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DEPARTMENT OF

BIOTECHNOLOGY

Academic year 2024-2025 (Even Sem)

Date	2nd April 2025	Maximum Marks	60
Course Code	BT242TC	Duration	120 min
Sem	IV Semester	Closed Book Offline Quiz & Test -1	

Biosafety Standards and Ethics

Sl. No	Questions (Quiz)	M	BT-L	CO
1.	What is the role of the Institutional Biosafety Committee (IBC) in India?	1	2	2
2.	The Recombinant DNA Advisory Committee (RCGM) is a part of which Department of Govt of India?	1	1	2
3.	The committee of an Institutional Biosafety Committee (IBC) comprise of _____ and _____	1	1	2
4.	Biosafety levels indicate _____	1	1	1
5.	_____ is the primary mode of transmission of many viral biohazards.	1	1	1
6.	Which PPE is essential for BSL 4 labs?	1	2	1
7.	In class II biosafety cabinet, which direction does the air flow	1	2	2
8	The Cartagena Protocol was adopted in which year?	1	3	2
9.	Mention the 3 types of mechanism which takes place in HEPA filters	2	1	2

Sl. No	Questions (Test)	M	BT-L	CO
1.	Comment on various types of Biohazards, and their impact on human health.	10	2	1
2.	Explain Biosafety level II class B2 with a neat diagram	10	2	1
3.	Discuss the importance of biosafety guidelines in India and how they contribute to public health and safety.	10	3	2
4.	Farmers in the Northern part of India are protesting against the genetically modified Mustard seeds. In this context discuss in detail the pros and cons of the GM Mustard seeds.	10	3	2
5.	How do the Biosafety guidelines of the Government of India align with international biosafety standards? Discuss any significant differences or similarities.	10	2	2

BT-L-Blooms Taxonomy, CO-Course Outcomes, M-Marks

	Particulars		CO1	CO2	CO3	CO4	L1	L2	L3	L4	L5	L6
Marks Distribution	Test	Max Marks	24	36	---	---	5	33	22	---	---	---

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Scheme and solution

Sl. No	Questions (Quiz)	M
1.	What is the role of the Institutional Biosafety Committee (IBC) in India? Ans To oversee and ensure the safe use of genetically modified organisms (GMOs) and recombinant DNA research at the institutional level.	1
2.	The Recombinant DNA Advisory Committee (RCGM) is a part of which Department of Govt of India? Ans Department of Biotechnology (DBT), Ministry of Science and Technology.	1
3.	The committee of an Institutional Biosafety Committee (IBC) comprise of _____ and _____ **Ans:** Institutional members and a nominee from the Department of Biotechnology (DBT).	1
4.	Biosafety levels indicate _____ The degree of containment required based on the risk associated with the handling of infectious agents.	1
5.	_____ is the primary mode of transmission of many viral biohazards. **Ans:** Aerosol transmission. Or air droplets	1
6.	Which PPE is essential for BSL 4 labs? Fully encapsulating, positive-pressure suits.	1
7.	In class II biosafety cabinet, which direction does the air flow Vertically downward and then recirculated through HEPA filters.	1
8	The Cartagena Protocol was adopted in which year? **Ans:** 2000	1
9.	Mention the 3 types of mechanism which takes place in HEPA filters 1. Interception 2. Impaction 3. Diffusion	2

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	(pathogenic strains) • **Impact:** Can cause a range of infections, from mild food poisoning to life-threatening diseases like tuberculosis and sepsis. Drug-resistant strains pose a serious global health challenge. **2. Viral Hazards:** • **Examples:** HIV, Influenza virus, SARS-CoV-2, Hepatitis B and C • **Impact:** Viruses can cause acute or chronic infections, immunosuppression (as in HIV), respiratory failure (as in COVID-19), and even cancer (as in Hepatitis B leading to liver cancer). **3. Fungal Hazards:** • **Examples:** *Aspergillus fumigatus*, *Candida albicans*, *Histoplasma capsulatum* • **Impact:** Mostly affect immunocompromised individuals, leading to respiratory infections, systemic candidiasis, and severe allergic responses. **4. Parasitic Hazards:** • **Examples:** *Plasmodium falciparum* (malaria), *Entamoeba histolytica*, *Toxoplasma gondii* • **Impact:** Parasitic infections can lead to organ damage, malnutrition, and neurological disorders; some, like malaria, are major causes of morbidity and mortality in tropical regions. **5. Prions:** • **Examples:** Creutzfeldt-Jakob disease (CJD), Bovine Spongiform Encephalopathy (BSE) • **Impact:** Prions are misfolded proteins that can cause fatal neurodegenerative disorders. They are highly resistant to standard decontamination methods. **Overall Impact on Human Health:** • Acute infections • Chronic diseases • Increased healthcare burden • Death in severe cases	
2.	Explain Biosafety level II class B2 with a neat diagram	10

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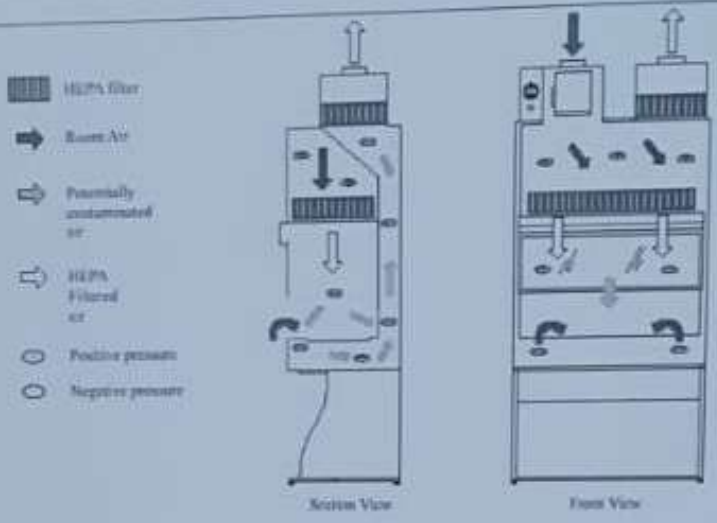

Biosafety Level II (BSL-2) is a containment level used for work involving moderate-risk biological agents that can cause human disease but are not typically transmissible via the airborne route.
A **Class II, Type B2 Biosafety Cabinet (BSC)** is a specialized containment device used in BSL-2 and higher labs to handle infectious materials safely.

Key Features of Class II, Type B2 Biosafety Cabinet:

1. **Total Exhaust (100% Exhaust):**
   - Unlike Type A2 cabinets that recirculate a portion of air, **Class B2 cabinets exhaust all of the air to the outside** via a hard-ducted ventilation system.
   - This prevents any internal recirculation, making it suitable for working with volatile chemicals and radionuclides in addition to biological agents.
2. **Airflow Pattern:**
   - **Vertical laminar airflow** (from top to bottom) protects the sample.
   - **Inward airflow at the front opening** protects the user.
   - **HEPA-filtered exhaust** protects the environment.
3. **Ducted to External Ventilation:**
   - Must be connected to the building's exhaust system to ensure contaminants are fully removed.

- Handling moderate-risk biological agents (e.g., *Hepatitis B virus*, *Salmonella spp.*)
- Procedures involving **low levels of volatile toxic chemicals** or radionuclides along with infectious materials
- Clinical, diagnostic, research, and pharmaceutical settings

User Safety Measures:

- Use of **PPE**: lab coat, gloves, face protection
- Regular **cabinet certification**

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	• Strict adherence to **standard operating procedures (SOPs)** Class B2 cabinets offer **superior safety** where chemical hazards are present in addition to biological risks. However, they are **more expensive and complex** to install and maintain due to the need for external exhaust systems.	
3.	Discuss the importance of biosafety guidelines in India and how they contribute to public health and safety. Biosafety guidelines are regulatory frameworks designed to ensure the safe handling, transport, and use of biological agents — especially genetically modified organisms (GMOs), pathogens, and lab-derived biohazards. In India, these are enforced under the **Rules, 1989** of the **Environment (Protection) Act, 1986**, and guided by organizations like the **Department of Biotechnology (DBT)** and **Ministry of Environment, Forest and Climate Change (MoEFCC)**. **a. Preventing Laboratory Accidents and Infections** India has a growing number of biotechnology labs and clinical research facilities. Without strict biosafety standards, there is a real risk of laboratory-acquired infections, cross-contamination, or even unintended release of pathogens. Biosafety guidelines enforce use of **Biosafety Cabinets (BSCs), Personal Protective Equipment (PPE), containment levels (BSL-1 to BSL-4)**, and proper waste disposal practices. **b. Safe Use of GMOs** With the rise of agricultural and pharmaceutical biotechnology, biosafety ensures that genetically modified crops or organisms don't pose threats to biodiversity, human health, or the environment. **Institutional Biosafety Committees (IBCs)** and **Review Committee on Genetic Manipulation (RCGM)** regulate and monitor all recombinant DNA research and field trials. **c. Response to Emerging Diseases** COVID-19 was a wake-up call — biosafety isn't optional. India's guidelines ensure that labs dealing with high-risk pathogens (like SARS-CoV-2, Nipah virus, etc.) operate under strict containment (BSL-3 or BSL-4) to **prevent outbreaks and protect lab personnel and the wider community**. **d. International Compliance** India is a signatory to the **Cartagena Protocol on Biosafety**, which means it is obligated to ensure safe handling of living modified organisms (LMOs) across borders. Aligning with global biosafety norms builds **international credibility** and facilitates safe trade and scientific collaboration. India's biosafety guidelines are **not just about compliance** — they are **a frontline defense** protecting **scientists, communities, ecosystems, and the nation's health infrastructure**. As research expands into more complex areas like synthetic biology and pandemic preparedness, **strict enforcement and constant updating of biosafety norms are non-negotiable**.	10
4.	Farmers in the Northern part of India are protesting against the genetically modified Mustard seeds. In this context discuss in detail the pros and cons of the	10

GM Mustard seeds.

Pros of GM Mustard Seeds

1. Higher Yield Potential
- GM mustard is engineered for **30–35% higher productivity** compared to traditional varieties.
- Can reduce India's dependency on **imported edible oils** (especially palm oil).

2. Facilitates Hybridization
- Uses a genetic mechanism (barnase-barstar system) to create **viable hybrids**, which is difficult through conventional breeding in mustard.
- Hybrid vigor can enhance **stress tolerance and oil content**.

3. Efficient Land Use
- Higher yield per acre means **less land needed** to produce the same quantity of mustard, potentially freeing up land for other crops.

4. Reduced Edible Oil Import Bill
- India imports over **60% of its edible oil**, costing billions.
- Boosting mustard production could improve **self-sufficiency** in oilseeds.

Cons

1. Environmental Impact
- Risk of **genetic contamination** of indigenous mustard varieties and wild relatives.
- Concerns about impact on **pollinators (especially bees)**, which play a vital role in mustard pollination and biodiversity.

2. Corporate Control & Seed Sovereignty
- Though DMH-11 is a public-sector innovation, the broader fear is **eventual monopolization by seed companies**.
- Farmers may become dependent on **commercial seeds**, leading to rising costs and loss of traditional seed-saving practices.

3. Health Concerns
- Though no conclusive evidence links GM foods to health risks, long-term studies in Indian conditions are **limited or lacking**.
- Skepticism persists among consumers and activists.

4. Lack of Transparent Public Consultation
- Protests stem from **poor communication** and lack of **farmer participation** in decision-making.
- The clearance by GEAC (Genetic Engineering Appraisal Committee) was viewed as **hurried and opaque**.

5. Agro-Ecological Unsuitability
- Northern Indian farmers argue that **indigenous mustard** is already well-suited to their climate and soil.
- The input-intensive GM mustard may not align with **local agronomic practices**, especially in rainfed areas.

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5.	How do the Biosafety guidelines of the Government of India align with international biosafety standards? Discuss any significant differences or similarities.	10

India's biosafety regulations are largely in sync with international norms, especially due to its **obligations under global treaties** like the **Cartagena Protocol on Biosafety**. The backbone of India's framework is the **"Rules, 1989"** under the **Environment (Protection) Act, 1986**, supplemented by guidelines from the **Department of Biotechnology (DBT)**.

Risk Assessment Protocols

India follows **scientific, step-wise risk assessment**, just like in the **OECD**, **WHO**, and **FAO** guidelines.
Evaluates **environmental, health, and socio-economic impacts** of GMOs.
Biosafety Levels (BSL 1–4)
India's laboratory biosafety classification aligns with **WHO's biosafety level standards**, covering containment, PPE use, and equipment like **Class II biosafety cabinets**.
Institutional Biosafety Oversight
India's **Institutional Biosafety Committees (IBCs)** and **Review Committee on Genetic Manipulation (RCGM)** function similarly to **Institutional Biosafety Committees (IBCs)** in the US or **Institutional Biosafety Officers (IBOs)** in the EU.
Adherence to Cartagena Protocol
India is a **signatory** and enforces the protocol's provisions on:

Safe transfer, handling, and use of LMOs
Informed consent prior to import/export
Public awareness and access to information

Differences

1. Transparency & Public Participation

- **Global best practices** (e.g., EU) involve **robust public consultations**, published risk assessments, and third-party reviews.
- In India, processes (like the clearance of GM mustard) have often been **criticized for lack of transparency** and limited public dialogue.

2. Independent Regulatory Authority

- Many countries have **autonomous biosafety regulators** (e.g., EFSA in

	Europe). • India's regulatory structure is **multi-tiered and ministry-controlled** — sometimes leading to overlap, delays, or political interference. **3. Monitoring & Enforcement** • Post-approval **monitoring of GMOs** is a strong feature in developed countries. • India lacks **robust field-level monitoring**, especially after commercial release, due to poor manpower and coordination at the **State Biotechnology Coordination Committees (SBCCs)** and **District Level Committees (DLCs)**.	

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Academic year 2024-2025 (Even Sem)

SCHEME AND SOLUTION OF CIE 2

Date	May 6th 2025	Maximum Marks	60
Course Code	BT242TC	Duration	120 min
Sem	IV Semester	Closed Book Offline Test-2	
Bio Safety Standards and Ethics (Basket course)			

Instructions: Answer all questions from Part A and Part B, Write Part A in sequence first two pages of answer booklet.

Sl. No	PART A Questions (Quiz)	M
1.	HACCP is a joint management system developed by _____ and _____ U.S. National Aeronautics and Space Administration (NASA)	2
2	A man found a copper wire in pizza and human finger in ice cream. Mention the different types of the hazards. Physical and biological	2
3	Mention the 2 – hour and 4 – hour rule for food storage **Initial Cooling (2 hours):** After cooking, potentially hazardous foods (like meat, poultry, seafood, eggs, and dairy) should be cooled from 60°C (140°F) to 21°C (70°F) within two hours. This is done to slow down the growth of bacteria. **Continued Cooling (4 hours):** Within the next four hours, the food needs to be cooled from 21°C (70°F) to 5°C (41°F). This is crucial for preventing bacterial multiplication. **Refrigeration:** Refrigerated food is generally safe for up to four hours if the refrigerator door was kept shut and the power was not out for more than four hours,.	2
4	 Decode the above fssai license number of campa cola. the 14-digit FSSAI license number: **(First Digit):** Indicates whether the FBO has a license or registration. **(Digits 2-3):** Represents the state code where the FBO is registered. **(Digits 4-5):** Indicates the year the FBO received the license. **(Digits 6-8):** Represents the number of enrolled masters. **(Digits 9-14):** Contains the unique license number assigned to the FBO	2

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5	Expand the term GAP and GHP give its importance **Good Agricultural Practices (GAP**) in agriculture refers to a set of guidelines and standards that focus on ensuring the safety, quality, and sustainability of agricultural products from farm to consumer. These practices aim to optimize resource use, improve worker health and working conditions, and create new market opportunities, especially for farmers and exporters in developing countries. **GHP stands for Good Hygiene Practices**, a crucial set of guidelines and procedures designed to prevent food contamination. These practices are essential throughout the entire food chain, from production to processing, storage, distribution, and preparation. They aim to ensure food safety by mitigating risks associated with biological, chemical, or physical hazards.	2

Sl. No	PART B Questions (Test)	M
	In the wheat processing from farm to customer, the following steps are involved. (ANSWER Q1, Q2, Q3) a. Farmers spend time planting seeds, checking for disease and monitoring plant health until harvest. Combines harvest the wheat kernels, which are then loaded into a semi-truck. b. The harvested grain is sold at market price to a local grain elevator. The elevator can store the grain until the right market price, or it can sell it. c. Country elevators sell their grain to terminal elevators, which clean, separate and maintain the value of the grain. The grain is then sold to flour millers for domestic consumption, or it is loaded into ships bound for overseas markets. d. The flour mills grind the grain into different types of flour — whole wheat, all-purpose, bread flour, etc. The mills can also use the flour to make ready-to-eat products. Both the flour and wheat products are shipped to grocery stores and other food retailers. e. Bakers and chefs also use flour to make a wide variety of delicacies. Consumers can either buy these products, or buy flour produced by the flour mills to make their own creations at home. Finally, wheat products make their way to your table. These products are essential to many holidays and celebrations and go through a safe process to get to you. Whenever you purchase breads, buns, pizza, rotis think of a wheat farmer and all of those in between.	
1	Identify and elaborate on the type of hazard in each step of the wheat processing.	7

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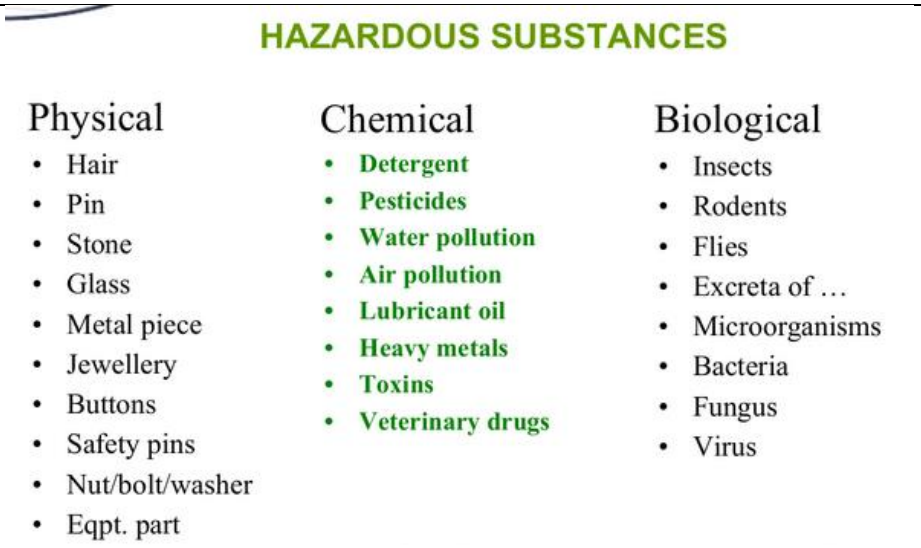
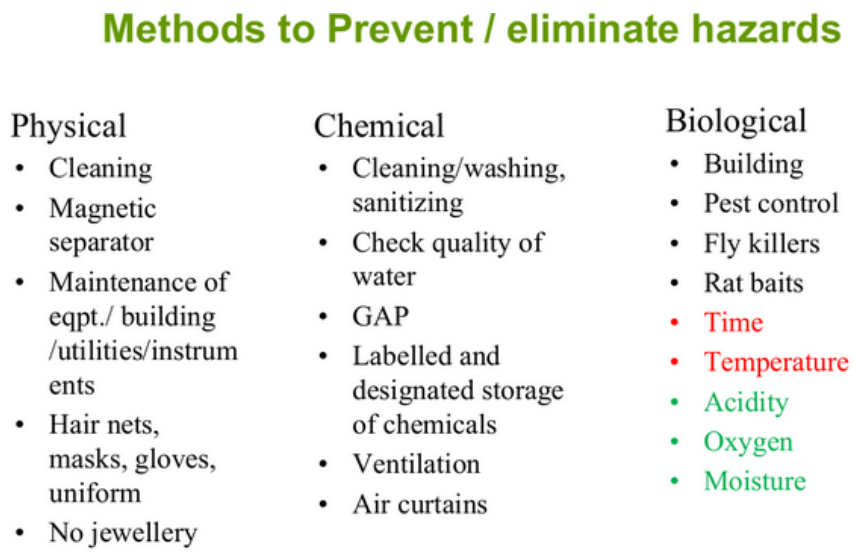
	 IDENTIFICATION 3 ELABORATION 4	
2	Mention and justify the elimination method for identified hazard during the wheat processing  METHOD IDENTIFICATION 2 ELABORATION 4	6
3	How we can implement the HACCP for the wheat processing.	7

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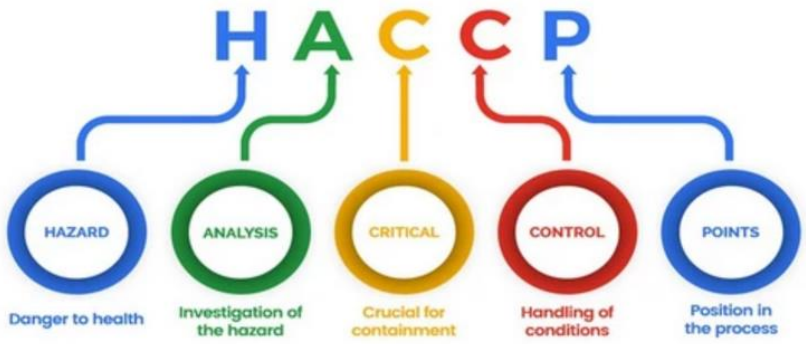

HACCP (Hazard Analysis Critical Control Point) is defined as a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. The goal of HACCP is to prevent and reduce the occurrence of food safety hazards.

It is based on the application of scientific principles to food processing and production. The University of Nebraska has been providing educational programs and assistance to food processing and food production professionals since 1993.

HACCP training is for meat and poultry processors, food processors, and food service operators.

The Seven Principles of HACCP

HACCP is based on seven principles, which are the most important steps in writing a HACCP plan. The first two steps provide the foundation for the HACCP plan. The remaining five steps are the application steps of the HACCP plan and provide the structure for conducting the workings of the HACCP plan in the processing plant.

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 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 (a_w), 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. 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 RELATED THEORY : 3M IMPLEMENT FOR WHEAT PROCESSING 4M	
4	Illustrate on various techniques that take place in a food testing laboratory Food testing involves a variety of techniques used to assess a food product's safety, quality, and nutritional value. These methods can be broadly categorized into microbiological, chemical, physical, and sensory testing. 1. Microbiological Testing: **Purpose:** To detect and identify microorganisms (bacteria, viruses, fungi) that can cause foodborne illnesses.	10

Methods:
Culture-based procedures: Involve growing microorganisms on a specific medium to identify and count colonies.
Molecular methods (PCR): Amplify DNA sequences of specific pathogens, making it highly sensitive for detection.
Immunoassays: Use antibodies to detect specific antigens in food samples, providing high specificity.

2. Chemical Testing:
Purpose:
To analyze the chemical composition of food, including contaminants, residues, and nutritional content.
Methods:
Gas chromatography (GC) and mass spectrometry (MS): Powerful techniques for separating and identifying volatile compounds and contaminants.
High-performance liquid chromatography (HPLC): Used for separating and analyzing non-volatile compounds.
Spectroscopy (IR, NMR): Techniques used for identifying and quantifying specific molecules.
Residue analysis: Detects pesticides, heavy metals, and other contaminants in food.

3. Physical Testing:
Purpose:
To evaluate the physical properties of food, such as texture, color, and appearance.
Methods:
- **Visual inspection:** Assessing color, texture, and overall appearance.
- **Texture analysis:** Measuring hardness, softness, and chewiness.
- **Density and viscosity measurements:** Determining the physical properties of food products.

4. Sensory Evaluation:
Purpose:
To assess food quality based on human sensory perception (taste, smell, sight, texture).
Methods:
Panel testing: Trained panelists assess food attributes based on their sensory perception.
Consumer testing: Gathering feedback from a wide range of consumers.

5. Other Important Techniques:
Allergen testing: Detecting the presence of common allergens like nuts, dairy, gluten, etc.,
Shelf-life testing: Determining how long a food product will remain safe and palatable under specific conditions.
Nutritional analysis: Determining the macronutrient and micronutrient content of food.
Food contact material testing: Ensuring that packaging materials do not contaminate the food.

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	GMO testing: Detecting the presence of genetically modified organisms in food. TESTING METHODS LISTING 4M, EXPLANATION 6MARKS	
5	Elaborate on food borne diseases and food allergens Foodborne diseases are the illnesses contracted from eating contaminated food or beverages. Illnesses include foodborne intoxications and infections, which are often incorrectly referred to as food poisoning 5 foodborne MICROBES causing illness Norovirus. Salmonella (non-typhoidal) Clostridium perfringens. Campylobacter. Staphylococcus aureus foodborne diseases can be classified into two main types: food infection and food poisoning. Food infections are classified as bacterial, viral, parasitic or fungal. Food poisoning is classified according to the type of toxin that causes it which may be natural, bacterial, fungal or chemical Bacterial: Salmonella: A common cause of food poisoning, often associated with undercooked poultry, eggs, and dairy products. Symptoms include diarrhea, fever, and abdominal cramps. E. coli: Certain strains of E. coli can cause severe illness, including bloody diarrhea, and are often linked to contaminated beef, produce, and unpasteurized milk. Listeria: Listeriosis can be particularly dangerous for pregnant women, the elderly, and those with weakened immune systems. It's often found in ready-to-eat foods like deli meats, soft cheeses, and hot dogs. Campylobacter: A common cause of food poisoning in developed countries, often linked to undercooked poultry, unpasteurized milk, and contaminated water. Clostridium botulinum (Botulism): A rare but serious illness caused by consuming the toxin produced by this bacteria. It can lead to paralysis. Bacillus cereus: Can cause two types of food poisoning, one characterized by vomiting (usually 30 minutes to 6 hours after eating) and the other by diarrhea (usually 6-15 hours after eating), often linked to cooked rice. Staphylococcus aureus: A common cause of food poisoning, often associated with contaminated foods like mayonnaise, cream-filled pastries, and ham.	10

	Food allergens are substances, typically proteins in food, that can trigger an allergic reaction in susceptible individuals. These reactions occur when the body's immune system mistakenly identifies the allergen as a threat and releases chemicals to combat it The Food and Drug Administration (FDA) identifies eight major food allergens: milk, eggs, fish, crustaceans, tree nuts, peanuts, wheat, and soybeans. Other common allergens include sesame and sesame products. How Food Allergies Occur: When a person with a food allergy consumes the allergen, their immune system overreacts, releasing chemicals like histamine, which cause symptoms like: **Mild symptoms:** Hives, itching, swelling of the mouth, lips, or tongue. **Severe symptoms:** Difficulty breathing, wheezing, dizziness, fainting, and in some cases, anaphylaxis, a life-threatening reaction. **Food intolerance is not the same as a food allergy:** While both can cause digestive upset, food intolerances do not involve the immune system. **Any food can cause a reaction:** However, the majority of food allergies are triggered by a limited number of foods. **Accurate labeling is crucial:** Food labels must clearly identify the presence of major allergens to help individuals with allergies make informed choices. **Cross-contamination is a concern:** Even small amounts of an allergen can trigger a reaction, so food preparation and storage should be carefully managed to avoid cross-contamination. The eight major food allergens, as defined by the Food and Drug Administration, are milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans. Additionally, sesame is recognized as a major food allergen **Cow's milk:** A common allergy, especially in infants and young children, affects about 2-6% of children. **Eggs:** A highly prevalent food allergy. **Fish:** Examples include cod, bass, and flounder. **Shellfish:** Including crab, lobster, and shrimp. **Tree nuts:** This includes almonds, walnuts, pecans, cashews, and hazelnuts. **Peanuts:** A very common and serious allergen, especially in children. **Wheat:** Contains gluten, a protein that can cause problems in people with celiac disease. **Soy:** Soybeans are a legume that can trigger allergic reactions. **Sesame:** Added to the list of major allergens in 2023, it's found in many foods, including tahini in hummus. **Other allergens:** While the "Big 8" are the most common, other foods like celery, mustard, and certain fruits or vegetables can also cause allergic reactions FOOD DISEASES: 5M, ALLERGENS : 5M	
6	**Justify GMP and GLP in food processing.** Good Manufacturing Practices (GMP) in food processing are a set of guidelines and procedures designed to ensure food products are consistently produced and controlled	10

according to quality standards, ultimately promoting food safety. GMPs cover various aspects of the food production process, including personnel hygiene, facilities, equipment, and production controls. By adhering to GMPs, food manufacturers can minimize risks like contamination, adulteration, and mislabeling, ensuring safe and high-quality food for consumers.

Key aspects of GMP in food processing:

Sanitation and Hygiene:

GMPs emphasize the importance of maintaining a clean and sanitary environment within the food processing facility, including proper cleaning and sanitization procedures.

- **Personnel:**

GMPs outline requirements for personnel training, hygiene, and responsibilities to ensure that food handlers are competent and follow proper procedures.

- **Facilities and Equipment:**

GMPs specify the standards for building and equipment design, maintenance, and calibration to prevent contamination and ensure accurate processing.

- **Production Controls:**

GMPs cover various production stages, including ingredient handling, processing, packaging, and storage, with the goal of minimizing risks and maintaining product quality.

- **Record Keeping:**

GMPs require manufacturers to maintain detailed records of production processes, including batch records, cleaning procedures, and equipment maintenance logs, to ensure traceability and accountability

Benefits of GMP in food processing:

Ensuring food safety:

GMPs help prevent foodborne illnesses and other health hazards by minimizing contamination and ensuring safe production practices.

- **Meeting regulatory requirements:**

GMPs are often mandated by regulatory agencies, and compliance with GMPs is crucial for obtaining and maintaining licenses and permits.

- **Enhancing brand reputation:**

Adherence to GMPs demonstrates a commitment to quality and food safety, which can enhance a company's reputation and build consumer trust.

- **Improving efficiency:**

GMPs can streamline production processes, reduce waste, and improve overall efficiency, leading to cost savings and increased productivity.

- **Protecting consumers:**

GMPs help safeguard consumers from purchasing unsafe or substandard food products, which can lead to health problems and legal consequences for manufacturers

DEPARTMENT OF
BIOTECHNOLOGY
Academic year 2024-2025 (Even Sem)

	In the food industry, **Good Laboratory Practice (GLP)** is a quality system that ensures the integrity and reliability of non-clinical studies used to assess the safety of food additives, chemicals, and other substances. It provides a framework for designing, conducting, and documenting these studies, ensuring they meet regulatory requirements and produce accurate data. GLP aims to ensure the quality and integrity of data generated during non-clinical safety studies, such as those evaluating the safety of food additives or the impact of pesticides on crops. GLP applies to various aspects of non-clinical studies, including the planning, execution, monitoring, documentation, and reporting of studies. **Key Components:** GLP principles cover several areas, including: **Test Facility Organization:** Ensuring the test facility is appropriately organized and staffed. **Quality Assurance:** Implementing a quality assurance program to monitor and ensure compliance with GLP principles. **Standard Operating Procedures (SOPs):** Developing and following SOPs for all study procedures. **Record Keeping:** Maintaining accurate and complete records of all study activities. **Reporting:** Preparing clear and accurate study reports that can be reviewed by regulatory agencies. **Importance in Food Industry:** GLP plays a crucial role in ensuring the safety and quality of food products by providing a reliable foundation for regulatory decisions related to food additives, pesticides, and other substances JUSTIFICATION OF GMP 5M, GLP 5M	

RV College of Engineering

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R V College of Engineering

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Mysuru Road Bengaluru - 560 059

IV Semester BE Regular / Supplementary Examinations June/July-2025
Course : Bio safety Standards and Ethics-BT242TC

Time : 3 Hours Hours

Maximum Marks : 100

Instructions to the students

1. Answer all questions from Part A. Part A questions should be answered in first three pages of the answer book only.
2. Answer FIVE full questions from Part B. In Part B question number 2 is compulsory. Answer any one full question from 3 and 4, 5 and 6, 7 and 8, and 9 and 10.

Part A

Question No	Question	M	CO	BT
1.1	Mention the purpose of autoclaving biohazard waste?	02	1	1
1.2	Mention the type of airflow pattern in a Class I BSC?	02	2	1
1.3	List the roles of the legal and regulatory framework for biosafety levels in India.	02	2	1
1.4	Which ministry governs GEAC in India?	01	2	1
1.5	Why IBSCs responsible for laboratory-level approvals?	01	2	1
1.6	Which food safety system focuses on identifying hazards?	01	3	1
1.7	Mention two sources through which food can become contaminated with microorganisms.	02	3	1
1.8	Mention any two principles of a Food Safety Management System (FSMS).	02	3	3
1.9	Define GAP and how it helps in food production?	02	3	2
1.10	What are the different types of packaging materials?	02	3	2
1.11	Who sets the safety limits for drug residues in food?	02	2	1
1.12	what is the limits of sodium benzoate in soft drinks?	01	4	1

Part B

Question No	Question	M	CO	BT
2a	List and explain any four biosafety principles followed at all biosafety levels.	08	1	2
2b	Explain the construction, classification, working, and applications of Biosafety Cabinets in biotechnology and biomedical research.	08	2	3
3a	Illustrate the composition and operational scope of the Institutional Biosafety Committe (IBC)	08	2	2
3b	Illustrate on Cartagena protocol and list out the key aspects of the protocol	08	2	3
	OR			
4a	Discuss the composition and function of the GEAC	04	2	1
4b	Differntiate between first, second and third generation GM crops	12	2	4
5a	Analyze the implementation challenges of food safety standards in the Indian unorganized food sector. Suggest practical solutions.	08	3	4
5b	Discuss and elaborate on techniques used in the food testing laboratories.	08	3	5
	OR			
6a	Elaborate on methods of food analysis add a note on the instruments used for analysis	10	3	4
6b	Discuss the causes, symptoms, and prevention of foodborne illnesses.	06	3	2
7a	What is thermal food processing? Explain its advantages and disadvantages.	06	3	3
7b	Discuss the importance of food preservation, processing, and packaging in the food industry.	06	3	3
7c	Compare and contrast refrigeration and freezing as methods of food preservation.	04	3	2
	OR			
8a	"*Understanding food processing principles and operations is key to designing efficient systems that meet safety, nutritional, and economic demands of the modern food industry*". justify the statement	16	3	5

9a	Elaborate on the use of antibiotics in animal and its impact on human health.	08	4	3
9b	What constitutes plagiarism and which all activities were considered as plagiarism?	08	4	3
	OR			
10a	Give an account of merits and demerits of food safety	08	4	3
10b	Elaborate on the 4 main ethical principles of research?	08	4	2