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General review of Biotechnology Role of Production Genetic Modified Organisms

Zeina S. M. Al-Hadeithi[*,1]

[1] Department of Clinical Laboratory Science, College of Pharmacy, Al-Nahrain University, Kadhimiya,
***Corresponding author**
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ABSTRACT

The area of Biotechnology has been both interesting and surprising from the beginning. At first, the scientists were filled with apprehension regarding the cessation of this technology's usage. It is more prudent to be cautious when making alterations to nature as the resulting outcomes remain unpredictable. Utilizing this innovative technology to enhance the nutritional value of food and combat illnesses is a logical approach. The process of creating GMOs involves extracting specific genes from one organism and inserting them into a different organism to generate modified living entities. This process usually gives the new organism specific traits that we want it to have. GMOs can be plants, animals, or enzymes that have been genetically modified. Some genetically modified organisms (GMOs) have been given permission by government agencies to be used for business and to be eaten, while others are still being reviewed by these agencies. Some GMOs are still being tested in laboratories. Genetic modification or genetic engineering of organisms can be put into groups:
Green genetic engineering, also known as agro-genetic engineering, is all about creating genetically modified plants for use in farming and food production , Genetic engineering in red/yellow is used in medicine, tests for genetics, and gene therapy, as well as to make drugs like insulin and vaccines , Bacteria or yeast: These micro-organisms are created by changing their genes to make them produce specific chemicals. The chemicals they produce are used in industries to make things like medicine or other products.
Keywords: GMOs, Biotechnology, Cloning, Vectors, Genetic engineering

INTRODUCTION

Biotechnology refers to a collection of sophisticated technologies that harness the power of living organisms or their biological processes to produce innovative and beneficial goods and procedures [1]. Biotechnology encompasses a diverse array of practices, ranging from traditional beer and bread production techniques to genetically modifying plants, animals, and even humans.[2]

The current period highly values the importance of biotechnology as a technology. It can be used in many different ways in farming, healthcare, making food, protecting the environment, mining, and even for very small electronic devices. Nevertheless, apprehensions persist regarding the safety and ethical ramifications linked to the application of emerging technologies in altering the genetic structure and attributes of living organisms, encompassing humans, plants, and animals.[3]

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1.1 Biotechnology and Health

For the past few decades, the primary objective of genetic engineering in modern biotechnology has shifted towards improving human health, instead of concentrating on genetically modified crops and food products, which have received significant attention from the public. The main focus of global research and development in biotechnology today is to enhance health, including advanced utilization of gene technology.

Many different methods are used in modern medicine to develop drugs and treat diseases. Sometimes, genetic engineering is used to make both the process and the result. In simple terms, gene technology is sometimes used as a tool to make new products like medicines [4].

1.2 Biotechnology Development

In red biotechnology, scientists harness organisms to produce medication by engineering bacteria capable of eradicating other bacteria and manipulating genes to treat diseases. Green biotechnology involves using science to improve plants for farming. This could mean choosing plants that are better at growing or making plants that can handle different difficult conditions [5]. White biotechnology encompasses the generation of important industrial chemicals using living organisms or their enzymes, which fall under the scope of white biotechnology. This can include designing organisms to make helpful chemicals or using enzymes to produce valuable substances or get rid of dangerous ones. Blue biotechnology refers to the use of technology and scientific knowledge in marine and water environments [6]. In the past, people used biotechnology to make different foods. They made wine by fermenting fruit juices, cheese by turning milk, and used yeast to bake. Modern biotechnology originated from Mendel's experiments on how plants inherit genetic traits during the 1800s. In 1953, Watson & Crick discovered the double spiral shape of DNA, which started a big change in biology to understand how genes work. Modern biotechnology uses techniques to change genetic information in order to move genes from one organism to another and highlight specific traits. This process called "genetic engineering" creates a genetically modified organism (GMO) [7]. The methods are used in both new and old industries, like making beer, producing vaccines, getting rid of pests, and manipulating genes. Biotechnology is divided into different areas. The main ones are industrial biotechnology, tissue culture, and molecular biotechnology [8,9].

1.3 Genetically modified organisms (GMO)

The area of genetic engineering has been both interesting and surprising from the beginning. The scientists were worried and agreed to temporarily stop using this technology.

We cannot have total assurance when modifying nature, due to the potential for unpredictable consequences [10]. It is recommended to exercise caution for this very purpose. Employing this new technology to enhance nutrition and combat disease appears to be a sensible decision. GMOs are created by combining different genes together. A GMO is a living thing that can be very small, like a Microorganisms, or bigger, like an animal or a plant. Right now, most genetically modified organisms (GMOs) that are sold are plants [11].

1.4 Genetically Modified Microorganism

1) Microorganisms are tiny living things that can reproduce or transfer genetic material. Examples include cellular and non-cellular entities such as viruses, viroids, and laboratory-cultivated animal and plant cells.

2) A genetically modified micro-organism (GMM) refers to a micro-organism whose genetic material has been intentionally modified in a manner that does not occur naturally through mating or natural recombination [12].

In 1986, the European Commission (EC) embarked on research regarding genetically modified (GM) crops and foods. There is no proof of potential harm to humans or the environment in this study [13].

1.5 Genetically Modified Plant

Through the utilization of conventional breeding techniques, individuals have been able to produce plants possessing favorable attributes for a considerable duration. They pick the traits they want, mix them together, and then spread them to many generations through mixing their genetic material. This takes a very long time, up to 15 years, to make new types of plants [14].

Plants that have been altered through the use of recombinant DNA are known as genetically modified plants. This technique can add genes that are not normally found in plants or modify the genes that are already inside the plants. These genes make proteins that give the plant special advantages [15,16].

DNA recombinant technology can be used in many different ways, such as making plants able to withstand tough conditions like lack of water, very hot or cold temperatures, or high salt levels. It can also protect plants from harmful bugs and diseases that would usually harm or kill them. Technology can also be used to make plants more nutritious, which could be very helpful in poorer countries. Scientists are making new types of genetically modified crops that are used to make medicines and products like antibodies, vaccines, plastics, and biofuels [17].

1.6 Application of GMOs in Food:

Since the 1990s, there has been ongoing discourse between scientists and the public regarding the integration of GMOs into the environment and the commercialization of food products derived from them [18].

The use of recombinant DNA technology is perceived as an advantageous method for enhancing crop yield (first generation GMOs) and promoting healthier food options (second generation GMOs). It can also be used to create vaccinations and medicines (third generation GMOs). People who support GMOs say that they are important for making farming more sustainable. They believe that GMOs can help protect the environment by using less pesticides, saving fossil fuels, producing less carbon dioxide, and keeping soil and water healthy. People who like GM crops believe they are very important for solving the big problem of not having enough food and good nutrition in poor countries [19].

When it comes to human health, there are two main concerns. One is that allergens could get into new foods, which could cause allergic reactions in people. The other concern is that genes from genetically modified foods could end up in human cells or in gut bacteria, and this could cause problems. This discovery explains when genetic material is transferred, it can have bad adverse health effects [20].

1.7 Aquatic Genetically Modified Organisms: Transgenic Salmon:

Transgenic salmon is at the very top of the list. Some people who are involved in aquaculture believe that (GMOs) in water could make aquaculture even better [21].

Making food conversion rates more efficient or enhancing the digestion of plant-based feed. It could also happen by controlling how often animals reproduce and what sex they are (sometimes one sex grows better than the other; only breeding one sex can prevent loss of growth due to competition). Animals could also become better at fighting off diseases or parasites, or better at handling certain environmental conditions like temperature. Changes in behavior, such as aggression, may also occur. Some people believe that (GMOs) created for aquatic environments can help reduce the harmful impact of fish farming on the environment. Moreover, they may develop fresh organisms that possess medicinal qualities or possess the capacity to recognize and assess pollutants [22,23].

1.8 Genetically Modified Organism (GMO) in Medicines & Pharmacy:

The study of gene therapy and (GMO) medicines is being carried out by scientists to explore their potential effectiveness in various medical conditions. There is a significant increase in the number of clinical trials testing this new type of treatment [24]. Cytotoxic drugs, which are potentially dangerous, are skillfully dealt with by pharmacists. On the other hand, genetically modified drugs often utilize viral vectors, which can be perceived as a biological risk [25].

Medicines derived from (GMOs) involve the use of altered genes to effectively combat various diseases [26]. The Therapeutic Goods Administration (TGA), which is a local organization, defines GMO medicines as organisms that have been changed genetically and are made to be used as medicines. This means the different types of vaccines that are used, which can include vaccines with weakened viruses, vaccines with modified viruses that act as carriers, and vaccines with altered body cells [27].

Since ancient times, humans have utilized plants and their extracts to cure various ailments, dating back to the Neanderthal era. Throughout history, people have relied on the healing properties of plants and their derivatives to combat illnesses. From the Neanderthal period onwards, individuals have employed plants and their extracts as remedies for human diseases. In the 17th century, botanical gardens gave a lot of materials and medicines for teaching how to use plants for healing. Herbal medicine became popular until the 17th century when more scientific remedies were found.

In many cases, the active compounds in medicinal plants have been identified and isolated. Currently, around 25% of prescription medicines come from plants [28]. Biotechnology has made people more interested in finding new medicines from plants. Genetic engineering is a process that uses plants to make various proteins like antibodies, blood substitutes, vaccines, and other medical treatments. [29].

The implementation of drug delivery systems contributes to mitigating the detrimental consequences and enhancing drug absorption and effectiveness in the body [30]. Extensive research has led to the development of various drug delivery systems. Two of these carriers are made using chemicals and the other two are made using genetic engineering [31]. These two types of carriers are different in many ways, such as their features, how they are made, and how harmful they are to cells.

Despite advancements in genetic engineering, it still possess the capacity to manipulate the fundamental molecules utilized for creating minuscule carriers [32]. This ability allows for the creation and changes of unique qualities, such as how a substance breaks down in the environment, and the structure of the substance itself, in order to meet specific needs for different uses. Genetically engineered drug carriers are not being studied as much as chemically made ones, but they have a lot of potential for different uses. When it appeared, it created several carriers that have special abilities for medical use. Examples of these technologies could be a powerful but safe form of doxorubicin [33], a tiny, engineered particle that specifically attacks the coxsackievirus and adenovirus receptor, and proteins derived from nature that trap and deliver drugs that are not soluble in water [34].

2. Polymerase Chain Reaction (PCR):

Polymerase Chain Reaction (PCR) is a method in biology that creates many copies of a specific segment of DNA. It can make thousands to millions of copies from just one or a few initial copies. Polymerase Chain Reaction (PCR) was created in 1984 by Kary Mullis, an American biochemist. Mullis got two important awards, the Nobel Prize and the Japan Prize, in 1993 for inventing PCR [35]. In 1971, Gobind Khorana explained the concept of DNA replication by utilizing two primers [36]. PCR is commonly used and is a very important technique in medical and biological research labs. It is used for many different purposes [37]. (PCR) has rapidly gained popularity in molecular biology due to its speed, affordability, and user-friendly nature. Despite poor quality DNA, this technique effectively enhances the quantity of targeted DNA fragments, even if they are originally present in minimal amounts. Role of PCR technique in Biotechnology field considered useful tool in clinical diagnostics, forensic investigations, and agricultural biotechnology. These applications require reliable performance, superb sensitivity, and stringent specifications. As such, thermal cyclers and reagents must be compliant to and specially designed for these purposes. Examples of molecular diagnostics include genetic testing, detection of oncogenic mutations, and testing for infectious diseases. In forensics, human identification by PCR relies on amplification of unique short tandem repeats (STRs) on gDNA to differentiate individuals. In agriculture, PCR plays an integral role in food pathogen detection, plant genotyping for breeding, and GMO testing [38].

2.1 PCR Steps:

There are three important steps in the PCR technique: separating the DNA strands, attaching the primers, and copying the DNA strands (see Figure 1).

During the denaturation phase, DNA is exposed to high temperatures ranging from 90 to 97 degrees Celsius. In the second step, primers stick to the DNA strands and prepare for extension. In step three, the annealed primers at the end are extended to make a matching copy of the DNA strand. This makes the amount of DNA double during the third part of the PCR process. To make more copies of a specific part of DNA using PCR, the sample is first heated to separate the DNA into two single strands. Afterwards, a special protein called "Taq polymerase" creates two fresh copies of DNA by using the original DNA strands as a guide. This process makes more copies of the original DNA [37]. Each of the new copies has one strand from the original DNA and one new strand. Then each of these strands can be used to make two more exact copies. The heating process occurs at a cooler temperature, between 50 to 60 degrees Celsius. This helps the primers to join with the matching template strands, which is quite helpful in forensic chemistry. The new DNA strand made from the primer attached to the template is used to make exact copies of the original template strands that are wanted. Taq polymerase adds nucleotides to the primers that are joined together. During the extension phase, the primers are amplified by an enzyme called Taq polymerase at a temperature of around 72°C for a duration of 2-5 minutes. DNA polymerase I cannot be used to make the primers longer because it doesn't stay strong enough at the high temperatures needed for PCR. The PCR process is much quicker than other methods, and in each cycle, the number of desired DNA copies is doubled. After repeating the process 25-30 times, there will be enough copies of the initial DNA sample to use for experiments [39].

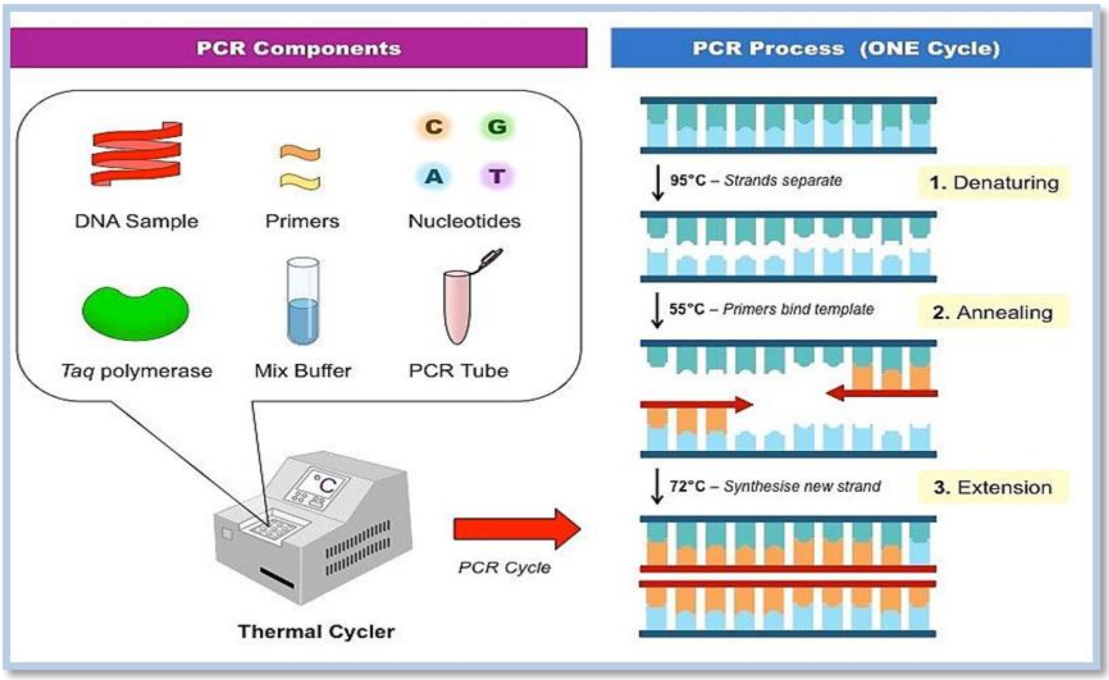

Figure 1. Polymerase Chain Reaction Technique. [39]

2.2 Applications of PCR

PCR has been instrumental in facilitating the investigation and discovery of a growing range of illnesses. This method has been used for a long time in laboratories that study or work with nucleic acids. Determining and measuring changes in how genes are expressed has helped us understand diseases better. Additionally, it assists in the creation of diagnostic instruments and the execution of fundamental investigations in microbiology and molecular biology [36]. Forensic labs utilize PCR, which is advantageous due to its requirement of only a small quantity of initial DNA. For instance, that can collect enough DNA from a drop of blood or a single hair. Qualitative PCR can be used to find human genes as well as genes of bacteria and viruses. Many viruses have RNA as their genetic material. Therefore, before performing PCR, the viral RNA must be converted to DNA. This process is called transcription. Reverse transcription (RT-PCR) is utilized for this reason [40].

The genetic code is universal. It means that genetic information is always borne by DNA whatever the organism (bacteria, fungus, plant or animal). Thus, DNA is easily recombined and transferred from one organism to another. Furthermore, DNA is a ubiquitous molecule as all the cells that form an organism contain the same DNA. In addition, DNA is a resistant molecule, in the sense that it is quite resistant to heat and acidity variations [41].

2.3 Plant Tissue Culture:

In vitro culture methods play a crucial role in multiple aspects concerning plants, such as producing disease-free plants, rapidly cultivating uncommon plant varieties, altering genetic traits in plants, and extracting valuable commercial compounds from plants [42].

2.4 Methods of Plant Tissue Culture:

There are many ways to grow plants in a lab, and two of the most popular methods are shown in figure (2). Organogenesis is the process of making plant organs like roots or shoots. This can happen either directly from meristems (where cells divide and grow) or indirectly from dedifferentiated cells called callus. The cultures that are formed can be used later to make a lot of plants or to make specific parts of plants grow bigger (like roots in hairy root culture). The process of callogenesis creates a shapeless group of cells when explants are exposed to various growth stimulants. The hard and thickened tissue called callus can be used to grow new plants. It can also be increased in size to produce important substances in cell cultures (see Figure. 2) [42].

Plant tissue culture methods have certain steps. To begin, it chooses the plant that we are interested in. This choice usually depends on what we want to study, but it is best to choose plants without diseases or insects. Sometimes, we may need to use chemicals like fungicides and pesticides before proceeding. The next thing that do is start the process of growing something outside of its natural environment. To complete the process, we need to cut small parts of plants (called explants) or use seeds and clean them with chemicals to remove any germs on the surface. The plant tissues are put into the right liquid and kept for a little while. If some of the tissues are contaminated, they're thrown away. The ones that are still okay are moved to the next part of the process. The steps needed depend on the type of culture you want. During organogenesis, explants are grown on specific culture media to produce more shoots or roots. In callogenesis, the callus is also multiplied. Next, the callus and root cultures are grown in larger quantities using special containers called bioreactors. As for micropropagation, the shoots that have been grown are moved to a different type of culture media that helps them develop roots. Finally, the small plants that were grown using a special method are made stronger so that they can grow on their own and make food through photosynthesis. The hardening process is done slowly, which helps the plants get used to conditions outside of their usual environment. Usually, the plants are moved from places with a lot of moisture to places with less moisture, and from places with less light to places with more light [43].

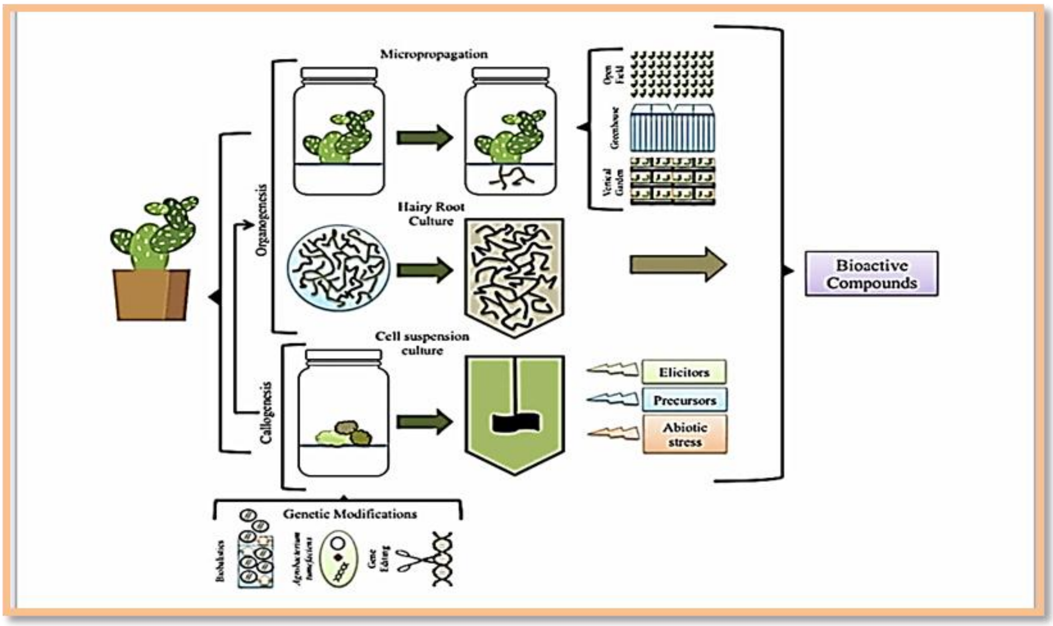

Figure 2. Diagram of current methods employed for the large-scale production of bioactive compounds using plant in vitro tissue culture. [42]

2.5 Growth, Nutrition and Prevention of Pathogens in Tomato

Transformation of LeMYC2 gene in tomato:

From a commercial standpoint, tomatoes that are shorter in stature are preferable to those that are higher since reproductive growth is more significant than vegetative growth. Several genetic promoters have been found to favor reproductive growth while suppressing vegetative development. The promoters in charge of promoting root development and suppressing vegetative length are LeMYC2 and MYC2. In the end, they are said to increase tomato crop output by promoting fruit growth. Thus, their modification is advantageous for tomato yield [44].

2.6 Against Viruses:

Transformation of Coat protein gene from Tobacco Mosaic Virus in tomato:

The primary natural adversaries of living things are viruses. In a similar vein, viral infections can very easily infect plants. The tomato crop has suffered losses due to the tobacco mosaic virus (TMV) and tomato mosaic virus (ToMV). Due to this viral onslaught, yield reductions in the tomato crop of between 25 and 30 percent have been documented. More than 90% of tomato plants' resistance to TMV and ToMV is produced by coat protein genes (CP genes). Using Agrobacterium-mediated transformation, CP genes were incorporated into tomato genetic makeup to produce viral resistance [45].

2.7 Against Fungus:

Wasabi defensing gene (WD) expression in tomato:

The fungus that causes the most trouble for tomatoes is *Fusarium oxsporium*. According to studies, peptides rich in cysteine can prevent the growth of fungus. The tomato crop is protected from fungal attack by wasabi defending (WD) genes, which are abundant in cysteine peptides. With an Agrobacterium-mediated transformation technique, the wasabi defense (WD) gene was introduced into tomato plants. Wasabi defense genes (WD) were expressed in roots using root-specific promoters, such as LjNRT2. Hence In tomato plants, WD genes can successfully inhibit fungus [46].

2.8 Applications of Genome Editing CRISPR-Cas9 in Plant Biotechnology

CRISPR/Cas genome editing has been becoming a mature cutting-edge biotechnological tool for crop improvement that is already used in many different traits in crops, including pathogen resistance, abiotic tolerance, plant development and morphology and secondary metabolism and fiber development.

CRISPR/Cas9 system is a robust and powerful biotechnological tool for targeting an individual DNA and RNA sequence in the genome. It can be used to target a sequence for gene knockin, knockout and replacement as well as monitoring and regulating gene expression at the genome and epigenome levels by binding a specific sequence. *Agrobacterium*-mediated method is still the major and efficient method for delivering CRISPR/Cas regents into targeted plant cells. However, other delivery methods, such as virus-mediated methods, have been developed and enhanced the application potential of CRISPR/Cas9-based crop improvement. PAM requirement offers the CRISPR/Cas9-targted genetic loci and also limits the application of CRISPR/Cas9. Discovering new Cas proteins and modifying current Cas enzymes play an important role in CRISPR/Cas9-based genome editing. Developing a better CRISPR/Cas9 system, including the delivery system and the methods eliminating off-target effects, and finding key/master genes for controlling crop growth and development is two major directions for CRISPR/Cas9-based crop improvement. [47]

2.9 Plant-made Pharmaceuticals and other Bioengineered Products:

Transgenic plants were often used as another way the production of pharmaceutical proteins. A transgenic system has many benefits, which include effective costs, more ease of scale-up and delivery, less risk of contamination with mammalian pathogens, and eukaryotes protein processing. Even though there was quite the potential for the method, the last 20 years since its preface, transgenic biomolecules (mostly orally delivered, plant-made vaccines) continued to decline in Phase I of clinical trials of humans. It was only in the present decade that a breakthrough has been made, and plant-dependent products are now getting into Phase II trials and beyond that [48].

Table 1 shows the first ever plant-made recombinant therapeutic proteins for humans confirmed for commercial sale in 2014. Examples include, the first vaccine approved by the FDA to use against Newcastle disease virus, Manufactured by Dow Agrosciences. The vaccine is based on tobacco suspension cultures. Also, the human-made antibody by Synthon and Nijmegen, for non-Hodgkin’s lymphoma, is plant-based on Duckweed leafy biomass. The antibody for HIV and Serum albumin are among other examples [49]. This shows that field growth can be assigned to some of the difficulties of the method, such as low products, undesired glycosylation of the yields, purification and processing obstacles, and the challenges presented in creating a new manufacturing industry [50]. Some of these difficulties can be fixed by proper plant selection. For example, using maize or lettuce, that are both edible and harm-free, can minimize the necessity for purification demanded for parenteral pharmaceuticals preparation, thereby decreasing the costs [51,52].

In addition, valuable traits can be preserved by selecting desirable characteristics and utilizing appropriate techniques such as backcrossing or inbreeding. [53]. Plants have small amounts of active substances and some new useful compounds, such as vaccines, that are not normally found in plants. This has created a need for tools that can alter the genetic material of plants. Plant genetic engineering has been used since the 1980s. At first, it was done using Agrobacterium, and later, through a process called transformation mediated by particle bombardment. These two methods have been helpful for many different plants. They allow for the increased production of special substances or the creation of medicines using plants. However, despite being successful, these techniques encounter several obstacles that limit their use in many situations [54].

Table 1. List of some pharmaceuticals produced in plants [49]

Plant-made pharmaceutical	Plant	Use	Manufacturer/Notes
Vaccine (NDV)	Tobacco suspension cultures	Newcastle disease virus	Dow Agrosciences, LLC, Indianapolis, USA First tobacco cell-based vaccine approved by the FDA against Newcastle disease virus in poultry
Antibody	Duckweed leafy biomass	Non-Hodgkin's lymphoma	Synthon, Nijmegen, The Netherlands LEX system Stable expression Speed quality
Antibody	Tobacco leaves	HIV	Fraunhofer IME, Aachen, Germany Stable Nuclear Expression Scale Cos
Serum albumin	Rice seed		Healthgen, Wuhan, Hubei, China Stable Expression Quality Scale

3. Risks and consequences of using genetically modified organisms

3.1 *Potential risks about GMOs on human health:*

• Allergic risk: the introduction of a foreign gene in a plant might lead to the emergence of new allergens.
• Toxicity: most transgenic plants are modified to make them resistant, by producing an insecticide that kills the attacking insect, or herbicide resistant, they survive while weeds die, but they absorb the herbicide. These insecticides and herbicides might be concentrated in the alimentary chain, producing disease
• Antibiotic resistance: the use of GMOs might lead to an increase of bacterial antibiotic resistance. Most genetically modified plants contain antibiotic resistant genes that could be transmitted to bacteria dangerous to human beings. Since our choice of antibiotics to treat human diseases is restricted, the possible emergence of antibiotic-resistant bacteria is rather worrying.
• On the environment: Neighboring field contamination risk: the growing of GMO's next to traditional crops might lead to cross-pollination, so that traditional products would no longer be considered as non- GMOs.
• Pesticide adaptation risk: the possible transmission of a herbicide resistant gene from a GMO crop to a weed would result in the weed becoming resistant to the herbicide. [55].

3.2 *Risk Assessment of GMO Medicines*

The potential risk that GMO medicine may present in regard to adverse effects on the environment and human health should be assessed by a senior pharmacist in terms of pathogenicity, infectivity, replication mechanism, stability and other characteristics. Bamford *et al*[56]. describe their risk assessment procedure for GMO medicines: assessing the viral vector used, assessing the genetic material to be delivered and then assessing the combination of these components together. Given the emerging nature of GMO medicines and the lack of local guidance, the evaluation of these medicines may be best suited to the pharmacist in charge of clinical trials who has experience in reviewing and preparing novel, unregistered medicines. The evaluation process may also involve the consultation of other staff, such as the pharmacist in charge of manufacturing or a member of the hospital's Drugs and Therapeutics Committee.

Guidelines for the management of hazardous medicines are readily available, such as the National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings and the American Society of Health System Pharmacists Guidelines on Handling Hazardous Drugs. Whilst these documents do not specifically address GMO medicines, they offer pertinent advice for evaluating hazardous medicines in general. [57].

CONCLUSION

Genetic engineering could turn out to be the greatest gift science has to offer the next century. It is vastly more precise than crossbreeding, which has been used for centuries to alter the genetic makeup of plants and animals. it can foresee that plant biotechnology will potentially be able to provide several benefits and address many challenges in food production. However, the environment does not bear also crucial that the release of GM crops in new risks and irretrievable consequences and/or threats for human health. Use of plants as factories for the production of novel vaccines, antibodies and other therapeutic proteins will undoubtedly continue to develop Molecular farming may become the premier expression system for a wide variety of new biopharmaceuticals and 'plantibodies'.

RECOMMENDATIONS

We propose future studies that include practical experiments using the necessary techniques in specialized laboratories to study genetic stability.

Studying the genetic fingerprint of the strains of living organisms which was included as a model for the study using one of the Marker DNA techniques and showing the genetic relationship between strains.

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REFERENCES

1. Sasson A. *Medical Biotechnology: Achievements, Prospects and Perceptions.* United Nations University Press; 2005. p. 152.
2. Reynolds RW. Agricultural biotechnology: Opportunities and risks. *USA Today.* 1999; p. 54–6.
3. United Nations Economic Commission for Latin America and the Caribbean (CEPAL). *Opportunities and risks arising from the use of bioenergy for food security in Latin America.* United Nations; 2007. p. 11.
4. United Nations Economic Commission for Latin America and the Caribbean (ECLAC). *Policy Brief: Implications for the use of biofuels with special reference to the Caribbean.* LC/CAR/L.148. United Nations; 2007. p. 8.
5. United Nations Economic Commission for Latin America and the Caribbean (ECLAC). *Biotechnology: Origins and development in the Caribbean.* LC/CAR/L.186. United Nations; 2008. p. 39.
6. United Nations Economic Commission for Latin America and the Caribbean (ECLAC). *Policy Brief: Biotechnology with special reference to the Caribbean.* LC/CAR/L.184. United Nations; 2008. p. 11.
7. United Nations Economic Commission for Latin America and the Caribbean (ECLAC). *Biotechnology development and climate change in the Caribbean. Focus: Newsletter of the Caribbean Development and Cooperation Committee.* 2009; Issue 2: p. 14.
8. Al-Hadeithi ZSM. Using ISSR markers to build a phylogenetic of barley genotypes. *Iraqi Journal of Science.* 2015;56(2C):1682–8.
9. Al-Hadeithi ZSM. Detection of genetic polymorphism in Iraqi barley using SSR-PCR analysis. *Iraqi Journal of Science.* 2016;57(2B):1158–64.
10. Facts on GMOs in the EU. Available from: http://www.europa.eu.int/comm/environment/index_en.htm.

11. Belgian Biosafety Server. *EU legislation.* Available from: http://www.biosafety.ihe.be/Menu/BiosEur3.htm.
12. European Union (EU). *GMO releases and legislation.* Available from: http://www.groundup.org/eugene.htm.
13. SCADPlus. *Genetically Modified Organisms.* Available from: http://europa.eu.int/scadplus/scad_en.htm.
14. Sticklen M. Plant genetic engineering to improve biomass characteristics for biofuels. *Curr Opin Biotechnol.* 2005;17:315–9.
15. Al-Hadeithi ZSM, Jasim SA. Study of plant genetic variation through molecular markers: An overview. *J Pharm Res Int.* 2021;33(45B):464–73.
16. Al-Hadeithi ZSM, Jasim SA. Diagnosis of *Hordeum vulgare* genomic profile: Review. *Asian Plant Res J.* 2021;8(3):32–42.
17. Ma JKC, Drake PMW, Christou P. The production of recombinant pharmaceutical proteins in plants. *Nat Rev Genet.* 2003;4:794–805.
18. Conner AJ, Glare TR, Nap JP. The release of genetically modified crops into the environment part II. *Plant J.* 2003;33:19–46.
19. Nap JP, Metz PLJ, Escaler M, Conner AJ. The release of genetically modified crops into the environment part I. *Plant J.* 2003;33:1–18.
20. Melamed P, Gong ZY, Fletcher GL, Hew CL. The potential impact of modern biotechnology on fish aquaculture. *Aquaculture.* 2002;204:255–69.
21. Berge GB, Baeverfjord G, Skrede A, Storebakken T. Bacterial protein grown on natural gas as protein source in diets for Atlantic salmon (*Salmo salar*) in saltwater. *Aquaculture.* 2005;244(1–4):233–40.
22. Mente E, Deguara S, Santos MB, Houlihan D. White muscle free amino acid concentrations following feeding a maize gluten dietary protein in Atlantic salmon (*Salmo salar* L.). *Aquaculture.* 2003;225(1–4):133–47.
23. Ginn SL, Amaya AK, Alexander IE, Edelstein M, Abedi MR. Gene therapy clinical trials worldwide: An update. *J Gene Med.* 2017;e3015.
24. Vulto AG, Stoner N, Balasova H, Cercos A, Hoppe-Tichy T, Genestar JL. European Association of Hospital Pharmacists (EAHP) guidance on the pharmacy handling of gene medicines. *EJHP Pract.* 2007;5:29–39.
25. Stoner N. Are UK hospital pharmacy departments ready for the rise of gene therapy medicinal products? [editorial]. *Expert Opin Biol Ther.* 2018;18:837–40.
26. Therapeutic Goods Administration. *Guidance 21: Medicines produced by genetic manipulation.* 2013.
27. Winslow LC, Kroll DJ. Herbs as medicines. *Arch Intern Med.* 1998;158:2192.
28. Fischer R, Emans N. Molecular farming of pharmaceutical proteins. *Transgen Res.* 2000;9:279–99.
29. Langer R. Drug delivery and targeting. *Nature.* 1998;392:5–10.
30. Rabotyagova OS, Cebe P, Kaplan DL. Protein-based block copolymers. *Biomacromolecules.* 2011;12(2):269–89.
31. Anib SM, Pastuszka MF, Aluri S. A quantitative recipe for engineering protein polymer nanoparticles. *Polym Chem.* 2014;5(5):1614–25.
32. MacKay J, Chen M, McDaniel JR, Liu W, Simnick AJ, Chilkoti A. Self-assembling chimeric polypeptide-doxorubicin conjugate nanoparticles that abolish tumours after a single injection. *Nat Mater.* 2009;8(12):993–9.
33. Uehler DC, Toso DB, Kickhoefer VA, Zhou ZH, Rome LH. Vaults engineered for hydrophobic drug delivery. *Small.* 2011;7(10):1432–9.
34. Bartlett JMS, Stirling D. A short history of the polymerase chain reaction. *Methods Mol Biol.* 2003;226:3–6.
35. Kleppe J. *J Mol Biol.* 1971;56:341–6.
36. Saiki RK, Scharf S, Faloona F, Mullis KB, Horn GT, Erlich HA, Arnheim N. Enzymatic amplification of beta-globin genomic sequences and restriction site analysis for diagnosis of sickle cell anemia. *Science.* 1985;230(4732):1350.
37. Erlich HA. *PCR Technology: Principles and Applications for DNA Amplifications.* New York: Stockton Press; 1989.
38. Ochman H, Gerber AS, Hartl DL. Genetic applications of an inverse polymerase chain reaction. *Genetics.* 1988;120:621–3.
39. Apfalter P, Blasi F, Boman J, Gaydos CA, Kundi M, Maass M, et al. Multicenter comparison trial of DNA extraction methods and PCR assays for detection of *Chlamydia pneumoniae* in endarterectomy specimens. *J Clin Microbiol.* 2001;39:519–24.

40. Al-Hadeithi ZSM, Jasim SA, Salahdin OD. Relation between resistance of *Klebsiella pneumoniae* to certain antibiotics and ESBL/PBP genes. 2022.
41. Al-Hadeithi ZSM, Jasim SA, Salahdin OD. Detection and genotyping of papillomavirus by real-time PCR in Iraqi patients. *J Arch Clin Infect Dis.* 2022;7(3):e121143.
42. Altpeter F, Springer NM, Bartley LE, Blechl AE, Brutnell TP, Citovsky V, et al. Advancing crop transformation in the era of genome editing. *Plant Cell.* 2016;28:1510–20. https://doi.org/10.1105/tpc.16.00196.
43. Morales-Rubio ME, Espinosa-Leal C, Garza-Padrón RA. Cultivo de tejidos vegetales y su aplicación en productos naturales. In: Rivas-Morales C, Oranday-Cardenas MA, Verde-Star MJ, editors. *Investigación en plantas de importancia médica.* 1st ed. Barcelona: Omnia Science; 2016. p. 351–410. https://doi.org/10.3926/oms.315.
44. Gupta N, Prasad VB, Chattopadhyay S. LeMYC2 acts as a negative regulator of blue light-mediated photomorphogenic growth and promotes the growth of adult tomato plants. *BMC Plant Biol.* 2014;14(1):38.
45. Nelson RS, McCormick SM, Delannay X, Dubé P, Layton J. Virus tolerance, plant performance of transgenic tomato plants expressing coat protein from tobacco mosaic virus. *Nat Biotechnol.* 1988;6(4):403–9.
46. Kong K, Ntui VO, Makabe S, Khan RS, Mii M. Transgenic tobacco and tomato plants expressing *Wasabi* defensin genes driven by root-specific *LjNRT2* and *AtNRT2.1* promoters confer resistance against *Fusarium oxysporum. Plant Biotechnol.* 2014.
47. Dangquan Z , Zhiyong Z , Turgay U , Baohong Z, CRISPR/Cas: A powerful tool for gene function study and crop improvement, *Journal of Advanced Research*. 2020. 21;29:207–221.
48. Thomas DR, Penney CA, Majumder A, Walmsley AM. Evolution of plant-made pharmaceuticals. *Int J Mol Sci.* 2011;12:3220–36. https://doi.org/10.3390/ijms12053220.
49. Yao J, Weng Y, Dickey A, Wang KY. Plants as factories for human pharmaceuticals: Applications and challenges. *Int J Mol Sci.* 2015;16:28549–65. https://doi.org/10.3390/ijms161226122.
50. Tusé D, Tu T, McDonald KA. Manufacturing economics of plant-made biologics: Case studies in therapeutic and industrial enzymes. *BioMol Res Int.* 2014;1–16. https://doi.org/10.1155/2014/256135.
51. Czyz M, Dembczynski R, Marecik R, Pniewski T. Stability of S-HBsAg in long-term stored lyophilised plant tissue. *Biologicals.* 2016;44:69–72. https://doi.org/10.1016/j.biologicals.2015.12.001.
52. Su J, Zhu L, Sherman A, Wang X, Kamesh A, Norikane JH, et al. Low-cost industrial production of coagulation factor IX bioencapsulated in lettuce cells for oral tolerance induction in hemophilia B. *Biomaterials.* 2015;70:84–93. https://doi.org/10.1016/j.biomaterials.2015.08.004.
53. Pniewski T, Czyz M, Wyrwa K, Bociag P, Krajewski P, Kapusta J. Micropropagation of transgenic lettuce containing HBsAg as a method of mass-scale production of standardised plant material for biofarming purposes. *Plant Cell Rep.* 2017;36:49–60. https://doi.org/10.1007/s00299-016-2056-1.
54. Altpeter F, Springer NM, Bartley LE, Blechl AE, Brutnell TP, Citovsky V, et al. Advancing crop transformation in the era of genome editing. *Plant Cell.* 2016 ;28:1510–20. https://doi.org/10.1105/tpc.16.00196.
55. Ruth Espinosa García (former Robert Schuman scholar) European Parliament L-2929 Luxembourg DIRECTORATE-GENERAL FOR RESEARCH Directorate A: Medium- and long-term Research Division for Industry, Research, Energy, Environment and STOA. 2001. PE 309.707.
56. Anliker B, Longhurs S, Bucholz CJ. Environmental risk assessment for medicinal products containing genetically modified organisms. Bundesgesundheitsbl 2010; 53:52–7.
57. American Society of Health-System Pharmacists. ASHP guidelines on Handling Hazardous drugs. AM J Health-Syst Pharm 2018; 75: 1996–2013.

مراجعة عامة لدور التقانة الاحيائية في إنتاج الكائنات المعدلة وراثيًا

زينه سيف الدين محمد [1,*]

[1]فرع العلوم المختبرية السريرية, كلية الصيدلة, جامعة النهرين, الكاظمية, بغداد, العراق.

الخلاصة

مجال التقانة الاحيائية كان دائمًا مثيرًا للدهشة والاهتمام منذ بدايته. في البداية، شعر العلماء بالقلق بشأن وقف استخدام هذه التقنية. فمن الحكمة توخي الحذر عند إجراء تغييرات على الطبيعة، نظرًا لأن النتائج المترتبة على ذلك تظل غير متوقعة. يُعد استخدام هذه التقنية المبتكرة لتعزيز القيمة الغذائية للأطعمة ومكافحة الأمراض نهجًا منطقيًا.

تتضمن عملية إنتاج الكائنات المعدلة وراثيًا استخراج جينات معينة من كائن حي وإدخالها في كائن آخر لإنشاء كيانات حية معدلة. تمنح هذه العملية الكائن الجديد سمات محددة نرغب في توافرها. يمكن أن تشمل الكائنات المعدلة وراثيًا النباتات أو الحيوانات أو الإنزيمات التي خضعت لتعديلات جينية. وقد حصل بعض الكائنات المعدلة وراثيًا على موافقة الجهات الحكومية لاستخدامها تجاريًا وللاستهلاك البشري، بينما لا تزال بعض الأنواع الأخرى قيد التقييم من قبل هذه الجهات. كما أن بعض الكائنات المعدلة وراثيًا لا تزال تخضع للاختبارات داخل المختبرات.

يمكن تصنيف التعديل أو الهندسة الوراثية للكائنات إلى مجاميع:

الهندسة الوراثية الخضراء (المعروفة أيضًا باسم الهندسة الزراعية الوراثية): وهي تهدف إلى إنتاج نباتات معدلة وراثيًا لاستخدامها في الزراعة وإنتاج الغذاء,

الهندسة الوراثية الحمراء/الصفراء: تُستخدم في المجال الطبي، بما في ذلك الفحوصات الجينية والعلاج الجيني، وكذلك في إنتاج أدوية مثل الإنسولين واللقاحات ,

الهندسة الوراثية الرمادية/البيضاء: تشمل تعديل البكتيريا أو الخميرة وراثيًا لإنتاج مواد كيميائية معينة تُستخدم في الصناعات المختلفة، مثل صناعة الأدوية أو منتجات أخرى.

الكلمات المفتاحية: الكائنات المعدلة وراثيًا، التقانة الاحيائية، الكلونة، النواقل، الهندسة الوراثية.