CBD

UNEP

Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/4/9
7 April 2008

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITYY
SERVING AS THE MEETING OF THE PARTIES TO
THE CARTAGENA PROTOCOL ON BIOSAFETY
Fourth meeting
Bonn, 12 -16 May 2008
Item 10 of the provisional agenda*

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

Synthesis of information on experience gained with the use of sampling of living modified organisms and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques (Paragraph 2(a) of Article 18)

Note by the Executive Secretary

I. INTRODUCTION

1. Paragraph 2(a) of Article 18 of the Biosafety Protocol requires each Party to take measures to require that documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment. It also requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to take a decision on the detailed requirements for this purpose, including specification of the identity of living modified organisms and any unique identification. Decision BS-III/10 from the third Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) 1/ includes these detailed requirements.

2. In paragraph 11 of decision BS-III/10, the COP-MOP requested Parties and invited other Governments, regional and international organizations and interested stakeholders to submit to the Executive Secretary information on experience gained with the use of sampling of living modified organisms and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques. The Executive Secretary was also requested to compile the information received and to prepare a synthesis report for the consideration of the fourth COP-MOP.

* UNEP/CBD/BS/COP-MOP/4/1.

1/ See annex II for a list of all acronyms used in this document.

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3. The Executive Secretary had received fifteen submissions by 12 February 2008. These consisted of eleven submissions from the following Parties: Armenia, China, Colombia, the European Community, 1/ Germany, Italy, Mexico, New Zealand, Norway, Slovenia and South Africa; two submissions from other Governments, namely Canada and the United States; and two submissions from international organizations, namely the Codex Alimentarius Commission and the Global Industry Coalition (GIC). A compilation of the information received has been prepared as document UNEP/CBD/BS/COP-MOP/INF/2. The document below contains the requested synthesis in section II and elements of a draft decision for consideration by the fourth meeting of the Parties to the Protocol in section III.

II. SYNTHESIS OF INFORMATION ON EXPERIENCE GAINED WITH THE USE OF SAMPLING OF LIVING MODIFIED ORGANISMS AND DETECTION TECHNIQUES AND ON THE NEED FOR AND MODALITIES OF DEVELOPING CRITERIA FOR ACCEPTABILITY OF, AND HARMONIZING, SAMPLING AND DETECTION TECHNIQUES (Paragraph 2(a), Article 18)

4. The synthesis of information received is presented below according to a number of themes that were common across many of the submissions. It should also be pointed out that a number of the submissions included at least some information that did not deal directly with sampling and detection techniques of living modified organisms (LMOs) intended for direct use as food or feed, or for processing but covered closely related aspects. Given the relevance of these experiences, the information from these submissions has been included in this synthesis.

A. Objectives of sampling and detection

5. The European Community stated that the driving force behind its detection activities has been the introduction of food and feed labelling regulations that are aimed at ensuring freedom of choice for consumers.

6. Mexico has established a monitoring system of genetically modified organisms (GMOs) in products for human consumption with the following objectives:

- Determining the proportions of shipments that come into the country that contain GMOs destined for human consumption;
- Determining the specific events contained in such shipments; and
- Detecting the presence of unauthorized GMOs in order to protect public health in compliance with the country's biosafety law.

7. The submission from New Zealand stated that the purpose of its testing regime is to ensure that genetically modified (GM) seeds that have not been approved for release into the Party's environment are not inadvertently imported in consignments of seeds for sowing and then commercially planted. Currently, New Zealand has not received any applications nor issued any approvals to release GM crops into the environment or for commercial planting and so all shipments tested are intended to be non-GM.

8. Norway explained that it has gained experience with the use of sampling and detection techniques in order to verify that imported food and feed do not contain LMOs that are not allowed in

1/ The submission from the European Community was in the form of an interactive document with embedded links to websites and other materials. As well as being made available in the compilation of submission, a record with the entire document and its links has been added to the Biosafety Clearing-House at the following location: http://bch.cbd.int/database/record.shtml?id=43770.

Norway and that any content of LMO approved in the European Union (EU) does not exceed the threshold of 0.9 per cent and is adventitious or technically unavoidable.

B. Scope of sampling activities

9. Mexico submitted that while it has approved the release for commercialization of 47 transformation events, not all of these events are included in its sampling activities. The events that are not included are generally those where the products of the GMOs do not contain traces of DNA but only of proteins, where the events are no longer on the market or where the organisms are primarily used to feed animals. Events that are included in its sampling activities include those used extensively for human consumption in Mexico either directly or as the basis of other foods, events that may not have been approved in Mexico but have been approved in countries that export the organism to Mexico, and events that may not have been approved in any country but for which there have been cases of contamination in commercial crops.

10. The submission from New Zealand stated that it does not routinely sample and test for living modified organisms in shipments for food, feed or processing. The Party does, however, have an extensive pre-border testing regime for all imports of seeds for sowing in New Zealand that have genetically modified varieties grown commercially overseas.

11. Slovenia reported that it has been performing tests of GMOs in food, feed and seeds since 2002. Its National Institute of Biology performs analyses for official control in food, feed and seed samples received from the responsible inspection services – approximately 200 samples are tested per year. The results of monitoring are published on the internet site of the Slovenian biosafety portal. 2/

12. Canada stated that it does not require the mandatory testing of seed, food, feed or commodities for the presence of LMOs. Canadian regulatory departments and agencies do, however, have a compliance and enforcement mandate as well as the capability for the sampling and detection of seed, novel foods, feeds and commodities, including LMOs.

C. Sampling protocol

13. Germany explained that the *Länder* ministries responsible for food, feed and seed controls define specific surveillance activities and monitoring plans for how the regional food and veterinary offices in the cities and rural districts conduct random checks for the presence of GMOs and examinations of the respective labelling provisions. Regional food inspectors take random samples during on-site inspections at producers or traders and then send them to the responsible *Länder* control laboratory for GMO analysis. Besides control of documentation, samples are taken from food, feed and seeds and analyzed for GMOs at all relevant stages along the production chain. About 6,000 food, 600 feed and more than 700 seed samples were analyzed in 2004 and 2005.

14. Germany stated that practice-oriented guidance for sampling and analysis of food products are covered by two recent documents of an expert working group of food chemists. In general, food sampling is done in accordance with Recommendation 2004/787/EC of the European Community and the technical specification CEN TS15568:2007. For feed, sampling was said to be currently conducted according to the German Feed Sampling and Analysis Regulation, which transposes European Commission Directive 76/371/EEC 3/ and further sampling directives. A sampling plan adapted to the requirements needed for GMO testing and harmonized with the sampling plan used for food products is in preparation. The

2/ See http://www.biotechnology-gmo.gov.si/eng/index.html.

3/ First Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feeding stuffs.

detection methods listed above for the analysis of food products are also used for the analysis of feed products.

15. In Mexico, the *Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* (SAGARPA, the Secretary of Agriculture, Ranching, Rural Development, Fisheries and Food) has established a protocol, which describes sampling techniques applied to genetically modified organisms. These sampling techniques do not differ essentially from those applied to any other group of organisms. Mexico stated that the taking and sending of the sample would be coordinated by the Committee on Sanitary Operations, which has agents at the Party's borders. The procedure for the sampling and reference laboratory would be developed according to the Party's "Procedures Manual for the Sampling and Handling of Grain". The number of samples to be taken for each of the products included in the sampling activities would be fixed by the Party on an annual basis based on statistical information on the imports of these products.

16. The submission from New Zealand noted that the country collects a sample of 3,200 seeds from a seed lot and that its sampling procedure is designed to collect a representative sample from the seed lot. New Zealand reported now using the freely available software 'SeedCalc' from the International Seed Testing Association (ISTA) to develop its sampling plan.

17. According to the Slovenian submission, this tool can be used to design sampling and testing plans for purity/impurity estimates of seed lots for the adventitious presence/absence or levels of genetically modified seeds in conventional seed lots. 4/

18. Norway stated that the Norwegian food safety authority Mattilsynet takes up to 100 samples from food products and 110 samples from feed products for analysis every year. Norway has adopted different sampling methods for food versus feed products and also between packaged and bulk or other large consignments of products. Norway stated that its method of sampling from bulk or other large consignments of food products is based on European Commission Directive 98/53/EC, 5/ which lays down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs and the guideline for aflatoxin. Each sample of a food product for import is divided into three: one part is left at the business where the sample is taken; one is sent to the Norwegian Veterinary Institute for analysis; and the last part is kept at the local branch of the Norwegian food safety authority that took the sample.

19. According to Norway, the size of the sample taken from packaged products or small consignments depends on the type of product. For soy seeds/kernels, the size of the sample should be a minimum of 1,000 grams. For corn seeds/kernels, the size of the sample should be a minimum of 1,700 grams. The size of the sample taken from other products should be a minimum of 1,000 grams. These sample sizes are necessary in order to achieve a detection level of 0.1 per cent and a level of quantification of 0.9 per cent. These levels are set in order to detect the lowest possible amount of LMO presence, which in turn, is intended to avoid the import of LMOs not permitted in Norway and LMO presence above the limit for LMO labelling in Norwegian legislation.

20. The Norwegian method of sampling from bulk or other large consignments of *feed* products follows the European Commission instruction pursuant to Directive 76/371/EEC. Samples are taken in connection with import either by the Norwegian food safety authority or in cooperation with Norwegian Cargosurvey. Samples are taken from all shipments of soy, corn or rape seed from countries outside the European Community and from every fourth shipment from within the European Community.

4/ The programme can be downloaded for free from the ISTA web site, http://www.seedtest.org/en/home.html.

5/ Commission Directive 98/53/EC of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs.

21. Given the differences of sampling methods applied to food and feed, the Norwegian food safety authority intends during 2008 to harmonize its sampling method and to develop a protocol based on recommendations given by European Commission Recommendation 2004/787/EC 6/ of 4 October 2004 on technical guidance for sampling and detection.

22. Slovenia described seed sampling as the first substantial part of seed quality control, beginning from drawing the primary samples from the seed lot in the warehouse to obtaining the representative working sample of a suitable size for the appropriate seed test. Test results are expected to reflect the average quality of the seed lot; therefore accuracy in sampling is of fundamental importance. Incorrect sampling may lead to misleading test results, discarding seed lots of high quality, or to the approval of seed lots of low quality, which may reduce crop yield or even result in complete failure.

23. According to Slovenia, the European Commission Recommendation 2004/787/EC states that the "general principles and methods of sampling seeds and other plant propagating material should be in accordance with the ISTA rules and the associated ISTA Handbook on Seed Sampling". These documents contain methods for how samples should be taken and prepared in order to report accurate, representative and uniform test results on an ISTA certificate. GMOs are not specifically addressed.

24. The United States of America reported that its Department of Agriculture (USDA) has established sampling methodology that has been used for the sampling of bulk grain in international commerce for many years.

D. Institution responsible for analysis of samples

25. Colombia reported that as a result of the implementation of the Global Environment Facility (GEF)-World Bank project "Capacity Building in Colombia to Implement the Cartagena Protocol", the country created the Central Institutional Laboratory for the detection and monitoring of genetically modified organisms, which is part of the country's three national competent authorities dealing with GMO biosafety. The objectives of the laboratory are to develop and implement the procedures and techniques for the detection and monitoring of LMOs including raw and processed materials in accordance with the powers of each sector (human health, environment and agriculture), as well as the design and implementation of plans to do sampling techniques on different types of LMOs including raw and processed materials, according to the field of competence of the parties involved (human health, environment and agriculture).

26. Italy reported that its ministry of health is the competent authority for the implementation of Regulations (EC) 1829/2003 and 1830/2003. 7/ Furthermore, the control of commercialized GMOs is implemented through a system with services in the different regions of the country and in central bodies. The control system is implemented in strict cooperation with the Community Reference Laboratory, which acts with the assistance of the European Network of GMO Laboratories (ENGL). In Italy, national reference laboratories in the framework of the Commission Regulation (EC) 1981/2006 8/ are the *Istituto Superiore di Sanità* (ISS, the Italian national health institute), the *Istituto Zooprofilattico Sperimentale*

6/ Commission Recommendation of 4 October 2004 (2004/787/EC) on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003.

7/ Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed; and Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

8/ Commission Regulation (EC) No. 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms.

Lazio e Toscana (IZSLT, the Lazio and Tuscany regional institute for animal prophylaxis and research) and *Ente Nazionle Sementi Elette* (ENSE, the Italian national agency for certified seeds) while in the framework of Regulation (EC) 882/2004, 9/ the national reference laboratories are ISS and IZSLT.

27. Italy stated that the IZSLT national reference centre for GMO analysis assists the ministry of health in the collection and analysis of data and results related to the national official control of GMOs in food and feed. The reference centre is developing an internet-accessible database that would facilitate data input, output and elaboration while assuring consistence, completeness and confidentiality of information.

28. Mexico stated that with the support of the GEF, the United Nations Development Program (UNDP) and the *Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados* (CIBIOGEM, the inter-ministerial commission on the biosafety of genetically modified organisms), it has created and/or strengthened three laboratories for the detection of GM material. Regarding analytical techniques, the *Comisión Federal para la Protección contra Riesgos Sanitarios* (COFEPRIS, the federal commission for the protection against sanitary risks) has a project under UNDP with the objective of establishing methodologies for developing a monitoring system and monitoring the presence of transgenic sequences in grain and corn products in Mexico and then transferring the most appropriate methods to the national laboratories at the ministry of health.

29. In Norway, analyses of the samples are conducted by the Norwegian Veterinary Institute (a governmental agency.)

30. Slovenia reported that the National Institute of Biology (NIB), Department of Biotechnology and Systems Biology has been in charge of GMO detection since 2000. In 2006, the NIB was nominated as the Slovenian national reference laboratory in accordance with Regulation (EC) 882/2004.

E. Inspection and detection methods

31. China stated that its government authorities have established a series of standards and guidelines for sampling and detection. The General Administration of Quality Supervision, Inspection and Quarantine has established "sampling and detection methods of transgenic materials in plant and its products" and other detection methods on transgenic materials in different crops. These have been incorporated into the quality detection of imported agricultural products. The ministry of agriculture has also promulgated a series of detection methods on genetically modified crops to improve the biosafety management of domestic transgenic crops.

32. Colombia stated that its Central Institutional Laboratory uses standardized methodologies for DNA-based detection of GMOs, the same reference methods employed by the Community Reference Laboratory of the European Commission, employing both conventional polymerase chain reaction (PCR) (qualitative) and real-time PCR (quantitative). Progress has been made in the screening methodologies to identify promoters and terminators most commonly used in GMOs.

33. According to Colombia, by employing these methodologies, the *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (INVIMA, akin to a food and drug administration) has proposed projects to assess the presence of different transformation events of corn through the sampling of cargo arriving at ports and to conduct an assessment of processed foods on the market. This is aimed at determining how easy it is to recover DNA from these products, identify whether or not they have been produced from GMOs, standardize the sampling protocol and validate detection techniques. Additionally, Colombia is

9/ Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

planning to implement qualitative methods for protein detection at ports in view of the fact that these tests are easy and quick to use, allowing a pre-selection of the lots that should be sent for analysis to the Central Institutional Laboratory for subsequent quantitative analysis.

34. The submission from the European Community stated that there are two classical approaches used to detect GMO compounds in crops and derived products: the detection of the new transgenic DNA that was inserted into the organism, or of the new protein or proteins prompted by the transgenic DNA. For the first approach, PCR is used to detect novel DNA sequences present in the genome of a crop. The method indicates the absence or presence of GMO-specific DNA in a given sample. The determination of a specific GMO in a sample allows the segregation of its source and the identification of unapproved GMOs on the market. Traceability thereby becomes possible throughout the supply chain of GM crops. For the second detection approach, enzyme-linked immunosorbent assay (ELISA) uses antibodies that specifically bind to the new protein compounds of GMOs.

35. According to the European Community's submission, DNA detection has been the standard method used in the European Union to determine the identity and amount of GMOs in a tested product. It is explained that the reasons for the dominance of this method include the comparatively high sensitivity of PCR-based detection methods and the inability of protein-based approaches to discriminate between varying GMOs that express the same or similar proteins. Furthermore, industrial processing is said to easily denature proteins and impede the use of ELISA methods for food products.

36. It is stated that qualitative detection methods can be used for the initial screening of food and feed products. Initially, the goal is to investigate whether GMO-specific compounds such as DNA elements and/or proteins are present in a particular product. If the presence and identity of GMOs in a sample has been determined, a subsequent quantitative test must be executed in order to determine whether the GMO content in a food or feed sample complies with the EU labelling provisions. Only PCR-based methods are able to fulfil the legal requirement regarding qualitative analysis in the Commission Recommendation 2004/787/EC of 4 October 2004.

37. The European Community submission stated, though, that the ELISA test can be a useful, cost-effective and quick approach to the detection of GMOs, at least in raw products and in the field. The submission reported on a number of research projects of the Joint Research Centre to explore the potential of protein-based detection methods.

38. The submission also described the use of biochips or micro-arrays. It is stated that micro-arrays based on DNA hybridization are the most recent tools to be developed and validated in the EU for the detection of GMOs. Such micro-arrays respond to a need for screening tools that allow the simultaneous detection of different GMOs in a sample in one step.

39. The European Community also commented on the validation and harmonization of GMO detection methods in the EU. The EU has a centralized validation procedure to validate and harmonize GMO detection methods within EU Member States and beyond. There are four institutions and networks that are mainly responsible for this work:

- The Community Reference Laboratory on Genetically Modified Food and Feed (CRL-GMFF);
- The European Network of GMO Laboratories (ENGL);
- The Institute for Reference Materials and Measurements (IRMM); and
- The European Committee for Standardization (CEN).

40. The Joint Research Centre has been appointed as the Community Reference Laboratory for Genetically Modified Food and Feed.. Under Regulation (EC) No. 1829/2003, the CRL-GMFF has the mandate to validate analytical methods for the detection of GMOs in food and feed. This same regulation

establishes that biotechnology companies must develop specific detection methods for GMOs. Applicants must provide these detection methods to the CRL-GMFF for validation as part of the application dossier. Detection methods are tested by CRL-GMFF for their 'fitness of purpose' and subsequently are validated by collaborative trials at the expense of the biotechnology company. A CRL-GMFF document sets out specific performance criteria. Failure to meet these criteria leads to rejection of the method and, consequently, to a delay in the authorization of the GMO.

41. The methods are also published on the CRL-GMFF website, facilitating their use by private detection laboratories and official control laboratories. Moreover, the methods are proposed for standardization in CEN and the International Organization for Standardization (ISO).

42. ENGL was established in 2002 as a consortium of national enforcement laboratories. The network supports CRL-GMFF in evaluating new analytical methods and is coordinated by the Joint Research Centre's Biotechnology and GMO Unit. The twin goals of the network are the international harmonization of analytical approaches and the solution of the many technical and analytical problems faced by enforcement laboratories in addressing GMOs in food and the environment. The network currently consists of members from more than 120 laboratories representing all 27 EU Member States as well as Norway and Switzerland. In addition, laboratories from other countries such as China and Turkey participate as observers.

43. IRMM supports ENGL by providing certified reference materials and by delivering advice on their correct use. Such certified reference materials are said to be necessary for reliable calibration and quality control of the quantification methods applied. The submission stated that certified reference material is available for every approved GMO in the European food and feed chains.

44. The description of responsible bodies and supporting networks for validation and harmonization of GMO detection methods in the EU as contained in the submission from the European Community concludes with a discussion of the European Committee for Standardization. Standardization efforts are discussed in more detail in annex I, below.

45. Germany noted that its experts on sampling and detection are interlinked in working groups, which are coordinated by the German Federal Office of Consumer Protection and Food Safety. These working groups have developed several detection methods, which have been validated in ring trials. These methods are published in an official method collection according to German food and feed law (§ 64 LFGB) or German genetic engineering law. Germany has also adopted several methods from relevant ISO standards (ISO 21569, ISO 21570, ISO 21571.) 10/

46. Germany outlined its detection procedures for food and feed products and for seeds. For food products, Germany stated that detection methods used in the laboratories are based on the protocols published in the German official method collection, in the ISO standards 21569, 21570 and 21571 or are available on the website of the CRL-GMFF of the EU. The way feed products in Germany are analyzed for GMO content has been comprehensively summarized in a practice-oriented guidance document of another working group. To assure a practice-oriented implementation of seed inspections, a German *Länder* working group on genetic engineering has elaborated two guidance documents describing detailed plots for a harmonized strategy of sampling and analysis of control samples. Germany reported consistently positive experiences from the use of these guidelines.

47. Italy noted that the ministry of health in collaboration with the ISS and Mycotoxins Unit and the IZSLT national reference centre for GMO analysis have put forward participation in the European Network of GMO laboratories for the tasks outlined in the annex of Regulation (EC) 1829/2003, mainly

10/ See annex I for the full titles of these ISO standards and others referenced elsewhere in this document.

in the testing and validation of methods for sampling, detection, identification and quantification of GMOs.

48. Mexico intends to look at the number of samples using a statistical random sampling. Until the Party has statistical information on the prevalence of transgenic events in shipments of imports, it is using a prevalence of 50 per cent, a limit of error of 1.5 per cent and a standard deviation of 10. The samples will be sent to the laboratory of public health of the State of Veracruz for analysis of the specific event and the results will be forwarded to COFEPRIS for analysis and decision-making.

49. Mexico stated that the laboratory of molecular biology of the *Dirección General del Centro Nactional de Investigación y Capacitación Ambiental* (DGCENICA, the directorate general of the national centre for environmental research and training) routinely uses end-point PCR amplification as its detection method to identify events with event specific markers. For each analysis, they use certified reference materials and positive and negative controls that provide evidence that the tests have been properly performed. Since 2002, DGCENICA has accredited 30 analytical tests and since 2005, this accreditation includes those tests developed in its own laboratory. DGCENICA is the only institution authorized at the national level to grant such accreditation. Currently, they are in the process of accreditation of real-time PCR tests for the identification and quantification of cotton events, which have been released for field trials in Mexico using reference materials provided by the developers of these events.

50. According to Mexico, the results generated in the DGCENICA are also backed by an international certification granted by the alliance of laboratories of Genetic ID. The laboratory is also in the process of joining the ring of USDA laboratories. Mexico held its first forum for detecting GMOs in September 2007 and its first monitoring workshop in November 2007 with the aim of harmonizing methodologies at the national level.

51. Mexico considers it extremely important to have certified laboratories capable of analyzing samples for detection of LMOs with quality controls sufficient to ensure the quality of the results obtained. It is also important to have reference materials and protocols to facilitate the development of these methodologies and also to generate opportunities for technical discussions to improve the protocols and identify their limitations.

52. New Zealand's sampling and detection protocol requires a high level of confidence (95 per cent) that one GM seed in 1,000 seeds will be detected. The Party's submission stated that the confidence level was selected after considering best agricultural practice in producing seeds, the ability to test to this level and the Party's need to continue to access new varieties of seed. The sampling procedure is based on methodologies developed by the ISTA and the Grain Inspection, Packers and Stockyards Administration (GIPSA) of the USDA.

53. New Zealand's testing is done by government-approved laboratories using validated qualitative PCR to determine the presence or absence of specific GM sequences in seed material. The test is not designed to indicate the concentration of GM seeds in a seed lot nor the specific type of modification that has been made as seed lots that test positive for GM seeds are not allowed to be imported into the Party. ISO standards may also form the basis for testing procedures and methodology. New Zealand also noted that its protocols have a few additional options to facilitate the importation of small volumes of seeds for breeding, trial and research purposes. New Zealand reported having four seed import protocols: maize and sweet corn (*Zea mays*); soybean (*Glycine max*); oilseed rape (*Brassica napus* var. *oleifera*); and lucerne (*Medicago sativa*).

54. In Norway, the analyses conducted by the Norwegian Veterinary Institute are mainly event-specific and cover the following LMO varieties: RRS, P35S, GA21, Bt11, Bt176, Mon810, Mon 863,

NK603, TC1507, LL601, LL62, Shanyou Bt63 of P35S-CaMV, CaMV, P35S-FMV and nptII for products containing rape seeds.

55. Slovenia stated that its National Institute of Biology primarily uses PCR and quantitative PCR for GMO detection. The NIB also actively cooperates with the European Commission's CRL-GMFF.

56. The NIB is also accredited for qualitative and quantitative testing of genetically modified organisms. In 2006, the partially flexible scope of accreditation was gained. The accreditation was granted for genetically modified organisms and their products in foodstuffs and agricultural products of plant origin.

57. Slovenia noted that some standards for GMO detection have been published. These describe instructions for nuclear and protein-based analyses and some individual methods are included as information annexes to the standards (see ISO 21571:2005, ISO 21572:2004, ISO 21569:2005, ISO 21570:2005, and ISO 24276:2006). Detection of individual GMOs in official control laboratories in the European Union is primarily based on the methods proposed by the applicant and validated by the CRL. Slovenia commented that it would appreciate if these latter methods would also become part of the standards.

58. Slovenia also stated that the development of screening or detection methods is outside the responsibility of the CRL and therefore falls on laboratories. From Slovenia's perspective, there are different reference genes used in the methods proposed by applicants, which is difficult for individual laboratories to handle. The usage of one or two reference genes per plant would simplify detection.

59. South Africa stated that it uses detection techniques including PCR analysis and the ELISA strip test.

60. Canada reported that, for regulatory purposes, detection techniques validated at Canadian government laboratories may be performed on plants with novel traits, including genetically engineered food and novel feeds. Canadian government laboratories do not maintain a comprehensive catalogue of detection methods. Examples of the types of analytical testing that Canadian government laboratories may use include:

- detection and identification of selected transgenic events;
- screening and differentiation of selected multiple events;
- quantification of the amount of an event present;
- testing seeds or plants including feed, seed or grain, and fresh food.

61. Canada also reported using laboratory sampling and detection techniques for specific LMOs in the rapid application of detection methods to respond to regulatory non-compliance. Routine seed diagnostics are also conducted but are not applied to all LMOs. Examples of some diagnostic methods include event specific testing for:

- trait purity (glyphosate and glufosinate ammonium herbicide bioassays for seed);
- low-level presence of unauthorized LMOs (screening using PCR);
- low-level presence of authorized LMOs in seed (bulk screening of seed using PCR);
- quantitative testing for LMOs in seed using herbicide bioassays.

Crops tested on an event-specific basis by government laboratories include corn, canola and rice. Methods used include serology and PCR-based test methods.

62. The United States of America noted that once a representative sample has been obtained, a valid analytical method must be utilized. It described DNA-based tests as being reliable and sensitive but

expensive, time-consuming and requiring sophisticated laboratory facilities and prudent quality control to minimize the possibility of false-positive and false-negative results, particularly at very low levels of detection. In addition, some developers of LMO products consider detection techniques and the requisite reference materials to be proprietary and confidential and, as such, they are not widely available. It stated that protein-based tests are convenient, fast and inexpensive but not as sensitive as DNA-based tests. Furthermore, these tests may not be able to distinguish between specific LMO events and they have not been developed for all LMO products in commercial channels.

63. The Global Industry Coalition recounted that biotechnology companies develop and validate detection methods and create reference materials as part of the assembly of dossiers for submission to regulatory agencies. They stated that the companies provide methods that are developed in accordance with existing national and international standards as published by the ISO, Codex and the Organisation for Economic Co-operation and Development (OECD).

F. Sampling, detection and illegal imports

64. The European Community noted that its control system is challenged by the occasional import of unauthorized GMOs. The Commission has mandated the CRL-GMFF to coordinate emergency measures to exclude illegal imports from the EU market. This is to be executed through the rapid validation of appropriate detection procedures and the provision of control samples for unauthorized GMOs. The submission included information on the EC's response to the appearance of the unapproved GM strains of Bt10 maize and LL rice 601.

65. Germany noted that as a result of its sampling and detection activities, infringements concerning labelling or non-authorized GMOs have been detected.

66. The experience of the Norwegian food safety authority is that their sampling and detection may reveal an LMO content that was either not declared or that was declared at a different level.

G. Sources of error in sampling and detection

67. The European Community commented that GMO detection aims to gain information on the composition of a large body of target material. With only a small portion of sample material being subject to the analytical procedure, reliable results can only be guaranteed using appropriate sampling strategies. A heterogeneous distribution of GM material must be expected in bulk commodities or grain lots. The EC stated that only one set of sampling guidelines for GMO testing was specifically developed for GMO surveys, namely Commission Recommendation 787/2004, which is reportedly free of assumptions regarding distribution and therefore is applicable even in cases of heterogeneity. The submission also referred to research projects undertaken and software tools that have been developed within the EU to support the accuracy of sampling protocols.

68. New Zealand noted that sources of error in sampling and detection fall into three basic categories: sampling, sample preparation, and analytical method. As regards sampling, the submission stated that no sampling and detection regime can guarantee that no GM seeds are present in consignments of seeds for sowing. To achieve certainty would require testing every seed and then there would be nothing left to plant as the testing process destroys the seed. Furthermore, the testing protocol must not be so sensitive that it regularly yields false results. To be sure of this, the size of the seed sample needs to be smaller than the number of seeds needed to support the technical limit of detection.

69. As regards errors from sample preparation, New Zealand commented that the test accuracy can be affected if the seed sample is not thoroughly homogenized after grinding the sample. The laboratory equipment used to grind seeds should produce material of a uniform and optimum size. Finally, as

regards analytical method, the limit of detection (sensitivity) of the PCR analytical methods is defined as the lowest concentration of analyte that will be detected at least 95 per cent of the time. This is generally considered to be 0.01 per cent or one GM seed in 10,000 seeds (i.e., there is a 5 per cent chance of a false result.)

70. Slovenia noted different documents on measurement uncertainty and commented that it would be useful to decide on defined measurement uncertainty to be used in official control to harmonize decision-making on the compliance or non-compliance of samples.

71. The submission from the United States of America stated that sampling can be a significant source of error in testing bulk grains and oilseeds for any attribute. Since time and cost constraints preclude examining an entire shipment of grain, obtaining a representative sample is the only practical alternative. In cases where a target LMO is likely to be present in low concentrations, representative sampling becomes especially important. Sampling error can occur when the sample is being taken from the lot, when the sample is being prepared for analysis and during the analysis itself. The United States Department of Agriculture has developed information specifically about considerations that should be taken with respect to sampling for the detection of biotechnology grains. 11/

H. Laboratory accreditation, proficiency and competence

72. The European Community stated that, as the Community Reference Laboratory for GMOs, the duties of the Joint Research Centre include providing assistance in regard to official controls performed to ensure the verification of compliance with feed and food law to the national reference laboratories of the EU Member States in fulfilling their official control activities; providing the national reference laboratories with the details of analytical methods, including reference methods; and coordinating the application of these methods, in particular by organizing comparative testing and by ensuring appropriate follow-up of comparative testing in accordance with internationally accepted protocols, when available.

73. The European Community stated that, in order to secure and to improve the practice of GMO control, EU inspections of responsible national authorities and enforcement laboratories are regularly conducted. The Food and Veterinary Office plays an important role in such inspections as it works to assure effective control systems on national levels and to evaluate compliance with EU standards for food and feed that contain, consist of or are produced from GMOs. The Food and Veterinary Office evaluates the supervision performed by the competent authority to ensure that market placement of genetically modified food and feed complies with Regulation (EC) 1829/2003 as well as the application of Regulation (EC) 1830/2003, which concerns the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

74. The Biotechnology & GMOs Unit of the Joint Research Centre holds a series of training courses for food control laboratory staff within the European Union and beyond. The aim is to provide analytical biotechnology skills and to promote the use of validated and harmonized methods for the detection, identification and quantification of GMOs in food and feed.

75. New Zealand stated that laboratories approved by its Ministry of Agriculture and Forestry to test seeds must participate in proficiency testing, use internal quality controls, and be accredited to the ISO standard ISO 17025: 2000, “General requirements for the competence of testing and calibration laboratories”.

11/ The information is available via this website: http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=rd-bi.

76. According to Slovenia, one of the important indicators of laboratory performance is cooperation in proficiency tests. NIB participates in three to four such tests per year.

77. The submission from Slovenia included information from the seed-testing laboratory at the Agricultural Institute of Slovenia. The laboratory is an official and independent seed-testing laboratory in Slovenia and has been a member of the ISTA for more than 60 years. It is accredited according to ISTA standards for conventional seed quality traits (e.g., purity, germination, moisture content) and since 2007, for variety verification and/or identification and GMO detection. The submission includes information on ISTA's approach to the detection, identification and quantification of GM seeds. 12/

78. Canada noted that Canadian government laboratories participate in proficiency test programs for GMO detection such as those offered by the Genetically Modified Material Analysis Scheme, the ISTA and GIPSA, which is part of the United States Department of Agriculture's marketing and regulatory program.

79. The United States of America reported that, in 2002, the USDA created a voluntary proficiency program that helps testing laboratories around the world identify areas of concern and take corrective actions to improve testing capability and reliability. Through this program, USDA periodically provides participants with corn and soybean samples containing specific LMO events at known concentrations. The participants test the samples and return their results to USDA to assess the accuracy and reliability of their testing methodologies. Currently, the program has over 50 participating laboratories worldwide. 13/

I. International standard-setting

80. Colombia noted that the harmonization of methodologies for detection would result in a tool that would allow post-market inspection between importing and exporting countries. This is the reason why the Codex Alimentarius, through the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, has urgently requested the Committee on Methods of Analysis and Sampling of the same body to review the subject of the detection and identification of foods derived from biotechnology. Colombia thus recommends that the Parties take into account the technical and scientific work of this body on this matter as a modality for the acceptance and harmonization of sampling and detection techniques.

81. The European Community noted that once a GMO detection method has been validated by the CRL-GMFF, it may be accepted as an international standard by the European Committee for Standardization (CEN) or by ISO. The submission commented that standardization of reliable detection methods is an important tool for fair trade under the umbrella of the World Trade Organization. The submission remarked that European and international standardization organisations have established common standards for GMO detection, including a general document on performance criteria and laboratory organization requirements. CEN has approved a set of six general standards on methods of analysis for the detection of genetically modified organisms and derived products. The standards comprise methods of sampling, DNA extraction and methods of protein and DNA analysis. A number of these standards have also been adopted as ISO standards.

82. The submission also remarked the contribution of EU Member States to the development of international standards for the validation process of GMO detection methods particularly through the Codex Alimentarius Commission's Committee on Methods of Analysis and Sampling (CCMAS). EU

12/ See annex I for more information on ISTA and other standard setting organizations mentioned elsewhere in this document.

13/ Additional information on the programme, including the results of participating laboratories, is available here: http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=rd-bi.

participants at CCMAS meetings have stated that international standards for GMO detection are needed to ensure traceability. Tracing requires adequate methods of analysis and, in light of several problems of methodology in the identification of foods derived from biotechnology, the EU participants further stressed the importance of such standards.

83. Germany commented that its control laboratories support the guidelines of a draft document of the Codex Alimentarius Commission, which describe an international agreement on the exchange of information, detection methods and positive control materials concerning the low level presence of GMOs.

84. New Zealand considered that Parties should not be determining criteria or techniques for sampling and detection independently of competent bodies such as ISTA and CCMAS so as to avoid duplication of work by the Protocol.

85. Canada referred to several international organizations involved in establishing methods of sampling and detection. CCMAS of the Codex Alimentarius establishes criteria for the acceptability of methods. The Codex Committee on Food Labelling establishes standards by which sampling and detection results are interpreted. Other international organizations, including ISO, OECD, the ISTA, the Association of Official Seed Analysts and the Association of Analytical Communities International are also involved in setting standards or harmonizing methods for sampling and detection. The submission noted that Canadian government laboratories are involved in activities that contribute to the harmonization of sampling and detection methods such as participation in committees of various international organizations such as CCMAS and the ISO Technical Committee 34.

86. The United States of America noted that there are currently no internationally or universally recognized sampling and detection methods for LMOs. The United States of America believes that it would be helpful to have sampling and detection methods standardized and it noted that a number of international standard-setting bodies are currently working on these issues, including the International Life Sciences Institute, ISO and most notably from the perspective of the United States of America, CCMAS.

87. The United States of America expressed the view that the Codex Alimentarius Commission is the world's most respected and widely followed standard-setting body for food safety. The Government therefore suggested that Parties to the Biosafety Protocol and other Governments rely on Codex for any necessary criteria for the acceptability and harmonizing of sampling and detection techniques. In the view of the United States of America, charging another international forum with the responsibility to develop criteria for sampling and detection methods would likely produce a separate set of sampling and detection standards, creating confusion among Parties and non-Parties as to which set of standards to implement.

88. The submission from the Global Industry Coalition referred to the work of four organizations in the area of standard setting: ISO; the Codex Alimentarius Commission (and CCMAS in particular); the *Bureau International des Poids et Mesures* (BIPM, International Bureau of Weights and Measures); and the OECD. GIC found that these organizations have a great deal of experience and success in establishing systems and standards, including references standards and detection methods in the medical field. Furthermore, over the past three years, they have become directly engaged in developing globally harmonized standards and systems for detecting LMOs in commerce. GIC stated that these organizations and the experts they convene are able to conduct a science-based assessment and to determine the appropriate integrated systems, standards, and specifications to best enable global trade in LMOs intended for direct use as food or feed, or for processing for the long term. GIC recommended that, in order to create synergies and avoid duplication of efforts, Parties should focus on sharing information

with these and other relevant international bodies rather than developing criteria for acceptability and harmonization of sampling and detection techniques under the Protocol.

J. Challenges in sampling and detection

89. China stated that the main problems it has faced are insufficient information sharing on imported LMOs, lack of standards for monitoring and detection techniques, and lack of reference materials.

90. The European Community identified the lack of harmonization of GMO detection and the lack of synchronicity between different countries and regions in regard to GMO approval processes as the main causes of problems in GMO control. It also listed a number of problems in GMO detection and control. One such problem is the detection of unauthorized or unknown GMOs due to the lack of molecular knowledge of their genetic contents. It was stated that it is precisely this lack of knowledge and the illegality of such unapproved or unknown GMOs on all levels in Europe and in most other countries that necessitates their detection.

91. Another problem was that analytical results may be interpreted differently owing to the different testing regimes among countries; for example, the use of different units of measurement can cause an inequality of test results. A third problem cited by the European Community was that reference material is not available for all GMO events on the global market.

92. A further challenge to GMO detection noted by the European Community was the detection of transgenic material in crops with varying chromosome numbers and in crops with a large genome (e.g., wheat). This restricts the minimum quantity of GM DNA that can be analyzed due to limitations of DNA quantities in PCR analysis.

93. The European Community pointed to an inconsistent legal status of products containing ‘trace botanical impurities’ derived from GMOs. In the EU, Regulation (EC) 1829/2003 determines a threshold of 0.9 per cent for adventitious presence of material derived from GMOs. However, two issues arise. First, when a cargo contains mixed GMOs (for example, maize and soybean), the 0.9 per cent threshold applies for each species. In this case, the maize may contain 0.3 per cent authorized GMO and the soybean 1.2 per cent authorized GMO. Such cargo would thus need labelling concerning the GM soybeans. Secondly, the term ‘trace botanical impurities’ refers to cases in which, for example, maize commodities (GMO content below 0.9 per cent) are mixed with traces (0.01 per cent) of pure GMO soybeans. According to Regulation 1829/2003, such a shipment is defined as 100% GMO and must be labelled accordingly.

94. The European Community stated that there is a considerable need for rapid and economic detection methods, which would not only benefit the EU control system but also particularly would enable developing countries to establish effective GMO control measures.

95. The submissions from the European Community, Canada and GIC noted the challenge posed by ‘stacked’ events where more than one transformation event occurs in the same plant. The European Community stated that unless a specific marker is introduced into the hybrid plant, the determination of whether a sample solely contains the hybrid itself or a mixture of two different GM plants is almost impossible when conducted on material other than seeds or grains. The current available detection methods do not solve the problem of stacked genes and the only available approach in such cases at the moment is the analysis of single grains.

96. GIC stated that the existence of multiple traits and thus multiple detection method target sequences in a single LMO can confound the determination of the percentage of LMO kernels in a seed or grain sample. GIC provided the example of bulk commodity shipments, which usually contain a

mixture of single-trait LMOs, combined-trait LMOs, and conventional grain. Current testing approaches utilized to meet low-level mandatory labelling laws involve grinding samples taken from a bulk commodity shipment into meal, which is then analyzed. Once individual LMOs have been reduced to meal, the lack of a predictable ratio of detection method target sequences per individual LMO precludes the ability to accurately determine the percentage of LMO kernels in a sample. The problem of bias introduced by combined events is said to be a practical limitation of measuring DNA or protein and thus is independent of the type or quality of detection method used.

97. The German submission noted that it is difficult to verify the compliance of labelling products according to the 0.9 per cent threshold defined by Regulation (EC) 1829/2003. Control laboratories in Germany have expressed the view that compliance with this threshold is no longer assessable. The submission stated that it is necessary to solve this problem.

98. New Zealand reported that its approach to sampling and detection will become more difficult as GM technologies become more sophisticated (for example, as different promoter and/or terminator sequences are used, or if lines of GM seeds are approved for planting in the country so that it would need to distinguish between approved and unapproved GM seeds in shipments).

99. Norway commented on the difficulty of detecting LMOs that may or may not be authorized in other countries but that are not authorized in the EC and Norway.

100. Slovenia stated that the detection of GMOs not approved in a particular country is a special challenge. CRL is providing quick and efficient assistance on the methods for GMOs unexpectedly appearing in the European market. Furthermore, detection of unknown GMOs is very challenging and NIB is cooperating in a working group of ENGL that is dealing with the topic.

101. Canada remarked on a number of challenges in the establishment of sampling and detection techniques for LMOs. First, access to suitable, validated detection methods for specific events is variable with some internationally-recognized methods, some methods provided by companies applying for environmental release of plants with novel traits, and some methods developed within government laboratories on an ad hoc basis. Access to sufficient, reliable reference material on a timely basis is also variable and is important for determining and verifying the performance characteristics of some methods. Limits of detection vary depending on the method used and standards by which results will be assessed are not defined.

102. A challenge noted by the GIC submission was the many first-generation LMOs already discontinued and removed from commerce as part of their product life cycle. These products will gradually diminish in presence within commercial trade channels, ultimately to *de minimis* levels. According to the GIC, such products will likely never be approved in any additional countries and approvals may not be renewed; therefore, they represent a situation where Parties may be committed to test for these products for many years even though the probability of an illegal transboundary movement would be almost non-existent.

K. Other information

103. Armenia stated that it has approved a bylaw which states that living modified organisms that are subject to transboundary movement be handled, packaged and transported in accordance with international rules and standards including the requirements of Article 18.

104. The European Community noted that Regulation (EC) 1946/2003 14/ establishes a common legal framework for the exports of GMOs to third countries. It requires exporters to ensure that documentation accompanying GMOs confirms that the export contains or consists of GMOs and provides the unique identification code(s) assigned to these GMOs if such codes exist.

105. The submission from the European Community pointed to a number of research projects on GMO control and detection methods being financed by the Community. It also pointed to a number of dissemination and training activities. These include the provision of a central database containing suitable detection methods for GMOs and general information on each specific GMO.

106. The European Community also highlighted the upcoming first Global Conference on GMO Analysis to be held in Como, Italy from 24 to 27 June 2008. The conference is an initiative of the Joint Research Centre and ENGL and, according to the European Community, may present a major step in the dissemination and harmonization of GMO detection approaches at an international level. The conference will address a broad range of topics related to a functional and internationally harmonized GMO control and analysis system including challenges in the fields of sampling for GMO analysis, the appropriateness of analytical tools and the consistency and interpretation of test results.

107. Germany believes that a worldwide harmonization of sampling and detection techniques is necessary. It suggested that, in addition to the harmonization initiated at the Codex Alimentarius, that an international working group should be established where experts in the field compile all commonly agreed and practice-oriented guidelines needed for the sampling and detection of GMOs.

108. The German submission remarked that the German *Länder* are aiming towards a harmonized approach for sampling and detection techniques applied for the analysis of food and feed products and to this end, the general legislative framework should be developed. It identified a number of areas where thresholds or harmonized approaches are needed. One such future requirement will be efforts to develop and validate advanced detection techniques, primarily with regard to screening methods, in light of an anticipated increase in the number of GM crops, particularly those with stacked events. It has been suggested that standardized sampling protocols for agricultural harvest products are necessary, consisting of material from the whole plant. The control laboratories of the German *Länder* noted that a threshold for the labelling of seed concerning the GM presence is missing. It was said that the introduction of EU-wide legislation defining a threshold for the labelling of seeds containing GM material will be helpful for the seed control authorities. The German submission also identified the need for prospective harmonization for the quantification of the amounts of GM impurities in conventional seeds. Germany considers it necessary to develop a harmonized approach for sampling and analysis for non-authorized GMOs across the EU Member States, including reporting and result interpretation in the EU. Finally, the German *Länder* have begun to elaborate a harmonized approach for the inspection of facilities for the contained use of GMOs and for the detection of the GMOs used in these facilities.

109. Italy noted that the ministry of health in collaboration with the ISS and Mycotoxins Unit and the IZSLT national reference centre for GMO analysis have planned additional activities including: funding research projects at the national level; analytical support to laboratories involved in the national monitoring office to promote exchange of information, materials and expertise; and endorsement of an Italian network of GMO laboratories.

110. With regards to monitoring in Mexico, the National Ecology Institute (a body of the *Secretaría de Medio Ambiente y Recursos Naturales*, SEMARNAT or the Secretariat of Environment and Natural Resources) has carried out monitoring and detection of the adventitious presence of genetically modified

14/ Regulation (EC) No. 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.

material in a number of regions in Mexico with a high genetic diversity of maize landraces. From this experience, Mexico believes that it is important for this type of monitoring to involve local communities and keep them informed in a transparent manner of the information obtained from the samples they provide to the government.

111. New Zealand requires the importer to meet the costs of GM seed testing. Such testing typically takes two to seven days. New Zealand reported that most importers arrange for testing to be conducted offshore prior to shipment of seeds so that delays at the border are minimized.

112. New Zealand drew three conclusions from its experience with sampling and detecting unapproved GM seeds in non-GM consignments of seeds for sowing:

- Even leaving out the possibility of human error, testing cannot provide complete certainty;
- Pre-border testing requires sophisticated technology, is costly, and importers of small volumes of seed face disproportionately higher costs; and
- The costs fall equally on GM and non-GM seed alike.

113. The Norwegian submission stated that importers in its country generally require that the food and feed they import does not contain, consist of and is not produced from LMOs not allowed in Norway, and that any content of LMO approved in the European Community is below the threshold of 0.9 per cent and is adventitious or technically unavoidable. The importers also require this to be documented by different means varying from identity preservation programs with sampling and detection at different stages to declarations that the imported products do not contain LMOs.

114. Norway concluded that sampling and detection are important tools for the enforcement of national legislation implementing the Protocol but that results may vary depending on the methods used. It felt that the development of criteria for the acceptability and harmonization of sampling and detection techniques would contribute to reducing the variations in results and could also contribute to reducing the number of sampling and detections needed. The consequence could be a reduction in costs for both industry and commerce as well as the authorities and that the enforcement of national legislation would therefore be generally more effective. Norway favoured the appointment of a scientific committee with the specific task of providing scientific and technical guidance and possibly developing a proposal.

115. Slovenia commented that different accreditation bodies have different approaches for evaluating laboratories being considered for accreditation. There are also differences between the national interpretations of the term ‘flexible scope’. The Party stated that it would appreciate harmonization. Furthermore, with many new GMOs coming onto the market, a higher flexibility of the scope of accreditation provides better possibilities to accredit methods rapidly.

116. South Africa stated that a lack of standardized sampling and testing systems contributes to variability of test results between different laboratories and raises questions regarding the certainty of GMO test results. Due to the difficulties in measuring adventitious presence of GMOs and not being able to distinguish between individual GM events, acceptable levels of co-mingling need to be determined and the threshold levels for LMO presence need to be harmonized in order not to create additional trade barriers.

117. The Global Industry Coalition discussed considerations for capacity-building for sampling and detection. They stated that, in order for Parties to demonstrate compliance with measures addressing illegal transboundary movements of LMOs, it is critical that validated detection methods are used with appropriate reference materials. GIC further stated that testing laboratories need to abide with internationally-accepted testing protocols and proficiency standards. GIC felt that Parties to the Protocol

can benefit from the existing work of standardization organizations when considering their capacity-building needs for compliance with the Protocol's requirements.

118. GIC felt that Parties should recognize that the magnitude of testing will be ever expanding and more complex and costly as the globalization of the technology continues. GIC was of the view that Parties would be better served to encourage and enable standardization of the global regulatory system through OECD and Codex and to train local regulatory personnel to review dossiers and approve products and include tolerance levels of products that are approved in at least one country (low level presence) rather than create a system that requires perpetual testing of food and feed for possible illegal transboundary movements of LMOs. It was said that while testing may be helpful in determining the integrity of certified systems of identity-preserved production, the optimum approach to identity-preserved production requires the establishment of commercially reasonable, widely-trusted systems comparable to those already in use for controlling and detecting plant pathogens.

119. GIC recommended that, in order to create synergies and avoid duplication of efforts, Parties should focus on information-sharing with ISO, Codex Alimentarius, the OECD and other relevant international bodies rather than expending resources on the development of criteria for acceptability and harmonization of sampling and detection techniques under the Protocol. Information sharing should also aim to ensure that information on sampling and detection methods for LMOs are available to Parties through the Biosafety Clearing-House.

III. ELEMENTS FOR A DRAFT DECISION

120. From the above synthesis of information, there appears to be a convergence of views that the harmonization of sampling and detection methods would be useful.

121. In light of this, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to consider the following proposals from the synthesis above:

- Supporting and relying on the Codex Alimentarius Commission and/or other international standard-setting bodies for any necessary criteria for the acceptability and harmonizing of sampling and detection techniques;

- Sharing information with ISO, the Codex Alimentarius Commission, the *Bureau International des Poids et Mesures*, the OECD and other relevant international bodies;

- Establishing a working group where experts in the field compile all commonly agreed and guidelines needed for the sampling and detection of LMOs and/or appointing a scientific committee with the specific task of providing scientific and technical guidance on criteria for acceptability and harmonization of sampling and detection techniques;

- Recommending the establishment of standards for acceptable levels of co-mingling and harmonizing the threshold levels for LMO presence;

- Involving local communities in domestic monitoring and detection for the adventitious presence of genetically modified materials in the environment and keeping them informed in a transparent manner of the information obtained from the samples they provide to the government;

- The need for accreditation of laboratories involved in sampling and detection of living modified organisms including the need for flexibility in the scope of accreditation in order to accommodate the entry of new living modified organisms onto the market;

- The need for reference material for all LMO events on the global market;

- Requesting Parties and encouraging other Governments and international organizations to ensure that information related to rules and standards on the sampling of living modified organisms and detection techniques are available via the Biosafety Clearing-House; and/or

- Encouraging Parties and other Governments to cooperate in the exchange of information on and experience with sampling and detection techniques, including the training of local regulatory and scientific personnel.

122. From the information in the synthesis above, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may also wish to welcome the first Global Conference on GMO Analysis to be held in Como, Italy from 24 to 27 June 2008 as a potential major step in the dissemination and harmonization of GMO detection approaches at an international level.

123. In accordance with recommendation 4 of the Compliance Committee (see the annex to document UNEP/CBD/BS/COP-MOP/4/2), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to decide to encourage Parties and other Governments to implement paragraph 10 of decision BS-III/10 relating to exchanging experiences and building capacities in the use and development of techniques for sampling and detecting living modified organisms with a view to, *inter alia*, facilitating the prevention, detection and reporting of illegal transboundary movements of living modified organisms, especially in developing country Parties, in particular the least developed and small island developing States among them, as well as in Parties with economies in transition.

Annex I

INFORMATION ON RELEVANT WORK OF STANDARD SETTING ORGANIZATIONS AS CONTAINED IN THE SUBMISSIONS

A. Codex Alimentarius Commission

Codex Committee on Methods of Analysis and Sampling (CCMAS)

For over 40 years, CCMAS has examined the highly technical and complex issues surrounding sampling and detection methods. CCMAS defines procedures, protocols, guidelines for the assessment for food laboratory proficiency and quality assurance systems. In recent years, CCMAS scientific experts have taken up the subject of sampling and detection of LMOs. Among the issues CCMAS is currently covering in this area are protein and PCR-based testing methods, quantitative and qualitative testing methods, criteria for method validation, and the development of collaborative trials on detection methods. The document "Consideration of the methods for the detection and identification of foods derived from biotechnology – general approach and criteria for the methods" has been developed by CCMAS (CX/MAS 09/29/8), and was to be considered for advancement to the step process at the Twenty-ninth Session of the Committee, held in Budapest, Hungary, from 10 to 14 March 2008. Technical Committee 34 of ISO (see below) is currently evaluating whether this document is consistent with ISO standards.

Issues considered during the Twenty-Eighth Session of CCMAS in March 2007 included: (i) the information required for the validation of quantitative and qualitative methods; (ii) the characteristics that could be used to consider existing validated methods; (iii) issues related to measurement uncertainty and interpretation of the results; and (iv) proficiency testing.

CCMAS also works with other Codex Committees that address LMO issues such as the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology and the Committee on Food Labelling.

See also the annex to document UNEP/CBD/BS/COP-MOP/4/8 for a description of the work of CCMAS and the Codex Committee on Food Import and Export Inspection and Certification Systems.

B. International Seed Testing Association (ISTA)

The ISTA is aimed at ensuring uniformity in seed testing on an international level. It is spread over 76 countries worldwide and has approximately 100 accredited member laboratories. ISTA develops, adopts and publishes standard procedures for sampling and testing seeds and issues certificates of seed quality. The ISTA International Seed Analysis Certificate of seed quality is widely accepted and is used for transactions of seed in international trade. ISTA uses a performance-based approach to ensure the reliability and accuracy of results. Under this approach, laboratories are free to choose the methods they use, with the ISTA International Rules for Seed Testing setting minimum requirements for the performance of laboratories carrying out such tests.

Since the adventitious presence of genetically modified seeds in non-GM seed lots has increasingly become a problem for the international seed trade, ISTA established, in 2001, the GMO Task Force to focus on activities to develop a system targeting the uniformity in GMO testing results, not only by the uniformity in GMO testing methodology but by a performance-based approach. To make this approach a reality, the ISTA GMO Task Force was active in the following areas: establishing an ISTA Rules Chapter for the detection, identification and quantification of GMO in conventional seed; in the

organization of proficiency tests on GMO testing; in the exchange of information between laboratories at workshops; and offering training programmes.

During the 2005 ordinary meeting in Bangkok, the new version of the ISTA Rules Chapter 8 was adopted, which came into force on 1 February 2006. Since then, it has been possible for laboratories to become ISTA accredited for the testing of seeds with specified traits under the performance-based approach. ISTA member laboratories must demonstrate their competence in specified trait testing that the GMO detection, identification or quantification methods used for reporting results on the ISTA certificate fulfil requirements concerning repeatability and reproducibility. Laboratories seeking accreditation for performance-approved methods and accredited laboratories must participate in the corresponding ISTA Proficiency Test rounds. Prior to on-site audits, the laboratories must also present the performance data for each method-species-trait combination in order to demonstrate that it is completely handled by the laboratory.

C. International Organization for Standardization (ISO)

ISO is a network of national standards institutes from 150 countries which provides a technological and scientific reference framework that takes into consideration safety, health and the environment.

ISO has released a number of standards related to nucleic acid extraction, nucleic acid and protein-based methods of analysis as shown below. ISO standards in this area have been developed by technical committee 34 on 'food products' and its working group 7, 'Genetically modified organisms and derived products', which developed standards in the area of biomolecular testing.

ISO had adopted the following standards and specifications concerning the detection of LMOs:

- ISO 21572, Foodstuffs — Detection of genetically modified organisms and derived products – Protein based methods;
- ISO 21569, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods;
- ISO 21570, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods;
- ISO 21571, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products – Nucleic acid extraction;
- ISO 24276, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products – General requirements and definitions; and
- ISO TS21098, Foodstuffs — Nucleic acid based methods of analysis of genetically modified organisms and derived products — Nature of the information to be supplied and procedure to annex methods to the International Standards ISO 21569, ISO 21570 and ISO 21571.

A standard on "Detection of genetically modified organisms in oleaginous seeds" is also under development and performance standards for methods to be used to determine the gene technology derived content of seed lots, will also be considered.

D. BIPM and national metrology institutes

The *Bureau International des Poids et Mesures* (BIPM, the International Bureau of Weights and Measures) operates under the terms of the Metre Convention and the exclusive supervision of the International Committee for Weights and Measures (CIPM, *Comité International des Poids et Mesures*). The CIPM itself comes under the authority of the General Conference on Weights and Measures (CGPM, *Conférence Générale des Poids et Mesures*). The CGPM elects the members of the CIPM and brings together periodically, at present once every four years, representatives of the governments of member

states. The CIPM has established a number of consultative committees that bring together the world's experts in their specified fields as advisers on scientific and technical matters.

The *Comité consultatif pour la quantité de matière – métrologie en chimie* (CCQM, Consultative Committee for Amount of Substance – Metrology in Chemistry) was established in 1993. Its members are the national metrology institutes in those countries that belong to the Metre Convention. Present activities concern primary methods for measuring amount of substance, and international comparisons; establishment of international equivalence between national laboratories; and advice to the CIPM on matters concerned with metrology in chemistry.

Within the CCQM, the Joint Committee for Traceability in Laboratory Medicine (JCTLM) is a practical example of how DNA metrology best practices could be harmonized. The goal of the JCTLM is to provide a worldwide platform to promote and give guidance on internationally-recognized and accepted equivalence of measurements in laboratory medicine and traceability to appropriate measurement standards.

A long-term effort is in place to eventually work through the Bio-analysis Working Group of the CCQM to establish internationally recognized DNA metrology standards.

E. The Organisation for Economic Co-operation and Development (OECD)

The OECD brings together the governments of countries committed to democracy and the market economy from around the world to enable sustainable economic growth, including world trade in new technologies. The organisation provides a setting where governments compare policy experiences, seek answers to common problems, identify good practice and coordinate domestic and international policies.

The majority of OECD Member countries have a system of regulatory oversight for the products of modern biotechnology (including genetically engineered organisms), which are intended for release to the environment. The OECD has formed the Task Force on the Safety of Novel Foods and Feeds and the Working Group on Harmonization of Regulatory Oversight in Biotechnology with the goal of promoting international harmonization in biotechnology.

Through the work of the Task Force and the Working Group, OECD Member countries want to ensure that environmental health and safety aspects are properly evaluated, while avoiding non-tariff trade barriers to products of the technology. The outcome will be used by governments, industry and other stakeholders.

The other important part of the programme is an outreach activity including the development of BioTrack Online. This includes information related to the regulatory contacts in OECD countries and online databases on the products of modern biotechnology.

The OECD Member countries have recently adopted an agreed set of "Guidelines for Quality Assurance in Molecular Genetic Testing". The Guidelines address genetic testing for variations in DNA sequences in humans to assess conditions of health. Although the guidelines focus on molecular genetic testing for the diagnosis of a particular disease or condition and predictive genetic testing, guidelines of this kind represent the capability of the OECD to mobilize the experts required to develop standard protocols and references for detection measurements.

Annex II

ACRONYMS

BIPM	*Bureau International des Poids et Mesures* (International Bureau of Weights and Measures)
CCMAS	Codex Alimentarius Commission's Committee on Methods of Analysis and Sampling
CCQM	*Comité consultative pour la quantité de matière – métrologie en chimie* (Consultative Committee for Amount of Substance – Metrology in Chemistry)
CEN	European Committee for Standardization
CGPM	*Conférence Générale des Poids et Mesures* (General Conference on Weights and Measures)
CIBIOGEM	*Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados* (Inter-ministerial commission on the biosafety of genetically modified organisms) (Mexico)
CIPM	*Comité International des Poids et Mesures* (International Committee for Weights and Measures)
COFEPRIS	*Comisión Federal para la Protección contra Riesgos Sanitarios* (the federal commission for protection against sanitary risks) (Mexico)
COP-MOP	Conference of the Parties serving as the meeting of the Parties to the Protocol
CRL-GMFF	Community Reference Laboratory on Genetically Modified Food and Feed (European Commission)
DGCENICA	*Dirección General del Centro Nactional de Investigación y Capacitación Ambiental* (Directorate general of the national centre for environmental research and training) (Mexico)
ELISA	enzyme-linked immunosorbent assay
ENGL	European Network of GMO Laboratories
ENSE	*Ente Nazionle Sementi Elette* (Italian national agency for certified seeds)
EU	European Union
GEF	Global Environment Facility
GIC	Global Industry Coalition
GIPSA	Grain Inspection, Packers and Stockyards Administration (United States of America)
GM	genetically modified
GMO	genetically modified organism
INVIMA	*Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (Colombia)
IRMM	Institute for Reference Materials and Measurements (European Community)
ISO	International Organization for Standardization
ISTA	International Seed Testing Association
ISS	*Istituto Superiore di Sanità* (the Italian national health institute)
IZSLT	*Istituto Zooprofilattico Sperimentale Lazio e Toscana* (Lazio and Tuscany regional institute for animal prophylaxis and research)
JCTLM	Joint Committee for Traceability in Laboratory Medicine
LMO	living modified organism
NIB	National Institute of Biology (Slovenia)
OECD	Organisation for Economic Co-operation and Development
PCR	polymerase chain reaction
SEMARNAT	*Secretaría de Medio Ambiente y Recursos Naturales* (Secretariat of environment and natural resources) (Mexico)
SAGARPA	*Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* (Secretary of agriculture, ranching, rural development, fisheries and food) (Mexico)
UNDP	United Nations Development Programme
USDA	United States Department of Agriculture
