Regulatory framework of GMOs and hybrid seeds in Nepal

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Abstract

Most of the farmers are aware of about hybrid seeds; however almost all farmers and even technicians are not quite known about GMOs and associated effects. It is unspoken that use of hybrids has no adverse effect on the environment, human/animal health and our ecosystem if managed properly. Since, Nepal is in a very infant stage in hybrid research and development; however the demand is increasing over time. National legislative mechanism, human resources and physical facilities are not well established in testing and regulation of GMOs. So it is necessary to encourage policy-makers to strengthen their commitment and provide strong policy and financial support to promote hybrid research and development in Nepal through public private partnership for import substitution. Strong regulatory mechanism should be developed and adopted to reduce the inflow of hybrids and regulation of GMOs from abroad. National legislative, administrative and technical competency on research and testing of seed, plants, food, feed and animals with GMOs should be strengthened and regularized along with public participation for making decision whether to allow or restrict the import of the GMOs. Public participation is necessary in the decision making process of production, import, handling and use of GMOs and hybrids. As GMOs are very new and unknown about its implication on human health and the biological diversity, people at all levels should be aware of both the positive and negative aspects of GMOs. As a part of the public awareness program, it is required to disseminate available information on GMOs and products thereof through appropriate media, languages and publications and concerned stakeholders including growers, consumers, and business entrepreneurs.

Key words : GMOs, hybrid, regulatory frame work, awareness, legislation

Introduction

Since crop quality and productivity primarily depend upon the quality of seed owing to its relationship with the genetic traits. New crop varieties and quality seeds are the most viable options to improve agricultural production and food security in a sustainable way. Modern biotechnological innovations have provided diverse opportunities in seed dynamic and varietal options with desirable traits through hybridization and DNA alteration techniques i.e. genetic modification. Use of hybrid seeds with recommended technology aims to increase the yield potential of crops beyond the level of inbred high-yielding varieties (HYVs) by exploiting the phenomenon of hybrid vigor or heterosis. This technology has been successfully developed and widely adopted by many farmers in developed and developing countries including Nepal for increasing production, ensuring food security and reduce poverty. Genetically modified organism (GMOs) or transgenic crops have been developed in an attempt to improve food quality and solve some of the problems associated with commercial agriculture, including yield, enhanced nutritional value, biotic (disease, weed and pest), abiotic (drought, frost, acid or salty soil) and stress management.

Sine Nepal has a high population growth rate, low seed replacement rate (SRR) of major crops, low productivity (Table 1) and limited land for cultivation are main factors leading to food insecurity every year. There must be an increase in production per unit area per unit time in order to obtain food and feed security. Testing and regulation/control of GMO, increasing trend of hybrid seeds use of vegetables, maize and rice becoming an opportunity as well as challenge for meeting this objective.

Table 1. Seed replacement rate and productivity of main crops in Nepal during 2011/12

Crop	TSR (Mt)	TSS (Mt)	SRR %	Yield (Kg/ha)
Paddy	76574	8027	10.5	3312
Maize	21784	2496	11.3	2501
Wheat	91833	9554	10.4	2412
Lentil	6829	105	1.5	1003
Rape seed	1985	144	7.3	834

By considering the above facts, an attempt has been made in this brief paper, to know the types of seeds available in seed market, to find out the status and implication of GMOs and hybrid seeds in Nepal and to analyze the regulatory and policy gaps for future actions.

Methodology

The study was carried out by reviewing the literatures, internet browsing, personal communications with researchers, extension personnel and field surveys, focused group discussion with farmers, seed importers, agro-vets, DADOs, and other concerned stakeholders in Chitwan, Makawanpur, Kailali, Dadeldhura, Doti, Parsa, Bara and Rauthat districts from 27th Dec, 2011 to 2nd Feb, 2012.

Status of genetically modified organisms (GMOs) and hybrids

GMOs

GMOs are microorganisms, plants and animals that have had their genes altered to produce a desired effect that is meant to benefit people in some way. Usually they are modified either to further scientific research or to alter the food supply. Common genetic modifications include**; c**loning of both animals and plants, injecting growth hormones in animals, adding antibacterial genes to plants, introducing genes that make organisms bigger or hardier, and making new foods by mixing genes from existing ones. GM crop is a plant into which one or more genes have been artificially inserted instead of the plant acquiring them natural conditions of cross-breeding or natural recombination. The inserted gene sequence, known as the transgene, may be from same species, a different species within the same kingdom or even from a different kingdom (e.g. Bt Corn, which produces the natural insecticide, contain a gene from a bacterium).

The global area in which GM crops are grown is increasing. Its area has been increased more than 30-fold, from 1.7 million hectares in 1996 to 52.6 million hectares in 2001 and reached 134 million hectares in 2009 (www.gmo). The main GM crops are soybean (63%), maize (19%), cotton (13%) and canola (5%). GM crops are topics of ongoing debate worldwide. Some countries have adopted them and rests of them are skeptic about the adverse effects. Herbicide tolerance (e.g., Roundup Ready in soybean-Monsanto) is the dominant trait in GM crops, followed by insect resistance.

However, in case of Nepal, formally, no GM crops/seeds are registered, introduced and grown so far. Recently issue has been raised by civil society, media and farmers' right based organizations regarding GMOs and terminator seeds. Terminator technology is not allowed in Nepal as per provision of national policy/legislation. Whereas, Nepal is very infant stage in GM crop testing, quality control and development of legislation. Research can be done with the permission from authorized agency but government can ban import and research on any GMOs with potential risk to alter diversity and negative impact on health and environment.

Hybrids

The use of hybrids is common in vegetable crops, maize and rice in Nepal. It is due to the commercialization, eases avail of hybrid seeds in agro-vets however costlier, developed by multinational seed companies. Unavailability and poor quality source seeds of national open pollinated varieties (OPVs) also forcing farmers to use hybrid seeds in particular vegetable crops. The estimated crop area under hybrid seeds in maize and rice is around 10 and 2 percent respectively in 2010. Hybrid vegetable seeds are planted in 60 percent of commercial production pockets (SQCC/NSB 2011). Demand of these hybrids seeds are met solely by import at present. Hybrids vegetable seeds are imported from Thailand, China, Korea, Japan and India. Currently, about 30 foreign companies are supplying seeds of vegetables, maize and rice, in Nepal. The official/legal import of seeds of 21 vegetable crops from Japan, Korea, Thailand and India is 31 mt and seeds of 9 maize varieties is 225 mt having total cost of NRs. 94 million in 2067/68 (SQCC, 2011).The actual seed import data from different sources is not available due to porous border with India and systematic channel to obtain data from unregistered importing dealers/companies has not established yet.

Still there is huge gap between the demand and supply of vegetable seed in Nepal. The requirement of vegetable seed for the year 2010/11 has been estimated 1977 mt, of which around 1158 mt (58%) is supplied by domestic production and rest 829 mt (42%) is met either by import or by seed saved through farmer-to-farmer exchange. Nearly eighty-five percent of the total vegetable seeds import occupies by hybrid (VDD 2066/67). The main reasons are that commercialization of fresh vegetables in urban and periurban area is increasing at a faster rate, less varietal options and poor quality of national seeds. Also, the price of imported seed is still nearly six times higher than the price of locally produced seed (SDC 2009). Attraction to hybrids is mainly due to well packed, branding and higher profit margins for agro-vets. On the other hand, locally produced seeds are facing problems of timely inspection, labeling, packaging, branding and marketing at full strength.

Hybrid maize seed marketing to farmers' was started since 1980, via open border between India and Nepal. However, Seed companies and Agro-vets working in the field of seed and pesticide business involved intensively in hybrid maize seed marketing after 2000 (NMRP 2011). Maize mission program run by DoA/CDD occupies 7000 ha area under hybrid maize seed in Chitwan, Bara, Rautahat, Sarlahi, Sunsari, Kavre, Nawalparasi, Rupandehi and Dang districts (CDD, 2066/67). Hybrid maize is mostly grown in terai and plains during winter season and partly in mid hills during normal season. Similarly, hybrid rice also grown mainly in terai regions and partly in foot hills and mid hills during normal season.

The policy

The Agriculture Perspective Plan (2052-2072). Use of good quality seeds of improved varieties is widely recognized as fundamental to ensure increased crop production and productivity, APP has not given due recognition to this.

The National Agricultural Policy 2061 (NAP).

In order to raise production and productivity, the NAP ensures the supply of main production inputs (seeds, fertilizers and breeds) based on market demand. It promotes the use of hybrid seeds and regular monitoring of genetically modified organisms.

National Seed Policy 2056 (NSP). NSP asks for doing necessary research and study on GMO, transgenic plants and tissue culture.

Seed Act, 2045 and its first amendment, 2064. As per the act, Government of Nepal must regulate the import and export of seeds of notified kind/varieties by issuing import and export permission. Also GoN can restrict the imports and export of seeds that has adverse effect on agriculture and other environments on the basis of risk analysis.

National Agro Biodiversity Policy, 2063. It has provision on receiving permission from authorized agency to conduct research on Genetically Modified Organisms and government can ban import and research on any GMO with potential risk to alter diversity and negative impact on environment.

National Biosafety Framework, 2063. It authorises the concerned agencies for regulatory measures and guidelines to avoid or minimise potential risks of GMO plant & their products, GM microorganism & their products and GMO animals and their products.

Development and regulatory functions

Hybrid development

Hybridization is a technique to create variability with increased vigour (hetrosis) in variety development. It is obvious that hybrids have high yielding ability by 15-25 percent as compared to open pollinated varieties (Virmani SS, M. Hossain, and T. Bayarsaihan 2006). For this reason, there is an increasing trend of using hybrids among farmers. The first hybrid variety in Nepal was officially released in maize (Gaurav) in 2004; however it could not be widely adopted due to non synchronization nature of inbred lines. Recently NSB has released hybrid variety of maize "Rampur hybrid- 2" and some varieties of maize hybrid are also in pipeline to submit proposal for release by Agri Botany Division NARC. A hybrid variety in tomato (Srijana) was registered in 2010. Hybridization work has not initiated yet in case of rice in Nepal. A large number of imported hybrids in vegetables are being popular among farmers in Nepal. Recently, hybrids in maize and rice are also increasingly becoming popular among farmers in Terai and lower hills. Many of them are imported from abroad. As of 2013, 272 hybrids are registered for cultivation in Nepal (Table 2).

Research in hybrid development is being initiated in maize and vegetables by National Maize Research Program and in Horticultural Research Division, NARC respectively. Despite the high

demand of hybrids, research in hybrid variety development is limited in Nepal due lack of trained human resources, infrastructure and investment by both public and private sectors. Seed vision 2025, envisaged that 20 hybrids comprising, 10 in vegetables, 6 in maize and 4 in rice will be developed and promoted to meet the increased domestic demand and import substitution in public sector. In addition, 40 hybrids comprising 20 in vegetables, 10 in maize and 10 in rice are expected to be developed and promoted by private sector.

Table 2. Number of varieties notified through registration

SN	Crops	Varieties		Total
		OPVs	F1 (Hybrid)	Varieties
1	Rice	1	16	17
2	Maize	0	34	34
3	Vegetables	30	222	252
	Total	31	272	303

Source: SQCC, 2013

Process and regulation of imported hybrids

As per provision of the seed Act of Nepal, there is restriction to sell seeds of non notified varieties and without labeling. In case of imported crop varieties notification is done through registration process. For this, proponent should submit the proposal for national crop inventory (Registration) of a crop variety to National Seed Board (NSB) as per standard format provided. The minimum requirements and data on general information, varietal characteristics, and morphological descriptions, identifying characteristics of a crop variety for its distinctness and recommendation domain are compulsory. In addition, following points are the general requirements to facilitate the process of variety listing smoothly.

- Minimum two-season data on varietal performance from researcher designed and researcher managed replicated trials or participatory trials along with farmers and other stakeholders' preferences;
- Supporting information from farmers, processors and consumers from participatory trials or other forms of on farm experimentation under farmers' management should be included. Both quantitative and qualitative data are encouraged to be incorporated;
- Submission of data on DUS for introduced variety is necessary if NSB does not satisfied with submitted agronomic and morphological characters but can be obtained from other countries in case of landraces, data/information on Distinctness and Stability will be sufficient and indigenous knowledge and information will be accepted to satisfy these requirements;
- A sample of the nominated variety will have to be submitted to the variety approval, release and registration subcommittee. The quantity of the sample should be 50 g for small grain crops, 500 g for medium grain crops and 1 kg for large grain crops;
- Varieties developed using terminator gene technology will not be entertained for national crop inventory. Variety developed using any biotechnological tools should also be disclosed,
- Color photo and herbarium of different growth stages should be submitted to NSB.

If the submitted proposal fulfils above requirements, it passes through the series of meetings and finally approves by NSB for notification in Nepal Gazette.

Process and regulation of GMOs

As Nepal has signed the Cartagena Protocol on Biosafety, on 2 March 2001, originated from the framework of CBD, 1992. It deals with the regulations related to the safety of the GM technologies and effects of GM products on human health, biodiversity and environment. It entered into force from 11 September, 2003 and binds the members to implement precautionary principle in handling & trade of GMOs with the development of national legislation and institutional framework. In this regard, Nepal has made provision of National Focal Point of CBD and Biosafety Clearing House (BCH), for Ministry of Forest and Soil Conservation (MoFC). In addition, government of Nepal also formed National Biodiversity Coordination Committee, National Biosafety Committee/ National Competent Authority and establishment of Six Sectoral Competent Authorities (SCA) for effective monitoring and regulation of GM products (Table 3).

Table 3. Sectoral competent authorities and responsibilities

Name of Institution	**GMOs and Products thereof**
Department of Agriculture	Plants, Micro-organism and Fish for Agriculture Purpose,
Department of Food Technology and Quality Control	Food and Feed
Department of Livestock and Animal Health	Animal, Birds and Forage
Seed and Quality Control Centre	Seed for Agricultural Purpose
Department of Plant Resources	Seed and Plant for Forestry Purpose
Department of Drug Administration	Pharmaceuticals

These competent authorities are supposed to fulfill the procedures in respective sectors as per prescribed process for the response of civil society and other stakeholders. GMOs may be seed, plants animals for the agriculture or forestry purpose, and products of GMOs or products containing GMOs such as food, feed or pharmaceuticals. Therefore, depending upon the types of the GMOs and products thereof, respective sectoral line agencies will be responsible for the evaluation of the respective proposals and its risk assessment report, monitoring of the implemented proposals, ensure that the GMOs or its products permitted for testing, storage, use are properly labeled with the description of its composition, direction for use, potential risk, and management of the risks arising from implementation of the proposal.

The SCA evaluates a proposal on GMOs and products thereof, and the risk assessment report in consultation with experts of the concerned GMO, biodiversity, ecology, social science and representative of consumers or farmers association. Moreover, depending upon the type of GMO, the SCA consults with any or group of the experts in the field of nucleic acid technology or molecular biology, molecular genetics, population genetics, taxonomy, microbiology, virology, botany, zoology, entomology, veterinary science, agronomy, forestry, pathology, epidemiology, process technology, biochemistry and toxicology and so on as required. Any tests of the GMOs have to be carried out in accredited laboratory. The SCA submits its comments to the NCA on the

basis of any laboratory tests and the evaluation conducted in consultation with the concerned experts of different fields.

In case of seed, no any GM seeds are registered and introduced in Nepal so far. GMO laboratory under SQCC carries out detection test on seeds of maize and soybean every year for imported samples collected from border districts by using PCR technique. In 2067/68 five varieties of imported hybrid maize seed samples (India) were collected from Nepalgunj, Bhairhwa, Butwal and Janakpur tested by using Cry 1Ab/Bt11 event kit through lateral flow stripe test method for GMO, found negative. Similarly five imported samples (China) of soybean were collected and tested by using Envirologix-RUR- Round Up Ready Event lateral flow stripe test also, found negative for GMO. The decisions whether introduce or not GM seeds in Nepal shall be made based on evaluation of biosafety report submitted by the party or produced by concerned sectoral competent authority.

Discussions

In recent days, an issue of hybrid seeds and GMO has obtained a big coverage in Nepalese media. It generates concern from three different prospects of nature namely, food and agriculture, environment and economy. It is a people's right to debate about pros and cons but it is realized that there is a big confusion in understanding some of the terminologies of biotechnology. Hybrid crop, biotech crop and GM crop are three different terminologies erroneously used interchangeably. Past experience of hybrid seed use showed that some of serious issues/problems rose in hybrid maize failure in Bara, Parsa, Rautahat and Sarlahi in 2010 winter season. Compensation was claimed by farmers from areas where maize mission program was carried out by DoA/CDD. In fact farmers in these districts used to grow hybrid since long time back however, the crop got failure in 2010. According to field observation, monitoring, survey conducted by technical team found that it was due to longer cold wave below 10 ^{o}C during silking and tasseling stage affected in pollination and fertilization resulted in poor grain filling. According to an innovative farmer Mr. Ram Ashray Prasad and his group members from Prastoka, Bara district told that they are shifting date of hybrid maize seeding one month later than usual date of seeding could escape the cold injury for safe production (Interviewed during field visit on 18 Magh, 2068 at Bara). Thus the technical information, extension teaching and specific package of practices need to be provided duly by seed companies, extension workers and researchers to target growers. Some of the issues in the context of Nepalese seed sector are as follows.

- Many farmers are using hybrid seeds are not produced in Nepal commercially. Hence seed import is encouraged.
- Hybrid seeds are very expensive for small and subsistence farmers. Hybrid seed production system has not established in Nepal.
- Confusion arises between GM seeds and hybrid seeds. Lack of perfect knowledge and awareness about genesis of these.
- Large number of agro-vet (2200 registered in NSB) owners are from non agriculture background are not technically capable enough for handling and provide appropriate information to farmers on hybrid seeds.

- Lack of awareness programs on potential risks and benefits GMOs and products thereof and the biosafety measures to be adopted.
- Lack of strong policies, mechanism, physical facilities and skilled human resources for GMO control and regulation.

Policy gaps/weakness

The existing laws and rules do have various provisions with regard to maintaining quality of seeds, food, feed, and medicines. However, the Acts relating to Export Import, Plant Protection, Food, Feed, Drug, National Park and Wildlife Protection, and Aquatic Animal Protection have been formulated and enacted quite long ago before the emergence of the issues of the modern biotechnology. Hence it is inevitable that these Acts lack the explicit provisions relating to the modern biotechnology and GMOs. Following are some of important policy gaps need to be addressed as early as possible.

- No concrete policy on hybrid research and GMO regulation/control
- Delayed in amending seed regulation and enforcement of the seed Act only in 33 districts.
- Many provisions in the NSP are progressive, but some require amendment in redefining the terms in line with international treaties, licensing the private seed laboratories, and many others.
- Seed Act need to be harmonized with GMOs, IPR and PVPFR laws. There are some areas like its coverage, inability to fulfil the emerging demand of quality seeds including hybrids, apply truthfully labelled system of quality assurance, and implement effective law enforcement procedures, address farmers and plant breeder's rights.
- Existing Environment Protection Act need to be amended (which do not require EIA for the activities with less threshold level of work than the specified ones. But according to Cartegena protocol on Biosafety, it is required to conduct risk assessment for the development, handling, transfer, transport, use and release of GMOs, which does not specify any threshold level of the activity).
- Lack of bio-safety provision in constitution and Bio-safety judiciary.
- Lack of integrated bio-safety act policy and guidelines.

Future actions

In fact, use of hybrids should not have adverse effect on the environment, human/animal health and our ecosystem if managed properly. Since, Nepal is in a very infant stage in hybrid research and development; however the demand is increasing over time. National legislation mechanism, human resources and physical facilities are not well established in testing and regulation of GMOs. So it is necessary to encourage policy-makers to strengthen their commitment and provide strong policy and financial support to promote hybrid research and development in Nepal through public private partnership for import substitution. Strong regulatory mechanism should be developed and adopted to reduce the inflow of hybrids and regulation of GMOs from abroad. Based on discussion and issues, some realized actions to be taken in future are as follows.

1. NARC should be responsible for research and development of national hybrids with strengthening its human, financial, technical and physical resources, so as to reduce the dependency of imported hybrids slowly. NARC should have Hybrid Research Unit (HRU) under National Commodity Programmes and Divisions with adequate fund and human resources.
2. Remove the present subsidies provided in imported hybrid seeds and increase the subsidies in national seeds.
3. Control and regulation of GMOs based on bio-safety report and ban/don't allow import and use of terminator technology.
4. Enhance technical and physical capacity of GMOs laboratory under SQCC for proper detection, identification and quantification of GMOs.
5. Strengthening the partnership between public and private sector for producing hybrid seed is essential.
6. Seed production zones should be identified, declared and provide priority on support to transportation, agriculture soft loan as stipulated in ABPP, 2063. Similarly identify the zone where seed for import substitution and export can be produced and prioritize for facility provisions.
7. The official linkage mechanism should be developed between Nepali and foreign seed dealers to facilitate import and export of seed.
8. Priority should be given for hybrid research and development on maize, rice and vegetables (cauliflower, cabbage, tomato, cucurbits and many crops).
9. Effective quality monitoring policy supported with strengthened SPS measures required.
10. Select very useful hybrid variety, which fits to the national interest and suitable to our environment.
11. Develop hybrid village concept (don't allow everywhere).
12. Strengthen the capabilities of researchers, extension workers and seed enterprises in hybrid seed production and marketing.

Conclusion

National legislative, administrative and technical competency on research and testing of seed, plants, food, feed and animals with GMOs should be strengthened along with public participation for making decision whether to allow or restrict the import of the tested GMOs. Public participation is necessary in the decision making process of production, import, handling and use of GMOs and hybrids. As GMOs affect human health and the biological diversity, people at all levels should be aware of both the positive and negative aspects of GMOs. As a part of the public awareness program, it is required to disseminate available information on GMOs and products thereof through appropriate media, languages and publications. It is an urgent need for research and development of national hybrids with strengthening its human, financial, technical and physical resources, so as to reduce the dependency of imported hybrids slowly. In addition national seed system should be strengthened through increased public, private and cooperatives involvement in seed multiplication,

quality control; processing, storage and marketing of farmers' preferred crop varieties for sustainable seed supply with the technical support from research, development and academia.

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