



MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT

**THE NATIONAL ACTION PLAN TO 2010
FOR IMPLEMENTATION OF
THE CARTAGENA PROTOCOL ON BIOSAFETY**

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PREAMBLE

Over the last more than two decades, biotechnology has made great headway, thereby contributing to bringing about great achievements for the humankind. Modern biotechnology enables genetic modification from one species to another, change genetic materials to create new species with desired traits. On the one hand, genetically modified organisms (GMO) and their products with superior traits have had positive and profound effects on agriculture, food industry and health care. On the other hand, GMOs and their products pose potential threats to human health, environment and sustainable use of biological diversity. Therefore, the Cartagena Protocol on Biosafety (to the Convention on Biological Diversity) was finalized and adopted on 29 January 2000 in Montreal at the extraordinary meeting of the Conference of the Parties. This is the first ever legal document prepared by the international community that derive maximum benefit from the potential that biotechnology has to offer while minimizing the possible risks to the environment and to human health.

Vietnam is well endowed with abundant and diversified biological resources. The State and Government have attached great importance to making policies that facilitate the development of science and technology, especially biotechnology. The Resolution No. 18 NQ/CP dated 11 March 1994 on the development of biotechnology in Vietnam by 2010 clearly states: “biotechnology is defined and recognized as one of key national programs in socio-economic development”.

Coupled with promoting the development of biotechnology, Vietnam is also well aware of and pays due attention to biosafety management. On 27 November 2003, the State President signed the decision to accede to the Cartagena Protocol on Biosafety. On 19 January 2004, Vietnam ratified the Protocol.

Although the Cartagena Protocol focuses specifically on transboundary movement of any living modified organism (LMO), this Action Plan attempts to touch upon a wider scope of supporting the implementation of the Protocol in an effective manner. By so doing, the Action Plan incorporates science and technology research and development (R&D), field trial, production, commercialization, use, storage, and transport of LMOs and their products that may have adverse effects on human health, conservation and sustainable use of biodiversity.

The Action Plan to 2010 to implement the Cartagena Protocol on Biosafety was prepared to undertake the obligation of Vietnam as the Contracting Party and promote biosafety management in a way to avoid risks possibly caused by biotechnology.

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Part I. Practical and legal base for formulating the Action Plan 2010 to implement the Cartagena protocol on biosafety

I. world situation of biotechnology development and biosafety management

1. Status quo of biotechnology development

Biotechnology (biological technology) is the use of biological traits of biological cells and molecules (ADN, ARN, protein, sugar, starch and lipid) to solve questions in life and create products useful for human beings.

Biotechnology is given top priority to development for the benefit of socio-economic activities. Biotechnology has undergone through 3 stages of development, i.e. traditional, contemporary, and modern times featured by a number of revolutions. Notably, the following revolutions have brought about significant effects on human life, environment and organisms:

- a) Discovery of ADN structure;
- b) Polymerase Chain Reaction (PCR) Technology;
- c) Genetically modified organisms (GMO) and their GM products;
- d) Presymptom diagnosis;
- e) Gene Map of the Human Genome project;
- f) Gene therapy.

At present, modern biotechnology, especially gene technology, has been intensively invested and widely applied not only in developed countries but developing countries have gradually given priority to investment in modern biotechnology to create new and highly applicable products. Thanks to gene technology, we can create new crop and livestock varieties with high yielding, quality and resistance, and other desired traits. For example, we can create crop varieties containing protein with rich lysine, metionine and tryptophan, and low intensity of photosynthesis etc. as well as fast growing livestock breeds having lean meat and milk with low fatty content; can multiply animals to produce valued proteins for human beings, blood coagulation factor to make interleukin, provide viscera (internal organs) for grafting; can create new and effective antibiotic generations and vaccines; and can produce anesthetic drugs, biological products and disease diagnostic kits and so on. In general, biotechnology brings about fundamental and long-term benefits, particularly in minimizing negative use of chemical fertilizers in cultivation,

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mitigating pollution to environment and improving human health.

Although modern biotechnology has created GMOs that bring about socio-economic benefits, the most serious concerns are that genetically modified crops and livestock may adversely affect the environment, biodiversity and human health. For example, traits of anti-herbicide, anti-insecticide, anti-antibiotic, anti-disease etc. in crops are likely to transfer to weeds. These potential threats must be taken into due consideration. Planting of genetically modified crops on a large scale will erode the nature of biodiversity in ecosystems and jeopardize organisms in surrounding environment, e.g., Bt corn (a genetically modified crop with pest resistance) is suspicious of killing a few useful butterflies and bees. Biologists believe that in some cases, unknown or alien genes in crops may transfer to other species and turn them into potentially threatened organisms. However, for the time being, our knowledge and understanding of this matter is not sufficient yet since biotechnology is developing in a much faster pace than that of the scientific awareness and understanding of the potential risks and threats as well as that of the legal system to monitor and control the use of GMOs.

Thus, scientists are given the task to study and examine these potential risks and threats and therefrom work out proper measures to mitigate them. In fact, GMOs have not recognized by many countries yet.

2. Status quo of R&D and use of GMOs and their GM products

Being well aware of the worldwide significance made by modern biotechnology, especially in agricultural sector, field trial and commercialization of GM crops have been carried out widely and recorded satisfactory achievements. Since 2002, GM crops have been planting in all six continents: North America, South America, Asia, Oceania, Europe and Africa. During 1996-2003, genetically GM were planted in 21 countries, totaling 300 million hectares. The United States, Argentina, Canada, Brazil and China are ranked amongst the top countries of GMO coverage. And soybean, corn, colza and cotton are major GM crops. Traits resulted from genetic modification, which are popularly applied, are anti-herbicide and pest resistance. The number of growing GM crops in 2003 is 7 million. More than 85% of these beneficiaries are Bt corn growers, who are poor people primarily from China and South Africa (James, 2003).

According to the statistics as of October 2002, there are 55 GM varieties (of 13 different species) that were licensed in the United States. As of 3 March 2004, there are 57 GM varieties (of 6 species) in Japan, 12 GM varieties (of 5 species) in Australia and New Zealand, 4 GM varieties (of 3

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species) in South Africa. In the EU, as of July 2003, there are 15 GM varieties (of 4 species) that were permitted to be used as food. Noticeably, on 9 March 2004, the UK Government decided to allow growing GM corn on a large scale. Germany also prepared a draft code, including pre-conditions for cultivating GM crops. Not only developed countries, but several Asian countries, namely China, India, Indonesia, Thailand, South Korea, and the Philippines are conducting R&D and initially started commercial production of GM crops.

3. Status quo of biosafety management in some countries

Biosafety means safety issues in relation to application of biotechnology and release of GMOs in the environment, particularly microorganisms that may have negative effects on genetic resource, human health and environment.

When GM products from America and Japan penetrating into Europe, there appeared a new wave of safe use of GM products originating from Europe and spreading all over the world. At that time, countries have divided their standpoints into 3 major categories as follows:

a) Big GMO exporters and importers, particularly the United States, Canada, Australia, Argentina, Chile and Uruguay, push up preparation of a Protocol with terms favorable for use and export of GMOs.

b) European countries and some international organizations and associations, together with some developing countries support a stringent Protocol that absolutely ensures the safety for GMO users and environment.

c) The rest majority of developing countries, however, are not clear since they have not produced GMOs and their products for export or been in need of import yet.

Against that backdrop, in 1996 the United Nations Environment Program (UNEP) organized a series of international conferences attracting participation from hundreds of countries (including Vietnam) with a view to preparing a so-called Protocol on safety in use and transport of GMOs. This Protocol is under the framework of the Convention on Biological Diversity that was opened for signature of heads of state in Rio de Janeiro (Brazil) on 5 June 1992. Since then, UNEP further organized 6 meetings of the expert groups. The 5th Meeting of the Conference in February 1999 in Cartagena (Colombia) prepared the Cartagena Protocol but failed to adopt it due to deep disagreement between America and Europe. On 29 January 2000 at the 6th Meeting of the Conference in Montreal (Canada), after five years of intensive debates, the final document of the draft Protocol was adopted by 133 countries (including those from Europe and America). The Protocol recommends that GMOs

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and their products, before being recognized as consumer goods, must be tested in glass houses and on fields to evaluate and examine their potential risks. Besides, the use of these GMOs and their products must be in accordance with each national law on biosafety of GMOs and their products. In the face of controversial issues about GMOs and how to evaluate and examine the biosafety level of them, policy makers seem to be confused and puzzled with two new challenges. First, commercialization of GMOs has become a global trend rather than a domestic issue of an individual country. Second, the issue is beyond the concerns of all the Governments. In many countries, different communities such as consumer and environment groups, non-governmental organizations (NGOs), business and industry sectors have also expressed growing concerns over the issue.

Biosafety management is of importance and necessity, particularly safety management of GMOs. Therefore, regulations on management of GMOs have been prepared and enforced in developed countries since mid 1980s. Meanwhile, most developing countries do not have sufficient scientific capacity and enforcement power to manage GMOs. There appeared opposite views about safety management of and product labeling for GMOs. Some countries (the EU, Brazil, Japan, and China) require compulsory labeling for genetically modified food whereas others (the US, Canada, Argentina) do not. The EU already implemented a number of regulations on biosafety management. They are, amongst others, as follows: Instruction 90/220/EEC regarding safety for environment and food, feedstuff, biotech seeds; Regulation on new genetically modified food safety and labeling for every food containing genetically modified products or made from biotechnology; Regulation 50/2000 on labeling for additives and flavourings having biotech ingredients; Regulation 49/2000 on labeling requirements for traditional food cases infected by non-negative biotech material (Stamps, 2002). Recently, the EU has been formulating new rules to apply labeling for food and feedstuff. Some Asian countries such as China, India, Thailand, Malaysia and the Philippines are putting effort in building and implementing a regulation framework for management of products made from advanced biotechnology.

To facilitate the implementation of the Convention on Biological Diversity and the Cartagena Protocol, the UNEP has carried out several projects under the auspices of the Global Environment Facility (GEF) to provide supports to different countries in biosafety management.

II. Status quo of biotechnology development and biosafety management in Vietnam

1. Status quo of biotechnology development in Vietnam

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Over almost the last decade, thanks to the growing concern and investment of the State and Government of Vietnam, coupled with efforts made by different organizations at various levels as well as those made by scientists and biologists, biotechnology in Vietnam has made great progress compared to that of the two and three last decades. Below are some prominent achievements:

- **Science and technology base of biotechnology has been enhanced considerably.** Biotechnology research institutions have increased in both quantity and quality. Almost 100% of major universities in Vietnam have established training in biotechnology; research institutes have actively engaged in biotechnology training. Many trainees have been selected to study abroad and a large number of them participated in study tours and workshops to learn and update knowledge or cooperate with their colleagues in advanced biotechnology institutes in other countries. Network of laboratories was in shape and their locations allocated evenly throughout the country. Up to now, Vietnam has had more than 60 laboratories with annual investment capital of hundreds of VND billion. The Prime Minister decided to establish five focal biotechnology laboratories in 2000 and a focal laboratory of plant cell technology was recently established for the Southern part of Vietnam.

The level of science and technology in Vietnam has been elevated to a new height. Over the last five years, Vietnam has perceived and mastered some advanced technologies, and produced a number of internationally accepted research publications, which substantially contribute to production activities. Conservation and maintenance of genetic resources (gene fund) have been promoted, e.g., establishing a network preserving genes of animals, plants and microorganisms, which include 12 focal agencies and 70 coordinating agencies from 8 Ministries and branches. This network of gene fund in Vietnam already integrated into the Asia-Pacific genetic fund network.

- **Biotechnology has been widely applying in production and social activities.**

Microbiotechnology: Vietnam has developed some technologies for production of bio-pesticides, bio-fertilizers; for environmental pollution treatment; for preservation and processing of agro-products; and for production of antibiotic used in husbandry. At present, there are 9 out of 10 vaccines produced for the expanded vaccination program. Thanks to the domestically produced polio vaccine, Vietnam announced elimination of polio in 2000. Vietnam is now conducting research and preparing for production of measles vaccine. These vaccines are also for export. Recently, Vietnam managed to apply high technology to researching the process of producing re-combination vaccine against hepatitis B.

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Enzyme technology: Vietnam has developed some technologies to produce biomedical products used for tonic and medicinal purposes from biological resources in Vietnam; enzyme products are used in the textile industry, food processing, amino acid, unisugar etc.

Cell technology: Vietnam has developed technologies for fast multiplication, revigoration and disease clearing of plant varieties, which are widely used in local areas; create artificial human and animal germs, which started being applied in human in-vitro fertilization, germ transplantation into cows; and develop technologies for maintenance, storage, and transplantation of animal germs and sperms.

Gene technology: as considered a key and advanced technology, Vietnam has mastered a number of technologies such as gene multiplication, gene decryption, ADN, and gene modification. These technologies are applied to creating plant varieties with pest resistance and tolerance, producing new generation vaccines, identifying bloodlines, developing criminal techniques, and identifying martyr remains.

Biotechnology for environment protection: treatment of organic liquid waste, treatment of livestock dung, treatment of oil pollution after mechanical and chemical treatment. To different extents, these treatment technologies were already translated to reality. Application of biotechnology in environmental pollution treatment is highly recognized as an effective and economic way of environmental protection.

From a very low starting level of development, biotechnology base in Vietnam has taken shape and developed. The Government laid down a policy to diversify biological products and improve their quality by applying advanced technologies, establishing small-scale customized establishments (factories, center, stations etc.), and if conditions and efficiency are met, the Government will consider the establishment of large-scale factories for the benefit of agricultural and healthcare development.

In spite of gaining encouraging achievements, biotechnology base in Vietnam is still at low level compared to that of many other countries in the world. Within ASEAN, Vietnam is a bit above the average. In order to improve the biotechnology base, Vietnam has to solve the following source of problems:

- Domestic education and training fail to meet the quality demand, let alone meeting the international standard. This could be explained by relatively low professional level of teachers and backward teaching tools and facilities.

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- Though laboratory base in Vietnam is much improved, there is still a wide gap between Vietnam and the region to narrow. Moreover, to compare with the world average level, investment in biotechnology R&D in Vietnam is very limited.

- R&D capacity, as a result, is limited, particularly in application and introduction of new (and proven) technologies to production.

- Objectives for establishing and developing a so-called Vietnamese biotechnology are yet to be met. Pharmaceutical industry, which can make most use of biotechnology achievements, has not taken shape in Vietnam yet. One of the objective reasons is that biotechnology industry often requires huge investment (e.g. investment capital required for an antibiotic production project estimated to be nearly USD 100 million), while Vietnamese enterprises are in a financially unhealthy situation and many of them rely on state budget allocation.

2. Status quo of state management of biotechnology and biosafety

2.1. Structure of state management agencies and national research institutions

State management of biotechnology can be grouped into the following activities: research and development (R&D), application of biotechnology to socio-economic activities (namely industry, agriculture, forestry, health care, environmental protection); prevention of adverse impacts caused by biotechnology on human health, environment and entire society (e.g. asexual multiplication). Therefore, these above-mentioned activities relate to many sectors and industries and require the involvement of relevant Ministries and institutions.

The **Ministry of Science and Technology (MOST)** is responsible to the Government for state management of R&D activities in science and technology, including biotechnology. In the current context, it is MOST that is in a crucial position to raise the science and technology capacity of the country.

The **Ministry of Agriculture and Rural Development (MARD)** is responsible to the Government for state management of agriculture, forestry, salt industry, irrigation and rural development throughout the country. In the field of biotechnology and biosafety, MARD undertakes the state management function of application of biotechnology to agricultural sector, namely, agricultural crop varieties, agricultural livestock breeds, forest plant seeds, forest materials; management and conservation of genetic resources; research, selection and breeding, field trial, certification

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of varieties; genetic protection; production and commercialization and quality control of varieties. Besides, MARD also manages the protection of plants, veterinary, plant quarantine; quarantine organization of agricultural livestocks, wild animals and plants for export and import. Particularly, the Ministry undertakes unified management of plant and animal gene banks (including wild plants and animals), microorganisms used in agriculture, forestry and salt industry.

The **Ministry of Industry (MOI)** is responsible to the Government for state management of the industrial sector namely mechanical engineering, metallurgy, new energy, renewable energy, oil and gas, minerals mining, chemicals (including pharmaceutical industry), industrial explosion materials, consumer-goods industry, foodstuff industry and other processing industries throughout the country. In the field of biotechnology, MOI assumes responsibility for application of biotechnology in promoting industries, particularly in consumer-goods industry, food processing and others.

The **Ministry of Fisheries (MOFI)** is responsible to the Government for state management of fishery, consisting of: aquaculture, exploitation, processing protection and development of fishery resources in the whole country's land and sea territories. Similar to MARD's role, MOFI undertakes management of biotechnology application activities in aquaculture and development of fishery resources; provision of regulations on export and import of fishery varieties, migration and domestication, conservation, selection and breeding, certification of new varieties, production and commercialization of varieties; unified management of varieties quality, construction and management of varieties system, registration of national varieties, management and conservation of fishery genetic resources; research, breeding, selection, field trial, certification of new fishery plant and livestock varieties; production, commercialization, and quality control of fishery varieties.

The **Ministry of Natural Resources and Environment (MONRE)** is responsible to the Government for state management of soil, water, minerals, environment, hydrometeorology, conducting survey and mapping all over the country. As for biotechnology, MONRE takes responsibility for state management of application of biotechnology and bio-products in environmental pollution treatment; biotechnology impacts on the environment; migration of alien organisms. Although no regulations on biosafety are officially promulgated yet, MONRE is the body assisting the Government in managing biosafety issues.

The **Ministry of Health (MOH)** is responsible to the Government for state management of taking care of the people's health. As

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for biotechnology and biosafety, MOH manages the activities of biotechnology application in production of vaccines and medicinal bio-products, various types of chemicals, bactericide and insecticide products in health care sector; provision of requirements for production and commercialization of vaccines, medicinal bio-products; promulgation of standards and conditions for organizations and individuals to produce, deliver and import drugs, materials for making up drugs; management of cosmetics harmful to human health; promulgation of standards for food safety and hygiene, technical process and procedures for ensuring food safety and hygiene; unified management of issuing and revoking certificates of food safety and hygiene.

The **Ministry of Trade (MOT)** is responsible to the Government for state management of export, import and handling of goods in the whole country and trade services.

Therefore, given the special nature of biotechnology, i.e. cross-cutting relations to and effects on many sectors and areas, the structure of state management of biotechnology in Vietnam is relatively complex and thereby reveals a number of shortcomings as follows:

- Overlapping and cumbersomeness in functions, tasks and responsibilities of Ministries and other relevant agencies over state management of biotechnology and biosafety, which lead to poor and ineffective coordination and disclamation of responsibility between and among these Ministries and agencies.
- Due to the above overlapping, biotechnology has been developed in an arbitrary, uneven, and rampant manner, without a proper and integrated planning. Investment in biotechnology has also been put unwisely and ineffectively.

2.2. Legal framework and policies for biotechnology and biosafety

As mentioned in the above part of the report, thanks to due consideration and close guidance of the Party and State at central and local levels, biotechnology in Vietnam has achieved encouraging achievements over the last few years. Since mid 1990s, the Party and State of Vietnam have attached great importance to development of biotechnology, considering it as one of the four key scientific and technological areas of the country. The Political Report of the VIII Party Congress clearly points out: "Perception and master of advanced technologies such as information technology, biological technology, new material technology, new technology in machinery engineering and so on are needed to quickly enter

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into modernization in key areas”¹. Specifically: “Develop biotechnology to create and breed new varieties; processing of agricultural, forest and aquaculture products; production of different vaccines and antiserum, products for quick and accurate diagnosis; develop technologies for environment pollution treatment... Establish high-tech zones in Ha Noi and Ho Chi Minh City (including biotechnology) as the hub of domestic and foreign agencies and enterprises in the field of high technology and high-tech based industries”².

As the 21st century entered, with the goal of intensified industrialization and modernization, the 6th meeting of the Central Committee of the IX Party Congress on science and technology reaffirms: “The second line of priority is to develop biotechnology, focusing on research and application for developing agriculture, forestry and fishery, food processing, protection of human health and environment. It is of special importance to build and develop gene technology, biochemical and enzyme technology, cell technology, micro-organism technology, and ferment technology (as key technologies of biotechnology)”³.

On 11 March 1994, the Government promulgated the Resolution 18/CP on development of biotechnology in Vietnam to 2010, clearly stating the standpoints of the Vietnamese Government about biotechnology as follows:

- a) Developing biotechnology in such a way to optimally exploit the biological resources of the country and at the same time duly considering the protection and development of the biological resources.
- b) Developing biotechnology for the benefit of sustainable development of agriculture, forestry and fishery, as well as protection of human health and living environment.
- c) Developing biotechnology on the basis of selectively perceiving and taking advantage of world achievements and in accordance with specific conditions in Vietnam; quickly approaching advanced biotechnologies (by creating a small and medium but advanced base) and at the same time modernizing traditional technologies.

The Resolution also identifies the objectives for biotechnology development in Vietnam by 2010 as follows:

- a) Conducting research and widely applying scientific and technological achievements in the field of biotechnology in the world to facilitate the national economy as well as

¹ Political Report of the VIII Party Congress, National Political Publishing House, 1996, p. 105.

² -ditto-, p. 189.

³ National Political Publishing House, 2002, p. 120.

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protect the people's health and living environment in a practical and effective way.

b) Establishing a developed biotechnology base that lay a firm foundation for production of various products for domestic consumption and export.

c) Establishing a proper structure of science and technology agencies and institutions operating in the field of biotechnology, which are capable of conducting R&D at an advanced level and creating new and advanced technologies for the benefit of the national economy.

To this end, the Resolution puts forward four fundamental guidelines:

1) To enhance endogenous strength of biotechnology in the country;

2) To implement measures and incentives aimed at promoting a developed biotechnology base in Vietnam;

3) To promote international cooperation; and

4) To increase investment in biotechnology development.

Coupled with guidelines and policies of the Party and State for biotechnology development, a legal system for biotechnology development and biosafety has been created in a relatively synchronous manner, namely, legal regulations on science and technology research (including biotechnology); establishment, conservation and development of genetic resources (including crop and livestock genetic resources); management of export-import of animals, plants and micro-organisms; management of plant protection drugs; quarantine of animals and plants, quarantine at border; management of food safety and hygiene; protection of rare and endangered animals and plants.

Vietnam already promulgated the Law on Science and Technology in 2000 and Decree No. 81/2002/ND-CP dated 17 October 2002 of the Government providing detailed provisions on the implementation of the Law, including those on the structure of science and technology, individuals conducting science and technology, organization of science and technology activities in general and biotechnology in particular. The State also promulgated a number of incentives for increasing investment in science and technology activities (including biotechnology), namely, Decree 199/1999/ND-CP dated 18 September 1999 of the Government providing some policies and financial regimes to encourage enterprises to invest in science and technology activities; Joint Circular 2341/2000/TTLT/BKHCNMT-BTC dated 28 November 2000 of the

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former Ministry of Science, Technology and Environment (MOSTE) and Ministry of Finance (MOF) guiding the implementation of the Decree 119. These above-mentioned legal documents and many others relevant have created a relatively completed legal framework for state management of science and technology in general and biotechnology in particular. However, due to the special nature of the biotechnology research, it is necessary to prepare and promulgate more specific legal regulations on biotechnology.

Regarding the conservation and development of genetic resources, the Standing Committee of the National Assembly promulgated the Ordinance on Crop Varieties and the Ordinance on livestock varieties providing regulations on management and conservation of crop genetic resources, research, breeding, field trial, control and certification of new varieties; assessment and selection of mother plants, elite line plants, planting material supply gardens, production and commercialization of crop varieties, and management of crop varieties' quality. These Ordinances are of superior validity and value, which replace all the previous subordinate legal documents in this field. Nonetheless, no subordinate legal papers have been prepared yet to provide detailed regulations for implementation of these above-mentioned Ordinances.

The Law on Environment Protection in 1993 provides that export-import of biotechnology and bio-products, animals and plants, gene sources and micro-organisms related to environment protection must be permitted by relevant line agencies and state management bodies on environment protection. The Government also promulgated Decree 11/2002/ND-CP on management of export-import activities and transit of animals, plants, wild animals, providing detailed regulations on export, import, re-export and re-import according to the schedule of wild animals and plants under the CITES Convention and the law of the S.R. Vietnam.

The State and Government of Vietnam have promulgated numerous legal documents and policies to regulate the quarantine of animals and plants, quarantine at border in order to enhance management of biosafety for human health. They are: Law on Protection of Animals, Plants and Environment; Ordinance on Veterinary in 1993; Ordinance on Plant Protection and Quarantine in 2001; Decree 26/2003/ND-CP dated 19 March 2003 of the Government providing regulations on administrative penalty on violation of plant protection and quarantine; Decree 41/CP dated 11 June 1998 of the Government of the S.R. Vietnam providing regulations on quarantine at border; and many other subordinate legal documents.

Regarding management of food safety and hygiene, there is a large amount of subordinate regulations (about 50) in this field. They are, amongst others, Circular 04/1998/TT-BYT dated

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23 March 1998 of the Minister of Health guiding the implementation of management of food safety and hygiene in trade, services and culinary service; Decision 2418/QD-BYT dated 18 December 1996 of the Minister of Health introducing "the Regulation on food quality registration"; Decision 867/QD-BYT dated 04 April 1998 of the Minister of Health introducing the List of food hygiene standards; Directive 08/1999/CT-TTg dated 15 April 1999 of the Prime Minister on enhancement in the quality of food safety and hygiene. In spite of the above legal strengthened base, concerned Ministries, agencies and local authorities have not coordinated in an effective and close manner and therefore failed to fulfill their state management of food safety and hygiene in food production, commercialization, service, culinary enterprises. It is the main cause for a number of suffers and damages not only to the life, health and economic condition of each individual or family but also to the labor-force of the entire society, thereby damaging the reputation of goods and services and resulting in a reduction in consumption of processed foods from domestic materials.

2.3. General assessment of weaknesses and remaining problems, and direction for improvement in the time to come

Thanks to preparation and promulgation of relatively completed and thick legal documents and policies in the biotechnology-related areas over the last years, biotechnology in Vietnam has thrived on and made remarkable contribution to the socio-economic development, particularly to agriculture, forestry, aquaculture, health care, food processing, post-harvest maintenance, environment protection and national security.

However, in addition to the mentioned weaknesses and shortcomings in each area, the legal framework and institution have some basic weaknesses as follows:

- Lack of an official document covering regulations on state management of biotechnology and biosafety; lack of clear-cut and transparent assignments of responsibility amongst relevant Ministries and agencies or between central and local levels, which result in overlapping and cumbersomeness in functions and responsibilities of state management of biotechnology and biosafety amongst them.

- Legal documents and policies for management of advanced biotechnology R&D (gene technology, cell technology, molecular biology etc.) are still quite few and incomplete, especially those for gene technology, GMOs and their products.

- Similarly, Vietnam has not finalized and officially promulgated legal documents and policies for management of biosafety and prevention of potential risks of GMOs and their

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products that may do harm to human health, environment and biodiversity.

Taking into account these above weaknesses, it is necessary to focus on the following activities in the time to come:

- With respect to mechanism and policy, it is necessary to implement incentives for research of GMOs and their products and management of biosafety. These incentives should give top priority to establishment of supervision standards, methods and procedures, applied technology and specialized equipment, techniques for environmental impact assessment (EIA) of GMOs and their products. Besides, policies for commercialization, export-import of GMOs and their products for the benefit of human health and environment protection should be further promoted. To this end, the guiding policy for GMOs and their products should be categorized into different approaches according to their level of risks. For example, commercialization and use of risk-free GMOs and their products should be encouraged; those having low potential risks must have EIA and license; those having an average level of risks should be limited by strict procedures and absolute compliance with regulation on licensing, production scale, scope and duration of business; and those that have high level of risks must be strictly prohibited. In parallel with these mentioned policies, it is necessary to implement policies aimed at socializing management of GMOs and their products. At present, raising public awareness of biosafety is also an important and urgent task. The customers (local communities) have the rights to be provided with sufficient information, especially about potential risks of GM products so that they can whether choose or reject using these products. A proper mechanism for public participation in biosafety will improve the effectiveness of the management in this field.

- With respect to legal aspect, it is an immediate need to formulate and set in place the Law on Biodiversity, including basic regulations on state management of biosafety, rules for biosafety, prevention and handling of risks that may be caused by biotech products. MONRE already prepared and submitted to the Prime Minister for approval the draft Decision on biosafety management of GMOs and their products. This Decision should be approved and promulgated as soon as possible.

In addition to the general regulations on biosafety management, it is necessary to prepare and promulgate specific regulations as follows:

+ Regulations on biosafety management of each specific sector, namely, agriculture, forestry, pharmaceutical industry, and food industry. These regulations should center on basic content of GMOs and their products such as procedures for research, field trial, production, trade, use, export-import;

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conditions for research, field trial, production, trade, use, export-import; process for risk assessment; guideline on biosafety management in laboratories, field trial, production and trade; guideline on monitoring and assessing the impacts of GMOs and their products after commercialization.

+ Regulations on EIA of GMOs and their products. The objective of EIA is to make accurate assessment of GMOs and their products' possible impacts on the environment.

+ Regulations on management of production and trade of GMOs and their products, including licensing process and procedures, list of permitted GMOs and their products; labeling requirements for goods that contain GMOs and their products.

3. Challenges facing Vietnam in biosafety management

Biotechnology in Vietnam has been lately developed and still lagged behind many developed countries in the world, including some ASEAN countries. Under the sound guidance of the Party and the State, biotechnology is always placed in the top priority (as important as information technology) and has therefore gained significant achievements.

However, taking into account of potentials for development and demand for agricultural production, biotechnology is confronting with severe difficulties and drawbacks as follows:

- Limited human resource: Human factor is obviously of decisive importance to the success of biotechnology R&D. Biotechnology experts must be trained in the long run in modern laboratories and taught by qualified teachers and professors. Up to now, Vietnam cannot afford to meet this requirement. Consequently, the percentage between biotechnology researchers and total national scientists in Vietnam is at the lowest in the world. Also, Vietnam has much more traditional biotechnology researchers than the experts in advanced biotechnology.

- Limited and inefficient investment: Biotechnology requires intensive investment and continuously renewed equipments. Although the State has paid due attention to this field, many laboratories remain incomplete and dated. Meanwhile, some laboratories possessing relatively modern equipment and facilities have not been in use or in low capacity operation.

Investment in biotechnology research and transfer is very low and largely dependent on state budget while exploitation of capital resources is inefficient. In fact, biotechnology should have been mostly invested and used by enterprises. Enterprise investments in R&D in industrialized countries (such as the United States, Germany and Japan) and in newly

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industrialized countries (such as South Korea and Singapore) account for 70% and 30% respectively. In Vietnam, the ratio is not worth considering.

- Drawback to technology development: Vietnam biotechnology is in the initial stage of development. Out of 10 ASEAN countries, Vietnam is ranked a bit below the average, let alone compared with industrialized countries. The Key National Science and Technology Research Programme on Biotechnology has been carried out for 18 years. In 1999, the Government established the Technical and Economic Programme on Biotechnology. However, no break-through has been made. Many research results are lying on the laboratory's bookshelf and not applied to production yet.

- Weaknesses in organization and R&D: Vietnam has established a biotech lab network consisting of research institutes and universities at both central and local levels. However, the coordination in research has not brought about expected results. R&D activities remain slow due to incomplete or inappropriate technology. Despite the fact that world biotechnology has gained a firm foothold and made significant contribution to the global economy, Vietnam have only a few biotech products produced at industrial scale.

- Weaknesses in the legal framework: Biotechnology is a sensitive and cross-cutting issue relating to science and technology, society and economy, environment, and even politics and religion. Therefore, it is necessary to establish a legal framework for development of biotechnology. At present, Vietnam is lacking crucial legal documents on biosafety with respect to research, application and development of biotechnology.

III. Legal base for formulation of the Action Plan

1. The Cartagena Protocol on Biosafety and requirements for the Parties to the Protocol (Annex 2)
2. Law on Environmental Protection, 1993
3. National Strategy for Environmental Protection to 2010 with vision to 2020, 2003
4. Law on the People's Health Protection, 1989
5. Science and Technology Law, 2000
6. Fishery Law, 2003
7. Ordinance on Plant Protection and Quarantine, 2003

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8. Veterinary Ordinance, 2004

9. Ordinance on Crop Varieties, 2004

10. Ordinance on Livestock Breeds, 2004.

Part II. The national Action Plan to 2010 for implementing the Cartagena protocol on biosafety

I. TERMS AND definitions

1. **Biosafety** means safe management measures in scientific research, technology development; field trial; production, commercialization and use; import, export, storage and transport of genetically modified organisms (GMOs) and the products thereof.

2. **Gene Technology** refers to gene transfer from one organism to another one compelling DNA of the latter receives the new gene.

3. **DNA** (deoxyribonucleic acid) means biochemical structure of the gene that plays a role of organism's genetic material.

4. **Genetically modified organism (GMO or LMO)** refers to any animal, plant , and micro-organism having modified gene structure from gene technology.

5. **GMO's product** means the product originated from GMO.

6. **Release** of GMOs' means the deliberate introduction of GMOs into the environment.

7. **Risk assessment** is to identify the potential adverse effects and damage level, if any, in the activities concerning the use and release of GMOs and their products on human health, the environment and biodiversity.

8. **Risk management** means the implementation of safe measures to reduce, handle and overcome hazards in the activities concerning GMOs and their products on human health, the environment and biodiversity.

9. **Field trial** refers to controlling activity on biosafety level of GMOs and their products in the concrete conditions of Vietnam before any production, commercialization and use.

10. **Competent Ministries** refer to the ministries including Ministry of Agriculture and Rural Development, Ministry of Industry, Ministry of Fishery and Ministry of Health to be assigned for the management concerning the field trial, production, commercialization and use; import, export, storage and transport of GMOs and their products.

II. OBJECTIVES AND Principles for formulating the Action Plan

1. Objectives

a) Overall objective

The National Action Plan is made to fulfill the requirements posed on the Parties to the Cartagena Protocol on biosafety, at the same time minimize the risks resulting from modern biotechnology and its products that may have adverse effects on the human health, environment and biological diversity.

b) Specific targets to 2010

- Formulating policies and regulations on safety management of GMOs and GM products, including policies and regulations on scientific research, technology development, field trial, commercialization, use, import, export, storage and transport of GMOs and their products.
- Promoting capacity-building for the state management agencies in biosafety: the National Focal Point or competent national authorities in biosafety should have adequate material and human resource base to deal with biosafety-related issues; the National Council and ministerial level commissions on biosafety should be established and put into operation.
- Promoting capacity-building in biosafety research: strengthening capacity of key national laboratories, enabling them to analyze and evaluate risks posed by GMOs and their products; developing skills and expertise of human resources in biosafety; and establishing risk classification, assessment and management systems.
- The Biosafety Clearing-House should be created and put into operation.
- Raising public awareness of biosafety.
- One hundred percent of GMOs and their products, which are permitted to be placed on the market, should be subject to risk assessment upon particular circumstances of Vietnam, and to labeling requirements in accordance with regulations and under appropriate monitoring.
- Establishing cooperation with international organizations in risk management of GMOs and their products.

2. Principles

- Harmonizing and coordinating the implementation of the Cartagena Protocol on biosafety with related domestic laws and regulations in order to undertake effective biosafety management throughout the country.
- Prevention of risks must be recognized as a guiding principle for the process of review and decision-making for GMOs and their products.
- Combining state management with public participation in biosafety management and monitoring.

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- Mobilizing domestic resources in combination with promoting international cooperation in implementation of the Action Plan.

III. Action programmes for the Action Plan

Programme 1: strengthening legal and regulatory framework on biosafety

Biosafety management must be seen as the whole process commencing from production of GMOs and their products, including research, field trial, commercialization, export, import, handling and use. The legislative and regulatory framework on biosafety therefore must be provided for every above activity.

In research and field trial of GMOs and their products: It is necessary to develop a system of technical standards, guidance and procedures in compliance with the national biosafety policy. The Vietnamese Government strongly support biosafety-related R&D activities and give priority to facilitating and assisting the research and establishment of monitoring standards, methods and procedures, applied technologies and specialized equipment for biosafety. The long-term and continuous monitoring of GMOs and GM products and environmental impact assessment (EIA) of them, as well as the implementation of data management measures should be enhanced.

Commercialization of GMOs and their products: The principle of commercialization and marketing is to encourage and promote development, production, trade and use of GMOs and their products in Vietnam for the benefit of protection of human health and environment. Therefore, incentives, restrictions or prohibition measures should be applied to commercialization, trade and use of GMOs and their products according to their respective levels of risks. Production, commercialization and utilization of low risk products should be encouraged, in order to minimize the adverse impacts on human health, environment and biodiversity.

Import and export of GMOs and their products: Import of GMOs must comply with regulations provided for in the Cartagena Protocol. Export of GMOs must meet Vietnamese Government's regulations on biosafety before transboundary movement of GMOs and their products via Vietnamese territory.

Import and export of GMOs and GM product are conducted by specific case. The risk prevention approach should be applied to the import of GMOs and their products. Import of products having an average level of risks should be limited, and those having a high level of risks must be strictly prohibited. GMOs and their products must be labeled when import and export. And they must be specially packaged when transport and trade.

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Handling and use of GMOs and their products: It is difficult to identify the potential risks caused by GMOs and their products in short time. Even when GMOs and their products were already undertaken risk assessment and permitted to be placed on market, they must still be strictly monitored and controlled to identify any adverse effect that has not been reckoned during risk assessment. Due to rapid development of biotechnology, handling of GMOs and GM products has dramatically increased and thus may cause adverse effects on human health and daily life. Therefore, it is necessary to develop an appropriate mechanism for public participation in environmental impact assessment (EIA) and access to information. The affected people will be advanced informed and public hearings conducted for their consent of GMO handling.

Raising the public awareness of biosafety is an important aspect of biosafety management. Customers have the rights to access full information on GMOs and their products, then they are well aware of potential risks of GMOs and their products and have the rights to whether choose or reject them. At the same time, a proper mechanism should be developed to enable public participation to biosafety management.

Action 1: Incorporating biosafety in the Law on Biodiversity

The Law on Biodiversity will be drafted in 2006. The Law will govern essential provisions on conservation and sustainable use of biodiversity resources. Below are some issues needed to be considered and incorporated in the Law:

- a) Biosafety management principles;
- b) Biosafety for modern biotech products;
- c) Prevention, precaution and resolution of risks posed by modern biotech products; and
- d) State management of biosafety.

Action 2: Formulating and promulgating the Government Degree on biosafety management of GMOs and the products thereof.

The Ministry of Natural Resources and Environment (MONRE) is now presiding over the preparation of the draft Decision of Prime Minister on the promulgation of biosafety management Regulation of GMOs and their products (annex III), in which provide provisions on biosafety management of scientific research, technology development; field trial; production, trade and use; import, export, storage and transport of GMOs and their products. Due to the urgent need of biosafety management, early promulgation of the above-mentioned Regulation is of extreme importance.

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Once the Regulation has been promulgated for a while, a Government Degree on safety management of GMOs and their products should be drafted and approved.

Action 3: Formulating regulations on biosafety management by sectors

Based on the characteristics and situations of each sector, regulations on biosafety management in each sector will contain specific and practical provisions. These regulations will be under the framework of the regulations on national biosafety. The regulations at sectoral level shall be applied to developing biotechnology research and devising effective risk prevention measures to protect human health, environment and biodiversity. Formulation of such regulations will be based on the following principles:

a) Management by sector: according to the direction for gene technology commercialization, gene technology shall be categorized into 3 sectoral groupings: agriculture-forestry, health care, and foodstuff (by sector). Respective biosafety-related regulations shall be issued in accordance with this principle. If demand is growing, wild animals and plans shall be added in the regulation.

b) Sector specific nature: based on different types of gene technology, it is necessary to create safety assessment systems and safety classification standards, and take safety control measures to evaluate gene technology types and safety levels.

c) Enforceability: based on successful experience of foreign countries and on the status quo of Vietnam, management procedures and monitoring measures shall be taken in a strict, scientific and appropriate manner for making them effective and enforceable.

d) United coordination: Since activities from research to commercialization of GMOs and their products are all posing potential risks to human health and environment, they therefore must be well coordinated. For this reason, cooperation and coordination among concerned Ministries and agencies are of crucial importance. The regulations must be in accordance with both international law and Vietnamese law, in a way that conform with current legal documents and enhance interdisciplinary coordination as well as avoid changes in current regulations and procedures governing the operation of the Ministries and agencies.

Regarding specific regulations, it is essential to clearly identify sectoral management scale of GMOs and their products.

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- Agriculture - Forestry: GMOs and their products can be used in biotech applicable fields such as are genetically modified animals and plants; marine microorganisms, animals and plants relating to agricultural productions; genetically modified animals & plants, botanical organs closely relating to forestry ecosystem.
- Pharmaceutical industry: GMOs and their products can be used in pharmaceutical industry such as in precaution, diagnosis and treatment. Moreover, GMOs are applied to medicinal products using genes, including both ex vivo and in vivo products.
- Food industry: GMOs and their products are used in production of food, additives, and food maintenance.

Sectoral regulations should define the requirements for safety control of GMOs and their products. The development and promulgation of legal regulations should focus on the following issues:

- Register procedures for research, field trial, production, trade, use, export and import of GMOs and their products;
- Conditions for research, field trial, production, trade, use, export and import GMOs and their products;
- Procedures for risk assessment of GMOs and their products;
- Guideline on biosafety management in laboratory, field trial, production and trade of GMOs and their products;
- Guideline on monitoring and impact assessment of GMOs and their products after commercialization.

Action 4: Establishing regulations governing environmental impact assessment of GMOs and their products

The objectives of environmental impact assessment (EIA) is to precisely evaluate the effects imposed by GMOs and their products on environmental quality and ecosystem evolution when undertaking research, commercialization, application of and releasing GMOs and GM products to agricultural ecosystem, grasslands, forestry, water environment and other natural elements. Based on these assessments, effective measures will be taken to prevent or minimize adverse effects. Below are detailed requirements for environmental impact assessment:

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- a) Identifying impacts of GMOs and their products on the environment; defining level and frequency of such impacts.
- b) Evaluating mode of impact.
- c) Analyzing environmental elements and identifying them for evaluation and protection objectives.
- d) Description of EIA results according to studies and analyses.
- e) Comparing and analyzing socio-economic and environmental benefits of various protection measures.
- f) Proposing impact prevention or mitigation measures.

EIA main contents:

Source analysis

Sources are GMOs - types and traits of GMOs. Source analysis help identify factors affected by GMOs.

- a) Species (animals, plants and microorganisms), number and natural situation of GMOs.
- b) Structure, expression and recreation capacity of GMOs.
- c) Reproduction capacity and gene transference to other organism.
- d) Various products of transferred genes and their natures.

Assessment of status quo or recipient organism

Assessment of status quo or recipient organism provides some information relating to each individual, population, biological groups and ecosystem, as well as information on soil, water and air, and factors that may be affected by GMOs. This information includes possibly affected objectives, expression, and life or evolution cycles of recipient organism.

Impact forecast

Impact forecast is an important part of environmental impact assessment. Impact forecast comprises descriptions of impact process and its outcomes. The process will analyze GMOs impacts posed to recipient organisms or protection objectives

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Description of environmental impacts should point out what genes have been transferred, when and where the impacts may occur and what consequences of the identified impacts should it occur.

Uncertainty analysis

Uncertainty analysis is a kind of danger assessment that considers and weighs the possibility of sudden and harmful risks. Environmental impacts of GMOs could be caused by some uncertain factors. Environmental impacts could increase or decrease in emergency. Therefore, uncertainty analysis is need for releasing GMOs to environment, especially GMOs possible to harm environment and ecosystem or those difficult to isolate or destroy in environment but their dispersion could be prevented by advanced technology.

Environmental protection measures

Environmental protection measures are a part of environmental impact assessment. They could be divided into two groups: prevention of gene dispersion and removal of remaining GMOs (for example: safe package of seeds, isolation to prevent external dispersion of genes, removal of remaining GMOs by burning, burying and other safe measures.

Action 5: Establishing legal regulations on import and export GMOs

Provisions on import and export of GMOs and their products have been included in the draft Regulation on Safety Management of GMOs and their products. However, they are just general provisions, providing overall guiding principles. Therefore, it is necessary to work out specific provisions facilitating safety management of export-import of GMOs and their products. These specific provisions should touch upon conditions for import, export, processes and procedures of import and export, advanced notification, safety monitoring and management in import-export process, investment activities, damage compensation and dispute settlement procedures.

Action 6: Establishing regulations on management of production and trade of GMOs and their products

It is necessary to promulgate regulations and guidelines on the implementation of safety management of production and trade to encourage the development of risk-free GMOs and their products and at the same time safely and carefully manage GMOs and their products at low, medium and high levels of risks based on the risk classification stipulated by the Government. In the next five years, the following regulations on safety

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management of GMOs and their products must be established as follows:

- a) Processes and procedures of registration for production and trade of GMOs and their products.
- b) List of GMOs which are permitted to production and trade.
- c) Labeling requirements for commodities containing GMOs and their products.

Programme 2: Promoting state management capacity in biosafety

Action 1: Establishment of the National Focal Point and Competent National Authorities in Biosafety

The Ministry of Natural Resource and Environment (MONRE) are entrusted by the Government to be the national focal point to the Cartagena Protocol on Biosafety. MONRE will be the contact point between the Contracting Party and the Secretariat to the Protocol. MONRE is also the national focal point for the Biosafety Clearing House (BCH), taking responsibility for receiving and exchanging related information on GMOs.

The competent national authorities in biosafety include:

- a) The Ministry of Agriculture and Rural Development (MONRE) is responsible for management of GMOs and their products that are used in agricultural and forestry sectors;
- b) The Ministry of Industry (MOI) is responsible for management of GMOs and their products that are used in the industrial sector;
- c) The Ministry of Fisheries (MOFI) is responsible for management of GMOs and their products that are used in the fishery sector;
- d) The Ministry of Health (MOH) is responsible for management of GMOs and their products that are used in health, foodstuff and cosmetics.

The competent national authorities are responsible for performing administrative functions required by the Protocol and must be authorized by the Vietnamese Government to act on its behalf in relation to these functions.

The competent national authorities will:

- a) Receive notification of proposed transboundary

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movement of a GMO that falls within the scope of the Advanced Informed Agreement procedure (Article 8 of the Protocol);

b) Acknowledge receipt of the notification (Article 9);

c) Request further information from the notified, if necessary (Articles 9 and 10);

d) Notify the decision of the Party of import to the notifier and the Biosafety Clearing-House (with reasons where required) (Article 10(3));

e) Respond to requests by the Party of export or notifier to review decisions (Article 12);

f) Consult with the notifier, where necessary, on treatment of confidential information (Article 21).

Action 2: Assessment of needs and capacity-building in safety management of the National Focal Point or competent national authorities in biosafety.

Biosafety is a new issue that requires not only biosafety managers to acquire professional skills and modern biotechnology knowledge but also an appropriate base for them to conduct research and field trial to get sufficient information before making decision on biosafety.

Biosafety management capacity of the national focal point or competent national authorities in biosafety should be strengthened in order to meet the given requirements. In the short term, a study should be carried out to make overall assessment of capacity-building needs for the national focal point or competent national authorities in biosafety, including those for human resources, infrastructure, and other conditions for biosafety management implementation, i.e. decision-making, monitoring and assessment. Based on the study, capacity building will be promoted through following activities:

a) Education and training of professional staff in charge of biosafety;

b) Study tours to learn safety management experiences in foreign countries;

c) Infrastructure building for monitoring and assessment of biosafety; and

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- d) Establishment of coordination mechanism amongst concerned Ministries and agencies in biosafety management.

Programme 3: capacity building in biosafety research

Biosafety is a new sector with many issues needed to be conducted research, especially basic research. According to a preliminary assessment, biosafety research capacity in Vietnam fails to meet the management requirements.

- a) Inadequate and poorly established infrastructure; inadequate and dated specialized equipments;
- b) Lack of scientific and technical manpower, particularly professionally trained experts.

Action 1: Evaluating R&D capacity in biotechnology and biosafety and formulating a strengthening plan.

R&D capacity consists of technical and material base and facilities, quality and qualification of manpower. Capacity building in scientific and technical research of biosafety management in the immediate period should:

- a) Conduct a survey and overall evaluation of technical and material base and facilities of institutions in the field of biotechnology and biosafety R&D;
- b) Conduct survey, assessment of current status of manpower in the field of biotechnology and biosafety R&D;
- c) Prepare plans and planning to enhance capacities and institutional structure of institutions in charge of biotechnology and biosafety research and application in order to meet the given management requirements.

Action 2: Establishing risk classification of GMOs and their products.

One of the most important activities in biosafety management is to identify the safety levels of using GMOs and their products posed to human health, environment and biodiversity. In Vietnam, no study or document has mentioned about risk or biosafety classification yet. Therefore, it is necessary to conduct research to define appropriate criteria for biosafety classification in accordance with Vietnamese conditions and international integration.

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Contents of establishing criteria and scientific base for biosafety classification are as follows:

- a) Studying experiences of developed countries;
- b) Identifying and classifying biological agents into respective groups based on their potential risks to human health and environment;
- c) Studying and identifying possibilities of risks posed to human health, environment and biodiversity due to use of GMOs;
- d) Studying conditions for equipment of laboratories, field trial & production establishments, isolation conditions, measures in the event of wrongly releasing GMOs and their products;
- e) Establishing specific classification criteria for risks that may be caused by GMOs and their products. The criteria must be in accordance with Vietnamese conditions and international integration.

Action 3: Developing guidelines on risk assessment and management

At present, none of the Ministries, agencies and research institutes in Vietnam has any guideline on risk assessment and management pertaining to using GMOs. Risk assessment is an advanced technical tool, which requires advanced technical and scientific infrastructure and facilities, skilled and professional staffs. Risk assessment process must be carried out in certain conditions and in compliance with identified rules and procedures. Therefore, it is necessary to develop technical guidelines on risk assessment and management, which are tailored to each sector (agriculture, fishery, industry, medicine etc.). Following are some main contents of risk assessment and management:

- a) Study of existing risk assessment techniques;
- b) Collection and study of relevant documents of concerned ministries and agencies;
- c) Development of guidelines on specific techniques and procedures for risk assessment within the scope of ministries and agencies.

Action 4: Strengthening capacity of the 3 key national laboratories to carry out risk assessment

Risk assessment of using GMOs and their products requires investment in advanced facilities such as equipment of gene

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isolation and gene order identification; studying in gene expression; gene design and modification. It also requires the association and training of scientists and experts with professional knowledge on bio-molecules, molecular genetics, gene and biochemical technology, tissue and cell technology etc. Vietnam has established six key national laboratories in biotechnology. These laboratories should be taken full advantage by providing more equipment and enhancing human resources in order to develop them into reliable scientific centers in risk assessment.

The main contents of this Action are:

- a) Conducting survey and evaluation of technical capacity of these key laboratories in risk assessment posed by GMOs and GM products;
- b) Preparing a capacity building plan for 3 selected laboratories to meet management requirements;
- c) Providing more equipment and facilities for the 3 selected laboratories;
- d) Strengthening professional expertise for the 3 selected laboratories.

Action 5: Survey of research and use of GMOs and their products

Vietnam has conducted research on GMOs such as GM crops with pest and drought resistance; GM animals containing modified growth hormone. Various genetically transferred or modified methods have been researched and applied to transferring or modifying valuable genes in a wide range of important crops. However, there is a lack of official statistics of these research studies, of the scope of research and use of GMOs and their products. Therefore, overall survey and evaluation of the current status of research, use and biosafety management of GMOs and their products in agriculture, forestry, industry, fishery and other sectors should be conducted.

Action 6: Developing and strengthening scientific manpower in biosafety research

According to a general estimation of the Ministry of Science and Technology (MOST), Vietnam has had about 2000 scientific researchers who are directly conducting biotechnology R&D in more than 60 institutes and research centers. And more than 25% of them are postgraduates. However, Vietnam is lacking key staff and high-level experts in biotechnology, particularly biosafety. To this end, it is necessary to develop and strengthen human resources in biosafety in terms of both

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quantity and quality, who are capable of dealing with relevant domestic and international issues.

Contents of this Action are as follows:

- a) Conducting survey and assessment of the current status of scientific and technical manpower working in biotechnology and biosafety;
- b) Evaluating training needs through survey, investigation, and review conferences;
- c) Preparing manpower plans and planning;
- d) Proposing short and long-term training solutions;
- e) Developing a training strategy to strengthen specialized scientific and technical manpower.

Programme 4: Raising public awareness, information sharing and public participation in biosafety management

Biosafety management largely depends on relevant information and data. Information sharing and public participation is a must for national biosafety management. Decision and policy making of biosafety management must be based on accurate and specific information. As a result, it is necessary to establish a national biosafety information system to collect, classify, and exchange information amongst concerned Ministries, agencies and localities, as well as quickly receive information provided by the international biosafety. Through the national biosafety information system, the Government and the public can be frequently reported about domestic and international biosafety situations and development trends.

Action 1: Establishing a Biosafety Clearing House (BCH)

One of the requirements posed to each Party to the Cartagena Protocol is to establish a National Biosafety Clearing House in order to ensure information exchange.

The main contents of establishing biosafety information system consist of:

- a) Developing methods for collecting, recording, storing and exchanging biosafety data;
- b) Preparing guide documents for management of biosafety data and information linkage;
- c) Establishing a biosafety databank;

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- d) Establishing information sharing mechanism between the National Biosafety Clearing House and sectoral BCHs;
- e) Establishing international information sharing mechanism; and
- f) Establishing a biosafety information system to provide public access to biosafety information.

Action 2: Developing and implementing a media program on biosafety

Although people are relatively familiar with biotechnology, their awareness of biosafety remains low and incorrect. On the one hand, we are all pleased with rapid development of modern biotechnology, creation of genetic modified agricultural products on a large scale, production of a great amount of genetic modified drugs, and extensive introduction of various genetic modified foods to the market. On the other, we have to face with the potential risks caused by GMOs and their products. Raising public awareness and education on biosafety therefore become an increasingly important and demanding issue. The objective of the program is to provide community with adequate and accurate awareness on scientific situation and efficiency of modern biotechnology, then raising their knowledge on research, production and, particularly, use of GMO products. Moreover, raising public awareness will help promote public participation in biosafety management. By and large, it is necessary to develop a comprehensive media program on biosafety in the immediate.

The main contents of the action are:

- a) Preparing, editing and disseminating documentary films and TV serials on biotechnological issues (namely biotechnology's achievements, prospects, social impacts and challenges);
- b) Publishing general knowledge textbooks about modern biotechnology and biotechnology; and
- c) Organizing training courses, workshops and seminars on biosafety for all public target groups.

Action 3: Promoting public participation in biosafety-related decision-making

Biosafety management of GMOs and their products are best handled by public participation due to the close relationship between biosafety and public health. For that reason, promotion of public participation in biosafety-related

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decision-making is necessary and should focus on the following main actions:

- a) Establishing a website on biosafety for public access and information exchange;
- c) Establishing public groups participating in biosafety management;
- d) Conducting public hearings for decision-making process of use and management of GMOs and their products;
- e) Promoting public participation in detection, assessment and management of risks posed by GMOs and their products; and
- f) Introducing biosafety into school education. Vietnam has more than 24 million of pupils at all levels, accounting for around 30% of total population. It is the target group on which provision of information and awareness raising of biosafety must be focused.

PRogramme 5: enhancing international cooperation in biosafety

Coupled with the expansion of transboundary movement and release of GMO and their products, biosafety has become an environment issue of highly international concern. A number of European countries, which has built up their long history of biosafety management, have rich experience in this issue. Vietnam should actively enhance international cooperation in order to share information and learn from their experience and successful lessons in biosafety management, monitoring, and risk assessment and management.

Action 1: Promoting regional and international cooperation in biosafety

Vietnam will continue to actively take part in the negotiations of "the Cartagena Protocol on Biosafety" and fulfill its obligation as a Party to the Protocol, and at the same time, promote regional and international cooperation in biosafety, including sending its experts to regional and international working groups on biosafety, cooperation in modern technological and biotechnological transfer. Vietnam will promote cooperation with the EU and OECD countries in learning risk assessment techniques and genetically modified food market management.

Action 2: Attracting foreign investment in biosafety

In face of limited resources, mobilization of bilateral and multilateral financial assistances is an essential task. It is

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necessary to work out a project calling for fundings of publishing some leaflets that brief about Vietnam biosafety management situation and introduce a list of priority projects calling for financial assistance. The International Assistance Group on Environment is considered a strong supporting vehicle for this action.

iv. Implementation of the Action Plan

1. Responsibilities of Ministries, agencies and localities

The Ministry of Natural Resources and Environment (MONRE) is responsible for presiding over and coordinating with the concerned ministries and agencies at central level, People's Committees of provinces and cities under central authority, production and business establishments under central and provincial authorities to implement the Action Plan. MONRE is responsible for annual reporting to the Government on the implementation results.

The Ministry of Planning and Investment (MPI), Ministry of Finance (MOF), and Provincial People's Committees are responsible for budget balance and allocation from the State Budget, local budget and other financial resources in order to effectively implement the Action Plan.

The other concerned Ministries, agencies and local authorities within their respective scope of duties and functions shall implement the Action Plan according to their given assignments.

2. Plan for implementation, monitoring and evaluation

a) Specific actions need to be implemented under project type with defined objectives, content, location, scale, timetable, subjects and results. The project must be under appraisal before being financed and be assessed under each implementation phase and final check;

b) Establishing a Steering Committee on implementation of the National Action Plan, comprising representatives from the Ministry of Natural Resources and Environment (MONRE), Ministry of Planning and Investment (MPI), Ministry of Science and Technology (MOST), Ministry of Agriculture and Rural Development (MARD), Ministry of Fisheries (MOFI), Ministry of Health (MOH), Ministry of Industry (MOI), and Ministry of Trade (MOT);

c) Establishing a Consultant Council, including a number of leading experts on biotechnology and biosafety;

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d) Establishing a Secretariat located in MONRE to assist the Steering Committee. The Secretariat shall take responsibility for storing documents, providing information, preparing reports, monitoring activities of relevant ministries and agencies, and acting as a contact point with the Secretariat to the Cartagena Protocol.

3. Finance

Financial sources to implement the Action Plan is allocated from the State Budget, funded by international cooperation projects and programs, and mobilized from domestic and international enterprises, organizations and individuals, and from other sources.

**Annex I: Phases for implementation of priority projects
2005-2010**

No.	Name of Project	Implementing Agencies	Implementation Phases	
			2005-2007	2008-2010
1.	Integration of biosafety in the Law of Biodiversity	MONRE	x	
2.	Formulation and promulgation of the Degree of the Government on Biosafety Management of GMOs and their products	MONRE	x	
3.	Establishing Regulation on biosafety management in isolated using of GMOs	MOST	x	
4.	Preparing guidelines on implementation of biosafety management in agriculture and forestry	MARD	x	
5.	Preparing guidelines on implementation of biosafety management in fishery sector	Ministry of Fisheries (MOFI)	x	
6.	Preparing guidance for biosafety management on industries	MOI	x	
7.	Establishing Regulation on biosafety management on genetically modified foods	Ministry of Health (MOH)	x	
8.	Establishing regulations on environmental impact assessment of GMOs and their products	MONRE	x	
9.	Socio-economical impact assessment of commercialization of GMOs and their products	MOT		x
10.	Establishing labeling regulations on GMO-contained goods and GMO products.	MOST	x	
11.	Establishing legal regulation on import and export of GMOs	MARD	x	
12.	Preparing guidelines on implementation of the Advance Information Agreement (AIA)	MONRE	x	

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13.	Preparing plans of and promoting the establishment of the national focal point, the national competent authorities on biosafety, the national biosafety commission and sectoral biosafety commissions	MONRE	x	x
14.	Assessment of demand for capacity-building in biosafety management of focal points and the national competent authorities on biosafety.	MONRE	x	
15.	Enhancing capacity-building in biosafety management of focal points and the national competent authorities on biosafety	MONRE		x
16.	Assessment of R&D capacity in biotechnology and biosafety; and preparing a strengthening plan	MOST	x	
17.	Developing criteria for risk classification of GMOs and their products	MOST		x
18.	Preparing guidelines on risk assessment and management	MONRE	x	
19.	Strengthening capacity of 3 key national laboratories in risk assessment	MOSTE	x	x
20.	Survey of the status quo of research and use of GMOs and their products	The Academic Institute for Science and Technology	x	x
21.	Establishing observation and monitoring regulations on biosafety of GMOs and their products after release and commercialization	MONRE		x
22.	Observation and monitoring of biosafety of GMOs and their products after release and commercialization	MONRE and line ministries concerned		x
23.	Development and strengthening of biosafety manpower	MOST	x	x
24.	Establishment of a Biosafety Clearing House (BCH)	MONRE	x	
25.	Developing and implementing a media program on biosafety	Ministry of Culture and Information (MOCI)		x

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26.	Promotion of public participation in decision-making process of biosafety	Vietnam Association on Protection of Nature and Environment		x
27.	Enhancing regional and international cooperation in biosafety	MONRE	x	x
28.	Attracting foreign investment in biosafety activities	MPI	x	x
29.	Impact assessment of biosafety policies during the process of WTO accession	MOT	x	

**Annex II: Requirements for the Parties to the Protocol on
Biosafety
(Intergovernmental Committee for the Cartagena Protocol: Recommendation 3/5,
Annex III, Implementation tool kit)**

This implementation tool kit provides a compilation, as a checklist, of obligations found in the Cartagena Protocol on Biosafety. These obligations are organized in the following categories:

- Administrative tasks (initial and future)
- Legal requirements and/or undertakings
- Procedural requirements (AIA and Article 11)

I. ADMINISTRATIVE TASKS

	Tasks	Article
	Initial actions	
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)
3.	Provide to the Biosafety Clearing-House: – any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMO-FFPs; and – any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)–(b), 11(5), 14(2)
4.	Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13(1)(a)
5.	Specify to the Biosafety Clearing-House imports of LMOs exempted from the AIA procedures.	13(1)(b)
6.	Notify the Biosafety Clearing-House if domestic regulations shall apply with respect to specific imports.	14(4)
7.	Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)
8.	Notify the Secretariat if there is a lack of access to the Biosafety Clearing-House and hard copies of notifications to the Clearing House should be provided.	(e.g., 11(1))
	Follow-up actions	

9.	Provide to the Biosafety Clearing-House: – Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15; – Final decisions concerning the import or release of LMOs; and – Article 33 reports.	20(3)(c)-(e)
10.	Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25(3) 287
11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33
12.	Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.	

II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

	Tasks	Article
1.	Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)
2.	Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.	8(2) 11(2)
3.	Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)
5.	Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)
6.	Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)
7.	Take appropriate measures to prevent the unintentional	16(3)

	transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	
8.	Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)
9.	Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)
10.	Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)
11.	Take measures to require that documentation accompanying LMO-FFPs <ul style="list-style-type: none"> – clearly identifies that they “may contain” LMOs and are not intended for intentional introduction into the environment; and – provides a contact point for further information. 	18(2)(a)
12.	Take measures to require that documentation accompanying LMOs destined for contained use: <ul style="list-style-type: none"> – Clearly identifies them as LMOs; – Specifies any requirements for their safe handling, storage, transport and use; – Provides a contact point for further information; and – Provides the name and address of individuals or institutions to which they are consigned. 	18(2)(b)
13.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: <ul style="list-style-type: none"> – Clearly identifies them as LMOs – Specifies the identify and relevant traits and/or characteristics; – Provides any requirements for the safe handling, storage, transport and use; – Provides a contact point for further information; – Provides, as appropriate, the name and address of the 	18(2)(c)

	importer and exporter; and – Contains a declaration that the movement is in conformity with the requirements of the Protocol.	
14.	Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21(1),(6)
15.	Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)
19.	Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)
21.	Endeavor to inform the public about the means of public access to the Biosafety Clearing-House.	23(3)
22.	Adopt appropriate measures aimed at preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)
23.	Dispose, at its expense, of LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)

III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

	Tasks	Article
1.	Provide written acknowledgement of receipt of notification to notifier within 90 days, including: – Date of receipt of notification; 9(2)(a) – Whether notification meets requirements of annex I β the protocol; 9(2)(b)	10(2)(a), 9(2)(c) 10(2)(b)

	<ul style="list-style-type: none"> – That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; OR – Whether the import may proceed after 90 days without further written consent. 	
2.	<p>Communicate in writing to the notifier, within 270 days of receipt of notification:</p> <ul style="list-style-type: none"> – Approval of the import, with or without conditions; – Prohibition of the import; – A request for additional relevant information in accordance with domestic regulatory framework or Annex I of the Protocol; or – Extension of the 270 day period by a defined period of time; <p>- Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.</p>	<p>10(3)(a)–(d)</p> <p>10(4)</p>
	3. Provide in writing to the Biosafety Clearing-House the decision communicated to the notifier.	10(3)
	4. Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2),(3)

IV. PROCEDURAL REQUIREMENTS: LIVING MODIFIED ORGANISMS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

	Tasks	Article _
1.	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II of the Protocol.	11(1)
2.	Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing-House.	11(1)

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3.	Provide additional information contained in paragraph (b) of Annex II of the Protocol about the decision to any Party that requests it.	11(3)
4.	In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMO-FFPs: – either as approved under the domestic regulatory framework consistent with the Protocol; OR – in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III of the protocol within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11(4),(6)

Annex III. Biosafety Management regulation for GMOs and their products
(promulgated pursuant to the Decree No: ... / 2005 / QĐ - TTg
of .. 2005
by the Prime Minister)

General provisions

Article 1. Scope.

This regulation shall stipulate the biosafety management of all genetically modified organisms and their products and shall apply to all relevant activities, including research and development, contained use, field trial, use, handling and production, release and management, commercialization, transboundary movement, import, export, storage and transport.

Article 2. Objects

This regulation applies to all internal and external organizations and individuals (hereafter referred to as organizations and individuals) conducting the activities related to GMOs and their products in Vietnam.

Article 3. Interpretation of terms

In this regulation, the following terms are construed as follows:

1. **Biosafety** means safe management measures in scientific research, technology development; field trial; production, commercialization and use; import, export, storage and transport of genetically modified organisms (GMOs) and the products thereof.
2. **Gene Technology** refers to gene transfer from one organism to another one compelling DNA of the latter receives the new gene.
3. **DNA** (deoxyribonucleic acid) means biochemical structure of the gene that plays a role of organism's genetic material.
4. **Genetically modified organism (GMO or LMO)** refers to any animal, plant , and micro-organism having modified gene structure from gene technology.
5. **GMO's product** means the product originated from GMO.
6. **Release** of GMOs' means the deliberate introduction of GMOs into the environment.
7. **Risk assessment** is to identify the potential adverse effects and damage level, if any, in the activities concerning the use and release of GMOs and their products on human health, the environment and biodiversity .
8. **Risk management** means the implementation of safe measures to reduce, handle and overcome hazards in the

activities concerning GMOs and their products on human health, the environment and biodiversity.

9. **Field trial** refers to controlling activity on biosafety level of GMOs and their products in the concrete conditions of Vietnam before any production, commercialization and use.

10. **Competent Ministries** refer to the ministries including Ministry of Agriculture and Rural Development, Ministry of Industry, Ministry of Fishery and Ministry of Health to be assigned for the management concerning the field trial, production, commercialization and use; import, export, storage and transport of GMOs and their products.

Chapter II

Scientific Research, Technological Development and Field trial

Article 4. Scientific research and technological development

1. Scientific research and technological development activities on GMOs and their products should comply with existing stipulations on science and technology and other concerning legal rules.

2. Organizations and individuals, only be permitted to implement scientific research and technological development activities on GMOs and their products, when they have enough facilities, equipment and technical staff relevant to scientific research and technological development for each GMO and its products.

3. Organizations and individuals, when implementing scientific research and technological development activities on GMOs and their products should register to the Ministry of Science and Technology and the respective competent ministry.

4. Organizations and individuals carrying out scientific research and technology development on GMOs and their products will be responsible for maintenance, safe storage of GMOs and their products and avoidance of their escape and other related materials into the environment.

Article 5. Field trial

Organizations and individuals carrying out field trial GMOs and their products, should comply with the following stipulations:

1. Registration conditions:

- a. To have enough facilities, equipment and technical staff relevant to the field trial of each GMO and its product to control and handle any risk according

- to stipulations from the respective competent ministry;
- b. The GMOs and their products should have undergone scientific research and already evaluated by the competent authority;
 - c. To have measures for monitoring and management of any risk in the field trial process;
 - d. The field trial area should be isolated according to stipulations from the respective competent ministry.
2. Registration file:
 - a. Registration form;
 - b. Approval by the People's Committee at provincial level where field trial will be carried out;
 - c. Document that shows to have enough conditions according to the conditions 1 mentioned above;
 - d. Other concerning information in necessary case if the agency issuing registration form requires.
 3. Procedural order
 - a. Organizations and individuals would send field trial registration file to the respective competent ministry;
 - b. In 60 days dating from the legal registration file has been received, the respective competent ministry is responsible for appraisal and permission of carrying out field trial for any case having enough conditions. In insufficient case, the respective competent ministry will notify the organizations/individuals on the reason by writing material.
 4. The respective competent ministry is responsible for notification to the Ministry of Natural Resources and Environment before delivering the permission for field trial.

Chapter III

Production , Commercialization and use

Article 6. Conditions of production and commercialization

1. Organizations, individual will only be permitted to make the production and commercialization of GMOs and their products under biosafety certificate belonging to the list permitted GMOs and products issued by the respective leading ministry.

2. Organization, individual making the production and commercialization of GMOs and their products should have the registered certificate on respective field.

Article 7. Goods labeling

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Organizations/ individuals having products and goods resulting from GMOs and their products that circulate on the market, in addition to follow existing legal stipulations on labeling, should label in Vietnamese "Having applied gene technology" on the envelop.

Article 8. Monitoring, supervising and reporting

Organizations/individuals producing, commercializing and using GMOs and their products should monitor, supervise in permanence the biosafety level on human health, the environment and biodiversity and report to the respective competent ministry and the Ministry of Natural Resources and Environment if there is any risk.

Chapter IV Import , Export , Storage and Transport

Article 9. Conditions of GMOs import

1. Organizations, individuals importing GMOs for research should meet the following requirements;

- a) Ensure that the GMOs are permitted to use as the same purpose in the exporting country;
- b) Having risk management measures.

2. Organizations, individuals importing GMOs aiming at field trial, producing and commercializing should meet the following requirements:

- a) Ensure that the GMOs are permitted to use as the same purpose in the exporting country;
- b) Ensure that the GMOs are assessed for risk under concrete conditions in such an exporting country in the case of import for production, commercialization and use
- c) Ensure that the GMO has been assessed for risk under concrete conditions of Vietnam,
- d) Ensure that the exporting country has established a safe management mechanism for this/these GMO(s);

Article 10. Conditions for import of GMO's product

1. Organizations/individuals importing GMO's product for research should meet the requirement in the provision Article 10 of this regulation.

2. Organizations/individuals importing GMO's product for production and commercialization should comply with the following requirements:

- a) The GMO's product is permitted to use as the same purpose in the exporting country;
- b) The GMO's product has been assessed for risk under concrete conditions of such an exporting country;
- c) The exporting country has established a safe management mechanism for that GMO's product;

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d) If there is mutual approval by writing material between the exporting country and Vietnam on the GMO's product, the conditions of import will be considered and based on that material.

Article 11. Import procedures

The import of GMOs and their products should comply with existing stipulations of the state on import and should meet the following procedural order:

1. Importing Organizations/individual will send writing demand accompanying needed information as requires in Annex A of this Regulation to the respective competent ministry for consideration;
2. The respective competent ministry will examine the document and make its decision by writing on the safe issue in the import of GMOs and their products and notify this to the Ministry of Natural Resource and Environment to follow together.

Article 12. Export

Any export of GMOs and their products to abroad should comply with the stipulations of Vietnam the importing country and international treaties that the Republic Socialist of Vietnam has signed or engaged.

Article 13. Storage and Transport

During storage and transport, the GMOs and their products should be safely packaged to avoid any drop or loss by hole on the way; they should be recorded and labeled with signs relevant to international standards.

1. In the case of in-country transport, prior to transport GMOs and their products, the proprietor of goods should notify to the respective competent ministry by writing material clear information on the labeled package, such as production place, storage, method of conservation, transport means, departure, arrival, and specific transport duration.
2. In transit of GMOs and their products through Viet Nam that need loading and unloading, the proprietor of goods provider the respective competent ministry with needed information by writing according to the form in Annex A of this Regulation for consideration. The General Custom Department will only make concerning procedures after the biosafety is recognized by the respective competent ministry.
3. In the case of transit of GMOs and their procedure thought Vietnam without loading and unloading, the provision 3 will not be applied.

Article 14. Risk assessment

1. Organization/individual, prior to introduce GMOs and their products into environment or for productions and commercialization, should assess and identify their potential risk on human health, the environment and biodiversity according to stipulations of the respective competent ministry.
2. Risk assessment should be carried out in a scientific manner with technical measures that have been confirmed and based on stipulated information as in Annex B of this regulation and other scientific evidences.
3. The process of risk assessment should be carried out under supervision of a specialized scientific institution which is recognized by the respective competent ministry.
4. The result of risk assessment will be expressed in the concerning formulated by related organizations/individuals under the form in Annex B of this Regulation

Article 15. Risk management

1. The activities of scientific research, technological development, field trial, production, commercialization and use, import, export, storage, transport, of GMOs should comply strictly with risk preventing, handling and overcoming its measures.
2. Organization /individuals researching science, developing technology, field trial of GMOs and their products should assist the part ness for the application of risk preventing and overcoming measures in the process of field trial and application of GMOs and their procedure created by them ,
3. Organization /individuals importing and using and releasing GMOs and their products are responsible for the application of appropriate management measures to prevent, reveal timely happened risks to handle and overcome its consequences and notify timely to concerning institution on the risk which have occurred during their activity.

Article 16. Biosafety certificate

1. GMOs and their products already undergo field trial and risk assessment, if having enough biosafety conditions according to the provisions of this Article, may be certificated for biosafety by the respective leading ministry under the list of permitted GMOs and their products for production, commercialization and use. Any respective competent ministry delivering the biosafety certificate will have its right to withdraw this certificate concerning GMOs and their products.
2. The respective competent ministry is responsible for notification to the Ministry of Natural Resources and Environment when biosafety certificate has been delivered.

Chapter VI
Responsibility of state management on biosafety

Article 17. Content of state management on biosafety for GMOs and their products

1. Formulation and promulgation of strategies, plans, policies and writing materials of legal rules on biosafety of GMOs and their products;
2. Formulation and development of information system and database on biosafety;
3. Appraisal for any registration ,field trial, release, production, commercialization and export, import, storage, transport of GMOs and their products; licensing issuing and with drawing the certificate relating to biosafety;
4. Training and raising awareness on biosafety;
5. International cooperation, implementing international treaties concerning GMOs and their products;
6. Inspection, monitoring of the realization in compliance with laws concerning GMOs and their products.

Article 18. Responsibilities of the Ministry of Natural Resources and Environment

1. This is a focal point to assist the Government for unification of state management on biosafety of GMOs and their products;
2. Formulation and submission for promulgation, and promulgation of strategies, plans, policies and writing materials of legal rules on biosafety of GMOs and their products according to its competence;
3. Guide, coordinate and organize the activities of biosafety management of GMOs and their products;
4. Coordinate training extension and raise awareness on biosafety of GMOs and their products;
5. Receive and handle data and information on GMOs and their products provided by the respective competent ministries and concerning organizations/individuals; establish and develop a data base and information system on biosafety for GMOs and their products be a focal point for international information exchange;
4. Inspection, monitoring and handling of violations relating to GMOs and their products.

Article 19. Responsibilities of the Ministry of Science and Technology

1. Organize the implementation and guide the activities of state management on biosafety of GMOs and their products in the field of its management;

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2. Formulate and promulgate according to its competence writing materials of legal rules, standards of its sector on biosafety management of GMOs and their products;
3. Guide in detail registration procedures, concrete conditions for organization/individuals for scientific research and technological development of GMOs and their products;
4. Identify, screen and approve the themes of scientific research and technological development regarding GMOs and their products.
5. Build and development of GMOs and their products;
6. Provide information concerning GMOs and their products to the Ministry of Natural Resources and Environment.

Article 20. Responsibilities of respective competent ministries

1. Assign responsibilities
 - a) The Ministry of Agriculture and Rural Development is responsible for the management of GMOs and their products aiming at agro-forestry application;
 - b) The Ministry of Industry is responsible for the management of GMOs and their products aiming at industrial application;
 - c) The Ministry of Fishery is responsible for the management of GMOs and their product aiming at aquaculture application;
 - d) The Ministry of Health is responsible for the management of GMOs and their products aiming at the application in health service, and for food and cosmetics.
2. General responsibilities of respective competent ministries
 - a) Ensure needed conditions for the activity of specialized institutions/organizations, build and develop capacity of super agencies for assessment on biosafety of GMOs and their products management by the respective ministry;
 - b) Organize for implementation and guide the activities of state management on biosafety of GMOs and their products management by the respective ministry;
 - c) Formulate and promulgate according to their competence writing materials of legal rules and sector standards on biosafety management of GMOs and their products managed by the respective ministry;
 - d) Stipulate order, procedure and condition for risk assessment;
 - e) Designate specialized scientific institution for supervision of risk management;
 - f) Appraise the registration for field trial, release, production, commercialization and use; export, import, storage and transport of GMOs and their products managed by the respective ministry;
 - g) Appraise, issue, and withdraw biosafety certificate for GMOs and their products, and list GMOs and their products that are permitted to production and commercialization under ministerial management;

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- h) Inspect, control the compliance with law on biosafety of GMOs and their products under their management.
- i) Guide the handling and overcoming of any hazard to the environment and human health caused by the activities relating to GMOs and their products under their management.
- j) Provide information concerning GMOs and their products to Ministry of Natural Resources and Environment.

Article 21:Responsibilities of concerning ministries/sectors;

The Ministry of Trade, Ministry of Finance and others concerned, according to their function and the Ministry of trade, Ministry of Finance and other concerned, according to their function and task, should coordinate with the Ministry of Natural Resources and respective competent ministries to implement the state management contents on biosafety.

Article 22. Responsibilities of People's Committee at provincial and city level directly under the Central Authority

- 1.Organize the realization of state management activities on biosafety of GMOs and their products at the locality;
- 2.Propagandize,disseminate and educate on biosafety of GMOs and their products;
- 3.Coordinate with concerning ministries/sectors and organizations/individuals in the activities relating to GMOs and their products in the locality;
- 4.Planning production areas for GMOs and their products;
- 5.Inspect,control and handle the violations of activities regarding GMOs and their products according to its competence in the locality.

Chapter VII Handling of violations

Article 23. Handle violations

1. Organizations/individuals that commit acts of violating the Decree provisions will, depending on the nature and seriousness of their violations, be sanctioned or examined for penal liability before law; if causing serious damage, they will have to pay compensation according to provisions stipulated by law.
3. Those who abuse their positions and powers to commit acts of violating the stipulations of this Decree and commit other acts contrary to the stipulations of law, depending on the nature and seriousness of their violations, be disciplined or examined for penal liability according to law provisions.

Article 24. For export activity

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1. In the import contract for GMOs and their products to Vietnam, the importer should require the exporter to undertake compensation when causing damage by the imported goods, undertake technical and financial contribution to handle and overcome the bad consequences on human health and the environment in happened place.

2. In the case of disagreement between the importer and the exporter on the measures of safety that are stipulated and on undertaking compensation when the breakdown takes place, but the importer still deliberately imports the GMOs and their products, if any hazard or risk happens by the use of imported product and causes damage to human health, the environment, economy and society, the importer should be responsible for compensation and acceptance of any cost for handling and overcoming the consequences. If causing severely damage, organizations/individuals will be examined for penal liability according to law provisions.

Chapter VIII Implementation provision

Article 25. Implementation provision

In the process of Regulation implementing, any involvement can be reflected to the Ministry of Natural Resources and Environment for examination, systemization and submission to the Prime Minister.

The Prime Minister

Annex A: Information required according to the Provisions in Articles 11,13

(Accompanying biosafety management regulation for GMOs and their products promulgated pursuant to the Decree No /2005/QD-TTg of /.../ 2005 by the Prime Minister)

1. Name, address and contact details of organization/individual from the exporter.
2. Name, address and contact details of organization/individual from the importer or the applicant.
3. Intended date of arrival at the importing port, or application place.
4. Quantity or volume of GMOs and their products to be imported, transferred and in transit.
5. Name and characteristics of GMOs and their products. Classification of biosafety level.
6. Taxonomic status, common name (local name, scientific name),and characteristics of donor organism(s) related to biosafety.
7. Centre(s) of origin/genetic diversity of GMOs and their products. Description of the habitats where the organism may persist, develop or proliferate.
8. Intended use of the GMO(s) and its/their products.
9. Risk assessment plan (for scientific research purpose)or risk assessment report (for other purposes).
10. Suggested methods for safe management (management, storage, packaging, labeling, transport, use protocol and safe management, and related documentation).
11. Legal status of the GMOs and their products in question within the exporting country: Have they been approved for general use? Are they prohibited in the state of import? If they are prohibited, what are the reasons for such a prohibition? Are they banned in any state of import? If any, the reasons for such a ban.

Annex B: Report on risk assessment

(Accompanying the Biosafety Management Regulation for GMOs and their products promulgated pursuant to the Decree No /2005/QD-TTg of / / 2005 of the Prime Minister).

I. Objective

1. The objective of risk assessment is to identify the potential adverse effects and evaluate the damage level, if any, in the activities related to GMOs and their products on the environment and conservation and sustainable use of biodiversity, as well as on human health.

2. The results of risk assessment are used to provide information required by the competent authorities to make decision on research, field trial, release, production, commercialization and use import, export and transport of GMOs and their products.

II. General principles

1. Risk assessment is mainly based on precautionary approach; It identifies the potential risk or damage level that may be acceptable.

2. Risk assessment should be carried out in a scientific and transparent manner.

3. Risk assessment should be carried out on a case-by-case basis, depending on the relation of GMOs and their products with the purpose and manner of use and the receiving environment.

III. Content

The report on risk assessment should include the main following contents:

1. Identification of characteristics of the GMOs and their products that may have adverse effects on the environment and conservation and sustainable use of biodiversity, and on human health.

2. Identification of the likelihood of potential risks, the level and kind of exposure of the receiving environment to the GMOs and their products.

3. Evaluation of the consequences, damage level of each risk, if any.

4. Recommendation as to whether or not the risks are acceptable or manageable. If necessary, identification of measures to manage these risks and minimize the likelihood of adverse consequences.

5. Depending on the case, risk assessment should take into account:

-Information relating to intended use of the GMOs and their products, including new or changed use compared to the unmodified recipient organism;

-Receiving environment: information on the location, geographical, climatic, and ecological characteristics of the receiving environment;

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- Receiving environment : information on the effect of GMOs and their products on the environment and conservation and sustainable use of biodiversity and on human health;
- Socio-economic issues.

Date:

*Representative of risk assessment organization
(Name, signature and stamp)*