

## Overview on Legal Framework on Biosafety in Vietnam

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## An introduction to the Cartagena Protocol on Biosafety

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## Cartagena Protocol on Biosafety (CPB)

- First international legal instrument
- Regulates import/export of *LMOs*
- Entry into force on Sept. 11, 2003
- Vietnam become the party since 19 Jan 2004

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## Obligations under the CPB

### Advance Informed Agreement (AIA) procedure:

- Parties importing LMOs for intentional release must receive notification *before the first* shipment of LMO enters the country
- Sufficient information must be provided to help make decisions

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## Obligations under the CPB

### Advance Informed Agreement (AIA) procedure (cont'd)

- Decision based on risk assessment (RA)
- RA result: Party of import can either allow or refuse the importation
- Decision within 270 days

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## Obligations under the CPB

### Advance Informed Agreement (AIA) procedure (cont'd)

- Shipment has to be identified as:
  - ❖ “LMOs for contained use”
  - ❖ “LMOs for intentional introduction to the environment”
- Information needed in accompanying documents

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## Obligations under the CPB

### AIA procedure *Exempted* for:

- LMOs for food, feed & processing (FFP)
- LMOs for contained use
- Pharmaceuticals for humans

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## Decision making

- Conduct risk assessment
- Review risk management strategies
- Plan post-release monitoring
- Review emergency response plan
- Compare RA result with current scenario
- Consider socio-economic impact

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## NBF Development

- Help to implement the CPB
- Establish regulatory mechanism
- Establish administrative structure
- Capacity building in decision making (RA, RM & Monitoring)
- Increased public participation

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## Legal framework on biosafety management in Vietnam

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## Relating legal document system

- Law on Environment Protection (2005);
- Ordinance on livestock breeds (2004);
- Ordinance on plant varieties (2004);
- Decree on Labelling (2006);
- Regulation on management of biological safety of GMOs; products and goods originating from GMOs (2005)
- Decision No 79/2007/QĐ-TTg May 31, 2007, Promulgating National Action Plan on Biodiversity to 2010 and toward to 2020 implementing Convention on Biodiversity and Cartagena Protocol on Biosafety.
- Decision No 102/2007/QĐ July 10, 2007, Promulgating Overall Project on Strengthening Biosafety Management of genetically modified organisms; products and goods originating from genetically modified organisms

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## Law on Environment Protection

### Article 87: Biological Safety

1. Organizations and individuals engaged in production, business and service activities related to GMOs and products thereof must observe the provisions of law on biodiversity, food safety and hygiene, cultivated plant varieties and live-stock breed, and other relevant laws.
2. Organizations and individuals may only research into, experiment, produce, trade in, use, import, export, store and transport GMOs and products thereof on the list of those permitted by law must meet all conditions on biological safety and procedures provided for by law.

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## Ordinance on livestock breed

- **Article 6.** The research into, selection, creation, experimentation, production, trading, use, international exchange of genetically modified livestock breeds and cloned livestock breeds and other activities related thereto shall comply with the Government's regulations.

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## Ordinance on plant varieties

- **Article 6.** The research into, selection, creation, field trial, production, trading, use, international exchange of, and other activities related to, genetically modified plant varieties shall comply with the Government's regulations

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## Ordinance on Food Safety and Hygiene

- **Article 20:**
- Genetically modified food raw material must have their labels inscribed in Vietnamese with "thuc pham co gen da bien doi" (**genetically modified food**).
- The Government shall prescribe in detail the management and use of genetically modified food

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## Decree on Labeling

### Article 19

- Goods or constitutions of goods which is treated by radiation or generated by **genetic engineering** must be inscribed on the goods labels under the international regulations already publicized for application by Vietnam

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## Regulation on management of biological safety of GMOs; products and goods originating from GMOs

### Scope of the regulation:

- Regulates:
  - ✓ Research,
  - ✓ Field trial,
  - ✓ Production, use and trade,
  - ✓ Exportation, importation, storage and transportation.

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## Scientific research, technological development

- comply with current regulations on scientific and technological management and other relevant provisions of law;
- have all conditions regarding material foundations, equipment, technology and professional personnel suitable;
- must register such activities with the Ministry of Science and Technology and ministries managing this issue;
- have to safely preserve GMOs and other related dangerous materials.

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## Field trial

1. **Conditions for register:**
  - Having adequate material and technical foundations, technology and specialized staff;
  - Must be the outcome of the process of scientific research which has been tested and accepted by a competent state agency;
  - Having risk monitoring and management measures in the assay process;
  - The area where an assay takes place must be isolated from population quarters and nature conservation zones;
2. **Registration dossier:**
  - An application for registration of assay;
  - Written consent of the People's Committee of the province or centrally-run city where the assay is planned to be conducted;
  - Papers proving full satisfaction of the conditions
  - Other necessary relevant information as requested by the registry.
3. **Applying:**
  - Send dossier to concerned ministry;
  - Concern ministry evaluates the dossiers and issue decisions to permit
4. **The concerned managing ministry shall have to report it to the MONRE, the focal point of the Government.**

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## Production, commercialise and use

1. **Conditions on production and trading:**
  - Having biological safety certificates
  - On the list of those permitted for production, trading and use under regulations of the concerned ministries
  - have relevant production or business registration certificates
2. **Labeling:**
  - “Products using gene transfer technology”
3. **Monitoring, supervision and reporting:**
  - regularly monitor and supervise their level of safety for human health, the environment and biodiversity
  - When a risk occurs, they must immediately report it to the MONRE and the concerned managing ministries

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## Import, export, storage and transportation

Conditions for import	GMOs	Products, goods originating from GMOs
<i>For the purpose of research</i>		
- Having been permitted by the exporting country for the same purpose	✓	✓
- Having effective risk management measures	✓	✓
<i>For the fidtrial, production, trading or use purposes</i>		
- Having been permitted by the exporting country for the same purpose	✓	✓
- Having gone through risk assessment	✓	✓
- have also undergone risk assessment in the practical conditions of Vietnam	✓	✓
- The exporting country has established an effective safety management mechanism for such GMOs	✓	✓

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## Import, export, storage and transportation

### Import procedures

- Comply with current provisions of law on import.
- Send written applications for permission for import to the concerned managing ministries for consideration.
- The concerned managing ministries shall examine dossiers and issue written decisions

### Export

- comply with legal provisions on export of Vietnam and the exporting country as well as treaties which the Socialist Republic of Vietnam has signed or acceded to

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## Storage and transportation

- **When transportation: Must be carefully packaged and labeled in accordance with current provisions of Vietnamese law and international practices;**
- **Before transportation: Send written notices thereon to the concerned managing ministries**

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## Risk assessment, risk management and grant of biological safety certificates

### Risk assessment

- conduct risk assessment according to regulations of the ministries responsible for this issue
- Risk assessment must be conducted using the methods and techniques of risk assessment already recognized and based on information specified in Appendix I to this Regulation (not printed herein) and other relevant scientific evidence

### Risk management

- risk prevention, handling and remedy measures must be taken.
- must assist concerned organizations and individuals in applying measures to prevent, handle and overcome risks
- have to apply appropriate control measures to prevent, detect in time and handle risks so as to overcome their consequences

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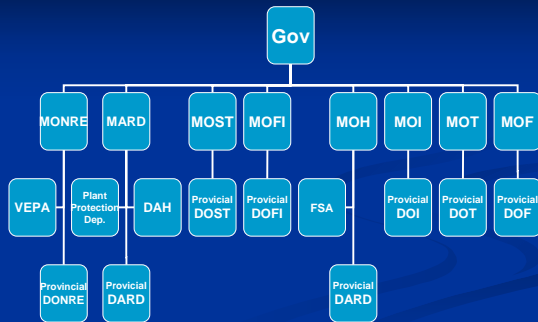
## Risk assessment, risk management and grant of biological safety certificates

### Grant of biological safety certificates

1. Conditions:
  - Not causing any toxicity or allergy to human health;
  - Not causing adverse impacts on the environment and biodiversity.
2. The managing ministries shall consider to grant biological safety certificates
3. The managing ministries shall have to report to the Ministry of Natural Resources and Environment

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## Institutional structure on biosafety



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## Ministry of Natural Resources and Environment

- Acting as the focal point of the Government for managing biological safety of genetically modified organisms; products and goods originating from genetically modified organisms;
- Having the task of assisting the Government in performing the unified state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms throughout the country.

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## Ministry of Science and Technology

- Performing tasks of state management of scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;
- Evaluating, selecting, approving and directing the implementation of programs, schemes and projects on scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;
- Building and developing potentials in service of scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

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## Function of other related Ministries

- **MARD**: shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in agriculture and forestry.
- **MOFI**: shall perform state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the fisheries sector.

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## Function of other related Ministries

- **MOH:** shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the health sector; biological safety and food hygiene and safety of genetically modified organisms; products and goods originating from genetically modified organisms used as pharmaceuticals, food or cosmetics.
- **MOI:** shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the industrial sector.

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## Decision 79/2007/QĐ-TTg

### I. Target to 2010

- ❖ Consolidating and strengthening state management, particularly national focal point and national competent authorities
- ❖ Building and improve mechanism systems; policy and legal documents on biosafety.
- ❖ Strengthening material foundations, equipment, focus on conducting training and building staffs being suitable for speciality and profession
- ❖ Propagandise, educate to enhance public awareness. Getting more 50% of population to access to biosafety information and to participate in making decision on biosafety certificate.
- ❖ Guarantee that 100% GMO on market is made risk assessment in Viet Nam, labeling and supervise according to the provisions of law

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## Decision 79/2007/QĐ-TTg

### II. Toward to 2020

- ❖ Manage Biosafety effectively in order to protecting human health, environment and biodiversity.
- ❖ Implementing fully international commitments that Viet Nam is party.
- ❖ Complete organise system, mechanism, policy and legal document on biosafety

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## Decision 79/2007/QĐ-TTg

### III. Mainly Tasks

- ❖ Unify state management. Consolidate and strengthening state management for organise system, particularly national focal point and national competent authorities.
- ❖ Building, promulgating and complete mechanism system, policy, legal documents
- ❖ Building and strengthening potential about material foundations and conduct training human resources for scientific research

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## Decision 79/2007/QĐ-TTg

- ❖ Research scientific basics and build technic guidelines for riskassessment, risk levels and risk management
- ❖ Research and apply successful scientific solutions and advance technologies
- ❖ Building, upgrade, complete, license for activities and using effectively laboratory system, in that national main point laboratoties are suitable for analyse, assess and specify GMO.

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## Decision 79/2007/QĐ-TTg

- ❖ Building, enter activities and unify in managing biosafety database system.
- ❖ Building and enter to using Biosafety Clearing House (BCH).

### IV. Main solutions

1. Consolidate organization and strengthening power for biosafety state management organizations; complete mechanism system; policy; legal documents on biosafety.

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### Decision 79/2007/QĐ-TTg

2. Apply scientific solutions: research for technology deliver in order to find out and specify GMO; analyse, assess, riskassessment and biosafety management of GMO.
3. Strengthening propaganda, education and improve public awareness to sharing information and public participation on making decision on GMO: Building and organise regularly communication programs; training about biosafety;

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### Decision 79/2007/QĐ-TTg

- Guarantee right and participation of community on progressing make decision about biosafety.
4. Strengthening and diversify investment source of capital for biosafety.
    - ❖ Make advanced mechanisms to attract interior and exterior organisms, individuals in investment, technology mutation for biosafety management.
    - ❖ **Intergrade biosafety contents to priority grant fields, such as: alleviate poverty, relieve the poor, medical and rural development**

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### Decision 79/2007/QĐ-TTg

5. Strengthening international co-operation in biosafety
  - ❖ Strengthening co-operation with ASEAN countries in building information system, database, forum, experience network about biosafety.
  - ❖ Actively participate conventions, international activities
  - ❖ Diversify bilateral and multilateral co-operations, focus on experience and expert exchange

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### Decision 79/2007/QĐ-TTg

- ❖ Education, technology mutation about biosafety.
- V. Execute organization**
1. **MONRE:**
    - ❖ Focal point to implement Cartagena Protocol; coordinate with relevant Ministries and Localities; every year report to Prime Minister liên quan.
    - ❖ Preside over building, signing or submit authority levels promulgating and organize execution: Project for consolidating biosafety state management organization; project for strengthening biosafety state management capacity; propaganda, education, improve public awareness programs about biosafety.

### Decision 79/2007/QĐ-TTg

- biosafety database and sharing information building project.
- ❖ Establish interdisciplinary Steering Committee, in that Minister of MONRE is header.
2. **Ministries: Mard; Mofi; Most;** Ministry of Education and Training; MoF; Viet Nam Administration of Tourism; Viet Nam science and technology institute base on function, task and authority to implement 2007 BAP

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### Decision 79/2007/QĐ-TTg

3. **Ministry of Investment, Ministry of Finance: response to balance, arrange and guide to use resource of capital to implement 2007 BAP effectively**
4. Tasks of People's Committees of provinces or centrally run cities : response to implement effectively relevant contents in 2007 BAP; building and implement 2007 BAP of high diversity regions and territories.

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## Decision 102/2007/QĐ-TTg

### Objectives:

1. Building, promulgating and perfecting legal documents system, mechanism about biosafety management.
2. Building, strengthening and consolidating biosafety management system unify from central government to locality.
3. Building and strengthening material foundation according to trend advanced, modern; guarantee all laboratories in Viet Nam (include: North, Medium and South) having machines, comprehensive and modern equipments, enough power for analyse, identify and specify correctly GMO; risk assessment; risk management and control risks that subjects cause, responsibility fully requires in intergrade into internation. Building and entering biosafety national information system.
4. Educating fully human resource about expertise, specialist response to biosafety management requires in Ministries, Localities
5. Improving biosafety public awareness for GMO

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### Plan to promulgate relevant legal documents

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I. Now, MONRE is building Biodiversity Law, expecting this law is promulgated in 2008. Law consist of 7 chapters in that there is a chapter about biosafety. This chapter consist of 21 articles:

**Article 1:** General provisions; **Article 2:** Responsibilities of State; **Article 3:** Research and Development; **Article 4:** Listing; **Article 5:** Risk assessment; **Article 6:** Biosafety Certificate; **Article 7:** Risk Management; **Article 8:** Field Trial; **Article 9:** Release; **Article 10:** Domestic cultivation, breeding, processing and placing on the market.

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**Article 11:** Handling, storage, transport, packaging and identification; **Article 12:** Import; **Article 13:** Export; **Article 14:** Confidential information; **Article 15:** Unintentional release and emergency measures; **Article 16:** Illegal transboundary movements; **Article 17:** Monitoring and reporting; **Article 18:** Inspection; **Article 19:** Information sharing; **Article 20:** Public awareness and participation; **Article 21:** International cooperation and agreements.

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II. Implementing Decision 212/2005/QĐ-TTg, relevant Ministries/sectors has plan to develop setoral legal documents.

#### 1. Some legal documents are being developed

- ❖ MARD is drafting the Regulation on field trial and granting biosafety certification for GMC which will be promulgated in the next future.
- ❖ MOH is drafting Regulation on biosafety management of GMF which will be promulgated in Sept, 2007.

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#### 2. Tasks and projects will be taken according to Overall Project on Strengthening Biosafety Management (**Decision 102/2007/QĐ-TTg**)

##### MONRE:

- Invest intensively on facility and equipment for national focal point and other agencies under relevant Ministries.
- Raise awareness on biosafety and strengthen capacity for social monitoring on GMO.
- Extend and enhance bilateral and multilateral cooperation with other countries in the world to learn experience, attract investment and strengthening capacity for biosafety management in Vietnam.
- Strengthen biosafety management capacity for managers at central and local levels.

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**MOST**

- Draft the Regulation on biosafety management in scientific research and technological development of GMO;
- Draft the Regulation on biosafety management of GMM;
- Intensify relevant facilities, evaluate and grant labs which have enough capacity to analysis, identify GMO and to do risk assessment, risks management and monitor potential risks caused by GMO;

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**MARD:**

- Draft regulation on biosafety management to production and business of crops and feeds originated from GMO;
- Draft regulation on fieldtrial, risk assessment, risk management and granting biosafety certification to GM animals;
- Design model for field trial, risk assessment, risk management and monitor of GMC;

**MOH**

- Draft the Regulation on biosafety management of foods originated from GMO;

**MOT**

- Draft the Regulation on biosafety management of importation, exportation, storage and transport of GMO;

**MOET**

- Train staffs to have enough skill and capacity in doing fieldtrial, risk assessment, risk management, analysis and identification of GMO

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**THANK YOU FOR YOUR ATTENTION**

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