To perform a hazard analysis for the development of a HACCP plan, food processors must gain a working knowledge of potential hazards. The HACCP plan is designed to control all reasonably likely food-safety hazards. Such hazards are categorized into three classes: biological, chemical and physical.

Biological hazards include harmful bacteria, viruses or parasites (e.g., salmonella, hepatitis A and trichinella). Chemical hazards include compounds that can cause illness or injury due to immediate or long-term exposure. Physical hazards include foreign objects in food that can cause harm when eaten, such as glass or metal fragments.

It is important to understand that, for the purposes of HACCP, hazards only refer to the conditions or contaminants in food that can cause illness or injury to people. Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage. Economic fraud and violations of regulatory food standards are equally undesirable. All of these defects must be controlled in food processing. However, they often are not directly related to the safety of the product. Unless these conditions directly affect food safety, they are not included in a HACCP plan.
Notes:

It is not within the scope of this course to go into detail on foodborne hazards. That topic is too large and would be covered better in separate microbiology, toxicology and food-processing courses. However, this chapter will increase awareness of the kinds of hazards that may occur in foods. This awareness will prepare participants for recognizing what is and is not appropriate to control with HACCP. Food processors may find it necessary to work with technical experts to develop a HACCP plan.

**Biological Hazards**

Foods can contain biological hazards. These hazards can come from raw materials or from food-processing steps used to make the final product. Table A (at the end of the chapter) provides a list of biological hazards.

- **Microorganisms**

Organisms too small to be seen with the naked eye are called microorganisms. Microorganisms live everywhere: air, dirt, fresh and salt water, skin, hair, animal fur and plants.

Microorganisms are classified into various groups. A few groups important in foods include yeasts, molds, bacteria, viruses and protozoa. Since microorganisms are so widespread, it is important to understand when to be concerned about them and how to deal with them.

Although thousands of kinds of microorganisms exist, only a few pose hazards to humans. These hazardous microorganisms, or pathogens, will be discussed in more detail later.

Many microorganisms are beneficial. Certain kinds of yeast, molds and bacteria help make cheese, sour cream, yogurt and other fermented dairy products. Particular kinds of yeast are used in making beer, wine and other fermented beverages. We add these microorganisms to our foods intentionally, and they cause no harm. In fact, studies show that some of these microorganisms contribute to good health.
People may come into contact with thousands of kinds of yeasts, molds, bacteria, viruses and protozoa daily without ill effect. Therefore, when foods are processed and preserved, food processors and regulators need only be concerned with some microorganisms, particularly pathogens.

Although microorganisms are too small to be seen without a microscope, they are alive and have certain needs to live and grow. Without adequate food, water and temperature, microorganisms stop growing and multiplying. Some die; others stop functioning until they get the elements they need. Some preservation methods, such as drying or smoking, control the water or nutrients in food, making these essential elements unavailable to microorganisms.

Different microorganisms respond differently to air. Like most plants and animals, many microorganisms need air to live and will die or stop growing if deprived. However, many microorganisms can function without air. Some are poisoned by it. Unfortunately, pathogens exist in each of these categories. Although some microorganisms can be controlled by the amount of air they receive, it is not an effective way of controlling all pathogens.

Microorganisms multiply in different ways. The most common method, especially for yeasts, bacteria and protozoa, is to grow large and divide. One microorganism splits into two, two into four, four into eight, eight into sixteen, and so on. By doubling, microorganisms multiply quickly. Under ideal conditions, some bacteria double every 20 minutes. Potentially, one microorganism can multiply to more than 30,000 in five hours and to more than 16 million in eight hours. Fortunately, most microorganisms grow more slowly than this, and we can slow them even more by controlling the food, water and temperature that they need to grow and multiply.
Many pathogenic microorganisms reproduce by dividing in two:

When they grow, microorganisms produce by-products.
- Yeast — bread, beverages, fruit
- Lactic acid bacteria — yogurt, cheese, meats
- *Staphylococcus aureus* — enterotoxin

Most spoiled foods do not present a health risk, and not all food that appears normal is safe to consume.

When microorganisms grow, they often produce by-products. The more they grow, the more by-products they produce. Some of the by-products are desirable in the right foods. For example, when yeasts grow in dough, they produce carbon dioxide, acids and flavors. The dough rises and we make bread. However, when the same yeasts grow and produce the same by-products in another food, such as fruit juice, it may not be desirable. Then we call it spoilage. Such spoilage is undesirable, and processors strive to avoid it in food. In addition, some by-products produced by pathogens are toxic and can cause disease.

Food spoilage or decomposition that can result in a food-safety problem should be prevented or controlled by a HACCP program.

Spoiled food may not look, smell or taste good, but only food spoiled by pathogens or contaminated by toxic microbial by-products can make a person sick. Food spoilage or decomposition that can result in food-safety problems should be prevented or controlled by a HACCP program.

During the processing of foods, the amounts and types of microorganisms can be increased, held constant, reduced or destroyed. Even though processing can be used to destroy harmful microorganisms, many safe microorganisms can survive the treatment and continue to live.

*Example:* Milk is pasteurized, or heat-treated, to destroy pathogens. After pasteurization, milk is safe to drink even though nonpathogenic microorganisms survive.
Among the five groups of microorganisms described earlier, only bacteria, viruses and protozoa include the kinds of microorganisms that can make food unsafe. Generally, yeast and molds do not pose a biological hazard in food. Some molds produce hazardous toxins, but these toxins are considered chemical hazards.

**Bacterial Hazards**

Bacterial hazards are defined as those bacteria that, if they occur in food, may cause illness in humans, either by infection or intoxication. Food-borne infections are caused by swallowing live pathogens that grow within the body, usually in the intestinal tract. They differ from food-borne intoxication, which is a condition caused by swallowing preformed toxins (i.e., toxins produced by microorganisms in the food before it is eaten).

Bacterial hazards can also be grouped into sporeformers and non-sporeformers. Certain types of bacteria (e.g., *Clostridium* and *Bacillus* spp.) pass through a dormant stage in their life cycle called a spore. Although the microorganism exists as a spore, it is very resistant to chemicals, heat and other treatments that would normally be lethal to nonsporeforming bacteria. Because they are dormant, spores are not hazardous as long as they stay spores. Unfortunately, if they survive a processing step designed to kill nonsporeforming bacteria, they may become a hazard in the food if they are allowed to grow. When sporeformers are a concern, the process steps used to control them are often much more severe than if only nonsporeformers need to be controlled.
Notes:

Sporeforming Bacteria (Pathogens):
- *Clostridium botulinum*
  - Proteolytic
  - Nonproteolytic
- *Clostridium perfringens*
- *Bacillus cereus*

Nonsporeforming Bacteria:
- *Brucella abortis, B. suis*
- *Campylobacter* spp.
- Pathogenic *Escherichia coli* (e.g., *E. coli* 0157:H7)
- *Listeria monocytogenes*
- *Salmonella* spp. (e.g., *S. typhimurium, S. enteriditis*)
- *Shigella* spp. (e.g., *S. dysenteriae*)
- Pathogenic *Staphylococcus aureus*
- *Streptococcus pyogenes*
- *Vibrio* spp. (e.g., *V. cholerae, V. parahaemolyticus, V. vulnificus*)
- *Yersinia enterocolitica*

Example:
The following are examples of bacterial hazards found in food and why they are considered hazards:

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Clostridium botulinum</em></td>
<td>Causes an intoxication that affects the central nervous system and causes shortness of breath, blurred vision, loss of motor capabilities and death.</td>
</tr>
<tr>
<td>(sporeformer)</td>
<td></td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>Causes an infection with mild flulike symptoms. Severe forms of listeriosis are possible in people with weakened immune systems, causing septicemia, meningitis, encephalitis and stillbirths.</td>
</tr>
<tr>
<td>(nonsporeformer)</td>
<td></td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Causes an infection with the following symptoms: nausea, vomiting, abdominal cramps, diarrhea, fever and headache. Death is possible in people with weakened immune systems.</td>
</tr>
<tr>
<td>(nonsporeformer)</td>
<td></td>
</tr>
</tbody>
</table>
• **Viral Hazards**

Like other microorganisms, viruses exist everywhere. They are very small particles that cannot be seen with a light microscope and cannot reproduce by themselves. Although they are alive, viruses differ from other microorganisms in what they need to live and how they multiply. Viruses exist in foods without growing, so they need no food, water or air to survive. They do not cause spoilage. Viruses cause illness by infection. They can infect living cells and reproduce inside the host cell using material from it. Viruses only grow once they enter a suitable host. Only some viruses consider humans a suitable host. Viruses can survive in human intestines, contaminated water and frozen foods for months.

*Overhead 12*

### Hazards from viruses in foods
- What are viruses?
- Where do they come from?
- How do they reproduce?
- How can they be controlled?
- What are some examples? (Table A)

Viruses can be found in people who were previously infected but are no longer ill. Viruses can also be present in people who show no outward signs of illness (carriers). Transmission of viruses to foods is usually related to poor hygienic practices. People who have viruses shed the particles when they defecate. Food handlers with viruses can transmit them to food if they forget to wash and sanitize their hands properly. This route can also result in contamination of food with bacterial hazards.

*Example:*
The following are examples of viral hazards found in food:

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Hepatitis A virus</em></td>
<td>Causes fever and abdominal discomfort, followed by jaundice.</td>
</tr>
<tr>
<td><em>Norwalk virus</em></td>
<td>Causes nausea, vomiting, diarrhea and abdominal pain (gastroenteritis). Headache and low-grade fever may also occur.</td>
</tr>
</tbody>
</table>

*Continued*
Parasites are organisms that need a host to survive, living on or within it. Thousands of kinds of parasites exist worldwide. Only about 20 percent can be found in food or water, and less than 100 are known to infect people through consumption. There are two types of parasites that can infect people through food or water: parasitic worms and protozoa. Parasitic worms include roundworms (nematodes), tapeworms (cestodes) and flukes (trematodes). These worms vary in size from barely visible to several feet in length. Protozoa are single-cell animals, and most cannot be seen without a microscope.

Table A at the end of the chapter lists the parasitic protozoa and worms most likely to be found in the U.S. food supply. For most foodborne parasites, the food is part of their natural life cycle (e.g., nematode worms in fish and meat). They have the opportunity to infect humans when people eat them along with the food. The two factors most important to parasitic survival are a proper host (i.e., not all organisms can be infected by parasites) and a suitable environment (i.e., temperature, water, salinity, etc.).

Some parasites may be transmitted through food or water that is contaminated by fecal material shed by infected hosts. Methods of preventing transmission of parasites to foods by fecal contamination include:

- good personal hygiene practices by food handlers,
- proper disposal of human feces,
- elimination of insufficiently treated sewage to fertilize crops, and
- proper sewage treatment.
Consumer exposure to parasites depends on food selection, cultural habits and preparation methods. Most parasites do not harm humans but may be aesthetically unpleasant. Parasitic infections are normally associated with raw or undercooked foods because thorough cooking of foods eliminates all foodborne parasites. In specific instances, freezing can be used to destroy parasites in food.

Example:
The following are examples of parasite hazards found in food:

<table>
<thead>
<tr>
<th>Organism</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Giardia lamblia</em></td>
<td>This protozoa causes diarrhea, abdominal cramps, fatigue, nausea, flatulence (intestinal gas) and weight loss. Illness may last for one to two weeks, but chronic infections can last months to years.</td>
</tr>
<tr>
<td><em>Entamoeba histolytica</em></td>
<td>This protozoa causes dysentery (severe, bloody diarrhea).</td>
</tr>
<tr>
<td><em>Ascaris lumbricoides</em></td>
<td>This roundworm causes intestinal and lung infection.</td>
</tr>
<tr>
<td><em>Diphyllobothrium latum</em></td>
<td>This tapeworm attaches itself to the intestinal wall and can grow to 3 to 7 feet. Symptoms include abdominal pain, cramping, flatulence and diarrhea.</td>
</tr>
</tbody>
</table>

Parasitic Protozoa and Worms:
- *Cryptosporidium parvum*
- *Diphyllobothrium latum*
- *Entamoeba histolytica*
- *Giardia lamblia*
- *Ascaris simplex*
- *Ascaris lumbricoides*
- *Taenia solium, T. saginata*
- *Trichinella spiralis*
- *Pseudoterranova dicepiens*
Chemical Hazards

Chemical contamination can happen at any stage in food production and processing. 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.

Chemical hazards can be separated into three categories:
- Naturally occurring chemicals.
- Intentionally added chemicals.
- Unintentionally or incidentally added chemicals.

The types of chemicals included in these categories are listed in Table B at the end of the chapter.

**Naturally Occurring Chemicals (including allergens)**

These chemicals are derived from a variety of plants, animals or microorganisms. In most cases, these naturally occurring chemicals are found prior to or during harvest. Although many naturally occurring toxins are biological in origin, they are traditionally categorized as chemical hazards.

*Example:*
The following are examples of foods containing naturally occurring chemical hazards:

<table>
<thead>
<tr>
<th>Source</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain fish species (e.g., tuna, mahi-mahi)</td>
<td>Spoilage of certain species of fish can result in production of toxic levels of histamine and related compounds.</td>
</tr>
<tr>
<td>Nuts, Seafood</td>
<td>Certain varieties or species produce an allergic reaction in sensitive people.</td>
</tr>
<tr>
<td>Corn</td>
<td>Certain molds that grow on corn can create toxins (e.g., aflatoxin).</td>
</tr>
<tr>
<td>Molluscan shellfish</td>
<td>Some of the microscopic organisms and plants upon which they feed can produce a toxin, such as domoic acid, that affect people but not shellfish.</td>
</tr>
</tbody>
</table>

Explanatory Note:
Some of these limits (such as for aflatoxin, lead and histamine) can be found in Title 21 of the Code of Federal Regulations and in the FDA Compliance Policy Guides.

Explanatory Note:
Allergic reactions are caused by proteins (allergens) that react with the body’s natural immune system. This type of chemical hazard is of concern to individuals who are sensitive to the allergen.*

* It is particularly important that foods formulated with components that are known to produce these types of reactions clearly identify these ingredients on the label. HACCP-type controls may be necessary when it may not be obvious that the food contains the allergen.
• Intentionally Added Chemicals

These chemicals are intentionally added to food at some point during the food’s growth and distribution. Intentionally added chemicals are safe when used at established safe levels but can be dangerous when those levels are exceeded.

Example:
The following are examples of food additives that may be chemical hazards if used improperly:

<table>
<thead>
<tr>
<th>Source</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>FD&amp;C Yellow No. 5</td>
<td>Can produce an allergic-type reaction in (food coloring) sensitive people.</td>
</tr>
<tr>
<td>Sodium nitrite</td>
<td>Can be toxic in high concentrations.</td>
</tr>
<tr>
<td>(preservative)</td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td>Can be toxic in high concentrations.</td>
</tr>
<tr>
<td>(nutrient supplement)</td>
<td></td>
</tr>
<tr>
<td>Sulfiting agents</td>
<td>Can cause allergic-type reaction in sensitive people.</td>
</tr>
<tr>
<td>(preservative)</td>
<td></td>
</tr>
</tbody>
</table>

Types of Naturally Occurring Chemical Hazards:

- Mycotoxins (e.g., aflatoxin)
- Scombrotxin
- Ciguatoxin
- Shellfish toxins
  - Paralytic shellfish poisoning (PSP)
  - Diarrheic shellfish poisoning (DSP)
  - Neurotoxic shellfish poisoning (NSP)
  - Amnesic shellfish poisoning (ASP)/Domoic Acid

Notes:

Explanatory Note:

Certain food additives must have prior approval before they can be used in foods. Before using a new food additive, food processors should review the appropriate regulations for approval status and any limitations on its use.

Chemicals such as lubricants, cleaning compounds, sanitizers and paints must have prior approval.
Unintentionally or Incidentally Added Chemicals:

- Agricultural chemicals (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones)
- Prohibited substances (Code of Federal Regulations, Chapter 21, Section 189)
- Toxic elements and compounds (e.g., lead, zinc, arsenic, mercury, cyanide)
- Secondary direct and indirect
  - Plant chemicals (e.g., lubricants, cleaning compounds, sanitizers, paint)

**Unintentionally or Incidentally Added Chemicals**

Chemicals can become part of a food without being intentionally added. These incidental chemicals might already be in a food ingredient when it is received. For example, certain seafood may contain small but legal residues of approved antibiotics. Packaging materials that are in direct contact with ingredients or the product can be a source of incidental chemicals, such as sanitizers or inks. Most incidental chemicals have no effect on food safety, and others are only a concern if they are present in too high an amount. Incidental chemicals also include accidental additions of prohibited substances such as poisons or insecticides that may not be allowed at any level.
Example:
The following are examples of incidental contaminants that may be chemical hazards:

<table>
<thead>
<tr>
<th>Source</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agricultural chemicals (e.g., pesticides, herbicides)</td>
<td>Can be acutely toxic if present in the food at high levels and may cause health risks with long-term exposure.</td>
</tr>
<tr>
<td>Cleaning chemicals (e.g., acids, caustics)</td>
<td>Can cause chemical burns if present in the food at high levels.</td>
</tr>
<tr>
<td>Maintenance chemicals (e.g., lubricants, paint)</td>
<td>Chemicals that are not approved for food use and may be toxic.</td>
</tr>
</tbody>
</table>

**Physical Hazards**

Physical hazards include any potentially harmful extraneous matter not normally found in food. When a consumer mistakenly eats the foreign material or object, it is likely to cause choking, injury or other adverse health effects. Physical hazards are the most commonly reported consumer complaints because the injury occurs immediately or soon after eating, and the source of the hazard is often easy to identify. Table C at the end of the chapter lists the types of materials that can be physical hazards in foods.

Example:
The following are examples of materials that may be physical hazards:

<table>
<thead>
<tr>
<th>Material</th>
<th>Why a hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glass</td>
<td>Cuts, bleeding; may require surgery to find or remove.</td>
</tr>
<tr>
<td>Metal</td>
<td>Cuts, broken teeth; may require surgery to remove.</td>
</tr>
</tbody>
</table>

Explanatory Note:
A partial list of prohibited substances can be found in Title 21, part 189 of the Code of Federal Regulations, “Substances Prohibited from Use in Human Food.”

Explanatory Note:
Exercise caution in listing bone fragments as physical hazards. The presence of bone should be kept as low as possible, which would be product and process dependent. However, in many products (especially seafood), bone fragments are uncontrollable quality defects and not consumer-safety hazards.
## TABLE A

### Biological Hazards

#### I. Bacteria

**A. Sporeformers**
- *Clostridium botulinum*
- *Clostridium perfringens*
- *Bacillus cereus*

**B. Nonsporeformers**
- *Brucella abortis, B. suis*
- *Campylobacter spp.*
- Pathogenic *Escherichia coli* (e.g., *E. coli* O157:H7)
- *Listeria monocytogenes*
- *Salmonella* spp. (e.g., *S. typhimurium, S. enteriditis*)
- *Shigella* spp. (e.g., *S. dysenteriae*)
- *Staphylococcus aureus*
- *Streptococcus pyogenes*
- *Vibrio* spp. (e.g., *V. cholerae, V. parahaemolyticus, V. vulnificus*)
- *Yersinia enterocolitica*

#### II. Viruses

- *Hepatitis A and E*
- *Norwalk virus group*
- *Rotavirus*

#### III. Parasitic Protozoa and Worms

- *Anasakis simplex*
- *Ascaris lumbricoides*
- *Cryptosporidium parvum*
- *Diphyllobothrium latum*
- *Entamoeba histolytica*
- *Giardia lamblia*
- *Pseudoterranova dicepiens*
- *Taenia solium, T. saginata*
- *Trichinella spiralis*
**TABLE B**

Types of Chemical Hazards

I. **Naturally Occuring Chemicals**
   - Mycotoxins (e.g., aflatoxin)
   - Scombrotoksin (histamine)
   - Ciguatoxin
   - Mushroom toxins
   - Shellfish toxins
     - Paralytic shellfish poisoning (PSP)
     - Diarrheic shellfish poisoning (DSP)
     - Neurotoxic shellfish poisoning (NSP)
     - Amnesic shellfish poisoning (ASP)/Domoic acid
   - Pyrrolizidine alkaloids
   - Phytohemagglutinin

II. **Intentionally Added Chemicals**
   - Food additives
     - Direct (allowable limits under GMPs)
     - Preservatives (e.g., nitrite and sulfiting agents)
     - Nutritional additives (e.g., niacin)
     - Color additives

III. **Unintentionally or Incidentally Added Chemicals**
   - Agricultural chemicals
     - (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones)
   - Prohibited substances
     - (Code of Federal Regulations, chapter 21, section 189)
   - Toxic elements and compounds
     - (e.g., lead, zinc, arsenic, mercury and cyanide)
   - Polychlorinated biphenyls (PCBs)
   - Plant chemicals
     - (e.g., lubricants, cleaning compounds, sanitizers and paints)
**TABLE C**
Physical Hazards and Common Sources

<table>
<thead>
<tr>
<th>Material</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glass</td>
<td>Bottles, jars, light fixtures, thermometers, gauge covers</td>
</tr>
<tr>
<td>Metal</td>
<td>Machinery, agricultural fields, buckshot, birdshot, wire, staples, buildings, employees</td>
</tr>
</tbody>
</table>