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WORKSHOP ON CAPACITY BUILDING AND EXCHANGE OF EXPERIENCES AS RELATED TO THE IMPLEMENTATION OF PARAGRAPH 2 OF ARTICLE 18 OF THE BIOSAFETY PROTOCOL
Bonn, 1-3 November 2004

REPORT OF THE WORKSHOP ON CAPACITY-BUILDING AND EXCHANGE OF EXPERIENCES AS RELATED TO THE IMPLEMENTATION OF PARAGRAPH 2 OF ARTICLE 18 OF THE BIOSAFETY PROTOCOL

INTRODUCTION

A. Background

1. At its first meeting serving as the meeting of the Parties to the Cartagena Protocol on Biosafety the Conference of the Parties requested the Executive Secretary to convene a workshop on capacity-building and exchange of experiences on the safe handling, transport, packaging and identification of living modified organisms, as related to the implementation of paragraph 2 of Article 18 of the Protocol (decision BS-I/6 D). Accordingly, following financial contributions by the Governments of Germany and Canada, and the European Community, the Workshop on Capacity-building and Exchange of Experiences as Related to the Implementation of Paragraph 2 of Article 18 of the Biosafety Protocol was held in Bonn from 1 to 3 November 2004.

2. The Workshop was convened in recognition of the urgent need to address critical capacity-building requirements regarding the implementation of the documentation requirements of paragraph 2 of Article 18, and was intended to provide an opportunity for exchange of information and experiences, in particular for participants from developing countries and countries with economies in transition, regarding the understanding of the requirements and their appropriate implementation.

B. Attendance

3. The Workshop was attended by participants from the following countries: Argentina, Australia, Austria, Bahamas, Bangladesh, Barbados, Bhutan, Bolivia, Brazil, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, China, Congo, Costa Rica, Cuba, Denmark, Djibouti, Dominica, Ecuador, Egypt, Estonia, Ethiopia, European Community, Finland, France, Germany, Ghana, Japan, Jordan, Kenya, Latvia, Lithuania, Malaysia, Mali, Mongolia, Mozambique, Myanmar, Netherlands, Niger, Norway, Peru, Philippines, Republic of Korea, Romania, Senegal, Slovenia, South Africa, Sudan, Switzerland, Thailand, Togo, Tonga, Tunisia, Uganda, Ukraine, the United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America, and Yemen.

4. Observers from the following intergovernmental and non-governmental organizations also participated:

(a) United Nations Environment Programme (UNEP);

/…

(b) African Centre for Biosafety, Assessoria e Servicios a Projetos em Agricultura, Christian Care, Church Development Service, Deccan Development Society, EcoNexus, Greenpeace International, Grupo de Estudios Ambientales, Institute for Integrated Rural Development, Institute of Science in Society, International Grain Trade Coalition, PELUM, Pietermaritzburg Agency for Christian Social Awareness, SIBAT Inc., Third World Network, and UBINIG.

5. The following resource persons were also present at the workshop: Ms. Christine von Weizsacker (ECOROPA), Mr. Kees Noome and Ms. Marsha Stanton (Global Industry Coalition), Mr. Klaus Schumacher (International Grain Trade Coalition), Ms. Maddalena Querci (Joint Research Centre, Institute for Health and Consumer Protection, European Commission), Mr. S.R. Rao (Indian Ministry of Science and Technology), Mr. Bertrand Dagallier and Mr. Masahiro Miyazako (Organisation for Economic Co-operation and Development (OECD)), Ms. Rosa Garcia Couto (United Nations Economic Commission for Europe (UN/ECE)), and Mr. Chris Viljoen (University of the Free State, South Africa).

ITEM 1. OPENING OF THE MEETING

6. The Workshop was opened at 10 a.m. on 1 November 2004 by Ms. Cyrie Sendashonga, senior Programme Officer from the Secretariat of the Convention Biological Diversity, on behalf of the Executive Secretary of the Convention on Biological Diversity. She welcomed participants to the meeting and expressed gratitude to the Government of Germany for its financial contribution and for hosting the Workshop, as well as to the Government of Canada and the European Community for their financial contributions. She stated that the Workshop was also intended to facilitate future discussions in the Open-ended Technical Expert Group on Identification Requirements of Paragraph 2 (a) of Article 18, to be held in March 2005, through the exchange of views, information and experiences that should help to enhance mutual understanding and appreciation of the issues involved.

7. Ms. Regina Wollersheim, Director-General, German Federal Ministry of Consumer Protection, Food and Agriculture, welcomed participants on behalf of the Government of Germany, underscoring the importance of the topic, which had led to lively and sometimes controversial debate. The conservation and sustainable use of biological diversity called for adequate regulations on the transboundary movement of LMOs and the Biosafety Protocol contained the most important legally-binding rules governing living modified organisms (LMOs). She noted that the optimum level of knowledge was a key element in decision-making in such a complex field as biotechnology and proper documentation at all stages in the handling, transport, packaging and identification of LMOs was a guarantee of safety.

8. The representative of Canada, speaking as one of the co-hosts of the Workshop, emphasized how important it was for the implementation of the Biosafety Protocol for all Governments to exchange views and express their concerns.

ITEM 2. ORGANIZATIONAL MATTERS

2.1 Election of officers

9. At the opening the workshop, Mr. Manfred Lückemeyer (Germany) was elected as Chair, with Mr. David Hafashimana (Uganda) as Vice-Chair, and Mr. Leonard O'Garro (Barbados) as Rapporteur.

2.2 Adoption of the agenda

10. The Workshop adopted the following agenda on the basis of the provisional agenda contained in document UNEP/CBD/BS/WS-CB/HTPI/1/1:

1. Opening of the meeting.
2. Organizational matters:
   2.1 Election of officers;

2.2 Adoption of the agenda;

2.3 Organization of work;

3. Existing documentation systems and their use to implement the requirements of paragraph 2 of Article 18 of the Biosafety Protocol with respect to living modified organisms that are:

3.1 Intended for direct use as food or feed, or for processing;

3.2 Destined for contained use;

3.3 Intended for intentional introduction into the environment;

4. National and regional experiences in implementing existing documentation systems and capacity needs of developing countries and countries with economies in transition.

5. The use of unique identifiers in documentation accompanying living modified organisms.

6. Other issues relevant to documentation/identification of living modified organisms.

7. General discussion and conclusions.

8. Other matters.

9. Adoption of the report.

10. Closure of the workshop.

2.3 Organization of work

11. Participants adopted the organization of work proposed by the Executive Secretary in annex I to the annotated provisional agenda (UNEP/CBD/BS/WS-CB-HTPI/1/1Add.1).

2.4 Documentation

12. In addition to the provisional agenda and the annotations thereto, the Workshop also had before it a compilation of views and relevant information on paragraph 2 (a) of Article 18 of the Cartagena Protocol on Biosafety (UNEP/CBD/BS/WS-CB-HTPI/1/INF/1).

ITEM 3. EXISTING DOCUMENTATION SYSTEMS AND THEIR USE TO IMPLEMENT THE REQUIREMENTS OF PARAGRAPH 2 OF ARTICLE 18 OF THE BIOSAFETY PROTOCOL WITH RESPECT TO LIVING MODIFIED ORGANISMS

3.1 Intended for direct use as food or feed, or for processing

13. Mr. Klaus Schumacher, International Grain Trade Coalition (IGTC), explained that the Coalition was composed of 19 existing grain trade associations comprising both importers and exporters. Its objectives included, *inter alia*, providing Governments with advice on how to implement the Biosafety Protocol while at the same time meeting the needs of the world's food, feed or processing industries. He drew attention to some of the special features of the grain trade, namely, the relatively limited number of exporters and the significant number of importers and the way in which grain changed hands so many times between the seed supplier and the food manufacturer. He added that, in a bulk transport system, it was impossible to keep varieties totally separate or to avoid co-mingling at each link of the supply chain. Consequently, zero thresholds were not achievable.

14. IGTC recommended that invoices which were already in mandatory use in international trade should be the main channel for implementing paragraph 2 (a) of Article 18 rather than stand-alone documents. Doing so would facilitate transactions and allow officials to find the relevant information speedily. Where appropriate, the "may contain" language could be included in the invoice, but adventitious presence should not trigger its inclusion. Although a zero threshold could not be achieved, some threshold should be established. IGTC further recommended that 95 per cent purity for non-LMO shipments might be appropriate. Regarding the contact point to be specified in the documentation system, the IGTC proposed that it be the last exporter before the transboundary movement and the first importer.

15. He indicated that, without a fully functional Biosafety Clearing-House, it would be extremely difficult to obtain the necessary information in a timely manner. There was currently no internationally acceptable LMOs-FFP sampling system compatible with the requirements of modern bulk handling systems and, in any event, no sampling and testing technique provided 100 per cent certainty.

16. He added that the impact of implementing paragraph 2 (a) of Article 18 should be examined very closely because the rules that would ultimately be adopted would have financial implications and, as a result, would affect the cost of food. The International Food and Agricultural Trade Policy Council (IPC) was reviewing various aspects of the issue with a view to finding solutions and had already reached the conclusion that there would be financial implications, but that they would be unevenly distributed along the supply chain of the commodities concerned, as well as among importing countries.

17. Ms. Christine von Weizsacker (ECOROPA) pointed out that many existing regulations and documentation systems were relevant to the implementation of paragraph 2 (a) of Article 18, but their current effectiveness was no indicator of their future usefulness. Any new agreement presented new aspects and the precautionary approach followed in the Biosafety Protocol called for more than a bare minimum of information. The Protocol needed a system geared to its own needs and not subordinate to other international agreements and, in her view, that meant stand-alone documentation. It would be no more difficult for port authorities to process stand-alone documentation than additions to existing documents such as invoices. The system had to be transparent and provide the means for public participation required by Article 23 of the Protocol. If information was incorporated into a commercial invoice, that would be detrimental to public information as invoices were often of a confidential nature. There needed to be clear and precise identification of LMOs-FFP in order to prevent general paralysis of implementation of the Protocol. She was concerned at the trend towards generalized use of "may contain" labels because they could negate all efforts to segregate LMO-free products and she underlined the need to document "serious intention of direct use" in the form of final-use certificates and/or a firm commitment to mill the LMOs either before or directly after entry into the country of import.

18. Following the presentations, comments were made and questions posed by the representatives of Australia, Bahamas, European Commission, Germany, Malaysia, the Netherlands, Uganda, and the Institute for Science in Society.

20. Responding to issues raised, Mr. Schumacher, said that a threshold represented a starting point and did not prevent Governments from imposing more stringent rules if they so wished. He did not agree that there was a trend towards indiscriminate use of "may contain" labels and pointed out that, if the information was included in the invoice, it would be available to all controlling authorities. He added that grain traders would not ship an event to a country that had not yet authorized it, but in order to have reliable information on authorized events the Biosafety Clearing-House needed to be effective. He explained that, in the case of transit shipments, the last exporter meant the exporter prior to the first transboundary movement.

3.2 Destined for contained use

21. Ms. Rosa Garcia Couto, United Nations Economic Commission for Europe, reviewed the existing systems under the United Nations Model Regulations on the Transport of Dangerous Goods, and explained the classification criteria, how dangerous goods were classified into various categories and

what packaging regulations applied to them on the basis of that classification. She mentioned the relevant class and documentation requirements for genetically modified micro-organisms and genetically modified organisms that were considered to be infectious substances, on the one hand, and those organisms which did not meet the definition of infectious substances but which were capable of causing harm to plants, animals and microbiological substances, on the other.

22. In response to a question concerning the liability and competence of carriers, she said that a carrier, by accepting a consignment, accepted responsibility and declared competence to carry dangerous goods. She also clarified that the United Nations did not have any system for the certification of carriers.

23. Ms. Marsha Stanton, Global Industry Coalition, said that the Coalition comprised 2,300 companies in 130 countries, and that its purpose was to provide input from its members to the Protocol discussions. She reviewed shipping documentation provisions for LMOs for contained use, and the voluntary guidance that the Coalition gave to its members. The majority of shipments for contained use were for research and development, mainly for health reasons. The Coalition had conducted a survey among its members and found that the existing language was working satisfactorily in identifying shipments of LMOs, in conjunction with other country-specific information. Shipments of Article 18 paragraph 2 (b) goods classified as dangerous were already regulated appropriately even in the absence of any Biosafety Protocol documentation requirements. In order to maintain the smooth movement of material, a simple, consistent and practical system was needed. The Coalition recommended that Parties clarify that the recommendations by the Expert Working Group for language on existing documentation should be used for shipping documentation or indicate that existing import rules applied. Furthermore, exporting countries should infer that existing approval for an LMO in the importing country meant that no further approval was required before shipping the LMO and a permit number for experimental use in the importing country indicated that no additional clearance was required.

24. At the conclusion of the presentations, comments were made by the representatives of Australia, Ethiopia, Slovenia and the United Nations Environment Programme (UNEP).

3.3 Intended for intentional introduction into the environment

25. Mr. Bertrand Dagallier, Organisation for Economic Co-operation and Development (OECD), highlighted the OECD Schemes for the Varietal Certification or the Control of Seed moving in International Trade (commonly known as the "OECD Seed Schemes"). He drew attention to the possible use of OECD Seed Certificates and Labels to satisfy the documentation requirements of the Protocol for genetically modified seeds. The OECD Seed Schemes were an official certification/information system for all seed in international trade. The Schemes were open to non-members of the organization and they covered 185 species with 52 participating countries. The advantages of membership were that it offered countries more trade opportunities and encouraged the development of domestic certification systems. Any country could buy OECD-certified seed. The OECD also had a Scheme for the Control of Forest Reproductive Material Moving in International Trade.

26. The basic principles underlying OECD Seed Certification Schemes were implemented by national authorities. The Scheme harmonized procedures for production and control through the seed multiplication chain, promoted high-quality seed multiplication, and facilitated international trade. It only applied to varieties that had been officially released. The latest issue of the OECD list comprised some 33,000 varieties eligible for certification, the majority of which were conventional although some were genetically modified. There were two identification requirements: certificates and labels. The former applied to a particular seed lot whereas the latter were affixed to each bag of the seed. The advantages of using OECD certificates and labels were that they constituted a "one-stop shop" for seeds, provided a traceable, quality product recognized at the international level as trustworthy, reliable, and easy to handle. The OECD had suggested some elements to be added to the OECD certificates and labels in order to satisfy the requirements of the Protocol and had received positive feedback, although one country and one organization had stated that they would prefer to use commercial invoices.

27. The choice left to Parties by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety between the use of commercial invoices, existing systems or possible stand-alone document was felt to be very good because it would cover the diversity of countries' seed sector: Parties would have first to decide on the use of "non-official" or "official" documents for transboundary movements of GM seed to satisfy the Protocol information requirements. Should the exporting or the importing country need official documents, the OECD Schemes could offer an efficient and low-cost solution in a number of cases.

28. Following the presentation, comments were made and questions posed by the participants from Barbados, Cameroon, Ethiopia, Germany, Kenya, Uganda, the United Republic of Tanzania, UNEP, EcoNexus, Greenpeace International, and the Third World Network.

29. In response to questions, Mr. Dagallier said that OECD certificates and labels had to be in one of the two official languages of the OECD, namely, English and French, although national authorities were free to add their own language. He clarified that the OECD schemes did not at present cover ornamental plants, fruit trees, or roots and tubers.

ITEM 4. NATIONAL AND REGIONAL EXPERIENCES IN IMPLEMENTING EXISTING DOCUMENTATION SYSTEMS AND CAPACITY NEEDS OF DEVELOPING COUNTRIES AND COUNTRIES WITH ECONOMIES IN TRANSITION

Africa

30. Mr. Chris Viljoen reviewed international regulations on labelling of GMOs and South Africa's legislation, consisting of the comprehensive GMO Act of 1997 and the draft GMO Amendment Bill of 2004 intended to incorporate the provisions of the Biosafety Protocol. He emphasized that LMO identification could not be seen in isolation. He shared the view that a comprehensive database on GMOs in the Biosafety Clearing-House was essential to permit accurate identification and labelling. Experience had shown that, when asked to test a product, a laboratory was often unable to obtain the necessary information, which might not be in the public domain. He drew attention to the disparity in the requirements imposed on domestic producers and those applicable to importers in terms of producing crops that were not genetically modified under an identity preservation system, which could mean that the former were subject to higher costs than the latter, leading to a price difference between domestic and imported products. One other issue that had to be considered was who would bear liability in transit countries.

31. Following the presentation, comments were made and questions raised by the participants from Canada, Ecuador, Mozambique, South Africa, and the African Centre for Biosafety.

32. Responding to questions, Mr. Viljoen said that South Africa required an environmental study to be carried out in South Africa for GMOs intended for environmental release, but that the environmental study for LMOs for food, feed or processing in another country could also be considered. He clarified that South Africa imposed mandatory labelling for products containing modified animal or human genes or allergens.

33. The representative of Uganda then indicated that many African countries were in the process of drafting their national biosafety frameworks and it was expected that, once developed, the frameworks would contain provisions regarding implementation of the requirements under paragraph 2 of Article 18 of the Protocol.

Asia/Pacific

34. Mr. S.R. Rao indicated that in many Asian countries, research and development was government rather than privately funded. India had had biosafety guidelines since 1989; no genetically modified seed was allowed directly for trade, and illegal entry was a punishable offence. He explained the different

steps in the approval procedure for GMOs and their products. In order to produce reliable and consistent results, testing and sampling methods worldwide should be standardized. GM labelling had to be precise, giving all necessary details, but it was important to remember that labelling was related to trade and thus to WTO issues. One other aspect to be borne in mind was cost: who would meet the cost of testing, which would inevitably increase the cost of a product? Transboundary problems were another issue when a neighbouring country had no strict regulations and contamination spread across the border. Scientific capacity in the developing world could be boosted through regional cooperation and dialogue could be initiated with existing regional organizations.

35. Mr. Masato Fukushima, Japan, explained the Japanese legislation relating to GMOs and which Ministries were competent. Exporters that shipped LMOs for direct use for food, feed or processing were required to affix the "may contain" language and to indicate that the LMOs were not intended for intentional introduction into the environment, together with the contact point for further information on the form prescribed in the Japanese regulations, on packages or invoices. Regarding the detailed requirements referred to in the second sentence of paragraph 2 of Article 18, for LMOs-FFP, which were separated and exported as LMO cargo, Japan recommended that the OECD unique identifier be used. In the case of LMOs-FFP whether separated or not, the "may contain" language had to be used if there was a possibility of co-mingling. The Biosafety Clearing-House was the appropriate forum for information on LMOs that could be co-mingled and should be expanded to include commercial cultivation of LMOs. For LMOs-FFP, which were separated and exported as non-LMO cargo, however, the documentation was not necessary when the degree of co-mingling met the acceptable levels determined independently by the importing Party. He added that Japan would not accept any threshold for unapproved LMOs.

36. At the conclusion of the presentation, comments were made by the participants from Barbados, Canada, the Philippines, Switzerland, ECOROPA, and the Institute for Integrated Rural Development.

Latin America and the Caribbean

37. Ms. Alejandra Sarquis described the Argentine situation and said that 60 per cent of Argentina's export earnings were derived from agrifood products. The majority of its corn and soybean crops was genetically modified. In order to maintain its position as an exporter, the regulations imposed by importers were important to Argentina. An evaluation of corn and soybean chains had been conducted with a view to segregation and to developing options for the production, marketing and export of LMO and non-LMO corn and soybean segregated products in accordance with the provisions of the Biosafety Protocol and the national regulations of the main importing countries. Segregation had a cost, however, both in financial terms and in terms of infrastructure and training. The evaluation had estimated costs taking into account threshold levels.

38. Mr. Luis Guilherme Parga Cintra, Brazil, outlined the status of the biosafety regulations in his country.

39. Comments were made by the participant from Ecuador.

North America

40. Mr. Robert Carberry highlighted the cornerstones of the regulatory system in Canada, adding that Canada had many years of experience in regulating LMOs. The regulatory framework was product-based. The primary trigger for assessment was the novelty of the product rather than the specific means by which it was produced. The regulatory framework built on the pre-existing system and no LMO-specific legislation had been developed. There were prerequisites and options to managing the potential risk of LMOs to the environment and decisions had to be taken well in advance of the first transhipment. Canada's focus had been on pre-approving products for import, long in advance of the first transboundary shipment, moving the import decision away from the dock. Canada therefore used a system approach and not a transaction approach. Consequently, Canada did not require LMO-specific documentation for imports of agricultural commodities. The focus of Canada's regulatory approach was

science-based. While zero risk was impossible to achieve, risk-mitigation measures could be used to minimize it. Before regulations were implemented, the focus should be on the desired outcome and the policy objectives, and systems for public participation needed to be developed with simplified and transparent procedures. Once the regulations had been adopted, it was necessary to ensure compliance.

41. Following the presentation, questions were raised and comments made by the participants from Barbados, Canada, Germany, Switzerland, the United Nations Environment Programme (UNEP), the Deccan Development Society, EcoNexus, Greenpeace International, Grupo de Estudios Ambientales, and the Institute of Science in Society.

42. In response to the questions, Mr. Carberry stated that Canada had no science-based threshold. The up-to-5-per-cent threshold mentioned in the trilateral arrangement among Canada, Mexico and the United States of America was strictly used to define non-LMO shipments for purposes of documentation requirements under contractual arrangement between a buyer and a seller and that that commercial threshold did not supplant the domestic import regulations nor sanction the movement of unapproved events. Mr. Carberry also mentioned that, under the North American Biotech Initiative, Canadian, Mexican and United States biosafety regulators maintained ongoing scientific and technical information exchange.

European Union

43. Mr. Nicola Notaro, European Commission, described the European Union's legislative framework on GMOs, developed during the 1990s. Regulation 1946/2003, adopted subsequently, concerned the export of GMOs and had been specifically developed to meet commitments under the Protocol. For all GMOs, the documentation requirements did not include the "may contain" language but it must be mentioned that the shipment "contains or consists of GMOs". Additional requirements applied to LMOs-FFP, to LMOs for contained use and for deliberate release mirroring the language of the Protocol and decisions of the meeting of the Conference of the Parties serving as the Parties to the Cartagena Protocol on Biosafety. The EU also had a regulation on traceability and labelling. A threshold of 0.9 per cent for LMOs-FFP was applied for adventitious or technically unavoidable presence. Technical guidance had been developed for sampling and testing and detection methods to be validated at the Community level.

44. After the presentation, comments were made and questions raised by the representatives of Australia, Canada, Ecuador, Republic of Korea, Togo, the United States of America, ECOROPA, the International Grain Trade Coalition, and UBINIG.

45. Mr. Notaro, responding to questions, said that the reason why the European Union had used the term "GMOs" rather than "LMOs" was that European regulations predated the Biosafety Protocol and, in any case, the European Union considered that the two terms were equivalent. Moreover, it was felt that the words "may contain" were not useful and, in addition, the Protocol allowed Parties to impose stronger measures. The threshold of 0.9 per cent had been deemed appropriate as absolute purity was impossible to achieve, but the tolerance was zero for any unapproved GMOs with one temporary exception of 0.5 per cent for some products that had already received a favourable assessment. Regarding whether or not the traceability requirement could be considered a type of risk management, he agreed that it was possible in the broadest sense and that the primary factor had been to protect consumers. Experience with implementing the regulations was not very extensive as they had only been in effect since April 2004, but they would be the subject of regular reports. All the new members of the European Union were committed to applying the regulations in the same way as all existing EU legislation.

Others

46. The participants from the Bahamas, Norway and Switzerland then explained briefly the regulatory framework in their respective countries.

47. The participant from Togo requested that the Workshop consider recommending that regional action be taken in Africa on LMOs and urged the Secretariat to assist by financing the holding of a regional Workshop of experts to discuss problems that were particularly relevant to Africa. He also informed the Workshop that he had circulated a paper on the national experience of the Republic of Togo in the implementation of the Cartagena Protocol on Biosafety.

48. In response, the representative of the Secretariat said that such a workshop could only be convened if it had been so decided by the meeting of the Conference of the Parties serving as the Parties to the Cartagena Protocol on Biosafety and budgetary provision had been made. Nevertheless, if some donors were prepared to finance the workshop, it would be given consideration.

49. She also noted that many representatives had referred to the need for a fully functional Biosafety Clearing-House. In that regard, she emphasized that the infrastructure and modalities existed for a fully operational and functional Biosafety Clearing-House but the information to be found therein had to be provided by Governments and she urged them to make it available either through the Central Portal of the Biosafety Clearing-House or through their own databases interoperable with the Biosafety Clearing-House.

50. One participant asked whether there was a time-frame for supplying information to the Biosafety Clearing-House and another representative underlined the critical importance of information for implementation of the Protocol. One representative also suggested that, in preparation for the meeting of the Open-ended Technical Expert Group in 2005, the Secretariat compile information on the cost implications of implementing the Biosafety Protocol documentation requirements provided in paragraph 2 of Article 18.

51. In reply, the representative of the Secretariat pointed out that certain time-frames for providing information to the Biosafety Clearing-House were to be found in the Protocol itself and failure to fulfil those requirements would mean that a country was in non-compliance. In addition, consideration was being given to establishing time-frames in the longer-term programme of work for the Biosafety Clearing-House for consideration by the meeting of the Conference of the Parties serving as the Parties to the Cartagena Protocol on Biosafety.

ITEM 5. THE USE OF UNIQUE IDENTIFIERS IN DOCUMENTATION ACCOMPANYING LIVING MODIFIED ORGANISMS

52. Mr. Masahiro Miyazako, Organisation for Economic Co-operation and Development (OECD), said that the purpose of a unique identifier was to ensure that there was no confusion in links between national or international databases providing information on products approved for commercial use. It constituted a key to accessing information in the OECD product database and interoperable systems for the products of modern biotechnology approved for commercial application. A unique identifier should be simple, should not require a centralized authority for implementation, and should be based around a transformation event. After explaining the significance of the digits composing the identifier, he said that it had been designed so that it could be used by developers of products and transmitted to national authorities when seeking commercial approval. Unique identifiers had been assigned for the majority of approved products. They could all be found on the OECD product database and had been sent to the Biosafety Clearing-House through the interoperable system. At its first meeting serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, the Conference of the Parties had encouraged OECD to develop a unique identification system for micro-organisms and animals. The Working Group for the Harmonisation of Regulatory Oversight in Biotechnology had had a preliminary discussion on whether the system for plants could be applied to micro-organisms or whether other systems existed. It would subsequently consider the question of animals.

53. Following the presentation, comments were made and questions raised by the participants from Australia, Bangladesh, the European Commission, India, the United Nations Environment Programme (UNEP), the International Grain Trade Coalition (IGTC), and EcoNexus.

54. The participant from Switzerland informed participants that the register of unique identifiers was also available in the Biosafety Clearing-House and it was not necessary to go through the OECD site.

55. The participant from the European Commission pointed out that the European Union had decided that it would apply the OECD unique identifier for micro-organisms.

56. In response to questions, Mr. Miyazako said that it had been agreed that, for practical reasons, unique identifiers should be based or established around transformation events. Varieties could be registered through another scheme. In principle, a unique identifier had to be attached to all products approved for commercialization. With regard to the inclusion of local names, it was a matter of seeing whether the Biosafety Clearing-House included local names or not. Regarding capacity-building, OECD was willing to give further information on unique identifiers at workshops provided that the necessary resources were available.

ITEM 6. OTHER ISSUES RELEVANT TO DOCUMENTATION/IDENTIFICATION OF LIVING MODIFIED ORGANISMS

57. Ms. Maddalena Querci, European Commission Joint Research Centre, said that the Centre provided scientific support to the European Commission for decision-making. It involved laboratories throughout the European Union as well as in Norway and Switzerland. She explained how the GMO laboratories assisted compliance with European Union legislation through GMO detection, identification and quantification. The availability of an event-specific method validated by the Community Reference Laboratory (CRL) was a prerequisite for approval of a GMO in Europe. One important factor in testing was sampling and she described various types of sampling methods. The European Commission had developed a recommendation on a sampling protocol involving a three-step procedure, which should come into effect in the near future. The Joint Research Centre also had training activities such as joint JRC-WHO training courses, with participants from outside the European Union, manuals and a web page.

58. Mr. Chris Viljoen said that there were two broad types of LMO detection methods, namely, transgenic protein detection and transgenic DNA detection, and described how they both worked. He drew attention to the importance of sampling, DNA extraction and the polymerase chain reaction (PCR) method. As it was impossible to achieve zero tolerance within a GM environment, quantitative GM determination would play an important role in determining whether an LMO exceeded a given threshold. While effective techniques existed to detect GMOs, care had to be taken in respect of method verification, the implementation of a laboratory quality system, the use of controls, sampling methods and the method limits of detection and limits of quantification. Additional considerations included sample inhibition and contamination. Countries that did not yet have detection systems should try to use methodology already developed rather than developing their own, which was extremely costly.

59. Following the presentations, comments were made and questions raised by the participants from Australia, Barbados, Brazil, Costa Rica, Ecuador, Ghana, India, Mali, United Republic of Tanzania, United States of America, ASPTA, Deccan Development Society, ECOROPA, International Grain Trade Coalition, and UBINIG.

60. In reply to questions, Ms. Querci said that disputes over results usually related to discrepancy, hence the importance of using validated methods in competent laboratories. It should be borne in mind that no result below the detection level could be deemed reliable.

61. Mr. Viljoen, responding to questions, explained that strip tests were not available for all events, but for the most commonly available LMOs. Testing could be used to verify quality traits, as well as determine the presence of LMOs, not only for the purposes of biosafety. In some cases, reference materials could be useful, while in others, copy number standards would be preferable. Both were equally valid and had their advantages and disadvantages. His facility provided training on an ad hoc basis but did not have any formal programmes. Event-specific information could be obtained through patent applications and requests for information provided with risk assessments, but varietal specific information was more difficult to obtain. Concerning the strip-test method, it only took approximately 20

minutes to perform and there was no more rapid method at present. It was emphasized that the term "non-GM" should be used in a GM environment to indicate that the GM content was below the limit of detection or a predetermined threshold and that the term "GM-free" was inappropriate under such conditions.

ITEM 7. GENERAL DISCUSSION AND CONCLUSIONS

62. In light of the presentations made by the resource persons, the presentations on national and regional experiences in the implementation of paragraph 2 of Article 18, and the discussions and exchange of views that followed the presentations, the following observations were made by participants of the workshop:

(a) Participants found the Workshop to be a useful forum for the exchange of information and experiences on the implementation of paragraph 2 of Article 18, as intended by the decision of the first meeting of the Conference of the Parties serving as the Parties to the Cartagena Protocol on Biosafety. In particular, the presentations by resource persons were found to be informative on various issues related to the effective implementation of paragraph 2 of Article 18;

(b) The participants emphasized the importance of the Biosafety Clearing-House (BCH) in the implementation of paragraph 2 of Article 18 and the need for governments to make available to the BCH the information required by the Protocol in a timely manner;

(c) It was also recognized that, for appropriate implementation of the documentation requirements under paragraph 2 of Article 18, there was a need for continuous capacity-building activities for developing countries, in particular the least developed and small island developing States amongst them, and countries with economies in transition. In that regard, the following areas were highlighted as requiring capacity-building for the appropriate implementation of the documentation requirements of the Biosafety Protocol: provision of and access to information in the BCH; scientific and technical capacities for testing and detection of LMOs; handling and understanding the information provided on the documentation accompanying transboundary movements of LMOs.

ITEM 8. OTHER MATTERS

63. No matters were raised under agenda item 8.

ITEM 9. ADOPTION OF THE REPORT

64. The Rapporteur presented the draft report of the Workshop (UNEP/CBD/BS/WS-CB-HTPI/1/L.1 and Add.1) at its 6th meeting, on 3 November 2004. The draft report, as orally amended, was adopted.

65. It was agreed that the Rapporteur, with the assistance of the Chair, the Vice-Chair and the Secretariat, would be entrusted with the finalization of the last part of the proceedings.

ITEM 10. CLOSURE OF THE MEETING

66. Following an exchange of courtesies, the Chair declared the Workshop closed at 4.30 p.m. on Wednesday, 3 November 2004.
