Editorial

Advances in Genetics in Defiance of the Law of Nature

The tortuous evolutionary journey from Charles Darwin's natural selection to Gregor Mendel's genetics, and to modern molecular biology, in defiance of the laws of nature, has reached a crucial phase enhancing the debate on what is good and bad for the wellbeing of humankind.

This edition of Vidurava, which takes on the theme of 'Genetics Past and Present', places in perspective the panorama of possibilities and probabilities, of advances in molecular biology.

Conservation of nature, and living in harmony with the natural environment have been the prime factors of sustainable livelihoods in ancient times. However, the phenomenal erosion of this philosophy over the last 300 years, or more specifically since the Industrial Revolution of Europe, has seen an unprecedented worldwide turbulence, and spread of upheavals and natural disasters.

Nevertheless, recent advances in molecular biology, despite consequences of defying the laws of nature, has seemingly shown both positive and negative effects. Thanks to scientific intuition combined with multi-axial dispensation of technological interventions, has in many instances tipped the scales in favour of the new outcomes in molecular biology.

Among the many episodes of success stories in this field are, 1) the detection of various agents of disease infections, 2) diagnosis of hereditary diseases, 3) finger printing for paternity testing and in forensics, 4) development of insect-resistant transgenic food crops to enhance food production, and 5) development of the vitamin A rich Golden Rice.

Unfortunately, despite these favourable dispensations, countries like Sri Lanka with pristine rain forests, and a unique biological diversity, faces serious threats of illegal smuggling of the precious genetic material by unscrupulous people of both local and foreign origin. Such cross-border gene piracy has been of such magnitude in recent times that global cooperation to combat this menace has led to interventions by INTERPOL. Although Sri Lanka has instituted a Biodiversity Protection Unit within the Customs Department since 1993, which is considered to be the only one of its kind in the global Customs institutions, but, there is need to strengthen appropriate legal instruments for its effective implementation.

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Food Science

GM Foods : Myths and Facts

Prof. K.K.D.S. Ranaweera

Higher plants, animals and human beings are generally made up of millions of cells. Inside each of these cells is a nucleus which contains genes. Gene is a natural unit of the hereditary material, which is the physical basis for the transmission of the characteristics of living organisms from one generation to another. The genetic information is stored in the base sequence of the DNA molecule which can either generate more copies of itself through replication or be copied by the process of transcription into RNAs. These RNAs act as intermediary in the flow of genetic information from the nucleotide language of nucleic acids to the amino acid language of proteins through **translation**.

The word **biotechnology**, coined in 1919 by Karl Ereky, was used to describe the interaction of biology with human technology. In simple terms, biotechnology is the means or way of manipulating life forms (organisms) to provide desirable products for human use. In this context, biotechnology is not new. Beekeeping and cattle breeding can be considered as biotechnology-related endeavours and making of beer, wine, bread, yoghurt and cheese was practised by ancient civilizations such as the Babylonians, the Romans and the Chinese. Production of basic chemicals like glycerol, citric acid and lactic acid and the development of antibiotics by exploiting the properties of microorganisms appeared in later times (For example, production of penicillin from *Penicillium* species). Use of the term biotechnology has come to mean all parts of an industry that knowingly create, develop and market a variety of products through the wilful manipulation of living organisms or their parts at molecular level.

Although, **recombinant DNA** is one of the many techniques used to derive products from organisms or parts of both plants and animals for the biotechnology industry, it is not the only area of biotechnology. Hence, biotechnology may include areas such as recombinant DNA, plant tissue culture, rDNA or gene splicing, enzyme systems, plant breeding, meristem culture, mammalian cell culture, immunology, molecular biology, fermentation and the like. With the development of gene manipulation techniques in the 1970s, there was a major paradigm shift. For the first time microorganisms were used to synthesize compounds that they had never synthesized before, e.g. insulin production in *E. coli*. One of the earliest commercial applications of gene-manipulation techniques using bacteria was the production of human proteins with therapeutic applications.

Genetically modified organisms (GMOs) are organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The initial focus of plant biotechnology was on improving agronomic traits through the protection of crops against pests, pathogens and weeds thereby increasing yields. Scientific approaches revealed that, in many cases, single genes transferred from another organism can provide high levels of protection. The technology is often called "modern biotechnology" or "gene technology" or else as mentioned above "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another or between non-related species. Genetically modified foods (GM) refer to those foods which are derived from GMOs. Genetically modified foods (GM foods) are the focus of a current public debate that asks whether we should be eating (and growing and selling) these foods. One side of the argument claims GM foods hold the potential to end world hunger and the use of pesticides. The other side claims the risks still are unclear, speaks of "frankenfoods" and warns of superpests or superweeds.

With all criticisms, GM foods are being accepted by the consumers in many countries, because there are some perceived advantages either to the producer or consumer of these foods such as lower price, improved qualities like nutritional value and pharmaceutical value etc. However, generally consumers like Sri Lankans consider that traditional foods that have often been eaten for thousands of years are safe. One of the major concerns about GM crops is whether they will have negative effects on health. Some giant Biotechnology companies have claimed that genetic engineering is no more unpredictable and dangerous than traditional cross-breeding, and as a result, GM crops should not be subjected to special or extensive safety assessments.

Public debate on the use of GMOs in seeds, crops and foods continues to be highly polarised. There are at least two sides for each problem if not multi-faceted. For example, medical professional and researchers appreciate aspirin one time and then rejects later depending on the updates of findings on the use of aspirin. This argument continues alternatively and endlessly. A negative view on a matter at one time can be turned into a positive acceptance later depending on perceptions of people, current scientific findings and the direct benefit that the people would get out of it. Hence, an optimistic belief in a food whether it is GM or natural can be a myth today and alternatively it can be a fact tomorrow. There is neither absolute truth nor fraudulence. Therefore, this article focuses on both good and bad sides of GM foods leaving the reader to decide on what myth is and what facts are. In order to do so, let's have a closer look at GM foods, their potential benefits and possible threats.

How GM foods are made?

As mentioned above, a GM plant is one that has had one of its genes altered. GM gives plants new, useful properties, like being able to resist insects or the cold and drought. Sometimes GM means putting a gene from another species into a plant. Innovations leading to an increased range of food products from currently available raw materials and introduction of new raw materials with better quality characteristics are the strategies to meet increasing consumer demand for high quality food products. In a way this is true specially when the world badly needs food to feed the people.

Herbicide tolerance of food crops

Weeds being real competitors against crop plants for nutrients, water and space severely affect the crop yield. Both crops and weeds carry out similar biochemical reactions within their cells. Therefore, developing herbicides that are selective for weeds is somewhat difficult. As an alternative measure, herbicide tolerance is achieved through the introduction of a gene from a bacterium conveying resistance to some herbicides. In situations where weed pressure is high, the use of such crops has resulted in a reduction in the quantity of the herbicides used. Hence, modifying crop plants to become resistant to broad-spectrum herbicides is more feasible and economical. This property can be achieved through two ways; in first instance, the target molecule in the cell either is rendered insensitive or is overproduced and in the second instance, a pathway that degrades or detoxifies the herbicide is introduced into the plant.

The benefit of herbicide-resistant transgenic crops reflects in the increased yield and seed quality as competing weed species are eliminated. Initially, there was a public concern saying that the use of herbicide-resistant transgenic crops would lead to excessive use of herbicides which in turn would have a serious impact on the environment. However, contrary to these predictions, the introduction of herbicide resistant plants has actually reduced chemical use by up to 80% in many areas, as farmers adopt better weed-control policies and switch to herbicides with low use rates. Another public concern was that these transgenic plants might transfer these genes in to weed species, resulting in a new breed of 'superweeds'. This may be true, but it is too early to make a conclusion on this issue. We have to think of both benefits and risks of herbicide-resistant crops on one hand and strategies to combat adverse effects associated with gene transfer to weeds on the other hand.

The availability of molecular-genetic techniques also enabled the insertion of specific genes that impart specific quality traits to fruits or inhibit degradation mediated by enzymes that otherwise would lead to rapid deterioration of the fruits. For example, some GM crops (e.g. Tomato) were modified with specific genes to inhibit ethylene biosynthesis and cell wall polymer degradation. Biotechnology has become one of the techniques available to the food industry, for increasing its competitiveness, quality, and range of products. Inhibition of cell wall degradation through genetic engineering has been used as a strategy to enhance the shelf life and firmness of tomato fruits and to improve the qualities of processed tomato products. The production of GM tomatoes with improved processing parameters (e.g. acceptable colour, flavour, firmness, texture, essential rheological properties and handling characteristics to satisfy consumer etc.) may offer such an opportunity in the near future.

Resistance to viruses

There is a useful phenomenon known as cross-protection, in which infection of a plant with one strain of virus protects against "super-infection" with a second, related strain. The mechanism of cross-protection is believed to be based on the viral coat protein. Different transgenic plants that express the Tobacco Mosaic Virus (TMV) coat protein and less vulnerability to virus infection have been developed. Transgenic squash containing multiple viral coat-protein genes and demonstrating resistance to cucumber mosaic virus, water-melon mosaic virus 2. It is worth while noticing that no control measures have been developed yet against viral diseases, by using conventional methods.

Resistance to insects and other pests

Insect pest problems represent one of the most serious biotic constraints to crop production. For example, more than a quarter of all the rice grown in the world is lost due to insect pest attacks. At present, almost all commercially produced insect-resistant transgenic crops express toxin proteins from the Gram-positive bacterium *Bacillus thuringiensis* (Bt). During sporulation, *B. thuringiensis* produces protoxins called crystal proteins. These proteins are potent and highly specific insecticides. Bt toxins have been used as topical insecticides since the 1930s, but it was not that popular because of their rapid breakdown rate on exposure to light.

As a solution to this problem, Bt genes were initially introduced into tomato and tobacco and later into cotton which enabled the production of insecticidal proteins remarkably. However, field tests of these plants revealed that higher levels of the toxin in the plant tissue would be required to obtain commercially useful plants. After a series of trials, first transgenic insect-resistant potato crop was released to the market by Monsanto company. The same company also released the first commercial transgenic, insect-resistant varieties of cotton and maize. Many other biotechnology companies have now produced Bt-transgenic crop plants resistant to a range of insects.

GM crops for modified starches

Food and other industries use a wide range of different starches. These different starches are obtained by sourcing the starch from different plant varieties coupled with chemical and enzymatic modification. The genetic modification of plants offers a new approach to creating novel starches with new functional properties.

Golden Rice

According to the World Health Organization (WHO), Vitamin A deficiency (VAD) affects millions of people worldwide and about 250,000 to 500,000 children go blind every year and half of them die within 12 months due to VAD. The creation of Golden Rice, a GM rice synthesising β-carotene, goes far back to 1984. A team from the Swiss Federal Institute of Technology in Zurich had succeeded in inducing genetically modified rice to produce β-carotene (provitamin A). The human body can use this provitamin A to bio-synthesise essential vitamin A. Since grains of rice took on a yellow colour from the provitamin, this variety was named as Golden Rice.

One argument brought up by opponents of Golden Rice is that it might interfere with existing vitamin A supplementation and fortification programs and campaigns. This argument suggests that we should opt for the status quo. Such an attitude disregards the potential of Golden Rice to provide viable, sustainable alternatives.

This new technology has also aroused controversial debates on its nutritional impact and cost-effectiveness which are remaining unclear. On the other hand, we need to assess the current burden of VAD in the world from a public health perspective, and simulate the potential alleviating impact of Golden Rice using representative household food consumption data. Assessing the health benefits and overall costs suggests that Golden Rice is very cost-effective. High-value-added crops like GM rice can promote human health remarkably. Hence, GM foods of this nature should be socially accepted irrespective of their genetic modification status by virtue of a net positive in any risk–benefit analysis.

Plant edible vaccines

Since recent past, edible vaccines have received considerable attention from researchers in both academia and industry. Scientists have pioneered edible vaccines by introducing selected genes into the plants to facilitate the production of the encoded protein. The main goal of an oral vaccine is to induce a mucosal immune response and a subsequent systemic immune response. For biotech and drug industries, biopharming offers economic and health benefits once the current cycle of product development reaches the commercialization stage (Table 1).

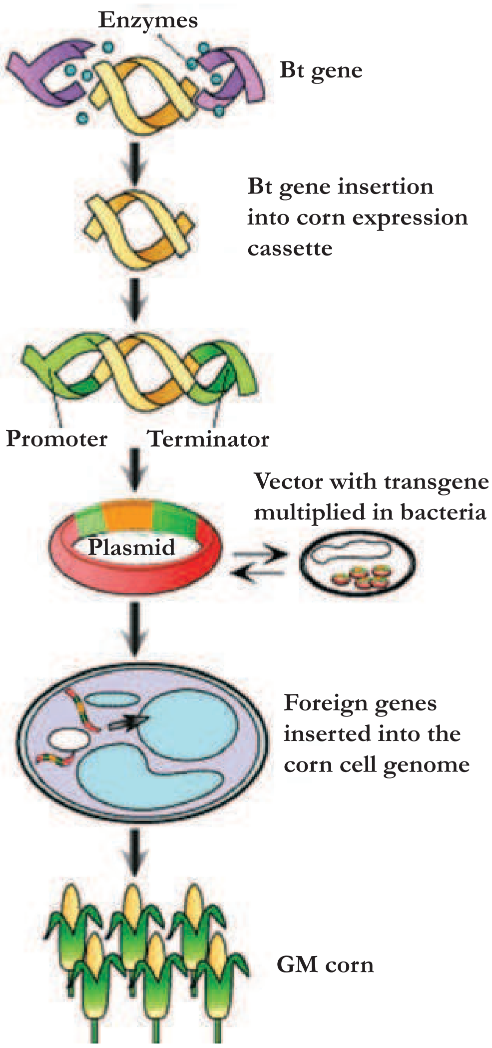
Table 1 Advantages and disadvantages of edible vaccines

Advantages	Disadvantages
The plants producing the edible vaccines can be grown in countries like Sri Lanka	Plants as living organisms can be subjected to changes and therefore the continuity of the vaccine production might not be guaranteed.
Plants are regularly used in pharmaceuticals, and there may be purification protocols established	The edible vaccines could be mistaken for regular fruits and consumed in larger amounts than might be safe.
Growing plants (edible vaccines) is much cheaper than producing vaccines.	The dosage of the vaccines might be variable depending of the size of the fruit.
Plants cannot host most human pathogens, so the vaccines will not pose a danger to humans.	If the vaccines were grown in fields or on trees, safety would become a big issue.

In this connection, study species include potatoes, tomatoes, bananas, lettuces, rice, wheat, soybean, corn and legumes. Fruits, vegetables and leafy salads can be suitable for the production of recombinant subunit vaccines, food additives and antibodies for tropical passive immunotherapy. Potatoe is being widely used for the production of plant-derived vaccines that have been administered to humans in most of the clinical trials. Tomatoes were used to produce the first plant-derived rabies vaccine. Bananas have been considered as hosts for the production of recombinant vaccines, since they are widely grown in those countries where vaccines are most needed Banana can be easily used as edible vaccines as it is often the first solid to be given to infants. In addition, banana does not require to be refrigerated as conventional vaccines do. The additional advantage of bananas is that they can be consumed raw or as a puree by both adults and children. Would not a normal layman prefer eating a banana or tomato rather than having an injection?

There can be two main concerns over edible vaccines; contamination of food crops through cross pollination and the vaccine itself in plant debris spreading as dust and as pollutants in surface and groundwater. The vaccine antigen may affect browsing animals and humans living in the area drinking vaccine-polluted water or breathing vaccine-polluted dust. Therefore, it is of paramount importance that the cultivation and production of pharmaceutical crops should be limited to controlled production facilities such as greenhouses or plant tissue culture laboratories. The main safety concern is that the oral vaccine preparations will induce "immune tolerance", thereby making the individual susceptible to, for example, the hepatitis B virus.

Plants have advantages compared with traditional systems for molecular farming of pharmaceutical proteins. However, for these benefits to be fully realized, issues like risk to the food industry and the environment need to be attended. A combination of strong and adaptable regulatory oversight with technological solutions are required in order to realise the full potential of plant molecular farming. For all, plants need to be viewed as a possibility among many for manufacturing therapeutic proteins.



General schematic of GM crop production

Pharmaceutical production through GM animals

The first GM mammals (mice) were produced in the mid 1970. In 1982, a mouse was genetically modified to produce a foreign protein, rat growth hormone, which caused it to grow visibly oversize. Animals have been genetically modified by the insertion of human genes coding for therapeutic proteins, which are generally produced in the animal's milk. Similarly, there are attempts to modify chickens to produce drugs in eggs as well. There is a wide range of benefits that human can obtain from GM animals. But there are strong criticisms. Those opposing GM animals claim that the genetic modification of animals is an assault on the integrity of another species. Not only can genetic modification cause considerable suffering to the animals involved, but it also changes our relationship with the natural world and contributes to the commodification of animals by using them as we wish merely for maximum commercial gain.

Do milk, eggs and meat from GM-fed animals contain GM material?

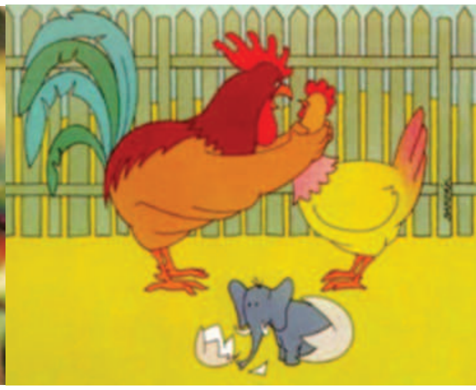
Earlier it was believed that GM crop material is degraded during processing into feed and during digestion. Some literature showed that no GM DNA materials were found in foods like the milk, eggs or meat of GM-fed animals. In recent past, several of these studies found that plant chloroplast DNA from animal feed is present in milk, eggs and meat.

Similarly, another study detected GM soya and GM sequences in shop-bought milk. Some studies have suggested that the DNA may have been a result of contamination of the milk by dust from the GM feed in the dairy. Whilst this is unproven, this points to a potential common source of contamination with the use of GM feed and does not change or undermine what was found with GM DNA in the milk. Nevertheless, biotechnology companies have claimed that genetic engineering is no more unpredictable and dangerous than traditional cross-breeding, and as a result GM crops should not be subjected to special or extensive safety assessments.

Food for thought

Production of GM plants/animals/foods usually involves introducing a package of genetic material derived from one organism (or several) into the DNA of another, often a completely different species. It is never based on the plant's normal reproductive processes. Instead, the foreign DNA is inserted into the plants own DNA either by using the infective process of a disease bacteria or by bombarding the

GM labelling issues



GM food; even sky is not the limit

Possibilities of GM crops

cells with fine metal particles coated with the foreign DNA. This artificial DNA insertion breaks down the natural biological mechanisms that normally maintain the genetic integrity of species.

Since the inserted genes usually come from other organisms such as bacteria or are synthetically produced, the proteins they produce are often new to the animal or human diet. The production of these proteins may also involve a new biochemical pathway in the plant or affect an existing one. This may result in the production of other novel protein or biochemical by-products, some of which could be allergenic or toxic. This explains why GMOs have been associated with allergic reactions.

Another issue is that, unlike naturally occurring genes which are generally only active at certain times and in certain cells, transgenes are usually active the whole time and in all cells. This means that the gene's products and any by-products are present in all of the plant's tissues. For example, unlike normal non-GM maize, the Bt toxin is present in all the cells in Bt maize, the main GM maize used in animal feed.

It has now been found that genes usually do not operate in isolation or completely dictate to the plant. Genes are instead themselves controlled by numerous interactive plant regulatory mechanisms, including other genes and cellular processes, in a complex system which is not yet understood fully. The result is that the same gene can behave in different ways at different locations, depending on the regulatory elements it ends up next to. As genetic engineers do not know the effects of the different locations and cannot control where the genes end up in the plant DNA, their unpredicted side effects may easily occur.

A study carried out by Australian scientists who inserted a previously harmless bean protein into a pea, which then caused allergic reactions in mice, revealed that a harmless protein in one organism can become harmful when inserted into another organism, even if its sequence of amino acids remains completely identical. This phenomenon is called "post-translation modification" according to which, different sugars, lipids or other molecules attach to the protein and modify its function.

The number of people who were in danger of malnutrition worldwide has decreased significantly in the past 30 years thanks in part to the Green Revolution of the 20th century. However, an estimated 800 million people still lack adequate access to food. The world now looks in to a second potential revolution; "Gene Revolution" in which the production of GM crops/animals/foods may be tailored to address ongoing agricultural problems. One may ask a question "Can the GM foods be useful or beneficial to the Humans?" The answer to this question is "Yes and No".

GM foods exhibit the potential to have much wider impact, solving many of the current problems in agriculture worldwide. Despite its attendant challenges and alternatives, the GM crop technology shows great promise. Like the Green Revolution which flourished in earlier times, the GM revolution has the potential

Dolly and surrogated mother (Born in February 1997)

Dolly, the first cloned sheep was born in February 1997

to achieve substantial production increases and to reduce the need for agricultural chemicals and scarce resources like water. Both the successes and failures of the Green Revolution provide useful lessons for how to make GM crop technology a desirable and sustainable agricultural concept applicable for the countries that suffer from less production than the local demand. As far as Sri Lanka is concerned, we have enough cultivatable lands and resources. With the end of 30-year war, now our cultivatable land in the country has increased back remarkably. If the policy makers and relevant authorities pay due attention to facilitate rational cultivation, distribution, value-addition and marketing of agricultural produce within the island and beyond, we will not have any issue. Hence, for Sri Lanka to switching to GM food production is not a burning issue yet. But if we need to produce foods for export market, we may need to be dependant on GM technology. In this context, as the Green Revolution demonstrated, in order for people to make GM crops truly beneficial to the developing world, plant breeders and other scientists must be familiar with the local environment and the planting methods of each district for which they are developing GM crops.

One of the most remarkable facts about the development of GM crops is that, despite years of immense public concern, political controversy and the developing scientific understanding of the risks of GMOs, very few of these risks are actually assessed in the official regulatory approval process. Those who are for GM foods merely want to introduce them without a thorough and systematic testing procedure as it is superiorly profitable. On the other hand, those opposed to GM foods generally believe that any overall assessment of the list of risks indicates that GM crops are currently far too risky to be used for food or animal feed. Within this debate we are talking about GM food myths and facts. Gene Revolution is a relatively new area based on molecular level techniques. This is hardly visible to normal layman and hence there is room for myths and insincere capitalisations.

A perceived safety concern on GM foods has been raised about unintended entry to the food chain. We need to treat foods as a valuable production factory for foods, vaccines and other pharmaceutical products as we have done for other food-producing organisms like microorganisms. Yeast, for example, is used to produce pharmaceuticals and vaccines, as well as bread and beer. In this way, we will bring beneficial products to the marketplace, to save lives without unnecessary risk. In this context, local and international authorities should allow the production of GM crops/animals/foods after having the produce assessed on a 'case-by-case' basis as there is no way that one can give a blanket endorsement to GM foods as a whole. The giant countries have begun the Gene Revolution. Willy-nilly, we are compelled to become victims or beneficiaries. We Sri Lankan, as an intelligent nation, should be able to select the good and to reject the bad. We may give green light to products like edible vaccines as new pharmaceuticals from botanical sources. Likewise, the world should prioritise what is to be promoted and what is not. In this context, institutions like media, decision-makers and Academia have an essential role to play in an unbiased manner. Still, one should remember that, GM foods or any other intervention alone will not eliminate hunger. It has to be a complementary approach. Then only can it be a true "Gene Revolution."

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Medical Science

Genetics in Medicine

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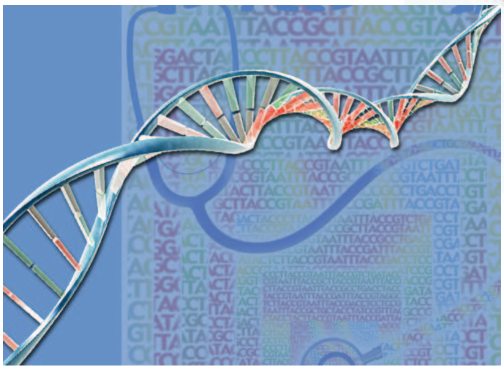
Advances in Genetics are transforming medicine faster than ever before. Genetics is everywhere in medicine. This article briefly reviews how genetics is making an impact in medicine.

Genetic testing is used to diagnose inherited diseases. Take the example of thalassaemia. There are two types of thalassaemia – alpha thalassaemia and beta thalassaemia. When a child is diagnosed to have thalassaemia a genetic test can be used to find out whether the mutation is in the alpha gene or the beta gene. If the mutation is in the alpha gene, then the child has alpha thalassaemia. If the mutation is in the beta gene, then the child has beta thalassaemia. Genetic testing is also useful to diagnose acquired diseases that are the result of a genetic change. In case of these diseases, the person gets normal genes from his/her parents, but he/she develops a genetic change in his/her own cells resulting in an illness. There are many examples of this. One of the well known examples is chronic myeloid leukaemia (CML). In this condition, some cells in the bone marrow acquire a chromosomal abnormality – a balanced translocation between chromosome no. 9 and chromosome no. 22. This translocation results in the creation of an abnormal fusion gene called the bcr/abl fusion gene. This is transcribed in to the bcr/abl mRNA. The abnormal mRNA is translated into a fusion protein which causes CML. We can diagnose CML by detecting the presence of bcr/abl mRNA in the body of a person who is suspected to have the condition based on bone marrow histopathological findings using a genetic test. Not only that, once the person is treated, we can find out whether he/she has responded to treatment by finding out whether the abnormal cells have cleared from the body by repeating the same test. These are only two examples of genetic diagnostics. Thousands of conditions can now be diagnosed based on genetic tests. You can read about them at http://www.ncbi.nlm.nih.gov/sites/GeneTests/?db=GeneTests.

Genetic testing can also be used to detect infectious diseases. There are many examples. The common ones are the genetic tests for Mycobacterium Tuberculosis, Hepatitis B virus, Hepatitis C virus, cytomegalovirus, and Dengue virus. These enable fast and reliable diagnosis of infectious diseases. Take for example the genetic test for the Dengue virus. It is very commonly used in people with fever to find out whether they have Dengue. The test for cytomegalovirus is used commonly in a special group of people, people who have undergone kidney transplantation. These people are prone to cytomegalovirus infection. Antiviral treatment for cytomegalovirus is very expensive. So finding whether the patient has the infection definitely is important. In addition it is necessary to find out whether the patient has responded to treatment by repeating the test after treatment. A special genetic test called quantitative real time PCR makes it possible to do that. It is the same type of test that is used in the case of the bcr/abl mRNA that was mentioned before.

People are protected against infectious diseases by immunizing using vaccines. Recombinant genetic technologies are used to develop vaccines against infectious diseases. Most vaccines now in the market are based on recombinant genetic technology.

People are protected against infectious diseases by immunizing using vaccines. Recombinant genetic technologies are used to develop vaccines against infectious diseases. Most vaccines now in the market are based on recombinant genetic technology. Infectious agents however, undergo change and develop resistance to commonly used antibiotics. Genetic testing can be used to identify resistant strains of bacteria. In addition knowledge about the structure of bacterial as well as viral pathogens can be used to design new antibiotics to combat infectious diseases. Genetic knowledge is also used to develop treatment for other illnesses. Again take the example of CML. The treatment for CML is a drug that blocks the action of the bcr/abl fusion protein. Recombinant gene technology can also be used to make therapeutic products (for example, insulin, interferons) more affordable.



Medicine is not all about diagnosing and treating illnesses. It is also about creating an environment in which people can live a healthy life. Genetic technologies are used to improve the environment – e.g. sanitation, clean water, bioremediation, etc. In addition genetically modified food with increased nutrients have been developed to counter nutritional deficiencies

Genetics was once thought of as most useful for those who could pay for it in affluent countries. The appreciation that much could be done for the developing world about a decade ago (1,2) resulted in a shift in emphasis which has made it possible for us in the developing world to benefit from these technologies. Genetics is not a foreign concept anymore. Genetics is here to stay in Sri Lanka. Hundreds of genetic tests are ordered by doctors in Sri Lanka daily. The people of this country are increasingly experiencing genomic medicine when they seek health care.

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Genetics: Present & Future

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When you plant a mango seed you always get a mango tree growing from the seed, never a coconut tree and vice-versa you never have a mango tree growing from a coconut. The reason for this is the genetic code that is embedded inside the seed that carries the blueprint for what type of a tree it should grow into. The same applies to all living organisms. The term "genetics" is an ancient greek term used to describe the study of the science of genes, heredity and variation in living organisms. The investigation of single genes is the primary focus of genetics, identified by some as "molecular biology". This is in comparison to genomics which involves studying the whole genome or complete set of genes found in an organism. Modern genetics was started by Gregor Mendel, a monk and scientist who traced the inheritance patterns of certain characteristics in pea plants and explained them through simple rules and ratios. Even though Mendel started this work in the mid 19th century, it was only in the early 20th century that the importance of his work was understood and the term "genetics" was used and popularized by William Bateson.

Later on in the 20th century, DNA or deoxyribonucleic acid was identified in 1944 by Avery, McLeod and McCarty as being responsible for transferring "genetic material". Then in 1953 the famous duo Watson and Crick determined the structure of DNA, the now familiar double helix shown in figure 1. As depicted the string of DNA is composed of sugars (blue pentagons), phosphates (cream-colored circles) and four types of nucleotides: Adenine (A), cytosine (C), guanine (G) and thymine (T). The A & T form two hydrogen bonds and G and C form a triple bond to form what is known as base pairing to assemble the double helix. All genetic material (other than in some viruses) exists as a combination of these four nucleotides with base pairing in a double helix and form the alphabet of all genomes, which is an organism's complete length of DNA. For example the human genome consisting of over 3 billion nucleotides, has various combinations of these A, C, G and T's. Only 22,000 to 25,000 genes are found encoded within the human genome. However, these genes only cover 2% of the 3 billion base pair genome and the remainder consists of non-coding regions which contain among other things, regions that regulate gene expression. To make things more interesting it was discovered that 99.9% of the genome is similar in all humans and our genome is 99% similar to the chimpanzee! Further details of the human genome project can be found at the following website: http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml.

As outlined in figure 2 the genes carry the information that forms proteins that perform the various functions in the cells. The figure depicts the hemoglobin gene as

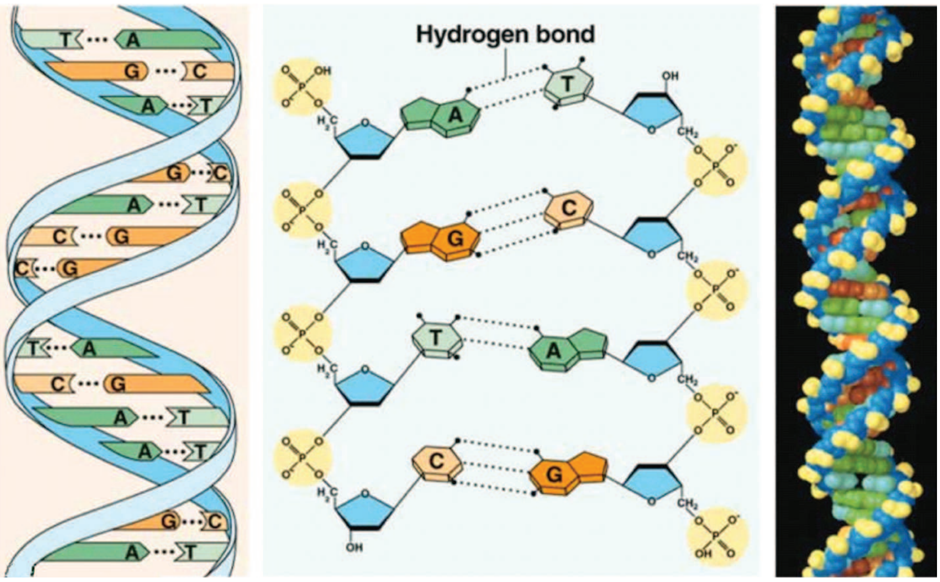

Figure 1

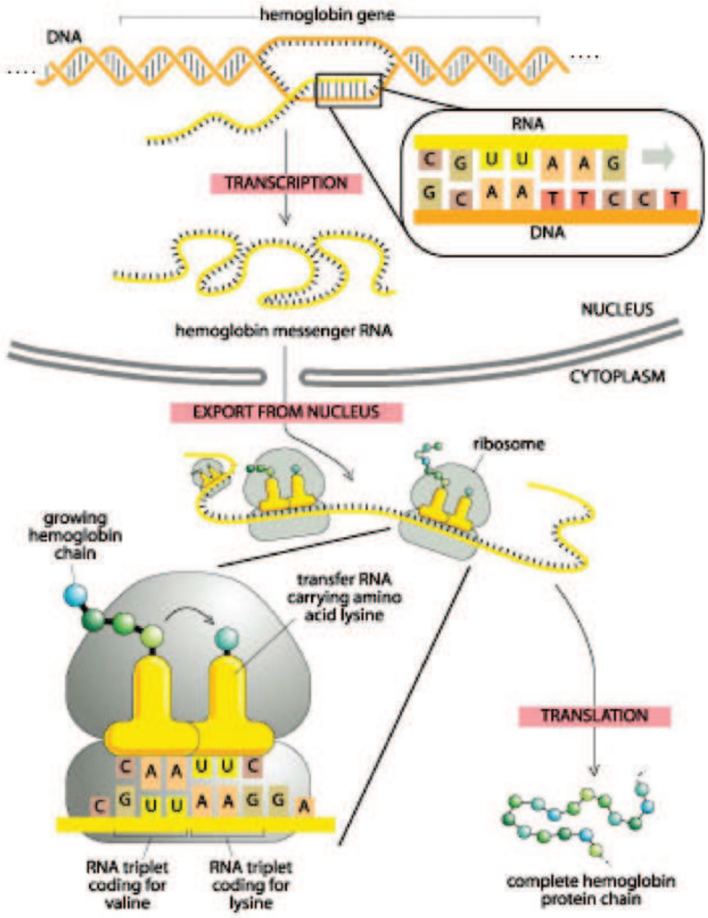

Figure 2

an example. In essence the proteins are the real work horses of each cell, giving each cell its form and function. As geneticists started to understand how to decipher the genes and the genomes of organisms, they increasingly started to study the functions of individual genes and the proteins that are eventually made from the instructions given in these genes.

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Procedures and discoveries that changed the field of Genetics

A number of discoveries have changed the field of genetics allowing it to expand in leaps and bounds to be at the advanced state it is in today.

One of the major developments was the ability to read the DNA molecule using chain termination DNA sequencing. This method was developed by Frederick Sanger in 1977. This revolutionalized the field and allowed scientists to read the nucleotide sequence of DNA molecules and identify genes. More details about this method can be found at this web site: http://jgi.doe.gov/education/how/

Currently, there are instruments that allow this type of sequencing in Sri Lanka at universities and private sector laboratories.

Another major development is the development of a technique called "polymerase chain reaction" or PCR. This method allows one to make millions or even billions of copies of a particular DNA sequence starting from just a few copies. While this method is a combination of several well established reactions no one had really tried it until Kary Mullis developed it in 1983 and won the Nobel prize for it in 1993. His Nobel lecture is interesting reading for scientists as well as non-scientists and can be found at this site: (http://nobelprize.org/nobel_prizes/chemistry/laureates/1993/mullis-lecture.html). This procedure which allows us to bypass the need to use bacteria for amplifying DNA is quicker and more convenient than using bacteria. PCR has become one of the most widely used indispensible techniques in medical and biological research laboratories for a wide range of applications. This includes the detection of various infectious agents, such as bacteria and viruses, the diagnosis of hereditary diseases and even genetic finger printing for paternity testing and forensics. As mentioned before it is a very powerful technique which allows us to amplify tiny amounts of

DNA to a large enough amount for other uses. Due to the lack of space I will not be going into detail in this article, but the following website explains the method in detail: www.dnalc.org/resources/animations/pcr.html

A number of laboratories in Sri Lanka do PCR-based diagnostics for various pathogens that cause Dengue, tuberculosis and HIV among many others. Even though the technique maybe relatively expensive it is fast and accurate.

Present

These above mentioned techniques among others have allowed us to understand the different genes and genomes to a level that has not been possible before. The field of genetics has rapidly moved forward and currently whole organisms are being sequenced and their genomes are freely available online for use by scientists and others. Table 1 depicts a list of genomes that have been completely sequenced and these sequences are available online at the following site: www.ncbi.nlm.nih.gov/sites/genome

Table 1 Genomes that have been sequenced and the year of completion

- The first complete sequence of an organism – *Haemophilus influenzae* (1.8 Mb) - 1995
- *S.cerevisiae* bakers yeast (12.1 Mb) – 1996
- *C.elegans* round worm (97 Mb) -1998
- *D. melanogaster* Fruit fly (180 Mb) -2000
- *Arabidopsis thaliana* Weed (125 Mb) Dec 2000
- *H. sapiens* (3000 Mb) – Draft sequence 2001
- *Plasmodium* genome - 2002
- Rice genome - 2005
- Corn (Maize) - 2008

We currently have the knowledge to identify a useful gene, clone it into bacteria and then express it to make the protein. Many useful proteins are made in this manner. One prominent example is insulin for diabetics. It used to be that insulin was purified from pigs for use in humans and this was very costly since one pig only gave a small amount of insulin. However, by cloning the gene and expressing it in bacteria or other types of cells we are able to make large amounts of insulin at a very cheap cost.

Knowing the unique DNA sequence of various organisms allows us to specifically identify them using techniques such as PCR. Molecular based diagnostics allows us to identify various pathogens. A number of laboratories in Sri Lanka do PCR-based diagnostics for various pathogens that cause Dengue, tuberculosis and HIV among m any others. Even though the technique maybe relatively expensive it is fast and accurate. Further detailed genetic studies of such pathogen strains allow more information about the pathogen to be gathered and valuable epidemiological data can be obtained. Knowing the sequence of human genome has also allowed doctors to identify changes in our genomes that make us vulnerable to various diseases. A specific mutation in the hemoglobin gene can cause sickle cell anemia and this can be identified using a genetic test. Cystic fibrosis, Down syndrome and Muscular dystrophy are some of the debilitating disorders that can be identified by genetic tests even before the disease is apparent. Increasingly more mutations in genes are being identified that lead to increased susceptibility to various other diseases including cancers.

Another aspect of genomics that directly touches our lives is the ability to establish paternity in humans. By genetic testing you can confirm whether the child is really from those parents. The most well known paternity case in Sri Lanka was that of baby 81 who was claimed by a number of parents in the aftermath of the tsunami in 2004. Genetic testing clearly established the parents and allowed the case to be resolved. Similarly, genetic testing is used in forensic cases in Sri Lanka as well as elsewhere to identify persons that were present at a crime scene.

Genetic engineering and its effects are highlighted in various films such as Jurassic Park. Unfortunately they tend to exaggerate what is possible with current technology and this tends to create an unnecessary fear in the minds of the general public. We still have a lot of technological hurdles before we can take dinosaur DNA that is preserved in amber and resurrect a dinosaur. One needs to understand that having only the DNA is not sufficient and that we need the proper environment for the proteins to get transcribed in the proper sequence to make the proper organs at the correct time. This is much more complicated and humans have not been able to take DNA from an animal and have it grow into an organism without the proper "cells" from the same species to implant the DNA. Dolly the transgenic sheep that we have all heard of was done in a similar manner; the DNA was put back into egg cells from another sheep. Therefore we are still a long way away from making dinosaurs!

Even though we cannot create dinosaurs we are starting to insert useful genes into different organisms that can serve a useful purpose for humans. Such organisms are called "transgenics" and both transgenic animals and plants have been constructed. The gene of the green fluorescent protein (GFP) has been cloned from the jelly fish and has been expressed in various cells of different species. By using different promoters (DNA regions found before genes in genomes to promote expression) to express GFP in different cell types, they are used to mark cells for tracking them inside the body. This method is used extensively in transgenic mice to understand basic biological processes. In addition, various transgenic plants have been made and are used in various countries. The first transgenic plant, a pesticide resistant tobacco plant was created in 1983. This plant contained genes from a bacterium,(*Bacillus thurengiensis*) that kill insects, thus creating a pesticide resistant plant, preventing the need to spray toxic chemicals to kill the insects. Similarly one of the most successful genetically engineered (GE) crops currently in use is the Roundup (herbicide) resistant gene inserted in crops. Monsanto (the US company that developed it) have turned this product into a very profitable business since they also manufacture the herbicide Roundup (active ingredient is Glyphosate). This transgenic plant allowed farmers to stop the growth of other weeds by spraying the whole area with Roundup, thus stopping weeds from growing, but not affecting their crop. Countries such as the United States have widely adopted GE crops. This is to a point where in 2010, 93% of Soya beans and ~75% of cotton plants grown in the US were GE crops. However, most of Europe has prevented the use of GE crops and until 2006 the European Union had a formal ban on GE crops. Now it is allowed in very limited areas, but heavily regulated. China was one of the first countries to allow the use of GE crops, while India has more recently approved the use of some GE crops, such as transgenic cotton.

Future

The field of genetics has matured to a level that many different areas rely on the information (or the DNA coding information) found in the various genomes. We are rapidly approaching a point where within the next few years almost all organisms that are of importance to humans would have been completely sequenced providing all the genetic information for further studies. Once this information is available the next step will be how we harness the knowledge to our benefit. Already one sees this happening in various areas.

While the use of GE crops has been widely successful in countries such as the US, it has not been adapted as widely in countries such as Sri Lanka and India with small farming plots and a bigger diversity of pests. But considering the growing demands for increased food production, pollution problems and production efficiencies, GE crops may need to be seriously considered as an option in the future.

Transgenic animals are another new area that is expanding due to new knowledge of genetics. Scientists have recently made a goat (named "Sweetheart") that has the human gene, antithrom bin, inserted in its genome. This allows antithrombin to be produced in its milk and can be easily purified for human use. This is the first drug produced in the milk of a genetically engineered animal that has been approved by the US Food and Drug Administration. The amazing thing about this is that we have done away with all the previous manufacturing facilities that were needed and once the goat is produced all you need to do is feed the goat and milk it. You need some expertise to purify the antithrombin from the milk and each goat can annually produce the equivalent of what we get from 90,000 blood donations. If it is necessary to expand production you breed the transgenic goats. This is the future of high end manufacturing of protein-based biopharmaceuticals.

What does Sri Lanka need to do to build up resources and take advantage of the knowledge offered in the field of genetics

Educate people about the true benefits of genetics and have them understand genetic engineering and its true potential. This will go a long way in making the benefits of genetics research widely available to the population. One such example is paternity testing in which the Police, Judicial officers and others in the field have been educated about the benefits and the relevant information has been disseminated. As a result the man or woman on the street accepts the results and trusts the result that is given from this paternity testing.

Provide grants and funding for setting up sequencing facilities and databases to genetically characterized plants and other living organisms found in Sri Lanka.

This should be setup as a complement to existing institutes such as the Plant Genetics Resource Center in Peradeniya and other Research Institutes in Sri Lanka.

The next step is training bioinformaticians and setting up databases for accessing the information as the need arises. Such a program is already being done by the Human Genetics Unit at the Medical Faculty Colombo for various human genetic variations found in the Sri Lankan population. Such databases can be expanded to include our indigenous plants and other unique organisms such as bacteria, and this will help to prevent piracy and protection of our indigenous resources.

As shown in table 1, many of the important plant species and animals have already been sequenced and the data is freely available. All the major Sri Lankan crops such as tea, rubber, coconut and rice have been sequenced. This knowledge can be harnessed to look at other varieties of the same species found in Sri Lanka and elsewhere. One such example is rice, in which Sri Lankan scientists can look for changes in genes in our local varieties which may have enhanced useful characteristics such as drought tolerance. Once the presence and sequence of such genes are known they can be bred into the more popular varieties of rice. This has been traditionally done in all the crops using phenotypic characterization (not using genetics) and takes a long time to develop a new variety. By using genetics and gene marking techniques such as "marker assisted selection", one can reduce the time period to generate the new strains. Focused research with adequate funding can thus drastically increase the number of new varieties and allow us to obtain them faster to be given to farmers.

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Another area that needs to be developed is the regulatory authorities for handling GE foods and plants that will inevitable come to our shores. Countries such as Sri Lanka have to setup the proper regulatory authorities with personnel knowledgeable on the science as well as social and economic aspects before the adaptation of genetically engineered crops. Even though the science is relatively clear, the economics and social aspects of adaptation of these GE crops has to be evaluated and thought out. Even though certain efficiencies can be gained by having GE crops it may upset the export markets (example; tea) we have carefully developed over the many years.

The field of genetics has developed rapidly over the last few decades and a proper understanding of these advances combined with the proper adaptation of new technologies can bring vast benefits to the people of Sri Lanka. It is the job of scientists and teachers to make sure the larger population understands this and accepts the vast benefits that this field can bring to Sri Lanka.

Dr Dharshan De Silva

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Bio-piracy and the legal regime in Sri Lanka

Jagath Gunawardana

The taking of Intellectual Property Rights(IPR) over the biological material, including genetic material, has been a problem confronting Sri Lanka for the past three decades. It is known as Bio-piracy and is usually, but not always, associated with the export of biological material. What happens in Bio-piracy is the gaining of exclusive monopoly rights over the biological material of one country by individuals, institutions or companies of other countries that leads to the restriction of the obstruction of, or the denial of the rights of the country of origin. This infringement of the rights prevents, restricts or interferes with the use of the material and products. This has nothing to do with the physical loss of the biological material but denote the loss of rights. The act of bio-piracy involves the use of force as it is in other types of piracy, but the difference is that the force is exerted through the intellectual property laws.

The intellectual property tool widely used to commit bio-piracy is the Patent, while there are a few instances in which it is a Plant Breeders Right , which is known as the Plant Variety Protection Right in some countries such as the U.S.A. It is interesting to note that the incident that led to the coining of the word bio-piracy was committed with the help of the Plant Variety Protection Rights, in which a resident of U.S.A got two Plant Variety Protection Rights certificates for two coloured cotton varieties that are indigenous to Peru. The Canadian public interest body then known as RAFI, which publicized this incident in 1993 coined the term bio-piracy to describe this activity and the term has since become popular and has been used widely.

The law that provides for the granting of IPR in Sri Lanka is the Intellectual Property Act, No.36 of 2003. This, however, does not cover the Plant Breeders' Rights. An Act to grant Plant Breeders Rights in Sri Lanka has not yet been passed and hence the possibility is there only for obtaining patents. According to Section 63 of this Act, an invention is patentable if it is new, involves an inventive step and is industrially applicable. The term invention is defined (in Section 62(1)) to mean an idea of an inventor, which permits in practice the solution to a specific problem in the field of technology. According to Section 62(2), an invention may be, or may relate to a product or process.

An invention has to fulfill the following three criteria for it to be eligible for a patent;

1. It has to be new – Novelty

   Since there is no way to define what is new, the Act defines what is new by defining what is not new. Accordingly, Section 64(1) states that an invention is new if it is not anticipated by prior art. The term "prior art" is in turn defined in Section 64(2) and shall consist of;

(a) Everything disclosed to the public, anywhere in the world, by written publication, oral disclosure or the use in any other way, prior to the filing or, where appropriate to the priority date of the patent application claiming the invention.

However, there are two exceptions to this, which are,

i. If the disclosure has happened within one year proceeding the date of application and is the results of activities by the applicant or predecessor in title,
ii. If the disclosure happened within six months preceding the date of application and is the

consequence of an abuse of the rights of the applicant or the predecessor in title.

(b) The content of a patent application made in Sri Lanka having an earlier filing date, or where appropriate, a previous priority date.

2. Inventive Step/Non-Obviousness
This is defined in Section 65, which says that an invention shall be considered to involve an inventive step if having regard to the prior art relevant to the patent application, the step should not have been obvious to a person having ordinary skill in the act.

3. Industrial Application/Usefulness
This is defined in Section 66 which says that an invention shall be considered industrially applicable if it can be made or used in any kind of industry

However, any invention that meets these three criteria are not awarded a patent if it falls within one of those that are stated explicitly under the exclusions as set out in Section 62(3).
Among these are;

i. Plants
ii. Animals
iii. Micro-organisms except transgenic micro-organisms
iv. Essentially biological processes for the production of plants and animals
v. Methods for the treatment of the human or animal body by surgery or therapy
vi. Diagnostic methods practiced on the human or animal body.

In addition to these restrictions, according to section 62(3)(f), a patent can be denied to any invention if there is a need to prevent it being commercially exploited within Sri Lanka in order to protect the public order or morality, including the protection of human, animal or plant life or health or the avoidance of serious prejudice to the environment. The word public order is derived from the French term "*Ordre Public*" which means "the well-being of the society". In using the provisions of Section 62(3)(f), the merits and demerits of the invention has to be studied.

The exclusions listed in the Act show that the only living beings that could be patented are

transgenic micro-organisms. The term "transgenic micro-organism" is to be interpreted according to the interpretation of the word "transgenic" in Section 212 of this Act which is "an organism that expresses a characteristic not attainable normally by the species under natural circumstances, but which has been added by means of direct human intervention in its genetic composition." Biological material, including bio-chemical compounds and genetic material cannot be patented as they are discoveries, but not inventions. However, it is possible to get a patent on a novel gene construct if it satisfies the three criteria. The IPR system in Sri Lanka has effectively prevented any abuse of biological material by getting patents.

However, it is seen that in some countries such as U.S.A.,a discovery can qualify as an invention and thus become patentable. Hence, it is important to prevent any unauthorized export of biological material and to subject all legal exports to a Material Transfer Agreement (MTA) that lays down all relevant aspects

such as the granting of IPR to processes and products and the sharing of profits. Therefore, the laws that regulate the export of animals and plants also play a crucial role in preventing bio-piracy by regulating and controlling all exports.

The export of any wild animal or their parts, and plants are regulated under the Fauna and Flora Protection Ordinance. According to Section 40, no person can export any animal (living or dead) or any part of an animal except under a permit issued by the Department of Wildlife Conservation. Such permits can, according to Section 40(2), be issued only for the promotion of scientific knowledge including supplies to museums and zoological gardens as supplies and in exchange for others.

It is stated in Section40(3), that the provisions of Section 40 shall have the effect as if it formed part of the Customs Ordinance and therefore the provisions of the Customs Ordinance will apply accordingly.

The protection of plants is dealt with mainly under the provisions of Section 42 which makes it an offence to remove, uproot, destroy, or cause any damage to or injury to any plant that is deemed to be a protected species (those that are included in Schedule VIII under this section) or sell or expose to sell any plant or part thereof. Hence it is not possible to export any plant or part, including extracts, of any plant that is protected as it involves the damage, injury or destruction of a plant.

Section 45 provides for the minister to issue orders by way of regulations to prohibit or regulate the exportation of any plant. This applies to those species that have not been protected. There are two sets of regulations made under this section that have regulated the export of plants belonging to the genera of *Cinnamomum* and *Salacia*. The amendment No.22 of 2009 has provided protection to all species of plants belonging to the genus *Salacia* and therefore the regulations apply only in the exportation of plants or material of plants belonging to the genus *Cinnamomum*.

The Forest Ordinance has regulations that deal with the export of forest produce. The definition of "forest produce" include not only the plants and their parts, but an extract of a plant as well. The regulations published in Gazette Extraordinary No.1161/1 of 05.12.2000 has made it mandatory to get a permit from the Forest Conservation Department for the export of any forest produce. These regulations also cover the export of leaf litter and topsoil that is exported to isolate useful micro-organisms.

Jagath Gunawardana, Attorney-at-law

Monitoring and Enforcement to prevent Gene Piracy

Samantha Gunasekara

Background

Gene piracy is a word that became familiarized among the public in the recent past. Therefore we have to analyze the origin of gene piracy. With the development of genetic engineering, scientists can isolate, insert, recombine, snip, re-arrange, edit, programme and produce a new biological and genetic material.

Developing countries which have higher biodiversity are the home for many important genetic materials. The indigenous knowledge on traditional medicine enhances the value of those materials. With the increasing demand, bio prospecting is a good source of revenue for both science and business. Gene piracy occurs as a result of this background.

It is regarded as piracy because the beneficial parties use the indigenous knowledge of the people to locate and understand the uses of medicinal plants etc., and then exploit them commercially, giving back little or no benefits to the source, while retaining the exclusive rights with themselves.

Gene piracy is not just the product of new science and the incorporated greed, but also of new law. The economic stimulation for bio prospecting was supported in 1980, by a US Supreme court decision.

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In 1971, an Indian microbiologist Ananda Mohan Chakraborthy, as an employee of General Electric Company (GE), developed a new bacteria that could digest oil, and GE applied for a patent to the US Patent and Trademark Office (PTO) for this new mutant bacteria. After several appeals, the U.S. Supreme courts ruled that a patent should be granted. Since then many bio products have been patented in many countries which supported gene piracy.

According to a report of the World Health Organization (WHO), 70% - 90% of the world population, especially in developing countries, uses plant based remedies for their health problems. About 50% - 60% of Western drugs are derived directly or indirectly from plant materials.

It has been estimated by American scientists that 12,000–50,000 times of testing is needed for primary isolation part for producing a new medicine. It is a very costly exercise. Development of a new drug involves extraction, isolation, testing for bio-activity, synthesizing the new drug etc. This process takes at least 10 years and costs about US $ 250 million. But if the researches are aware of the particular plant and it's curative properties, it will cut-off the cost by 90%. The pharmaceutical company has to follow only the clinical part and the marketing part.






Sri Lanka has a heritage of indigenous knowledge based on traditional medicinal practices, which has come down over thousands of years. The indigenous plants and derivatives that are exported are clearly not materials found by accident but are very selective and based on the indigenous knowledge associated with traditional medicines. There are hundreds of Sri Lankan plants that are subjected to patents in a number of countries such as USA, Japan, India, EU, Australia & etc.

Salacia reticulata (Kothala Himbutu) is one such example where we were able to expose the various facets of gene piracy taking place in Sri Lanka. There are large numbers of patents available on various products of this plant, and in the genus Salacia at present.

The number of local plant materials that are victims of bio piracy include, *Cryptolepis buchananii* (wal rukaththana), *Azadirachta indica* (Magosa/Kohomba), *Trichosanthes krilowii* (Snake gourd), *Momordica charantia* (Bitter melon), *Myristica fragrans* (Sadikka), *Nigella sativa* (Kaluduru), *Sida cordifolia* (Heen bevila), *Embelia ribes* (Walangasal), *Pongamia glabra* (Magul karanda), *Strychnos nux-vomica* (Goda kaduru), *Quercus infectoria* (Masakka), *Syzygium aromaticum* (Enasal), *Tephrosia purpurea* (Katupila), *Coscinium fenestratum* (Weniwel), *Gymnema sylvestre* (Masbedda), *Mormodica cochinchinensis* (Thumba karawila), *Anacardium occidentalis* (Kadju), *Aloe vera* (Komarika), *Cinnamomum zeylanicum* (Cinnamon), *Pterocarpus indicus* (Gammalu), *Lagerstroemia speciosa* (Murutha). These are some of the medicinal plants in which products have been patented.

In the field of horticulture, endemic *exacum* (Binara) species have been hybridized and patents obtained in USA, Denmark and Australia with the support of well known local personal. *Chirita moonii* and *Chirita walkeri* have also been pirated by Japanese horticulturists recently.

Not only the flowring plants, but micro-organisms such as *micromonospora*, *sporangium* and lichens like *Usnea barbata* have been subjected to gene piracy.

Hortonia floribunda (Wewiya) which belongs to an endemic genus, has also been pirated by top branded beauty care products under the name of 'clarins'.

Those examples show how expansion of gene-piracy has taken place in new areas of beauty culture, horticulture, agriculture etc. Unlike the general wildlife trade or bio –theft, the owner of the genetic resources looses not only the due revenue, but also the rights and the ownership in gene piracy. In cases of Exacum, Bitter Melon, Snake Gourd, the pirates have taken exclusive rights for the productions which have not been invented by them so far.

The issue of Jasmine rice of Thailand, Basmathi (Taxamati) rice of India and Pakistan, neem issue raised by India, Agroyapatha issue of Kani tribe of India, the story of Ethiopian Endod, *Prunus africanus* of Africa, *Hoodia* issue in Africa, human cell line and *Canarium* issue in Solomon Islands, are some of the well known issues which brought the world's attention on gene piracy.

Monitoring and Enforcement

Monitoring and enforcement mechanism is based on the existing legislation. The protected plants are listed under the schedule VIII of the amended Fauna and Flora Protection Ordinance {(FFPO) Amend Act 22-2009}. Under this same legislation no plant or animal can be removed from any protected area. No animal or their parts can be exported as per the provisions under Section 40 of FFPO.

The protected plants are listed under the schedule VIII of the amended Fauna and Flora Protection Ordinance {(FFPO) Amend Act 22-2009}. Under this same legislation no plant or animal can be removed from any protected area. No animal or their parts can be exported as per the provisions under Section 40 of FFPO.

Regulations may be made under Section 45 of FFPO for prohibiting or regulating the exportation of any plant.

No forest produce can be exported without a permit from the Conservator General of Forests as per the Gazette notification No. 1161/6 of 05.12.2000, published under the Forest Ordinance (Ord. No. 16 of 1907).

No live form can be patented in Sri Lanka as per provisions of the Intellectual Property Act (Act no. 36 of 2003).

Certain species of fish are restricted or prohibited under the Gazette notification issued as per the provisions of section 3 of Fisheries and Aquatic Resources Act (Act No. 02 of 1996).

Under the provisions of section 12 and schedule B of Customs Ordinance (Ord. No. 17 of 1869), Customs can enforce at entry and exit points any material which is listed as prohibited or restricted under any enactment. Customs Department as the front-line and the end-barrier organization, Custom officers have a special role to enforce the existing legislation. Biodiversity Protection Unit of Customs (BPU), is the first of it's kind among the world's Customs institutions established in 1993 to control the illegal disposal of Fauna and Flora including gene-piracy.

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There are many international trade agreements which support gene-piracy. But there are reasonable approaches that can be observed in certain conventions such as Convention on Biological Diversity (CBD).

There are provisions under Article 8 of CBD for access and benefit sharing. Article 15 states "recognizing the sovereign right of states over their natural resources, the authority to determine the access to genetic resources rests with the national governments and is subject to national legislation", access on mutually agreed terms,

Challenging patents is another option to control gene piracy. India's Turmeric case and Taxamathy rice case are such examples that can be used. Controlling the exportation of raw materials and semi raw materials (extractions) which could be subjected to gene piracy is another method. Vigilance, education, awareness and publicity among the officials and public, also can be useful in controlling gene piracy. In co-operation with certain International conventions such as CBD, Kancoon Agreements which fight for "Biodemocracy", are also useful in monitoring gene piracy.

subject to prior informed consent etc. Article 16 says that access for the transfer, fair and most favourable terms to developing countries should be on mutual agreed terms subject to patents and intellectual property rights. Article 19 of CBD states about the handling of biotechnology and distribution of its benefits, and refers to the participation in biotechnological research within developing countries which provide genetic resources. Regulations have not been formulated to legalize any of those conventions in our country.

There are many gaps in the existing local rules and regulations. There is no proper mechanism for access, benefit sharing or conservation of those resources. As a result various forms of gene piracy take place without generating the due revenue to the country.

There are many gaps in the existing local rules and regulations. There is no proper mechanism for access, benefit sharing or conservation of those resources. As a result various forms of gene piracy take place without generating the due revenue to the country.

The monitoring and enforcement will not be successful until those loopholes are filled.

It can be observed that large scale exploitation of the genetic resources is on the increase. Those who are in the exploitation exercise take the mean advantage of the absence of proper legislation or such procedure.

Therefore it is high time to formulate legislation for access and benefit sharing of genetic resources on Mutually Agreed Terms (MAT) and Prior Informed Consent (PIC). Establishing and promoting local productions on biological resources is the best remedy to prevent gene piracy. This should be supported with fully equipped modern laboratory facilities. The second option is to have collaborative projects on proper legal agreements for the access and benefit sharing.

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Writer feels that the most important controlling mechanism is that every citizen of this country should have an idea and real patriotism on the natural heritage of our country. People should be motivated on this.

Samantha Gunasekara
Deputy Director of Customs
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Sri Lanka Customs

Agriculture

New Genetic Inventions in Agriculture

Dr Renuka Karunagoda

Genetics is the area in biology, where studying of heredity is involved. Genes are components of cells which are responsible for all the characters of living organisms. A gene is a length of DNA, which codes for a particular protein. DNA occurs in pairs of strands intertwined with each other and connected by chemicals called bases. Two strands of DNA and the bases between the strands compose a specific gene. A major breakthrough in genetics took place when scientists developed the process of genetic engineering where they transfered genes from one organism to another between distinctly related organisms. It is possible to remove genes which are responsible for certain characters and introduce them into another organism, so that the given character is introduced into the recipient organism (Fig. 1). This technology, which is known as 'Recombinant DNA Technology' is used to alter the characters of microorganisms, plants or animals. Plants which have been genetically modified are known as 'transgenic plants'. Production of transgenic plants with new characters is an area of new science, known as 'plant biotechnology', with many potential applications in agriculture to increase agricultural production.

Agriculture constitutes a major sector of the global economy. The applications of biotechnology in agriculture have a highly potential market, and therefore, various groups are working towards development of transgenic plants with greater productivity, resistance to pests and diseases, improved nutritional quality and better tolerance to environmental stresses. There has been a rapid expansion in the commercial cultivation of genetically modified crops, rising from the first plantings in 1995 to 44.5 million hectares worldwide in 2000. Most

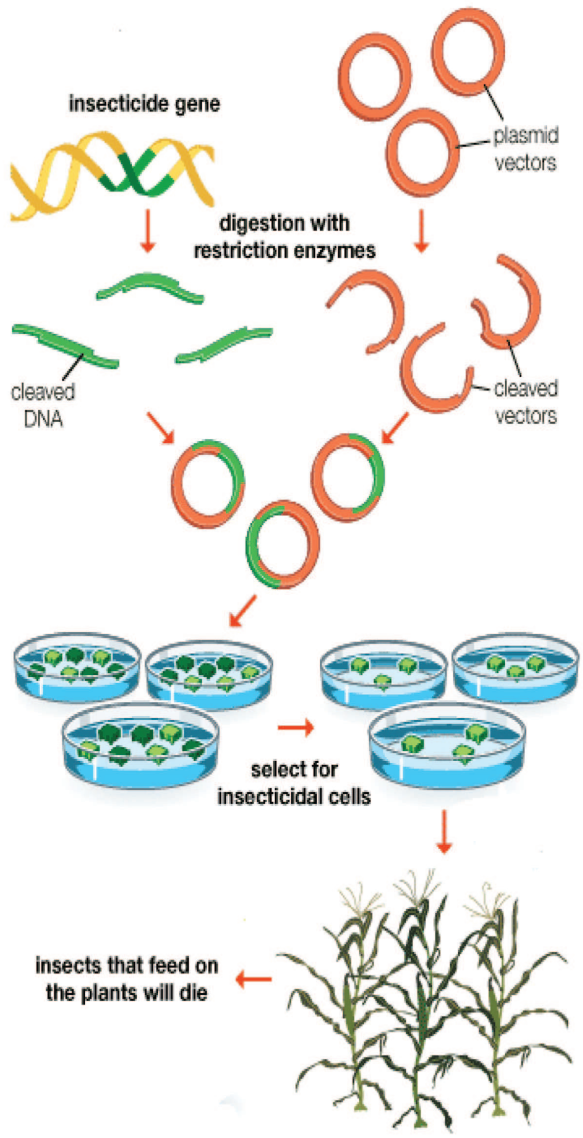

Figure 1 Procedure for the production of transgenic plants with insecticidal properties

genetically modified crops are cultivated in the USA (68%), Argentina (23%) and Canada (7%). Of the total 44.5 million hectares planted worldwide in 2000, 58% was soybean, 23% corn, 12% cotton and 6% oil seed rape. Other GM crops include potato, squash and papaya.

Recombinant DNA technology is used in plant biotechnology where it can contribute to increase crop production via two areas. Firstly, plant biotechnology can be used to add new lands for agricultural production. New plant varieties can be produced with more tolerance to drought and poor soil conditions, such as, saline or acidic soils. In this way, it is possible to expand the existing lands which have been unable to be cultivated so far. Secondly, biotechnology can be used to reduce crop losses, either caused by pests and diseases or transportation or storage problems. Pests, diseases and weeds not only reduce the crop yields, but also increase the cost of production, and therefore reduce the profitability of agriculture.

Development of crop varieties resistant to herbicides

Herbicides are used in agriculture to control weeds that compete with crop plants for space, water, nutrients and sunlight. It is important to control weeds to increase the productivity of crops. There is no single herbicide designed for broad-spectrum weed control to control all types of weeds. Some herbicides are effective in controlling weedy grasses, but not effective against broad-leaf weed species. The development of crop varieties tolerant to herbicides has been a major focus for biotechnology companies and today there are varieties of various crop species with resistance to herbicides that kill all types of plants except the crop variety. The U.S. company Monsanto developed the first transgenic crop varieties resistant to the herbicide called 'Roundup' which contains the chemical glyphosate that kills both broad-leaf weeds and weedy grasses. These varieties are known as Roundup Ready as they are resistant to the herbicide Roundup. In 1996, Roundup Ready soybean variety (Fig. 2) was made commercially available followed by Roundup Ready corn in 1998. Roundup Ready varieties allow farmers for more efficient and economic weed control with application of only one herbicide by reducing the number of herbicide applications needed and amount of chemicals applied to the land. Other than soybean and corn, herbicide resistance was introduced to sugar beet, canola (oil seed rape) and cotton.

Development of crop varieties with enhanced nutrition

A transgenic rice variety, named 'Golden Rice' has been developed in 2000, which has elevated levels of β-carotene, a precursor to vitamin A (Fig. 3). This rice variety can help to fight blindness resulting from a deficiency of vitamin A, a critical problem in developing countries. Within this rice plant, the biochemical

Figure 2 Herbicide tolerant Roundup Ready Soybean

Figure 3 Golden rice with enhanced levels of β-carotene

pathway for β-carotene was introduced by inserting relevant genes from daffodil and a fungus. The grains of this genetically modified rice are similar to those of other varieties, but the core of the grain is pale yellow, instead of white, due to β-carotene. Golden rice can be considered a particular advantage to poor people in underdeveloped countries, particularly in areas of Asia, where most of the population live on rice throughout the day.

Development of crop varieties resistant to insects

Insect resistance is achieved by incorporating a gene from the bacterium *Bacillus thuringiensis* into the food plant. *Bacillus thuringiensis* produces a protein that is toxic to the larvae of the Lepidopteran insects. When the caterpillars eat plant leaves on which the bacterial spores have been deposited, the bacteria grows in the digestive tract and a protein-like crystal (Bt-toxin) is produced, which kills the insect. The Bt-toxin gene has been transferred to varieties of corn, cotton, tobacco, potato and other species to control caterpillars (Fig. 4). Bt crop varieties synthesize the Bt toxin in their own tissue, and therefore after eating the plant matter, the caterpillars die within 2 days. This has dramatically reduced the amount of insecticides needed to control the insect in crops. If Bt-toxin is ingested by mammals, it rapidly degrades in the digestive tract, making it one of the safest chemicals to man and the environment.

Development of crop varieties with longer shelf life

The first transgenic crop commercialized was a tomato variety named 'Flavr Savr' which was released to the market in 1994 (Fig. 5). This was the first genetically modified food available to consumers. This tomato variety has a long shelf life and is genetically modified to produces less of the substance that causes tomatoes to rot, so it remains firm and fresh for a long time. This is important in harvesting because tomatoes can be allowed to ripen in the sun before picking, resulting in a better tasting tomato. Further, they can tolerate a lengthier transport time, which reduces postharvest losses.

Figure 4 Genetically modified corn with Bt-toxin gene

Figure 5 Genetically modified Flavr Savr tomato with longer shelf life

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