

**2008 Meeting
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Item 5 of the agenda

**Consideration of national, regional and
international measures to improve biosafety
and biosecurity, including laboratory safety
and security of pathogens and toxins**

NATIONAL MEASURES AND VIEWS ON BIOSAFETY AND BIOSECURITY

Submitted by Brazil

1. The concern with both biosafety and biosecurity has been increasingly present in Brazilian internal legislation and initiatives. On the one hand, the concept of biosafety is already widely known and applied in Brazil and is defined by the Ministry of Health as “the safety condition achieved through a series of actions designed to prevent, control, reduce or eliminate risks inherent to activities that may be hazardous to the health of humans, animals, plants and to the environment”¹.
2. On the other hand, the somewhat recent international discussion on biosecurity has also had its effect among Brazilian experts, with an increased effort in awareness raising and both top-down and bottom-up initiatives. In regard to the definition of the concept of biosecurity, Brazil agrees with the priority, given within the BWC, to both biosecurity in public health settings² and “laboratory biosecurity”³. It is necessary, however, that other aspects of biosecurity are also taken into account when discussing the subject.

¹ Translated into English from the definition of biosafety present in the “General Guidelines for Working with Biological Agents in Containment”, published by the Brazilian Ministry of Health (2nd edition, 2006. Page 11).

² Biosecurity in public health settings, as defined in the Background Information Document submitted by the ISU to this Meeting of Experts and entitled *Biosafety and Biosecurity*, concerns “the protection of microbiological assets from theft, loss or diversion, which could lead to the inappropriate use of these agents to cause public health harm” (page 2).

³ “Laboratory biosecurity” is defined in the Background Information Document entitled *Biosafety and Biosecurity* (submitted by the ISU) as meaning “the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release” (page 2).

3. Among others, Brazil also deems relevant the analysis of biosecurity related to veterinary and agricultural fields (denoting “protecting biological resources from foreign or invasive species”⁴). The lack of this type of biosecurity could lead, by means of criminal insertion of such foreign and/or invasive species, to the intentional destruction of crops and/or livestock, with deleterious effects not only to the economy but also – and most importantly – to food security around the globe. These concerns are related to the concepts of bioterrorism and biopiracy, which are also of relevance to the BWC. It is the Brazilian view, therefore, that the excessive narrowing of the definition of biosecurity should be avoided.

4. As a result of the international discussions and growing concern with biosafety and biosecurity, the Brazilian legislation on these matters has been significantly improved in recent years. Act n.º 11,105, dated March 24, 2005 (known as the Biosafety Act), for example, bears in its guidelines the need to support scientific development in the field of biosafety and biotechnology and establishes safety standards and mechanisms to monitor activities involving genetically modified organisms (GMOs) and their derivatives. These control mechanisms include aspects such as the construction, cultivation, production, handling, transportation, transfer, import, export, storage, research, marketing, consumption, release into the environment and disposal of GMOs. The Biosafety Act is regulated by Decree n.º 5,591 of November 22, 2005, which controls activities involving both research and commercial use while establishing punitive measures for any violators.

5. This legislation also establishes the parameters for the functioning of several governmental institutions in charge of biosafety, such as:

- (i) The National Technical Biosafety Commission (CTNBio), a multidisciplinary collegiate body of advisory and deliberative functions, created to provide technical support and advice to the Federal Government. It is also responsible for establishing technical safety rules and for authorizing activities involving both research and commercial use of GMOs;
- (ii) the Biosafety National Council (CNBS), responsible for formulating and implementing the National Policy on Biosafety (PNB);
- (iii) The Biosafety Internal Committees (CIBios), which must be created in all institutions that deal with GMOs. Among other responsibilities, the CIBios are in charge of informing workers about biosafety and establishing both preventive and inspection programs to guarantee the well-functioning of their institutions;
- (iv) The Biosafety Information System (SIB), for the management of information on GMOs.

6. The Normative Resolution n.º 2 of CTNBio (November 27, 2006) increases the control on GMOs, classifying such organisms according to their degree of risk and establishing the levels of biosafety to be applied to activities and projects employing GMOs and their derivatives in containment.

⁴ This concept is also mentioned in the Background Information Document entitled *Biosafety and Biosecurity* (page 2).

Among other national efforts in the biosafety area, the Standard Regulation 32 should also be highlighted. The NR 32, of the Ministry of Labor and Employment (MTE), was published on November 11, 2005 and establishes basic guidelines for the implementation of protection measures in order to guarantee the safety of Health workers.

7. Guidebooks on best practices comprising biosafety and biosecurity matters have also been published separately by national research institutions. Benchmark publications in this area are the “General Guidelines for Working with Biological Agents in Containment” and the “Risk Classification of Biological Agents”, both by the Ministry of Health. These guidelines set out the necessary measures for safely working with biological agents in containment, and were conceived after research carried out by the Commission of Biosafety on Health (CBS). It is important to recall the active role of CBS in defining biosafety strategies in the Health area.

8. With regard to biosafety and biosecurity applied to agriculture, a decree dating back to the 1930s pioneered the provision of regulations for “Plant Health Defense” (decree n.º 24,114, dated April 12, 1934). It draws attention to the need for risk analysis of imports (including the danger of contamination and pests between crops) and lists several safety procedures (such as quarantine, among others) for such imports.

9. With the view to promoting professional training in biosafety and biosecurity and raising awareness among professionals, Brazilian institutions and universities offer undergraduate and postgraduate courses on those subjects. With similar goals, the Brazilian government (through the Ministry of Health, the National Council of Scientific Research - CNPq and federal universities) sponsors a course on both biosafety and biosecurity, aimed at laboratory researchers and regulation officers from Brazil and Latin America. The objectives of the course – named “Strengthening biosecurity actions inside a Biosafety Protocol” – are to better meet the need for risk analysis procedures (especially level 3 ones), and to enable professionals to act as part of Biosafety Committees. The first of these seminars took place in 2007 and the last one from the 4th to the 8th of August, 2008 at the Federal University of Pernambuco, in Recife. Three other similar events are to be held in the next six months, in the cities of Brasilia, Manaus and Florianopolis, thus comprising the whole of the country.

10. A milestone in Brazilian efforts towards biosecurity is the well-known National Program for the Promotion of Dialogue between the Private Sector and the Government in Matters related to Sensitive Assets (Pronabens). It is the result of a partnership between the Ministry of Science and Technology (MCT), the Brazilian Intelligence Agency (Abin) and the Office of Institutional Security of the Presidency of the Republic (GSI/PR), and it consists of technical visits to industries and state-owned companies whose activities are related to sensitive, dual-use assets and technologies.

11. The Program has the following goals:

- (i) to inform businessmen on existing government controls in the area of non-proliferation of weapons of mass destruction, and to stress the importance of working with the Government at a national level;
- (ii) to increase the quality of Brazilian companies and their performance in the world market;

- (iii) to identify and analyze the potential occurrence of any commercial activity that might be considered illegal and/or prohibited under the international mechanisms that regulate transfers (exports or imports) of sensitive products or controlled technologies;
- (iv) to publish and publicize the lists of sensitive goods currently in effect in Brazil;
- (v) to offer support and information to assist the deliberations and analysis of the Interministerial Commission for the Control of Export/Import of Sensitive Goods (CIBES);
- (vi) To help identify any implications of exports or imports in areas of concern.

12. The Pronabens initiative stands out as a model program among others conceived within a federal system, achieving national scope and reaching different types of operators, as well as public and private industries, laboratories and research institutions. It also proposes an unprecedented form of involvement of such operators, by not limiting its efforts to the mere accountability in the event of wrongful manipulation of risky biological agents. In fact, the Program's main goal is the incorporation of agents and experts as partners in the definition of procedures for controlling sensitive goods.

13. The involvement of operators in the control process raises awareness and favors the creation of a mindset focused on the adequate handling of sensitive goods, which is of particular importance in the case of biological agents that can be easily obtained. Such awareness is essential to the effectiveness of biosecurity strategies.

14. Besides Pronabens and the training courses referred above, the Fifth National Workshop on the Control of Sensitive Goods is also designed to tackle some of the most important issues related to the BWC. Titled "Biological Weapons versus Scientific and Technological Development – Challenges and Prospects", the seminar will be held next September, in Manaus, and will address the following topics: disarmament and non-proliferation; biosafety, biosecurity and access to biodiversity; protection of genetic heritage and the fight against biopiracy. Thus, all the aforementioned courses and seminars, including Pronabens, are also intended to satisfy the need for State Parties to "promote the development of training and education programs for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins", as urged by the Sixth Review Conference final document⁵.

15. The most recent effort towards biosecurity, in Brazil, is the creation of a Working Group (GT) on the subject, which will consider developing and/or improving specific regulatory legislation. The Working Group on Biosecurity is an interministerial effort, organized by the National Authority (General Coordination for Sensitive Assets – CGBE, of the Ministry of Science and Technology) through its Coordination for Implementation, Monitoring and Control of Biological Issues (COCB).

⁵ BWC/CONF. VI/6, article IV, para. 14.