# CHAPTER- 2

# Genesis of Genetically Modified Crops and Traditional Knowledge: International Perspective

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## 2.1 Introduction

From the very existence of human life, we can see the traces of traditional knowledge. The word "tradition" ipso facto indicates that it is a traditional word that varies from time to time in a particular society and may vary according to the lifestyle of individuals, communities and societies. It is closely linked to the geographic, regional, sub-regional and local systems of the world. It is clear that traditional knowledge is not basic knowledge. The topic may be available in certain areas of society; even it can be available in the particular individual in the given section of the society. The term "traditional and indigenous knowledge" does not have to be a single word, but is used interchangeably in the international legal scenario.[14]

The traditional knowledge as a subject is closely related to biological resources, including plants, animals and other genetic resources. A clear understanding of the elements of traditional knowledge shows that countries with a rich biodiversity are also strong and rich in traditional, indigenous and local knowledge. Traditional knowledge is an essential part of biological resources. On the other hand, it should also be understood that traditional knowledge about biodiversity as such is only part of the subject and covers different areas such as agriculture, animal husbandry, traditional medicine, health care, pharmacy, nutrition, food processing, cosmetics, handicrafts, aesthetics and others.[15] Further the quality of life is determined by the quality of the environment. Of course, man strives to improve the quality of life. Food, shelter and clothing are the basic needs of people. Their availability and accessibility are the basic parameters for determining the quality of human civilization and its progress. Food has been symbolized in prayer for centuries and is related to security, personal satisfaction and cultural or ethnic identity.

[14] Article 8(j), 16, 19, 10(c) of CBD, 'Traditional Knowledge, Innovations and Practices'
[15] Secretariat of the Convention on Biological Diversity, *'Global biodiversity outlook 2'*, Montreal, 81 + vii pages. (2006)

Feeding the more than nine million people expected to be living by 2050 is a serious challenge.[16] Therefore, food security must be guaranteed. According to the committee on World food security (2012), food security is defined as when "Everyone has physical, social and economic access at all times to adequate, safe and nutritious food that meets their dietary preferences for active life and in good health ". Food security is and remains one of our biggest challenges for development. We must not only provide food and nutrition to a growing world population, but we must face growing environmental challenges. The global climate is changing and the land suitable for agriculture and food production is changing with it. Solidification and desertification, floods, droughts and natural disasters threaten agriculture around the world. With changes in temperature, new risks arise from pests and diseases.[17]

As advances in science and technology have led to a smoother and safer life for humans in many areas, this has also affected agriculture. The world is now at the beginning of a new agricultural revolution - the "Gene Revolution" in which modern biotechnology enables the production of Genetically Modified (GM) crops that can be adapted to global food security. New "genetic e modified" technologies are being introduced that promise a solution to increase food production, reduce environmental degradation and promote sustainable development. On the one hand, genetically modified crops have a better yield and can therefore be seen as an alternative to food security. However, GMOs have sparked much controversy. The use of GM technology is considered a threat to the quality of the environment. Problems associated with genetically modified crops have triggered intense public debate in many parts of the world on the costs and benefits of genetically modified crops and related safety issues. In India too, this debate not only attracted the government, but also agriculture and civil society. However, it is generally acknowledged that biotechnology, particularly genetically modified crop, offers important opportunities to meet some of the greatest challenges of the 21st century.

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[16] Gray Nathan, '*What does the road map to food security really look like?*' published on 19th January, 2015

[17] Lisa Cornish, "Are GMOs the key to global food security?", *available at* https://www.devex.com/news/are-gmos-the-key-to-global-food-security-91862 (Visited on 18 March, 2015)

As with all new technologies, there are prejudices as well as known and unknown risks.

In the past, agriculture has often been seen as a controversial source of food, labor and finance for a growing urban and industrial sector on which sustainable income growth will depend. Productivity gains are usually required for this transition if food prices do not rise, hampering both industrial growth and poverty reduction. In industrialized countries, technological change and institutions in the agricultural sector are considered crucial for the industrial revolution. There are political and economic issues related to genetically modified crops at international and national level. The Uruguay Round was an eight-year negotiation between 1986 and 1994 between more than 100 governments around the world to establish new trade rules. The GATT took over the economic law from 1948 to 1994, when the WTO was founded to implement the new rules of the Uruguay Round. Trade in Genetically Engineered or Modified Organisms was not a high priority at the time. In most cases, we consider Genetically Modified Organisms (GMOs) as food, but the term also includes seeds that are included in the conclusion of important agreements of the WTO negotiations.

The World Trade Organization Membership remains vertically divided on the issue of trade in GMOs. The United States, one of the largest exporters of genetically modified products, is removing all barriers to GMO trade, but the EU and many other countries are doubtful about the potential impact of GMOs on the health and safety of GMOs. The European Union (EU) has made cautious arguments for restricting trade in GMOs. The precautionary principle is based on the principle that the ban should be maintained unless it is known that GMOs have potential effects. The EU also supports mandatory labeling to separate genetically modified foods from organic foods. The argument put forward is that consumers should be able to make informed choice.

The researcher gives an overview of the genesis of genetically modified crops, the advantages and disadvantages of genetically modified crops and the situation in countries such as the United States, Canada and Europe. The researcher shall also study the legal aspects/ legal protection to traditional knowledge and also study how TK is protected in the above mentioned countries.

## 2.2 Agricultural World before Genetic Engineering

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For millions of years, people have been hunters and gatherers. The history of agriculture documents the domestication of plants and animals, as well as the development and spreading of techniques to build them productively. They simply lived off the bounty of the land. Wild grains were collected and eaten from at least 20,000 BC. From around 9500 BC, the eight Neolithic founder crops – emmer wheat, einkorn wheat, hulled barley, peas, lentils, bitter vetch, chick peas, and flax. At about the same time, they discovered that they could collect the seeds of some wild species, plant them near their homes, protect weeds and pests, provide water, and harvest more crops, Fruits, vegetables and nuts for his family. Rice was grown in China around 6200 BC. Rice was domesticated in China by 6200 BC with earliest known cultivation from 5700 BC. Sugar cane and some root vegetables dated from around 7000 BC domestically in New Guinea. In the South American Andes, the potato was grown between 8,000 and 5,000

[18] Picture taken from article, 'A Brief History Of Genetically Modified Organisms: From Prehistoric Breeding To Modern Biotechnology, *available at:*https://www.medicaldaily.com/brief-history-genetically-modified-organisms-prehistoric-breeding-modern-344076(Visited on 28 March, 2016)

BC. Bananas were grown and hybridized in Papua New Guinea during the same period. Cotton was domesticated in Peru by 3600 BC.[19]

Agriculture was born from these discoveries. Recent evidence shows that agriculture was born independently in seven regions of the world -

- in the fertile Crescent of the Middle East about 10,000 years ago
- in the Yangtze River corridor in southern China about 8,500 years ago
- in the Yellow River Valley in northern China about 7,800 years ago
- in central Mexico about 4,800 years ago
- about 4,500 years ago in the south of the Andes
- in the eastern United States about 4,400 years ago
- And 4000 years ago in sub-Saharan Africa.


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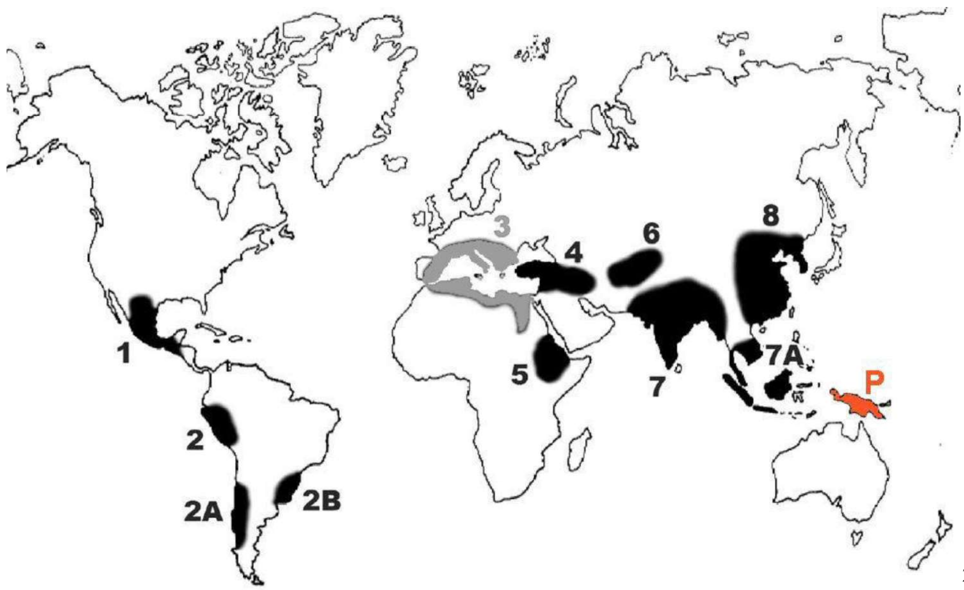
[19] Broudy, Eric,"The Book of Looms: A History of the Handloom from Ancient Times to the Present" published in UPNE.ISBN 978-0874516494, (1979).

[20] Ploughing with a yoke of horned cattle in Ancient Egypt. Painting from the burial chamber of Sennedjem, c. 1200 BC. Picture *available at* https://en.wikipedia.org/wiki/History_of_agriculture (Visited on 12 April, 2015)

Gregor Mendel was a scientist and an Augustinian monk. He lived today in the Czech Republic. He is considered the father of modern genetics because of his experiments on plant hybridization. In hybridization, plants (or animals) of different species are grown. Plants hybridize more frequently because pollen often spreads to other flower species. He played between 1856 and 1863 mainly with pea plants, then his work was later drawn upon in genetic engineering.[21]



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**Centres of origin identified by Nikolai Vavilov in the 1930s.**

Agriculture began independently in different parts of the globe. At least 11 separate regions of Agriculture started independently in different parts of the world. At least eleven different regions of the Old and New World were involved as independent centers of origin. The scientific basis of today's incredible hybrid crops goes back over 150 years, but it was not until the early 1930s that hybrids caught the attention of farmers in the Midwest. Maize was the first common hybrid seedling and is still the largest crop in the United States.

The review of corn selection gives a good overview of the science of hybridization or considers the wonder of corn. When local Aztec ancestors started growing wild

[21] Abigail Cardinal, 'Gregor Mendel's Influences for his Pea-Plant Experiments' *available at:* https://sites.google.com/a/wisc.edu/ils202fall11/home/student-wikis/group8(Visited on 12 April, 2015)

[22] Centres of origin identified by Nikolai Vavilov in the 1930s *available at*https://en.wikipedia.org/wiki/History_of_agriculture(Visited on 26 April, 2015)

grass called Teosinte, they did not know they were producing the ancestors of maize and corn. Teosinte had many small stalks, each with several small grains spikes. For millennia, farmers have selected the best plants of each generation, and corn plants have been processed into a single stalk. The seeds are well packed in a few large, easily harvested cobs. Modern corn could not survive as species without human intervention the cobs are so full of seeds and shells that the plant itself cannot spread its own seeds. People have to break the cobs off the stalks, husk the cobs, break the kernels off the cob and plant the seeds -- otherwise the species would die out.

## 2.3 Traditional Knowledge

The indigenous peoples of the world have an extraordinary knowledge of their environment, based on a natural life of many centuries. They live in and out of the wealth and diversity of complex ecosystems. They know the characteristics of plants and animals, the functioning of ecosystems, and the techniques and methods for using and managing these ecosystems. Rural communities in developing countries use local species for many foods, medicines, fuels, construction materials, and other products. Similarly, humans have knowledge and perceptions of the environment and their relationships with them are often important elements of cultural identity. Traditional knowledge is the foundation of humanity, because the knowledge stored at that time helps to building the future. The most popular assets of humanity are the ideas and wealth of knowledge of the communities. In the simplest sense, traditional knowledge can be defined as part of the knowledge accumulated by a group or transmitted from generation to generation. A probable definition presented to the World Trade Organization is that knowledge, which consists essentially of innovations, creations and cultural expressions created or managed by current owners who may be defined and identified as holders of rights who are either individuals or whole communities, natural or legal persons.[23]

Traditional knowledge is the result of intellectual activity in various traditional contexts that have travelled from generation to generation over the years. The term

[23] The Protection of Traditional Knowledge and Folklore *available at*http://www.wto.org/english/tratop e/trips e/ipcw370 e.doc(Visited on 2 February, 2015)

"traditional knowledge" is a very broad term that encompasses indigenous knowledge in various categories such as agricultural knowledge and medical knowledge; bio diversity related knowledge as well as expressions of folklore in the form of music, dance, songs, handicraft, designs etc. It has played and still plays an important role in the life of indigenous communities. But here the researcher would only focus on the traditional knowledge in the area of agriculture and biodiversity. The traditional knowledge includes the knowledge possessed by the local communities including farmers and indigenous peoples e.g. A plant varieties locally developed by the farmers over the year.

### 2.3.1 Meaning and Definition of Traditional Knowledge

The term "traditional knowledge" has been the subject of many conceptualizations. The various terms such as traditional knowledge (TK), indigenous knowledge (IK) and local knowledge are used interchangeably to refer to the long-standing traditions and practices of particular regional, indigenous or local communities, often expressed through stories, legends, folklore, rituals songs, and even laws. TK is information that members of a particular community have developed over time through their experience and adaptation to local culture and environment. Knowledge and practices, explicit or implicit, are used to guide the socio-economic and environmental aspects of life.

Traditional knowledge is generally considered as information existing in society and transmitted by previous generations. This may include, but is not limited to, information about the product, its use, the method of use, and the process or manufacturing process. All this information was in use and majority are still being used by the members of the society.[24] Community, society and culture are preserved through the proper processing of traditional knowledge, which is also used to conserve the genetic resources necessary for the sustainability of the community.

TK is implanted in the local culture of indigenous communities. This knowledge is an essential basis for a holistic vision of the natural and artificial foundations of

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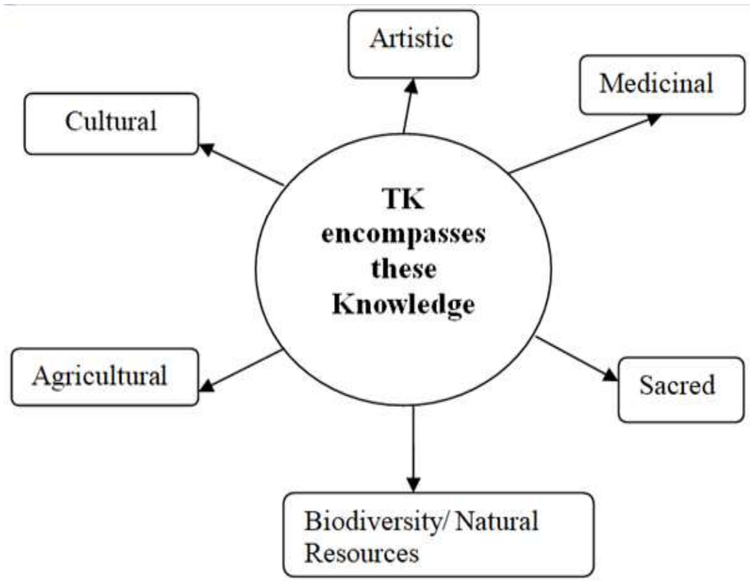
[24] N. S. Gopalakrishnan, '*The Impact of Patent system on Traditional Knowledge*', Cochin University Law Review, Vol. XXII, p. 220. (1998)

the life of these peoples. TK includes belief systems that play an important role in livelihoods, health care and sustainable development of people. In general, the term covers a wide range of indigenous issues, including the population's medical knowledge, folklore and various teachings. Traditional knowledge is also a commonly used term for indigenous knowledge, defined as a coherent system that combines social behavior, human physiology and botanical observations. It is a body of knowledge made up of a group of people through generations of living close to nature. It includes a classification system, a set of empirical observations on the local environment and an autonomous system governing its use.[25]

According to Article 8 (j) of the 1992 Convention on Biological Diversity, traditional knowledge is defined as follows: 'knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.' According to WIPO, traditional knowledge includes tradition-based, literary, artistic or scientific works, performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed information and any other innovations and creations based on tradition and resulting from the intellectual activity in the industrial, scientific, literary or artistic fields. Therefore, the term generally refers to knowledge held by indigenous people in one or more societies and in one or more forms, including art, dance and music, medicines, expressions of culture, biodiversity, knowledge and protection of plant varieties, handicrafts, designs, and literature. It also contains information on the use of biological material and other materials for medical treatment and agriculture, production processes, rituals and other techniques. TK is a global concept that

[25] Johnson Lore, *'Capturing Traditional Environmental Knowledge'*, Dene Cultural Institute and International Development Research, Ottawa, Canada, 1992.

covers many areas of human creativity.[26]




[27]

The understanding of the traditional knowledge and its topic by the contributors was different. According to the indigenous contributors, a review of the protection of traditional knowledge begins with an understanding of the relationship between land, as the source of their knowledge, and self-determination. A group of indigenous people's organizations emphasized the link between land and self-determination in a statement that indigenous peoples, as guardians and the owners of their knowledge have the exclusive right to control and manage them.

The treaty on Intellectual, Cultural and Scientific Resources recognizes self-determination as a unanimous priority of indigenous peoples and subjects fundamental rights such as the recognition and respect of their cultures, societies and languages as well as ownership of and control over their own land and even within territories and control over the resources that are associated with those lands and territories. Intellectual, cultural and scientific property rights are considered to be the starting point for defining a more useful category of traditional values, knowledge and resources that are often used and misused without authorization,

[26] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,*available at*https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_6-main1.pdf (Visited on February. 2015)

[27] Areas of TK, Intergovernmental Committee on Intellectual Property and Genetic Resources Traditional Knowledge and Folklore *available at* https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_3/ wipo_grtkf_ic_3_9.pdf (Visited on February. 2015)

recognition of origin, or just compensation. The Covenant presumes that fundamental right of indigenous peoples, which it regards as a "fundamental element of self-determination" for all its elements. "Their right not to sell dispose of or seize certain areas of knowledge and certain sacred places, plants, animals and objects". According to the World Council of Indigenous Peoples, the right to self-determination is a right of indigenous peoples to freely decide on their political, economic, social, religious and cultural development.[28]

### 2.3.2 Features of Traditional Knowledge

Some key features of TK can be recognized as follows:

i. It is passed from generation to generation
ii. In many cases, it is transmitted verbally from one generation to another from one person to another.
iii. Communities measure it as a reward for God and not as a personal wealth.
iv. This knowledge generally distinguishes one community from another
v. It is usually impossible to identify the originator of the information
vi. He is educated by constant observation, experience and practice
vii. it is an inseparable part of the collective and cultural life of its owners and
viii. it is usually associated with biological ownership.

Usually, traditional knowledge is that knowledge

i. Traditional only to the extent that its conception and use constitute a separation of the cultural traditions of a community; essentially, this does not mean that knowledge is old or static.
ii. representative of people's cultural values and therefore generally collectively
iii. is not limited to any particular field of engineering or the arts, and
iv. Belongs to a community and its use is often limited to specific members of that community.[29]

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[28] Indigenous Heritage and Intellectual Property, '*Genetic ResourcesDeclaration of Principles of the World Council of Indigenous Peoples*,' as reprinted in Posey and Dutfield (1996).
[29] Daniel Gervais, '*Traditional Knowledge and Intellectual Property: A TRIPS Compatible Approach*',
Michigan State Law Review - Spring (2005)

Traditional knowledge has been acquired through thousands of years of experience. Local and indigenous communities have been responsible for the development and preservation of traditional knowledge for centuries, as stratagem for their endurance in the biosphere. Traditional knowledge is often part of the social and day-to-day life of a community, and is generally considered not to be "knowledge" separate from the civilization of the community, but essential to the culture and his identity as a community. In most cases, TK is known to the entire community and remains fully there, although knowledge of a particular skill or art may from time to time be restricted to some members of the community. This knowledge and its components are usually necessary for a normal lifestyle in society. It is passed on from generation to generation and retains its original individuality. Traditional knowledge is essentially culturally or rooted and forms an integral part of the cultural identity of the social group in which it operates and is preserved.

Traditional knowledge is neither written nor transmitted in any form, but transferred verbally through rehearsals. However, these properties do not affect the reliability or importance of this knowledge. TK therefore lives naturally and is a system of continuous improvement that modifies and refines existing knowledge in a unique way. TK does not always mean that this knowledge must be old; recently established knowledge based on existing knowledge can also be traditional knowledge. What is traditional about the TK is not its antiquity but the way it is acquired and used. The social process of knowledge exchange, unique in each indigenous and local culture, is the core of its traditionalism. Although traditional knowledge is not old, it has unique social significance.

Traditional knowledge co-operates and is often measured as the wealth of the whole community and does not belong to anyone in the community. It is transmitted through clearly defined cultural and traditional information exchange mechanisms, obtained from elders or specialists such as healers, breeders, etc. Some variants of traditional knowledge are formalized or codified in one way or another. The lion's share of traditional knowledge, however, is not codified and transmitted orally from generation to generation. However, another category of TK that only concerns "elders" in the affected community may be relevant to the rest of the world. Traditional knowledge may belong to individuals or members of a particular group or to all members of an indigenous group or community. In the end, the number of knowledge carriers does not influence the degree of sophistication and novelty of this knowledge in the outside world. However, traditional knowledge can also be disseminated around the world, particularly with regard to the dissemination of genetic resources.

The Alaska Native Science Commission (ANSC) summarizes these features as follows: A common sense based on lessons and experiences passed down from generation to generation. Traditional knowledge concerns the knowledge of the country.

- This includes knowledge of the environment (snow, ice, weather, resources) and relationships between elements. It's holistic.
- It cannot be compartmentalized or separated from people who hold it. It is rooted in the spiritual health, culture and language of the people.
- It is a way of life in which a system of authority sets the rules for the use of resources and the obligation to share.
- It's dynamic, cumulative and stable. It's the truth. Traditional knowledge is a way of life - wisdom means the wise use of traditional knowledge.
- He uses the heart and the head together. It comes from the mind to survive.
- It gives credibility to the population. Alaska Native Science Commission ANSC[30]

Although traditional knowledge in its various forms has been developed in ancient times, it has been modified, improved and adapted to the needs of a society in constant evolution and continues to grow. Traditional knowledge is not really contemporary, it has been used for generations and, in many cases, collected and published by anthropologists, historians, botanists or other researchers and observers. Traditional knowledge expressed in various documented and undocumented forms may have economic value depending on potential or actual use. Where TK can be used and understood outside of their local / community

[30] See Alaska Native Science Commission [ANSC]. (n.d.). What is Traditional Knowledge? Retrieved November 9, 2008, from http://www.nativescience.org/html/traditional_knowledge.html (Visited on 12 May, 2015)

context, they acquire commercial value. Traditional knowledge is used differently in the industry. In the pharmaceutical industry, traditional knowledge seems to be mainly used when an active ingredient has been identified for further research. In the seed industry, traditional knowledge is often not used directly, but much traditional knowledge is incorporated into the genetic material that companies acquire from other organizations. Although the application, and in particular the provision of TK-based products, can be made via commercial channels, TK may have commercial value. Knowledge that cannot be used outside the context of the community has little or no commercial value, although it may be useful to the community of origin.[31]

### 2.3.3 Significance and Scope

Traditional and indigenous knowledge has been used for centuries by indigenous and local communities under local laws, customs and traditions. It has been transmitted and evolved from generation to generation. TK has played, and still plays, an important role in vital areas such as medical treatment, food security and the development of agriculture. TK is also the cause of a great variety of artistic expressions, including musical works and handicrafts.

TK is a central component for the daily life of millions of people in developing countries. Traditional Medicine (TM) serves the health needs of a vast majority of people in developing countries where access to modern health care services and medicine is limited by economic and cultural reasons. It is often the only affordable treatment available to poor people and in remote communities. TK constitutes the ancient knowledge of humanity, the deepest layer on which our science and culture have developed, the local solutions that have allowed the creation and management of ecosystems and cultural landscapes on the entire surface of the planet. It enables the development of solutions with a low energy and resource use that are able to adapt to environmental variability and to react to emergencies and catastrophes in flexible and multifunctional ways. Today, while entire planet systems risk ecological collapse, TK shows how to interact with the environment enhancing its

[31] Martine Koning, *'Biodiversity Prospecting and the Equitable Remuneration of Ethnobiological Knowledge, Reconciling Industry and Indigenous Interests,'* Intellectual Property Journal, No. 12,p. 265, (1998)

resource potential without exhausting it.[32] In addition, it cannot be excluded that traditional knowledge might have an industrial application, even if the tangible object to which the intangible knowledge relates has not been subject to any scientific interference or modification.[33]

## 2.4 Genetic Modification

**Timeline of Genetic Modification**

| YEAR | DEVELOPMENT |
|---|---|
| 1935 | DNA Discovered |
| 1973 | Recombinant DNA created |
| 1975 | Asilomar Conference |
| 1980 | Firs GMO Patent Issued on Micro organisms |
| 1982 | FDA Approves First GMO |
| 1988 | China, First Country to grow Commercial crop: Tobacco |
| 1994 | GMO Hits Grocery Stores |
| 1996 | GMO Resistant Weeds |
| 1997 | Mandatory Labels in Europe |
| 1999 | GMO Crops Dominate |
| 2003 | GMO Resistant Pest appear |
| 2011 | Bt Toxin Discovered in US |
| 2012 | Farmer Wins Battle |
| 2014 | GMO Patent Expires |

Genetic Engineering is also called as Genetic Modification or Genetic Manipulation using Biotechnology. The terms 'gene technology', 'genetic engineering' and 'genetic manipulation', 'genetic enhancement', 'gene splicing',

32 Traditional Knowledge World Bank, available at http://www.tkwb.org/web/?page_id=4 &language =i.t (Visited on 27 January, 2015)
33 See, G. Dutfield., "Indigenous Peoples, Bioprospecting and the TRIPS Agreement", in P. Drahos and M. Blakeney (ed.), Perspectives on Intellectual Property: IP in Biodiversity and Agriculture", Sweet and Maxwell, London, p. 146, (2001)

'transgenics' or the use of 'recombinant DNA' are terms used to describe genetic modification processes. They all refer to one application of biotechnology.

According to the Merriam-Webster dictionary defines “Genetic Engineering as the group of applied techniques of genetics and biotechnology used to cut up and join together genetic material and especially DNA from one or more species of organism and to introduce the result into an organism in order to change one or more of its characteristics.”[34]

According to Encyclopedia Britannica, “Genetic Engineering is the artificial manipulation, modification, and recombination of DNA or other nucleic acid molecules in order to modify an organism or population of organisms.

The term genetic engineering initially referred to various techniques used for the modification or manipulation of organisms through the processes of heredity and reproduction. As such, the term embraced both artificial selection and all the interventions of biomedical techniques, among them artificial insemination, in vitro fertilization (e.g., “test-tube” babies), cloning, and gene manipulation. In the latter part of the 20th century, however, the term came to refer more specifically to methods of recombinant DNA technology (or gene cloning), in which DNA molecules from two or more sources are combined either within cells or in vitro and are then inserted into host organisms in which they are able to propagate.

The possibility for recombinant DNA technology emerged with the discovery of restriction enzymes in 1968 by Swiss microbiologist Werner Arber. The following year American microbiologist Hamilton O. Smith purified so-called type II restriction enzymes, which were found to be essential to genetic engineering for their ability to cleave a specific site within the DNA (as opposed to type I restriction enzymes, which cleave DNA at random sites). Drawing on Smith’s work, American molecular biologist Daniel Nathans helped advance the technique of DNA recombination in 1970–71 and demonstrated that type II enzymes could be useful in genetic studies. Genetic engineering based on recombination was

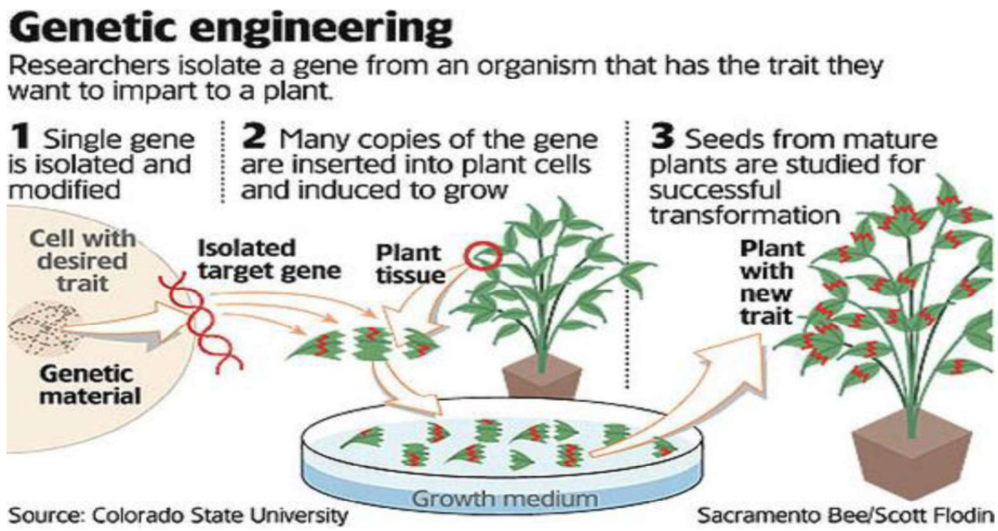
[34] Merriam-Webster dictionary, https://www.merriam-webster.com (Visited on 2 June, 2015)

pioneered in 1973 by American biochemists Stanley N. Cohen and Herbert W. Boyer, who were among the first to cut DNA into fragments, rejoin different fragments, and insert the new genes into E. coli bacteria, which then reproduced.

A subsequent generation of genetic engineering techniques that emerged in the early 21st century centered on gene editing. Gene editing, based on a technology known as CRISPR-Cas9, allows researchers to customize a living organism's genetic sequence by making very specific changes to its DNA. Gene editing has a wide array of applications, being used for the genetic modification of crop plants and livestock and of laboratory model organisms (e.g., mice). The correction of genetic errors associated with disease in animals suggests that gene editing has potential applications in gene therapy for humans.

Genetic engineering involves the manipulation of genes within a species, and may also involve the transfer of genes—and thus the characteristics governed by those genes—from one species to another. Genetic modification is also used with plants. Genes can be found in and moved between different plants, animals or micro-organisms such as viruses or bacteria. Genes can also be altered within a specific plant, animal or micro-organism. For example, an undesirable characteristic such as susceptibility to a particular disease can be 'switched off' or modified in some way to benefit the plant or animal.

Genetic engineering goals in plants include flower color and in agriculture include improving crop production and introducing new traits, such as enhanced nutrients, temperature resistance, or the ability to grow in saltier soils. Certain characteristics may allow a Genetically Modified (GM) crop to be grown, harvested, or shipped at lower cost or with less damage and may allow the crop to be grown using less pesticide.This involves the deliberate modification of an organism's genetic material by moving, introducing or eliminating specific genes. For example, scientists can now take a single gene from a plant or animal cell and insert it into another plant or animal cell to give the second cell a desired characteristic such as the ability for a plant to withstand certain herbicides. Two types of GM crops are produced. One is herbicide resistant, incorporating a gene capable of resisting an herbicide meant to kill weeds. The second is insect tolerant. Here, a gene of a soil bacterium, *Bacillus thuringiensis*, produces a toxin capable of killing the cotton pest, namely bollworm. When inserted into the plant, it becomes tolerant to bollworm attack. Names of genetically modified plants are prefixed with Bt cotton, Bt corn, Bt soy and Bt maize.




[35]


**[36]**

[35]http://kmbiology.weebly.com/genetic-engineering---notes.html (Visited on 12 June, 2015)
[36]Transgenic Organisms in Agriculture, http://kmbiology.weebly.com/genetic-engineering---notes.html (Visited on 21 June, 2015)

### 2.4.1 Genetic Modified Organisms

Genetically Modified Organism (GMO) is any organism whose genetic material has been altered using genetic engineering techniques. A wide variety of organisms have been genetically engineered, from animals to plants and microorganisms. Genes have been transferred within the same species, across species (creating transgenic organisms) and even across kingdoms. New genes can be introduced, or endogenous genes can be enhanced, altered or knocked out. Creating a genetically modified organism (GMO) is a multi-step process. Genetic engineers must isolated the gene they wish to insert into the host organism and combine it with other genetic elements, including a promoter and terminator region and a selectable marker. A number of techniques are available for inserting the isolated gene into the host genome. GMOs have been used in biological and medical research for example in agriculture golden rice, resistance to herbicides. Plants have been engineered for scientific research, to create new colours in plants, deliver vaccines and to create enhanced crops.

### 2.4.2 Genetically Modified crops

Genetically Modified Organisms, are the ones in which the genetic material (DNA) has been altered in such a way as to get the required quality. This technology is often called 'gene technology', or 'recombinant DNA technology' or 'genetic engineering' and the resulting organism is said to be 'genetically modified', 'genetically engineered' or 'transgenic'. GM products (current or those in development) include medicines and vaccines, foods and food ingredients, feeds and fibre. Genetically modified (GM) crops are the creation of human beings. GM crops are genetically modified organisms (GMO) and an organism whose genetic[37]characteristics have been altered by the insertion of a modified gene or a gene from another organism using the techniques of genetic engineering is called a genetically modified organism. In other words GM Organisms are plants (or in some cases animals or microorganism) that contains genes extracted from deferent

[37] Word 'Genetic' is connected with the units in the cells of living things (Genes) that control what a person or plant is like. Oxford Intermediate Learner's Dictionary, at p.283, (2000)

type of organisms, be they viruses, bacteria, plants, animals, and so forth, inserted artificially into the subject organism.[38]

Genetically modified organisms (GMOs) are organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally[39]. All living organisms, from viruses to human beings, are made up of cells, with a nucleus at the centre, which contains a unique set of instructions regarding their size, strength and other qualities. These instructions are found on a long molecule called DNA (Deoxyribonucleic Acid), which is divided into small sections called genes. It is the sequencing of genes on DNA that determines an organism's characteristics. Very simple organisms such as bacteria may have fewer genes than the more complicated ones. In simple terms, the complete set of genetic material of an organism, i.e., the entire DNA contained in an organism, is called a genome. The process of isolating gene(s) from the genome of one organism and inserting the same into the genome of another organism is known as Genetic Engineering. In nature, exchange of genes happens only between compatible or closely related species. However, the modern technique of genetic engineering facilitates the removal of group of genes from one species and insertion into another, there being no need for compatibility. The transfer process involves shifting the desired gene from the chromosome of a particular plant or animal or any other organism into a cell. This genetically modified cell is then regenerated to produce a 'genetically modified organism' (GMOs). The modified organism passes the new gene onto its progeny. Such methods are now being used to create GM plants, of desired quality, growth and strength. Basic idea is to have plant varieties with high yield, pest/ disease resistant, or other such qualities mainly for better marketability and durability. This is different from the processes of modifying crops/plants from their wild ancestors through selective breeding or mutation breeding, which have been practised by farmers as part of their regular farming activity.[40]

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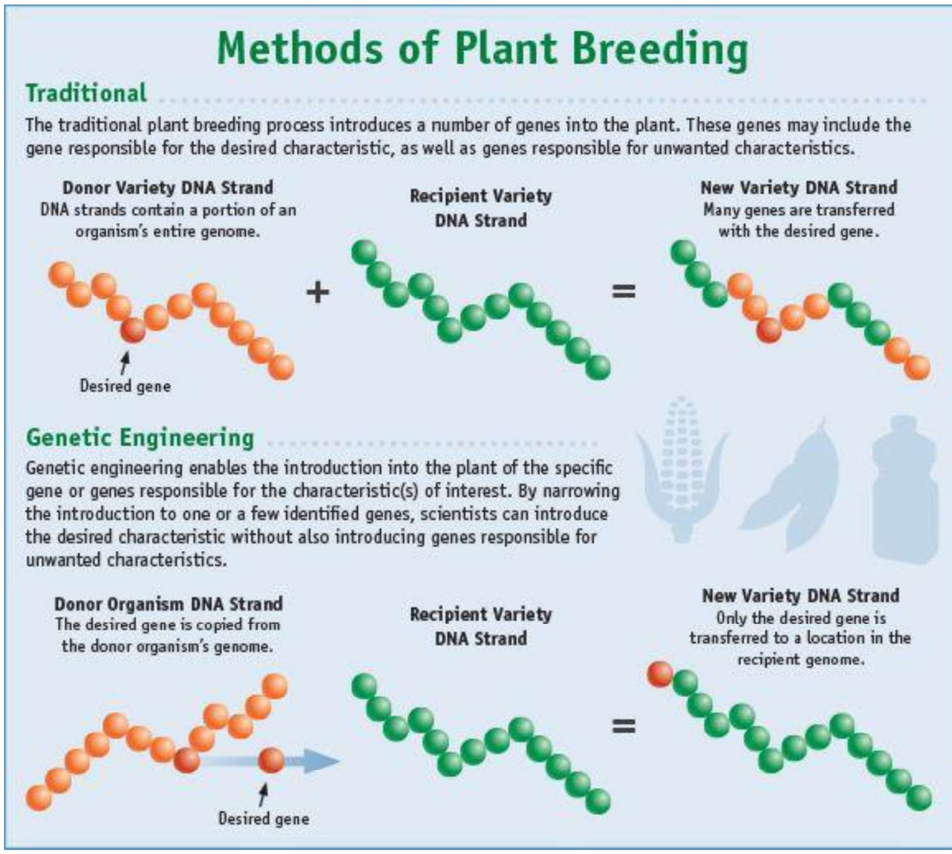
[38] Michael L. Mckinny et. al. (edt.) *Environmental Sciences: System and Solutions,* 357, (2007).
[39] "Naturally" meaning by mating or natural recombination.
[40] Genetically Modified Crops: Issues And Challenges In The Context Of India Research Unit Larrdis Rajya Sabha Secretariat( New Delhi 2009)

The technology used to do this genetic modification[41]allows selected individual genes to be transferred from one organism into another, either from the same species or from a non-related species. Genetic modification is one of a number of a activities that are often referred to by the term “modern biotechnology” Modern Biotechnology is usually understood to refer to the application of scientific and engineering principles to biological materials to produce goods and services.



[42]

The history and future of GM crops can be better understood by discussing about the three generations of GMOs:

- ***First generation GMOs*** are often identified as the major reason why biotechnology in the agriculture/food sectors has proved so controversial. This refers to the application of the new technologies to generate arguably private benefits for biotechnology companies. Products include herbicide resistant

[41] Sometimes also called “recombinant DNA technology” or “genetic engineering”.
[42]https://gmoanswers.com/get-know-gmos-month-science-gmos (Visited on 11 August, 2015)

Soya or maize.[43] Seeds of these products, which claim wide agronomical benefits, may be sold at a premium as a result of the reduced need for plant protection products such as insecticides- frequently produced by the same companies, The first generation of GMOs may produce the substantial environmental benefits claimed, but, particularly in the light of the moratorium existing in the Community, the opposing sides in the biotechnology debate unsurprisingly have not reached agreement on this vital point.

- ***The second generation of GMOs*** are largely developed, but have not yet been authorized for commercial release in the Community. Resulting products include viral-resistant race, "terminator gene' GMOs (the so-called "suicide seeds"), and frost-tolerant fruit or vegetables. Terminator GMOs have proved the most controversial of second generation products, as they ensure that seeds saved after harvest (common farming practice particularly in the third world) will not germinate. Application of this technology is thought to be capable of transferring considerable power from the farming community to small number of biotechnology companies.

- ***Third generation GMOs*** are generally not yet fully researched. This generation has, however, already been credited with the ability to alter dramatically the debate on use of GM technology in food, and to revolutionize consumer acceptance of GM technology. Resulting products are multi-functional and generally possess clear benefits for parties other than their manufacturers. These would include "neutraceuticals" (crops boosted with vitamins or minerals); vaccine crops ( at present banana and potato ) containing genetic material from pathogens that operate as vaccines when eaten; and physiologically altered crops to increase efficiency of use of natural resources such as nutrients in soil and water in drought areas, for example, and by accelerating growth. Third generation GMOs, more than any other product of

[43] Michael I. Jeffory et .al. (edt.), *Biodiversity conservation + Livelihoods : Bridging the North South Divide,* 485 (2008).

the biotechnology industry, are thought to have an important role to play in sustainable development.[44]

### 2.4.3 Genetically Modified Seeds

GMO stands for Genetically Modified Organism, and it can describe the way many products in industries like medicine, scientific research and agriculture are made. When it comes to food, GMO refers to seeds. They grow in the ground like any other seed, only genetically modified (GM) seeds have certain desirable traits setting them apart. These seeds grow into plants that might use water more efficiently or better withstand pests like bugs or weeds, which means they may require less farmland to grow.[45]

#### 2.4.3.1 Process of Genetic Modification

Genetic modification of plants occurs in several stages:

1. An organism that has the desired characteristic is identified.
2. The specific gene that produces this characteristic is located and cut out of the plant's DNA.
3. To get the gene into the cells of the plant being modified, the gene needs to be attached to a carrier. A piece of bacterial DNA called a plasmid is joined to the gene to act as the carrier.
4. A type of switch, called a 'promoter', is also included with the combined gene and carrier. This helps make sure the gene works properly when it is put into the plant being modified. Only a small number of cells in the plant being modified will actually take up the new gene. To find out which ones have done so, the carrier package often also includes a marker gene to identify them.
5. The gene package is then inserted back into the bacterium, which is allowed to reproduce to create many copies of the gene package.
6. The gene packages are then transferred into the plant being modified. This is usually done in one of two ways: By attaching the gene packages to tiny particles of gold or tungsten and firing them at high speed into the plant

[44] Brian Sheridan ,*EU Biotechnology Law And Practice : Regulating Genetically Modified & novel food products*. 4 (2001).
[45]https://modernag.org/innovation/the-science-inside-gmo-seeds/ (Visited on 18 March, 2018)

tissue. Gold or tungsten are used because they are chemically inert – in other words, they won't react with their surroundings by using a soil bacterium, called *Agrobacterium tumefaciens*, to take it in when it infects the plant tissue. The gene packages are put into *A. tumefaciens*, which is modified to make sure it doesn't become active when it is taken into the new plant.

7. The plant tissue that has taken up the genes is then grown into full size GM plants.
8. The GM plants are checked extensively to make sure that the new genes are in them and working, as they should. This is done by growing the whole plants, allowing them to turn to seed, planting the seeds and growing the plant again, while monitoring the gene that has been inserted. This is repeated several times.[46]

## 2.5 GM Debate

In some cases, GM crops may yield entirely new products that are not normally derived from traditional crops—such as medicines. Supporters of this technology point to the potential of GM crops to improve human health and increase environmental protection. However, some concerned groups and individuals have argued that the risks of GM crops may outweigh their benefits. These groups urge avoiding GM crops or, at the very least, subjecting them to more rigorous scrutiny by government regulators.

The technology of genetic modification is practiced in the field of medicine, For example, animal insulin and growth hormones are modified so as to be identical to hormones produced by the human body. A scientific approach to plant breeding has been practiced since the early years of the last century; Genes have long been moved into crops by cross-pollination. The use of GM Technology, however, may be distinguished from conventional plant breeding in two ways:

- The technology employed is much more precise—only a few specific genes are inserted;

[46]http://www.deskuenvis.nic.in/pdf/gm.pdf(Visited on 21 August, 2017)

- The range of possible genes that may be inserted by GM techniques is much greater.

Here, the researcher had discussed the concept of genetically modified crops and GMOs in context of legal regulation and environmental implications.

**Case in favor of GM Crops**

GM foods may

- Resist damage due to weather, like frost or drought.
- Grow more easily in some environments
- Produce more crops helping to keep food prices lower and ensuring food security
- Ripens slower and last longer during shipping
- Bruise less easily
- Need less pesticides like herbicides and insecticides
- Have less disease caused by insects or viruses
- Have more of a certain nutrient.

## 2.6 Position on TK and GM: USA

Farmers have grown commercial GM crops for about 20 years, but genetic modification in crops is much older. Farmers have been intentionally changing the genetic makeup of all domesticated crops for about 10,000 years.

*"The first ideal of the pioneer was that of conquest. It was his task to fight with nature for the chance to exist. Not as in older countries did this contest take place in a mythical past, told in folk lore and epic. It has been continuous to our own day. Facing each generation of pioneers was the unmastered continent. Vast forests blocked the way; mountainous ramparts interposed; desolate, grass-clad prairies, barren oceans of rolling plains, arid deserts, and a fierce race of savages, all had to be met and defeated."*[47]

[47] Available at Frederick Jackson Turner recounted in his influential work *The Frontier in American History* (1920)

The farm in early America was not the home to a settled people but a sign of the conquest of nature by mobile and entrepreneurial newcomers. Americans experienced a very different sense of space and landscapes. When the settlers disembarked in the New World, they found seemingly unlimited land and resources. From the beginning, therefore, farming has been associated by Americans with the need to win a livelihood.

In mid-19th century America, Partly because of the way agriculture has practiced as the occupation oriented to pioneers, farming was sometimes portrayed as a disturbance into the natural landscape, not a part of it, and still less the highest form of cultivating it. Farming in the 1930s on the Great Plains was perhaps the most difficult occupation in the world. Farmers not only faced a global economic slowdown of historic proportions, but they also faced one of the worst and longest droughts in America's history. In 1944, Oswald Avery tentatively identified DNA as the true carrier of molecular information, and his findings were confirmed in 1952. Less than a year later, in 1953, James Watson and Francis Crick described DNA's molecular shape as a double helix. That opened the door to genetic engineering. Dust Bowl conditions of the 1930s. No-till farming and other kinds of conservation tillage, which involve less significant disruption of the soil, were first adopted in the United States in the 1950s, but only really caught on in the 1970s, following the development of herbicides and specialized planting equipment necessary to farm without plowing.

People around the world had no money to buy the crops and animals that farmers produced, and the drought made it almost impossible to plant and harvests the crops in the first place. As a result, many farmers lost their farms. Many moved west out of the Great Plains of the United States, looking for any kind of work they could find. Many became migrant farm laborers on the West Coast. There have been depressions and economic slowdowns in other times in history, but this is the only one known as the "Great" Depression, and it changed history.

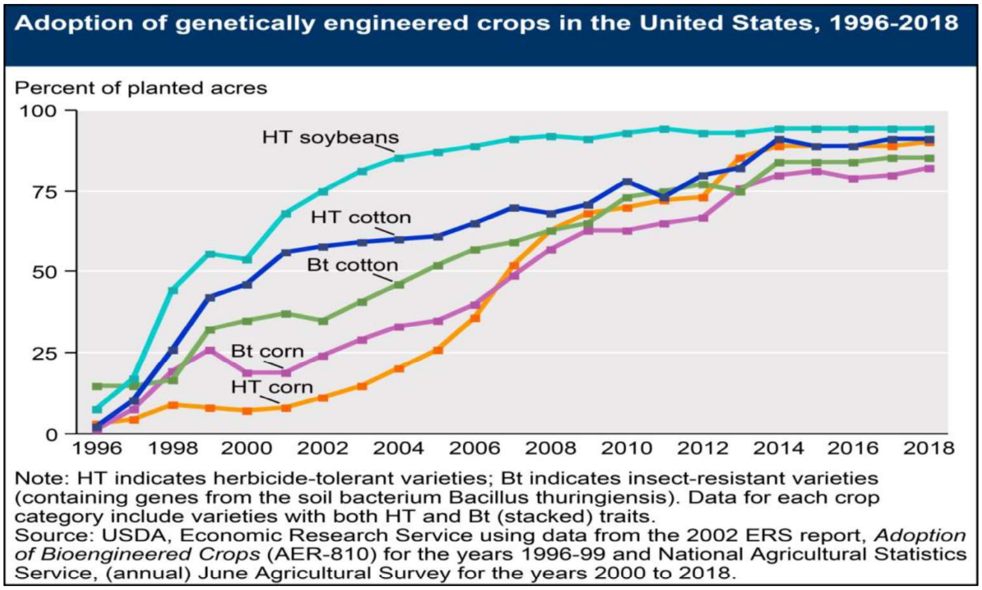
In the late 19$^{th}$ century, the preservation of untouched wilderness became an important goal for the American environmentalist movement, though others would emphasize the conservation of natural resources for human use. Americans have moved away from the traditional practice of plowing. Among its other advantages, plowing helps to destroy weeds prior to planting, making the use of herbicides less necessary. However, plowing also dries and condenses the soil, and in drier climates like those that prevail in the central United States, this can lead to extensive erosion, as witnessed by American farmers in the shattering.

After describing the historical and cultural roots of the American attitudes, it is worth saying a bit about what genetically modified foods are and the reasons they are grown at all. There are many genetic modification technologies that can accomplish this, with varying degrees of efficiency. Breeding techniques have been used by farmers for millennia to select plants or animals with the best genes for their purposes but breeding does not directly manipulate DNA in organisms; rather it changes the prevalence of different kinds of genetic variants in the population. The first modern method for genetic modification employed recombinant DNA technology in which enzymes are used to cut specific DNA sequences out of one organism's genome to insert it into the genome of another. The inserted DNA sometimes comes from related species, but can also come from unrelated species.

The art of gene splicing dates from 1972. In that year, Stanley Cohen and Herbert Boyer developed techniques that made it possible to chemically cut and splice strands of DNA at specific places in the sequence. Boyer used an enzyme to cut the code for a specific protein and attach it to other DNA. Cohen added a way to introduce these DNA sequences into bacteria and yeast cells. Together the two scientists turned these microbes into hormone factories. In 1976, they founded the new company Genentech and introduced human genes that produce insulin into strains of bacteria. Those bacteria started manufacturing insulin. Next, they manufactured human growth hormone.

The next step in genetically modifying organisms for food was to ramp up from bacteria with thin cell walls to plants that have thick, tough cell walls. In 1976, agricultural researchers at the University of Washington discovered that a small, circular DNA molecule called a plasmid could insert itself into the nucleus of a plant cell and cause tumors. They had discovered what amounted to a natural form of gene splicing.  Some of the most successful varieties of GM crops in the United States have been corn and soybeans designed to be resistant to glyphosphate, an herbicide better known by its trade name, Roundup. The company that produces Round Up, Monsanto, created genetically engineered varieties of corn, soybean, and a few other crops that would survive being sprayed by the herbicide, allowing farmers to spray their fields extensively with the herbicide to destroy weeds.

The first genetically modified plant approved for agricultural production was the Flavr Savr tomato, which had been modified to produce less of the enzyme responsible for the softening of fruit as it ripens. First approved in the United States in 1994, production ceased in 1997 because of high production costs and poor sales. More successful GM varieties soon followed, but they have not been as conspicuously marketed to consumers and retailers as the Flavr Savr tomato. Rather, they have been designed to appeal to farmers and marketed as more efficient and profitable than non-modified varieties. Because the traits of GM crops are not designed chiefly with consumers in mind, and because the most successful GM crops are plants like soybean and corn that are incorporated into processed foods more than they are purchased fresh by consumers. GMOs have come to dominate the American corn and soybean markets other than a few varieties of zucchini and papaya, there are very few GM fruits or vegetables on the market, and only a single genetically modified animal the Aqua Advantage salmon has been approved by the U.S. Food and Drug Administration for human consumption. Nevertheless, according to one estimate, as much as 70 to 80 percent of the foods consumed in the United States contain some amount of GM ingredients.

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### 2.6.1 GMO problems in the U.S.

Even within the U.S., several controversies over GMOs have reached the boiling point since the turn of the century. In 2000, a genetically modified variety of corn called StarLink developed by Aventis had been approved for use in animal feed only. But that year, the EPA found traces of the StarLink genes in corn tacos intended for human consumption. Some consumers and studies suggested that StarLink caused allergic reactions.

In 2001, the EPA decided to ban even trace amounts of StarLink materials into the human food chain. In the meantime, other competing varieties like Bt corn had taken over the market. But the fact that a GMO corn had crossed over into supposedly non-GMO food stockpiles provided fuel to critics, especially in Europe.

Another controversy centered on organic food producers. While most production farmers here have embraced GMO varieties, there is a significant number of consumers who have not and are willing to spend a little more to find food that is

[48]U.S. Department of Agriculture Economic Research Service, https://www.ers.usda.gov/data products/adoption-of-genetically-engineered-crops-in-the-us/documentation/ (Visited on 20 July, 2015)

grown organically without GMO genes, artificial fertilizers or pesticides. The US Department of Agriculture adopted strict guidelines to ensure that "organic" foods didn't come in contact with GMO varieties. That took cooperation between neighboring farmers. But in 2009, farmers growing GMO sugar beets in Washington State, for example, refused to map out where they were growing the engineered crops. These farmers said they were afraid of ecoterrorism and burned crops. Their organic growing neighbors were flummoxed and sued. Organic farmers pointed out that pollen from the genetically modified plants can travel significant distances, and if even a trace of GMO material gets into the DNA of their crops, their markets would dry up.[49]

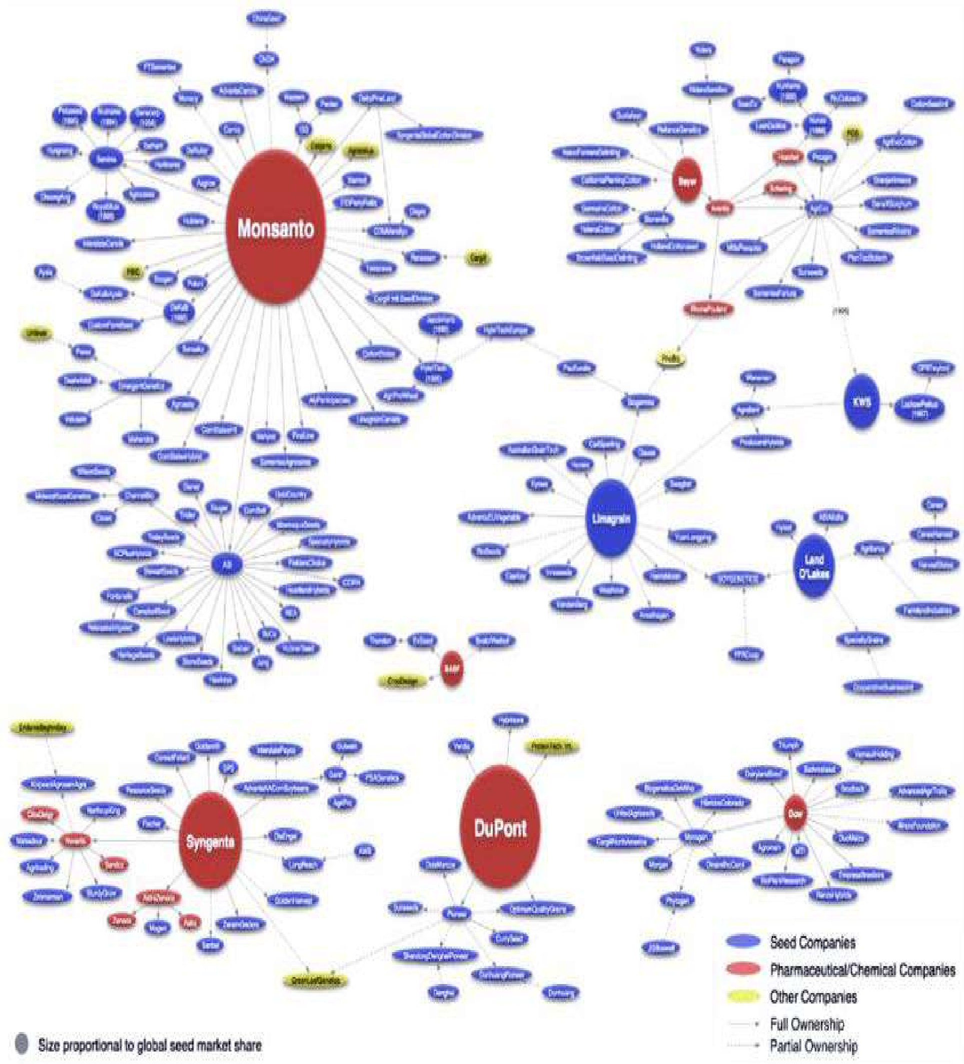
Environmentalists were also concerned when it was revealed that as many as 25 percent of GMO farmers were no longer complying with federal rules intended to maintain the resistance of the crops to damage from insects. Farmers and environmentalists have known for years that insects can mutate and build up a resistance to specific pesticides over several generations. So, around the turn of the 21st century, regulations were adopted that required farmers planting Bt crop varieties to plant at least 20 percent of their fields in non-Bt varieties. The theory is that if an insect becomes impervious to the Bt toxin, it is more likely to mate with a nonresistant insect from the refuge, and the offspring would not be resistant. But many farmers just couldn't see the reason to plant 20 percent of their fields with crops that will get lower yields or require costly application of traditional insecticides. The regulations were voluntary.

In the U.S., there are strict rules for each crop or livestock species set out by the USDA if a farmer or agricultural corporation wants to advertise and sell their products as organic. Congress enacted the Organic Foods Production Act in 1990, and the rules have evolved since then. Certification agencies and processes have been in place since 2002.

As an example, a farmer who wants to grow an organic crop, like wheat or corn, will need to follow these general rules:

[49] https://livinghistoryfarm.org/farminginthe70s/crops_14.html (Visited on 11 July, 2015)

- Organic products have to be grown on land that has NOT received any prohibited substances for a minimum of three years before the harvest of the first crop to be labeled "organic."
- Prohibited substances include synthetic herbicides and pesticides, synthetic fertilizers, and genetically modified organisms (like Bt or Roundup Ready seeds).
- The varieties of grain planted must come from certified organic seed stocks, and this regulation prohibits GMO varieties.
- Instead of artificial fertilizers, organic farmers rely heavily on crop rotation systems where organic legumes (like alfalfa) are grown for a few seasons and then plowed under to fertilizer the next year's crop of wheat or corn. Nutrients also come from animal manures, compost and naturally mined rocks like lime and rock phosphate.
- Crop rotation also helps with insect control and weed control because it breaks up cycles in pest species. In addition, organic weed control uses mechanical cultivators of cover crops.
- To make sure that prohibited pesticides and fertilizers stay away from organic fields, farmers have to maintain a buffer zone from their neighbors or roads. Typically, this buffer is 25-30 feet wide.
- All of these practices have to be carefully documented. Organic farmers will admit that there may be more work involved, but they don't buy nearly as many inputs.
- At the end of the first decade of the 21$^{st}$ century, organic farming supplies a niche of the overall food market. Supporters of the organic movement would like to see that market grow by leaps and bounds. They believe it is the only way to a healthier food supply, healthier rural economy and healthier planet.

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## 2.7 Position on TK and GM: CANADA

Agriculture of Canada has experienced a markedly distinct evolution in each region of the country. A varied climate and geography have been largely responsible for the condition but in addition to that each region was settled at a different period. Canadian agriculture has experienced a noticeably distinct evolution in each region of the country. Agricultural development in the early 19th century was limited by the skills possessed by the immigrants. Most of the famers were from the Highland

[50] Available at Diagram of the " Life Sciences " corporations (Visited on 22 September, 2015)

Scots and most of them were not trained for agriculture practice. All started from 1818 when a Halifax merchant named John Young started with new and improved farming methods named "Agricola". Agricultural societies were developed as a result which were government sponsored. As no locals of that time were much interested in farming so farmers could not cultivate in surplus for sale. Gradually by mid of the century farming communities grew and with that grew the need for the agriculture protection.

### 2.7.1 Relevant Legislation

The US had patented its first commercialized GM crop called FLavr Savr later it also was trying to patent same in Canada. Since than many GM crops have been commercialized. GMO's are used to grow GM foods. Before a GM food can be sold in Canada. By the year 1993 the government of Canada established the Federal Regulatory Framework for Biotechnology. And because of coming of this framework, the useful move toward regulating biotechnology was resulted as a harmony between federal regulatory departments on principles for an efficient, useful approach in biotechnology.[51] The framework initiated on instead of creating new regulations for new products produced via biotechnology they should regulated under existing regulations that cover traditional products. To avoid the duplication among regulatory agencies, no separate agency and separate legal framework for the regulation of biotechnology was created.

If the GMO's wants to enter the market either as a food or the animal feed they must be approved. The process of approval in based on the many regulations that are being imposed by Health Canada for foods, the Canadian Food Inspection Agency (CFIA) for seeds and livestock feed, and Environment Canada for any of the new substance released in the environment. Heath Canada makes sure it is safe to eat and will not harm ones health and environment. Since, 1994 about 85 GM foods are had been approved for sale in Canada. This includes GM food growth in Canada and GM foods that have been imported from other countries. Only four

[51] Canadian Food Inspection Agency (CFIA), Regulation of Agricultural Biotechnology in Canada: A Post-Secondary Educator's Resource 13 (2007) *available at* http://publications.gc.ca/collection/collection_2007/cfia-acia/A104-24-2007E.pdf. (Visited on 2 September, 2015)

main GM crops are currently grown in Canada including Canola, Soybean, Corn and Sugar beet. In Canada regulatory body reviews the new product rather than the process. In other word, the focus center is on the traits expressed in the products and not on the process used to introduce those qualities. This type of approach applies to both traditional breeding methods and as well as genetic engineering. So it can be said unlike other countries Canada depends on the conception of novelty in that way enabling the regulation of a wider compilation of new seeds or foods.

To assess the security and nutritional value of genetically modified foods released in Canada is granted to Health Canada and the CFIA.Genetically modified or genetically engineered foods are principally regulated by the Food and Drugs Act, R.S.C., 1985, c. F-27 and its subsidiary regulations.[52]Health Canada is accountable, under the above legal framework:

*For provisions related to public health, food safety and nutrition. Through science-based regulation, guidelines and public health policy, as well as health risk assessments concerning chemical, physical and microbiological contaminants, toxicants and allergens in the food supply, Health Canada works to protect the health and safety of Canadians. Health Canada also conducts pre-market evaluations to assess the safety and nutritional adequacy of novel foods proposed for sale in Canada, including foods derived from biotechnology.*[53]

Under the Canadian regulations both the GM and GE foods are being kept in the one class of **"Novel Foods".** And these Novel foods are regulated under Health Canada for the sale of such foods in Canada through pre-market notification prerequisite which is summarized under Division 28 of Part B of the Food and Drugs Regulations. And whereas CFIA is accountable for regulating the environmental release of a plant with a novel trait and all of this is regulated through various laws like the Plant Protection Act, S.C. 1990, c. 22, Plant Protection Regulations, SOR/95-212, the Seeds Act, R.S.C., 1985 and Seed Regulations (Part V)., C.R.C., c. 1400. Hence, in Canada Health Canada takes care

[52] Food and Drugs Act, R.S.C., 1985, c. F-27 *available at* http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html (Visited on 22 November, 2015)
[53] The Regulation of Genetically Modified Food, Health Canada *available at* http://www.hc-sc.gc.ca/sr sr/pubs/biotech/reg_gen_mod-eng.php (Visited on 22 November, 2015)

of consumption of novel foods and the CFIA protect the environment by various legislation, so this two dimension of legislations governs GMO's in Canada.

### 2.7.2 Condition pertaining to Research, Marketing and production

CFIA's Plant Biosafety Office (PBO) looks into the development and planting of Plants with Novel Traits (PNTs) for research purpose. The role of PBO is to evaluate application for confined research field trials and to set up various rules and conditions for their conduction. Prior to a GMO are released into the environment more usually or sold for human use it must go through an authorization procedure. To review GM plants and authorize their release into the environment is mandated to CFIA and on the other side Health Canada is being authorised to sale of GM foods for consumption.

### 2.7.3 Condition pertaining to release of organism in Environment

CFIA being given the responsibility for regulating GM plants and favoring GM feed for animals. Under the rights of the Plant Protection Act, Plant Protection Regulations, the Seeds Act, and Seed Regulations are being done. The principle of substantial equivalence when comparing the characteristics of the novel food with its "conventional counterpart" in respect to various components "molecular, compositional, toxicological and nutritional makeup" is applied by CFIA. Therefore the product should be approved if its conventional counterpart matches the substantial equivalent.

### 2.7.4 Labelling

Labelling of GM foods is challenging. This is because a food like GM corn can be used as an ingredient in many other foods like cereal, yogurt, frozen NTrees and canned soup. So, all of these foods would need to be labeled as having GM labelling ingredients. Recognizing the problem with labeling, GM foods do not have to be labeled in Canada.

Health Canada and CFIA had a joint responsibility for federal food labeling policies under the Food and Drugs Act.,R.S.C., 1985. It's the responsibility of Health Canada for setting food labelling policies with respect to the health and safety matters. Even the genetic engineered foods along with all types of foods are included. On the other hand CFIA has accountability for the development of non-health and safety food labelling regulations and policies and enforcement of all food labelling legislation. CFIA sets standards for Canadian food labels for being truthful and not misleading. There had been three major public consultation processes since 1993 in Canada on the labeling of novel foods derived from genetic engineering. So there had been set of certain guidelines for food importers and a manufacturer which were developed. Guidelines as follows

- Requirement of mandatory labelling if there is a health or safety concerns, in order to notify consumers of the allergen or change;
- To ensure that labeling is understandable, truthful, and not misleading;
- Permission of voluntary labeling on the condition that the claim is not misleading or illusory and the claim itself is factual.
- Permission of voluntary negative labeling on the condition that the claim is not misleading or deceptive and the claim itself is factual.

Hence, in Canada labelling in the product is required if there is any health or safety issues with the food. This rule is applicable to all the novel foods inspite of them being GM or not. In the case of only labelling GMO's, national standard for voluntary labelling of foods derived through biotechnology.

So here the researcher has attempted to overview regulatory frameworks that pertain to seed governance in Canada that are the Plant Protection Act, S.C. 1990, c. 22, Plant Protection Regulations, SOR/95-212, the Seeds Act, R.S.C., 1985 and Seed Regulations (Part V)., C.R.C., c. 1400.

## 2.8 Position on TK and GM: EUROPE

The Middle Ages saw further improvements in agriculture. Monasteries spread throughout Europe and became important centers for the collection of knowledge related to agriculture and forestry. Some farmers in Europe moved from a two field crop rotation to a three field crop rotation in which one field of three was left fallow every year. This resulted in increased productivity and nutrition. Crops included wheat, rye, barley and oats. Peas, beans, and vetches became common from the 13th century onward as a fodder crop for animals and also for their nitrogenfixation fertilizing properties. Crop yields peaked in the 13th century, and stayed more or less steady until the 18th century.[54] The field systems in Medieval Europe included the open-field system, so called because there were no barriers between fields belonging to different farmers. The landscape was one of long and uncluttered views. In its typical form, cultivated land consisted of long, narrow strips of land in a distinctive ridge and furrow pattern. Individual farmers owned or farmed several different strips of land scattered around the farming area. The reason for farmers possessing scattered strips of land was apparently to reduce risk; if the crop in one strip failed, it might succeed in another strip.

Two patterns of cultivation were typical of the open-field system. In the first, the arable land was divided into two fields. One half was cultivated and the other one was left fallow every year. Crops were rotated between the two fields every year, with the fallow field being allowed to recover its fertility and used for livestock grazing when not dedicated to crops.

### Two Field System

| Year | Field 1 | Field 2 |
|---|---|---|
| Year I | Winter Crop | Fallow |
| Year II | Fallow | Winter Crop |
| Year III | Winter Crop | Fallow |

A three-field pattern was typical of the later Middle Ages in northern Europe with its wetter climate. One field was planted in fall, one field was planted in spring, and the third field was left fallow. Crops were rotated from year to year and field to field. Thus, cultivation was more intensive than it was under the two-field pattern. In both patterns, common areas of wood and pasture as well as fallowed fields were used for communal grazing and wood-gathering.[55] The Technique of growing rotational or three crops so their result or outcome could be increased was followed during that era. The traditional knowledge of agriculture was freely enjoyed by the farmers over the years.

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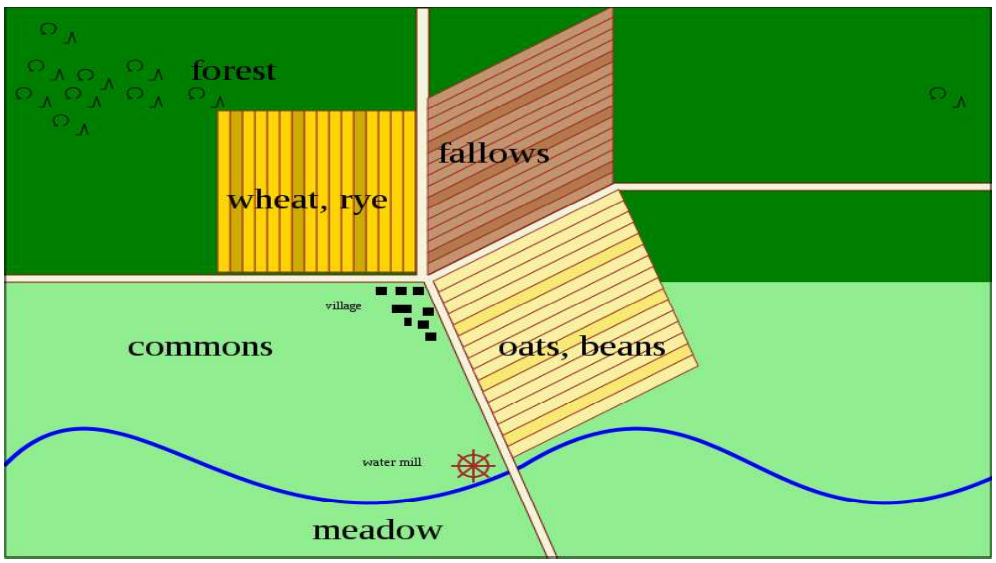
[54] Campbell, Bruce M.S.; M. Overton, *'A New Perspective on Medieval and Early Modern Agriculture: Six Centuries of Norfolk Farming'*, c.1250-c.1850". *Past and Present*. **141**: 38–105 (1993).

[55]Hopcroft, Rosemary L., '*Regions, Institutions, and Agrarian Change in Europe History, Ann Arbor*', University of Michigan Press, pp. 16-17, (1999)

## Three Field System

| Year | Field 1 | Field 2 | Field 3 |
|---|---|---|---|
| Year I | Winter Crop | Summer Crop | Fallow |
| Year II | Fallow | Winter Crop | Summer Crop |
| Year III | Summer Crop | Fallow | Winter Crop |
| Year IV | Winter Crop | Summer Crop | Fallow |



[56]

## Three Field System

The breeding and production of seeds as a profession started first in Europe and then in the US towards the end of the 19th century, first within specialized farms, and then among specialized companies. This was the beginning of the separation of seed production from farming. Hence, from here the farming and the seed production started into the journey of two different directions. Seed exchange between farmers at the local level is based on honesty and the basic rules of being a good neighbor. Everyone knew that the farmer providing the seed and how good

[56] Hopcroft, Rosemary L., '*Regions, Institutions, and Agrarian Change in Europe History, Ann Arbor*', *available at* https://en.wikipedia.org/wiki/File:Three_Field_System.svg (Visited on 1 November, 2015)

his or her seeds were. Seed exchange between farmers at the local level was based on honesty and the basic rules of being a good neighbor. Everyone knows the farmer providing the seed and how good his or her seeds are. It was believed that it's more risky to mislead your neighbor than a farmer who lives at the other end of the country whom you will never be seen again. As with the increase the area of seed exchange, risk also started increasing. The qualities of seed were not visible from the naked eyes and the market was soon invaded by fraudsters who sold any old seed.

Farm-saved seed were free seed and this was not tolerated by commercial seed producers. The seeds which were not on the European seed catalogues were considered to be illegal for selling and exchange seeds cannot be used without the permission of the Plant Breeders' Rights (PBR) owner when they were proprietary. Farmers were not stopped from saving, exchanging or to selling their seed harvest for re-sowing. Farmers select their own "local" varieties and become again completely independent from seed producers. Farmers wishing to use farm-saved seed would regularly send their seed to a seed cleaner. Seed cleaners were those experts who used to remove the poor quality of seeds and weed seeds, chaff and awns, and treat the seeds against pests and diseases from the seeds. That required the important equipments which were not available to the small and medium sized farms.

Upto 1990 Europe's regulations were not that strict as compared to that of United States. Then over the time the New European Union (EU) laws were stricter for GMO regulations in the world. A complete and stringent lawful regime on genetically modified organisms that the food and feed made consisting or containing from GMO's, the EU's legislation and policy on GMOs, based on the preventive principle enshrined in EU and international legislation, is designed to prevent any adverse effects on the environment and the health and safety of humans and animals, and it reflects concerns expressed by skeptical consumers, farmers, and environmentalists. All GMO were considered as new food and were subject to extensive case-by-case science based food evaluation by the European Food Safety Authority (EFSA). They all were divided into following four criteria "safety", "freedom of choice", "labelling" and "traceability".

In Europe the EFSA reports to the European Commission who then draft a proposal for granting or refusing the authorisation. This proposal is submitted to the Section on GM Food and Feed of the Standing Committee on the Food Chain and Animal Health and if accepted it will be adopted by the EC or passed on to the Council of Agricultural Ministers. Once in the Council it has three months to reach a qualified majority for or against the proposal, if no majority is reached the proposal is passed back to the EC who will then adopt the proposal. The European Parliament's Committee on the Environmental, Public Health, and Consumer Protection pushed forward and adopted a "safety first" principle regarding the case of GMOs, calling for any negative health consequences from GMOs to be held liable. However, even after authorization, individual EU member states can ban individual varieties under a 'safeguard clause' if there are "justifiable reasons" that the variety may cause harm to humans or the environment. The member state must then supply sufficient evidence that this is the case.

### 2.8.3 European Food Safety Authority EFSA

The European Food Safety Authority (EFSA) is the agency of the European Union (EU) that provides independent scientific advice and communicates on existing and emerging risks associated with the food chain. EFSA was established in February 2002, is based in Parma, Italy. The work of EFSA covers all matters with a direct or indirect impact on food and feed safety, including animal health and welfare, plant protection and plant health and nutrition. EFSA supports the European Commission, the European Parliament and EU member states in taking effective and timely risk management decisions that ensure the protection of the health of European consumers and the safety of the food and feed chain.

#### 2.8.3.1 Regulating Legislation

At the EU level, two basic and comprehensive pieces of legislation regulate various aspects of GMOs: Regulation No. 1829/2003 on **Genetically Modified Food and Feed**, and Directive 2001/18/EC on the **Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive**

90/220/EEC.[57] Both the regulations are directly applicable in the legal systems of the twenty-eight EU Member States. EU Members are required to comply with the requirements contained within but are free to choose the method of implementation.

However, in 2010, the Commission prepared its Guidelines for the Development of National Co-existence Measures to Avoid the Unintended Presence of GMOs in Conventional and Organic Crops. The guidelines pushes EU Members to develop their own national measures based on their specific local and regional conditions in order to avoid the unintended presence of GMOs in conventional and organic crops. Additional recommendation is the possibility for EU Members to exclude GMO cultivation from large areas of their territory to male it GM free areas to avoid the unplanned existence of GMOs in conventional and organic crops. In such a case, EU Members should show that purity from GMO contamination cannot be achieved through other methods[58].

Purpose and scope of guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming was to take the form of non-binding recommendations addressed to the Member States. They are intended to provide general principles for the development of national measures to avoid the unintended presence of GMOs in conventional and organic crops. It is recognised that many of the factors that are important in this context are specific to national, regional and local conditions.

### 2.8.3.2 Condition pertaining to Research, Marketing and production

For research EU Members and the Commission have to ensure that research on GMOs is conducted prior to their being released into the environment or placed on

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[57] Directive 2001/18/EC of the European Parliament, Environment of Genetically Modified Organisms and Repealing , *available at*: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038 :EN:PDF (Visited on 13 December, 2015)

[58] Commission Recommendation of 13 July 2010 on Guidelines for the Development of National Co-existence Measures to Avoid the Unintended Presence of GMOs in Conventional and Organic Crops, 2010 O.J. (C 200) 1, *available at:* http://ecob.jrc.ec.europa.eu/documents/CoexRecommendation.pdf (Visited on 13 December, 2015)

the market. Each EU Member must allot appropriate funding for such research, in compliance with budgetary procedures. Researchers of GM must be granted access to all pertinent materials, provided that intellectual property rights are fully respected. Member States have the right to invoke the safeguard clause and temporarily ban the cultivation or use of a GMO in their territory. Members have to validate their actions with new or additional information that an authorized GMO can pose a threat to the environment or human health. The Commission may ask EFSA to provide a scientific opinion on the information provided by Member States.

#### 2.8.3.3 Condition for releasing GMO in Environment

**Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive** European Parliament and the Council on 12 March 2001 necessitates EU Members to ensure that the intentional release of GMOs into the environment is possible only if it is in compliance with part B of Directive.

"Deliberate release" is defined as "any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment." In 2012, the Court of Justice held that the "location of release" of genetically modified organisms is determined by all the information relating to the location of the release submitted by the notifier to the competent authorities of the Member State on whose territory the release will occur.[59] Intentional release of GMO into the environment may take place, prior to the release of the GMO or GMO's submits the notification to the national competent authority of the Member State where the release will take place. Other than these following items must be prepared or done.

- A record containing information should be mentioned
- An environmental risk assessment consistent with the requirements of the Directive should be done.

[59] Case C-552/07, 2001/18 Judgment of the Court (Fourth Chamber) of 17 February 2009 (reference for a preliminary ruling from the Conseil d'État (France))—Commune de Sausheim v. Pierre Azelvandre (Visited on 25 December, 2015)

- Open consent prior to release
- A monitoring plan pursuant to the requirements should be designed to detect the adverse effects of the GMO's on human health and the environment.
- Disclosure of information to the public on the release and results of the release and provide a reasonable time frame for the public to respond.[60]

If there are modifications or unintended changes to the release of a GMO into the environment, or additional information emerges on new risks that could potentially affect human health after the competent authority has granted its consent, the individual in charge must take measures to avoid such risks and must inform the competent national authorities about the same.

### 2.8.3.4 Condition on GMOs in food

Regulation No. 1829/2003 **Genetically Modified Food and Feed** forbids inclusion on the EU market a GMO for food use, or a food containing or consisting of GMOs or food products produced from GMOs except an authorization is granted. Food and feed produced with a GMO are excluded from the scope of this Regulation. The critical determining factor is whether material derived from a GMO is present in the food or feed. Therefore, if a GMO is not present in the food or feed then such food or feed does not fall within the purview of Regulation.

GMOs should be authorized before it is sold or imported into the EU market. However, any food or feed produced from the GMO that contains or consists, must not cause any adverse effects on human and animal health and the environment. It should also not mislead consumers or differ from the food it intends to replace to the extent that nutritionally.

### A. Authorization under Genetically Modified Food and Feed Regulation

The application sent to the national competent authority must include the name and address of the applicant, designate the food and its specifications should meet the following necessities:

[60] Directive 2001/18/EC, (Visited on 25 December, 2015)

- Comply with Issues to be considered for risk characterization to the Cartagena Protocol on Biosafety, if applicable
- Describe the method of production and manufacturing in detail
- Include a copy of independent peer-reviewed studies
- State that the food will not raise ethical or religious concerns of consumers
- Indicate conditions for placing the GMO food or feed on the market
- Provide for post-market monitoring, if the food is intended for human consumption

The application must also include the required technical compliance and also a monitoring plan to evaluate environmental effects in compliance with this Directive. Within 14 days the national competent authority must inform the applicant that it received the application and forward all information to the EFSA. It must also inform the Commission and the EU Members of the application. The EFSA must then provide its opinion within a six-month deadline. The Commission, within three months after receiving the opinion must submit to the Standing Committee on the Food Chain and Animal Health a draft of its decision. The draft must include all the appropriate and relevant information, including the name of the authorization holder and the unique identifier that is given to each GMO approved in the EU.

**B. Condition for Labeling and Traceability**

The right of consumers to information is recognized in article 169 which empowers the EU to act for consumer protection of the **Treaty on the Functioning of the European Union** TFEU. Based on article 169, the EU is compelled to promote this right in legislation for affecting consumers.

Labeling requirements to apply to all final product that are reaching to the consumers or even to the mass caterers are either containing or consisting of GMOs or produced from the ingredients produced from GMOs.

1. The relation very clearly provides that the phrase "genetically modified" or "produced from genetically modified name of the organism" must be clearly next to the ingredient list.

2. Where there is no list of ingredients the same phrase must appear on the label.

3. In the case of non-packaged food, the same labeling must appear on the food display or next to it

4. If a very minute amount of GMOs are found in food which is due to their adventitious technically unavoidable presence during cultivation, harvest, or transport than the food is not subject to labeling provided that the amount present is less than 0.9%. Similar labeling requirements are contained in Directive.[61]

### 2.8.4 Genetically Modified Food and Feed

The traceability and labeling of GMOs and the traceability of food and feed products produced from GMOs are governed by Regulation (EC) No. 1830/2003. Traceability also plays equal role as same as the labelling. General traceability requires EU members to ensure traceability at all stages of marketing for the GMOs. Before placing the product containing or consisting of GMOs in market the operators are required to provide in writing two important items

a) a statement that the product contains or consists of GMOs, and
b) the unique identifier assigned to each GMO (a numeric or alphanumeric code) in order to facilitate the identification of the GMO. This type of information must be forwarded from one operator to the next.[62]

However, the operators should ensure that the pre-packed products consisting of or containing GMOs carry a label with the words, that the product contains GMOs. For non- prepacked products which is offered to consumers the same must appear on the product or where the product being displayed. The traceability or labeling requirements do not apply when there are traces of GMOs of no higher than 0.9% and when they are adventitious or technically unavoidable.

## 2.9 Conclusion

Vedic literature provides some of the earliest written trace of agriculture in India, which can be found from the Rigveda. Other historical evidence suggests rice and cotton were cultivated in the Indus Valley. Other crops cultivated in India 3000 to 6000 years ago, include sesame, linseed, safflower, mustards, castor, mung bean,

[61]Restrictions on Genetically Modified Organisms: European Union *available at:* https://www.loc.gov/law/help/restrictions-on-gmos/eu.php (Visited on July 24, 2017).
[62]https://www.loc.gov/law/help/restrictions-on-gmos/eu.php#_ftn65 (Visited on July 24, 2017).

black gram, horse gram, pigeon pea, field pea, grass pea (khesari), fenugreek, cotton, jujube, grapes, dates, jackfruit, mango, mulberry, and black plum.

The transformation of the traditional knowledge can be considered as the base for the development of the agriculture. So ever since the agriculture might have started, the traditional knowledge for developing the same also might have evolved, which altogether started evolving new practices as per the requirement faced by the communities of that time. Many traditional farmers are still in India practicing traditional methods of farming with the help of the Traditional knowledge and seed saving pattern India. When local knowledge and practices developed over centuries are shared in farmers' groups who work on the land together, it clearly supports sustainable agro-ecosystem management in the region. In India farmers have created their traditional calendars to control the scheduling of agricultural activities. Some ancient farmers developed sustainable agriculture practices that allowed them to produce food and fiber for thousands of years with few outside inputs. Traditional knowledge of a community in a particular region is derived from the local people's farming experience and is handed down from generation to generation.

Cultivation of tobacco, introduced by the Portuguese spread rapidly. The Malabar Coast was the home of spices, especially black pepper that had stimulated the first European adventures in the East. Coffee had been imported from Abyssinia and became a popular beverage in aristocratic circles by the end of the century. Tea, which was to become the commoner's drink and a major export, was yet undiscovered, though it was growing wild in the hills of Assam. Vegetables were cultivated mainly in the vicinity of towns. New species of fruit, such as the pineapple, papaya, and cashew nut, also were introduced by the Portuguese. The quality of mango and citrus fruits was greatly improved.[63]

The agriculture changed with the independence, with the growing economy agricultural techniques also started growing and the Hybrid and GMO entered in

[63] History of Agriculture by Britannica Educational Publishing *available at:* https://books.google.com/books// (Visited on July 4, 2017).

agricultural system. When it comes to the GE/GMO Regulation in India for agriculture is mainly in the hands of the Ministry of Environment and Forests in the Central Government of India, through the 1989 Rules of the Environment Protection Act, 1986. The Rules were brought into force from December 1989 "with a view to protecting the environment, nature and health in connection with the application of gene technology and microorganisms". Under these Rules, a Committee called **Genetic Engineering Approval Committee** (GEAC) has been set up under the Ministry of Environment & Forests. From the environmental viewpoint, approval of activities involving large scale use of hazardous micro-organism and recombinant in research and industrial production. This Committee is also responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.

The Rules under 7(1) evidently mention that "No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee".

Section (8) of the 1989 Rules clearly states that "Production in which genetically engineered organisms or cells or micro-organisms are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee with respect of discharge of genetically engineered organisms or cells into the environment". Thus, the Rules clearly lay down the authority of GEAC, including for allowing or disallowing GM imports into the country.

Various other institutions being created by the 1989 Rules to help the GEAC to regulate the GE/GMO in agriculture are research agencies, which are handling micro-organisms/genetically engineered organisms, it is mandated that an **Institutional Bio-Safety Committee** (IBSC) is to be created, which includes a representative of the **Department of Bio-Technology** (DBT) under the Ministry of Science & Technology. Even under the Biotechnology department a **Review Committee on Genetic Manipulation** (RCGM) set up to monitor the safety related aspects of ongoing research projects and activities related to GE/GMO, Ongoing project on high risk category and controlled field experiments are reviewed to check whether guidelines are followed or not.

The Researcher has analysed the laws how the GMOs in Europe can be brought under the umbrella of regulation and now in the last part of chapter researcher tries to lay down the position of India.

The Researcher shall in next chapter analyse The Seed Act, 1966, various Seed Rules and the pending Seed Bills to trace their importance with the various rights available to the farmers.