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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY 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

Compilation of information submitted by Parties, other Governments and relevant international organizations on experience gained with the use of techniques for the sampling and detection of living modified organisms and on the need for and modalities of developing criteria for the acceptability of, and harmonizing sampling and detection techniques (paragraph 2(a) of Article 18) *

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SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS

ARMENIA

[28 DECEMBER 2007]
[SUBMISSION: ENGLISH]

In Armenia it was developed draft law on "LMOs", which will soon be presented to public audience and then to the National Assembly of RA by the Government for its endorsement. The law regulates all the functions of LMOs. Thus, I would like to mention during 2007 in Armenia no LMO was imported.

As to article 18 paragraph a, b and c we approved by-law, that the LMOs that are subject to transboundary movement, be handled, packaged and transported according to international rules and standards, as well as requirements of article 18.

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, as well as a contact point for further information.

[...]

CANADA

[18 DECEMBER 2007]
[SUBMISSION: ENGLISH]

Information on Canada's experience with the use of sampling and detection methods and the need for harmonization of sampling and detection methodologies in the implementation of the requirements of paragraph 18(2)(a).

Laboratory Sampling and Detection Techniques for LMOs

The Government of Canada does not require the mandatory testing of seed, food, feed or commodities for the presence of LMOs. However, Canadian regulatory departments and agencies 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. For regulatory purposes, detection techniques validated at Canadian government laboratories may be performed on plants with novel traits (PNTs), 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.

Diagnostic Testing

The Government of Canada uses 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 polymerase chain reaction - PCR)
- low-level presence of authorized LMOs in seed (bulk screening of seed using polymerase chain reaction – 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.

Challenges for Detection Methods:

Many challenges exist 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 (PNTs), 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. Finally, distinguishing between two or more very similar products may be difficult, e.g. in the case of gene stacking or different events of the same construct.

Fora for International Methodology Harmonization

The Government of Canada refers to several international organizations in the establishment of its methods of sampling and detection. The Codex Committee on Methods of Analysis and Sampling (CCMAS) of the Codex Alimentarius establishes criteria for acceptability of methods. The Codex Committee on Food Labelling (CCFL) establishes standards by which sampling and detection results are interpreted. Other international organizations, including the International Organization for Standardization (ISO), Organisation for Economic Co-operation and Development (OECD), International Seed Testing Association (ISTA), Association of Official Seed Analysts (AOSA) and Association of Analytical Communities (AOAC) International, are also involved in setting standards or harmonizing methods for sampling and detection.

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 the CODEX Committee on Methods of Analysis and Sampling and the International Organization for Standardization Technical Committee 34. These Canadian laboratories participate in proficiency test programs for GMO detection, such as those offered by the Genetically Modified Material Analysis Scheme (GeMMA), the ISTA and the Grain Inspection, Packers and Stockyards Administration (GIPSA), which is part of the United States Department of Agriculture’s marketing and regulatory program.

[...]

CHINA

[11 DECEMBER 2007]
[SUBMISSION: ENGLISH/CHINESE]

Paragraph 2 (a), Article 18, Living modified organisms for direct use as food, feed or for processing: The COP-MOP requests, Parties and invites other Governments, regional and international organizations and interested stakeholders, to submit to the Executive Secretary, information on experience gained with the used 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 (decisions BS-III/10, paragraph 11);

In terms of sampling and detection techniques on living modified organisms, a series of standards and guidelines had been established by related government authorities. “Sampling and detection methods of transgenic materials in plant and its product” and other detection methods on transgenic materials in different crops, established by the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), has been put into the quality detection on imported agricultural products. The ministry of Agriculture also promulgated a series of detection methods on genetically modified crops to improve the Biosafety management on domestic transgenic crops. The main problems China has to face are insufficient sharing of imported LMOs and lack of standards for detection techniques, detection criterions and reference materials.

[...]

COLOMBIA

[4 DECEMBER 2007]
[SUBMISSION: SPANISH]

[...]

Información sobre la experiencia obtenida al usar muestras de OVM y las técnicas de detección y commentarios sobre la necesidad de (y posibles modalidades para) desarrollar un criterio para la aceptación y armonización de las técnicas de muestreo y detección.

Como resultado de la ejecución del proyecto GEF-Banco Mundial “DESARROLLO DE CAPACIDADES PARA IMPLEMENTAR EN COLOMBIA EL PROTOCOLO DE CARTAGENA”, el país creo el Laboratorio Central Interinstitucional de Detección y Monitoreo de Organismos Genéticamente Modificados (OGM) del cual hacen parte el INVIMA, el ICA y el Instituto Alexander von Humboldt en representación de cada una de las Autoridades Nacionales Competentes en el tema de Bioseguridad de OGM. Como parte de los objetivos de este laboratorio están el Desarrollar e implementar procedimientos y técnicas para la detección y monitoreo de OVM incluyendo materias primas y procesades, de acuerdo con las competencies de cada uno de los sectores (salud humana, medio ambiente y agropecuario). Diseñar e implementar planes y técnicas de muestreo de los diferentes tipos de OVM incluyendo materias primas y procesadas, de acuerdo con los ámbitos de competencia de los sectores particpantes (salud humana, medio ambiente y agropecuario).

Actualmente en el Laboratorio se están estandarizando metodologías basadas en ADN para detección de OGM, las cuales siguen los métodos de referencia empleados por el Laboratorio de Referencia de la Unión Europea (CRL), empleando tanto PCR convencional (cualitativo) como PCR en Tiempo Real (cuantitativo). Se ha avanzado en las metodologías de screening identificando promotores y terminadores consenso utilizados ampliamente en los OGM.

Empleando estas metodologías, el INVIMA tiene dentro de los proyectos propuestos, evaluar la presencia de diferentes eventos de transformación en maíz, a través de muestreos de los cargamentos que llegan a puertos, igualmente realizar una evaluación en alimentos procesados presentes en el mercado, con lo que se busca contar con resultados sobre la facilidad de recuperación de ADN e partir de estos productos, identificar si han sido o no producidos a partir de OGM, estandarizar protocolos de muestreo y validar las técnicas de detección.

Adicionalmente se plantea la implementación de métodos cualitativos basados en la detección proteica en puertos, dichas pruebas son fáciles y rápidas de utilizar, permitiendo de esta manera una preselcción de lotes a muestrear para su envió al Laboratorio Central Interinstitucional y su subsiguiente análisis de cuantificación.

Es importante resaltar que la armonización de las metodologías de detección, resultaría en una herramienta que permita realizar una vigilancia post-mercado comunidad de criterios entre los países importadores y exportadores. Es así como el Codex Alimentarius a través del CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY solicitó con carácter urgente solicitó al Comité de Métodos de Análisis y Muestro del mismo órgano, retornar el tema en detección e identificación de alimentos derivados de la biotecnología.

Con base en lo anterior, Colombia recomienda que se tenga en cuenta el trabajo técnico y cientifico de dicha instancia sobre este tema, como una modalidad para la aceptación y armonización de las técnicas de muestreo y detección.

[...]

EUROPEAN COMMUNITY [31 JANUARY 2008]
[SUBMISSION: ENGLISH]

The submission by the European Community is issued as document UNEP/CBD/BS/COP-MOP/4/INF/2/Add.1. An interactive version with hyperlinks is available as record number 43770 in the Biosafety Clearing-House, http://bch.cbd.int/database/record.shtml?id=43770.

GERMANY [23 JANUARY 2008]
[SUBMISSION: ENGLISH]

Unofficial translation of a German report to the EU-Commission (2007-11-06)

4th Meeting of the Conference of the Parties of the Cartagena Protocol on Biosafety from 12. – 16 May 2008

Subject: E-Mail of 07.09.2007 / Submission of information from Germany about their experience gained with the use of sampling and detection techniques for detection of GMO - Follow-up WPIEI (Biosafety) of 03.09.2007

As the German competent authority regarding the GMO EU-Regulations, the Federal Office of Consumer Protection and Food Safety (BVL) has consulted the regional authorities (Länder) to provide information on their experiences concerning sampling and detection of GMO. Please find enclosed a summary report on the feedback obtained from the Länder. At first, a short introduction and summary is given by the BVL describing the specific conditions in Germany.

In Germany performance of inspections and controls concerning genetically modified food, feed and seeds is in the responsibility of the Länder. The Länder ministries responsible for food, feed and seed controls define specific surveillance activities and monitoring plans how the regional Food and Veterinary Offices in the cities and rural districts conduct random checks for presence of GMO and examinations of the respective labelling provisions. Besides the controls of documents, samples are taken from food, feed and seeds and analysed for GMO at all relevant stages along the whole production chain.

Regional food inspectors take random samples during on-site inspections at producers or traders and sent them to the responsible Länder control laboratory for GMO analysis. About 6.000 food, 600 feed and more than 700 seed samples were analysed in 2004 and 2005, respectively. Infringements concerning labelling or non-authorised GMOs have been detected (see FVO Inspection Report 8105/2006 – Annex 1).

In the following text the answers to the query at the Federal Länder concerning their experiences with sampling procedures and detection methods for GMO analyses are summarized.

Experiences gained with the use of sampling and detection techniques
German official control laboratories in charge with sampling and use of detection techniques for GMO are to some part experienced for more than 10 years. Experts working in this area are interlinked in working groups; the BVL participates by co-ordinating these activities. As a result of these working groups several detection methods have been developed and validated in ring trials. These methods are published in an official method collection according to the German food and feed law (§ 64 LFGB) or the German genetic engineering law, respectively. Several methods have been also adopted in relevant ISO standards (ISO 21569, ISO 21570, ISO 21571).

Furthermore, based on the general legislative EU framework concerning GMO (Directive No. 2001/18, Regulation No. 1829/2003) these working groups have worked out practice oriented comments and guidance documents, which allow practical implementation of the EU legislative provisions.

Food products
Practice-oriented guidance for sampling and analysis of food products are covered by two recent documents of an expert working group of food chemists (ALS sampling plan – Annex 2; ALS comments "GMO detection" – Annex 3). In general, food sampling is done according to Recommendation 2004/787/EC of the EU commission and the technical specification CEN TS15568:2007. Detection methods used in the laboratories are based on the protocols published in the German official method collection (§ 64 LFGB), in the ISO standards 21569, 21570 and 21571 or are available on the internet website of the Community Reference Laboratory for GMO (CRL-GMFF).

Feed products
The way how feed products are analyzed for GMO content has been comprehensively summarized in a practice-oriented guidance document of another working group (Futtermittelkonzept – Annex 4). Sampling is currently conducted according to the German Feed Sampling and Analysis Regulation (*Futtermittel-Probenahme– und Analysen-Verordnung*, FPA) which transposes Commission Directive 76/371/EEC and further sampling Directives. A sampling plan adapted to the requirements needed for GMO testing and harmonised with the sampling plan used for food products is in preparation.

For GMO testing of feed products those detection methods applied for the analysis of food products are in use (§ 64 LFGB method collection; ISO standards 21569, 21570, and 21571; CRL-GMFF methods).

Seeds

No threshold for labelling of seed consignments originating of GM plants or containing any GM amounts have been agreed at national or at the EU level. As a result, any assured detection of DNA sequences of genetically modified plants authorised for cultivation in the EU has to be labelled. In addition, cultivation of such seed consignments has to be notified to the GMO location register operated by the BVL. The current experience in Germany has shown that seed lots with low level presence of GMO will not be placed on the market. This year GMO cultivation in Germany consists exclusively of genetically modified maize MON810 at a scale of 2.685 hectare at 174 locations.

Seeds play a key role in the production chain of food and feed. Besides the efforts of seed producers to avoid unintended entry of genetically modified material, seeds are intensively controlled by the official seed inspection authorities. To assure a practice-oriented implementation of seed inspections a German Länder working group 'genetic engineering' (LAG) has elaborated two guidance documents describing detailed plots for a harmonised strategy of sampling and analysis of control samples (Saatgutkonzept – Annex 5; Harmonisierte Saatgutüberwachung – Annex 6). Consistently positive experiences were obtained by using these guidelines.

Requirements and approach for developing criteria for acceptability and harmonizing of sampling and detection techniques

The Federal Länder in Germany are aiming towards a harmonised approach for the sampling and detection techniques applied for the analysis of food and feed products. For this purpose the general legislative framework should be further developed. Based on this, future requirements concerning sampling and detection techniques used for food and feed testing are summarised and reported.

Food and feed products

The supply with appropriate reference materials for GMO controls needs improvement. In particular, it is criticised that a rather long period of time is needed to make reference materials available for which an EU authorisation is applied and pending. Because the number of distributors of GMO reference materials is constantly growing it is suggested that all available materials are centrally available at an EU institution.

In view of the increased use and expected authorisation of an increased number of GM crops within the next years, particularly of combinations of GM events (stacked events), it will be necessary to continue the efforts to develop and to validate advanced detection techniques, primarily to with regard to screening methods.

In frame of the authorisation of hybrids of different GM lines for the EU market it is considered to be difficult to verify the compliance of labelling of products according to the 0.9% threshold defined by Regulation (EC) No. 1829/2003. Control laboratories in Germany express the view that compliance with this threshold is no longer assessable. It will be necessary to solve this problem.

Furthermore, the need for standardised sampling protocols available for agricultural harvest products consisting of material from the whole plant (e. g. silage maize) has been suggested.

Concerning the detection methods which are verified and validated by the CRL-GMFF in frame of the authorisation process according to Regulation (EC) No. 1829/2003 it is the opinion of the official control laboratories that prospective methods are more comprehensible in terms of practicability and routine use in the laboratory.

To illustrate the problems arising in the area of traceability a case study was reported concerning shredded and extracted soybeans, which are frequently used as feed product and widely labelled as genetically modified. However, these GM labelled soya feed are byproducts of the processing of soybeans for oil

production. In practice an authorised expert is not able to decide whether the soya oil which is coming out of the soybeans processing and afterwards is placed on the market will actually be labelled as GM material. Such oil products are not accessable for GMO analysis. It is therefore suggested to review the implementation of Regulation (EC) No. 1830/2003 concerning the traceability of GMO during the processing of soybeans in the oil production.

Seeds

Regarding sampling and analysis of seeds it was noted by the German control laboratories of the Länder that a threshold for labelling of seed concerning the GM presence is missing. Introduction of an EU wide legislation defining a threshold for labelling of seeds containing GM amount will be helpful for the seed control authorities.

Needs for a prospective harmonisation is seen also for the quantification of the amounts of GM impurities in conventional seeds. The currently used approach to calculate the GMO amount on basis of the ratio between determined genetically modified haploid genome copies and the copy number determined for a corresponding plant species-specific reference gene will not be sufficient to fulfil the future requirements, particularly in order to quantify up to quintuplicate GMO hybrids (stacked events).

Non-authorised GMO

Because of different potential implications on food safety, the requirements for sampling and detection techniques for inspections and controls in respect of GMO not authorised in the EU are described as a separate issue.

Worldwide the acreage of GM crops is constantly growing. This expansion is accompanied by a constantly increasing number of different GMO which are tested in field trials or globally marketed outside the EU. In order to assure detection of all GMO possibly marketed in the EU, it is necessary that information about the genetic modification actually inserted in the GMO is available in a central database (molecular register). Respecting confidentiality of data provided by the notifier this database might be accessible only for official control authorities. In this regard the German control laboratories support the guidelines of a draft document of the Codex Alimentarius, which describes an international agreement on the exchange of information, detection methods and positive control materials concerning the low level presence of GMO.

Furthermore, it is considered to be necessary across the EU member states to develop a harmonised approach for sampling and analysis for non-authorised GMO, including reporting and result interpretation in the EU. In addition, in the EU no official institution is in place coordinating a harmonised approach for GMO testing which is based on a constant investigation of the global acreage situation.

Based on this the BVL is of the opinion that across the board of the EU a worldwide harmonization of sampling and detection techniques is necessary. It is therefore suggested that in addition to the harmonisation initiated at Codex Alimentarius level an international working group should be established, where the experts on this field compile all commonly agreed and practice-oriented guidlines needed for sampling and detection of GMO.

Contained use of GMO

It is noticed that neither an EU wide harmonised concept nor a generally accepted guideline so far exist for the inspection of genetic engineering facilities (contained use) and for detection of the respective GMO used in these facilities. In order to establish a harmonised approach for control of GMO in contained use the German Federal Länder have started to elaborate such a concept.

ITALY

[1 FEBRUARY 2008]
[SUBMISSION: ENGLISH]

Managing Italian Biosafety, sampling and detection.

As an EU member state, Italy participates in GM product decisions according to the common EU legislature.

The following information deals with systems in place in Italy for the implementation of legislation in force in EU, for the control system for GMOs and for the activities of Italian government linked to GMOs.

The development on Safety Assessment of Novel foods and Feeds is carried out jointly by the Ministry of Environment and by the Ministry of Health.

Ministry of Environment

The Ministry of Environment has been managing since 2003 the issues of Italian biosafety. The Directorate General for Nature Protection of the Italian Ministry of Environment, Land and Sea Protection has played the double role of National Focal Point for the Cartagena Protocol and of National Competent Authority (NCA) for the EU Directive on GMOs (Dir 2001/18/CE). In the framework of Regulation 1829/2003 the Directorate challenge with the art.11 and Annex II of the Cartagena Protocol

- The information and communication technologies played a key role in managing Italian biosafety in the framework of the implementation of the Cartagena Protocol, the Italian Biosafety Clearing-House (http://bch.minambiente.it) has been developed as a information and communication technology mean to create the liaison between different actors around the GMOs, namely the researchers, the NGOs, citizens, industry and other National Competent Authorities. As such, the Italian Biosafety Clearing-House also implements tasks required by the EU Directive, Aarhus Convention as National Focal Point.

  All such actors can either contribute or use the BCH according to their specific interests. Information published in the BCH include: notifications from industry; results of main research on GMOs, legal framework, general information. The public can accede the information published in the BCH to participate in the public consultation process and forward their comments to the NCA, through the BCH.

- As NCA for Dir. 2001/18/CE, the Biosafety Unit of Ministry of Environment:
  - Is responsible for the evaluation of the Notifications (including risk assessment and risk management);
  - Chairs the Interministerial Assessment Committee (IAC);
  - Is responsible for the authorization process (according to IAC positions).

The Interministerial Assessment Committee (IAC), is a technical and scientific body, established according to domestic legislation (Decree 224/2003 receiving Dir. 2001/18/CE), which is responsible for the assessment of notifications.

The IAC produces a position to the NCA, which forms the basis for the authorisation. Ministry of Health, Ministry of Agriculture and representative of Italian Regions in collaboration with experts of scientific institutions, play a relevant role in IAC.

In fact the Governance system is implemented through the collaboration of different Institutional bodies, each one providing a "*gear*". The main gears are represented by the NCA, the IAC, and the Surveillance system (implemented locally through the Regional Authorities).

The Governance process is triggered by an input, in the form of a notification, or a critical issue or a question on GMOs on which a decision needs to be taken.

The "gears" interact and the NCA provides an output, in the form of a risk assessment, a risk management, indications on the surveillance, or responses on the specific issues.

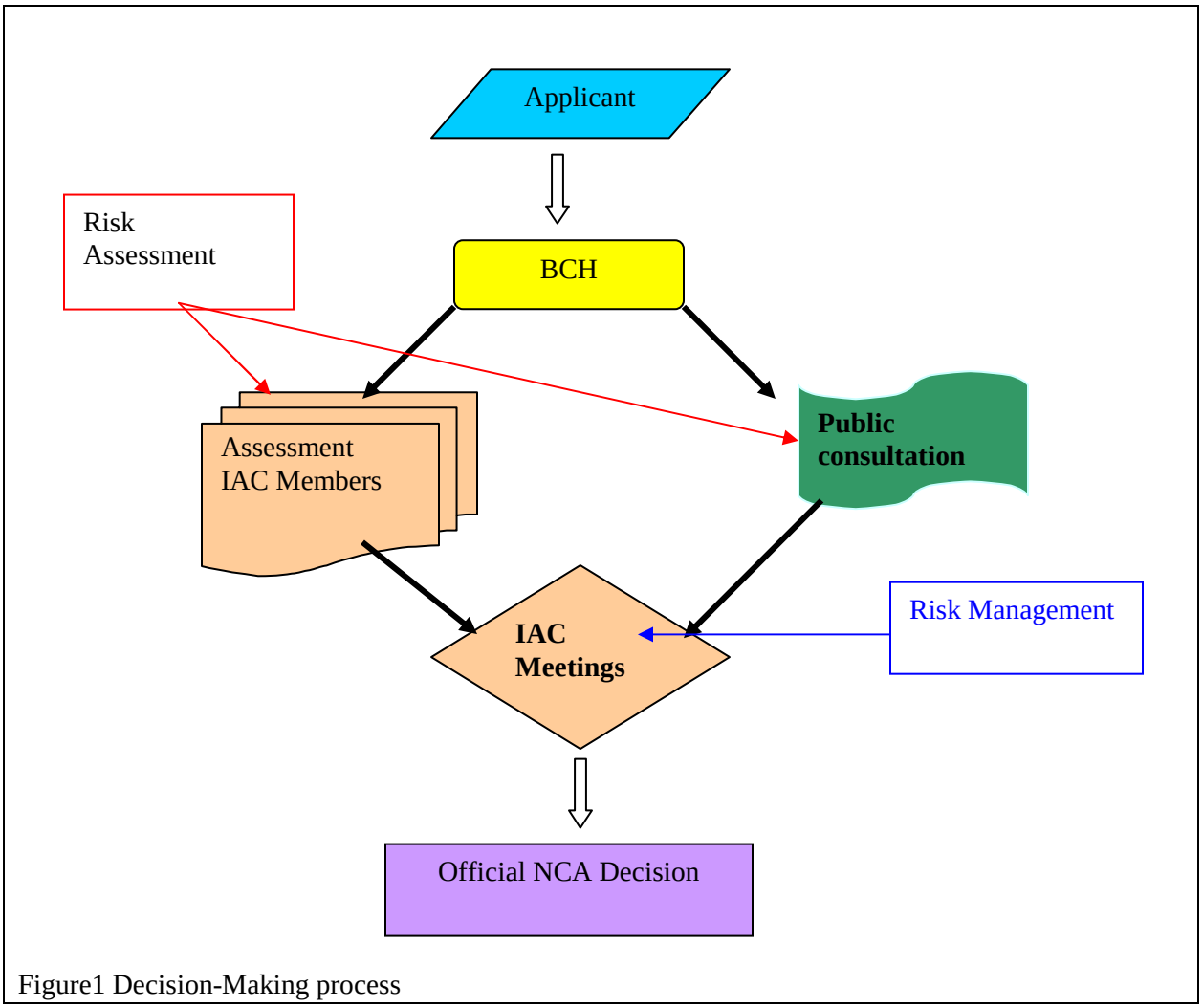

Figure1 Decision-Making process

As for the decision-making process (figure 1) when a notification is presented to the National Competent Authority, it follows these steps:

1. It is published in the BCH;
2. The members of the IAC and the public can access the documents and can make their own assessments (risk assessment phase);
3. The IAC members meet and prepare a position on the notification (identification of risk management procedures);
4. The NCA takes an official decision.

Ministry of Health

Ministry of Health is the Competent Authority for the implementation of EU Regulations 1829/2003 and 1830/2003.

- As for the authorization process Italy is fully in line with the other Member States of the EU where the risk assessment is conducted by EFSA and in the Standing Committee on the Food Chain and Animal Heath the Competent Authority for the final decision on the authorization is the Ministry of Health.

- The control of commercialized GMOs is implemented through a system implying both services all over the countries and central bodies as shown in figure 2*
  The control system is implemented in strict cooperation with the Community reference Laboratory that acts with the assistance of the ENGL (European network of GMOs laboratory). National Reference Laboratories (NRL) in the framework of the EU Regulation 1981/2006 are the Istituto Superiore di Sanità (ISS), the Istituto Zooprofilattico Sperimentale Lazio e Toscana (IZSLT) and Ente Nazionle Sementi Elette (ENSE).

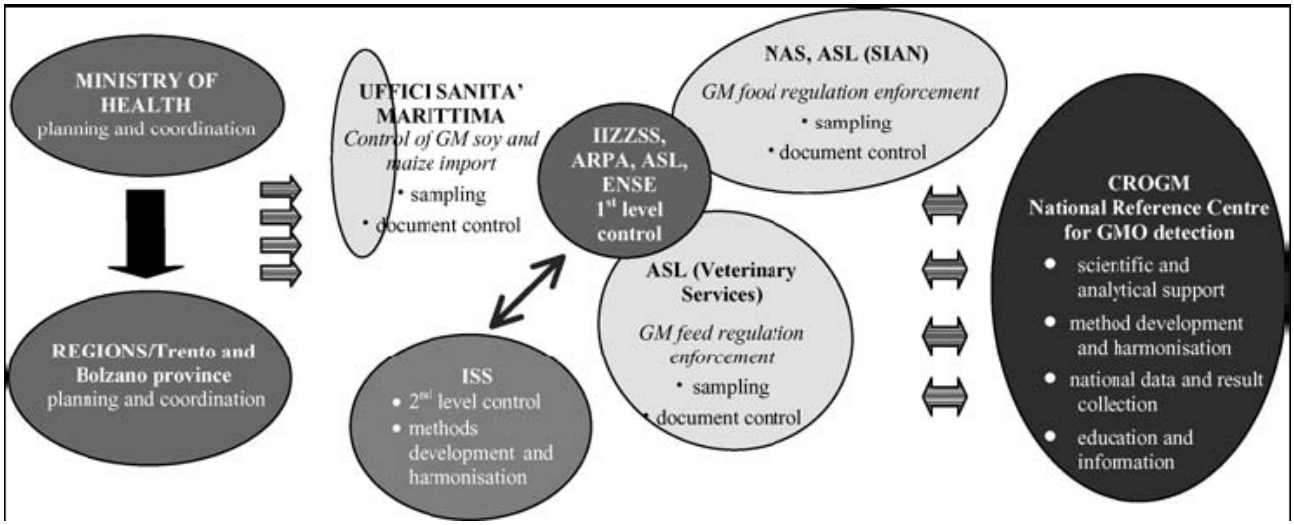

Figure 2. The official national control of GMOs in food and feed institutions and relative tasks are schematically represented by the circles

In the framework of EU Regulation 882/2004 the NRL are ISS and IZSLT.

Additional activities have been put forward by the Ministry of Health in collaboration with the ISS - GMO and Mycotoxins Unit (ISS Is an Italian governmental institute involved in scientific-technical research, control and advice functions in public health as a technical and scientific body, under the authority of the Minister of Health) and the IZSLT National Reference Centre for GMO analysis (CROGM):

- funding research projects at national level
- participation to the European Network of GMO laboratories (ENGL) for the tasks outlined in the annex of Regulation CE 1829/2003, mainly in the testing and validation of methods for sampling, detection, identification and quantification of GMOs.
- Analytical support to laboratories involved in the national official control promoting exchange of information, materials and expertise
- endorsement of an Italian network of GMO laboratories

Furthermore the CROGM assist 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. This is currently being performed as shown in Figure 3* but the Reference Centre is developing a database available on the Internet, which would facilitate data input, output and elaboration, while assuring consistence, completeness and confidentiality of information.

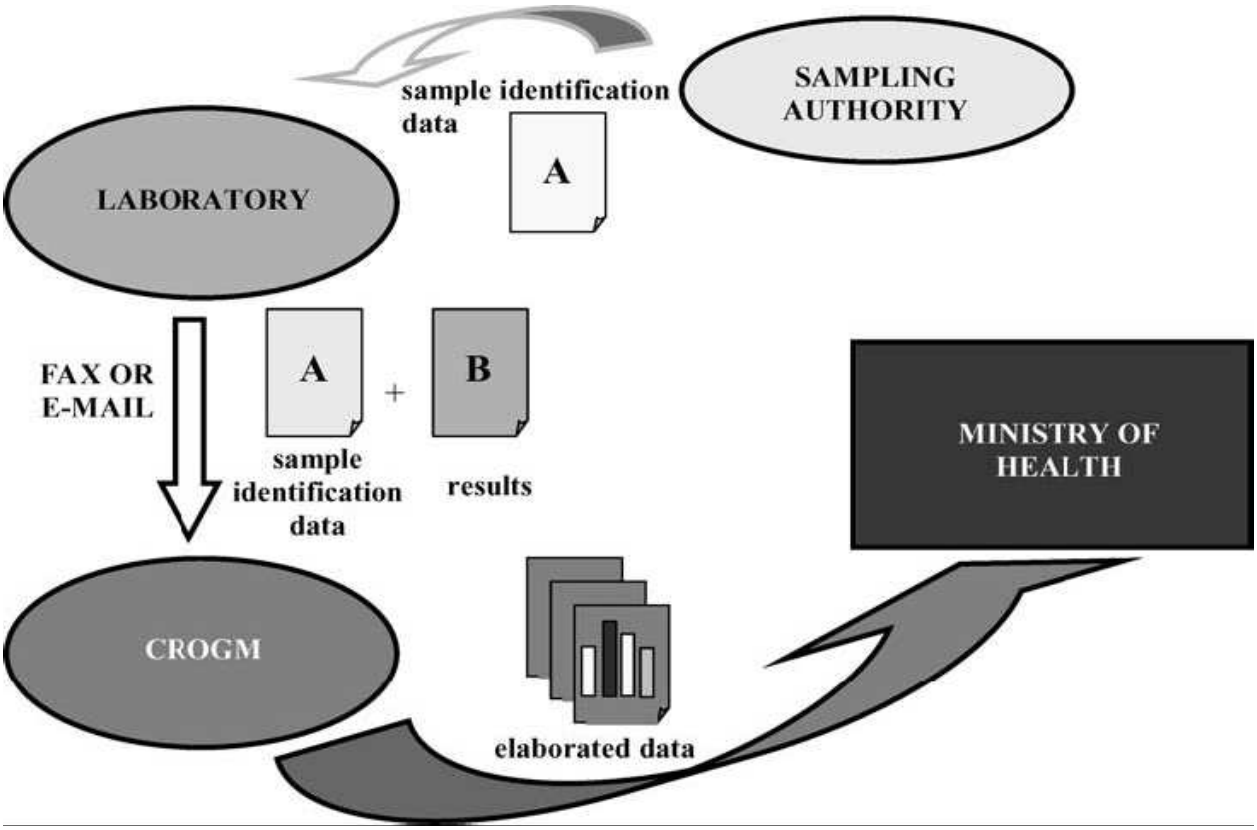

Figure 3, Flow of data and results for the official national control of GMOs in food and feed

* (Ciabatti I.et al. 2005 *Veterinary Research Communications*, 29 Suppl. 2 31–34).

MEXICO [3 DECEMBER 2007]
[SUBMISSION: SPANISH]

De conformidad con el párrafo 11 de la decisión BS-III/10 Manipulación, transporte, envasado e identificación de organismos vivos modificados: párrafo 2 (a) del Artículo 18, que dice a la letra:

Pide a las Partes en el Protocolo e *invita* a otros Gobiernos, organizaciones regionales e internacionales e interesados directos, a presentar al Secretario Ejecutivo, a más tardar tres meses antes de su cuarta reunión, información sobre la experiencia adquirida en el uso de las técnicas de muestreo y detección y sobre la necesidad de elaborar criterios de admisibilidad y armonizar las técnicas de muestreo y detección y las modalidades de los mismos, y *pide* al Secretario Ejecutivo que recopile la información recibida y prepare un informe sumario a ser considerado por la cuarta reunión de la Conferencia de las Partes que actúa como reunión de las Partes en el Protocolo

El Gobierno de México informa lo siguiente.

Autoridades competentes.

Las actividades de monitoreo se han llevado a cabo por la Secretarías de Salud (SSA), Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT) y la Secretaría de Agricultura, Desarrollo Rural, Pesca y Alimentación (SAGARPA) cada una utilizando metodologías específicas de acuerdo con sus competencias.

Desde el año 1995, la Secretaría de Salud ha evaluado Organismos Genéticamente Modificados (OGMs), habiendo aprobado hasta el momento 47 eventos de transformación que incluyen productos como tomate, alfalfa, papa, algodón, canola, soya, remolacha y maíz.

Objetivos del monitoreo y detección de OGMs

La Secretaría de Salud (SSA) es l autoridad competente para autorizar la utilización de OVMs como alimento humano, animal y para el procesamiento.

La Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) órgano desconcentrado de la SSA consideró necesario establecer un sistema de monitoreo de OGMs en los productos destinados al uso o consumo humano, que busque alcanzar los siguientes objetivos:

- Determinar la proporción de embarques que ingresan al país con OGMs destinados al uso o consumo humano.
- Determinar los eventos específicos contenidos en dichos embarques.
- Detectar la presencia de OGMs no autorizados por esta Comisión Federal para proteger la salud pública dando cumplimiento a lo establecido en la Ley de Bioseguridad de Organismos Genéticamente Modificados.

Eventos liberados de OGMs

Dentro de los eventos liberados para su comercialización por parte de la COFEPRIS figuran: algodón, canola, papa, tomate, remolacha, alfalfa, arroz, soya y maíz.

Los OGMs de algodón y canola se emplean básicamente para la obtención de aceites, productos que por su propio proceso no presentan restos de ADN y solo trazas de proteínas. Debido a que las nuevas proteínas

se encuentran presentes en muy bajas concentraciones; estos productos no son elegibles para ser incluidos en el muestreo.

Los eventos de tomate y papa aprobados en los años 1995, 1996 y 1998, no se encuentran actualmente en el mercado por no haber presentado buena aceptación ni desempeño.

La alfalfa y la remolacha no son productos que se empleen como base para un gran número de alimentos de consumo humano, siendo sus usos casi exclusivamente para alimentación animal.

Por lo anterior, los productos elegidos para el muestreo son los siguientes:

Maíz (base de la alimentación en México y cultivo de alta sensibilidad social). Como etapa inicial del programa de monitoreo y a modo de programa piloto, se propone enfocarse exclusivamente a este cultivo.

Arroz (existen muchos desarrollos a nivel mundial aunque ninguno está disponible de manera comercial; pese a lo cual se han presentado casos de contaminación de cultivos comerciales).

Soya (extractos proteicos de esta oleaginosa son empleados extensamente en leches de soya, sopas instantáneas, etc.).

Trigo (cereal que se emplea como base de numerosos productos alimentarios, que si bien no está liberado para su comercialización en México, existen desarrollos aprobados en otros países que proveen trigo a México).

Procedimiento para llevar acabo el monitoreo y la detección de OVMs

La toma y envío de la muestra estaría coordinada por la Comisión de Operación Sanitaria y la realizaría la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación debido a que es esta dependencia la que cuenta con personal en frontera para realizar esta actividad. El procedimiento para la toma de muestra y remisión a laboratorio se desarrollaría de acuerdo al “Manual de Procedimientos para el Muestreo y Tratamiento de Granos” de la SAGARPA en su Parte I “Muestreo de Granos”.

La cantidad de muestras a tomar para cada uno de los productos anteriormente señalados y de los puntos de ingreso a nuestro país, serían fijadas por la COFEPRIS de manera anual con base en la información estadística sobre importaciones de estos productos. Para tal fin se consideraría el número de muestras estadístico siguiendo un muestreo aleatorio estratificado. Hasta que se cuente con información estadística sobre la prevalencia de eventos transgénicos en embarques de importación, se considerará una prevalencia del 50%, un límite de error del 1.5% y un desviación estándar de 10.

Las muestras serían remitidas al Laboratorio Estatal de Salud Pública del Estado de Veracruz para su análisis del evento específico. La información resultante se remitiría a la COFEPRIS para su análisis y toma de decisiones.

Experiencia en muestreo y detección de liberaciones no intencionales de OVMs

En cuanto al monitoreo llevado a cabo por la SEMARNAT, el Instituto Nacional de Ecología (INE), órgano desconcentrado de esta Secretaría, ha llevado a cabo monitoreo y detección de presencia accidental de material genéticamente modificado en regiones de alta diversidad genética de maíz criollo: Oaxaca (2001-2007), Jalisco (2002), Michoacán (2003), Puebla (2006-2007), DF (2007), Guerrero (2002) y Sinaloa (2007) a solicitud de una ONG y una Universidad estos dos últimos, respectivamente. Al menos para los casos de Oaxaca (algunos años) y Jalisco, la Comisión Nacional para el Conocimiento y Uso de la Biodiversidad (CONABIO) participó proponiendo junto con el INE la metodología de muestreo y de detección, en pocas ocasiones saliendo a campo y en otras financiando los estudios.

El monitoreo sistemático de la Sierra de Juárez, Oaxaca ha creado y mantenido una colaboración estrecha con las comunidades de la zona, y por otro lado este trabajo demuestra el compromiso del gobierno de México para buscar un uso seguro de la biotecnología. Consideramos una experiencia importante de compartir para este tipo de monitoreo que se debe involucrar a las comunidades locales y mantenerlas informadas y con un manejo transparente de la información obtenida de los monitoreos, a partir de las muestras que ellos proporcionan al gobierno para este fin. Parte de la investigación que se ha realizado respecto a liberaciones no intencionales de OVMs en nuestro territorio ha sido publicada en revistas arbitradas internacionales[1-3] y ha sentando un precedente de monitoreo muy importante para México como centro de origen y de diversidad genética de maíz.

La SAGARPA ha establecido un protocolo en el cual se describen las técnicas de muestreo aplicadas a los organismos genéticamente modificados (OGMs), que no difieren en esencia de las técnicas de muestreo aplicadas a cualquier otro grupo de organismos. Lo que se busca es la representatividad de las muestras respecto a los atributos a evaluar de la población original.

Con el apoyo de los proyectos GEF y PNUD- CIBIOGEM se han creado y/o fortalecido tres laboratorios para la detección de material GM: el laboratorio Estatal de Salud Pública de Veracruz (SALUD), el Laboratorio de Biología Molecular de la Dirección General de Investigación y Capacitación Ambiental, INE (DGCENICA) y el Laboratorio de Detección, del Centro Nacional de Referencia Fitosanitaria de la Dirección General de Sanidad Vegetal de la SAGARPA.

En cuanto a las técnicas analíticas, la COFEPRIS, Salud tiene un proyecto en el marco del PNUD, cuyo objetivo central es establecer metodologías que permitan elaborar un sistema de monitoreo y vigilancia respecto de la presencia de secuencias transgénicas en granos y productos de maíz en México, para posteriormente transferir los métodos más apropiados a los laboratorios nacionales de la Secretaría de Salud. El desarrollo del proyecto se visualiza en dos etapas, ambas de seis meses: una para seleccionar métodos cualitativos y determinar en una primera aproximación el tipo y variedad de eventos que se encuentran en la mezcla de granos de importación, y una segunda etapa para llevar a cabo las cuantificaciones correspondientes. Estas metodologías se transferirán al laboratorio Estatal de Salud Pública de Veracruz (al cual se lo está equipando en el marco del mismo proyecto para poder realizar las determinaciones analíticas de rutina tal como se expuso al inicio (TOMA DE MUESTRAS).

En cuanto a los métodos de detección en el laboratorio de Biología Molecular de la DGCENICA se realiza de manera rutinaria el análisis de muestras mediante la amplificación por PCR punto final, tanto para hacer una detección de amplio espectro (con marcadores comunes en los OGMs, como el promotor 35s y el terminador ***nos***), como para establecer la identidad de los eventos (con marcadores "evento-específicos"). Para cada lote analítico se cuenta con materiales de referencia certificados, controles positivos y negativos que proporcionan la evidencia del correcto desempeño de las pruebas.

Desde el año 2002 la DGCENICA tiene acreditadas ante la única entidad a nivel nacional que tiene dicha atribución, 30 pruebas analíticas y desde el año 2005 esta acreditación incluye las desarrolladas en su propio Laboratorio de Biología Molecular[4]. Actualmente se encuentra en proceso de acreditación de las pruebas de PCR en tiempo real para identificación y cuantificación de eventos específicos en algodón, debido a que las empresas promoventes han provisto de los materiales de referencia para los eventos que se han liberado a nivel pre-comercial en nuestro país.

Además, los resultados generados en la DGCENICA también están respaldados por una certificación técnica internacional otorgada por la Alianza de Laboratorios de Genetic ID. Debido a que el laboratorio pertenece a esta alianza, tiene acceso a la aplicación de todos los métodos de extracción de ADN y de amplificación por PCR en punto final y en tiempo real que se han desarrollado en Genetic ID para la

detección, identificación y cuantificación de OGMs, los cuales incluyen todos los eventos comerciales de maíz, así como otros cultivos como algodón, tomate, calabaza, entre otros. Actualmente nuestro laboratorio se encuentra en el proceso de incorporación al anillo de laboratorios de la USDA.

En cuanto a la armonización de metodologías a nivel nacional se ha organizado el Primer Foro de Detección de OGMs el pasado septiembre y el Primer taller de Monitoreo que se celebró el 22 y 23 de noviembre de 2007.

México considera sumamente importante contar con laboratorios certificados y capaces de analizar las muestras para detección de OVMs con controles de calidad suficientes para garantizar la calidad de los resultados obtenidos. Consideramos también importante contar con materiales de referencia y protocolos que faciliten el desarrollo de estas metodologías. Así como generar espacios para discusiones técnicas que permitan mejorar protocolos y determinar limitaciones metodológicas.

Bibliografía

1. Ortiz-García, S., et al., Replay to Cleveland et al.'s "Detecting (trans)gene flow to landraces in centers of crop origin: lessons from the case of maize in Mexico". Environmental Biosafety Research, 2005. **4**: p. 209-215.
2. Ortiz-García, S., et al., Absence of detectable transgenes in local landraces of maize in Oaxaca, Mexico (2003–2004). Proceedings of the National Academy of Science, 2005. **102**: p. 12338-12343.
3. Ortiz-García, S., et al., Transgenic Maize in Mexico. BioScience, 2006. **56**: p. 709-710.
4. Rocha, M. y A. D. Nava. 2006. Montaje de técnicas moleculares para la identificación de eventos específicos de organismos genéticamente modificados (OGMs) en maíz. Informe anual de actividades, Centro Nacional de Investigación y Capacitación Ambiental, Instituto Nacional de Ecología

NEW ZEALAND

[28 NOVEMBER 2007]
[SUBMISSION: ENGLISH]

Background

New Zealand does not routinely sample and test for Living Modified Organisms in shipments for food, feed or processing.

However, New Zealand has an extensive pre-border testing regime for all imports of seeds for sowing in New Zealand that have genetically modified (GM) 1/ varieties grown commercially overseas. Four seed import protocols exist: maize and sweet corn (*Zea mays*) 2/, soybean (*Glycine max*) 3/, oilseed rape (*Brassica napus* var. *oleifera*) 4/ and lucerne (*Medicago sativa*) 5/.

1/ Genetically modified organism means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material—

(a) Have been modified by in vitro techniques; or

(b) Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques:

Hazardous Substances and New Organisms Act. 1996. Section 2, Interpretation

2/ http://www.biosecurity.govt.nz/files/imports/plants/papers/gm-seeds/zea-mays-protocol.pdf

3/ http://www.biosecurity.govt.nz/files/imports/plants/papers/gm-seeds/glycine-max-protocol.pdf

4/ http://www.biosecurity.govt.nz/files/imports/plants/papers/gm-seeds/brassica-napus-protocol.pdf

The purpose of this regime is to ensure that GM seeds that have not been approved for release to the environment in New Zealand are not inadvertently imported in consignments of seeds for sowing and commercially planted.

Currently there have been no applications or approvals for commercial planting or to release GM crops to the environment in New Zealand, therefore the shipments tested are all intended to be non-GM.

The testing is done by laboratories approved by New Zealand's Ministry of Agriculture and Forestry (MAF) using qualitative polymerase chain reaction (PCR) to determine the presence or absence of specific GM sequences in seed material.

The sampling and detection protocol

New Zealand's protocol requires a high level of confidence (95%) that 1 GM seed in 1000 seeds will be detected. This confidence level was selected after considering best agricultural practice in producing seeds, the ability to test to this level, and New Zealand's need to continue to access new varieties of seed.

The sampling procedure is designed to collect a representative sample from the seed lot, and is based on International Seed Testing Association (ISTA) methodology 6/.

New Zealand used the sampling spreadsheet of the Grain Inspection, Packers and Stockyards Administration, United States Department of Agriculture 7/, to develop the sampling plan for the first protocol that was implemented in 2002. This spreadsheet is no longer used and has been replaced by the ISTA software program SeedCalc7. This computer software can be downloaded from the internet free of charge. The software enables users to design testing plans for purity/impurity characteristics, including testing for GM traits in conventional seed lots 8/.

The test is designed to indicate the presence or absence of GM seeds, but not the concentration of GM seeds in the seed lot, nor the specific type of modification that has been made. Seed lots which test positive for GM seeds are not allowed to be imported into New Zealand.

The laboratories approved by MAF to test seeds must participate in proficiency testing, use internal quality controls, and be accredited to the International Standardisation Organisation (ISO) standard ISO 17025: 2000 *General requirements for the competence of testing and calibration laboratories.*

Standards for testing procedures and methods

The laboratories approved by MAF must use validated PCR methods capable of detecting GM seed in the seed sample at the lowest reliable limit of detection. ISO standards may form the basis for testing procedures and methodology, and include:

- ISO 21569: 2005 Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Qualitative nucleic acid based methods

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5/ http://www.biosecurity.govt.nz/files/imports/plants/papers/gm-seeds/medicago-sativa-gm-testing-protocol.pdf

6/ http://www.seedtest.org/en/productdetail---1--1082--203--88.html

7/ http://archive.gipsa.usda.gov/biotech/samplingplan1.xls

8/ http://www.seedtest.org/en/content---1--1143.html

- ISO 21570: 2005 Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Quantitative nucleic acid based methods

- ISO 21571: 2004 Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Nucleic acid extraction

Cost

The importer is required to meet the costs of GM seed testing. The testing costs vary between NZ$200 (US$150 in November 2007) and NZ$650 (US$488 in November 2007), depending on the laboratory and PCR tests used.

Testing typically takes two to seven days, depending on laboratory workloads. Most importers arrange for testing to be conducted offshore prior to shipment of seeds so that delays at the border are minimised.

Testing costs are disproportionately higher for small volume imports of breeders and pre-basic seeds (the earliest generations of seed produced by a breeding programme). These seeds cost a lot more to buy than bulk seed because they are more expensive to produce, and there is often a very limited amount. The protocols therefore have a few additional options to facilitate the importation of small volumes for breeding, trial and research purposes.

Limitations of using 95% confidence that shipments contain less than 0.1% GM

Sources of error fall into three basic categories:
- sampling,
- sample preparation, and
- analytical method.

Sampling

The test is destructive. A sample of 3200 seeds is sampled from a seed lot, and tested for specific GM sequences. 9/

No sampling and detection regime can ever guarantee that no GM seeds are present in consignment of seeds for sowing. To achieve certainty would require testing every seed and then there would be nothing left to plant.

If the number of GM seeds in a consignment is very small then a successful positive test relies on some of those GM seeds being in the sample. For example, if a bag contains 100 marbles and 30 are sampled and all are black, this doesn't guarantee that all the marbles are black, but it does give a high level of confidence that many of them are black.

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.

Sample preparation

The laboratory equipment used to grind seeds should produce material of a uniform and optimum size. The test accuracy can be affected if the sample is not thoroughly homogenised after grinding the sample.

9/ http://www.biosecurity.govt.nz/imports/plants/genetically-modified-organisms/plants-seeds.htm

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% of the time. This is generally considered to be 0.01% or 1 GM seed in 10,000 seeds (i.e. there is a 5% chance of a false result).

As the sample size approaches the limit of detection, repeat testing may be needed to resolve inconclusive test results. This can create delays before decisions can be made. A sample size less than the limit of detection should be selected to avoid false results and delays.

Four types of results (and consequences) are possible from tests:

GM is: Test reads	Present	Absent
Positive	**True positive**, shipment containing GM not allowed to enter New Zealand	**False positive**, non-GM shipment not allowed to enter New Zealand
Negative	**False negative**, shipment containing low-level GM allowed to enter New Zealand and planted	**True negative**, non-GM shipment allowed to enter New Zealand and planted

Both types of false results can have flow on effects:

- for a false positive, there are costs to the importer of a non-GM shipment being rejected; and

- for a false negative, in addition to the potential risks of the GM organism itself, there are potential costs for the importer or grower if an unapproved GM organism is detected after planting leading to subsequent management or destruction of the planted crop.

New Zealand's approach will also 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 New Zealand so that it would need to distinguish between approved and unapproved GM seeds in shipments). New Zealand will need to consider alternative strategies to cope with these changes.

Conclusions

There are three conclusions from New Zealand's 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.

The need for modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques

Sampling and detection of living modified organisms is a highly technical and specialised field that is being considered by relevant competent organisations such as ISTA and within the Codex Alimentarius Commission.

The ISTA is developing rules for performance-based accreditation of laboratories for testing for specified traits, including testing for GM material.

The Codex Committee on Methods of Analysis and Sampling is working on criteria for methods of detection and identification of foods derived from biotechnology.

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

NORWAY [13 DECEMBER 2007]
[SUBMISSION: ENGLISH]

[…]

Decision BS-III/10 – Sampling and Detection
Paragraph 11 of Decision BS-III/10 on Article 18, paragraph 2 (a) of the third Meeting of the Parties to the Cartagena Protocol requests requests Parties and invites other Governments to submit to the Executive Secretary information on experience gained with the use of sampling and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques.

As stated in the Norwegian submission regarding experience gained with the use of existing documentation referred to in paragraph 1 of Decision BS-III/10, Norway has gained very little experience due to the fact that LMOs approved in the EC are either prohibited in Norway or the need for restrictions or prohibitions are under consideration, and that no genetically modified food and feed is produced, imported to or marketed in Norway.

We do however have gained experience with the use of sampling and detection techniques in order to verify that imported food and feed do not contain LMO which are not allowed in Norway and that any content of LMO approved in the EU does not exceed the threshold of 0,9 % and is adventitious or technically unavoidable. Each year, the Norwegian Food Inspection Authority Mattilsynet takes up to 100 samples from food products and 110 samples from feed products for analysis. Presently, the method of sampling differs between food and feed products and also between packaged and bulk or other large consignments of products. The reason for the difference between food and feed products is that the controls of feed and food have been carried out in different control programs.

The method of sampling from bulk or other large consignments of food products is based upon EC Directive 98/53/EC laying 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. The sample is divided into three parts; one is left at the business where the sample is taken, one is sent to the Norwegian Veterinary Institute for analysis and the last one is kept at the local branch of the Norwegian Food Safety Authority that took the sample. The size of the sample taken from packaged products or smaller

consignments depends on the type of product. For soy seeds/kernels, the size of the sample should be minimum1000g. For corn seeds/kernels the size of the sample should be minimum 1700g. The size of the sample taken from other products should be minimum 1000g. These sample sizes are necessary in order to achieve a level of detection of 0,1 % and a level of quantification of 0,9 %. These levels are set in order to detect the lowest possible amount of LMO presence to avoid import of LMOs not allowed in Norway, and LMO presence above the limit for LMO labelling in Norwegian legislation.

The method of sampling from bulk or other large consignments of feed products follows the EC instruction pursuant to Directive 76/371/EC. 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 EC and from every fourth shipment from within the EC.

Given the differences of sampling methods applied to food and feed, the Norwegian Food Safety Authority intends during the 2008 to harmonise the way of sampling and to develop a protocol based on recommendations given by Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection.

The analysis are made by the Norwegian Veterinary Institute. The analysis made are mainly event-specific and cover the following LMO varieties: RRS, P35S, GA21, Bt11,Bt176, Mon810, Mon863, NK603,TC1507, LL601,LL62, Shanyou Bt63 og P35S-CaMV, CaMV, P35S-FMV and nptII for products containing rape seeds.

For reasons explained above, importers in Norway are generally requiring that the food and feed they import are not containing, consisting of or produced from LMO not allowed in Norway, and that any content of EC approved LMO is below the threshold of 0,9 % and adventitious or technically unavoidable. They 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 LMO.

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. Another experience is 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.

Sampling and detection are important tools for the enforcement of national legislation implementing the Cartagena Protocol on Biosafety. The results may however vary depending on the methods used. Development of criteria for 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. It could as a consequence also reduce the costs both for the industry and commerce and the authorities. The enforcement of national legislation implementing the Protocol would therefore in general be more effective.

Norway is therefore in favour of developing criteria for acceptability and harmonization of sampling and detection techniques. Given the technical nature of these issues, we favour a scientific committee being appointed with the specific task of providing scientific and technical guidance and possibly develop a proposal.

[...]

SLOVENIA

[18 JANUARY 2008]
[SUBMISSION: ENGLISH]

DEVELOPMENT OF GMO DETECTION AT THE NATIONAL INSTITUTE OF BIOLOGY (NIB) AND CURRENT ISSUES IN GMO DETECTION

1. *EXPERIENCES GAINED IN GMO DETECTION*

DEVELOPMENT OF GMO DETECTION AT THE NATIONAL INSTITUTE OF BIOLOGY

Previous experiences

Decision for GMO detection in National Institute of Biology (NIB), Department of Biotechnology and Systems Biology was taken in 2000 on the basis of previous experiences with molecular biology, including transformation of plants and on the other hand experiences with analyses for official control in phytodiagnosis. In the meantime methods for GMO detection, mostly using PCR and Q PCR were introduced. Testing of GMOs is performed in food, feed and seeds from 2002.

Training

Valuable experiences on GMO detection were gained in the training courses on detection techniques for Genetically Modified Organisms (GMOs) in foods, organized by The European Commission (Joint Research Centre, Biotechnology and GMOs Unit) and the World Health Organisation (WHO Food Safety Programme in Europe) (http://gmotraining.jrc.it/). Workshops were organized also in Slovenia in the frame of UNEP-GEF project Development of National Biosafety Frameworks. Additional knowledge was gained by visiting some other GMO detection laboratories (Swiss, Austrian).

CURRENT STATUS OF NATIONAL INSTITUTE OF BIOLOGY IN GMO DETECTION

National institute of biology as national reference laboratory

NIB was nominated as Slovenian National reference laboratory (NRL) according to EC 882/2004 in 2006.

NIB is providing scientific and technical assistance to the competent authorities: Ministry of the Environment and Spatial planning, Ministry of Agriculture, Forestry and Food, Ministry of Health as well as their inspection services.

NIB is actively cooperating with Community reference laboratory (CRL), which is Commission's Joint Research Centre. It is also participating in the validations of the methods proposed by the applicants of new GMO in the EU market organized by Community reference laboratory (EC 1981/2006).

International cooperation

One of the most important places for exchange of information on GMO detection was and still is the experts platform European Network of GMO laboratories (ENGL). The chairmanship of the network is under the responsibility of the Unit "Biotechnology and GMOs" of the European Commission’s Joint Research Centre's Institute for Health and Consumer Protection. NIB cooperated in ENGL from very beginning, first as observer and from 2004 as a member (http://engl.jrc.it/). NIB researchers also actively cooperate in working groups of ENGL.

NIB had/has bilateral projects on GMO detection with laboratories in Portugal, Spain and France.

NIB is cooperating in research project GM and non GM supply chains: their CO-EXistence and TRAceability (COEXTRA), started in 2005 as project in 6th European framework programme (http://www.coextra.eu/). Co-Extra is a research programme on co-existence and traceability. The goal of the project is to support their implementation and to foster a science-based debate among stakeholders. NIB is heading Workpackage 5: development and integration of analytical traceability tools.

Accreditation

The National Institute of Biology, Department of Biotechnology and Systems Biology is accredited by Slovenian accreditation for qualitative and quantitative testing of genetically modified organisms Reg. No. LP-028 from 22nd August 2003 (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.

One of the important indicators of laboratory performance is cooperation in proficiency tests, where NIB is participating in 3 to 4 tests/year.

Detection of GMOs in samples of food, feed and seeds

NIB is performing analyses for official control in food, feed and seed samples received from responsible inspection services. Around 200 samples are tested per year. The results of official control in Slovenia can be seen also from the final report of the EC-Food and Veterinary office (FVO) mission in Slovenia in 2006. (http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=5262).

The results of monitoring are published in the internet side of Slovenian Biosafety portal (http://www.biotechnology-gmo.gov.si/eng/index.html).

2. THE NEED FOR AND MODALITIES OF DEVELOPING CRITERIA FOR ACCEPTABILITY OF, AND HARMONIZING, SAMPLING AND DETECTION METHODS

SOME ACTUAL TOPICS IN GMO DETECTION

Standardized methods

Some standards for GMO detection were published describing instructions for nuclear and protein based analyses and some individual methods are added as informative annexes (ISO 21571:2005, ISO 21572:2004, ISO 21569:2005, ISO 21570:2005, ISO 24276:2006). Detection of individual GMOs in offical control laboratories in EU is based mostly on the methods proposed by applicant and validated by CRL. It will be appreciated if these methods will also become part of the standards.

Methods for screening elements and reference genes

Methods for screening elements are not in responsibility of CRL, therefore development is subject to development and introduction by laboratories.

There are different reference genes used in methods proposed by applicant, what is difficult to handle for individual laboratory. The usage of one or two reference genes per plant will simplify the detection.

Measurement uncertainty (MU)

ENGL Working group on measurement uncertainty produced a Guidance Document on Measurement Uncertainty for GMO Testing Laboratories (EUR Report 22756 EN). giving guidance on possible approaches.

Document Measurement uncertainty revisited: Alternative approaches to uncertainty Evaluation (EuroLab Technical Report No. 1/2007) is referring on different possible options of calculations of MU and proposes that they should be compared to obtain uncertainty estimates.

On the bases of both documents it will be useful to decide on defined MU to be used in official control to harmonize the decision making of compliance/non-compliance of samples.

Scope of accreditation

Different accreditation bodies have different approaches for evaluation of laboratories to be accredited. There are also differences between the national interpretations of the term flexible scope. Harmonization will be appreciated. With a lot of new GMOs coming on the market higher flexibility of the accreditation scope is giving better possibilities to accredit methods rapidly.

Detection of numerous GMOs

NIB is participating in COEXTRA project which is developing high throughput methods.

Detection of unknown GMOs

Special challenge is detection of GMOs not approved in particular country. CRL is providing very efficient and quick assistance on the methods for GMOs unexpectedly appearing in European market, like Bt 10, LLrice601.

Detection of unknown GMOs is very challenging and NIB is cooperating in working group of ENGL dealing with the topic.

SOME NIB PUBLICATIONS IN GMO DETECTION

TOPLAK, Nataša, OKRŠLAR, Veronika, STANIČ RACMAN, Darja, GRUDEN, Kristina, ŽEL, Jana. A high-throughput method for quantifying transgene expression in transformed plants with real-time PCR analysis. Plant. mol. biol. report., 2004, vol. 22, 237-250.

CANKAR, Katarina, RAVNIKAR, Maja, ŽEL, Jana, GRUDEN, Kristina, TOPLAK, Nataša. Real-time polymerase chain reaction detection of Cauliflower mosaic virus to complement the 35S screening assay for genetically modified organisms. J. AOAC Int., 2005, 88, 3, 814-822.

JERMAN, Sergej, PODGORNIK, Aleš, CANKAR, Katarina, ČADEŽ, Neža, SKRT, Mihaela, ŽEL, Jana, RASPOR, Peter. Detection of processed genetically modified food using CIM monolithic columns for DNA isolation. J. chromatogr., 2005, vol.1065, 107-113.

ŽEL, Jana, CANKAR, Katarina, RAVNIKAR, Maja, CAMLOH, Marjana, GRUDEN, Kristina. Accreditation of GMO detection laboratories: improving the reliability of GMO detection. Accredit. qual. assur., 2006, 10, 531-536.

CANKAR, Katarina, VAN DIJK, J.E., GRUDEN, Kristina, BLEJEC, Andrej, MCNICOLL, Jim, KOK, Esther. An approach to the analysis of DNA microarray data and its use in food safety. Informatica medica slovenica, 2006, 11, št. 1, 34-39.

CANKAR, Katarina, ŠTEBIH, Dejan, DREO, Tanja, ŽEL, Jana, GRUDEN, Kristina. Critical points of DNA quantification by real-time PCR-effects of DNA extraction method and sample matrix on quantification of genetically modified organisms. BMC Biotechnol, 2006, vol. 6, no. 37.

Jana Žel, Kristina Gruden, Katarina Cankar, Dejan Štebih, and Andrej Blejec:Calculation of Measurement Uncertainty in Quantitative Analysis of Genetically Modified Organisms Using Intermediate Precision—A Practical Approach, Journal of AOAC International Vol. 90, No. 2, 2007

TRAPMANN, S., BURNS, M., BROLL, H., MACARTHUR, R., WOOD, R. K. S., ŽEL, Jana. Guidance document on measurement uncertainty for GMO testing laboratories, (EUR - Scientific and technical research series). Luxembourg: Office for official publications of the European communities, 2007. 41 ISBN 978-92-79-05566-9.

Testing and sampling for GM seeds

ISTA and testing for GMO

ISTA is aimed at ensuring uniformity in seed testing on international level. It is spread over 76 countries worldwide and has around 100 accredited member laboratories. ISTA develops, adopts and publishes standard procedures for sampling and testing seeds (ISTA 2007) and issues certificates of seed quality. The ISTA International Seed Analysis Certificate (ISTA certificate) of seed quality is widely accepted and is used for transactions of seed in international trade.

Since the adventitious presence of genetically modified (GM) seeds in non GM seed lots has increasingly become a problem for the international seed trade, in 2001 ISTA established 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. For realisation of this approach the ISTA GMO Task Force was active in the following directions: establishing an ISTA Rules Chapter for the detection, identification and quantification of GMO in conventional seed; in organisation of proficiency tests on GMO testing and in exchange of information between laboratories at workshops and offering training programmes.

During the Ordinary Meeting 2005 in Bangkok the new version of the ISTA Rules Chapter 8 was adopted, which came into force on February 1, 2006. From that date on it is possible for laboratories to become ISTA accredited for the testing of seeds with specified traits under the performance based approach.

Specified trait testing including the detection, identification and quantification of GM seeds is a relatively new area of seed quality testing that ISTA has become involved in. Due to the complexity of specified trait testing, the approach adopted by ISTA to ensure reliability and accuracy of results all over the world, when testing seeds for specific traits, differs from the traditional standardised methodology used when testing other seed quality attributes. It is founded on a Performance Based Approach (PBA) under which laboratories are free to choose the methods they use with the ISTA International Rules for Seed Testing (2007) setting minimum requirements for the performance of laboratories carrying out such tests. The ISTA Member Laboratories have to 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 audit 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.

Seed sampling

Seed sampling is the first substantial part of seed quality control, starting from drawing the primary samples from the seed lot in the warehouse, up to obtaining the representative working sample of a suitable size for the appropriate seed test (Figure 1) (Kruse et al. 2004). The 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 (Bould 1986).

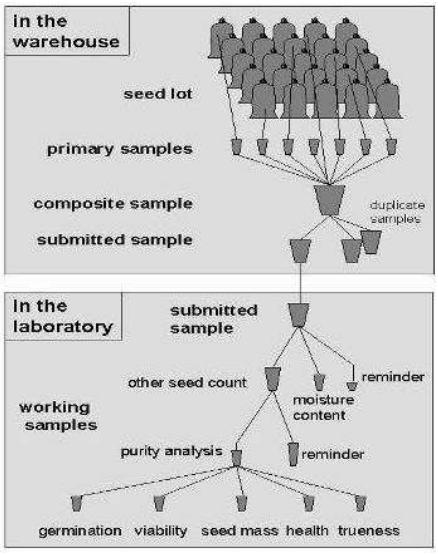

Figure 1: A schematic flow diagram of samples from the seed lot to the laboratory sample (figure from Kruse et al. 2004).

In the Commission Recommendation of 4 October 2004 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 it is stated that 'The general principles and methods of sampling seeds and other plant propagating material should be in accordance with the International Seed Testing Association (ISTA) rules and the associated ISTA Handbook on Seed Sampling'(Kruse 2004). In these documents methods are prescribed how the samples should be taken and prepared in order to report accurate, representative and uniform test results on an ISTA certificate. The GMOs are not addressed specifically.

A group of researchers within ISTA Statistics committee and ISTA GMO Task Force has developed a statistical tool named Seedcalc with a number of different software packages which can be used to design sampling and testing plans for purity/impurity estimation of seed lots for the adventitious presence/absence or levels of genetically modified seeds in conventional seed lots. The programme can also be applied for purity testing of other types of traits as well as for sampling and testing grains. The programme can be downloaded from the ISTA web page free of charge (http://www.seedtest.org/en/home.html). The concepts and directions to help in designing appropriate testing plans that minimize the risk to consumers and to seed producers using Seedcalc programme are given in the papers by Remund et al. (2001) and in Laffont et al. (2005) are overviewed in Šuštar-Vozlič and Rutar (2007).

A document was published by Central Science Laboratory (2005) on Statistical theory and analysis of GMO enforcement where sampling for GM seeds is addressed.

Literature:

Bould A. 1986. ISTA Handbook on Seed Sampling. 1st Edition. The International Seed Testing Association (ISTA), Bassersdorf, Switzerland.

International Rules for Seed Testing, Edition 2007. International Seed Testing Association

International Seed Testing Association. http://www.seedtest.org/en/home.html.

Kruse M (Ed.) 2004. ISTA Handbook on Seed Sampling. The International Seed Testing Association (ISTA), Bassersdorf, Switzerland.

Lafont J.L., Remund K., Wright D., Simpson R., Gregoire S. 2005. Testing for adventitious presence of transgenic material in conventional seed and grain lots using quantitative laboratory methods: statistical approaches and their implementation. Seed Science Research 15:197-204.

Remund K.M., Dixon D.A., Wright D.L., Holden L.R. 2001. Statistical considerations in seed purity testing for transgenic traits. Seed Science Research, 11, 101-119.

Statistical theory and analysis of GMO enforcement (stage). Defra Project CB0209. Final Project Report, January 2005. Central Science Laboratory, Sand Hutton, York

Šuštar-Vozlič J., Rutar R. Sampling for Seeds. In: Co-extra Deliverable D 4.3: Existing sampling plans and needs for the development of novel sampling approaches for Genetically Modified Organisms (GMO) evaluation. In press.

SOUTH AFRICA

[13 DECEMBER 2007]
[SUBMISSION: ENGLISH]

Paragraph 2(a), Article 18, LMO's for direct use as food, feed or for processing: Information on experience gained with the use of sampling of LMO's and detection techniques and the need for modalities of developing criteria for acceptability of, and harmonizing sampling and detection techniques.

In South Africa recognized detection techniques include PCR analysis and the ELISA strip test. 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 GMO's 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.

[...]

UNITED STATES OF AMERICA (USA) [21 DECEMBER 2007]
[SUBMISSION: ENGLISH]

Paragraph 2 (a), Article 18, Living modified organisms for direct use as food, feed or for processing: *The COP-MOP requests Parties and invites 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 (decision BS-III/10, paragragh 11).*

Currently there are no internationally or universally recognized sampling and detection methods for living modified organisms (LMOs). The United States believes that it would be helpful to have sampling and detection methods standardized, and we note that a number of international standard-setting bodies are currently working on these issues, including the International Life Sciences Institute, International Standards Organization, and most notably, the Joint FAO/WHO Codex Alimentarius Commission's 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. In the 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. 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.

The Codex Alimnetarius Commission is the world's most respected and widely followed standard-setting body for food safety. For this reason, the United States suggests that Parties to the Protocol, and other governments, rely on Codex for any necessary criteria for acceptability of, and harmonizing, sampling and detection techniques. 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.

U.S. experience with respect to sampling and detection of LMOs: The U.S. Department of Agriculture has established sampling methodology that has been used for sampling bulk grain in international commerce for many years. 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 product is likely present in low concentrations, representative sampling becomes especially important. Sampling error can occur when the sampling is being taken from the lot, when the sample is being prepared for analysis, and during the analysis itself. USDA had developed information specifically about considerations that should be taken with respect to sampling for detection of biotech grains. This information is available through this website:

http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=rd-bi

Once a representative sample has been obtained, a valid analytical method must be utilized. DNA-based tests can be reliable and sensitive but are expensive, time-consuming, and require 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 the detection techniques and requisite reference materials to be proprietary and confidential, and as such not

widely available. Protein-based tests are convenient, fast, and inexpensive, but are not as sensitive as DNA-based tests. In addition, 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.

In 2002 USDA created a voluntary Proficiency Program which 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 and 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. Additional information, including participating laboratories' results, is available at the same website listed above.

SUBMISSIONS FROM ORGANIZATIONS

CODEX ALIMENTARIUS COMMISSION [30 NOVEMBER 2007]
[SUBMISSION: ENGLISH]

[…]

Handling, Transport, Packaging and Identification

Apart from the above work by the Codex Task Force, the Codex Alimentarius Commission has been undertaking on: 1) appropriate labelling provisions to genetically modified food through the Codex Committee on Food Labelling (CCFL); 2) methods of analysis and sampling for the detection of genetically modified foods through the Codex Committee on Methods of Analysis and Sampling (CCMAS); and 3) more general work on traceability/product tracing through the Codex Committee on Import and Export Inspection and Certification Systems (CCFICS).

Committee on Food Labelling (CCFL)
The Committee on Food Labelling (CCFL) has been considering, since 1996, appropriate food labelling provisions for foods derived from biotechnology. This work aims at establishing "Definitions and Guidelines for the Labelling of Foods obtained through Certain Techniques of Genetic Modification/Genetic Engineering".

However, these draft texts are still under discussion due to lack of consensus. The most controversial point is whether or not mandatory labelling provisions should be established for the case where the difference between original products and genetically modified products is solely the production method.

The 35th Session of the Codex Committee on Food Labelling in May 2007 discussed the Draft Definitions and Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions and could not come to a consensus on how to proceed with the development of the text. After some discussion, the Committee agreed to establish a physical working group, which would consider the approaches taken by governments to labelling of GM/GE foods and the possible ways forward for the Committee to address this issue. It was agreed that the physical working group would take place in Ghana in early 2008. The Committee agreed to retain the texts at the current steps, for further consideration at the next session taking into account the outcome of the physical working group.

Committee on Methods of Analysis and Sampling (CCMAS)
The Codex Committee on Methods of Analysis and Sampling (CCMAS) has been discussing appropriate methods of detection and analysis for the GM foods since 2002. In view of the absence of precise provisions for GMOs in Codex and of difficulties with the practical application of methodology in this area, the CCMAS proposed to develop recommendations with respect to criteria for methods of analysis and for quality control measures that should be introduced in laboratories offering GM analysis (Guidelines for the Validations and Quality Control Requirements for the Analysis of Foods derived from Biotechnology).

The 28th Session of the Codex Committee on Methods of Analysis and Sampling, in March 2007, considered a new revised document on the criteria for the detection and identification of foods derived from biotechnology, including: 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. After some discussion, the Committee agreed that the electronic working group led by the Delegations of Germany

and the United Kingdom would revise the current document and, in addition, would give consideration to the development of guidelines for governments and prepare a project document as a proposal for new work.

Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)
Following the adoption by the Codex Alimentarius Commission of the definition of "traceability/product tracing", the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), at its 13th Session in December 2004, started new work to develop the principles on traceability/product tracing in the context of food import and export inspection and certificate systems. The Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System were subsequently adopted by the 29th Session of the Commission in July 2006 and have been published in the Codex Alimentarius (CAC/GL 60-2006).

The CCFICS at its 16th Session on 26-30 November 2007 discussed the need for further guidance on traceability/product tracing by Codex and agreed to continue discussion on this matter at its next session, to address the present gaps in the implementation of traceability/products tracing, the key elements that would address these gaps, and the technical and economical feasibility of countries to implement traceability/product tracing.

The Collaboration with other relevant International Organizations
The Codex Alimentarius Commission has maintained its collaboration with other multilateral regulatory instruments and conventions. Since the international standards and related texts produced by Codex are recognized as international benchmarks by the WTO Agreements, the Commission is closely cooperating with the SPS and TBT Committees of WTO and their secretariats. On the matter of food and biotechnology, the Commission is maintaining cooperation and coordination with other standard setting bodies such as the World Organization for Animal Health (OIE), the Convention on Biological Diversity (CBD) and the Organisation for Economic Co-operation and Development (OECD).

GLOBAL INDUSTRY COALITION (GIC) [12 FEBRUARY 2008]
[SUBMISSION: ENGLISH]

Response to Request for Comments on Article 18.2(a) of the Cartagena Protocol on Biosafety: Views of the Global Industry Coalition 10/

Further to the request by the Parties to Cartagena Protocol on Biosafety (Protocol), other Governments and relevant international organizations to submit to the Executive Secretary further information on experience gained with the use of sampling and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques,11/ please find the views of the Global Industry Coalition (GIC) below. The GIC appreciates the opportunity to comment on acceptable systems and standards for sampling and detection techniques used to monitor transboundary movement of living modified organisms (LMOs). This submission draws on key learnings from the considerable experience gained during the past two years in the use of detection methods to enable global trade.

10/ The Global Industry Coalition (GIC) for the Cartagena Protocol on Biosafety receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

11/ See Decision BS-III/10.

A number of international organizations, such as the International Standards Organization (ISO), *Codex Alimentarius* (Codex) and the Organisation of Economic Co-operation and Development (OECD), have well-established work plans focused on development and harmonization of systems and standards for LMOs in commerce. These organizations incorporate applicable scientific expertise and experience to determine the appropriate integrated systems, standards, and specifications to best enable global trade in LMOs. Therefore, and in order to create synergies and avoid duplication of efforts, the GIC recommends that Parties focus on information-sharing with these and other relevant international bodies rather than developing criteria for acceptability and harmonization of sampling and detection techniques under the Protocol.

I. Sampling and Detection Methods for LMOs: Status of Existing Guidance

A total of 250 million acres of biotechnology-derived crops were planted globally in 2006 (ISAAA, 2007). It is expected that biotechnology-derived crop production will rise as increasing demand for alternative fuels and changing diets in developing nations, combined with the reduction of arable land due to development, necessitate enhanced agricultural productivity to meet global demand. As a result, biotechnology-derived crops are now a major component of global commodities trade.

Most grain used for food, feed or processing is shipped by bulk handling systems. Bulk systems are characterized by high volumes needed to achieve low costs (economies of scale). To comply with the requirements of the country-of-import, commodity exporters, importers, and governmental authorities must work together to meet national needs, including any documentation requirements, in a manner that is consistent with global standards.

This need to comply with any national documentation requirements necessitates the availability of easy-to-use, rapid, reliable, and cost-effective sampling and detection techniques for LMOs which are intended for direct use as food or feed, or for processing (LMO-FFPs). For the past three years, four significant international organizations with decades of experience and success in establishing systems and standards, including reference standards and detection methods in the medical field, have become directly engaged in developing globally harmonized standards and systems for detecting LMOs in commerce. 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 LMO-FFPs for the long term. Parties to the Protocol can benefit from the experience and expertise of these organizations in considering the Protocol's plan of work and Parties' capacity building needs as implementation of the Protocol progresses. Annex I provides a detailed overview of the work of these organizations relevant to products that fall under the scope of the Protocol.

II. Background on Sampling and Detection Method Applications and Technologies

A number of different entities are involved in developing, assessing, and utilizing detection methods for products of modern biotechnology. As part of the assembly of dossiers for submission to regulatory agencies, biotechnology companies develop and validate detection methods and create reference materials. Biotechnology companies provide methods that are developed in accordance with existing national and international standards as published by the ISO, Codex and the OECD. Some governments choose to develop their own methods in addition to the method provided by the biotechnology company applicant. These various detection methods may be used to conduct safety and regulatory studies on newly-developed LMOs, ensure the genetic purity of LMOs and conventional seed varieties, and analyze food and feed matrices as required by governments that implement mandatory labeling laws. Due to the wide variety of uses, these analyses may be performed by seed companies, grain handlers, food/feed companies and/or government agencies to verify the presence or absence of LMOs, presence or identity of particular transgenic events, or to quantify a transgenic event. For further information on types of detection methods, see Annex II.

III. Deploying Sampling and Detection Methods Globally – Considerations for Capacity Building

In order for Parties to demonstrate compliance with measures addressing illegal transboundary movement of LMOs, it is critical that validated detection methods are used with appropriate reference materials. Additionally, testing laboratories need to abide with internationally-accepted testing protocols and proficiency standards. As indicated above, there are multiple international organizations working towards common (recognized) standards for reference materials and detection method validation. The Parties to the Protocol can benefit from the existing work of these organizations when considering their capacity building needs for compliance with Protocol requirements.

To fulfill the obligations of the Protocol, Parties will need to build the analytical capacity to test for all commercialized biotechnology traits. Currently there are ~100 traits in ten or more crop species which have been approved by one or more regulatory agencies in the world. Building capacity for testing for all these events will require Parties to test for all LMOs which are not approved (i.e. illegal) in their country. Beyond the ~100 events currently approved, Parties will also need to consider new products that will be entering the market as well as a number of other situations. Examples of these include stacks or combined-event and the many first-generation LMOs already discontinued and removed from commerce but that linger for a while in the commodity chain (further details can be found in Annex II). Significant resources are required to implement a single analytical method in an existing laboratory. In developing countries, this will not only require building the capacity to independently test for each event but will also include the need to build and equip facilities, train personnel, develop validation and quality-control procedures which are aligned with international standards, and staff the facility to a level sufficient for routine sampling and analysis, potentially at multiple ports of entry, and a sample throughput level which does not hinder trade. Beyond the technical development, validation and analysis capacity, enforcement personnel, information systems, and a management/decision-making structure will be required.

The Parties should recognize that the magnitude of testing will be ever expanding and more complex and more costly as the globalization of the technology continues. For this reason, it is the view of the GIC 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 at least in one country (low level presence) rather than create a system which requires perpetual testing of food and feed for possible illegal transboundary movement of LMOs. 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.

IV. GIC Conclusions

Due to the large number of LMOs that are in research and development, that are currently commercialized, and that will be commercialized in the future, and the associated needs of Parties with respect to sampling and detection methods, it is the view of the GIC that:

- The Secretariat of the Convention on Biological Diversity should focus its efforts on information-sharing with relevant international bodies working on sampling and detection methods to ensure that information on sampling and detection methods for LMOs are available to the Parties via the Biosafety Clearing-House.

- Parties should take advantage of the work of these relevant international bodies related to sampling and detection techniques of LMOs to ensure awareness of existing work and to create synergies and avoid duplication of efforts, rather than expending resources on the development of criteria for acceptability and harmonization of sampling and detection techniques under the Protocol.

Annex I

ORGANIZATIONS WITH TECHNICAL EXPERTISE AND GLOBAL MANDATES RELEVANT TO THE HARMONIZATION OF DETECTION METHODS AND REFERENCE STANDARDS FOR LMOS

1. International Standards Organization (ISO)

Description:
ISO, a network of national standard institutes of 150 countries, provides a technological and scientific reference framework that takes into consideration safety, health and environment.

Current Relevant Initiatives:
It 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 TC 34 (WG 7) which developed standards in the area of Biomolecular testing.

ISO Standards and specifications concerning detection of LMOs:

1. ISO 21572, Foodstuffs — Detection of genetically modified organisms and derived products - Protein based methods
2. ISO 21569, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods;
3. ISO 21570, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods;
4. ISO 21571, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products – Nucleic acid extraction.
5. ISO 24276, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions.
6. 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.

2. Codex Alimentarius

Description:
Codex, a joint FAO/WHO body, is the global reference point and standards setting body for consumers, food producers and processors, national food control agencies and international food trade.

Current Relevant Initiatives:
The Codex Committee on Methods of Analysis and Sampling (CCMAS) defines procedures, protocols, guidelines for the assessment for food laboratory proficiency and quality assurance systems. 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 will be considered for advancement to the step process at the Twenty-ninth Session in Budapest, Hungary, 10 – 14 March 2008. ISO/TC 34 is currently evaluating whether this document is consistent with ISO standards.

3. BIPM and National Measurement Institutes

Description:

The BIPM (Bureau International des Poids et Mesures) operates under the terms of the Metre Convention and the exclusive supervision of the International Committee for Weights and Measures (Comité International des Poids et Mesures, CIPM). The CIPM itself comes under the authority of the General Conference on Weights and Measures (Conférence Générale des Poids et Mesures, CGPM). 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 CCQM (Comité consultatif pour la quantité de matière) was set up in 1993. Its members are the National Metrology Institutes (NMI's) 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.

Current Relevant Initiatives:

Within the CCQM, the JCTLM (Joint Committee for Traceability in Laboratory Medicine) 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 BAWG (Bio-analysis Working Group) of the CCQM to establish internationally recognized DNA metrology standards.

4. OECD

Description:

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.

Current Relevant Initiatives:

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 harmonisation in biotechnology.

Through the work of the Task Force and the Working Group, the 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

DETECTION METHODS AND CHALLENGES

The presence of LMOs or their derivatives can be determined by the detection of either DNA sequences present as a result of insertion of a new transgene or the protein produced by the inserted gene.

Protein-based detection methods are rapid and relatively inexpensive and offer a high degree of selectivity and sensitivity. Lateral flow strips can be used to show the presence or absence of a particular protein. Enzyme-linked immunosorbent assays (ELISAs) provide a means of quantifying the amount of a novel protein present in a sample. However, protein-based detection methods have limitations such as an inability to differentiate between genetic events that produce the same protein or to detect an LMO when no new protein is present in the food.

Methods of detection of the transgenic insertion of DNA based on the polymerase chain reaction (PCR) have also been used for the detection of LMOs. Qualitative PCR methods can be used to show the presence or absence of a particular DNA sequence in a sample. Quantitative PCR detection methods provide a means of estimating the amount of a target DNA sequence in a sample. DNA-based methods can be used to distinguish between transgenic events and are amenable to global standardization. However, the methods are time-consuming, costly, and technically complex.

Beyond the many events currently approved for which detection methods have been developed, Parties will also need to consider a number of other situations. For example, stacks or combined-event products represent a new and growing challenge in the area of LMO detection. These plant biotechnology products are created by combining multiple traits in a single LMO. However, 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. For example, bulk commodity shipments usually contain a mixture of single-trait LMOs, combined-trait LMOs, and conventional grain. Current testing approaches utilized to meet low-level mandatory labeling laws involve grinding samples taken from a bulk commodity shipment into meal which is then analyzed. Once individual LMOs have been reduced into 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. Unfortunately, the problem of bias introduced by combined events is a practical limitation of measuring DNA or protein and is thus, independent of the type or quality of detection method used.

An additional category for testing are the many first-generation LMOs already discontinued and removed from commerce as part of their normal life cycle. These products will gradually diminish in presence within commercial trade channels -- ultimately, to *de minimis* levels -- this is a stage that all products will pass through as a natural progression of the typical product life cycle. 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 vanishingly small.
