SRINIVASAN COLLEGE OF ARTS & SCIENCE

(Affiliated to Bharathidasan University, Trichy)

PERAMBALUR – 621 212.

DEPARTMENT OF MICROBIOLOGY

Course : B.Sc Year: **III** Semester: **VI**

Course Material on:

FOOD MICROBIOLOGY

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FOOD MICROBIOLOGY

OBJECTIVES

The subject aims to study about the food microflora, food fermentations, food preservation, food spoilage, food poisoning and food quality control.

Unit I

Concepts of food and nutrients - Physicochemical properties of foods - Food and microorganisms – Importance and types of microorganisms in food (Bacteria, Mould and Yeasts) - Sources of contamination- Factors influencing microbial growth in food – pH, moisture, Oxidation-reduction potential, nutrient contents and inhibitory substances.

Unit II

Food Fermentations – Manufacture of fermented foods - Fermented dairy products (yoghurt and Cheese) - plant products- Bread, Sauerkraut and Pickles - Fermented beverages- Beer. Brief account on the sources and applications of microbial enzymes – Terminologies - Prebiotics Probiotics and synbiotics. Advantages of probiotics.

Unit III

Contamination, spoilage and preservation of cereals and cereal products - sugar and sugar products -Vegetables and fruits- meat and meat products- Spoilage of canned food.

Unit IV

Food borne diseases and food poisoning – *Staphylococcus*, *Clostridium*, *Vibrio parahaemolyticus* and *Campylobacter jejuni. Escherichia coli* and *Salmonella* infections, Hepatitis, Amoebiosis. Algal toxins and Mycotoxins.

Unit V

Food preservations: principles- methods of preservations-Physical and chemical methods- food sanitations- Quality assurance: Microbiological quality standards of food. Government regulatory practices and policies. FDA, EPA, HACCP, ISI. HACCP – Food safety- control of hazards.

UNIT 1

CONCEPT OF FOOD AND NUTRITION

The term 'food' brings to our mind countless images. We think of items not only that we eat and drink but also how we eat them and the places and people with whom we eat and drink. Food plays an important role in our lives and is closely associated with our existence. It is probably one of the most important needs of our lives. The food that we eat is composed of small units that provide nourishment to the body. These are required in varying amounts in different parts of the body for performing specific functions. This means that good nutrition is essential for good health. However, if our diet provides the important units in incorrect amounts, either very less or in excess of what is required, it results in an imbalance of nutrients in your body. The condition is responsible for various deficiency diseases and slow or no growth of the body. In this lesson you will learn about why food is essential, its functions and components. You will also be introduced to the terms like ‘nutrition’ and ‘nutrients’. After learning the meaning of these terms, you will then learn the sources and functions of the nutrients and the amounts required by different individuals.

WHAT IS FOOD?

The term ‘food’ refers to anything that we eat and which nourishes the body. It includes solids, semi-solids and liquids. Thus, two important features for any item to be called food are: (i) It should be worth eating, that is, it should be ‘edible’. (ii) It must nourish the body.

Have you ever wondered why food is considered a basic necessity?

Food is anything that we eat and which nurishes our body. It is essential because it contains substances which perform important functions in our body.

FUNCTIONS OF FOOD

There are basically three important functions of food:

1. Social Function Food and eating have significant social meaning. Sharing food with any other person implies social acceptance. Food is also an integral part of festivity every where in the world. Have you noticed that certain occasions such as birth of a child or a marriage or birthdays, are celebrated by

having feasts and serving delicacies? Food also has a specific significance and meaning in the religious context.

2. Psychological Function We all have emotional needs, such as need for security, love and affection. Food is one way through which these needs are satisfied. For example, how do you feel when your mother prepares your favourite food or dish? You feel that she loves you and cares for you. Food is often served as a reward also. Do you recall giving a chocolate because some one had been good to you? Similarly, certain foods become associated with sickness, such as khichri and bland foods. Sickness is an unpleasant experience, hence, even the food items served during this state may be associated with unpleasant feelings.

3. Physiological Function There are three physiological functions performed by food. These are energy giving, body building, regulating body processes and providing protection against diseases. Let us see them in detail.

(i) Food provides energy Everybody needs energy to do work. Energy is required for walking, studying, eating, working in the house or outside. You get this energy from the food that you eat. You need energy even when you are resting. Can you tell why? Different organs inside your body are always working, for example, heart is pumping blood, stomach is digesting food, lungs are breathing in air, etc. All these organs need energy for their respective functions and food provides that energy. (ii) Food helps in body building Have you ever wondered how a small child grows into an adult? Our body is already made up of thousands of small cells. New cells are added to these to help the body to grow. Food is needed for the formation of new cells. Cells also die or are damaged due to injury. New cells need to be formed and this repair work is done with the help of food.

(iii) Food regulates body processes and provides protection against diseases Regulatory functions refer to the role of food in controlling body processes, for example, our body temperature is maintained at 98.60 F or 370 C. Similarly, the heart beats are also maintained at 72 beats/minute. Excretion of waste products from the body is also regular. If not, the body suffers from a disease called constipation which can lead to further complications. All these processes are regulated by the food that you eat. The food that we eat gives us strength to fight against disease germs. Look at the illustration 4.1 to learn about the functions of food.

NUTRITION AND NUTRIENTS Let us now read about the meaning of nutrition. All of us eat food. Food provides nourishment to the body and enables

it to stay fit and healthy. The food that we eat undergoes many processes, like, first the food is digested, then it is absorbed into blood and transported to various parts of the body where it is utilized. The waste products and undigested food are excreted from the body.

NUTRITION is the process by which food is taken in and utilized by the body.

NUTRITION = Eating ---Digestion---- Absorption---- Transportation ---- Utilization

Nutrients and their Functions

We all know that food helps in the nourishment and health of our body. The nourishment is brought about by small units called nutrients present in food. Now what are these nutrients?

Nutrients are the chemical substances present in food and are responsible for nourishing the body.

Nutrients are of two types:

1. Macronutrients

2. Micronutrients

Both macronutrients and the micronutrients are equally essential for good health. Each nutrient plays a significant role in the body.

Macronutrients

These are present in large quantities in foods and are also required in large amounts by the body.

Carbohydrates, proteins, fats and oils are macronutrients.

A. Carbohydrates

(i) Available carbohydrates

Carbohydrates are present in a large quantity as starch in cereals, legumes, pulses and potatoes. They are present as simple carbohydrates in sugar, jaggery, fruits, honey and milk. Starch and sugars are easily digested and provide energy to the body.

(ii) Unavailable carbohydrates or dietary fibre

They are present in the form of cellulose and hemicellulose which are not digested in our body. They add bulk to the stool and help in easy defecation process.

Energy can be derived from carbohydrates, fats and proteins and it is measured in kilo calories. However, carbohydrates are cheapest sources of energy. If there is a short supply of carbohydrates and fats in our body, proteins are utilized for energy production. Function of proteins is to provide for body building. Therefore, carbohydrates have to be consumed in proper amounts to spare proteins for body building purpose.

Functions of carbohydrates are summarized here:-

Carbohydrates provide energy

Carbohydrates are the main source of energy

Carbohydrates spare proteins for body building function

Dietary fibre increases the bulk in stool and helps in defecation

1 gm of carbohydrate gives 4kcal of energy. Kilocalorie is the measure of energy in food.

Food sources of carbohydrates are:

Cereals - wheat, rice, bajra, maize, etc.

Pulses - Rajma, channa, all dals

Roots and tubers - potatoes, sweet potatoes, beetroot and tapioca Sugar, jaggery

B. Proteins

Protein are needed in the body for body building.

1 gm of protein gives 4kcal of energy

Proteins are made up of smaller units known as amino acids. There are all together 22 amino acids, out of which there are 8 amino acids which our body cannot manufacture. Rest of the amino acids can be manufactured by the body. Essential amino acids are those which our body cannot manufacture and hence have to be supplied through the diet. Non essential amino acids are those amino acids which our body can manufacture.

Functions and sources of proteins

Functions

(i) Needed for growth, maintenance and repair of tissues.
(ii) Necessary for production of enzymes, hormones, antibodies, haemoglobin, etc.
(iii) Help in the clotting of blood
(iv) Provide energy, if necessary

Sources

–Meat, poultry, fish, eggs

- Milk, cheese, paneer, curd

- soybeans, peas, pulses,

- cereals, nuts and oilseeds like til, groundnuts, etc.

Special features

(i) Animal proteins, i.e., proteins from meat, eggs, milk, etc., are better than vegetable proteins, i.e., proteins, from pulses, cereals, etc. This is because proteins from vegetable sources do not contain all essential amino acids.
(ii) (ii) Including two or more sources of vegetable proteins in each meal helps to improve the quality of proteins and their utilization.

C. Fats and Oils

Fats and oils are the concentrated source of energy in our diet. 1 gm of fat gives 9 kcal of energy. Fats are made up of small units called fatty acids. The nature of fats is dependent on the type of fatty acids present. Fatty acids may be saturated or unsaturated. Saturated fatty acids are found in solid fats whereas oils contain more of unsaturated fatty acids. Vegetable oils are rich in unsaturated fatty acids.

Do you know there is a difference between fats and oils? If a substance is liquid at room temperature it is called oil and if it is solid at the room temperature, it is known as fat.

Structure and physical properties of foods
Physical properties of food are aspects such as colour, structure, texture, rheology and interfacial properties, and composition. We have a range of instrumental methods for objectively characterising and measuring food structure and physical properties. These are useful for applications such as new

product development, benchmarking, reformulation and specification.

Colour

Consistent and accurate measurements of the colour and visual appearance of food products is extremely important. Various methods are available for colour measurement, allowing a wide variety of sample types to be measured. Colour measurement results are typically provided on the CIELAB scale. Others are available on request.

Structure

The structure of food influences texture. Examples include porous products such as aerated foods and bakery products where the bubble structure affects softness, and starch-based snacks where it affects crispiness.

Food structure analysis using X-ray micro-CT

X-ray micro-CT offers non-destructive imaging and structure measurement in 3D. Images and movies showing the internal structure of products can be generated. Measurements of porosity, bubble size distribution and structure thickness (wall size) can be performed.

Texture

Food texture is an important sensory attribute as it affects the way food tastes and how it feels in the mouth. The texture depends on the rheological properties of the food and evaluation involves measuring the response of a food when it is subjected to forces such as cutting, shearing, chewing, compressing or stretching.

Rheology and interfacial properties

The rheological properties of food materials are important in determining the texture as well as how they behave physically when subjected to physical forces and forced to flow. The rheological properties of raw materials, intermediate products such as batters and doughs as well as final products can be studied.

Thermal analysis

Thermal analysis techniques measure the physical and chemical properties of foods as a function of temperature or time.

Compositional mapping

Many food products have a non uniform distribution of composition. For example, fried products have a higher fat content near surfaces, and baked products have a higher moisture content in the centre of the product. Compositional mapping techniques allow these gradients to be measured and visualised.

introduction to the Microbiology of Food

The Microorganisms

The tiniest life forms are bacteria, yeasts, molds, and viruses, termed "microorganisms" because of their size (micro meaning small and organism meaning living being).

Bacteria

Bacteria are the most important microorganisms to the food processor. Most are harmless, many are highly beneficial, some indicate the probable presence of filth, disease organisms, spoilage and a few cause disease. There are thousands of species of bacteria, but all are single-celled and fall into three basic shapes: spherical, straight rods, and spiral rods. To see them, you need a microscope that magnifies about 1000-fold. All bacteria reproduce by dividing into two cells. The two cells then divide to become 4, 4 become 8, and so forth. Under ideal conditions, this doubling may occur as frequently as every 15 minutes, so that within 5 hours there will be more than a million cells from the original single cell. If there are 1000 original cells instead of a single one, there will be over 1 billion cells in 5 hours.

Some rod-shaped bacteria are capable of existing in two forms, dormant spores and active vegetative cells. Vegetative cells form spores under adverse conditions as a means of survival. Spore forms preserve the bacteria from starvation, drying, freezing, chemicals, and heat. When conditions become favorable, the spores germinate, with each spore again becoming a vegetative cell with the ability to reproduce. Among the bacteria, sporulation is not a means of reproduction since each cell forms a single spore which later germinates into a single cell again. Most sporulating bacteria that grow in the presence of air belong to the Genus Bacillus, and most that grow only in the absence of air belong to the Genus Clostridium.

Yeasts and Molds

Yeasts are oval-shaped and slightly larger than bacteria. They reproduce most often by budding. In budding each cell can produce several buds, or swellings, which break away to form new, fully formed daughter cells.

Molds as found on bread, fruit, damp paper, or other surfaces are actually composed of millions of microscopic cells joined together to form chains. The chains usually have numerous branches, called hyphae. Molds can thrive in conditions too adverse for bacteria or yeasts. They reproduce by spores that are frequently present as green or black masses on the protruding hyphae.

Yeasts and molds grow on most foods, on equipment, and building surfaces where there are small amounts of nutrient and moisture. Since bacteria grow faster, they greatly outnumber yeasts and molds in most foods. However, bacteria find conditions of low pH, moisture, or temperature and high salt or sugar unfavorable. In such environments, yeasts or molds predominate. Thus, they can be a problem in dry foods, salted fish, bread, pickles, fruits, jams, jellies, and similar commodities.

Viruses

Viruses are the smallest and simplest microorganisms. Unlike bacteria, yeasts, and molds, viruses are incapable of reproducing independently. Instead, they must first invade the cells of another living organism called the host, before they can multiply. Hence, they are parasitic. Viruses are normally specific in their selection of host cells, some infecting but one species, while others are capable of infecting closely related species. As a result, viruses which infect bacteria, called bacteriophages, cannot infect human beings or other animals. On the other hand, several animal viruses, known as zoonotis, can infect human beings.

The viruses are important to the food process in two respects:

1. As a bacteriophage of lactic or other fermentative bacteria. Bacteriophage infections of starter cultures can interfere seriously with the manufacture of cheese, buttermilk, sauerkraut, pickles, wine, beer, and other desirable fermentative products.
2. As disease transmitted by food to human beings. Although viruses require a live host cell and cannot multiply in foods, they can remain viable and infectious for long periods of time, even under highly adverse conditions, such as drying, freezing, and pasteurization.

Factors Affecting Growth of Microorganisms

The food processor reduces potential problems from microorganisms in several ways:

- Removing or destroying them by trimming, washing, heating, pickling, by adding chemicals, or by encouraging competition by acid- or alcohol-forming organisms.
- Minimizing contamination from equipment, people, the environment, and from unprocessed food.

- Minimizing microbial growth on equipment, by cleaning and sanitizing, and in the product itself by adjusting storage temperature, pH, and other environmental factors.

  Although each factor affecting growth is considered separately in the following discussion, these factors occur simultaneously in nature. When more than one condition is somewhat adverse to microbial growth, their inhibitory effects are cumulative.

  Temperature

  Temperature is the most efficient means to control microbial growth. Based on their tolerance of broad temperature ranges, microorganisms are roughly classified as follows:

1. Psychrophies grow only at refrigeration temperatures.
2. Psychrotrophs grow well at refrigeration temperatures, but better at room temperature.
3. Mesophiles grow best at or near human body temperature, but grow well at room temperature.
4. Thermophiles grow only at temperatures about as hot as the human hand can endure, and usually not at all at or below body temperature.

  To be more specific about these temperature limits of growth is to enter the controversy that has continued since the infancy of microbiology, for there are many species that grow in temperature ranges overlapping these. However, for food microbiology these conclusions are pertinent:

1. Some psychrotrophic microorganisms grow very slowly in foods below freezing, but usually not below 19°F. There are a few reports of growth, usually of molds, at 14°F, but no reliable reports of growth below that temperature. This means that the standard storage temperature for frozen foods, O°F, does not permit microbial growth. However, many microorganisms survive freezing (Michener and Elliott, 1964).
2. Most psychrotrophs have difficulty growing above 90°F.
3. Most foodborne disease organisms are mesophiles. The food processor can feel safe in the knowledge that foods held above or below the limits in Figure 1 and rotated properly will remain safe. A good rule of thumb is to store perishable foods below 40°F or above 140°F.
4. In the temperature range where both mesophilic and psychrotrophic organisms grow (about 41°F. to about 90°F), the psychrotrophs grow more rapidly,

causing spoilage and at the same time frequently interfering with the growth of foodborne disease organisms (Elliott and Michener, 1965).

Within the growth range, the rate of growth increases rapidly as the temperature is raised (Figure 2). Conversely, microbial growth rates decrease rapidly as the temperature is lowered and, hence, food spoilage occurs much more slowly. This effect is especially marked near the freezing point. Note in Figure 3 that a drop from about *41°F* to about 32°F will more than double the shelf life (time before spoilage).

Water Activity

Water activity (a_w) is a term describing the availability of water to microorganisms. It is only roughly related to percent moisture. Pure water has an a_w of 1.00, and the atmosphere above the water in a closed container will have an equilibrium relative humidity (ERH) of 100%. If we add an ounce of rocks to a quart of water in such a container, the ERH and the a_w will not change. But if we add an ounce of salt, the ERH will fall to about 98 % and the a_w to 0.98. Rocks do not dissolve in water but salt does, thereby reducing the proportion of water that can enter the atmosphere. Likewise, the amount of water available to microorganisms present in the solution is reduced. Yet the percent moisture is the same in the container with rocks as it is in the container with, salt, namely, 98%.

The GMP regulations for low-acid canned foods defined water activity as the vapor pressure of the food product divided by the vapor pressure of pure water under identical conditions of pressure and temperature. The regulations define low-acid foods as foods, other than beverages, with a finished equilibrium pH value greater than 4.6 and a water activity greater than 0.85.

Table 1. The water activity (a_w) limits for growth of principal foodborne disease organisms.*

Microorganism	**Minimal a_w for growth**	**Reference**
Salmonella	0.945	Christian & Scott, 1953
Clostridium botulinum	0.95	Scott, 1957
Clostridium perfringens	0.93	Kang, et al., 1969
Staphylococcus aureus	0.86**	Scott, 1962
Vibrio parahaemolyticus	0.94	Beuchat, 1974

*These limits are the lowest reported, with all other growth conditions optimal. If other conditions are less than optimal, the minimal a_w will be higher.

**Troller and Stinson (1975) have shown that minimal a_w for toxin production is higher than that for growth – 0.93 in their experiments.
Most bacteria fail to grow in a food or other medium where the a_w is lower than 0.94. Bacteria require a higher a_w than yeasts, which in turn require a higher a_w than molds. Thus, any condition that lowers the a_w first inhibits bacteria, then yeasts, and finally molds (Elliott and Michener, 1965). But each species has its limits which are interrelated with other growth factors. Table 2 gives the a_w limits for growth of principal foodborne disease organisms held under otherwise optimal conditions.
Certain molds and bacteria can grow on fish immersed in saturated salt solution where the a_w is about 0.75. Some molds can grow in foods with a_w 0.62 – 0.65 (Elliott and Michener, 1965). At these lower limits, growth is very slow. The a_w of fully dried foods, such as crackers or sugar, is about 0.10 and such products are microbiologically stable because of this factor alone. The stability of intermediate moisture foods (aw 0.75 – 0.90), such as dried fruits, jams, and soft moist pet foods, depends on combinations of factors, such as low a_w, low pH, pasteurization, chemical additives, and impervious packaging.

pH

pH is a term used to describe the acidity or alkalinity of a solution. At pH 7, there is an equal amount of acid (hydrogen ion: H +) and alkali (hydroxyl ion: OH-), so the solution is “neutral”. pH values below 7 are acidic, while those above 7 are alkaline. pH expresses the H + concentration logarithmically, that is, in multiples of 10. For example, at pH 5 there are 10 times as many H + as at pH 6; at pH 3 there are 100 times as many H + as at pH 5, and so on.

pH has a profound effect on the growth of microorganisms. Most bacteria grow best at about pH 7 and grow poorly or not at all below pH 4. Yeasts and molds, therefore, predominate in low pH foods where bacteria cannot compete. The lactic acid bacteria are exceptions; they can grow in high acid foods and actually produce acid to give us sour milk, pickles, fermented meats, and similar products. Some strains, called Leuconostoc contribute off-flavors to orange juice. The pH values of certain foods are given in Table 2.

Table 2. Mean pH Values of Selected Foods (Lopez, 1987)

pH Value	**Selected Foods**
2.3	Lemon juice (2.3), Cranberry sauce (2.3)

3.0	Rhubarb (3.1) Applesauce (3.4), Cherries, RSP (3.4) Berries (3.0 – 3.9), Sauerkraut (3.5)Peaches (3.7), Orange juice (3.7) Apricots (3.8)
4.0	Cabbage, red (4.2), Pears (4.2) Tomatoes (4.3)
4.6	Ravioli (4.6) Pimientos (4.7)
5.0	Spaghetti in tomato sauce (4.9) Figs (5.0)Onions (5.2) Carroes (5.2) Green Beans (5.3), Beans with pork (5.3)Asparagus (5.5), Potatoes (5.5)
6.0	Lima beans (5.9), Tuna (5.9), Tamales (5.9) Codfish (6.0), Sardines (6.0), Beef (6.0) Pork (6.1), Evaporated milk (6.1) Frankfurters (6.2), Chicken (6.2) Corn (6.3) Salmon (6.4)
7.0	Crabmeat (6.8), Milk (6.8) Ripe olives (6.9) Hominy (7.0)

The lowest pH limits for growth of foodborne disease organisms are shown in Table 3. Many of the investigators who reported these values also determined that adverse factors, such as low temperature or low water activity, increased the minimal pH for growth. But the processor can be sure that these minimal values will prevent growth of these pathogens under any and all circumstances.

Table 3. The minimal pH minimal for growth of principal foodborne disease organisms*

Microorganism	Growth reported at but not below	Reference
Staphylococcus aureus	pH 4.5	
Salmonella	4.0	Chung and Goepfer, 1970
Clostridium botulinum		
Types A and B	4.8	National Canners Assn., 1971a
Type E	5.0	National Canners Assn., 1971a
Clostridium perfringens	5.0	
Vibrio parahaemolyticus	4.8	Beuchat, 1973
Bacillus cereus	4.9	Kim and Goepfer, 1971

*Note: These limits are the lowest recorded, with all other growth conditions optimal. If other conditions are less than optimal, the pH limit will be higher.

Population

A high initial bacterial load increases the likelihood that spoilage will occur under marginal circumstances (Chung and Goepfert, 1970) (see Figures 4 and 5). This fact is of major importance to the processor of refrigerated foods, the shelf-life of which is enhanced by good sanitation. A high level of spores also increases the possibility that a few will survive to spoil heat processed products.

Oxygen

Oxygen is essential for growth of some microorganisms; these are called aerobes. Others cannot grow in its presence and are called anaerobes. Still others can grow either with or without oxygen and are called microaerophilic.

Strict aerobes grow only on food surfaces and cannot grow in foods stored in cans or in other evacuated, hermetically sealed containers. Anaerobes grow only beneath the surface of foods or inside containers. Aerobic growth is faster than anaerobic. Therefore, in products where both conditions exist, such as in fresh meat, the surface growth is promptly evident, whereas subsurface growth is not.

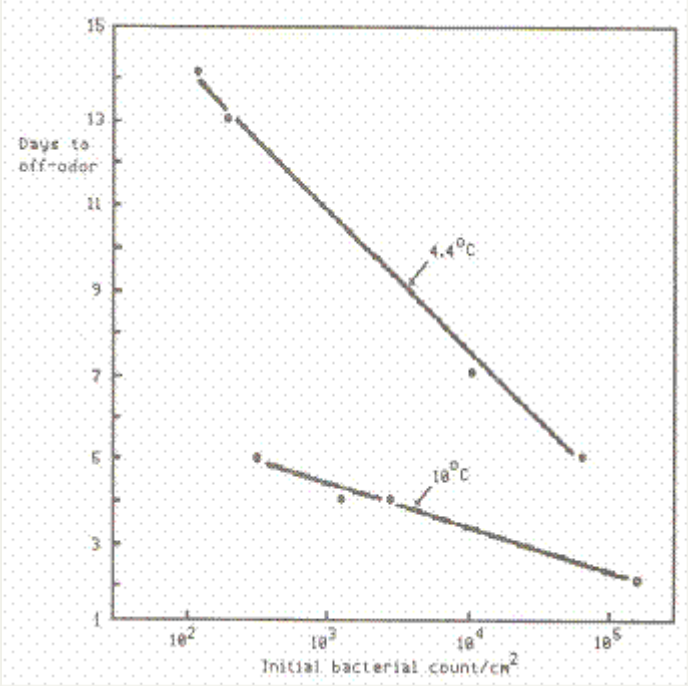

Figure 5. Effect of numbers of contaminating bacteria on the spoilage time of chicken meat. (Ayres et. al., 1950)

Lethal Effects of Temperature

Heat is the most practical and effective means to destroy microorganisms. Microbial cell reduction occurs slowly just above maximal growth temperatures. However, the rate of death increases markedly as the temperature is raised. Pasteurization, the destruction of vegetative cells of disease-producing microorganisms, consists of a temperature of 140°F for 30 minutes, or about 161°F for 16 seconds. Yeasts, molds, and the vegetative cells of spoilage bacteria also die at pasteurization temperatures. To render log-acid foods commercially sterile requires a retort capable of operating at temperatures above 212°F. Canners process certain canned foods at 240°F or 250°F for a considerable length of time, sometimes an hour or more depending upon the product and can size. Commercial sterility is the destruction and/or inhibition of the organisms of public health significance as well as organisms of non-health significance which could spoil the product. Microbiologists sterilize media at

250°F (121C) for 15 or 20 minutes. These examples illustrate the need for high temperatures and sufficient time to kill a population of bacteria.

In thermal destruction studies, also called thermal death time studies, the logarithm of the numbers of survivors is plotted against the length of time test cultures are subjected to a given temperature. The result is usually a straight line (Figure 6), although there are many exceptions (Humphrey and Nickerson, 1961). The slope of this line becomes steeper as the temperature is increased, indicating that less time is required to kill a population at higher temperatures. It also takes longer to kill a high population of organisms than it does to kill a low population (Table 4).

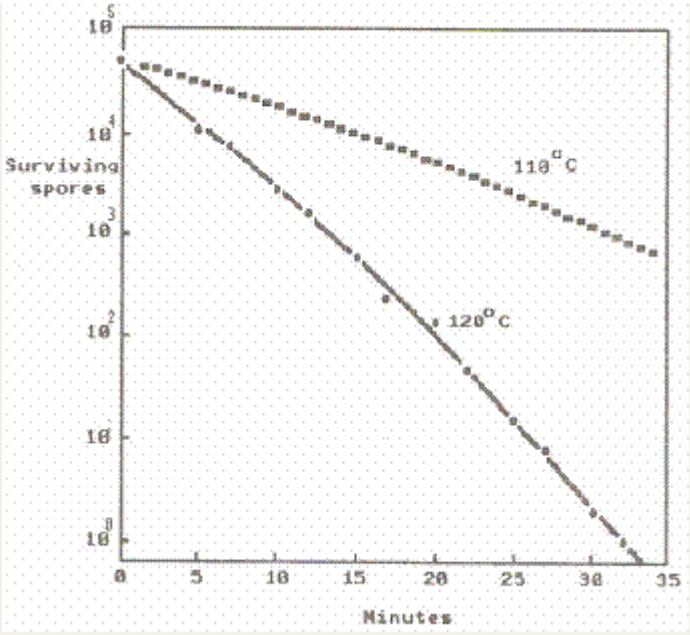

Figure 6. Reduction in numbers of bacterial spores during exposure to lethal temperatures.(Williams et. al., 1937)

The rate of thermal destruction is greater in foods with high a_w than in those with low a_w (Calhoun and Frazier, 1966). Microbial contaminants in dry foods, such as chocolate (Goepfert and Biggie, 1968) or dried bone meal (Riemann, 1968), are hard to destroy with heat. The recommended pasteurization process to destroy Salmonella in liquid egg albumen prior to freezing is 140°F (60C) for 3.5 minutes (USDA, 1969), whereas that for dried egg albumen is 140 (60C) to 158°F (70C) for several days (Banwart and Ayres, 1956). Riemann (1968) was able to kill Salmonella in meat and bone meal more readily at 194°F (90C) after water was added to bring the a_w to 0.90.

Table 4. The effect of the size of the initial spore population on destruction time. (From Reed and Bohrer, 1961)

Microorganism	Spores (number)	Temperature °F (°C)	Destruction time (minutes)
Flat sour #26	45,000	239 (115.9)	62 to 65
	400	239 (115.9)	25 to 28
Clostridium botulinum #90	90,000	221 (105.8)	18 to 20
	900	221 (105.8)	12 to 14

Clostridium botulinum spores are highly resistant to thermal destruction at water activities between 0.2 and 0.4 (dry heat) and are much less resistant to heat at water activities above this range. This finding may be practical for high temperature-short time dry heat sterilization (National Canners Association, 1976a).

Other factors that affect the thermal destruction rate of bacteria are the presence or absence of organic matter, oil or fat, pH, strain of organisms, quality of available nutrients, and age of the culture. In general, bacteria are killed more rapidly at lower and higher pH values than in more neutral ranges. In the processing of many foods, careful control of pH is an important factor.

Chilling to temperatures below the growth range, but above freezing, stops reproduction but kills few cells except for extremely sensitive organisms, such as vegetative cells of Clostridium perfringens. Freeze kills part of a microbial population within a few hours and storage continues to be lethal at a much slower rate. The rate of population reduction varies with the nature of the food, as illustrated in Figure 7; the most rapid drop in aerobic plate count (“total count”) occurred in orange juice, which is an acid product. Bacterial spores die very slowly, if at all, during freezing and frozen storage. For example, the vegetative cells of Clostridium perfringens generally all die, but the spores survive. Staphylococcus aureus and related organisms survive well, but in most cases there is wide variation of susceptibility among microorganisms, even among closely related species (Figure 8). In any case, freezing is not a dependable means to destroy microorganisms since some cells of the original population almost always survive.

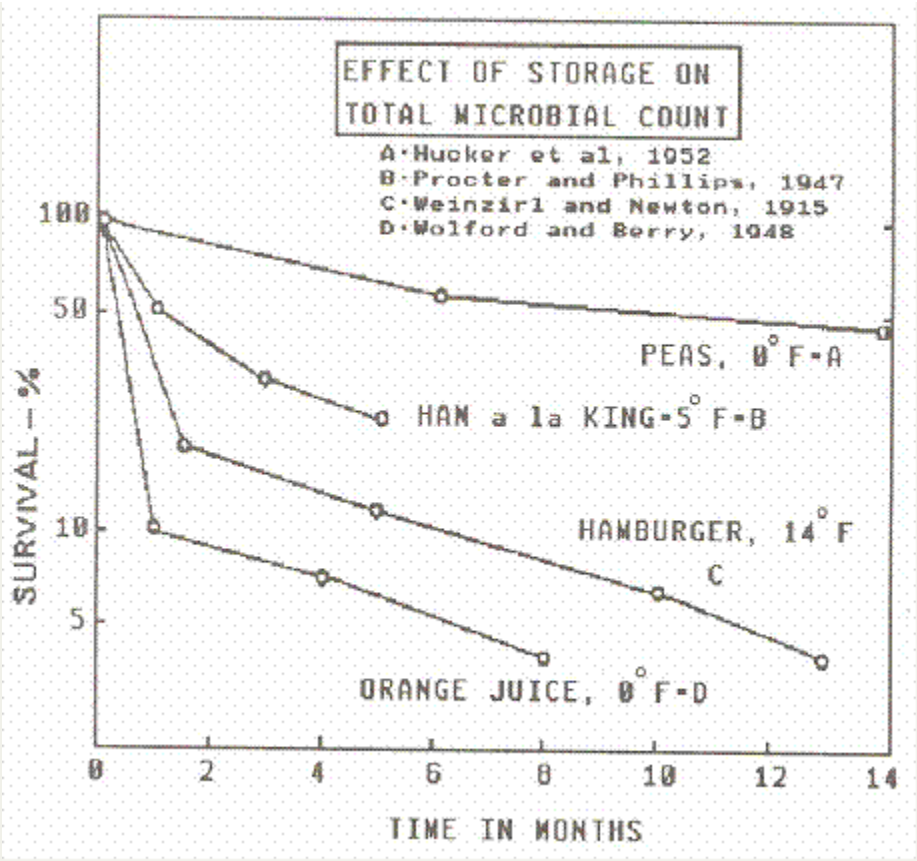

Figure 7. Effect of frozen storage on bacterial level in various foods.

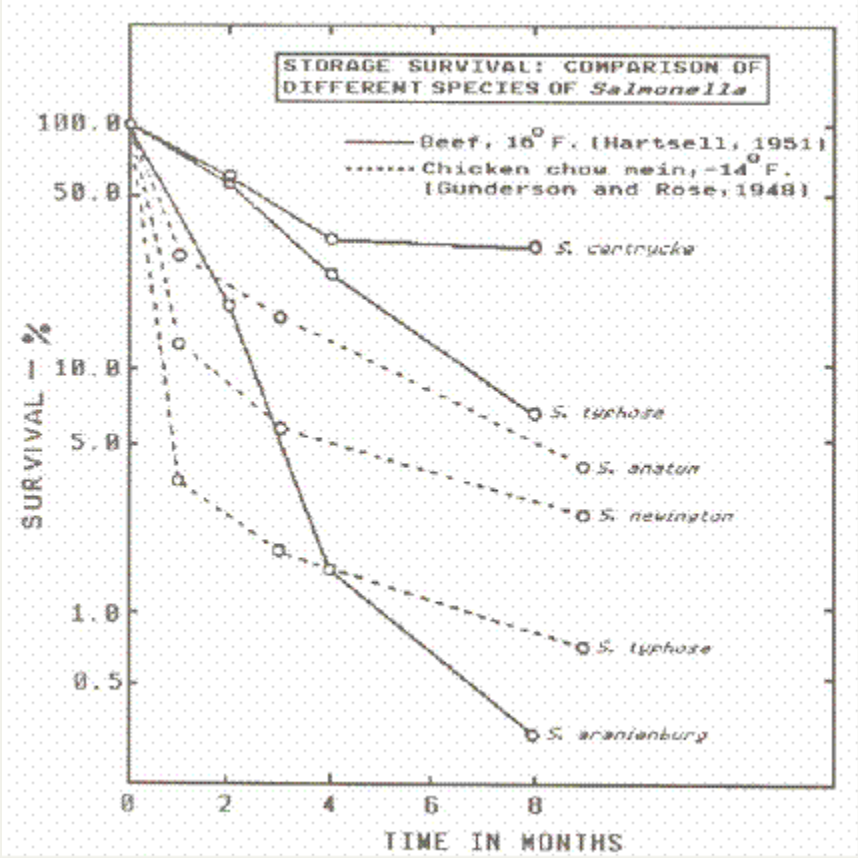

Figure 8. Survival of Salmonella in frozen storage.

The “Indicator” Organisms

The “indicator” organisms are so called because their presence in large numbers in food signifies one of three contamination possibilities: disease bacteria or filth; spoilage or low quality; or preparation under insanitary conditions.

Aerobic Plate Count

The aerobic plate count (APC) measures only that fraction of the bacterial flora that is able to grow to visible colonies under the arbitrary test conditions provided in the time period allowed. It does not measure the total bacterial population in a food sample, but is the best estimate. Altering conditions, such as composition of the agar medium or temperature of incubation, changes the spectrum of organisms that will grow. It is necessary to adhere rigidly to the standardized test conditions that have encouraged some to call the APC a “standard plate count.”

Depending on the circumstances, a high APC may indicate that a food has been grossly mishandled or that it contains a poor quality ingredient. Interpretation depends on knowing what the normal APC is for this food. An abnormal APC indicates that something is out of control. The microbiologist can frequently suggest that cause, thereby aiding the sanitarian. Some of the problems that investigation of a high APC might reveal include:

- Failure of sorting, trimming, washing, and destroying operations to remove or destroy bacteria from raw ingredients adequately.
- Inadequate heat processing.
- Insanitary equipment, particularly near the end of the process.
- The food has reached or is approaching the end of its refrigerated shelf-life.
- The food has been stored at or above room temperature for too long.
- The food is at least partly decomposed.

Coliform Bacteria

The coliform bacteria are non-spore forming rods that occur in large numbers in human and animal feces. They are normally present on raw animal products, such as meats, milk, and eggs, and also occur naturally in soil, water, and surfaces of plants. They are heat sensitive and die rapidly during blanching or pasteurizing. Large numbers of coliforms after a heat process indicate an unacceptable degree of post-heating contamination or indicate time-temperature abuse of the food sufficient to permit growth. High coliform levels warrant investigations to determine the source of contamination or temperature mishandling.

The presence of Escherichia colia, member of the coliform group, in food usually indicates direct or indirect human or animal fecal contamination. Although this may be true in a broad sense, one must not assume a quantitative relationship between the numbers of E. coli and the degree of contamination with feces. E. coli grows well outside the animal body and thrives in unclean food handling equipment.

Food Poisoning

Human illnesses caused by foodborne microorganisms are popularly referred to as food poisoning. The common use of a single classification is due primarily to similarities of symptoms of various food-related diseases (see Table 5). Apart from illness due to food allergy or food sensitivity, foodborne illness may be divided into two major classes, food infection and food intoxication. Food infection results when foods contaminated with pathogenic, invasive, food

poisoning bacteria are eaten. These bacteria then proliferate in the human body and eventually cause illness. Food intoxication follows the ingestion of preformed toxic substances which accumulate during the growth of certain bacterial types in foods.

The period of time between the consumption of contaminated foods and the appearance of illness is called the incubation period. The incubation period can range anywhere from less than one hour to more than three days, depending on the causative organisms or the toxic product.

Table 5. Characteristics of the important bacterial food intoxications and foodborne infections. (NAS-NRC, 1975)*

Disease	**Etiologic Agent**	**Incubation Period**	**Symptons**
Botulism	*Clostridium botulinum* A.B.E.F toxin	Usually 1 to 2 days; range 12 hours to more than 1 week	Difficulty in swalling, double vision, difficulty in speech. Occasionally nausea, vomiting, and diarrhea in early stages. Constipation and subnormal temperature. Respiration becomes difficult, often followed by death from paralysis of muscles of respiration.
Staphylococcal food poisoning	Staphyloccal enterotoxin	1 to 6 hours; average 3 hours	Nausea, vomiting, abdominal cramps, diarrhea, and acute prostration. Temperature subnormal during

			acute attack, may be elevated later. Rapid recovery-usually within 1 day.
Salmonellosis	Specific infection by *Salmonella*sp p.	Average about 18 hours; range 7 to 72 hours	Abdominal pains, diarrhea, chills, fever, frequent vomiting, prostration. Duration of illness: 1 day to 1 week.
Shigellosis (bacillary dysentery)	Shigella sonnei, s. flexneri, s. dysenteriae, s. boydii	Usually 24 to 48 hours; range 7 to 48 hours	Abdominal cramps, fever, chills, diarrhea, watery stool (frequently containing blood, mucus, or pus), spasm, headache, nausea, dehydration, prostration. Duration: a few days.
Enteropathogenic *Escheric hia coli*infection	*Escherichia coli*serotypes associated with infant and adult infections	Usually 10 to 12 hours; range 5 to 48 hours	Headache, malaise, fever, chills, diarrhea, vomiting, abdominal pain. Duration: a few days.
Clostridium perfringens food poisoning	*Clostridium perfringens*	Usually 10 to 12 hours; range 8	Abdominal cramps and diarrhea, nausea, and malaise, vomiting very rare. Meat and

		to 22 hours	poultry products usually involved. Rapid Recovery.
*Bacillus cereus*food poisoning	*Bacillus cereus*	Usually about 12 hours; range about 8 to 16 hours	Similar to *Clostridium perfringens* poisoning
*Vibrio Parahaemolyticus*food poisoning	*Vibrio Parahaemolyticus*	Usually 12 to 14 hours; range 2 to 48 hours	Abdominal pain, server watery diarrhea, usually nausea and vomiting, mild fever, chills and headache. Duration: 2 to 5 days.

*Repeated from Prevention of Microbial and Parasitic Hazards Associated with Processed Foods, pages 6-7, with the permission of the National Academy of Sciences, Washington, DC.

Beneficial Role of Microorganisms in Food Industry

Microorganisms play an important role in food industry. As already discussed in the earlier article **Contributions of Microbiology in Food Industry**, they are used in production of various food products, and are also responsible for food spoilage thereby causing intoxication and diseases.

Microbial contamination of food products takes places usually on the way from the field to the processing plant, or during processing, storage, transport and distribution or before consumption. The microorganisms that cause food spoilage and also find the maximum exploitation in production of food and food products are mainly bacteria, molds and yeasts.

Bacteria

Bacteria are the largest group of unicellular microorganisms. The shapes of medically important bacteria are classified into-cocci, or spherical cells; bacilli, or cylindrical or rod shaped cells; and spiral or curved forms. The pathogenic or disease causing bacteria are usually gram negative, however, three gram-positive rods are known to cause food intoxications : *Clostridium botulinum,C. perfringens,and Bacillus cereus*

Some of the other most common bacteria causing food spoilage, infections and disease are *Acinetobacter, Aeromonas, Escherichia, Proteus, Alcaligenes, Flavobacterium, Pseudomonas, Arcobacter, Salmonella, Lactococcus, Serratia, Campylobacter, Shigella, Citrobacter, Listeria, Staphylococcus, Micrococcus, Corynebacterium, Vibrio Enterobacter, Paenibacillus, Weissella, Enterococcus, Yersinia*

Different strains of bacteria are also used in production of various food and dairy products. Strains of Streptococcus, *Lactobacillus Bifidobacterium*, Erwiniaetc. are used in the production of fermented food and dairy products. *Streptococcus thermophilus* and *Lactobacillusbulgaricus* are used to produce yogurt.

Molds:

Molds are multicellular filamentous fungi whose growth on foods is usually readily recognized by their fuzzy or cottony appearance. They are mainly responsible for food spoilage at room temperature 25- 30oC and low pH, and have minimum moisture requirement. Molds can rapidly grow on grains and corns when these products are stored under moist conditions. Molds require free oxygen for growth and hence grow on the surface of contaminated food. Molds also find their use in manufacturing of different foods and food products. They are used in ripening of various types of food products as cheese (e.g. Roquefort,Camembert). Molds are also grown as feed and food and are employed to produce ingredients such as enzymes like amylase used in making bread or citric acid used in soft drinks. Molds are major contributors in the ripening of many oriental foods. A species of *Bothrytiscinerea*, is used in rotting of grape for production of wine. Lactic fermentations using molds results in a unique Finnish fermented milk called viili.

Yeasts:

Yeasts have the ability to ferment sugars to ethanol and carbon-dioxide and hence they are extensively in food industry. The most commonly used yeast, the baker’s yeast is grown industrially. *Saccharomyces carlsbergensis* is most

commonly used in fermentation of most beers. The other yeast strains of importance are

Brettanomyces, Schizosaccharomyce,, Candida, Cryptococcus, Debaryomyces, Zygosaccharomyces, Hanseniaspora, Saccharomyces

Few major Beneficial Role of Micro-Organism

1. Antibiotics are important components of human welfare against infections and diseases. These are manufactured in industries using bacteria. For example, penicillin is one of the important antibiotics and it is produced by the bacteria, *Penicillium notatum*.
2. The production and preservation of beverages like whiskey, brandy, beer, and rum are done by *Saccharomyces cerevisiae*.
3. Microorganisms are also involved in the commercial production of enzymes. Example: Production of lipase.
4. Ethanol is one of the important commercial chemicals which is produced by *Saccharomyces cerevisiae*.
5. Immunosuppressive agents like Cyclosporin are prepared from the fungus, *Trichoderma*.
6. Microorganisms have been widely used in lactic, propionic, and ethanolic fermentations from time immemorial.
7. They are characteristically used in the production of about 2,000 distinct varieties of cheese throughout the world.
8. They are used in the production of different alcoholic beverages using a variety of carbohydrate substrates.
9. Microorganisms can be used to transform raw foods into pickles, sausages, sauces, etc.
10. Microorganisms can themselves be used as a food source. The most common example is fungus (Agaricusbisporus) commonly as mushrooms.
11. Probiotics are being used successfully with poultry.

Points to remember

- Bacteria, molds and yeast are the most important microorganisms that cause food spoilage and also find the maximum exploitation in production of food and food products.

- Different strains of bacteria and fungus are used for fermentation of dairy products for production of a wide variety of cultured milk products. Both bacteria and fungi are used in these cheese production processes.
- Lactic acid bacteria are used for coagulation of milk that can be processed to yield a wide variety of cheeses, including soft unripened, soft ripened, semisoft, hard, and very hard types.
- Microorganisms such as *Lactobacillus and Bifidobacterium* are used as in food and health industry.
- *Spirulina*, a *cyanobacterium,* also is a popular food source sold in specialty stores.
- Molds are used for rotting of grapes for production of different varieties of wines.
- Mushrooms *(Agaricusbisporus)* are one of the most important fungi used as a food source.
- Alcoholic beverages as beer are produced by fermentation of cereals and grains using different strains of yeasts.

Factors that Influence Microbial Growth

In most cases, micro-organism utilizes our food supply as a source of nutrient for their growth.This course can result in deterioration(decay)of food.The organism not only deteriorates the food but may also pose risks of disease to the human being on consumption of such contaminated food.However, the growth of microorganisms in food may be affected by several factors like physical, chemical and biological.

These factors can broadly divide into two categories i.e.

1. **Intrinsic parameters or intrinsic factors**
2. **Extrinsic parameters or extrinsic factors**

Intrinsic Factors

Intrinsic parameters are natural or inherent properties of food.These parameters greatly affect the number and types of microorganism that will colonize the food and food product.Intrinsic parameters affect only microorganisms, not to the food itself.Intrinsic parameters of food include:-

1. pH value
2. Moisture contains(water activity)
3. Nutrients contain
4. Anti-microbial constituents
5. Biological structure

1. pH Value

Every organism has a minimal, maximal and optimal pH for growth.Some organism can grow better at low pH or acidic pH, some can grow in alkaline pH and while other grow at somewhat neutral pH.pH influence both the growth rate and types of organism that will predominant the food. In general yeast and mould are more acid tolerant than bacteria.

2. Moisture content or water activity(a_w)

Micro-organism has an absolute demand for water, however, the exact amount of water needed for growth of microorganisms varies.This parameter helps us to understand the movement of water from the environment to the cytoplasm or from cytoplasm to the environment.The water requirement of microorganisms is expressed in physical form, called water activity(a_w).

Water activity is the ratio of the vapour pressure of water present in food substrate(solution) to the vapour pressure of pure water at the same temperature.

a_w=P/ Po, P=vapour pressure of water present in food and Po=Vapour pressure of pure water at some temperature.

3. Nutrients Contained

The kinds and proportional of nutrient in food are all important in determining which micro-organism(microorganisms) is most likely to grow.In general, the simple compound is utilized first by the measuring microorganisms.The carbohydrate(simple sugar) is most commonly utilized as an energy source.Protein-rich food like meat, egg, fish etc.are always spoiled by protolytic organism because they can utilize protein as a source of energy if sugar is not available.In fact, protein-rich food promotes more growth of bacteria then yeast and mould .similarlly, in the general mould can grow in the higher concentration of sugar, yeast in fairly high concentration but most bacteria grow best in the low concentration of sugar.

4. Anti-microbial Constituents

Some foods possess naturally occurring substances which influence the activity of invading microorganisms, for example:-

In Plant

Clove:- Essential oil, Eugenol
Garlic:-Allicin
Mustard oil:-Allyl isothiocyanate

In Animal

-cows milk:-Lactoferrin, conglutinin, lactoperoxidase system.

-Egg:-Lysozyme,0vatransferrin(inhibit Salmonella enteritidis)

5. Biological Structure

The natural covering of some foods provides excellent protection against the energy of micro-organism and spoilage of food by such microorganisms. Natural covering of food like,

- Testa of seed
- Shell of egg/nuts
- peel of fruits/vegetable
- Hide of animal may limit the entry of microorganisms

Extrinsic Factors

Extrinsic parameters are environmental factors, in which food and food products are kept.Extrinsic parameters substrate independent and affect both micro-organism (mos) as well as food.Unlike intrinsic parameters, extrinsic parameters can be maintained and regulated well.The extrinsic parameters include:-

1. Temperature of storage
2. Relative humidity of the environment
3. Presence and concentration of gases
4. Presence and activities of micro-organism

1. Temperature of storage

Temperature of storage is highly important parameters that affect the spoilage of highly perishable food. Micro-Organisms are reported to grow between -34^0c to 100^0c and each organism exhibit a minimum, optimum and maximum temperature for growth and these are known as cardinal temperature. Yeast and mould can grow at the temperature range of 20 to 30^0c.Most bacteria can grow well at ordinary temperature(37^0c) ,however, some(thermophiles) grow at high temperature and other(psychrophilic) grow at low temperature.

2. Relative humidity

Humidity is the concentration of water vapour in the atmosphere.Relative humidity is the ratio expressed as the percentage of moisture in the air to the moisture present in food under the saturation condition at temperature and pressure.Relative humidity and water activity are inter-related i.e.when food with low water activity are stored in the environment of high humidity, water will transfer from gas phase (air) to the food and thus increased water activity of the food ,leading to spoilage by viable micro-organisms.

3. Presence and concentration of gases

Presence of different gases and its varying concentration may significantly affect the colonizing mos on the food i.e.surface spoilage is prevented by altering the gaseous composition.Oxygen is one of the most important gases which affects both food products as well as Mos.Oxygen gas when comes in contact with food, influence redox potential of food and finally the microbial growth.

Ozone added to food as a preservative action on certain food.Ozone has GRAS(generally recognized as safe) status in the US, effective range is 1-5 ppm.However, it has some demerits like strong oxidizing agents, causes the rancidity of high lipid-containing food.

4. Presence and activity of micro-organism

Inhibition or destruction of one population of micro-organism by the presence of other population of mos present in the same habitat is the microbial interference.Some Micro-organisms produced substances/metabolites (like secondary metabolites), that are either lethal or inhibitory to others.

UNIT 2

Fermentation

Fermentation is a metabolic process that consumes sugar in the absence of oxygen. The products are organic acids, gases, or alcohol. It occurs in yeast and bacteria, and also in oxygen-starved muscle cells, as in the case of lactic acid fermentation. The science of fermentation is known as zymology. **Fermentation in food** processing is the process of converting carbohydrates to alcohol or organic acids using microorganisms—yeasts or bacteria—under anaerobic conditions. **Fermentation** usually implies that the action of microorganisms is desired.

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Fermentation in Dairy Foods

Milk has been used to produce fermented milk products as far back as 10,000 B.C. in different regions all over the world. The many benefits of fermented milk products include enhanced digestibility, new and unique flavours, added probiotics, vitamins and minerals, and preservation products for a food that normally has a very short shelf life.

Fermenting Process

The processes used to turn milk into different fermented foods involves adding lactic-acid-producing microorganisms, such as bacteria and yeast, which ingest lactose, or milk sugar, and release lactic acid as waste. This result is a rise in milk acidity, which allows the production of kefir, yogurt, cheese and sour cream among other fermented foods.

Kefir

Kefir is a fermented yoghurt-like drink that dates back centuries to the shepherds of the Caucasus Mountains. The word “kefir” is derived from the Turkish word “Keif,” which means “good feeling”; a benefit this drink is said to provide for those who consume it. Kefir is produced with starter grains, known as kefir grains, which contain active microorganisms consisting of 83 to 90 percent lactic acid bacteria and 10 to 17 percent yeast. Kefir incorporates various essential vitamins, minerals, amino acids and enzymes, particularly phosphorus, magnesium, calcium and vitamins B2, B12, D, K and A.

Yogurt

A staple of the Middle Eastern diet for thousands of years, yoghurt is a fermented food that holds the same level of protein and fat as the milk from which it is produced. It is also a source of calcium and vitamins B2, B6 and B12. Yogurt, like other fermented milk products, is primarily cultured from cows milk but can be made from goat’s milk. Microorganisms can also be used to ferment non-dairy milk, including coconut milk, almond milk and soy milk, into yoghurt.

Cheeses

Cheese may be the most popular fermented milk product, using more than one-third of all milk produced in the United States each year for its production. Both soft and hard types of cheeses are produced by culturing milk for an extended period of time. Certain types of cheeses can be made simply by straining the moisture out of sour cream or yogurt. Some other types of cheese, however, require additional steps in the culturing and fermentation process. Over 2,000 varieties of cheeses exist, with some of the most notable being cheddar, feta, cream, goat and blue.

Sour Cream

The original process for making sour cream was to simply let cream sour on its own. Today, a more proactive process is used: the lactic-acid-producing bacteria Streptococcus lactis. The flavour of sour cream is mild and tangy and the texture is thick and smooth. With a fat content somewhere between 10 to 14 percent, sour cream has significantly fewer calories than mayonnaise – a food sour cream can replace in many applications. Sour cream also works well in baking recipes for cookies cakes, bread and pies.

Fermentation in Vegetables

Fermented vegetables begins with Lacto-fermentation, a method of food preservation that also enhances the nutrient content of the food. The action of

the bacteria makes the minerals in cultured foods more readily available to the body. The bacteria also produce vitamins and enzymes that are beneficial for digestion.

In eastern Himalayan regions of India, a wide range of fermented vegetable products are prepared for bioprocessing the perishable vegetable for storage and further consumption. Lactic acid fermentation vegetables such as gundruk, sinki, and khalpi are fermented vegetable products of Nepal, Sikkim, and Bhutan

Fermented food	Ingredients	Place of origin	Related Microorganisms
Rabdi (rabadi)	Flour of barley, pearl millet, corn or soybean and country buttermilk	Rajasthan	*Bacillus* and *Micrococcus* sp.
Kulu	Wheat flour, buttermilk	Himachal Pradesh	*Lactobacillus* sp.
Idli	Rice, black gram dhal, table salt, fenugreek seeds	South India	*L. mesenteroides, E. faecalis, P. cerevisiae*
Dosa	Rice, black gram dhal (either raw or parboiled rice), table salt	South India	*L. mesenteroides, E. faecalis*
Dhokla	Bengal gram dhal, rice and leafy vegetables	Gujrat	*L. fermentum, L. mesenteroides, E. faecalis*
Chilra or lwar	Wheat/barley, buckwheat flour and starter material Treh	North India	Not reported
Sinki	Radish root	North-east India	*L. casei, L. brevis, L. plantarum, L. fallax, L. ferme*
Kinema	Soybeans	Darjeeling, Sikkim	*E. faecium*
Kanji	Carrot or beet root, rice, mustard	North India	*L. pentosus, L. paraplantarum, L. plantarum*
Curd (Dahi)	Milk	India	

			S. cremoris, S. lactis, S.thermophilus, L. bulgaricus, acidophilus, L. helveticus, L. cremoris, , Lactobacill subsp. Indicus
Gundruk	Leaves of mustard/ radish/cauliflower	Arunachal Pradesh	*P. pentasaceous, L. fermentum, L. casei*

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Fermentation in Indian Foods

India is traditionally rich in fermented foods. In the Indian sub-continent, fermented food using local food crops and other biological resources are very common.

Fermented foods such as idli and dahi were described as early as 700 BC. At present, there are hundreds of fermented foods with different base materials and preparation methodology. Each fermented food is associated with a unique group of microbiota, which increases the level of proteins, vitamins, essential amino acids and fatty acids

Foods like idlis, dosas, dhoklas, wadas and kadhi are some of the lactobacillus fermented cereals and legumes that are commonly consumed in India. The fermented foods increase the absorption of vital minerals from the gastrointestinal tract, thus preventing mineral deficiencies. Bread, fish sauce, wine and beer are some of the yeast-based fermented food beverages.

Examples of some Indian fermented foods:-

Indian fermented foods are consumed by the local population not just as a diet but as traditional medicine too. Many of the foods were observed to have a beneficial effect during ailment by the local people and they are used as a special diet or medicine for ages. Fermented food idli is easily digested and often used as food for infant and invalids. Fermented milk dahi can be used to cure intestinal disease such as diarrhoea; intake of dahi has anti-cholesteric, anticarcinogenic, anti-diabetic, angiotensin-converting enzyme inhibition effect and anti-atopic dermatitis effect.

Fermentation in Bakery Products

Fermentation is a baking process in which yeasted dough rises and increases in volume and flavour is developed. Fermentation occurs when yeast converts sugar present in flour such as starch into carbon dioxide and ethyl alcohol. CO2 gas is trapped by gluten proteins the flour which causes the dough to rise. Fermentation results in a light and airy crumb.

Fermentation influences product volume, shape, crust colour, and crumb cell structure.

Fermentation in Alcoholic Beverages

Fermented beverages are produced through the process of fermentation. **Fermentation** in the case of alcoholic beverages refers to a metabolic process by which yeast converts sugar to ethanol. Yeast is a type of fungus used in the fermentation of alcohol. In order for fermentation to take place, you begin with some type of carbohydrate that is needed to feed the yeast. The type of carbohydrate used determines what the final product will be. Let's look at some examples. Beer is produced by fermenting grain. Wine or hard cider is produced by fermenting fruit. Mead is produced by fermenting honey. Milk and tree or plant sap can be used to produce fermented beverages as well.

There is a limit to the alcoholic content of fermented beverages because yeast cannot survive in alcohol. Once the concentration of ethanol produced by the fermentation process reaches about 15%, the yeast will die and fermentation process will end.

In order to produce beverages above the concentration of ethanol achieved through fermentation, a distillation process is used. **Distillation** of alcoholic beverages is the process by which water is removed from a mixture of ethanol and water.

Cheese Production

This page describes the general production of cheese and includes the legal Cheese Definitions, Ingredients, Bacterial Cultures, and General Manufacturing Procedure.

Cheese Definitions

Cheese comes in many varieties. The variety determines the ingredients, processing, and characteristics of the cheese. The composition of many cheeses

is defined by Standards of Identity in the U.S. Code of Federal Regulations (CFR).

Cheese can be made using pasteurized or raw milk. Cheese made from raw milk imparts different flavors and texture characteristics to the finished cheese. For some cheese varieties, raw milk is given a mild heat treatment (below pasteurization) prior to cheese making to destroy some of the spoilage organisms and provide better conditions for the cheese cultures. Cheese made from raw milk must be aged for at least 60 days, as defined in the CFR, section 7 CFR 58.439, to reduce the possibility of exposure to disease causing microorganisms (pathogens) that may be present in the milk. For some varieties cheese must be aged longer than 60 days.

Cheese can be broadly categorized as acid or rennet cheese, and natural or process cheeses. Acid cheeses are made by adding acid to the milk to cause the proteins to coagulate. Fresh cheeses, such as cream cheese or queso fresco, are made by direct acidification. Most types of cheese, such as cheddar or Swiss, use rennet (an enzyme) in addition to the starter cultures to coagulate the milk. The term "natural cheese" is an industry term referring to cheese that is made directly from milk. Process cheese is made using natural cheese plus other ingredients that are cooked together to change the textural and/or melting properties and increase shelf life.

Ingredients

The main ingredient in cheese is milk. Cheese is made using cow, goat, sheep, water buffalo or a blend of these milks.

The type of coagulant used depends on the type of cheese desired. For acid cheeses, an acid source such as acetic acid (the acid in vinegar) or gluconodelta-lactone (a mild food acid) is used. For rennet cheeses, calf rennet or, more commonly, a rennet produced through microbial bioprocessing is used. Calcium chloride is sometimes added to the cheese to improve the coagulation properties of the milk.

Flavorings may be added depending on the cheese. Some common ingredients include herbs, spices, hot and sweet peppers, horseradish, and port wine.

Bacterial Cultures

Cultures for cheese making are called lactic acid bacteria (LAB) because their primary source of energy is the lactose in milk and their primary metabolic product is lactic acid. There is a wide variety of bacterial cultures available that provide distinct flavor and textural characteristics to cheeses. For a more

detailed description of cheese cultures and microbiology, see Fox (2004), Kosikowski and Mistry (1997), and Law (1997).

Starter cultures are used early in the cheese making process to assist with coagulation by lowering the pH prior to rennet addition. The metabolism of the starter cultures contribute desirable flavor compounds, and help prevent the growth of spoilage organisms and pathogens. Typical starter bacteria include *Lactococcus lactis* subsp. *lactis* or *cremoris*, *Streptococcus salivarius* subsp. *thermophilus*, *Lactobacillus delbruckii* subsp. *bulgaricus*, and *Lactobacillus helveticus*.

Adjunct cultures are used to provide or enhance the characteristic flavors and textures of cheese. Common adjunct cultures added during manufacture include *Lactobacillus casei* and *Lactobacillus plantarum* for flavor in Cheddar cheese, or the use of *Propionibacterium freudenreichii* for eye formation in Swiss. Adjunct cultures can also be used as a smear for washing the outside of the formed cheese, such as the use of *Brevibacterium linens* of gruyere, brick and limburger cheeses.

Yeasts and molds are used in some cheeses to provide the characteristic colors and flavors of some cheese varieties. Torula yeast is used in the smear for the ripening of brick and limberger cheese. Examples of molds include *Penicillium camemberti* in camembert and brie, and *Penicillium roqueforti* in blue cheeses.

General Manufacturing Procedure

The temperatures, times, and target pH for different steps, the sequence of processing steps, the use of salting or brining, block formation, and aging vary considerably between cheese types. The following flow chart provides a very general outline of cheese making steps. The general processing steps for Cheddar cheese are used for illustration. For a more detailed explanation see the literature references by Fox (2004), Kosikowski and Mistry (1997), Law (1997), Walstra et al. (1999), and the website by Goff, www.foodsci.uoguelph.ca/dairyedu/cheese.html.

General Cheese Processing Steps

- Standardize Milk
- Pasteurize/Heat Treat Milk
- Cool Milk
- Inoculate with Starter & Non-Starter Bacteria and Ripen
- Add Rennet and Form Curd
- Cut Curd and Heat
- Drain Whey

- Texture Curd
- Dry Salt or Brine
- Form Cheese into Blocks
- Store and Age
- Package

The times, temperatures, and target pH values used for cheddar cheese will depend on individual formulations and the intended end use of the cheese. These conditions can be adjusted to optimize the properties of Cheddar cheese for shredding, melting, or for cheese that is meant to be aged for several years.

1. Standardize Milk

Milk is often standardized before cheese making to optimize the protein to fat ratio to make a good quality cheese with a high yield

2. Pasteurize/Heat Treat Milk

Depending on the desired cheese, the milk may be pasteurized or mildly heat-treated to reduce the number of spoilage organisms and improve the environment for the starter cultures to grow. Some varieties of milk are made from raw milk so they are not pasteurized or heat-treated. Raw milk cheeses must be aged for at least 60 days to reduce the possibility of exposure to disease causing microorganisms (pathogens) that may be present in the milk.

3. Cool Milk

Milk is cooled after pasteurization or heat treatment to 90°F (32°C) to bring it to the temperature needed for the starter bacteria to grow. If raw milk is used the milk must be heated to 90°F (32°C).

4. Inoculate with Starter & Non-Starter Bacteria and Ripen

The starter cultures and any non-starter adjunct bacteria are added to the milk and held at 90°F (32°C) for 30 minutes to ripen. The ripening step allows the bacteria to grow and begin fermentation, which lowers the pH and develops the flavor of the cheese.

5. Add Rennet and Form Curd

The rennet is the enzyme that acts on the milk proteins to form the curd. After the rennet is added, the curd is not disturbed for approximately 30 minutes so a firm coagulum forms.

6. Cut Curd and Heat

The curd is allowed to ferment until it reaches pH 6.4. The curd is then cut with cheese knives into small pieces and heated to 100°F (38°C). The heating step helps to separate the whey from the curd.

7. Drain whey

The whey is drained from the vat and the curd forms a mat.

8. Texture curd

The curd mats are cut into sections and piled on top of each other and flipped periodically. This step is called **cheddarin**g. Cheddaring helps to expel more whey, allows the fermentation to continue until a pH of 5.1 to 5.5 is reached, and allows the mats to "knit" together and form a tighter matted structure. The curd mats are then milled (cut) into smaller pieces.

9. Dry Salt or Brine

For cheddar cheese, the smaller, milled curd pieces are put back in the vat and salted by sprinkling dry salt on the curd and mixing in the salt. In some cheese varieties, such as mozzarella, the curd is formed into loaves and then the loaves are placed in a brine (salt water solution).

10. Form Cheese into Blocks

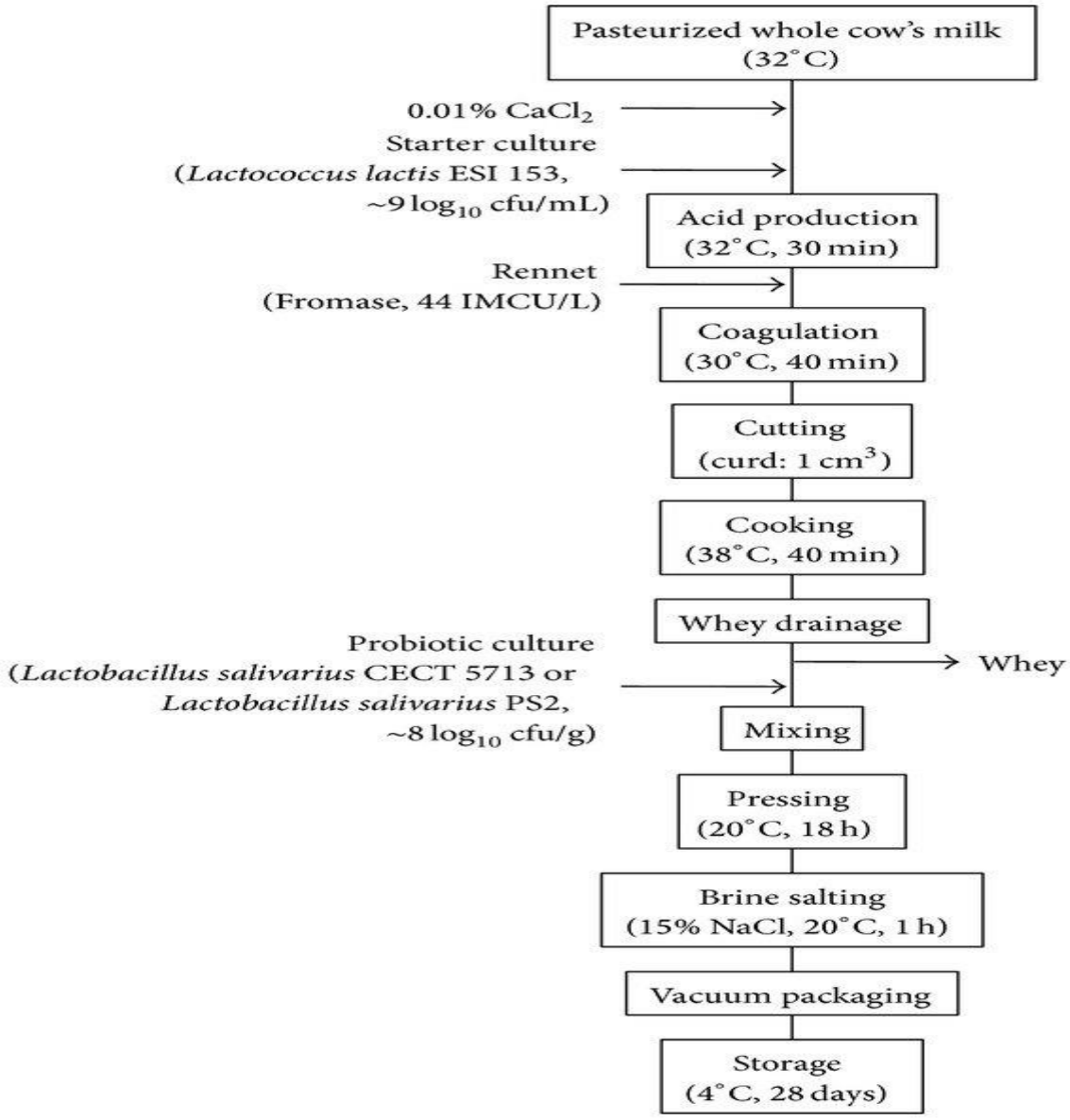
The salted curd pieces are placed in cheese hoops and pressed into blocks to form the cheese.

11. Store and Age

The cheese is stored in coolers until the desired age is reached. Depending on the variety, cheese can be aged from several months to several years.

12. Package

Cheese may be cut and packaged into blocks or it may be waxed.



TYPES

1. Fresh Cheese

Fresh cheeses are also known as "unripened" cheeses because they aren't aged at all. They are soft, spreadable cheeses with creamy textures and very mild flavors. Like other cheeses, fresh cheeses can be made from different types of milk and varying amounts of salt, which gives them distinct flavors.

The texture of fresh cheese also depends on how much whey and moisture is drained from the final product, resulting in everything from soupy (cottage cheese) to crumbly (queso fresco).

"You can make fresh cheeses on your kitchen counter," says Wright, who makes her own cottage cheese by using lemon juice instead of rennet to curdle the milk.

Some popular fresh cheeses are:

- cottage cheese
- queso fresco
- cream cheese
- mascarpone
- ricotta
- chevre

2. Pasta Filata

This category refers to the classic Italian stretched-curd cheese preparation made famous in Italy. Pasta Filata is Italian for "spun paste." Fresh cheese curds are steeped in a hot water bath and then stretched, spun or kneaded into different shapes.

Mozzarella is arguably the most famous Pasta Filata. The heating and kneading process aligns the protein structure of the cheese, making it stretch more when melted — perfect for pizza! Spun mozzarella balls can either be stored in brine or water for fresh eating or packed into bricks and aged for a longer shelf life.

Other Pasta Filata cheeses like provolone are tied up and air-cured for weeks or months. Pasta Filata cheeses can also be smoked for added flavor.

Examples of Pasta Filata cheeses are:

- mozzarella
- burrata
- provolone
- queso Oaxaca
- scamorza affumicata
- caciocavallo

3. Soft-ripened (Bloomy Rind) Cheese

Camembert (left) and Brie are both examples of soft-ripened or bloomy rind cheeses.

These cheeses ripen from the outside in, so the inside may be runnier than the outside. The best-known soft-ripened cheeses are Brie and Camembert, both from France. The distinguishing characteristic of these creamy, earthy cheeses is a thin white rind of blooming mold. Yup, mold.

During a short aging period, soft-ripened cheeses are exposed to particular strains of mold, like *Penicillium camemberti* that work from the outside in converting fats into aromatic compounds called ketones. The ketones created by *P. camemberti* impart a mushroomy, ammonia edge to Camembert.

Wright says that soft-ripened cheese, like all cheese, is best eaten at room temperature when the flavor profile is maximized. If it smells too strongly of ammonia, though, toss it out.

Soft-ripened cheeses include:

- Brie
- Camembert
- Cambozola

4. Semi-soft Cheese

This category focuses on texture rather than the mechanics of how the cheese is made. What semi-soft cheeses share in common is a short aging period, typically only a few months, which results in a moist, flexible cheese with a

creamy consistency. Havarti is a classic semi-soft cheese with a very mild flavor.

Examples of semi-soft cheeses are:

- Havarti
- Muenster (American)
- Jarlsberg
- Chaumes
- **5. Washed-Rind Cheese**

  Here's where things get exciting. The washed-rind category is responsible for some of the biggest stinkers in the cheese world. The famed (and defamed) Limburger cheese packs a powerful aroma reminiscent of old sneakers, and that's not a coincidence.

  The stinkiest washed-rind cheeses are rinsed down twice a week with seawater, beer, wine or liquor for about two months. Why wash the rind? Wright says the practice began with monks who wanted to keep mold from growing on their cheese. By washing it with brine or beer, they not only killed the mold, but promoted the growth of a bacteria called *Brevibacterium linens*.

  B. linens, it turns out, is also one of the main bacteria found on unwashed feet. But don't be scared off by Limburger and other stinky rind-washed cheeses.

  "Their bark is worse than their bite," says Wright. "They're much more approachable if you can get past the smell."

  The list of washed-rind cheeses include:

- Limburger
- taleggio
- Epoisses
- Alsatian Munster

  6. Blue Cheese

While soft-ripened cheeses like Brie are externally treated with mold, blue cheeses are inoculated with mold internally. The particular strains of mold that make blue-streaked cheese include *Penicillium roqueforti*, named for a mold common to caves in the region of Roquefort, France.

Interestingly, the blue mold will only grow when exposed to air. When blue cheeses are first pressed into molds, they have pristine white interiors. But at some point in the aging process, the cheesemakers pierce the skin of the wheel, introducing air, which kick-starts the mold-growing process.

Blue cheeses have strong, salty, nutty flavors and include varieties like:

- Roquefort
- Stilton
- Gorgonzola
- Danish blue

7. Semi-hard Cheese

Cheddar is a classic semi-hard cheese, which is by far the largest category of cheeses on the market. Semi-hard cheeses get their flavor from two sources: the strain of bacteria introduced to the milk and how long the particular cheese is aged.

Fun fact: Cheese is fermented. When bacteria are added to milk, they go to work converting natural sugars in the milk (lactose) into lactic acid. That lactic

acid is part of what gives cheese its distinctive tang. Other bacteria contribute to the formation of complex flavor proteins. Still other bacteria burp up carbon dioxide gas, which creates the telltale holes of Swiss cheese.

Different strains of bacteria are used as "starter cultures" to produce different varieties of cheese. A strain called *Lactococcus lactis ssp. cremoris* is the bacteria behind cheddar. *Lactobacillus helveticus* will give you Swiss.

Then there's aging. With semi-hard cheeses, the length of the aging process will determine the hardness of the cheese and the "sharpness" of its flavor profile. That's because cheese loses moisture as it ages, hardening the cheese and amplifying the natural flavor of the proteins created by the bacterial cultures.

Semi-hard cheeses include:

- cheddar
- Gouda
- Edam
- Monterey Jack
- Emmental
- Swiss
- Gruyere

8. Hard Cheese

This category is reserved for extra-hard, extremely low-moisture cheeses like Parmesan, Machego and Asiago. These cheeses are characterized by their pungent saltiness and rich umami flavor profile. Because of their hardness, these cheeses are often grated over dishes like pasta and soup, not sliced.

This selection of Spanish tapas shows manchego cheese pieces surrounded by Spanish chorizo, olives, bread slices and grapes. Machego is an example of a hard cheese.

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Parmesan is a generic name for the original Parmigiano-Reggiano from Italy. To make this classic cheese, large wheels of freshly curdled milk are first soaked in a salt bath for three months, then aged for at least 24 months, but up to three years. The cheese forms a thick natural rind that's hard on the teeth but is a great addition to soups and stocks.

If you notice little crunchy bits in a well-aged, hard cheese, don't fret. Those aren't hunks of salt, says Wright, but cheese crystalsthat form as a natural byproduct of the slow-aging process. The crystals themselves don't impart any flavor, but they are a sign that bacteria are doing their work breaking down the lactose and amino acids in the cheese, which will result in a more robust flavor.

Hard cheeses include:

- Parmigiano-Reggiano
- Asiago
- pecorino
- manchego

Yogurt Production

This page describes the production of yogurt and includes the legal Yogurt Definitions, Ingredients, Bacterial Cultures, and General Manufacturing Procedure.

Yogurt Definitions

Yogurt is a fermented milk product that contains the characteristic bacterial cultures *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. All yogurt must contain at least 8.25% solids not fat. Full fat yogurt must contain not less than 3.25% milk fat, lowfat yogurt not more than 2% milk fat, and nonfat yogurt less than 0.5% milk. The full legal definitions for yogurt, lowfat yogurt and nonfat yogurt are specified in the Standards of Identity listed in the U.S. Code of Federal Regulations (CFR), in sections 21 CFR 131.200, 21 CFR 131.203, and 21 CFR 131.206, respectively.

The two styles of yogurt commonly found in the grocery store are set type yogurt and swiss style yogurt. Set type yogurt is when the yogurt is packaged with the fruit on the bottom of the cup and the yogurt on top. Swiss style yogurt is when the fruit is blended into the yogurt prior to packaging.

Ingredients

The main ingredient in yogurt is milk. The type of milk used depends on the type of yogurt – whole milk for full fat yogurt, lowfat milk for lowfat yogurt, and skim milk for nonfat yogurt. Other dairy ingredients are allowed in yogurt to adjust the composition, such as cream to adjust the fat content, and nonfat dry milk to adjust the solids content. The solids content of yogurt is often adjusted above the 8.25% minimum to provide a better body and texture to the finished yogurt. The CFR contains a list of the permissible dairy ingredients for yogurt.

Stabilizers may also be used in yogurt to improve the body and texture by increasing firmness, preventing separation of the whey (syneresis), and helping to keep the fruit uniformly mixed in the yogurt. Stabilizers used in yogurt are alginates (carageenan), gelatins, gums (locust bean, guar), pectins, and starch.

Sweeteners, flavors and fruit preparations are used in yogurt to provide variety to the consumer. A list of permissible sweeteners for yogurt is found in the CFR.

Bacterial Cultures

The main (starter) cultures in yogurt are *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. The function of the starter cultures is to ferment lactose (milk sugar) to produce lactic acid. The increase in lactic

acid decreases pH and causes the milk to clot, or form the soft gel that is characteristic of yogurt. The fermentation of lactose also produces the flavor compounds that are characteristic of yogurt. *Lactobacillus bulgaricus* and *Streptococcus thermophilus* are the only 2 cultures required by law (CFR) to be present in yogurt.

Other bacterial cultures, such as *Lactobacillus acidophilus, Lactobacillus subsp. casei,* and Bifido-bacteria may be added to yogurt as probiotic cultures. Probioticcultures benefit human health by improving lactose digestion, gastrointestinal function, and stimulating the immune system.

General Manufacturing Procedure

The following flow chart and discussion provide a general outline of the steps required for making yogurt. For a more detailed explanation see the literature references by Staff (1998), Tamime and Robinson (1999), Walstra et al. (1999)and the website by Goff, www.foodsci.uoguelph.ca/dairyedu/yogurt.html.

General Yogurt Processing Steps

- Adjust Milk Composition & Blend Ingredients
- Pasteurize Milk
- Homogenize
- Cool Milk
- Inoculate with Starter Cultures
- Hold
- Cool
- Add Flavors & Fruit
- Package

1. Adjust Milk Composition & Blend Ingredients

Milk composition may be adjusted to achieve the desired fat and solids content. Often dry milk is added to increase the amount of whey protein to provide a desirable texture. Ingredients such as stabilizers are added at this time.

2. Pasteurize Milk

The milk mixture is pasteurized at 185°F (85°C) for 30 minutes or at 203°F (95°C) for 10 minutes. A high heat treatment is used to denature the whey (serum) proteins. This allows the proteins to form a more stable gel, which prevents separation of the water during storage. The high heat treatment also further reduces the number of spoilage organisms in the milk to provide a better environment for the starter cultures to grow. Yogurt is pasteurized before the

starter cultures are added to ensure that the cultures remain active in the yogurt after fermentation to act as probiotics; if the yogurt is pasteurized after fermentation the cultures will be inactivated.

3. Homogenize

The blend is homogenized (2000 to 2500 psi) to mix all ingredients thoroughly and improve yogurt consistency.

4. Cool Milk

The milk is cooled to 108°F (42°C) to bring the yogurt to the ideal growth temperature for the starter culture.

5. Inoculate with Starter Cultures

The starter cultures are mixed into the cooled milk.

6. Hold

The milk is held at 108°F (42°C) until a pH 4.5 is reached. This allows the fermentation to progress to form a soft gel and the characteristic flavor of yogurt. This process can take several hours.

7. Cool

The yogurt is cooled to 7°C to stop the fermentation process.

8. Add Fruit & Flavors

Fruit and flavors are added at different steps depending on the type of yogurt. For set style yogurt the fruit is added in the bottom of the cup and then the inoculated yogurt is poured on top and the yogurt is fermented in the cup. For swiss style yogurt the fruit is blended with the fermented, cooled yogurt prior to packaging.

9. Package

The yogurt is pumped from the fermentation vat and packaged as desired.

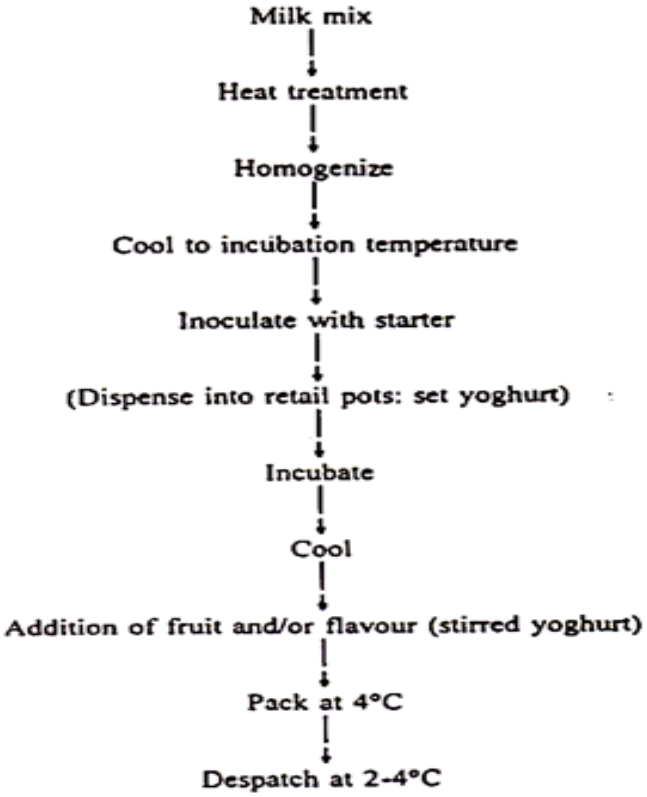


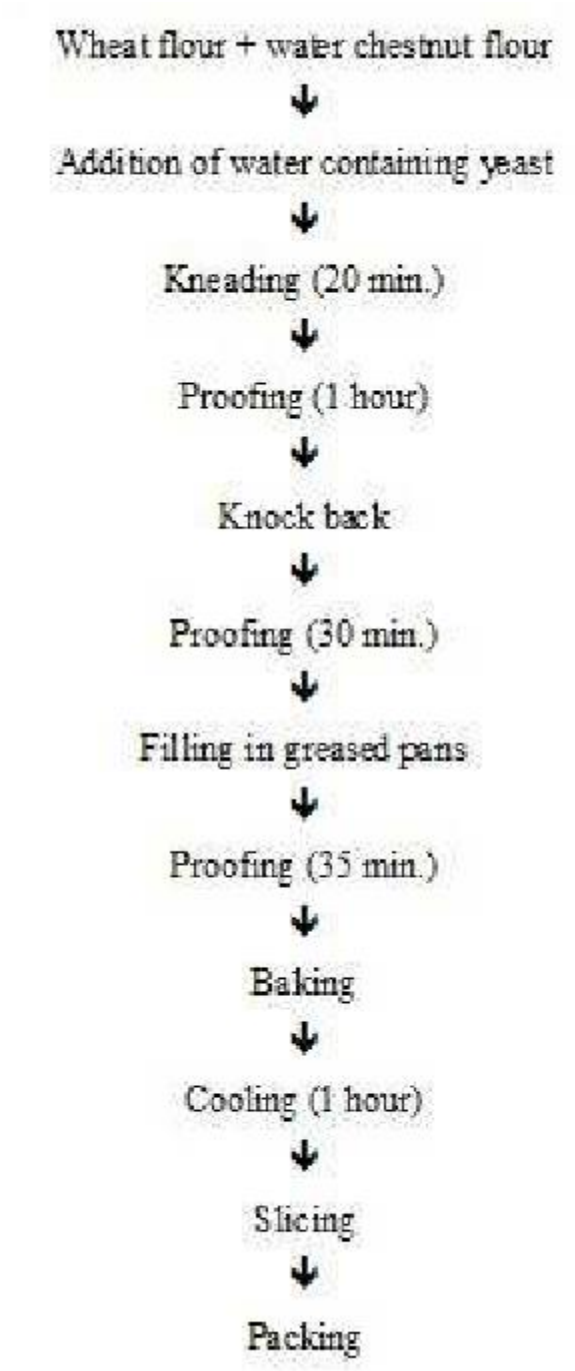
Figure 9.4 *Yoghurt production*

Bread

Bread making from the dough by employing microorganisms is one of the oldest examples of fermentation processes known to mankind. There is evidence that bread was prepared in Egypt in 3000 BC. Primarily, bread is a fermented product of cereal flours such as wheat and rye. The cereal flour mixed with water, salt, sugar, fat and other ingredients (as desired for enrichment of bread) is subjected to fermentation by yeast, Saccharomyces cerevisiae (top fermenting strain). The main reaction that occurs during bread formation is the fermentation of hexoses to CO_2 and ethanol.

$C_6H_{12}O_6 \rightarrow 2C_2H_5OH + 2CO_2$

The ethanol produced either gets evaporated or forms esters. The CO_2 gets entrapped in the dough resulting in its expansion. The expansion and stretching of the dough, particularly with wheat is due to the unique elastic protein namely gluten. Gluten is mainly responsible for retaining the shape of bread. Besides yeast enzymes, the enzymes (e.g. amylases) of other microorganisms also help in fermentation and baking of bread. The texture of bread is influenced by fats and emulsifiers added to the dough.



The bread making is carried out with three objectives:

i. Good leavening due to CO_2 formation.

ii. Flavour development.

iii. Good texture.

The yeast fermented bread has the above characteristics. This is in contrast to the bread produced with baking powder which also produces CO_2. But this does not have the same flavour and texture as that produced by yeast. Thus the yeast,

which is appropriately referred to as baker's yeast is a package of enzymes to give a desired product.
In recent years, some workers have reported the development of genetically engineered strains of Saccharomyces cerevisiae with improved fermentation properties. Such organisms, when used in baking industry, are believed to further enhance the quality of bread with regard to flavour, texture etc.

Sour-dough breads:
In some parts of the world, sour breads are prepared by using the yeast, Candida milleri and bacterium, Lactobacillus San Francisco.

Baker's Yeast:
The living cells of aerobically grown Saccharomyces cerevisiae are collectively referred to as baker's yeast. Baker's yeast is commercially available either as a dried powder i.e. dry yeast with about 95% dry weight or in the form of cakes (about 25-30% dry weight). These commercially available yeast preparations can be used in bread making.

Production of baker's yeast:
The medium for baker's yeast production contains molasses, ammonium salts (or ammonia), vitamins, phosphates and antifoam agents. Sugar cane or sugar beet molasses can be used. A commercially available molasses with a sugar concentration of 45-50% is usually preferred. Baker's yeast production is carried out by an aerobic fed-batch process.

The flow chart for the production of baker's yeast is depicted in Fig. 28.3. The actual production process and the strain of Saccharomyces cerevisiae used depend on the company. The desired strain is maintained in a frozen state. The inoculum is prepared in stages so that large volumes are finally obtained.

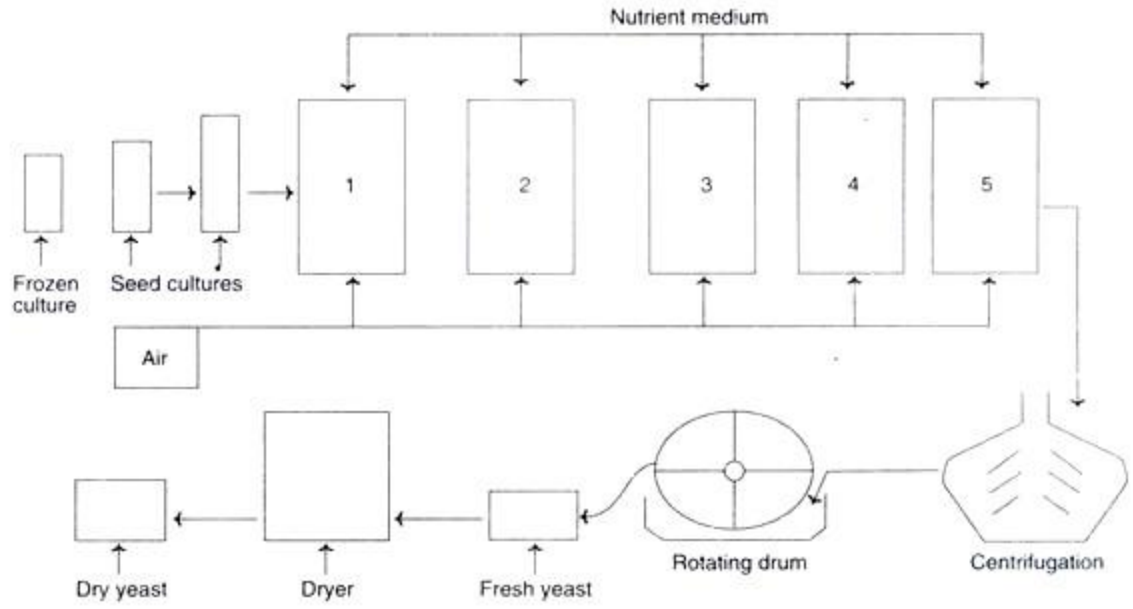


***Fig. 28.3** : Flow chart for the production of baker's yeast (1 is the inoculation reactor, 2–5 are production reactors).*

From the inoculation reactor (fermenter), the culture is transferred to production reactors. The process is carried out in air-lift or bubble column type reactors at pH 4-5, temperature 28-30°C for about 12-18 hours. The yeast cells are washed, centrifuged and then dewatered on a rotating drum. The fresh yeast obtained can be either directly used or dried and stored.

The yeast cells may be mixed with plasticizer (e.g. vegetable oil) and prepared in a block form. This block can be cut into small pieces, wrapped and stored (at -4°C) until used. The samples of yeast are usually tested for baking properties before they are put in use.

Preparation of Bread:

Flours and meals for the preparation of bread are usually made from wheat or rye, occasionally from maize or barley. They are all high in starch, and the first two contain a considerable proportion of protein, commonly designated as 'gluten'.

In addition, there are traces of sugar and some diastase enzyme. Flour is mixed with water to form a dough. For some types of bread, little sugar is also added. The series of changes which occur in the flour and other constituents of the dough before baking into bread is termed 'panary fermentation'.

An alcoholic fermentation by yeast is an essential step in the production of bread; this process is known as the 'leavening of bread'. A product of action of microorganisms is involved in the production of bread.

Types of Bread:

However, there are following three basic types of rising breads, which are the following:

(i) White or Common Bread:

In this bread preparation the moistened flour is mixed with yeast, Saccharomyces cerevisiae, and is allowed to stand for several hours in a warm place.

Flour itself contains little free sugar, but there are sufficient quantities of starch splitting enzymes in it to produce some sugar during the leavening process. The sugar is rapidly fermented by the yeast with the production of alcohol and carbon dioxide, the latter causing the rising of the bread. During the baking process the alcohol is driven off.

(ii) Sour Bread:

This bread is a sour dough, from which a 'starter' is saved to inoculate the next batch. The organisms appear to be Escherichia coli and Enterobacter species which produce a mixed lactic acid fermentation, i.e., accompanying the gas there is always some lactic acid which tends to make the bread taste sour.

(iii) Salt-Rising Bread:

This type of bread is dependent upon the spontaneous fermentation by (probably) wild yeasts and common contaminating bacteria, E. coli and Enterobacter types. In this case, salt is added to the bread which cuts down some of the extraneous contamination and allows the bread to rise during fermentation.

Abnormal Fermentation of Bread:

The most common abnormal fermentations in bread are the following:

(i) Undesirable High Acidity:

Too high acidity may develop as a result of the growth of lactic bacteria for too long a period in the dough before baking and the bread thus becomes unpalatable as a result of the development of sourness in it.

(ii) Ropiness:

Ropiness results in from the growth of certain highly resistant spore-producing bacteria after baking. Several such species have been described which are mostly the varients of Bacillus subtilis. They are probably present in most bread, but do not develop and cause ropiness except when there has been too little development of acid in the leavening process and the bread has been stored at a relatively high temperature.

In other words, in order to prevent rapid deterioration of the bread after baking, it is necessary that a certain amount of acid be present in the dough. This is usually formed as a result of the growth of certain lactic acid species.

(iii) Bloody Bread:
Some bacteria may form coloured spots or areas in the bread. Serratia marcescens (sometimes termed Bacillus prodigiosus) produces a red pigment. The red spots were interpreted before the development of modern science as spots of blood, hence the name bloody bread.

Sauerkraut

Sauerkraut (/ˈsaʊ.ərkraʊt/; German:[ˈzaʊɐ̯ˌkʁaʊt] (listen), lit. "sour cabbage"[1]) is finely cut raw cabbagethat has been fermented by various lactic acid bacteria.[2][3] It has a long shelf life and a distinctive sour flavor, both of which result from the lactic acid formed when the bacteria ferment the sugars in the cabbage leaves.

Overview and history

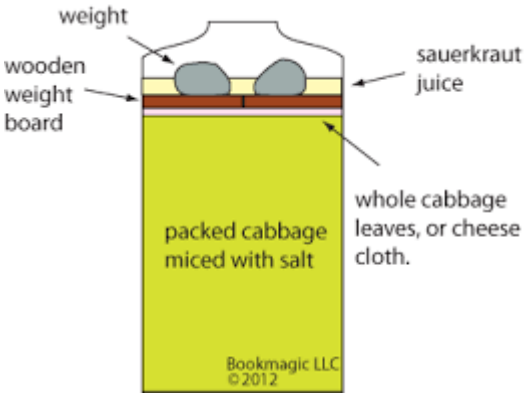
Polish *kiszona kapusta*

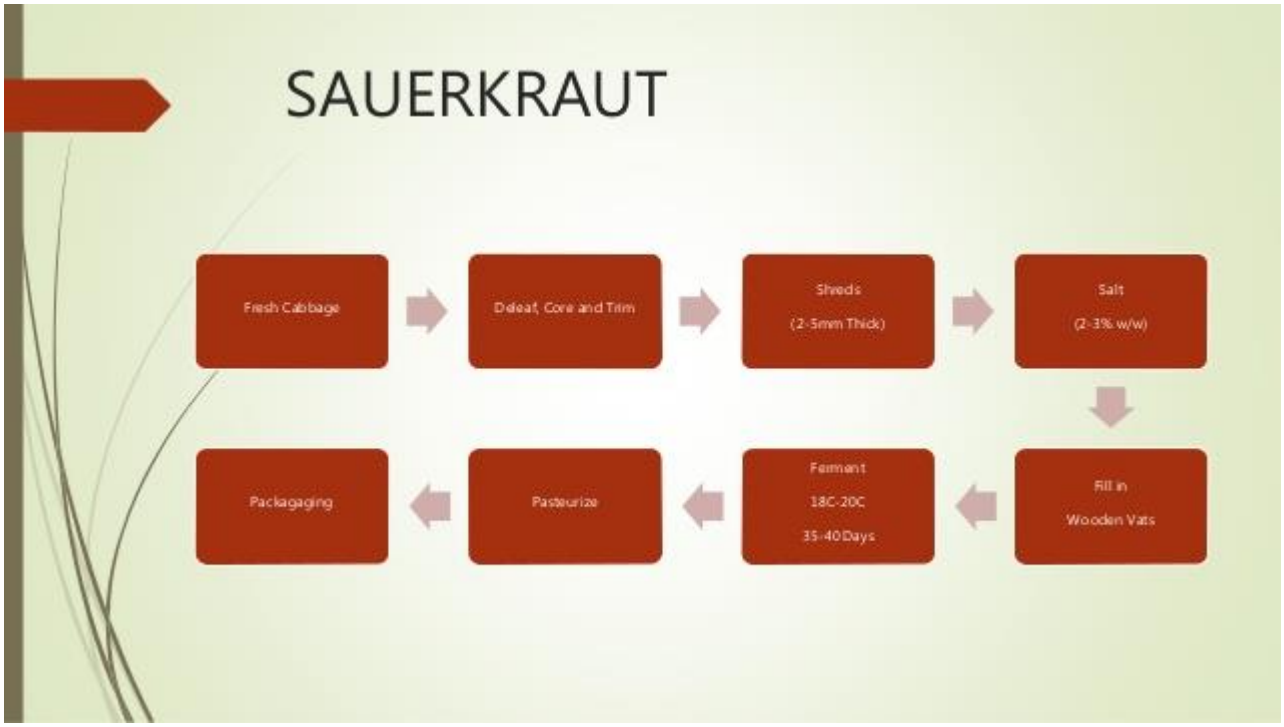
Fermented foods have a long history in many cultures, with sauerkraut being one of the most well-known instances of traditional fermented moist cabbage side dishes.[6][*better source needed*] The Roman writers Cato (in his *De Agri Cultura*) and Columella (in his *De re Rustica*) mentioned preserving cabbages and turnips with salt.[*citation needed*]

Although "sauerkraut" is a German word, the dish did not originate in Germany. Some claim that the Mongol Emperor Genghis Khan brought it to Europe.[7] Others claim that it originally came from China and surrounding areas and that the Tatars brought it to Europe,[8] and improved upon the original Chinese recipe by fermenting it with salt instead of rice wine.[9] It took root mostly in Central and Eastern European cuisines, but also in other countries including the Netherlands, where it is known as *zuurkool*, and France, where the name became *choucroute*.[10] The English name is borrowed from German where it means literally "sour herb" or "sour cabbage".[11] The names in Slavic and other Central and Eastern Europeanlanguages have similar meanings with the German word: "fermented cabbage" (Albanian: *lakër turshi*, Azerbaijani: *kələm turşusu*,[12] Belarusian: квашаная капуста, Czech: *kysané zelí*, Lithuanian: *rauginti kopūstai*, Polish: *kiszona kapusta*, Russian: квашеная капуста, tr. *kvašenaja kapusta*, Ukrainian: квашена капуста) or "sour cabbage" (Bulgarian: кисело зеле, Czech: *kyselé zelí*, Estonian: *hapukapsas*, Finnish: *hapankaali*, Hungarian: *savanyúkáposzta*, Latvian: *skābēti kāposti*, Polish: *kwaszona kapusta*, Romanian: *varză murată*, Russian: кислая капуста, tr. *kislaya kapusta*, Serbo-Croatian: *кисели купус / kiseli kupus*, Slovak: *kyslá kapusta*, Slovene: *kislo zelje*, Ukrainian: кисла капуста, *kisla kapusta*).[13]

Before frozen foods, refrigeration, and cheap transport from warmer areas became readily available in northern, central and eastern Europe, sauerkraut – like other preserved foods – provided a source of nutrients during the winter. Captain James Cook always took a store of sauerkraut on his sea voyages, since experience had taught him it prevented scurvy.[14][15]

The word "Kraut", derived from this food, is a derogatory term for the German people.[16] During World War I, due to concerns the American public would reject a product with a German name, American sauerkraut makers relabeled their product as "Liberty Cabbage" for the duration of the war.[17]





Production

Homemade sauerkraut

Sauerkraut is made by a process of pickling called lactic acid fermentationthat is analogous to how traditional (not heat-treated) pickled cucumbersand kimchi are made. The cabbage is finely shredded, layered with salt, and left to ferment. Fully cured sauerkraut keeps for several months in an airtight container stored at 15 °C (60 °F) or below. Neither refrigeration nor pasteurization is required, although these treatments prolong storage life.

Fermentation by lactobacilli is introduced naturally, as these air-borne bacteria culture on raw cabbage leaves where they grow. Yeasts also are present, and may yield soft sauerkraut of poor flavor when the fermentation temperature is

too high. The fermentation process has three phases, collectively sometimes referred to as population dynamics. In the first phase, anaerobic bacteria such as *Klebsiella* and *Enterobacter* lead the fermentation, and begin producing an acidic environment that favors later bacteria. The second phase starts as the acid levels become too high for many bacteria, and *Leuconostoc mesenteroides* and other *Leuconostoc* species take dominance. In the third phase, various *Lactobacillus* species, including *L. brevis* and *L. plantarum*, ferment any remaining sugars, further lowering the pH.[18] Properly cured sauerkraut is sufficiently acidic to prevent a favorable environment for the growth of *Clostridium botulinum*, the toxins of which cause botulism.[2][3]

A 2004 genomic study found an unexpectedly large diversity of lactic acid bacteria in sauerkraut, and that previous studies had oversimplified this diversity. *Weissella* was found to be a major organism in the initial, heterofermentative stage, up to day 7. It was also found that *Lactobacillus brevis* and *Pediococcus pentosaceus* had smaller population numbers in the first 14 days than previous studies had reported.[19]

The Dutch sauerkraut industry found that inoculating a new batch of sauerkraut with an old batch resulted in an excessively sour product.
This sourdough process is known as "backslopping" or "inoculum enrichment"; when used in making sauerkraut, first- and second-stage population dynamics, important to developing flavor, are bypassed. This is due primarily to the greater initial activity of species *L. plantarum*.[20]

Regional varieties

Eastern European-style sauerkraut pickled with carrots and served as a salad

In Azerbaijani, Belarusian, Polish, Russian, Baltic states and Ukrainian cuisine, chopped cabbage is often pickled together with shredded carrots. Other ingredients may include whole or quartered apples for additional flavor or cranberry for flavor and better keeping (the benzoic acidin cranberries is a common preservative). Bell peppers and beetsare added in some recipes for colour. The resulting sauerkraut salad is typically served cold, as *zakuski* or a side dish. A home made type of very mild sauerkraut is available, where white cabbage is pickled with salt in a refrigerator for only three to seven days. This

process results in very little lactic acid production. Sometimes in Russia the double fermentation is used, with the initial step producing an exceptionally sour product, which is then "corrected" by adding 30-50% more fresh cabbage and fermenting the mix again. The flavor additives like apples, beets, cranberries and sometimes even watermelons are usually introduced at this step.

Sauerkraut may be used as a filling for Polish *pierogi*, Ukrainian *varenyky*, Russian *pirogi* and *pirozhki*.[21] Sauerkraut is also the central ingredient in traditional soups, such as *shchi* (a national dish of Russia), *kwaśnica* (Poland), *kapustnica* (Slovakia), and *zelňačka* (Czech Republic). It is an ingredient of Polish *bigos* (a hunter's stew). [1]

In Germany, cooked sauerkraut is often flavored with juniper berries[22] or caraway seeds; apples and white wine are added in popular variations. Traditionally it is served warm, with pork (e.g. *eisbein*, *schweinshaxe*, *Kassler*) or sausages (smoked or fried sausages, *Frankfurter Würstchen*, Vienna sausages, black pudding), accompanied typically by roasted or steamed potatoes or dumplings (*knödel* or *schupfnudel*).[23] Similar recipes are common in other Central European cuisines. The Czech national dish *vepřo knedlo zelo*consists of roast pork with *knedliky* and sauerkraut.

In France, sauerkraut is the main ingredient of the Alsatian meal *choucroute garnie* (French for "dressed sauerkraut"), sauerkraut with sausages (Strasbourg sausages, smoked Morteau or Montbéliard sausages), charcuterie(bacon, ham, etc.), and often potatoes.

Sauerkraut, along with pork, is eaten traditionally in Pennsylvania on New Year's Day. The tradition, started by the Pennsylvania Dutch, is thought to bring good luck for the upcoming year.[24] Sauerkraut is also used in American cuisine as a condiment upon various foods, such as sandwiches and hot dogs.[4][5][25] In Maryland, particularly in Baltimore and on the Eastern Shore, sauerkraut is a traditional accompaniment for the Thanksgiving turkey.[26]

- 

Cooked sauerkraut

- 

  Dutch *zuurkoolstamppot*includes sauerkraut mashed with potatoes.

- 

  Pierogi with sauerkraut

- 

  Kapuśniak made with sauerkraut

- 

  Central European-style sauerkraut and sausages is a popular snack dish in pubs.

- 

  Czech *Vepřo-knedlo-zelo*

- 

  Pickled *Eisbein* served with sauerkraut

- 

Alsacian *Choucroute garnie*

Health effects

Benefits

Sauerkraut (including liquid)	
Nutritional value per 100 g (3.5 oz)	
Energy	78 kJ (19 kcal)
Carbohydrates	4.3 g
Sugars	1.8 g
Dietary fiber	2.9 g
Fat	0.14 g
Protein	0.9 g
Vitamins	**Quantity%DV**†
Vitamin B6	10% 0.13 mg
Vitamin C	18% 15 mg
Vitamin K	12% 13 μg

Minerals	**Quantity%DV†**
Iron	12% 1.5 mg
Sodium	44% 661 mg
Other constituents	**Quantity**
Water	92 g

Units
μg = micrograms • mg = milligrams
IU = International units

†Percentages are roughly approximated using US recommendations for adults.
Source: USDA Nutrient Database

Many health benefits have been claimed for sauerkraut:

- It is a high source of vitamins C and K;[27] the fermentation process increases the bioavailability of nutrients rendering sauerkraut even more nutritious than the original cabbage.[28] It is also low in calories and high in calcium and magnesium, and it is a very good source of dietary fiber, folate, iron, potassium, copper and manganese.[27]

- If unpasteurized and uncooked, sauerkraut also contains live lactobacilli and beneficial microbes and is rich in enzymes. Fiber and probiotics improve digestion and promote the growth of healthy bowel flora, protecting against many diseases of the digestive tract.[28][29]

- During the American Civil War, the physician John Jay Terrell (1829–1922)[30] was able to successfully reduce the death rate from disease among prisoners of war; he attributed this to feeding his patients raw sauerkraut.[31]

- Sauerkraut and its juice is a time-honored folk remedy for canker sores. The treatment is to rinse the mouth with sauerkraut juice for about 30 seconds several times a day, or place a wad of sauerkraut against the affected area for a minute or so before chewing and swallowing the sauerkraut.[32]

- In 2002, the *Journal of Agriculture and Food Chemistry* reported that Finnish researchers found the isothiocyanates produced in sauerkraut fermentation inhibit the growth of cancer cells in test tube and animal studies.[33] A Polish study in 2010 concluded that "induction of the key detoxifying enzymes by cabbage juices, particularly sauerkraut, may be responsible for their chemopreventive activity demonstrated by epidemiological studies and in animal models".[34][35][36][37][38][39][40][41]

- Sauerkraut is high in the antioxidants lutein and zeaxanthin, both associated with preserving ocular health.[42]

Disadvantages

Excessive consumption of sauerkraut may lead to bloating and flatulence due to the trisaccharide raffinose, which the human small intestine cannot break down.[43]

Scientific discovery

One of the early scientists who was involved in identifying the biology and function of Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), Philippe Horvath, focused on the genetics of a lactic-acid bacterium used in the production of sauerkraut.[44]

Pickles are cucumbers preserved in a solution of vinegar, salt, and other flavorings. They are typically fermented with naturally-occurring bacteria prior to vinegar preservation. While pickling technology has been known since ancient times, pickles are still a popular food, with over 5 million lb (2.27 million kg) consumed daily.

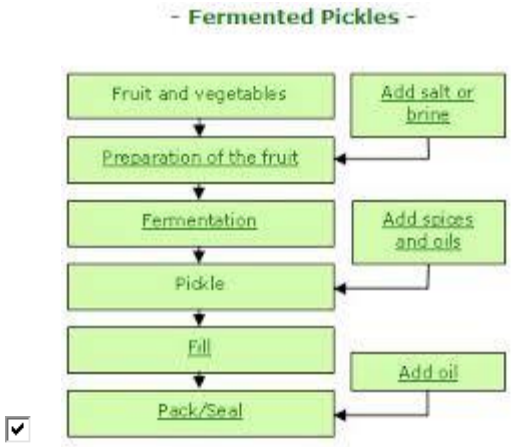
Pickling

Pickling is the process of preserving or extending the shelf life of food by either anaerobicfermentation in brine or immersion in vinegar. In East Asia, vinaigrette (vegetable oil and vinegar) is also used as a pickling medium.[1] The pickling procedure typically affects the food's texture, taste and flavor. The resulting food is called a *pickle*, or, to prevent ambiguity, prefaced with *pickled*. Foods that are pickled include vegetables, fruits, meats, fish, dairy and eggs.

A distinguishing characteristic is a pH of 4.6 or lower,[2] which is sufficient to kill most bacteria. Pickling can preserve perishable foods for months. Antimicrobial herbs and spices, such as mustard seed, garlic, cinnamon or cloves, are often added.[3] If the food contains sufficient moisture, a pickling brine may be produced simply by adding dry salt. For example, sauerkrautand Korean kimchi are produced by salting the vegetables to draw out excess water. Natural fermentation at room temperature, by lactic acid bacteria, produces the required acidity. Other pickles

are made by placing vegetables in vinegar. Like the canning process, pickling (which includes fermentation) does not require that the food be completely sterile before it is sealed. The acidity or salinity of the solution, the temperature of fermentation, and the exclusion of oxygen determine which microorganisms dominate, and determine the flavor of the end product.[4]

When both salt concentration and temperature are low, *Leuconostoc mesenteroides* dominates, producing a mix of acids, alcohol, and aroma compounds. At higher temperatures *Lactobacillus plantarum* dominates, which produces primarily lactic acid. Many pickles start with *Leuconostoc*, and change to *Lactobacillus* with higher acidity.[4]



History

Pickling of plant and animal foods is a relatively old method of food preservation. It is estimated that the first pickles were produced over 4,000 years ago using cucumbers native to India. The ancient Egyptians and Greeks both have written about the use of pickles for their nutritive value and healing power. Pickles were a common food during the time of the Roman Empire and they soon spread throughout Europe. In America, pickles have always been popular. The first travelers to America kept pickles in large supply because they were nutritious and did not spoil during the long journeys. It is interesting to note that Amerigo Vespucci, America's namesake, was also a pickle salesman. He was the main pickle supplier to many ships. The first large-scale commercial production of pickles did not take place until 1820, when Nicholas Appert began selling pickles in jars. Over the years, the pickle production process has become more automated, however the basic pickling methods have changed very little since the technology was first developed.

While there are many different types of pickles, some characteristics are common to all. In general, pickled cucumbers are crisp vegetables, which can be described as having a strong, biting flavor caused by the vinegar in which they are stored. Different pickle manufacturers normally add spices to give their pickles a unique flavor. Dill-flavored pickles are perhaps the most common of

all pickles. There are also sweet pickles, which are packed with added sugar. These are typically used for making relishes. Kosher pickles were pickles that were approved by the Jewish Orthodox Congregations of America, but the word kosher is now often used to describe any garlic flavored pickle.

Raw Materials

There are six basic types of ingredients used for pickle making. The main bulk food is the cucumber. The additional ingredients include acids, flavorings, colorants, preservatives, and stabilizers that make up the liquid, or liquor, in which the pickle is sold. Many of the ingredients are only available at certain times of the year, so steps have to be taken to use fresh materials.

Undoubtedly, the most important ingredient in pickle manufacturing is the cucumber. Special seeds are used to produce cucumbers that are straight, thin skinned, have a predictable number of warts, and are properly sized. These characteristics are important for uniform pickle manufacturing. Technically, pickles can actually be made using all kinds of foods such as onions, peppers, olives, pears, peaches, and even fish and meat. These are usually referred to as pickled foods to indicate the type of processing required to make them.

Acetic acid (vinegar) is the primary ingredient used in pickle manufacturing. After water, it makes up the bulk of the pickle liquor and contributes significantly to the flavor of the pickle giving it a sour taste. Additionally, it also has a preservative effect and is nontoxic. Vinegar is derived from naturally occurring sugars or starches through a two-step fermentation process. Starch is converted to sugar, which is then yeast fermented to form alcohol. The alcohol is exposed to an acetobacteria, which converts it to vinegar. Vinegar can be obtained from many sources and each one has a slightly different taste. Therefore, depending on its source, the vinegar can have a significant effect on the taste of the final pickle product.

Other ingredients, which impact the final taste of the pickles, are added to the liquor. Sugar is used to provide a sweetness to offset the sour taste of the vinegar. It also helps to make pickles more plump and firm. Artificial sweeteners like aspartame and saccharine can be used for a similar effect without increasing the calories. Salt is added for flavor and it also has an added preservative effect. Pure granulated salt is typically used since it is devoid of anti-caking ingredients that could make the liquor cloudy.

While vinegar, sugar, and salt make up the bulk of all pickle liquors, it is the various spices and herbs that differentiate between pickle types. Dill weed is the most common type of aromatic spice and is used to make all forms of dill pickles. Other aromatic spices include allspice, cassia, cinnamon, cloves, fennel, fenugreek, and nutmeg. For more potent pickles, hot spices such as capsicum, black pepper, ginger, and mustard are used. Herbs like basil, marjoram, mint

tarragon, and thyme are also used to give pickles a unique taste. Flavorful vegetables including onions and garlic are often included in a pickle liquor. Typically, the pickle manufacturer has a standard spice mix made for each type of pickle they manufacture.

Some additional ingredients may be added to ensure the pickles meet standards set by the manufacturer. In general, pickles do not require any colorants because their natural color is acceptable. However, to create a standardized product and overcome the effects of processes such as bleaching, manufacturers often add color. Two common types of colorants are turmeric caramel and cholorphyll. The caramel provides a slightly brown to yellow color and chlorophyll gives a green color. To inhibit color changes in pickles, sulfur dioxide is added. Firming agents such as lime and alum may also be added. These materials help make pickles crispier without significantly impacting the flavor. Surfactants such as polysorbate are also used to couple ingredients in the liquor solution.

The Manufacturing Process

Making cucumber pickles can take up to 42 days depending on the manufacturer's recipe. Production involves four primary steps including harvesting, preservation, pasteurization, and final processing. The process is highly automated once the cucumbers are delivered to the processing plant.

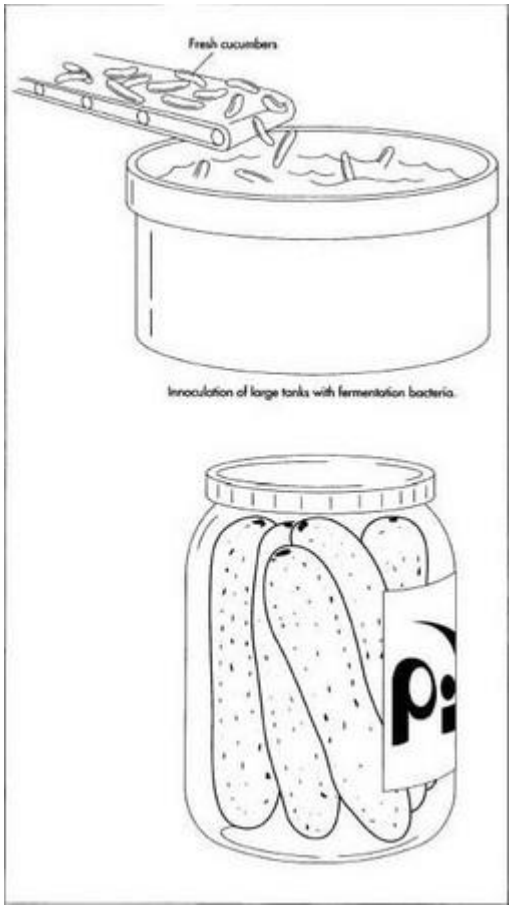
Harvesting

- 1 Once harvested by field workers, cucumbers are put in large bins and transported to a receiving station. If the cucumbers are transported a long distance, refrigerated trucks are used. This helps to maintain the fresh appearance and flavor of the vegetable. At the receiving station, the cucumbers are poured out onto a conveyor where they are subjected to a cleaning process that removes the excess stems, blossoms, dirt, and other foreign matter. This step is important because trace amounts of bacteria on unwashed cucumbers can ruin the final pickle product. They are then moved to an inspection station where rotten vegetables are removed and the rest are separated by size. From here they are moved to a chiller and stored until they are ready to be used.

Preservation

- 2 Depending on the manufacturer, conversion of the cucumber into a pickle can be done in one of three ways including fermentation, pasteurization, and refrigeration. The first and oldest method is a process known as fermentation. In this method, the cucumbers are transferred to large, air tight, fiber-glass or stainless steel tanks. Some of these

containers can hold over 40,000 lb (18,160 kg) of cucumbers. The tanks are filled with a brine solution, which is made up of water and 10% salt. The manufacturer can take



During a storage period of about five weeks, the fermentation bacteria breakdown the sugars present in the vegetable and produce carbon dioxide. To prevent adverse effects from the carbon dioxide, the tanks are periodically degassed. Pickles made in this way have a shelf life of many months.

advantage of a naturally-occurring bacteria that is present on the cucumbers or innoculate with a specifically desired bacteria. In either case, the bacteria are halophyllic, or salt tolerant. During the storage period of about five weeks, these bacteria breakdown the sugars present in the vegetable and produce carbon dioxide. To prevent adverse effects from the carbon dioxide, the tanks are periodically degassed. Pickles made in this way have a shelf life of many months.

The other two methods of preservation do not require a fermentation step. One method is by direct pasteurization. In this method, the cucumbers are

bottled and then exposed to very high temperatures for a set amount of time. This has the effect of killing all of the natural bacteria that may is present. These sterilized cucumbers can then be further processed into pickles. This method of production results in pickles that have a shelf life of only a few months. The third method is by refrigeration and acidification. These pickles depend on the cold temperature and vinegar solution to prevent spoilage. While they are much faster to manufacture, they have a much shorter shelf life.

Processing and packaging

- 3 After the pickles have adequately fermented, the salt solution is drained. The pickles are then immersed in water to remove all of the salt they may have acquired during the cure. From this point, the pickles are moved along a conveyor to a slicing machine which cuts the pickles to the correct size depending on the type of product desired. They can be cut into slices, chips, or can even be diced. Attempts are made to maintain as clean an environment as possible for the pickles as contamination by microbes could result in an undesirable product.
- 4 After being cut, the pickles are typically placed in glass jars although cans, plastic bottles, and pouches have also been used. The packing machines are designed to deliver the correct amount of vegetable to each jar. The jars are moved along to a liquid filling machine, which fills them with the liquor. The pickle liquor consists of vinegar, salt, and other materials mentioned previously. This liquor is premixed in a large container prior to filling. To ensure an adequate distribution of spices, these are some-times filled into the jars before the liquor. From the filling machine, the jars are capped and moved along for pasteurization.

Pasteurization and sealing

- 5 The problem of spoilage is evident throughout the pickle making process. Cucumbers can spoil during the brining process and even during packing if they are exposed to air for too long. For this reason the pickles are pasteurized. In order to pasteurize the pickles, they are typically exposed to high temperatures for an extended period of time. Depending on how long the pickles are heated, pasteurization can either kill off all of the acetic acid-tolerant organisms or inactivate all of the enzymes in the vegetable. In both cases, pasteurization increases the shelf life of the pickles.
- 6 Most pickles are vacuum packed which means the air is removed from the jar before it is sealed. This helps maintain the pickle taste and prevents contamination by microorganisms. In order to vacuum pack the

pickles, air in the jar is replaced with steam just before the cap is sealed. When the steam cools and condenses, it creates a vacuum, reducing the amount of free oxygen present in the jar. The vacuum seal is responsible for the familiar pop that is heard when a jar of pickles is opened.

- 7 The jars are next moved along a convey-or to a labeling machine. Labels are automatically affixed and a freshness date is stamped on the jar. From here the jars are moved to automatic packing machines which put them in cardboard boxes. They are transferred to pallets and shipped out to the local retailers.

Quality Control

Quality control is an important part of any food preparation process. It is particularly important in pickle making because poor quality control will result in an unpalatable product. The process begins in the field while the cucumbers are being harvested. Trained workers inspect the cucumbers for any signs of spoilage. If any spoiled cucumbers are found, they are discarded. Most manufacturers set specifications that the cucumbers must meet before use. During production, regular quality control measures include laboratory tests for the level of acid in the pickle liquor. This is done through a titration method using an automatic buret (test tube-like container). Other measurements that are taken on the final pickle liquor are pH, refractory sugar readings, and salt readings. Most of the methods for these tests are described by government regulations in publications by the United States Food and Drug Administration.

The Future

Research focusing on improvements in pickle technology is being done by the various seed companies and universities. One of the primary areas of interest is the development of improved pickling cucumbers. Many university groups are using biotechnology and plant grafting techniques to produce cucumbers that are larger, more plentiful, and resistant to microbial and insect-born diseases. New fanring methods concentrating on obtaining a larger harvest with fewer plants are also being tested. In addition, pickle manufacturers are also coming up with new flavors of pickles by varying the composition of the liquor and using different fermentation organisms.

Beer

Background

The family of beverages generally referred to as "beer" has been brewed for centuries. Beers are obtained by the yeast fermentation of malted cereal grains, to which hops and water have been added. Brewing has evolved from a cottage craft into a modern industry where large breweries export their beers worldwide. On a per capita basis, Germans consume the most beer at about 40

gallons (151 1) per person per year. Beer drinkers in the U.S. rank fourteenth in the world, with American breweries producing approximately 156,900 million barrels of beer a year. Each barrel is the equivalent of 117 liters or approximately 31 gallons.

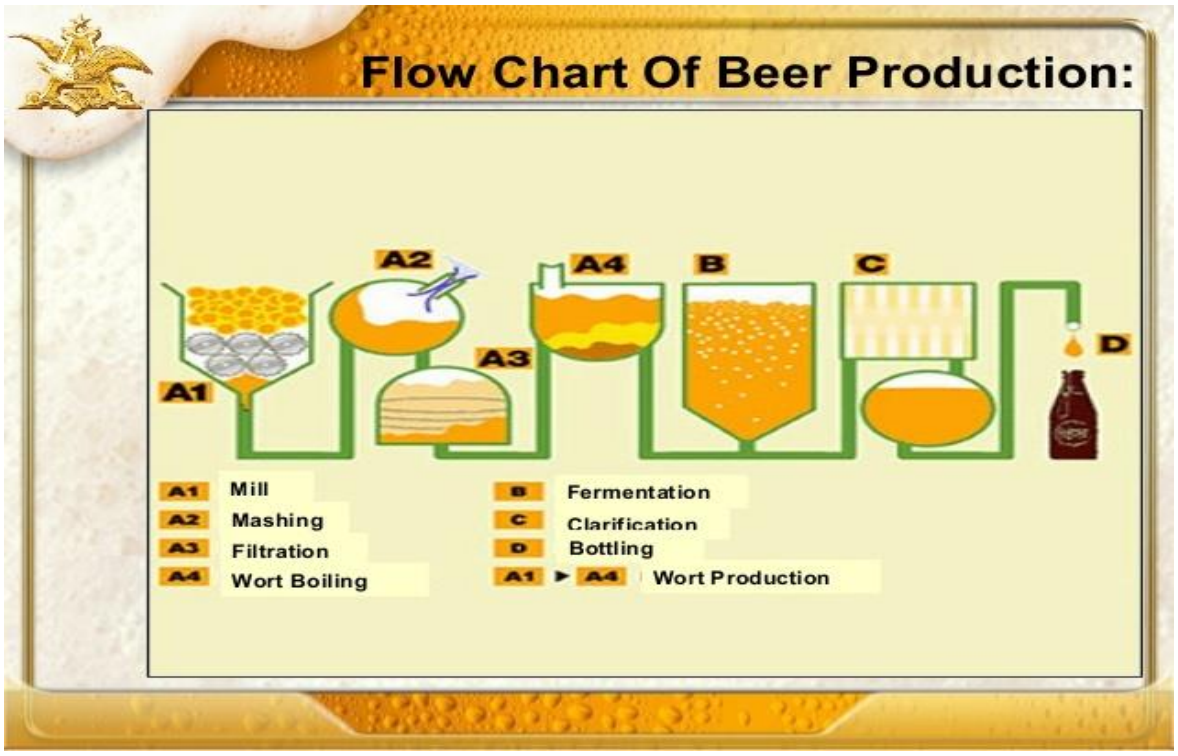
The true origin of beer can only be conjectured. Early attempts at brewing occurred around 7000 B.C. in Mesopotamia. The Egyptians and Greeks also brewed alcoholic beverages by various methods, but the term "beer" did not appear in these early languages. The Babylonians offered brewing recipes, and there are various references to beer in the Bible. The English word "beer" seems to stem from the Celtic word "beor," which referred to a malt brew made by monks at a North Gaul monastery. In the Middle Ages, monasteries were the leading producers of beer, and monks are credited with many early brewing techniques, such as the addition of hops to improve the aroma and help preserve the beer. The distinction between ales, lagers, and darker bock beers began to appear in French and Irish writings in the 13th century. It is generally accepted that the modern beers as we know them today date to the 1600s.

Beer brewing was already a thriving industry in Europe when the United States declared its independence in 1776. European immigrants brought their brewing skills to America and founded a thriving beer industry. Some technological advancements—the yeast separator, for example—made mass production of beer possible. Bottled beer was introduced in 1875 by the Joseph Schlitz Brewing Company in Milwaukee, Wisconsin, a city famed for its breweries. Canned beer first came on the market in the 1930s. The American beer market today is dominated by several large companies such as Miller and Anheuser Busch, though microbreweries and brew pubs that produce their own brands are becoming increasingly popular.

Raw Materials

Beer requires these ingredients for brewing: properly prepared cereal grain (usually barley and corn or rice), hops (scientific name *Humulus lupulus),* pure water, and brewer's yeast. Each ingredient can affect flavor, color, carbonation, alcohol content, and other subtle changes in the beer. Grains are carefully stored and handled to promote highest quality. Hops are a form of cultivated perennial hemp, and the useful portions of the vine, the sticky cones, are developed from the bloom. About 35 pounds (16 kg) of barley malt and 15 pounds (7 kg) of grain are used to make each 31-gallon barrel of beer. Large quantities of pure water are extremely important not only as an ingredient, but for maintaining the cleanliness of the brewing equipment. In beer, water high in lime or iron can interfere with the fermentation process and discolor the final product. Yeasts are fungi, which are microorganisms that reduce sugars to alcohol by fermentation. Some types of brewer's yeast are closely guarded trade secrets.

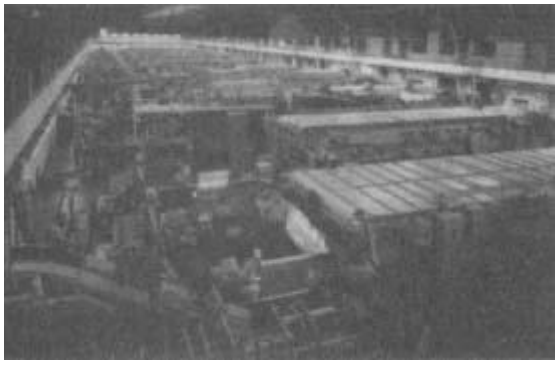
Outside of the beer itself, the process also requires various acids and cleaning chemicals to maintain and sterilize the brewing equipment. The finished product also requires packaging, which includes card-board products for boxes, aluminum for cans, glass for bottles, and stainless steel for kegs and other commercial dispensing equipment. The majority of the brewing equipment is stainless steel, with the exception of the brew kettles, which are copper.



The Brewing Process

Malting

- 1 Fully ripened barley grains are "steeped," or soaked in cold water until they are fully saturated. The water is changed once a day, and after 45-72 hours the grains are placed in shallow tanks. The grain is aerated and stirred, which causes it to germinate, releasing enzymes such as malt diastase. Malt diastase converts the starches contained in the grain to sugar for fermentation. As soon as the germination is adequately complete, usually six days, the grain is roasted to stop the germination process. The exact point at which the roasting starts and ends affects the flavor and color of the beer. The product at this point is referred to as malt.



The automatic canning machinery dwarfs the workers in this 1970s brewery canning room.

(From the collections of Henry Ford Museum & Greenfield Village.)

While amateur brewers swap recipes at will, the commercial recipes for beer are held tightly as any state secret. Until recent decades, the production of beer, like wine, was a wonderful combination of art, science, and luck. At the heart of the process has been the brewmaster, a traditional handcraftsman wrapped in the lab coat of a scientist and carrying the clipboard of a production engineer. In the 20th century, corporate breweries have evolved into an intriguing combination of flow production In the brewing process and automated canning, bottling, and warehousing.

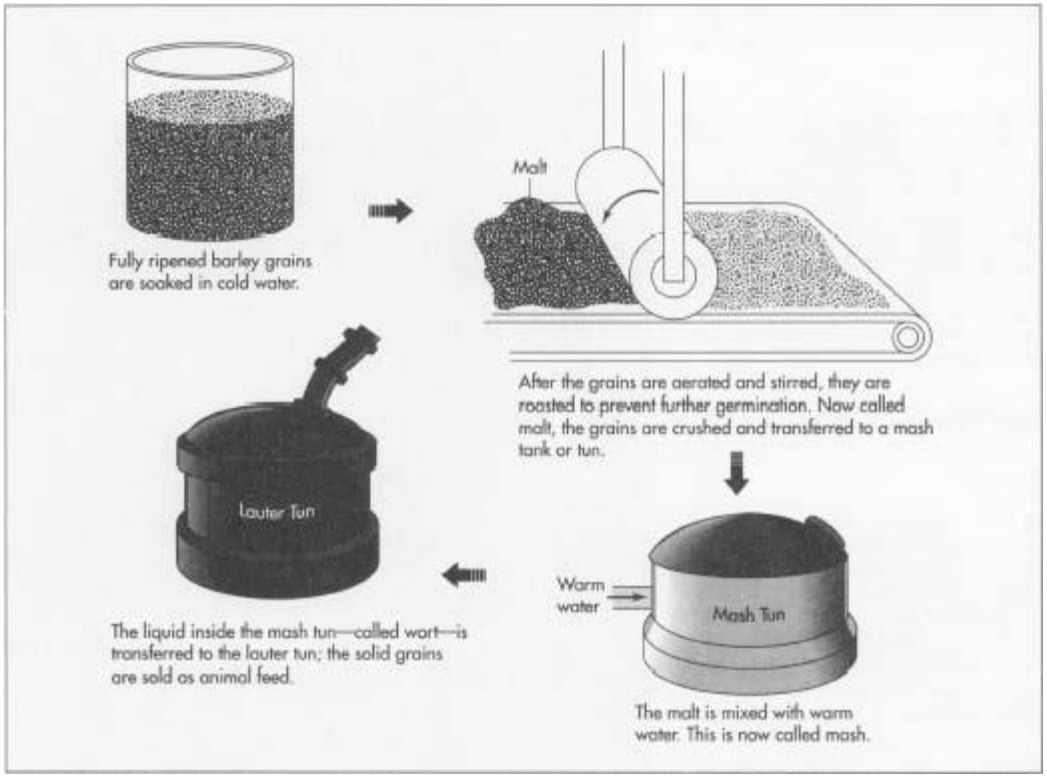
In the 19th century, the brewing industry flourished as numerous brewmasters drew on their European heritages and functioned as chemists, biologists, engineers, inventors, and salesmen. The combination of local ingredients, water quality, and the brewmaster's traditions and skill meant that many regions, even locales, could have their own brands. Before mechanical refrigeration, pasteurization, and rapid transportation facilities, national distribution was, of course, impossible. One result of this was that the United States has always enjoyed a wide variety of regional beers. In 1867 there were breweries in every state and territory, an astonishing total of 3,700; in 1934 there were still over 800 in operation; in 1994 there wore about 500. After Prohibition and with the development of steel cans for beer in 1935, breweries shifted their focus away from primary interest in bars and toward home consumption.

Despite the seeming pervasiveness of national brands from the mega-breweries supported by their huge advertising budgets, this tradition of hundreds of local brands continues. In recent years it has even been augmented by the proliferation of so-called "microbreweries" which often display the brewing equipment as part of the decor of a drinking establishment and distribute their products primarily on-site.

William S. Pretzer

Preparing the mash

- 2 The malt is crushed using iron rollers and transferred to the mash tank (or "tun"). This tank is a large copper or stainless steel vessel that mixes the malt with warm water until it is of porridge-like consistency. This mixture is called mash. After mixing with similarly prepared cereal grains, the temperature of the mash is raised incrementally from 100-170°F (38-77°C) so that the enzymes react. The enzymes break down the starch in the grain and convert it to simple sugars. Later, the yeast will convert the sugars into alcohol. Once complete, the mash is allowed to sit undisturbed so the solids can descend to the bottom of the tank.



Beer requires these ingredients for proper brewing: prepared cereal grain (usually barley and corn or rice), hops, pure water, and brewer's yeast. Each ingredient can affect flavor, color, carbonation, alcohol content, and other subtle changes in the beer.

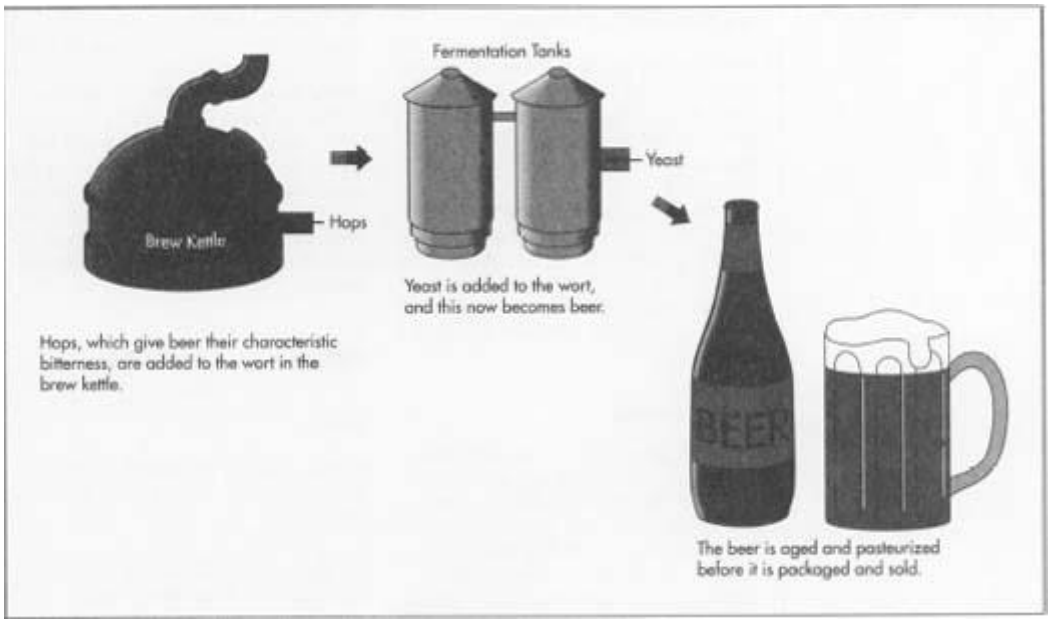
Brewing the wort

- 3 The liquid contained in the mash is transferred into another tank called a lauter tun. This is accomplished by drawing the liquid out through the bottom layer of mash solids, which acts as a filter. Hot water is added to the top of the mash tank to rinse the remaining liquid, now called wort, from the mash. The solid remains of the grain are dried and sold by the

brewery as animal feed. The wort travels on to the brew kettles, where it is boiled to sterilize it, and where the carefully prepared hops are added. The addition of the hops is important because they contribute to the bitterness of the beer. The brew kettles are the most impressive equipment in the process. Gleaming copper, they can be 7-12 feet (2-3.6 m) in diameter and two stories high. Steam usually provides the heating energy to the brew kettles. After brewing is complete, the finished wort is filtered again and pumped to the fermentation tanks.

Fermenting

- 4 In the fermentation tanks, the atmosphere must be carefully controlled to prevent any "rouge" bacteria from interfering with the yeast. Carefully maintained yeast (approximately one pound per barrel of wort) is added to the wort, and the temperature of the mixture is slowly reduced over a period of days to between 50°F and 60°F (10-15°C). In this temperature range, the yeast grows, consuming the sugar in the wort, and bubbles of carbon dioxide form. The wort has now become beer. The new beer is filtered and transferred once more into the aging casks, where the temperature is controlled at 33°F (°C) for 2-24 weeks. The shorter storage time produces a pale lager beer while the European lagers (called



Pilsner) are aged longer to increase the alcohol content.

Pasteurizing

- 5 After aging, the beer can be pasteurized to kill the remaining yeast and prevent further alcohol production. This is accomplished by heating the

beer above 135°F (57°C). This process, named after Louis Pasteur, is widely known for preserving milk. Interestingly, Pasteur originally developed this process to preserve beer in the 1860s. Pasteurization, however, is not used in the production of genuine draft beers. These beers are also known as "ice" beers, since they must be kept refrigerated to preserve their flavor and slow the remaining yeast activity. Many consider the draft beers best in aroma as well as taste.

Packaging

- 6 Whether packaged into cans, bottles, or kegs, the beer is always moved gently through the maze of piping in the bottling area. This is to preserve the natural carbonation. During bottling, additional carbon dioxide gas from the fermentation kettles is used to improve the aroma of the beer. High-speed packaging lines can process thousands of cases of beer per day, and with modern computerized control, the inventory can be tracked throughout the distribution network. Most beer is delivered from local distributors who have purchasing contracts with the major breweries.

  Most beer is available in the following package sizes: "pony" cans and bottles of about 8 fluid ounces, standard 12-ounce cans and bottles, 16- and 32-ounce jumbo cans, 40-ounce "picnic" bottles, 8-gallon "pony" kegs, and the standard 16-gallon beer keg. Other novelty and party packages are also available. Cans and bottles are packed in 6, 8, 12, or 24 each to a box or case. Most states require a deposit at point of sale to encourage the return of the bottles and cans.

  When beer is dispensed from the keg, a pressure apparatus called a "tapper" is used to apply a light pressure of carbon dioxide (usually 2-6 PSI) to the tapper head for dispensing.

Byproducts/Waste

Beer brewing produces several byproducts that can be used by other industries. During the malting of the barley, rootlets form on the grain and drip off. These can be collected and used for animal feed. The hops that is filtered out from the finished wort can also be collected and used again as fertilizer. The residual yeast from the brewing process is a rich source of B vitamins. It can be put to use by pharmaceutical companies to make vitamins or drugs, or used as a food additive. Used beer cans and beer bottles are routinely recycled.

The Future

Recently, concern among citizens' groups over the excessive consumption of alcoholic beverages by some individuals has initiated additional government regulation of beer. New warnings have been added to labels, warning of

impaired driving, hazards to pregnant women, and other health ailments associated with alcohol consumption. Reduced tolerance for drunk driving, for example, encouraged many brewing companies to advocate responsible consumption. As a result, certain states have established laws to control the alcoholic content of beer for sale within their jurisdiction. The beer industry will continue to contend with these large social issues.

Much research is currently conducted in the area of plant engineering. Brewery researchers are manipulating the genes of barley and other common grains to increase their resistance to disease and to encourage helpful mutations. This genetic research also extends to improving the yeast. Current research is aimed at producing yeast strains that resist contamination and to making new varieties of yeast that can ferment carbohydrates, which common yeasts cannot process.

The brewing industry is also making advances in the area of rapid testing for contaminants. New technology such as DNA probes and protein and chromosome finger-printing is being developed by brewers to detect microorganisms that can adversely affect the brewing process. Some of this technology is already in use in medical science for drug screening, AIDS testing, and pregnancy testing. Brewers are eager to adapt this cutting edge research to the beer industry.

Industrial applications

Enzymes are used in the chemical industry and other industrial applications when extremely specific catalysts are required. Enzymes in general are limited in the number of reactions they have evolved to catalyze and also by their lack of stability in organic solvents and at high temperatures. As a consequence, protein engineering is an active area of research and involves attempts to create new enzymes with novel properties, either through rational design or *in vitro* evolution.[106][107] These efforts have begun to be successful, and a few enzymes have now been designed "from scratch" to catalyze reactions that do not occur in nature.

Microbial enzymes play a major role in food industries. Microorganisms are used in food fermentation in ancient times and still fermentation processes are applied in the preparation of many of the food items. Various microorganisms and microbial enzymes are used in food industries. Microbial enzymes are more stable than plant and animal enzymes, hence they possess wide preference. Microbial enzymes can be produced through fermentation

techniques in a cost effective manner with less time and space requirement. Microbial enzymes possess high consistency and process modification and optimization can be done very easily. Many of these enzymes find numerous applications in various industrial sectors. For example, amylolytic enzymes find applications in food, detergent, paper and textile industries. It is used for the production of glucose syrups, crystalline glucose, high fructose corn syrups, maltose syrups etc. In detergent industry, it is used as an additive to remove starch based stains. In paper industry, it is used for the reduction of viscosity of starch for appropriate coating of paper. In textile industry, amylases are used for warp sizing of textile fibers. Similarly, enzymes like proteases, lipases, xylanases etc. have wide applications in food sectors. The following sections give detailed and updated information about various food enzymes of microbial origin. Table 1 gives an overview of applications of microbial enzymes in food industry

Application	**Enzymes used**	**Uses**
Biofuel industry	Cellulases	Break down cellulose into sugars that can be fermented to produce cellulosic ethanol.[109]

	Ligninases	Pretreatment of biomass for biofuel production.[109]
Biological detergent	Proteases, amylases, lipases	Remove protein, starch, and fat or oil stains from laundry and dishware.[110]
	Mannanases	Remove food stains from the common food additive guar gum.[110]
Brewing industry	Amylase, glucanases, proteases	Split polysaccharides and proteins in the malt.[111]:150–9
	Betaglucanases	Improve the wort and beer filtration characteristics.[111]:545
	Amyloglucosidase and pullulanases	Make low-calorie beer and adjust fermentability.[111]:575
	Acetolactate decarboxylase (ALDC)	Increase fermentation efficiency by reducing diacetyl formation.[112]
Culinary uses	Papain	Tenderize meat for cooking.[113]
Dairy industry	Rennin	Hydrolyze protein in the manufacture of cheese.[114]

	Lipases	Produce Camembert cheese and blue cheesessuch as Roquefort.[115]
Food processing	Amylases	Produce sugars from starch, such as in making high-fructose corn syrup.[116]
	Proteases	Lower the protein level of flour, as in biscuit-making.[117]
	Trypsin	Manufacture hypoallergenic b aby foods.[117]
	Cellulases, pectinases	Clarify fruit juices.[118]
Molecular biology	Nucleases, DNA ligase and polymerases	Use restriction digestion and the polymerase chain reaction to create recombinant DNA.[1]:6.2
Paper industry	Xylanases, hemicellulases and li gnin peroxidases	Remove lignin from kraft pulp.[119]
Personal care	Proteases	Remove proteins on contact lenses to prevent infections.[120]
Starch industry	Amylases	Convert starch into glucose an d various syrups.[121]

Prebiotics vs. Probiotics

While PREBIOTICS and PROBIOTICS sound similar, these supplements are very different and have different roles in the digestive system (or gut).

- **PREBIOTIC FIBER** is a ***non-digestible part of foods*** like bananas, onions and garlic, Jerusalem artichoke, the skin of apples, chicory root, beans, and many others. Prebiotic fiber goes through the small intestine undigested and is fermented when it reaches the large colon.

This fermentation process feeds beneficial bacteria colonies (including probiotic bacteria) and helps to increase the number of desirable bacteria in our digestive systems (also called the gut) that are associated with better health and reduced disease risk.

- **PROBIOTICS** are ***live beneficial bacteria*** that are naturally created by the process of fermentation in foods like yogurt, sauerkraut, miso soup, kimchi, and others.

Probiotics are also available in pill form and as an added ingredient in products like yogurt and health drinks.

Kefir, a milk drink that has been fermented using kefir grains, is an especially potent source of probiotics. According to Jeannette Hyde, a nutritional therapist, and high-profile advocate for kefir, "it contains lactobacilli and bifidobacteria in high doses, and also helps diversity too – more than 50 different types of bacteria can

be found in kefir. When you drink kefir (it has the consistency of a drinking yoghurt), these bacteria travel through the digestive tract to colonise the colon."

While many types of bacteria are classified as probiotics, most come from two groups: *[Laurence 2018]*

- **Lactobacillus –** the most common probiotic found in yogurt and other fermented foods. Can help with diarrhea and may help with people who can't digest milk sugar (lactose).
- **Bifidobacterium** – also found in some dairy products. May ease symptoms of irritable bowel syndrome (IBS) and related conditions. Naturally present in the large intestine, bifidobacteria fight harmful bacteria in the intestines, prevent constipation and give the immune system a boost. Furthermore, evidence indicates that bifidobacteria help reduce intestinal concentrations of certain carcinogenic enzymes.

A helpful metaphor to understand the difference between a prebiotic and a probiotic may be a garden. You can add seeds—the probiotic bacteria—while the prebiotic fiber is the water and fertilizer that helps the seeds to grow and flourish. See below for a video description of the difference between probiotics and prebiotics presented by gastroenterologist, Dr. Frank W. Jackson.

Both probiotics and prebiotics have been added to some commercial infant formula and child food products to improve intestinal health. [Thomas 2010]

Benefits of PROBIOTICS

The beneficial effects of probiotics have been widely demonstrated. *[Toscana 2016]* Health professionals often recommend ***probiotics*** in supplement form to patients on antibiotics in an attempt to repopulate the colon with desirable bacteria after the course of antibiotics has wiped out both beneficial and undesirable bacteria. *[Hyman 2016]*

Some find taking probiotics can combat gastrointestinal side effects of the medication and reduce the bacterial growth leading to yeast infections.

Since each body is different, it is necessary to determine which probiotics will be helpful to one's own system. *[Laurence 2018]* In addition, it is important to make sure the bacteria in probiotic supplements are alive. Probiotic bacteria are fragile and can easily be killed by stomach acid, time, and heat.

"The biggest influence you can have on the state of your gut lining, and a healthy microbiome, is your diet—which you control." — Jeannette Hyde, Nutritional Therapist BSc., a leading nutritional therapist, regular BBC commentator, and author of ***The Gut Makeover*** *and* ***The Gut Makeover Recipe Book.***

Benefits of PREBIOTICS

Researchers have found that ***prebiotics*** are helpful in increasing the helpful bacteria already in the gut that reduce disease risk and improve general well being. *[Florowska 2016]* Prebiotic fiber is not as fragile as probiotic bacteria because it is not affected by heat, stomach acid, or time. Nor does the fermentation process differ depending on the individual.

Scientific literature indicates that increasing prebiotic fiber intake supports immunity, digestive health, bone density, regularity, weight management, and brain health.

Which foods help me to boost PREBIOTICS and PROBIOTICS in my diet?

As discussed earlier, fermented foods like sauerkraut, kefir, and yogurt are rich sources of probiotic bacteria that go directly to populate the colon.

By boosting your total daily fiber consumption, you will also boost the prebiotic fiber you ingest to feed probiotic and other desirable strains of bacteria in the gut for improved health and well being. *[Pandey 2015]*

Many high fiber foods are also high in prebiotic fiber. The following chart includes a sample of foods high in total fiber—and prebiotic fiber.

Foods Rich in Prebiotic Fiber:

Chicory Root  *Source: dietaryfiber.org*	About 65% of the chicory root is fiber by weight and is an extraordinarily rich source of prebiotic fiber.
Onions and Garlic 	2 grams of fiber per ½ cup – about 17% is prebiotic fiber
Oatmeal 	2 grams of fiber per ½ cup—very high in prebiotic fiber content.
Wheat Bread with Wheat Bran 	About 1 gram of fiber per slice; nearly 70% of the total fiber in wheat bran is prebiotic fiber.

Asparagus 	2-3 grams of prebiotic fiber per 100 gram serving (about ½ cup)
Dandelion Greens 	4 grams of fiber per 100 gram serving (about ½ cup) – most of this fiber is prebiotic
Jerusalem artichoke 	2 grams of fiber per 100 gram serving (about ½ cup) – 76% comes from inulin prebiotic fiber
Barley 	3-8 grams of prebiotic fiber per 100 gram serving (about ½ cup)
Apple with skin 	2 grams of fiber per ½ apple (mainly in the skin) Pectin, which has prebiotic benefits, makes up about 50% of the total fiber in the apple.

Why take supplements when we can eat fiber-rich and fermented foods?

It is clearly vital to nourish a healthy bacterial mix in the colon. We can start with a foundation of healthy eating, focusing on fresh, organic vegetables and fruits, while avoiding processed food products and sugary foods and drinks.

However, it is sometimes difficult with a typical modern diet that includes processed foods and high amounts of sugar and synthetic ingredients to eat enough fermented foods and foods high in fiber. Therefore, adding supplements may be a healthy addition to one's diet. *[Verspreet 2016][Kechagia 2013]*

Research has determined that the best of the prebiotic supplements include the two types of fiber derived from the chicory root, inulin and oligofructose (not a sugar), a subset of inulin. Prebiotin™ Prebiotic Fiber includes oligofructose-enriched inulin (OEI) naturally derived from the chicory root. It is a full-spectrum prebiotic fiber that nourishes bacteria on *both* sides of the colon and inhibits the growth of undesirable microbiota.

Suggested Fiber Amounts*

- *Dietary fiber:* ***25-38g***
- *Prebiotic fiber:* ***5g-20g***

**** From the International Scientific Association for Probiotics and Prebiotic***
Average amounts of total dietary fiber actually consumed daily: 15-18 grams per day
(according to USDA statistics: https://www.ars.usda.gov/)

Comparing PROBIOTICS and PREBIOTICS

Supplementing with both probiotics and prebiotics can be helpful, but it is important to understand that probiotics, especially as supplements, are fragile. ***Probiotic bacteria in supplements are only effective if they are alive.*** They can be killed by heat, stomach acid, or simply die with time.

In addition, since hundreds of types of probiotics are available, it is hard to determine which strains are beneficial for our unique systems.

Prebiotin™ Prebiotic Fiber has the advantage of ***not*** being affected by heat, digestive juices, or time. Prebiotin nourishes the beneficial bacteria already in the gut and inhibits the growth of undesirable microbes.

This impact is universal and is not determined by the body's unique requirements. Prebiotin fiber (in white powder form) can easily be sprinkled on foods and dissolved in drinks.

The following chart compares prebiotics and probiotics.

PREBIOTIC VS PROBIOTIC	
PREBIOTICS	**PROBIOTICS**
PREBIOTICS are a special form of dietary fiber that acts as a fertilizer for the good bacteria in your gut.	PROBIOTICS are live bacteria that can be found in yogurt and other fermented foods. There are hundreds of probiotic species available. Which of these species are best for the average healthy person is still unknown.
PREBIOTIC powders are not affected by heat, cold, acid, or time.	PROBIOTIC bacteria must be kept alive to be active. They may be killed by heat, stomach acid, or simply die with time.

PREBIOTICS nourish the good bacteria that everyone already has in their gut.	PROBIOTICS must compete with the over 1000 bacteria species already in the gut.
Research has determined that supplementing with an oligofructose enriched inulin-based (OEI) PREBIOTIC fiber can be helpful with a wide range of conditions and disorders, including digestive disorders, obesity, and bone loss.	Certain PROBIOTIC species have been shown to be helpful for childhood diarrhea, irritable bowel disease, and for recurrence of certain bowel infections such as C. difficile.

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When is the best time to take Prebiotics and Probiotics?

The best time to take prebiotics and probiotics is regularly. Both can be taken at the same time, daily. We recommend taking them at the same time each day in order to establish a healthy routine. Your gut microbiome will be grateful!

Synbiotics

Synbiotics refer to food ingredients or dietary supplements combining probiotics and prebiotics in a form of synergism, hence synbiotics.[1] The synbiotic concept was first introduced as "mixtures of probiotics and prebiotics that beneficially affect the host by improving the survival and implantation of live microbial dietary supplements in the gastrointestinal tract, by selectively stimulating the growth and/or by activating the metabolism of one or a limited number of health-promoting bacteria, thus improving host welfare".[2] As of 2018, the research on this concept is preliminary, with no high-quality evidence from clinical research that such benefits exist.

Synbiotics may be complementary synbiotics, where each component is independently chosen for its potential effect on host health, or synergistic synbiotics, where the prebiotic component is chosen to support the activity of the chosen probiotic.[3] Research is evaluating if synbiotics can be optimized,

(known as 'optibiotics')[3] which are purported to enhance the growth and health benefits of existing probiotics.[4]

Probiotics are live bacteria which are intended to colonize the large intestine, although as of 2018, there is no evidence that adding dietary bacteria to healthy people has any added effect.[5] A prebiotic is a food or dietary supplement product that may induce the growth or activity of beneficial microorganisms. A prebiotic may be a fiber, but a fiber is not necessarily a prebiotic.[3]

Using prebiotics and probiotics in combination may be described as synbiotic, but the United Nations Food & Agriculture Organizationrecommends that the term "synbiotic" be used only if the net health benefit is synergistic.[6] Synbiotic formulations in combination with pasteurized breast milk are under preliminary clinical research for their potential to ameliorate necrotizing enterocolitis in infants, although there was insufficient evidence to warrant recommending synbiotics for this use as of 2016.[7]

Examples

- Bifidobacteria and Fructooligosaccharides (FOS)
- *Lactobacillus rhamnosus* GG and inulins
- Bifidobacteria or lactobacilli with FOS or inulins or galactooligosaccharides (GOS)
- Polyphenol

UNIT 3

MICROBIAL SPOILAGE OF CEREALS AND BAKERY FOODS

Introduction

Cereals are important foods which provide bulk of our dietary requirements. They are also source of carbohydrates which are metabolized by body for energy generation. Besides cereals also provide minerals, proteins and vitamins. India produces a large variety of cereals such paddy, wheat, maize, barley millets like, jowar, bajra, ragi. Various types of products are prepared from cereals. Cereal products can be broadly classified into the following groups:

- Whole cereals where only the husk of the grain is removed, e.g. rice, wheat, gram, lentils, etc.
- Milled grain products are made by removing the bran and usually the germ of the seed and then crushing the kernel into various sized pieces. These include wheat flour, maida, semolina (rawa), etc.
- Processed cereals like weaning food, breakfast cereals, etc.
- Ready mixes like cake mix, idli mix, vada mix etc.

The country is self sufficient in grain production and is the second largest rice producer in the world with a 20% share. But due to constantly increasing population there is still a shortfall in cereals. A large amount of these cereals are spoilt every year due to various factors.

Spoilage Factors

The grains are low moisture commodities due to which they are less susceptible to spoilage and have greater shelf-life. The spoilage mainly occurs due to moisture absorption during storage leading to fungal growth at high temperature and humidity. Before bulk packaging and storage, the whole grains are fumigated to reduce microbial load and increase storage period. The factors influencing the quality of cereals are:

Physical

Physical losses are caused by spillages, which occur due to use of faulty packaging materials.

Physiological

Physiological losses include respiration and heating in grains, temperature, humidity and oxygen.

Biological

Biological losses occurs due to micro-organisms, insects, rodents, etc.

The sources of contamination in cereals are:

- Soil
- Air
- Insects
- Natural microflora of harvested grains

Cereal Grains and Flours

At initial stages, the grains are contaminated by *Pseudomonas*, Micrococci, *Lactobacillus* and *Bacillus.* The initial bacterial population may vary from 10^3 to 10^6 per gram while mold population may be more than 10^4 spores per gram.

Due to low moisture content grains and flours usually have long shelf life if these are properly harvested or stored under proper conditions as microbial growth is not supported. If due to any reason they attain moisture, the microbial growth may occur with molds growing at initial stages of moisture while yeasts and bacteria may grow with increasing moisture.

Spoilage of stored grains by molds is attributed to the following factors:

- Type and number of microorganisms
- Moisture content of more than 12-13%
- Storage temperature
- Physical damage

Most common species of molds are *Aspergillus, Rhizopus, Mucor*, *Fusarium*. A significant aspect of spoilage of molds is production of mycotoxins, which may pose danger to health.

The process of flour making such as washing, milling reduce the microbial content. Moisture content of less than 15% does not allow growth of molds. Most molds and bacteria in flours can grow only above 17% moisture, thus moistening of flours is essential for spoilage by microbes

Stem rot and head blight of wheat and barley- *Fusarium culmorum* and *Fusarium graminearum*

Storage fungi- *Penicillium, Aspergillus* and *Fusarium* when grain stored under moist conditions.

Spoilage of Bread

Bread is a major product prepared using flours. Dough is prepared from flours which undergo fermentation for which desirable microorganisms must grow. If this fermentation exceeds the required limits, it causes souring. Excessive growth of proteolytic bacteria reduces the gas holding capacity which is otherwise required for dough rising. Spoilage of bread is usually of two types viz. moldiness and ropiness.

During bread making, it is baked at very high temperature, thereby there are less chances of survival of microorganisms. Thus the contamination usually occurs when cooling is done as well as during packing, handling and from the environment. The molds which are prevalent are *Rhizopus stolonifer* (referred as bread mold),*Penicillium expansum, Aspergillus niger*. *Mucor* and *Geotrichum* also develop.

Ropiness in bread is usually due to bacterial growth and is considered more prevalent in home made breads. The chief causative organism is *Bacillus subtilis* or *B. licheniformis.* These are spore forming bacteria with their spores surviving baking temperatures. These spores can germinate into vegetative cells, once they get suitable conditions as heat treatment activates them. In ropiness, the hydrolysis of bread flour protein (gluten) takes place by proteinases. Starch is also hydrolysed by amylases, which encourage ropiness. The manifestation of ropiness is development of yellow to brown color and soft and sticky surface. It is also accompanied by odor.

Another type of spoilage of bread is chalky bread which is caused by growth of yeast like fungi *Endomycosis fibuligera* and *Trichosporon variable.* This spoilage is characterized by development of white chalk like spots.

An unusual spoilage of bread is Red or Bloody bread, which is due to the growth of bacteria *Serratia marcescens*. This organism produces brilliant red color on starchy foods giving blood like appearance. *Neurospora* and*Geotrichum* may also be involved in imparting pigmentation during spoilage of bread.

Green spored mold- *Penicillium expansum*

- Bread mold- *Rhizopus stolonifer*.
- White cottony mycelium and black spots

- Ropiness of home-made breads- *Bacillus subtilis (Bacillus mesentericus).*
- *Ropyness due to hydrolysis of flour protein by proteinase of the bacillus and capsulation of bacillus*

Chalky bread—chalk like white spots due to yeast like fungi ----*Endomycopsis fibuligera* and *Trichonospora variable*

MICROBIOLOGY OF MEAT, POULTRY AND SEA FOODS

Introduction

The microbiological profile of meat products presented to the consumers is the sum total of the slaughtered animal health, conditions under which it was reared, quality of slaughtering, processing, packaging and conditions under which the meat was stored. Meat pathogens can cause self-limiting human enteric diseases or systemic and fatal infections of the immunocompromised, the elderly and the young. Meat can act as an ideal substrate for microbial proliferation. Major meat associated pathogenic bacteria include *Clostridium perfringens, Staphylococcus aureus*,*Salmonella spp*, pathogenic strains *of Escherichia coli, Campylobacter spp, Yersinia enterocolitica, Listeria monocytogenes* and *Aeromonas hydrophila*

Microorganisms Associated with Meat During Processing

Meat spoilages indicate (a) color changes (b) textural changes and (c) development of off-flavour or off-odor or slime as a result of microbial growth. *Salmonella* is the primary microbial challenge for poultry. The primary microbial to the beef industry is *Escherichia coli* O157: H7. *Listeria*, which is an adulterant with zero tolerance, is the major problem for ready to eat meat products. Treatment with organic acids, hot water steam carcass pasteurization and steam carcass vacuuming, trisodium phosphate, acidified sodium chlorite, chlorine dioxide, lactoferrins, peroxyacetic acid, sodium lactate, sodium acetate and sodium diacetate, ozone and radiation have been used as microbial decontaminants during meat processing operations. Carcass washing with hot water of 80°C for 10 seconds can reduce microbial loads by 2 logs. Current regulatory policies and inspection in the meat industry include the HACCP (Hazard Analysis Critical Control Point) food safety system with an objective to provide safe food for consumption and prevent chemical, physical and biological hazards.

Gram-negative bacteria (Aerobes)

Neisseriaceae: *Psychrobacter immobilis, P. phenylpyruvica, Acinetobacter* spp., *A. twoffii, A. Johnsonii,*

Pseudomonadaceae: *Pseudomonas fluorescens, P. lundensis, P. fragi, P. putida*

Gram-positive bacteria: *Brochothrix thermosphacta, Kurthia zophii, Staphylococcus spp., Clostridium estertheticum, Clostridium frigidicarnis, Clostridium casigenes, Clostridium algidixylanolyticum* sp. *nov.*

Spoilage

Fresh Meat

In contrast to fruits and vegetables, meats are composed mainly of protein and fats rather than carbohydrates. Water content is 71–76% and therefore moisture is not an issue except for spoilage microbes on cured meats. Muscles of healthy animals do not contain any bacteria or fungi but as soon as animals are slaughtered, meat is exposed to contaminants and good sanitation practices are essential to produce high quality meats. The number of spoilage organisms on meat just after slaughter is a critical factor in determining shelf life. The surface of beef carcasses may contain anywhere from 10^1 to 10^7 cfu/cm2, most of which are psychrotrophic bacteria. Chopping and grinding of meats can increase the microbial load as more surface area is exposed and more water and nutrients become available. A large variety of microbes are commonly found on fresh meat, but different microbes become dominant during spoilage of different meats depending on pH, composition and texture of processed meats, temperature and packaging atmosphere. *Pseudomonas* spp. is the predominant spoilage bacteria in aerobically stored raw meat and poultry. Once the initial low levels of glucose are depleted by various microbes,*Pseudomonas* has an advantage because it can catabolize gluconates and amino acids more readily than other microbes. Break down of these compounds results in production of malodorous sulfides, ammonia, and amines, including the biogenic amines putrescine and cadaverine. Dark, firm and dry meat with a relatively high pH of 6.0 spoils more rapidly because deamination of amino acids starts earlier. *Shewanella putrefaciens* does not grow on meat at pH<6.0 but can produce sulfides and ammonia even when glucose is still available. These sulfides not only smell bad but also cause color changes in meat, and therefore Shewanella has a high spoilage potential on fresh, high pH meats stored aerobically even when it is not a dominant microbe. *Brochothrix thermosphacta* is often a significant spoilage organism on fresh meat stored aerobically at refrigeration temperatures.*Enterobacteriaceae*, particularly species of *Serratia*, *Enterobacter*, and *Hafnia*, are major causes of spoilage in vacuum-packed, high pH fresh meats. These organisms are facultative anaerobes that produce organic acids, hydrogen sulfide and greening of meats.

Lactic acid bacteria (LAB) grow on meat and poultry packaged under vacuum and modified atmospheres, producing organic acids from glucose by fermentation. This gives rise to aciduric off-odors which may be accompanied by gas and slime formation and greening of meat. However, LAB are weakly proteolytic and so do not produce large amounts of amines or sulfides, and spoilage of meat by LAB is not as offensive. Psychrophilic, anaerobic *Clostridium* spp. are associated with spoilage of vacuum-packaged meats. "Blown pack" meat spoilage is characterized by excessive gas formation

with off odors due to formation of butyric acid, butanol and sulfurous compounds. Yeasts and molds grow relatively slowly on fresh meat and do not compete well with bacteria. Therefore, they are a minor component of spoilage flora.

Processed Meat

Addition of sodium chloride, nitrites and/or nitrates, along with various other seasonings, emulsifiers and preservatives to ground or whole muscle meats changes the environment significantly and also the spoilage flora of processed meats. Dried and dry-fermented meats generally do not support microbial growth although process deviations may allow growth of some organisms. Spoilage organisms can grow on fresh and cooked cured meats, so they are best stored chilled, under a vacuum or modified atmosphere. *Pseudomonas* spp. are not usually important causes of spoilage in processed meats because of their sensitivity to curing salts and heat pasteurization and their inability to grow well in meats packed with a vacuum or high carbon dioxide atmosphere. However, when packages have been opened and there has been insufficient curing, these bacteria may spoil refrigerated processed meats. Some cold- and salt tolerant *Enterobacteriaceae* have been found to cause spoilage in some specific processed meats, such as ham or bacon.

Lactic acid bacteria (LAB) is the group of bacteria primarily associated with spoilage of processed meats. They produce sour off-flavors, gas, slime, and greening, and this spoilage may be more severe than in fresh meat because of the presence of added carbohydrates. Competitive ability of different LAB strains is related to pH and water activity of the meat, cooking and storage temperatures and oxygen and carbon dioxide levels. Sporeformers (*Clostridium* and *Bacillus*) are usually not a spoilage problem in processed meats because of the presence of nitrite and other curing salts. However, faulty cooking/cooling procedures, including long cooling periods and temperature abuse, has allowed growth of these organisms in some cases. Spores of these organisms may be introduced with spices or other ingredients. Yeasts cause some spoilage in processed meats but are generally only important when sulfite is used as a preservative or when meats have been irradiated or are stored aerobically in the cold. Slime may be produced along with vinegary or malty off-odors in some sausages.

Spoilage under aerobic condition

> *1.)* Surface slime, caused by *Pseudomonas acinetobacter, Moraxella alcaligenes Streptococcus, Leuconostuoc, Bacillus* and *Micrococcus.*

2.) Change in colour of meat pigment. The red colour of meat may be changed to shades of green, brown or grey
by *Lactobacillus* and *Leconostocs* spp.

3.) Changes in fat. The unsaturated fat in meat gets oxidized by lypolitic bacteria which produce off odours due to hydrolysis of fats and production of aldehydes and acids. This type of spoilage is caused by lypolitic*Pseudomonas*, Achromobacter and yeast.

4.) Surface color change. The red pigment producing bacteria, *Serratia marcescens*, caused red spots on meat. Blue color surface is caused by *Pseudomonas syncyanea* and yellow color is caused by *Micrococcus*species.

5.) Off odor and off taste. Volatile acid like formic, acetic, butyric and propionic acid produce sour odor and*Actinomycetes* produce musty or earthy flavor. Yeast also cause sliminess discoloration and off odor and taste defects.

6.) Aerobic mold also cause spoilage in meat. These are stickiness, whiskers, black-spot, white-spot, green patches off odor and off taste.

7.) Spoialage under anerobic condition.

i) Souring is caused by production of formic, acetic, butyric, lactic, succinic and propionic acid.

ii) Putrefaction. It is caused by decomposition of proteins under anaerobic condition by *Clostridium*species. The foul smell is due to production of hydrogen sulphide, mercaptans, indol, scatol, ammonia and amines.

Egg

Freshly laid eggs are generally sterile particularly the inner contents. However the shells get contaminated from the environmental sources such as fecal matter of the bird, beddings, by the handlers and wash water and also the packaging materials in which the eggs are packed. There are several extrinsic and intrinsic mechanisms through which the egg protects itself from the microbial invasion. Waxy shell membrane retards the entry of microorganisms. Further, the shell also prevents the entry of microorganisms. The membranes inside the shell behave as mechanical barriers to the entry of microorganisms. Further lysozymes present in the egg white is effective against Gram positive bacteria and avidin in the egg white forms a complex with biotin, thus making it unavailable for the microorganisms. Also high pH (pH 9-10) of albumin inhibits

the microbial growth. Binding of riboflavin by the apo protein and chelation of iron by conalbumin further helps in hindering the growth of microorganisms that might have gained entry inside the egg.

Spoilage of egg

Breaks or cracks in egg shell taking place due to transportation or mechanical damage may allow microorganisms to enter in to the egg yolk and cause spoilage on storage. Eggs on storage may lose moisture and, therefore, weight. The white of the egg becomes thinner and more watery on storage. The major changes in the egg take place due to spoilage organisms. In general the spoilage of eggs is caused by bacteria as compared to molds and can be described as green rot due to the growth of *Pseudomonas fluorescens*, colourless rot due to the growth of*Pseudomonas, Acinetobacter* and other species; black rots due to *P roteus, Pseudomonas;* red rots due to *Serratia*spp. and custrad rots due to *Proteus vulgaris* and Pseudomonas *intermedium.* Growth of *Aeromonas* in the egg yolk turns it to black colour and also there is strong putrid odour due to the formation of hydrogen sulphide (H_2S). Storage of eggs in high humid atmosphere may help in growth of several molds on the surface of the egg shell. Molds causing spoilage of eggs include species *of Pencillium, Mmucor, Alterneria* , etc.

Poultry Meat

Poultry meat like meat of other animals is also susceptible to contamination by various sources. Contamination of skin and lining of the body cavity take place during various processing operations. The organisms of great importance in poultry are *Salmonella* spp. and *Campylobacter jejuni.* Several Gram negative psychrotropic
bacteria *viz., Pseudomonas, Acenitobacter* and *Flavobacterium* have also been isolated from poultry carasses. Ground turkey also may carry fecal streptococci. It is important to freeze the poultry fast in order to keep it in good condition for several months. Freezing further reduces the number of microorganisms in the poultry meat provided the temperature is maintained quite low (-18 ° C or below).

Fish Spoilage

Fish is a very perishable, high-protein food that typically contains a high level of free amino acids. The lipid content of the fish is up to 25%. It has very low content of connective tissue, i.e. approximately 3% of the total weight as compared with around 15% in meat. Fish flesh generally contains 15-20% protein and less than 1% carbohydrate. Non-fatty fish such as teleosts cod,

haddock and whiting, the fat levels are only about 0.5%, while in fatty fish such as mackerel and herring, levels can vary between 3 and 25%.

Composition of a fish

Water 65 – 80 %

Fat 1 – 20 %

sProtein 14 – 20 %

Microbes metabolize these amino acids, producing ammonia, biogenic amines such as putrescine, histamine, and cadaverine, organic acids, ketones, and sulfur compounds. Degradation of lipids in fatty fish produces rancid odors . In addition, marine fish and some freshwater fish contain trimethylamine oxide that is degraded by several spoilage bacteria to trimethylamine (TMA), the compound responsible for fishy off odors. Iron is a limiting nutrient in fish, and this favors growth of bacteria such as *pseudomonas* that produce siderophores that bind iron. Spoilage bacteria differ somewhat for freshwater and marine fish and for temperate and tropical water fish. Storage and processing conditions also affect microbial growth. *Pseudomonas* and *Shewanella* are the predominant species on chilled fresh fish under aerobic conditions. Packing under carbon dioxide and addition of low concentrations of sodium chloride favor growth of lactic acid bacteria and *Photobacterium phosphoreum*. Heavily wet-salted fish support growth of yeasts while dried and salted fish are spoiled by molds. Addition of organic acid select for lactic acid bacteria and yeasts. Pasteurization kills vegetative bacteria but spores of Clostridium and Bacillus survive and may grow, particularly in unsalted fish.

Spoilage of fish and sea foods : Halophilic bacteria like *Serratia, Micrococcus, Bacillus, Alcaligenes* and*Pseudomonas* cause spoilage of salt fish. Shell fish are spoiled by *Acenetobacter*, *Moraxella* and *Vibrio*. Crab meat is spoiled by *PseudomonasAcinetobacter* and *Moraxella* at low temperature and by *Proteus* at high temperature.

Microbial loads in shrimps, oysters, and clams depend on the quality of the water from which they are harvested. If the sewage is drained to water bodies, the microbial quality deteriorates. During handling, fecal coliforms, fecal streptococci, and *S. aureus* may be incorporated into the product. *Salmonella* also is found in oysters possibly due to contaminated water. Seafood also is the source for *Pseudomonas* spp., *C. perfringens, L. monocytogenes, Vibrio parahemolyticus*, *Salmonella enterica* serovar *enteritidis* and *typhimurium*, *Campylobacter jejuni*, *Yersinia enterocolitica*, and Enteroviruses (Hepatitis A). Smoked salmon and shrimps also are found to carry pathogenic *L. monocytogenes*.

Meat Borne Diseaeses

Food borne microbial hazards have a devastating impact on human suffering. Microbial pathogens of current concern that need to be controlled in the fresh meat include *Salmonella, Campylobacter*, enterohaemorrhagic*Escherichia colli* including serotype O157:H7 and other enteric pathogens. Infection due to *Listeria monocytogenes* following consumption of ready to eat meat and poultry products is a major problem in the recent years. Also there are food borne infections caused by *Yersinia enterocolitica, Staphylococcus aureus, Clostridium botulinum, Clostridium perfringens* and *Bacillus cereus*. Prevalence of some food borne pathogens recognized since 1970's include *Vibrio cholerae, Vibrio vulnificus*, Noro virus,, *Enterobacter sakazakii*, prions and resistant bacteria. In recent years the food borne pathogens associate with animal health pandemics include Avian Influenza (AI) and Foot and Mouth Disease (FMD) viruses. Avian influenza is not of concern to poultry meat safety, because it is inactivated by proper cooking with a temperature of 70°C and more. Also the oral route of transmission is less important than the non food borne route. Presently there is continuous adaptation and development of resistance by pathogenic microorganisms to antibiotics and potentially to traditional food preservation barriers, like low pH, heat, cold temperatures, dryness, low water activity and chemical additives. Development of antibiotic resistance in food borne pathogens is very important from public health view point in present days and in the future.

Control of meat borne pathogens

Effective control of meat borne pathogens and enhancement of meat safety can be achieved by control of latent infections among livestock, animal welfare and humane treatment, application of antimicrobial interventions at the farm, during harvesting, dressing and product processing, improvement in process food hygiene and potential application of new or novel processing and preservation technologies. Animal stress can damage meat quality and lead to more contamination and increased pathogen shedding. Antimicrobial intervention technologies can be used effectively to improve the microbiological quality of meats. These technologies include reduction of contamination on the raw product, minimization of microbial access to the products, reduction of contamination that has gained access to the product, inactivation of the microbes on the product without cross contamination and prevention and control of the growth of non-inactivated microbes, which have gained access to the meat. An effective pathogen control at pre-harvest, postharvest, processing, storage, distribution, merchandizing, preparation, food-service and consumption of meat include activities employed during pre-harvest or in the field, during post harvest or processing in the plant, at retail and food service and at home. Pre-harvest pathogen control interventions include diet manipulation, use of

food additives, antibiotic, bacteriophage therapy, and immunization of the animals, complete exclusion, probiotics and proper animal management practices like pen management, clean feed, clean and chlorinated water, and clean and unstressful transportation. Antimicrobial intervention activities during harvest and post harvesting should be designed to minimize introduction of microbial contaminants and reduce existing contaminant levels through implementation of decontamination and sanitization interventions, processing treatments for partial or complete destruction of contaminants and antimicrobial procedures for inhibition or retardation of microbial growth. Certain inspection regulations should be followed in meat and poultry plants, such as establishment of sanitation standard operating system, operations under the HACCP system and performing HACCP verifications to meet microbiological standards, establishment of good manufacturing practices (GMP) and good hygiene practices (GHP). Antimicrobial interventions used to control pathogens in further processed meat products include physical hurdles (low and high temperature, non thermal process like irradiation and high pressure and packaging treatments), physiochemical interventions (low pH, reduced water activity, modification of oxidation reduction potential through packaging and application of antimicrobial additives), and biological interventions (microbial competitors, such as lactic acid bacteria and antimicrobial products, such as bacteriocins). Events of the most food borne illness happen due to mishandling of foods in various ways. So, there should be provisions to educate the food handlers and consumers particularly on culinary tips.

MICROBIAL SPOILAGE OF FRUITS AND FRUIT JUICES

Introduction

Fruits are natural sources of minerals, vitamins besides carbohydrates and other essential substances. Naturally fresh fruits and juices made out of them contain high amount of water thereby making them highly prone to attack by microorganisms. While most of the fruits are naturally provided with coatings and coverings in the form of skins, but these are fragile enough to be easily disturbed by various biological and mechanical factors. Like vegetables, fruits being produce of plants get contaminated through different sources by a variety of microorganisms which may play significant role in their spoilage. These are soil, water, diseased plant, harvesting and processing equipments, handlers, packaging and packing material and contact with spoiled fruits.

Microorganisms Associated with Spoilage in Fruits and Juices

The microorganisms associated with fruits depend on the structure of fruit. The fruits contain different organic acids in varying amounts.The types of acids which are predominately found are citric acid, malic acid and tartaric acid. The

low pH of fruits restricts the proliferation of various types of organisms. The pH and type of acids found in different fruits is given in Table 7.1.

Due to the low pH, a large number of microorganisms are restricted to grow on fruits. Fungi are most dominating organisms to grow on fruits because of the ability of yeasts and molds to grow under acidic conditions. A small number of bacteria which are aciduric (ability to resist acidic conditions) also grow. Also the dry conditions prevailing on the skin and surface do not allow the growth of certain microorganisms. Besides these plants also produce certain antimicrobial

components too.

Despite the high water activity of most fruits, the low pH leads to their spoilage being dominated by fungi, both yeasts and molds but especially the latter.

Yeasts

Yeasts are unicellular fungi which normally reproduce by budding. Of the 215 species important in foods, about 32 genera are associated with fruits and fruit products . Only a few species of yeasts are pathogenic for man and other animals. None of the pathogenic species are common contaminants of fruits and fruit products. Fruit that has been damaged by birds, insects, or pathogenic fungi usually contain very high yeast populations. The yeasts are introduced into the exposed tissue, often via insects, and are able to use the sugars and other nutrients to support their growth. Types of yeasts growing in fruits depend upon the nature of the fruit and the strain of yeast. Growth of a strongly fermentative type such as certain strains *of Saccharomyces cerevisiae* may produce sufficient CO_2(90 lb/in. or more) to burst the container,. Growth of some species in a clear fruit juice may produce only slight haze and sediment. While carbon dioxide and ethanol are the predominant metabolic products of yeasts, other products such as glycerol, acetaldehyde, pyruvic acid, and a -ketoglutaric acid are also formed. Oxidative yeasts such as species of *Brettanomyces* produce acetic acid in wines and other fruit products. Although yeasts produce hydrolytic enzymes which degrade pectins, starch, and certain proteins, enzymatic activity is usually much less than that exhibited by other aciduric microorganisms, molds in particular.

Molds

These are filamentous fungi which are important group of microflora of fruit products due to following reasons

1. Some of the members are xerophilic, thereby having potential to spoil foods of low water activity such as dried fruits and fruit juice concentrates.

2. Some of the species have heat resistant spores such as ascospores which can survive the commercial pasteurization treatments that are given to most fruit products.
3. Growth of molds on processing equipment such as wooden tanks can result in the generation of off-flavors in wines, juices, and other fruit products.
4. Mold-infected raw fruit may become soft after processing because pectinases were not inactivated by the thermal treatment.
5. The metabolic products of many molds are toxic to humans. Of these toxins, mycotoxins are important components.

Molds are aerobic microorganisms, but many of them are very efficient scavengers of oxygen. Due to this property of molds, processed fruits, including those hermetically sealed in cans or glass, are susceptible to spoilage. In case of limited vegetative growth, evidence of spoilage may be the changes produced by fungal enzymes such as the breakdown of starch or pectins while in case of heavy growth, colonies develop in the headspace or as strands throughout a beverage or similar product. Some types of spoilage by fungi are shown in the Figure 7.1 to 7.10.

Penicillium italicum (blue mold) and *Penicillium digitatum* (green mold) seen in oranges, lemons and citrus fruits (Figure 7.1).

Bacteria

Various groups of bacteria have ability to grow on fruits and its juices. These bacteria by virtue of their diversity in metabolism grow on fruits and produce different types of compounds. The major group of bacteria which are involved are:

- Lactic acid bacteria
- Acetic acid bacteria
- Spore formers

Lactic acid bacteria

The lactic acid bacteria are Gram-positive, catalase negative organisms which can grow under anaerobic conditions. These are rod-shaped (lactobacilli), or cocci (pediococci and leuconostocs) . The homofermentative species produce mainly lactic acid from hexose sugars; the heterofermenters produce one molecule of lactic acid, one molecule of carbon dioxide, and a two-carbon compound, which is usually acetic acid or ethanol or a combination of the two.

Growth of lactic acid bacteria in juices and other fruit products cause the formation of haze, gas, acid, and a number of other changes. Certain heterofermentative lactobacilli lead to slime in cider. The lactobacilli and

leuconostocs that are present in citrus juices generate acetylmethylcarbinol and diacetyl, compounds that give the juices an undesirable, buttermilk-like flavor. Some strains, being extremely tolerant to ethanol grow in wines.*Lactobacillus fructivorans* can grow in appetizer and dessert wines containing as much as 20% ethanol. Lactic acid bacteria have the ability to decarboxylate malic acid to lactic acid. This malolactic fermentation is often desirable in high-acid wines because the acidity is reduced and desirable flavors are produced. *Oenococcus oenos*is the most acid and alcohol-tolerant species and often is isolated from wines that are undergoing a malo-lactic fermentation.

Acetic acid bacteria

These are Gram negative, aerobic rods having two genera, viz. *Acetobacter* and *Gluconobacter* . Both of these species oxidize ethanol to acetic acid under acidic condition, *Acetobacter* species can oxidize acetic acid to carbon dioxide thus, the genus is called as over oxidizer. Because the bacteria are obligate aerobes, juices, wines, and cider are most susceptible to spoilage while held in tanks prior to bottling. Some strains of *Acetobacter pasteurianus* and *Gluconobacter oxydans* produce microfibrils composed of cellulose, which leads to formation of flocs in different fruit juice beverages.

Spore formers

Spores are heat resistant, so role of organisms producing spores is important in heat treated juices and beverages. Variuos spore formers such as *Bacillus coagulans, B. subtilis, B. macerans, B. pumilis, B. sphaericus* , and *B. pantothenticus* have been found to grow in different types of wines. Some of these organisms have also been involved in canned fruits. Spore-forming bacilli that actually prefer a low pH have been responsible for spoilage of apple juice and a blend of fruit juices.

MICROBIAL SPOILAGE OF VEGETABLES

Introduction

Vegetables form an integral part of diet due to their role in providing various types of vital nutrients such as carbohydrates, minerals, vitamins, roughage etc. Vegetables being a part of fresh produce, contain high moisture which makes them highly perishable foods and hence more prone to spoilage. Microorganisms gain entry into vegetables from various sources. These sources include:

- Soil

- Water
- Diseased plant
- Harvesting and processing equipments
- Handlers
- Packaging and packing material
- Contact with spoiled vegetables

The conditions in which vegetables are stored and transported after harvesting also contribute to rate of spoilage. Other than microbial, sources, the spoilage of vegetables can also occur due to the activity of native enzymes.

Types of Spoilage in Vegetables

The microbial spoilage of vegetables is predominately of following types

Spoilage due to pathogens

The plant pathogens which infect stem, leaves, roots, flowers and other parts or the fruit itself.

Spoilage due to saprophytes

Vegetables have general microflora inhabiting them. These organisms under certain conditions can grow on these vegetables and spoil them. The list of these organisms is given in Table 8.1. There are certain secondary invaders which may enter the healthy food or grow after growth of pathogens.

It is well known that plant diseases are mostly caused by fungi. Thus most of the spoilage causing pathogens in vegetables are fungi. Fungi have specific characteristics when spoiling food as it leads to mushy areas which may be water soaked. The fungi produce characteristic spores which may be pigmented. The pigmentation helps in identification of the type of spoilage by fungi. The bacterial diseases too cause spoilage of vegetables but to a lesser extent. Figure 8.1 represent bacterial and fungal diseases of tomato.

The major types of spoilages by pathogens in vegetables

Spoilage in vegetables is largely affected by composition of vegetable. The non acidic foods are thus spoiled by bacterial rot while acidic foods with dry surfaces are more prone to mold spoilage. The product on which organism grows and types of organisms growing largely determine the character of spoilage.

Bacterial Soft Rot

Caused by *Erwinia carotovora* and *Pseudomonas* such as *P. marginalis*. *Bacillus* and *Clostridium* spp. are also implicated.

Breaks down pectin, giving rise to a soft, mushy consistency, sometimes a bad odour and water-soaked apperance.

Vegetables affected- onions, garlic, beans, carrot, beets, lettuce, spinach, potatoes, cabbage, cauliflower, radishes, tomatoes, cucumbers, watermelons.

Some types of spoilage in vegetables by bacteria

Fungal spoilage of vegetables

Penicillium, Cladosporium, Rhizopus, Aspergillus spp. are responsible for various defects in vegetables.

Some types of spoilage in vegetables by fungi are shown in the Figure 8.8 to 8.13.

Gray mold rot – caused by *Botrytis cinera* in vegetables. Favoured by high humidity and warm temperature

Fungal spoilage of vegetables

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Some types of spoilage in vegetables by fungi are shown in the Figure 8.8 to 8.13.

Gray mold rot – caused by *Botrytis cinera* in vegetables. Favoured by high humidity and warm temperature

MICROBIAL SPOILAGE OF CANNED FOODS

Introduction

Canning is one of important method of packaging food for long term storage. Normally food is stored in metallic containers along with heat treatment. The heat treatment varies depending upon type of food. There is always a chance that microorganisms may survive if the heat treatment is not proper thereby leading to spoilage of food. Usually the incidences of food spoilage in cans are low. The spoilage of can could be due to biological or chemical reasons or combination of both. The biological spoilage is primarily due to microbial growth while chemical spoilage is due to hydrogen produced due to reaction of acid in food and iron on can. The degree of swelling can also be increased by

high summer temperature and high altitudes. Certain other factors such as overfilling, buckling, denting or closing the can while cool may also be responsible for spoilage of foods in cans.

Causes of Spoilage in Cans

Chemical spoilage

The chemical spoilage in most cases is due to production of hydrogen gas produced in can because of action of acid of food on iron of can. This spoilage is termed as Hydrogen swell. It occurs due to following factors:

a) Increased storage temperature.

b) Increased acidity of food

c) Improper exhaust

d) Presence of soluble sulfur and phosphorous compounds

e) Improper timing and lacquering of can at internal surfaces

Biological spoilage

The cause of biological spoilage is microbial activity. In heat treated cans, the growth of microorganisms occur due to:

Leakage of can

It occurs because of manufacturing defects, punctures or rough handling. Bacteria are introduced into can by either in holes or improper seams. In this type, the microorganisms are not usually heat resistant and wide array of organisms had been found to cause spoilage as it is post processing contamination. Microbes may also get entry into can due to cold water, used to cool cans after heat treatment. Leakage may also be responsible for release of vacuum, which can favor the growth of microorganisms. Presence of low heat resistance organisms usually indicates leakage of can.

Under processing

It includes sub-optimal heat treatment, faulty retort operations, excessive microbial load and contamination in product, change in consistency of the product.

Stages in Appearance of Can

A can undergo different transformations from being a normal can to completely spoilt can as it depend upon various factors. All these stages are described based on appearance of can from outside

Microbial Spoilage of Canned Foods

The microbial spoilage of canned food is classified as caused by thermophilic bacteria and mesophilic organisms. Most common spoilages of microbial origin are known as flat sour spoilage, Thermophilic anaerobic (TA) spoilage and putrefaction. These different types are briefly described here.

Spoilage by thermophilic spore forming bacteria

Spoilage by these types of bacteria is most prevalent in under processed heat treated canned foods. Their spores survive the heat treatment and undergo vegetative cell formation and subsequent growth in canned conditions. Major spoilages by these organisms are:

Flat sour spoilage

This is caused by souring bacteria. One characteristic of this spoilage is that ends of can remain flat during souring. Because of this condition, the detection of spoilage from outside is not possible thereby culturing of contents become necessary to detect the type of organisms. Main organisms involved are *Bacillus,* while it occurs more frequently in low acid foods. *Bacillus* spp. has ability to produce acid without gas formation.

TA spoilage

This type of spoilage is caused by thermophilic anaerobe not producing hydrogen sulfide. *Clostridium thermosaccharolyticum* is the main organism involved. It produces acid and gas in foods. Spoiled food produces sour or cheesy smell.

Sulfur stinker spoilage

This type of spoilage occurs in low acid foods and primarily *Desulfotomaculum nigricans* is involved. The spores of these organisms are destroyed at optimal heat treatment, thus presence of this organism usually indicates under processing in terms of heat treatment. It produces hydrogen sulfide which produce typical odour.

Spoilage By Mesophillic Spore formers

Bacillus and Clostridium are involved in this type of spoilage which is usually indicative of under spoilage.

Spoilage by Non-Spore Formers

Presence of non spore formers in cans indicate post processing contamination. The organisms whose vegetative cells are heat resistant are more readily found. Following organisms are more prominent:

Enterococcus	*Streptococcus thermophilus*
Micrococcus	*Lactobacillus*
Leuconostoc	*Microbacterium*

Presence of these organisms indicates leakage of container. Cooling water is one of the important source of contamination, thus coilforms also gain entry into the can through leakage.

Spoilage by Fungi

Yeasts

Yeasts and their spores are not thermo tolerant, thus they are not found in suitably heat treated cans. Their presence indicates under processing or post pasteurization contamination through leakage. Fermentative yeasts are more prominent and they produce carbon dioxide, thus causing swelling of cans. Film yeasts too can grow on the surface of the food products.

Molds

Among molds, *Aspergilus* and *Penicillium* are most spoiling organisms. These can grow at high sugar concentration. Acidification is considered method of preventing growth of molds. Some of the molds are resistant to heat. Molds are more common in home canned foods where heating as well as sealing is not under total aseptic conditions.

Foodborne Illness

Foods contaminated with pathogenic microorganisms usually do not look bad, taste bad, or smell bad. It is impossible to determine whether a food is contaminated with pathogenic microorganisms without microbiological testing. To avoid potential problems in foods, it is very important to control or eliminate these microorganisms in food products.

Pathogenic microorganisms can be transmitted to humans by a number of routes.

Diseases which result from pathogenic microorganisms are of two types: **infection** and **intoxication.**

- **Foodborne infection** is caused by the ingestion of food containing live bacteria which grow and establish themselves in the human intestinal tract.
- **Foodborne intoxication** is caused by ingesting food containing toxins formed by bacteria which resulted from the bacterial growth in the food item. The live microorganism does not have to be consumed.

For a **foodborne illness** (poisoning) to occur, the following conditions must be present:

- The microorganism or its toxin must be present in food.
- The food must be suitable for the microorganism to grow.
- The temperature must be suitable for the microorganism to grow.
- Enough time must be given for the microorganism to grow (and to produce a toxin).
- The food must be eaten.

Symptoms of Foodborne Illness

The most common symptom associated with foodborne illnesses is diarrhea. Each pathogenic microorganism has its set of characteristic symptoms.

The severity of the foodborne illness depends on the pathogenic microorganism or toxin ingested, the amount of food consumed (dose), and the health status of the individual. For individuals who have immunocompromised health conditions, or for the aged, children, or pregnant women, any foodborne illness may be life-threatening.

UNIT 4

Food Microbiology and Foodborne Illness

Bacteria, yeasts, and mold are microorganisms associated with foods. The individual microorganism cannot be seen without the aid of a microscope. The size of these microorganisms are measured in microns (1 micron is 1/1000 of a millimeter or U25,40A of an inch). More than a thousand microorganisms in a cluster are barely visible to the eye.

Microorganisms may be classified into three groups according to their activity:

1. **Beneficial microorganisms** may be used in the process of making new foods. Cheese is made with microorganisms which convert the milk sugar to an acid.
2. **Spoilage microorganisms** cause food to spoil and are not harmful to humans. A spoilage microorganism is responsible for souring milk.
3. **Pathogenic microorganisms** are disease-causing microorganisms. The living microorganism or a toxin (microbial waste product) must be consumed to cause symptoms associated with specific pathogenic microorganisms.

Microorganisms can be found virtually everywhere. Bacteria and molds are found in the soil and water. Yeasts are found mainly in the soil. Plant and animal food products support the growth of microorganisms. Bacteria have been detected on plants and animals; molds are usually found on fruits and vegetables; yeasts are generally found on fruits. Many bacteria are part of the normal *microflora* of the intestinal tracts of man and animals.

- Microorganisms may be transferred from soil and water to plants and animals.
- Raw food stuffs contain microorganisms which may be transferred to processed foods by careless handling.
- Food handlers with poor hygiene practices may transfer microorganisms to food.
- If suitable conditions exist, some of these microorganisms may grow to create a public health concern.
- Specific bacterial species (pathogenic microorganisms) are the main causes of foodborne illnesses in humans.

Growth Factors of Microorganisms

All microorganisms require moisture, a food source, enough time, and suitable temperatures to grow and multiply.

Moisture

Microorganisms are composed of about 80% water which is an essential requirement for microorganisms to grow. Moisture requirements vary for each species of microorganism. In general bacteria need more water than yeasts. Yeasts require more water than molds to grow. If water is not available for microorganisms in a food product, the microorganisms may remain but will not grow and multiply.

Certain components in foods will make water unavailable for microorganisms *(and thus can inhibit growth).*

Salt & Sugar

Salt and sugar added to foods "tie" up water and lower the water activity. When enough salt or sugar is added to a food, the water activity will be lowered to a level that will prevent microorganisms from growing.

- In general, bacterial growth is inhibited by the addition of 5-15% salt. Yeasts and molds can tolerate up to 15% salt.
- To inhibit mold growth, 65-70% sugar must be added. The addition of up to 50% sugar will inhibit bacteria and yeast growth.

Some microorganisms are tolerant of certain conditions.

- Halophilic (salt-liking) microorganisms require salt to be present for the organism to grow.
- Osmiophilic (sugar-liking) microorganisms, usually yeasts, grow best at high concentrations of sugar.
- Xerophilic (dry-liking) microorganisms can grow with limited moisture.

Food

Microorganisms need a source of nutrients to grow and multiply.

Time

Microorganisms need time to grow and multiply. Under favorable conditions (enough moisture and food available with the desired temperature), cell division (reproductive growth) may occur every 20 to 30 minutes. The time for a microbial cell to double is called the *generation time*.

Temperature

Microorganisms grow best within certain temperature ranges. Bacteria are classified into three groups, depending on the temperature at which the bacteria grows best.

- Psychrophilic (cold-liking) bacteria (responsible for food spoilage in refrigerators, grow rapidly at room temp.)
  - Growth range 32-77°F
  - Optimum temperature 68-77°F
- Mesophilic (middle-liking) bacteria
  - Growth range 68-110°F
  - Optimum temperature 68-113°F
- Thermophilic (heat-liking) bacteria
  - Growth range 113-158°F
  - Optimum temperature 122-131°F

Other factors affecting growth:

- Varying requirements for Oxygen (aerobic vs. anaerobic bacteria, e.g.)
- pH - acidity or alkalinity (most microorganisms prefer a pH near neutral [pH = 7.0])
- Darkness vs. Light (Ultraviolet light is lethal to microorganisms)

Botulism Food Poisoning

What is botulism food poisoning?

Botulism is a disease caused by the bacterium scientifically known as Clostridium botulinum. Botulism food poisoning occurs when a toxin produced by the bacteria is consumed in improperly preserved foods. The disease is caused by a potent neurotoxin produced by the bacteria. It manifests as abdominal cramping, double or blurred vision, difficulty breathing, muscle weakness, and other serious symptoms. Botulism is not spread from person to person.

Botulism food poisoning is a rare disease in the United States. About 110 cases of botulism occur in the United States every year, and the majority occur in infants (Source: PubMed).

Most commonly, people contract botulism food poisoning from eating home-canned foods or other contaminated foods, which may contain honey, corn

syrup, baked potatoes, and cured meats or fish. Large outbreaks have been described involving commercially-prepared food products – most were outside of the United States.

The signs and symptoms of botulism food poisoning can last for one to two weeks or even longer. The disease course varies among individuals. Symptoms usually appear 12 to 36 hours after ingesting contaminated food, and can include muscle paralysis caused by the extremely potent toxin. Botulism food poisoning is treated with botulinum antitoxin and hospitalization (Source: CDC).

Botulism food poisoning is a life-threatening condition. **Seek immediate medical care (call 911)** if you suspect botulism food poisoning or if you, or someone you are with, have symptoms of difficulty breathing, abdominal pain or cramping, blurred or double vision, weakness (loss of strength), paralysis or inability to move a body part, vomiting, or drooping eyelids.

Symptoms

What are the symptoms of botulism food poisoning?

Botulism food poisoning causes a number of symptoms related to the effects of the botulinum toxin. The symptoms differ in adults and infants.

Common symptoms of botulism food poisoning in adults

Symptoms of botulism food poisoning in adults include:

- Abnormal pupil size or reactivity to light
- Abdominal pain or cramping
- Blurred or double vision
- Difficulty breathing
- Difficulty swallowing and speaking
- Dry mouth
- Nausea with or without vomiting
- Paralysis (on both sides of the body)

- Weakness (on both sides of the body)

Common symptoms of botulism food poisoning in infants

The most common symptoms of botulism food poisoning in infants include:

- Difficulty controlling head movement
- Difficulty sucking or feeding
- Drooping eyelids
- Fatigue
- Hypotonicity (flaccid limbs)
- Irritability
- Muscle weakness
- Paralysis
- Weak cry

Serious symptoms that might indicate a life-threatening condition

Symptoms from botulism food poisoning may be so severe that a life-threatening situation can develop. **Seek immediate medical care (call 911)** if you, or someone you are with, have any of the following symptoms:

- Abnormal pupil size or reactivity to light
- Blurred or double vision
- Difficulty breathing
- Difficulty swallowing
- Drooping eyelids
- Facial weakness (both sides of the face)
- Garbled or slurred speech or inability to speak
- Nausea, vomiting, and abdominal pain or cramping
- Paralysis or inability to move a body part

Causes

What causes botulism food poisoning?

Clostridium botulinum is found in soil and untreated water. The bacteria create spores that subsist in incorrectly preserved or canned food, where they lead to the presence of bacteria that produce the botulinum toxin. Botulism food poisoning commonly occurs when the toxin is ingested. Ingesting even minute

quantities can cause severe poisoning. The foods most commonly known to cause botulism food poisoning are smoked or raw fish, cured pork and ham, honey or corn syrup, and home-canned vegetables. The disease has also occurred from oil infused with garlic and baked potatoes. In infants, the most common causes are exposure to contaminated soil and eating contaminated honey.

What are the risk factors for botulism food poisoning?

Risk factors for botulism food poisoning include the consumption of home-canned foods and foods that have been improperly preserved. Not all people with risk factors will get botulism food poisoning.

Reducing your risk of botulism food poisoning

You can lower your risk of botulism food poisoning by:

- Discarding bulging cans of food, any bad-smelling food, and expired preserved foods
- Refraining from giving honey to infants
- Refrigerating foil-wrapped baked potatoes instead of leaving them out at room temperature
- Sterilizing home-canned foods by pressure cooking them for 30 minutes at 250 degrees Fahrenheit

Treatments

How is botulism food poisoning treated?

Botulinum antitoxin in injected form is the mainstay of treatment for botulism food poisoning in adults. Infants are usually treated intravenously with immune globulin.

If the patient experiences breathing difficulty, hospitalization is required to establish a clear airway and provide ventilator support. A tube may be inserted through the patient’s mouth or nose or into the windpipe to provide an airway

for oxygen. A breathing machine may be needed. Intravenous fluids are commonly prescribed if swallowing difficulty prevents adequate fluid intake. If the patient is unable to eat, a feeding tube may be inserted in the nose to provide nutrients.

What are the potential complications of botulism food poisoning?

Complications of botulism food poisoning include:

- Aspiration pneumonia and infection
- Long-lasting weakness
- Permanent disability
- Prolonged nervous system problems
- Respiratory distress

Vibrio parahaemolyticus infection

Vibrio parahaemolyticus is a bacterium found in marine, coastal and tidal waters, and most commonly causes gastroenteritis (gastro).

How *Vibrio parahaemolyticus* is spread

Vibrio parahaemolyticus infection can be acquired by eating raw or undercooked shellfish or drinking contaminated water. Eating raw oysters is the most common way the infection is spread as the organism naturally lives in the warm tidal waters where oysters grow. Eating raw or undercooked fish and crustaceans, such as crabs and lobsters, has also been associated with food-borne outbreaks of this infection.

Less commonly, the organism causes wound infections when seawater contaminates open wounds.

V. parahaemolyticus does not usually spread from person to person, however, person-to-person spread is possible if there is poor personal hygiene.

Signs and symptoms

Vibrio parahaemolyticus infection causes symptoms of gastro including:

- watery diarrhoea (occasionally bloody diarrhoea)
- abdominal cramps
- nausea
- vomiting
- fever

- headache.

Symptoms usually occur within 24 hours of eating the contaminated food.

Usually symptoms are mild to moderate in severity and lasts around 3 days (range from 8 hours to 12 days). However, the infection can be severe in people with immunosuppression, such as people receiving cancer treatment.

Where *V. parahaemolyticus* infects a wound, symptoms around the wound may include:

- pain
- redness
- warmth
- pus or discharge.

Diagnosis

Diagnosis is made by testing of faeces, wound swab or other clinical specimens.

Incubation period

(time between becoming infected and developing symptoms)
Usually around 24 hours but can be between 4 to 96 hours.

Infectious period

(time during which an infected person can infect others)
V. parahaemolyticus does not usually spread from person to person.

Treatment

Antibiotic treatment is not usually needed for *V. parahaemolytiticus* gastro, however, in cases with prolonged diarrhoea, antibiotic therapy may be needed. The following are general recommendations for the treatment of gastro:

- Give plenty of fluids. Oral rehydration solution is highly recommended for children and adults with mild to moderate dehydration. It is available at pharmacies and should be administered following the instructions on the packaging.
- Give mildly unwell children their usual fluids more often; however avoid carbonated (fizzy) drinks or undiluted juice.
- Do not give medicines to prevent vomiting or diarrhoea (especially in children), except where specifically advised by a doctor.
- Continue to breastfeed babies throughout their illness.

- Children on formula or solid diets should restart their normal diet (including full strength lactose containing milk) following rehydration with oral rehydration solution.
- Give children who are hungry their usual foods, but avoid foods high in sugar or fat.

Seek medical advice if wound infection is suspected. Wound infections should be treated with antibiotics. Also seek medical advice if any of the following symptoms develop:

Adults

- signs of dehydration, such as being thirsty, decreased urination, lethargy, dry mouth, feeling faint on standing
- fever
- severe abdominal pain
- bloody diarrhoea.

Children

- signs of dehydration, such as thirst and decreased urination, lethargy, dry mouth, sunken eyes, feeling faint on standing
- fever
- abdominal pain
- bloody diarrhoea
- any symptoms in a child less than 12 months of age.

Prevention

Infections with *V. parahaemolyticus* can be prevented by the following measures:

- Exclude people with *Vibrio parahaemolyticus* infection from childcare, preschool, school and work until there has been no diarrhoea for 24 hours. If working as a food handler in a food business, the exclusion period should be until there has been no diarrhoea or vomiting for 48 hours. People with *Vibrio parahaemolyticus* wound infections do not require exclusion.
- Avoid consumption of raw or undercooked seafood such as oysters, especially during warm summer periods or if at increased risk of severe diseases (such as people with immune suppression).
- Keep raw seafood separated from ready to eat foods when preparing or storing food.

- Wash hands with soap and clean water before and after handling raw seafood.
- Wash hands after going to the toilet, after changing a nappy and after handling rubbish.
- Avoid using seawater for cooking.
- Avoid exposing open wounds to seawater. If wounds are exposed then wash with soap and clean water.

What Is Campylobacter Infection?

When people worry about eating undercooked chicken, they usually focus on getting sick from salmonellabacteria. But another common type of bacteria called campylobacter can also make you ill if you eat poultry that isn't fully cooked.

Like a salmonella infection, campylobacteriosis can cause diarrhea and sometimes other serious complications.

Infants and children have a greater chance than adults for campylobacter infection, but it can strike anyone at any age. Males are also more likely than females to become infected. It's more common in summer than winter.

About 1.3 million people are infected in the United States every year, and that doesn't include the many people who never report their symptoms or become officially diagnosed.

Causes

Campylobacter bacteria can get into your system if you eat undercooked poultry or you eat food that has touched raw or undercooked poultry.

The bacteria usually live in the digestive systems of animals, including poultry and cattle. Unpasteurized milk can also have campylobacter bacteria.

Campylobacteriosis usually develops in isolated cases. Sometimes, though, there can be an outbreak when several people have the same infection.

In developing countries, the bacteria can be found in water and sewage systems.

Symptoms

The infection usually lasts about a week. If you've been infected, symptoms start within a couple of days of consuming the bacteria.

The most common symptom is diarrhea. The stool may have blood in it. You may also be sick to your stomachand vomit.

Other signs of infection include:

- Belly cramps
- Bloating
- Fever

Some people never get any symptoms. When you have a weakened immune system, the bacteria can cause a very serious infection of your bloodstream.

When to Call a Doctor

If you have a weakened immune system, see your doctor soon after diarrhea and other symptoms appear. Your immune system can be weakened by an infection, such as HIV, or by medications to treat cancer, for example.

If you're generally in good health and you get a bout of diarrhea, you may wait a couple of days. Treat it as you would any illness that causes diarrhea.

If you feel very sick, which can happen in serious cases, then see your doctor sooner. Some of the symptoms to watch for include:

- Diarrhea for more than 2 days
- Signs of dehydration (dark pee, dry mouth and skin, dizziness)
- Severe pain in your gut or rectum
- Fever of 102 F or more

Tests and Diagnosis

Diarrhea and vomiting are common campylobacteriosis symptoms, but they can also be symptoms of many other illnesses. This is true for bloody stools, too.

To make an official diagnosis, your doctor may ask for a stool sample, which will be sent to a lab.

Someone at your doctor's office will give you a special container in which to collect the sample. It can take several days to get the results.

In rare cases, a doctor may order a blood test, but these results take even longer -- up to 2 weeks.

Treatment

Most people get over the infection without medicine or special treatments. You should drink lots of fluids while you have diarrhea.

Unless your doctor tells you otherwise, don't take anything to prevent vomiting and diarrhea. That's your body's way of getting rid of the infection.

If your immune system is weak, your doctor might prescribe medicine to fight the infection.

Doctors will often first try levofloxacin (Levaquin). If you can't take it for some other reasons, they may prescribe one of these common antibiotics that are used to treat several types of infections:

- Azithromycin (Zithromax, Zmax)
- Ciprofloxacin (Cipro, Cetraxal, Ciloxan)

Possible Complications

Usually, the infection clears up within 2 to 10 days. If left untreated, campylobacteriosis may lead to serious consequences for a very small number of people.

Some problems can happen early on. One example is a gallbladder infection (cholecystitis).

There can also be complications from the later stages of the infection, too, though serious long-term problems are unusual.

The infection is associated with arthritis in rare cases. It may also lead to Guillain-Barre syndrome. It's a disorder in which your immune system attacks nerves in your body. You can be partially paralyzed and be in the hospital for weeks.

Prevention

The most effective way to avoid campylobacteriosis is to cook poultry to at least 165 F. The meat should be white, not pink. You should never eat chicken that looks undercooked.

Heating foods and pasteurizing dairy products are the only ways of knocking out the bacteria in foods that have been contaminated.

Here are some other tips:

- Wash your hands before cooking and after touching raw poultry or meat.
- Keep uncooked meat and poultry away from other foods, such as vegetables, by using separate cutting boards, utensils, and cooking surfaces.
- Wash your hands after touching a pet or pet feces.
- Make sure your child or anyone with diarrhea washes his or her hands well.

What is an intestinal infection due to E. coli?

E. coli is a type of bacteria that normally live in the intestines of people and animals. However, some types of *E. coli*, particularly *E. coli* O157:H7, can cause intestinal infection. *E. coli* O157:H7 and other strains that cause intestinal sickness are called Shiga toxin–producing *E. coli* (STEC) after the toxin that they produce.

Symptoms of intestinal infection include diarrhea, abdominal pain, and fever.

More severe cases can lead to bloody diarrhea, dehydration, or even kidney failure.

People with weakened immune systems, pregnant women, young children, and older adults are at increased risk for developing these complications.

Most intestinal infections are caused by contaminated food or water. Proper food preparation and good hygiene can greatly decrease your chances of developing an intestinal infection.

Most cases of intestinal *E. coli* infection can be treated at home. Symptoms generally resolve within a few days to a week.

Symptoms of intestinal infection due to E. coli

Symptoms of intestinal infection generally begin between 1 and 10 days after you've been infected with *E. coli*. This is known as the incubation period. Once symptoms appear, they usually last around 5 to 10 days.

Symptoms can include:

- abdominal cramping
- sudden, severe watery diarrhea that may change to bloody stools

- gas
- loss of appetite or nausea
- vomiting (uncommon)
- fatigue
- fever

Symptoms can last anywhere from a few days to more than a week.

Symptoms of a severe *E. coli* infection may include:

- bloody urine
- decreased urine output
- pale skin
- bruising
- dehydration

Call your doctor if you experience any of these severe symptoms.

According to the Centers for Disease Control and PreventionTrusted Source, about 5 to 10 percent of those who are infected develop hemolytic uremic syndrome (HUS), a condition in which the red blood cells are damaged. This can lead to kidney failure, which can be life-threatening, especially for children and the elderly. HUS generally begins about 5 to 10 days after the onset of diarrhea.

Causes of E. coli infection

People and animals normally have some *E. coli* in their intestines, but some strains cause infection. The bacteria that cause infection can enter into your body in a number of ways.

Improper food handling

Whether food is prepared at home, in a restaurant, or in a grocery store, unsafe handling and preparation can cause contamination. Common causes of food poisoning include:

- failing to wash hands completely before preparing or eating food
- using utensils, cutting boards, or serving dishes that aren't clean, causing cross-contamination
- consuming dairy products or food containing mayonnaise that have been left out too long
- consuming foods that haven't been stored at the right temperature
- consuming foods that aren't cooked to the right temperature or duration of time, especially meats and poultry
- consuming raw seafood products
- drinking unpasteurized milk
- consuming raw produce that hasn't been properly washed

Food processing

During the slaughtering process, poultry and meat products can acquire bacteria from the animals' intestines.

Contaminated water

Poor sanitation can cause water to contain bacteria from human or animal waste. You can get the infection from drinking contaminated water or from swimming in it.

Person to person

E. coli can spread when an infected person doesn't wash their hands after having a bowel movement. The bacteria are then spread when that person

touches someone or something else, like food. Nursing homes, schools, and child care facilities are particularly vulnerable to person-to-person spreading.

Animals

People who work with animals, especially cows, goats, and sheep, are at increased risk for infection. Anyone who touches animals or who works in an environment with animals should wash their hands regularly and thoroughly.

Risk factors of E. coli infection

While anyone can experience an *E. coli* infection, some people are more at risk than others. Some risk factors include:

- **Age:** Older adults and young children are more likely to experience serious complications from *E. coli*.
- **A weakened immune system:** People with weakened immune systems are more susceptible to *E. coli* infections.
- **Season:** *E. coli* infections are more likely to occur during the summer months, June to September, for unknown reasons.
- **Low stomach acid levels:** Medications used to decrease stomach acid levels can increase your risk of *E. coli* infection.
- **Certain foods:** Drinking unpasteurized milk or juices and eating undercooked meat can increase your risk of *E. coli*.

When to see a doctor

Intestinal infection can lead to dehydration and serious complications, such as kidney failure and sometimes death, if it’s not treated. You should see your doctor if:

- You have diarrhea that isn’t getting better after four days, or two days for an infant or child.
- You have a fever with diarrhea.

- Abdominal pain doesn't get better after a bowel movement.
- There is pus or blood in your stool.
- You have trouble keeping liquids down.
- Vomiting has continued for more than 12 hours. For a baby under 3 months old, contact your pediatrician as soon as symptoms begin.
- You have symptoms of intestinal infection and have recently traveled to a foreign country.
- You have symptoms of dehydration, such as a lack of urine, extreme thirst, or dizziness.

A doctor can confirm an *E. coli* infection with a simple stool sample.

How E. coli infection is treated

In most cases, home care is all that's required to treat an *E. coli* infection. Drink plenty of water, get lots of rest, and keep an eye out for more severe symptoms that require a call to your doctor.

If you have bloody diarrhea or fever, check with your doctor before taking over-the-counter antidiarrheal medications. **You should always check with your pediatrician before giving medications to infants or children**.

If dehydration is a concern, your doctor may order hospitalization and intravenous fluids.

Most people show improvement within five to seven days after the onset of an infection, and make a full recovery.

How to prevent E. coli infection

Practicing safe food behaviors can decrease your chances of developing an intestinal infection due to *E. coli*. These include:

- washing fruits and vegetables thoroughly
- avoiding cross-contamination by using clean utensils, pans, and serving platters
- keeping raw meats away from other foods and away from other clean items
- not defrosting meat on the counter
- always defrosting meat in the refrigerator or microwave
- refrigerating leftovers immediately
- drinking only pasteurized milk products (avoiding raw milk)
- not preparing food if you have diarrhea

You should also make sure that all meat is cooked properly. The U.S. Department of Agriculture provides guidelines for cooking meat and poultry to proper temperatures to make sure all bacteria are killed. You can use a meat thermometer to check that meat is cooked to these temperatures:

- **poultry:** 165˚F (74˚C)
- **ground meat, eggs:** 160˚F (71˚C)
- **steaks, pork chops, roasts, fish, shellfish:** 145˚F (63˚C)

One of the easiest things you can do to prevent an *E. coli* infection is to regularly wash your hands. You should wash your hands before handling, serving, or eating food, and especially after touching animals, working in animal environments, or using the bathroom. Practicing good hygiene and following food safety guidelines can go a long way to decreasing your risk of infection.

Salmonella (Salmonellosis)

What Is Salmonella?

Salmonella is the type of bacteria that's the most frequently reported cause of food-related illness in the United States. You can't see, smell, or taste it.

Illness from these bacteria is officially called salmonellosis. It can cause an upset stomach, diarrhea, fever, and pain and cramping in your belly. Most people get better on their own at home within 4 to 7 days.

How Common Is Salmonella?

Salmonella infections are very common. When people mention food poisoning, they're usually talking about salmonella. Tens of millions of cases are reported around the world every year.

In severe cases, you need to go to the hospital. Rarely, it can be life-threatening.

Infections are more common in the summer than the winter. This is because salmonella grows quickly in higher temperatures, when food isn't refrigerated.

Salmonella Causes

People and animals can carry salmonella in their intestines and their feces. The bacteria often spread through contaminated foods. Common food sources of salmonella infection include:

- **Raw and undercooked meat,** including chicken, turkey, duck, beef, veal, and pork
- **Raw fruits or vegetables**
- **Unpasteurized milk and other dairy products,**including soft cheese, ice cream, and yogurt
- **Raw or undercooked eggs**
- **Processed foods** like chicken nuggets and nut butters

You can also get salmonella directly through:

- **Poor handwashing.** You might pass along the bacteria by not washing your hands well after using the bathroom or changing a diaper.
- **Pets.** Animals like dogs, cats, birds, and reptiles can carry the bacteria.

Salmonella Risk Factors

Children, especially those under 5, are more likely than adults to get sick from salmonella. Older adults and people with weak immune systems are also more likely to be infected. Other risk factors include:

- **International travel.** Salmonella is more common in places with poor sanitation.
- **Taking certain drugs.** Cancer drugs or steroidscan weaken your immune system. Antacids lower how much acid is in your stomach, which makes it

easier for salmonella to survive there. Antibioticscan kill “good” bacteria in your body and make an infection harder to fight.

Salmonella Poisoning Symptoms

Most of the signs and symptoms of a salmonella infection are stomach-related. They include:

- Cramps in your stomach
- Bloody poop
- Diarrhea
- Cold and chills
- Fever
- Headache
- Upset stomach
- Throwing up

Symptoms tend to start 8 to 72 hours after infection. Most symptoms usually don’t last more than a week, but it can take several months for your bowel movements to get back to normal.

When should I call a doctor?

See your doctor if you’re still having general symptoms more than a week after first getting the infection.

A young child, an older adult, or someone who has a weakened immune system should see a doctor if they have any of these symptoms for more than a couple of days:

- Bloody poop
- Ongoing high fever
- Dehydration, when they’ve lost too much fluid. Signs include peeing only in small amounts, a dry mouth, and sunken eyes

Salmonella Complications

You can become dehydrated if you don’t get enough fluids to replace what you lose because of diarrhea.

A few people who get a salmonella infection also get pain in their joints. You might hear a doctor call it reactive arthritis or Reiter’s syndrome. It can last several months or longer. This condition can also cause painwhile peeing and itchy, stinging, or sore eyes.

If the salmonella infection gets into your blood, it can infect other parts of your body, including:

- The tissues around your brain and spinal cord
- The lining of your heart or heart valves
- Your bones or bone marrow
- The lining of your blood vessels

Salmonella Diagnosis

Your doctor may have you take blood tests, or they might ask for a sample of your poop.

Sometimes, they may want to do testing to figure out the exact kind of bacteria you have. This can help health officials trace the source if there's an outbreak in your area.

Salmonella Treatment

For healthy adults: If you have diarrhea, drink a lot of water and other fluids. Your doctor might suggest that you drink a rehydration liquid like Pedialyte or take a medication like loperamide (Imodium) if your diarrhea is severe.

- **Inflammatory bowel disease.** This can damage the lining of your intestines, making it easier for salmonella to take hold.
- If your doctor confirms that you have a salmonella infection, they might prescribe antibiotics. Take them exactly as directed, and be sure to finish the prescription.
- **For children:** If your child has a healthy immune system, the doctor might just let the infection run its course. If they have a high fever, you may want to give acetaminophen. As with adults, they should drink lots of water.
- **In special cases:** Infants, the elderly, and people who have weakened immune systems may need antibiotics.

Salmonella Prevention

Salmonella can hide in a variety of foods, but you can do a lot of things to help ensure the bacteria stay away:

- Don't eat raw or barely cooked eggs or meat.
- Don't eat or drink anything with unpasteurized milk or juice.
- Don't wash raw poultry, meat, or eggs before cooking.
- Wash raw fruits and vegetables well, and peel them if possible.
- Don't prepare food for other people if you're vomiting or have diarrhea.
- Refrigerate food properly, both before cooking it and after serving it.
- Wash your hands well with soap and warm water before and after handling food.

- Keep kitchen surfaces clean before preparing food on them.
- Don’t mix cooked food with raw food or use the same utensils to prepare them. For example, don’t use the same knife to cut raw chicken and then to slice mushrooms, and use different plates or cutting boards to slice them on.
- Cook meat to its correct minimum temperature. Use a food thermometer to be sure.
- Wash your hands with soap and water after touching animals, their toys, and their bedding.

Staphylococcal (Staph) Food Poisoning

What is Staph food poisoning?

Staph food poisoning is a gastrointestinal illness caused by eating foods contaminated with toxins produced by the bacterium *Staphylococcus aureus* (Staph) bacteria.

About 25% of people and animals have Staph on their skin and in their nose. It usually does not cause illness in healthy people, but Staph has the ability to make toxins that can cause food poisoning.

How do people get Staph food poisoning?

People who carry Staph can contaminate food if they don’t wash their hands before touching it. If food is contaminated with Staph, the bacteria can multiply in the food and produce toxins that can make people ill. Staph bacteria are killed by cooking, but the toxins are not destroyed and will still be able to cause illness.

Foods that are not cooked after handling, such as sliced meats, puddings, pastries, and sandwiches, are especially risky if contaminated with Staph.

Food contaminated with Staph toxin may not smell bad or look spoiled.

What are the symptoms of Staph food poisoning?

- Staph food poisoning is characterized by a sudden start of nausea, vomiting, and stomach cramps. Most people also have diarrhea.
- Symptoms usually develop within 30 minutes to 8 hours after eating or drinking an item containing Staph toxin, and last no longer than 1 day. Severe illness is rare.
- The illness cannot be passed from one person to another.

How do I know if I have Staph food poisoning?

You can suspect Staph food poisoning based on the type of symptoms and their fast resolution. Although laboratory tests can detect toxin-producing Staph in stool, vomit, and foods, these tests are usually not ordered except during an outbreak. If you think you might have Staph food poisoning and are experiencing severe symptoms, contact your health care provider.

How is Staph food poisoning treated?

The most important treatment is drinking plenty of fluids. Your healthcare provider may give you medicine to decrease vomiting and nausea. People with severe illness may require intravenous fluids.

Antibiotics are not useful in treating this illness because the toxin is not affected by antibiotics.

How can I prevent Staph food poisoning?

The best way to avoid food poisoning by Staph is to prevent food from being held at an unsafe temperature (between 40°F and 140°F) for more than 2 hours.

Remember to always follow these food safety tips:

- Use a food thermometer and cook foods to their safe minimum internal temperatureExternal.
- Keep hot foods hot (140°F or hotter) and cold foods cold (40°F or colder).
- Store cooked food in wide, shallow containers and refrigerate within 2 hours (or 1 hour if it's hotter than 90° F outside).

The following tips that are part of the four steps to food safety – clean, separate, cook, and chill – also can help protect you and your loved ones from food poisoning:

- Wash your hands for 20 seconds with soap and water before, during, and after preparing food, and before eating.
- Do not preparing food if you are ill with diarrhea or vomiting.
- Wear gloves while preparing food if you have wounds or infections on your hands or wrists.

Hepatitis A

Hepatitis A is the only common foodborne disease preventable by vaccine. It is one of five hepatitis viruses that infect the liver. While hepatitis B and C can turn into chronic hepatitis, hepatitis A generally does not; although it can lead to liver failure and death.

Hepatitis A is rare in the United States, with 30,000 to 50,000 cases occurring each year. However, in most other countries, poorer sanitation systems lead to easier transmission of the disease, and therefore more cases.

Hepatitis A is a contagious disease. It travels in feces, and can spread from person to person, or can be contracted from food or water. In cases of contaminated food, it is usually the person preparing the food who contaminates it. The food handler will probably not know they have the virus, since the virus is most likely to be passed on in the first two weeks of illness, before a person begins to show symptoms.

Symptoms of Hepatitis A

Symptoms of hepatitis A usually appear around 28 days after infection, but can start as early as two weeks after catching the virus. Only 30 percent of children with the virus actually develop symptoms. Early symptoms of this hepatitis virus include:

- Muscle aches

HeadacheLoss of appetiteAbdominal discomfortFeverWeakness and fatigue

After a few days of experiencing these symptoms, 70 percent of patients develop jaundice, a yellowing of the skin, eyes, and mucous membranes. Jaundice also causes dark urine and light, clay-colored feces.

Length of Symptoms

Symptoms usually last less than two months, although they sometimes last up to six months, and jaundice can linger for up to eight months. Patients can also experience severely itchy skin for a few months after symptoms first appear. Most patients fully recover.

Complication of Hepatitis A

An acute hepatitis A case can develop into **Fulminant Hepatitis A**. This is a rare but severe complication of Hepatitis A, in which the toxins from the hepatitis virus kill an abnormally high number of liver cells (around ¾ of the liver's total cells), and the liver begins to die. Fifty percent of patients with this condition require an immediate liver transplant to avoid death. Fulminant hepatitis A can also cause further complications, including muscular dysfunction and multiple organ failure.

Diagnosis of Hepatitis A

Hepatitis symptoms can be extremely similar among all human forms of hepatitis. Therefore a blood test is needed to determine the specific hepatitis virus one has. The virus shows up in a person's blood 10 to 12 days after a person is infected, at which point a doctor can draw a blood sample to determine which form of hepatitis a person has.

Prevention of Hepatitis A

Hepatitis A is completely avoidable, since a hepatitis A vaccine exists to prevent it. However, since the vaccine only became recommended for all children in 2006, many people are not vaccinated. Hepatitis transmission is still possible, and prevention techniques are still important. Food handlers should always wash hands after using the bathroom or changing a diaper and before preparing food.

Prevention of Acute Hepatitis After Infection

After a person has been exposed to Hepatitis A, immune globulin (IG) is 80 to 90 percent effective in preventing clinical hepatitis when it is injected within two weeks of exposure.

Who should get the Hepatitis A Vaccine?

Starting in 2006, this hepatitis vaccine became recommended for all children ages 12-23 months. The vaccine is also recommended for the following groups of people:

- Travelers to areas with higher rates of hepatitis A
- Men who have sex with men
- Drug users (both injecting and non-injecting)
- Those with blood clotting disorders (e.g. hemophilia)
- Those with chronic liver disease
- Those who risk infection in the workplace (e.g. hospital or laboratory workers)

- Children living in regions of the U.S. with increased rates of hepatitis A
- Members of households with an adopted child arriving from a country with a high rate of Hepatitis A

Treating Hepatitis A

Once the symptoms for hepatitis A appear, there is no direct treatment for the virus. Patients should rest according to how tired they feel, and should receive enough nutrition either by eating or through fluids, since the disease can cause a lack of appetite.

Treatment for Fulminant Hepatitis A

Treatment for this complication will vary depending on a person's individual case. In cases of advanced liver failure, a liver transplant may be the only option available to avoid death.

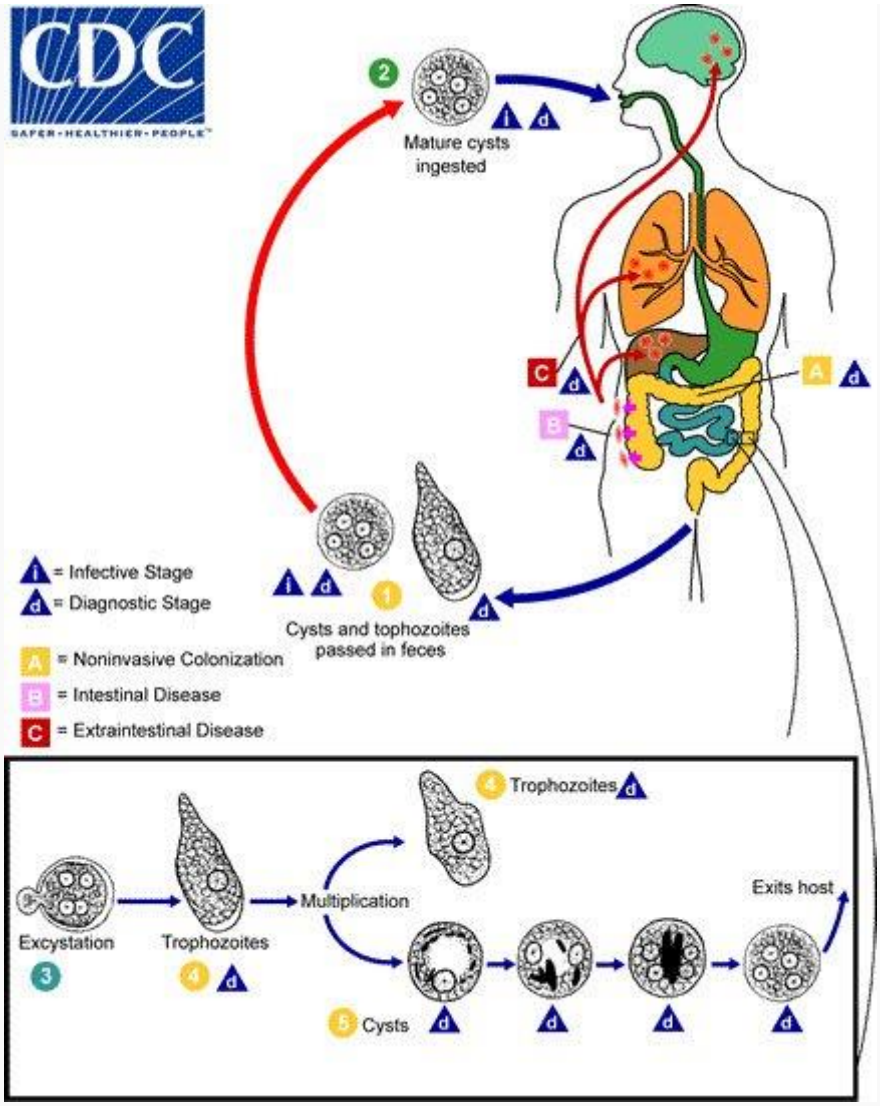
Additional Resources for Hepatitis A

About-Hepatitis.com is a comprehensive site with in-depth information about hepatitis A virus and hepatitis A infection.

Hepatitis Blog provides up-to-date news related to hepatitis A outbreaks, research, and more.

Amebiasis (Entamoeba Histolytica Infection)

Amebiasis facts



Life cycle of E. histolytica; SOURCE: CDC

- Amebiasis is a disease caused by infection with a parasitic amoeba that, when symptomatic, can cause dysentery and invasive extraintestinal problems.
- The cause of amebiasis is mainly the protozoan parasite *Entamoeba histolytica*.
- Some risk factors for amebiasis include consuming contaminated food or water, association with food handlers whose hands are contaminated, contact with contaminated medical devices such as colonic irrigation devices, and being pregnant.

- Amebiasis is contagious and may stay contagious for weeks to many years if untreated.
- Only about 10%-20% of infected individuals show symptoms and signs. The **symptoms and signs include**
    - loose stools,
    - mild abdominal cramping,
    - frequent, watery, and/or bloody stools with severe abdominal cramping (termed amoebic dysentery) may occur,
    - flatulence,
    - appetite loss, and
    - fatigue.
- Amebiasis is diagnosed from your medical and travel history and from testing stool samples for the presence of *E. histolytica* cysts; other tests may also be included such as liver function tests.
- Some asymptomatic infections are not treated; others may be treated with medications that work to eliminate the parasite from inside the intestines
- or other areas of the body.
- Surgical treatment infrequently may be required to remove large abscesses or if certain other complications such as gastrointestinal bleeding, perforation of the intestinal tract, or toxic megacolon occurs.
- It is possible to prevent amebiasis by avoiding contaminated food and/or water, good sanitation techniques, and avoidance of contaminated food handlers and other carriers of the parasite. There is a vaccine available for animals, and researchers are working on a vaccine for humans.
- The prognosis for most patients infected with amebiasis is good, however, if complications develop, the prognosis begins to drop.

What is amebiasis?

Amebiasis is a parasitic disease (also known as amebic dysentery or amoebic dysentery and/or amoebiasis) caused by infection with *Entamoeba histolytica* or another amoeba (for example, *E. dispar*). Most individuals with the disease may have no symptoms. *E. histolytica* is the species that produces symptoms only in about 10% of those infected. The single or one-celled, flash-shaped or shifting shaped organism usually produces dysentery and occasionally invasive extra intestinal problems (invasive amebiasis), the most common of which are liver abscesses, although other organs can be involved. The disease is most common in people who live in tropical areas with poor sanitary conditions. It is estimated that amebiasis causes 50,000-100,000 deaths worldwide each year.

What causes amebiasis?

The cause of amebiasis is infection by the protozoan parasite *Entamoeba histolytica*. It begins when a person drinkscontaminated water or eats foods contaminated with the cystic form (infective stage), comes in contact with contaminated colonic irrigation devices or the fecally contaminated hands of food handlers, or by oral-anal sexual practices.

The cystic form changes into trophozoites (invasive form) in the ilium or colon and invade the mucosal barrier, leading to tissue destruction and diarrhea. These trophozoites can reach the portal blood circulation to the liver and eventually go to other organs. It only infects humans, and the CDC does not classify it as a free-living organism.

What are risk factors for amebiasis?

Risk factors include

- drinking contaminated water,
- eating contaminated foods,

- association with food handlers whose hands are contaminated,
- anal sexual practices,
- contaminated medical devices such as colonic irrigation devices,
- malnourishment,
- recipients of corticosteroids,
- pregnancy,
- very young patients, and
- travelers to endemic areas such as Southeast Asia or Central America.

What is the incubation period for amebiasis?

The incubation period for amebiasis is variable. Symptoms begin to appear in about one to four weeks after ingestion of the cysts; however, the range may be from a few days to years.

Is amebiasis contagious? If so, what is the contagious period for amebiasis?

Yes, amebiasis is contagious person to person. It is spread by the fecal-oral route by an infected person. The contagious period lasts as long as the infected patient excretes cysts in their stools. Consequently, the contagious period may last for weeks to many years if untreated.

What are amebiasis symptoms and signs?

Although only about 10%-20% of people infected with the parasites become ill, those individuals may produce the following symptoms and signs:

- Early symptoms (in about 1-4 weeks) include loose stools and mild abdominal cramping
- If the disease progresses, frequent, watery, and/or bloody stools with severe abdominal cramping (termed amoebic dysentery) may occur.

- If the trophozoites reach the intestinal walls and go through them, symptoms of liver infection such as liver tenderness and fever are the initial signs and symptoms of liver abscess formation (hepatic amebiasis).
- Other organs (heart, lungs, brain [meningoencephalitis], for example) may produce symptoms specific to the organ and produce severe illness and/or death.
- Abdominal tenderness and/or stomach pain
- Tenesmus
- Flatulence
- Appetite loss
- Weight loss
- Fatigue
- Anemia
- Occasionally cause skin lesions (cutaneous amebiasis)

What specialists treat amebiasis?

In addition to your primary care physician, the following specialists may be consulted:

- Gastroenterologist
- Infectious disease specialist
- General surgeon (especially if the patient develops severe disease like fulminant colitis)
- Occasionally, dermatologist

What tests do health care professionals use to diagnose amebiasis?

If your recent health history and travel history suggests a possibility of amebiasis, your doctor may ask you to provide several stool samples to screen for the presence of *E. histolytica* cysts in your stools. In addition, some routine

blood tests as well as other tests to determine if parasites spread to other organs may be initiated for laboratory diagnosis. These tests may include the following:

- Liver function tests
- Serological tests
- Enzyme-linked immunosorbent assay (ELISA)
- Ultrasound of the liver
- CT scan of the liver and perhaps other organs
- Colonoscopy of the large intestine to search for parasites
- Your doctor may run other serological tests to rule out other infectious diseases like giardiasis, paragonimiasis, and arboviral brain infections, for example.

What are medical treatment options for amebiasis?

Asymptomatic infections are not treated unless they are occurring in non-endemic areas. If patients are shedding *E. histolytica* cysts, the following luminal agents (drugs that work on cysts that are not invading the gastrointestinal epithelium) are as follows:

- Paromomycin (Humatin)
- Iodoquinol (Yodoxin)
- Diloxanide furoate

To treat invasive amebiasis, metronidazole (Flagyl, MetroGel, Noritate) is recommended even for amoebic liver abscesses (up to 10 cm sized abscesses). Tinidazole (Tindamax) is FDA approved for treatment of both intestinal or extraintestinal (invasive) amebiasis. Other countries have similar drugs for treatments, but they are not available in the United States.

Amoebic colitis can be treated with nitroimidazoles, but they should be followed up by a luminal agent.

Treatment of hepatic amebiasis has been successful in some patients with chloroquine (Aralen) or dehydroemetine (which is only available from the CDC and is not a preferred treatment because of potential heart toxicity).

If the gastrointestinal tract is suspected to be perforated (perforation can occur with fulminant amoebic colitis), broad-spectrum antibiotics may be used to prevent peritonitis.

What are surgical treatment options for amebiasis?

Surgical treatments are required or indicated for amebiasis treatment due to the following:

- Gastrointestinal bleeding (massive or uncontrolled)
- Perforated amoebic colitis
- Toxic megacolon
- Failure to respond to metronidazole after four days of treatment
- Amoebic liver abscesses greater than 10 cm in size
- Empyema after the liver abscess rupture
- Amoebic liver abscess representing risk of rupture to the pericardium
- Impending abscess rupture (no medical response in about 3-5 days to expanding abscess)
- Percutaneous drainage by catheter can be lifesaving in patients with amoebic pericarditis

Are there home remedies for amebiasis?

There are many home remedies for amebiasis available on the Internet. They range from increased fluid intake, coconut water, buttermilk, black tea, and herbal tea to garlic, Indian lilac, oregano, and apple cider vinegar. If you think you have amebiasis, you should discuss your symptoms with a doctor before trying any self-treatment remedies.

What are complications of amebiasis?

Although infrequent, there can be serious complications of the disease. They include

- liver abscesses (it is possible to develop these abscesses without the typical diarrhea stage),
- lung abscesses,
- brain abscesses,
- ameboma (a large local lesion of the bowel caused by the response to the infecting parasite),
- fulminant or necrotizing colitis,
- rectal rational fistula,
- bloody dysentery,
- toxic megacolon,
- increased risk for cancer, and
- death.

Is it possible to prevent amebiasis?

Yes, amebiasis can be prevented by stopping the fecal contamination of food and water by the Centers for Disease Control personnel by correcting poor sanitation. Identification and treatment of food handlers or other carriers of the parasite can reduce the chance of getting food-borne amebiasis. Avoiding sexual practices that involve fecal-oral contact also may reduce the chance of getting the disease. Avoiding malnutrition and alcohol use can reduce risk of the disease.

Gal-lectin, an antigen from the parasite, has been used as a vaccine to protect animals against intestinal amebiasis and against amoebic liver abscesses. Other parasitic components are being tried as possible vaccine components to use in

humans. Unfortunately, amebiasis doesn't result in any long-term immunity so that individuals can be reinfected multiple times.

What is the prognosis of amebiasis? What is the recovery time for amebiasis?

In general, the prognosis of amebiasis is good since the vast majority of infected individuals showed little or no symptoms. However, if complications develop such as abscesses, peritonitis, or toxic megacolon, the prognosis may vary from fair to poor depending on the availability of medical support services.

Recovery time for amebiasis is related to the severity of the disease. If a person has no symptoms, there is no recovery time. Recovery time after medical treatment varies from about 1-2 weeks to as many as four weeks or more after surgery. You and your doctor need to discuss your estimated recovery time once treatment begins.

Mycotoxin

A **mycotoxin** (from the Greek μύκης *mykes*, "fungus" and τοξικόν *toxikon*, "poison")[1][2] is a toxic secondary metabolite produced by organisms of the fungus kingdom[3] and is capable of causing disease and death in both humans and other animals.[4] The term 'mycotoxin' is usually reserved for the toxic chemical products produced by fungi that readily colonize crops.[5]

Examples of mycotoxins causing human and animal illness include aflatoxin, citrinin, fumonisins, ochratoxin A, patulin, trichothecenes, zearalenone, and ergot alkaloids such as ergotamine.[6]

One mold species may produce many different mycotoxins, and several species may produce the same mycotoxin.[7]

p**roduction**

Most fungi are aerobic (use oxygen) and are found almost everywhere in extremely small quantities due to the diminute size of their spores. They consume organic matter wherever humidity and temperature are sufficient. Where conditions are right, fungi proliferate into colonies and mycotoxin levels become high. The reason for the production of mycotoxins is not yet known; they are not necessary for the growth or the development of the

fungi.[8] Because mycotoxins weaken the receiving host, the fungus may use them as a strategy to better the environment for further fungal proliferation. The production of toxins depends on the surrounding intrinsic and extrinsic environments and these substances vary greatly in their toxicity, depending on the organism infected and its susceptibility, metabolism, and defense mechanisms.[9]

Major groups[

Aflatoxins are a type of mycotoxin produced by *Aspergillus* species of fungi, such as *A. flavus* and *A. parasiticus*.[10] The umbrella term aflatoxin refers to four different types of mycotoxins produced, which are B_1, B_2, G_1, and G_2.[11] Aflatoxin B_1, the most toxic, is a potent carcinogen and has been directly correlated to adverse health effects, such as liver cancer, in many animal species.[10] Aflatoxins are largely associated with commodities produced in the tropics and subtropics, such as cotton, peanuts, spices, pistachios, and maize.[10][11]

Ochratoxin is a mycotoxin that comes in three secondary metabolite forms, A, B, and C. All are produced by *Penicillium* and *Aspergillus*species. The three forms differ in that Ochratoxin B (OTB) is a nonchlorinated form of Ochratoxin A (OTA) and that Ochratoxin C (OTC) is an ethyl ester form Ochratoxin A.[12] *Aspergillus ochraceus* is found as a contaminant of a wide range of commodities including beverages such as beer and wine. *Aspergillus carbonarius* is the main species found on vine fruit, which releases its toxin during the juice making process.[13] OTA has been labeled as a carcinogen and a nephrotoxin, and has been linked to tumors in the human urinary tract, although research in humans is limited by confounding factors.[12][13]

Citrinin is a toxin that was first isolated from *Penicillium citrinum*, but has been identified in over a dozen species of *Penicillium* and several species of *Aspergillus*. Some of these species are used to produce human foodstuffs such as cheese (*Penicillium camemberti*), sake, miso, and soy sauce (*Aspergillus oryzae*). Citrinin is associated with yellowed rice disease in Japan and acts as a nephrotoxin in all animal species tested.[14] Although it is associated with many human foods (wheat, rice, corn, barley, oats, rye, and food colored with Monascus pigment) its full significance for human health is unknown. Citrinin can also act synergistically with Ochratoxin A to depress RNA synthesis in murine kidneys.[15]

Ergot Alkaloids are compounds produced as a toxic mixture of alkaloids in the sclerotia of species of *Claviceps*, which are common pathogens of various grass species. The ingestion of ergot sclerotia from infected cereals, commonly in the form of bread produced from contaminated flour, causes ergotism, the human disease historically known as St. Anthony's Fire. There are two forms of

ergotism: gangrenous, affecting blood supply to extremities, and convulsive, affecting the central nervous system. Modern methods of grain cleaning have significantly reduced ergotism as a human disease; however, it is still an important veterinary problem. Ergot alkaloids have been used pharmaceutically.[15]

Patulin is a toxin produced by the *P. expansum*, *Aspergillus*, *Penicillium*, and *Paecilomyces* fungal species. *P. expansum* is especially associated with a range of moldy fruits and vegetables, in particular rotting apples and figs.[16][17] It is destroyed by the fermentationprocess and so is not found in apple beverages, such as cider. Although patulin has not been shown to be carcinogenic, it has been reported to damage the immune system in animals.[16] In 2004, the European Community set limits to the concentrations of patulin in food products. They currently stand at 50 μg/kg in all fruit juice concentrations, at 25 μg/kg in solid apple products used for direct consumption, and at 10 μg/kg for children's apple products, including apple juice.[16][17]

Fusarium toxins are produced by over 50 species of *Fusarium* and have a history of infecting the grain of developing cereals such as wheat and maize.[18][19] They include a range of mycotoxins, such as: the **fumonisins**, which affect the nervous systems of horses and may cause cancer in rodents; the **trichothecenes**, which are most strongly associated with chronic and fatal toxic effects in animals and humans; and **zearalenone**, which is not correlated to any fatal toxic effects in animals or humans. Some of the other major types of *Fusarium* toxins include: beauvercin and enniatins, butenolide, equisetin, and fusarins.[20]

Occurrence

Although various wild mushrooms contain an assortment of poisons that are definitely fungal metabolites causing noteworthy health problems for humans, they are rather arbitrarily excluded from discussions of mycotoxicology. In such cases the distinction is based on the size of the producing fungus and human intention.[15] Mycotoxin exposure is almost always accidental whereas with mushrooms improper identification and ingestion causing mushroom poisoning is commonly the case. Ingestion of misidentified mushrooms containing mycotoxins may result in hallucinations. The cyclopeptide-producing *Amanita phalloides* is well known for its toxic potential and is responsible for approximately 90% of all mushroom fatalities.[21] The other primary mycotoxin groups found in mushrooms include: orellanine, monomethylhydrazine, disulfiram-like, hallucinogenic indoles, muscarinic, isoxazole, and gastrointestinal (GI)-specific irritants.[22] The bulk of this article is about mycotoxins that are found in microfungi other than poisons from mushrooms or macroscopic fungi.[15]

In indoor environments

Buildings are another source of mycotoxins and people living or working in areas with mold increase their chances of adverse health effects. Molds growing in buildings can be divided into three groups — primary, secondary, and tertiary colonizers. Each group is categorized by the ability to grow at a certain water activity requirement. It has become difficult to identify mycotoxin production by indoor molds for many variables, such as (i) they may be masked as derivatives, (ii) they are poorly documented, and (iii) the fact that they are likely to produce different metabolites on building materials. Some of the mycotoxins in the indoor environment are produced by *Alternaria*, *Aspergillus* (multiple forms), *Penicillium*, and *Stachybotrys*.[23] *Stachybotrys chartarum* contains a higher number of mycotoxins than other molds grown in the indoor environment and has been associated with allergies and respiratory inflammation.[24]The infestation of *S. chartarum* in buildings containing gypsum board, as well as on ceiling tiles, is very common and has recently become a more recognized problem. When gypsum board has been repeatedly introduced to moisture, *S. chartarum* grows readily on its cellulose face.[25] This stresses the importance of moisture controls and ventilation within residential homes and other buildings. The negative health effects of mycotoxins are a function of the concentration, the duration of exposure, and the subject's sensitivities. The concentrations experienced in a normal home, office, or school are often too low to trigger a health response in occupants.

In the 1990s, public concern over mycotoxins increased following multimillion-dollar toxic mold settlements. The lawsuits took place after a study by the Center for Disease Control (CDC) in Cleveland, Ohio, reported an association between mycotoxins from *Stachybotrys*spores and pulmonary hemorrhage in infants. However, in 2000, based on internal and external reviews of their data, the CDC concluded that because of flaws in their methods, the association was not proven. *Stachybotrys* spores in animal studies have been shown to cause lung hemorrhaging, but only at very high concentrations.[26]

One study by the Center of Integrative Toxicology at Michigan State University investigated the causes of Damp Building Related Illness (DBRI). They found that *Stachybotrys* is possibly an important contributing factor to DBRI. So far animal models indicate that airway exposure to *S. chartarum* can evoke allergic sensitization, inflammation, and cytotoxicity in the upper and lower respiratory tracts. Trichothecene toxicity appears to be an underlying cause of many of these adverse effects. Recent findings indicate that lower doses (studies usually involve high doses) can cause these symptoms.[24]

Some toxicologists have used the Concentration of No Toxicological Concern (CoNTC) measure to represent the airborne concentration of mycotoxins that

are expected to cause no hazard to humans (exposed continuously throughout a 70–yr lifetime). The resulting data of several studies have thus far demonstrated that common exposures to airborne mycotoxins in the built indoor environment are below the CoNTC, however agricultural environments have potential to produce levels greater than the CoNTC.[27]

In food

Mycotoxins can appear in the food chain as a result of fungal infection of crops, either by being eaten directly by humans or by being used as livestock feed.

In 2004 in Kenya, 125 people died and nearly 200 others were treated after eating aflatoxin-contaminated maize.[28] The deaths were mainly associated with homegrown maize that had not been treated with fungicides or properly dried before storage. Due to food shortages at the time, farmers may have been harvesting maize earlier than normal to prevent thefts from their fields, so that the grain had not fully matured and was more susceptible to infection.

Spices are susceptible substrate for growth of mycotoxigenic fungi and mycotoxin production.[29] Red chilli, black pepper, and dry ginger were found to be the most contaminated spices.[29]

In animal food

Dimorphic fungi, which include Blastomyces dermatitidis and Paracoccidioides brasiliensis, are known causative agents of endemic systemic mycoses [30].

There were outbreaks of dog food containing aflatoxin in North America in late 2005 and early 2006,[31] and again in late 2011.[32]

Mycotoxins in animal fodder, particularly silage, can decrease the performance of farm animals and potentially kill them.[33] Several mycotoxins reduce milk yield when ingested by dairy cattle.[33]

Mycobacterium is derived from its "fungus-like" nature [34]

In dietary supplements

Contamination of medicinal plants with mycotoxins can contribute to adverse human health problems and therefore represents a special hazard.[35][36] Numerous natural occurrences of mycotoxins in medicinal plants and herbal medicines have been reported from various countries including Spain, China, Germany, India, Turkey and from the Middle East.[35] In a 2015 analysis of plant-based dietary supplements, the highest mycotoxin concentrations were found in milk thistle-based supplements, at up to 37 mg/kg.[37]

Health effects

Some of the health effects found in animals and humans include death, identifiable diseases or health problems, weakened immune systems without

specificity to a toxin, and as allergens or irritants. Some mycotoxins are harmful to other micro-organisms such as other fungi or even bacteria; penicillin is one example.[38] It has been suggested that mycotoxins in stored animal feed are the cause of rare phenotypical sex changes in hens that causes them to look and act male.[39][40]

In humans

Mycotoxicosis is the term used for poisoning associated with exposures to mycotoxins. Mycotoxins have the potential for both acute and chronic health effects via ingestion, skin contact,[41], inhalation, and entering the blood stream and lymphatic system. They inhibit protein synthesis,
damage macrophage systems, inhibit particle clearance of the lung, and increase sensitivity to bacterial endotoxin.[25]

The symptoms of mycotoxicosis depend on the type of mycotoxin; the concentration and length of exposure; as well as age, health, and sex of the exposed individual.[15] The synergistic effects associated with several other factors such as genetics, diet, and interactions with other toxins have been poorly studied. Therefore, it is possible that vitamin deficiency, caloric deprivation, alcohol abuse, and infectious disease status can all have compounded effects with mycotoxins.[15]

Mitigation

Mycotoxins greatly resist decomposition or being broken down in digestion, so they remain in the food chain in meat and dairy products. Even temperature treatments, such as cooking and freezing, do not destroy some mycotoxins.[42]

Removal

In the feed and food industry it has become common practice to add mycotoxin binding agents such as montmorillonite or bentonite clay in order to effectively adsorb the mycotoxins.[43] To reverse the adverse effects of mycotoxins, the following criteria are used to evaluate the functionality of any binding additive:

- Efficacy of active component verified by scientific data
- A low effective inclusion rate
- Stability over a wide pH range
- High capacity to absorb high concentrations of mycotoxins
- High affinity to absorb low concentrations of mycotoxins
- Affirmation of chemical interaction between mycotoxin and adsorbent
- Proven *in vivo* data with all major mycotoxins
- Non-toxic, environmentally friendly component

Since not all mycotoxins can be bound to such agents, the latest approach to mycotoxin control is mycotoxin deactivation. By means of enzymes

(esterase, de-epoxidase), yeast (*Trichosporon mycotoxinvorans*), or bacterial strains (Eubacterium BBSH 797 developed by Biomin), mycotoxins can be reduced during pre-harvesting contamination. Other removal methods include physical separation, washing, milling, nixtamalization, heat-treatment, radiation, extraction with solvents, and the use of chemical or biological agents. Irradiation methods have proven to be effective treatment against mold growth and toxin production.[43]

Regulations

Many international agencies are trying to achieve universal standardization of regulatory limits for mycotoxins. Currently, over 100 countries have regulations regarding mycotoxins in the feed industry, in which 13 mycotoxins or groups of mycotoxins are of concern.[44]The process of assessing a need for mycotoxin regulation includes a wide array of in-laboratory testing that includes extracting, clean-up and separation techniques.[45] Most official regulations and control methods are based on high-performance liquid techniques (e.g., HPLC) through international bodies.[45] It is implied that any regulations regarding these toxins will be in co-ordinance with any other countries with which a trade agreement exists. Many of the standards for the method performance analysis for mycotoxins is set by the European Committee for Standardization (CEN).[45] However, one must take note that scientific risk assessment is commonly influenced by culture and politics, which, in turn, will affect trade regulations of mycotoxins.[46]

Food-based mycotoxins were studied extensively worldwide throughout the 20th century. In Europe, statutory levels of a range of mycotoxins permitted in food and animal feed are set by a range of European directives and EC regulations. The U.S. Food and Drug Administration has regulated and enforced limits on concentrations of mycotoxins in foods and feed industries since 1985. It is through various compliance programs that the FDA monitors these industries to guarantee that mycotoxins are kept at a practical level. These compliance programs sample food products including peanuts and peanut products, tree nuts, corn and corn products, cottonseed, and milk. There is still a lack of sufficient surveillance data on some mycotoxins that occur in the U.S.[47]

Use in fiction

A fictional use of a mycotoxin occurs in William Gibson's seminal novel *Neuromancer* (1984). A "Russian war-time mycotoxin" is administered to Case, the novel's protagonist.

Mycotoxins	*Fungal species*	*Toxicity*	*References*
Aflatoxins	*Aspergillus section Flavi*: *A. flavus*; *A. parasiticus*	Hepatotoxic, Carcinogenic, and other harmful effects to human, poultry, pigs and cattle can be noticed.	Wu (2004)
Citrinin	*Penicillium citrinum*; *P. expansum*	Nephrotoxic	Peraica et al. (1999)
Cyclopiazonic acid	*Penicillium cyclopium*, *Peniccillium camemberti* *Aspergillus flavus*	Induces hyperemia and ulceration of proventriculus; focal necrosis in the liver and spleen; increased weight of pancreas and kidney.	Dorner et al. (1983), Gentles et al. (1999)
Deoxynivalenol	*Fusarium graminearum*; *F. culmorum*	Provokes barley acute human toxicosis, internal disturbances, growth inhibition in pigs.	Pestka (2008)
Diacetoxyscirpenol	*Fusarium sporotrichioides*; *F. poae*	Provokes ill-thrift, decrease feed consumption, slow growth, diarrhea and abortion.	Pronk et al. (2002)
Ergot alkaloids	*Claviceps purpurea*	Responsible for vasoconstriction, neural disorders, skin necrosis and agalactia.	Dyer (1993), Cross (2003)
Fumonisins	*Fusarium moniliforme*; *F. verticillioides*; *F. proliferatum*	Suspected to cause esophageal cancer in human pulmonary edema in pigs and leukoencephalomalacia inequines.	Marasas (2001)
Ochratoxin A	*A. ochraceus*; *A. carbonarius*; *Penicillium verrucosum*	May be carcinogenic, kidney damage and other harmful effects in pigs and poultry.	Gentles et al. (1993)
Patulin	*P. expansum*; *A. clavatus*	Neurotoxic; responsible for haemorrhages of lung and brain.	Peraica et al. (1999)

Algal Toxins & its Effects

What is algal toxin?

Algal toxins are organic molecules produced by a variety of algae in marine, brackish and fresh waters.

- They are a problem in Fisheries when they are produced in sufficient quantities, with sufficient potency, to kill cultured organisms, decrease feeding and growth rates, cause food safety issues, or adversely affect the quality of the product.

ENVIRONMENT

- Algal toxins do not enter the marine environment from an external source but are generated during blooms of particular naturally

occurring marine algal species.

- Algal species,suchas *Alexandrium* and *Dinophysis* can cause poisoning through the food chain when shellfish ingest these algae (and their toxins) and are then subsequently consumed by fish, birds and potentially humans.

The occurrence of toxic algae is perfectly natural but there are concerns that increases in the supply of essential nutrients through human activities may be contributing to the increased frequency and magnitude of these events

Different SYNDROMES

N SP Neurotxic shellfish poisoning;

PSP - paralytic shellfish poisoning;

ASP - amnesic shellfish poisoning;

DSP - diarrhoetic shellfish poisoning;

All are caused by toxins synthesized by dinoflagellates, except for ASP, which is produced by diatoms of the genus *Pseudonitzschia*

- Released either when algal cells are ingested by filter feeding animals, or when algal cells are broken down after a bloom crashes.
- Some dinoflagellate species of toxic algae form cysts that can accumulate in the sediment and act as an inoculums for a new population when conditions favour germination of the cysts.

Effects on the marine environment

Effects on marine organisms:-

- sub-lethal and lethal toxicity, especially to fish, birds and sea mammals;
- physical damage to fish gills.

Toxic phytoplankton can be filtered from the water by shellfish, such as clams, mussels, oysters, or scallops, which then accumulate the algal toxins to levels which can be lethal to consumers, including humans.

Algae have also been implicated in fish kills by the following

direct methods:

- Mechanical damage to gills by algal spines, notably the serrated spines of *Chaetoceros* spp.
- Irritation of gills resulting in over-production of mucilage within the gills leading to suffocation.
- Physical blocking of the secondary lamellae of fish gills.

Increased water viscosity due to the secretion of polysaccharides

The indirect effects arise from changes in the oxygen balance. super saturation with oxygen during the day and oxygen depletion during the night. Algae have been implicated in fish kills by the following indirect methods:

- Asphyxiation caused by oxygen depletion.
- Gas bubble trauma from extreme oxygen super saturation. Bioaccumulation

- Many algal toxins readily bio accumulate in marine animals and significantly bio magnify through food chains posing a hazard to consumers at higher trophic levels (fish, birds and sea mammals).

Ciguatera poisoning:-

- ✓ caused by potent neurotoxins produced by Gambierdiscus *toxicus*,a dinoflageletes.
- ✓ These toxins build-up in the food chain, starting from small fish grazing on algae on coral reefs which are then eaten by larger top-order predators such as coral trout, red bass, chinaman fish, mackerels etc.

✓ **Common types of algal poisoning:-**

Paralytic shellfish poisoning:-

- ✓ Paralytic shellfish poisoning (PSP) is probably the best known of all the shellfish poisonings.
- ✓ Around 20 species of dinoflagellates have been implicated in

producing the alkaloid toxin saxitoxin, a potent neuromuscular blocking agent that finds its way through shellfish to humans.

- ✓ Dinoflagellate species known to produce this toxin include *Gymnodinium catenatum*, *Alexandrium catenella*, *A. minutum etc.*
- ➢ *Diarrhetic shellfish poisoning*
- ➢ *Dinophysis fortii* and *D. acuminate* identified as responsible.

Eating shellfish contaminated with diarrhetic shellfish toxins (akodoic acid, dinophysistoxins and pectenotoxins) causes severe gastrointestinal problems

- *Amnesic shellfish poisoning*
- The amnesic shellfish toxin, domoic acid, is produced by the diatoms *Nitzschia pungens*, *Nitzschia pseudodelicatissima* which accumulate in shellfish and affect their consumers.
- High-performance liquid chromatography or mouse bioassay techniques can be used to detect the toxin. Shellfish containing more than 20 parts per million domoic acid are considered unfit for human consumption

Cyanobacterial toxins

- Most cyanotoxins are either neurotoxins or hepatotoxins.
- Neurotoxins are produced by several genera of cyanobacteria including *Anabaena*,*Microcystis*, *Arthrospira*, *Phormidium* and *Oscillatoria*.
- Neurotoxins usually have acute effects in vertebrates, with rapid paralysis of the peripheral skeletal and respiratory muscles. Other symptoms include loss of coordination, twitching, irregular gill movement, tremors, altered swimming, and convulsions before death by respiratory arrest.
- Identification of the conditions that trigger harmful algal blooms may aid in developing strategies to prevent red tides or freshwater cyanobacterial blooms
- Controlling nutrient loading through reduced fertilizer use, improved animal waste control, and improved sewage treatment may reduce the number, or likely locations, of toxic algal blooms.

UNIT 5

GENERAL PRINCIPLES OF FOOD PRESERVATION-PHYSICAL METHODS

Introduction

Foods are mainly composed of biochemical compounds which are derived from plants and animals. Carbohydrates, proteins and fats are the major constituents of food. In addition, minor constituents such as minerals, vitamins, enzymes, acids, antioxidants, pigments, flavours are present. Foods are subject to physical, chemical, and biological deterioration. The major factors affecting food spoilage are

1) Growth and activities of microorganisms (bacteria, yeasts, and molds)

2) Activities of food enzymes and other chemical reactions within food itself

3) Infestation by insects, rodents

4) Inappropriate temperatures for a given food

5) Either the gain or loss of moisture

6) Reaction with oxygen

7) Light

The vast majority of instances of food spoilage can be attributed to one of two major causes: (1) the attack bymicroorganisms such as bacteria and molds, or (2) oxidation that causes the destruction of essential biochemical compounds and/or the destruction of plant and animal cells. Chemical and/or biochemical reactions results in decomposition of food- due to microbial growth. There is a adverse effect on appearance, flavour, texture, colour, consistence and/or nutritional quality of food.

Food Preservation

Food preservation is the process of treating and handling food to stop or greatly slow down spoilage (loss of quality, edibility or nutritive value) caused or accelerated by micro-organisms. Preservation usually involves preventing the growth of bacteria, fungi, and other micro-organisms, as well as retarding the oxidation of fats which cause rancidity. It also includes processes to inhibit natural ageing and discolouration that can occur during food preparation such as the enzymatic browning reaction in apples after they are cut. Preservative for food may be defined as any chemical compound and/or process, when applied

to food, retard alterations caused by the growth of microorganisms or enable the physical properties, chemical composition and nutritive value to remain unaffected by microbial growth.

Principles of Food Preservation

The principles of various methods for food preservation are as

1) Prevention or delay of microbial decomposition

• By keeping out microorganisms (asepsis)
• By removal of microorganisms
• By hindering the growth and activity of microorganisms (e.g. by low temperatures, drying, anaerobic conditions, or chemicals)
• By killing the microorganisms (e.g. by heat or radiation)

2) Prevention or delay of self decomposition of the food

• By destruction or inactivation of food enzymes (by blanching)
• By prevention or delay of chemical reactions (By using antioxidant)

Methods of Food Preservation

Preservation of food is achieved by application of physical, chemical and/or biological methods are as follows:

Physical methods

• Cooling to
→ Low temperature refrigeration (0 to 7°C) - preserves for shorter period (days) → Freezing - preserves for several months
• Heating → pasteurization, cooking, sterilization etc
• Exposure to ionizing radiation → U.V., γ, etc
• Application of high pressure
• Drying → removal of water to a level which does not support the growth of microorganism

Chemical methods

• Quite often it is either impossible or undesirable to employ conventional physical methods of the preservation.
• In such situation one has to opt for chemical methods of preservation.
• It involves application of chemical additives which act as antimicrobial agents.

Biological methods

Souring (fermentation) lactic and acetic acid, e.g. cheese and cultured milk.

Thermal treatment

The term "thermal" refers to processes involving heat. Heating food is an effective way of preserving it because the great majority of harmful pathogens are killed at temperatures close to the boiling point of water. In this respect, heating foods is a form of food preservation comparable to that of freezing but much superior to it in its effectiveness. A preliminary step in many other forms of food preservation, especially forms that make use of packaging, is to heat the foods to temperatures sufficiently high to destroy pathogens.

In many cases, foods are actually cooked prior to their being packaged and stored. In other cases, cooking is neither appropriate nor necessary. The most familiar example of the latter situation is pasteurization. Conventional methods of pasteurization called for the heating of milk to a temperature between 145 and 149 °F (63 and 65 °C) for a period of about 30 minutes, and then cooling it to room temperature. In a more recent revision of that process, milk can also be "flash-pasteurized" by raising its temperature to about 160 °F (71 °C) for a minimum of 15 seconds, with equally successful results. A process known as ultra high pasteurization uses even higher temperatures of the order of 194 to 266 °F (90 to 130°C) for periods of a second or more.

Low temperature

The lower the temperature, the slower will be chemical reactions, enzyme action, and microbial growth. Each microorganism present has an optimal temperature for growth and a minimal temperature below which it cannot multiply. As the temperature drops from this optimal temperature toward the minimal, the rate of growth of the organism decreases and is slowest at the minimal temperature. Cooler temperatures will prevent growth, but slow metabolic activity may continue. Most bacteria, yeasts, and molds grow best in the temperature range 16-38^{o}C (except psychrotrophs). At temperatures below 10^{o}C, growth is slow and becomes slower the colder it gets. The slowing of microbial activity with decreased temperatures is the principal behind refrigeration and freezing preservation.

Drying

One of the oldest methods of food preservation is by drying, which reduces water activity sufficiently to prevent or delay microbial growth. The term water activity is related to relative humidity. Relative humidity refers to the atmosphere surrounding a material or solution. Water activity is the ratio of vapour pressure of the solution to the vapour pressure of pure water at the same temperature. Under equilibrium conditions water activity equals RH/100. At the usual temperatures permitting microbial growth, most bacteria require a water activity as low as 0.90-1.00. Some yeasts and molds grow slowly at a water activity as low as 0.65. Food is dried either partially or completely to preserve it against microbial spoilage.

Irradiation

The lethal effects of radiation on pathogens has been known for many years. The radiation used for food preservation is normally gamma radiation from radioactive isotopes or machine-generated x rays or electron beams. One of the first applications of radiation for food preservation was in the treatment of various kinds of herbs and spices, an application approved by the United States Food and Drug Administration (FDA) in 1983. In 1985, the FDA extended its approval to the use of radiation for the treatment of pork as a means of destroying the pathogens that cause trichinosis. Experts predict that the ease and efficiency of food preservation by means ofradiation will develop considerably in the future.

Preservation of Food through Irradiation

Radiation processing of food involves exposure of food to short wave radiation energy to achieve a specific purpose such as extension of shelf-life, insect disinfestation and elimination of food borne pathogens and parasites. In comparison with heat or chemical treatment, irradiation is considered a more effective and appropriate technology to destroy food borne pathogens. It offers a number of advantages to producers, processors, retailers and consumers.
Radiation processing of food involves exposure of food to short wave radiation energy to achieve a specific purpose such as extension of shelf-life, insect disinfestation and elimination of food borne pathogens and parasites.

Type of Radiation

The type of radiation used in processing materials is limited to radiations from high energy gamma rays, X-rays and accelerated electrons. These radiations are also referred to as ionizing radiations because their energy is high enough to dislodge electrons from atoms and molecules and to convert them to electrically-charged particles called ions.
Gamma rays and X-rays, like radiowaves, microwaves, ultraviolet and visible light rays, form part of the electromagnetic spectrum and occur in the short-wavelength, high-energy region of the spectrum and have the greatest penetrating power. They have the same properties and effects on materials, their origin being the main difference between them. X-rays with varying energies are generated by machines. Gamma rays with specific energies come from the spontaneous disintegration of radionuclides.
Naturally occurring and man-made radionuclides, also called radioactive isotopes or radioisotopes, emit radiation as they spontaneously revert to a stable state. The time taken by a radionuclide to decay to half the level of radioactivity originally present is known as its half-life, and is specific for each radionuclide of a particular element. Only certain radiation sources can be used in food irradiation. These are the radionuclides cobalt-60 or cesium-137; X-ray

machines having a maximum energy of five million electron volts (MeV) (an electron volt is the amount of energy gained by an electron when it is accelerated by a potential of one volt in a vacuum); or electron accelerators having a maximum energy of 10 MeV. Energies from these radiation sources are too low to induce radioactivity in any material, including food.

Unit of Radiation Dose

Radiation dose is the quantity of radiation energy absorbed by the food as it passes through the radiation field during processing. It is measured using a unit called the Gray (Gy).

In early work the unit was the rad (1 Gy = 100 rads; 1 kGy =1000 Gy).

Application of Radiation processing of food

Interest in the practical application of the process is emerging for many reasons. High food losses caused by insect infestation, microbial contamination and spoilage; mounting concern over food borne diseases, harmful residues of chemical fumigants and the impact of these chemicals on the environment, the stiff standards of quality and quarantine restrictions in international trade are some of the reasons. Though irradiation alone can not solve all the problems of food preservation, it can play an important role in reducing post-harvest losses and use of chemical fumigants.

CHEMICAL PRESERVATION OF FOOD

Introduction

Preservative for food may be defined as any chemical compound and/or process, when applied to food, retard alterations caused by the growth of microorganisms or enable the physical properties, chemical composition and nutritive value to remain unaffected by microbial growth. Some chemicals have been used traditionally since several decades as direct or indirect inhibitors of microbial growth and are still widely used despite their limitations

The majority of food preservation operations used today also employ some kind of chemical additive to reduce spoilage. Of the many dozens of chemical additives available, all are designed either to kill or retard the growth of pathogens or to prevent or retard chemical reactions that result in the oxidation of foods.

Some familiar examples of the former class of food additives are sodium benzoate and benzoic acid; calcium,sodium propionate, and propionic acid; calcium, potassium, sodium sorbate, and sorbic acid; and sodium and potassium sulfite. Examples of the latter class of additives include calcium,

sodium ascorbate, and ascorbic acid (vitamin C); butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT); lecithin; and sodium and potassium sulfite and sulphur dioxide.

Classification of Preservatives

According to FSSA rules → class I and class II preservatives

Class I preservatives

a. Common salt
b. Sugar
c. Dextrose
d. Glucose
e. Spices
f. Vinegar or acetic acid
g. Honey
h. Edible vegetable oil

Addition of class I preservatives in any food is not restricted, unless otherwise provide in the rule.

Class II preservatives

a. Benzoic acid including salts their of
b. Sulphurous acid including salts theirof
c. [Nitrates of] nitrites of sodium or potassium
d. Sorbic acid including its sodium, potassium and calcium salts
e. Nicin
f. Propionic acid including salts theirof
g. Methyl or propyl para-hydroxy benzoate
h. Sodium diacetate
i. Sodium, potassium and calcium salts of lactic acid

Use of class II preservatives is restricted. They shall be added to only specified product and at a concentration not exceeding the proportion specified for the product

Use of more than one class II preservative is prohibited. No person shall use in or upon a food more than one class II preservative

Benzoic acid and its salt

Widely use as an antimicrobial agent. Benzoate is more effective against yeasts and bacteria than molds. Antimicrobial activity is achieved by inhibition in enzymatic system of microbial cells, affecting acetic acid metabolism, citric acid cycle and oxidative phosphorylation.

Antimicrobial activity is affected by pH of medium The maximum inhibition occurs at pH value of 2.5 to 4.0 and it decreases when pH rises above 4.5.

The food products preserved with the benzoate include fruit juices and drinks, salads, jams and jellies, pickles, dried fruits and preserves, ketch up and sauce, syrup, carbonated beverages, bakery items, salad dressings, margarine and other fat spreads, spices.

Sulphur dioxide and sulfites

Sulphur dioxide (SO2) gas is one of the oldest antimicrobial agents. It is a colourless, nonflammable gaseous compound or liquid under pressure with a suffocating pungent odour. When dissolved in water of foods, it yields sulphurous acid and its ions, owing to its solubility in water.

Sulphite salts such as sodium sulphite, sodium bisulphite, potassium sulphite, potassium bisulphite, sodium metabisulphite, potassium metabisulphite used as preservatives. When dissolved in water, form sulphurous acid, bisulphite and ions. Sulphurous acid formed from these compounds is an active antimicrobial substance. The effectiveness of sulphurous acid is enhanced at low pH values. Antimicrobial activity of sulfites against yeasts, molds and bacteria is selective, with certain species being more sensitive to inhibition them others. Bacteria are generally more sensitive to inhibition than yeasts and molds. In addition to antimicrobial action, they are also used, to prevent enzymatic and non enzymatic changes as well as discoloration in some foods. Sulphur dioxide and sulphites are used in fruit products such as fruit juice concentrate, squashes, pickles and chutneys.

Sorbic acid and its salts

Sorbic acid and its salts (calcium, potassium or sodium salts) are effective antimicrobial agents against yeast and molds, as well as bacteria. They are less effective against bacteria. Sorbate has an upper pH limit for activity around 6.0-6.5. The food products preserved with sorbates are carbonated beverages, salad dressings, tomato products, jams, jellies, syrup, candy and chocolate syrup, cheese, sausages, smoked fish, fruit juices, grains, breads and cakes.

Propionic acid and its salts

Propionic acid & its salts (Ca & Na) are used most extensively in the prevention of mold growth and rope development in baked goods and for mold inhibition in many cheese foods and spreads. They are more effective against molds as compared to yeasts and bacteria. Propionates has an upper pH limit for activity

around 5 to 6.

Lactic acid and its salts

Lactic acid is formed during fermentation of lactose by lactic acid bacteria. Lactic acid & its salts are not very common & not easily available. It can be used in pickles (with acetic acid), fermented dough crispy biscuits, some beverages, dairy products & meat & meat products. Calcium lactate is used as a firming agent in pickles, fruits & vegetables. Na & K lactate are also recommended with sodium diacetate for control of food poisoning & other bacteria in meat product.

Acetic acid

Acetic acid has antimicrobial properties. The action tends to be static rather than cidal. It is more effective against bacteria & yeast then molds. A 5 to 10 % solution of acetic acid is known as Vinegar. Acetic acid in the form of vinegar is used in mayonnaise, pickles, sauce, pickled sausage etc.

Sodium chloride (common salt)

Antimicrobial action of NaCl arises from its lowering water activity (aw) of the food product. This reduces available water in food to the extent which renders condition unfavorable for microbial growth. At higher concentration it has a pronounced bacteriostatic action. The 10% NaCl inhibits the growth of most bacteria. Delaying action upon microorganisms- Creates dehydration of microbial cell—by osmosis—altering results into plasmosis of the cell. Reduction in solubility of oxygen in water decreases oxygen level in food—reduce growth of aerobic microorganisms. It is more effective against bacteria & mold compare to yeast.

One of the traditional method of food preservation. Mainly used to preserve pickles, meat & fish. Fish is usually salted by immersing in brine or by mixing with dry salt. High important as a preservative for cheese & table butter. Depending upon type of cheese salt content varied from 1 to 5 %. In table butter salt is added at a max concentration as 3%.

Sucrose (sugar)

More effective against bacteria & mold compared to yeast. Antimicrobial action of sucrose arises from, lowering water activity (aw) of the food product—reduce the available water in food to the extent which renders condition unfavourable for microbial growth. This creates dehydration of microbial cell—

by osmosis results into plasmosis of the cells. The food products preserved with sugar are fruit products (jam, jellies, squash etc.), dairy products (sweetened condensed milk, sweets).

Modern industrial techniques

Techniques of food preservation were developed in research laboratories for commercial applications.

Pasteurization

Pasteurization is a process for preservation of liquid food. It was originally applied to combat the souring of young local wines. Today, the process is mainly applied to dairy products. In this method, milk is heated at about 70 °C (158 °F) for 15–30 seconds to kill the bacteria present in it and cooling it quickly to 10 °C (50 °F) to prevent the remaining bacteria from growing. The milk is then stored in sterilized bottles or pouches in cold places. This method was invented by Louis Pasteur, a French chemist, in 1862.

Vacuum packing

Vacuum-packing stores food in a vacuum environment, usually in an air-tight bag or bottle. The vacuum environment strips bacteria of oxygen needed for survival. Vacuum-packing is commonly used for storing nuts to reduce loss of flavor from oxidization. A major drawback to vacuum packaging, at the consumer level, is that vacuum sealing can deform contents and rob certain foods, such as cheese, of its flavor.

Freeze drying

Preservative food additives can be *antimicrobial*—which inhibit the growth of bacteria or fungi, including mold—or *antioxidant*, such as oxygen absorbers, which inhibit the oxidation of food constituents. Common antimicrobial preservatives include calcium propionate, sodium nitrate, sodium nitrite, sulfites (sulfur dioxide, sodium bisulfite, potassium hydrogen sulfite, etc.), and EDTA. Antioxidants include butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT). Other preservatives include formaldehyde (usually in solution), glutaraldehyde (insecticide), ethanol, and methylchloroisothiazolinone.

Irradiation

Irradiation of food[11] is the exposure of food to ionizing radiation. Multiple types of ionizing radiation can be used, including beta particles(high-energy electrons) and gamma rays (emitted from radioactive sources such as cobalt-60 or cesium-137). Irradiation can kill bacteria, molds, and insect pests, reduce the ripening and spoiling of fruits, and at higher doses induce sterility. The technology may be compared to pasteurization; it is sometimes

called "cold pasteurization", as the product is not heated. Irradiation may allow lower-quality or contaminated foods to be rendered marketable.

National and international expert bodies have declared food irradiation as "wholesome"; organizations of the United Nations, such as the World Health Organization and Food and Agriculture Organization, endorse food irradiation.[12][13] Consumers may have a negative view of irradiated food based on the misconception that such food is radioactive;[14] in fact, irradiated food does not and cannot become radioactive. Activists have also opposed food irradiation for other reasons, for example, arguing that irradiation can be used to sterilize contaminated food without resolving the underlying cause of the contamination.[15] International legislation on whether food may be irradiated or not varies worldwide from no regulation to a full ban.[16]

Approximately 500,000 tons of food items are irradiated per year worldwide in over 40 countries. These are mainly spices and condiments, with an increasing segment of fresh fruit irradiated for fruit fly quarantine.[17][18]

Pulsed electric field electroporation

Pulsed electric field (PEF) electroporation is a method for processing cells by means of brief pulses of a strong electric field. PEF holds potential as a type of low-temperature alternative pasteurization process for sterilizing food products. In PEF processing, a substance is placed between two electrodes, then the pulsed electric field is applied. The electric field enlarges the pores of the cell membranes, which kills the cells and releases their contents. PEF for food processing is a developing technology still being researched. There have been limited industrial applications of PEF processing for the pasteurization of fruit juices. To date, several PEF treated juices are available on the market in Europe. Furthermore, for several years a juice pasteurization application in the US has used PEF. For cell disintegration purposes especially potato processors show great interest in PEF technology as an efficient alternative for their preheaters. Potato applications are already operational in the US and Canada. There are also commercial PEF potato applications in various countries in Europe, as well as in Australia, India, and China.[19]

Modified atmosphere

Modifying atmosphere is a way to preserve food by operating on the atmosphere around it. Salad crops that are notoriously difficult to preserve are now being packaged in sealed bags with an atmosphere modified to reduce the oxygen (O_2) concentration and increase the carbon dioxide (CO_2) concentration. There is concern that, although salad vegetables retain their appearance and texture in such conditions, this method of preservation may not retain nutrients, especially vitamins. There are two methods for preserving grains with carbon dioxide. One method is placing a block of dry ice in the bottom and filling the

can with the grain. Another method is purging the container from the bottom by gaseous carbon dioxide from a cylinder or bulk supply vessel.

Carbon dioxide prevents insects and, depending on concentration, mold and oxidation from damaging the grain. Grain stored in this way can remain edible for approximately five years.[20]

Nitrogen gas (N_2) at concentrations of 98% or higher is also used effectively to kill insects in the grain through hypoxia.[21] However, carbon dioxide has an advantage in this respect, as it kills organisms through hypercarbia and hypoxia (depending on concentration), but it requires concentrations of above 35%,[22] or so. This makes carbon dioxide preferable for fumigation in situations where a hermetic seal cannot be maintained.

Controlled Atmospheric Storage (CA): "CA storage is a non-chemical process. Oxygen levels in the sealed rooms are reduced, usually by the infusion of nitrogen gas, from the approximate 21 percent in the air we breathe to 1 percent or 2 percent. Temperatures are kept at a constant 0–2 °C (32–36 °F). Humidity is maintained at 95 percent and carbon dioxide levels are also controlled. Exact conditions in the rooms are set according to the apple variety. Researchers develop specific regimens for each variety to achieve the best quality. Computers help keep conditions constant." "Eastern Washington, where most of Washington's apples are grown, has enough warehouse storage for 181 million boxes of fruit, according to a report done in 1997 by managers for the Washington State Department of Agriculture Plant Services Division. The storage capacity study shows that 67 percent of that space—enough for 121,008,000 boxes of apples—is CA storage." [23]

Air-tight storage of grains (sometimes called hermetic storage) relies on the respiration of grain, insects, and fungi that can modify the enclosed atmosphere sufficiently to control insect pests. This is a method of great antiquity,[24] as well as having modern equivalents. The success of the method relies on having the correct mix of sealing, grain moisture, and temperature.[25]

A patented process uses fuel cells to exhaust and automatically maintain the exhaustion of oxygen in a shipping container, containing, for example, fresh fish.[26]

Nonthermal plasma

This process subjects the surface of food to a "flame" of ionized gas molecules, such as helium or nitrogen. This causes micro-organisms to die off on the surface.[27]

High-pressure food preservation

High-pressure food preservation or pascalization refers to the use of a food preservation technique that makes use of high pressure. "Pressed inside a vessel

exerting 70,000 pounds per square inch (480 MPa) or more, food can be processed so that it retains its fresh appearance, flavor, texture and nutrients while disabling harmful microorganisms and slowing spoilage." By 2005, the process was being used for products ranging from orange juice to guacamole to deli meats and widely sold.[28]

Biopreservation

Biopreservation is the use of natural or controlled microbiota or antimicrobials as a way of preserving food and extending its shelf life.[29] Beneficial bacteria or the fermentation products produced by these bacteria are used in biopreservation to control spoilage and render pathogensinactive in food.[30] It is a benign ecological approach which is gaining increasing attention.[29]

Of special interest are lactic acid bacteria (LAB). Lactic acid bacteria have antagonistic properties that make them particularly useful as biopreservatives. When LABs compete for nutrients, their metabolites often include active antimicrobials such as lactic acid, acetic acid, hydrogen peroxide, and peptide bacteriocins. Some LABs produce the antimicrobial nisin, which is a particularly effective preservative.[31][32]

These days, LAB bacteriocins are used as an integral part of hurdle technology. Using them in combination with other preservative techniques can effectively control spoilage bacteria and other pathogens, and can inhibit the activities of a wide spectrum of organisms, including inherently resistant Gram-negative bacteria.[29]

Hurdle technology

Hurdle technology is a method of ensing that pathogens in food products can be eliminated or controlled by combining more than one approach. These approaches can be thought of as "hurdles" the pathogen has to overcome if it is to remain active in the food. The right combination of hurdles can ensure all pathogens are eliminated or rendered harmless in the final product.[33]

Hurdle technology has been defined by Leistner (2000) as an intelligent combination of hurdles that secures the microbial safety and stability as well as the organoleptic and nutritional quality and the economic viability of food products.[34] The organoleptic quality of the food refers to its sensory properties, that is its look, taste, smell, and texture.

Examples of hurdles in a food system are high temperature during processing, low temperature during storage, increasing the acidity, lowering the water activity or redox potential, and the presence of preservatives or biopreservatives. According to the type of pathogens and how risky they are, the intensity of the hurdles can be adjusted individually to

meet consumer preferences in an economical way, without sacrificing the safety of the product.[33]

Principal hurdles used for food preservation (after Leistner, 1995)[35][36]		
Parameter	**Symbol**	**Application**
High temperature	F	Heating
Low temperature	T	Chilling, freezing
Reduced water activity	a_w	Drying, curing, conserving
Increased acidity	pH	Acid addition or formation
Reduced redox potential	E_h	Removal of oxygen or addition of ascorbate
Biopreservatives		Competitive flora such as microbial fermentation
Other preservatives		Sorbates, sulfites, nitrites

FOOD SANITATION AND HYGIENE

Food hygiene constitutes a basic necessity of Good Manufacturing/Agricultural Practices and the development of Hazard Analysis Critical Control Point (**HACCP**), as well being as a component of all **GFSI**-benchmarked **food safety standards**. Government, industry and consumers all play a role in safe sanitation and food hygiene practices.

Studies have shown that an appreciable percentage of **foodborne illness** cases can be attributed to poor sanitation and food hygiene, including poor personal hygiene and contamination of equipment and/or environments. Examples of **food recalls** related to sanitation issues include the contamination and subsequent recall of deli meats in Canada in 2008, when cells of Listeria monocytogenes were transferred to the product after surviving in equipment niches, where they were protected from sanitation procedures. The company was very public about the changes made to the sanitation program since then, including regular testing to monitor the success of the strategy in reducing environmental contamination.

Due to the risk, the **Codex Alimentarius Commission** provides an international code of practice concerning food hygiene: **http://www.fao.org/docrep/005/Y1579E/y1579e02.htm**. Within it, the following general prerogatives of the guidelines are laid out:

- Identify the essential principles of food hygiene applicable throughout the food chain (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption
- Recommend a **HACCP-based approach** as a means to enhance **food safety**
- Indicate how to implement those principles
- Provide guidance for specific codes which may be needed for – sectors of the food chain; processes; or commodities; to amplify the hygiene requirements specific to those areas

When designing a food hygiene and sanitation program, a total supply chain approach is crucial. The major areas to cover are:

- Equipment
- Environment
- Air
- Water

A key thing to note about these areas is that they function not as a static entity, but as a constantly evolving system. This is why good food hygiene programs need to be responsive to the dynamics of the plant environment and emerging risks – the same proactive approach used when developing HACCP.

According to the **Codex Alimentarius Commission**, food hygiene should cover all of these elements throughout the supply chain (all GFSI-benchmarked standards have similar requirements for housekeeping and food hygiene, with details laid out in their respective guidance documents):

- Primary Production (environmental hygiene, hygienic production, handling storage & transport, cleaning, maintenance and personnel hygiene)
- Establishment – design and facilities (location, premises and rooms, equipment, facilities)
- Control of operation (food hazards, hygiene control systems, incoming materials, packaging, water, management & supervision, documentation & records, recall procedures)
- Establishment – maintenance and sanitation (maintenance & cleaning, cleaning programmes, pest control systems, waste management, monitoring effectiveness)
- Establishment – personal hygiene (health status, illness and injuries, personal cleanliness, personal behaviour, visitors)
- Transportation (general, requirements, use & maintenance)
- Product information and consumer awareness (lot identification, product information, food labelling, consumer education)
- Training (awareness & responsibilities, training programmes, instruction & supervision, refresher training

Cleaning and food hygiene procedures for the building, plant and equipment should be validated using visual, analytical or microbiological methods – and records should be maintained. For instance, swab samples can be taken from various places on equipment, floors, walls or drains, to test for the presence of contamination. Then, after applying a sanitation step, samples can be taken again and compared with the original results to ensure that the step is effective at reducing harmful microbes to safe levels. For certain high-risk materials (e.g. allergens, ruminant protein or ready-to-eat products), validation of procedures is mandated, with individual governments designating acceptable methods for cleaning of high-risk materials.

A comprehensive food hygiene and sanitation program leaves nothing to chance. Responsibility should be designated for each parameter:

- Frequency of cleaning

- Method (chemicals used, concentrations, materials – including colour-coded/segregated tools to prevent cross contamination of high-risk materials)
- Verification records to ensure that procedures are being carried out consistently and effectively.
- Acceptable limits for CCPs must also be scientifically-established and maintained with regular monitoring
- Training and communication throughout the organization, with clear leadership from management on food hygiene and sanitation

As with other areas of food safety, sanitation and food hygiene should be proactive. End-product testing is important, but a positive result in the end-product doesn't tell you where the contamination originated. The overall food hygiene system, when applied at each point in the supply chain, is about managing risks before they result in a case of food contamination. Using common sense and **food science** based approaches, a well-designed food hygiene program can provide for proactive responses and risk-mitigation from farm.

Food Safety

The safety of food produced, served & consumed is of utmost importance to everyone, more so to those who habitually eat outside their homes and are unaware of the intrinsic quality of food that is served to them, even though their taste buds approve it.

Food production centres or kitchens provide all conditions necessary for the growth of microorganisms, such as food, humidity & right temperature. All of which are conducive to the spread of infection, disease & infestation if not controlled & monitored through strict regimens with respect to hygiene & sanitation practices.

Definition: – Food safety is defined as keeping food safe to eat at every stage of (purchasing, receiving, storage, preparing, cooking, holding, cooling, reheating, and serving) handling as it passes through the flow of food from farm to table. The relationship of safe food & wealth is well established & has been linked to the cultural practices of the country. The problem of getting safe food is more

severe in public eating places where a large quantity of food is pre-prepared, held & finished on demand for service.

Food safety problems can be tackled at various levels in different ways with training in safety being organized. Training in safety can be organized into 3 distinct categories usually abbreviated as the 3E's, namely safety education; safety engineering and enforcement of safety.

Safety Education

- Should start during induction of the employee to the establishment.
- Is effective by the formation of safety committees in the establishment.
- Should include giving info. about the legal and financial implication of accidents.
- Should be done using audio-visual aids discussion, bulletin board, weekly safety theme.

Safety Engineering

This involves the building in of safety features in the structure of the establishment in the equipment, furniture and fittings, and their proper arrangements within the spaces equipment should be selected with care to ensure safety in design that can make it possible to maintain sanitation of parts that come in contact with food.

Enforcement of Safety

That means implementation or practice safety rules need to be enforced by rule, law or custom and practice. Also by

- Discipline at work
- Close supervision of all activities in vulnerable areas and at peak hours
- Closing all switches for fuel supply and water taps when not in use.
- Immediate attention to repair of leaks and regular maintenance and servicing of equipment to ensure optimum operation

Thus food safety is the protection of food product from unintentional contamination (means cross contamination)

Safety programs and policies can only be effective if the staffs are trained to think and act safety at work for this, educating them in the following areas is necessary.

(i) Teaching safe methods, with particular emphasis on areas of potential dangers, & how these can be guarded against.

(ii) Demonstrating the use of safety equipment installed in the established and location and use of first aid material.
(iii) Inculcating in people the ability to recognize the signs of the hazard around them, in colleagues and equipment e.g. – an unwell person or an unusual sound from an equipment.

(iii) Teaching staff the legal implication of non-adherence to safety procedures.

Food Hazards

According to 2005 FDA food code, a hazard is a biological, chemical or physical property that may cause a food to be unsafe for human consumption

Biological hazard

Biological hazard includes bacterial viral and parasitic microorganisms bacteria: e.g. Bacillus cereus, Campylobacter jejuni, Clostridium botulinum, E. coli, salmonella spp, Shigella spp.

The majority of biological hazards are bacteria that can be controlled through time, temperature, acidity and water activity. Some bacteria from spores that and highly assistant and may not be destroyed by cooking and drying.

Viruses can exist in food without growing, but they can rapidly reproduce once they are on a living host, most typically a human being. Viruses can best be controlled by good personal hygiene, because that limits the transmission of viruses via human contact or common food contact e.g. hepatitis A and E, rotavirus, nor virus, reo virus.

Parasites also need a host. They are mostly animals – host specific. What the can survive in humans. Adequate cooking or freezing destroys parasites. Special attention to foods such as pork, fish and bear, the are known to carry parasites. E.g. taenia spp, trichinella spiralis.

Chemical hazards

Chemical hazards also cause foodborne illness. Chemical hazards may occur naturally or may be introduced during any stage of food production. Natural occurring chemicals can be found in some species of fish or shellfish some plant

foods and mushrooms e.g. some chemicals added to food also make them unsafe. These include sulfites, sodium nitrates, mono sodium glutamate or lead, copper environmental additives (fertilizers pesticides) and cleaning agents (sanitizers, lubricants)
Tetrodoxim (fish), mycotoxin like aflatoxim (corn), patulin (appejuice) paralytic shellfish poisoning (psp).

Physical hazards

Any physical material or foreign object not normally found in a food that can cause illness and injury it may result from contamination carelessness, mishandling and implementing poor procedures at many points. From harvest to consumers. e.g. Glass, wood, stone, metal, fragments, bone, plastic.

Contaminants

Contaminants are substances that have not been intentionally added to *food*. These substances may be present in *food* as a result of the various stages of its production, packaging, transport or holding. They also might result from environmental *contamination*. Contamination generally has a negative impact on the quality of food and may imply a risk to human health,

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Food hygiene

Food hygiene may be defined as the sanitary science which aims to produce food that is safe for the consumer and of good keeping quality. It covers a wide field and includes the rearing, feeding, marketing and slaughter of animals as well as the sanitation procedures designed to prevent bacteria of human origin reaching foodstuffs.

As per WHO, Food hygienes are the conditions and measures necessary to ensure the safety of food from production to consumption. Food can become contaminated at any point during slaughtering or harvesting, processing, storage, distribution, transportation and preparation. Lack of adequate food hygiene can lead to foodborne diseases and death of the consumer.

HACCP

Hazard Analysis and Critical Control Points or *HACCP* is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe, and designs measurements to reduce these risks to a safe level.

HACCP Basic Principles:-

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.

The application of this principle involves listing the steps in the process and identifying where significant hazards are likely to occur. The HACCP team will focus on hazards that can be prevented, eliminated or controlled by the HACCP plan. A justification for including or excluding the hazard is reported and possible control measures are identified.

Principle 2: Determine the critical control points (CCPs).

A critical control point (CCP) is a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. The HACCP team will use a CCP decision tree to help identify the critical control points in the process. A critical control point may control more that one food safety hazard or in some cases more than one CCP is needed to control a single hazard. The number of CCP's needed depends on the processing steps and the control needed to assure food safety.

Principle 3: Establish critical limits.

A critical limit (CL) is the maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The critical limit is usually a measure such as time, temperature, water activity (Aw), pH, weight, or some other measure that is based on scientific literature and/or regulatory standards.

Principle 4: Establish monitoring procedures.

The HACCP team will describe monitoring procedures for the measurement of the critical limit at each critical control point. Monitoring procedures should describe how the measurement will be taken when the measurement is taken, who is responsible for the measurement and how frequently the measurement is taken during production.

Principle 5: Establish corrective actions.

Corrective actions are the procedures that are followed when a deviation in a critical limit occurs. The HACCP team will identify the steps that will be taken

to prevent potentially hazardous food from entering the food chain and the steps that are needed to correct the process. This usually includes identification of the problems and the steps taken to assure that the problem will not occur again.

Principle 6: Establish verification procedures.

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The HACCP team may identify activities such as auditing of CCP's, record review, prior shipment review, instrument calibration and product testing as part of the verification activities.

Principle 7: Establish record-keeping and documentation procedures.

A key component of the HACCP plan is recording information that can be used to prove that the food was produced safely. The records also need to include information about the HACCP plan. A record should include information on the HACCP Team, product description, flow diagrams, the hazard analysis, the CCP's identified, Critical Limits, Monitoring System, Corrective Actions, Recordkeeping Procedures, and Verification Procedures.

HACCP includes steps designed to identify food safety risks, prevent food safety hazards before they occur, and address legal compliance. The most important aspect of HACCP is that it is a ***preventive*** system rather than an inspection system of controlling food safety hazards. Prevention of hazards cannot be accomplished by end product inspection. Controlling the production process with HACCP offers the best approach.

Implementing HACCP in 12 steps:-

1. **Assemble a HACCP team** with the appropriate product-specific knowledge and expertise to develop an effective Food Safety Plan. The team should comprise individuals familiar with all aspects of the production process, plus specialists with expertise in specific areas, such as engineering or microbiology. It may be necessary to use external sources of expertise in some cases.
2. **Describe the product** in full detail, including composition, physical/chemical structure, microbial/static treatments, packaging, storage conditions, and distribution methods.
3. **Identify the intended/expected use** of the product by the end user. It is also important to identify the consumer target groups. Vulnerable groups, such as children or the elderly, may need to be considered specifically.
4. **Construct a flow diagram** that provides an accurate representation of each step in the manufacturing process—from raw materials to end product—and may include details of the factory and equipment layout, ingredient specifications, features of equipment design, time/temperature data, cleaning and hygiene procedures, and storage conditions.
5. **Perform an on-site confirmation of the flow diagram** to confirm that it is aligned with actual operations. The operation should be observed at each stage and any discrepancies between the diagram and normal practice should be recorded and amended. It is essential that the flow diagram is accurate since the hazard analysis and identification of Critical Control Points (CCPs) rely on the data it contains.
6. **Conduct a hazard analysis** for each process steps to identify any biological, chemical, or physical hazards. This assessment also includes rating the hazard using a risk matrix, determining if the hazard is likely to occur, and identifying the preventive controls for the process step.
7. **Determine Critical Control Points (CCPs)**—those areas where previously identified hazards may be eliminated. The final HACCP Plan will focus on the control and monitoring of the process at these points.

8. **Establish critical limits** and develop processes that limit risk at CCPs. More than one critical limit may be defined for a single step. Criteria used to set critical limits must be measurable and include rating and ranking of hazards for each step of the flowchart.
9. **Monitor CCPs** and develop processes for ensuring that critical limits are followed. Monitoring procedures must be able to detect loss of control at the CCP and should provide this information in time to make appropriate adjustments so that control of the process is regained before critical limits are exceeded. Where possible, process adjustments should be made when monitoring results indicate a trend towards a loss of control at a CCP.
10. **Establish preplanned corrective actions** to be taken for each CCP in the HACCP plan that can then be applied when the CCP is not under control. If monitoring indicates a deviation from the critical limits for a CCP, action (e.g., proper isolation and disposition of affected product) must be taken that will bring it back under control.
11. **Establish procedures for verification** to determine whether the HACCP system is working correctly. Verification procedures should include detailed reviews of all aspects of the HACCP system and its records. The documentation should confirm that CCPs are under control and should also indicate the nature and extent of any deviations from the critical limits and the corrective actions taken in each case.
12. **Establish proper documentation and recordkeeping** for all HACCP processes to ensure that the business can verify that controls are in place and are being properly maintained.

Developing and implementing a HACCP program requires a significant investment of time and effort. Though HACCP continues to evolve, it is up to the company to design and customize HACCP programs to make them effective and workable. These twelve steps break HACCP into manageable chunks and will help ensure that the company is consistently and reliably producing safe food that will not cause harm to the consumer.

Food and Drug Administration

The **Food and Drug Administration** (**FDA** or **USFDA**) is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical

drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed[4] and veterinary products.

The FDA was empowered by the United States Congress to enforce the Federal Food, Drug, and Cosmetic Act, which serves as the primary focus for the Agency; the FDA also enforces other laws, notably Section 361 of the Public Health Service Act and associated regulations, many of which are not directly related to food or drugs. These include regulating lasers, cellular phones, condoms and control of disease on products ranging from certain household pets to sperm donation for assisted reproduction.

The FDA is led by the Commissioner of Food and Drugs, appointed by the Presidentwith the advice and consent of the Senate. The Commissioner reports to the Secretary of Health and Human Services. Stephen M. Hahn, MD is the acting commissioner, as of December 2019.[5]

The FDA has its headquarters in unincorporated White Oak, Maryland.[6] The agency also has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands, and Puerto Rico.[7] In 2008, the FDA began to post employees to foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.[8]

FDA Building 31 houses the Office of the Commissioner and the Office of Regulatory Department of Health and Human Services.[9] The agency consists of fourteen Centers and Offices:[note 1]

Location

Building 66 at the site of the former Naval Ordnance Laboratory

In recent[*when?*] years, the agency began undertaking a large-scale effort to consolidate its 25 operations in the Washington metropolitan area, moving from its main headquarters in Rockville and several fragmented office buildings to the former site of the Naval Ordnance Laboratory in the White Oak area of Silver Spring, Maryland.[6][13] The site was renamed from the White Oak Naval Surface Warfare Center to the Federal Research Center at White Oak. The first building, the Life Sciences Laboratory, was dedicated and opened with 104 employees on the campus in December 2003. Only one original building from the naval facility was kept. All other buildings are new construction.[14] The project is slated to be completed by 2021, assuming future Congressional funding[15]

Regional facilities

The Arkansas Laboratory in Jefferson, Arkansas is the headquarters of the National Center for Toxicological Research

While most of the Centers are located in the Washington, D.C. area as part of the Headquarters divisions, two offices – the Office of Regulatory Affairs (ORA) and the Office of Criminal Investigations(OCI) – are primarily field offices with a workforce spread across the country.

The Office of Regulatory Affairs is considered the "eyes and ears" of the agency, conducting the vast majority of the FDA's work in the field. Consumer Safety Officers, more commonly called Investigators, are the individuals who inspect production and warehousing facilities, investigate complaints, illnesses, or outbreaks, and review documentation in the case of medical devices, drugs,

biological products, and other items where it may be difficult to conduct a physical examination or take a physical sample of the product.

The Office of Regulatory Affairs is divided into five regions, which are further divided into 20 districts. Districts are based roughly on the geographic divisions of the federal court system. Each district comprises a main district office and a number of Resident Posts, which are FDA remote offices that serve a particular geographic area. ORA also includes the Agency's network of regulatory laboratories, which analyze any physical samples taken. Though samples are usually food-related, some laboratories are equipped to analyze drugs, cosmetics, and radiation-emitting devices.

Jamaica, Queens, NY Regional Office - USFDA

The Office of Criminal Investigations was established in 1991 to investigate criminal cases. Unlike ORA Investigators, OCI Special Agents are armed, and don't focus on technical aspects of the regulated industries. OCI agents pursue and develop cases where individuals and companies have committed criminal actions, such as fraudulent claims, or knowingly and willfully shipping known adulterated goods in interstate commerce. In many cases, OCI pursues cases involving Title 18 violations (e.g., conspiracy, false statements, wire fraud, mail fraud), in addition to prohibited acts as defined in Chapter III of the FD&C Act. OCI Special Agents often come from other criminal investigations backgrounds, and work closely with the Federal Bureau of Investigation, Assistant Attorney General, and even Interpol. OCI receives cases from a variety of sources—including ORA, local agencies, and the FBI—and works with ORA Investigators to help develop the technical and science-based aspects of a case. OCI is a smaller branch, comprising about 200 agents nationwide.

The FDA frequently works with other federal agencies, including the Department of Agriculture, Drug Enforcement Administration, Customs and Border Protection, and Consumer Product Safety Commission. Often local and state government agencies also work with the FDA to provide regulatory inspections and enforcement action.

Scope and funding

The FDA regulates more than US$2.4 trillion worth of consumer goods, about 25% of consumer expenditures in the United States. This includes $466 billion in food sales, $275 billion in drugs, $60 billion in cosmetics and $18 billion in vitamin supplements. Much of these expenditures are for goods imported into the United States; the FDA is responsible for monitoring imports.[16]

The FDA's federal budget request for fiscal year (FY) 2012 totaled $4.36 billion,[7] while the proposed 2014 budget is $4.7 billion.[17]About $2 billion of this budget is generated by user fees. Pharmaceutical firms pay the majority of these fees,[17] which are used to expedite drug reviews.[18] The FDA's federal budget request for fiscal year (FY) 2008 (October 2007 through September 2008) totaled $2.1 billion, a $105.8 million increase from what it received for fiscal year 2007.[19]

In February 2008, the FDA announced that the Bush Administration's FY 2009 budget request for the agency was just under $2.4 billion: $1.77 billion in budget authority (federal funding) and $628 million in user fees. The requested budget authority was an increase of $50.7 million more than the FY 2008 funding – about a three percent increase. In June 2008, Congress gave the agency an emergency appropriation of $150 million for FY 2008 and another $150 million.[16]

Most federal laws concerning the FDA are part of the Food, Drug and Cosmetic Act,[20] (first passed in 1938 and extensively amended since) and are codified in Title 21, Chapter 9 of the United States Code. Other significant laws enforced by the FDA include the Public Health Service Act, parts of the Controlled Substances Act, the Federal Anti-Tampering Act, as well as many others. In many cases these responsibilities are shared with other federal agencies.

Regulatory programs

Regulation of therapeutic goods in the United States

Prescription drugs
Over-the-counter drugs

Law[show]

Government agencies[show]

As of 2015, the agency regulates more than $1 trillion in consumer products, including:

- $466 billion in food
- $275 billion in drugs
- $60 billion in cosmetics
- $18 billion in vitamin supplements[21][*failed verification*]

The programs for safety regulation vary widely by the type of product, its potential risks, and the regulatory powers granted to the agency. For example, the FDA regulates almost every facet of prescription drugs, including testing, manufacturing, labeling, advertising, marketing, efficacy, and safety—yet FDA regulation of cosmetics focuses primarily on labeling and safety. The FDA regulates most products with a set of published standards enforced by a modest number of facility inspections. Inspection observations are documented on Form 483.

In June 2018, the FDA released a statement regarding new guidelines to help food and drug manufacturers "implement protections against potential attacks on the U.S. food supply".[22] One of the new guidelines includes the Intentional Adulteration (IA) rule, which requires strategies and procedures by the food industry to reduce the risk of compromise in facilities and processes that are significantly vulnerable.

The FDA also uses tactics of regulatory shaming,[23] mainly through online publication of non-compliance, warning letters, and "shaming lists." Regulation by shaming harnesses firms' sensitivity to reputational damage. For example, in 2018, the agency published an online "black list," in which it named dozens of branded drug companies that are supposedly using unlawful or unethical means to attempt to impede competition from generic drug companies.[24]

Canada-United States Regulatory Cooperation Council

On February 4, 2011, Prime Minister of Canada Stephen Harper and United States President Barack Obama issued a "Declaration on a Shared Vision for Perimeter Security and Economic Competitiveness"[25][26] and announced the creation of the Canada-United States Regulatory Cooperation Council (RCC) "to increase regulatory transparency and coordination between the two countries".[27]

Health Canada and the U.S. Food and Drug Administration (FDA) under the RCC mandate, undertook the "first of its kind" initiative by selecting "as its first area of alignment common cold indications for certain over-the-counter antihistamine ingredients (GC 2013-01-10)."[28]

Food and dietary supplements

: Regulation of food and dietary supplements by the U.S. Food and Drug Administration

The regulation of food and dietary supplements by the Food and Drug Administration is governed by various statutes enacted by the United States Congress and interpreted by the FDA. Pursuant to the Federal Food, Drug, and Cosmetic Act ("the Act") and accompanying legislation, the FDA has authority to oversee the quality of substances sold as food in the United States, and to monitor claims made in the labeling about both the composition and the health benefits of foods.

The FDA subdivides substances that it regulates as food into various categories—including foods, food additives, added substances (man-made substances that are not intentionally introduced into food, but nevertheless end up in it), and dietary supplements. Specific standards the FDA exercises differ from one category to the next. Furthermore, legislation had granted the FDA a variety of means to address violations of standards for a given substance category.

"FDA-Approved" vs. "FDA-Accepted in Food Processing"

The FDA does not approve applied coatings used in the food processing industry.[29] There is no review process to approve the composition of nonstick coatings, nor does the FDA inspect or test these materials. Through their governing of processes, however, the FDA does have a set of regulations that cover the formulation, manufacturing, and use of nonstick coatings. Hence, materials like Polytetrafluoroethylene (Teflon) are not, and cannot be, considered as FDA Approved, rather, they are "FDA Compliant" or "FDA Acceptable".

Medications

FDA Building 51 houses the Center for Drug Evaluation and Research.

The Center for Drug Evaluation and Research uses different requirements for the three main drug product types: new drugs, generic drugs, and over-the-counter drugs. A drug is considered "new" if it is made by a different manufacturer, uses different excipients or inactive ingredients, is used for a different purpose, or undergoes any substantial change. The most rigorous requirements apply to *new molecular entities*: drugs that are not based on existing medications.

New medications

New drugs receive extensive scrutiny before FDA approval in a process called a new drug application (NDA).[30] Critics, however, argue that the FDA standards are not sufficiently rigorous, allowing unsafe or ineffective drugs to be approved.[31] New drugs are available only by prescription by default. A change to over-the-counter (OTC) status is a separate process, and the drug must be approved through an NDA first. A drug that is approved is said to be "safe and effective when used as directed".

Some very rare limited exceptions to this multi-step process involving animal testing and controlled clinical trials can be granted out of compassionate use protocols, as was the case during the 2015 Ebola epidemic with the use, by prescription and authorization, of ZMappand other experimental treatments, and for new drugs that can be used to treat debilitating and/or very rare conditions for which no existing remedies or drugs are satisfactory, or where there has not been an advance in a long period of time. The studies are progressively longer, gradually adding more individuals as they progress from stage I to stage III, normally over a period of years, and normally involve drug companies, the government and its laboratories, and often medical schools and hospitals and clinics. However, any exceptions to the aforementioned process are subject to strict review and scrutiny and conditions, and are only given if a substantial amount of research and at least some preliminary human testing has shown that they are believed to be somewhat safe and possibly effective.

Advertising and promotion

The FDA's Office of Prescription Drug Promotion reviews and regulates prescription drug advertising and promotion through surveillance activities and issuance of enforcement letters to pharmaceutical manufacturers. Advertising and promotion for over-the-counter drugs is regulated by the Federal Trade Commission.

The drug advertising regulation[32] contains two broad requirements: (1) a company may advertise or promote a drug only for the specific indication or medical use for which it was approved by FDA. Also, an advertisement must contain a "fair balance" between the benefits and the risks (side effects) of a drug.

The term off-label refers to drug usage for indications other than those approved by the FDA.

Postmarket safety surveillance

After NDA approval, the sponsor must review and report to the FDA every patient adverse drug experience it learns of. They must report unexpected serious and fatal adverse drug events within 15 days, and other events on a quarterly basis.[33] The FDA also receives directly adverse drug event reports

through its MedWatch program.[34] These reports are called "spontaneous reports" because reporting by consumers and health professionals is voluntary.

While this remains the primary tool of postmarket safety surveillance, FDA requirements for postmarketing risk management are increasing. As a condition of approval, a sponsor may be required to conduct additional clinical trials, called Phase IV trials. In some cases, the FDA requires risk management plans ("Risk Evaluation and Mitigation Strategies" or "REMS") for some drugs that require actions to be taken to ensure that the drug is used safely.[35][36] For example, thalidomide can cause birth defects but has uses that outweigh the risks if men and women taking the drugs do not conceive a child; a REMS program for thalidomide mandates an auditable process to ensure that people taking the drug take action to avoid pregnancy; many opioid drugs have REMS programs to avoid addiction and diversion of drugs.[35] There is also a REMS program called iPLEDGE for the drug, isotretinoin.[37]

Generic drugs

Generic drugs are chemical and therapeutical equivalents of name-brand drugs whose patents have expired.[38] Approved generic drugs should have the same dosage, safety, effectiveness, strength, stability, and quality, as well as route of administration.In general, they are less expensive than their name brand counterparts, are manufactured and marketed by other companies and, in the 1990s, accounted for about a third of all prescriptions written in the United States.[38] For approval of a generic drug, the U.S. Food and Drug Administration (FDA) requires scientific evidence that the generic drug is interchangeable with or therapeutically equivalent to the originally approved drug.[39] This is called an "ANDA" (Abbreviated New Drug Application). As of 2012, 80% of all FDA approved drugs are available in generic form.[*citation needed*]

Generic drug scandal

In 1989, a major scandal erupted involving the procedures used by the FDA to approve generic drugs for sale to the public.[38] Charges of corruption in generic drug approval first emerged in 1988, in the course of an extensive congressional investigation into the FDA. The oversight subcommittee of the United States House Energy and Commerce Committee resulted from a complaint brought against the FDA by Mylan Laboratories Inc. of Pittsburgh. When its application to manufacture generics were subjected to repeated delays by the FDA, Mylan, convinced that it was being discriminated against, soon began its own private investigation of the agency in 1987. Mylan eventually filed suit against two former FDA employees and four drug-manufacturing companies, charging that corruption within the federal agency resulted in racketeering and in violations of antitrust law. "The order in which new generic drugs were approved was set by the FDA employees even before drug manufacturers submitted applications" and, according to Mylan, this illegal procedure was followed to give preferential

treatment to certain companies. During the summer of 1989, three FDA officials (Charles Y. Chang, David J. Brancato, Walter Kletch) pleaded guilty to criminal charges of accepting bribes from generic drugs makers, and two companies (Par Pharmaceutical and its subsidiary Quad Pharmaceuticals)[40] pleaded guilty to giving bribes.

Furthermore, it was discovered that several manufacturers had falsified data submitted in seeking FDA authorization to market certain generic drugs. Vitarine Pharmaceuticals of New York, which sought approval of a generic version of the drug Dyazide, a medication for high blood pressure, submitted Dyazide, rather than its generic version, for the FDA tests. In April 1989, the FDA investigated 11 manufacturers for irregularities; and later brought that number up to 13. Dozens of drugs were eventually suspended or recalled by manufacturers. In the early 1990s, the U.S. Securities and Exchange Commission filed securities fraud charges against the Bolar Pharmaceutical Company, a major generic manufacturer based in Long Island, New York.[38]

Over-the-counter drugs

Over-the-counter (OTC) drugs like aspirin are drugs and combinations that do not require a doctor's prescription.[41] The FDA has a list of approximately 800 approved ingredients that are combined in various ways to create more than 100,000 OTC drug products. Many OTC drug ingredients had been previously approved prescription drugs now deemed safe enough for use without a medical practitioner's supervision like ibuprofen.[42]

Ebola treatment

In 2014, the FDA adden Ebola treatment being developed by Canadian pharmaceutical company Tekmira to the Fast Track program, but halted the phase 1 trials in July pending the receipt of more information about how the drug works. This is seen as increasingly important in the face of a major outbreak of the disease in West Africa that began in late March 2014 and continued as of August 2014.[43]

Vaccines, blood and tissue products, and biotechnology

FDA scientist prepares blood donation samples for testing

The Center for Biologics Evaluation and Research is the branch of the FDA responsible for ensuring the safety and efficacy of biological therapeutic agents.[44] These include blood and blood products, vaccines, allergenics, cell and tissue-based products, and gene therapy products. New biologics are required to go through a premarket approval process called a Biologics License Application (BLA), similar to that for drugs.

The original authority for government regulation of biological products was established by the 1902 Biologics Control Act, with additional authority established by the 1944 Public Health Service Act. Along with these Acts,

the Federal Food, Drug, and Cosmetic Act applies to all biologic products, as well. Originally, the entity responsible for regulation of biological products resided under the National Institutes of Health; this authority was transferred to the FDA in 1972.

Medical and radiation-emitting devices[edit]

The Center for Devices and Radiological Health

The Center for Devices and Radiological Health (CDRH) is the branch of the FDA responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance and safety of these devices.[45] The definition of a medical device is given in the FD&C Act, and it includes products from the simple toothbrush to complex devices such as implantable neurostimulators. CDRH also oversees the safety performance of non-medical devices that emit certain types of electromagnetic radiation. Examples of CDRH-regulated devices include cellular phones, airport baggage screening equipment, television receivers, microwave ovens, tanning booths, and laser products.

CDRH regulatory powers include the authority to require certain technical reports from the manufacturers or importers of regulated products, to require that radiation-emitting products meet mandatory safety performance standards, to declare regulated products defective, and to order the recall of defective or noncompliant products. CDRH also conducts limited amounts of direct product testing.

"FDA-Cleared" vs "FDA-Approved"

Clearance requests are for medical devices that prove they are "substantially equivalent" to the predicate devices already on the market. Approved requests are for items that are new or substantially different and need to demonstrate "safety and efficacy", for example it may be inspected for safety in case of new toxic hazards. Both aspects need to be proved or provided by the submitter to ensure proper procedures are followed.[46]

Cosmetics

Cosmetics are regulated by the Center for Food Safety and Applied Nutrition, the same branch of the FDA that regulates food. Cosmetic products are not, in general, subject to premarket approval by the FDA unless they make "structure or function claims" that make them into drugs (see Cosmeceutical). However,

all color additives must be specifically FDA approved before manufacturers can include them in cosmetic products sold in the U.S. The FDA regulates cosmetics labeling, and cosmetics that have not been safety tested must bear a warning to that effect.[47]

According to the industry advocacy group the American Council on Science and Health, though the cosmetic industry is predominantly responsible in ensuring the safety of its products, the FDA also has the power to intervene when necessary to protect the public but in general does not require pre-market approval or testing. The ACSH says that companies are required to place a warning note on their products if they have not been tested and that experts in cosmetic ingredient reviews also play a role in monitoring safety through influence on the use of ingredients, but also lack legal authority. According to the ACSH, overall the organization has reviewed about 1,200 ingredients and has suggested that several hundred be restricted, but there is no standard or systemic method for reviewing chemicals for safety and a clear definition of what is meant by 'safety' so that all chemicals are tested on the same basis.[48]

Veterinary products

The Center for Veterinary Medicine (CVM) is a center of the FDA that regulates food additives and drugs that are given to animals.[49]CVM regulates animal drugs, animal food including pet animal, and animal medical devices. The FDA's requirements to prevent the spread of bovine spongiform encephalopathy are also administered by CVM through inspections of feed manufacturers.[50] CVM does not regulate vaccines for animals; these are handled by the United States Department of Agriculture.[51]

Tobacco products

Since the Family Smoking Prevention and Tobacco Control Act became law in 2009, the FDA also has had the authority to regulate tobacco products.[52]

In 2009, Congress passed a law requiring color warnings on cigarette packages and on printed advertising, in addition to text warnings from the U.S. Surgeon General.[53]

The nine new graphic warning labels were announced by the FDA in June 2011 and were scheduled to be required to appear on packaging by September 2012. The implementation date is uncertain, due to ongoing proceedings in the case of R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration.[54] R.J. Reynolds, Lorillard, Commonwealth Brands Inc., Liggett Group LLC and Santa Fe Natural Tobacco Company Inc. have filed suit in Washington, D.C. federal court claiming that the graphic labels are an unconstitutional way of forcing tobacco companies to engage in anti-smoking advocacy on the government's behalf.[55]

A First Amendment lawyer, Floyd Abrams, is representing the tobacco companies in the case, contending requiring graphic warning labels on a lawful product cannot withstand constitutional scrutiny.[56] The Association of National Advertisers and the American Advertising Federation have also filed a brief in the suit, arguing that the labels infringe on commercial free speech and could lead to further government intrusion if left unchallenged.[57] In November 2011, Federal judge Richard Leon of the U.S. District Court for the District of Columbia temporarily halted the new labels, likely delaying the requirement that tobacco companies display the labels. The U.S. Supreme Court ultimately could decide the matter.[58]

In July 2017, the FDA announced a plan that would reduce the current levels of nicotine permitted in tobacco cigarettes.[59]

Regulation of living organisms

With acceptance of premarket notification 510(k) k033391 in January 2004, the FDA granted Dr. Ronald Sherman permission to produce and market medical maggots for use in humans or other animals as a prescription medical device. Medical maggots represent the first living organism allowed by the Food and Drug Administration for production and marketing as a prescription medical device.

In June 2004, the FDA cleared *Hirudo medicinalis* (medicinal leeches) as the second living organism to be used as a medical device.

The FDA also requires milk to be pasteurized to remove bacteria.[*citation needed*]

International Cooperation

The FDA cooperated with international regulatory and law enforcement agencies through Interpol as part of Operation Pangea XI[60] from October 9 to October 16, 2018.[61] The FDA targeted 465 websites that illegally sold potentially dangerous, unapproved versions of opioid, oncology and antiviral prescription drugs to U.S. consumers. In terms of money laundering, the FDA targeted transaction laundering schemes in order to uncover the complex online drug network.[62]

Science and research programs

FDA lab at Building 64 in Silver Spring, Maryland

In addition to its regulatory functions, the FDA carries out research and development activities to develop technology and standards that support its regulatory role, with the objective of resolving scientific and technical challenges before they become impediments. The FDA's research efforts include the areas of biologics, medical devices, drugs, women's health, toxicology, food safety and applied nutrition, and veterinary medicine.[63]

Data management

The FDA has collected a large amount of data through decades. In March 2013, OpenFDA was created to enable easy access of the data for the public.

History

Main article: History of the Food and Drug Administration

Up until the 20th century, there were few federal laws regulating the contents and sale of domestically produced food and pharmaceuticals, with one exception being the short-lived Vaccine Act of 1813. The history of the FDA can be traced to the latter part of the 19th century and the U.S. Department of Agriculture's Division of Chemistry, later its **Bureau of Chemistry.** Under Harvey Washington Wiley, appointed chief chemist in 1883, the Division began conducting research into the adulteration and misbranding of food and drugs on the American market. Wiley's advocacy came at a time when the public had become aroused to hazards in the marketplace by muckraking journalists like Upton Sinclair, and became part of a general trend for increased federal regulations in matters pertinent to public safety during the Progressive Era.[64] The 1902 Biologics Control Act was put in place after a diphtheria antitoxin—derived from tetanus-contaminated serum—was used to produce a vaccine that caused the deaths of thirteen children in St. Louis, Missouri. The serum was originally collected from a horse named Jim, who had contracted tetanus.

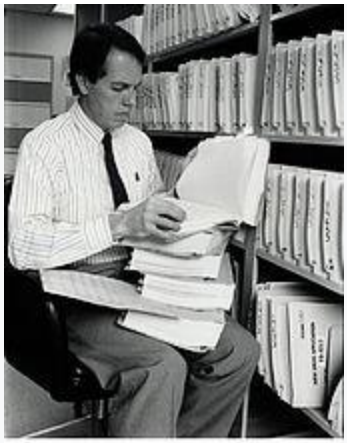
Harvey W. Wiley, chief advocate of the Food and Drug Act

In June 1906, President Theodore Roosevelt signed into law the Pure Food and Drug Act, also known as the "Wiley Act" after its chief advocate.[64] The Act prohibited, under penalty of seizure of goods, the interstate transport of food that had been "adulterated". The act applied similar penalties to the interstate marketing of "adulterated" drugs, in which the "standard of strength, quality, or purity" of the active ingredient was not either stated clearly on the label or listed in the *United States Pharmacopeia* or the *National Formulary*.[65]

The responsibility for examining food and drugs for such "adulteration" or "misbranding" was given to Wiley's USDA Bureau of Chemistry.[64] Wiley used these new regulatory powers to pursue an aggressive campaign against the manufacturers of foods with chemical additives, but the Chemistry Bureau's authority was soon checked by judicial decisions, which narrowly defined the bureau's powers and set high standards for proof of fraudulent intent.[64] In 1927, the Bureau of Chemistry's regulatory powers were reorganized under a new USDA body, the Food, Drug, and Insecticide organization. This name was shortened to the Food and Drug Administration (FDA) three years later.[66]

By the 1930s, muckraking journalists, consumer protection organizations, and federal regulators began mounting a campaign for stronger regulatory authority by publicizing a list of injurious products that had been ruled permissible under the 1906 law, including radioactive beverages, the mascara Lash lure, which caused blindness, and worthless "cures" for diabetes and tuberculosis. The resulting proposed law was unable to get through the Congress of the United States for five years, but was rapidly enacted into law following the public outcry over the 1937 Elixir Sulfanilamide tragedy, in which over 100 people died after using a drug formulated with a toxic, untested solvent.[67]

President Franklin Delano Roosevelt signed the new Food, Drug, and Cosmetic Act (FD&C Act) into law on June 24, 1938. The new law significantly increased federal regulatory authority over drugs by mandating a pre-market review of the safety of all new drugs, as well as banning false therapeutic claims in drug labeling without requiring that the FDA prove fraudulent intent. Soon after passage of the 1938 Act, the FDA began to designate certain drugs as safe for use only under the supervision of a medical professional, and the category of "prescription-only" drugs was securely codified into law by the 1951 Durham-Humphrey Amendment. These developments confirmed extensive powers for the FDA to enforce post-marketing recalls of ineffective drugs.[64]



Medical Officer Alexander Fleming, M. D., examines a portion of a 240-volume new drug application around the late 1980s. Applications grew considerably after the efficacy mandate under the 1962 Drug Amendments.

Outside of the US, the drug thalidomide was marketed for the relief of general nausea and morning sickness but caused birth defects and even the death of thousands of babies when taken during pregnancy.[68] American mothers were largely unaffected as Dr. Frances Oldham Kelsey of the FDA refused to authorize the medication for market, the 1962 Kefauver-Harris Amendment to the FD&C Act was passed, which represented a "revolution" in FDA regulatory authority.[69] The most important change was the requirement that all new drug applications demonstrate "substantial evidence" of the drug's efficacy for a marketed indication, in addition to the existing requirement for pre-marketing demonstration of safety. This marked the start of the FDA approval process in its modern form.

These reforms had the effect of increasing the time, and the difficulty, required to bring a drug to market.[70] One of the most important statutes in establishing the modern American pharmaceutical market was the 1984 Drug Price Competition and Patent Term Restoration Act, more commonly known as the "Hatch-Waxman Act" after its chief sponsors. The act extended the patent exclusivity terms of new drugs, and tied those extensions, in part, to the length of the FDA approval process for each individual drug. For generic manufacturers, the Act created a new approval mechanism, the Abbreviated New Drug Application (ANDA), in which the generic drug manufacturer need only demonstrate that their generic formulation has the same active ingredient, route of administration, dosage form, strength, and pharmacokinetic properties ("bioequivalence") as the corresponding brand-name drug. This act has been credited with in essence creating the modern generic drug industry.[71]

Concerns about the length of the drug approval process were brought to the fore early in the AIDS epidemic. In the mid- and late 1980s, ACT-UP and other HIV activist organizations accused the FDA of unnecessarily delaying the

approval of medications to fight HIV and opportunistic infections.[72] Partly in response to these criticisms, the FDA issued new rules to expedite approval of drugs for life-threatening diseases, and expanded pre-approval access to drugs for patients with limited treatment options.[73] All of the initial drugs approved for the treatment of HIV/AIDS were approved through these accelerated approval mechanisms.[74] Frank Young, the commissioner of the FDA was behind the Action Plan Phase II, established in August 1987 for quicker approval of AIDS medication.[75]

In two instances, state governments have sought to legalize drugs that the FDA has not approved. Under the theory that federal law passed pursuant to Constitutional authority overrules conflicting state laws, federal authorities still claim the authority to seize, arrest, and prosecute for possession and sales of these substances,[*citation needed*] even in states where they are legal under state law. The first wave was the legalization by 27 states of laetrile in the late 1970s. This drug was used as a treatment for cancer, but scientific studies both before and after this legislative trend found it to be ineffective.[76][77] The second wave concerned medical marijuana in the 1990s and 2000s. Though Virginia passed a law with limited effect in 1979, a more widespread trend began in California in 1996.

Historical first: FDA and Endo Pharmaceutical's Opana ER (2017)

When the FDA requested Endo Pharmaceuticals on June 8, 2017 to remove *oxymorphone hydrochloride* from the market, it was the first such request in FDA history.[78]

21st century reforms

Critical Path Initiative

The Critical Path Initiative[79] is FDA's effort to stimulate and facilitate a national effort to modernize the sciences through which FDA-regulated products are developed, evaluated, and manufactured. The Initiative was launched in March 2004, with the release of a report entitled Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products.[80]

Patients' rights to access unapproved drugs

The Compassionate Investigational New Drug program was created after *Randall v. U.S.* ruled in favor of Robert C. Randall in 1978, creating a program for medical marijuana.[81]

A 2006 court case, *Abigail Alliance v. von Eschenbach*, would have forced radical changes in FDA regulation of unapproved drugs. The Abigail Alliance argued that the FDA must license drugs for use by terminally ill patients with "desperate diagnoses," after they have completed Phase I testing.[82] The case

won an initial appeal in May 2006, but that decision was reversed by a March 2007 rehearing. The US Supreme Court declined to hear the case, and the final decision denied the existence of a right to unapproved medications.

Critics of the FDA's regulatory power argue that the FDA takes too long to approve drugs that might ease pain and human suffering faster if brought to market sooner. The AIDS crisis created some political efforts to streamline the approval process. However, these limited reforms were targeted for AIDS drugs, not for the broader market. This has led to the call for more robust and enduring reforms that would allow patients, under the care of their doctors, access to drugs that have passed the first round of clinical trials.[83][84]

Post-marketing drug safety monitoring

The widely publicized recall of Vioxx, a non-steroidal anti-inflammatory drug now estimated to have contributed to fatal heart attacks in thousands of Americans, played a strong role in driving a new wave of safety reforms at both the FDA rulemaking and statutory levels. Vioxx was approved by the FDA in 1999, and was initially hoped to be safer than previous NSAIDs, due to its reduced risk of intestinal tract bleeding. However, a number of pre- and post-marketing studies suggested that Vioxx might increase the risk of myocardial infarction, and this was conclusively demonstrated by results from the APPROVe trial in 2004.[85]

Faced with numerous lawsuits, the manufacturer voluntarily withdrew it from the market. The example of Vioxx has been prominent in an ongoing debate over whether new drugs should be evaluated on the basis of their absolute safety, or their safety relative to existing treatments for a given condition. In the wake of the Vioxx recall, there were widespread calls by major newspapers, medical journals, consumer advocacy organizations, lawmakers, and FDA officials[86] for reforms in the FDA's procedures for pre- and post- market drug safety regulation.

In 2006, a congressionally requested committee was appointed by the Institute of Medicine to review pharmaceutical safety regulation in the U.S. and to issue recommendations for improvements. The committee was composed of 16 experts, including leaders in clinical medicinemedical research, economics, biostatistics, law, public policy, public health, and the allied health professions, as well as current and former executives from the pharmaceutical, hospital, and health insurance industries. The authors found major deficiencies in the current FDA system for ensuring the safety of drugs on the American market. Overall, the authors called for an increase in the regulatory powers, funding, and independence of the FDA.[87][88] Some of the committee's recommendations have been incorporated into drafts of the PDUFA IV bill, which was signed into law in 2007.[89]

As of 2011, Risk Minimization Action Plans (RiskMAPS) have been created to ensure risks of a drug never outweigh the benefits of that drug within the postmarketing period. This program requires that manufacturers design and implement periodic assessments of their programs' effectiveness. The Risk Minimization Action Plans are set in place depending on the overall level of risk a prescription drug is likely to pose to the public.[90]

Pediatric drug testing

Prior to the 1990s, only 20% of all drugs prescribed for children in the United States were tested for safety or efficacy in a pediatric population. This became a major concern of pediatricians as evidence accumulated that the physiological response of children to many drugs differed significantly from those drugs' effects on adults. Children react different to the drugs because of many reason, including size, weight, etc. There were several reasons that not many medical trials were done with children. For many drugs, children represented such a small proportion of the potential market, that drug manufacturers did not see such testing as cost-effective.[91]

Also, because children were thought to be ethically restricted in their ability to give informed consent, there were increased governmental and institutional hurdles to approval of these clinical trials, as well as greater concerns about legal liability. Thus, for decades, most medicines prescribed to children in the U.S. were done so in a non-FDA-approved, "off-label" manner, with dosages "extrapolated" from adult data through body weight and body-surface-area calculations.[91]

An initial attempt by the FDA to address this issue was the 1994 FDA Final Rule on Pediatric Labeling and Extrapolation, which allowed manufacturers to add pediatric labeling information, but required drugs that had not been tested for pediatric safety and efficacy to bear a disclaimer to that effect. However, this rule failed to motivate many drug companies to conduct additional pediatric drug trials. In 1997, the FDA proposed a rule to require pediatric drug trials from the sponsors of New Drug Applications. However, this new rule was successfully preempted in federal court as exceeding the FDA's statutory authority.[91]

While this debate was unfolding, Congress used the 1997 Food and Drug Administration Modernization Act to pass incentives that gave pharmaceutical manufacturers a six-month patent term extension on new drugs submitted with pediatric trial data. The act reauthorizing these provisions, the 2002 Best Pharmaceuticals for Children Act, allowed the FDA to request NIH-sponsored testing for pediatric drug testing, although these requests are subject to NIH funding constraints. In the Pediatric Research Equity Act of 2003, Congress codified the FDA's authority to mandate manufacturer-sponsored pediatric drug

trials for certain drugs as a "last resort" if incentives and publicly funded mechanisms proved inadequate.[91]

Priority review voucher (PRV)

The priority review voucher is a provision of the Food and Drug Administration Amendments Act (HR 3580) signed by President George W. Bush signed the bill in September 2007 which awards a transferable "priority review voucher" to any company that obtains approval for a treatment for a neglected tropical diseases. The system was first proposed by Duke University faculty David Ridley, Henry Grabowski, and Jeffrey Moe in their 2006 *Health Affairs* paper: "Developing Drugs for Developing Countries".[92] In 2012, President Obama signed into law the FDA Safety and Innovation Act which includes Section 908 the "Rare Pediatric Disease Priority Review Voucher Incentive Program".[93]

Rules for generic biologics

Since the 1990s, many successful new drugs for the treatment of cancer, autoimmune diseases, and other conditions have been protein-based biotechnology drugs, regulated by the Center for Biologics Evaluation and Research. Many of these drugs are extremely expensive; for example, the anti-cancer drug Avastin costs $55,000 for a year of treatment, while the enzyme replacement therapy drug Cerezyme costs $200,000 per year, and must be taken by Gaucher's Disease patients for life.[94]

Biotechnology drugs do not have the simple, readily verifiable chemical structures of conventional drugs, and are produced through complex, often proprietary techniques, such as transgenic mammalian cell cultures. Because of these complexities, the 1984 Hatch-Waxman Act did not include biologics in the Abbreviated New Drug Application (ANDA) process, in essence precluding the possibility of generic drug competition for biotechnology drugs. In February 2007, identical bills were introduced into the House to create an ANDA process for the approval of generic biologics, but were not passed.[94]

Mobile medical applications

In 2013, a guidance was issued to regulate mobile medical applications and protect users from their unintended use. This guidance distinguishes the apps subjected to regulation based on the marketing claims of the apps.[95] Incorporation of the guidelines during the development phase of such app has been proposed for expedite market entry and clearance.[96]

Criticisms

The FDA has regulatory oversight over a large array of products that affect the health and life of American citizens.[64] As a result, the FDA's powers and decisions are carefully monitored by several governmental and non-governmental organizations. A $1.8 million 2006 Institute of Medicine report

on pharmaceutical regulation in the U.S. found major deficiencies in the current FDA system for ensuring the safety of drugs on the American market. Overall, the authors called for an increase in the regulatory powers, funding, and independence of the FDA.[97][98]

Nine FDA scientists appealed to then president-elect Barack Obama over pressures from management, experienced during the George W. Bush presidency, to manipulate data, including in relation to the review process for medical devices. Characterized as "corrupted and distorted by current FDA managers, thereby placing the American people at risk," these concerns were also highlighted in the 2006 report[97] on the agency as well.[99]

The FDA has also been criticized from the opposite viewpoint, as being too tough on industry. According to an analysis published on the website of the libertarian Mercatus Center as well as published statements by economists, medical practitioners, and concerned consumers, many feel the FDA oversteps its regulatory powers and undermines small business and small farms in favor of large corporations. Three of the FDA restrictions under analysis are the permitting of new drugs and devices, the control of manufacturer speech, and the imposition of prescription requirements. The authors argue that in the increasingly complex and diverse food marketplace, the FDA is not equipped to adequately regulate or inspect food.[100][*verification needed*] In addition, excessive regulation is blamed for the rising costs of health care and the creation of monopolies, as potential competitors are unable to get FDA approval to enter the market to compete and keep health care costs down.[101]

However, in an indicator that the FDA may be too lax in their approval process, in particular for medical devices, a 2011 study by Dr. Diana Zuckerman and Paul Brown of the National Research Center for Women and Families, and Dr. Steven Nissen of the Cleveland Clinic, published in the Archives of Internal Medicine, showed that most medical devices recalled in the last five years for "serious health problems or death" had been previously approved by the FDA using the less stringent, and cheaper, 510(k) process. In a few cases the devices had been deemed so low-risk that they did not need FDA regulation. Of the 113 devices recalled, 35 were for cardiovascular health purposes.[10

United States Environmental Protection Agency

"EPA" and "Environmental Protection Agency" redirect here. For other uses, see EPA (disambiguation).

Environmental Protection Agency
EPA

Seal of the Environmental Protection Agency

Flag of the Environmental Protection Agency

Headquarters of the EPA at the William Jefferson Clinton Federal Building

Agency overview	
Formed	December 2, 1970; 49 years ago
Headquarters	William Jefferson Clinton Federal Building Washington, D.C., U.S. 38.8939°N 77.0289°WCoordinates: 38.8939°N 77.0289°W

Employees	14,172 (2018)[1][2]
Annual budget	$8.1 billion (2018)[1]
Agency executives	Andrew R. Wheeler, Administrator Henry Darwin, Acting Deputy Administrator
Website	www.epa.gov

The **Environmental Protection Agency** (**EPA**) is an independent agency, specifically an independent executive agency, of the United States federal government for environmental protection.[3] President Richard Nixon proposed the establishment of EPA on July 9, 1970;[4] it began operation on December 2, 1970, after Nixon signed an executive order. The order establishing the EPA was ratified by committee hearings in the House and Senate. The agency is led by its administrator, who is appointed by the president and approved by Congress. The current administrator is former deputy administrator Andrew R. Wheeler, who had been acting administrator since July 2018.[5] The EPA is not a Cabinetdepartment, but the administrator is normally given cabinet rank.

The EPA has its headquarters in Washington, D.C., regional offices for each of the agency's ten regions, and 27 laboratories.[6] The agency conducts environmental assessment, research, and education. It has the responsibility of maintaining and enforcing national standards under a variety of environmental laws, in consultation with state, tribal, and local governments. It delegates some permitting, monitoring, and enforcement responsibility to U.S. states and the federally recognized tribes. EPA enforcement powers include fines, sanctions, and other measures. The agency also works with industries and all levels of government in a wide variety of voluntary pollution prevention programs and energy conservation efforts.

In 2018, the agency had 14,172 full-time employees.[7] More than half of EPA's employees are engineers, scientists, and environmental protection specialists; other employees include legal, public affairs, financial, and information technologists.

The Environmental Protection Agency can only act under statutes, which are the authority of laws passed by Congress. Congress must approve the statute and they also have the power to authorize or prohibit certain actions, which the EPA has to implement and enforce. Appropriations statutes authorize how much money the agency can spend each year to carry out the approved statutes. The

Environmental Protection Agency has the power to issue regulations. A regulation is a standard or rule written by the agency to interpret the statute, apply it in situations and enforce it. Congress allows the EPA to write regulations in order to solve a problem, but the agency must include a rationale of why the regulations need to be implemented. The regulations can be challenged by the courts, where the regulation is overruled or confirmed. Many public health and environmental groups advocate for the agency and believe that it is creating a better world. Other critics believe that the agency commits government overreach by adding unnecessary regulations on business and property owners.[8]

Contents

History

Stacks emitting smoke from burning discarded automobile batteries, photo taken in Houston in 1972 by Marc St. Gil [cs], official photographer of recently founded EPA

Same smokestacks in 1975 after the plant was closed in a push for greater environmental protection

Beginning in the late 1950s and through the 1960s, Congress reacted to increasing public concern about the impact that human activity could have on the environment.[9][10][11] Senator James E. Murray introduced a bill, the Resources and Conservation Act (RCA) of 1959, in the 86th Congress. The 1962 publication of *Silent Spring* by Rachel Carson alerted the public about the detrimental effects on the environment of the indiscriminate use of pesticides.[12]

In the years following, similar bills were introduced and hearings were held to discuss the state of the environment and Congress's potential responses. In 1968, a joint House–Senate colloquium was convened by the chairmen of the Senate Committee on Interior and Insular Affairs, Senator Henry M. Jackson, and the House Committee on Science and Astronautics, Representative George P. Miller, to discuss the need for and means of implementing a national environmental policy. In the colloquium, some members of Congress expressed a continuing concern over federal agency actions affecting the environment.[13]

The National Environmental Policy Act of 1969 (NEPA)[14] was modeled on the Resources and Conservation Act of 1959 (RCA).[15] RCA would have established a Council on Environmental Quality in the office of the president, declared a national environmental policy, and required the preparation of an annual environmental report.[16][17][18][19]

President Nixon signed NEPA into law on January 1, 1970. The law created the Council on Environmental Quality (CEQ) in the Executive Office of the President.[9][20] NEPA required that a detailed statement of environmental impacts be prepared for all major federal actions significantly affecting the environment. The "detailed statement" would ultimately be referred to as an environmental impact statement (EIS).[9]

Ruckelshaus sworn in as first EPA administrator.

On July 9, 1970, Nixon proposed an executive reorganization that consolidated many environmental responsibilities of the federal government under one agency, a new Environmental Protection Agency.[21] This proposal included merging antipollution programs from a number of departments, such as the combination of pesticide programs from the United States Department of Agriculture, Department of Interior, and U.S. Department of Interior.[22] After conducting hearings during that summer, the House and Senate approved the proposal. The EPA was created 90 days before it had to operate,[23] and officially opened its doors on December 2, 1970. The agency's first administrator, William Ruckelshaus, took the oath of office on December 4, 1970.[11] In its first year, the EPA had a budget of $1.4 billion and 5,800 employees.[22] At its start, the EPA was primarily a technical assistance agency that set goals and standards. Soon, new acts and amendments passed by Congress gave the agency its regulatory authority.[24]

EPA staff recall that in the early days there was "an enormous sense of purpose and excitement" and the expectation that "there was this agency which was going to do something about a problem that clearly was on the minds of a lot of people in this country," leading to tens of thousands of resumes from those eager to participate in the mighty effort to clean up America's environment.[25]

When EPA first began operation, members of the private sector felt strongly that the environmental protection movement was a passing fad. Ruckelshaus stated that he felt pressure to show a public which was deeply skeptical about government's effectiveness, that EPA could respond effectively to widespread concerns about pollution.[26]

The burning Cuyahoga River in 1969 had led to a national outcry. In December 1970 a federal grand jury investigation led by U.S. Attorney Robert W. Jones began, of water pollution allegedly being caused by about 12 companies in northeastern Ohio.[27] It was the first grand jury investigation of water pollution in the area. The attorney general of the United States, John N. Mitchell, gave a Press Conference December 18, 1970 referencing new pollution control litigation, with particular reference to work with the new Environmental Protection Agency, and announcing the filing of a law suit that morning against the Jones and Laughlin Steel Corporation for discharging substantial quantities of cyanide into the Cuyahoga River near Cleveland.[28] Jones filed the misdemeanor charges in District Court, alleging violations of the 1899 Rivers and Harbors Act.[29]

Partly based on such litigation experience, Congress enacted the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act. This act established a national framework for addressing water quality to be implemented by agency in partnership with the states.[30]

In 1972, Congress also amended the Federal Insecticide, Fungicide, and Rodenticide Act, requiring the newly formed EPA to measure every pesticide's risks against its potential benefits.[31] Four years later, in October 1976, Congress passed the Toxic Substances Control Act, which like FIFRA related to commercial products rather than pollution.[32] This act gave the EPA the authority to gather information on chemicals and require producers to test them, gave it the ability to regulate chemical production and use (with specific mention of PCBs), and required the agency to create the National Inventory listing of chemicals.[32]

The same year, the Resource Conservation and Recovery Act was passed, significantly amending the Solid Waste Disposal Act of 1965. It tasked the EPA with setting national goals for waste disposal, conserving energy and natural resources, reducing waste, and ensuring environmentally sound management of waste. Accordingly, the agency developed regulations for solid and hazardous waste that were to be implemented in collaboration with states.[33]

In 1980, Congress passed the Comprehensive Environmental Response, Compensation, and Liability Act, nicknamed “Superfund,” which enabled the EPA to cast a wider net for parties responsible for sites contaminated by previous hazardous waste disposal (such as Love Canal) and established a funding mechanism for assessment and cleanup.[34]

In April 1986, when the Chernobyl disaster occurred, the EPA was tasked with identifying any impacts on the United States and keeping the public informed. Administrator Lee Thomas assembled a cross-agency team, including personnel from the Nuclear Regulatory Commission, National Oceanic and Atmospheric Administration, and the Department of Energy to monitor the situation. They held press conferences for 10 days.[35] This same year, Congress passed the Emergency Planning and Community Right-to-Know Act, which authorized the EPA to gather data on toxic chemicals and share this information with the public.[32]

The EPA also researched the implications of stratospheric ozone depletion. Under the leadership of Administrator Lee Thomas, the EPA joined with several international organizations to perform a risk assessment of stratospheric ozone,[36] which helped provide motivation for the Montreal Protocol, which was agreed to in August 1987.

In 1988, during his first presidential campaign, George H. W. Bush was vocal about environmental issues. He appointed as his EPA administrator William K. Reilly, an environmentalist. Under Reilly's leadership, the EPA implemented voluntary programs and a cluster rule for multimedia regulation. At the time, the environment was increasingly being recognized as a regional issue, which was reflected in 1990 amendment of the Clean Air Act and new approaches by the agency.[37][38]

Organization

The EPA is led by an administrator of the Environmental Protection Agency. From February 2017 to July 2018, Scott Pruitt served as the 14th administrator. The current administrator is former deputy administrator Andrew R. Wheeler.

Offices

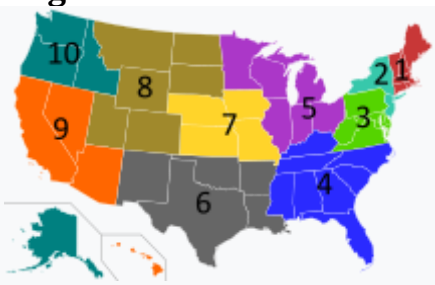
- Office of the Administrator (OA). As of March 2017 the office consisted of 11 divisions:[39]
  - Office of Administrative and Executive Services
  - Office of Children's Health Protection
    - Children's Health Protection Advisory Committee
  - Office of Civil Rights
  - Office of Congressional and Intergovernmental Relations
  - Office of the Executive Secretariat
  - Office of Homeland Security
  - Office of Policy
  - Office of Public Affairs
  - Office of Public Engagement and Environmental Education
  - Office of Small and Disadvantaged Business Utilization
  - Science Advisory Board
- Office of Air and Radiation (OAR)[40]
- Office of Chemical Safety and Pollution Prevention (OCSPP)[41]
- Office of the Chief Financial Officer (OCFO)[42]
- Office of Enforcement and Compliance Assurance (OECA)[43]
- Office of General Counsel (OGC)[44]
- Office of Inspector General (OIG)[45]
- Office of International and Tribal Affairs (OITA)[46]
- Office of Mission Support (OMS) [47]
- 

  The Andrew W. Breidenbach Environmental Research Center in Cincinnati is EPA's second-largest R&D center.[48]

Office of Research and Development (ORD) which as of March 2017 consisted of:[49]

  - National Center for Computational Toxicology
  - National Center for Environmental Assessment[50]
  - National Center for Environmental Research
  - National Exposure Research Laboratory
  - National Health and Environmental Effects Research Laboratory
  - National Homeland Security Research Center
  - National Risk Management Research Laboratory
- Office of Land and Emergency Management (OLEM) which as of March 2017 consisted of:[51]
  - Office of Superfund Remediation and Technology Innovation
  - Office of Resource Conservation and Recovery
  - Office of Underground Storage Tanks
  - Office of Brownfields and Land Revitalization
  - Office of Emergency Management
  - Federal Facilities Restoration and Reuse Office
- Office of Water (OW)[52] which as of March 2017 consisted of:[53]
  - Office of Ground Water and Drinking Water (OGWDW)
  - Office of Science and Technology (OST)
  - Office of Wastewater Management (OWM)
  - Office of Wetlands, Oceans and Watersheds (OWOW)

Regions



The administrative regions of the United States Environmental Protection Agency.

Creating 10 EPA regions was an initiative that came from President Richard Nixon.[54] *See*Standard Federal Regions.

Each EPA regional office is responsible within its states for implementing the agency's programs, except those programs that have been specifically delegated to states.

- Region 1: responsible within the states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont (New England).
- Region 2: responsible within the states of New Jersey and New York. It is also responsible for the US territories of Puerto Rico, and the U.S. Virgin Islands.
- Region 3: responsible within the states of Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and the District of Columbia.
- Region 4: responsible within the states of Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.
- Region 5: responsible within the states of Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.
- Region 6: responsible within the states of Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.
- Region 7: responsible within the states of Iowa, Kansas, Missouri, and Nebraska.
- Region 8: responsible within the states of Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.
- Region 9: responsible within the states of Arizona, California, Hawaii, Nevada, the territories of Guam and American Samoa, and the Navajo Nation.[55]
- Region 10: responsible within the states of Alaska, Idaho, Oregon, and Washington.

Each regional office also implements programs on Indian Tribal lands, except those programs delegated to tribal authorities.

Related legislation

EPA has principal implementation authority for the following federal environmental laws:

- Clean Air Act
- Clean Water Act
- Comprehensive Environmental Response, Compensation and Liability Act ("Superfund")
- Emergency Planning and Community Right-to-Know Act
- Federal Insecticide, Fungicide, and Rodenticide Act
- Resource Conservation and Recovery Act
- Safe Drinking Water Act
- Toxic Substances Control Act

- Frank R. Lautenberg Chemical Safety for the 21st Century Act

There are additional laws where EPA has a contributing role or provides assistance to other agencies. Among these laws are:

- Endangered Species Act
- Energy Independence and Security Act
- Energy Policy Act
- Federal Food, Drug, and Cosmetic Act
- Food Quality Protection Act
- National Environmental Policy Act
- Oil Pollution Act
- Pollution Prevention Act

Programs

A bulldozer piles boulders in an attempt to prevent lake shore erosion, 1973 (photograph by Paul Sequeira, photojournalist and contributing photographer to the Environmental Protection Agency's DOCUMERICAproject in the early 1970s)

It is worth noting that, in looking back in 2013 on the agency he helped shape from the beginning, Administrator William Ruckelshaus observed that a danger for EPA was that air, water, waste and other programs would be unconnected, placed in "silos," a problem that persists more than 50 years later, albeit less so than at the start.[56]

- The **EPA Safer Choice** label, previously known as the Design for the Environment (DfE) label, helps consumers and commercial buyers identify and select products with safer chemical ingredients, without sacrificing quality or performance. When a product has the Safer Choice label, it means that every intentionally-added ingredient in the product has been evaluated by EPA scientists. Only the safest possible functional ingredients are allowed in products with the Safer Choice label.
- Through the **Safer Detergents Stewardship Initiative** (SDSI),[57] EPA's Design for the Environment (DfE) recognizes environmental leaders who voluntarily commit to the use of safer surfactants. Safer surfactants are the

ones that break down quickly to non-polluting compounds and help protect aquatic life in both fresh and salt water. Nonylphenol ethoxylates, commonly referred to as NPEs, are an example of a surfactant class that does not meet the definition of a safer surfactant. The EPA Safer Choice, has identified safer alternative surfactants through partnerships with industry and environmental advocates. These safer alternatives are comparable in cost and are readily available. CleanGredients[58] is a source of safer surfactants.

- In 1992 the EPA launched the **Energy Star** program, a voluntary program that fosters energy efficiency. This program came out an increased effort to collaborate with industry. At the start, it motivated major companies to retrofit millions of square feet of building space with more efficient lighting.[59] As of 2006, more than 40,000 Energy Star products were available including major appliances, office equipment, lighting, home electronics, and more. In addition, the label can also be found on new homes and commercial and industrial buildings. In 2006, about 12 percent of new housing in the United States was labeled Energy Star.[60]
- The EPA estimates it saved about $14 billion in energy costs in 2006 alone. The Energy Star program has helped spread the use of LED traffic lights, efficient fluorescent lighting, power management systems for office equipment, and low standby energy use.[61]
- EPA's **Smart Growth Program**, which began in 1998, is to help communities improve their development practices and get the type of development they want. Together with local, state, and national experts, EPA encourages development strategies that protect human health and the environment, create economic opportunities, and provide attractive and affordable neighborhoods for people of all income levels.[62]
- EPA regulates **pesticides** under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (which is much older than the agency) and the Food Quality Protection Act.[31] It assesses, registers, regulates, and regularly reevaluates all pesticides legally sold in the United States. A few challenges this program faces are transforming toxicity testing, screening pesticides for endocrine disruptors, and regulating biotechnology and nanotechnology.[31]
- The **Land Disposal Restrictions Program** sets treatment requirements for hazardous waste before it may be disposed of on land. I began issuing treatment methods and levels of requirements in 1986 and these are continually adapted to new hazardous wastes and treatment technologies. The stringent requirements it sets and its emphasis on waste minimization practices encourage businesses to plan to minimize waste generation and prioritize reuse and recycling. From the start of the program in 1984 to 2004, the volume of hazardous waste disposed in landfills had decreased 94% and

the volume of hazardous waste disposed of by underground injection had decreased 70%.[33]

- In the late 1970s, the need to clean up sites such as Love Canal that had been highly contaminated by previous hazardous waste disposal became apparent. However the existing regulatory environment depended on owners or operators to perform environmental control. While the EPA attempted to use RCRA's section 7003 to perform this cleanup, it was clear a new law was needed. In 1980, Congress passed the Comprehensive Environmental Response, Compensation, and Liability Act, nicknamed "**Superfund**." This law enabled the EPA to cast a wider net for responsible parties, including past or present generators and transporters as well as current and past owners of the site to find funding. The act also established some funding and a tax mechanism on certain industries to help fund such cleanup. The latter was not renewed in the 1990s, which means funding now comes from general appropriations. Today, due to restricted funding, most cleanup is performed by responsible parties under the oversight of the EPA and states. As of 2016, more than 1,700 sites had been put on the cleanup list since the creation of the program. Of these, 370 sites have been cleaned up and removed from the list, cleanup is underway at 535, cleanup facilities have been constructed at 790 but need to be operated in the future, and 54 are not yet in cleanup stage.[34]
- The **Brownfields Program**, which was started as a pilot program in the 1990s and signed into law in 2002, provides grants and tools to local governments for the assessment, cleanup, and revitalization of brownfields. As of September 2015, the EPA estimates that program grants have resulted in 56,442 acres of land readied for reuse and leveraged 116,963 jobs and $24.2 billion to do so. Agency studies also found that property values around assessed or cleaned-up brownfields have increased 5.1 to 12.8 percent.[34]
- EPA's **oil spill prevention program** includes the Spill Prevention, Control, and Countermeasure (SPCC) and the Facility Response Plan (FRP) rules. The SPCC Rule applies to all facilities that store, handle, process, gather, transfer, refine, distribute, use or consume oil or oil products. Oil products includes petroleum and non-petroleum oils as well as: animal fats, oils and greases; fish and marine mammal oils; and vegetable oils. It mandates a written plan for facilities that store more than 1,320 gallons of fuel above ground or more than 42,000 gallons below-ground, and which might discharge to navigable waters (as defined in the Clean Water Act) or adjoining shorelines. Secondary spill containment is mandated at oil storage facilities and oil release containment is required at oil development sites.[63]
- The **Toxics Release Inventory** (TRI) is a resource established by the Emergency Planning and Community Right-to-Know Actspecifically for the public to learn about toxic chemical releases and pollution prevention activities reported by industrial and federal facilities.[32] TRI data support

informed decision-making by communities, government agencies, companies, and others.[64] Annually, the agency collects data from more than 20,000 facilities.[32] The EPA has generated a range of tools to support the use of this inventory, including interactive maps and online databases such as ChemView.[32]

- **WaterSense** is an EPA program launched in June 2006 to encourage water efficiency in the United States through the use of a special label on consumer products.[65] Products include high-efficiency toilets (HETs), bathroom sink faucets (and accessories), and irrigation equipment. WaterSense is a voluntary program, with EPA developing specifications for water-efficient products through a public process and product testing by independent laboratories.[66]
- EPA regulates **underground storage tanks** (USTs) containing petroleum and hazardous chemicals under Subtitle I of the Solid Waste Disposal Act. This program was launched in 1985 and covers about 553,000 active USTs. Since 1984, 1.8 million USTs have been closed in compliance with regulations.[33] 38 states, the District of Columbia and Puerto Rico manage UST programs with EPA authorization.[67] When the program began, EPA had only 90 staff to develop a system to regulate more than 2 million tanks and work with 750,000 owners and operators. Administrator Lee Thomas told the program's new manager, Ron Brand, that it would have to be done differently that EPA's traditional approach. This program therefore behaves differently than other EPA offices, focusing much more on local operations.[68] It is primarily implemented by states, tribes, and territories.[33] Today, the program supports the inspection of all federally regulated tanks, cleans up old and new leaks, minimizes potential leaks, and encourages sustainable reuse of abandoned gas stations.[33]
- EPA ensures safe **drinking water** for the public, by setting standards for more than 160,000 public water systems nationwide. EPA oversees states, local governments and water suppliers to enforce the standards under the Safe Drinking Water Act. The program includes regulation of injection wells in order to protect underground sources of drinking water. Select readings of amounts of certain contaminants in drinking water, precipitation, and surface water, in addition to milk and air, are reported on EPA's Rad Net web site[69]in a section entitled Envirofacts.[70] Despite mandatory reporting certain readings exceeding EPA MCL levels may be deleted or not included.[71][72] In 2013, an EPA draft revision relaxed regulations for radiation exposure through drinking water, stating that current standards are impractical to enforce. The EPA recommended that intervention was not necessary until drinking water was contaminated with radioactive iodine 131 at a concentration of 81,000 picocuries per liter (the limit for short term exposure set by the International Atomic Energy Agency), which was

27,000 times the prior EPA limit of 3 picocuries per liter for long term exposure.[73]

- The **RCRA Corrective Action** program is a federal and state cleanup program. Established by RCRA, it requires that facilities that treat, store, or dispose of hazardous wastes investigate and clean up hazardous releases at their own expense.[33] For this purpose, the EPA has developed guidance and policy to assist facilities. It is largely implemented through permits and orders.[74] As of 2016, the program has led to the cleanup of 18 million acres of land, of which facilities were primarily responsible for cleanup costs.[33] The goal of EPA and states is to complete final remedies by 2020 at 3,779 priority facilities out of 6,000 that need to be cleaned up according to the program.[33]
- EPA's Indoor Air Quality **Tools for Schools** Program helps schools to maintain a healthy environment and reduce exposures to indoor environmental contaminants. It helps school personnel identify, solve, and prevent indoor air quality problems in the school environment. Through the use of a multi-step management plan and checklists for the entire building, schools can lower their students' and staff's risk of exposure to asthma triggers.[75]
- The National **Environmental Education** Act of 1990 requires EPA to provide national leadership to increase environmental literacy. EPA established the Office of Environmental Education to implement this program.[76]
- **Clean School Bus USA** is a national partnership to reduce children's exposure to diesel exhaust by eliminating unnecessary school bus idling, installing effective emission control systems on newer buses and replacing the oldest buses in the fleet with newer ones. Its goal is to reduce both children's exposure to diesel exhaust and the amount of air pollution created by diesel school buses.[77]
- The **Green Chemistry Program** encourages the development of products and processes that follow green chemistry principles.[32] It has recognized more than 100 winning technologies.[78] These reduce the use or creation of hazardous chemicals, save water, and reduce greenhouse gas release.[32]
- The **Section 404 Program** regulates the discharge of dredged or fill material into waters of the United States. Permits are to be denied if they would cause unacceptable degradation or if an alternative doesn't exist that does not also have adverse impacts on waters.[30] Permit holders are typically required to restore or create wetlands or other waters to offset losses that can't be avoided.
- The **State Revolving Loan Fund Program** replaced the Construction Grants Program, which was phased out in 1990. This program distributes grants to states which, along with matching state funds, are loaned to

municipalities for wastewater infrastructure at below-market interest rates.[30] These loans are expected to be paid back, creating revolving loan funds. Through 2014, a total of $36.2 billion in capitalization grants from the EPA have been provided to the states' revolving funds.[30]

- Established by a 2000 amendment to the Clean Water Act, the **Beaches** Environmental Assessment and Coastal Health (BEACH) Act, this program was established for specific attention to be paid to the coastal recreational waters, and required the EPA to develop criteria to test and monitor waters and notify public users of any concerns.[79] The program involves states, local beach resource managers, and the agency in assessing risks of stormwater and wastewater overflows and enables better sampling, analytical methods, and communication with the public.[30]
- The EPA has also established specific **geographic programs** for particular water resources such as the Chesapeake Bay Program, National Estuaries Program, and Gulf of Mexico Program.[30]
- When the Toxic Substances Control Act was passed in 1976, it required the EPA to create and maintain a **national inventory of all existing chemicals** in U.S. commerce. When the act was passed, there were more than 60,000 chemicals on the market that had never been comprehensively cataloged. To do so, the EPA developed and implemented procedures that have served as a model for Canada, Japan, and the European Union. For the inventory, the EPA also established a baseline for new chemicals that the agency should be notified about before being commercially manufactured. Today, this rule keeps the EPA updated on volumes, uses, and exposures of around 7,000 of the highest-volume chemicals via industry reporting.[32]
- **Advance identification**, or ADID, is a planning process used by the EPA to identify wetlands and other bodies of water and their respective suitability for the discharge of dredged and fill material. The EPA conducts the process in cooperation with the U.S. Army Corps of Engineers and local states or Native American Tribes. As of February 1993, 38 ADID projects had been completed and 33 were ongoing.[80]

Fuel Economy

The testing system was originally developed in 1972 and used driving cycles designed to simulate driving during rush-hour in Los Angeles during that era. Until 1984 the EPA reported the exact fuel economy figures calculated from the test.[*citation needed*] In 1984, the EPA began adjusting city (aka Urban Dynamometer Driving Schedule or UDDS) results downward by 10% and highway (aka HighWay Fuel Economy Test or HWFET) results by 22% to compensate for changes in driving conditions since 1972, and to better correlate the EPA test results with real-world driving. In 1996, the EPA proposed updating the Federal Testing Procedures[81] to add a new higher-speed test (US06) and an air-conditioner-on test (SC03) to further improve the correlation

of fuel economy and emission estimates with real-world reports. In December 2006 the updated testing methodology was finalized to be implemented in model year 2008 vehicles and set the precedent of a 12-year review cycle for the test procedures.[82]

In February 2005, EPA launched a program called "Your MPG" that allows drivers to add real-world fuel economy statistics into a database on the EPA's fuel economy website and compare them with others and with the original EPA test results.[83]

The EPA conducts fuel economy tests on very few vehicles. "Just 18 of the EPA's 17,000 employees work in the automobile-testing department in Ann Arbor, Michigan, examining 200 to 250 vehicles a year, or roughly 15 percent of new models. As to that other 85 percent, the EPA takes automakers at their word—without any testing-accepting submitted results as accurate."[84] Two-thirds of the vehicles the EPA tests themselves are randomly selected and the remaining third is tested for specific reasons.

Although originally created as a reference point for fossil-fueled vehicles, driving cycles have been used for estimating how many miles an electric vehicle will get on a single charge.[85]

National Pollutant Discharge Elimination System

See also: United States regulation of point source water pollution

The National Pollutant Discharge Elimination System (NPDES) permit program addresses water pollution by regulating point sourceswhich discharge to US waters. Created in 1972 by the Clean Water Act, the NPDES permit program authorizes state governments to perform its many permitting, administrative, and enforcement aspects.[86] As of 2018, EPA has approved 47 states to administer all or portions of the permit program.[87] EPA regional offices manage the program in the remaining areas of the country.[86] The Water Quality Act of 1987 extended NPDES permit coverage to industrial stormwater dischargers and municipal separate storm sewer systems.[88] In 2016, there were 6,700 major point source NPDES permits in place and 109,000 municipal and industrial point sources with general or individual permits.[30]

Radiation Protection

EPA has the following seven project groups to protect the public from radiation.[89]

1. Radioactive Waste Management[90]
2. Emergency Preparedness and Response Programs[91] Protective Action Guides And Planning Guidance for Radiological Incidents: EPA developed a manual as guideline for local and state governments to

protect the public from a nuclear accident,[92] the 2017 version being a 15-year update.

3. EPA's Role in Emergency Response – Special Teams[93]
4. Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) Program[94]
5. Radiation Standards for Air and Drinking Water Programs[95]
6. Federal Guidance for Radiation Protection[96]

Past programs

- The former **Construction Grants Program** distributed federal grants for the construction of municipal wastewater treatment works from 1972 to 1990. While such grants existed before the passage of the Clean Water Act of 1972, it expanded these grants dramatically. They were distributed through 1990, when the program and funding were replaced with the State Revolving Loan Fund Program.[30]
- In 1991 under Administrator William Reilly, the EPA implemented its voluntary **33/50 program**.[97] This was designed to encourage, recognize, and celebrate companies that voluntarily found ways to prevent and reduce pollution in their operations.[98] Specifically, it challenged industry to reduce Toxic Release Inventory emissions of 17 priority chemicals by 33% in one year and 50% in four years.[32] These results were achieved before the commitment deadlines.[32]
- Launched in 2006, the voluntary **2010/2015 PFOA Stewardship Program** worked with eight major companies to voluntarily reduce their global emissions of certain types of perfluorinated chemicals by 95% by 2010 and eliminate these emissions by 2015.[32][99]

OSV *Bold* docked at Port Canaveral, Florida

- In March 2004, the U.S. Navy transferred USNS Bold (T-AGOS-12), a *Stalwart* class ocean surveillance ship, to the EPA. The ship had been used in anti-submarine operations during the Cold War, was equipped with sidescan sonar, underwater video, water and sediment sampling instruments used in study of ocean and coastline. One of the major missions of the *Bold* was to monitor for ecological impact sites where materials were dumped from dredging operations in U.S. ports.[100] In 2013, the General

Services Administration sold the *Bold* to Seattle Central Community College (SCCC), which demonstrated in a competition that they would put it to the highest and best purpose, at a nominal cost of $5,000.[101]

Controversies (1983–present)

EPA headquarters in Washington, D.C.

Fiscal mismanagement, 1983

In 1982 Congress charged that the EPA had mishandled the $1.6 billion program to clean up hazardous waste dumps Superfund and demanded records from EPA director Anne M. Gorsuch. She refused and became the first agency director in U.S. history to be cited for contempt of Congress. The EPA turned the documents over to Congress several months later, after the White House abandoned its court claim that the documents could not be subpoenaed by Congress because they were covered by executive privilege. At that point, Gorsuch resigned her post, citing pressures caused by the media and the congressional investigation.[102] Critics charged that the EPA was in a shambles at that time.[103] When Lee Thomas came to the agency in 1983 as Acting Assistant Administrator of the Office of Solid Waste and Emergency Response, shortly before Gorsuch's resignation, six congressional committees were investigating the Superfund program. There were also two FBI agents performing an investigation for the Justice Department into possible destruction of documents.[104]

Gorsuch, appointed by Ronald Reagan, resigned under fire in 1983. Gorsuch based her administration of the EPA on the New Federalism approach of downsizing federal agencies by delegating their functions and services to the individual states.[105] She believed that the EPA was over-regulating business and that the agency was too large and not cost-effective. During her 22 months as agency head, she cut the budget of the EPA by 22%, reduced the number of cases filed against polluters, relaxed Clean Air Act regulations, and facilitated the spraying of restricted-use pesticides. She cut the total number of agency employees, and hired staff from the industries they were supposed to be

regulating.[106] Environmentalists contended that her policies were designed to placate polluters, and accused her of trying to dismantle the agency.[107]

TSCA and confidential business information, 1994 (or earlier)–present

TSCA enables the EPA to require industry to conduct testing of chemicals, but the agency must balance this with obligations to provide information to the public and ensure the protection of trade secrets and confidential business information (the legal term for proprietary information). Arising issues and problems from these overlapping obligations have been the subject of multiple critical reports by the Government Accountability Office. How much information the agency should have access to from industry, how much it should keep confidential, and how much it should reveal to the public is still contested. For example, according to TSCA, state officials are not allowed access to confidential business information collected by the EPA.[32]

Political pressure and scientific integrity, 2001–present

In April 2008, the Union of Concerned Scientists said that more than half of the nearly 1,600 EPA staff scientists who responded online to a detailed questionnaire reported they had experienced incidents of political interference in their work. The survey included chemists, toxicologists, engineers, geologists and experts in other fields of science. About 40% of the scientists reported that the interference had been more prevalent in the last five years than in previous years. The highest number of complaints came from scientists who were involved in determining the risks of cancer by chemicals used in food and other aspects of everyday life.[108]

EPA research has also been suppressed by career managers.[109] Supervisors at EPA's National Center for Environmental Assessment required several paragraphs to be deleted from a peer-reviewed journal article about EPA's integrated risk information system, which led two co-authors to have their names removed from the publication, and the corresponding author, Ching-Hung Hsu, to leave EPA "because of the draconian restrictions placed on publishing".[110] EPA subjects employees who author scientific papers to prior restraint, even if those papers are written on personal time.[111]

EPA employees have reported difficulty in conducting and reporting the results of studies on hydraulic fracturing due to industry[112][113][114] and governmental pressure, and are concerned about the censorship of environmental reports.[112][115][116]

In February 2017, U.S. representative Matt Gaetz (R-Fla.) sponsored H.R. 861, a bill[117] to abolish the EPA by 2018. According to Gaetz, "The American people are drowning in rules and regulation promulgated by unelected bureaucrats. And the Environmental Protection Agency has become an

extraordinary offender." The bill was co-sponsored by Thomas Massie (R-Ky.), Steven Palazzo (R-Ms.) and Barry Loudermilk (R-Ga.).[118]

Fuel economy, 2005–2010

In July 2005, an EPA report showing that auto companies were using loopholes to produce less fuel-efficient cars was delayed. The report was supposed to be released the day before a controversial energy bill was passed and would have provided backup for those opposed to it, but the EPA delayed its release at the last minute.[119]

In 2007, the state of California sued the EPA for its refusal to allow California and 16 other states to raise fuel economy standards for new cars.[120] EPA administrator Stephen L. Johnson claimed that the EPA was working on its own standards, but the move has been widely considered an attempt to shield the auto industry from environmental regulation by setting lower standards at the federal level, which would then preempt state laws.[121][122][123] California governor Arnold Schwarzenegger, along with governors from 13 other states, stated that the EPA's actions ignored federal law, and that *existing* California standards (adopted by many states in addition to California) were almost twice as effective as the *proposed* federal standards.[124] It was reported that Stephen Johnson ignored his own staff in making this decision.[125]

After the federal government had bailed out General Motors and Chrysler in the Automotive industry crisis of 2008–2010, the 2010 Chevrolet Equinox was released with an EPA fuel economy rating abnormally higher than its competitors. Independent road tests[126][127][128][129] found that the vehicle did not out-perform its competitors, which had much lower fuel economy ratings. Later road tests found better, but inconclusive, results.[130][131]

Mercury emissions, 2005

In March 2005, nine states (California, New York, New Jersey, New Hampshire, Massachusetts, Maine, Connecticut, New Mexico and Vermont) sued the EPA. The EPA's inspector general had determined that the EPA's regulation of mercury emissions did not follow the Clean Air Act, and that the regulations were influenced by top political appointees.[132][133] The EPA had suppressed a study it commissioned by Harvard University which contradicted its position on mercury controls.[134] The suit alleged that the EPA's rule exempting coal-fired power plants from "maximum available control technology" was illegal, and additionally charged that the EPA's system of cap-and-trade to lower average mercury levels would allow power plants to forego reducing mercury emissions, which they objected would lead to dangerous local hotspots of mercury contamination even if average levels declined.[135] Several states also began to enact their own mercury emission regulations. Illinois's proposed rule would have reduced mercury emissions from power plants by an average of 90% by 2009.[136] In 2008—by which point a total of fourteen states

had joined the suit—the U.S. Court of Appeals for the District of Columbia ruled that the EPA regulations violated the Clean Air Act.[137]

In response, EPA announced plans to propose such standards to replace the vacated Clean Air Mercury Rule, and did so on March 16, 2011.[138]

Climate change, 2007–2017

In December 2007, EPA administrator Stephen L. Johnson approved a draft of a document that declared that climate change imperiled the public welfare—a decision that would trigger the first national mandatory global-warming regulations. Associate Deputy Administrator Jason Burnett e-mailed the draft to the White House. White House aides—who had long resisted mandatory regulations as a way to address climate change—knew the gist of what Johnson's finding would be, Burnett said. They also knew that once they opened the attachment, it would become a public record, making it controversial and difficult to rescind. So they did not open it; rather, they called Johnson and asked him to take back the draft. Johnson rescinded the draft; in July 2008, he issued a new version which did not state that global warming was danger to public welfare. Burnett resigned in protest.[139]

A $3 million mapping study on *sea level rise* was suppressed by EPA management during both the Bush and Obama administrations, and managers changed a key interagency report to reflect the removal of the maps.[140]

On April 28, 2017, multiple climate change subdomains at EPA.gov began redirecting to a notice stating "this page is being updated."[141]The EPA issued a statement announcing the overhaul of its website to "reflect the agency's new direction under President Donald Trump and Administrator Scott Pruitt."[142] The removed EPA climate change domains included extensive information on the EPA's work to mitigate climate change, as well as details of data collection efforts and indicators for climate change.[143]

Gold King Mine waste water spill, 2015

In August 2015, the 2015 Gold King Mine waste water spill occurred when EPA contractors examined the level of pollutants such as leadand arsenic in a Colorado mine,[144] and accidentally released over three million gallons of waste water into Cement Creek and the Animas River.[145]

Collusion with Monsanto chemical company

In 2015, the International Agency for Research on Cancer (IRC), a branch of the World Health Organization, cited research linking glyphosate, an ingredient of the weed killer Roundup manufactured by the chemical company Monsanto, to non-Hodgkin's lymphoma. In March 2017, the presiding judge in a litigation brought about by people who claim to have developed glyphosate-related non-Hodgkin's lymphoma opened Monsanto emails and other documents related to

the case, including email exchanges between the company and federal regulators. According to an article in *The New York Times*, the "records suggested that Monsanto had ghostwritten research that was later attributed to academics and indicated that a senior official at the Environmental Protection Agency had worked to quash a review of Roundup's main ingredient, glyphosate, that was to have been conducted by the United States Department of Health and Human Services." The records show that Monsanto was able to prepare "a public relations assault" on the finding after they were alerted to the determination by Jess Rowland, the head of the EPA's cancer assessment review committee at that time, months in advance. Emails also showed that Rowland "had promised to beat back an effort by the Department of Health and Human Services to conduct its own review."[146][147][148]

Chief Scott Pruitt, 2017

On February 17, 2017, Scott Pruitt was selected Administrator of the EPA by president Donald Trump. This was a seemingly controversial move, as Pruitt had spent most of his career countering environmental policy. He did not have previous experience in the field and had received financial support from the fossil fuel industry.[149] In 2017 the Trump administration proposed a 31% cut to the EPA's budget to $5.7 billion from $8.1 billion and to eliminate a quarter of the agency jobs.[150] However, this cut was not approved by Congress.[38]

Pruitt resigned from the position on July 5, 2018, citing "unrelenting attacks" due to ongoing ethics controversies.[151]

Environmental justice

The EPA has been criticized for its lack of progress towards environmental justice. Administrator Christine Todd Whitman was criticized for her changes to President Bill Clinton's Executive Order 12898 during 2001, removing the requirements for government agencies to take the poor and minority populations into special consideration when making changes to environmental legislation, and therefore defeating the spirit of the Executive Order.[152] In a March 2004 report, the inspector general of the agency concluded that the EPA "has not developed a clear vision or a comprehensive strategic plan, and has not established values, goals, expectations, and performance measurements" for environmental justice in its daily operations. Another report in September 2006 found the agency still had failed to review the success of its programs, policies and activities towards environmental justice.[153] Studies have also found that poor and minority populations were underserved by the EPA's Superfund program, and that this situation was worsening.[152]

Barriers to enforcing environmental justice

Many environmental justice issues are local, and therefore difficult to address by a federal agency, such as the EPA. Without strong media attention, political

interest, or 'crisis' status, local issues are less likely to be addressed at the federal level compared to larger, well publicized incidents.

Conflicting political powers in successive administrations: The White House maintains direct control over the EPA, and its enforcements are subject to the political agenda of who is in power. Republicans and Democrats differ in their approaches to environmental justice. While President Bill Clinton signed the executive order 12898, the Bush administration did not develop a clear plan or establish goals for integrating environmental justice into everyday practices, affecting the motivation for environmental enforcement.[154][*page needed*]

The EPA is responsible for preventing and detecting environmental crimes, informing the public of environmental enforcement, and setting and monitoring standards of air pollution, water pollution, hazardous wastes and chemicals. "It is difficult to construct a specific mission statement given its wide range of responsibilities."[155][*page needed*] It is impossible to address every environmental crime adequately or efficiently if there is no specific mission statement to refer to. The EPA answers to various groups, competes for resources, and confronts a wide array of harms to the environment. All of these present challenges, including a lack of resources, its self-policing policy, and a broadly defined legislation that creates too much discretion for EPA officers.[156][*page needed*]

The EPA "does not have the authority or resources to address injustices without an increase in federal mandates" requiring private industries to consider the environmental ramifications of their activities.[157]

Freedom of Information Act processing performance

In the latest Center for Effective Government analysis of 15 federal agencies which receive the most Freedom of Information Act FOIA requests, published in 2015 (using 2012 and 2013 data, the most recent years available), the EPA earned a D by scoring 67 out of a possible 100 points, i.e. did not earn a satisfactory overall grade.[158]

Scientific integrity official barred from Congressional hearing

On July 17, 2019 the top scientific integrity official from the EPA, Francesca Grifo, was not permitted to testify by the EPA in front of a House committee hearing. The EPA offered to send a different representative in place of Grifo and accused the committee of "dictating to the agency who they believe was qualified to speak." The hearing was to discuss the importance of allowing federal scientists and other employees to speak freely when and to whom they want to about their research without having to worry about any political consequences.[159]

ISI mark

ISI mark	
	
Expansion	Indian Standards Institution
Standards organization	Bureau of Indian Standards(formerly Indian Standards Institution)
Effective region	India
Effective since	1955
Product category	Industrial products
Legal status	Mandatory for 90 products[a], advisory for others

The **ISI mark** is a standards-compliance mark for industrial products in India since 1955. The mark certifies that a product conforms to an Indian standard (IS) developed by the Bureau of Indian Standards (BIS), the national standards body of India.[1] The ISI mark is by far the most recognised certification mark in the Indian subcontinent. The *ISI* is an initialismof *Indian Standards Institution*, the name of the national standards body until 1 January 1987, when it was renamed to the Bureau of Indian Standards. The ISI mark is mandatory for certain products to be sold in India, such as many of the electrical appliances[2] like switches, electric motors, wiring cables, heaters, kitchen

appliances, etc., and other products like Portland cement, LPG valves, LPG cylinders, automotive tyres[3], etc. In the case of most other products, ISI marks are optional.[4][5]

Counterfeiting

It is very common in India to find products with fake ISI marks. That is, industrial traders cheat customers by affixing ISI marks on the product without actually getting certified.[6]Fake ISI marks usually do not carry

> (i) the mandatory 7-digit licence number (of the format CM/L-*xxxxxxx*, where *x* signifies a digit from the licence number) required by BIS; and
> (ii) the IS number on top of the ISI mark which signifies the Indian standard a particular product is in compliance with.[7]
>
> For example, if a kitchen grinder's box has a small ISI mark on it with the ISI code of the appliance's wire, one can conclude that the wire is BIS-certified but the appliance itself is not an BIS-certified product. Counterfeiting ISI marks is a punishable offence by the law, but enforcement is uncommon.[8]