 to 6 hours after consuming contaminated food and can persist for 1-2 days. Some secondary symptoms are dehydration, headache, chills and sweating also may appears. However, the severity of symptoms may vary among individuals in an outbreak.

Prevention

The prevention methods of Staphylococcal enterotoxication include:

- Ensure that raw materials used for the production of high risk foods are kept refrigerated before use.
- Ensure that high risk foods are kept rapidly cooled below 5°C after cooking if not consumed.
- Cover cuts or wounds with waterproof dressings.

Botulism

Importance of *Cl. botulinum*

Foodborne botulism result from the ability of *Clostridium botulinum* to produce a potent neurotoxin that initiates neurological symptoms with high mortality rate (ca. 10%) unless rapid treatment is administered. Moreover, infant botulism occurs when an infant less than one year old consumes ingests food contaminated mainly honey with

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Cl. botulinum spores that germinate and produce toxins in his/her gastrointestinal. Intoxication with *Cl. botulinum* is mainly associated with consumption of low acid foods (i.e. Canned green beans, Corn, Spinach, Pepper and Mushroom and home canned food) that are inadequately heat processed and then packaged anaerobically (metal can) and held in the food temperature zone.

Characteristics of *Cl. botulinum*

Cl. botulinum cells obligate anaerobes that can not grow at low a_w (0.93), relatively high salt (5.5%) and low pH (<4.6). Vegetative cells are heat sensitive that can be killed at moderate heat (pasteurization) while the *s*pores are highly heat resistant (killed at 115°C). The spores cannot germinate in food containing 250 ppm nitrite.

Source of *Cl. botulinum*

Cl. botulinum is ubiquitous microbe that is widely distributed in the nature. The spores can exist in intestinal contents of animals, sewage, soil, mud, fresh water and marine sediments.

Toxins and Toxin Production

Based on the serological specificity, seven types of the botulinum toxin are recognized: A, B, C, D, E, F and G. Types A, B, E, F and G cause disease to humans that are extremely potent, and only a small amount of toxin is required to produce the symptoms and cause death. These toxins can be produced by either proteolytic (active form) or non-proteolytic strains (not fully activated; trypsin treatment is necessary to activate them). All toxin-producing strains have been placed in one of four groups: I, II, III, IV. Table 3.1 summarizes their production requirements.

Group	Toxin	Protolytic	Lipolytic	Minimum growth temp. (°C)	Salt concentration inhibition (%)
I	A,B,F	+	+	10-12	10
II	D, E, F	-	+	3.3	5
III	C, D	+ or -	+	15	3
IV	G	+	-	12	>3

Table 3.1: Growth requirements of proteolytic and non proteolytic toxin production.

Disease and Symptoms

Botulism is caused following ingestion of the preformed neurotoxin botulin in food. It is absorbed at the upper portion of the intestine and reaches the peripheral nerves through blood stream. The toxins cause paralysis of all involuntary through blocking signal transfers. During the first 12 to 36 hour of ingestion the toxin, some gastrointestinal disorders like vomiting, nausea, diarrhea, and constipation may appear. Neurological symptoms include; dizziness, double vision, dryness of the mouth, difficulty in breathing, swelling and speaking, paralysis of different inventory muscles and then death. Usually, 1 ng/kg body weight of the toxin is required to develop illness.

Prevention

The use of proper temperature and time in home canning of low-acid products is the most important control method. For commercial processors apply 12 D concept to ensure that low acid foods receive a botulism cook (10^{12} spores/g). For canned meat product the addition of nitrite will minimize the risk of *Cl. botulinum*. To avoid infant botulism, it is recommended not to feed infant with honey or raw herbs.

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Clostridium perfringens

Importance

Gastroenteritis (Toxicoinfections) caused by *Cl. perfringens* results from its ability to produce certain exotoxins. The outbreak is mainly associated with foods cooked in advance and then kept at food danger zone for several hours before serving.

Characteristics

Cl. perfringens is anaerobic bacterium that can tolerate the presence of some oxygen in its growth environment. Even *Cl. perfringens* spores can survive boiling temperatures for several hours, the vegetative cells are heat sensitive that can be inactivated by low-heat treatment such as pasteurization. Rapid growth rate of *Cl. perfringens* cells occur at ~ 45°C while the spores germinate and outgrowth at temperature between 10 and 52°C. The cells grow well at a_w, > 0.93 and pH > 5.0.

Sources

Spores and vegetative cells are found in intestinal contents of humans (Human feces contain 10^3-10^6 spores/ g of feces), animals and birds, dust, soil; and sewage. Many foods contain spores of the organism particularly animal carcasses that become contaminated during slaughter.

Toxins and Toxin Production

The *Cl. perfringens* enterotoxin, produced in the digestive tract, is associated with sporulation in the intestine accompanied by the production of intracellular enterotoxin (Spore-specific protein). Five types are recognized: Types A, B, C, D, and E. The vast majority of food poisoning outbreaks. The toxin binds and affects the villus tip cells of the small intestine resulting in a disruption of the ability to maintain membrane ionic balance and initiation of diarrhea symptoms.

Disease and Symptoms

The enterotoxin causes only gastroenteritis: diarrhea, severe abdominal pain. However, vomiting and fever are not typical symptoms. The symptoms usually appear after 8 to 24 of ingestion of a large amounts of vegetative cells (10^5/g) and last for 12-24 h.

Prevention

The main strategy of preventing outbreaks associated with *Cl. perfringens* is to keep the cell numbers below the infection dose. This can be achieved by avoiding keeping food in the food danger zone through rapid cooling of cooked food to refrigerated temperature (< 4°C) with 1-2 hours or and keeping hot meals at temperature > 60°C.

Vibrio Spp.

The most important four species from the genus *Vibrio* that have been implicated in foodborne illnesses are:

- *V. parahaemolyticus.*
- *V. cholerae (01 and non 01 serotype).*
- *V. vulnificus.*
- *V. mimicus.*

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Vibrio Parahaemolyticus G gastroenteritis

Importance of *V. parahaemolyticus*

Gastroenteritis caused by *V. parahaemolyticus* is the leading cause of foodborne illness in Japan that accounts for 40 to 70% of the total outbreaks. The high incidence is directly related to the consumption of raw seafoods.

Characteristics

The optimum growth temperature of *V. parahaemolyticus* is 30 to 37°C, but it still can multiply at a wide range of temperature (5 to 42°C). The cells multiply rapidly in the presence of 3-5% NaCl (Halophilic), but their growth will be inhibited 10% salt. The cells grow well at pH > 5.0 and can be inactivated by pasteurization.

Sources

V. parahaemolyticus is found in oceanic and coastal waters (Pollution of estuaries), and it is found in the intestinal contents of marine animals. Its numbers are higher in summer months when water heats up (> 15°C), seasonality. The organism is usually less than 10^3 cfu/g on fish and shellfish where in warm waters the count may increase to 10^6 cfu/g.

Toxin and toxin production

Not all strains of *V. parahaemolyticus* are pathogenic, but Kanagawa positive are considered as foodborne pathogen. They produce thermostable direct hemolysin toxin that cause hemolysis.

Disease and symptoms

Gastroenteritis syndrome consists of diarrhea, cramps, weakness, nausea, chills, headaches, vomiting and fever are results from the consumption of contaminated food with 10^5-10^7 CFU/g.

Prevention

Gastroenteritis associated with *V. parahaemolyticus* can be controlled through following:

- Ice or refrigerate fish immediately after harvesting and keep at low temperatures until consumed.
- Avoid eating raw fish and raw shellfish.
- Since the organism is very sensitive to heat, cook fish to internal temperature > 65°C.
- Prevent cross contamination from raw fish to cooked fish.

Vibrio cholerae

Importance of *V. cholerae*

V. cholerae serovar 01 is the organism that causes *cholerae* which is a waterborne disease. It is a noncontagious disease but can cause large epidemics with high mortality.

Characteristics of *V. cholerae*

V. cholerae are heat sensitive that can be eliminated by proper cooking temperatures (> 70°C). The optimum growth temperature is 30-35°C over a range of 8-42°C. The cells do not multiply in well in live oysters, live crabs, or fish, but in cooked seafoods, rapid growth can occur at 25 to 35°C and can survive at 5 to 10°C in cooked foods. *V. cholerae* grow at pH 6-9.6.

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Sources

Cholera is a human disease. The disease results from the ingestion of infective doses of *V. cholerae* cells through food and water contaminated with feces of humans suffering from the disease. It can be spread by foods contaminated with sewage, washed with contaminated water or by direct fecal contact from food handlers.

Toxins and toxin production

V. cholerae 01 and non-01 serotypes are involved in cholera cases. Infection of *V. cholera* begins with the ingestion of food or water contaminated with the pathogen. After colonization the small intestine, the organism produces cholera toxin (CT) that causes massive secretion of water along with chloride and potassium in the lining of the intestine.

Disease and symptoms

V. cholerae is not contagious and a person must ingest 10^6 viable cells through contaminated water or food in order to initiate the illness. The symptoms include the sudden onset of vomiting and profuse watery diarrhea that leads to dehydration. The main symptoms of 01 toxin are watery diarrhea and vomiting, painful muscle cramps, renal shut down while non 01 toxin are diarrhea and septicemia. Death especially among children and the elderly results from the loss of water up to 1L / hr. Consequently, oral rehydration salts is necessary.

Prevention

Cholera can be controlled through the followings:

- Use treated municipal water.
- Seafood should not be harvested from polluted water nor from water found to harbor *V. cholerae.*
- Sea food should not be eaten raw or undercooked.

Bacillus Cereus gastroenteritis

Importance

In some European countries, the incidence of foodborne gastroenteritis by *B. Cereus* is relatively higher than U.S. It has the ability to form heat resistant endospores and capacity to cause two different types of illness: One vomiting, the other diarrheal form.

Characteristics

B. Cereus is a spore forming bacterium that forms endospores in the middle of the cells. The vegetative cells grow at a range of temperature of 4-50°C, with the optimum at 35 to 40°C, pH 4.9 to 9.3 and $a_w > 0.95$. Even though the spores are heat resistance, the vegetative cells are killed by pasteurization.

Sources

B. Cereus vegetative cells and spores are common in soil and dust and can be readily isolated in small numbers in foods including fresh and processed foods.

Toxins and toxin production

B. Cereus produces two different types of enterotoxins 1) Emetic (Vomiting) form that is produced in the food and 2) Diarrheal form that is produced in the intestinal tract of infected person.

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Disease and symptoms

Emetic syndrome

This form of *B. Cereus* food poisoning is more severe and acute than the diarrheal syndrome. The Symptoms usually appear after 1-6 hour of consumption of food containing the preformed enterotoxin. The symptoms resemble *S. Aureus* food poisoning in its symptoms and incubation period that include nausea, vomiting and abdominal cramps that usually last from 6 to 24 hours after onset. The emetic form is most often associated with fried and cooked rice, pasta and noodles. The disease is often associated with Chinese restaurants. The disease is diagnosed by the isolation of *B. Cereus* from the incriminated food.

Diarrheal form

This form of food poisoning develops within 8-16 hours of ingestion of contaminated food with > $5x10^5$-$9.5x10^8$ cells/g. The symptoms resemble more food poisoning caused by *Cl. Perfringens* that include abdominal cramps and watery diarrhea and usually the illness lasts from 6 to 12 hours after onset. In a few patients, symptoms may last longer. Diarrheal form of food poisoning is frequently associated with meat, vegetable, cereal products containing corn and corn starch after cooking. The diarrheal form is diagnosed by isolation of the organism from stool and food. Isolation from stools alone is not sufficient because 14% of healthy adults have been reported to have transient gastrointestinal colonization with *B. Cereus.*

Prevention

Most outbreaks of *B. Cereus* food poisoning are associated with temperature abuse. Therefore, the most important control measure is to avoid keeping food at food danger zone (5 - 60°C) in order to prevent *B. cereus* spore germination. This can be achieved by uniform quick chilling of the food to < 5°C or holding the food above 60°C.

ENTERIC VIRUSES

Worldwide, viruses are increasingly recognized as a major cause of foodborne outbreak. Several types of viruses exist in the human gut, but few of them has been recognized as important foodborne pathogens. These can be classified into three main groups, according to the type of illness they cause:

1. Viruses that cause gastroenteritis.
2. Enterically transmitted hepatitis viruses.
3. Viruses that replicate in the human intestine but cause illness after they migrate to other organs, such as the central nervous system or the liver.

Unlike bacterial foodborne pathogens, a potentially hazardous food is not needed to support survival of viruses since they do not multiply in food systems. Foodborne viruses typically are quite stable outside the host and are acid-resistant. Also, they are difficult to detect and recover from a contaminated food. However, there are some important differences between viral and bacterial infections:

1. Few particles of viruses are needed to cause illness.
2. High numbers of viral particles are shed in the stools from infected persons (Up to 10^{11} particles per gram stool).
3. Viruses need specific living cells in order to multiply and causes illness.

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In general, foods can be contaminated by through the following roots:

1. Contact with (human) faeces or faecally contaminated water.
2. Contact with faecally soiled materials (including hands).
3. Contact with vomit or water contaminated with vomit.
4. Contact with environments in which infected people were present, even if the surface was not directly contaminated with stool or vomit, and.
5. Aerosols generated by infected people.

Hepatitis A Virus (HAV)

HAV causes a liver disease called hepatitis. The prevalence of HAV is higher in developing countries than developed ones. The liver is the main site of replication and the only tissue known to be damaged by the infection. The virus is released in the bile and eliminated with the feces. One of the major challenges to food industry related to HAV is its long incubation period (10-50 days). The greatest danger of spreading the disease to others occurs during the middle of the incubation period before the presentation of the symptoms. The symptoms of hepatitis A are fever, nausea, vomiting, abdominal pain, loss of appetite, dark urine, light colored stool, swelling of the liver and jaundice. These symptoms may last up to 6 months before recovery noted. Patients suffer from feeling chronically tired during recovery and their inability to work can cause financial loss and approximately 15% of patients require hospitalization. The most common foods associated with HAV are sandwiches, fruits, and fruit juices, milk, and milk products, vegetables, salads ice drink and shellfish and water.

Norwalk virus

Norwalk virus causes viral gastroenteritis that is responsible for almost half the cases of viral gastroenteritis in USA. It is mainly associated with water from municipal supplies, well, recreational lakes, swimming pools, shellfish, and salad ingredients. The virus invades and damages the gastrointestinal tract result in mucosal lesions of the small intestinal tract, which cause nausea, vomiting, diarrhea, abdominal pain, headache, fever, chills and weakness. Usually the symptoms develop after after 24-48h of eating contaminated food or water.

PARASITES

Parasites may be present in food or in water and can be identified as causes of foodborne or waterborne illness in many countries. Parasites can be transmitted by food including many protozoa and helminths. The most common foodborne parasites are protozoa such as *Toxoplasma gondii*, *Giardia intestinalis, Cryptosporidium* spp, and *Cyclospora cayetanensis*, roundworms such as *Trichinella spp,* and *Anisakis* spp, and tapeworms such as *Diphyllobothrium* spp, and *Taenia* spp. They can be transmitted by water, soil, or person-to-person contact.

Toxoplasmosis

Toxoplasma gondii is the causative agent of Toxoplasmosis. The primary hosts are cats and human infection takes place when contact is made with their feces. It can be transmitted to human by consumption of raw or undercooked meat from middle hosts as swine, cattle, goats, chicken or brides raw milk contaminated with oocysts. In many people, it does not cause any problems. Toxoplasmosis symptoms generally include; flu-like, with fever and headache. Transplacental infection can result in fetal death if it occurs in early stages of pregnancy and it causes hydrocephalus and blindness in children.

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Preventative measures include proper cooking of meat to a minimal internal temperature of 70°C or freezing at –20°C and avoid eating food potentially contaminated with oocysts from cat feces.

Anisakiasis

Anisakis simplex is a nematode that causes Anisakiasis. It is mainly associated with ingestion of raw or undercooked, brined, or smoked fish containing larval stage of the nematodes Anisakis simplex. The primary hosts are warm-blooded marine mammals such as seals, and dolphin. Fertilized eggs from the female parasite pass out of the host with the host's feces. In seawater, the eggs develop into larvae that hatch in seawater. The larvae grow and become infective for the next host, a fish. The larvae may penetrate through the digestive tract into the muscle of the second host. Some evidence exists that the nematode larvae move from the viscera to the flesh if the fish hosts are not gutted promptly after catching. Usually, symptoms appear as little as an hour to about 2 weeks after consumption of contaminated food that involves tickling sensation in the throat and coughs. In more severe cases, there is acute abdominal pain, much like acute appendicitis accompanied by a nauseous. Preventive measures include; proper cooking, salting, or freezing at-20°C for 3 days.

Trichinosis

Trichinella spiralis is a roundworm that causes Trichinosis. It is mainly associated with the ingestion of contaminated raw or insufficiently cooked pork originated from pigs feeding garbage. The infected meat contains encysted larvae. Upon consumption of the meat, the cysts dissolve in the intestine, releasing the larvae, which then infect the GI tract epithelium. Here, the parasites mate and deposit larvae in the lymphatic system. Through lymphatic circulation, the larvae infect other body tissues. Initial symptoms are gastroenteritis and it may develop to irregular fever (39-41°C), muscle pain, difficulty in breathing talking or moving. The larva can be killed by a number of methods: heating to 65.5°C, freezing at -15°C for 3 weeks or at -30°C for 1 day.

Giardiasis

Giardia lamblia causes Giardiasis. It is a water and foodborne disease with higher incidence in countries with inadequate sanitation facilities and improper water supplies. The major causes of the disease are consumption of contaminated raw vegetables and foods such as salad, sandwiches with water containing the causative agent (oocysts) and poor personal hygiene. The main symptoms are abdominal pain and acute or chronic diarrhea. Proper sanitary conditions and personal hygiene are important preventative procedures.

Cryptosporidiosis

Cryptosporidium parvum is an intestinal protozoan and causes cryptosporidiosis. It is mainly associated with consumption of contaminated water and food with the oocysts. The reservoirs are human and domestic animals like cattle. The oocysts can survive in the environment for long periods of time. They are capable of resisting chemicals used to purify drinking water. The major symptoms of infection in humans are fever, diarrhea, abdominal pain and anorexia. The disease subsides in less than 30 days but may cause death to immunocompromised people.

Cyclosporiasis

Cyclospora cayetanensis is a coccidian intestinal protozoan and is considered a newly emerging foodborne pathogen. It is found mainly in tropical water and causes watery diarrhea explosive bowel movements, loss of appetite, vomiting, nausea, fatigue and substantial weight loss. It has been linked to the consumption of raspberries, lettuce, and fresh basil which are contaminated with oocysts. The agent can be shed in the feces for more than 3 weeks.

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Chapter 4

FOOD CHEMICAL HAZARDS

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Chapter Objectives

- Overview the most relevant risks associated to naturally present or added chemical compounds in food ingredients and formulated food products with a potential impact on health and safety
- List the process conditions able to trigger reactions with formation of products with potential safety risk

Introduction

Food products can become contaminated with chemical hazards that are introduced at any stage in food production and processing. Some ingredient-related chemical hazards are natural components of food, such as food allergens, or are produced in the natural environment, such as mycotoxins, whereas other ingredient-related hazards (e.g., pesticides, drug residues, heavy metals, environmental contaminants) are contaminants of raw materials and other ingredients. Some process-related chemical hazards may be included in product formulation (e.g., sulfites that are a hazard for those consumers who are sensitive to them), whereas other process-related chemical hazards may be unintentionally introduced into food, such as industrial chemicals that are used in a facility for purposes other than food production. Process contaminants may also form during heating (e.g., acrylamide).

General Side Effects

A chemical hazard may cause immediate effects, or may be associated with potential long-term effects after chronic exposure to the chemical. One example of an immediate effect is gastrointestinal illness such as nausea, which can be caused by elevated levels of industrial chemicals (such as caustic cleaning compounds). Caustic cleaning compounds can also cause burning of the mouth and esophagus. Ammonia in food contaminated by a refrigerant leak has caused gastrointestinal illness (stomachache and nausea) and headaches. Sulfites have resulted in diarrhea, headache, breathing difficulty, vomiting,

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nausea, abdominal pain and cramps in sulfite-sensitive individuals. Examples of long-term effects include impaired cognitive development in children chronically exposed to relatively low levels of lead (e.g., in contaminated candy) and liver cancer resulting from chronic exposure to the mycotoxin and aflatoxin.

FDA has set action levels and tolerances for some contaminants (FDA, 2015f). FDA also has issued guidance to provide information to industry on methods to reduce levels of specific chemicals in foods. For example, FDA has issued guidance providing information to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods (FDA, 2016a). Similarly, the Codex Alimentarius Commission has established a number of codes of practice for controlling mycotoxins, heavy metals, and other chemicals in foods (CAC, 2012).

Chemical residues in a food are not always considered hazards and their occurrence may be unavoidable. Because the particular chemical and its levels in the food determine whether it is a hazard, and because mechanisms whereby a chemical hazard can be introduced into a food product are both varied and dependent on the nature of the chemical, the preventive controls that you identify and implement to control specific chemical hazards should be based on the characteristics of those chemicals and the mechanisms whereby they could be introduced into your food product.

Chemicals can be helpful and are purposefully used with some foods, such as pesticides on fruits and vegetables. Chemicals are not hazardous if properly used or controlled. Potential risks to consumers increase when chemicals are not controlled or the recommended treatment rates are exceeded. The presence of a chemical may not always represent a hazard. The amount of the chemical may determine whether it is a hazard or not. Some may require exposure over prolonged periods to have a toxic effect. Regulatory limits are set for some of those contaminants.

Source	**Example**
Ingredient-related chemical hazards	• Pesticide residues on produce raw agricultural commodities • Drug residues in milk • Heavy metals in or on produce raw agricultural commodities • Environmental contaminants (e.g., Dioxins) • Mycotoxins in grains • Histamine in some aged cheeses • Radiological hazards in foods from areas after a nuclear accident • Unapproved food or color additives • Food allergens and substances associated with a food intolerance or food disorder (e.g., sulfites, gluten)
Source	**Examples**
Process-related chemical hazards	• Undeclared food allergens due to mislabeling or cross-contact • Improper addition of substances associated with a food intolerance (e.g., Sulfites) • Improper use of a color additive such as Yellow No. 5 • Contamination with industrial chemicals such as cleaners or sanitizers • Radiological hazards from use of contaminated water supply
Facility-related chemical hazards	• Heavy metals due to leaching from equipment, containers, or utensils

Table 1: Shows a guide of common sources of chemical hazards.

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INGREDIENT-RELATED CHEMICAL HAZARDS

Pesticides

Pesticide residues may be of concern in food crops and in foods of animal origin (as a result of pesticide residues in animal food). The term pesticide is used for products such as insecticides, fungicides, rodenticides, insect repellents, herbicides or weed killers, and some antimicrobials that are designed to prevent, destroy, repel, or reduce all types of pests. Three federal government agencies in the U.S. share responsibility for the regulation of pesticides. Pesticides that have been registered (i.e., approved) with the U.S. Environmental Protection Agency (EPA) may be applied according to label directions directly to raw agricultural commodities or food. The most common reasons for adulteration of food products with pesticide residues are the improper treatment of raw materials with registered pesticides, and raw materials being exposed to prohibited pesticides.

Fruits and vegetables that have been grown in the United States usually are in compliance with EPA's pesticide tolerance regulations. If you obtain produce from a foreign country you should take steps to ensure that the imported produce will be in compliance with U.S. pesticide tolerance regulations, such as by considering pesticide residues to be chemical hazards that warrant preventive controls, such as supply-chain controls with a supplier verification program.

Animal drug residues

Animal drug residues may be of concern for foods of animal origin, including muscle meat, organ meat, fat/skin, eggs, honey, and milk. In the United States, animal drugs require approval by FDA before they can be administered to food-producing animals. Depending on the chemical property of the drug, residues of certain drugs can become concentrated during food manufacturing and processing. For example, if a fat-soluble, heat-stable drug residue is present in raw milk, the drug can get concentrated when the milk is converted to full fat cheese. Potential effects of drug residues range from short-term effects as a result of acute allergic reactions (e.g., penicillin) to long-term effects from drug resistant bacteria. An example of an unapproved drug residue that has adulterated food is fluoroquinolone, which is an antibiotic that has not been approved for use on honey bees in the United States and has been detected in honey products from certain regions outside the United States.

Drug residues in a food derived from an animal (such as milk) are considered a hazard if a tolerance has not been established for the particular drug-food combination, or if the tolerance level has been exceeded. Animal drugs used according to labelled directions should not result in residues in meat, poultry, milk, or egg products. When your hazard analysis identifies drug residues that require a preventive control, supply-chain controls with a supplier verification program could be an appropriate preventive control to manage the potential risk.

Heavy metals

Heavy metals, including lead, cadmium, arsenic, and mercury, may be of concern in certain foods as a result of agricultural practices (e.g., use of pesticides containing heavy metals or because crops are grown in soil containing elevated levels of heavy metals due to industrial waste), or the leaching of heavy metals from equipment, containers or utensils that come in contact with foods. Consumption of heavy metals in foods can lead to adverse health consequences. For example, lead exposure can impair cognitive development in children. Consumption of inorganic arsenic has been associated with cancer, skin lesions, developmental effects, cardiovascular disease, neurotoxicity, and diabetes in humans.

When your hazard analysis identifies a heavy metal that requires a preventive control, the type of control would depend on how the heavy metal could get into your food product. In some cases, high levels of heavy metals may

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result from the environment (e.g., high lead levels in carrots that were grown in lead-contaminated soil). If your food product contains a food crop that is known to have been contaminated with a heavy metal through contaminated soil, a preventive control such as a supply-chain control with a verification program to ensure that the grower conducts an assessment of the growing region prior to its use for agriculture may be appropriate. In other cases, an unsafe level of a heavy metal such as lead could be introduced into a food product as a result of a food-contact surface constructed with lead solder. In such cases, chemical hazards such as heavy metals that can leach from food-contact surfaces must be controlled.

Environmental contaminants

Environmental contaminants may be of concern in certain foods as a result of their presence in the environment. When your hazard analysis identifies an environmental contaminant that requires a preventive control, the type of control would depend on how the environmental contaminant could get into your food product. In some cases, high levels of environmental contaminants (e.g., dioxin) may result from accidental contamination of animal feed. In 1999, high levels of dioxins were found in poultry and eggs from Belgium and in several other countries. The cause was traced to animal feed contaminated with illegally disposed PCB-based waste industrial oil. Because dioxins tend to accumulate in the fat of food-producing animals, consumption of animal-derived foods (e.g., meat, poultry, eggs, fish, and dairy products) is considered to be the major route of human exposure, and FDA has developed a strategy for monitoring, method development, and reducing human exposure.

Mycotoxins and other natural toxins

Natural toxins, such as mycotoxins, histamines and other biogenic amines, and plant-produced substances (such as the toxin hypoglycin A found in the tropical fruit ackee) are well recognized as hazards in raw or processed agricultural commodities.

Mycotoxins are a common group of natural toxins that include aflatoxin, fumonisin, deoxynivalenol (vomitoxin), ochratoxin, and patulin. Mycotoxins are toxic metabolites produced by certain fungi (i.e., molds) that can infect and proliferate on agricultural commodities (e.g., grains such as wheat and corn, peanuts, fruits, and tree nuts) in the field and during storage. Mycotoxins may produce various toxicological effects. Some mycotoxins are teratogenic, mutagenic, or carcinogenic in susceptible animal species and are associated with various diseases in domestic animals, livestock, and humans in many parts of the world. The occurrence of mycotoxins in human and animal foods is not entirely avoidable; small amounts of these toxins may be found on agricultural commodities. Occurrence of these toxins on commodities susceptible to mold infestation is influenced by environmental factors such as temperature, humidity, and the extent of rainfall during the pre-harvesting, harvesting, and post-harvesting periods. The molds that produce mycotoxins typically grow and become established in the agricultural commodity during stressful growing and holding conditions, such as insect damage to the crop, drought stress, and wet storage (e.g., from condensation). Although mycotoxins are not a hazard requiring a preventive control during times and locations with good growing and harvest conditions, a preventive control such as supply-chain controls with a supplier verification program may be appropriate if you use agricultural commodities susceptible to mycotoxin formation, because growing and harvest conditions varied from year to year.

Histamines and other biogenic amines are produced from the breakdown of amino acids by bacteria in animal-derived foods (e.g., histamine is produced from the amino acid histidine). Effects of foodborne histamines or other biogenic amines generally are acute effects, including headache, nausea, heart palpitations, facial flushing, itching, urticaria (hives), and gastrointestinal upset. Consumption of certain cheeses, especially aged cheeses, has been associated with illness from histamines. If you determine that cheeses you use as a raw material present a histamine hazard, you must identify and implement a preventive control. If you purchase such cheeses, we recommend a

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supply-chain control with a supplier verification program as well as temperature controls to minimize growth of histamine-producing microorganisms.

An example of a natural toxin produced by a plant is hypoglycin A, a heat stable toxin found in the tropical fruit ackee. The level of hypoglycin A in the edible portion of the ackee fruit decreases as the fruit ripens. Only properly ripened and processed ackee products with hypoglycin A at negligible levels are safe for consumption (FDA, 2015f). Although some persons consume unripe ackee with no adverse effects, other persons who consume unripe ackee with hypoglycin A exhibits symptoms that range from mild (e.g., vomiting) to severe (e.g., vomiting with profound hypoglycemia, drowsiness, muscular exhaustion, and possibly coma and death).

CHEMICAL HAZARDS THAT CAN BE EITHER INGREDIENT-RELATED OR PROCESS-RELATED

Food Allergens

Researchers estimate that up to 15 million Americans and more than 17 million Europeans have food allergies. A number of foods contain allergenic proteins, which are natural constituents of the food that can pose a health risk to certain sensitive individuals. The symptoms of food allergies can include a tingling sensation in the mouth, swelling of the tongue and throat, nausea, difficulty in breathing, chest pain, hives, rash, itchy skin, vomiting, abdominal cramps, diarrhea, sudden drop in blood pressure, loss of consciousness, and, in severe cases, death. Symptoms of a food allergy usually come on suddenly, can be triggered by a small amount of food, and happen every time the food is eaten. The symptoms are the result of the body's immune system reacting to a specific food or an ingredient in the food.

Allergic consumers must avoid allergens to prevent potentially life threatening reactions. Undeclared food allergens are chemical hazards that can get into food because either: **(1)** The food manufacturer did not properly declare a food allergen ingredient on the product label; or **(2)** unintended (and, thus, undeclared) food allergens are present in a food due to incorrect labeling or due to allergen cross-contact.

The "Big Eight" Food Allergens

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 amended the FD&C Act and defined the following eight foods and any ingredients that contain protein derived from these eight foods as major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. The eight foods or food groups cause more than 90% of the food allergies in the United States and are commonly referred to as "the big eight" food allergens.

Undeclared Food Allergen Hazards Due to Incorrect Label Design

FALCPA also amended section 403 of the FD&C Act (21 U.S.C. 343) to prescribe certain requirements for what you must declare on the product label for any food product that contains any of the "big eight allergens," including allergenic whole foods (such as milk) and any ingredients that contain protein derived from these foods (such as casein derived from milk). See section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (FDA, 2006b).

An undeclared food allergen (including a food allergen contained in flavorings, colorings, and incidental additives) due to an incorrect label design that does not address all of the labeling requirements of FALCPA is a chemical hazard.

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Undeclared Food Allergen Hazards Due to Incorrect Application or Use of a Product Label

If you apply the wrong label to a food, or use the wrong packaging (e.g., using packaging for "chocolate ice cream" rather than for "chocolate ice cream with almonds"), consumers who have a food allergy could purchase a food that would cause an allergic reaction. An undeclared food allergen due to applying the incorrect food label to a product, or using the wrong packaging, is a chemical hazard.

Undeclared Food Allergen Hazards Due to Allergen Cross-Contact

Cross-contact results from the unintentional incorporation of undeclared allergens into foods that are not intended to include those allergens. Cross-contact can occur either between foods that contain different food allergens or between foods with and without food allergens. Introduction of an allergen through cross-contact may occur during receiving, handling, processing and cleaning of equipment, utensils, and facilities; and through improper facility design.

An undeclared food allergen due to allergen cross-contact is a chemical hazard.

Allergen cross-contact can result from:

- Failure to schedule the production of two different products appropriately, resulting in an allergen-containing product contaminating a product without food allergens.
- Failure to adequately clean between two different formulations of a product that do and do not contain allergens, resulting in an allergen-containing product contaminating a product without the allergen.
- Failure to store allergen-containing ingredients separately from ingredients that do not contain allergens, where leakage of allergen-containing materials results in contamination of the non-allergen containing product.
- Failure to handle powdered allergens in a way that prevents particles from blowing onto foods or food contact surfaces for foods that do not contain that allergen.

Food additives, color additives, and GRAS substances

A substance that is added to food requires premarket review and approval as a food additive unless it satisfies the statutory exclusion from the definition of "food additive" for a substance that is generally recognized as safe (GRAS) under the conditions of its intended use or is otherwise excepted from the statutory definition of food additive (e.g., as a color additive, as a dietary ingredient intended for use in a dietary supplement, or as a new animal drug), a color additive requires premarket review and approval; there is no statutory GRAS exclusion applicable to a color additive.

Generally, a food additive, color additive, or GRAS substance is known to be safe for use in food only under specific conditions of use, such as a maximum level of use or use only in certain food categories. The potential risk to consumers increases when these substances are not properly controlled, such as exceeding the usage rates or accidentally introducing an additive into a food for which it was not approved.

For some consumers, certain substances (including substances that are lawfully used in food as food additives, color additives, GRAS substances, and components of whole foods such as milk) can cause hypersensitivity reactions because the substance irritates the stomach, or the body cannot properly digest it. The symptoms include nausea, abdominal pain, diarrhea, vomiting, gas, cramps or bloating, heartburn, headaches, irritability, or nervousness. Symptoms of food intolerance usually occur gradually, in comparison with the sudden onset from an allergic reaction, and may only occur when a lot of a food is consumed or the food is consumed often such as:

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- **Lactose:** Some people are intolerant to lactose, a sugar that is a component of milk, because they lack the enzyme to digest lactose. The symptoms include abdominal pain, diarrhea, vomiting, gas, cramps or bloating. People who have a lactose intolerance avoid milk or milk products and rely on the allergen labeling for milk to identify the types of products that may cause them problems.
- **Sulfiting agents:** Sulfiting agents are used as chemical preservatives in various products. People sensitive to sulfiting agents can experience symptoms that range from mild to life-threatening reactions. As noted previously, sulfites have resulted in diarrhea, headache, difficulty breathing, vomiting, nausea, abdominal pain and cramps in sulfite-sensitive individuals. The sulfiting agents permitted in foods that must be listed on the ingredient label, unless they are added to food as an "incidental substance," are: sulfur dioxide, sodium sulfite, sodium bisulfate,sodium metabisulfite, potassium bisulfite and potassium metabisulfite. Sulfiting agents are considered to be incidental only if they have no technical effect in the finished food and are present at less than 10 parts per million (ppm). The quantity of sulfiting agents added to food should not exceed the amount necessary to achieve the intended technical effect(s).
- **Yellow No. 5:** Yellow No. 5 (tartrazine) is a color additive subject to color certification under section 721(c) of the FD&C Act. (21 U.S.C. 379e) People sensitive to Yellow No. 5 can experience symptoms that range from mild to moderately severe. For example hives occur in some intolerant individuals, but in asthmatic individuals Yellow No.5 can trigger allergic-type reactions (including bronchial asthma). To help protect people who are sensitive to Yellow No. 5, FDA's regulation for Yellow No. 5 states that any food for human use that contains Yellow No. 5 must specifically declare the presence of the color additive by listing it as an ingredient (21 CFR 74.705(d)(2)). If Yellow No. 5 is added but is not declared, the product would be both misbranded under section 403(m) of the FD&C Act (21 U.S.C. 343(m) and adulterated under section 402(c) of the FD&C Act (21 U.S.C 342(c)).
- **Cochineal extract and carmine:** Cochineal extract and carmine are color additives permitted for use in foods in the United States under conditions of safe use listed in 21 CFR 73.100. For sensitive consumers, cochineal extract and carmine can cause severe allergic reactions, including anaphylaxis. Although the color additives cochineal extract and carmine cause allergic reactions, they are not included in the eight major food allergens identified in FALCPA. As a result, the color additives cochineal extract and carmine are not included in the definition of "food allergen" in part 117 and are not subject to the food allergen controls specified in the PCHF requirements. In addition, FDA's specific labeling requirement in the color additive listing for cochineal extract and carmine, rather than the more general labeling requirements of FALCPA, govern the food labeling requirements cochineal extract and carmine. All human foods containing cochineal extract or carmine are required to declare the presence of the color additive by listing its respective common or usual name, "cochineal extract" or "carmine," in the statement of ingredients. Additional information on the labeling requirements for these two color additives can be found in FDA industry guidance, Cochineal Extract and Carmine: *Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives; Small Entity Compliance Guide* (FDA, 2009a). Control strategies for cochineal extract and carmine are similar to those applied to food allergen labeling controls.
- **Gluten:** In addition, some consumers have celiac disease, which is a hereditary, chronic inflammatory disorder of the small intestine triggered by the ingestion of certain storage proteins (referred to as gluten) occurring in wheat, rye, barley, and crossbreeds of these grains.

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Unapproved food additives and color additives

A substance that is a food additive or a color additive must be used in accordance with a food additive regulation permitting that specific use or a color additive listing. Otherwise, the presence of that substance in food would make the food adulterated.

Under the PCHF requirements, an unapproved food or color additive is a chemical hazard. Some food and color additives are specifically prohibited from use in food because we have determined that the chemical additive poses a potential risk to public. Examples of such food and color additives are coumarin, safrole, and FD&C Red No. 4 (Red No. 4) (FDA, 2015b. An additional resource for you is the Food Additive Status List on our website (FDA, 2014b).

Misformulation

A ingredient can be a chemical hazard if it is added in excess of a maximum use level, regardless of whether the maximum use level is established due to food intolerance (such as for sulfites) or is otherwise a condition of safe use of a food additive, color additive, or GRAS substance. Control strategies to prevent misformulation of substances generally include process controls to ensure that excessive amounts are not added.

Incorrect labeling of substances associated with food intolerance or disorders

Although the mechanisms whereby persons' experience food intolerance or food disorder are different from the mechanisms that cause food allergy, reactions due to food intolerance or food disorder can cause significant health problems for those affected, and the principal means that consumers have to avoid the symptoms of food intolerance are the same means that consumers use to avoid symptoms of food allergy – i.e., avoid foods containing the substance that causes the problem. For example, people who are intolerant to lactose, a sugar that is a component of milk, avoid food products containing milk to avoid the symptoms associated with lactose intolerance. In addition, people who have celiac disease avoid food products containing wheat and other sources of gluten.

Undeclared substances associated with a food intolerance or food disorder are chemical hazards that can get into food because either: (1) The food manufacturer did not properly declare the substance on the product label; (2) unintended (and, thus, undeclared) substances are present in a food due to incorrect labeling. Control strategies to prevent incorrect labeling of substances associated with a food intolerance or food disorder are analogous to those used to prevent incorrect labeling of food allergens and, thus, you may find Chapter 11—Food Allergen Controls helpful in preventing incorrect labeling of substances associated with a food intolerance or food disorder. The preventive controls in that comprehensive guide to food allergen control do not explicitly address substances associated with food intolerance or food disorder, but may nonetheless be useful in addressing chemical hazards due to incorrect labeling of such substances.

Process contaminants produced during heating

There are several process-related contaminants that are produced during heating of specific ingredients or finished foods that may be a health (e.g., cancer) concern. For example, acrylamide is formed during high-temperature cooking processes (including frying, roasting, or baking) due to interaction between sugars and amino acids that are naturally present in foods.

Acrylamide is found mainly in foods made from plants, including potato products, grain products, and coffee.

Guidance for Industry: Acrylamide in Foods (FDA, 2016a) help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods. Control strategies to reduce acrylamide in food may include controlling temperatures during cooking and ingredient substitution.

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Radiological hazards

Radiological hazards rarely occur in the food supply; however, when they do occur, these hazards can present a significant risk when exposures occur over a period of time (WHO, 2011). Consuming food contaminated with radionuclides will increase the amount of radioactivity a person is exposed to, which could have adverse health effects. The health effect depends on the radionuclide and the amount of radiation to which a person is exposed. For instance, exposure to certain levels of radioactive iodine is associated with increased risk of thyroid cancer (WHO, 2011).

Radiological hazards can become incorporated into food through the use of water that contains the radionuclides during food production or manufacture. There are areas in the United States where high concentrations of some radionuclides, such as radium-226, radium-228, and uranium, can be detected in well water (Ayotte et al., 2007; Focazio et al., 2001). You should be aware of the condition of the water used for production and manufacture in your facilities. For example, if your facility uses well water and there are elevated levels of radionuclides in the well water, you should not use the water. The CGMPs require that water that contacts food, food-contact surfaces, or food-packaging materials be safe and of adequate sanitary quality. Radiological hazards also may result from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. In 2011, following damage to a nuclear power plant during an earthquake and tsunami in Japan, radioactivity was subsequently detected in foods, particularly milk, vegetables, and seafood produced in areas neighboring the plant (WHO, 2011). You should be vigilant regarding accidental releases of radiological hazards and their potential to contaminate your food product, either directly due to contamination of natural resources near your facility or as a result of raw materials and other ingredients that you obtain from a region that has experienced an accidental release of radiation.

FACILITY-RELATED CHEMICAL HAZARDS

Industrial chemicals or other contaminants from the food processing environment can contaminate food during production – e.g., if chemicals used to clean a production line are not adequately removed from the production line or if heavy metals are leaching from containers or utensils. In this guidance, we do not discuss preventive controls for facility-related chemical hazards such as cleaning chemicals and the leaching of heavy metals from containers or utensils, because such hazards are usually addressed through CGMPs.

ANTIMICROBIAL RESISTANCE CONTROL

There can be little doubt that the use of antibiotics in aquaculture selects for antimicrobial resistance among bacteria in farmed fish and in the environment surrounding fish farms. It is well established that antibiotics given to animals have resulted in the emergence of some resistant germs that can infect humans via the food chain. Additionally, illegal residues have been reported in aquaculture products in export markets.

Antibiotics should never be used as an easy alternative to good fish farming practices. National governments need to put in place control program for residues of antimicrobials in aquaculture production. Such control program should control the approval or licensing of antimicrobials and should control their sale and use in fish farming. What is required at national level is up-to-date legislation and standards that are based on sound science, a monitoring program and adequate resources for enforcement of the legislation.

Consumers can protect themselves against antibiotic resistant bacteria as these are just as susceptible to heat and hygiene as their non-resistant counterparts. Thorough cooking, frequent hand washing, prevention of cross-

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contamination by separating raw seafoods from other foods and proper chilled storage will minimize the incidence of seafood poisoning.

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Chapter 5

PHYSICAL AND MECHANICAL HAZARDS

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Chapter Objectives

- Overview the most relevant physical and mechanical hazards in foods and in food processing
- List the most important preventive methods

Definition

A physical hazard is any extraneous object or foreign matter in a food item which may cause illness or injury to a person consuming the product.

EXAMPLES OF MOST IMPORTANT/COMMON PHYSICAL HAZARDS - EFFECTS ON HUMAN HEALTH

Foreign objects are the most obvious evidence of a contaminated product and are therefore most likely to be reported by production or by consumer complaints. However, they are also less likely than chemical or biological contaminants to affect large numbers of consumers.

The most important / common physical hazards, their sources and their effects on human health are shown on below **Table 1**.

The Food and Drug Administration (FDA) maintains a passive surveillance system for the reporting and follow up of complaints related to food items. A total of 10,923 complaints about food items consumed in fiscal year 1989 was reported to the FDA Complaint Reporting System. The largest single category of complaints involved the presence of foreign objects in food, accounting for 2,726 (25%) of all complaints. Of the 2,726 persons who reported a foreign object in their food, 387 (14%) also reported an injury or illness resulting from eating the food. Of the 387, 123 complainants (32%) reported consulting a health professional for the problem; 62 (50%) were attended to in a private office, 53 (43%) were treated in an emergency room, and 8 (7%) were hospitalized.

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Material	Sources	Health Effects
Glass	Bottles, jars, light fixtures, utensils	Cuts, bleeding; may require surgery to find or remove
Wood	Fields, pallets, boxes, buildings	Cuts, infection, choking; may require surgery to remove
Stones	Fields, buildings	Choking, broken teeth
Metal	Machinery, wire, jewellery, employees	Cuts, infection; may require surgery to remove
Insects, pests, animals	Fields, plant post-process entry	Illness, trauma, choking
Bones	Fields, improper plant processing	Choking, trauma
Plastic	Fields, packaging material, pallets, employees	Choking, cuts, infection; may require surgery to remove
Personal items	Employees (jewellery, hair, buttons, nails, cigarettes, etc.)	Choking, cuts, broken teeth; may require surgery to remove

Table 1: Physical hazards / Common sources / Effect on Health.

The most common foreign object reported in food is glass, and the most common injury is a laceration or abrasion of soft tissues of the perioral area, including the throat. There was a disproportionate representation of children younger than age 3 years with documented illness or injury. Only 3% of the complaints came from attending health professionals; 82% were self-reported.

The top most common food categories implicated in reported foreign objects complaints are shown on below **Table 2**.

Food Category	Number of Complaints	(%)[B)]
Bakery	272	10.2
Soft Drinks	228	8.4
Vegetables	226	8.3
Infants Foods	187	6.9
Fruits	183	6.7
Cereal	180	6.6
Fishery	145	5.3
Chocolate and Cocoa Products	132	4.8

[a)] Does not include meat and poultry categories
[b)] % of total (2726) reported foreign object complaints received by the FDA Complaint
Source: (Hyman, F.N., Klontz, K.C., and Tollefson, L. 1991)

Table 2: Eight most common food categories implicated in reported foreign object complaints [a)]

GLASS AND HARD PLASTIC POLICY IN FOOD INDUSTRY

Glass and hard plastic present particular difficulties given their nature and prevalence in food operations. These materials can often be transparent and difficult to detect when present in food. Hard plastic is used widely in food production equipment and machinery and can be subject to damage, wear and tear. Glass and hard plastic is a major contributor to injury when consumed with the product. They can result in claims and on occasion litigation. These and other factors require glass and hard plastic to be eliminated from food production areas where possible. Where this is not practicable control must be exercised over these materials to ensure the risk of contamination is reduced to an acceptable level. An effective glass and hard plastic control system will normally comprise the following elements:

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- Glass and hard plastic policy – purpose/scope.
- Glass and hard plastic risk assessment determines the frequency that the items of glass or hard plastic are checked in order to ensure that.
- There are no missing pieces.
- The condition of the items is acceptable.
- Glass and hard plastic control procedure, where controlling measures are identified. This procedure should include controlling actions for all glass or hard plastic items in production or storage area.
- New equipment assessment and risk reduction, where all new equipment should be assessed and included in the company's policy.
- Glass and hard plastic register. A map of all glass and hard plastic items in production or storage areas should be available. A register listing of all the items with ticks or crosses to be added, depending on condition and availability.
- Glass and hard plastic audit program. A check list could be used in order to easily check availability and condition of each item and safety of each area.
- Glass and hard plastic breakage procedure, where exact actions are described in case of shattered/broken/damaged glass or hard plastic items in a production or storage area. The procedure should define all actions from the time that the damaged item is detected until the final approval of supervisor that the procedure is concluded.

The system should be focused on identifying, eliminating, reducing or protecting all glass and hard plastic material in the operation that may present a risk in terms of food safety.

PREVENTIVE METHODS

Systems should be in place to prevent contamination of foods by foreign bodies such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices should be used where necessary *(Codex Alimentarius, 2003)*

The most common source of physical hazards is employees/personnel. So it is really important to focus on personnel hygiene and especially on the following elements (depending on job description of each employee):

- Use of protective clothing, which should completely cover or replace personal clothing.
- Use of protective gloves.
- Use of protective footwear.
- Use of protective head caps (for hair).
- Use of protective facial masks (for beards and mustache).
- Press studs or velcro fastening should be preferred over buttons.
- Jewelry, such as rings, necklaces, earrings, etc. should be strictly prohibited.
- Smoking should be strictly prohibited.
- Training on personnel hygiene and on personnel behavior.

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Another important source of physical hazards is equipment/machinery used in the facility. It is really important to apply a maintenance plan in order to keep the machinery in a good condition. Lack of equipment maintenance could lead to serious malfunctions and contamination of food with metal, glass or plastic items. Lack of machinery maintenance could also lead to improper food processing and contamination of food (for example presence of bones in meat products without bones or presence of pits in pitted olives).

Buildings and plant facilities should be in good condition in order to avoid physical contamination. An effective pest control system and a cleaning program should be applied in order to prevent insects, pests or other animals from entering the facilities.

Incoming products and packaging material should be carefully inspected before entering the facilities in order to ensure that they comply with safety standards.

In food processing facilities there is a variety of equipment which is used to detect and/or remove dangerous material from food products (related to physical hazards). Some examples are:

- Screens, sieves, filters (for stones or insects for example).
- Metal detectors.
- X-ray technology (to detect for example bone fragments or pits).
- Magnets.
- Other optical systems or on line visual inspection.

Proper equipment design, selection, maintenance and calibration is vital in order to ensure the effective monitoring of physical hazards.

Food operators should implement a HACCP plan in order to identify potential physical hazards and finally achieving to reduce or eliminate the risk of contamination. Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) are essential for achieving this goal.

Food companies that implement Food Safety Management Systems (for example ISO22000:2005, IFS, BRC, etc.) should include physical hazards analysis (probability/severity) in order to evaluate physical hazards and to determine their significance. Based on the hazard analysis, critical control points (CCPs) that can be controlled are set to eliminate the hazard or minimize the likelihood of its occurrence. A critical control point shall be a point, procedure, operation or stage at which control shall be applied and shall be essential to prevent, reduce to acceptable levels or eliminate a hazard related to food safety.

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Chapter 6

ALLERGENIC HAZARDS

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Chapter Objectives

- To give an overview of the main issues related to the food allergens and allergies
- To give some guidelines to risk management on food allergens in food processing

Introduction

Food Allergy is one of the most commonly encountered health problem worldwide. The etiologic agents of this clinical condition are known as allergens which simple are proteins that are capable of producing an abnormal immune response in sensitive segments of the population. In principle, Allergic reactions to food usually involve IgE antibodies. Symptoms of an allergic reaction range from mild conditions like skin rash and slight itching of the mouth, to migraine headaches, to a life threatening condition known in the medical practice as anaphylactic shock which ultimately leads to death. Several factors are involved in determining the type and severity of an allergic response including dosage, route of administration, frequency of exposure, and most importantly the genetic predisposition.

In general, there is no ultimate cure for food allergies and the only successful method for susceptible individuals is to manage food allergy through avoiding the specific allergen however, alleviating the symptoms are usually achieved by using immunosuppressive drugs. Accordingly, accurate information (e.g. ingredient list) on food labels to manage food allergy are of at most importance. Inaccurate, undeclared or hidden allergens on food labels can pose a significant health hazard to susceptible individuals. This ultimately lead to the development of international strategies and plans like ensuring the strict adherence to good manufacturing practices (GMP), Hazard Analysis Critical Control Points (HACCP), and allergen prevention plans which has significantly reduced the likelihood of cross contamination of the allergen to food product in its finished form.

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BASICS OF FOOD ALLERGY AND FOOD INTOLERANCE

What is Food Allergy?

Food Allergy is simply defined as the development of certain specific clinical symptoms after ingesting food ingredients. General mild symptoms including but not restricted to skin rashes (hives), itching and swelling of lips, face and tongue shortening of breath, nausea, light-headedness and runny nose typically appear after minutes to couple of hours after the exposure **(2)**. The immune system of the human body triggers a response against a protein in the food leading to the development of certain types of Immunoglobulin known as IgE which will activate allergy related White blood cells called Mast cells. The activated mast cells produce histamine and other chemical agents which will lead to physiological changes that appear on the exposed individuals.

It is important to differentiate between food allergy and food intolerance because the management and treatment regimens vary. Food intolerance is an abnormal physiological response to a specific food which appears mostly as cramps, diarrhoea and bloating. Food intolerance is not a life threatening condition and is usually managed by avoiding the exposure to the causative food type and does not need immunosuppressive therapies. Neither mast cells nor IgE are involved in food intolerance. The best typical example of food intolerance is the intolerance to dairy products which is known as lactose intolerance. This is one of the most common food intolerances worldwide which occurs in people who lack an enzyme called lactase, which is needed to digest sugar milk lactose **(3)**.

In the developed world, about 4% to 8% of people have food allergy **(4)**. Recently, the frequency of food allergy has increased particularly among children compared to adults with higher incidence among males. It is important to note that food allergy varies in frequencies or severity among the different geographical communities in addition to ethnic groups where genetic factors are believed to be responsible for this phenomenon **(5)**. Potential risk factors for food allergy usually include vitamin D insufficiency, unhealthful dietary fat, obesity, increased hygiene, and the timing of exposure to foods.

Pathophysiology

Food allergy is developed as a natural reaction of the immune system to the allergen, which is a protein in the food that is considered abnormal by the immune system in the susceptible individuals. Generally, workers of the medical practice classify food allergies into two classes according to the mechanism of the allergic response **(5)**.

Class I food allergy is known as the classical form of food allergy which relays on the development of antibodies of the class IgE to the food allergen. This class is the most common type, and typically occurs shortly after eating and may ultimately develop to a life threatening condition known as anaphylaxis which leads to death (6). When immune cells recognize the allergenic protein, IgE antibodies are produced in a similar fashion to the immune system's reaction against foreign pathogens. The IgE antibodies identify the allergenic proteins as harmful and initiate the allergic reaction. IgE antibodies bind to a receptor on the surface of especially immune cells called mast cells which contain histamine and other inflammatory mediators in their cytoplasm. When the allergen binds to the IgE on the surface of the sensitized mast cells, histamine is produced leading to increase in the diameter of blood vessels (vasodilatation) and tightening of wind pipe (bronchoconstriction) exhibiting the principle manifestations and signs of hypersensitivity.

Class II food allergy usually is less common and less severe that class I. In this class, the symptoms usually develop late and after 12 hours of exposure. The mechanism of this class of food allergy is not IgE antibodies dependent and it involves improper activation of T cell lymphocytes in the stomach mucosa **(7)**. Here, the immune system can harm

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the human gut gradually leading to symptoms related to the gastrointestinal system. It is noteworthy to diagnose this class of food allergy because if exposed individuals are not cured, the condition might develop to chronic phase and end with damage of certain parts of the gut leading to maldigestion and malabsorption.

The pathological effects of food allergy usually exhibit two phases. In the acute phase, the immunological reaction occurs immediately after exposure to an allergen and depending on the nature and amount of allergen, it can either subside or progress into a "late-phase reaction" which can substantially prolong the symptoms of a response, and result in tissue damage. Proteins constitutes the chemical nature of almost all allergens, since they possess unique properties that allow them to become allergens, such as stabilizing forces in their tertiary and quaternary structures making these proteins resistant to degradation during digestion. Many theoretically allergenic proteins cannot survive the destructive environment of the digestive tract, thus do not trigger hypersensitive reactions.

Food allergens

Allergens are chemical agents that when entered to human body triggers an allergic reaction by the immune system of the exposed individuals. In case of food allergy, numerous types of allergens are present in different types of food ingredients. Food allergens might be present in herbal food and in animal products as well. Food allergy can also be developed to chemically modified product that is added to food product like additives, preservatives and some flavours **(8, 9)**.

The international survey programs have list the most common food allergens for which 95% of food allergy cases are attributed to. These allergens include (arranged according to the highest incidence):

- Peanuts and tree nuts (Almonds, Brazil nuts, Cashews, Hazelnuts, Macadamia nuts, Pecans, Pine nuts, Pistachio nuts, and walnuts).
- Soy.
- Seafood (Fish, Crustaceans, and Shellfish).
- Sesame seeds.
- Milk and Eggs.
- Wheat.
- Sulphites.
- Mustard.
- Banana.

Most of the individuals do not know exactly what food allergen they are susceptible for and thus making inaccurate generalization about their food which might cause malnutrition. It is important to note that cross reactivity is a common challenge in food allergies **(10)**. Simply, if a person is allergic to shrimp, he or she may be allergic to other types of shellfish, such as crab or crayfish. This happens when proteins in one food are similar to the proteins in another food because IgE antibodies can share similar specificities to chemically similar allergens typically observed in cases of proteins. The case is much complicated in some people who have allergies to pollens, such as ragweed and grasses. Proteins in the pollens are like the proteins in some fruits and vegetables. This condition is called oral allergy syndrome which is reported in approximately 60% of cases of food allergies in adults.

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Diagnosis

Diagnosis of food allergies is one of the most important tools required for proper management and treatment of such conditions. It is actually an integral task in the preventive measures adopted by health agencies worldwide.

The first approach for the diagnosis of food allergies relays on the medical history of the exposed individual. Actually, the full the description of the medical history of the exposed individual, the faster and the accurate the diagnosis will be.

The diagnostic tools used depend on either the development of typical symptoms after injecting a suspected allergen into the skin in the so called skin-prick tests or by the measurement of total IgE antibodies and their specificities to a panel of suspected allergens in the laboratories *(in vitro*).

In the skin test, the procedure involves the introduction of a tiny board with protruding needles containing the allergens of interest directly beneath the skin followed by monitoring the development of allergy related symptoms. If a hive appears within minutes, the person is considered positive for the allergy. The drawbacks of this test include its insensitivity in cases of allergic reactions caused by antibodies other than IgE and the risk of the invasive procedure **(11)**. These factors collectively make the use of this test restricted to confirm an allergy in light of a patient's history of reactions to a particular food.

The most sensitive and specific testing for food allergies is the blood testing of the total IgE concentration (Antibody titier) and their specificity to certain allergens. The most widely used template for IgE is known as radioallergosorbent testing (RAST). The score taken from the RAST when compared to predictive values can predict the likelihood of the tested allergen to be a cause of allergy. One advantage of this test is that it can test a panel of allergens at one time. The disadvantage of this test is similar to skin test in which the non IgE mediated food allergies cannot be detected.

Recent efforts have been widely exerted to test for allergens other than those caused by IgE. Food challenges test is a recently developed method to achieve this goal. In this test, the allergen is given to the person in the form of a pill, so the person can ingest the allergen directly and subsequently, the person is closely monitored for the development of signs and symptoms. The risk of developing anaphylaxis is one of the major drawbacks of this approach this limits the test to be performed in the hospital under careful watch.

As in most clinical conditions, differential diagnosis is required and important especially in cases of lactose intolerance and celiac disease which is an autoimmune disorder triggered by gluten proteins such as gliadin (present in wheat, rye, and barley). In addition, Irritable bowel syndrome should be first excluded particularly in cases of gastric symptoms.

In conclusion, the diagnosis of food allergies is not a simple task and has many drawbacks particularly when we consider the cost of the tests and the need for patient's compliance to the test procedures.

Management and treatment

Management of food allergies is a central part of most health agencies worldwide. Not only, the preventive measures contributed to decrease the incidence of food allergies and exposure to food allergens, but also they improved individual health and reduces the cost of treatment of such disorders.

Among the early preventive measures of food allergies is breastfeeding for more than four months which according to several studies is a successful approach in preventing atopic dermatitis, cow's milk allergy, and wheezing in early childhood. In addition, early exposure to potential allergens may be protective especially in cases of allergy to eggs and peanuts **(12)**.

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Allergen free strict diet is one of the best approaches in avoiding food allergies and its effectiveness depends on the medical history and the proper diagnosis of the cause of the allergy. However, since it is difficult to determine the amount of allergenic food required to elicit a reaction, complete avoidance should be attempted. Moreover, hypersensitivity can be triggered by exposures to food allergens through indirect ways like skin contact, inhalation, kissing, blood transfusions and cosmetics.

Treatment of symptoms related to food allergies is important particularly in children and elderly to prevent the development of anaphylaxis. Different drugs are commonly used depending on the severity of reactions. In cases of anaphylaxis, epinephrine (adrenaline hormone) must be promptly used to reverse the situation and alleviating the symptoms by improving blood circulation through tightening of blood vessels and increasing heart rate. The person should then be transported to the emergency room, where additional treatment can be given and after complete check of the patient to ensure no organ damage occurs **(13)**.

Administration of antihistamines and steroids is the first line of treatment of food allergies **(12)**. Antihistamines alleviate the early symptoms of food allergies by blocking the action of histamine, which causes blood vessels to dilate and increasing itchiness by acting on sensory nerve terminals. The most common antihistamine given for food allergies is diphenhydramine. Steroids are used to suppress the immune system cells that are attacked by the chemicals released during an allergic reaction. Steroids are usually administered as nasal spray or taken orally, and in emergencies, through injection, by which every part of the body can be reached and treated.

REGULATORY ASPECTS OF FOOD ALLERGENIC HAZARDS

Risk estimation and Risk Assessments for Food Allergens

One of the essential tasks of health and food agencies is to evaluate and assess the risk of food allergens in order to improve quality of life of human beings. Allergen risk assessment programs aim to determine the risks due to unintentional presence of allergens which can help in making the decision of labelling or restriction of a food ingredient is taken.

Risk assessment of food allergens must cover several points including the chance of allergenic hazard get into contact with food products, the amount of the allergenic food generally needed to provoke a reaction in allergic people, the frequencies and severity of adverse reactions and if increase susceptibility of subgroups or geographical region to certain allergens **(14)**.

Practically speaking, risk assessment with the current knowledge and tools is not optimal. Several challenges encounter proper risk evaluation of allergens specifically the allergen thresholds (lower limits under which food allergens will not cause any symptoms). In addition to, the amount of food allergen that may trigger allergic reactions visible for others range from a tenth of milligram in rare cases up to grams, and sometimes tens of grams, with considerable variability between individuals as well as between allergens **(15)**. A review conducted since the 1970s reported that the most of food-allergic individuals tested would need to eat more than 500 mg of the offending food to trigger allergic reactions, but a significant minority responded to lower doses.

Recently, scientists and regulatory authorities have started discussions on what is the best way to make statistical evaluations of the individual data taking into consideration the allergenic hazards. To the best of our knowledge, the Australian Food and Grocery Council is the first organization to develop and recommend the use of an allergen risk assessment tool to harmonise the application of allergen precautionary labelling. This effort concluded that the best measure for decreasing allergenic hazard is to prevent and minimize the cross contact in the premises of food industry **(16)**.

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Food allergy awareness is another tool that is increasingly used to decrease the risk of allergenic hazard **(17)**. In the U.S., the efforts of Food Allergen Labeling and Consumer Protection Act of 2004 remarkably aided people to be reminded of allergy problems every time they handle a food package, and restaurants have added allergen warnings to menus. In addition, chef training courses in allergen-free cooking and a separate teaching kitchen **(18)** were conducted by the Culinary Institute of America. Standard protocols about what foods can be brought into the school were also adopted. Lastly, for children with allergies, their quality of life is also affected by actions of their peers. The increased occurrence of bullying including threats or acts of deliberately being touched with foods they need to avoid, increased the contamination of their allergen-free food **(19)**.

Regulation of labelling

Recently, most countries have responded to the risk for food allergens by instituting labeling laws that require food products to clearly inform consumers if their products contain major allergens or by products of major allergens. Moreover, customers are compulsory warned by companies when food has been prepared around certain allergens that have been known to cause severe reactions. Under the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282), companies are required to disclose on the label whether the product contains any of eight major food allergen, cow's milk, peanuts, eggs, shellfish, fish, tree nuts, soy and wheat, in clear plain language. In addition, all allergens have to clearly be called out in the ingredient statement. Section 112 of the federal law the Food Safety and Modernization Act of 2010 (S510/HR2751, 111th Congress) established voluntary food allergy and anaphylaxis management guidelines for public kindergartens and elementary and secondary schools **(20)**.

In Europe, molluscs, celery, mustard, lupin, sesame and sulfites in addition to the allergens mentioned above must be listed in the ingredient lists if present. The EU Food Information for Consumers Regulation 1169/2011 – requires food businesses to provide allergy information on food sold unpackaged, for example, in catering outlets, deli counters, bakeries and sandwich bars **(21)**. The allergenic ingredients need to be clarified using a typeset that clearly distinguishes it from the rest of the ingredients usually by means of the font, style or background color. In cases of byproducts originated from a single allergenic ingredient, the labelling should make this clear for each ingredient or processing aid concerned as in case of milk in the following products skimmed milk powder, whey (milk), lactose (milk).

In some cases, foods are offered to sale to the final consumer or to mass caterers without packaging. In these cases, information about allergenic ingredients is mandatory and must be provided. Similarly, if foods are packed on the sales premises at the consumer's request or prepacked for direct sale. In addition, when allergen information is not provided upfront for non-prepacked foods, written or oral formats with clear signposting of the allergen information should be provided to the consumers.

Responsibilities of food industry

The control of food allergens has become one of the major issues regarding food safety worldwide. As part of the industrial processes, food manufacturers have mandatory established controlled measures and process validation which ensure the avoidance of cross contamination of food allergens **(22)**. Currently, authorities recommend an approach to allergen control based on the HACCP principles that have been so successful in managing other food safety hazards as in case of guidance from the UK-based Institute of Food Science and Technology (IFST). By this approach, the following well controlled strategy was adopted:

- The entire manufacturing process should be analysed in relation to allergen hazards as recommended by HACCP plan.

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- Segregation of manufacturing operations especially those involving the allergen-containing food is mandatory in multi-product companies.
- Formulation of foods should be free of all unnecessary major allergens as ingredients when possible.
- All raw materials supplies, storage and handling, production schedules and cleaning procedures should be organized to prevent cross-contamination of products by 'foreign' allergens.
- Proper and Sufficient training should be provided to all personnel.
- Compliance with the relevant labelling legislation.
- Availability of a valid recall system for any product found to contain a major allergen not indicated on the product label (**23**).

Adherence to GMP procedures is the key stone for the food manufacturers to ensure best practice of avoiding mis-formulation, cross contamination, inadequate cleaning and re-work. Most manufacturers utilize separate equipment for products containing specific allergens, while larger manufacturers set up separate manufacturing facilities for products containing allergens to eliminate the risk of cross contaminating other products.

Allergen control plans have been recently more implemented by each manufacturer. The plans generally focus on identifying and tracking ingredients that contain allergens using an allergen map, dedication of processing equipment to allergenic products and strict control of rework and packaging. Clear validation measures and protocols using sampling and testing for allergen residues on equipment and surfaces are required to ensure effective cleaning and decontamination.

It is noteworthy to mention that undeclared allergens in food remains one of the main reasons for recalling products from the market despite all the advice available and the adoption of the proven HACCP-based approach to controlling allergen contamination. In 2010, over 120 recall incidents related to food allergens were recorded by US FDA, while in the UK in 2011, the Food Standards Agency issued 50 Food Alerts, but no less than 57 Allergy Alerts. Accordingly, manufacturers increased their awareness of applying the term "may contain" warnings on many foods. Widespread use of precautionary labelling also presents problems for allergic consumers, who may find their choice of products severely limited and may be tempted to ignore valid warnings.

The problem of genetically modified food

genetically modified organisms (GMO) which are foods generated by biotechnology and bioengineering methods have been increasingly placed in the markets for consumers. Since reports regarding increasing the incidence of food allergies after the introduction of these products, major concerns are now considered regarding GMOs as being responsible for allergic reaction (**24**). The major concern is the effect of genetic engineering itself would increase the likelihood that an allergy-provoking food more allergic, meaning that smaller portions would suffice to set off a reaction. The best example is seen in case of GMO soybeans which have been significantly identified as a common allergen. This is remarkably illustrated for the fact that soybean proteins known to trigger allergic reactions, there is more variation from strain to strain than between those and the GMO varieties. Nevertheless, National Academy of Sciences report concluded no relationship between consumption of GE foods and the increase in prevalence of food allergies (**25**). A second concern of GMOs is the potential of converting a non-allergenic food into allergenic one when genes are transferred from on species to another. The situation was clearly investigated by an attempt to enhance the quality of soybean protein by adding genes from Brazil nuts due to tree nut allergy in human volunteers (**25**).

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Currently, clear criteria need to be met prior to a new GMO food receiving government approval. These include: the risk of the donor species to be allergenic, degree of similarity of the amino acid sequence between the transferred proteins to sequence of known allergenic proteins and the susceptibility of transferred proteins to digestion. Lastly, there are requirements in some countries and recommendations in others that all foods containing GMO ingredients be so labeled, and that there be a post-launch monitoring system to report adverse effects (much there exists in some countries for drug and dietary supplement reporting) (**24**) According to a 2015 report from the Center for Food Safety, 64 countries require labeling of GMO products in the marketplace (**26**).

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Chapter 7

FOOD SAFETY AND INNOVATION

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Chapter Objectives

- To review the main innovation aspects in food processing and products including innovative technologies, Novel Foods, Genetically Modified Organisms and Nanotechnology
- List the main regulations dealing with innovation and food safety

INNOVATION IN FOOD PROCESSING AND INNOVATIVE PRODUCTS

Food has a main role in everyday life for its intrinsic nutritional value. Since the early stages, the history of food preparation and processing worldwide has been influenced by the need to guarantee the preservation of the raw materials obtained from nature, agriculture and breeding as well as their safety. From the empirical use of natural ingredients (such as salt and honey), the development of old methodologies like drying, fermentation and the use of heat for cooking, up to the conventional processing technologies based on high temperatures like pasteurisation and sterilisation, the main target has been the control of alterative factors and the inhibition/inactivation of pathogenic microorganisms, main cause of food spoilage and human illnesses.

In the last two decades, advances in food microbiology and instrumental techniques have allowed to identify and detect a number of foodborne pathogens as well as presence and concentration of contaminants and other undesired chemicals, at nano level, higher than any other period in history. Moreover, the importance of the quality attributes of a food product has been continuously changing responding to the more modern consumers' expectations. Currently an increased relevance of healthy, sensory and convenience aspects of foods even if the nutritional value and food safety are still key and intrinsic aspects for high quality products.

For sanitisation purposes pasteurization and sterilisation are the heat-based process technologies more widely used in the twentieth century in food manufacturing. However, severe heat processing causes not only the desired inactivation microorganisms but also destroys main food nutrients as well as degrades some quality properties like the textural and physical characteristics of food products impairing their acceptability.

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All these aspects have been the major motivating factor driving the interest in developing novel methods that can retain the freshness of processed foods, while achieving the same safety and nutritional value. In the last decades, innovative, non-thermal technologies like High hydrostatic Pressure (HHP), Pulsed Electric Fields (PEF), Ultrasound (US) and Cold plasma (CP) have been developed with a science-based approach to obtain high quality and safe foods. Moreover, microwaves have been introduced as non-conventional heat treatments, as alternative to the conventional use of water or vapour as heat transfer media.

Overall, beyond their effects on food stabilisation and sanitisation these innovative processes are contributing to environmentally friendly and sustainable food manufacturing with low energy requirements and reduced water use.

Researches on innovative technologies and processes are still ongoing and only in a limited number of processes they have found application. In fact, there are main issues to their implementation in food manufacturing. Despite the innovative processes determine main effects on microbial and enzyme inactivation, high costs of the plants and equipment (especially for HHP) and the not uniformity of the treatment (e.g. microwaves) that requires plant and equipment development and process optimisation, are limiting the application in food processing and production.

The lack of scientific and objective equivalence of the lethal effects on pathogenic microorganism of the innovative technologies compared to the conventional ones, is the main obstacle to their use for pasteurisation and sterilisation purposes. Currently only the microwave-based thermal treatments have been approved for industrial pasteurization and sterilization by the FDA and in Europe manufacturers willing to apply innovative technologies for sanitisation (pasteurisation/sterilisation) purposes require to obtain official approval by EFSA according to the "novel products" regulation.

NOVEL FOODS

Novel food has been become an issue in reaction to the results of the advancements in new and innovative technologies and scientific knowledge as well as food market globalisation and related safety concerns. Products can be processed with newly developed technologies or imported from foreign countries, without a history of consumption in a given place and for this they have to be assessed for their safety and nutritional value.

Novel foods may be introduced into the food chain to contribute to the improvement of quality, health attributes of foods, and as response to specific societal or environmental needs to humans wellbeing.

Main concerns on the commercialisation and consumption of novel foods is the absence of a history on their impact on humans in terms of safety and nutritional value, but also their potential allergenicity. For instance, the introduction of novel ingredients (like some extracted plants proteins) or new foods into the food chain (e.g. insects) and the human diet may result in new and unexpected cases of food allergy.

In general, the term "novel food" refers to a food or a food ingredient that has not been traditionally used as a food. However, the definition of what a "novel food" is, varies depending on global location or area of interest. Actually some countries, and in particular the European ones, have adopted specific definitions and regulations, while others have not.

Due to their potential impact on consumers' safety, production and market of novel foods is generally regulated even if in a varying manner and with different procedures depending on the country. Official regulation systems, where exists, are generally based on a safety assessment review model and require notification and approval before a novel food reaches the market. Lists of approved novel foods are typically maintained by regulators and are made publicly available.

In Europe, novel foods are regulated under the Regulation (EU) 2051/2283 of 25 November 2015 which has substituted an old one to take care of the technological developments and new scientific advice and to reduce the

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current length for authorisation. According to this recently adopted EU law, the definition of "novel food" applies to any food that was not used for human consumption to a significant degree within the Union before 15 May 1997. It regulates not only tech-foods but also to "exotic (or imported) foods" with a long history of consumption outside Europe as traditional foods, but not in Europe.

In United States, no formal regulations for "novel foods" have been issued by the Food and Drug Administration that, in turn, has defines a food ingredient as novel "when has not previously been used as food ingredients." In this case suppliers and marketers take as reference the Dietary Supplement Health and Education Act (DSHEA, 1994), which established a definition for the term "new dietary ingredient" (NDI). Based on this, the FDA set specific procedures, including documents on its safety, scientific studies and related research along with a notification process that companies intending to produce and market a NDI must follow.

China has established a similar regulation system to the European one that, however, takes into account the specific local habits and cultural history where novel foods and health food are linked as certain materials can be used for both food and medicine.

Novel foods in Europe

According to recently adopted EU law, the definition of "novel food" applies to any food that was not used for human consumption to a significant degree within the Union before 15 May 1997 and currently includes, among others,

- Foods with a new or intentionally modified molecular structure; foods from cell culture or tissue culture derived from animals, plants, microorganisms, fungi, or algae.
- Food from microorganisms, fungi, or algae.
- Food from material of mineral origin.
- Whole insects and their parts.
- Plants obtained by non-traditional propagating practices with significant changes in the composition or structure of the food, affecting its nutritional value, metabolism, or level of undesirable substances.
- Foods consisting of engineered nanomaterials, micelles or liposomes.
- Foods "exotic" or "imported", without a history of use in Europe, but they are currently used in other parts of the world ("novel imported foods").

Examples of novel foods include agriculture products from non-EU countries (e.g., chia and quinoa seeds), newly produced nutrients (e.g., synthetic zeaxanthin), synthetic minerals (zeolites), extracts from existing food (rapeseed protein).

Under the definition of "novel foods" are also considered those processed with emerging, innovative technologies. For them, the regulation specifies that a food should be considered a novel food when it results from a production process "not used for food production within the European Union before May 15,1997, if that process results in significant changes in the composition or structure of a food, affecting its nutritional value, metabolism, or level of undesirable substances".

The novel food regulation does not apply to genetically modified foods (GMOs), food enzymes, food used solely as additives, food flavourings and extraction solvents whose use is regulated by other European laws.

In order to be placed on the market or used in food for human consumption, a novel food has to be included in a European Union list of authorized products (https://ec.europa.eu/food/safety/novel_food/catalogue_en). To

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this aim, the product has to be authorised by the European Food Safety Authority (EFSA) according to procedures and minimum requirements including the description of the novel food, production process, compositional data, specification, proposed uses and use levels, and anticipated intake of the novel food. Additional information required is the history of use of the novel food and/or its source, absorption, distribution, metabolism, excretion, nutritional information, toxicological information, and allergenicity. To evaluate its safety, toxicological data are required and, in particular, those on toxicokinetics (absorption, distribution, metabolism, and excretion—ADME) relevant to assess both nutritional and toxicological impact of the novel food.

The current EU regulation has also included a simplified procedure for manufacturers to introduce novel food ingredients to market in the EU, known as the "substantial equivalence" procedure. It applies when an ingredient was deemed by a scientific committee to be similar to another ingredient already authorized as a novel food.

GENETICALLY MODIFIED FOODS (GMOS)

Genetically modified foods (GMOs) are derived from organisms whose genetic material (DNA) has been modified by genetic engineering techniques to an extent that does not occur naturally.

This implies the introduction of a gene from a different organism or its removal from the organisms via recombinant-DNA technology in modern plant breeding and biotechnological

food production systems. The resulting organism is said to be 'Genetically modified (GM)', 'Genetically engineered' or 'Transgenic'.

The majority of the currently available GMOs are obtained from plants, but ongoing experiments will lead to introduce in the market as "future foods" also those derived from GM microorganisms or GM animals. The application of biotechnological techniques has developed crops with innovative performances with main advantages conferred in the agrifood sector with improved agronomic traits and yield. This is achieved through the introduction of resistance to plant diseases, environmental stresses (drought, low temperature) or of increased tolerance of herbicides and insecticide resistance (soybeans, corn, cotton and canola). These modifications have no direct benefit for consumers. However, future genetic modification and field-test are ongoing to obtain organisms with specific sensory quality properties, increased nutritional value (e.g. rice with increased iron and vitamins that may alleviate chronic malnutrition in Asian countries) and health attributes, with increased resistance to spoilage (e.g. sweet potato resistant to a virus that could destroy most of the African harvest), thereby an improved efficiency of food production systems and human health could be achieved. Examples include bananas that produce human vaccines against diseases (e.g. Hepatitis B), fish that mature more quickly, fruit and nut trees that yield years earlier and plants that produce new plastics with peculiar properties.

Some of the benefits obtained by genetic engineering could be achieved by conventional breeding programs. However, while genetic modification permits the expression of the target gene(s) alone, most of the traditional breeding techniques are aimed to change as many genes as possible in the plant genotype with a broader effect and impact on the process efficiency and food quality changes.

Since the early stage of the development of biotechnology to produce GMOs main safety issues have been perceived by the consumers including:

- Impact of the processes applied to the genetic modification.

- Risks related to the new proteins safety and allergenicity.

- Impact of the gene transfer to gut microflora.

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- Role of the GM food in the "conventional" food diet.

- Influence of food processing.

Currently all GM foods should be assessed before being allowed on the market. Harmonized evaluation strategies for the safety assessment of GM foods have been defined since the early stages of the introduction of modern genetic engineering procedures in food production systems, and several organisations have developed guidelines (e.g. International Food Biotechnology Council-IFBC, Organisation for Economic Cooperation and Development-OECD, Food and Agriculture Organization of the United Nations-FAO, World Health Organization-WHO, International Life Sciences Institute-ILSI), taken as reference by most of the countries worldwide for the official regulations for GM foods approval and production. In general, the concept of substantial equivalence has been taken as core concept of the safety evaluation framework for GM foods based on the idea that existing foods can serve as a reference for comparing the properties of a GM food with the appropriate counterpart. Based on the genetic modification, three main categories of genetically modified plant or food could be identified (i) GM substantially equivalent; (ii) substantially equivalent except for the inserted trait; or (iii) not equivalent at all.

The safety evaluation includes a series of compositional analysis of key components, nutrients and natural toxicants along with the evaluation of the phenotypic and agronomic characteristics of the genetically modified plant.

In general, national regulations on GMOs are harmonised on the evaluation procedures of their safety assessment despite some differences exist among countries and geographical areas (eg. Australia, Europe, US, Canada).

GMOs legislation in the European Union

In Europe, a legal framework has been established to ensure that the development of modern biotechnology and of GMOs could occur with respect of safety and human wellbeing and to guarantee that authorized GMOs, or more in general GM products derived from a GMOs, could freely circulate within Europe. It is based on the internationally applied "precautionary principle" that requires the definition of measures to prevent adverse effects on human health and the environment due to the intentional release of GMOs into the environment or the marketing/import of GMOs or products made from GMOs into the EU. It is based on the following aspects:

- High standards safety assessment before any GMO is placed on the market.
- Harmonised procedures for risk assessment and efficient, time-limited and transparent authorisation of GMOs.
- Clear labelling of GMOs placed on the market to allow an informed choice of consumers and end-users.
- Traceability of GMOs when placed on the market.

The reference regulation is the Regulation (EC) 1829/2003 on genetically modified food and feed complemented by the Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and the Directive 2009/41/EC on contained use of genetically modified micro-organisms. Moreover, in 2015 the European Commission has issued a new regulation that allows member states freedom to restrict of prohibit use of authorised GMOs.

The current regulation allows the marketing only of authorised GMOs, foods or feeds made from GMOs according to the results of strict evaluation procedures and safety assessment. Authorizations are granted for a ten-year period by the European Commission through a centralized procedure chaired by the EFSA that conducts the required risk assessments.

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NANOMATERIALS

Nanoscience and nanotechnology are the study and application of extremely small things (nanomaterials) engineered at an a nano-size (molecular and atomic scales) and exert special properties and can be used for applications in various sciences and manufacturing fields, like chemistry, biology, physics, materials science, and engineering.

Current applications of nanomaterials in the food sector include, among others, the following:

- Packaging materials and other materials intended for food contact and used for food containers or tools (e.g. pans).
- Ingredients for foods and feeds to deliver nutritional and health components.
- Nanoencapsulated ingredients and biocomponents.
- Biosensors to detect quality and safety indices during processing and storage.
- Other applications including chemicals, pesticisers and fertilisers.

Nanomaterials can be structured in various forms that allow them to achieve specific performances and technological functionalities. However, there are some main characteristic that make them both valuable in a wide range of practical applications and also cause of some concern about their health and environmental effects, such as:

- Larger surface area for any given mass than conventional materials having the same chemical composition. This may imply a higher chemical reactivity and ability to penetrate cells than bulk materials. Sometimes a material is inert in its larger size form but it becomes reactive at the nanoscale. This could have a potential main impact in our environment like climate change, biodiversity loss and ecosystem loss.
- Lack of instrumental and analytical techniques to determine presence and concentration of nanomaterials in foods and food packaging materials. The current available tools have still difficulties to identify and characterise nanomaterials, in particular when integrated in products, i.e. to measure particle size and size distribution.
- Difficult to estimate and predict exposure.

Nanomaterials intended for food use need to be regulated to guarantee safety of consumers and/or users. In Europe there are sector¬- or product- related legislation (cosmetics, novel foods, biocidal products, medical devices, chemicals) including also aspects on nanomaterials, the requirements for labelling and assessment of their safety.

However, the novel and/or nanospecific properties and peculiar behaviour of nanomaterials as compared to "ordinary" materials arises some uncertainties. Specific actions have to be taken to address the safety of nanomaterials and find the proper tools to assess it properly. Several international regulations require hazard testing of nanomaterials before authorisation to be used in the food sector. However, in most of the cases optimised assessment tools for the evaluation of their safety for the specific use are lacking and specific tests need to be developed.

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Chapter 8

BASIC EU FOOD SAFETY REGULATIONS

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Chapter Objectives

- To review the most important legislation in the European Union on food safety

Introduction

The food safety policy of the European Union (EU) aims to ensure a high level of protection of public health, by assuring that all citizens in the Member States have safe and nutritious food produced from healthy animals and plants. For this purpose, the EU policy guarantees safety along the whole "food chain", from animal feed and food primary production to processing, storage, transport and distribution. This integrated approach means that all food produced in the EU Member States can be traced from "farm to fork" and that consumers are well informed on the origin, composition and way of use of their food.

The free movement of safe food is an essential aspect of the EU internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests. However, this free movement can be achieved only if food safety requirements do not differ significantly from Member State to Member State. Measures adopted by the Member States and the Community governing food and feed should generally be based on risk assessments that should be undertaken in an independent, objective and transparent manner based on the available scientific information and knowledge. It is necessary to ensure that both consumer confidence and the confidence of trading partners are secured through the open and transparent development of food law and through competent authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.

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With regards to this aspect, Regulation (EC) No 178/2002 affirms that food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned (article 14, paragraph 7).

The basic EU legislation on food and feed is laid down in Regulation (EC) No 178/2002 which deals with a wide range of issues related to food safety, such as good hygiene practices, control of food contamination, improvement of a tracking system for live animals as well as feed and food, and a rapid alert system for food and feed (RASFF) that do not satisfy the safety requirements. In addition to these basic rules, more specific food and feed laws cover other important areas such as animal nutrition, including medicated feedstuffs, food and feed hygiene, zoonoses, animal by-products, residues of veterinary medicinal products, contaminants, control and eradication of animal diseases with a human health impact, food and feed labelling, plant protection products, food and feed additives, food contact materials, drinking water, novel foods and genetically modified organisms (GMOs). Moreover, a good information for consumers and a better nutrition by clear labelling and accurate health claims are also implemented. By all these laws, the European citizens benefit from some of the highest food safety standards in the world.

THE EVOLUTION OF FOOD LEGISLATION FROM DIRECTIVE 93/43/EEC TO "HYGIENE PACKAGE"

The basic principles for the EU food safety policy are defined in the EU food legislation that has been reviewed and amended in the past decades, to make it more coherent, comprehensive and flexible, and to provide a greater transparency to consumers. The main objectives are to ensure the same high level of consumer protection in all Member States and to facilitate the free movement of food across all EU countries. There have been many developments with regards to food production and processing, as well as to the official controls required to ensure that acceptable safety standards are met.

The Council Directive 93/43/EEC of 14 June 1993 already described the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules. Article 3 of this Directive declares that preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs must be carried out in a hygienic way and food business operators (FBOs) are required to identify any step in their activities which can be critical to ensuring food safety. Among its basic goals, the EU food law aims to assign the primary responsibility for safe food on industry, producers and suppliers by using the Hazard Analysis and Critical Control Points (HACCP) system, which must be backed up by effective official control and enforcement, and to ensure that food legislation is primarily based on scientific evidence and risk assessment (Green Paper, 1997). After the Commission's Green Paper on food law (COM (1997) 176 final) and subsequent consultations, a new legal framework was proposed by the White Paper on Food Safety (COM (1999) 719 final), in which the roles of all stakeholders in the food chain (i.e. feed manufacturers, farmers and food manufacturers/operators; the competent authorities in the Member States and third countries; the Commission; consumers) have been clearly defined. In that document it is specified that farmers, feed producers and FBOs have the primary responsibility for food safety, whereas the competent authorities monitor and enforce this responsibility through the operation of national surveillance and control systems. Then, the EU Commission evaluates the ability of competent authorities to deliver these systems through audits and inspections at national level for each Member State. Finally, consumers

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must recognize that they are responsible for the proper storage, handling and cooking of food and therefore they are engaged in managing the security of what they will eat (Figure 1). In this way, the "farm to table" policy covering all sectors of the food chain, from primary production to food processing, storage, transport and distribution up to final consumption, can be implemented systematically and in a consistent manner.

Figure 1: The main actors in food safety

It can be resumed that the responsibility for safe food production is shared among FBOs, competent authorities and the EU Commission. The FBOs are responsible for compliance with legislative provisions, and for minimizing risk and health effects on humans. The competent authorities are responsible for ensuring that food safety rules are respected by FBOs. The Commission uses the best available scientific knowledge in developing food safety measures and making proposals to proceed together with EU Parliament and Council in the implementation of new legislative acts by means of the ordinary legislative procedure.

Currently, the EU food legislation covers both primary production of agricultural products and industrial production of processed food. It has evolved over the last thirty years, reflecting a blend of scientific, political and economic purposes, always in the framework of enforcing the EU internal market. The direct consequence of this policy has been the publication of the "Hygiene Package" consisting of five main Regulations, together with many other Regulations aiming to complete the several aspects of food safety legislation (see the Annex).

The Regulation (EC) No 178/2002 provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, ensuring in the meantime an effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient arrangements and procedures to underpin decision-making in matters of food and feed safety. However, to take account of technical and scientific progress in the knowledge of potential hazards to human health, opinions and advices should frequently underpin the EU legislation on food hygiene. To this end, the European Food Safety Authority (EFSA) should be consulted whenever necessary, and a close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health.

The EFSA has been established by Regulation (EC) No 178/2002, and specifically Chapter III of this Regulation describes its mission and tasks (articles 22-23), organization (articles 24-28), operation (articles 29-36) and some other important characteristics such as independence, transparency, confidentiality, and communication (articles 37-42). On the other hand, the EU Commission is assisted by a Standing Committee on Plants, Animals, Food and Feed, as reported in article 58 of Regulation (EC) No 178/2002. This Committee is organized in sections to deal with

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all relevant food safety matters and is consulted each time there is a notification procedure made to the Commission by a Member State which deems necessary to adopt national measures in addition to the EU law, giving the specific reasons and justifying them.

THE OBLIGATIONS OF FOOD BUSINESS OPERATORS

One of the main objectives achieved by the current food legislation is the high level of responsibility given to FBOs with respect to the past years, when the public authorities were engaged to ensure that an adequate supply of safe food was available to consumers. The article 17 of Regulation (EC) No 178/2002 declares that food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met. The Regulation (EC) No 852/2004 reinforces this concept by declaring that primary responsibility for food safety rests with the food business operator (article 1, paragraph 1, letter a), and FBOs shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation (article 3).

The principal goal of Regulation (EC) No 852/2004 is to ensure a high level of consumer protection with regards to food safety. For this purpose, an integrated approach is necessary from primary production up to placing food on the market. So, this Regulation established general rules for FBOs on the hygiene of foodstuffs and as consequence, it repealed the Directive 93/43/EEC, as references to that Directive should be construed as being made to this Regulation (article 17, paragraph 2).

The general approach to be used by FBOs is the application of the Hazard Analysis Critical Control Point (HACCP) system, which identifies specific hazards and preventative measures for their control. The HACCP system consists of seven principles, that have been reported into Regulation (EC) No 852/2004. More in detail, the article 5 of this Regulation specifies that FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the following HACCP principles:

a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels.

b) Identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels.

c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards.

d) Establishing and implementing effective monitoring procedures at critical control points.

e) Establishing corrective actions when monitoring indicates that a critical control point is not under control.

f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively.

g) Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

This general implementation of procedures based on the HACCP system, together with the application of good hygiene practice (GHP), serves to reinforce the FBOs' responsibility. But it can be applied only to FBOs carrying out any stage of production, processing and distribution of food after primary production. Even if the food hazards

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present at level of primary production should be identified and adequately controlled, the application of the HACCP System is not generally feasible, and just only appropriate hygiene practices at this level, such as measures to ensure that primary products are protected against contamination, as well as measures relating to plant health and animal health, including programs for the monitoring and control of zoonoses and zoonotic agents, are recommended (Annex I of Regulation (EC) No 852/2004). It must be highlighted however, that there are interactions between FBOs, including the animal feed sector, and connections between animal health, animal welfare and public health considerations at all stages of production, processing and distribution. This requires adequate communication between the different stakeholders along the food chain from primary production to retail.

The general hygiene requirements intended to all FBOs are well described in the Annex II of Regulation (EC) No 852/2004. The layout, design and construction of both food premises and rooms where food is processed, and the hygienic conditions in which they must be kept and maintained, are detailed in the abovementioned Annex, together with other aspects regarding equipment and facilities, food waste and water supply, sanitation and pest control, personal hygiene and training. Other general hygiene measures to be adopted by all FBOs regard the compliance with the microbiological criteria for foodstuffs set in Regulation (EC) 2073/2005 and following amendments, the maintenance of the cold chain for perishable food, an appropriate storage of raw materials and other ingredients, intermediate and finished products, as well as the material used for wrapping and packaging of foodstuffs.

Besides general rules, specific hygiene rules have been set by Regulation (EC) No 853/2004 for food of animal origin in which microbiological and chemical hazards have frequently been reported. These specific rules supplement those laid down by Regulation (EC) No 852/2004 and apply both to unprocessed and processed products of animal origin. The article 4 of this Regulation affirms that FBOs can place products of animal origin on the market only if they have been prepared and handled exclusively in establishments that have been registered of approved by the competent authorities. Indeed, according to Regulation (EC) No 852/2004 (article 6, paragraph 2), every FBO shall notify the appropriate competent authority of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Moreover, products of animal origin can be placed on the market only if their producers apply a health mark in accordance with Regulation (EC) No 854/2004 or an identification mark as specified in Annex II, Section I of Regulation (EC) No 853/2004. More in detail, this identification mark must be applied before the product leaves the establishment of production, and when a product's packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place. The mark must be oval and indicate: i) the name of the country in which the establishment is located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard; ii) the approval number of the establishment; and iii) the abbreviation of European Community (EC) in proper language of each Member State, only if the product is produced in an establishment located within the Community. The mark must be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging.

With regards to the production of the different food categories reported in the Annexes of Regulation (EC) No 853/2004, FBOs must sometimes put in place procedures that can require some specific skills, e.g. the task to evaluate the health and/or welfare state of animals on arrival at the slaughterhouse, or the compliance with freshness criteria for fishery products that are placed on the market. It is however specified that it is necessary to maintain and, where required to ensure consumer protection, to tighten detailed hygiene rules for products of animal origin.

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The Regulation (EC) N. 2073/2005 on microbiological criteria for foodstuffs

According to Regulation (EC) No 178/2002, food shall not be placed on the market if it is unsafe, and it can be considered unsafe when it is injurious to health or unfit for human consumption (article 14). Furthermore, in this Regulation it is specified that if FBO considers or has a reason to believe that a food imported, produced, processed, manufactured or distributed is not in-compliance with the food safety requirements; the FBO shall immediately initiate procedures to withdraw the food in question from the market and inform the competent authorities thereof (article 19). One of circumstances in which a food can be withdrawn or recalled from the market is when testing against the food safety criteria set out in Chapter 1, Annex I of Regulation (EC) 2073/2005 provides unsatisfactory results.

The need of establishing microbiological criteria for foodstuffs is due to the implementation of the general and specific hygiene measures referred to in article 4 of Regulation (EC) No 852/2004. As consequence, FBOs must perform testing against the microbiological criteria set out in Annex I of Regulation (EC) No 2073/2005, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and GHP. The frequency of sampling may be adapted to the nature and size of the food businesses, except where Annex I provides for specific sampling frequencies. Samples shall be taken from the processing areas and equipment used in food production, but the number of sample units of the sampling plans set out in Annex I may be reduced if the FBO can demonstrate by historical documentation that he has effective HACCP-based procedures (article 5, paragraph 3). With regards to the analyses, FBOs are required to apply the reference methods reported in Annex I or alternative tests if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees (article 5, paragraph 5).

Besides food safety criteria, FBOs must also comply with some process hygiene criteria indicating the acceptable functioning of the production process. These criteria are not applicable to products placed on the market because they reveal an indicative contamination value above which corrective actions are required to maintain the hygiene of the process. Therefore, the stage where the criterion applies depends on the considered food category, i.e. the sampling can vary from the end of the manufacturing process to the specific step of the flow diagram when the number of the microorganisms to be investigated is expected to be the highest.

In this context, the competent authority shall verify compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005, without prejudice to its right to undertake further sampling and analyses with the purpose of detecting and measuring other microorganisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

Simplification of the food safety management system in small retail establishments

Article 4 of Regulation (EC) No 852/2004 on the hygiene of all foodstuffs requires FBOs to comply with the general hygiene requirements detailed in its Annexes I and II, that represent what are called prerequisite programs (PRPs) in an international context (e.g. WHO, FAO, Codex, ISO), whereas the article 5 requires FBOs to put in place, implement and maintain a permanent procedure based on HACCP principles. These two articles constitute the legal basis for a Food Safety Management System (FSMS) to be complied with by all FBOs. This FSMS can be considered as a holistic system of preventive and own-check activities to manage food safety and hygiene in a food business. It includes Good Hygiene Practices (e.g. appropriate cleaning and disinfection, personal hygiene), Good Manufacturing Practices (GMP, e.g. correct dosage of ingredients, appropriate processing temperature), HACCP-based procedures and other management policies and interactive communication aiming to ensure traceability and efficient withdraw/

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recall systems such as RASFF carefully described in Regulation (EC) No 178/2002 and Regulation (EU) No 16/2011 laying down its implementing measures.

Sometimes, the regulations of the "Hygiene Package" contain also flexibility provisions to be adapted to the nature and the size of some establishments. Derogations to general rules may be just granted to facilitate their implementation also in small enterprises, even if the application of such flexibility must remain risk-based and should not compromise food safety. With regards to HACCP-based procedures for instance, in small food businesses it is not always possible to identify the critical control points and, in some cases, the implementation of the PRPs including GHP can be sufficient to control hazards. The European Commission Notice on the implementation of FSMS (Notice 2016/C 278/01) has recently specified the flexibility provided for certain food establishments by the EU legislation. In those sectors where there is a lot of commonality between businesses or the manufacturing process is linear and short, and where the hazard prevalence is well known, generic HACCP guides may be appropriate (e.g. slaughterhouses, establishments handling fishery products, dairy establishments, etc.). Another example can be the retail sector, where the handling of food is in accordance with procedures that are well known and that are part of the usual training of the personnel, as for instance restaurants, catering sectors or retail shops. The definition of "retail" can be found in Regulation (EC) No 178/2002 (article 3), and means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centers and wholesale outlets. Recently, the European Commission requested that the EFSA provided a scientific opinion on hazard analysis approaches within FSMS for small retail establishments, specifically a butcher shop, a grocery, a bakery, a fish shop and an ice cream shop (EFSA Journal 2017;15(3):4697). Given the problems for small retail businesses in developing and implementing effective FSMS, the overriding principle in answering the Commission question was to develop guidelines for a hazard analysis approach (hazard identification, ranking and control options) that were easy to understand and implement. Thus, a simpler, more user-friendly, but equally effective hazard analysis methodology/approach was developed ("simplified" approach). As an example, it was considered sufficient for the retailer to know whether or not a biological, chemical or physical hazard or allergen might occur at each stage without necessarily describing each specific hazard in detail, but instead realizing that a failure to undertake key control activities, such as correct chilled storage or separation of raw from ready to eat/ cooked products, etc. could contribute to the increased exposure of consumers to the hazard.

THE ROLE OF THE COMPETENT AUTHORITIES

The responsibility to enforce the EU legislation lies with the Member States, whose competent authorities monitor and verify, through the organization of official controls, that all rules are effectively complied with. The article 17, paragraph 2 of Regulation (EC) No 178/2002 declares that the Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. However, the performance of official controls shall be without prejudice to FBOs' primary legal responsibility for ensuring food safety, as laid down in Regulation (EC) No 178/2002.

The competent authorities are designated by the Member States for all the areas that fall within the scope of food legislation. They perform the official controls regularly, on a risk-basis and with appropriate frequency, on all the sectors and in relation to all operators, activities, animals and goods governed by the EU legislation. Regulation (EC) No 882/2004 is the main regulation laying down general rules for the performance of official controls aiming to verify the compliance with food and feed law. Official controls must be carried out at any of the stages of production, processing and distribution of feed or food, and any process, material, substance, activity or operation, including

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transport, that are applied to feed or food and on live animals. The competent authorities must ensure the impartiality, quality and consistency of their activity at all levels. These official controls must be carried out using appropriate techniques such as inspections, verifications, audits, sampling and the testing of samples. A correct implementation of these techniques requires appropriate training of the staff performing official controls. Training is also required to ensure that the competent authorities take decisions in a uniform way, regarding specifically the implementation of the HACCP principles. However, the competent authorities may delegate specific tasks related to official controls to one or more control bodies provided that these control bodies have the expertise, equipment and infrastructure required to carry out the delegated tasks.

Official controls on feed and food include the following activities (article 10, paragraph 2 of Regulation (EC) No 882/2004):

(a) Examination of any control systems that feed and food business operators have put in place and the results obtained.

(b) Inspection of.

(i) Primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food.

(ii) Raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food.

(iii) Semi-finished products.

(iv) Materials and articles intended to come into contact with food.

(v) Cleaning and maintenance products and processes, and pesticides.

(vi) Labelling, presentation and advertising.

(c) Checks on the hygiene conditions in feed and food businesses.

(d) Assessment of procedures on GMP, GHP, good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation.

(e) Examination of written material and other records which may be relevant to the assessment of compliance with feed or food law.

(f) Interviews with feed and food business operators and with their staff.

(g) The reading of values recorded by feed or food business measuring instruments.

(h) Controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators.

(i) Any other activity required to ensure that the objectives of this Regulation are met.

In order to have a global and uniform approach with regard to official controls, Member States establish and implement multiannual national control plans in accordance with broad guidelines drawn up at Community level. The multiannual national control plans establish a solid basis for the Commission inspection services to carry out controls in the Member States aiming to verify whether the official controls are organized in accordance with the criteria laid down in Regulation (EC) No 882/2004.

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Specific rules for official controls on products of animal origin are necessary to take account of all aspects that are important for protecting public health and, where appropriate, animal health and animal welfare. The Regulation (EC) No 854/2004 has as its main scope to mirror the scope of the specific hygiene rules for FBOs laid down in Regulation (EC) No 853/2004. Then, it applies only in respect of activities and persons to which Regulation (EC) No 853/2004 applies, even if the official controls include also the verification of FBOs' compliance with Regulation (EC) No 852/2004 with regards to GHP and HACCP-based procedures. They also determine whether these procedures guarantee, to the extent possible, that products of animal origin (i) comply with microbiological criteria laid down under Community legislation; (ii) comply with Community legislation on residues, contaminants and prohibited substances; and (iii) do not contain physical hazards, such as foreign bodies. The Annexes to this Regulation include specific tasks for the competent authorities referred to the different food categories as reported in Regulation (EC) No 853/2004.

Work in progress: Regulation (EU) N. 625/2017

There are many provisions regarding food legislation, the enforcement of which has not, or has only partially, been governed by Regulation (EC) No 882/2004. In order to rationalize and simplify the overall legislative framework, the rules applicable to official controls in specific areas should be integrated into a single harmonized legislative framework for official controls. For that purpose, Regulation (EC) No 882/2004 and other EU acts currently governing official controls in specific areas should be repealed and replaced by Regulation (EU) No 625/2017. In detail, it will repeal Regulations (EC) No 854/2004 and (EC) No 882/2004 and shall apply, unless otherwise provided for in paragraphs 2 to 4 of article 167, from 14 December 2019. Then, the paragraph 2 specifies that it shall apply from 29 April 2022 with regards to the area governed by the rules referred to in:

- Point (g) of Article 1(2), referred to protective measures against pests of plants.
- Article 34(1), (2) and (3), i.e. the methods used for sampling, analyses, tests and diagnoses.
- Point (e) of Article 37(4), i.e. the official laboratory designated by the competent authority that operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008.
- Article 37(5), which declares that the scope of the accreditation of an official laboratory as referred to in point (e) of paragraph 4: (a) shall include those methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses, when it operates as an official laboratory; (b) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods; (c) may be defined in a flexible manner, so as to allow the scope of accreditation to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods.

Instead, the paragraph 4 declares that article 163 of Regulation (EU) No 625/2017 shall apply from 28 April 2017. This article regards the amendments to Regulation (EU) No 652/2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

Finally, articles 92 to 101 of Regulation (EU) No 625/2017 regarding the rules for reference laboratories and reference centres shall apply from 29 April 2018.

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Besides repealing the two major regulations on official controls that are actually in force, this new Regulation shall amend many other acts regarding several rules for competent authorities. All these amendments are reported in specific articles in the body of the text of Regulation (EU) No 625/2017, as well as in correlation tables at the end of the text.

The subject matter of this Regulation is described in article 1 as follows:

(a) The performance of official controls and other official activities by the competent authorities of the Member States.

(b) The financing of official controls.

(c) The administrative assistance and cooperation between Member States in view of the correct application of the rules referred to in paragraph 2.

(d) The performance of controls by the Commission in Member States and in third countries.

(e) The adoption of conditions to be fulfilled with respect to animals and goods entering the Union from a third country.

(f) The establishment of a computerized information system to manage information and data in relation to official controls.

Moreover, the paragraph 2 specifies that the official controls will regard the following areas:

(a) Food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food.

(b) Deliberate release into the environment of GMOs for the purpose of food and feed production.

(c) Feed and feed safety at any stage of production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information.

(d) Animal health requirements.

(e) Prevention and minimization of risks to human and animal health arising from animal by-products and derived products.

(f) Welfare requirements for animals.

(g) Protective measures against pests of plants.

(h) Requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment.

(i) Organic production and labelling of organic products.

(j) Use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

The official controls and other official activities in certain areas, e.g. the production of products of animal origin intended for human consumption (article 18), need of new specific definitions such as "under the responsibility of the official veterinarian" that means that the official veterinarian assigns the performance of an action to an official

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auxiliary; and "under the supervision of the official veterinarian" that means that an action is performed by an official auxiliary under the responsibility of the official veterinarian and the official veterinarian is present on the premises during the time necessary to perform that action. However, the official veterinarian shall remain responsible for the decisions taken following official controls provided for meat production at the slaughterhouses, even if the performance of an action is assigned by him or her to the official auxiliary.

Other specific rules regards the residues of relevant substances in food and feed (article 19), animals, products of animal origin, germinal products, animal by-products and derived products (article 20), welfare requirements for animals (article 21), plant health (article 22), GMOs for the purpose of food and feed production and genetically modified food and feed (article 23), plant protection products (article 24), organic production and labelling of organic products (article 25), protected designations of origin, protected geographical indications and traditional specialities guaranteed (article 26), and newly identified risks in relation to food and feed (article 27).

Nevertheless, while complying with the objectives of this Regulation and in particular as regards food safety requirements, the Member States may adopt national measures implementing pilot projects limited in time and extent, to evaluate alternative practical arrangements for the performance of official controls on the production of meat. Those national measures shall be notified in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 1535/2015. The outcome of the evaluation conducted through the pilot projects shall be communicated to the Commission as soon as available

THE CONSUMERS' - INTEREST ON FOOD SAFETY

The Regulation (EC) No 178/2002 declares among its purposes that food law aims at the protection of the interests of consumers and provides a basis for consumers to make informed choices in relation to the foods they consume (article 8, paragraph 8). Moreover, the article 16 of this Regulation reports that without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the way by which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

The Regulation (EU) No 1169/2011 is the specific provision regarding the labelling of food and the correct information to consumers. It applies to FBOs at all stages of the food chain, as well as to all foods intended for the final consumer, including foods delivered by mass caterers, and foods intended for supply to mass caterers. The provision of food information shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food. Food information includes its identity and composition, specific properties, durability, correct storage and use, but also some compositional attributes that may be harmful to the health of certain groups of consumers, i.e. allergic people. The latter refers to any ingredient or processing aid causing allergies or intolerances that has been used in the manufacture or preparation of a food and is still present in the finished product, even if in an altered form. This information is mandatory both for prepacked and non-prepacked food, i.e. where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale (article 44).

Moreover, for foods that are highly perishable and therefore may constitute an immediate danger to human health after a short period of storage, the date of minimum durability must be replaced by the "use by" date. After the "use by" date a food shall be deemed to be unsafe in accordance with article 14 (paragraph 2 to 5) of Regulation (EC) No 178/2002 and therefore it cannot be placed on the market. Consumers can benefit also from other important

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particulars that are mandatory in the label, such as any special storage conditions and/or conditions of use, as well as the instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions.

Nowadays, consumers show an increasing interest towards the relationship between diet and health and in the choice of an appropriate diet to suit individual needs, so that Regulation (EU) No 1169/2011 added among the mandatory food information requirements also the nutrition declaration, that must include the energy value and the amounts of fat (saturates, mono-unsaturates, polyunsaturates), carbohydrate (sugars, polyols, starch), protein, vitamins or minerals, and salt. However, food information law must prohibit the use of information that would mislead the consumer with regards to the characteristics of the food, food effects or properties, or attribute medicinal properties. Food labels should be clear and understandable to assist consumers who want to make better-informed food and dietary choices, and FBOs should facilitate the accessibility of that information also to visually impaired. For this reason, the mandatory particulars on the label of a prepacked food must be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. The characters must have a font size equal to or greater than 1,2 mm, except for packaging or containers the largest surface of which has an area lower than 80 cm2 so the font size can be equal to or greater than 0,9 mm.

Besides Regulation on food labelling, education and information campaigns can be important strategies to improve consumers' understanding of potential risks to their health. There are many examples of recommendations or advisories intended to final consumers, such as advices that pregnant women, women who may become pregnant, nursing mothers, and young children should avoid eating fish that contain high levels of methylmercury, or the recommendation that in case of raw, marinated or not fully cooked fish the product must be frozen for at least 96 hours at -18°C in domestic freezer, in order to kill viable parasites such as Anisakis spp. that could be present in the flesh of fish.

Furthermore, consumers are today expected to increase their awareness of the potential hazards associated to food and a certain responsibility is required also to them, since both Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 do not apply to:

(a) Primary production for private domestic use.

(b) The domestic preparation, handling or storage of food for private domestic consumption.

(c) The direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer.

In addition, unless expressly indicated to the contrary, Regulation (EC) No 853/2004 shall not apply to retail (article 1, paragraph 5), as defined in Regulation (EC) No 178/2002.

Finally, also consumers are involved into RASFF because where the product to be withdrawn may have reached them, FBOs shall effectively and accurately inform of the reason for withdrawal, and if necessary, recall of products already supplied to consumers when other measures are not sufficient to achieve a high level of health protection (article 19, paragraph 1 of Regulation 178/2002/EC). Moreover, the principles of transparency of Regulation (EC) No 178/2002 require that consumers are informed with regards to food hazards. Article 9 (Public consultation) of this Regulation declares that there shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it, whereas article 10 (Public information) says that where there are reasonable grounds to suspect that a food

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or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

ANNEX – List of laws of interest for food and feed safety (in chronological order)

- Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.
- Commission of the European Communities. Commission Green Paper. The general principles of food law in the European Union. Brussels, 30.04.1997, COM (97) 176 final.
- Commission of the European Communities. White Paper on Food Safety. Brussels, 12 January 2000, COM (1999) 719 final.
- Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (Decision 2002/657/EC).
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene.

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- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
- Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
- Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat.
- Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
- Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.
- Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.
- Commission Regulation (EC) No 589/2008 of 23 June 2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs.
- Commission Regulation (EC) No 598/2008 of 24 June 2008 amending Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards the marketing standards of eggs.
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.
- Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.
- Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries.
- Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

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- Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
- Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council.
- Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing.
- Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002.
- Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.
- Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed.
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.
- Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs.
- Commission Implementing Regulation (EU) No 125/2013 of 13 February 2013 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries.
- Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC.
- Directive (EU) 1535/2015 of the European Parliament and of the Council of 9 September 2015 laying down

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a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

- Regulation (EU) 2283/2015 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.
- Commission Notice 2016/C 278/01 on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/ flexibility of the implementation in certain food businesses.
- Regulation (EU) No 625/2017 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/ EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC.
- EFSA Panel on Biological Hazards (BIOHAZ), 2017. Scientific opinion on hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems.

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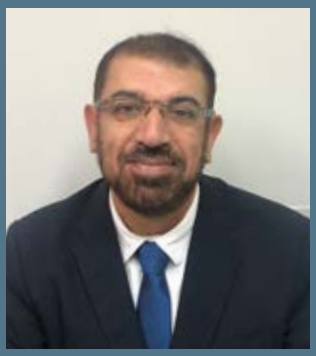

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