Introduction

One of the main parts of modern biotechnology is genetic modification or gene manipulation by introducing or eliminating a single gene through modern molecular biology techniques. Genetically modified organisms or living modified organisms are “any living organisms that possess a novel combination of genetic material obtained through the use of modern biotechnology techniques” [1]. Genetically modified organisms are applicable in agriculture, health, industries and other sectors and can provide a powerful tool for sustainable development. GMOs are those their genetic material is engineered in the laboratory by introducing a small foreign DNA fragment carrying a gene of interest in to the native DNA of the organism. The foreign gene is attached with the necessary regulatory element to help its expression in the new genetic environment. This expression pattern may be different from the original expression to the extent that GMO may overproduce, under produce, different produce or may not be produce the protein it has been known to produce. When DNA is engineered in the laboratory and transferred in to the organism, it is within the confines of the specialized laboratory with skilled scientists and people handling the GMO who are trained to deal with the positive and negative outputs as well as the perceived consequences which may comprises the risk involved. When it comes out of the laboratory’s confinement, the element of risks associated with it passes in to the hands of those who may not be aware about the unique feature of GMOs or who may not have complete understanding on the techniques used. Hence, GMOs requires to be handled with in confinement until it is established by tests and trails that its release in to the environment would not be harmful. Post release monitoring also plays a crucial role in environment risk assessment and management, and it is undertaken by gathering information on short, medium and long term effects of GMOs on the environment [2].

Genetic modification used for crop improvement by enhancing abiotic and biotic stresses and by improving the nutritional quality of the product [3]. The increased crop yield and better food quality have reduced world hunger and malnutrition. In addition to these, it reduces the use of agrochemicals and reduced pollutions. Current evidence showed that GM technology has a great potential to improve agricultural productivity and farmers livelihood in the developing countries. There for, GM technology must be allowed to play a part in alleviating hunger and poverty in Africa [4].

Now a day with the rapid advance research and development in agricultural biotechnology, countries are approving many genetically modified crops for commercial release and agricultural production. ISAA reported, the total accumulated hectarage covered...
with GM crops in 2016 are surged to 2.1 billion or 5.3 billion acres since 1996. In 2016 about 26 countries are planted biotech crops, of these, 19 are developing countries and 7 are developed countries. In the year 2016 about 185.1 million hectare were covered with biotech crops which is almost equivalent to 20% of the total arable land. Between 2015 and 2016 there was a 3% increment equivalent to 13.3 million acre. Economic gain of farmers from biotech crops in 20 years of commercialization (1996-2015) is about 167.8 billion additional incomes, of this US $81.7 billion were generated by industrial countries and US $86.1 billion in developing countries [5].

The cultivation GM crops are increasing [5] and concerns are raising with respect to general safety issues of GM crops on environment, food/feed safety, socio-economic etc. Toxicity and allergen city are main concerns raised from the food and its product perspective. From the environmental sides, the possible risks raised include, the introgression of transgene in to the natural landscape, gene flow, non-target effect, evolution of pest resistance and loss of biodiversity etc. The GM technology has also evoked a range of social, economic and ethical concerns. There is no common consensus or no inclusive information on definitive negative impact of GMOs on human health and environment, even if the scientific evidences are still emerging. Nevertheless public perceptions about GMOs in food and agriculture are divided with a tendency toward GM food and product in many developed and developing countries [6]. Several developing countries lack awareness, technical capacity to handle risk assessment, and monitor compliances [7]. In Africa, the biosafety regulatory capacity of many countries are limited by lack of trained personnel as well as absence of coherent regulatory instruments and institutions for risk assessment and management relation to genetic engineering. Furthermore, where instruments have been formulated and adopted by the government, there are often weak institutional arrangements for the enforcements of regulatory procedures [8].

Ethiopia amended its biosafety law in 2015 as Amended biosafety proclamation No 896/2015. And the country is in the 2nd year of Bt-cotton confined field trial in the year 2017, supposed to be commercialized in 2018 cropping season. The government is fully willing to capacitate and/or to develop GM crops in the country and adopt and commercialize other GM crops. Major challenges in using or involving in GM research &development is lack of awareness, trained man power, low regulatory mechanism and institutional capacity and fear of risks of GM crops. There is very limited number of biosafety research Incorporated in to crops this may produce protein that leads to allergens. WHO concludes, GM foods have the potential to cause allergen reaction but this risk is comparable to the risks associated with traditional grown foods. The proteins produced by any newly introduced genes have the potential to cause allergies [10]. When introducing a gene in to an organism the level of allergens in the modified organism may be increased above the natural range in the convectional food or new allergen may be introduced. Since the primary product of gene expression is protein, and most of food allergens are proteins, there exists a possibility that any novel protein introduced in to a plant might be an allergen. However, most foods do not cause allergic reaction in most peoples, but for peoples who have any kind of food allergy, certain proteins in food can cause unusual immense reaction. Therefore introducing new allergen is the primary concern and subject of extensive food safety evaluation during GM crop development. For example a proposal to incorporate a gene from Brazil nut to soybean was abandoned because of the fear of causing unexpected allergic reaction [11]. Bean crop that were genetically modified to increase the level of cysteine and methionine content were discarded after the discovery that the expressed protein of the transgene were highly allergenic [12]. Testing of GM foods may be required to avoid the harm of consumers with food allergens.

Toxicity

Toxicity results from the change in the metabolism and the composition of the organism. A research article examined the effect of GM potato on the digestive track on rats were published in lancet. More over the gene introduced in to potatoes was snowdrop flaver lectin, a substance to known to be toxic to mammals [13]. Toxic substances are found in foods naturally but these compounds usually occur at levels of not harmful to humans when foods are consumed or processed appropriately. Concerns are raised on the possibility of introducing new toxic substances or increasing the levels those naturally occurring toxins which are harmful to human health with respect to GM foods [14]. The research by Allan [14], tried to conclude, the level of naturally occurring toxins are not increased above the natural level, plus the source of the gene routinely investigated to ensure that the gene product itself has no harmful toxic effect. This possibility assessed by safety assessment of toxic risks using qualitative and quantitative methods.

Horizontal Gene Transfer

The genetic material can be transferred from GE foods to the cell of human body or bacteria in the intestinal tract [15] and recently raised concerns are that DNA from GM crops might transfer to soil microbes. Because, the DNA from ingested GM foods are not completely degraded by digestion and could found in different part of gastrointestinal tract. There for, gene may be transferred horizontally due to absorption of DNA fragment by gut microflora or somatic cells lining the intestinal cells. Even if scientists have postulated the uptake of GM DNA in to cells of gastrointestinal tract will not have any biological consequences because this DNA will be degraded in the cells. However, this may cause gastrointestinal disease in humans [16]. Beside this, the use of antibiotics marker genes could pass the trait of antibiotic resistance rapidly and widely to the humans and animals. Their presence in the environment, soil and in the food eaten by humans and animals can occur the transfer of antibiotic resistance genes to bacteria in the guts of animals or humans or to bacteria in the environment. Many bacteria have the ability to pick up genes from their surroundings and to pass these on to other species of bacteria, including antibiotic resistance genes. Such genes might eventually find their way in to disease causing bacteria, resulting in antibiotic resistance and therefore making
treatment more difficult or could create antibiotic resistance pathogen in livestock. In fact research revealed the transfer can happen in human mouth contain bacteria capable of taking up and express DNA containing antibiotic resistance marker genes [17]. There should be a comprehensive, rigorous and mandatory pre-market approval system that examines the safety of GM crops for human health and the environment.

**Feed Safety**

The concerns of GM crops and their product on animal health is mainly when used as directly a feed for ruminants, poultry, pigs etc. In addition, safety concerns on chemical composition, nutritional parameters, digestibility of GM feeds, and quality of milk subjected to GM feeds [18]. Concerns of feed safety is not only concentrated on this, but also risks of herbicide and insecticide tolerant GM feeds on animal health. To minimize this, feeding study should be needed before released to the environment of GM crops.

**Environmental Issues**

Concerns on the environment mainly focus on the possible negative effect of GM crops on a biotics and biotics of like, gene flow, loss of biodiversity, weediness, non-target effect etc. GM crops may also cause direct or indirect side effect on life support systems such as air, water and soil [18]. This paper tried to illustrate the environmental issues of GM crops directly on the biotics as follow:

**Loss of biodiversity**

Cultivation of genetically modified crops considered by some people as the possible source of biodiversity loss, mainly though impacts on environment [19]. Loss of biodiversity risk relayed to GM crops are expressed in different ways, the first one is a plant which have a biotic stress resistance gene have more chance to become popular in short period because of its fitness and preferential selection [20]. This selection could cause “genetic erosion” situations where the affected gene become quite rare with severs chance of disappear from the natural gene pool of the population [21]. Farmers restrict themselves to few popularly grown varieties, this results reduced genetic diversity in response to GMOs [22]. In other hand GM crops are not exist in natural process, the release of these new gene containing crop could cause unpredictable ecological and evolutional response or change and these process may contaminate the natural flora by GM traits and degradation and erosion of the commonly used genetic resources [23]. Post release monitoring is very essential in minimizing risks of genetic erosion that could gain from using GM crops especially in countries those are rich in diversified crop species.

**Newweeds**

Now a day most of genetically modified crops under commercialization are herbicide tolerance or insect resistance which are important in to protect the crop from infestation. This gene may flow due to cross pollination for the traits involving resistance and might result in development of resistance or tolerant weeds that are difficult to eradicate [24]. The gene through cross pollination among the compatible genomes might lead to super weed which compete benefits to the GM crops [25]. According to R. Paarlberg [26] a GM could transfer modified to wild relatives and this creates super weed or itself becomes a weed, potential threaten biodiversity. Additionally, the article emphasizes; the use of pest resistance GM crops may increase the development of pest resistance crops [26]. And, plants are susceptible to diseases caused by viruses often transmitted by insects. Controlling the spread of viral disease can be very difficult and could cause devastating losses to crops; to control this virus resistance GM crops are under cultivation, like virus resistance potato, papaya, yellow squash etc. The risks are same with pest and insect resistance GM crops but needs special attention due difficult to control the risk acquire from virus resistance GM crops. The risk of GM crops in developing new weeds could be minimized through careful case-by-case assessment and management.

**Gene flow**

Gene may flow through seed or pollen. This flow could result GM contamination and occur in different ways; may be through human error. The report in Cban [27], proven over the past twenty years genetic material from GM crops has mixed with non-GM crops and foods. GM crops can pollinate either to the related species or wild relatives [28]. The study showed herbicide resistance transgenic rapeseeded (Brassica napus) in the UK, gene flow through cross pollination ranged between 0.0156%-0.0038% at the distance of 200m and 400m respectively [29]. The risk of gene flow to the wild relative or related species is raised as threat to the biodiversity in might causing unpredictable change on the ecology in total. This should be ceased by case by case assessment or conducting broad discipline biosafety researches starting from the initial developmental stage of GM crops.

**Non-target effects**

USDA in 2013 reported, GM plants may have environmental effects on non-target organisms such as, birds, insects, worms, fish, bees etc. in general beyond GM crops developed for targeted organism. Non-target effects are intended or unintended effect on the environmental interaction [30]. Non-target organisms might be affected by GMs through direct feeding of GM crops or through the interference with production of volatile chemicals responsible for the plants attractiveness to the natural enemies or GM plants can affect natural enemies by deploying the population of their pray or host [31]. The non-GMOs campaigns argue that the GM technology doesn’t consider the non-targests, their concern is this may misbalance the natural ecosystem. The risk has to be evaluated during at the developmental stage prior to release to the environment.

**Economic, Social and Political Concerns**

**Economic concerns**

The economic concerns of GM crops are consumers worried about patenting these new plant varieties will raise the price of seeds so high that small farmers and farmers in developing...
countries are unable to afford seeds for GM crops. There is also risk of bringing GM food to the market is costly and lengthy process. The other one is fear of introducing suicide gene in to GM plants which is viable for only one growing season or produce sterile seed that do not germinate [32].

Social concerns

GM crops could affect the traditional social interaction of farmers in saving, reusing, sharing and selling farm saved seeds. This threats especially developing countries where such practices are common among farmers. Generally this threatens the long term food security of rural communities [28]. GM crops on religious and social aspect raised controversies in many countries where religion remain the dominant societal force, for example GMOs can be considered as halal or haram in Muslim communities [33]. The Cartagena protocol on biological diversity give emphasis on article 26 in saying "the parties in reaching a decision on importurn this protocol or under its domestic measures implementing the protocol, may take in to account, consistence with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities. And the parties are encouraged to cooperate on research and information exchange on any socio economic impacts of living modified organisms, especially on indigenous and local communities". The protocol gives attention, every member country involved on GMOS and their product development and transaction should take in to account the social and economic affairs. Wendt & Isqueiro [34], they point out the social threats of GM crops is that the private sector and powerful agribusiness companies could control the majority of GM research and markets. The intellectual property rights under world trade organizations are not sufficient to protect traditional knowledge and biodiversity. There need to be balance between protecting the right of traditional users and modern innovators.

Political concerns

The adoption of GM products is not solely on scientific considerations as also political motives plays a vital role in the adoption of GM technology. Political economy analyzes how economic theory and methods influence political ideology and studies how institutions and regulations develop under different circumstances. For example, there are major differences in biotechnology regulations among various countries and in particular between the EU and US. This difference may result from minor difference from consumer’s preference but may have long lasting effect on the competitiveness of the sector. These political factors affect the trade and environmental regulations [35]. The other political concern is, countries should label genetically modified foods, for example USA do not label GM foods. There should be common consensus on labeling genetically modified crops and their products in all countries under law.

The status of genetically modified crops in Ethiopia and regulatory mechanisms

Genetically modified crop development at global level is increasing and many GM crops are commercialized in developing countries to hasten agricultural productivity and nutritional status of important crops. Starting to amendment of biosafety law toward workable in Ethiopia, the first GM crop approved for confined field trail in the country is Bt-cotton in 2016 cropping season which is resistance to boll worm. GM Bt-cotton adopted from Indian JK Seeds Company and from Sudan and now it is in second season of confined field trial in eight different ecological locations to evaluate the agronomic performance and to compare with high vigor local varieties. It is expected to be commercialized in 2018. This encourages to overlook in other GM crops to introduce and try in confined field trials of like, Bt (insect resistance) and DT (drought tolerance) GM maize of WEMA project works in water efficiency maize for Africa and to start GM crops product development in other crops at National Agricultural Biotechnology Research Laboratory found in Holeta 29km far from Addis Ababa. Different Ethiopian scientists are feeling to initiate genetic engineering projects starting to the amendment of the Biosafety law. But the major challenging in the country is the availability of limited evidences on the concerns/biosafety issues of GM technology. And few biosafety research papers are published and there is dilemma on the benefit and risk of GM technology, these results denying the technology and believe in propagandas of GM cons.

The Cartagena protocol was first adopted 29th January 2000 and entered in to force starting from September 11th 2003 with the objective of ensuring adequate level of protection in the field of safe handling, transfer and using of living modified organisms that may have adverse effects. Currently around 164 countries signed the protocol. Ethiopia also becomes a member in January 23, 2000. According to the Cartagena protocol regulatory framework, every member countries should have a minimum of policy statement by the government, regulatory regime designed to address safety of GMOs law proclamation, decree, directives, regulations, guidelines to govern the transboundary movement, system to handle notification or requests for authorizations import, export, transit, release, contained use placing in the market, a system for enforcement and monitoring for environmental effect, a mechanisms for public participation, awareness, education and also optional mechanism for testing, verification presence of GMOs. There are also other international organization and regional regulations or treaties and conventions involved in controlling a transboundary movement of GMOS (LMOS) and safe GM product development. Some of these are, international plant protection convection, Union for the protection of new varieties of plants, World trade organization, WHO, FAO, European union, African union, OECD, FDA, etc.

Ethiopia enacted its own Biosafety law in 2009 as proclamation No 655/2009 and amended in to workable in 2015 as “Amended Ethiopian Biosafety Law proclamation No 896/2015”. The
country is developing national regulatory system. The ministry of environment forest and climate change is the responsible ministry for implementation of the protocol and biosafety laws. However, weak regulatory systems in developing countries are the drawbacks which allow international agri-businesses and industries to promote genetic engineering technologies without considering its impact [36].

**Conclusion**

With the emerging of agricultural biotechnology science, many genetically modified crops have developed and commercialized to feed the world. With its rapid commercialization every year, concerns are raising continuously about safety issues of GM crops on human health, food/feed safety, on environment, social, economic and political. Some researchers are proved that GMOs could cause negative impact on human, animal and socio-economic. A number of genetically modified crops are reported at global level and attracted much attention. After more than 20 years of GM crops cultivation agricultural productivity and nutritional status of several important crops have been increased. Though many concerns are also raise time to time, the application of GM crops must be fully analyzed case by case. Complete and transparent assessment of GM crops application and recognition of their long, medium and short term effects should be needed; this can less the debate and make more constructive. Implementing all Biosafety laws, regulations and protocols are important for safe product development and for safe utilization of the technology. Strong regulatory implementation mechanism needed to reduce risks could acquire from the use of GM crops. Developing countries should continuously create awareness among researchers, producers, users, administratives, policy makers, environmentalists and the public in general. Even if many countries have placed regulatory policies and regulatory bodies for research and development of GM crops but strict compliance to the biosafety guideline is still required in many developing countries.

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