

Fidel Castro Ruz, President of the Council of State of the Republic of Cuba.

LET IT BE KNOWN: that the Council of State has agreed the following.

WHEREAS: Law 81 of the Environment, of July 11, 1997, establishes the principles that rule the environmental policy of the country and the basic standards to regulate the actions of the citizens and the society in general so as to protect the environment and contribute to reach the goals of the sustainable development of the country. According to Article 12, paragraph h) it disposes that the Ministry of Science, Technology and Environment, together with other competent bodies and state agencies, is responsible for implementing the Environmental Policy regarding biological safety and controlling its implementation.

WHEREAS: The Convention on Biological Diversity, to which Cuba is signatory, refers as a duty of contracting parties the establishment and maintenance of the means to regulate and control the risks derived from the use and release of living modified organisms as a result of biotechnology.

WHEREAS: The Convention on the Prohibition of Development, Production and Storage of Bacteriological (Biological) and Toxin Weapons and on their Destruction, to which Cuba is a Party, refers as a duty of the Parties to adopt the necessary measures to assure the fulfilment of the Convention at national level.

WHEREAS: The increasing number of research, production, diagnosis and teaching facilities in our country, and thus the complexity of the research and the diversity of organisms and micro-organisms with potential risk of biological contamination for the environment and particularly for the population, the workers, the plants and the animals demands the existence of a proper legal framework regarding biological safety.

THEREFORE: The Council of State, in exercise of the powers it is conferred by Article 90, paragraph c) of the Constitution of the Republic, adopts the following:

DECREE LAW No. 190
OF BIOLOGICAL SAFETY

CHAPTER I

GENERAL PROVISIONS

Article 1: This Decree Law has the objective of establishing the general principles that regulate, in the national territory:

- a) The use, research, test, production, import and export of biological agents and its products thereof, organisms and parts of them with genetic information:
- b) The releases into the environment of biological agents, organisms and fragments with genetic information, the actions to guarantee the fulfilment of international agreements assumed by the Cuban State regarding biological safety or related to it, the prevention of accidents that may happen and the adoption of measures to protect the environment and in particular, the population, the workers, animals and plants, from negative effects that may cause the activities related to biological agents, organisms and their fragments with genetic information.

Article 2: This Decree Law shall apply to all natural and legal persons that fulfil, in the national territory, the activities listed in Article 1.

Article 3: The following terms are defined for the best understanding and implementation of this Decree Law:

Biological agents: Viable micro-organisms and their products thereof, prions and other organisms that cause or may cause diseases to man, animals and plants.

Release area: Zone defined in the environment by the Ministry of Science, Technology and Environment, in co-ordination with competent bodies and institutions where the introduction of biological agents, organisms and their fragments with genetic information is produced.

License of Biological Safety: A modality of the Environmental License through which the Ministry of Science, Technology and Environment, after assessing the risks, authorises a natural or legal person to fulfil the activities foreseen and under the conditions and requirements established.

Containment barriers: All that opposes the spreading of potentially dangerous materials. They can be primary or secondary. They include, among other elements, the system for waste treatment

Facilities: Laboratories that carry out biotechnological activities, namely: diagnosis, research, production and teaching. It also includes rooms and areas where biological risk is present.

Organism: All genetically modified biological entity or exotic for the country, able to reproduce itself or transfer genetic material.

Genetically Modified Organisms: Organism which genetic material has been modified by the man in a way different to normal.

Biological Safety: A group of scientific and organisation measures. They include human, technical and engineering measures including physical ones aiming at protecting the workers of the facility, the community and the environment from the risks that pose the work with biological agents or the release of organisms into the environment being them genetically modified or exotic; diminish to the minimum the effects that can present and quickly eliminate their possible consequences in case of contamination, negative effects, releases or loses.

Use: The use, handling, storage, transport and control of biological agents and genetically modified organisms or not.

CHAPTER II

Competence

First Section

ABOUT THE MINISTRY OF SCIENCE, TECHNOLOGY AND ENVIRONMENT

Article 4: The Ministry of Science, Technology and Environment is the agency of the Central Administration of the State in charge of setting up, fulfil and control the policy of the State and the Government regarding biological safety. To this purpose, in co-ordination with the bodies and competent state agencies it will have the following functions and attributions:

- a) Evaluate, guide the risk management and approve field trials or research and releases into the environment of biological agents and their products, organisms and their fragments with genetic information, independently of the risk group to which they may belong.

- b) Organise, direct and fulfil inspections to facilities and all national area where biological agents and their products, organisms and their fragments with genetic information are used or released.
- c) Grant, suspend and revoke authorisations for carrying out activities related to the use, research, test, production, release, import and export of biological agents and their products, organisms and their fragments with genetic information;
- d) Establish classifications regarding:
- The organisms that are released into the environment taking into account their origin and the risk they pose for human health and the environment.
 - The biological agents that affect the man, animals and plants and their distribution in risk groups.
 - The facilities that use biological agents and their products, organisms and their products with genetic information.
- e) Establish mechanisms for the study, assessment and management of the risks of the release into the environment of biological agents and their fragments with genetic information and the procedures to control, mitigate and treat dangerous biological wastes.
- f) Establish the National System of Accountancy and Control of biological and toxin agents and organisms that will be released into the environment:
- g) Guide and carry out checking to containment barriers existing in the facilities that handle biological agents and organisms:
- h) Arrange the total or partial closing of facilities that handle biological agents and organisms if these facilities do not have safety measures and pose risks for human health and the environment:
- i) Study, assess, organise, co-ordinate, promote, participate and perform, as the case may be, all activity derived from the responsibilities and functions assigned to Cuba as State Party of International Conventions on the matter or related to it.

j) Appoint reference centres from different bodies and institutions according to their technical and scientific conditions and specify the functions to be developed in co-ordination with them;

k) Adopt necessary measures to prohibit, prevent and control the development, production, storage, acquisition or retention of:

Biological agents and toxins, be it as it may be their origin or way of production, of types and in quantities not justified for preventive, protection and other peaceful purposes, weapons, equipment or vectors aimed at using those agents or toxins with hostile purposes or in a war;

l) Establish proper procedures in the transfer, handling and use of organisms that may have negative effects for the conservation and sustainable use of biological diversity, particularly agriculture products;

m) Others assigned by the state and the Government.

Section Two

ABOUT OTHER BODIES AND STATE AGENCIES

Article 5: The Bodies and Agencies of the Central Administration of the State and, in particular, those in charge of facilities and release areas, will have the following duties, rights and functions without detriment of the ruling action of the Ministry of Science, Technology and Environment:

a) Establish the necessary conditions with the Ministry of Science, Technology and Environment to carry out any activity related to the use of biological agents and their products, organisms and their fragments with genetic information, as well as to establish the National System of Biological Safety.

b) Add the aspects regarding biological safety in its programs of research and development, inspections, investments and internal regulations, assigning the necessary resources for that, and promoting pure research regarding biological safety.

- c) Carry out a proper information of the public before any release into the environment of biological agents and their products, organisms and their fragments with genetic information;
- d) Send to the Ministry of Science, Technology and Environment the data that might result from the research of accidents and infections happened in areas of biological risk, plant health, epizootiological and epidemiological emergencies, as well as any other information required on biological safety;
- e) Promote the training and re-qualification of the personnel working in the facilities and release areas regarding biological safety;
- f) Work out and organise, in co-ordination with the Civil Defence, the emergency plans to be developed in their respective facilities and areas.

CHAPTER III

ABOUT THE FACILITIES

Article 6: The holders of entities in charge of facilities that use biological agents and their products, organisms and their fragments with genetic information, must meet the safety measures and requirements established to the following activities:

- a) The levels of biological safety in the facilities according to the risk group to which the organisms being manipulated belong and taking into account the practices, safety equipment and facility design;
- b) The handling, transport and sending of samples,
- c) The work with laboratory plants and animals,
- d) Setting up of structures that support biological safety in the facilities and the determination of its power and functions in agreement with current laws;
- e) The qualification, training and information of the personnel;

- f) Emergency plans and simulacrum;
- g) Treatment and disposal of dangerous biological wastes, and;
- h) The establishment of proper procedures to guarantee safeguard and safety.

CHAPTER IV

ABOUT THE RELEASE OF BIOLOGICAL AGENTS AND THEIR PRODUCTS, ORGANISMS AND THEIR FRAGMENTS WITH GENETIC INFORMATION INTO THE ENVIRONMENT

Article 7: The entities in charge of release areas will undergo a process of risk assessment and management that comprises a multiple analysis, on scientific basis, to characterise and identify the nature and the magnitude of hypothetical situations of danger, if they existed, their probability of occurrence and the possible extent of the damages caused by the activities related to the use and release of biological agents and their products, organisms and their fragments with genetic information and the measures aimed at guaranteeing that such a release be carried out in safe conditions.

Article 8: The holders of the entities referred to in the above article, that propose the release of biological agents and their products, organisms and their fragments with genetic information, should present to the Ministry of Science, Technology and Environment for their approval:

- a) The technical record for the proposed release;
- b) Proper recommendations for the protection of the worker and the environment in general and for setting up any negative effect, no matter the guarantees and authorisations they should give to other Bodies of the Central Administration of the State.

Article 9: The representatives of the Bodies and Agencies from the Central Administration of the State, the entities, and the researchers, in what they are concerned and once the view from the Ministry of Science, Technology and Environment is heard, are in the obligation of developing a proper information and preparation of the public. In one way or another, it will have the direct or indirect relation with the release once it is approved. For that, they should base on the services of the National System of Health, the political and mass organisations and the mass media.

CHAPTER V

ABOUT STATE ENVIRONMENTAL INSPECTION OF BIOLOGICAL SAFETY

Article 10: Objects of state environmental inspection of biological safety are: entities with facilities that handle biological agents and their products, organisms and their fragments with genetic information that may affect the man, animals and plants, and the areas where they are released into the environment.

Article 11: Inspectors from the Ministry of Science, Technology and Environment fulfil the biological safety inspection. In case the participation of inspectors from other Bodies and Agencies of the Central Administration of the State is required, the mentioned Ministry will issue the corresponding request. Once it is authorised by the Body or Agency in question, it will appoint the personnel.

Article 12: The inspection of biological safety has the objective of checking the fulfilment of current laws on the matter and will include, among others, the following aspects:

- a) Verification of containment barriers.
- b) Fulfilment of proper practices;
- c) Implementation of the plans to prepare and update the personnel regarding biological safety;
- d) Organisation, receipt and final destination of samples and biological agents;
- e) Checking of the standards and procedures for the use of biological agents and their products, organisms and their fragments with genetic information, their release into the environment, as well as the verification of their fulfilment;
- f) Checking the records and control of biological agents and their products, organisms and their fragments with genetic information existing in the facilities;
- g) Checking the safety program in the facility, as well as its physical protection and safety plan and its implementation.

- h) Checking if the conditions for the authorisation of biological safety granted remain the same:
- i) Fulfilment of the country agreements in virtue of International Agreements and Conventions regarding or related to biological safety, to which Cuba is a State Party.

CHAPTER VI

ABOUT AUTHORISATIONS OF BIOLOGICAL SAFETY

Article 13: The execution of the activities listed in this Article will require the authorisation granted by the Ministry of Science, Technology and Environment for each activity without detriment of those that should be granted by other Bodies or Agencies of the Central Administration of the State

- a) The siting, design, project, condition, remodelling, starting, operation and closing of facilities where biological agents and their products, organisms and their fragments with genetic information are used;
- b) Receipt or sending, transfer with advance request and assessment by the corresponding agencies of biological agents and toxins as well as organisms from risk groups previously agreed; equipment, technologies and materials in general among local facilities that use them or between Cuba and other States so as to avoid they are used to carry out prohibited activities at national or international levels;
- c) The procedures for the destruction or disabling of biological agents and toxins, when for their volume, characteristics and location they are considered dangerous or can violate international agreements to which Cuba is a Party;
- d) The research, production and field testing that involve biological agents and their products, organisms and their fragments with genetic information;
- e) The *environmental release* of biological agents and their products, organisms and their fragments with genetic information;
- f) The import and export of biological agents and their products, organisms and their fragments with genetic information;
- g) Transport of dangerous biological wastes and

h) Others related to the fulfilment of the agreements contracted by the Republic of Cuba in international legal instruments on this matter or related to it.

Article 14: the Ministry of Science, Technology and Environment will propose to competent Bodies and Agencies the conditions and requirements of knowledge, including the establishment of official courses on this subject. The personnel that work in facilities requiring a high level of biological safety for the risk they pose should receive these.

CHAPTER VII

ABOUT DANGEROUS BIOLOGICAL WASTES

Article 15: The holders of the agencies in charge of facilities and release areas whose operations may originate dangerous biological wastes, that is, those containing biological agents, organisms and their fragments with genetic information that pose a real or potential threat for the human health and the environment in general will be responsible for the use, treatment, and disposal under safe conditions and in keeping with current environmental provisions so as to guarantee the protection of the environment and, in particular, of the population and the workers:

Article 16: The authorities mentioned in the above article, who are responsible for the use, treatment, transport and waste disposal, will make provision in its budget for the monetary appropriations necessary to meet the costs generated by such operations.

CHAPTER VIII

ABOUT BIOLOGICAL EMERGENCIES

Article 17: The Ministry of Science, Technology and Environment, in coordination with the National General Staff of the Civil Defence will participate in the drafting, execution and control of a National Plan for Emergencies or any other situation caused by events that may originate a damage with immediate or delayed negative effects to the environment, the population

and the workers in particular due to the escape or release of organisms. Moreover, it will advise technically the Civil Defence from a biosafety point of view as well as in the assessment of the existing situations.

Article 18: The holders of the agencies in charge of facilities that manipulate biological agents and their products, organisms and their fragments with genetic information as well as the areas where they are released into the environment, will be responsible for the drafting, organisation and preparation of emergency plans that will be implemented in their respective facilities and areas.

TRANSITORY PROVISION

UNIQUE: The Centres, institutions and the bodies and agencies of the Central Administration of the State will submit the Ministry of Science, Technology and Environment, in a term of 90 days from the publication of this Decree Law, an information regarding the releases of organisms into the environment carried out in the country in the last five years for the corresponding risk assessment and prepare their record. The information will include:

- Scientific and common name;
- Designation;
- Treated or sowed hectares;
- Quantities released for years; and
- Risk assessment for the workers and the environment. •

FINAL PROVISION

FIRST: The Bodies and Agencies of the Central Administration of the State, having heard in each case the opinion of the Ministry of Science, Technology and Environment, will guarantee the existence of organising, advisory and consult structures that allow the fulfilment of what this Decree Law establishes.

SECOND: The Ministry of Science, Technology and Environment will issue as many provisions as it consider necessary for the best implementation of this Decree Law

THIRD: This Decree Law will take effect when published in the Official Gazette of the Cuban Republic.

SET FORTH at Palacio de la Revolución, in the city of Havana, on the twenty-eighth day of January, 1999.

Fidel Castro Ruz

Note:

This translation was completed at the National Centre for Biological Safety. Every effort was made to have an accurate, consistent and readable translation. Nevertheless, the original Spanish text remains the official version of the Decree Law and any interpretations of critical importance should continue to rely on it.