CARTAGENA PROTOCOL

The **Cartagena Protocol on Biosafety** is an international treaty that aims to ensure the safe handling, transport, and use of **living modified organisms (LMOs)** resulting from modern biotechnology.

It was adopted on **January 29, 2000**, and entered into force on **September 11, 2003**. The protocol is part of the **Convention on Biological Diversity (CBD)** and focuses on managing the movement of LMOs between countries to protect biological diversity and human health.

Objectives:

- **Vision**: Protect biological diversity from adverse effects of LMOs.
- **Mission**: Strengthen actions at global, regional, and national levels to ensure safe handling of LMOs.
- Protect biological diversity from potential risks posed by LMOs.
- Facilitate informed decision-making regarding the import of LMOs.
- Promote biosafety through established rules and procedures.
- The protocol includes an **AIA procedure (Advance Informed Agreement)**, which ensures that countries receive adequate information before agreeing to import LMOs.
- The AIA involves:
    - **Notification** by the exporter about the LMO.
    - **Acknowledgment** of the notification receipt by the importer.
    - A **decision procedure** (approve, prohibit, or request more information).
    - **Review of decisions** to ensure compliance.
- The **BCH** (**Biosafety Clearing-House)** serves as an information-sharing mechanism, facilitating the exchange of scientific, technical, and legal information on LMOs between countries. It helps countries implement the protocol and stay informed about LMOs

Focal Areas of Cartagena Protocol

1. Focal Area 1: Biosafety Systems

- Establish and further develop effective biosafety systems.
    a. Develop **National Biosafety Frameworks**.
    b. Ensure **coordination and support** among stakeholders.
    c. Implement **risk assessment and risk management** procedures.
    d. Establish protocols for **handling, transport, packaging, and identification** of LMOs.
    e. Consider **socio-economic factors** in biosafety decisions.

2. Focal Area 2: Capacity Building

- Enhance the ability of countries to implement biosafety measures.

a. Implement **National Biosafety Frameworks**.
b. Improve **risk assessment and risk management** capabilities.
c. Promote public awareness and **education** on biosafety.
d. Encourage **information sharing** and cooperation.
e. Provide **biosafety education and training** to relevant stakeholders.

3. Focal Area 3: Compliance and Review

- Ensure adherence to the Protocol's provisions.
    a. Monitor and assess **compliance** with the Protocol.
    b. Conduct periodic **reviews** to evaluate effectiveness and areas for improvement.

4. Focal Area 4: Information Sharing

- Facilitate the exchange of information related to biosafety.
    a. Enhance the effectiveness of the **Biosafety Clearing-House (BCH)**.
    b. Use the BCH for **online discussions and conferences**.
    c. Promote information sharing through channels outside the BCH.

5. Focal Area 5: Outreach and Cooperation

- Strengthen international collaboration on biosafety.
    a. Encourage **ratification** of the Protocol by more countries.
    b. Foster **cooperation** between nations on biosafety issues.
    c. Implement **communication and outreach** strategies to raise awareness about the Protocol and its objectives..

India and the Cartagena Protocol

- India ratified the Cartagena Protocol on **January 23, 2003**, and has a comprehensive regulatory framework for biosafety.
- The **Ministry of Environment, Forest and Climate Change (MoEF&CC)** serves as the **Competent National Authority** (CNA) for implementing the protocol in India.
- India uses terms like **Genetically Engineered Organism** or **Genetically Modified Organism** to refer to LMOs and has established guidelines to regulate them.

GMOs

Genetically Modified Organisms (GMOs) are living organisms whose genetic material has been altered using biotechnology. This modification is done to achieve specific traits, such as resistance to pests, improved nutritional content, or increased yield.

Types of GMOs: First Generation vs. Second Generation

1. First Generation GMOs

- **Definition**: First-generation genetically modified organisms primarily focus on enhancing agricultural traits. These organisms are engineered to improve yield, reduce losses due to pests, or enhance tolerance to herbicides.
- **Examples**:
    - Bt corn: Modified to express a bacterial toxin that is harmful to certain pests.
    - Herbicide-resistant crops: Engineered to survive applications of specific herbicides, allowing farmers to control weeds without harming the crops.
- **Focus**: Increased yield, pest and herbicide resistance, and reduced agricultural inputs.

2. Second Generation GMOs

- **Definition**: Second-generation GMOs focus on improving nutritional quality and functional traits rather than just agronomic characteristics. They aim to address health and dietary deficiencies in the human population.
- **Examples**:
    - Golden Rice: Genetically modified to produce beta-carotene, a precursor to Vitamin A.
    - Biofortified crops: Modified to contain higher levels of essential nutrients like iron or zinc.
- **Focus**: Improving health outcomes, addressing malnutrition, and contributing to sustainable agriculture.

Key Differences Between First and Second Generation GMOs

Aspect	First Generation GMOs	Second Generation GMOs
Main Focus	Agronomic traits (pest resistance, herbicide tolerance)	Nutritional enhancement and functional traits
Technological Approach	Traditional genetic engineering techniques	Advanced techniques, including gene editing
Examples	Bt Cotton, Roundup Ready Soybeans	Golden Rice, Iron-fortified Beans
Impact	Primarily agricultural yield and pest management	Human health and nutrition

1. Agriculture

- **Bt Cotton**: Resistant to certain insect pests due to the incorporation of Bt toxin.
- **Herbicide-Resistant Soybeans**: Tolerant to specific herbicides, allowing for easier weed management.
- **Drought-Resistant Corn**: Engineered to withstand periods of low water availability.

- **Virus-Resistant Papaya**: Modified to resist the Papaya Ringspot Virus, saving the industry in Hawaii.
- **Golden Rice**: Biofortified with Vitamin A precursors to combat deficiencies in developing countries.

2. Food Production

- **Golden Rice**: Enhanced with beta-carotene for better nutrition.
- **High-Oleic Soybean Oil**: Modified for higher monounsaturated fats, making it healthier.
- **Non-Browning Apples (Arctic Apples)**: Engineered to resist browning when cut or bruised.
- **Sugar Beets**: Modified for herbicide resistance, simplifying weed control.
- **Flavr Savr Tomato**: Engineered to have a longer shelf life by delaying ripening.

3. Environmental Protection

- **Drought-Resistant Corn**: Helps maintain yields under drought conditions.
- **Salt-Tolerant Rice**: Can grow in saline soils, improving agricultural viability.
- **Bioremediation Crops**: Engineered to absorb and detoxify pollutants from the soil.
- **Pest-Resistant Sugarcane**: Modified to reduce reliance on chemical insecticides.
- **Fast-Growing Poplars**: Developed for quicker timber and biofuel production.

4. Pharmaceuticals and Biotechnology

- **Insulin-Producing Bacteria**: *E. coli* engineered to produce human insulin for diabetes treatment.
- **Plant-Based Vaccines**: Tobacco plants modified to produce antigens for vaccines.
- **Transgenic Goats**: Engineered to produce therapeutic proteins in their milk.
- **Human Growth Hormone in Corn**: Modified corn to produce growth hormone for therapeutic uses.
- **Hepatitis B Vaccine**: Produced using genetically modified yeast.

5. Forestry

- **Disease-Resistant American Chestnut Trees**: Modified to resist chestnut blight, promoting forest restoration.
- **Fast-Growing Eucalyptus Trees**: Engineered for rapid growth for timber and pulp production.
- **Genetically Modified Poplars**: Designed for quicker biomass production for biofuels.
- **Balsam Fir Trees**: Modified to resist pests and diseases, enhancing Christmas tree production.
- **Genetically Modified Pine Trees**: Enhanced growth rates and disease resistance for better timber yields.

RCGM AND GEAC

RCGM (Review Committee on Genetic Manipulation) and GEAC (Genetic Engineering Appraisal Committee) are regulatory bodies in India that oversee the research, development, and commercialization of genetically modified organisms (GMOs).

1. RCGM (Review Committee on Genetic Manipulation)

The RCGM is a regulatory body in India that oversees research and development in genetic engineering and biotechnology. It operates under the Department of Biotechnology.

Functions:

1. **Approval of Projects:** Evaluates and approves research proposals involving genetically modified organisms (GMOs) to ensure they are safe and comply with regulations.
2. **Risk Assessment:** Assesses the potential environmental and health risks associated with GMOs before research can proceed.
3. **Guidelines Development:** Develops guidelines for conducting research involving GMOs, ensuring ethical and safety standards.
4. **Monitoring:** Monitors ongoing research projects to ensure compliance with approved guidelines.
5. **Public Awareness:** Facilitates information sharing to educate the public about the benefits and risks of GMOs.

2. GEAC (Genetic Engineering Appraisal Committee)

The GEAC is the central regulatory authority in India responsible for approving the commercial release of GMOs and products derived from them.

Functions:

1. **Commercial Approval:** Reviews applications for the commercial use of GMOs in agriculture and other fields.
2. **Safety Assessments:** Conducts safety evaluations to determine the impact of GMOs on human health and the environment.
3. **Policy Implementation:** Implements government policies related to genetic engineering and biotechnology.
4. **Coordination:** Coordinates with other regulatory bodies and organizations to ensure comprehensive oversight of GMOs.
5. **Public Consultation:** Engages with stakeholders, including the public, to address concerns and gather input on GMO usage.

In summary, RCGM focuses on research approvals and safety checks, while GEAC handles the approval for using GMOs in the environment and monitors their safety.

Institutional Biosafety Committee (IBSC)

The Institutional Biosafety Committee (IBSC) is a vital regulatory body established in India It is a key group that ensures safety in research involving genetically modified organisms (GMOs) and biohazardous materials. It helps protect human health and the environment while promoting responsible scientific work.

Objectives:

1. **Safety Assurance:**
    - Ensure that research with genetically modified organisms (GMOs) is done safely to protect people and the environment.
2. **Regulatory Compliance:**
    - Make sure that all research follows national and international biosafety rules and guidelines.
3. **Public Trust:**
    - Build confidence in biotechnological research by being transparent and ethical.

Functions:

1. **Proposal Review:**
    - Check research proposals involving GMOs for scientific soundness and safety.
    - Assess potential risks and benefits of the proposed research.
2. **Monitoring and Oversight:**
    - Regularly check ongoing research projects to ensure they follow approved safety protocols.
    - Inspect laboratories and facilities that work with GMOs.
3. **Training and Capacity Building:**
    - Organize training sessions to teach researchers about safe practices when handling GMOs.
    - Provide resources for proper containment and management of GMOs.
4. **Incident Reporting:**
    - Set up procedures for reporting and responding to accidents or safety breaches.
    - Ensure timely communication with authorities in case of incidents.
5. **Public Awareness:**
    - Engage with the public and stakeholders to explain biosafety issues.
    - Address any concerns related to GMOs and biotechnology.

Institutional Biosafety Norms:

1. **Regulatory Framework:**
    - The IBSC follows the **Biosafety Rules, 1989** and guidelines from the **Genetic Engineering Approval Committee (GEAC)**.
    - It aligns with international agreements like the **Cartagena Protocol on Biosafety**.
2. **Biosafety Levels:**
    - Research labs are classified into biosafety levels (BSL 1 to 4) based on the risk of the organisms they use.
    - Each level has specific safety measures and procedures.
3. **Risk Assessment:**
    - Conduct thorough evaluations to identify possible hazards related to GMOs.
    - Assess potential exposure pathways and implement safety measures accordingly.
4. **Good Laboratory Practices (GLP):**
    - Institutions must follow good practices to ensure quality in GMO research.
    - This includes keeping accurate records and following standardized procedures.
5. **Containment Measures:**
    - Use physical containment methods (like specialized lab designs and safety equipment) to prevent accidental release of GMOs.
    - Have procedures in place for safely disposing of waste generated during research.

The IBSC plays a vital role in ensuring that research involving GMOs is safe and compliant with regulations. By focusing on safety, public trust, and responsible practices, the IBSC supports the advancement of biotechnology while protecting health and the environment.
