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Agriculture

Farm and Foreign
Agricultural
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Notice to U.S. Food Aid Program Partners

Guidance for Meeting Documentation Requirements for Shipments of LMO's for Food, Feed, or for Processing Under the Cartagena Protocol on Biosafety

Background

The Cartagena Protocol on Biosafety, an international environmental treaty under the U.N.'s Convention on Biological Diversity, entered into force on September 11, 2003. As of that date, Parties to the Protocol are expected to implement its provisions. The Protocol addresses the environmental impact of transboundary movement of "living modified organisms" (LMOs). LMOs are those products of bioengineering that are capable of reproducing, including whole grains or oilseeds that have the potential to germinate. The United States is not a Party to the Protocol or the Convention on Biological Diversity. Several food aid recipient countries are Parties to the Protocol or may become Parties in the future.

Article 18(2)a of the Protocol requires Parties to take measures to ensure that documentation accompanies shipments of LMOs that are intended for direct use as food or feed, or for processing. The documentation must clearly identify that the shipments "may contain" LMOs and are not intended for intentional introduction into the environment, as well as a contact point for further information. Article 18(2)a of the Protocol reads as follows:

"2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol."

Currently, the only LMOs sent through U.S. food aid programs are whole corn and whole soybeans. Processed commodities, such as corn-soy blend, are not considered LMOs under the Protocol.

While no food aid-recipient Party countries have articulated specific requirements under the Protocol to date, it is expected that food aid shipments of LMOs destined for or transiting Party countries will need to be accompanied by "may contain" documentation. Omission of the "may contain" documentation could result in food aid shipments being

delayed or blocked at ports or other receiving points because of perceived failure in meeting the Protocol's documentation requirements.

Since the United States is not a Party to the Protocol, the U.S. Government cannot require that exporters comply with it. It is the responsibility of exporters to meet the Parties' requirements under the Protocol when exporting to Parties. The following guidance is provided for our food aid program partners:

1. Determine whether the destination or transit countries are Parties to the Protocol.

Check the Convention on Biological Diversity website to determine whether destination or transit countries are Parties to the Protocol, and confirm each country's date of entry into force. While the Protocol came into force on September 11, 2003, countries may have different entry-into-force dates depending on when they ratified.

The list of countries that have ratified the Protocol, and dates of the Protocol's entry into force for each country, is available at:

<http://www.biodiv.org/biosafety/signinglist.aspx>

2. Determine whether the country has specific regulations on the documentation requirements for LMO shipments for food, feed, or for processing.

Many countries are currently developing regulatory frameworks for implementing the Protocol. All recipient country regulations should be followed. If you are unfamiliar with recipient country requirements, the embassy or mission staff in recipient countries have recently been instructed to familiarize themselves with any regulatory requirements for bioengineered crops or products, including any requirements related to implementation of the Protocol, and can advise you further.

In addition, Parties are required to post their biotech regulations on the Biosafety Clearing-House, an internet-based database, which will serve as a repository for information on regulations and regulatory decisions related to the Protocol. The Clearing-House is currently in the pilot phase and contains little information from food aid recipient countries, but, once fully operational, should become a useful source of information on each country's biotech regulations. The Biosafety Clearing-House may be accessed at the following address:

<http://bch.biodiv.org/Pilot/Home.aspx>

3. If the recipient country does not have any regulations in place with regard to documentation of LMO shipments, and is a Party to the Protocol, the following steps should be implemented:

- Shipments of LMOs destined for or transiting Parties to the Protocol should be

accompanied by a “may contain” declaration on the commercial invoice.

The following declaration is suggested:

“Cartagena Protocol on Biosafety Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment.”

- The commercial invoice should also name the last exporter before the transboundary movement and the first importer after transboundary movement as contact points for further information.
 - For food aid shipments, the last exporter of record may be either the World Food Program, the private voluntary organization (PVO), or USAID. The first importer of record may be either: the same entity as the last exporter of record, another PVO, or the recipient country government.
- All whole grain shipments of commodities for which genetically engineered varieties are approved and grown in the U.S. should be accompanied by “may contain” documentation.
 - At this time, whole corn and whole soybeans are the only commodities that should be accompanied by “may contain” documentation.
- Adventitious presence (accidental commingling of LMO in a non-LMO shipment; e.g., genetically engineered corn in a sorghum shipment) should not be a trigger for the “may contain” documentation.



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Grain and Feed
Trade Association

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Association

National
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Association

North American
Export Grain
Association

National
Corn Growers
Association

Solvent Extractors'
Association
of India

Soybean
Processors
Association
of India

US Grains Council

US Wheat
Associates

Wheat Export
Trade Education
Committee

Notice to Trade

Documentation Requirements for Shipments of LMOs for Food, Feed or for Processing effective 11 September 2003.

The following summary is an overview of certain aspects of the Biosafety Protocol, an international agreement designed to protect global biodiversity. The summary is based upon the best information known to date and the advice provided by the International Grain Trade Coalition (IGTC) to governments on how to implement the Protocol to meet the needs of the world's food, feed and processing industry. The following is not intended as legal advice or opinion. Entities impacted by the Biosafety Protocol (those that are engaged in the international movement of products that may contain living modified organisms derived from modern biotechnology) are strongly encouraged to contact their legal counsel and regulatory affairs representatives for further information in order to make necessary decisions concerning the matters in this overview.

Introduction: The Cartagena Protocol on Biosafety comes into force on 11 September 2003. On this date those countries that have ratified the Protocol become Parties to the Protocol and are expected to implement its provisions. Article 18.2(a) of the Protocol says that each Party shall take measures to require documentation accompanying "living modified organisms (LMOs) that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol (COP/MOP) shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol." Thus the provisions of the first sentence take effect on September 11th while the COP/MOP has two years to decide whether further requirements are needed.

Companies shipping LMOs for food, feed or for processing to countries that have ratified the Protocol may find that they are expected to comply with the Protocol's provisions. However many of these countries are only now developing their regulatory frameworks and once developed these regulations may be more detailed than contained in the first sentence of Article 18.2(a). As a result the IGTC offers the following suggestions to industry:

1. Determine whether the country is a Party to the Protocol: Check the Biosafety Clearing House (BCH) to determine whether the importing country is a Party to the Protocol and confirm the date of entry into force for that particular

country. While the Protocol comes into force on September 11, 2003, countries can establish a different date for the Protocol to come into force in their particular country. See <http://www.biodiv.org/biosafety/signinglist.aspx>

2. Determine whether the country has specific regulations on the documentation requirements for LMO shipments for food, feed or for processing: Many countries are currently developing regulatory frameworks for the transboundary movement of LMOs. These provisions can be more detailed than contained within the Protocol. Parties must post their regulations on the BCH. See <http://bch.biodiv.org/Pilot/Home.aspx>. The BCH is currently in a pilot phase but when fully operational the BCH should become the major source for each country's biotechnology regulations. In the meantime exporters should seek clarification from importers before shipment on what regulations, if any, exist covering the transboundary movement of LMOs for food, feed or for processing.

3. Documentation on LMO shipments for food, feed or for processing: Unless notified by the importer otherwise, the IGTC recommends that the commercial invoice be used as the document to carry the "may contain" language, when required. If all exporters use the same document, then custom officers do not have to search through all shipping documents to see whether the cargo is an LMO shipment. The IGTC suggests that the following declaration be placed on the invoice:

"Cartagena Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

The last exporter prior to transboundary movement and the first importer after transboundary movement named on the invoice should be the contact points for further information.

4. When to use the documentation: The Protocol is silent on what constitutes an LMO shipment and therefore does not define when the documentation is needed. The IGTC continues to recommend to governments that the unintentional presence of approved LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation. The IGTC continues to advise governments therefore that the "may contain" declaration should be given for all LMO shipments of commodities intended for food or feed or for processing to countries that have ratified the Protocol except for those shipments for which:

- (i) The exporting country does not have in commerce any LMO of that species; or
- (ii) Such shipment achieves a minimum of 95% non-LMO content, and that such definition does not conflict with regulations of the importing country.

Number (i) is recommended to exempt shipments of crops such as wheat as there is no LMO wheat in commerce. The 95% purity threshold in (ii) was selected by the IGTC as some importing countries have selected this level of purity as the minimum purity level allowed and this level is being used in current bilateral negotiations. This exemption is designed to exempt non-LMO shipments of such commodities as soybeans when the non-LMO purity level is 95% or higher.

Conclusions

Although the Protocol comes into force on September 11th, there are still a considerable number of outstanding documentation issues that need to be resolved in Malaysia 23-27 February 2004 by the Conference of the Parties serving as the Meeting of the Parties (COP/MOP).

In the meantime companies should discuss with their legal counsel and government regulatory affairs officials IGTC recommendations. Effective September 11th, countries that have ratified the Protocol may require declarations for all LMO shipments for food, feed or processing.

“SAMPLE”

COMMERCIAL INVOICE

SHIPPER/EXPORTER:

USAID / OP / TRANS
1300 Pennsylvania Ave, NW, 7th Floor
Washington, DC 20156

Date: 02 JUL 2003

Invoice No.: AL03-0250

Order No.: 663-3834-00

CONSIGNED TO:

PVO NAME AND ADDRESS
IN RECEIPIENT COUNTRY

Terms: Gift shipment for
charitable purposes only.

MARKS: CORN
VEPE _____
50 KILO

VIA: ATLANTIC FOREST V04
B/L # 01

QUANTITY

DESCRIPTION

PRICE

16,285

BAGS: YELLOW CORN – 50 KILO
NET: 1,795,096 LBS 814,250 KGS

VALUE FOR CUSTOMS PURPOSES ONLY USD 105,726.67

HUMANITARIAN AID.

GIFT SHIPMENT FOR CHARITABLE PURPOSES ONLY. NOT FOR RESALE.

DONATION SHIPMENT.

CARTAGENA PROTOCOL ON BIOSAFETY PROVISION: THIS SHIPMENT MAY CONTAIN LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING, THAT ARE NOT INTENDED FOR INTENTIONAL INTRODUCTION INTO THE ENVIRONMENT.

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