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**REPORT OF THE REGIONAL MEETING ON
GENETICALLY MODIFIED FOODS**

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Introduction

1. The Meeting on the Safety of Foods Derived through Biotechnology was organized by the Pan American Health Organization (PAHO)/World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) with the collaboration of the Inter-American Institute for Cooperation on Agriculture (IICA). The event was held at the headquarters of the Pan American Institute for Food Protection and Zoonoses (INPPAZ), a specialized center of the PAHO/WHO Regional Program on Veterinary Public Health in Buenos Aires, Argentina, from 20 to 21 February 2003. A total of 49 participants were in attendance, including speakers, government delegates, and observers. The complete list of participants appears in Annex 1.
2. Dr. Juan Manuel Sotelo, PAHO/WHO Representative in the Republic of Argentina, greeted the participants on behalf of Dr. Mirta Roses Periago, Director of the Pan American Sanitary Bureau. He then pointed out the timeliness of this meeting, in view of the pressing need of the countries to receive information and technical orientation in regard to genetically modified organisms in general, and foods in particular.
3. Dr. Jörgen Schlundt, Director of WHO's Department of Food Safety, greeted the participants on behalf of Dr. Gro Brundtland, Director of WHO. He also noted the importance that WHO has given to food safety, from the 53rd World Health Assembly up to the recent creation of the Department of Food Safety. He presented the work developed by the Codex Alimentarius Task Force on Foods Derived from Biotechnology and an analysis of the topic from an international perspective.
4. The Minister of Health of Argentina, Dr. Ginés González García, mentioned the need to even out the distribution of knowledge about biotechnology and not simply technological innovation, to make the advances in biotechnology available to all mankind, since *food safety is decisive for human development*. He then declared the meeting open.
5. The national authorities from Argentina included the President of the National Service for Hygiene and Quality in Agricultural Products (SENASA), Dr. Bernardo Cané, who stated that in studying the safety of genetically modified foods, ***scientific principles should always prevail over religious, philosophical, political, and ideological principles***. Next, the Under Secretary of Agriculture and Livestock Policy and Foods of the Secretariat of Agriculture of the Nation, Dr. Roberto Doménech, spoke about the need for a broad debate in this area and pointed out that in Argentina, the use of biotechnology has made it possible to cut agricultural production costs and improve efficiency.
6. The Meeting's participants chose as President Dr. Matías de Nicola, Director of the National Institute of Foods of Argentina (INAL) and as Vice Presidents, Dr. Ricardo

Oliva, Director of Food and Toxicology of the National Sanitary Surveillance Agency of Brazil (ANVISA), and Ms. Elvira Espinoza Gutiérrez, Executive Director of International Trade and Communications Media of the Federal Commission on Sanitary Protection of the Ministry of Health of Mexico.

7. The purposes of the meeting were *to examine the actual situation of genetically modified foods around the world and in the Americas and to raise awareness in the countries about the need to develop and upgrade food safety systems*. The conclusions and recommendations that were suggested, discussed, and adopted are presented in the corresponding sections.

Background

8. It is well established that the foods that we ingest daily should be safe and that the measures to achieve such safety should be based on sound scientific principles. Since its birth in 1948, WHO has been promoting scientific research on food safety and the formulation of principles and standards for utilization by the Member States in their attempts to ensure the safety of their food supply. This has been done through consultative meetings with international experts and dissemination of the resulting recommendations to the Member States and the public through WHO publications, such as the Technical Report Series. Furthermore, in the past decade WHO has provided scientific advice in biotechnology.

9. Biotechnology is an area of science and technology that is developing very rapidly, with many potential applications to increase the quantity and quality of the food supply. As with any new technology, the safety of the products obtained through its use should be carefully evaluated, a fact that has led WHO to call a series of Expert Consultations to address the safety of foods obtained through its application. Many of those consultations are cosponsored by the Food and Agriculture Organization of the United Nations (FAO).

10. The first Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology was held at WHO headquarters in Geneva from 29 May to 2 June 2000 to address aspects related to the safety of genetically modified foods of plant origin. The second Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Allergenicity of Genetically Modified Foods, was held in Rome from 22 to 25 January 2001. In turn, the third Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Safety Assessment of Foods Derived from Genetically Modified Microorganisms, was held in Geneva from 24 to 28 September 2001.

11. Among the earlier WHO consultations on foods obtained through biotechnology the following are worthy of note: (1) In 1996 WHO and FAO held a joint advisory

meeting to formulate concrete practical recommendations for international standards for assessing the safety of foods obtained through biotechnology. (2) In 1995 the WHO Advisory Meeting on the Application of the Principle of Substantial Equivalence in Assessing the Safety of Foods and Food Components from Plants Obtained through Modern Biotechnology was held to offer practical guidance on the way the concept of substantial equivalence can be utilized to assess safety. (3) In 1993 WHO convened the Advisory Meeting on the Health Aspects of Genetic Markers in Genetically Modified Plants, at which the potential health implications of the genetic marker of resistance to antibiotics, in particular, were evaluated. (4) In 1990 WHO convened the FAO/WHO Joint Consultation on the Strategies to Evaluate Food Safety Obtained through Biotechnological Means, with the object of developing appropriate safety assessment procedures for ensuring the safety of foods obtained through biotechnology.

12. Consumers worldwide are concerned about potential health and environmental risks from genetically modified foods. It is expected that in June 2003 the Codex Alimentarius principles on risk assessment for genetically modified foods, designed to offer guidance for the respective issues at the national policy level, will be adopted. In view of the fact that the countries of the Region of the Americas are reviewing and updating their regulatory framework for foods, this meeting, in addition to providing information and scientifically based knowledge on genetically modified foods, could also raise awareness among national authorities about the importance of developing food safety systems to facilitate compliance with the respective regulations. The report of this meeting will be submitted to the 13th Inter-American Meeting, at the Ministerial Level, on Health and Agriculture (RIMSA 13), which will be held in Washington, D.C., on 23 and 24 April 2003.

Objectives of the Advisory Meeting

- . Analysis of the currently available technical and scientific information on genetically modified foods;
- . Examination of the actual situation of genetically modified foods worldwide and in the Americas; and
- . Heightened awareness among the Member States of WHO and PAHO about the need for developing adequate food safety systems, in support of the corresponding regulatory frameworks.

Genetically Modified Foods and Biotechnology: Current Knowledge and Outlook

Genetically Modified Foods: Explanation of the Technology

13. This presentation concerned genetically modified plants and the technologies for their production. The different stages of the process were described in detail. The steps in the genetic engineering of plants are: insertion of the new DNA into the nucleus of the plant cell, its incorporation into the genome, its detection in the transformed cell, and regeneration of a plant that permits stable heritability and expression of the incorporated DNA.

14. The initial successes in transferring genes to plants were achieved through the use of bacteria belonging to the genus *Agrobacterium*, which can transfer their genes coded for tumor-producing hormones to plants via their plasmids. DNA can also be inserted by opening fissures in the cell membranes through a variety of techniques, including the use of chemical substances, electric pulses, microinjections, and carbon fibers. DNA can also be transported by high-speed (biolistic) metallic particles. Most transgenic plants are generated through the use of *Agrobacterium* or biolistic transformation.

15. The fragment of DNA to be inserted has areas with different functions: promoter, marker, and finalizer. Among markers the most used are those of resistance to antibiotics or to herbicides. Due to the undesirable effect of the possible transfer of the resistance it is preferred that other markers be utilized or else that the marker be eliminated when it is no longer needed. Transposons can also be used to eliminate the markers.

16. The process of insertion is imprecise: (1) There is no specificity; integration occurs at random locations in the nuclear genome, depending on whether the insertion site can be expressed in different forms. (2) Usually it is not one fragment that passes but several, in different states; thus multiple, incomplete, or inverted (silent) sequences can be found. (3) There are also DNA particles whose origin is unknown. (4) Small fragments of DNA intercalated by co-integration have been found. All these characteristics of the process could have implications for biosafety. Insertions of a single copy are preferred, as they are more stable.

17. Concerning what will be done in the next five to ten years, it was thought that the biosafety of genetically modified organisms (GMOs) will be greatly increased since stacked and translocated DNA will be found in secondary parts of the plant. The work will focus on minimizing the amount of unnecessary transgenic DNA in the genome of the plant, minimizing the expression of the transgene, minimizing the rate of flow of the transgene, and providing a common identification sequence to facilitate the detection of genetically modified products. Different technical alternatives exist for the management of each of these points. This will be in the era of automatic sequencing (plant genome,

structures, profiles of expression, libraries of mutants), and it will be possible to control phenotypical expression, biosafety, and acceptance by the public.

18. In the discussion it was stated that it is difficult to predict how all the technology currently available will be utilized and that it will require five to ten years to achieve new advances, which will depend on scientific developments and commercial interest. The capacity to predict unintentional effects was discussed, and it was concluded that they will be difficult to predict even when the gene insertion sites are known. Finally, it was concluded that today, it is difficult to predict the safety of genetically modified foods, since there are no adequate analytical methodologies.

Use of Genetically Modified Organisms in Agriculture: Current Status, Challenges, and Outlook for the Future

19. A general approach to the topic was taken in the presentation, with the intention of addressing four basic areas: (a) the use of GMOs; (b) discussion of their current status in the world; (c) regulatory aspects; and (d) a description of what is being done in Cuba.

20. The conference began with the data indicating that in the developing countries, the population is growing and with it, the need for food; and that at the same time, the urban population is increasing while the rural population, which produces the food for the urban population, is declining. In a WHO study (*Causes of Under-Five Mortality*, Source: EIP/WHO www.who.int) it was shown that 60% of the deaths are associated with malnutrition. A hypothesis in the exposition was that the situation was associated with lack of food or with a distribution problem, since it is estimated that it takes 14.5 months to produce the food to cover the annual global consumption, which is untenable.

21. It was emphasized that the great challenge is to ensure food for the undernourished population. This implies tripling food production by 2050, utilizing less area for crops, with less water available. It was pointed out that the responses to these challenges will differ with the economic situation of each country, but that it is important to underscore the need for improving the redistribution of wealth. At the same time, it was established that better distribution of food and better food production technology are also necessary. It was also noted that a second green revolution, one that corrects the errors of the first one, is required. The use of biotechnology should be analyzed from the standpoint of agricultural sustainability and high efficiency in production systems.

22. The report presented indicated that since the appearance of the first transgenic registry in 1966, the area sown with these products has increased to 60 million hectares in countries where their cultivation is legal and [MISSING] in others where it is illegal. The United States of America is the principal producer of transgenics, followed by Argentina, while China has the highest rate of growth. With respect to the future, it was stated that

the trend is toward an increase in the area sown with transgenics, especially in the developing countries. It was emphasized that the most important crop is soybeans, followed by corn and cotton, and that the reasons for utilizing transgenics are high yield, reduction in the need for pesticides, and greater resistance to insect pests. Also expected are improvement in the organoleptic and nutritional qualities of these foods; the production of drugs (utilizing plants as bioreactors); increased resistance to environmental factors (droughts, increased water loss); and resistance to disease. It was explained that there are no commercial transgenic animals at this time, but there was assurance that in the future there will be shellfish and fish. Also mentioned was the production of animals that can supply organs for transplant.

23. It was also pointed out that health risks, such as allergenicity, toxicity, and the triggering of resistance, are real but unintentional, and it was asserted that these can and should be verified. Potential risk and environmental impact, which can involve the escape of genes, harm to species, the elimination of biodiversity, the generation of resistance, and the modification of nutrient content, are low and can be reduced but not eliminated. There are also ethical, social, and religious concerns, along with an increase in the gap between rich and poor countries. To this is added the public's perception of GMOs and its attitude, focused basically on price, nutritional value, and safety.

24. It was furthermore emphasized that it is important that this technology not remain in the hands of a few companies and that international agencies should promote the development technologies in the countries and impartial evaluations of products, technologies, and risks.

25. It was pointed out that in Cuba, this topic has been investigated for 15 years, and that in the market there are no Cuban genetically modified products, but there are imports. It was reported that the country is in the risk assessment stage, and that the approach is to develop local technologies to have freedom of operation and not depend on patents or intellectual property rights. Among the developments mentioned later on were those achieved with respect to tilapia, the vaccine against ticks, and the production of antibodies.

26. Some of the recommendations that emerged from the discussion include the following: (1) Strategic partnerships between transnational companies and the public sector should be promoted and established. (2) Prior to that, the capacity of the public sector to regulate and obtain the best possible arrangements with respect to intellectual property should be developed. (3) Concerning the time allotted for risk assessment and basic procedures with regard to the "boomerang effect," it was indicated that in Cuba biotechnology use is in the experimental phase and that it will take an estimated two years to go to market. (4) Finally, it was emphasized that the principle of substantial

equivalence is a very good tool for evaluating genetically modified foods (GMFs), even though it was noted that there is still no unanimity in this regard.

Regulatory Aspects of Genetically Modified Foods

27. The United States has developed a regulatory framework for foods obtained through bioengineering, which is overseen by three federal agencies:

- . The Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture (USDA), in charge of regulating the microorganisms and plants produced or modified through genetic engineering and assessing the potential risks to plants or their possible designation as pests.
- . The Environmental Protection Agency (EPA), which regulates and evaluates the use of pesticides and herbicides.
- . The Food and Drug Administration (FDA), which determines whether the genetically modified foods are as safe as the natural counterparts from which they were derived and also considers all aspects of labeling.

28. The FDA bases its actions on a policy statement on food safety that dates back to 1992, whereby industry is provided with guidelines for the preparation of the products. This agency promotes frequent communication with the industry to facilitate interpretation of the standards and compliance with them.

29. The Federal Food, Drug, and Cosmetic Act regulates all aspects of safety. In regard to food obtained through bioengineering, the following sections are particularly applicable: 402, which prohibits adulteration; 403, which regulates labeling; 409, relating to the approval of additives; and 20, which excludes as additives those defined as *generally recognized as safe* (GRAS).

30. Under the 1992 policy, a case-by-case evaluation of the safety of GMFs is made, based on the following criteria:

- . New varieties are evaluated in comparison with their conventional counterparts.
- . Use of a multidisciplinary approach, which includes the evaluation of agronomic and quality characteristics; the characteristics of the new substances and variations in their composition; genetic analysis, with emphasis on stability; chemical analysis, for known toxic substances; and nutritional analysis of the principal nutrients.

- Consultations between the industry and the FDA. Although these are voluntary, they have become common practice, through which the results of the analyses performed are evaluated step by step and presented.

31. As a result of the public hearings on FDA procedures, new initiatives were generated, which include a compulsory reporting scheme, greater transparency, strengthening of the scientific foundations for decision-making, and development of directives for labeling.

32. In the near future, the procedures above will be compulsory, since they involve an increase in transparency. Furthermore, information should be provided to the consumer 120 days before the authorization for marketing. If the background documentation is submitted electronically, it will be made available on the Internet. With regard to labeling, indicating whether a food is a product of bioengineering will be voluntary.

33. According to the report prepared, USDA/APHIS is in charge of overseeing the following aspects of bioengineering: importation, interstate movement, and field testing. In regard to the field tests, APHIS requires minimization of the potential adverse environmental impact and assurance that the impact on other organisms is insignificant.

34. Furthermore, APHIS allows for the possibility that foods created by bioengineering might obtain deregulated status. Applicants should demonstrate with sufficient data that the organism will pose no risk of becoming a pest, and APHIS will initiate the corresponding environmental risk analysis.

35. The decision to grant deregulated status is based on consideration of the following:

- information on biology, genotype, and phenotype;
- relevant experimental data that include field tests and, if it exists, unfavorable information;
- data on the comparison with the conventional crop.

36. To finally achieve deregulated status, products developed through bioengineering must be in the category "Finding of no significant impact" (FONSI). In these cases, the products can be marketed without APHIS supervision. When considered appropriate, GMOs should be reviewed concurrently by the EPA and FDA.

Codex Alimentarius Task Force on Foods Derived from Biotechnology

37. The Director of the WHO Department of Food Safety explored the subject.
38. First, he underscored the importance of Codex since the creation of the World Trade Organization, and the existence of this Task Force since 1999. For the purpose of standardizing the various terminologies for genetically modified foods (GMFs), the Task Force declared that it would refer to them as "genetically modified organisms" (GMOs).
39. It was stated that the Task Force, with annual meetings in Japan, had made progress in the following tasks:
- . The existence of preliminary principles for risk analysis.
 - . Scientific guides.
 - . Preliminary plan for the evaluation of foods produced through the use of microorganisms derived from recombinant DNA.
 - . List of analytical methods for GMOs.
40. Subsequently, risk analysis and its three components—risk assessment, risk management, and communication—were mentioned.
41. The speaker explained that the first two components now function jointly, almost overlapping, and that they are addressed within the general framework of communication of the risk.
42. Measures for risk management should be appropriate to the level of risk established during the assessment, and when other legitimate factors are relevant, they should be considered; among those measures, labeling and establishing the conditions for premarketing approval, and post-marketing monitoring can be included. Communication of risk should be ongoing, beginning with the start of the risk assessment, and it should involve all the stakeholders, be fully documented and open, and include consultations with the consumers.
43. It should be borne in mind that little is known of the long-term effects of these products in general, and, in addition, that there are difficulties involved in specifically identifying the effects, along with others in applying the epidemiological studies and study models in animals.

44. One of the relevant characteristics of GMO control in the United States is that the evaluations concentrate on the risks that they can pose to consumers without considering their benefits.

45. In particular, with respect to risk management, which includes aspects of decision- or policy-making, the speaker stated that the decisions that are made should be consistent with the existing risk, based on the result of the risk assessment done previously. Other aspects of risk management can include religious aspects, product labeling, the conditions for marketing approval, and monitoring or control of the product once it is marketed.

46. This post-marketing monitoring should verify, among other things, safety conditions and nutrient levels in the food.

47. With regard to communicating risk, it was noted that the communication should be as broad as possible; involve the public sector, industry, consumers, and academia; and include consultations with all stakeholders. This interaction is a model that works in the United States, but Europe has still not achieved this degree of progress in communication.

48. With regard to the evaluation of GMOs, it was declared that they are evaluated more thoroughly than conventional foods are.

49. Later on, reference was made to the work of the FAO/WHO Task Force on Biotechnology, established in March 2000—especially the great progress it has made. This group has worked on the differences and similarities between a GMO and its conventional counterpart. With respect substantial equivalence, Dr. Schlundt indicated that it should be the starting point for the subsequent evaluation of the safety of the food.

50. With regard to the long-term effects of GMOs, he said that any long-term effect is very difficult to predict, even with some conventional foods, but that to date, no adverse effects have been reported. However, it is impossible to make predictions for the long term.

Safety of Genetically Modified Foods

Food Safety and Biotechnology: An International Perspective

51. Although public health can probably benefit from the potential of biotechnology, the point of departure should be the precept that any modern technology destined to improve the way in which foods are produced needs to be evaluated. In particular, there

needs to be a detailed examination of the potential risks and adverse impact on human health that could arise from the consumption of genetically modified foods.

52. According to the report presented, one important aspect is the perception of these products by the public, since in certain parts of the world, it has caused problems for regulators and producers alike. The absence of participation by consumers and other interested parties in the risk analysis through consultation processes and the exchange of scientifically based factual information has been a mistake. This is possibly the result of opinions that hold that the process can be too complex for ordinary consumers. Actually, however, the problem stems from the scant success that producers and regulators have had in explaining the subject in simple language that can be understood by consumers. In fact, biotechnology has also been utilized for decades in the development of other products used in medicine. However, public perception of the those technologies and their developments is more favorable than in the case of genetically modified foods, perhaps because they understand that they need to know what benefits that technology can provide.

53. In general, the opposition to genetically modified crops and foods would also seem to be related both to political and social values and to concerns about health and safety.

54. There is no doubt that the impact of GMFs on health is a matter of importance at the international level. FAO and WHO have held a series of Expert Consultations to seek ways to assess the safety and potential risks of GMFs. This scientific effort will contribute to the work of the Codex Alimentarius Task Force on Foods Derived from Biotechnology for the development of international guidelines for performing the aforementioned assessments. The work is expected to end by 2003.

55. The first three Expert Consultations organized by FAO/WHO, whose reports are currently available, concentrated on GMFs derived from plants, GMFs derived from microorganisms, and the prevention of allergenicity in GMFs.

56. The clear message of the Expert Consultations has been that there is still the need for a case-by-case assessment of GMFs, considering both safety and nutrition. In that analysis, both the direct effects (related to the new gene) and the unintended effects (which could be related to changes elsewhere in the genome) should be investigated.

57. Another important aspect noted by the experts was the need for post-marketing monitoring in certain specific cases, particularly for foods with significant nutritional changes.

58. Although safety is fundamental, it is not the only consideration. It is also necessary to consider concerns about whether genetically modified foods are beneficial and for whom. Although some consumers are not impressed with the argument that GMFs should be consumed because it is more economical to produce them, thus boosting the profits of farmers, they may be more willing to listen to other arguments that posit that, since genetically modified plants can be made more resistant to insects, the environment would benefit through reduction in the use of pesticides.

59. However, it was stated that there is a need to explore more thoroughly the specific benefits attributed to genetically modified foods. For example, the efficiency of vitamin A-fortified rice to treat vitamin A deficiency and thus prevent the blindness and death that can result from that deficiency should be compared with that of other existing methods for preventing these problems. Also, the potential adverse impact on health and the environment should be considered. The scope of the assessment should include aspects of nutritional and environmental safety as well as ethical and socioeconomic considerations and efficiency.

60. When the subject is viewed in perspective, another important area with global implications that once more will justify a rethinking of the development of new food products as preventive agents, or as specific treatments for symptoms of serious illnesses, is related to the framework and the methodology of assessing safety, risks and benefits, and socioeconomic and other considerations.

61. The report of the Director of the WHO Department of Food Safety ended with the statement that the revolution in genome manipulation will continue to provoke ethical and social controversies. Really good public use of biotechnology should contribute to the sustainable production of nourishing foods, in keeping with regional needs, while preserving biodiversity and respect for the values of nature.

Public Perception of the Safety of Foods Derived from Biotechnology

62. During the presentation, the speaker pointed out the importance of the information provided to the consumer, describing how that information is provided and the information needs of the public. A survey was presented, which showed that the United States public widely supports the use of biotechnology in agriculture, while if the same concept is stated using terms such as transgenic, the support declines. This study showed that saying the same thing differently can produce different results. What is said and the way it is said are equally important.

63. The speaker explained that when communicating it is important to establish who is going to present the information and to take the differences in audiences into account.

In all cases, to be able to validate the equivalence of the messages to different population groups the messages should be clear, simple, and consistent.

64. After the topic was presented, the following experiences were shared:
- (a) The public expects information from the regulatory authorities, who are duty-bound to provide it. However, it was emphasized that it is important to do so without crossing the line into promotion. It was also noted that it is easier to report on than to promote GMFs and the desirability of educating the consumer instead of simply providing information was stressed. In conclusion, with reference to the term *bioengineered food*, it was pointed out that that was the term used in the United States, but that it was not well accepted. However, to date, a better term for GMFs has not been found.
 - (b) The representative from Barbados commented on the current situation in that country in particular and in the English-speaking Caribbean in general. He pointed out that many of the foods consumed were imported and that the national authorities of these countries generally based their decisions about food imports on whether they were registered in the country of origin.
 - (c) A variety of terms have been used to characterize foods obtained through biotechnology. This was clearly reflected at this meeting, demonstrating that an adequate standard terminology is the ideal. However, it was recognized that the use of biotechnology for food production evolving, and the importance of providing consumers with the best available information in a just and balanced way was emphasized.
 - (d) Reference was made to the differences between the perceptions of consumers in the United States and in Europe, and the importance of developing adequate strategies for the less developed countries in this regard was underscored. The significance of international cooperation in this area was stressed.
 - (e) With respect to the results of the surveys on perception, attention was called to the importance of properly designing the studies and questions to reduce the number of biased responses and the probabilities of error in the evaluations of public perception in general, and this area in particular.
 - (f) Concerning consensus in science and among scientists, it was emphasized that the differences in the scientific community should be addressed.
65. Reference was made to biotechnology in activities other than food production and how it affects public perceptions.

Genetically Modified Foods: Food Safety Systems and the Regulatory Framework in the Region of the Americas—Case Studies

Argentina

66. A function of the government agencies responsible for controlling food products, evaluation of the safety of foods produced through biotechnology is carried out through authorities such as the National Commission on Livestock Biotechnology (CONABIA), in charge of evaluations for release into the environment; the Advisory Committee of SENASA, which authorizes use for animal and human consumption; and the Office of the Director of Markets of the Secretariat of Agriculture, Livestock, Fishing, and Food, which evaluates the feasibility of marketing.

67. There is a regulatory framework for the operation of these advisory bodies, which includes several resolutions in sync with international developments in this area and in step with the progress in this regard. The sources for this framework have been the Codex Alimentarius and the discussions of the SENASA Advisory Committee, based in turn on documents of the European Union, Australia, the FDA, EPA, USDA, and Health Canada, among others.

68. The SENASA Advisory Committee contains members from the public sector, from the private sector (including producers, transformers, and distributors), and from scientific and teaching institutions. The committee can be advised externally in accordance with specific needs.

69. The risk assessment criteria for genetically modified organisms are based on the components of risk analysis, taking the toxicological and nutritional aspects of genetic modification into account. A key element of those criteria is substantial equivalence, the starting point for the assessment.

Barbados

70. In the English-speaking Caribbean countries, the modernization of food law has been very slow, and responsibility for food protection is fragmented across various governmental agencies. With regard to GMFs specifically, there is no regulatory framework, although that will be addressed in the near future.

71. The regulations are based on the Codex Alimentarius guidelines, and most of the processed foods that are imported are subject to a basic inspection, which primarily involves the monitoring of compliance with labeling requirements. The governments trust the regulatory framework of the supplier countries to evaluate food safety and quality.

72. Efforts are under way to consolidate initiatives—for example the creation of national agencies to oversee food safety and agricultural and livestock health. A project is under way to create a regional organization, the *Caribbean Agricultural Health and Food Safety Agency*, and work is continuing on the adoption of the Cartagena Protocol on Biosafety to make the food regulation system part of the institutional framework. A subregional mechanism has also been established—the *Caribbean Regional Organization for Standards and Quality* (CROSQ)—to accelerate the development of standards that will in principle facilitate intraregional trade. In addition, international cooperation is required to support these developments and coordinate Codex activities with a subregional perspective.

Brazil

73. There is a National Technical Commission of Biosafety which brings the public agencies together and also includes representatives of consumers, social security, and producers. This commission is linked to the Ministry of Science and Technology.

74. The Commission responds to applications for experimentation, based on three safety aspects of GMOs: (1) risks to the environment, (2) risks from the standpoint of agriculture and animals, and (3) risks to human health and to the production of food for human consumption. The oversight bodies have different responsibilities. Among the 800 processes analyzed by the National Commission, most correspond to experiments with plants. There are controversies that led to the banning, by judicial decree, of the use of GMOs in the country.

75. The role of the National Agency for Sanitary Surveillance (ANVISA) in evaluating the safety of GMOs is to guarantee that every food destined for human consumption does not pose a risk to human health. Thus, it complements the work of the National Commission in guaranteeing the safety of foods, mainly with respect to the labeling and traceability of the product.

76. The big challenges for ANVISA are:

- developing valid procedures for the control of GMOs;
- strengthening institutions for research in this areas;
- guaranteeing participation in international forums; and
- resolving public concerns through communication about the risks to reestablish consumer confidence.

Canada

77. In Canada, new foods, including those derived from biotechnology, are regulated through the law known as the *Canadian Food and Drugs Act and Regulations*, more specifically, under the *Novel Foods Regulations*. The manufacturers of these foods must notify Health Canada before proceeding with the sale of these products in the country. This enables Health Canada to carry out exhaustive evaluations of the safety of these foods before they reach the market to determine whether they are safe and nourishing.

78. The approach to this safety assessment is based on principles developed with the specialized technical assistance of international agencies such as OECD, FAO, and WHO. Compulsory labeling to alert consumers or susceptible groups in the population is required only if causes for concern about safety are identified, such as allergenicity or changes in composition or nutritional value.

Mexico

79. Responsibility for GMOs in Mexico lies with the Federal Commission for Protection against Health Risks, through the Sanitary Committee on Foods. In 1997 the term “biotechnology product,” which covers foods, cosmetics, pesticides, additives, and other products, was introduced into the general law. The different products are defined. This law has regulations aimed at the sanitary control of products and services, with a specific regulation for foods and their production, labeling, and advertising.

80. Since 1994, Mexico has evaluated biotechnology products with support from scientists, evaluating the use and authorization of these products in other countries, the characteristics of the genetic modification system, and the expected use of the product. Thus, organisms such as tomatoes, cotton, and corn have been evaluated with the support of subcommittees on the environment and agriculture.

81. The Codex directives have been an important foundation for these evaluations and decisions. In 1999, a multisectoral commission was created to decide on policies and strategies for biotechnology products and answer the concerns of ecologists and other sectors.

82. Future developments include working to modernize the legal framework, deciding on labeling, and conducting analyses to detect genetically modified organisms and studies to evaluate safety. The evaluation criteria should also be harmonized. Monitoring is needed in the market to generate scientific information and support the legal framework.

Venezuela

83. The Cartagena Protocol, the Río Summit, international agreements, and the Constitution of the Bolivarian Republic of Venezuela (the organic health law is under discussion) are the legal underpinnings for the regulation of foods produced through biotechnology.

84. The design of the policy depends on:

- (a) possible adverse effects on biodiversity;
- (b) hazards to human health and potential and known risks; and
- (c) the possibilities of contributions to human well-being.

85. In 2000 the Biodiversity Law was ratified to establish the principles for the conservation of biodiversity. The Law creates a National Biosafety Office under the Ministry of the Environment and Renewable Natural Resources for the development of the national strategy. This law prohibits the release of GMOs into the environment for the purpose of production and marketing. This has aroused a debate, since it clearly assigns a steering role to the Ministry of the Environment and the Renewable Resources within the National Office. The remaining agencies (Ministry of Health and Social Development, Ministry of Science and Technology, Ministry of Production and Trade, representatives of organized civil society, and representatives of the communities) demand a scientific basis for accepting this ban.

86. It has also been established that the National Executive will set the standards for the environmentally safe use of transgenic organisms and will establish the biosafety conditions necessary for averting real or potential dangers to biodiversity and human beings.

87. The Ministry of Health and Social Development has promoted programs and regulations with the object of developing a strategy to deal with the issue of GMOs—namely, the Food Hygiene Program, the General Food Regulation and its complementary standards (under review), and the Integrated Food Safety Program (partially implemented). It was emphasized that, contrary to what was said in previous sessions, it is very important in Venezuela to take ethical, social, cultural, and religious principles into account because of the country's inherent characteristics.

Conclusions and Recommendations

88. The central purpose of the meeting was to share knowledge and experiences on foods produced through biotechnology around the world and to examine the situation and perception of this issue in the Region of the Americas through case studies presented by national authorities from six countries. The timeliness of this meeting was generally recognized, given the countries' urgent need for information and technical orientation on genetically modified organisms and the safety of foods produced through biotechnology.

89. The conclusions and recommendations issued have been divided into "general" and "specific." The specific conclusions are subdivided into three categories consistent with the phases of risk analysis: evaluation, management, and communication of the risk.

General Conclusions

90. For the development of a commercial food or a genetically modified plant, the phenotype and characteristics related to biosafety and public acceptance should be developed. However, to date through the use of biotechnology in plants, only events of imprecise DNA integration have been achieved, with the disadvantages that this generates, such as lack of specific sites and the incorporation of multiple copies.

91. From the foregoing, the development of new promoters is required, along with indeed, continuous improvement of the transformation methodologies, with a view to improving biosafety and boosting production efficiency. However, this also has some disadvantages, mainly in the generation of imprecise information which is manifested in the final expression.

92. To improve biosafety and increase the efficiency of GMOs continuous improvement is required, involving the development of efficient transformation methodologies and adequate promoters, thus reducing the time invested in the development of these products, increasing the stability of gene expression, and reducing the introduction of DNA and the expression of unwanted transgenes.

93. However developed it may be in any country, biotechnology cannot improve crop production if it is not used in conjunction with technologies and strategic planning appropriate to the economic, ecological, and social environment.

94. In the coming years the spectrum of biotechnology applications will be very broad, ranging from the development of crops resistant to pests, herbicides, and diseases to the development of specific properties in the end products—for example, in their components, in nutrient levels, or in the characteristics that affect their industrial application, and all the way to the use of plants as natural bioreactors.

95. The application of biotechnology should respond to the equation consisting of sustainable agriculture, the development of agricultural biotechnology, and the development of a highly efficient production system, based on the biosafety and bioethics precepts to inspire the public confidence necessary for achieving the expected development.

96. The meeting agreed that developing and strengthening the infrastructure and training required for the application of risk analysis principles to these foods in the developing countries is basic, and it recommended:

- . The development of strategies to follow up on the recommendation issued in Paragraph 32 of the Codex Alimentarius document ALINORM 03/34 “*Report of the Third Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology*”, held in Yokohama, Japan, 4 to 8 March 2002.
- . The coordination and allocation of resources by international cooperation agencies and multilateral and bilateral organizations to strengthen efforts to generate scientific knowledge and evidence in this area in the international arena in general and the developing countries in particular; and
- . Utilization of the strategy of technical cooperation among countries and among regions as an appropriate mechanism to facilitate scientific advances in this area.

97. It was recognized that the countries have different views on ethical, religious, socioeconomic, and other matters. Thus, for the approval of foods produced by biotechnology, it was suggested that, in addition to assessing the associated benefits and risks to public health, socioeconomic, ethical, and religious considerations in each country be taken into account.

Specific Conclusions

Risk Assessment

98. It is necessary to complete an international frame of reference for evaluating genetically modified organisms (GMOs) utilized for food production. In this regard, the following were recommended:

- . The inclusion of animals, in addition to plants and microorganisms;
- . Continued efforts to develop international safety standards and guidelines for assessing the risks of foods obtained through biotechnology; and

- . The preparation, compilation, and dissemination of specific examples to illustrate the use of these standards and guidelines. WHO and FAO should continue their leadership in food security and food safety, in coordination, whenever necessary, with other international cooperation agencies.

Risk Management

99. The measures instituted to manage risk should be proportional to the level of risk determined during the evaluation. Moreover, when relevant, other legitimate factors should be considered in the adoption of regulatory measures. These measures could include labeling, establishment of the conditions for premarketing approval, and monitoring after marketing has commenced.

Communication of Risk

100. In general, the communication of risks with respect to food safety has received little attention in the past, particularly communication of the potential benefits and risks associated with foods produced through biotechnology. In addition, the right of consumers to be properly informed was emphasized. Thus, the following were recommended:

- The identification of mechanisms to facilitate clear and open communication among all stakeholders in the public, private, and consumer sectors, based on the available knowledge and scientific evidence;
- Greater efforts to generate and communicate the available scientific information through messages that are simple and clear, but in keeping with the available knowledge and scientific evidence. PAHO/WHO can and should play an active role in this area, because of its high level of public credibility.

Annexes

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Anexo A

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LIST OF WORKING DOCUMENTS

Plantas Genéticamente Modificadas – Tecnología Actual y Perspectivas Futuras.
David W. Ow.

El uso de los organismos genéticamente modificados en la Agricultura: El estado actual, los retos y las perspectivas futura. Dr. Carlos Borroto.

Aspectos normativos de los alimentos genéticamente modificados
Dra. Cindy Williams (presentado por Linda S. Kahl)

Bioengineered Foods, Linda S. Kahl, Ph.D. Codex

Fuerza de Trabajo Intergubernamental sobre Alimentos derivados de la Biotecnología,
Dr. Ezzedine Boutrif (presentado por Dr. J. Schlundt, OMS)

Seguridad Alimentaria y Biotecnología – Una perspectiva internacional,
Dr. Jørgen Schlundt

Percepción pública de la seguridad de los alimentos producidos mediante el uso de la biotecnología, Dr. Andrew Benson

Reglamentación canadiense sobre alimentos derivados de la biotecnología,
Luc Bourbonnière, Evaluador científico

Sistemas de Inocuidad de los Alimentos y Marco Normativo en la Región de las Américas: Estudio de Caso. Regulación Sanitaria en México
Lic. Elvira Espinoza,

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Dr. Ricardo Oliva

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Ing. Agr. Carlos Camaño

**INFORMATION DOCUMENTS AND SOME SITES
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