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Introductory Message

BY AHMED DJOGHLAF SCBD EXECUTIVE SECRETARY

The Cartagena Protocol on Biosafety entered into force more than four years ago. In the course of these years, Parties to the Protocol have developed important policies and tools with a view to promote its effective implementation. Prominent among these are the decisions taken in relation to paragraph 2 of Article 18 of the Protocol on the documentation requirements for living modified organisms (LMOs). This issue of the Biosafety Protocol News focuses on experiences and lessons learned in the implementation of these requirements.

The experiences show that exporters are increasingly incorporating the identification requirements of the Protocol and relevant decisions of the Parties into existing shipping documents.

The contributors to this newsletter have described their respective countries' or operators' experiences and lessons learned. The newsletter includes contributions by authors from Brazil, Japan, Mexico and South Africa as well as from the Global Industry Coalition and the Third World Network.

The contributions generally highlight the challenges and the opportunities faced in the ongoing development of national laws and standards for the purpose of implementing the Protocol, and in particular the requirements under Article 18. According to the first national reports received and analysed by the Secretariat in preparation for the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, several developing country Parties are in the process of establishing, at the national level, systems that are necessary for the implementation of the Protocol.

Towards this end, I believe Parties and other stakeholders have to continue to cooperate in building capacities in response to identified needs and to increase public awareness about the Protocol. The newsletter will serve as an important vehicle to increase public awareness and for the exchange of experiences that would help everyone move forward in implementing the Protocol.

I wish to extend my gratitude to all the contributors to this issue. I kindly invite others to continue this process in the coming newsletters.

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The Republic of Korea became the 143rd country to deposit its instrument of ratification to the Cartagena Protocol on Biosafety. The Protocol will enter into force for the Republic of Korea on 1 January 2008 in accordance with Article 37 (2) of the Protocol. The complete list of the status of ratification is available on line at: www.cbd.int/biosafety/signinglist.shtml

Experiences and Lessons Learned: Brazil

Mr. Rubens Onofre Nodari, (PhD in Genetics, Full Professor at Federal University of Santa Catarina, Manager of Genetic Resources of the Ministry of Environment and its representative in the CTNBio, the National Biosafey Committee)

Issues related to the identification and documentation for shipment of living modified organisms (LMOs) captured the attention of most delegates and observers at the third meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP/3) that was held in Curitiba, Brazil, in March 2006. At COP-MOP/2, Parties to the Protocol had postponed making a decision on whether the documentation of commodity shipments must be identified as "contain" or "may contain" living modified organisms intended for direct use as food, feed or for processing. Thus, at COP-MOP/3, Brazil was under tremendous pressure as the host country, as a Party to the Protocol and as both importer and exporter of living modified organisms, to finding a compromise.

The compromise position of the Brazilian delegation during the negotiations was primarily a reflection of the country's national legislation. To meet our main national legal obligations, the Consumer Protection Code (Law nº 8,078 of 1990), all imports must be clearly identified. Our legal instrument also requires that all components of any product be listed in the label, including the transgenic nature of the product (Decree nº 4,680, of 2003), if there is more than 1% derivatives from genetically modified organisms (GMOs). In addition, polls carried out from 2002 to 2005 indicated that approximately 92% of Brazilians would like to see transgenic proucts labelled as such.

It is important to mention that the Brazilian legislation covers not only living modified organisms (LMOs), but also their derivatives. This is the reason why we used the term GMO instead of LMO.

We also have a specific law for GMOs and their derivates (Law nº 11,105 from 2005 – www.planalto.gov.br), which requires approval for research, commercial activities and projects that involve GMOs. In that sense, GMOs and their derivates are considered by the Brazilian law to be different from conventional products.

Thus, the Brazilian government acted as expected, not only to meet its national legal obligations, but also to take into account the complete biosafety issues. The Ministry of the Environment prepared a full comprehensive document about the possible consequences if the accompanying documentation were not precisely informative. The main issues raised at that time were, among others, the handling of GMOs or products made from GMOs at ports of entry; transportation requirements; distinct handling of the imported GMOs; contamination of landraces if grains are to be used as seed and labeling systems if the imported product is for industrial use.

In 2006, many exporters, including several cooperatives, had in place very reliable tracing systems for the production of non-GMO soybean. These systems were not expensive (about one dollar per ton) and were very well accepted by the importers that frequently inspected the control points of those systems. In addition, several other systems, such as identity preservation (IP) for agroecological products are also in place for several products.

Since the approval of the Soybean Roundup Ready™ by the Brazilian Congress, Monsanto built a system across the country to collect the royalties from the farmers, in which any cargo of transgenic soybean could be identified and charged.

Such regulations and experiences were considered as examples that a production chain for GMO should be in place to allow the establishment of a specific segregating chain for GMO products to accomplish the biosafety and legal requirements.

However, the decision of the Brazilian government towards a full identification by 2012 for the transboundary movement of GMO, which was approved by COP-MOP/3, did not take into account certain proposals from other sectors, such as the industry and agriculture. These sectors would prefer no system at all, but they will agree to some general provisions provided they are not associated with any segregation or identity preservation measures. The main reason offered being the additional costs involved.

The importance of a clear and precise identification system for the shipments can be illustrated by an import to Brazil in March 2005. The Brazilian government authorized approximately 400,000 tons of maize originated from four distinct transformation events to be imported from Argentina and for use as animal feed only. The presence of one GMO event that had not been authorized was detected in the first shipment. The remaining shipments were discontinued because Argentina could not deliver the specific authorized GMOs in the shipments.

To date, Brazil has given approval for the Soybean Roundy Ready and Bollgard cotton. The country is exporting transgenic soybean, but not yet the transgenic cotton. The approval for transgenic maize is currently at the

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courts for a judicial decision, since its approval by the National Biosafety Committee was challenged.

However, measures to ensure the full implementation of the decision of COP-MOP/3 towards a clear and precise identification of the shipments by 2012 should have already begun but this is currently not the case in Brazil. Although Brazil does have some recognized segregation or identity-preservation systems with non-GMO products, the country has not yet put in place the necessary measures for GMO products.

These measures include legal, technical and procedural issues. In addition, Brazil should involve all the stakeholders in the production chain. Presently, neither the industry nor the farmers are fully aware of the segregation system needed to implement the COP-MOP decisions. However, in my opinion, the major stakeholders could actively help in establishing the segregation system. One example is that several farmers had their organic soybean production contaminated by Roundup Ready™ soybean. Those farmers have lost their money and the confidence of the consumers. That contamination occurred probably through mixing of seeds or manual cross pollination, since crosses among soybean plants can occur at a distance of 6 to 7 metres.

Some efforts by the federal prosecutors are being initiated to solve internal problems related to the coexistence of conventional and transgenic products and to the lack of specific rules for GMO presence in non-transgenic seeds. This will contribute not only to the accomplishment of internal legislation, but also to a more precise identification of conventional and transgenic products.

If those Parties to the Cartagena Protocol that are importers request for a clear and precise identification of LMOs present in shipments, exporting countries – whether or not they are Parties to the Protocol – will be obliged to develop and establish segregation or identity-preservation systems for the LMO products.

Thus, the internal and the external scenarios can contribute to the discussion towards the development and implementation of the measures to ensure clear and precise identification of shipments for transboundary movements.

Brazil depends strictly on the industrial, science and technology and agricultural sectors to develop and put in place the necessary measures to fulfil the COP-MOP/3 decision regarding identification and documentation for shipments of LMOs. All other government bodies are in favour of implementing the COP-MOP/3 decisions as soon as possible. It remains to be seen whether we will be able to fulfil our commitment in the next two years.

Experiences and Lessons Learned: Japan

Ms. Yuko WATANABE (Food Industry Promotion Division/Ministry of Agriculture, Forestry and Fisheries(MAFF)

To ensure the strict and smooth implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (so-called "Cartagena Law") was enacted in Japan on 18 June 2003, i.e., approximately three months before the Cartagena Protocol entered into force.

The Japanese Cartagena Law classifies uses of living modified organisms (LMOs) into two categories.

- Type 1 Use: the use of LMOs without preventive measures against their dispersal into environment
- Type 2 Use: the use of LMOs with preventive measures against their dispersal into environment

"Type 1 Use", for instance, are LMOs that are intended for direct use as food, feed or processing. In this category, 59 out of 116 LMOs are approved. Stakeholders that wish to apply for a LMO under this category shall stipulate a condition of "Type 1 Use" for each LMO. First, an applicant hands in an application form which includes a proposal of condition of "Type 1 Use" as well as a risk-assessment report including potential adverse effects on biological diversity. The proposed condition must include a definite plan on how the LMO will be used. Thereafter, the submitted assessment report is evaluated by experts for adverse effects on biological diversity. Finally, the competent ministers decide whether to approve it or not. Upon approval, the LMO may then be imported. Measures required under Article 18.2 of the Cartagena Protocol, however, are not clearly prescribed in the Japanese Cartagena Law, but, in practice,

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they are carried out through the Food Sanitation Law and the Law concerning Standardization and Proper Quality Labelling of Agricultural and Forestry Products (so-called "JAS Law").

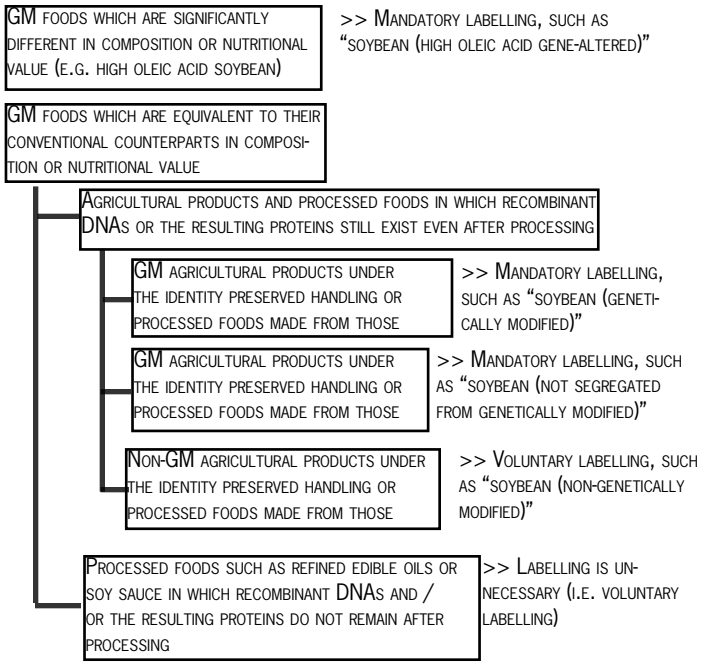
In April 2001, well before the entry into force of the Cartagena Protocol and the Japanese Cartagena Law, foods produced by recombinant DNA techniques, also known as genetically modified foods (GM foods), had to undergo a safety assessment under the Food Safety Law when they were imported, distributed or processed. Meanwhile,, regulations on food labelling for authorised GM foods were developed under the Food Safety Law and the JAS Law. Regulations by both laws are nearly all harmonized, while the former aims at securing public health and the latter aims at enabling consumers to make informed choices.

Food items subject to mandatory GM labelling are limited to those in which genetically modified DNA or proteins derived from the DNA can be detected even after processing, or those whose compositions or nutritional values differ in comparison to their conventional counterparts. As of December 2007, seven agricultural products and processed foods derived from GMOs have been designated as items for mandatory labelling. The list will be reviewed every year, taking into account the commercialization of new GM foods and newly developed detection methods.

Below are the seven agricultural products and processed foods derived from GMOs for which labelling is required:

1. Soybean (incl. green soybeans and soybean sprouts)
2. Maize
3. Potato
4. Canola (Rapeseed)
5. Cottonseed
6. Alfalfa
7. Sugar beet

If GM foods are in the market, they should be labelled:



Given the regulation of labelling scheme for authorized GM foods, many companies in the food manufacturing industry have begun shifting their agricultural products to non-GM alternatives. The decision to change products is stimulated by co-ops and large retailers that were afraid that foods with GM labelling would be avoided by consumers. Trading companies are also increasingly promoting the sales of non-GM agricultural products. Few agricultural products were distributed with labelling of "GM" or "no segregation practice with GM products" for a while after the labelling regulation was enforced. This confusion in importing agricultural products was rather limited in case of soybean. Soybean oil, which occupies the majority in the demand for imported soybean is not subject to labelling, because recombinant DNAs and / or the resulting proteins do not remain after processing. Therefore, the oil manufacturing industry kept importing GM soybeans, supported by its profound knowledge in handling GM products.

Another issue concerning labelling is the question of additional costs. As industry avoids extra costs of scientific testing of food, the GM or non-GM labelling is determined by a system of identity-preserved handling based on a series of identity certificates. Companies, however, often voluntarily carry out scientific testing for recourse against claims. These additional costs cannot fully be added on retail prices owing to strong [buying] power of retailers, which is rarely known to consumers. Conversely, we may now be at a turning point to give up insisting on non-GM foods under the current circumstance of skyrocketing international prices of

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grains and oilseeds. It will become more difficult to arrange a necessary amount of non-GM products since farmers are shifting their production to GM products. The change will be accepted rather smoothly if consumers have more confidence in GM foods, since distributed products are approved by the competent ministries. It is an issue of consumers' confidence rather than food safety.

In the end, measures required under Article 18.2 of the Cartagena Protocol must be assured through domestic regulations. It is of course, a matter Parties to comply with the Cartagena Protocol. In addition, consumers are informed whether foods contain GM products and therefore, they are able to choose GM or non-GM foods based on their rational understanding.

Experiences and Lessons Learned: Mexico.

Ms. Amanda Gálvez Mariscal, PhD (Universidad Nacional Autónoma de Mexico)

Mexico belongs to a regional economic block, NAFTA (North American Free Trade Agreement), with two non- Parties to the Protocol: USA and Canada. Ratification of the Cartagena Protocol (CP) in July 2003, initiated the implementation of its measures, while respecting the country's trade obligations. In particular, implementing Article 18.2 has been complicated.

There are important asymmetries between the NAFTA trading partners given that (i) less than 3% of the population in the US and Canada is dedicated to agriculture, while in Mexico approximately 25% of its inhabitants still depend on subsistence agriculture (18% of the employed population works in agriculture)[1,2,3], (ii) biological diversity in Mexico is far greater than in the other two countries (iii) the resources assigned to research and development in Mexico are very limited in comparison with those of its trading partners. Against this background, Mexico has to comply with both its commercial obligations as well as the protection of its biodiversity according to the CP. NAFTA created certain conflicting interests between trade and productivity growth, on the one hand, and conservation of natural resources and environmental protection, on the other hand, especially in the case of the Mexican staple food maize.

In spite of the complicated background mentioned above, measures required for the identification and documentation of food, feed and processing (FFPs) under the CP started as early as October 2003, when a trilateral arrangement was signed by the agricultural sector with respect to Article. 18.2 (a) of the CP[4], as an attempt to respect the different regulatory approaches in the three countries, and the different levels of adoption of transgenic crops. The arrangement has a technical annex designed to guide harmonization of procedures for the importation of grains that "may contain" LMOs. The level of unintentional or adventitious mixing with transgenic grains was set at 5%, under which grains will be handled without the need to use the "may contain" label in the shipment's documentation. Simultaneous filing in the three countries of bulk grain imports and voluntary release into the environment for grain production, as well as for experimental purposes was also proposed, requiring harmonization of procedures for applications[5].

Under the 2005 Mexican Law of Biosafety and GMOs (LBOGMs)[6], the release into the environment of LMO food crops requires an authorization from the Ministry of Health. Among the GM-crops released commercially are: cotton, canola, squash, potato, tomato, beet, alfalfa, rice, soybean and maize. The Ministry of Health is also responsible for LMO-FFPs authorizations, and for the measures required for labelling and identification of their imports. A more efficient exchange of information, regarding imports identification, is required: sampling and monitoring of all shipments would be too cumbersome and expensive given the enormous amount of analysis required to accomplish the Ministry of Health's mandate if only a "may contain" phrase is accompanying the transboundary movements of LMOs into the country.

The most pressing case for Mexico is the importation of GM maize, due to the possibility of transgene escape if these grains are used as seed, given the traditional seed exchange and utilization of such a natural resource[7]. These imported grains are, to quote the Protocol text, "LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of maize biodiversity". Maize is an open pollinated species, therefore if grains germinate, they could produce plants able

1 INEGI (2000) 'XXII Censo General de Población y Vivienda', INEGI, Mexico City.
2 Learning about Biosafety in Mexico: between Competitiveness and Conservation. Gálvez, Amanda and Chauvet, Michelle. Int. J. of Biotechnology. Vol. 7. Nos. 1,2, and 3: 62-71, 2005
3 INEGI (2000) 'Encuesta Nacional de Empleo, INEGI, Mexico City showed that 18% of the total employed population is economically active in the agricultural sector.

4 CIBIOGEM (2003) Agreement entitled "Documentation Requirements for Living Modified Organisms (LMOs) for Food, Feed and Processing. Internal Document of the Government of Mexico, Canada and the US. Restricted document.
5 CIBIOGEM (2003) Work plan for the Agreement on Documentation Requirements for Living Modified Organisms (LMOs) for Food, Feed, and Processing. Internal Document of the Government of Mexico, Canada and the US. Restricted document.

6 http://www.ciiemad.ipn.mx/opinion/pdf/leydebioseguridad.pdf
7 Louette, D. 1996. Intercambio de semillas entre agricultores y flujo genético entre variedades de maíz en sistemas agrícolas tradicionales. In: Serratos, J. A., M. C. Willcox, and F. Castillo (eds). Flujo genético entre maíz criollo, maíz mejorado y teocintle:
implicaciones para el maíz transgénico. CIMMYT. México, D. F. pp: 60-71.

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shed pollen, producing escape of transgenes in a centre of origin and diversity, where at least 30 different landraces have been identified and could receive such pollen, with potential consequences if they generate fertile progeny 7. Mexican Health authorities face the fact that there are 22 GM-maize transformation events registered in the BCH and Agbios databases, plus the stacked varieties. However, only nine events have been authorized as FFPs. The potential mixture imported into the country might then contain non-authorized varieties that under the Mexican regulations are prohibited for commercialization. Post-market monitoring in Mexico, until today, requires an enormous amount of resources given that not all of the LMOs commercialized in the USA have been submitted for authorization, it is not known if all of them enter the country, and there are no hints about which are the most probable varieties grown and sold in the previous couple of seasons that may be present in the loads exported to Mexico, because that is considered as confidential business information. No mechanism has been officially implemented for information exchange to this purpose, in spite of the proposals made to the trilateral organizations such as the North American Plant Protection Organization (NAPPO) and the North American Biotechnology Initiative (NABI).

Starting May 2007, the Ministry of Health began financing a one year project in the framework of the UNDP for the implementation of the analytical techniques required for the molecular detection (DNA as well as proteins) of LMOs-FFPs. Such expertise is currently being developed at the National University of Mexico (UNAM) and the techniques will be transferred to the government labs in the main port of entry: Veracruz in the Gulf of Mexico. Statistical sampling was a responsibility of the Ministry of Agriculture (SAGARPA) port authorities, in charge of quarantine and phytosanitary measures.

Regarding the CP, SAGARPA still continues the oversight it has implemented since 1995 of the intentional release into the environment (experimental, pilot field trials and commercial releases) under the LBOGMs.

The Ministry of Environment (SEMARNAT) has been involved in the monitoring and detection of GM material in maize landrace biodiversity regions: Oaxaca (2001-2007), Jalisco (2002), Michoacan (2003), Puebla (2006-2007), DF (2007), Guerrero (2002) and Sinaloa (2007). The National Commission for the Use and Knowledge of Biodiveristy in Mexico (CONABIO) has been involved along with the National Institute of Ecology (INE) in proposing methodologies for field sampling and detection, field trips and financing studies.

The systematic monitoring of the fields in Sierra de Juarez, Oaxaca, created and kept a close relationship with local farmers. The published results[8,9,10], show the efforts made in the governmental sector to maintain the safety of biotechnology applications in Mexico as a centre of origin and biodiversity of maize.

8 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.
9 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.
10 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.

Experiences and Lessons Learned: South Africa

Professor C.D. Viljoen Ph.D. (GMO Testing Facility, University of the Free State, Bloemfontein, South Africa.)

GMO Production in Africa

South Africa is currently the only country in Africa commercially growing genetically modified (GM) crops and is currently ranked eighth in terms of global commercial biotech production (James, 2006). It is estimated that 44% of white maize, an important food staple, 50% of yellow maize, 75% of soybean and 100% of cotton is GM in terms of total production area in South Africa. Hence, South Africa can serve as a good case-study for other developing countries in terms of implementing regulations for genetically modified organisms (GMOs).

Regulatory framework for GMOs in South Africa

South Africa is a Party to the Cartagena Protocol on Biosafety. It has a well developed regulatory system comprising different components that address the overall regulation of GMOs including monitoring:

- The GMO Act 15 of 1997 controls the development, production, use and application of GMOs including transboundary movement and environmental release (Department of Agriculture, 1997; 2005).

- Environmental legislation is provided by the National Environmental Management Act 107 of 1998 (NEMA) and the National Environment Management Biodiversity Act 10 of 2004 (NEMBA), that respectively, prescribe the requirements for environmental risk assessment (taking into account socio-economic and cultural considerations) and the measures to trigger a full environmental impact assessment of a GMO (Department of Environmental Affairs and Tourism, 1998 and 2004).

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• Regulation 25 of 2004 of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 makes provision for the mandatory labelling of GMOs with indications of risk to human health or that differ significantly from conventional crops in terms of composition and nutritional value (Department of Health, 2004).

Although the GMO Act as well as NEMA and NEMBA are either already implemented or in the process of implementation, there are a number of aspects that require additional consideration in South Africa:

• There is currently no formal system to verify the GM content of transboundary consignments.

• Although general GMO monitoring is currently performed in terms of permit provisions, it needs to be expanded to inform the regulatory decision-making process more efficiently.

• The Regulation for mandatory labelling of GMOs is currently inactive.

• No provision is being made for GMO labelling in terms of consumer preference.

Article 18 of the Biosafety Protocol

South Africa, as the only country in Africa currently growing GM crops commercially, is in a unique position to have to deal with implementing Article 18: Handling, Transport, Packaging and Identification of living modified organisms (LMOs). In addition, South Africa also acts as a transit country to the rest of Africa (including food aid). Thus, there are a number of different issues relating to Article 18 currently under consideration by the Conference of the Parties serving as the Meeting of the Parties (COP-MOP) that have pertinent relevance for South Africa. These include sampling and detection techniques and documentation.

LMO sampling and detection techniques

Although many countries in Africa do not have the proper facilities or expertise to perform LMO sampling and detection, such facilities exist nonetheless or are in the process of being established. Thus, although capacity-building to establish detection capabilities in Africa is still required, established LMO-detection laboratories are having to deal with specific technical issues relating to sampling and detection. Furthermore, it is also important to ensure that these laboratories are able to meet minimum proficiency requirements.

Harmonization of sampling and detection techniques is currently under consideration for COP-MOP. Complete harmonization of LMO sampling and detection may prove impossible and impractical given the diverse array of techniques and permutations thereof already in use by different laboratories. However, it is important to establish minimum internationally accepted performance criteria for LMO sampling and detection as well as guidelines for method validation and proficiency testing. The Codex Committee on Methods of Analysis and Sampling is currently establishing the "Criteria for the detection and identification of foods derived from biotechnology" which will include validation of protein and polymerase chain reaction (PCR) based methods as well as proficiency testing (www.codexalimentarius.net/download/report/679/al30_23e.pdf).

Thresholds for illegal and legal adventitious comingling of LMOs

It has also been suggested that a de facto universal threshold level has to be established for adventitious comingling of illegal LMOs. This will prove extremely difficult to implement due to a lack of validated event-specific methods to quantify illegal LMOs as well as the availability of event-specific LMO reference material. It is also impractical to proactively develop LMO event-specific quantification methods for LMOs that are not commercialized but that may become illegal. For example, event-specific detection methods were only developed and validated after the discovery of illegal Bt10 maize and LibertyLink rice. Therefore, it would be better for LMO-producing countries to ensure necessary levels of LMO segregation keeping in mind the legal status of LMOs in importing countries.

In contrast to this, thresholds could be considered for the certification of LMO consignments where adventitious co-mingling is a result of an LMO considered legal in the country of import. However, no threshold can be considered more "scientific" than another and for practical reasons the threshold should be above the limits of detection and quantification of the analytical method being used. Currently, the threshold range used by different countries is from 0% to 5%, which is above the practical limits of detection and quantification of PCR based methods and some protein methods (Viljoen, 2005; Viljoen et al., 2006). However, it is also important to take the threshold limit set by the receiving country into consideration for certification of LMO exports. Currently, South Africa applies a 1% threshold for the certification of LMO consignments but also takes into account the requirements of the Party of import.

Documentation required under Article 18

Also under consideration is the use of a commercial invoice or other documents for LMO certification under Article 18. South Africa uses a permit system for the certification of LMO consignments. A permit system has a number of advantages above the suggested use of the commercial invoice. These include the requirement for status verification as well as the absence of a vested interest in status certification.

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Lessons learned with the transboundary movement of LMOs.

In addition to LMO sampling and detection, there are other considerations that also need to be addressed. These include:

- Access to up-to-date information on the status of LMOs in different countries especially non-Parties.
- Documentation for transboundary movement of LMOs being issued in different languages.
- Documents for transboundary movement of LMOs originating from government sources other than the competent authority.

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Experiences and Lessons Learned: Industry

Global Industry Coalition (GIC)

1. Introduction

When the Cartagena Protocol on Biosafety entered into force on 11 September 2003, the Global Industry Coalition (GIC) members developed guidelines to meet the requirements outlined in the Protocol for shipments of LMOs under Article 18.2(b) and (c). The GIC then updated these guidelines to reflect the decision of the Parties on Article 18.2(b) and (c) taken at COP-MOP/1. These guidelines were created to provide assistance to entities shipping LMOs destined for contained use and intended for intentional introduction into the environment to or from Parties. They include a determination of whether there is necessary clearance for the shipment of the LMO, in addition to specific guidance to ensure the appropriate information is included on the shipping documentation specific to a shipment of LMOs for contained use or for intentional introduction into the environment. Experience to date indicates that Protocol guidance on documentation for shipments under Article 18.2(b) and (c) are working well and that those shipments are moving globally without problems. For some categories of LMOs that have special identification, handling, packaging or transport requirements, other international bodies already provide such requirements and are already in use to compliment Article 18.2 (b) and (c). Continued use of the existing guidelines under the Protocol and international bodies is therefore essential.

2. Existing Guidance on Shipping Documentation of LMO Shipments and Adequacy of Existing Rules and Standards for Identification, Handling, Packaging and Transport of Goods and Substances

(a) Transboundary movements of LMOs destined for contained use (Article 18.2(b))

With respect to Article 18.2(b), shipments comprise the entire range of organisms and microorganisms, including viruses, bacteria, fungi, parasites, insects, other animals and plants. The majority of shipments are for research and development purposes, mainly for the testing and treatment of disease, and are shipped in accordance with national regulations and pursuant to authorizations or permits as required. A survey conducted by the GIC and the International Seed Federation (ISF) indicates that shipments to and from Parties and non-Parties under Article 18.2(b) using the existing guidance provided by the Parties are working well, and no problems or concerns have been reported to date.

Certain categories of shipments of LMOs under Article 18.2(b) may also be covered by existing international transport regulations as well as Protocol shipping documentation. Experience to date indicates that no gaps have been identified; therefore, no further standards or requirements for these shipments need be developed under Article 18.3.

(b) Transboundary movements of LMOs intended for intentional introduction into the environment (Article 18.2(c))

The majority of shipments that fall under Article 18.2(c) are for commercial purposes, crop or seed production. In these cases, the LMO has completed approval for commercial release into the environment in the exporting and importing country. A smaller number of shipments are for research

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and development purposes, and are planted to assess the suitability of the crop variety for local use or to develop data in order to complete regulatory requirements for commercialization. These shipments move pursuant to regulatory approvals in accordance with a positive Advanced Informed Agreement under the Protocol or authorizations under national regulations. Any special requirements for safe handling of the LMO research material are typically specified in environmental release authorizations. Again, the GIC and ISF survey results indicate that such shipments under Article 18.2(c) are occurring globally without problems. The vast majority of shipments of LMOs of goods and substances falling under Article 18.2(c) are exempt from special standards for identification, packaging, handling and transport regulations.

3. International Bodies of Experts on the Identification, Handling, Packaging and Transport of Goods

(a) UN Committee of Experts on the Transport of Dangerous Goods and the UN Model Regulations

The United Nations Economic and Social Council Committee of Experts developed the "Model Regulations on the Transport of Dangerous Goods" (UN Model Regulations) which are general packing requirements, testing procedures for packages, marking or labeling and transport requirements for certain categories of substances. While not applicable to LMOs that are authorized for use by the competent authorities of the government of the countries of origin, transit and destination (i.e., the vast majority of shipments under Article 18.2(c)), these regulations apply to specific categories of LMOs, for example, those that meet the definition of an infectious substance under the UN Model Regulations (and which would ship under Article 18.2). Those that do are assigned to the appropriate category of infectious substance, thereby becoming subject to all requirements under that category.

Given this existing set of requirements and body of expertise, any further development or refinement of rules and standards for identification, handling, packaging and transport of LMOs subject to these recommendations and the UN Model Regulations should be referred to the United Nations Economic and Social Council Committee of Experts on the Transport of Dangerous Goods.

(b) International Air Transport Association Live Animals Regulations (LAR)

The 33rd edition of the LAR provides guidance on packaging and documentation needed for the transport of live animals[1]. The LAR has been developed by the International Air Transport Association. (IATA) in consultation with Parties to the Convention on International Trade of Endangered Species of Wild Fauna and Flora (CITES), the World Organization for Animal Health (OIE) and government authorities that implement the LAR for animal transportation to ensure safety in transport and humane transportation of live animals. The LAR is applicable to IATA members and to airlines that are parties to the Multilateral Interline Traffic Agreement for Cargo. To the extent that any live animal would qualify as an LMO, the LAR would govern its international movement by air.

1 Http://www.iata.org/ps/publications/lar.htm.

4. Lessons Learned

With respect to the adequacy of the existing guidance provided by the Parties on documentation requirements for shipments under Article 18.2(b) and (c), evidence shows that this existing guidance is working well and that the GIC guidance language provides sufficient information on the documentation to properly identify the contents of these shipments. In implementing Article 18.2 (b) and (c), and to create synergies and avoid duplication of efforts, Parties must focus on information-sharing with other relevant international bodies rather than developing any new rules or standards under Article 18.3 of the Protocol. Overall, one essential mechanism for collaboration, information-sharing and awareness is through the Biosafety-Clearing House.

Implementation of the Identification and Documentation Requirements under Article 18.2a of the Cartagena Protocol: Some Perspectives

The historic adoption of the decision on identification and documentation requirements of living modified organisms (LMOs) that are intended for food, animal feed or for processing (LMOs-FFPs) in March 2006 brought an end to long and difficult negotiations. The implementation of the decision of the meeting of the Parties of the Cartagena Protocol on Biosafety is critically needed.

Article 18.2 of the Cartagena Protocol sets out measures that Parties are obliged to take to identify LMOs in the accompanying documentation. The measures depend on the intended use of the LMO. Article 18.2 paragraph (a)

addresses LMO-FFPs, while paragraph (b) addresses LMOs for contained use, and paragraph (c) addresses LMOs that are intended for intentional introduction into the environment and any other LMOs within the scope of the Cartagena Protocol.

The implementation of Article 18.2(a) could help address transgenic contamination of bulk commodity shipments and in the food and animal feed supply chain. Such incidences have immense global trade ramifications, and have incurred huge costs.

Clear identification in the documentation that accompanies shipments of LMO-FFPs implies that a system of detection, segregation and identity preservation would need to be set up in exporting countries, that could help avoid and identify contamination, prior to export. A strict segregation and identity preservation system would help ensure that contamination does not occur. In addition, testing shipments for LMO content prior to export will help ensure that the system is working, and identify problems, if it is not.

This would rightfully place the burden and costs on exporting countries to ensure that contaminated shipments do not enter other countries. This would assist importing countries, particularly those that want to remain free of genetically modified products (GM-free), to ensure that they are not receiving unapproved or illegal LMOs, and to know more precisely what is coming into their countries.

It will assist traceability in the food and feed chain including other important biosafety functions such as monitoring, product recall in the case of harm, liability if damage occurs, and more meaningful labeling.

For all this to take place, importing Parties must urgently implement the decision, as a minimum standard, into their national laws. Exporting countries, whether Parties or not, will have to comply with the laws of importing countries.

Most Parties, exporting and importing, have not implemented the decision. Some countries have begun national processes to study the decision and made recommendations on implementation of the decision. The European Union considers that its existing directives and regulations (in particular its traceability and labelling regulations and its regulation on transboundary movement of GMOs) sufficiently implement this decision.

Most developing countries do not yet have operational biosafety laws. Most developing countries have developed a 'national biosafety framework (NBF)' under the United Nations Environment Programme-Global Environment Facility (UNEP-GEF) development project. The project began in 2001, and most countries have concluded their project. However, most developing countries, mainly countries that are importing LMOs, did not consider implementing the decision when drafting their NBFs, as the Protocol had not yet been adopted.

Clearly, capacity-building to assist countries to implement the decision is needed. The Third Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Capacity Building Activities held in February 2007 identified implementation of the LMO identification and documentation requirements as the most critical capacity-building need for many countries.

In July 2006, the International Grain Trade Coalition advised its members not to provide detailed documentation requirements until requested by governments, or to change current documentation until advised by Parties or requested by importers following discussions with their respective governments.

Thus, it is critical that importing Parties implement the decision, for changes to the current system to take place. It is also important for exporting Parties to implement the decision, as the cost of potential liability and clean-up measures arising from contamination incidences would likely surpass the cost of implementing a segregation and identity-preservation system.

Several aspects of the decision and their implementation are key.

The decision requires clear and detailed identification for shipments of LMO-FFPs in situations where the identity of the LMO is known through 'means such as identity-preservation systems'. In those cases, the shipment must be identified as one that 'contains' LMO-FFPs.

A two-stage approach is set out for cases where the identity of the LMO shipment is not known by 'means such as identity-preservation systems': the shipment can be identified as one that 'may contain' one or more LMO-FFPs. This requirement is subject to review and assessment, and by 2012, the documentation should clearly identify that the shipment 'contains' LMO-FFPs.

The term 'Identity-preservation systems' is not defined in the text or in the Cartagena Protocol. It can be understood to mean segregation and testing, and is non-exhaustive. The language is broad enough to cover different ways of ensuring that the identity of the shipment is preserved. As such, it would be important for the importing Party to define its requirements that meet this criterion in its national law, rather than leaving this to the country of export to define.

Whether or not a shipment is identified as one that 'contains' or 'may contain' LMOs, a list of transformation events or unique identifier codes that are or may be in the shipment, must be provided, along with other details. These specifications are required for all shipments. This requirement should be incorporated in national laws.
The 'may contain' provision is qualified as 'not requir[ing] a listing of LMOs of species other than those that constitute the shipment'. Arguably, 'adventi-

tious' (or technically unavoidable, unintentional and low-level) presence of LMOs of the same species is covered by the decision. This means that such adventitious presence must also be specified in the documentation, e.g. through the provision of the transformation event code of the LMO that is unintentionally present, if it is of the same species as the LMO in the shipment.

However, this does not mean that if a shipment is identified as one that 'contains' LMOs, there can be 'adventitious' presence of LMOs, whether it is of the same or different species. This is left to the national level to define, as the documentation requirements must be in 'compliance with the requirements of the country of import'.

It is also important to note developments in other areas. The 7th meeting of the Codex Intergovernmental Task Force on Foods Derived from Biotechnology met in September 2007 and developed a proposed draft Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food. This has been forwarded to the Codex Alimentarius Commission for adoption in July 2008.

A country has full flexibility to require zero tolerance of unapproved LMOs, as measures must be taken to ensure that LMO-FFPs are 'authorized in accordance with domestic regulatory frameworks' and the documentation is 'in compliance with the requirements of the country of import'.

Even though the documentation accompanying LMO-FFPs is qualified to be applicable for LMO-FFPs that are in 'commercial production' (i.e. not research and field trials), it must be 'authorized in accordance with domestic regulatory frameworks'. The documentation must be 'in compliance with the requirements of the country of import'. This means that the importing country can put in place strict requirements to ensure that contamination by LMOs in field trials and research is prohibited.

For a full analysis of the Article 18.2a decision by the same authors:
http://www.biosafety-info.net/article.php?aid=351

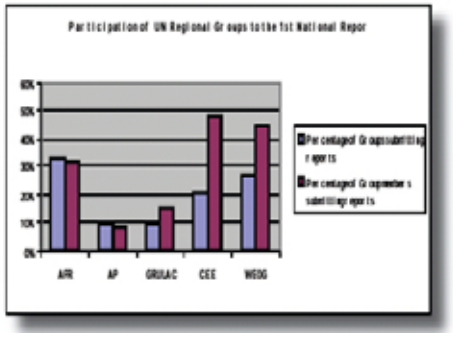
FIRST NATIONAL REPORTS

Since the last newsletter, support for the Protocol continued to grow.

More than 60 Parties and 3 non-Parties submitted their first national report the Protocol. Figure 1 shows the reports received by regional groups.

Figure 1

Groups	Members	Reports Recieved	% of Groups Sub-mitting Reports	% of Group Members Submitting Reports
AFR	53	17	33%	32%
AP	56	5	10%	9%
GRULAC	33	5	10%	15%
CEE	23	11	21%	48%
WEOG	31	14	27%	45%
Tot	196	52		



For more information:
http://bch.cbd.int/protocol/reporting/

PREPARATION FOR COP-MOP/4

Please visit: http://www.cbd.int/mop4/
For our summary: http://www.cbd.int/mop4/agenda/

The fourth meeting of the governing body, Conference of the Parties serving as the Meeting of the Parties, COP-MOP/4, is scheduled to take place from 12 May - 16 May 2008 in Bonn, Germany.

A new website for the meeting will be launched in 2008. It will, among other things, provide a summary of the issues, information for participants, pre-sessional documents and a calendar of side events.

NEW VERSION OF THE BIOSAFETY CLEARING-HOUSE (BCH)

On 1 November 2007, a new version of the BCH was released, accessible at http://bch.cbd.int/. The Secretariat decided to revamp the BCH in order to significantly improve its user-friendliness. For example, all of the primary search interfaces in the 'Finding Information' section have been merged as much as possible. This was done in order to maximize the capacity of BCH users to retrieve information and facilitate access to cross-referenced data. Grouping options have been enhanced in all search interfaces in order to allow for queries of all major geographical or political groupings of countries. Also, optional advanced search functions have been integrated into each primary search interface in order to reduce search time without compromising ease of use.

There is also now increased functionality to multiple languages support for Hermes, BCH Ajax Plug-Ins and the Central Portal. Also, national languages, other than the 6 UN Official languages, may now be technically implemented in all BCH features pending the availability of text translations from interested countries.

Another primary reason the Secretariat decided to revamp the BCH was to improve the quality of the information registered in it. For example, in order to optimize the management of information available in the BCH, a revised LMO registry, including all current OECD Unique Identifiers, has been consolidated. Also, documentation available in the Biosafety Information Resource Centre (BIRC) has been divided into two databases. The first is for purely scientific articles published in international scientific journals and is maintained by the ICGEB . The second contains "grey" literature (e.g. reports and case-studies; journals and newsletters; teaching materials, manuals, toolkits, presentations, etc.) Thanks to the kind contribution of the UNEP-GEF Biosafety Project, there has also been a significant increase of "grey" BIRC records (from 242 to over 700).

Despite all of these improvements having been made, much work remains to be done, particularly regarding the sections 'Registering Information', 'Resources' and 'Help' as well as on the completion of the translation of the entire site in all 6 UN languages.

However, the Informal Advisory Committee of the Biosafety Clearing-House (BCH-IAC) , which convened 4-5 October 2007 in Montreal, welcomed this revamped version of the BCH, and recommended to the Secretariat to proceed with its launch. The BCH-IAC also recommended that the Secretariat design a new survey targeting the following three groups: (i) general users; (ii) users who access the Management Centre; and (iii) IT experts (e.g. IT Regional Advisors). This survey was launched 10 December 2007 and is now available for completion at http://bch.cbd.int/survey/.

Any other feedback on the progress made so far on the BCH is also most welcome.

OVERVIEW OF RECENT BIOSAFETY MEETINGS

Liability and Redress

The fourth meeting of the Ad Hoc Open-ended Working Group of Legal and Technical Experts on Liability and Redress in the context of the Protocol was held in Montreal from 22 to 26 October 2007. The fourth meeting focused on streamlining operational text on liability and redress proposed in the context of Article 27 of the Protocol. The streamlined text will be used as the basis for further negotiations at the final meeting of the Working Group in March 2008 in Colombia.

Co-Chair of Working Group René Lefeber, Netherlands

Ben Turtur Donnie, Liberia, for the African Group

Sub-working-group Chair Jane Bulmer, the United Kingdom of Great Britain

Sub-working Group Chair Jürg Bally, Switzerland

MOP/3 President Fatimah Raya Nasron, Malaysia

Working Group Co-Chair Jimena Nieto, Colombia

Delegates from Japan and the EC

Duncan Currie, Greenpeace International

Piet van der Meer, Public Research and Regulation Initiative

Group of Latin American countries (GRULAC) members consulting

Compliance

The Compliance Committee under the Protocol held its fourth meeting in November 2007. At the meeting, the Committee reviewed general issues of compliance on the basis of the information made available by Parties through their first national reports submitted four years after the entry into force of the Protocol. The Committee also refined further its report on experiences of other multilateral environmental agreements regarding measures concerning repeated cases of non-compliance. It decided to submit to the upcoming fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol a report that consolidates the work and recommendations of its third and fourth meetings.

Chair of Compliance Committee, Viet Koester, Denmark

Compliance Committee, Montreal, Canada

Risk Assessment and Risk Management

The Secretariat organized three regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms. All three workshops aimed at enabling participants to, inter alia, exchange experiences and lessons learned in conducting/reviewing risk assessments and to review existing guidance materials. The workshops also considered the need for further guidance and to identify mechanisms for promoting cooperation and networking in risk assessment and risk management.

The first workshop was held for African countries from 23 to 25 August 2007 in Addis Ababa, Ethiopia. At this workshop, 57 participants from 25 countries and 16 organisations attended. The second workshop was held for the Central and Eastern Europe countries from 26 to 28 November in Chisinau, Republic of Moldova. At this workshop, more than 30 participants attended ranging from research scientists and regulators to decision-makers in the field. The third workshop was held for the Latin American and the Caribbean countries from 10 to 12 December in Bridgetown, Barbados. At this workshop, more than 40 participants attended including research scientists, regulators and decision makers in the field.

Workshop in Moldova

Workshop in Barbados

Biosafety-Clearing-House

In October 2007, the Secretariat organised the third meeting of the Informal Advisory Committee on the Biosafety Clearing-House (BCH-IAC) in Montreal. The members of the Committee welcomed the redesigned BCH, reviewed the progress made in its implementation and provided advice on various technical aspects. They also shared case studies and information on the status of and experiences in national implementation. These included presentations on ongoing BCH capacity-building activities and information-sharing partnership arrangements. The Committee made a number of recommendations with respect to the following: management of information at the national level, design of the BCH Central Portal, capacity-building and a new questionnaire to better evaluate the BCH.

For more information on the entire year of 2007, please read "the Year in Review 2007" on Biosafety

2008 CALENDAR OF EVENTS:

11 - 13 February 2008
New Delhi, India
Fourth Coordination Meeting for Gov ernments and Organizations Implementing or Funding Biosafety Capacity-Building Activities

14 - 15 February 2008
New Delhi, India
Fifth Meeting of the Liaison Group on Capacity-building for Biosafety

12 - 19 March 2008
Cartagena, Colombia
Fifth meeting of the Ad Hoc Open-ended Working Group of Legal and Technical Experts on Liability and Redress in the context of the Protocol

9 - 10 May 2008
Bonn, Germany
Biosafety Clearing-House (BCH) Training Workshop

11 May 2008
Bonn, Germany
Meeting of the COP-MOP Bureau

12 - 16 May 2008
Bonn, Germany
Fourth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP-4)

11 September 2008
A 5th Anniversary of the Entry Into Force of the Cartagena Protocol

For further information: http://www.cbd.int/biosafety/meetings-link.shtml

SCBD's newest gift in the museum of nature and culture: Peacock vase of India

Biosafety Protocol News

Director of Publications:
Ahmed Djoghlaf
Executive Secretary

Biosafety Editorial Team:
Giovanni Ferraiolo <giovanni.ferraiolo@cbd.int>
Kathryn Garforth <kathryn.garforth@cbd.int>
Charles Gbedemah <charles.gbedemah@cbd.int>
Mauoela Pessua de Miranda <mauoela.demiranda@cbd.int>
Ulrika Nilsson <ulrika.nilsson@cbd.int>
Erie Tamale <erie.tamale@cbd.int>
Worku Damena Yifru <worku.yifru@cbd.int>

Biosafety Support Team :
Andrew Bowers <andrew.bowers@cbd.int>
Johanne Huppe <johanne.huppe@cbd.int>

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DNA double helix graphics courtesy of the U.S. National Library of Medicine

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We would like to hear from you:

We are encouraging governments, particularly those that are Party to the Protocol and relevant stakeholders to send articles and digital photos on their implementation, awareness and outreach activities. Please send your contributions to secretariat@cbd.int or bch@cbd.int

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Secretariat of the
Convention on Biological Diversity
413 Rue St. Jacques, Suite 800
Montréal, Québec, H2Y 1N9 Canada
Tel. +1-514-288-2220 Fax: +1-514-288-6588
Email: secretariat@cbd.int
Web: www.cbd.int and bch.cbd.int/

CBD UNEP Achieving the 2010 Biodiversity Target