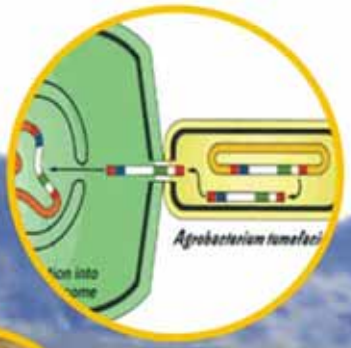

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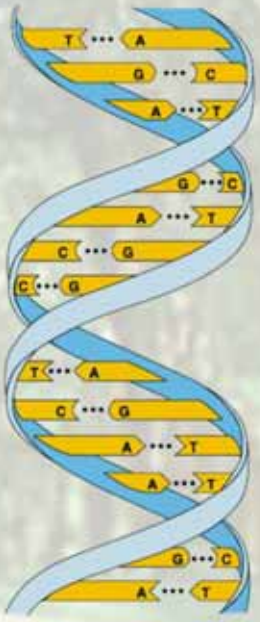
NATIONAL BIOSAFETY FRAMEWORK FOR PERU



NATIONAL ENVIRONMENTAL COUNCIL (CONAM)

NATIONAL BIOSAFETY FRAMEWORK FOR PERU

OCTOBER 2005

NATIONAL BIOSAFETY FRAMEWORK FOR PERU

The Project CONAM/UNEP-GEF (GFL-2328-2716-4577) for the development of the National Biosafety Framework for Peru was initiated in January 2003 and finished in October 2005.

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INTRODUCTION

The present day pressure to reduce the use of pesticides to protect the environment and human health; the need to increase production in existing agricultural areas to avoid greater deforestation and loss of biodiversity, as well as to implement better use of marginal areas affected by salinity, drought, floods and frost, along with the need to improve the quality of alimentation and human health added to the advance of genomics in the areas of agriculture, husbandry and humanity has brought about the exploration, development and use of biotechnology. The commercial adoption of transgenic crops and other products of biotechnology by farmers from different countries in recent times is one of the cases of more rapid diffusion of a technology in the history of agriculture and certainly offers an agricultural revolution more dramatic than that the green revolution.

The production of transgenic organisms by the incorporation of a gene from a biological entity — microbe, plant or animal — into another biological entity to incorporate a desirable characteristic differs from traditional genetic breeding. In the case of plants all desirable and undesirable genes contained in pollen combine with all the genes of the female progenitor. The progeny from that cross, selected after a long process (various years), will have the desirable character, but also many of the undesirable genes from both progenitors. With genetic engineering and the production of transgenics, the advantage is that only the gene of interest is transferred to a select organism, greatly accelerating genetic breeding. The technology is much more powerful than traditional breeding in that not only genes within the same specie can be moved, but also genes between distantly related species or to unrelated species, for example from a fish adapted to low temperature to a potato to give it frost resistance.

In the future, the potential use of biotechnology in plants will be of a wider spectrum than the present use, which is centered principally in integrated pest management. Currently, plants that serve as factories of important medicinal products, alternate energy sources, adhesives, lubricants, plastics and tools to decontaminate toxic waste deposits are being developed. There will be plants derived from biotechnology that will have greater benefits for health, for example, plants containing chemical compounds (drugs) used to fight diseases or plants with a greater content of essential vitamins and minerals.

Presently, modern biotechnology has provided tremendous benefits in medicine. Practically all the insulin used today to combat diabetes is produced using biotechnology and many of the medicines for fighting cancer and heart problems are produced this way.

The present day application of modern biotechnology in agriculture, fisheries, forestry, the food and fiber industry, the pharmaceutical industry, human and animal health, improvement of the environment, production of renewable energy, mining, and bio-remediation with its dizzying development, has an impressive potential and range of action.

In Peru, modern biotechnology provides the opportunity to increase exportation competitiveness, develop food security, reduce food production costs and improve quality; solve human health problems; construct a new and modern industrial base; conserve, valorize and use biodiversity; and preserve and improve the quality of life and of the environment.

As with any technology, modern biotechnology has benefits, but also risks. The concerns of possible influences of modern biotechnology on the environment and human health have stimulated the development of regulatory mechanisms to favor food safety and the environment. For this reason, in the last 30 years, different countries have implemented guidelines, regulatory systems and national frameworks for modern biotechnology safety (biosafety), the carrying out and enforcement of which requires the input of multidisciplinary experts and institutional capabilities that permit the best use of modern biotechnology without endangering human health and the environment.

On January 29, 2000, was adopted the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which constitutes a body of international standards that warrant the application of modern biotechnology in ways that are favorable for human health and for the environment was adopted.

Peru is considering the development of modern biotechnology and its applications a national priority and necessity, being a fundamental factor for competitiveness, economic growth and national welfare. On July 22, 2002, representatives of political organizations, religious groups, civil society groups and the government accepted and approved a set of government policies, creating a national agreement. The 19th National Policy is a commitment to integrate national environmental policy with economic, social, cultural and territorial policies to contribute to overcoming poverty and to accomplish sustainable development in Peru. To meet this objective the Government of Peru will stimulate investment in the environment and technology transfer for the sustainable use of biotechnology. In the same way, the 2021 Vision for Peru proposed by the Peruvian Strategic Planning Center (Centro de Planeamiento Estratégico del Perú (CEPLAN)) considers mega-diversity as a base for development and as a stepping-stone to global integration and for Peru to become a leader in biotechnology. Presently, the Peruvian Congress is considering the proposed Law N° 12033, Law of Promotion of Modern Biotechnology in Peru. As a mega-diverse country, Peru needs a framework for the better implementation of safety of modern biotechnology.

CONAM, the National Environmental Council (Consejo Nacional del Ambiente), the national environmental authority, coordinated the elaboration of the current National Biosafety Framework [NBF; Marco Estructural Nacional de Bioseguridad (MENB)] as part of the Global Project UNEP-GEF for the Development of National Biosafety Frameworks for carrying out the requirements of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity and Peruvian national biosafety regulations.

A National Coordination Committee [Comité Nacional de Coordinación (CNC)], which consisted of representatives of the institutions listed below, supported CONAM as the implementing agency of the Project for the development of the NBF:

Concejo Nacional de Ciencia y Tecnología (CONCYTEC); Colegio de Biólogos del Perú (COLBIOP); Dirección General de Salud (DIGESA); Instituto de Investigaciones de la Amazonía Peruana (IIAP); Instituto Nacional de Investigación y Extensión Agraria (INIEA); Ministerio de Comercio Exterior y Turismo (MINCETUR); Ministerio de

Relaciones Exteriores (RREE); Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA); Sociedad Nacional de Industrias (SNI); Sociedad Peruana de Derecho Ambiental (SPDA); Universidad Nacional Agraria La Molina (UNALM); Viceministerio de la Pesquería (PRODUCE-PESQUERIA); along with experts from the International Potato Center (CIP), seed producers and consultants.

THE NATIONAL ENVIRONMENTAL COUNCIL (CONAM)

CONAM, the National Environmental Council (Consejo Nacional del Ambiente), is the Peruvian national environment authority and principal entity of the National System of Environmental Management (Laws 28245 y 28611). Its institutional mission is to promote sustainable development, favoring a balance between economic growth, social well being and environmental protection, thus contributing to the improvement of the quality of life of Peruvians. It is a decentralized public organism under the direct authority of the President of the Ministerial Cabinet.

To carry out its objectives, CONAM coordinates the design and application of national environmental policies in all the State institutions, including national, regional and local governmental levels, promoting the participation of the private sector and civil society. CONAM provides the necessary instruments for environmental planning and management to all the actors involved so that they can efficiently carry out their functions.

One of the objectives of CONAM is the decentralization and dispersal of the capacities for environmental management. For that reason, there are six (6) Executive Regional Secretariats, with a total of 25 Regional Environmental Commissions — regional and local concentrations of environmental policies and management.

In order to execute adequately the commitments assumed, CONAM has developed financial and economic instruments for environmental policies and management that should promote the system of enforcement, monitoring and vigilance.

CONAM presides over the National Commission on Biological Diversity (Comision Nacional sobre Diversidad Biologica (CONADIB)), created in 2001 as an inter-sector coordinating mechanism for the management, conservation and sustainable use of the biological diversity. The CONADIB actively collaborates in the implementation of the National Strategy for Biological Diversity (Estrategia Nacional de la Diversidad Biológica, ENDB) and in the regions.

The Law Nº 28245, Law for the National System of Environmental Management (Sistema Nacional de Gestión Ambiental) assigns CONAM with the responsibilities of planning, promoting, coordinating, regulating, sanctioning and supervising activities related to the protection of the environment; of promoting environmental research as well as integrating and strengthening activities in this area with the objective of providing scientific and technical support to the different organisms involved in coordination with the competent entities of the public and private sector; and of providing opinions on proposed legislation with environmental legal implications, as well as promoting the development and use of cleaner technologies, methods, practices and processes of production and commercialization.

The Law 28611, General Law of the Environment (Ley General del Ambiente) specifies that in carrying out its functions, the national environment authority can establish ordinances related to environmental management that are in force trans-sectorially, without prejudice to the specific functions corresponding to the competent sectorial, regional or local authorities. In addition, it indicates that in accordance with the standing regulations and international treaties ratified by the Government of Peru, the State promotes the adoption of national technical policies, as well as labeling practices, that safeguard the rights of the consumer to know information related to health, environment and natural resources, without generating unnecessary or unjustified obstacles to free commerce. The Regulations for Responsibility for Damage to the Environment indicate that non-compliance of the regulations of Law 28611 will be sanctioned by the competent authority based on the General Regulations for Enforcement and Environmental Control. The authorities may establish complementary regulations as long as these do not contradict the General Regulations.

COMPONENTS OF THE NATIONAL BIOSAFETY FRAMEWORK

Five components have been considered:

- A policy for biosafety matters
- Legal regulations
- A system for processing petitions (administrative system, risk assessment and decision making and risk management)
- Follow-up activities (observance and verification of environmental effects)
- Public awareness and participation

NATIONAL BIOSAFETY POLICY

The following general principles or elements for a national biosafety policy have been extracted from agreements in the different workshops and meetings held during the development of the National Biosafety Framework. CONAM, as the national environmental authority, will coordinate the consolidation of these into the required regulations.

- The national regulations regarding biosafety should guarantee an adequate level of protection of human health, the environment, biological diversity and its sustainable use in the areas of the creation, research, production, transfer, manipulation, transport, storage, conservation, exchange, commercialization, confined use and intentional release into the environment of living modified organisms (LMOs) and products derived from them.

- The national regulations will be applied to LMOs and the products derived from them case by case and step by step, as pertinent, in the diverse activities indicated in the preceding paragraph.

- The labeling or non-labeling of products derived from LMOs will be decided by the Competent National Authority.

- The enforcement of national biosafety regulations should not be a limitation to the development of modern biotechnology, nor a technical obstacle or concealed restriction to its commercialization in Peru.

- In the management of LMOs, the concept of a reserve with high agrobiodiversity will be promoted as a way to minimize the erosion of the agrobiodiversity and of the cultural diversity associated with it.

- In the development of transgenics, research directed towards defining the potential risks associated with gene flow will be promoted.

- The evaluation, management and communication of potential risks should be based on scientific and technical knowledge, the characteristics of the biological entity, its environment, non-target biological entities, food safety and cultural, social and economic conditions.

- In risk analysis and management the Competent National Authorities will consider the harmony and co-existence between traditional, conventional, organic and transgenic agriculture.

- The oversight and risk assessment should be focused on the characteristics of the LMO or its product rather than the cellular or molecular techniques used for its production.

LEGAL FRAMEWORK

By the Legislative Decree N° 26181 Peru is part of the Convention on Biological Diversity since June 7, 1993. Article Six of this Convention, which refers to the general measures for conservation and sustainable use, establishes that each contracting Party elaborate strategies, plans or national programs for the conservation and sustainable use of the biodiversity.

Law N° 26839 – Conservation and Sustainable Use of the Biodiversity Law of June 17, 1997 and its regulations approved by Supreme Decree N° 068-2001-PCM of June 20, 2001 – states that the National Strategy of Biodiversity is the national instrument for national biodiversity planning.

The National Strategy for Biodiversity developed by a Technical Committee and 15 Regional Committees convened by CONAM was approved on September 4, 2001 (Supreme Decree N° 102-2001-PCM) and its fulfillment is obligatory. It should be included in policies, plans and sectorial programs. In its objectives, Strategies 2.9 y 3.3 on Biosafety and the Control of Living Modified Organisms, state that Peru should promote the establishment of mechanisms to regulate the manipulation of genetic resources, thus promoting biotechnology as an important tool for both the development and for the control of living modified organisms. In addition, it stipulates the following actions as priorities: The establishment of a National Biosafety Program according to

the Cartagena Protocol, which will consider the benefits and risks resulting from the activities carried out with living modified organisms and their products, with emphasis on agricultural and food aspects; the establishment of a National Biotechnology System; the implementation of national regulations on biosafety; and adequate legislation to improve control, prevention and risk assessment, as well as the development of national capabilities.

Peru, as part of the Convention on Biological Diversity (CBD), participated from the beginning in the negotiations of the Cartagena Protocol on Biosafety.

On January 29, 2000 the Cartagena Protocol on Biosafety to the Cartagena Convention on Biological Diversity was adopted in Montreal, Canada. Peru subscribed to this international instrument on May 24, 2000, thus demonstrating its intention to support these objectives and provisions, as well as its predisposition to ratify it and to be a part of this international agreement.

In respect to the national legal framework, Law No. 27104, “Law of Prevention of Risks Derived from the Use of Biotechnology” was proclaimed on May 12, 1999.

Law Nº 27104, Law of Prevention of Risks Derived from the Use of Biotechnology

Law 27104 (Annex 1) has the following objectives:

- Protect human health, the environment and biological diversity;
- Promote biosafety in both research and development of biotechnology;
- Regulate, administrate and control the risks derived from the use of confined and released LMOs;
- Regulate the interchange and commercialization of LMOs, inside the country and as well as throughout the world.

The above mentioned law encompasses research, production, introduction, manipulation, transport, storage, conservation, interchange, commercialization, confined use and liberation of LMOs, as well as any activity that involves the manipulation of molecules of recombinant deoxyribonucleic acid (DNA) or the use of LMOs as vectors, either as recipients or donors.

Afterwards, by means of the Supreme Decree Nº 108-2002-PCM, 08 October 2002, whose regulations are listed in Annex 2, the following institutions were established as Competent National Authorities (CNAs) or Competent Sectorial Organs (CSOs), the National Agricultural Research and Extension Institute (Instituto Nacional de Investigación Agraria, INIA) for agriculture (currently known as INIEA), the Vice-ministry of Fisheries, Ministry of Production, for the fishery sector and the General Directorate of Environmental Health (DIGESA) the health sector. The function of the CNAs (CSOs) is to comply with and to enforce the policies regarding on Biosafety established in the Convention of Biological Diversity, the regulations of Law 27104, and other international or national regulations regarding this subject. CONAM, the national environment authority (Law 28245, June 8, 2004), is the inter-sectorial coordinating entity and the focal point for the Cartagena Protocol on Biosafety and for the Biosafety Clearing House.

CONAM proposes directives regarding LMOs and is supported by the National Committee of Biological Diversity (Commission Nacional de Diversidad Biológica,

CONADIB) in aspects related to biodiversity. Later, CONAM will be supported by a consultative commission through a future law promoting biotechnology, which is in development, on biosafety related to the promoition of modern biotechnology.

CONAM should be informed of the actions taken by the CNAs in the area of biosafety. CONAM analyses, designs and proposes mechanisms to strengthen the functioning of national procedures for applying the regulations of Law 27104, as well as the sectorial policies on biosafety.

Presently, Law 27104 along with its regulations is in effect, but not being enforced because the internal regulations are in the process of being elaborated with the coordination and support of the National Biosafety Framework Project.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The technical group, National Group for Biosafety (Grupo Nacional Sobre Bioseguridad, GNSB), created by Presidential Resolution Nº 038-2001-CD/CONAM of November 29, 2001 (Annex 3), which functioned as the National Coordinating Committee (NCC) in the beginning of the development of the National Biosafety Framework (NBF), carried out a comparative revision of the Cartagena Protocol with the national legislation (Law 27104 and its regulations) as an activity of the NBF Project, with a view towards the ratification of this international instrument by the Government of Peru (Annex 4) . As a result of this study of the Protocol and its compatibility with the existing national legislation, on September 23, 2003, the GNSB agreed to recommend that Peru ratify the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Annex 5), and thus procedures required for the Congress of the Republic to ratify the referred to international instrument as soon as possible were carried out with the logistic support of the NBF Project.

The Congress of the Republic approved the Cartagena Protocol on Biosafety to the Convention on Biological Diversity by the Legislative Resolution N 28170 of February 13, 2004 (Annex 6), which was ratified by Supreme Decree Nº 022-2004-RE of February 24, 2004 (Annex 7). The Secretariat of the Convention on Biological Diversity officialized the ratification of the Protocol by Peru on April 14, 2004, and Peru is a Party of the Cartagena Protocol on Biosafety since July 13, 2004 (Annex 8).

The Protocol is an international regulatory framework to reconcile the respective needs of trade and the application of modern biotechnogy and the protection of human health and the environment. Its objective is:

"to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

PROCEDURES FOR PROCESSING PETITIONS AND MONITORING

These procedures are part of the Sectorial Internal Regulations on Biosafety (Reglamentos Internos sobre Bioseguridad) and have been developed with the support of the National Biosafety Framework Project. They are presently in the process of approval by the Competent National Authorities (Annexes 9, 10 y 11).

An important component for the system is the composition and activity of the Sectorial Technical Group (Grupo Técnico Sectorial, GTS) that will contribute to a credible biosafety system with a standard of excellence. The GTS will be made up of highly capable specialists from institutions of the sector, prestigious academic and research institutions as well as invited experts.

The consensual proposals in the development of the present framework include the following:

I. National Agricultural Research and Extension Institute (Instituto Nacional de Investigación y Extensión Agraria; INIEA). National Competent Authority for Agriculture

Internal regulations for the development of activities with living modified organisms in agriculture or their derived products

The internal regulations include the following aspects:

Objective
Scope of Application
Functions and Faculties of the Competent National Authorities(CNAs) and the Sectorial Technical Group (GTS).
Commercialization of Living Modified Orgainisms (LMOs) or derived products
Procedure for Decision Making.
Advance Informed Agreement Procedure
Process for obtaining an Administartive Resolution for activities encompassed in the scope of the present regulations
Confidential treatment
Risk assessment
Risk management
Internal Biosafety Committees (IBioC).
Certification of Biosafety Quality (CBQ)
Working with confined LMOs
Registration of individuals, companies or institutions that undertake activities governed by present regulations
Processes to control the cross-border movement of agriculturally related LMOs or their products.
Control of the importation and international transit of LMOs or their products. Control of the exportation of LMOs or their products
Emergency Plans
Transport, packaging and labeling of LMOs or their products.
Oversight
Mechanisms for information exchange
Rights to petition permits

Violations and sactions
ANNEXES:
Concept of substancial-equivalence (based on FAO document and the *Codex Alimentarius*).
Biosafety Protocols for installations (laboratories and greenhouses) where work takes place involving LMOs or their derived products
Formats
Glossary

The Regulations have the general objective of managing activities to guarantee biosafety in relation to LMOs or their derived products.

The specific objectives are:

- Establish procedures to regulate and control the creation, investigation, production, introduction, manipulation, transport, storage, conservation, exchange, commercialization, confined use, and release to the environment of living modified organisms (LMOs) and products derived from them.
- Establish procedures to regulate and control agriculturally related LMOs and their products, produced nationally or brought into the country, destined for direct use as human or animal food or for processing.
- Establish the methodology to make risk assessments for agriculturally related LMOs and their products, case-by-case and step-by-step.

Genetically modified living plants and animals, as well as biological controlling agents (including those in the veterinary sector), biologically formulated plaguicides, feed for economically important animals and insects, all of which under the present regulations are understood to be agriculturally related LMOs and their products are included in the scope of application of these regulations.

All researchers, academics, producers, importers, exporters, business persons, and in general any individual, or national or international company or institution that is carrying out or is planning to carry out any biotechnological activity related to agriculturally related LMOs or their products are under the range of authority of these regulations.

The functions of the National Agricultural Research and Extension Institute (Instituto Nacional de Investigación y Extensión Agraria – INIEA), as a Competent National Authority, are the following:

1. Receive the petitions and to emit, after the respective process of risk assessment and risk management, the corresponding Administrative Resolution authorizing or denying the petition to carry out said activities according to the present regulations.
2. Prepare the petition file and provide it to the Sectorial Technical Group (GTS) for risk assessment and risk management, keeping information classified as confidential as such.
3. Register any individual or company or institution that carry out activities under the range of authority of these regulations.
4. Verify, inspect and register the laboratories or installations where activities involving LMOs or their products take place.

5. Oversee and regulate activities with confined use and liberation of LMOs and products derived from them.
6. Implement and supervise at the cost of the petitioners, Emergency Plans, which are approved and developed to respond to the possible occurrence of undesirable effects in petitioned activities with authorized LMOs and their products.
7. Establish, maintain and strengthen a supervisory system for detecting possible adverse effects on human, animal or plant health or the environment generated by LMOs or their products imported or brought into the country illegally.
8. Create and implement an Internal Biosafety Commission (IBioC-INIEA) to which functions inherent to the area will be assigned.
9. Inform the Ministry of Agriculture and other competent sectors of the existence of the InBioC-INIEA.

The rights of INIEA are:

1. Authorize, reject, modify, suspend or cancel Administrative Resolutions emitted for agriculturally related LMOs and their products, based upon the report prepared and drawn up by the respective Sectorial Technical Group.
2. Authorize third parties in risk assessment and risk management for every activity petition regarding LMOs, always and whenever necessary and appropriate, according to standards established for that effect.
3. Issue the Biosafety Quality Certificate (BQC) for the installations used for any activity or project that involves the creation, production or use of LMOs or their products.
4. Apply sanctions for violations of these regulations.

The Sectorial Technical Group (GTS) is permanently a nominated member and an substitute from the following institutions:

- Instituto Nacional de Investigación y Extensión Agraria
- Instituto de Investigación de la Amazonía Peruana - IIAP
- Instituto Nacional de Recursos Naturales - INRENA
- Servicio Nacional de Sanidad Agraria – SENASA

Whenever necessary and depending on the types of LMOs or their products or the activity requested, the GTS could convene experts from universities related to the Sector or refer to national or international experts.

The functions of the GTS are:

1. Receive the petition file provided by INIEA to either begin the risk assessment and risk management for each activity or case, or if it is an evaluation to be carried by a third person, approve such evaluation.
2. Make recommendations for risk management whenever necessary.
3. Coordinate the implementation of emergency plans complementary to those presented in the petition for the detection of undesirable effects to human, animal or plant health, or the environment.
4. Receive and analyze the technical information provided by INIEA for the purpose of issuing an opinion to modify, suspend or cancel current Administrative Resolutions to use LMOs or their products.
5. Make pronouncements on accusations regarding activities with LMOs or their products.

6. The standing meetings of the GTS will take place trimesterly (four times a year). Extraordinary meetings will take place according to the requirements of the petitions that have been presented.
7. The standing meetings of the GTS will be called by the INIEA or by a simple majority of its members.

A procedure of advance informed agreement (AIA) will be applied to all agriculturally related LMOs or their products that either come into the country for the first time or that are released in the country, no matter what their use may be.

Depending on the types of agriculturally related LMOs or their products, or the type of petitioned activity, the risk assessment will be carried out by the experts from the following institutions:

1. LMOs or their products for direct use as human or animal food or for processing:

    - INIEA: National Research Program of Genetic Resources and Biotechnology (Programa Nacional de Investigación en Recursos Genéticos y Biotecnología): Identification of any new genotypic or phenotypic characteristic related with the LMO that may have adverse effects on the biological diversity and on the probable recipient.
    - SENASA: General Directorate of Plant and/or Animal Health (Dirección General de Sanidad Vegetal y/o Animal), in matters of animal feed and plant or animal health.
    - DIGESA: General Directorate of Environmental Health (Dirección General de Salud Ambiental) in matters of human health.
    - SENASA: General Directorate of Animal Health (Dirección General de Sanidad Animal): National authority for the registration of veterinary products (whenever necessary).
    - SENASA: General Directorate of Animal Health (Dirección General de Sanidad Animal): National authority for the registration of animal feed (whenever necessary).
    - IIAP: Research Institute for the Peruvian Amazon (Instituto de Investigaciones de la Amazonía Peruana): in matters of effects on the biological diversity and the environment of the Peruvian Amazon.
    - INRENA: National Institute for Natural Resources (Instituto Nacional de Recursos Naturales) in matters of possible effects on biological diversity and the environment.

2. LMOs or their products for use under confined conditions:

    - INIEA: National Research Program of Genetic Resources and Biotechnology (Programa Nacional de Investigación en Recursos Genéticos y Biotecnología): Identification of any new genotypic or phenotypic characteristic related with the LMO that may have adverse effects on the biological diversity and on the probable recipient.
    - INRENA: National Institute for Natural Resources (Instituto Nacional de Recursos Naturales) in matters of possible effects on biological diversity and the environment.
    - SENASA: General Directorate of Plant and/or Animal Health (Dirección General de Sanidad Vegetal y/o Animal), in matters of plant or animal health.

- IIAP: Research Institute for the Peruvian Amazon (Instituto de Investigaciones de la Amazonía Peruana): in matters of effects on the biological diversity and the environment of the Peruvian Amazon.
- SENASA: General Directorate of Plant Health (Dirección General de Sanidad Vegetal): National authority for seed varieties (whenever necessary).
- SENASA: General Directorate of Animal Health (Dirección General de Sanidad Animal): National authority for the registration of veterinary products (whenever necessary).
- SENASA: General Directorate of Animal Health (Dirección General de Sanidad Animal): National authority for the registration of animal feed (whenever necessary).

3. LMOs or their products to be intentionally released into the natural environment

- INIEA: National Research Program of Genetic Resources and Biotechnology (Programa Nacional de Investigación en Recursos Genéticos y Biotecnología): Identification of any new genotypic or phenotypic characteristic related with the LMO that may have adverse effects on the biological diversity and on the probable recipient.
- SENASA: General Directorate of Plant and/or Animal Health (Dirección General de Sanidad Vegetal y/o Animal), in matters of plant or animal health.
- INRENA: National Institute for Natural Resources (Instituto Nacional de Recursos Naturales) in matters of possible effects on biological diversity and the environment.
- IIAP: Research Institute for the Peruvian Amazon (Instituto de Investigaciones de la Amazonía Peruana): in matters of effects on the biological diversity and the environment of the Peruvian Amazon.
- SENASA: General Directorate of Plant Health (Dirección General de Sanidad Vegetal): National authority for seed varieties (whenever necessary).
- SENASA: General Directorate of Animal Health (Dirección General de Sanidad Animal): National authority for the registration of veterinary products (whenever necessary).
- SENASA: General Directorate of Animal Health (Dirección General de Sanidad Animal): National authority for the registration of animal feed (whenever necessary).

II. Ministry of Production, Vice-Ministry of Fisheries, Competent National Authority for Fisheries

Internal regulations for the development of activities with living modified organisms in fisheries

The internal regulations are quite similar to those of INIEA in their format and content with the variations required for the sector.

These regulations have the general objective of establishing biosafety procedures to regulate the development of activities of creation, research, trial use, production, commercialization, education, confined use, storage, transport, importation, transport, disposal or any other use or management of aquatic Living Modified Organisms

(LMOs), their derived products or products containing them to ensure the safe use of modern biotechnology.

The specific objectives are:

- Establish biosafety procedures for the development of activities with aquatic LMOs, their derived products or products containing them, in confined or contained environments, as well as for transboundary movements.
- Establish the methodology to make risk assessments for aquatic LMOs, their direct products or products containing them, case-by-case and step-by-step.

When the aquatic LMOs are to be used for human consumption, DIGESA (General Directorate of Environmental Health, Dirección General de Salud Ambiental) should be part of the Sectorial Technical Group (GTS). The supervision and sanitary control of living bivalve mollusks according to Supreme Decree Nº 001-2005-PRODUCE) is the responsibility of the national Fisheries Technical Institute (Instituto Tecnológico Pesquero, ITP), but the participation of DIGESA continues to be indispensable.

The transport and packaging of aquatic LMOs whether of national production or imported origin, is to be done according to the specifications based upon the risk assessment.

The identification of an aquatic LMO and the labeling of a derived product in fisheries and/or aquaculture is to be done according to current national regulations emitted by the competent authority and according to the specifications based on the risk analysis.

III. General Directorate of Environmental Health (Dirección General de Salud Ambiental, DIGESA) Competent Natinal Authority for Environmental Health

Internal regulations for the development of activities with products derived from living modified organisms for human consumption.

The internal regulations are quite similar to those of INIEA in their format and content with the variations required for the sector.

The internal regulations have the objective of regulating activities involving the use of products derived from LMOs for human consumption in accordance with the existing legal framework to ensure safe use of biotechnology.

The specific objectives are:

- Establish procedures for national production and transboundary movement of products derived from LMOs for direct use for human consumption.
- Establish the methodology to make risk assessments for products derived from LMOs for direct use for human consumption.

Products derived from both agriculturally related and aquatic LMOs are included in the range of authority of these internal regulations for products derived from LMOs for direct use for human consumption.

Activities involving the human genome, human vaccines and organisms whose genetic modifications are obtained through conventional techniques and traditional methods are not included in the scope of application.

Risk assessment will be made case-by-case for each LMO-derived product; the initial step of which could be based on a substancial-equivalence analysis before the first transboundary movement or its production in national territory.

The transport and packaging of products derived from LMOs for human consumption whether produced nationally or imported origin is to be done according to the specifications based upon the risk assessment.

The identification of products derived from LMOs for human consumption is to be done according to current national regulations emitted by the competent authority and according to the specifications based on the risk analysis

PUBLIC AWARENESS AND PARTICIPATION

The Seminars, Workshops and Fora that have taken place at a national level are activities through which information on modern biotechnology and the national biosafety framework has been disseminated. These events constituted an opportunity for public participation in this theme (Annex 12).

Information and publications on national biosafety processes are considered in the internal sectorial Biosafety regulations (Figure 1) to discover public opinion in this matter.

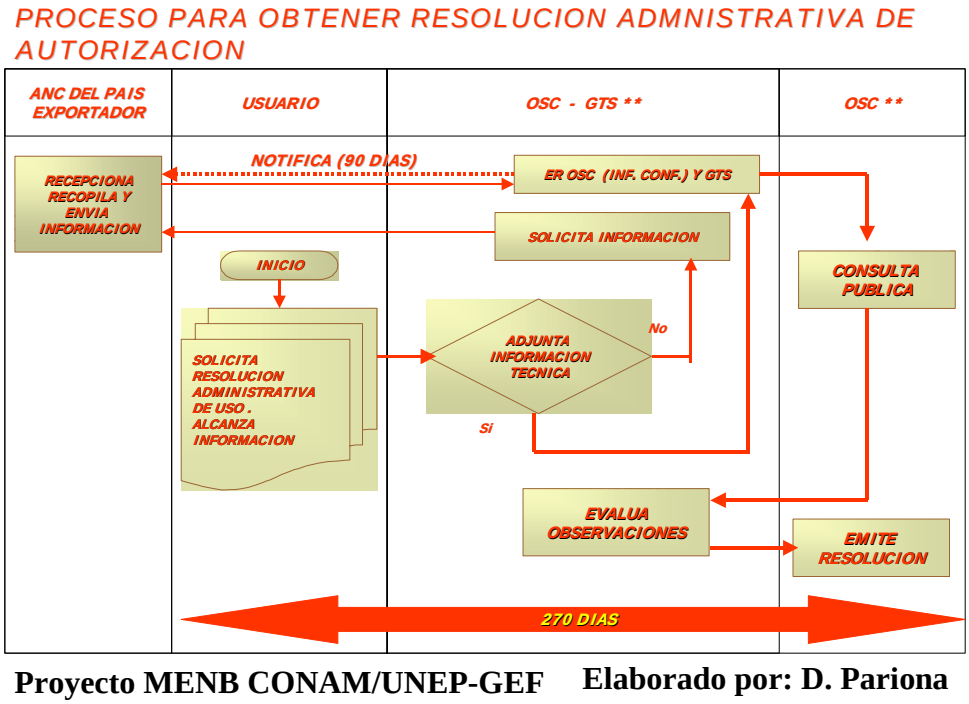


Figure 1. Public consultation in the process to obtain an administrative resolution for an activity related to the safe use of modern biotechnology

The Competent National Authorities will have a website to communicate and exchange information on national Biosafety activities.

CONAM, as the focal point for Peru in the Biosafety Clearing House (BCH, Centro de Intercambio de Información sobre Bioseguridad) of the Secretariat of the Protocol on Biosafety, is organizing a website know as the National-BCH to provide the information on national biosafety that Peru, as Party to the Protocol, should provide to the international community, e.g. contacts, regulations, national decisions and information on LMOs.

The National-BCH is to be interactive with the BCH. The BCH website is an Internet portal where Parties to the Protocol like Peru can register and access information on biosafety. The BCH facilitates the exchange of scientific, technical, environmental and legal information on LMOs, in addition to announcements of training opportunities.

Included in the obligations given to CONAM, as the Biosafety Protocol National Focal Point to the Secretariat of the Protocol on Biosafety, are analyzing, designing and proposing mechanisms by which the exchange of information between the participating national institutions (Article 5 of the Regulations of Law 27104), both nationally and internationally, will take place.

In addition to helping the general exchange of information, the National-BCH is the only means through which the Parties provide certain information required by the Protocol on Biosafety, including information provided by the Parties for the Procedure for Advance Informed Agreement (AIA). The National-BCH also will provide the mechanism by means of which the Parties will be informed of final decisions concerning national use (including placing in the market place) of living modified organisms (LMOs) that can be subject to transboundary movement for food or feed or for processing.

According to its mandate the BCH will provide a dynamic platform where information is registered and where it can be easily searched and downloaded. For that reason, it is of the highest importance to establish the necessary conditions to facilitate the information flow, both in the National Focal Point and in the Competent National Authorities (CNAs), which will be put at the disposal of the users of the web page of the BCH.

I. Information Management for the Biosafety Clearing House

Among the options available for the Parties and for other governments to provide information to the Biosafety Clearing House (BCH), Peru has chosen Option Nº 1, which consists in registering, updating, deleting or editing information directly on the BCH website portal through the Management Center. The registration of information through the Management Center of the Biosafety Clearing-House is restricted and access to this section of the web site is reserved for the Biosafety Protocol National Focal Points and other authorized users by means of authorized user accounts and passwords. However, all interested users may freely search and download information from the BCH website.

Once a document has been registered in the system, it can be searched for, located and downloaded through the Information Exchange Center on Biosafety. The entry data of a document includes the title, source, country, etc, along with a link to the document, which resides in a remote server. In other words, the content of the document does not reside at the Information Exchange Center on Biosafety, but on the server of the BCH (http://www.bch.biodiv.org).

1.1. The Biosafety Clearing House in Peru

1.1.1. CONAM

CONAM, as the Biosafety Protocol National Focal Point, can send and receive information related to decision making on LMOs at an international level through its Office for Biosafety Information Management directly to the Management Center of the BCH. This Office is also responsible for receiving, processing and sending information from the Competent National Authorities to the Management Center. Additionally, CONAM is responsible for compiling, processing and entering the required national documentation in the Management Center (Section III), as well as administering the national database, the national roster of experts and national registration of activities with LMOs.

1.1.2. Competent National Authorities

In Peru, the following Competent National Authorities (CNAs) are responsible for guarantying biosafety in the use of LMOs:

- General Directorate of Environmental Health (Dirección General de Seguridad Ambiental) – DIGESA, for the case of LMOs for direct human consumption, including products derived from aquatic LMOs.
- National Agricultural Research and Extension Institute (Instituto Nacional de Investigación y Extensión Agraria) – INIEA, for the case of living genetically modified plants and animals and their products.
- Vice-Ministry of Fisheries (Viceministerio de Pesquería) – VIMIPE, in the case of aquatic LMOs.

1.2. Information Flow

The information flow to and from the Biosafety Clearing House is exclusively through one channel — the Biosafety Protocol National Focal Point. The information generated through the functions of the Competent National Authorities (CNAs) goes from them to CONAM through the Office for Biosafety Information Management (See Figure 2, below).

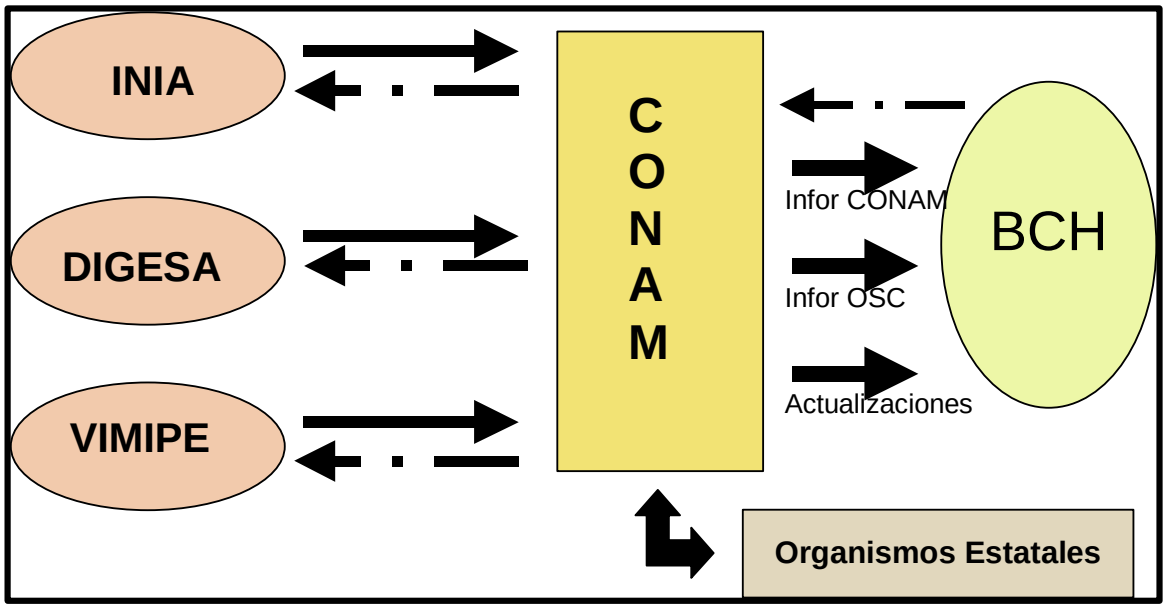


Figure 2. Information flow of the Biosafety Clearing House System.

II. Functions of CONAM in the Biosafety Clearing House

According to the Cartagena Protocol, CONAM, as the Biosafety Protocol National Focal Point and responsible authority in regard to the Biosafety Clearing House, has the function of providing access to information related to:

1. Existing national laws, regulations and guidelines for fulfilling the Protocol, as well as information required by the Parties for the procedure of advance informed agreement (Article 20, paragraph 3a).
2. National laws, regulations and guidelines regarding the importation of living modified organisms (LMOs) for direct use for food or feed, or for processing (Article 11, paragraph 5).
3. Bilateral, multilateral and regional agreements and arrangements (Article 14, paragraph 2; Article 20, paragraph 3b).
4. The contact points of the CNAs (Articles 19.2 and 19.3), national focal centers (Article 19, paragraphs 1 and 3) and emergency contacts (Article17, paragraph 3e).
5. The reports on the performance of the Protocol presented by the Parties (Article 20, paragraph 3e).

Functions of the Competent National Authorities in the Biosafety Clearing House

Each Competent National Authority (CNA), according to both its range of authority and to terms and conditions of the Cartagena Protocol, has the function of providing access to information related to:

1. Petitions and decisions taken by the CNA in regard to regulating the transport of specific living modified organisms (LMOs) (Article 6, paragraph1).
2. Involuntary transboundary movements of LMOs with likely adverse effects on biological diversity (Article 17, paragraph 1).
3. Illegal transboundary movements of LMOs (Article 25, paragraph 3).
4. Petitions and final decisions related to the importation or release of LMOs (in all instances, whether approved or disapproved: requests for more information, the continuances granted, the basis of decisions) (Article 10, paragraph 3; and Article 20, paragraph 3d).
5. Information on the enforcement of national regulations on specific imports of LMOs (Article 14, paragraph 4).
6. Petitions and final decisions related to the national use of LMOs (Article 14, paragraph 4)
7. Petitions and final decisions regarding the importation of LMOs for direct use as food or feed, or for processing that are taken in accordance with the national regulatory framework (Article 11, paragraph 4) or in accordance with Annex III (Article 11, paragraph 6) (requisite of Article 20, paragraph 3d).
8. The directives related to the national regulatory framework that will be enforced for LMOs for direct use for food or feed, or for processing (Article 11, paragraph 6).
9. Revisions and modifications of decisions on transboundary movements of LMOs (Article 12, paragraph 1).
10. The current situation of any LMOs liberated through its authorization (Article 13, paragraph 1).

11. Cases where intentional transboundary movement of LMOs may take place and the simultaneous notification of the importing Party of this possible transboundary movement (Article 13, paragraph 1).
12. Summaries of risk assessments or environmental evaluations of LMOs generated as a consequence of the regulatory processes in place, and pertinent information on products derived from LMOs (Article 20, paragraph 3c).

Because the option chosen by Peru to fulfill the terms and conditions of the Cartagena through the Biological Clearing House (BCH) is based on the registration of data using pre-established formats, the establishment of an Inter-institutional Database formed by each Competent National Authority (CNA) and CONAM is recommended. The respective offices responsible for managing the information destined for the BCH of each entity would have access.

The establishment of this database would permit CONAM, as the Biosafety Protocol National Focal Point, to have access to the complete information from each CNA that is intended for the BCH, thus enabling it to coordinate joint actions with each CNA, aiming to standardize criteria.

IV. Infrastructure, Mechanisms and Procedures

4.1. Competent National Authorities

In regard to infrastructure, it is recommended that each Competent National Authority (CNA) create an office to manage the information for the Biological Clearing House (BCH), or that such information be managed by an existing office in the CNA, which will be designated to take care of matters related to living modified organisms (LMOs) or their products. Minimally, this office must have a computer with the access restricted to staff responsable for the management of such information and with a permanent Internet connection. This infrastructure will permit a constant flow of information with the Office for Biosafety Information Management (OBIM).

Additionally, it is recommended that this office have at least two staff members responsible for managing and transmitting the information. One of them would be directly responsible for verifying and authorizing the information that is sent out from the CNA and the contact point among the institution, the other CNA and the Biosafety Protocol National Focal Point in matters regarding the BCH. This staff member would be registered in the Management Center of the BCH as the Competent National Authority. The other staff member would be the responsable for managing, compiling, processing and sending the information to the OBIM of CONAM within the established timeframes.

The information that should be sent from the CNA to the OBIM of CONAM for subsequent registration through the Management Center of the BCH is found detailed in Section IV of the website and should be transmitted in the formats set out in Section VII, corresponding to:

1. Risk assessment
2. Decisions on LMOs based on the system of advanced informed agreement
3. Decisions on LMOs for use as food or feed, or processing
4. Other decisions and declarations

To establish the Inter-institutional Database, each CNA will report to the Biosafety Protocol National Focal Point through the OBIM of CONAM complete information regarding:

1. Petitions to the CNA for authorization for activities involving LMOs.
2. Risk assessments for LMOs carried out according to its regulatory processes.
3. Environmental tests performed as a consequence of its regulatory processes.
4. Pertinent information regarding products derived from LMOs.
5. All the information on transboundary movements, voluntary or not, of LMOs that the CNA possesses.
6. Information regarding criteria used to classify certain information as confidential.

4.2. Biosafety Protocol National Focal Point

The Office for Biosafety Information Management (OBIM) of CONAM that is responsible for the functions of this institution in matters regarding the Biosafety Clearing House (BCH) should have the necessary infrastructure to permit it to serve as the nexus between the CNA and the Central Portal of the BCH at the same time that it fulfills the functions pertaining to the institution to which it belongs. For this reason, it is recommended that the OBIM be located in its own office to permit more convenient management of the information flow, as well as enough physical space to hold meetings with other institutions, whether they be for information, coordination, evaluation or pronouncement on matters regarding the BCH. It is recommended that the OBIM have at least two computers Pentium IV with 256 Mb of RAM memory, storage capacity of 40 Gb in the hard disk, permanent access to the Internet and regular technical service, in addition to a telephone/fax with a separate line.

The OBIM of CONAM will be constituted as follows:

1. Official Focal Point to the BCH: Responsible for approving the information to be registered in the BCH. Officially validates the data registered in the BCH.
2. Coordinator of the Biosafety Unit of CONAM: Responsible for the information that is to be sent out for registration in the BCH, as well as the information that is to be entered into the database.
3. Assistant: Registers, receives and organizes information and manages the database. Reports to the Coordinator of the Biosafety Unit of CONAM.

The information that should be transmitted from the OBIM of CONAM to the Management Center of the Central Portal of the BCH is detailed in Section VI of the website. Formats, and corresponds to:

1. Competent National Authorities
2. Laws, Regulations and Frameworks
3. International o Regional Agreements
4. Other decisions and declarations

Considering the type of information that is the responsibility of the OBIM of CONAM in matters regarding the BCH, it is recommended that there be a type of legal consultancy, either within the OBIM or outside of it, that permits a deeper understanding of the legal framework of of functions of CONAM in regard to the BCH.

4.3 Mechanisms and Procedures for Information Management

As was indicated formerly, the information flow to the Biosafety Clearing House (BCH) is through one single channel: The Biosafety Protocol Nacional Focal Point, represented by Office for Biosafety Information Management (OBIM) of CONAM. The general information flow is diagramed in Figure 3.

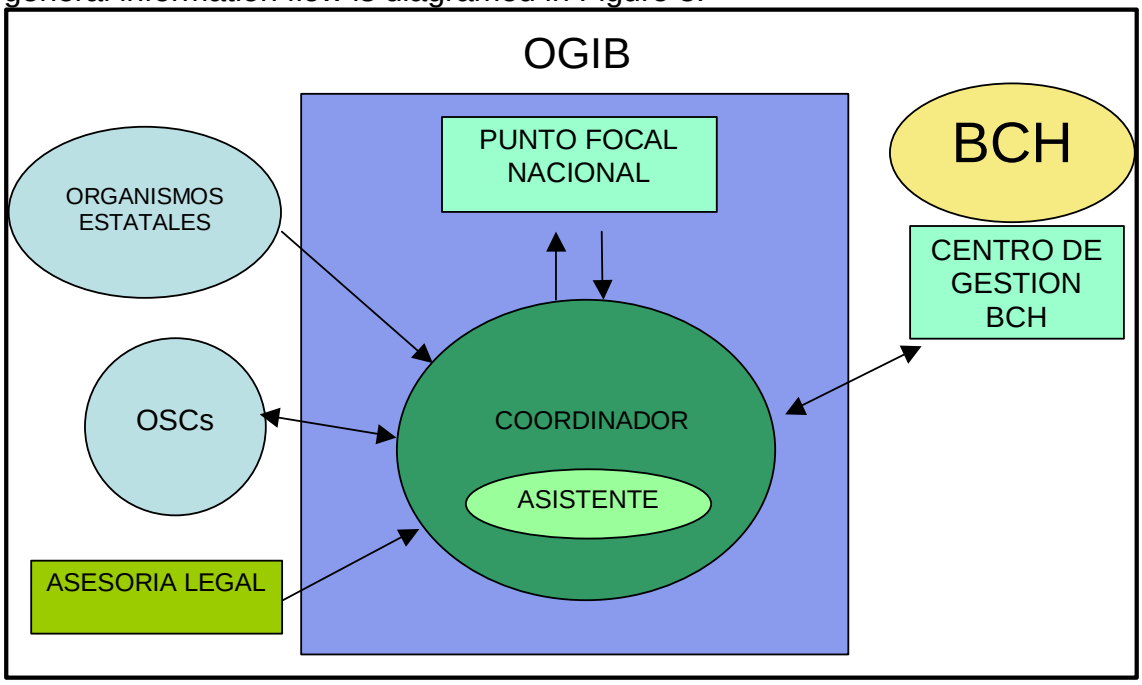


Figure 3. Structure and information flow in the OBIM.

4.3.1. Timeframe

The timeframes are established according to the source of information to be sent out. (Table 1). In the case of information to be sent from the Competent National Authorities (CNA) through the Office for Biosafety Information Management (OBIM) of CONAM, the timeframe is six (6) calendar days for the CNA to compile, process and send the information to the OBIM, which has seven (7) to revise this information, send confirmation of its acceptability to the CNA and to transmit it to the Central Portal of the Biological Clearing House (BCH) [UNEP-GEF Project on Development of National Biosafety Frameworks. Phase 3 Toolkit Module Part (ii)].

Table 1. Maximum time limits for transmitting pertinent information to the BCH

Activity	**CAN to CONAM**	**CONAM to BCH**
Risk assessment	< 7 calendar days from publication date	< 7 calendar days from receipt
Decisions on LMOs under the procedure for Advance Informed Agreements	<7 calendar days from publication date	< 7 calendar days from receipt
Decisions on LMOs for use as feed or forage, or for processing	<7 calendar days from publication date	< 7 calendar days from receipt
National Competent Authority		< 7 calendar days from designation
Laws, Regulations and Directives		< 7 calendar days from approval
International or Regional Agreements		< 7 calendar days from signature
Other decisions and declarations	Depending on the type of information	Depending on the type of information

The time limit for the transmission of information through the OBIM to the BCH is less than seven (7) calendar days as there is a direct channel for information flow between these two entities.

4.3.2. Confidentiality

Cases of confidentiality are decided and managed within each Competent National Authority (CNA) by the designated authorities of these institutions [Phase 3 Toolkit Module Part (ii): The Administrative System for Handling Applications]. It is necessary to establish Confidentiality Agreements to ensure that information, if authorized to be considered as confidential, is not divulged.

In the case of information required in the formats for registration with the Biosafety Clearing House (BCH), but considered as confidential, the CNA should inform the Office for Biosafety Information Management (OBIM) of CONAM by filling out the boxes regarding confidentiality in the respective formats.

It has been established that the information sent to the Central Portal of the BCH through Management Center should not include any delicate or confidential matters, as the objective is to put this information at the disposition of the public on the Information Exchange Center on Biosafety of the website.

4.3.3. Incomplete information

The Office for Biosafety Information Management (OBIM) of CONAM, when it considers appropriate, may request the ampliation, correction and/or justification of the information from the Competent National Authority (CNA) before the conclusion of the time limit set for transmitting it to Management Center of the Central Portal Biological Clearing House (BCH). The CNA will have a maximum of five (5) calendar days to revise and return the information with the ampliations, corrections and/or justifications requested by the OBIM, which will have a maximum of five (5) days to send it to the BCH.

V. Current Situation of the Competent National Authorities in Regard to the Biosafety Clearing House

The officials designated by INIEA and the Vice-Ministry of Fisheries and the representative of DIGESA were interviewed regarding biosafety matters for the purpose of establishing the current situation in these Competent National Authorities in regards to the initiation of activities related to the Information Exchange Center on Biosafety of the Biosafety Clearing House (BHC).

During the interviews, a brief description of the Information Exchange Center on Biosafety, its principal purpose, and the mechanism of information flow between the CNAs and the Center was presented. The scope of the responsibilities of each CNA according to Articles 7 (part p), 12 and 13 of Law Nº 27104, ´Risk Prevention in Biotechnology Use´ were delineated. In addition, each CNA was sent a survey form by electronic mail on the Current Situation of the Competent National Authority in regard to the BCH. The results and analysis are documented in a consultancy report prepared by R. Mansilla and will be taken into account for the development of the National-BCH website to provide information on national biosafety.

VI. Formats

The Formats to be utilized for the registration of information by the Office for Biosafety Information Management (OBIM) of CONAM on the Management Center of the Central Portal of the Biosafety Clearing House are found in Annex 13. The OBIM is directly responsable for completing Formats 1, 2, 3 and 7, while the Competent National Authorities are responsible for completing Formats 4, 5 and 6 and sending them to the OBIM.

VII: Databases

7.1. Database of Peruvian Experts

During the Conference of the Parties to the Convention on Biological Diversity, by means of decision EM-I/3, a list of experts was to be drawn up to provide advice or other support, as required and requested, in carrying out risk assessments, making soundly based decisions, developing national human resources and promoting the strengthening of institutional capacity in relation to transboundary movement of living modified organisms (LMOs) to the Parties who are considered as developing countries and those who are considered as countries with economies in transition. The list of experts is an instrument for developing capacities in the countries that are Parties of the Cartagena Protocol on Biosafety.

In this sense, a database of Peruvian experts in biosafey has been developed (Annex 14). This database has been created using Visual Fox Pro, and searches can be made using different fields. The format used for entering the data is the same as for the list of experts from the Cartagena Protocol on Biosafety found on the website of the Biological Clearing House at: http://bch.biodiv.org/roster/use/guidelines.shtml

The database of Peruvian experts will be available on the National-BCH website.

7.2. Database of Consultancies in Biotechnology and Biosafety

In this database is found relevant information from consultancies carried out in Peru related to biotechnology and biosafety. The database is in MSPowerpoint to permit visualization of the important tables and graphics. This database will be available on the National-BCH website.

This database includes information from the following consultancies:

- The State of Biotechnology in Peru and a Proposal for Adequate Biosafety Implementation (Estado de la Biotecnología Moderna en el Perú y Propuesta para la Adecuada Implementación de la Bioseguridad). Presented by Agro Consult S.A.C. for CONAM

- Baseline of the capacities for research and development in agricultural-agroindustrial biotechnology in Peru - II (internal document under revision) (Línea de Base de la situación de las capacidades de investigación y desarrollo en biotecnología agraria y agroindustrial en el Perú – II (documento interno en revisión de estudios)). Presented by Rolando Víctor Estrada Jiménez for INCAGRO, July 2004.

- Baseline of the capacities for research and development in agricultural-agroindustrial biotechnology in Peru - I (internal document under revision) (Línea de base de la situación de las capacidades de investigación y desarrollo en biotecnología agraria y agroindustrial en el Perú – I (documento interno en revisión de estudios)). Presented by Marcel Gutiérrez Correa for INCAGRO, July 2004.

- Biotechnology in Latin America: Panorama in 2002 (La Biotecnología en América Latina: Panorama al año 2002). Presented by Patricia Moreno Díaz and Javier Verástegui for CamBioTec (Canadian-Latin American Initiative on Biotechnology for Sustainable Development; Iniciativa Canadiense-Latinoamericana en Biotecnología para el Desarrollo Sustentable).

- Project: Biosafety Regulations in Latin America and the Caribbean in the Framework of the International Protocol on Biosafety OEA / CONCYTEC (Part B): Training Needs in Peru (Proyecto: Regulaciones de Bioseguridad en América Latina y el Caribe en el Marco del Protocolo Internacional de Bioseguridad. OEA / CONCYTEC (Parte B): Necesidades de Capacitación en el Perú). Consultancy report presented by Yris Milusqui Verástegui Peña, Lima, Peru, September 2002.

PERUVIAN TECHNICAL NORMS

The Technical Secretariat of the Technical Committee for Biosafety Norms for Living Modified Organisms (LMOs) of the National Institute for the Consumer and Intellectual Property Rights (Instituto Nacional de Defensa del Consumidor y Propiedad Intelectual; INDECOPI) is assigned to CONAM (Law 27104, Second Temporary Ordinance). The National Biosafety Framework Project has contributed to the development of the Peruvian Technical Norm (Norma Técnica Peruana) NTP 731.001 of 2004 on Biosafety in LMOs, Basic Terminology (Annex 15). Also this Project has supported the development of a draft Peruvian Technical Norm Project (Proyecto de Norma Técnica Peruana, PNTP) for Biosafety in the Commercialization of LMOs and their products. In this Peruvian Technical Norm Project, the norms for the manipulation, packaging, storage, transport and labeling of LMOs and their products will be the same as for the conventional equivalent, except for when the Competent National Authority specifies a certain type of treatment, care or special requirement (Annex 16).

During the different meetings of working groups of the Technical Committee (Annex 17) as well as the workshops and meetings for the development of the National Biosafety Framework, the following general principles related to the commercialization of LMOs have been consolitated and have been taken into consideration in the development of the Peruvian Technical Norm Project:

- The draft proposal for the Peruvian Technical Norm Project has been prepared to complement the national regulations and the internal regulations of the Competent National Authorities in biosafety aspects regarding transgenic products in a flexible way and according to technical-scientific development and in the interest of the users and the nation.

- Guarantee the consumers right to choose.

- Allow trazability for the purpose of monitoring effects in the environment and health.

- The Competent National Authority (Competent Sectorial Organ) for biosafety shall determine whether or not labeling is required on a case by case basis.

- The Competent National Authority (CNA) will pronounce decisions based on the report of its Sectorial Technical Group after risk assessment .

- The Sectorial Technical Groups are made of specialists from institutions in the sector, prestigious academic and research institutions and invited experts.

- According to the internal regulations the pronouncements of each Competent National Authority should be at the disposition of the public opinion for a period of thirty (30) days.

- All food products obtained from LMOs, even though the final product does not contain DNA or transgenic proteins, products produced with (not originating from) enzymes, fermentations or other substances genetically modified by biotechnology utilized in food processing as well as all foods derived from LMOs for animal feed and pharmaceuticals for veterinary use will be evaluated by the CNA.

- Labeling will be according to that used for the conventional equivalent except when the CNA requires labeling as LMOs as indicated by Peruvian Technical Norm Project.

- The method of labeling and the information required should be practical and with a reasonable cost.

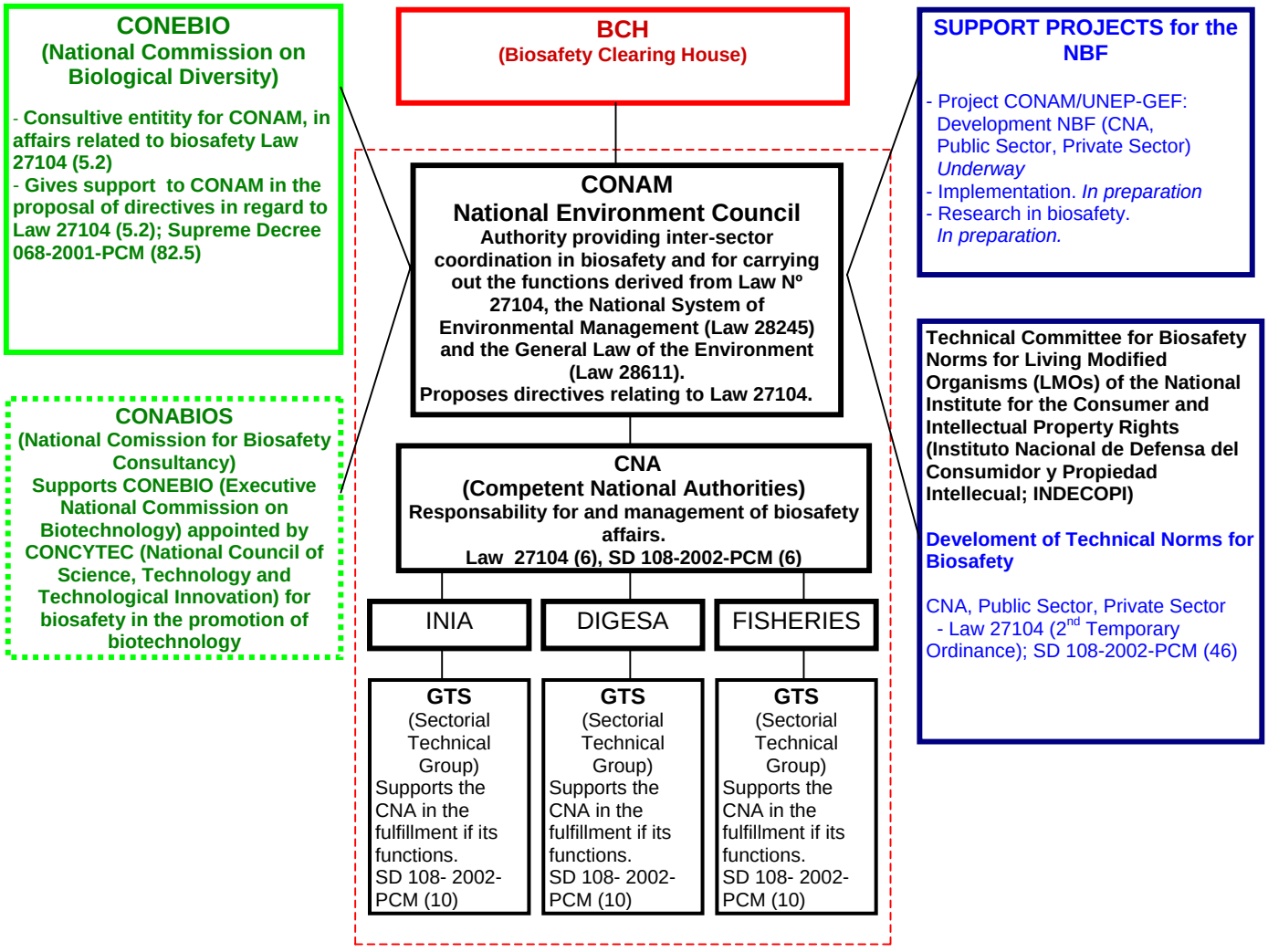
- The Peruvian Technical Norm Project will not contradict Law 28405 on labeling, nor NTP 209.038 2003 for Packaged Foods. Labeling.

- The labeling should be in accordance with substancial-equivalence and the Codex Alimentarius.

- Peruvian Technical Norm Project should be in harmony with plans to promote the use of modern biotechnology, international treaties under negotiation and national and international public opinion.

ORGANIGRAM OF THE NATIONAL BIOSAFETY FRAMEWORK

ORGANIGRAM OF THE NATIONAL BIOSAFETY FRAMEWORK (NBF)



CONAM: Av. Guardia Civil Nº 205, San Borja. Lima 41
Teléfono: 225 - 5370 anexo: 292

Consultancies carried out by CONAM/UNEP-GEF Project for the Development of the National Biosafety Framework

Nº	Consultancy Name	Date	Carried out by
1	The State of Modern Biotechnology in Peru and a Proposal for Adequate Biosafety Implementation (Estado de la Biotecnología Moderna en el Perú y Propuesta para la Adecuada Implementación de la Bioseguridad)	October 2003	Agro Consult S.A.C.
2	Regulations for the Development of Activities with Aquatic Living Modified Organisms (Reglamento para el Desarrollo de Actividades con Organismos Vivos Modificado de de Origen Hidrobiológico)	June 2004	Dora Pariona Javier, Engineer
3	Regulations for the Development of Activities with Living Modified Organisms in Agriculture and their derived Products (Reglamento para el Desarrollo de Actividades con Organismos Vivos Modificados Agropecuarios y sus Productos Derivados)	June 2004	Dora Pariona Javier, Engineer
4	Regulations for the Development of Activities with Living Modified Organisms for Human Consumption (Reglamento para el Desarrollo de Actividades con Organismos Vivos Modificados para Consumo Humano)	June 2004	Dora Pariona Javier, Engineer
5	Magnitude and Impact of the Liberation of Genetically Modified Organisms and their Commercial Products – Potato (Magnitud e Impacto de la Liberación de Organismos Geneticamente Modificados y sus Productos Comerciales – Papa)	June 2004	Alberto Salas, M.S.
6	Magnitude and Impact of the Liberation of Genetically Modified Organisms and their Commercial Products – Cotton (Magnitud e Impacto de la Liberación de Organismos Geneticamente Modificados y sus Productos Comerciales – Algodón)	June 2004	Abel Basurto, M.S.
7	Magnitude and Impact of the Liberation of Genetically Modified Organisms and their Commercial Products – Legumes (Magnitud e Impacto de la Liberación de Organismos Geneticamente Modificados y sus Productos Comerciales – Leguminosas)	June 2004	Dr. Félix Camarena
8	Magnitude and Impact of the Liberation of Genetically Modified Organisms and their Commercial Products – Maize (Magnitud e Impacto de la Liberación de Organismos Geneticamente Modificados y sus Productos Comerciales - Maíz.)	June 2004	Ricardo Sevilla, M.S.
9	Internal Biosafety Regulations for the Development of Activities with Products Derived from Living Modified Organisms for Human Consumption. Revision and Examination with Toolkit. Project UNEP-GEF (Reglamento Interno de Bioseguridad para el Desarrollo de Actividades con Productos Derivados de Organismos Vivos Modificados para Consumo Humano. Revisión y chequeo con el Conjunto de Instrumentos (Toolkit) Proyecto UNEP-GEF)	April 2005	Nelly Burga Montesinos, Biologist
10	Regulations for the Development of Activities with Aquatic Living Modified Organisms. Revision and Examination with Toolkit. Project UNEP-GEF (Reglamento Interno para el Desarrollo de Actividades con Organismos Vivos Modificados de Origen Hidrobiológico. Revisión y chequeo con el Conjunto de Instrumentos (Toolkit) Proyecto UNEP-GEF)	April 2005	Dr. Susana Sirvas C.
11	The Biosafety Clearing House of the Cartagena Protocol on Biosafety (Identificación de cómo se Almacenará y Manejará la Información sobre Seguridad de la Biotecnología del Protocolo de Cartagena (Biosafety Clearing House).	July 2005	Roberto Mansilla Samaniego, Biologist
12	Revision of draft of the National Biosafety Framework for Peru (Revisión del borrador del Marco Estructural Nacional de Bioseguridad del Perú)	July 2005	Dr. Augustín López Herrera

Suporting Information for CONAM/UNEP-GEF Project Workshops on the development of the National Biosafety Framework

Nº	Title of the Presentation	Fecha	Presented by
1	Provisions of the Cartagena Protocol on Biosafety. CONAM/UNEP-GEF Workshop II Options to Implement Relevant Provisions of the Cartagena Protocol on Biosafety – CONAM 12/14/05. (Provisiones del Protocolo de Cartagena sobre Bioseguridad. CONAM/UNEP-GEF. Taller II Opciones para Implementar Provisiones Relevantes del Protocolo de Cartagena sobre Bioseguridad - CONAM 14/12/05)	November 2004	Dr. Antonietta Gutiérrez Rosati
2	Revision of Information and National and International Policies to Propose Technical Standards for Commercialization of GMOs. CONAM/UNEP-GEF Workshop II Options to Implement Relevant Provisions of the Cartagena Protocol on Biosafety – CONAM 12/14/05.(Revisión de Información y Normatividades Nacional e Internacional para Proponer una Norma Técnica sobre Comercialización de OGMs. CONAM/UNEP-GEF Taller II Opciones para Implementar Provisiones Relevantes del Protocolo de Cartagena sobre Bioseguridad - CONAM 14/12/05)	November 2004	Roberto Mansilla Samaniego, Biologist
3	Revision of Information on Liability and Redress /Seminars – Regional Workshops/Proposal for the NBF and the Nacional Position (Revisión de información sobre Responsabilidad y Compensación/Seminarios-Talleres Regionales/Propuesta para MENB y Posición Nacional)	March-May 2005	Patricia Valdez Castro, Lawyer
4	Expert revision of the Internal Biosafety Regulations of the National Competent Authorities– Health. Consolidated with suggestions from external reviewer and legal expert (Apoyo de experto para revisión de Reglamentos Internos de Bioseguridad del Organo Sectorial Competente - Salud. Consolidación con sugerencias de revisor externo y experto legal)	July 2005	Nelly Burga, Biologist
5	Expert revision of the Internal Biosafety Regulations of the National Competent Authorities– Fisheries. Consolidated with suggestions from external reviewer and legal expert (Apoyo de experto para revisión de Reglamentos Internos de Bioseguridad del Organo Sectorial Competente - Pesquería. Consolidación con sugerencias de revisor externo y experto legal)	July 2005	Dr. Susana Sirvas C.
6	Revision and legal analysis of observations on the Law 27104, its regulations, and harmonization with the Cartagena Protocol, the internal sectorial biosafety regulations and related laws (Revisión y análisis legal de observaciones a la Ley 27104 y su reglamento y su armonización con el Protocolo de Cartagena, los reglamentos internos sectoriales de bioseguridad y las leyes relacionadas.	July 2005	Patricia Valdez Castro, Lawyer

ANNEXES

1. Law Nº 27104, ´Risk Prevention in Biotechnology Use (Ley Nº 27104: Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología)
2. Regulations of the Law of Risk Prevention in Biotechnology Use – Supreme Decree Nº 108-2002-PCM, 08. (Reglamento de la Ley de Prevención de Riesgos Derivados del uso de la Biotecnología – Decreto Supremo Nº 108-2002-PCM)
3. National Group for Biosafety created by Presidential Resolution Nº 038-2001-CD/CONAM (Grupo Nacional sobre Bioseguridad (GNSB) creado por Resolución Presidencial Nº 038-2001-CD/CONAM)
4. Report of the National Group for Biosafety on the Ratification of the Protocol (Informe del GNSB sobre la Ratificación del Protocolo)
5. Letter Nº 2112-2003-CONAM/PCD Requesting Ratification of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity (Carta Nº 2112-2003-CONAM/PCD Solicita Ratificación del Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convention sobre la Diversidad Biológica)
6. Legislative Resolution Nº 28170 – Resolution that Approves the Cartagena Protocol on Biosafety of the Convention on Biological Diversity (Resolución Legislativa Nº 28170 – Resolución Legislativa que Aprueba el Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convention sobre la Diversidad Biológica)
7. Cartagena Protocol on Biosafety of the Convention on Biological Diversity is Ratified – Supreme Decree .S. Nº 022-2004-RE (Ratifican el Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convention sobre la Diversidad Biológica – D.S. Nº 022-2004-RE)
8. The Secretariat of the Convention on Biological Diversity officialized the ratification of the Protocol. (La Secretaría de la Convención sobre la Diversidad Biológica oficializó la ratificación del Protocolo)
9. Internal Regulations for the Development of Activities with Living Modified Organisms in Agriculture or their derived Products (Reglamento Interno para el Desarrollo de Actividades con Organismos Vivos Modificados o sus Productos Derivados de Origen Agropecuario)
10. Internal Regulations for the Development of Activities with Living Modified Organisms in Fisheries (Reglamento Interno para el Desarrollo de Actividades con Organismos Vivos Modificados de Origen Hidrobiológico)
11. Internal Regulations for the Development of Activities with Products Derived from Living Modified Organisms for Human Consumption (Reglamento Interno para el Desarrollo de Actividades con Productos Derivados de Organismos Vivos Modificados para Consumo Humano)
12. National Seminars, Workshops and Fora (Relación de Seminarios, Talleres y Foros que se han desarrollado a nivel Nacional)
13. Formats (Formatos)
14. Database of Peruvian Biosafety Experts (Base de Datos de Expertos en Materia de Seguridad de la Biotecnología del Perú)
15. Peruvian Technical Norms (NTP 731.001, 2004) on Biosafety with Living Modified Organisms. Basic Terminology (Norma Técnica Peruana (NTP 731.001, 2004) sobre Bioseguridad en Organismos Vivos Modificados (BOVMs). Terminología Básica)
16. Draft Peruvian Technical Norms Project (PNTP XXXX, 2005) for Biosafety in the Commercialization of LMOs, and their products (Proyecto de Norma Técnica

Peruana (PNTP XXXX, 2005) sobre Bioseguridad en la Comercialización de Organismos Vivos Modificados (OVMs), sus Productos y Derivados)

17. Technical Committee for the Normalization on Biosafety in Living Modified Organisms – Participants (Comité Técnico de Normalización sobre Bioseguridad en Organismos Vivos Modificados (CTN-BOVMs) – Participantes)