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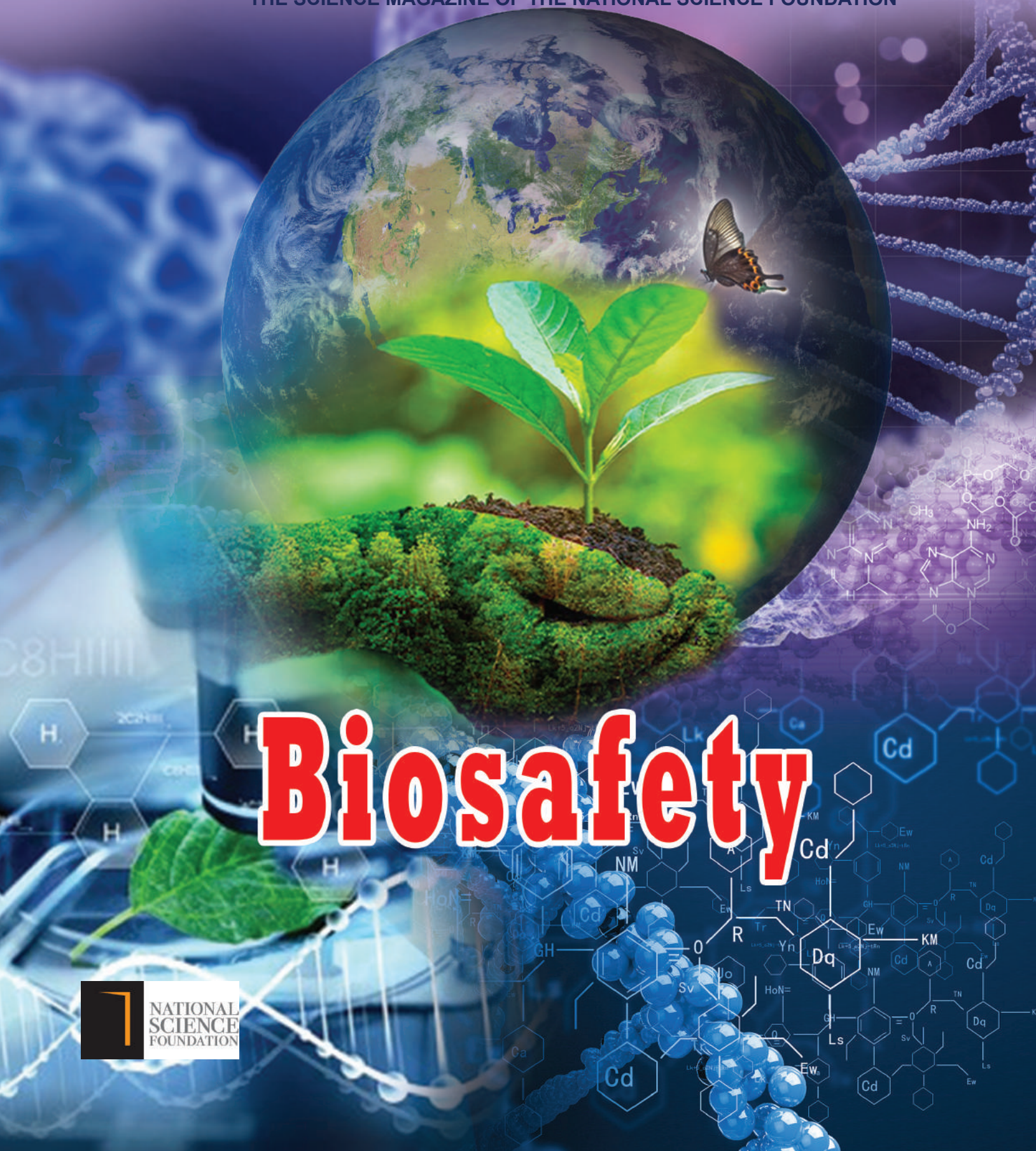

Biosafety

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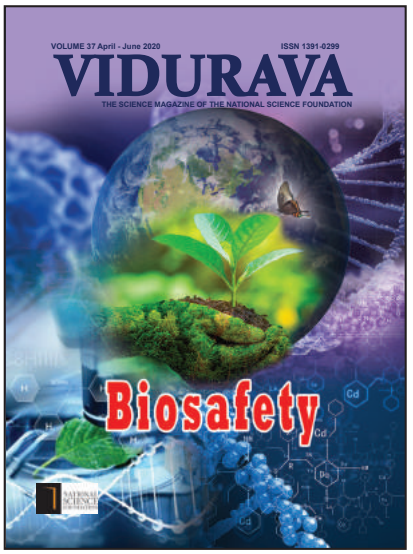

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Editorial

Biosafety and Biosecurity in the Context of Modern Biotechnology

The current issue of Vidurava concentrates on vital regulatory aspects of the safe manipulation, handling, transfer and utilization or application of the products of modern biotechnology. These include genetically modified organisms, food, feeds and processed products.

Historically, the discovery of Deoxyribo Nucleic Acid (DNA) and genes about 70 years ago, and the possibilities of implanting modified genetic material in living organisms using recombinant DNA technology, opened a new vista of scientific enterprise in biology. Nevertheless serious concerns in the risks of introducing genetically modified organisms to the natural environment without proper risk assessment in respect of their impact on conservation of biological diversity led to the introduction of various regulatory measures of which the best known was the Cartegena Protocol on Biosafety, which had since been formally adopted by Sri Lanka.

At this point it may also be relevant to recall that in the United States, the terror attack on the World Trade Centre Towers on 11th September 2001, followed subsequently within three weeks of postal mail deliveries of the vicious Anthrax spores, evidently created global concern of the hitherto unknown possibilities of what may be considered as the initial thrust towards "Biological Warfare".

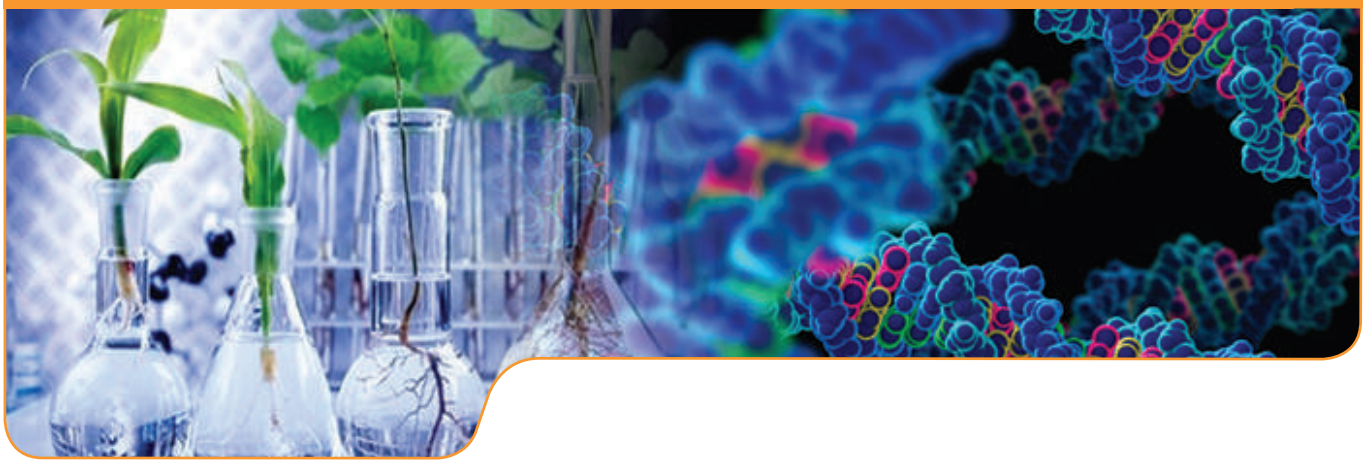
According to an official communication issued in 2007 on the concerns of Biosafety in microbiological and biomedical laboratories in the US, it had been claimed that the Anthrax attack of October 2001 had reopened a new chapter, and changed forever, the way scientific studies in biological and clinical laboratories should be conducted. Since then, Biosafety and Biosecurity, which are inexorably intertwined, had dominated the policy discourse of many countries. In 2006, the "WHO – Biorisk Management Guidelines on Laboratory Biosecurity", had defined Biosafety as comprising the "containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins or their accidental release". Biosecurity on the other hand had been defined as "the protection, control and accountability for valuable biological materials (including information) in laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release."

These two terms are claimed to be related, but often used interchangeably, and hence said to differ significantly, by what has been stated as "The crucial criterion of Interact".

M. Asoka T. De Silva

The proposed Biosafety Act of Sri Lanka ; Environmental Risk Assessment ensures the safe use of GMOs

Prof. Athula Perera



Biosafety, in this context, refers to Genetically Modified Organisms, Food, Feed and Processed products (GMO / FFPs). The GMOs (also known as Living Modified Organisms, Transgenic Organisms) are produced by using the modern biotechnological tool, recombinant DNA technology (rDNA technology % genetic engineering). In this procedure, genes can be isolated, cloned and transferred to the DNA of other unrelated organisms, i.e. genes can be transferred across species and even across Kingdoms. Hence, a GMO will carry a new gene that produces a new protein for a new character that the target organisms did not possess in its natural state.

Characters, Genes, Genomes

Every living being is described by using characters. How do characters appear? Characters appear due to the expression of genes. If we consider a single hair, it has several characters such as colour, thickness and shape. Colour appears due to the expression of a particular gene, which produces a protein that gives colour to the hair. Minor differences in the same gene gives different hair colours such as black, blond, brunet etc. Another gene produces the shape such as wavy hair. Minor differences in the same gene produces straight hair or curly hair. The gene for thickness acts in the same way. Hence, in order to produce all the characters of a human being, how many genes would be necessary? Up to date, around 40,000 genes have been identified.

What are genes and where are they?

A gene is a part of the DNA Deoxyribo Nucleic Acid molecule that resides in the nucleus of every

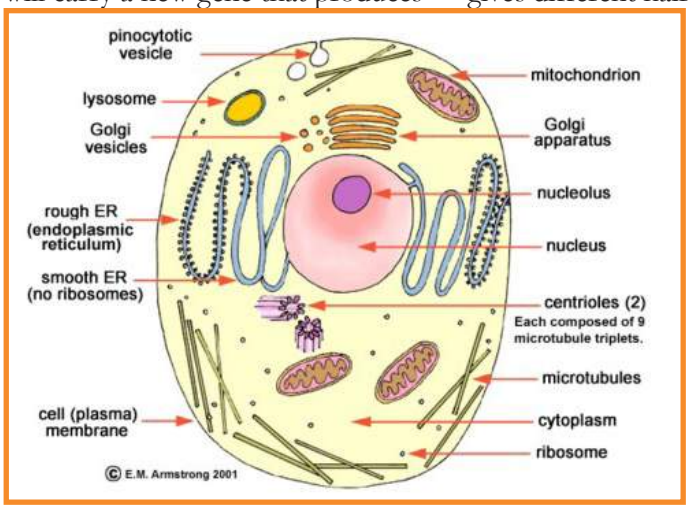


Fig. 1 : The components of a cell. Every cell has the nuclear material (DNA)

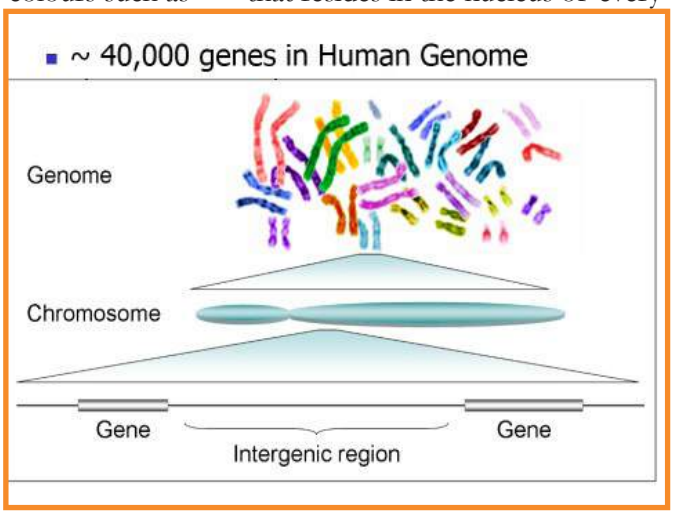


Fig. 2 : The 23 pairs of chromosomes = 46 chromosomes in a human cell
Genome = Total amount of DNA in the 23 chromosomes

cell (Fig.1). DNA is known as the nuclear material. It is a chemical, an acid and hence each DNA molecule is wrapped around a protein for stability. This structure is called a chromosome. A human cell has 46 chromosomes i.e. 46 DNA molecules (Fig.2). Of these, 23 come from the mother and the other 23 from the father. The total amount of DNA in a set of 23 chromosomes is known as the Genome.

The DNA molecule

The fundamental building block of DNA is the Nucleotide (Fig. 3).

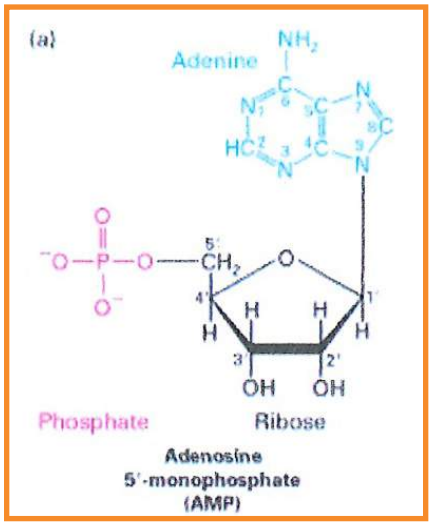


Fig. 3 : A nucleotide carrying a ribose sugar, phosphate and the base Adenine

A single nucleotide is made of a sugar entity (Ribose), a Phosphate and a base. Each nucleotide will carry one of the four types of bases Adenine (A) Guanine (G), Cytosine (C) or Thymine (T). The difference between nucleotides is the type of base that each will carry.

Nucleotides join together by strong bonds (phospho-diester bonds) to form a single strand. Two such strands join together by weak bonds (hydrogen bonds) to form a single DNA molecule (Fig. 4). As it is very long, it takes the form of a helical structure in order to fit into the nucleus (Fig.5).

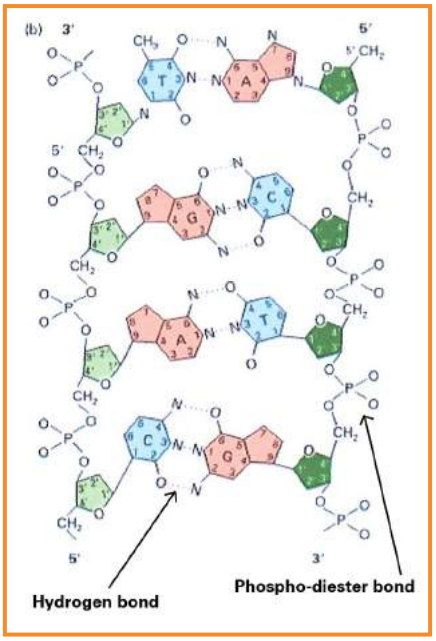


Fig. 4 : Joining of two strands forming the DNA molecule

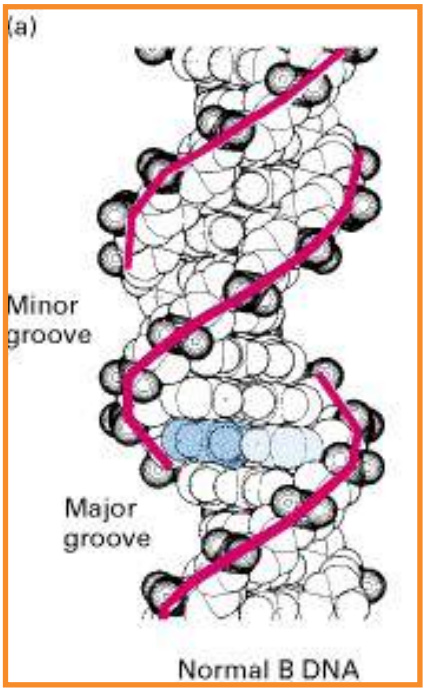


Fig. 5 : Twisting of the two strands forming the DNA double helix

A gene is made up of a sequence of these nucleotides joined together in a single strand and is denoted as the particular sequence of bases it is made up of, such as ……CCTGGCTGGAATC…. and so on, giving a message to produce a particular protein. Different genes have different sequences, thus producing different proteins for different characters. However, genes make up less than 10% of the genome.

Regulation of gene expression.

Are all the 40,000 genes in our cells functioning at the same time? No, of course not ! Some genes that were expressed when we were in our mothers' wombs are 'switched off' now and some that were 'switched off' then are 'switched on' now. A single cell in our heart will also carry the gene for hair colour, but it is 'switched off' from the beginning of life. Therefore,

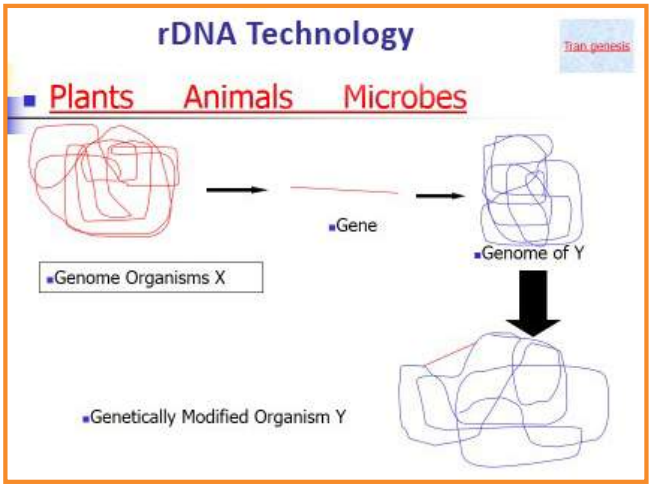


Fig. 6 : A simplification of the technology

we see that gene expression is regulated, and controlled. This is carried out by another fragment of DNA known as the Promoter. Hence, for a gene to be expressed, a promoter sequence is also necessary.

Recombinant DNA technology

It is now possible to identify and isolate any gene of interest from a known genome, clone it in a vector so as to multiply it, and then transfer it to a genome of another organism (Fig.6). The most commonly used techniques for gene transfer are the *Agrobacterium*-mediated gene transfer method and the use of the Gene Gun. Organisms produced from such a technology are known as Genetically Modified Organisms (GMOs). Any food or animal feed obtained from them are known as Genetically Modified Food and Genetically Modified Feed respectively, while processed products may also carry GM ingredients in them. All of these are designated as GMO/FFPs.

Products of GM technology

This includes plants, animals, insects and microbes.

Examples of GM plants

Some examples of GM plants grown extensively include Biotech Corn, Bt Cotton – Corn and Cotton plants carrying a bacterial gene conferring resistance to a particular Lepidopteran insect pest; Herbicide tolerant Soyabean – plant carrying a bacterial gene conferring resistance to a particular herbicide.

Some other GM plants include Flavr-Savr tomatoes, Virus resistant Papaya, Bt Brinjal.

Global use of GMOs

The global use of GMOs is shown in Figure 7.

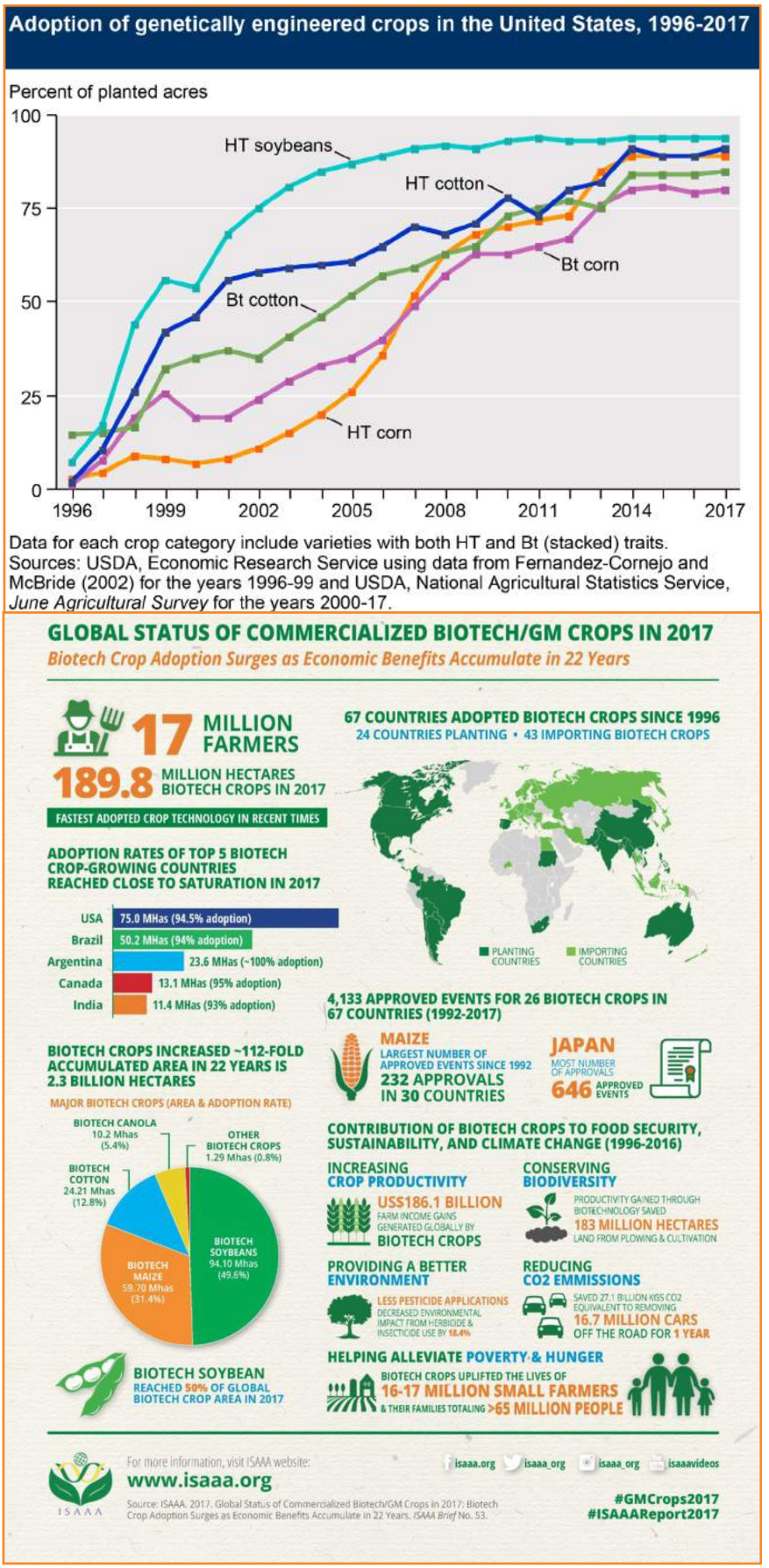


Fig. 7 : Global use of GMOs

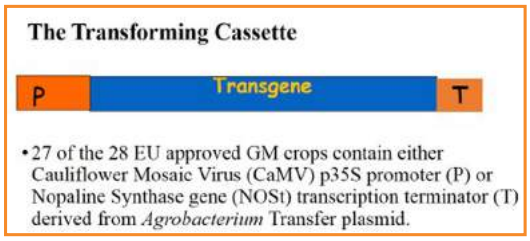


Fig. 8 : An example of a basic DNA cassette used for transformation

The Transforming Cassette

A DNA cassette is a DNA construct that carries the DNA parts that would be 'cut' and transferred to the recipient genome (Fig.8 & Fig.9).

Fundamentals of molecular biology reveal that a gene by itself cannot function or express itself to produce a protein. It is regulated by another fragment of DNA known as the Promoter that has the ability to 'switch' a gene ON or OFF. Hence, when transferring a gene to another genome, a Promoter sequence too must be included. Most GM plants contain the strong promoter (CaMV)p35S obtained from a microbe, in order to 'power' the maximum production of the protein. Could this promoter pose any risks?

In the production process of a GM plant, there are two stages that require selection –

(i) Selection of the vector that carries the transforming cassette from those that do not contain it. This requires a Marker gene, usually an antibiotic resistant gene and its promoter to be included in the cassette

(ii) Selection of the plant cells in which the cassette has been successfully inserted into the genome. Some cells may not take up the cassette. This requires another Marker gene or Reporter gene and its promoter to be included in the cassette.

The cassette also requires the insertion of a terminator sequence to denote the end of the gene sequence.

Possible Risks of GMO/ FFPs to human health and the environment

In observing the above details of the technology, scientists have acknowledged the possibility of this technology posing risks to the environment and human health, which should be considered before permitting the use of GMO/FFPs. This is indicated in the Convention on Biological Diversity, through which the Cartagena Protocol on Biosafety was established.

The Convention on Biological Diversity (CBD)

The CBD was inspired by the world community's growing commitment to sustainable development. It emphasizes the importance of conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefit arising from the use of genetic resources as many indigenous and local communities have a close and traditional dependence on biological resources. The CBD encourages the use of Modern Biotechnology (rDNA Technology) in this process. The CBD entered into force in December, 1993. Sri Lanka has signed and ratified the CBD.

Article 8 (g) of the CBD states thus:

Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms (includes GMOs)

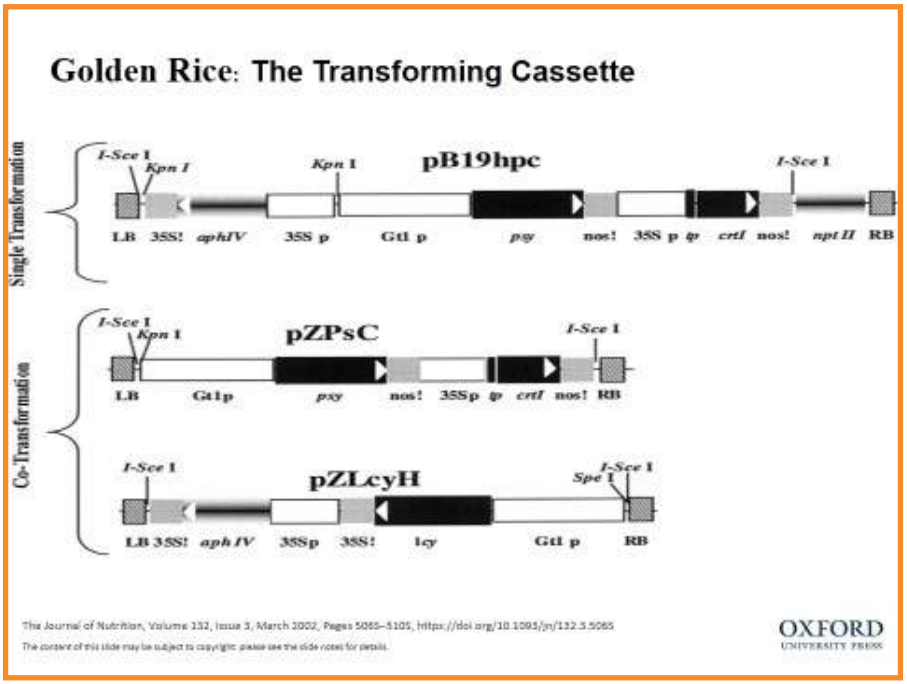


Fig. 9 : The transformation cassette used in the production of Golden rice

resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

Article 19, paragraph 3 proposes the need of an International Protocol setting out appropriate procedures to establish safety in the transfer, handling and use of LMOs / GMOs

The Cartagena Protocol (CP) on Biosafety

The result of this was the establishment of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It was adopted in January, 2000. Sri Lanka signed and ratified it.

The Protocol creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health, and specifically focusing on transboundary movements of the GMOs.

The CP is based on the Precautionary Principle [Article 11 (8)], which states thus:

" Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a Living Modified Organisms on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects."

Assessment of possible risks before releasing a GM plant to the environment, is an essential part of the CP.

Global Restrictions of GMOs

Due to the possible risks involved, many countries and regions have enacted restrictions regarding the movement and cultivation of GMOs.

(i) Cultivation banned, imports banned

Algeria, Bhutan, Kenya, Kyrgyzstan, Madagascar, Peru, Russia, Venezuela, Zimbabwe

(ii) Cultivation prohibited, imports (mostly animal feed) allowed

Austria, Azerbaijan, Belize, Bosnia, Bulgaria, Croatia, Cyprus, Denmark, Ecuador, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxemburg, Malta, Moldova, Netherlands, Northern Ireland, Scotland, Wales, Norway, Poland, Saudi Arabia, Serbia, Switzerland, Turkey, Ukraine

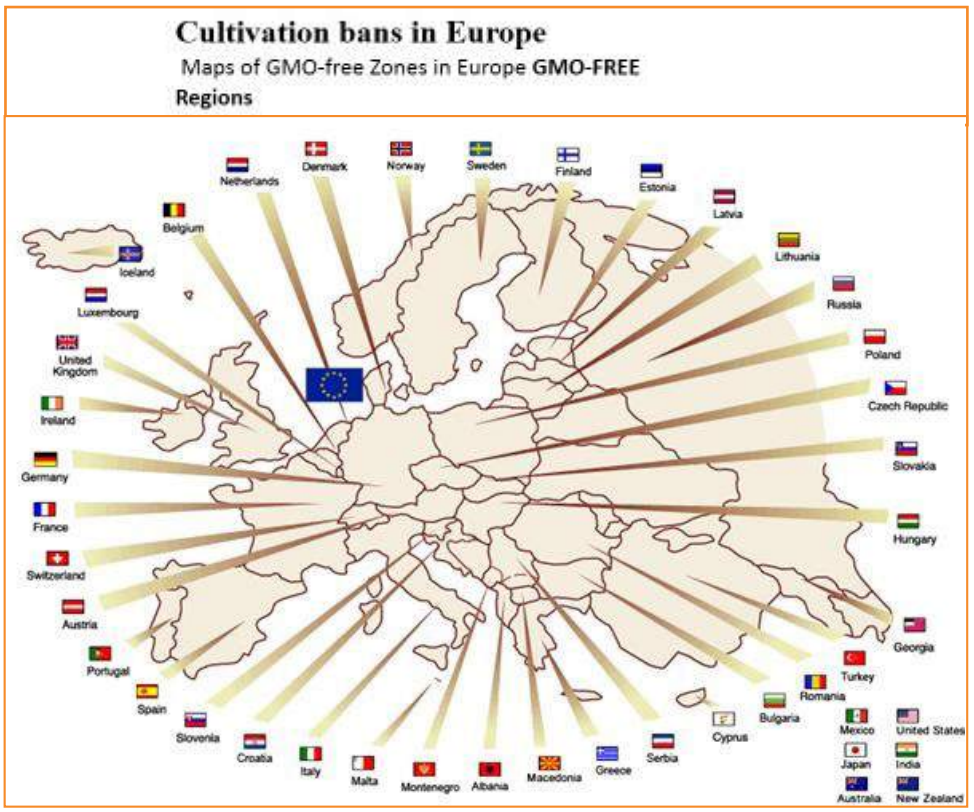


Fig. 10 : Map of GMO-free zones in Europe

(iii)GMO prohibited Regions

California, USA : Cultivation banned, imports allowed
Humboldt + Arcata city
Marin
Mendocino + Point Arena city
Trinity
Santa Cruz
Colorado, Boulder County, USA : planned ban of GM corn and GM sugar beet
Maine, USA
San Juan, Washington, USA
South Australia
Tasmania
Wallonian region, Belgium

The GMO-free zones in Europe are shown in Figure 10.

- Peru has extended its GMO moratorium and Mexico phases out glyphosate and GM maize in food and disallows GM maize releases (2021)

Environmental Risk Assessment

Important risks that arise due to introduction of GMOs to the environment are given below. They are the targets of the hazard/s.

(i) Effects of GMO on biological diversity / centres of origin and diversity
(ii) Movement of transgene to close relatives
(iii) Movement of transgene to non-GM varieties - contamination
(iv) Effect on non-target organisms, including pollinators and natural enemies
(v) Effects on soil organisms
(vi) Evolving resistance to the new protein
(vii) Arising of secondary pests
(viii) Creation of 'super weeds'
(ix) Introgression of the transgene in the population

Risk Assessment

Risk assessment is the core of biosafety, as it represents the science-based approach for decision making towards protection of human health and the environment when dealing with GMOs. The purpose of the risk assessment is to identify, characterize and evaluate potential risks.

A risk arises due to the function of the hazard, the exposure of the target to the hazard, and the consequences due to the exposure.

Risk *f* Hazard x Exposure x Consequences

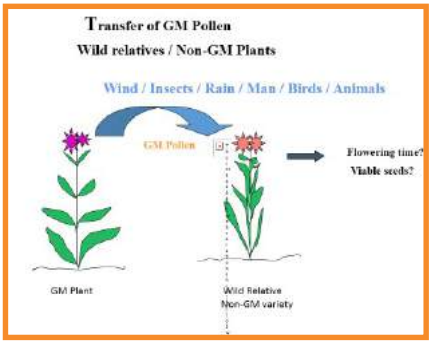
Risks to the Environment

Major Environmental Risks with regard to the release of GMOs to the environment are as follows.

1. Transfer of transgene to wild relatives / Non-GM variety through hybridization

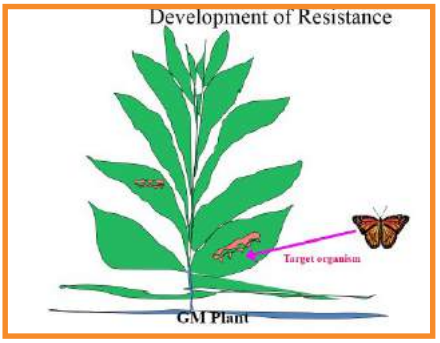
Can a GM plant hybridize with and cause the transfer of the transgene to a wild relative and/or to a non-GM variety through natural pollination?

The hazard in this case is the new gene present in the pollen of the LMO. The exposure of this pollen to the stigma of a wild relative / non-GM variety depends on many factors such as the cultivation distance between the two, the synchronization of flowering, the method of pollen transfer, distance such pollen can travel, pollinators present and the fertility of the resultant seed. The consequences of such an event can then be estimated and a risk assessment made.



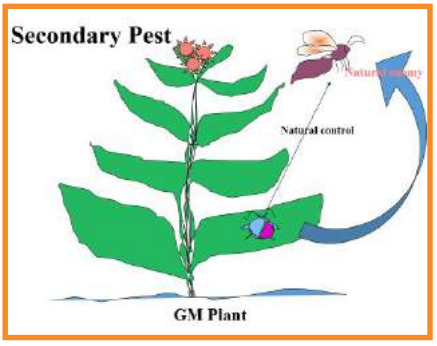
2. Development of resistance

The continuous cultivation of an insect resistant GM variety can, with time, cause the pest/insect to acquire resistance. It has been reported to have happened already. The hazard here is the new protein. The exposure will depend on the continuity of cultivation of the GM variety in the same field or area. In order to manage such a risk, mitigating factors need to be included in the management procedures such as establishment of non-GM refuges / buffer areas for the insects to feed on.



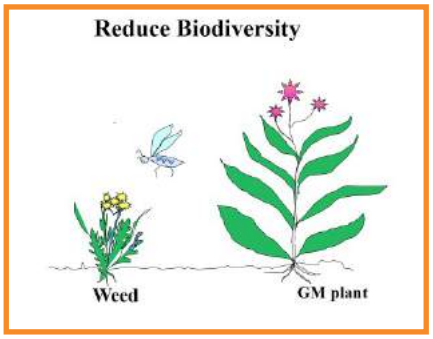
3. Emergence of secondary pests

A pest that the target organism usually controls in the natural environment may become a secondary pest due to the elimination of its predator, the target organism. Here, the hazard is the new protein



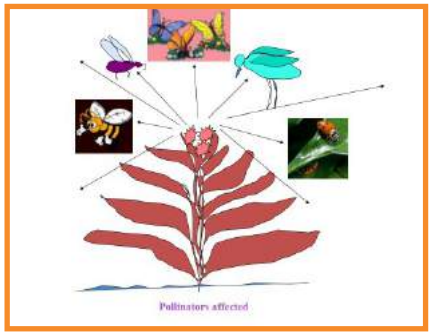
4. Reduction of biodiversity

This can occur, especially in the cultivation of herbicide tolerant GM varieties, where a total eradication of weeds will cause loss of farmland biodiversity due to reduction in food for beneficial insects, birds, other non-target organisms etc. The hazard here is the new protein and the target is the populations of weeds. The consequences will be the loss of biodiversity.



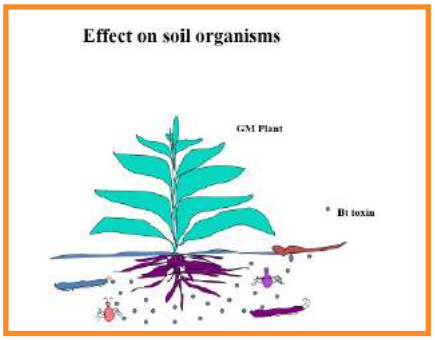
5. Effect on non-target organisms such as pollinators

The hazard here is the new protein. The exposure of this protein to non-target organisms such as butterflies, bees, moths, beetles, birds etc. needs to be estimated. Consequences will be only if the new protein becomes a toxin to such organisms.



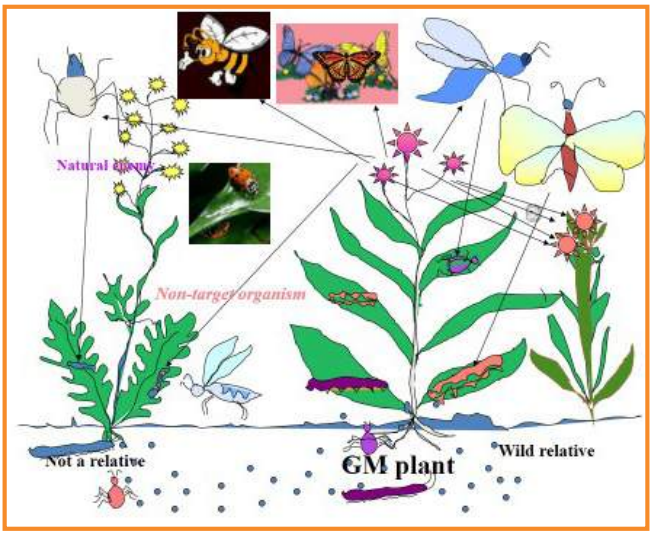
6. Effect on soil organisms

The hazard, which is the new protein can accumulate in the soil from fallen plant parts such as leaves, fruits etc. and harvested plants remaining in the field. A large number of soil organisms may be exposed to this new protein of the GM plant. The consequences would be the effect on the organisms and the resultant effects on soil quality for future cultivations.



7. Complex situation in agricultural fields

The cultivation of a GM plant, therefore, creates a complex set of possible risks. The new gene as well as the new protein are the major, possible hazards. Many targets exist in an agricultural field, each of which needs to be examined. The entire complex scenario must be considered in RA, RM & RC



Risk Analysis Methodology

Risk *f* Hazard x Exposure x Consequences

Risk Analysis of a GM plant (or any other GMO) involves the following steps.

1. Identification of the protection goal.
What are we trying to protect ? In this case it is the environment
(In the case of a GM food it is human health)

2. Identification and characterization of the hazard/s
In this case, we have to identify the hazard/s that could pose a risk.
In a GM plant, the possible hazards are:
The new gene
The new protein
Promoter sequences
Marker genes
Reporter genes.
Other DNA fragments in the cassette

3. For each hazard, we have to identify the target or end-point of the hazard.

E.g. If the hazard is the new gene, then a possible target would be a non-GM variety, where there is a possibility of the new gene contaminating the non-GM variety by moving to it through pollen.

4. For each end point per hazard, estimate the exposure and the consequences by using the RA Matrix (Fig.11).

E.g. What would the chances be of GM pollen contaminating a non-GM variety? What would be the consequences if it would?

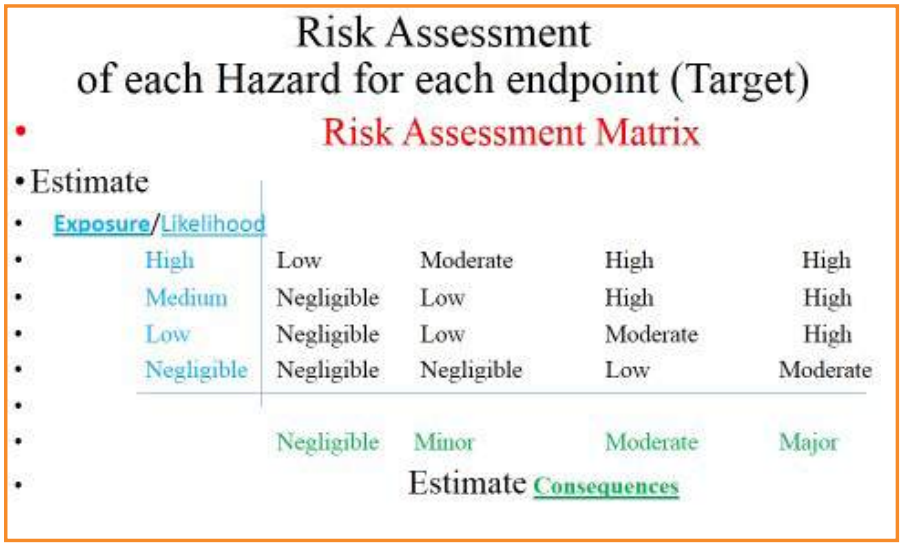


Fig. 11 : The Risk Assessment Matrix

5. Assess the risk for each hazard per each target end-point

Risk assessment *f* estimate of the exposure x estimate of the Consequences

6. Assess the overall risk for the GM orgnism, considering all the hazards and target of each hazard. and provide the Risk Management and Risk Communication procedures.

This information will be sent to the National Competent Authority to make the final decision regarding the release of this GMO to the environment.

As per the Cartagena Protocol, the proposed Biosafety Act of Sri Lanka has established the administrative structure in order to assess the above risks, as shown in Figure 12.

Every application to release a GMO to the environment, made to the National Focal Point / National Competent Authority (NCA) will be sent to the appropriate Sectoral Competent Authority (SCA) in order to carry out a Risk Assessment and report back to the NCA.

In the case of releasing a GM plant to the environment, the SCA will be the Department of Agriculture, who will conduct the Risk Assessment.

The proposed Biosafety Act, will therefore ensure that a scientific risk assessment is carried out before releasing any GMO to the environment.

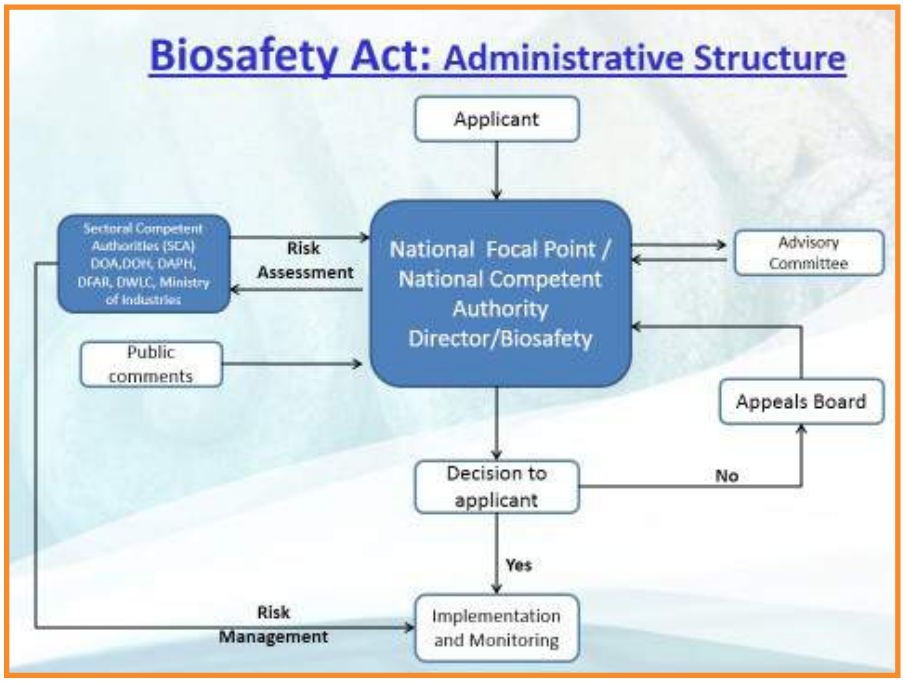


Fig. 12 : The administrative structure for risk assessment

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Legal framework with respect to Biosafety in Sri Lanka

R.H.M.P. Abeykoon

Background

The United Nations Convention was instituted by the entire world community including Sri Lanka as it was realized that biodiversity is being threatened due to the development activities taking place very fast all over the world. This convention was instituted with the objective of biodiversity conservation, sustainable use of the components of biodiversity, access to genetic resources and for reasonable, equitable and lawful sharing of the resulting benefits.

Sri Lanka signed this convention in 1992 and became a ratified party in 1994, a country becoming party to an international convention is bound to act according to the agreements tagged down by the convention, within the principles of the local institutions as well as the legal framework.

Biosafety is one of the important factors embodied in the biodiversity convention. Here attention has been drawn to possible harmful effects of the products of modern biotechnology on human health and environment. At the same time it has been accepted that modern biotechnology has an immense potential to enhance the benefits for humans. In this respect attention has been drawn also to the importance of food production, agriculture, health, facilities etc.

Clause 8 of the biodiversity convention has put forward the facts to be considered when *in-situ* conservation of biodiversity is carried out. Clause 8(g) of the Convention has pointed out the necessity to institute procedures for the regulation and arrangement for control of possible adverse effects on biodiversity conservation, sustainable use of biodiversity, conservation, and on human health of using genetically modified organisms produced through modern biotechnology and releasing them.

Cartagena Protocol on Biosafety

Cartagena Protocol on Biosafety was instituted on 29th January 2000 as an outcome of prolonged discussion and arguments between the parties to the biodiversity convention as well as all the relevant governmental, non-governmental organizations and community groups. It was instituted as a supplementary protocol to the biodiversity convention. This Protocol was instituted based on the exchange of genetically modified organisms and their use and handling while at the same time providing sufficient protection to biodiversity conservation, its sustainable use and human health.

The clauses 2.1 and 2.2 of the Cartagena Protocol states that the parties should certify that adequate national principles, laws and administrative procedures have been instituted to prevent or minimize the possible effects on biodiversity or human health when carrying out activities such as handling, transporting, exchanging, and releasing of genetically modified organisms.

Sri lanka signed this Protocol in 2000, and is a party to it. Therefore Sri Lanka should adopt the existing national principles, laws and administrative procedures so that Sri Lanka will acquire the capability to abide by the Cartagena Protocol as relevant to biosafety. Here it is necessary to identify a focal point in order to coordinate with Cartagena Protocol all activities relevant to biosafety. It is also necessary to identify the competent authorities for activities such as risk assessment, and monitoring with respect to the various groups of organisms that have been genetically modified. The Ministry which handles environmental affairs acts as the focal point institution. Department of Agriculture, Department of Marine and Aquatic Resources, Department of Health, Department of Wildlife Conservation and Department of Animal Welfare and Health have been identified as the competent authorities.

The present background policy and legal aspects as relevant to biodiversity conservation in Sri Lanka

The national policy regarding biosafety

The formulation of the national policy regarding biosafety, and obtaining the ministry approval for it in 2005, can be regarded as one of the steps that Sri Lanka has taken to implement the binding obligations regarding biosafety in the Cartagena Protocol.

The national policy regarding biosafety reconfirms the commitment of the government to ensure adequate security based on the Precautionary Principles and within a sustainable development plan when using modern biotechnology for the benefit to the present and future generations. Only the six main objectives of the policy are given below so as to be kept informed of the content of the policy.

1. Implementing the biosafety step in order to ensure the prevention of any adverse effect on health of the population, the environment, and biodiversity.

2. Ensuring the regulation and management in an effective manner the genetically modified organisms or food nutrients obtained from them, and any products prepared from them which are likely to be imported to Sri Lanka in keeping with an advance informed agreement as directed by the Precautionary Principle.

3. The regulation and management of any locally produced genetically modified organisms, or food nutrients obtained from them and products prepared from them.

4. Promoting the dissemination of knowledge regarding the use of modern biotechnology in a safe manner and its potential adverse impacts.

5. Development and adaptation of modern biotechnology while ensuring biosafety, and the bioethical expectations.

6. Developing the institutional framework to take decisions relevant to the subject of biosafety at the national level, and for supervision of research and development for international coorporation.

According to the 1st, 2nd and 3rd objectives stated above, the regulation and management of the

genetically modified organisms, food and nutrients obtained from them, whether they are imported to Sri Lanka or produced in Sri Lanka is possible. Here national laws and regulations are necessary. For this purpose provisions have been made available through laws and acts which are implemented under the supervision of various competent authorities mentioned above in the brief introduction. These are given below for your information.

The current legal framework regarding biosafety in Sri Lanka

1. The rules and regulations with respect to the regulation and management of food and products from genetically modified organisms are given in clause 32 of the Food Act Number 26 of 1980. The gazette notification bearing number 1456/22 and dated 2006.08.03 which has been made by the Minister of Health Security and Nutrition, after consultation with the Food Advisory Committee has given instructions regarding the control of import, labelling and sale of genetically modified food. Instruction number 2 states that no person should import, store, transport, distribute, sell or present for sellng purposes any genetically modified organisms; food produced from genetically modified organisms or food containing constituents obtained from genetically modified organisms as a food meant for human consumption without the approval of the main food authority. According to the instructions numbered 6 and 7, the approval for the use of genetically modified food and products will be given only after obtaining a scientific risk assessment report from a technical evaluation committee, and on the recommendations of this report. Also here the relevent regulations regarding the appointment of the technical evaluation committee on the recommendation of the advisory committee for scientific risk assessment and for the cost to belevied, apparels to be used have been clearly stated.

2. The Minister has been provided with the provisions to formulate the regulations by clause 12 of the Plant Protection Act Number 35 of 1999. The subjects for which provisions are available to make these regulations are given in clause 12 (2). It is possible to formulate regulations related to the import of plants, plant products and living organisms as indicated in the clause 12 (2). It is possible to use these provisions regarding genetically modified organisms. These regulations should be formulated as relevant, to be applied for the genetically modified organisms.

3. It is possible to apply clause 3 of the (revised) Animal Food Act Number 15 of 2016 for the regulation of the import of any food for animals. Here again these regulations should be formulated as relevant to be applied for the genetically modified organisms.

4. For this purpose it is possible to use clauses 37 and 38 of the Wild Animals and Plant Protection Act. The regulation of the import of mammals, birds, reptiles, amphibians, fishes and invertebrates is done by clause 37. It is not allowed to import animals without a licence to do so. Here again regulations should be formulated as relevant to be applied for the genetically modified organisms.

5. It is possible to regulate by clause 10(1) of the Consumer Affairs Authority Act the producers and the sellers who produce anything for consumption; who produce the finished product, package it or sell it.

6. Clause 30 of the Fisheries and Water Resources Act Number 2 of 1996 indicates that it is possible to enact regulations to regulate the import of fish. Here again regulations should be adapted as relevant to be applied for genetically modified organisms. Because the above mentioned acts do not cover all the requirements regarding biosafety, the new Biosafety Act and regulations have been drafted with the objective

of regulating and monitoring the national production, import and final use of genetically modified organisms using modern biotechnology. Information contained in the clauses of the Biosafety Act and regulations are yet in the draft stage. However given below is a summary of the proposed activities in the regulations.

Here research and development activities associated with genetically modified organisms conducted by government institutions, universities, government industries, international institutions, private institutions, non governmental institutions are regulated. The draft of the Biosafety Act has provided the powers pertaining to the risk assessment of the possible adverse effects of genetically modified organisms on biodiversity conservation, sustainable use and on human health.

In the draft Biosafety Act provisions relevant to the following are included.

i. The approving institution, its responsibilities and duties
ii. The methodology of granting approval
iii. The methodology for monitoring
iv. Powers for putting the Act into effect
v. Powers relevant to formulating regulations

The draft Biosafety Act has been prepared with the objective of regulating the following activities

i. The research and development activities in the laboratories associated with genetically modified organisms.
ii. Field studies conducted under safe conditions
iii. Introduction to the environment
iv. The impact and release to the environment of genetically modified organisms which have been produced for research, food and for the production of animal feed
v. Export
vi. Exchange of genetically modified organisms between institutions

The draft Act does not regulate the genetically modified materials used as human or animal food not possessing the ability to germinate or not having the capability to produce offspring, research studies carried out in the laboratories of government institution, research work carried out without commercial objectives.

Given below are the procedures that should be followed according to this draft Act and draft regulations

Any person intending to carry out research on genetically modified organisms, import them, use them, or want to release them to the environment etc. should make an application using the attachment of the Act to the local institution that has been authorised by the Act. The focal institution will direct these applications to the institution competent in the relevant subject. Prior to granting approval, the institutions with the relevant competencies should carryout a risk assessment with respect to the likely adverse effects on biodiversity conservation, sustainable use and on biodiversity, by the genetically modified organisms due to the relevant activity being applied to organisms to be approved. Risk assessment report should include the method of exchange of the genetically modified organisms, their use, the validity of the information submitted by the applicant, the risk and the recommendations to overcome the risks. The draft regulations indicate that in order to make decisions regarding the genetically modified organisms it is necessary to get the views of the public also, in addition to these recommendations. The recommendation of the risk assessment report should be forwarded to the advisory committee appointed in accordance with the provisions of the public opinion Act. The advisory committee after considering all these facts, should give a report stating whether the application is recommended or rejected giving reasons. The decision to grant approval or rejection is determined accordingly. There is also provision to appeal if the application is rejected.

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The National Biosafety Project

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Sri Lanka possesses a wealth of biological diversity. The country is classified as one of the global "biodiversity hot spots" based on its hosting a large number of endemic plants and vertebrates. Sri Lanka depends heavily on its biological resources to sustain its economy, making it very important to take note of any threats to biodiversity. The country has adopted a proactive approach to formulating environmental policy, and has been one of the first countries to ratify the Convention on Biological Diversity (CBD) in 1994.
Sri Lanka also ratified the Cartagena Protocol on Biosafety (CPB) in 2004, which aims to address the safe transfer, handling, and use of living modified organisms (LMOs) also known as genetically modified organisms (GMOs).

The Government of Sri Lanka has been taking several steps to ensure the safe use of LMOs. Recognizing the need for ensuring adequate levels of protection in the safe use of modern biotechnology, the Biodiversity Secretariat of the Ministry which is assigned the subject of environment, and acting as the national focal point for the CBD and CPB, formulated the National Biosafety Framework (NBF) and the National Policy on Biosafety. Both these documents were approved by the cabinet of ministers in 2005. Additionally, the national focal point drafted the Biosafety Act in 2014; a law to deal with the products of modern biotechnology.
Nevertheless, implementation of the NBF requires sufficient capacity in many aspects including regulations, risk assessment, detection, and awareness on the products of modern biotechnology. Therefore, there was an urgent need to build Sri Lanka's capacity to make greater use of the benefits of LMOs in a safe and sustainable manner.

Fig. 01 : Stakeholder consultative workshop for the drafts of the Biosafety Master Plan, Biosafety Regulations and the Manual on Administrative and Operational Procedure for Biosafety - February 2019

Fig. 02 : Stakeholder consultative workshop to discuss risk assessment guidelines for living modified organisms (LMOs) with technical support from Biotech Consortium India Limited (BCIL) and National Science Foundation (NSF) - September 2019

Understanding this requirement of building the capacity of Sri Lanka to establish biosafety in the country, the national focal point for biosafety partnered with the Food and Agriculture Organization of the United Nations for technical support, and initiated the National Biosafety Project (the implementation of the National Biosafety Framework in accordance with the Cartagena Protocol on Biosafety) in 2017. This ongoing 4-year project is funded by the Global Environment Facility (GEF), an international funding entity helping to tackle our planet's most pressing environmental problems.

The objective of the Biosafety Project is to strengthen the regulatory, institutional and technical capacities for the effective implementation of the NBF in conformity with the Cartagena Protocol on Biosafety. Component 1 of this project focuses on strengthening policy and institutional and regulatory

Fig. 03 : The national laboratories were assessed for their suitability to be upgraded to conduct regulatory testing of LMOs in Sri Lanka – May 2019

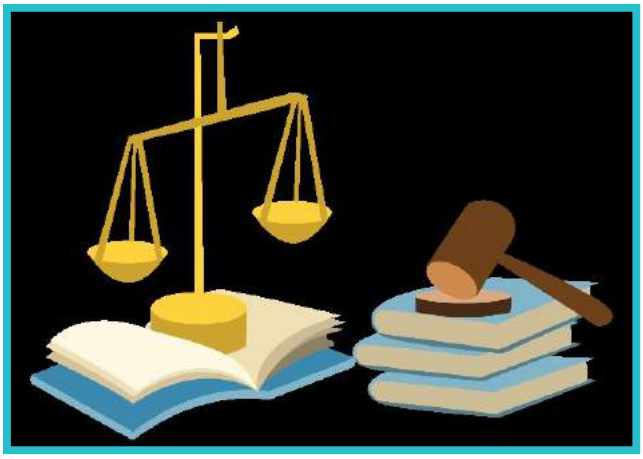
(i) National Plant Quarantine Services (NPQS), (ii) Government Analysist's Department, (iii) Sri Lanka Customs, (iv) Industrial Technology Institute (ITI), (v) Agricultural Biotechnology Centre (AgBC) - University of Peradeniya, and (vi) Institute of Biochemistry, Molecular Biology & Biotechnology (IBMBB).

Fig. 04 : Focus group discussion with vegetable farmers to assess their understanding on biotechnology, LMOs and biosafety - August 2018

frameworks for biosafety. Component 2 aims to enhance the system for risk assessment, risk management and risk communication. Component 3 focuses on developing technical capacity for the detection and identification of LMOs. Component 4 focuses on supporting targeted education and outreach campaigns to raise awareness about biosafety and enhance public participation in decision-making.

The success of the project is a result of effective technical support provided by FAO through national and international consultants as well as several implementing partners. The Biotech Consortium India Limited (BCIL), New Delhi, India is technically supporting components 1, 2 and 3. The Agriculture Biotechnology Center (AgBC) of the University of Peradeniya is technically supporting component 3 as well as preparing curriculum and educational material on biosafety for secondary and tertiary level education. The National Science Foundation (NSF) is technically supporting component 2 and the development of awareness material for dissemination of knowledge in biosafety among several stakeholder groups. The project has achieved many milestones throughout the past few years in all four components of the project. While it is essential to have an effective regulatory system to implement biosafety in the country, it is also Sri Lanka's national obligation as a signatory to the Cartagena Protocol on Biosafety. The most significant achievement towards strengthening the regulatory system of biosafety in Sri Lanka was the drafting of the Biosafety Act. The draft Biosafety Act outlines the regulatory process of the country identifying key role players and their responsibilities. This Act, which is the first law drafted specially to deal with LMOs in the country, outlines the roles of the national competent authority, sectoral competent authorities and other decision-making bodies to ensure that the LMOs are approved for use only if they are safe to the environment and human health. Since the Biosafety Act was drafted in 2014, the project revised the draft to improve its applicability, and moved it towards enactment. Also the Biosafety Regulations, the Biosafety Master Plan and the Manual on Administrative and Operational Procedure for Biosafety were drafted under the project. This work was technically supported by the international consultant, Dr. Ranjini Warrier from India and national consultants, Dr. Ananda Jayalal from the Ministry of Health, and Mr. Anandalal Nanayakkara (Attorney-at-Law). Under the first component of the project, a dedicated website for biosafety titled "Sri Lanka Biosafety Clearing House (BCH)" was established. The work on BCH was technically supported by BCIL and the national consultant Dr. Maheshi Atapattu.

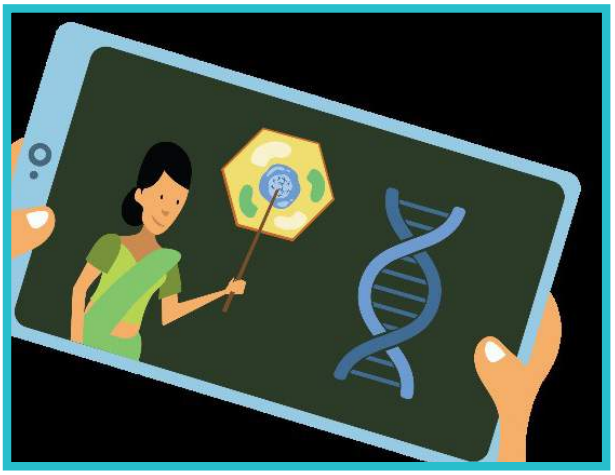
Article 15 of the CPB is about risk assessment of LMOs. This important element is identified in the draft Biosafety Act as a regulatory requirement so that the potential adverse effects of LMOs can be identified prior to their use. Thus, it is essential that Sri Lanka has the expertise to conduct risk assessment of LMOs in a scientifically sound manner. In order to strengthen this capacity in Sri Lanka, the project drafted the guidelines pertaining to risk assessment of LMOs with technical support from BCIL and NSF. They are (i) Guidelines for the safe use of LMOs in the lab, (ii) Guidelines for the environmental risk assessment of LM plants, (iii) Guidelines for the conduct of confined field



1. Strengthening policy and institutional and regulatory frameworks for biosafety

2. Enhancing the system for risk assessment, risk management and risk communication (i)

3. Developing technical capacity for the detection and identification of LMOs



4. Knowledge development, public awareness, education and participation

trials of LM plants, (iv) Guidelines for the safety assessment of foods derived from LM plants, (v) Guidelines for the testing of genetically modified mosquitoes, (vi) Guidelines for the institutional biosafety committees, and (vii) The risk analysis framework. Further, the project is planning to train relevant individuals to conduct risk assessment of LMOs. Some of these trainees will be obtaining foreign training to ensure that they are aware of the international best practices in this area.

Although LMOs are different from their non-LMO counterparts at the molecular level, they appear similar to each other. Therefore, it is important that Sri Lanka has the capacity to detect and identify the LMOs using the necessary tools and techniques. This requires molecular testing laboratories with suitable equipment and human resources in the country. The project visited and assessed several national laboratories to check if they have the prerequisite infrastructure which could be upgraded to conduct regulatory testing of LMOs. This activity was carried out with technical support from BCIL and AgBC. The assessed laboratories are

National Plant Quarantine Services (NPQS),
(ii) Industrial Technology Institute (ITI), (iii) Agriculture Biotechnology Centre (AgBC), University of Peradeniya,
(iv) Sri Lanka Customs,
(v) Government Analyst's Department (GAD) and
(vi) Institute of Biochemistry, Molecular Biology & Biotechnology (IBMBB), University of Colombo.
The assessment criteria included
(i) availability of dedicated space for LMO testing,
(ii) having competent personnel,
(iii) accessibility by users,

(iv) mandate of the organization,
(v) experience in regulatory testing procedures,
(vi) accreditation status and
(vii) willingness to work in this area.
Based on these criteria, NPQS and ITI were selected to be upgraded as national testing laboratories and the AgBC as the national reference laboratory. Additionally, GAD will be upgraded with capacity to test for LMOs at the protein level (through ELISA) and Sri Lanka Customs will be upgraded with capacity to conduct quick detection (through lateral flow strips).
Under the third component, the project conducted the first training workshop for LMO testing at the AgBC in May 2019. There will be more training workshops for LMO testing including foreign training organized through the National Biosafety Project.

Public awareness on biosafety is an integral part of the implementation strategy of the NBF in Sri Lanka. Participation of the general public is part of decision making when it comes to releasing LMOs into the environment or for human consumption. Article 23 of the Cartagena Protocol mentions "consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public." Therefore, it is important that the public is informed with relevant information about LMOs.

Whether people prefer to use LMOs or to avoid them, is a personal choice. However, misinformation and misconception about LMOs may lead to dire consequences in decision making. Therefore, it is important that the public is well aware about modern biotechnology, its products and biosafety. Especially when it comes to approval of an LMO in the country, it is crucial that people participate in informed decision-making. Thus, knowledge development and awareness on biosafety among all stakeholder groups including the public is essential towards successful implementation of the NBF in Sri Lanka.

As the first awareness activity, the project organized a media conference to make the public aware about the project and biosafety related to Sri Lanka.
To determine the level of understanding on LMOs and biosafety among several stakeholder groups, the project conducted a baseline survey through focus group discussions, key informant interviews and a questionnaire. The data collected in this survey indicated that there were many misunderstandings and misconceptions among some individuals of the public. The information collected through this survey is being utilized by the international consultant Dr Mahaletchumy Arujanan for awareness and outreach, in order to prepare the biosafety communication strategy for Sri Lanka.

Under component 4, the project is developing curricula and course material to integrate biosafety into secondary and tertiary education levels in Sri Lanka. This work is technically supported by the AgBC, which is working closely with the National Institute of Education and other relevant entities towards this task. The project has developed several awareness material in all three local languages to disseminate knowledge on biosafety among several stakeholder groups.
The NSF, which is a network of experts in biotechnology and other scientific fields, is providing technical support to this activity. The project initiated the publication of a biannual and trilingual newsletter on biosafety, and has released three issues up to now. The biosafety awareness activities that were initiated by the project will continue across many stakeholder groups to ensure that everyone has sufficient knowledge in biotechnology, modern biotechnology and biosafety to make informed decisions.
The progress of the National Biosafety Project is a result of the commitment of all the implementing partners, consultants, stakeholders and others who have contributed in many ways. The project team is appreciative of the support provided by everyone towards the successful implementation of the project.
Once the National Biosafety Project achieves its objective, Sri Lanka will have sufficient capacity to make greater use of the benefits of modern biotechnology in a safe and sustainable manner.

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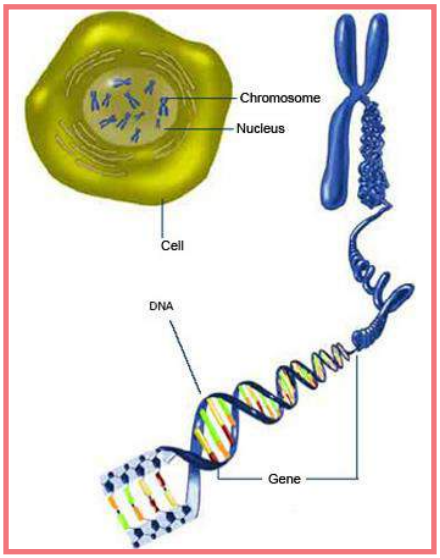
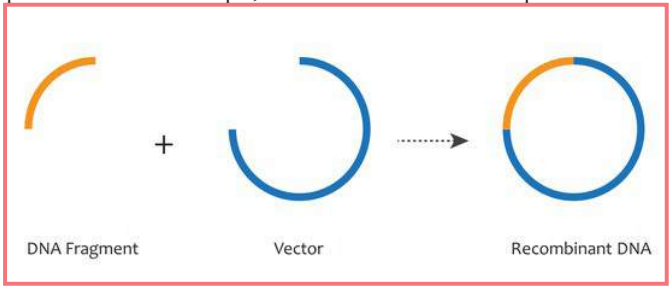
Molecular aspects of biotechnology (scope- Modern biotechnology in detail)

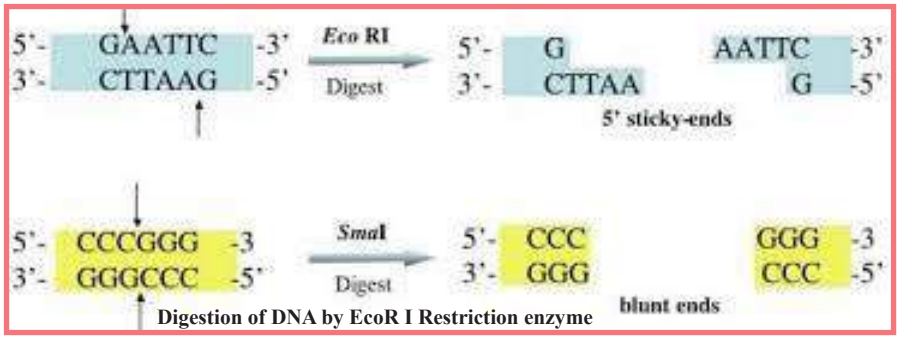
Prof. Chamari Hettiarachchi

Biotechnology is the use of living organisms and their components to solve problems or make useful products. This is not a novel technology. Since ancient times this technology had been used by humankind in agriculture, food production and medicine, and that is called traditional biotechnology or conventional biotechnology. However, the discovery of DNA and genes in the 1950's opened the path to a new era of biotechnology called modern biotechnology. The alternation of genetic material in an organism (a plant, an animal or a microorganism) using recombinant DNA technology is called modern biotechnology. Combining the DNA of one organism with the DNA of another organism is called recombining of DNA, and all the techniques that use to recombining DNA is called recombinant DNA technology. Recombinant DNA technology was first introduced in the 1970's with bacteria, and this is also known as "gene cloning" or "genetic engineering", which offers potentially unlimited opportunities for creating new combinations that does not exist under natural conditions. Hence, using this technique, the genes in living organisms can be altered, and the organisms thus produced are called genetically modified organisms (GMOs) or living modified organisms (LMOs).



Biotechnology, through genetic engineering, works directly with the genetic material of a cell. If one examines a cell under a high-powered microscope, one would see long, thread-like structures called chromosomes. These chromosomes, composed of DNA (deoxyribonucleic acid), are organized into sections called genes. Genes control the production of particular proteins, and these proteins, in turn, determine the characteristics of an organism. In some cases, a gene may govern one particular trait, such as an organism's resistance to disease, while in other cases, characteristics may be determined by many genes. Therefore, by changing genes in a precise and controlled manner, it is possible to produce the desired changes in the characteristics of the organism. The knowledge gained on this has allowed researchers to transfer genes between the cells of different organisms. The foreign DNA or gene is introduced into the genome of the recipient organism (host) in such a way that the total genome of the host is unchanged except for the single manipulated gene. Thus, DNA can be isolated from a cell of plants, animals or microorganisms (the donors), and be fragmented into groups of

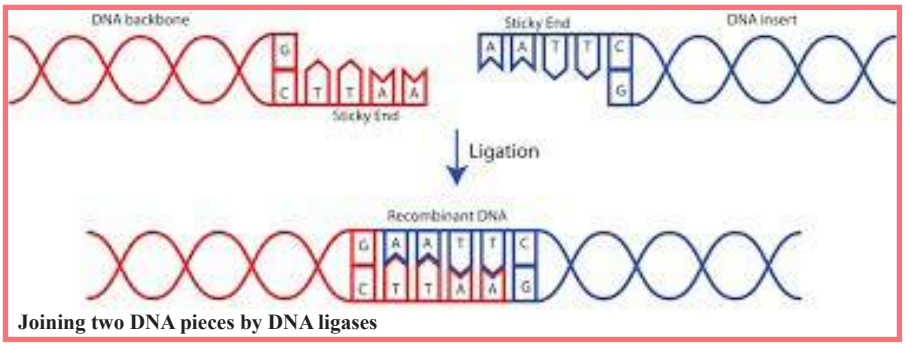




Digestion of DNA by EcoR I Restriction enzyme

one or more genes. Such fragments or genes can then be combined to another piece of DNA called the vector, and then passed into the host or recipient cell. The vectors are also called plasmids, which are small naturally occurring circular segments of DNA present in bacterial cells. Plasmid DNA can be taken outside of the bacterial cell, modified with the addition of a new gene, and replaced in the bacterial cell. With the new gene, the bacterial cell can now manufacture the product of the gene as its own. Because bacteria reproduce very rapidly, large volumes of bacteria containing the modified plasmid can be used to produce commercially significant quantities of a gene product, such as a food additive or an animal vaccine, in short periods of time. Hence, genetic engineering will enable the breeder to select the particular gene required for a desired characteristic, modify it, and transfer it to another organism.

The actual transfer of a gene between two organisms is carried out in a complex "cut and paste" procedure. Let's see, how it is possible to make animal protein (eg: insulin) in bacterial cells using this "cut and paste" procedure, in the same manner that was introduced above as the recombinant DNA technology. First, the gene which encode the insulin hormone should be identified and isolated from the

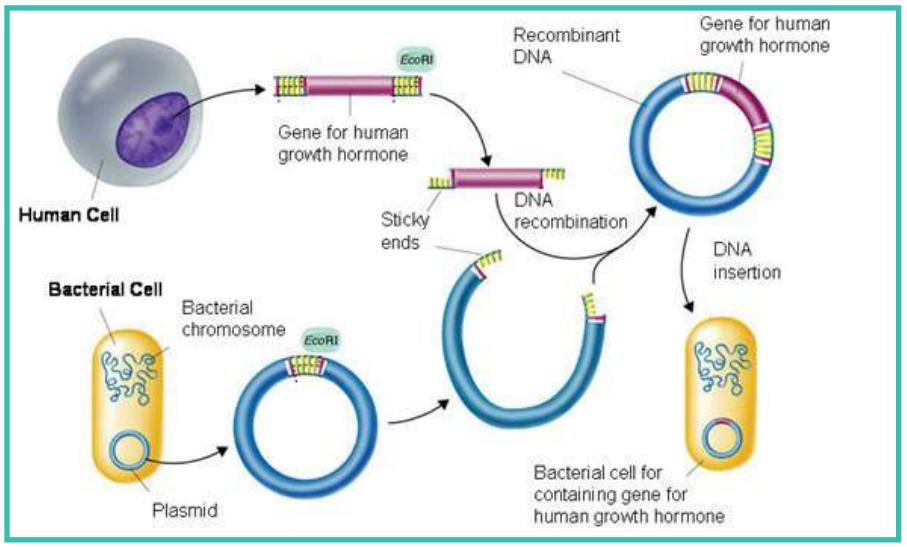


Joining two DNA pieces by DNA ligases

animal genome. Then the gene should be introduced into a cut vector before transforming into bacterial cells. Specialized enzymes that are used to cut vector DNA or DNA are called restriction enzymes. To paste or ligate the gene with cut vector, the edges of the both gene and the cut vector should be compatible. To make both edges of the gene and the cut vector compatible, both should be digested with the same restriction enzyme. Then they can be ligated together to form recombinant DNA molecule by the enzyme called DNA ligases. The ligated vector with the insulin gene cannot propagate outside of the living cells, and must be introduced into the bacterial cell to produce the desired animal protein in bacterial cells.

Not only bacterial cells, but also plant and animal cells can be used to transform genes to produce transgenic plants and transgenic animals. However, the techniques used to transform animal and plant cells are not the same as that used in bacterial transformation. Some of the techniques used in animal and plant transformations are microinjection, gene gun or particle bombardment, *Agrobacterium* mediated transformation and protoplast transformation. Among these techniques, the technique called micro-injection is the method often used to produce genetically engineered or transgenic animals. Through this technique, a very fine needle is used to inject a solution of DNA molecules containing genes that carry desired characteristics (such as disease resistance) into animal cells, usually at the embryo stage. The genes are incorporated into the animal cells genetic material, and the cells begin to express the characteristic determined by the new gene. Applying this micro-injection technique could have potential benefits for agriculture as well.

Plant cells have tough outer walls, making the delivery of genes into the plant cells a little more challenging than is the case for bacteria and animal cells. There are two main techniques by which this process is carried out. The first technique involves the use of a modified species of bacterium called *Agrobacterium*. In nature, the *Agrobacterium* invades a plant, then infects it with a segment of its own DNA that "codes" for the development of crown gall disease.



This DNA is incorporated into the plant's DNA and the plant becomes diseased with crown gall. When using *Agrobacterium* to genetically modify plants, these disease-causing parts of the *Agrobacterium*'s DNA are removed. They are replaced with genes that carry desired characteristics (such as improved nutritional value) by the "cut and paste" procedure. The *Agrobacterium* can then be introduced to plant cell material, where it can invade plant cells, and introduce the new gene with the desired characteristics. The full plants grown from these plant cells express the characteristic determined by the new gene. *Agrobacterium,* therefore, is a convenient delivery system by which new characteristics can be passed on to plants. The second technique used to deliver genetically engineered DNA into plants is the DNA "particle bombardment or gene gun" method. Tiny metal particles coated with genes with desired characteristics, such as improved nutritional value, are put into a particle gun and fired directly into plant cells. These genes are incorporated into the plant cell's DNA, and the cells are then grown into full plants. The new characteristic is thereafter present in the whole plant. These techniques have been used to introduce gene with special characters to plants and animals to produce transgenic plants and animals in a variety of fields; agriculture, medicine, pharmacology, environment etc. Let's take one example to see how modern biotechnology has been used in plant protection.

Crops plants such as corn, cotton, and potato have been successfully transformed through genetic engineering to make a protein that kills certain insects when they feed on the plants. The protein was isolated from the soil bacterium *Bacillus thuringiensis,* which has been used for decades as the active ingredient of some "natural" insecticides. In some cases, an effective transgenic crop-protection technology can control pests better and more cheaply than existing technologies. For example, with Bt engineered into a corn crop, the entire crop is resistant to certain pests, not just the part of the plant to which Bt insecticide has been applied. In these cases, yields increase as the new technology provides more effective control. In other cases, a new technology is adopted because it is less expensive than current technology. There are cases in which new technology is not adopted because for one reason or another it is not competitive with the existing technology. For example, organic farmers apply Bt as an insecticide to control insect pests in their crops, yet they may consider transgenic Bt crops to be unacceptable.

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Safety First: Are we ready?

Prof. Pradeepa C. G. Bandaranayake

Crop and animal production needs to be increased locally and globally to assure food and nutritional security of the growing population while reducing its impact on the environment. Advancements in biotechnological tools over the last three decades have revolutionized crop and animal improvement programs. It has broadened the agricultural research area, bringing in new opportunities to develop novel varieties by transgenic or cisgenic approaches and deletion of detrimental traits or the addition of significant characters with RNA-guided genome editing technology (Figure 01). Further, advances in genome sequencing give access to the large and complex genomes of domesticated species and their wild relatives, helping to identify a wide spectrum of genetic variation and association of genetic diversity with diverse agronomic phenotypes.

Nevertheless, like any other technology, modern biotechnology is also not completely risk-free. Considering the rapid development and commercialization of biotechnology and its products including living modified organisms (LMOs), recognition of the potential contribution that biotechnology can make to improving human well-being, and uncertainties regarding potential risks of LMOs on biodiversity and human health, international governments came together to negotiate a treaty to address issues of concern including mechanisms to address the concerns (Figure 02

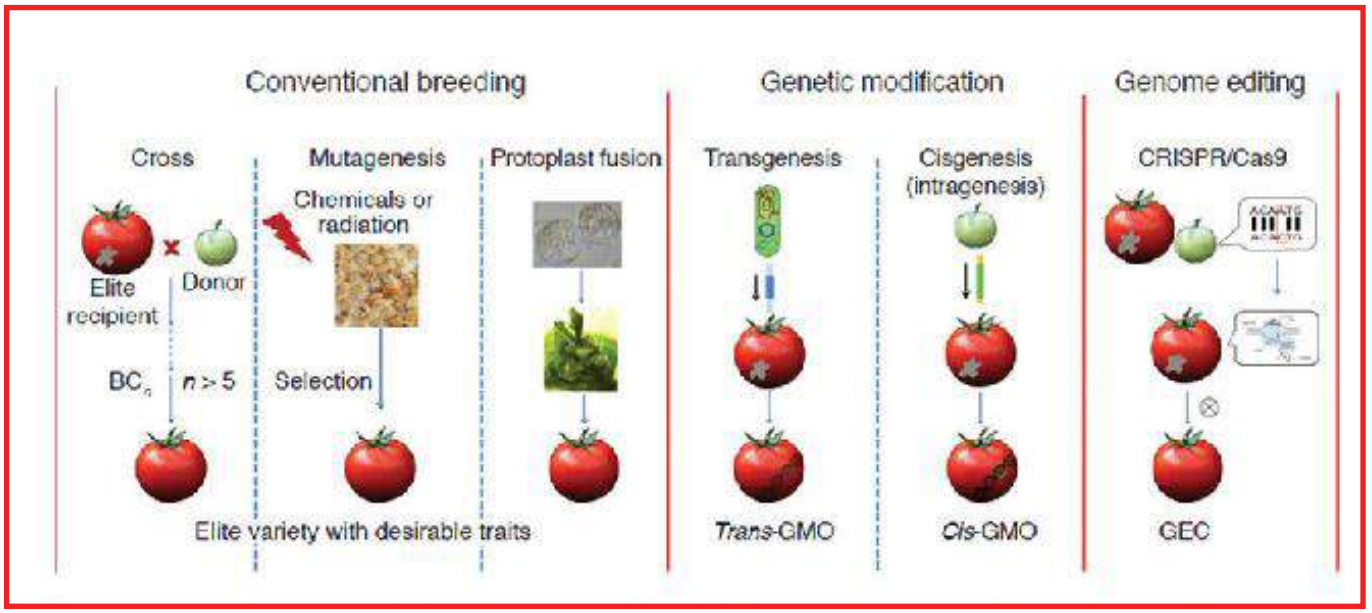


Fig. 1 : Comparison of Conventional breeding, Genetic modifications and Genome editing (From Huang S, Weigel D, Beachy RN, Li J (2016) Nature Genetics, 48, 109)

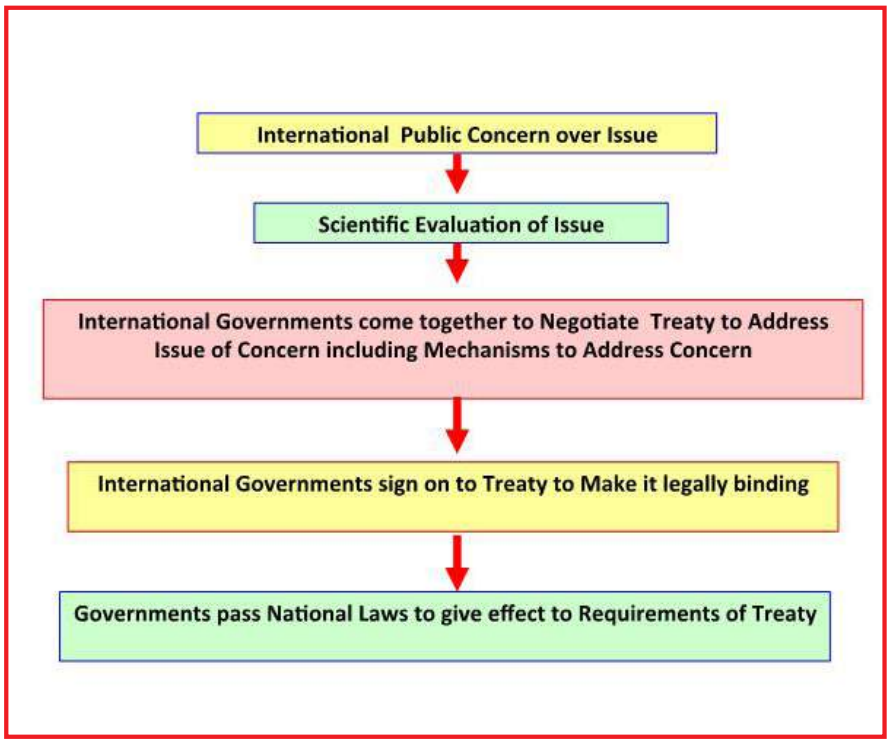


Fig. 2 : How does an international treaty work?

shows how does an international treaty works). The Convention on Biological Diversity (CBD) adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety (CPB). This Protocol entered into force on 11th September 2003 and currently, 172 parties have signed the Protocol. Sri Lanka signed the CPB on 24 May 2000 and ratified it on 28th April 2004. As a signatory to the CBD and CPB, Sri Lanka is obliged to implement the articles of the CPB and develop its own national regulatory framework for the safe transfer, handling, use, and release of LMOs.

As defined in the CBP, the objectives of the Protocol are to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling, and use of LMOs, often referred to as genetically modified organisms (GMOs), resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Recognizing the need for ensuring the regulation of biotechnology research and development activities, the Biodiversity Secretariat of Sri Lanka implemented the National Biosafety Framework Development Project in 2005, which led to the formulation of the National Biosafety Framework (NBF) in 2005. As part of the project, a National Policy on Biosafety was prepared to renew the commitment of the government to ensure adequate levels of protection in the safe use of modern biotechnology based on the precautionary principle, within the overall framework of sustainable development for the benefit of present and future generations. The Cabinet of Ministers approved the Policy in 2005.

The NBF is a system of legal, technical, and administrative mechanisms established under the MoEWR for implementation of the articles of the CPB. The National Policy on Biosafety (NPB) is an important element of the NBF and provides for safe application of modern biotechnology. The NPB covers, the need for a national policy for Sri Lanka, policy objectives, policy principles, and policy statements (Table 01). Nevertheless, NPB does not include policy strategies.

The draft Biosafety Act on the other hand clearly defined the approving authority (its composition, powers, and duties), the procedure for granting approval, monitoring mechanism and powers, enforcement powers, emergency powers, offenses and related aspects, and the powers to make regulations to enforce the provisions of the Act. Whereas the draft regulations include, the procedure for review of applications and decision making, risk analysis process, terms and conditions of permits issued, procedures for monitoring and supervision, procedures for export, and procedure for handling appeals.

Nevertheless, until the Biosafety Act and respective regulations are in place, following existing laws and regulations could cover some aspects of the safe transfer, handling, and use of LMOs resulting from modern biotechnology.

- Fauna and Flora Protection Ordinance No.2 of 1937

- Section 37 and 38(b) of this Ordinance has allowed importing of any GM – animal only for research purposes.

◆Animal Disease Act, No.59 of 1992c)

◆Animal Feed Act, no 15 of 1986

◆Plant Protection Act, No 35 of 1999

◆Consumer Affairs Authority Act No,9 of 2003

◆Food Act, No.26 1980 amended by act no. 20 of 1991.

◆Fisheries and Aquatic Resources Act, No. 2 of 1996

◆Intellectual property Act, No 36 of 2003

◆Water Hyacinth Ordinance, No. 09 of 1909

◆Regulations (2006) on GM Food under the Food Act

Among these, the Plant Protection Act has provisions to prevent the introduction of any organism harmful or injurious to plants or destructive to plants in Sri Lanka. These provisions can be used not only to prevent the entry of plants and animals but to prevent the import of any genetically modified plasmids that could be potentially harmful to plants (Section 15).

The Consumer Affairs Authority Act provides provisions to issue general directions to manufacturers or traders to label the goods in respect of price marking, packaging, sale, or manufacture of the goods (Section 10(1) (a)). Since all genetic modifications relate to the manufacture of a good product, this section can be used to label all goods with LMOs or materials derived from LMOs.

Regulations came in 2006 under the Food Act which prevents import, store, transport, distribute, sell, or offer for sale any LMOs or ingredients from LMOs meant for food unless approved by the chief food authority.

The Water Hyacinth Ordinance provides effective means to prevent the entry, or retain until any GM plants or parts are identified and named in a gazette regulation.

The capacity building both human and physical is important for the implementation of any regulatory system. It is especially true for this highly technical and evolving subject. Sri Lanka has identified this necessity, and currently is in the process of building such capacities. For example, human and physical capacity building on LMO detection, inspection, and monitoring are among the key expected outcomes of the on-going project on "Implementation of the National Biosafety Framework in accordance with Cartagena Protocol on Biosafety".

The Agricultural Biotechnology Centre, University of Peradeniya (AgBC) has taken the lead as a local partner organization of the above FAO funded project, and work in collaboration with the Biotechnology Consortium Indian Limited (BCIL). As such the country will be prepared for detection and identification of LMOs/GMOs with;

a) a fully pledged Accredited National GM referral laboratory at AgBC

b) two fully pledged Accredited GM testing laboratories at the Industrial Technology Institution (ITI) and the National Plant Quarantine Service (NPQS) of the Department of Agriculture of Katunayake,

c) a Small Quick detection facility (Strip based) at the Sri Lanka Customs,
and ;

d) an Enzyme Based Immunosorbent Assay (ELISA) based testing facility at the Government Analyst Department, Colombo, Sri Lanka.

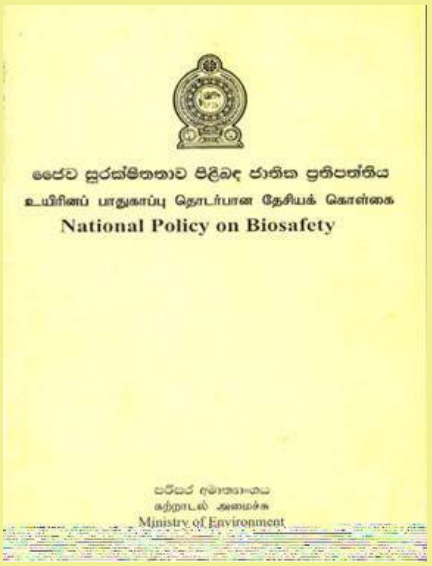
While few staff members from identified labs will be trained internationally, more members are identified to be trained locally at developed facilities.

Over three hundred (300) relevant officers are already trained on GM inspection, monitoring, and sampling. The methodologies, guidelines, and standard procedures of sampling, inspection, and monitoring of GMOs are being prepared to support the regulatory system of the country.

The preparation of future generations has been identified as a priority. The new Advanced Level Biology curriculum introduced by the National Institute of Education (NIE), includes considerable content on biotechnology and biosafety. Supportive teaching and learning materials are in preparation for both primary and secondary education levels. Similarly, biotechnology and biosafety will also be introduced at tertiary level education through certificate courses. Such programs are already developed and are at the implementation stage.

Several scientific surveys conducted have shown that the general public in Sri Lanka is not aware of LMO/GMO. The same studies have suggested that even the educated population has less awareness

Table 01: Policy statements of National Policy on Biosafety

	Recognizing the importance of protecting in people, environment and biodiversity while promoting a sustainable social and economic development through the implementation of biosafety measures
	Recognizing the human health, environment and socio-economic risks that may be incurred by careless or unscrupulous development of modern biotechnology and the use of its products
	Realizing the need for developing our own capabilities in biosafety through research and development and training
	Reaffirming the commitment to the obligations of the CBD and CPB

though they are interested in labeling GM food/products. Therefore, substantial efforts are being taken to improve public awareness of biotechnology and biosafety.

All the above preparatory steps are important for the country adapting the proper regulations and guidelines for safe use of modern biotechnology and to facilitate harnessing benefits while minimizing risks if there are any. Because, the Sri Lankan population is projected to increase by about 18 %, from 20.3 to 23.9 million before plateauing by 2050. Linear progress of 2% genetic gain has to be achieved to sustain the productivity to feed the growing population. It is a huge challenge when crop yields have reached a plateau, due to the narrow genetic base and lack of potential to increase harvest index within elite breeding stocks. The introduction of new promising alleles through rapid breeding cycles seems an efficient mechanism to improve the rate of gain significantly, and it could help to achieve the goal of feeding the projected population in 2050. There are many biotechnological tools available and applied around the world for the introduction of favorable alleles and to speed up the breeding efforts. It is clear that Sri Lanka has barely exploited the potential of biotechnology for crop improvement while the world is moving faster with new technologies.

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Genetically Modified Food: How Safe are They?

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What are Genetically Modified Foods?

An entire set of DNA molecules in the nucleus of eukaryotic organisms is called the genome. Genes are fragments of DNA that transfer inherent characteristics of organisms from one generation to the other. Sexual reproduction facilitates mixing of these genes and natural alterations to the genetic materials, leading to changes in phenotypic characters of organisms over time. The genomes of plants and animals were subjected to alterations through selection, seeking better phenotypic characters for many years using traditional breeding techniques. Artificial selection of organisms for specific, desired traits has resulted in a variety of different organisms, but this artificial selection, in which organisms that exhibit specific traits are chosen to breed subsequent generations, has been limited to naturally occurring variations.This natural transfer of genes is possible among organisms only when they are with close genetic distance.

With the discovery of the structure of DNA in 1953, and particularly since the development of tools and methods to manipulate DNA in the 1970s, it was discovered that DNA can be transferred between genetically distant organisms using artificial methods. In this method a specifically cut out gene from one organism is paste into a genome of another. As a result, a new scientific technology was evolved enabling specific modifications to the genetic material targeting introduction of new characteristics to the living organisms. Genetic engineering, also called genetic modification or genetic manipulation, is the direct manipulation of an organism's genes using biotechnology. Combining together of genes from two different species is known as recombinant DNA technology, which comes under the broad term biotechnology and the resulting organism is identified to be genetically modified (GM), genetically engineered (GE), live modified or transgenic. In brief, genetic modification or genetic engineering techniques enable scientists to find individual genes that control particular characteristics, separate them from the original source, and transfer them directly into the cells of an animal, plant, bacterium, or virus.These new genetic combinations paved the path to introduce new characteristics to the crop plants such as resistance to drought, soil salinity, pest and diseases, herbicides and elevated levels of nutrients and phytochemicals created a revolutionary change in crop improvement. A large number of genetically modified (GM) crops, including both food and non-food crops carrying novel traits have been developed over the years.

Table 01: Some of the genetically modified crops approved for human consumption

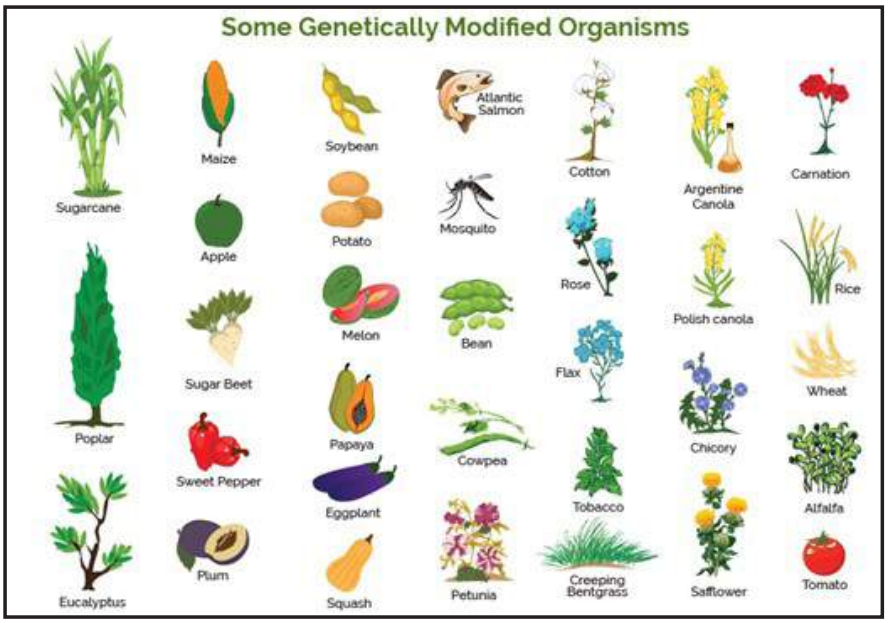
Crop	Scientific Name	Crop	Scientific Name
Apple	*Malus domestica*	Potato	*Solanum tuberosum*
Canola	*Brassica napus*	Rice	*Oryza sativa*
Bean	*Phaseolus vulgaris*	Soybean	*Glycine max*
Chicory	*Cichorium intybus*	Safflower	*Carthamus tinctorius*
Cowpea	*Vigna unguiculata*	Sugar Beet	*Beta vulgaris*
Eggplant	*Solanum melongena*	Tomato	*Lycopersicon esculentum*
Flax	*Linum usitatissimum*	Sugarcane	*Saccharum* sp.
Maize	*Zea mays*	Soya	*Glycine max*
Melon	*Cucumis melo*	Wheat	*Triticum aestivum*
Papaya	*Carica papaya*	Squash	*Cucurbita pepo*

Since the introduction of first GM crop for commercial cultivation in early 1990s, a large variety of GM food crops and their derived products are available as processed or unprocessed food items, food ingredients and animal feed in the world market. Some of these crop produce include potatoes, corn, tomatoes, soybean, canola, eggplant, strawberries, carrots, lettuce etc. (Table 1). Though there are a number of GM crops that are commercially available, GM salmon is approved as the only GM animal for human consumption up-to-date.

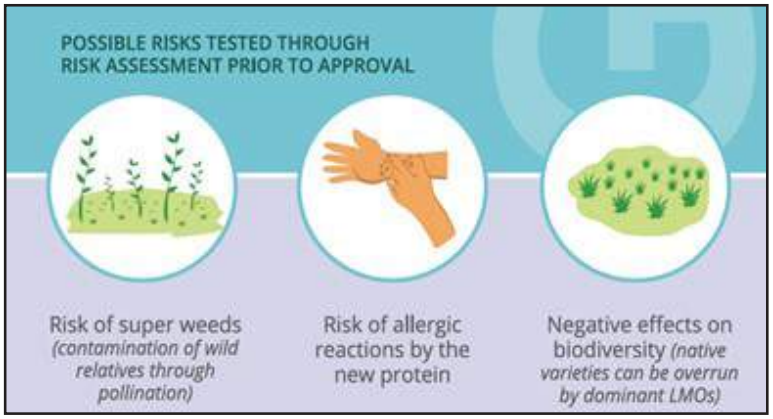
This technology has many potential applications. At present, recombinant DNA technology and GM crops are considered as promising applications in food and agriculture sectors in facing and overcoming the challenge of ever increasing demand for safe and nutritious food by mankind. Despite the growing use of genetically modified crops over the years, many including scientists appear to hold negative views about GM foods. The introduction of a gene into different cells can result in different outcomes, and the overall pattern of gene expression can be altered by the introduction of a single gene. It these outcomes become negative, will fall into two basic categories, the effects on human and animal health and the environmental consequences. Introduction of GM organisms to the natural environment has created public concerns related to biodiversity, environmental safety, food and feed safety, socio-economical and associated ethical issues. This article focuses on the major facts about GM food safety that the consumers should be aware of and how GM foods are made available to the market confirming their safety.

How Can They Become Unsafe During Development?

Consumption of GM foods by the general population should not pose any food safety risks leading to harmful health effects. The safety concerns associated with GM foods are mainly due to the possible development of hazardous molecules or compounds within the GM organisms. These hazardous materials can be either new proteins or secondary metabolites accumulated in the cells of GM organisms. The possible health risks associated with the above



hazardous compounds in the GM food crops upon consumption by human include development of toxicities and allerginicities among the consumers. The cellular mechanisms in GM organisms leading to the development of compounds with possible toxicities or allerginicities can be divided into three main categories. The first mechanism is due to the primary expression of unintentionally transferred genes in developing new proteins. The second mechanism involves secondary effects of transferred gene expression in altering cellular biochemical pathways in the host organism and insertional mutagenesis, creation of mutations of DNA resulting from gene integration is the last.



The primary products of gene expression are always proteins. The information available in the databases on the known allergenic and toxic protein producing genes in donors of desired gene traits help the scientists to get rid of such genes from introducing them into GM organisms. However, selection of genes from organisms that are previously not studied may result in transfer of hazardous proteins and lead to rejection or termination of developmental projects of GM organisms. A considerable number of examples exist as evidences of discarded GM food crops after discovering allergenic or toxic effects at different developmental stages (Domingo, 2007). In addition, foods that are frequently being reported to be allergenic such as peanut, soybean, wheat, eggs, milk, shellfish and mushroom etc. are studied thoroughly before using them as donors of selected genes. Due to the expansion of knowledge and awareness on genes with the above health considerations, early recognition of hazards in GM foods are possible.

The secondary effects of gene expression are intensively studied because, most of the proteins produced due to gene expression function as enzymes that regulate or alter cellular biochemical pathways. The new enzymes introduced to the GM organisms may express unknown or unintentional effects by modifying the expression of untargeted biochemical pathways that can accumulate new compounds with toxic or allergenic effects or trigger the production of such compounds that are naturally in existence at nonhazardous levels. These changes in metabolism can lead to an increase in toxin concentrations. Assessing of these changes in GM organisms is a challenge in genetic engineering and thus extensive research studies are carried out to investigate all associated adverse health effects.

The third mechanism of developing hazardous materials in GM foods is insertional mutagenesis that disrupts or changes the expression of existing genes in a host plant due to insertion of new genes or the DNA. Disruption of existing gene expression can be resulted due to nonspecific insertion of genes to the host organism. This will lead to the development of altered or fused proteins which are potentially of toxic or allergenic in nature. Further, insertional mutagenesis can either trigger the expression of silent genes or down regulate the expression of critical genes leading to the development of secondary toxic materials.

Though the above mentioned health related adverse effects are possible due to genetic modifications, generally they are identified at the developmental stages and addressed before releasing GM foods for human consumption. This is in line with the standard practice of removing lines of conventionally bred plants exhibiting undesirable properties during the course of a commercial selection programme. In addition, continuous market surveillance helps in early detection of any health concern targeting specific groups of consumers and ensures the implementation of mechanisms to rectify the negative effect through effective communication.

How GM Food Safety is Assured?

Safety assessment of GM food is performed mainly to assess the unintended effects of the genetic

modification, and in particular to identify whether these effects raise any food safety concerns. The safety assessment of GM foods is generally undertaken in accordance with internationally established scientific principles and guidelines. Internationally reputed organizations such as, Food and Agriculture Organization (FAO), World Health Organization (WHO), Codex Alimentarius Commision and Organization for Economic Cooperation and Development (OECD) are involved in developing such principles and guidelines. Even though strict guidelines are used in assessing safety of GM food, it does not mean that they are less safe than food produced by conventional means. Nevertheless, most of the non-GM food that are consumed today are not thoroughly assessed for their safety compared to the GM food, generally considering them as safe due to the long existence in the society.

The concept and principles of assessing safety of GM food involve a scientific comparison of the GM food to a conventional counterpart having a history of safe use, which is known as substantial equivalence. This assessment enables to develop a reasonable certainty that the particular GM food does not pose any harm to the consumer when it is processed and consumed as recommended. If the GM food is not substantially equivalent, or in other worlds if it contains unintentional hazardous material/s, it is further evaluated in relation to human health following a systematic safety assessment framework. This safety assessment procedure enables to identify the nature and the severity of the

hazard and possible measures of overcoming the risk. Moreover, intensive safety assessment focuses on the important characteristics of the recombinant gene/s, composition of the food, effects of processing and preparation, especially possible toxicities and allerginicities, etc. In this context, the possibilities of causing adverse health effects by the GM food to the consumers are considered to be very low. However, there may be special groups of individuals who are hypersensitive or susceptible to some of the new materials present in the GM foods that are non-toxic or non-allergenic to the general population. Therefore, different regulatory approaches are taken in approving the GM products for human consumption and communicating them to the consumers by different countries.

GM Food: Sri Lankan Standpoint

Similar to many countries that have approved GM food, Sri Lanka has also given the legal provision to import and consume GM food under the Food Act imposing a GM food (control of import, labelling and sale of genetically modified foods) regulation with effect from the year 2007. However, no permission is given in Sri Lanka to grow GM crops for food or feed purposes. According to the above GM food regulation, importers must obtain a prior approval to import GM food or feed to Sri Lanka, and risk analysis need to be done by the local authorities to confirm their safety. Further, if GM foods are marketed in Sri Lanka they must be properly labeled to communicate about the genetic modification to the consumer. Up-to-date no importer has obtained an approval to import GM food to Sri Lanka, thus no labeled GM food products are available in the market. With the rapid developments in the GM food industry, expansion of GM food volumes in the world market and introduction of advance techniques and tools in identifying GM food safety, it can be anticipated that GM food will reach Sri Lankan market in the future. In this context, assessment of safety of GM food becomes important to protect human health and the environment from the potential adverse effects. Several organizations are actively working in Sri Lanka to develop a system to establish biosafety of GM foods to proceed with evidence-based decision making to prevent harmful consequences.

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What have you learnt from the Vidurava 2020 April - June Q2 Issue? Scan your own memory!

1] Molecular Aspects of Biotechnology

True or False?

1. The discovery of DNA and genes in the 1950's opened the path to a new era of biotechnology called modern biotechnology.
2. Genetic engineering directly manipulates the genetic material of a cell.
3. The techniques used to transform animal and plant cells are the same as those used in bacterial transformation.
4. Genetic engineering will enable scientists to select the particular gene required for a desired characteristic from the genome of one organisms, modify it, and transfer it to the genome of another organism.
5. DNA cannot be isolated from a cell of plants, animals or microorganisms, and be fragmented into groups of one or more genes.

2] The National Biosafety Project

True or False?

1. The objective of the Biosafety Project is to strengthen the regulatory, institutional, and technical capacity for effective implementation of the NBF in conformity with the Cartagena Protocol on Biosafety.
2. The success of the project is a result of effective technical support provided by FAO through national and international consultants as well as several implementing partners.
3. Although LMO's are not different from their non-LMO counterparts, at the molecular level, they appear similar to each other.
4. Public awareness on biosafety is an integral part of the implementation strategy of the NBF in Sri Lanka.
5. Whether people prefer to use LMO's or to avoid them is not a personal choice.

3] Safety First : Are We Ready

True or False?

1. Like any other technology, modern biotechnology is also not completely free of risks.
2. In many countries including Sri Lanka, the focal point for the Cartagena Protocol on biosafety is the Ministry handling the subject of environment.
3. The National Policy on Biosafety is an important element of the NBF, that ensures for unsafe application of modern biotechnology.
4. Introduction of new promising alleles through rapid breeding cycles seems an inefficient mechanism to improve the rate of crops.
5. GM crop research in Sri Lanka has not gone beyond testing in contained environments.

4] The Proposed Biosafety Act of Sri Lanka – Environmental Risk Assessment Ensures the Safe Use of GMO's

True or False?

1. A gene is a part of the DNA molecule that resides in the nucleus of every cell.
2. A single cell in our heart will also carry the genes for hair colour, but it is switched off from the beginning of life.
3. The most uncommonly used technique for gene transfer is the *Agrobacterium* – mediated gene transfer method.
4. Fundamentals of molecular biology reveal that a gene by itself cannot function or express itself to produce a protein.
5. The continuous cultivation of an insect resistant GM variety cannot, with time cause the pest/insect to acquire resistance.

5] Legal Framework with Respect to Biosafety in Sri Lanka

True or False?

1. The draft Act does not regulate the genetically modified material used in human food or animal feed that do not possess the ability to germinate/rejuvenate.
2. Any person intending to carry out research on genetically modified organisms need not make an application using the attachment of the Act to the authorized institution.
3. It is possible to regulate by clause 10 (1) of the Consumer Affairs Authority Act, the producers and the sellers who produce anything for consumption.
4. Clause 30 of the Fisheries and Water Resources Act No. 2 of 1996 indicates that it is not possible to enact regulations to regulate import of fish.
5. Since the existing Acts do not cover all the requirements regarding biosafety, the new Biosafety Act and regulations have been drafted with the objective of regulating and monitoring the national production, import, and final use of GMO's.

Answers

01) 1. True, 2. True, 3. False, 4. True, 5. False
02) 1. True, 2. True, 3. False, 4. True, 5. False
03) 1. True, 2. True, 3. False, 4. False, 5. True
04) 1. True, 2. True, 3. False, 4. True, 5. False
05) 1. True, 2. False, 3. True, 4. False, 5. True

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