



Convention on Biological Diversity

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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

Seventh meeting

Pyeongchang, Republic of Korea, 29 September-3 October 2014

Item 16 of the provisional agenda*

COMPILATION OF SUBMISSIONS ON CHALLENGES AND EXPERIENCES RELATING TO UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS

Note by the Executive Secretary

1. Article 17 of the Cartagena Protocol on Biosafety requires each Party to take appropriate measures to notify affected or potentially affected States, the Biosafety-Clearing House and relevant international organizations when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States.
2. At its sixth meeting, the COP-MOP, in its decision BS-VI/16, requested Parties and invited other Governments and relevant organizations to submit to the Executive Secretary views and information on any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms. The COP-MOP also requested the Executive Secretary to prepare a synthesis of the views for consideration by the Parties at their seventh meeting.
3. In light of the above, the Secretariat issued a notification to Parties, other Governments and relevant organizations on 12 February 2014.¹ A reminder notification was issued on 1 April 2014.²
4. Nine Parties (Brazil, China, European Commission, Japan, Republic of Korea, Malaysia, Mexico, Norway and South Africa), one non-Party countries (United States of America) and five organizations (Global Industry Coalition - GIC, International Grain Trade Coalition - IGTC, NO! GMO Campaign, Testbiotech and the Third World Network - TWN) have submitted their views on this issue as of 21 May 2014.
5. Annexed hereto is a compilation of the full submissions.³ A synthesis of the views from the submissions can be found in document UNEP/CBD/BS/COP-MOP/7/14.

* UNEP/CBD/BS/COP-MOP/7/1.

¹ Notification: SCBD/BS/CG/ABw/83191.

² Notification: SCBD/BS/CG/DA/83191.

Annex

**COMPILATION OF SUBMISSIONS ON CHALLENGES AND EXPERIENCES RELATING TO
ARTICLE 17 AND THE UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LIVING
MODIFIED ORGANISMS INTRODUCTION**

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³ The notifications referred to in paragraph 3 also invited submissions of views on matters related to Article 18 on Handling, Transport, Packaging and Identification. The sections of the submissions containing information related to Article 18 were omitted from this compilation for clarity, as appropriate, and may be found in document UNEP/CBD/BS/COP-MOP/7/INF/2.

I. SUBMISSIONS FROM PARTIES

A. BRAZIL

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**Federative Republic of Brazil
Ministry of External Relations**

Brasília, 01 April 2014.

Notification 2014-020 – Brazil's submission

Ref.: SCBD/BS/CG/ABw/83191

2. BS-VI-16. Unintentional transboundary movements of living modified organisms (Article 17)

“4. Requests Parties and invites other Governments and relevant organizations to provide views and information to the Executive Secretary, six months prior to the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, on any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms.”

Brazil considers that any measure taken towards the implementation of Article 17 of the Protocol should focus on consultation and collaboration between possibly affected countries. For this reason, it is important that Parties keep reporting on the subject through their National Reports and keep updated information on national focal points for emergency measures in the BCH (Brazil is making internal consultations and expects to update the information regarding its own NFP for emergency measures in the coming weeks). Brazil is still analyzing the possibility of ratifying the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

B. CHINA

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II. About Article 17

Relevant authorities develop the Contingency Plan for Agricultural Genetically Modified Organisms Safety Emergencies and the Contingency Plan for Forestry Genetically Modified Organisms Safety Emergencies in line with their responsibilities.

Given that there exist several unlabeled LMO products transferred to China, China proposes that the CBD Secretariat suggest parties develop implementation guidelines on transboundary movement of LMOs and on Nagoya-Kuala Lumpur Supplementary Protocol.

C. EUROPEAN COMMUNITY

Notification 2014-020: response from European Union and its Member States

Further to notification 2012-149 of 6 December 2012, regarding the decisions of the COP-MOP/6 that require specific action, and particularly to Decisions BS -V/8 (handling, transport, packaging and identification) and BS-VI-16 (Unintentional transboundary movements), the European Union and its Member States would like to notify:

In its **decision BS -VI/16** on unintentional transboundary movements of living modified organisms, paragraph 4, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested Parties to provide views and information on any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms.

The EU set up a comprehensive legal framework which addresses the topic of unintentional transboundary movements of living modified organisms and emergency measures (art. 16.3 and art. 17 of the Cartagena Protocol), directly or indirectly:

- **Regulation EC 178/2002** of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

The General Food Law Regulation, under Chapter IV, established the Rapid Alert System for Food and Feed (RASFF) and set out provisions and procedures for crisis management and emergency cases. RASFF enables information to be shared rapidly and efficiently between food and feed control authorities in Member States and the European Commission where a health risk has been identified. In this way, countries can act rapidly and in a coordinated manner, in order to avert food safety risks before they can harm consumers.

- **Directive 2001/18/EC** of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

The European Union (EU) has adopted a legislative framework on the deliberate release of GMOs into the environment and the placing of GMOs on the market in accordance with the precautionary principle. A procedure for granting consent for the deliberate release (part B of the Directive) and placing on the market (part C of the Directive) of genetically modified organisms has been established, together with a common methodology for risk assessment.

Art.4.5 of the Directive requires EU Member States to take appropriate action when the unauthorized release or marketing of a GMO is found to have occurred.

Art. 23 of the Directive on safeguard clause establishes the conditions and the procedure in order to adopt emergency measures in case of an identified severe risk.

- **Regulation (EC) No 1829/2003** of 22 September 2003 on genetically modified food and feed; its implementing Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003; its implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament

and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006

Regulation (EC) 1829/2003 provides that no GMO shall be placed on the market for food or feed uses unless it is covered by an authorization granted in accordance with the procedure laid down in the Regulation itself. The GM food or feed shall undergo a safety assessment carried out by the European Food Safety Authority (EFSA). The requirements for the preparation and presentation of the applications for authorization are set out in the implementing Regulations.

Art. 34 of the Regulation sets conditions and procedure in order to adopt emergency measures, when it becomes evident that authorized products are likely to constitute a serious risk to human health, animal health or the environment.

- **Directive 2009/41/EC** of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms

This Directive establishes common measures for the evaluation and reduction of the potential risks arising in the course of all operations involving the contained use of GMMs and sets appropriate conditions of use.

- **Regulation (EC) No 1946/2003** of 15 July 2003 on transboundary movements of genetically modified organisms, which ensures full compliance with the obligations of the Cartagena Protocol regarding transboundary movements of GMOs.

As regards Article 17(1) of the Cartagena Protocol, the EU wishes to recall that Regulation (EC) No 1946/2003:

- under Article 14.1, establishes that Member States shall take appropriate measures to prevent unintentional transboundary movements of GMOs
- under Article 14.2(a), requires that, as soon as a Member State becomes aware of an occurrence, under its jurisdiction, resulting in a release of GMOs that leads, or may lead, to an unintentional transboundary movement that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, that Member State shall take the appropriate measures to inform the public and inform without delay the Commission, all other Member States, affected or potentially affected States, the BCH, and, where appropriate, relevant international organizations
- Under Article 15.1(d), establishes that Member States shall inform the BCH and the Commission of any information concerning cases of unintentional or illegal transboundary movements pertaining to them, in accordance with Articles 17 and 25 of the Protocol

As regards Article 17(2) of the Cartagena Protocol, the EU wishes to recall that Regulation (EC) No 1946/2003:

- under Article 15.1(b), requires that Member States shall, without prejudice to the protection of confidential information in accordance with the provisions of the Protocol, inform the BCH and the Commission of national contact points for notification of unintentional transboundary movements

As regards Article 17(3) of the Cartagena Protocol, the EU wishes to recall that Regulation (EC) No 1946/2003:

- under Article 14.3, requires that any notification of an unintentional transboundary movement of a GMO be accompanied by:
 1. Available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMO
 2. Information on the circumstances and estimated date of the release, and on the use of the GMO in the originating Party
 3. Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures
 4. Any other relevant information
 5. A contact point for further information

As regards Article 17(4) of the Cartagena Protocol, the EU wishes to recall that Regulation (EC) No 1946/2003:

- Under Article 14.2(b), requires that when a Member State becomes aware of an occurrence, under its jurisdiction, resulting in a release of GMOs that leads, or may lead, to an unintentional transboundary movement that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, that Member State shall without delay consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures in order to minimise any significant adverse effects
- Under Article 15.1(h), establishes that Member States shall inform the BCH and the Commission of any decision taken by a Member State on safeguard measures under Article 23 of Directive 2001/18/EC or emergency measures taken by a Member State under Community legislation on genetically modified food and feed

The above requirements, set out by Regulation (EC) No 1946/2003, on the unintentional transboundary movements of GMOs, are fully in line with Article 17 of the Cartagena Protocol and without prejudice to further specific requirements imposed by EU legislation.

Concerning challenges and practical experiences in the EU related to the implementation of Article 17 of the Protocol and the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms, the EU wishes to report and address the following issues:

- The competent authorities of the Member States in the EU are responsible for the official control of seeds. In case LMOs are detected in non-LMO seed lots, the affected seed lot:
 - needs to be labelled in case the detected LMO is authorised for cultivation in the EU, irrespective of the LMO concentration;
 - needs to be withdrawn from the (EU) market in case the detected LMO(s) are not authorised for cultivation in the EU.
 Shall the affected seed lot(s) be exported to a country outside EU, the advanced informed agreement (AIA) requirements according to the Cartagena Protocol apply. This export can be considered unintentional in case the export occurred before the LMOs were detected. In any case, Member States inform the competent authorities of the importing country

and regularly informs the European Commission concerning the results of seed controls for LMO presence.

- The competent authorities of the Member States in the EU are responsible for the official control of food and feed. They control several thousand food and feed samples per year on GMO content. In case GMOs are detected, the affected lot:
 - needs to be labelled according to EU requirements in case the detected GMO is authorised for food and/or feed purposes;
 - needs to be withdrawn from the (EU) market in case the detected GMO(s) are not authorised for food and/or feed purposes in the EU.
- Art. 17 refers to the release of an LMO that leads, or may lead, to an unintentional transboundary movement. This could be interpreted in such a way that, as long as the release is limited within the State borders, Art. 17 should not apply, since the release does not lead to a transboundary movement. These incidents ought to be covered under national rules. However, there might be situations where, even in the absence of transboundary movement, exchanging information through the BCH (for example risk assessment reports) could be beneficial. One can refer for instance to the accidental release of GM glyphosate-resistant wheat that took place in the US in 2013. This case triggered many reactions linked with potential transboundary movement of this LMO (e.g. prohibition of export of wheat in some countries, LMO detection in the EU).
- Art. 17 only applies to transboundary movements of LMOs that are likely to have significant adverse effects on biodiversity, taking into account risks to human health. This can only be determined if the LMO has been subject to a risk assessment in the context of the potential receiving environment(s), which may not necessarily be the case and may be difficult to perform in practice.
- The EU is of the opinion that reflecting on concrete case-studies (such as the GM wheat mentioned above) might help to interpret the provisions of Article 17 of the Protocol. This compilation of information on the experiences of Parties having encountered an unintentional release of a LMO will also help to define the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of LMOs. In that respect, it should be considered that dealing with unintentional transboundary movement might be more challenging with LMOs other than plants, for example GM insects.
- Finally the EU is of the opinion that, to a certain extent, the implementation of Art. 17 and Art. 25 (illegal transboundary movements) of the Protocol could face similar challenges. It is therefore suggested that any action taken for facilitating appropriate implementation of Article 17 be also considered in the context of Article 25.

D. JAPAN

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*Ministry of Foreign Affairs
Tokyo, Japan*

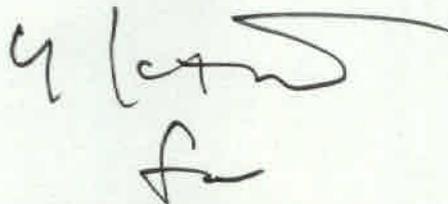
28 March 2014

Dear Dr. Braulio Ferreira de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity
413, Saint Jacques Street, suite 800
Montreal QC H2Y 1N9
Canada

Dear Dr. Braulio Ferreira de Souza Dias,

With reference to CBD Notifications 2014-020, I have the honour to hereby submit you Japan's comments on the implementation of Article 17 of the Cartagena Protocol (BS-VI-16).

Please accept the assurances of my highest consideration.



Mr. Kazuhiro TAKAHASHI

Director

Global Environment Division
International Cooperation Bureau
Ministry of Foreign Affairs, Japan

Japan's Comments on the Implementation of Article 17 of the Cartagena Protocol

The Government of Japan appreciates the effort of the Secretariat of the Convention on Biological Diversity for preparing the document for COP-MOP 7. As a country importing living modified organisms (LMO), especially crops, Japan is pleased to provide some ideas we have learned from previous experiences.

1. Challenges and Experiences relating to the implementation of Article 17 of the Protocol

Challenge

Taking into consideration that global exchange of LMO, especially in agricultural commodities, has increased and is expected to continue to increase, the exporting/importing countries should seriously consider how to determine appropriate responses and initiate necessary actions under Article 17 of the Protocol.

Japan would like to raise two key challenges; 1) to prepare guidance or tools by which Parties concerned may easily understand what appropriate step by step actions they should take, and 2) to develop close relationships between exporting/importing countries for this purpose.

Experiences

Japan believes there is already a lot of related knowledge for the above key challenges. For example, OECD has accumulated the knowledge relating to the issues through their discussion on Low Level Presence (LLP), which was made public with the related document on Sep.17, 2003. Also, FAO has set up an international information-exchange system called "GM Foods Platform."

We will start a discussion on the issues (including any challenges and experiences relating to the implementation of Article 17 of the Protocol, and the "Scope and Elements" of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of LMO) from COP-MOP 7. Japan believes once we agree on the "Scope", we should focus on preparing the "Elements" by taking full advantage of the current knowledge rather than starting discussion without any background. Also, we should realize that several organizations such as OECD and FAO have a lot of experiences relating to the issues through rigorous discussion. We have to consider the possibility of taking

advantage of such experiences.

Japan is strongly convinced that this approach enables us to avoid the duplication of discussion and to let us obtain more practical guidance or tools in a relatively brief period.

2. The scope and elements on possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms

Scope

“Seed” and “Commodity” are different in not only the way of trade but also the impact on the environment; they are as follows.

- “Seed” is usually traded in much smaller lots and is more highly valued than that of “commodity”. The amount of sample for GM testing has a huge impact on seeds trading. For example, large amounts of the sample may become a huge trade barrier in the international market.
- While seeds are aimed at being released into the environment, commodities are usually devitalized in factories. Therefore, seeds have much higher level of risk on the environment than commodities.
- A higher purity level of lots is generally required in the trade of seeds than in that of commodities. Inspection agencies for GM testing need to satisfy rigorous quality control for seeds.

Therefore, we should prepare two types of guidance or tools for seeds and for commodity that cover step-by-step procedures by which Parties concerned may easily understand what action they should take.

Elements

Two types of guidance or tools are necessary. The elements are as follows.

Seed	Commodity
I. Development of relationship between exporting/importing countries <ul style="list-style-type: none">- Clarification of contact point- Exchange of detection method, reference samples and relevant information	I. Development of relationship between exporting/importing countries <ul style="list-style-type: none">- Clarification of contact point- Exchange of detection method, reference samples and relevant information

<p>I. Risk assessment</p> <p>1. Risk assessment in the exporting countries</p> <ul style="list-style-type: none"> - Verification of the trait - Determination of the scale, i.e. how it occurred, where it was produced, which level of seed quality control was applied, what was the amount and when it was distributed, - Determination of the source that are not expected to contain unauthorized living modified organism - Preparation of the risk profile <p>2. Risk assessment in the importing countries</p> <ul style="list-style-type: none"> - Determination of the scale, i.e. where it was planted, what was the amount and when it was imported - Determination of the receiving environment - Preparation of the risk profile 	<p>II. Risk assessment</p> <p>1. Risk assessment in the exporting countries</p> <ul style="list-style-type: none"> - Verification of the trait - Determination of the scale, i.e. how it occurred (cross-pollination in field, or mixing during handling, storage or transport after harvest), which seaport and when it was used for export. - Preparation of the risk profile <p>2. Risk assessment in the importing countries</p> <ul style="list-style-type: none"> - Determination of the scale, i.e. which seaport, what was the amount and when it was imported - Determination of where and when it was processed - Determination of the receiving environment around the area where spillover might have occurred - Preparation of the risk profile
<p>III. Risk management</p> <p>1. Risk management in the exporting countries</p> <ul style="list-style-type: none"> - Appropriate quality control during seed production - Monitoring at the field for seed production <p>2. Risk management in the importing countries</p> <ul style="list-style-type: none"> - Measures according to the level of risk management taken by the exporting countries - Consideration of complex factors such as socio-economic factors for determining measure, although the principle is in proportion to the risk profile 	<p>III. Risk management</p> <p>1. Risk management in the exporting countries</p> <ul style="list-style-type: none"> - Appropriate quality control after harvest - Monitoring at the seaport <p>2. Risk management in the importing countries</p> <ul style="list-style-type: none"> - Measures according to the level of risk management taken by the exporting countries - Consideration of complex factors such as socio-economic factors for determining measure, although the principle is in proportion to the risk profile

E. REPUBLIC OF KOREA

May 02, 2014

Braulio Ferreira de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity

Dear Executive Secretary

According to the notification by the Secretariat of the Convention on Biodiversity (<http://www.cbd.int/doc/notifications/2014/ntf-2014-020-bs-en.pdf>), the government of the Republic of Korea submits the following information in regard to preparation for the 7th Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 7).

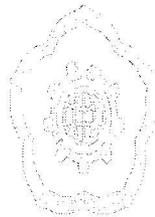
1. BS-V/8. Handling, transport, packaging and identification of living modified organisms: paragraph 2(a) of Article 18

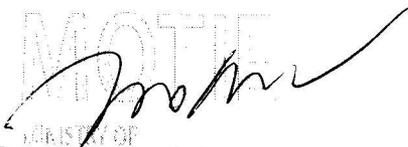
“ 7. Requests Parties and invites other Governments and relevant organizations to submit to the Executive Secretary, no later than six months prior to the seventh meeting of the Parties to the Protocol, further information on experience gained with the implementation of paragraph 4 of decision BS-III/10 as well as the present decision, including any information on obstacles that are encountered in the implementation of these decisions as well as specific capacity-building needs to implement these decisions, and requests the Executive Secretary to compile the information and prepare a synthesis report for consideration by the Parties at their seventh meeting.”

2. BS-VI-16. Unintentional transboundary movements of living modified organisms(Article 17)

“ 4. Requests Parties and invites other Governments and relevant organizations to provide views and information to the Executive Secretary, six months prior to the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, on any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms.”

Sincerely,




Chung, Seokjin

Director of Bio&Nano Technology Division
Ministry of Trade, Industry & Energy
Republic of Korea



2. BS-VI-16. Unintentional transboundary movements of living modified organisms(Article 17)

1) Views and information on any challenges and experiences relating to the implementation of Article 17 of the Protocol

When a problem occurs regarding unapproved LMOs in the Republic of Korea, this all has to do with imports. It is because there are yet no commercialized LMOs in the Republic of Korea, and also we have relatively strict safety management measures taken for LMOs that are in the R&D stages.

Major examples of unapproved LMO import cases in Korea involved

StarLinkcorn (2000, U.S.), Bt10 corn (2004, U.S.), LLRice 601 rice (2006, U.S.), Bt 63 rice (2006, China), and Roundup Ready wheat that occurred in the U.S. in May 2013.

The government of the Republic of Korea, after receiving notification from exporters (or developers) on information regarding the relevant cases, has been implementing strict quarantine measures for each of the involved LMOs. When unapproved LMOs are discovered in the process, measures for disposal or return are supposed to be taken.

2) Views and information on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms.

In the case of unapproved LMOs, we cantake the necessary measures by using the detection and identification method of the relevant LMOs from the information passed on by the export country(or developer) only after becoming aware that unintentional transnational movement has occurred.

Moreover, when LMOs that have not even been approved by the development country have been leaked, there is the possibility of unintentional transnational movement of the LMOs for a considerable period of time when such a fact is not known. Therefore, the guidance with special measure on unintended transnational movement can make it possible to provide a method for stringent management by which LMOs that have not received approval for commercialization in the development country are to be prevented from leaking outwards.

In addition, in case of LMOs that are currently under development, or those of

which development has been abandoned, which are considered to take preventive measures on their leaks and unintentional moving across national boundaries (which would require clear guidelines in guidance), we could consider registering minimum information regarding the LMOs in the Biosafety Clearing House.

When unintentional transnational movement has been detected, as demanded by Article 17 of the Biosafety Protocol, immediate notification must be made to the neighboring country and other countries that could be affected, as well as the Biosafety Clearing House, and other international organization, so that necessary measures can be taken.

It would help importing country with taking necessary measures if more specific procedure for such notification and measures could be presented in guidance. Also, we need to consider providing specific means of building a cooperative system on the regional and sub-regional level regarding unintended transboundary movement through guidance.

Finally, as to the guidance, we propose to include items of capacity building for developing countries and countries with economies in transition on quarantine, detection and monitoring of LMO's unintended transboundary movements, and of sharing information regarding reference materials and related matters that are regarded as essential for monitoring and detection.

F. MEXICO

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ATENCIÓN A LA NOTIFICACIÓN SCBD/BS/CG/ABw/83191

1. BS-VI/16. Movimientos transfronterizos involuntarios de organismos vivos modificados (artículo 17).

A la fecha México no ha presentado casos en los que se cumplan los requisitos de procedencia que indica el artículo 17 del Protocolo de Cartagena, por lo cual no se ha visto en la necesidad de realizar notificaciones ante el Secretariado o implementar medidas de emergencia relevantes en la esfera internacional.

Sin embargo, es apropiado indicar que se han desarrollado actividades en previsión, adoptando Protocolos consensuados entre las instancias de Gobierno Federal para atender las situaciones referentes al artículo 17, con casos de experiencias circunscritas en el territorio nacional. En caso de ocurrir una liberación no permitida que pudiera propiciarse durante el transporte de *commodities* de uno a otro estado, además de lo previsto en el Protocolo de Cartagena, el Estado Mexicano actuará en lo aplicable conforme al “*Protocolo de actuación coordinada para la atención de casos de liberación no permitida al ambiente de organismos genéticamente modificados*”, el cual incluye la participación de Autoridades Federales con las atribuciones para implementar no sólo las medidas de mitigación y contingencia pertinentes sino también las acciones administrativas que corresponda en este tipo de situación.

Por otro lado, ha habido situaciones en las cuales se presentan liberaciones involuntarias al ambiente pero dentro de los contextos de liberación accidental o sin conocimiento de que la semilla liberada se trataba de OGMs. Para estos supuestos se cuenta con un “*Protocolo complementario de actuación coordinada*” acordado entre las instancias que conforman la CIBIOGEM. Ambos instrumentos coordinan la actuación de las áreas técnicas y operativas (y en su caso involucra también a las áreas jurídicas) de la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación, la Secretaría de Medio Ambiente y Recursos Naturales, la Secretaría de Salud, así como la Secretaría Ejecutiva de la CIBIOGEM. Estos documentos se presentan como **Anexos 2 y 3**.¹

Abril 2014

¹ The documents can be accessed through the BCH at
<http://bch.cbd.int/database/record.shtml?documentid=105569>

G. MALAYSIA



DEPARTMENT OF BIOSAFETY

MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT

LEVEL 1, PODIUM 2, WISMA SUMBER ASLI

NO. 25, PERSIARAN PERDANA, PRESINT 4

FEDERAL GOVERNMENT ADMINISTRATIVE CENTRE

62574 PUTRAJAYA, MALAYSIA

TEL +603-8886 1580

FAX +603-8890 4935

URL <http://www.biosafety.nre.gov.my>

Our Ref.

JBK(S) 601-1/6 (54)

Date

28 March 2014

Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, Quebec, Canada, H2Y 1N9
Fax: +1 514 288 6588

Dear Sir,

Request for Submissions in Preparation for the Seventh Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 7)

We refer to your notification dated 12th February 2014 regarding the above matter.

ii) BS-VI-16. Unintentional transboundary movements of living modified organisms (Article 17)

There were no known occurrences under Malaysian jurisdiction that could have led to an unintentional transboundary movement of LMOs. As Malaysia biosafety law does not refer to unintentional movements of LMOs nor does the emergency response plan in this law condescend to details, the international level of elaborations on what constitutes unintentional transboundary movement of LMOs and how to respond to such situations should be welcomed. As for now, the emergency response plan mechanisms in place to address non-GM invasive alien species by Department of Agriculture Malaysia will be used and adopted accordingly for addressing emergency measures in any case of unintentional transboundary movements of LMOs.

Countries must be able to detect and respond to any unintentional transboundary movement of LMOs. This requires the ability and the capacity to do so thus efforts must continually be made to build the capacity to detect and respond to any unintentional transboundary movement of LMOs by providing guidance. Of particular relevance are the elements in the Guidance for the Risk Assessment of LM trees and LM mosquitoes which can be expanded into other LMOs as well. As the issues are largely technical and scientific, it should be best handled by the AHTEG on Risk Assessment and Risk Management. The description of the nature of the response measures in the Nagoya-KL Supplementary Protocol on Liability and Redress can also be a very useful tool.

As for the unintentional transboundary movements of LMOs-FFP, cooperation among Parties should be strengthened in term of exchanging experiences and building capacities in the use and development of easy to use, rapid, reliable and cost-effective sampling and detection techniques for LMOs including access to reference materials.

Thank you.

Yours sincerely,



(LETCUMANAN RAMATHA)

Director General
Department of Biosafety
Ministry of Natural Resources and Environment

c.c.

Madam Wan Hasmah binti Wan Mohd
Undersecretary
Biodiversity and Forestry Management Division
(Cum CBD and CPB Focal Point Malaysia)
Ministry of Natural Resources and Environment
62574 Putrajaya, Malaysia

H. NORWAY

/...

Norwegian submission to CBD Notification 2014-020

BS-VI-16 Unintentional transboundary movement of living modified organisms (Article 17)

No occurrences resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health has been recorded under Norwegian jurisdiction.

Although Norway cannot report on experiences regarding unintentional transboundary movement, Norway would like to emphasize the usefulness of the Guidance on Risk Assessment of Living Modified Organisms developed by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management as a tool to facilitate appropriate responses by parties to unintentional transboundary movement of living modified organisms. The practicability of this document may be improved by articulating the inter-linkages of the risk assessment process with risk management and risk communication.

I. SOUTH AFRICA



environmental affairs

Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

Private Bag X447, Pretoria, 0001 • Fedsure Building, 315 Pretorius Street, Pretoria, 0002. Tel (+27 12) 310 3911 Fax: (+27 12) 322 2682

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Mr Braulio Ferreira de Souza Dias
Executive Secretary: Convention on Biological Diversity
413, Saint Jacques Street, suite 800
Montreal QC H2Y 1N9
Canada

Tel: +1 514 288 2220

Fax: +1 514 288 6588

Dear Mr de Souza Dias

REQUEST FOR SUBMISSIONS IN PREPARATION FOR THE SEVENTH MEETING OF THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY (COP-MOP 7).

As per your request in the CBD 2014-020 notification, please note below the responses from South Africa relating to information on experience gained with the implementation of paragraph 4 of decision BS-III/101 and any challenges and experiences relating to the implementation of Article 17 of the Protocol.

**BS-VI-16. UNINTENTIONAL TRASBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS:
ARTICLE 17**

In terms of the detailed notification requirements as outlined in decision BS-VI/16, SA has incorporated the information requirements in the regulatory system in the form of the Genetically Modified Organisms Act, 1997), as amended by Genetically Modified Organisms Act, 2006 (Act No. 23 of 2006). To date, SA has no evidence of any released LMOs which had or may be regarded as having had an adverse effect on the conservation & sustainable use of biological diversity. We are however mindful that as the technology develops we will continue to implement risk management measures to limit any potential adverse impact on the human and animal health and the environment.

Yours sincerely,



Ms Nosipho Ngcaba

Director-General

Department of Environmental Affairs

Letter signed by: Ms Malta Qwathekana

Designation: Senior Policy Advisor: International Advisory Services (also CBD National Focal Point)

Date: 12/03/2014

II. SUBMISSIONS FROM OTHER GOVERNMENTS

J. UNITED STATES OF AMERICA

/...



United States Department of State

*Bureau of Oceans and International
Environmental and Scientific Affairs*

Washington, D.C. 20520

31 March 2014

Mr. Braulio Ferreira de Souza Dias
Executive Secretary
Convention on Biological Diversity
413 Saint-Jacques Street, Suite 800
Montréal QC H2Y 1N9
CANADA

Dear Mr. Ferreira de Souza Dias:

The United States appreciates the opportunity to provide information relevant to the Secretariat's 12 February 2014 Notification No. 2014-020 regarding the decisions of the sixth meeting of the COP-MOP that require specific action, and in accordance with relevant previous COP-MOP Decision BS-VI-16 "Unintentional transboundary movements of living modified organisms (Article 17), which requests information on "any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms."

The United States has many years of experience with LMOs in confined and unconfined environmental releases. We would like to recall the results of the second national report on the implementation of Party's obligations under the Cartagena Protocol on Biosafety. No parties reported difficulty implementing Article 17, and there have been no confirmed reports of harm to biodiversity or to human health from confined or unconfined releases of LMOs.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michael C. Trulson".

Michael C. Trulson
US National Focal Point for the Biosafety Clearing-House
Office of Conservation and Water
U.S. Department of State
2201 C Street, NW
Washington, DC 20520-2658

Attachment: 31 March 2014 submission entitled "information on experience gained with regard to the unintentional transboundary movements of living modified organisms, including any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by parties to unintentional transboundary movements of living modified organisms"

**INFORMATION ON EXPERIENCE GAINED WITH REGARD TO THE UNINTENTIONAL
TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS, INCLUDING
ANY CHALLENGES AND EXPERIENCES RELATING TO THE IMPLEMENTATION OF
ARTICLE 17 OF THE PROTOCOL AND ON THE SCOPE AND ELEMENTS OF POSSIBLE
GUIDANCE OR TOOLS THAT MAY FACILITATE APPROPRIATE RESPONSES BY
PARTIES TO UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LIVING
MODIFIED ORGANISMS**

**Submitted by the United States of America
31 March 2014**

Challenges and Experiences

While BS-VI-16 paragraph 4 appears to be seeking views and information regarding unintentional transboundary movement of *any* living modified organisms (LMO), the United States would like to recall the limited scope of Article 17. In particular, Article 17 specifically refers to the unintentional transboundary movement of LMO “likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health” (underline added).

To date, hundreds of LMOs have been evaluated prior to releases into the environment. There have been no confirmed reports of harm to biodiversity or to human health from confined or unconfined releases of LMOs. Some of these releases have been limited in area and duration (confined releases), whereas others have been evaluated for releases over larger areas over longer durations (unconfined releases). The experience gained from the environmental risk assessments and the subsequent releases indicates that many types of LMOs are unlikely to cause adverse effects to biodiversity. Over 200 species of LMOs have been evaluated in confined environmental releases, and these include bacteria, viruses, fungi, plants (probably a few others too). Unconfined releases of LM plants include over 16 species, most of which are used extensively in agricultural production of food, fiber, and biofuels.

The United States would like to recall the results of the second national report on the implementation of Party’s obligations under the Cartagena Protocol on Biosafety. No parties reported difficulty implementing Article 17. While a little more than half of the respondents indicated a need to establish and maintain measures to prevent unintentional transboundary movement of LMO and 6% reported incidents of unintentional transboundary movement of LMO, these represent a broader scope of LMO than stated in Article 17.

Therefore, the United States proposes that there is no need to commit resources to develop further guidance in implementing Article 17.

III. SUBMISSIONS FROM RELEVANT ORGANIZATIONS

K. GLOBAL INDUSTRY COALITION

CARTAGENA PROTOCOL ON BIOSAFETY

Article 17: Unintentional Transboundary Movements of Living Modified Organisms and Emergency Measures

The Global Industry Coalition (GIC) supports the decision on Article 17 of the Cartagena Protocol on Biosafety (Protocol) taken at the sixth meeting of the Parties (MOP-6) indicating that there is already sufficient guidance that Parties can use to facilitate their actions in response to unintentional transboundary movements, including emergency measures, of living modified organisms (LMOs). Experience to date indicates that Parties should focus on the requirements of Article 17 to make information available on the Biosafety Clearing-House (BCH) and there is no need to create a mechanism to develop further guidance in implementation of Article 17 at this time.

The GIC¹ is pleased to submit its views on any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of LMOs in response to the request for information from the Secretariat in accordance with Decision BS-VI/16.

GIC Views on Unintentional Transboundary Movements of LMOs and Emergency Measures

- The GIC is of the view that – as noted in Decision BS-VI/16 - there are numerous decisions, ongoing discussions and guidance that are relevant to the implementation of Article 17 requirements under the Protocol that already serve as guidance to facilitate detection and response action in the event of unintentional transboundary movements of LMOs.
- Decision BS-VI/16 highlights the resources providing guidance to Parties' efforts to implement the measures specified in Article 17 of the Protocol and to determine and take appropriate response measures, including emergency measures, in the event of an occurrence that leads or may lead to unintentional transboundary movement of an LMO. These include:
 - Decisions that have been or may be taken in the context of identifying LMOs under Article 18 of the Protocol, in particular those relating to the detection of LMOs; and
 - The Guidance on Risk Assessment of Living Modified Organisms developed by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management with input from the Open-Ended Online Expert Forum.
- Additionally, the GIC wishes to highlight:
 - The decision from the fifth meeting of the Parties to make available to the BCH methods for the detection and identification of LMOs and establish, through the BCH, an electronic network of laboratories to facilitate the identification of LMOs as well as the sharing of information and experiences²;
 - The Nagoya-Kuala Lumpur Supplementary Protocol, which applies to damage resulting from LMOs that finds its origin in a transboundary movement, including damage resulting from unintentional transboundary movements as referred to in Article 17 of the Protocol and that provides guidance on response actions that need to be taken beyond the notification and consultation measures specified in Article 17 of the Protocol;
 - The recommendation from the first Workshop of the Network of Laboratories for the Detection and Identification of Living Modified Organisms to “[u]rge Parties, with a view to facilitating the detection and identification of LMOs, to meet their obligations under Articles 17 and 25 and make available to the BCH information concerning cases of unintentional and illegal transboundary movements of LMOs”;

¹ 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.

² Decision BS-V/9 at <http://bch.cbd.int/protocol/decisions/?decisionID=12322>

- The website developed by CropLife International that provides its members' detection methods for commercialized biotech-derived products — and related materials and information — available in an online and searchable database: www.detection-methods.org and also available through the BCH;
 - The FAO GM Foods Platform (<http://www.fao.org/food/food-safety-quality/gm-foods-platform/en/>), an online platform developed by the Food and Agriculture Organization (FAO) to share information on safety assessment of biotech-derived foods and facilitate the effective utilization of food safety assessment in situations of Low Level Presence (LLP) of r-DNA plant materials in food; and
 - The conclusion from the Parties' second national reports that “no Party reported any difficulties arising from the implementation of the requirements under Article 17 of the Protocol”³ and the recommendation that “there is already a good deal of guidance that Parties could use to facilitate their actions in response to unintentional transboundary movements of living modified organisms”⁴.
- For these reasons, the GIC believes there is no need to create a mechanism to develop further guidance in implementation of Article 17 at this time and therefore recommends that Parties:
- Take note of the existing elements that constitute guidance to facilitate appropriate responses to unintentional transboundary movements and to initiate necessary actions, including the development and adoption of emergency measures;
 - Use this information in the event of an occurrence that leads or may lead to unintentional transboundary movement of an LMO that is likely to cause significant adverse effects on the conservation and sustainable use of biological diversity; and
 - Make available to the BCH the relevant details of their point of contact for the purposes of receiving notifications under Article 17 of the Protocol; establish and maintain appropriate national measures to prevent unintentional transboundary movements of LMOs; and establish a national mechanism for addressing emergency measures in case of unintentional transboundary movements of LMOs that are likely to have significant adverse effects on the conservation and sustainable use of biological diversity.

³ Paragraph 27 of UNEP/CBD/BS/COP-MOP/6/12.

⁴ Paragraph 32 of UNEP/CBD/BS/COP-MOP/6/12.

L. INTERNATIONAL GRAIN TRADE COALITION



INTERNATIONAL GRAIN TRADE COALITION

March 31, 2014

ANIAME (Mexico)	Mr. Braulio Ferreira de Souza Dias Executive Secretary Secretariat of the Convention on Biological Diversity United Nations Environment Program 413 Saint-Jacques Street, Suite 800 Montreal, QC H2Y 1N9, Canada	Grain and Feed Trade Association (Worldwide)
APPAMEX (Mexico)		Grain Trade Australia
Associação Brasileira das Indústrias de Óleos Vegetais	RE: Response to the "Request for submission in preparation for the seventh meeting of the Conference of Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 7)"	Hungarian Grain and Feed Association
Associação Nacional dos Exportadores de Cereais (Brazil)	Dear Mr. Secretary:	National Grain and Feed Association (USA)
Australian Grain Exporters Association	The following comments are responsive to Ref: <u>SCBD/BS/CG/ABw/83191</u> dated February 14, 2014 and to notification 2012-149 http://www.cbd.int/doc/notifications/2012/ntf-2012-149-bs-post-mop6-en.pdf regarding decisions taken at the sixth meeting of the COP-MOP (6).	National Corn Growers Association (USA)
Canada Grains Council	The International Grain Trade Coalition (IGTC) is an unincorporated coalition of 22 national and international non-profit trade associations and councils involving more than 8000 members whose purpose is to convene significant expertise and representation to provide advice to governments from a global perspective on the commercial requirements and economics of the world's food, feed and processing industries, including but not limited to implementation of the Cartagena Protocol on Biosafety.	North American Export Grain Association
Centro de Exportadores de Cereais (Argentina)		Paraguayan Chamber of Cereals & Oilseeds Exporters (CAPECO)
China Chamber of Commerce of Import and Export of Foodstuffs, Native Produce & Animal By- Products	IGTC seeks a least trade distortive policy environment for the international trade of grain, oilseeds, pulses and derived products. To do so the IGTC is committed to collaborate with and inform, from a global perspective, relevant thought leadership and decision making including COP-MOP. Governments have an important responsibility to ensure that products produced through modern biotechnology do not cause damage to the environment or human or animal health. But governments also have a responsibility to ensure that the biosafety frameworks that they develop do not cause food security problems or damage local industry and create unnecessary unemployment through trade disruptions.	Russian Grain Union
China National Association of Grain Sector		Solvent Extractors' Association of India
COCERAL (Europe)		Soybean Processors Association of India
Corn Refiners Association Inc. (United States)	Over the past few years, shipments have been placed into quarantine not because of risk to the environment or human or animal health but for regulatory compliance reasons. Such trade disruptions often hurt importers more than exporters as countries may not be able to secure needed supplies for food, or feed or for processing. And in some	US Grains Council US Wheat Associates

instances local industry has been forced to shut down and reduce employment for lack of commodities to process.

For example one shipment was placed into quarantine because one seed in 120,000 seeds tested positive to an unauthorized event. One seed in 120,000 seeds is unlikely to cause harm to the environment or human or animal health but the out of compliance requirements forcing the product into quarantine created significant trade disruptions with unfortunate consequences to both importers and exporters, but ultimately the consumers who are denied access to a product already deemed to be safe as a result of a safety review in at least one country. IGTC member organizations and their constituent companies and farmers have developed extensive experience addressing the issues posed in CBD SCBD/BS/CG/ABw/83191. CBD SCBD/BS/CG/ABw/83191 specifically asks for comments on two issues related to the implementation of the Cartagena Protocol on Biosafety for consideration at the upcoming COP/MOP 7:

- 1. BS –V/8, Handling, transport, packaging and identification of living modified organisms: paragraph 2(A) of Article 18**
- 2. BS-VI-16, Unintentional transboundary movements of living modified organisms (Article 17)**

Based on our history and experience we offer our comments, as follows:

Issue 1 - BS –V/8, Handling, transport, packaging and identification of living modified organisms: paragraph 2(A) of Article 18

According to the International Service for the Acquisition of Agri-biotech Applications, global biotech acreage reached 175 million hectares in 2013 and a significant percentage of the global grain trade now involves products produced through modern biotechnology. Therefore it is critically important that Article 18.2(a) which defines the documentation requirements for the transboundary movement of LMOs for food, or feed, or for processing, is implemented in a commercially acceptable manner.

The current widespread practice of documenting the possible presence of Living Modified Organisms on existing commercial documents with a simple “May Contain” clause has been shown to be practical and cost effective for commercial grain trade parties.

As nations have managed the handling, transport, packaging and identification of living modified organisms with the Cartagena Protocol as it has been implemented thus far, exporters and importers have often been able to trade commodities containing living modified organisms in international commerce in accord with the requirements invoked by most countries. In the event policy is not acceptable to the exporters or importers they have the freedom to avoid the trade or inflate their transaction costs to cover the additional or unusual costs that are associated with conformance with the unique requirements in that particular country. In these cases the beneficiaries of trade, including – consumers and the economies in the importing countries that restrict imports, risk insufficient supply, reduced sustainability and higher costs for essential food and energy needs.

The recently released FAO survey on levels of GM crops in international food and animal feed trade showed that 25 countries have blocked imports after finding traces of GMO's. The incidents have led to trade disruptions between countries with shipments of grain, cereal and other crops being blocked by importing countries and destroyed or returned to the country of origin. The 25 reported incidents are small in the context of the total number of global grain shipments which would be out of a total of more than 10,000 shipments or a very minor percentage of the total.

When regulatory interventions have occurred for reasons that are related to documentation and LMO content, they have been extremely expensive and disruptive to commercial activity. If the 25 instances of shipment rejection identified earlier were an average 50,000 mt cargo of soybeans or maize and the reason for rejection was improper documentation for commodities that have already gone through a CODEX compliant risk assessment process, then more than \$100 million and possibly as much as \$250 million USD worth of safe food or feed was possibly denied to the food chain.

International trade of grains, oilseeds, pulses, and derived products occurs at low cost margins due to the extremely competitive nature of the business with multiple origins and competitors vying for a finite volume of business. Highly efficient and low margin international trade is only possible when exporters and importers are able to define and manage their trade risks including those due to Living Modified Organisms. The current practice of allowing documentation on existing commercial documents and with the "May Contain" clause comports with the needs of the trade for transparency, simplicity and clarity and minimizes introduction of unknown documentation risks, which translated means lower costs.

Sampling of grain, oilseeds, pulses and derived products is often key to trade facilitation and verification of regulatory compliance. IGTC members believe that existing standards and procedures for sampling grains and oilseeds for other analytical needs including quality and safety are sufficient to sample grains for LMO's. Sound commercially viable and sufficiently representative sampling methods have been used successfully for decades. There is no need for a separate or unique sampling plan system for GMO analysis.

With regard to sampling, please note that past efforts to develop sampling methods for detection of genetically modified organisms in foodstuffs were considered to be in conflict with work conducted by CODEX Alimentarius; unnecessary. In 2006, similar unnecessary efforts were removed from the program of work of the International Standards Organization (ISO) committee that was addressing the provision. In the ISO Committee deliberations, it was argued that grain is already sampled for many factors and an additional sampling regime as proposed in the foodstuffs standard was and is not practicable in the real world. A separate ISO workshop in 2008 considered the issue of sampling of bulk grains including for the presence of GMO's in conjunction with a review of ISO 24333 for cereals and cereal products. The experts present at the workshop specifically stated that sampling for the presence of GMO's should not be addressed separately from the existing sampling practices. The European Technical Specification CEN/TS 15568 includes provisions of ISO standard 21568 for foodstuffs, but it is reportedly seldom, if ever, used. Experts in the field in several different venues have indicated that a separate and unique sampling plan for the presence of GMO's is not different than sampling plans for other characteristics.

Importers and exporters conducting business among and between the United States of America, Canada and Mexico have found the so-called "Trilateral Accord" covering the commodities traded among the three countries which may contain Living Modified Organisms to be extremely useful and favorable to efficient trade thus far. More details on the practical implications and effectiveness of the "Trilateral Accord" are recorded in the attached presentation entitled "The Mexican Experience for Documentation Accompanying Food/Feed/Processing Shipments of Living Modified Organisms".

In summary, the "may contain" language approach on existing documents provides parties the necessary information to use the BCH and their domestic regulatory frameworks to assure that the environment remains protected, while not imposing extra costs on consumers of food and feed which would accompany unnecessary event specific listing and testing requirements. For these reasons it is important that the implementation language continue to allow for "may contain" language on the existing commercial documents.

If additional actions are taken to require extraordinary, additional handling, testing and segregation requirements for the predominant bulk commodity trading system, the global grain trading and food systems will incur increased costs; experience unnecessary delivery delays, and major supply-chain interruptions, which would severely and adversely cripple efforts to address the growing global food security challenge.

Issue 2 - BS-VI-16, Unintentional transboundary movements of living modified organisms (Article 17)

The grain trade has always understood Article 17 to be applicable to unique and unusual transboundary movements not related to the commercial trade for food, feed and processing and we have no further comments in that regard beyond what we have already provided under Issue 1.

We thank you for this opportunity to offer these comments and welcome the opportunity to clarify or further explain any of this information before or during the upcoming MOP 7.

Sincerely,



Kirk Miller
Acting IGTC Secretary
c/o North American Export Grain Association
1250 Eye St., N.W., Suite 1005
Washington, DC 20005
(703) 352-0832
secretariat@igtglobal.com

M. NO! GMO CAMPAIGN

Public Comment regarding Ref.: SCBD/BS/CG/DA/83191

Dear Sir or Madam,

May 2, 2014

We respectfully offer the following comments in preparation for the seventh meeting of the COP-MOP7 regarding decisions BS-V/8 and BS-VI/16.

We are a coalition of civic society organizations and non-governmental organizations that are actively investigating and educating the public as well as discussing with the Japanese government the negative influence that living modified organisms (LMOs), such as genetically modified organisms, are having on biodiversity here in Japan.

During the seventh meeting of the Convention on Biological Diversity and the Cartagena Protocol Conference of the Parties (COP/MOP7) in South Korea later this year, the main themes are the 17th article of the Cartagena Protocol, "Unintentional transboundary movements of living modified organisms" and the 18th article, "Handling, transport, packaging, and identification [labeling] of living modified organisms."

We strongly request strict international rules to be put in place in order to prevent contamination by LMOs, and to avoid the bad influence on biodiversity that this will cause.

Specifically, we have investigated the spontaneous generation of genetically modified canola for ten years. Each year, some 1500 people participate in our investigation campaigns all over the country. We have carefully tested and reported about the findings of wild-growing GM canola growing near the main roads from import harbours leading directly to food oil companies. Also, we have found that the contamination of such GM canola is spreading to other areas including residential areas.

Moreover, we have found a number of cases of complications as the wild-growing GM canola creates hybrids with local varieties of mustard, broccoli and weeds. This indicates clearly the danger of introducing genetically modified organisms into ecosystems which have plants from the same or similar origin. Also, as our experience shows, decontamination is difficult unless massive efforts are made to locate, pick up, test, and destroy wild-growing GM plants.

Based on that, we have the following requests:

Regarding the 17th article, "Unintentional transboundary movements of living modified organisms," we ask for making it possible that such situations do not occur by taking precautionary measures. Moreover, in emergency situations, in order to minimize the damage, we ask for prompt notification and investigation so that the cause can be found and to ensure that similar occurrences are prevented.

Regarding the 18th article, "Handling, transport, packaging, and identification [labeling] of living modified organisms," we ask for measures to be put into practice so that contamination by GM seeds during transport and loading/unloading is prevented. Similarly, measures are needed for labeling to make it possible to access correct and detailed information regarding the contamination cases. Beyond that, we ask for measures to ensure that the current cases of wild-growing GM canola in Japan and the further contamination of local crop varieties and weeds will not spread to the rest of the world.

Sincerely Yours,

Amagasa Keisuke
No! GMO Campaign

N. TESTBIOTECH

Munich, 30 April 2014

Dear Sir or Madam

Request for submissions in preparation for the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 7)

Testbiotech is a non-profit making non-governmental organisation that is independent of industry and closely concerned with the impact assessment of biotechnological applications. In the course of our research in 2013, we became aware of several cases of transgenic plants that had moved into native populations and were likely to be persistent and possibly invasive. Several others are likely to escape spatio-temporal control in the near future. We are concerned that this development will create major problems with regard to the **unintentional trans-boundary movements of living modified organisms (Article 17 of CBD)**.

Please read our report and our publication as attached since we believe that the CBD should deal with this matter urgently. As far as we know, international regulations prohibiting the release of genetically engineered organisms that cannot be controlled in their spatio-temporal proliferation are largely missing. As our publication shows, spatio-temporal control is a prerequisite for any risk assessment. Further, in the context of the CBD it is evident that clear regulations are also necessary to avoid **unintentional trans-boundary movements**.

Please let us know if you require any further information.

With kind regards



Christoph Then, Executive Director, Testbiotech
Tel + 49 15154638040
e-mail: christoph.then@testbiotech.org

Annexes:

Bauer-Pankus A., Breckling, B., Hamberger, S., Then C. (2013): Cultivation-independent establishment of genetically engineered plants in natural populations: current evidence and implications for EU regulation. Environmental Sciences Europe 25:34.

Bauer-Pankus A., Hamberger, S., Then C. (2013), Transgene escape - Global atlas of uncontrolled spread of genetically engineered plants, www.testbiotech.org/sites/default/files/Testbiotech_Transgene_Escape.pdf

**TEST
BIOTECH**

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O. THIRD WORLD NETWORK



Third World Network

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Mr Braulio Ferreira de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity
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Montreal, Quebec
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Fax: + 1-514-288-6588

21 April 2014

Dear Mr Braulio Ferreira de Souza Dias

Submission from Third World Network related to decision BS-VI/16: Unintentional transboundary movements of living modified organisms (Article 17)

Reference is made to your notification dated 2 April 2014, requesting submissions related to decisions BS-V/8 and BS-VI/16.

We are pleased to attach herewith a submission from Third World Network related to decision BS-VI/16: Unintentional transboundary movements of living modified organisms (Article 17). In particular, we highlight important considerations that should be the basis of determining the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms. Some of the discussion is also relevant to paragraph 2(a) of Article 18 and thus also relevant to the request for submissions related to BS-V/8.

Thank you for your kind consideration.

Yours sincerely

A handwritten signature in black ink, appearing to read 'CYL', with a horizontal line underneath.

Chee Yoke Ling
Director
Third World Network

Submission from Third World Network related to decision BS-VI/16: Unintentional transboundary movements of living modified organisms (Article 17)

Introduction

The Cartagena Protocol on Biosafety seeks to protect biological diversity from the risks posed by living modified organisms (LMOs), taking also into account risks to human health. It establishes an advanced informed agreement procedure for ensuring that Parties are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. Decisions are made in accordance with the precautionary approach and following the conduct of a risk assessment.

However, unintentional transboundary movements of LMOs circumvent these central tenets of the Cartagena Protocol that preserve the right of Parties to have their prior informed consent sought, and to be able to make decisions on LMO approvals based on risk assessment and in accordance with the precautionary approach.

Article 17 of the Cartagena Protocol requires Parties to take appropriate measures to notify affected and potentially affected States, the Biosafety Clearing-House (BCH) and relevant international organizations when it knows of an occurrence under its jurisdiction that leads, or may lead, to an unintentional transboundary movement of a LMO. Notifications must be provided as soon as the Party knows of such situations, and relevant information must be communicated to the affected or potentially affected States. Consultations with affected or potentially affected States are also necessary to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Situation with regard to unintentional transboundary movements

There are several plausible scenarios of unintentional transboundary movements:

- Unintentional transboundary movements involve unauthorized LMOs that would not have undergone a risk assessment in the affected or potentially affected State.
- A risk assessment may or may not have been conducted in the Party or State of export (e.g. MIR162 maize, herbicide-tolerant alfalfa).
- In some situations, unintentional transboundary movement could involve a LMO that is unapproved anywhere in the world (e.g. LL601 rice, Monsanto herbicide-tolerant wheat, Bt10 maize).

Unintentional transboundary movement could also mean that untested and possibly higher-risk LM crops, e.g. those intended for production of industrial biochemical or pharmaceuticals would enter into the food and feed system, which is untenable from a safety point of view. When such contamination occurs in the form of seeds or grain, which are still able to reproduce and/or transmit their genetic information to other

organisms, this risk would extend to a potential spread and further contamination of food, feed, seed and wild species.

Incidents of unintentional transboundary movements of LMOs worldwide have occurred with alarming frequency. According to the GM Contamination Register (www.gmcontaminationregister.org), a total of 396 known contamination incidences and illegal releases have occurred to date since 2005, when the database was first set up. The GM Contamination Register is compiled from public reports and is managed by Greenpeace and GeneWatch UK. In 2013 alone, 26 individual incidences were recorded in countries in Asia, Africa, Europe and the USA, many involving unapproved LMOs.

There is a difference in the number of the records of unintentional transboundary movements that have occurred in developing and developed countries. It should be noted that the higher number of records of incidents in developed countries does not mean that there has been less occurrence of unintentional transboundary movements in developing countries, but could be attributed to a lack of monitoring, notification and information systems in these countries, pointing to the need to provide support to improve such systems.

In contrast to the high number of incidences compiled in the GM Contamination Register, from analysis carried out by the CBD Secretariat in 2012 (UNEP/CBD/BS/COP-MOP/6/12), only four Parties reported unintentional introduction of LMOs into their jurisdiction in the form of imports of food or seeds, while two other Parties reported potential or unverified transboundary transfer of LMOs into their territories.

In addition, very few Parties (only nine) had reported receiving information concerning occurrences that led, or may have led, to unintentional transboundary movements under their jurisdiction. The majority (133 Parties) reported that they have never received any such information, during the reporting period of the second national report.

Of the nine Parties, eight responded further, with two reporting that they have notified, for every occurrence, affected or potentially affected States and, where appropriate, relevant international organizations, of the release. Six of the other Parties reported that they have not provided any notification. Furthermore, one Party reported that it had immediately consulted the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, another reported that it has done so in some cases, and the remaining six reported that consultation was never conducted.

It is clear that there is disconnect between the known cases of unintentional transboundary movement and what is notified to potentially affected States. This could be because the source of some contamination incidents may be from non-Parties to the Protocol. When contamination originates from Parties to the Protocol, regrettably not all have appeared to fulfill their notification and consultation obligations.

Steps therefore need to be urgently taken to facilitate the implementation of Article 17. Efforts need to be made to encourage, facilitate and enable Parties to take appropriate measures to notify affected or potentially affected States of an unintentional transboundary movement. Furthermore, steps are needed in order to be able to assist Parties to detect and take measures to respond to unintentional transboundary movement of LMOs. These steps must happen even if notification is not given directly to the affected States, but information is available from other sources, e.g. media reports, non-government organizations, etc.

The following are important considerations that should be the basis of determining the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of LMOs. Some of this discussion is also relevant to paragraph 2(a) of Article 18, and thus also relevant to the request for submissions related to BS-V/8 (Handling, transport, packaging and identification of living modified organisms, paragraph 2(a) of Article 18).

Considerations for Parties from where unintentional transboundary movements may originate¹

1. Compliance with domestic regulations

Regardless of whether the source of unintentional transboundary movement is a Party to the Protocol or not, compliance with the domestic regulations of importing Parties' and those of affected or potentially affected States, including zero tolerance policies for unapproved LMOs, is necessary.

Zero tolerance policies are completely consistent with Decision BS-III/10 adopted at COP-MOP3 in 2006, as well as with Paragraph 6 of Annex 3 of the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 45-2008) (Codex Plant Guideline). The Codex Plant Guideline states that the Annex, which provides guidance on food safety assessment in situations of low-level presence² of recombinant-DNA plant material in food, "does not eliminate ... responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet importing countries' requirements, including in relation to unauthorized recombinant-DNA plant material".

2. Prevention of unintentional transboundary movements at the potential source

Proactive steps need to be taken on the part of Parties that are developing or growing LMOs, to establish and maintain measures to prevent unintentional transboundary movements. These include stringent controls of contained use, field trials and commercial plantings, including monitoring to ensure that there has been no unintentional escape of any LMO.

¹ These could include exporting Parties, and/or Parties that develop and produce or grow LMOs.

² Low-level situations are not defined in the Codex Plant Guideline, but refer to situations where low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Plant Guideline in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

Parties of export should also ensure the conduct of a risk assessment, for all LMOs in research and field trials. In relation to risk management, Article 16(3) of the Cartagena Protocol requires that the risk assessment needed before the first release of a LMO takes into account the possibility of unintentional transboundary movements³.

3. Segregation, identity preservation and testing

Related to Article 18.2(a) of the Cartagena Protocol, exporting Parties should implement Para 4(a) of Decision BS-III/10. This requires ensuring that the documentation accompanying LMOs intended for direct use as food or feed, or for processing, clearly states, in cases where the identity of the LMO is known through means such as identity preservation systems, that the shipment contains LMOs that are intended for direct use as food or feed, or for processing.

Clear identification can be achieved by implementing a system of segregation, identify preservation and testing such that no unauthorized GMO enters the food/feed chain. Such a system would reduce the chances of unintentional transboundary movements occurring.

4. Timely notification

Paragraphs 1 and 3 of Article 17 establish clear notification obligations for Parties when it knows of any occurrence under its jurisdiction that leads or may lead to unintentional transboundary movement. Steps need to be taken to facilitate and enable the notification process to happen in a timely manner and to reach all affected or potentially affected States. This could include, for example, the setting up of a rapid alert system that immediately notifies all affected and potentially affected States.

5. Provision of information, detection methods and reference materials

Two key elements to ensure that situations of unintentional transboundary movements are adequately and responsibly dealt with in affected or potentially affected States are:

- (i) having adequate information to address the risks; and
- (ii) having the technical capacity to detect the LMOs in question.

Paragraph 3 of Article 17 specifies the minimum information that any notification to affected or potentially affected States should contain. This includes information related to the quantities and particular characteristics of the LMO concerned, and the circumstances surrounding the occurrence leading to the unintentional transboundary movement. In addition, information should be provided on the possible adverse effects and possible related risk management measures. Paragraph 3(d) provides a 'catch all', requiring the provision of "any other relevant information".

There are thus clear obligations for the Party from which an unintentional transboundary movement originates to notify and provide adequate information to affected or potentially affected States. The source of contamination should be quickly

³ See p. 112 of *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN and FIELD (2003).

identified, along with the modes of contamination and pathways by which the contamination is spread.

Importantly, the sequence information necessary to enable detection must be provided. Regrettably, competent authorities are often not provided such sequence information and this is particularly so for LMOs in field trials.

At the international level, there are two important repositories for information related to LMOs:

- The BCH plays an important role in making the requisite information available, with paragraph 5 of Decision BS-III/10 inviting Parties and other Governments to make available to the BCH information about transformation events (what has been commercially produced, the cultivated geographical areas, the common, scientific and, where available, commercial names, the transformation event code or where available, the unique identifier code) that may presumably be inadvertently subject to transboundary movement.
- Annex 3 of the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 45-2008) asks Codex Members to make available, to a publicly accessible central database to be maintained by FAO, information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline, including “where detection method protocols and appropriate reference material ... suitable for low-level situations may be obtained” (Para 28(i)). Furthermore, “the product applicant should provide further information and clarification ... as well as a validated protocol for an event-specific or trait-specific detection method suitable for low level situations and appropriate reference materials (non-viable, or in certain circumstances, viable)” (Para 31).

Paragraph 5 of Decision BS-IV/9 further encourages those in possession of reference materials to provide access for those agencies that may need such materials for the purpose of detection of LMOs.

Considerations for affected or potentially affected States⁴

1. Right to have zero tolerance policy

It is the sovereign right of importing Parties’ and of affected or potentially affected States to decide on policy, including zero tolerance, and to require that all LMOs be risk assessed prior to approval. There is full flexibility for zero tolerance of unapproved LMOs:

- Article 25 of the Cartagena Protocol on Biosafety recognizes situations of illegal transboundary movement. Such situations, where transboundary movements of LMOs are carried out in contravention of domestic measures, are to be prevented, and if appropriate, penalized.

⁴ These could include importing Parties.

- Decision BS-III/10 states that measures must be taken to ensure that LMOs destined for food or feed, or for processing are “authorized in accordance with domestic regulatory frameworks” and documentation is “in compliance with the requirements of the country of import”.
- The Codex Plant Guideline (Paragraph 6, CAC/GL 45-2008) states that the conduct of a safety assessment in accordance with Annex 3 of the Guideline “does not eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries’ relevant import requirements, including in relation to unauthorized recombinant-DNA plant material”.

2. Capacity for sampling, testing and detection

Affected or potentially affected States need the technical capacity to sample, test and detect incidents of unintentional transboundary movement. This is an issue recognized in the Strategic Plan of the Cartagena Protocol, which among others, envisages the following outcomes:

- (i) Guidance developed to assist Parties to detect and take measures to respond to unintentional releases of LMOs (Operational Objective 1.8);
- (ii) Easy to use and reliable technical tools for the detection of unauthorized LMOs are developed and made available (Operational Objective 1.6); and
- (iii) Personnel are trained and equipped for sampling, detection and identification of LMOs (Operational Objective 2.3).

The COP-MOP has taken a series of decisions in relation to sampling, testing and detection, including encouraging Parties and other Governments to cooperate in exchanging experiences and building capacities in the use and development of easy to use, rapid, reliable and cost-effective sampling and detection techniques for LMOs (Paragraph 10 of Decision BS-III/10); as well as underlining the importance of accreditation of laboratories involved in sampling and detection of LMOs and encouraging those in possession of reference materials to provide access for those agencies that may need such materials for the purpose of detection (Paragraph 5 of Decision BS-IV/9).

Paragraph 5 of Decision BS-V/9 invites Parties to nominate national and international reference laboratories with the view to establishing, through the BCH, an electronic network of laboratories to facilitate the identification of living modified organisms as well as the sharing of information and experiences. Parties that do not have the infrastructure (laboratories) for detection could also benefit from the experiences and exchanges of this network of laboratories. At a November 2013 workshop of the network (UNEP/CBD/BS/WS-LMO/1/2), the development of an implementation strategy for the detection and identification of LMOs, including the specific needs for technical tools and guidance for the detection of unauthorized LMOs and unintentional releases, was discussed. Furthermore, the workshop elaborated a series of useful recommendations for the consideration of COP-MOP 7.

3. Mechanisms for implementing responses, actions and emergency measures

Guidance and capacity building is needed in relation to determination of appropriate responses and initiation of necessary actions, including emergency measures, in order to minimize any significant adverse effects of unintentional transboundary movements (Paragraph 4 of Article 17). No specificity is provided in Article 17 on the types of responses and actions that may be taken, therefore guidance on the issue would be useful.

Nonetheless, according to Article 25 on illegal transboundary movements, the affected Party may request the Party of origin to dispose, at its own expense, of the LMO in question by repatriation or destruction. This could be one option of response, action or emergency measure.

In addition, response measures are to be taken under the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress when there is damage or sufficient likelihood of damage, including that which arises from unintentional transboundary movements. These response measures, which are to be determined by the competent authority, and taken by the operator or in the event the operator fails to do so, by the competent authority, could be the same or complementary to the action envisaged under Article 17.