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MEETING OF TECHNICAL EXPERTS ON HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS
Paris, 13-15 June 2001
Item 3 of the provisional agenda*

COMPILATION OF INFORMATION ON EXISTING PRACTICES, RULES AND STANDARDS RELEVANT TO ARTICLE 18 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

CONTENTS

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ARGENTINA [26 April 2001]
[ORIGINAL: ENGLISH]

Regarding Article 18, paragraph 2 (a), in Argentina, the modalities for handling, transport, packaging and identification are mainly settled by private arrangements among the parties. Quality standards for grain marketing are compulsory, they are set up in Resolution from the Secretary of Agriculture, Livestock, Fisheries and Food (SAGYP) 1075/94 and its modifications (Ordered Text for Quality Standards and Sampling Methdology for Grains and byproducts).

In general, Argentina does not differentiate grain production, although under certain circumstances grain is segregated. An example of this is Flint maize which is segregated taking into account both quality and the absence of LMOs. Besides, there are regulations to differentiate organic from non organic products.

Recently, Regulation from the sanitary authority SENASA No. 61/2000 set up the institutional System for the Promotion and Certification of Grain Specialities, which is voluntary, this system involves IP for any type of differentiation (quality, non LMOs).

Regarding Article 18, paragraph 2 (b), living modified organisms that are destined for contained use in Argentina, are clearly identified. The importer should ask for authorization from the National Advisory Committee on Agricultural Biosafety (CONABIA), and from the sanitary authority SENASA in order to introduce the organisms in the country for research and development. In the case of living modified organisms destined for contained use produced in Argentina, the requirements are the same. Inspections on the contained use of LMOs are carried out by National Institute for Seeds (ex INASE) and SENASA, either for laboratory/greenhouse trials or for field trials.

In the case of Article 18, paragraph 2 (c), Argentina has a very long experience in the application of the Advanced Informed Agreement Procedure. The importer in Argentina needs to have authorization for an intentional introduction into the environment. The process is initiated by submitting to the CONABIA all the relevant information, public and confidential on the event of transformation. This information required in Argentina is the same information required for complying with Annex 1 of the Protocol and the procedure followed in order to make an informed decision is included in the National Resolution 289/97 which is similar to that included in Annex III of the Protocol.

In addition to the information on environmental risk assessment done by CONABIA, SENASA makes an evaluation on the use of LMOs for food and feed uses. Moreover, the National Bureau of Agrofoods Markets provides marketing information. The Secretary of Agriculture, Livestock, Fisheries and Food makes the final decision on the liberation of the LMOs to the environment.

The LMOs for commercialization will follow the identification procedure regulated by the argentine seed legislation in accordance with UPOV, where every seed package is identified and labeled. This identification include the relevant traits and characteristics, contact point, the name and address of importer and exporter and special requirements if needes for safe handling, storage, transport and use. Labels also contain the legend explaining that seeds had been obtained through biotechnological methods. The National Institute for Seeds (INASE) keeps a register on producers, importers, breeders, handlers, packagers and identifiers involved in the seed industry.

AUSTRIA

[14 March 2001]
[ORIGINAL: ENGLISH]

The EU Directives 90/219/EEC and 90/220/EEC have been implemented by the Austrian Law on Genetic Engineering (in force since 1 January 1995 and amended 22 May 1998).

The following additional Regulations (Ordinances) complement the framework law:

- March 1996: Ordinance on the Safety of contained uses of GMOs
- February 1997: Ordinance on Deliberate Release
- February 1997 (amended May 1998) : Ordinance on Public Hearings
- February 1997: Ordinance prohibiting the use and sale of the Bt-Maize 176
- November 1997 : Ordinance on the Limitation of GMO Emissions with Liquid Effluents
- February 1998 : Ordinance on Labelling of Products which Contain or Consist of GMOs
- July 1998 : Ordinanca on biological agents at work
- March 1999 : Ordinance on Labelling of genetically modified plant varieties and seeds of genetically modified plant varieties
- June 1999 : Ordinance prohibiting in particular the cultivation of Bt-Maize MON810
- April 2000 : Ordinance prohibiting the placing on the market of herbicide Tolerant maize T25

Other relevant regulations include:

- a revision in the year 2000 on the Federal Law on Environmental Impact Assessment, which also covers certain activities with genetically modified microorganisms in contained use (risk class 3, large scale), and
- the Federal Law on Environmental Information

In April 1998 the Austrian Codex Alimentarius Commission has adoptod a guideline on criteria for labelling food as 'gene technology – free'.

The following websites of the Competent Authorities contain relevant information, including databases. It is suggested to establish links between the BCH and these sites:

http://www,.gentechnik.gv.at. This is the Website of the Austrian Federal Ministry of Social Security and Generations, which is the lead competent authority. The site includes a link to the so-called GMO-Register.

http ://www.bmwf.gv.at/4fte/gentechnik/index.htm. This is the Website of the. Austrian Federal Ministry of Education, Science and Culture which is the Competent Authority responsible for GMO-activities in academia.

http://www.ubavie,gv.at/umweltregister/genbio/intro.htm. This is the website of the Austrian Federal Envimmment Agency, which is involved in the administrative procedure concerning deliberate release and placing on the market of LMOs and is the Austrian National Focal point for the ICCP.

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BELARUS [22 February 2001]
[ORIGINAL: ENGLISH]

At the time, in Belarus there is not information on practices, rules and standards relevant to Article 18 of the Cartagena Protocol on Biosafety (under the item 4.4. Handling, transport, packaging and identification (Article 18)).

CANADA [8 May 2001]
[ORIGINAL: ENGLISH]

Executive Summary*

One of the key underlying principles of the Canadian regulatory approach to biotechnology has been to build on current legislation where possible, rather than creating new legislation to govern new products, such as living modified organisms (LMOs) and other products developed through biotechnology. Evaluations for each product are conducted on the basis of its unique characteristics and appropriate safety levels are established based on the best scientific information. There is a vast array of products being developed or imported into Canada that are subject to regulation, including LMOs.

Depending on the type of product, where it comes from and the intended use, different control measures are applied. All potentially hazardous imported organisms are controlled to reduce the risk of the introduction of pests and deseases or potential hazards to the environment and biodiversity. Examples of such controls include the use of import permits, and where appropriate, testing, quarantine or inspection. All products new to Canada, whether produced by traditional means or derived through biotechnology would be included in this category.

Article 18.1

Handling, packaging and transportation requirement under Canadian legislation are complex in part because Canadian legislation is not specific to LMOs but covers the full range of substances new to Canada, including modified and non-modified organisms, as well as organisms that are not new but are known or suspected of posing a hazard.

In those instances where an organism is known to pose a hazard, e.g. is a human or animal pathogen, there are explicit requirements for its handling, packaging and transport identified under specific legislation such as the *Transport of Dangerous Goods Act*; *the Human Pathogens Importation Act* and the *Health of Animals Act.* In addition, veterinary biologics and pest control products must be packaged and transported in accordance with the *Transport of Dangerous Good Act.*

For all other instances, the Canadian approach is to require a notification and risk assessment prior to import, manufacture or sale of the organism, including LMOs. Specific requirements for handling, packaging or transport are determined on the basis of the risk assessment and the consequent risk management decision. Requirements are thus case-specific and tailored to the characteristics of the organism. The legislation provides for the notification and the risk assessment but does not prescribe details of the risk management decision.

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* Additional materials submitted by Canada will be made available at the Meeting of Technical Experts.

Article 18.2

As noted above, the general case for Canada is that, with few exceptions, documentation requirements are identified in a risk management decision determined as a result of a risk assessment required prior to import, manufacture or use of a substance new to Canada. The requirements are not specific to LMOs, but the legislation covers LMOs and individual risk management decisions will be specific to the LMOs assessed.

There are explicit documentation requirements for those organisms, including LMOs, that fall under the *Transport of Dangerous Goods Act* including human or animal pathogens, pest control products or veterinary biologics.

There are also general documentation requirements under certain product specific Acts including the *Fertilizers, Seeds, Feeds and* ***Health of Animals Acts***.

Documentation requirements are based upon the product and the associated risks rather than the end use as defined in the Protocol, i.e. contained, intentional introduction into the environment or for food, feed or processing. Canadian regulations and/or guidelines are consistent with international standards.

The transboundary movement of products, in addition to regulatory documentation, is usually accompanied by standard commercial documentation, such as bills of lading or product specific documents for purposes of verifying product quality issued by third parties or the seller.

In addition, a limited number of organisms, including some LMOs, for use as food, feed and processing, are produced and distributed as a segregated or identity preserved product to meet specific customer requirements.

ESTONIA

[27 March 2001]
[ORIGINAL: ENGLISH]

Transboundary movements of LMOs are not regulated by Estonian legislation.

Estonian legislation that deals with LMOs is harmonised with EU directives (90/219/EEC and 90/220/EEC). Estonia is going to change its legislation according to new GMO directive before accession to EU, ie before 2003.

According to Release into the Environment of Genetically Modigfied Organisms Act (Passed in 13 January 1999) all products containing GMOs or consisting of GMOs have to be labelled as such:

20. Packaging and labelling of products

(1) Products placed on the market must 6e *packaged and labelled.*
(2) Labelling applied on packaging of products shall include ::

1) the text "This product contains genetically modified orgganism(s), or the text "This product may contain genetically modified organism(s) " in case the presence of genetically modified organisms in the product is not certain ;
2) name of the genetically modified organism contained in the product ;
3) name (company name) of the producer ;
4) properties of the product and natural conditions suitable for the product.

Seed Act (under Ministry of Agriculture) contains a provision concerning GM seeds. Genetically modified seeds and reproduction material should be labelled with letters 'GMO'.

The Government is currently preparing an Act on the contained use of genetically modified micro-organisms, in conformity with Directive 90/219/EEC, as amended by Directive 98/187/EEC. The Ministry primary responsible for the preparation of this Act is the Ministry of Social Affairs. At the moment contained use of LMOs are not regulated.

EUROPEAN COMMISSION [28 March 2001]
[ORIGINAL: ENGLISH]

EC legislation does not strictly follow the categorisation of Article 18 CPB as regards LMOs (i.e. LMO-FFPs; LMOs intended for contained use; LMOs intended for intentional introduction into the environment), but all three categorisations are covered by it. As a general remark, EC legislation is, in most of the cases, more stringent and more detailed than the provisions of Article 18 CPB.

The texts of the pieces of legislation referred to in this document (see also the footnotes) are available via htlp://europa.eu.int/eur-lex/en/.

The basis of EC legislation concerning handling, packaging and identification of genetically modified organisms is Directive 90/220/EEC' on the deliberate release into the environment of genetically modified organisms, which has been in place since October 1991. This directive has been recently revised, and will be repealed by Directive 2001/18/EC once this legislation becomes applicable (18 months after its publication in the Official Journal of the European Communities).

Directive 90/220/EEC provides the horizontal legal framework and is complemented by sectoral legislation for specific type of GMOs and GM derived products. Transport of GMOs is subject to specific legislation. It has also to be noted that handling provisions exist under Member States legislation. EC and MS legislation are also complemented by standards developed by the CEN [2]

Further legislation relevant to article 18 CPB is, in particular, the following.

- Directive 90/219/EEC3 on the contained use of Genetically Modified Micro-Organisms as amended by Directive 98/81/EC[4];

[1] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, Official Journal L 117, 08/05/1990 P. 0015-0027.
[2] Comité européen de normalisation. More information at the following address: http://www.cenorm.be
[3] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms, Official Journal L 117, 08/05/1990 P. 0001 - 0014.
[4] Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms, Official Journal L 330, 05/12/1998 P. 0013 - 0031.

- Regulation (EC) No 258/97 on.'Novel Foods[5];
- Regulations (EC) No 1139/98/.EC[6] and No 49/2000/EC[7] on labelling of food products produced from genetically modified Soybean and Maize;
- Regulation (EC) No 56/2000[8] on the labelling of GMO additives and flavourings;

- Directive 98/95/EC[9] amending Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of GM seeds;

- Directive 1999/105/EC[10] on the marketing of forest reproductive material;

- Proposal for a Council Directive amending Directive 68/193/EEC", as amended by Directive 71/140/EEC[12] , on the Marketing of material for the vegetative propagation of vine;

- Directives 94/55/EC[13] on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road and

- Directive 96/49/EC[14] on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail;

5 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, Official Journal L 043 , 14/02/1997 p. 000 1 - 0007.

6 Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, Official Journal L 159, 03/06/1998 p. 0004 - 0007.

7 Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other .than those provided for in Directive 79/112/EEC, Official Journal L 006 , 11/01/2000 p. 0013 - 0014.

8 Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms, Official Journal L 006, 11/01/2000 p. 00 15 - 0017.

9 Council Directive 98/95/EC of 14 December 1998 amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species, Official Journal L 025 , 01/02/1999 P. 0001 - 0026.

10 Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material, Official Journal L 011 , 15/01/2000 p. 0017 - 0040.

11 Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine, Official Journal L 093 , 17/04/1968 P. 0015 - 0023. The proposed Council Directive amending the above Directive (COM/2000 0059 final) is published on OJ C 177 E, 27.06.2000, P. 77-82.

12 Council Directive 71/140/EEC of 22 March 1971 amending the Directive of 9 April 1968 on the marketing of material for the vegetative propagation of the vine, Official Journal L 071, 25/03/1971 P. 0016 - 0018.

13 Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road, Official Journal L 319, 12/12/1994 P. 0007 - 0013.

14 Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail, Official Journal L 235 17/09/1996 P. 0025 - 0030.

The present document is a non-exhaustive listing of EC legislation relevant to article 18 CPB. It should not be regarded as prejudging the application of Article 18 CPB to EC legislation.

1. Directive 2001/18/EC repealing Directive 90/220/EEC on the deliberate release of GMOs into the environment

The objective of Directive 2001/18 is, in accordance with the Precautionary Principle, to approximate the laws, regulations and administrative provisions of the EU Member States and to protect human health and the environment when:

- Carrying out the deliberate release into the environment of genetically modified organisms for any other purpose than placing on the market within the Community;

- Placing on the market genetically modified organisms as or in products within the Community.

As far as Article 18 CPB is concerned, Directive 2001/18 contains specific requirements for identification.

It imposes labelling requirements on GMOs as or in products intended for the placing on the EC market. The information to be mentioned on the label, or the accompanying document, is described in general terms in Annex IV of the Directive. The words "This product contains genetically modified organisms" must appear either on a label or in an accompanying document.

There is, according to the Directive, a possibility to establish a minimum threshold below which products do not have to be labelled when adventitious or technically unavoidable traces of authorised GMOs cannot be excluded.

It also contains a requirement to ensure traceability, at all stages of the placing on the market of GMOs.

Directive 2001/18 contains detailed information required in a notification, in particular, the conditions for placing a GMO on the market, including specific conditions of use and handling.

Directive 2001/18 requires packaging of GMOs as or in products to be specified when placed on the market.

2. **Directive 90/219 on the contained use of genetically modified microorganisms**

Directive 90/219/EEC, as amended by Directive 98/81/EC, lays down common measures for the contained use of genetically modified microorganisms with a view to protecting human health and the environment.

Directive 90/219 includes a wide range of specifications on contained use of GMMs whose requirements are related to the level of risk involved. Directive 98/81, amending Directive 90/219, specifies requirements for the use of GMMs in containment facilities like glass houses, growth-rooms, animal houses, laboratories and industrial production facilities.

3. **The Novel Foods Regulation (EC) 258/97**

Foods and food ingredients, consisting of or containing GMOs, have to be labelled according to EC Regulation 258/97 (Novel Foods Regulation). Without prejudice to the other requirements of Community law, this Regulation provides that the final consumer has to be informed of

- The presence in the food or food ingredient of genetically modified organisms,

- In case the food or food ingredient is no longer equivalent to an existing food or food ingredient, an indication of the characteristics or properties modified, together with the method by which that characteristic or property was obtained.

A novel food or food ingredient shall be deemed no longer equivalent, if scientific assessment, based on appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.

4. **Regulations 1139/98 and 49/2000 on labelling of food products produced from genetically modified Soybean and Maize**

Regulation 1139/98 was introduced to ensure the labelling of foods produced from a GM soya and GM maize that were approved under Directive 90/220/EEC before the Novel Foods Regulation entered into force. The criterion for labelling is the presence of genetically modified DNA or protein.

Regulation (EC) No 49/2000 introduces a *de minimis* threshold of 1% for the adventitious presence *of* genetically modified DNA or protein from authorized GM maize and soya varieties in conventional foodstuff. Accordingly, these products do not have to be labelled if less than 1% GM material is accidentally present.

The threshold aims at solving the problem faced by operators who have tried to avoid GMOs but due to accidental contamination (during cultivation, harvest, transport or processing), still find themselves with a low percentage of GM material in their products.

5. **Regulation (EC) 50/2000 on the labelling of GMO additives and flavourings**

Additives and flavourings are subject to Regulation 50/2000, which aims at ensuring that the final consumers are informed about such ingredients if present in a product.

6. **Marketing of GM seeds - Directive 98/95/EC amending Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC.**

Directives 66/400 on the marketing of beet seed, 66/401 on the marketing of fodder plant seed, 66/402 on the marketing of cereal seed, 66/403 on the marketing of seed potatoes, 69/208 on the marketing of the seed of oil and fibre plants and 70/458 on the marketing of vegetable seed, contain provisions aimed at ensuring the identity of seeds from one generation to the other during marketing as regards packaging, sealing and marking.

The labels should give the particulars needed both for official verification and for the information to the farmer. In particular, the reference to the lot number enables the certifying authorities to identify the link to the previous generations.

Additionally, Directive 98/95 specifies that for seeds of varieties that have been genetically modified, any label or document that is affixed or accompanies a seed lot shall clearly indicate that the variety has been genetically modified (in force since February 2000).

This legislation, as regard the authorisation procedure, will only enter into force for GM seeds once a Regulation has established equivalent procedures to those of Directive 90/220/EEC. Until such a Regulation is adopted, Directive 90/220/EEC applies.

7. **Directive 1999/105 on the Marketing of forest reproductive material**

This Directive applies to the production with a view to marketing and to the marketing of forest reproductive material within the European Community. Thus it also applies to forest reproductive material that is genetically modified.

The Directive requires in order to ensure, among other things, proper identification, that seed units of forest reproductive material shall only be marketed in sealed packages. Official control systems

shall ensure that reproductive material from individual approved units or lots remains clearly identifiable through the entire process from collection to delivery to the end user.

This legislation, as regard the authorisation procedure, will only enter into force for GM forestry reproductive material once a Regulation has established equivalent procedures to those of Directive 90/220/EEC. Until such a Regulation is adopted, Directive 90/220/EEC applies.

In the case of forest reproductive material derived from basic material that consists of a genetically modified organism, any label or document, official or otherwise, for the lot shall clearly indicate that fact (in force since January 2000)

8. **Proposal for a Council Directive amending Directive 68/193 on the Marketing of material for the vegetative propagation of vine**

Directive 68/193, as amended by Directive 71/140, lays down minimum standards to be met for the marketing of material for the vegetative propagation of vine.

A current Commission proposal to amend Directive 68/193 includes requirements on the approval of GM varieties and on the marketing of GM vine propagating material that, in effect, would reflect those in the revised Directive 90/220. Including such requirements in Directive 68/193 would follow the approach taken in other areas (i.e., Directive 98/95 on seeds).

The proposal includes provisions according to which propagating material of a variety which has been genetically modified, any labelling and documentation, official and otherwise, which is affixed to or accompanies the batch of material, shall clearly indicate that the variety has been genetically modified.

9. **Directive 94/55/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road and Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail**

At Community level, Directives 94/55/EC and 96/49/EC cover the transport of genetically modified micro-organisms. As for other GMOs than genetically modified micro-organisms no specific EC-transport legislation exists.

Those Directives require that transport operations of genetically modified micro-organisms, within or between Member States, by road or by rail must be in conformity with the ADR (road-Europe) or RID (rail -Europe). The provisions of the ADR or RID for genetically modified micro-organisms are consistent with the UN Recommendations on the transport of dangerous goods (11th revised edition 1999).

The specific provisions of the above-mentioned EC directives for genetically modified micro-organisms include:

- Special provisions 219, 634 and 637;
- Packing instruction P 904 which refers to P 001 (liquids) and P 002 (solids), and IBC 08 (intermediate bulk container);
- Mixed packaging MP 6;
- Special provisions for carriage (operation, loading, unloading and handling) V1, CV1, CV13, CV26, CV27 and S17.

Article 5.1 of these directives allows Member States to have more strict rules for reasons other than safety during transport, such as reasons of national security or environmental protection.

Article 6 of these directives allows Member States to have different or less stringent rules in some cases, The Commission has not yet received from Member States, any request based in Article 6 concerning the transport of genetically modified micro-organisms.

10. **Future work**

a) Legislation on labelling and traceability

Additional identification requirements will be proposed in a new legislation on traceability and labelling of GMOs to complement existing requirements of inforination and labelling. Upcoming international discussions on the definition of detailed requirements to identify GMOs and the concept of unique identifier are relevant to the EC regulation presently under development.

b) Novel feeds

The marketing of genetically modified organisms destined for feed use is currently covered by Directive 90/220/EEC until specific legislation covering these products comes into force.

INDIA

[30 March 2001]
[ORIGINAL: ENGLISH]

As per the EPA Rules 1989, requirements for handling, transport and packaging are confined to import of GMOs for research purposes only. The requirements are declaration of the contents of the package, adequate labeling of the package and standards for packaging GMOs in a manner that the possibilities of spillage is minimised. The other requirements are that the packaging should accompany a certificate declaring the contents in the package, the testing procedure of the contents, the purpose of movement of the GMO and the details about the recipient.

NORWAY

[3 April 2001]
[ORIGINAL: ENGLISH]

Norway has no programmes *per se* for regulating LMOs. A comprehensive legislation is established for regulating the field, *inter alia* risk assessments for releasing LMOs into the environment and procedures for evaluating products before marketing. All applications for marketing new LMOs are evaluated separately; so far, 32 applications have been evaluated. The Norwegian Research Council (NFR) has several programmes for analysing different aspects of biotechnology, *inter alia*, development of new LMO-products, medical research, research on social and environmental effects from LMOs.

LMO- and biotechnology-related research receives about US$ 17 million in funding a year of which about US$ 0.25 million goes directly to evaluation of unintended dispersal of LMOs in the environment. The Norwegian Competent authorities have much experience in building legal framework for regulation and management of biotechnology in general. Norway did also have a representative in the steering group of the UNEP/GEF project on implementation of UNEP-technical guidelines for safety in biotechnology in 18 developing countries. Norway has experiences with the following areas:

- Institutional capacity-building
- Developing:

- Legislation and guidelines
- Systems for risk assessments, management and control of LMOs, import/export and release into the environment, facilitating national / international information flow and cooperation between consumers, industry and authorities.

REPUBLIC OF KOREA [19 April 2001]
[ORIGINAL: ENGLISH]

Ministry of Agriculture & Forestry Notification 2000-31

We hereby enact and notify Guidelines for Labeling of Genetically Modified Agricultural Products in accordance with the provisions of Article 26 and 27 of the Presidential Decree of the Agricultural & Fishery Product Quality Control Act as follows.

April 22, 2000
Minister of Agriculture & Forestry

Guidelines for Labeling of Genetically Modified Agricultural Products

Article 1 (Purpose) This guideline aims to establish a list of genetically modified agricultural products (hereinafter referred to as "GM agricultural product") subject to labeling and detailed labeling standards and labeling methods in accordance with the provisions of Article 26 and 27 of the Presidential Decree of Agricultural & Fishery Product Quality Control Act (hereinafter referred to as "Presidential Decree").

Article 2 (Definitions of Terminology) Definitions of terminologies used in this Guideline are as follows.

1. "Recombinant DNA" shall mean DNA artificially modified in-vitro and Recombinant Technique shall mean a technique where recombinant DNA is constructed using enzymes, etc. or a technique where recombinant DNA is introduced into a host for the purpose of replication of the donor-DNA within the host.

2. "Agricultural Product" shall mean an agricultural product that did not go through processing such as crushing, cutting, pressing, heating, etc., thereby maintaining its original form. As for bean sprouts, however, those that are cut are included.

3. "Genetically Modified Agricultural Product" shall mean agricultural products produced from organisms that were genetically modified by foreign DNA introduced by recombinant DNA techniques.

Article 3 (Commodities Subject to Labeling) In accordance with the provision 1-3 of Article 26 of the Presidential Decree, GM commodities subject to labeling are as follows;

1. Soybean
2. Corn
3. Soybean Sprout
4. Potato

Article 4 (Labeling Standards) ←In accordance with provision 3 of Article 27 of the Presidential Decree, detailed labeling standards for GM agricultural products are as follows.

1. For GM agricultural products, it shall be labeled as "Genetically Modified (a name of agricultural product)". For bean sprouts grown with genetically modified soybean, however, it shall be labeled as "Genetically Modified (Bean Sprouts Grown with Soybean)".
2. For products containing GM agricultural products, it shall be labeled as "Containing Genetically Modified (a name of agricultural product)". For products containing bean sprout grown with GM soybean, however, it shall be labeled as "Containing Genetically Modified (Bean Spouts Grown with Soybean)".
3. If there is a possibility that GM agricultural products are contained, it shall be labeled as "It may contain Genetically Modified (a name of agricultural product)". For bean sprout grown with soybeans that may contain GM soybean, however, it shall be labeled as "It may contain Genetically Modified (Bean Spouts Grown with Soybean)".

↑ Taking into consideration of the possibility for GM agricultural products getting mixed together unintentionally, even when one segregates non-GM agricultural products in the production and marketing stage, if it contains less than 3% of GM agricultural products, labeling as required by the above ←-2 and-3 shall not be required. In this case, however, certificates proving that non-GM agricultural products are segregated and controlled shall be furnished.

Article 5 (Labeling Methods) Detailed labeling for GM agricultural products under the provision 3 of Article 27 of the Presidential Decree shall be made on its package or at the point of sell, etc. in accordance with the methods described in below.

1. When it is sold after packaging
    a. In principle, it shall be directly labeled on package. It shall be labeled with fonts that final purchasers can read easily, in a place where it can be easily recognized, and in a method which can not be easily erased or detached.
    b. Font shall be in a size that purchasers can recognize easily.

2. When it is sold without packaging
    a. It shall be marked at the sales point using a notice board, a post, etc. It shall be marked with fonts that purchasers can read easily, in a place where it can be easily recognized. If it is difficult to mark at the sales point when it is not sold to final purchasers, however, it can be marked on the invoice.
    b. Font shall be in a size that purchasers can recognize easily.

Article 6 (Agency, etc. Responsible for Investigation) ←In accordance with the provision 3 of Article 32 and the provision 4 of Article 27 of the Presidential Decree, the National Agricultural Product Quality Control Service (NAPQCS) shall be responsible for investigation of labeling of GM agricultural products. During investigation, NAPQCS can collect necessary samples and conduct the verification of samples. However, NAPQCS can request the sample verification to National Agricultural Sciences and Technology (NAST) of Rural Development of Agriculture for 1 year from the implementation date.

↑ The sample verification method shall be the internationally recognized method and details on verification methods and sampling methods shall be determined by the Head of NAPQCS.

Article 7 (Other Details)
← The Head of NAPQCS can establish and implement necessary details that are need for the operation of this Guideline.

↑ A list of commodities subject to labeling under Article 3 will be expanded taking into consideration of development situations of verification technics and local distribution situations of GM agricultural products.

→ Concerning the permissible level of unintentional mixing of GM agricultural products under the provision 2 of Article 4, it will be gradually lowered down to the level of 1-percent taking into consideration of precision of the verification technics and international trends.

Addenda

← This guideline shall go into effect on March 1, 2001.
↑ Potato, a commodity that is subject to labeling in accordance with Article 3, shall be applied by this guideline from March, 2002.

Please note that this is an unofficial translation.

Korea Food and Drug Administration

Labeling Standard for Genetically Modified Foods
(Unofficial Translation)

Korea Food and Drug Administration Notification 2000-43 (2000.8.30)

Commissioner

Article 1 (Objectives)

This notification is intended to provide correct information to consumers, in accordance with the provisory clause in Article 10 Paragraph 1 of the Food Sanitation Act (hereinafter referred to as "the Act"), by defining the matters concerning the labeling of foods or food additives manufactured or processed with ingredients obtained from agricultural, livestock, or fishery products grown or raised by recombinant DNA techniques, such as combining genes of an organism with beneficial genes taken from another organisms.

Article 2 (Definitions)

Definitions of the terms used in this standard shall be as follows;

1. "Genetically Modified Foods, etc." (hereinafter referred to as "GM foods") shall mean foods or food additives manufactured or processed with agricultural, livestock or fishery products grown or raised by recombinant techniques.
2. "Raw materials" shall mean substances, excluding intentionally added purified water, used in the manufacture, processing or preparation of foods or food additives to be contained in the final food products,.
3. "Principle Display Panel" shall mean the surface of a container or a package, where it could be typically seen by consumers when purchasing foods or food additives, on which trademarks, logos, and so forth are printed.
4. "Major raw materials" shall mean five raw materials used most in the manufacture or processing of foods or food additives.

Article 3 (Foods subject to labeling requirement)

Foods or food additives (including foods or food additives imported) subject to GM labeling requirements are any of the following foods or food additives among those manufactured or processed as major raw materials, one or more of the raw materials subject to GM labeling in accordance with the provisions of the Article 16 of the Agricultural and Fisheries Products Quality Control Act and it shall contain any residual recombinant DNAs or foreign proteins in the final products after manufacture or processing. Classification of food subject to GM labeling requirements shall be in conformity with "Standards and specifications of Food" in accordance with the Provision of the Article 7 of the Act.

1. Soybean flour among processed bean products classified under the ordinary processed food category;
2. Corn flour among processed grain products classified under the ordinary processed food category;
3. Processed bean products containing bean or bean flour classified under the ordinary processed food category;
4. Processed grain products containing corn or corn flour classified under the ordinary processed food category
5. Canned soybeans among processed bean products classified under the ordinary processed food category;
6. Canned corn among processed grain products classified under the ordinary processed food category
7. Bread and rice cake products classified under the confectioneries category
8. Dried confectioneries classified under the confectioneries category
9. Bean curd (Tofu) classified under the bean curd category
10. Processed bean curd classified under the bean curd category
11. Whole bean curd classified under the bean curd category
12. Soy milk products classified under the soft drinks
13. Infant formula classified under the Foods for special dietary uses
14. Formulas for growing period classified under the Foods for special dietary uses
15. Grain formulas for infants and babies classified under the Foods for special dietary uses
16. Other formulas for infants and babies classified under the Foods for special dietary uses
17. Nutritional supplements among Foods for special dietary uses
18. Soybean pastes classified under the seasoning
19. Hot pepper bean pastes classified under the seasoning
20. Fermented soybean pastes (Chung-Guk-Jang) classified under the seasoning
21. Mixed bean pastes classified under the seasoning
22. Hard boiled foods classified under the Kimchi/pickles category
23. Meju (fermented dry soybean paste - Korean soybean *koji*) classified under the miscellaneousr food category
24. Corn starch among starches classified under the miscellaneous food category
25. Processed corn products for Popcorn classified under the miscellaneous food category
26. Other food products using soybeans, corn and bean sprouts as major raw materials
27. Other food products using the foods specified in the Clauses from 1 to 26 above as major raw materials

Article 4 (Persons responsible for labeling)

Persons responsible for GM labeling shall be the operators of those food manufacturing and processing business, instant food sales / manufacturing / processing business, food additives manufacturing business, food re-packing ub a small scale business, specialized marketing sales business, and food imports and sales business, in compliance with the provisions of Article 7 of the Enforcement Decree of the Food Sanitation Act.

Article 5 (Labeling methods)

GM labeling shall be done in the following manners;

1. The labeling of GM foods shall be indicated using a 10-point or larger types of a character with a color clearly distinguishable from the background color of the container or package with indelible inks, stamp, **brand** and so forth so that the consumers could easily recognize the label.

2. The labeling of GM foods shall be indicated on the principle display panel in a way that the consumer may easily recognize the labels of "Genetically Modified Food(s)" or "Food(s) containing Genetically Modified OO" (OO refers to the name of the raw material), or shall be indicated in parentheses besides the name of the genetically modified agricultural or fishery products used as the raw material of the food as "Genetically Modified " or "Genetically Modified OO".

Article 6 (Exceptions to labeling requirements)

In spite of the provisions in Article 5 of this standard, the following cases may be labeled or displayed as such ;

1. When operators of an instant food sales / manufacturing / processing business are selling genetically modified foods, manufactured or processed, by the operator himself and displays labeling requirements on display panels or with separate signs, individual food items may notbe labeled.
2. In case of selling Tofu (Bean Curd products) in a transportable hygienic container and GM labels are placed on the containers or on separate display panels, individual food items may not be labeled.
3. When it is impossible to label the package of a product with inks, stamp or brand due to the characteristics of a package, and when importing foods or food additives, non-detachable stickers may be used for labeling purposes.

Addenda

This notification shall go into effect on 13 July 2001.

Please note that this is an unofficial translation.

SLOVENIA [29 March 2001]
[ORIGINAL: ENGLISH]

Currently, a comprehensive draft Act on the use of Gene Technology follows provisions of the EU directives and the Protocol is under Governmental procedure. The law set out procedures for

/...

contained use, deliberate release into the environment, placing on the market and intentional transboundary movement of LMO's. On the basis of the act control over handling, transport, packaging and identification of LMO's is introduce.

SWEDEN

[27 March 2001]
[ORIGINAL: ENGLISH]

The information below is complementary to EU-submission.

In Article 18 the Cartagena Protocol on Biosafety says that Parties shall take necessary measures to avoid adverse effects on the conservation and sustainable use of biological diversity when handling, transport, packaging and identification of LMO (Living Modified Organisms), taking into consideration relevant international rules and standards.

HANDLING

Sweden has implemented the main pieces regulating the handling and use of GMOs. These are Directive 90/220/EEC on the deliberate release of GMOs in the environment, Directive 90/219/EEC on the contained use of genetically modified micro-organisms (amended through Directive 98/81/EC), Regulation (EC) 258/97 on Novel Foods and novel food ingredients and Regulation (EC) 50/2000 on the labelling of GMO additives and flavourings.

These are implemented through the Swedish Environment Code (SFS 1998:808), the Ordinance (SFS 1994:901) on genetically modified organisms, the Ordinance (SFS 2000:271) on contained use of genetically modified plants and a number of specific competent authority regulations. According to the Swedish regulatory framework a genetically modified organism must be clearly labelled, as appropriate, as such.

In any decision allowing a GMO to be deliberately released or placed on the market specific requirements or conditions as how to handle, package or identify a GMO can be added.

TRANSPORT (AND PACKAGING)

Sweden has enacted the relevant EU-directives that address transport of GMOs:

- Directive 90/220/EEC
- Directive 90/219/EEC, amended by Directive 98/81/EC
- Directive 96/49/EC (transport of dangerous goods by rail)
- Directive 94/55/EC (transport of dangerous goods by road)
- Directive 93/75/EEC (vessels bound for or leaving Community ports and carrying dangerous or polluting goods)

The basis for these Directives is the UN recommendation on transport of dangerous goods. The UN recommendation refers to LMOs in either Class 6.2 (Infectious substances) or Class 9 (environmentally hazardous substances). Class 6.2 only refers to genetically modified micro-organisms (GMMs). The EU-rules on transport on roads (ADR) and rail (RID) are more or less identical as regards GMOs.

GMOs that have been approved under Directive 90/220/EEC for deliberate releases or placing on the market are by default not regulated as regards transport unless otherwise is stated in the consent given under that Directive.

Swedish regulations

Activities involving contained use and deliberate release of GMOs are regulated in Chapter 13 of the Environmental Code, (SFS 1998:808):

> "5 § Contained use is an operation where someone genetically modify organisms or cultivate, store, use, **transport**, destroy or dispose such genetically modified organisms and where specific containment measures are used to limit the organisms contact with the general population and the environment" (unofficial translation)

Accordingly, transportation of GMOs is generally regarded as contained use. In Regulation (SFS 2000:271) on contained use of genetically modified organisms:

> "5 § Rules 7-34 §§ of this Regulation does not cover storage, cultivation, **transport**, destruction, disposal or use of genetically modified organisms released on the market consistent with
> 1. EU Directive 90/220/EEC of 23 April 1990 on deliberate release of genetically modified organisms into the environment, latest amended through Directive 97/35/EEC,
> 2. Other European community law on regulation of certain environmental risk assessment consistent to Directive 90/220/EEC, or
> 3. Swedish Regulation (1994:901) on genetically modified organisms.
>
> The exceptions in the first paragraph may not be applied if the contained use diverges from conditions in the consent for market release.
>
> 6 § Rules in 8-11 and 13-29 §§ of this Regulation does not apply to **transport** of genetically modified organisms on road, rail or inland waterway, by sea or by air." (unofficial translation)

7-34 §§ of the Regulation covers all handling, operations, consent and authorisation. For GMOs lacking consent for placing on the market the Swedish Rescue Services Agency, the Swedish Environmental Protection Agency and the Swedish Advisory Board of Gene Technology must be consulted before the competent authority decides detailed rules on transport to protect the environment.

Swedish Board of Agriculture has issued detailed rules as regards transport of GMOs:

SJVFS 1995:33 (amended by SJVFS 2000:17) on the use of genetically modified animals:

> "17 § Genetically modified animals must be **transported** in a cage, container or transport wagon ensuring the animals are not able to escape or otherwise come into contact with the environment. The cage, container or wagon must be constructed to stop unplanned opening or trespassing during transportation. The packaging must be labelled to clearly state that the content is genetically modified animals." (unofficial translation)

SJVFS 1999:124 on deliberate release of genetically modified plants:

> "9 § By **transportation** of genetically modified plants or plant material, the packaging must be designed to prevent spreading of the plants or plant material to the environment. Every unit containing genetically modified plants or plant material will be labelled to clearly state that the content is genetically modified plants. Also, the species name, the genetically modified trait, and the sender plus the receiver names and addresses clearly visible on the packaging unit." (unofficial translation)

SJVFS 1999:122 on release of genetically modified plants, Annex B, point H (unofficial translation):
> "4. Suggestion of packaging, designed to prevent unintended release of genetically modified plants during storage or under other circumstances."

SJVFS 2000:xxx (to be adopted in the very near future) on contained use of genetically modified plants: 210§ By transportation of genetically modified organisms (plants), these must be packed and labelled in such a way that on every unit it clearly states that it contains genetically modified organisms (plants). This does not apply to shorter transfer, e.g. between a greenhouse and a climate chamber."

Swedish National Chemical Inspectorate has issued detailed rules on biotechnological organisms (including GMOs), KIFS 1998:8 Chapter 13:

"Consent to release products on the market

7 § By Chapter 13, 12 § of the Environmental Code, release of a product containing or consisting of genetically modified organisms may only follow after consent has been granted.

By 20 § in the Swedish regulation (1994:901) on genetically modified organisms, notification to get such consent for products containing or consisting of genetically modified micro-organisms, nematodes, arachnids, or insects, must be sent to the Chemical Inspectorate.

/.../

8 § A notification must contain /.../ including specific handling constraints, and a suggestion for labelling that at least is consistent with Annex III in the Commission Directive 97/35/EC on adaptation /.../ Directive 90/220/EEC" (unofficial translation).

Swedish Board of Forestry has issued detailed rules of genetically modified forest trees, SKSFS 1996:1 (unofficial translation):

" 11 § By **transport** of genetically modified forest trees or parts of such forest trees, the packaging shall be designed as to avoid spill or gene spreading to the environment. /.../ shall be labelled in such manner it is evident the content is genetically modified forest trees (unofficial translation). "

Swedish Rescue Services Agency is the competent authority for implementing and enforcing the EU-directives ADR and RID. The Law (SFS 1982:821) and Regulation (SFS 1982:923) on transport of dangerous goods authorises the Swedish Rescue Services Agency to decide detailed rules. GMO is not mentioned in a special clause or paragraph. As regards maritime or air transportation of GMOs no special national rules exists, other than relevant international agreements on transport of dangerous goods.

They shall be treated as other contagious material, but in Sweden a text must be added on the consignment note: "genetically modified organisms". The Swedish Rescue Services Agency publishes regulations on dangerous goods (ADR-S; RID-S). GMO/GMM that are not infectious are classified in Class 9 (Misc.) under "Environmentally hazardous substances". Labelling is required also under Class 9.

SWITZERLAND

[9 April 2001]
[ORIGINAL: ENGLISH]

OVERVIEW

In Switzerland, several laws and practices (related ordinances) control handling, transport, packaging and identification of genetically modified organisms. The general purpose is to protect people and the environment, in particular animals and plants as well as their communities and habitats, against harmful effects or nuisances of the use of organisms (contained system or intentional introduction in the environment) or provide consumers with relevant information. The laws and ordinances shall also contribute to maintaining biological diversity as well as soil fertility (www.buwal.ch/stobobio/biotechnologie/recht_biotech.htm)

Article 18.1: Safe handling, transport, packaging and identification of living modified organisms

Article 14 of the Ordinance on the Contained Use of Organisms regulates the transport of genetically modified organisms by stating that anyone transporting genetically modified organisms must observe national and international regulations regarding labelling and packaging.

Article 18.2

(a) Living modified organisms that are intended for use as food or feed, or for processing

The Swiss Federal Law on Food Products and its related Ordinance on Food Products regulate the designation of food products. Article 22*b* of the Ordinance on Food Products regulates the genetically modified organisms used as food products or for processing. It prescribes an overall mandatory designation of genetically modified organisms used as food products or for processing. Food products, additives or substances that are genetically modified organisms or that contain or are derived from genetically modified organisms must bear the indication "made from X modified by genetic engineering " or "made from X genetically modified" (where X is the name of the genetically modified organism). Mandatory designation is not required for food products or derived food products containing less than 1% of genetically modified organisms.

The Swiss Federal Law on Agriculture ant its related Ordinance on Feed Products regulates the mandatory designation of feed products. Article 23 of the Ordinance on Feed Products regulates the identification of genetically modified organisms used as feed products. Raw materials, single feed products, additives, conservative agents that are genetically modified organisms or that contain more than 3% of genetically modified organisms must be designated as such.

(b) Living modified organisms that are destined for contained use

Rules and regulations concerning living modified organisms that are intended for contained use can be found in the Ordinance on the Contained Use of Organisms. Article 13 regulates the mandatory information by stating that anyone placing on the market potentially harmful organisms must inform the purchaser:

- of the properties of the organisms
- whether the organisms are genetically modified
- that the use of the organisms is subject to containment

(c) Living modified organisms that are intended for intentional introduction into the environment

The Law on the Protection of the Environment and the related Ordinance on the Release of Organisms into the Environment regulate the use of genetically modified organisms intended for intentional introduction into the environment. Article 29*d* of the law provides a mandatory designation for products containing genetically modified organisms. This prescription is firmed up by Article 16 of the ordinance. It stipulates that anyone placing on the market genetically modified organisms must inform the recipient about the nature of the organisms by an easily recognisable label or some other equivalent means. This information is not required for products that contain genetically modified organisms in small amounts (unavoidable despite reasonable care) or in trace amounts.

UNITED KINGDOM

[2 April 2001]
[ORIGINAL: ENGLISH]

This paper complements a submission by the European Community on its existing practices, rules and standards relevant to Article 18 of the CPB (handling, transport, packaging and identification).

Most UK legislation on the handling, transport, packaging and identification of Living Modified Organisms (LMOs) implements or enforces EC legislation. This document describes the specific provisions of this UK legislation (particularly where there are differences between the provisions of UK and EC legislation) and highlights other UK-specific practices, rules and standards.

1. LMOs for direct use for food or feed or for processing (LMO-FFPs) and LMOs destined for intentional introduction into the environment – Articles 18.2(a) and 18.2(c)

Summary

- Genetically Modified Organisms (Deliberate Release) Regulations 1992
  SI[1] 1992/3280; ISBN[2] 0 11 033152 4
  URL: http://www.hmso.gov.uk/si/si1992/Uksi_19923280_en_1.htm
- Genetically Modified Organisms (Deliberate Release) Regulations 1995
  SI 1995/304; ISBN 0 11 052433 0
  URL: http://www.hmso.gov.uk/si/si1995/Uksi_19950304_en_1.htm
- Genetically Modified Organisms (Deliberate Release) Regulations 1997
  SR 1997/1900; ISBN 0 11 064773 4
  URL: http://www.hmso.gov.uk/si/si1997/97190001.htm
- Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994
  SR[3] 1994/144
- Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 1995
  SR 1995/413
- Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations (Northern Ireland) 1997
  SI 1997/534; ISBN 0 33 792591 7
  URL: http://www.hmso.gov.uk/sr/sr1997/Nisr_19970534_en_1.htm

The above Regulations are made under the following:

- The Environmental Protection Act 1990, Part VI, and, for Northern Ireland, The Genetically Modified Organisms (NI) Order 1991
- The European Communities Act 1972 (c.68)

1 Statutory Instrument of England, Scotland or Wales (depending on the context)

2 International Standard Book Number

3 Statutory Rule of Northern Ireland

Together the Regulations implement:

- Council Directive of the European Communities 90/220/EEC on the deliberate release into the environment of genetically modified organisms [OJ[4] No L 117, 8.5.1990, p15].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1990/en_390L0220.html
- Commission of the European Communities Directive 94/15/EC adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [OJ No L 103, 22.4.1994, p20].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394L0015.html
- Commission of the European Communities Directive 97/35/EC adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [OJ No L 169, 27.6.1997, p72].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394L0015.html

and subsidiary EC legislation (Decisions):

- 91/274/EEC: Commission Decision of 21 May 1991 concerning a list of Community legislation referred to in Article 10 of Council Directive 90/220/EEC [O J No L 135, 30.5.1991, p56].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1991/en_391D0274.html
- 91/596/EEC: Council Decision of 4 November 1991 concerning the summary notification information format referred to in Article 9 of Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [O J No L 322, 23.11.1991, p1].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1991/en_391D0596.html
- 94/211/EC: Commission Decision of 15 April 1994 amending Council Decision 91/596/EEC concerning the summary notification information format referred to in Article 9 of Council Directive 90/220/EEC [O J No L 105, 26.4.1994, p26].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394D0211.html
- 92/146/EEC: Commission Decision of 11 February 1992 concerning the summary notification information format referred to in Article 12 of Council Directive 90/220/EEC [O J No L 060, 05.3.1992, p19].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1992/en_392D0146.html
- 93/584/EEC: Commission Decision of 22 October 1993 establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC [O J No L 279, 12.11.1993, p42].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1993/en_393D0584.html
- 94/730/EC: Commission Decision of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6.5 of Council Directive 90/220/EEC [O J No L 292, 12.11.1994, p31].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394D0730.html

Detail

The UK Genetically Modified Organisms (Deliberate Release) Regulations 1992 and their 1995 and 1997 amendments are relevant to the requirements of Articles 18.2(a) and Article 18.2(c) of the CPB, which specify the requirements for documentation accompanying LMO-FFPs and LMOs. These Regulations are generally in line with the requirements of the CPB, although the transport of LMOs and LMO-FFPs is not covered by the UK Regulations.

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4 Official Journal of the European Communities

The UK Government believes that all foods should be labelled so that consumers are made aware when foods contain any genetically modified material. Under the above UK Regulations, applications for consent to market LMOs and LMO-FFPs must include proposals for appropriate safe packaging and labelling of the products and specific instructions or recommendations for storage and handling of the product.

Applicants should state whether labelling is to be in the form of a label on the product or document supplied with the product. The label or document should not only state that the product is, or contains, Genetically Modified Organism (GMO), but it should also indicate the main purpose of the modification, with the major traits stated. If the product is mixed with non-GMOs, the label or document should make it clear that GMOs may be present. Applicants should supply at least summary information on the labelling of:

- the name of the product and the name of the GMOs in the product;
- the specificity of the product and the exact conditions of use including, where appropriate, the type of environment and/or the geographical areas within the Community for which the product is suited;
- the measures to be taken in the event of the escape of the organisms in the product or misuse of the product; and
- specific instructions or recommendations for storage and handling of the product.

Applicants who choose not to include some or all of this information on labelling should give substantive reasons for not doing so.

The UK Regulations also require that adequate information on identification and detection techniques is given in an application for LMO-FFPs.

Enforcement of the UK Regulations

The Secretary of State for the Environment, Transport and the Regions and the UK Central Science Laboratory (CSL) have entered into an agreement whereby CSL inspects parties importing and acquiring LMOs (including LMO-FFPs) or placing LMOs (including LMO-FFPs) on the market, in order to ensure that the above UK Regulations are enforced.

Agreement on principles for risk assessment and monitoring

In December 1998 it was agreed that, until Directive 2001/18/EC is implemented in Member States, EU competent authorities will require applicants for consent to release or market LMOs (including LMO-FFPs) to apply a more comprehensive approach for risk assessment than that required by Directive 90/220/EEC. This includes the requirement for holders of consents to submit with their applications a plan for the post-release monitoring of the LMOs concerned.

ACRE

In making decisions on releases and marketing of LMOs and LMO-FFPs (including issues on handling, transport, packaging and identification), the UK competent authorities are advised by the statutory Advisory Committee on Releases to the Environment (ACRE), established under Part VI of the Environmental Protection Act 1990. ACRE consists of a number of independent experts, each specialising in a particular discipline, such as plant ecology, toxicology, farming, entomology, and microbiology.

ACRE's main statutory role is to advise the UK competent authorities on the safety of proposed releases and marketing of LMOs and LMO-FFPs. Consent applications are evaluated critically by experts on ACRE, and only if the risks of the proposed release or marketing of a GMO are considered to be low will the Committee advise that consent may be issued. When making decisions in issuing a consent, the Ministers will also take account of safety issues raised by experts in other Government departments, the Statutory Nature Conservation Agencies, the Health and Safety Executive and the general public.

For more information, please see: http://www.environment.detr.gov.uk/acre/index.htm
(**NB:** this website address is likely to change shortly).

ACAF

The Advisory Committee on Animal Feedingstuffs (ACAF) is a non-statutory body which advises UK Ministers on the safety and use of animal feeds and feeding practices, with particular emphasis on protecting human health and with reference to new technical developments. The remit of the advisory committee includes consideration of genetically modified animal feed and its labelling.

For more information, please see:
http://www.foodstandards.gov.uk/committees/acaf/summary.htm

Future changes to the UK Regulations

The advent of Directive 2001/18/EC and Community plans for a new Regulation on the labelling and traceability of LMOs mean that these UK Regulations will be superseded by transitional provisions and new implementing legislation later in 2001. This information will be updated following these changes.

a) Novel Foods and GMO additives and flavourings

Summary

- Novel Foods and Novel Foods Ingredients Regulations 1997
  SI 1997/1335; ISBN 0 11 063723 2
  URL: http://www.hmso.gov.uk/si/si1997/97133501.htm
- Genetically Modified and Novel Foods (Labelling) (England) Regulations 2000
  SI 2000/768; ISBN 0 11 099029 3

URL: http://www.hmso.gov.uk/si/si2000/20000768.htm

- Genetically Modified and Novel Foods (Labelling) (Scotland) Regulations 2000
  SI 2000/83; ISBN 0 11 059303 0
  URL: http://www.hmso.gov.uk/legislation/scotland/ssi2000/20000083.htm
- Genetically Modified and Novel Foods (Labelling) Regulations (Northern Ireland) 2000
  SR 2000/189; ISBN 0 33 793912 8
  URL: http://www.hmso.gov.uk/sr/sr2000/20000189.htm
- Genetically Modified and Novel Foods (Labelling) (Wales) Regulations 2000
  SI 2000/1925 (W. 134); ISBN 0 11 090115 0
  URL: http://www.hmso.gov.uk/legislation/wales/wsi2000/20001925e.htm

In the UK, the above Regulations enforce the following EU Regulations:

- European Communities Novel Foods Regulation 258/97 [OJ No L 043, 14.2.1997, p1].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1997/en_397R0258.html
- Commission Regulation 1139/98 [OJ No L 159, 3.6.1998, p4] concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC as amended by Commission Regulation 49/2000 [OJ No L 006, 11.1.2000, p13].
  URLs: 1139/98: http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398R1139.html
  49/2000: http://europa.eu.int/eur-lex/en/lif/dat/2000/en_300R0049.html
- Commission Regulation 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms [OJ No L 006, 11.1.2000, p15].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/2000/en_300R0050.html

Detail

Food and food ingredients in the UK, produced, in whole, or in part, from GMOs, and additives and flavourings produced, in whole or in part, from GMOs, have to be labelled according to EC Regulations 258/97 and 1139/98, and EC Regulation 50/2000 respectively, except where neither protein nor DNA resulting from the generic modification are present. The labelling provisions of these Regulations are covered in the submission from the European Community on its existing practices, rules and standards relevant to Article 18 of the CPB.

The only extra requirement in the UK beyond the provisions of these EC Regulations is for the labelling of GM foods in catering establishments (as well as retail establishments, which are covered by the EC Regulations).

ACNFP

The Advisory Committee on Novel Foods and Processes (ACNFP) is a UK non-statutory advisory body which gives advice to Ministers on any matters relating to the manufacture of novel foods or foods produced by novel processes. ACNFP also provides the UK assessment body for all novel food and novel food process applications submitted under EC Regulation 258/97.

For more information, please see: http://www.foodstandards.gov.uk/committees/acnfp/summary.htm

b) Labelling of GM seeds

Summary

- The Beet Seeds Regulations 1993
  SI 1997/2006; ISBN 0 11 035006 5
  URL: http://www.hmso.gov.uk/si/si1993/Uksi_19932006_en_1.htm
- The Cereal Seeds Regulations 1993
  SI 1993/2005; ISBN 0 11 035005 7
  URL: http://www.hmso.gov.uk/si/si1993/Uksi_19932005_en_1.htm
- The Fodder Plant Seeds Regulations 1993
  SI 1993/2009; ISBN 0 11 035009 X
  URL: http://www.hmso.gov.uk/si/si1993/Uksi_19932009_en_1.htm
- The Oil and Fibre Plant Regulations 1993
  SI 1993/2007; ISBN 0 11 035007 3
  URL: http://www.hmso.gov.uk/si/si1993/Uksi_19932007_en_1.htm
- The Seed Potatoes Regulations 1991
  SI 1991/2206; ISBN 0 11 015206 9
  URL: http://www.hmso.gov.uk/si/si1991/Uksi_19912206_en_1.htm
- The Vegetable Seeds Regulations 1993
  SI 1993/2008; ISBN 0 11 035008 1
  URL: http://www.hmso.gov.uk/si/si1993/Uksi_19932008_en_1.htm

The above Regulations are amended in England by:

- The Beet Seeds (Amendment) (England) Regulations 2000
  SI 2000/1791; ISBN 0 11 099769 7
  URL: http://www.hmso.gov.uk/si/si2000/20001791.htm
- The Cereal Seeds (Amendment) (England) Regulations 2000
  SI 2000/1793; ISBN 0 11 099771 9
  URL: http://www.hmso.gov.uk/si/si2000/20001793.htm
- The Fodder Plant Seeds (Amendment) (England) Regulations 2000
  SI 2000/1792; ISBN 0 11 099772 7
  URL: http://www.hmso.gov.uk/si/si2000/20001792.htm
- The Oil and Fibre Plant (Amendment) (England) Regulations 2000
  SI 2000/1789; ISBN 0 11 099770 0
  URL: http://www.hmso.gov.uk/si/si2000/20001789.htm
- The Seed Potatoes (Amendment) (England) Regulations 2000
  SI 2000/1788; ISBN 0 11 099773 5
  URL: http://www.hmso.gov.uk/si/si2000/20001788.htm
- The Vegetable Seeds (Amendment) (England) Regulations 2000
  SI 2000/1790; ISBN 0 11 099768 9
  URL: http://www.hmso.gov.uk/si/si2000/20001790.htm

The original 1991 and 1993 UK Regulations are amended in Scotland by:

- The Beet Seeds (Amendment) (Scotland) Regulations 2000
  SI 2000/246; ISBN 0 11 059404 5
  URL: http://www.hmso.gov.uk/legislation/scotland/ssi2000/20000246.htm
- The Cereal Seeds (Amendment) (Scotland) Regulations 2000
  SI 2000/248; ISBN 0 11 059405 3
  URL: http://www.hmso.gov.uk/legislation/scotland/ssi2000/20000248.htm
- The Fodder Plant Seeds (Amendment) (Scotland) Regulations 2000
  SI 2000/247; ISBN 0 11 059408 8
  URL: http://www.hmso.gov.uk/legislation/scotland/ssi2000/20000247.htm
- The Oil and Fibre Plant (Amendment) (Scotland) Regulations 2000
  SI 2000/249; ISBN 0 11 059406 1
  URL: http://www.hmso.gov.uk/legislation/scotland/ssi2000/20000249.htm
- The Seed Potatoes (Amendment) (Scotland) Regulations 2000
  SI 2000/201; ISBN 0 11 059383 9
  URL: http://www.hmso.gov.uk/legislation/scotland/ssi2000/20000201.htm
- The Vegetable Seeds (Amendment) (Scotland) Regulations 2000
  SI 2000/250; ISBN 0 11 059407 X
  URL: http://www.hmso.gov.uk/legislation/scotland/ssi2000/20000250.htm

Other non-GM specific amendments also apply to the original 1991 and 1993 Regulations.

The above Regulations are made under the following:

- The Plant Varieties and Seeds Act 1964 (c.14)

- The European Communities Act 1972 (c.68)

Separate corresponding regulations apply in Northern Ireland which are made under:

- The Seeds Act (Northern Ireland) 1965

Together the Regulations implement:

- Council Directives of the European Communities 66/400/EEC [OJ No L 125, 11.7.1966, p2290], 66/401/EEC [OJ No L 125, 11.7.1966, p2298], 66/402/EEC [OJ No L 125, 11.7.1966, p2309], 66/403/EEC [OJ No L 125, 11.7.1966, p2320], 69/208/EEC [OJ No L 169, 10.7.1969, p3], 70/457/EEC [OJ No L 225, 12.10.1970, p1] and 70/458/EEC [OJ No L 225, 12.10.1970, p7] on the marketing of beet seed, fodder seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species, as amended, in respect of the consolidation of the internal market, by Council Directive 98/95/EC including provisions on genetically modified plant varieties and plant genetic plant resources [OJ No L 025, 1.2.1999, p1].

URLs:
66/400/EEC: http://europa.eu.int/eur-lex/en/lif/dat/1966/en_366L0400.html
66/401/EEC: http://europa.eu.int/eur-lex/en/lif/dat/1966/en_366L0401.html
66/402/EEC: http://europa.eu.int/eur-lex/en/lif/dat/1966/en_366L0402.html
66/403/EEC: http://europa.eu.int/eur-lex/en/lif/dat/1966/en_366L0403.html
69/208/EEC: http://europa.eu.int/eur-lex/en/lif/dat/1969/en_369L0208.html
70/457/EEC: http://europa.eu.int/eur-lex/en/lif/dat/1970/en_370L0457.html
70/458/EEC: http://europa.eu.int/eur-lex/en/lif/dat/1970/en_370L0458.html
98/95/EC: http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0095.html

and subsidiary EC legislation (Decisions):

- 95/513/EC: Commission Decision on the equivalence of seed potatoes produced in third countries [OJ No L 296, 9.12.1995 p31].
- 95/514/EC: Commission Decision on the equivalence of field inspections carried out in third countries on seed producing crops and on the equivalence of seed produced in third countries [O J No L 296, 9.12.1995, p34].
- 2000/326/EC: Commission Decision of 2 May 2000 amending Decision 95/513/EC on the equivalence of seed potatoes produced in third countries and Decision 95/514/EC on the equivalence of field inspections carried out in third countries on seed producing crops and on the equivalence of seed produced in third countries [O J No L 114, 13.5.2000, p30].

These Decisions are implemented in England by:

- General Licence 2000/1

Detail

The UK Regulations implement the labelling and identification provisions of the EC Directives and listed above. These provisions are described in the submission from the European Community on its existing practices, rules and standards relevant to Article 18 of the CPB.

General Licence 2000/1 implements the Council Decisions listed above. The General Licence, which applies to beet, cereal, fodder plant and oil and fibre seeds, requires that GM varieties be clearly labelled as such in an official certificate and in an attached or accompanying label or document.

2. LMOs destined for contained use – Article 18.2(b)

Summary

- Genetically Modified Organisms (Contained Use) Regulations 2000[5]
  SI 2000/2831; ISBN 0 71 761758 0

These Regulations are made under:

- Health and Safety at Work etc. Act 1974 (c.37); and
- European Communities Act 1972 (c.68)

The Regulations 2000 implement:

- Council Directive of the European Communities 90/219/EEC on the contained use of genetically modified micro-organisms (GMMs) [OJ No L 117, 8.5.1990, p1].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1990/en_390L0219.html
- Council Directive of the European Communities 98/81/EC [OJ No L 330, 5.12.1998, p13].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0081.html

and subsidiary EC legislation (Decisions):

- 91/448/EEC: Commission Decision of 29 July 1991 concerning the guidelines for classification referred to in Article 4 of Directive 90/219/EEC [OJ No L 239, 28.8.1991 p23].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1991/en_391D0448.html
- 96/134/EC: Commission Decision of 16 January 1996 amending Decision 91/448/EEC concerning guidelines for classification referred to in Article 4 of Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms [O J No L 31, 9.02.1996, p25].
  URL: http://europa.eu.int/eur-lex/en/lif/dat/1996/en_396D0134.html
- 2000/608/EC: Commission Decision of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified micro-organisms [O J No L 258, 12.10.2000, p43].

5 For the text of the Regulations, plus an explanation of the requirements in non legal terms refer to the Guide to the Genetically Modified Organisms (Contained Use) Regulations 2000, ISBN 0 71 761758 0, Price £13.50 obtainable from HSE Books, PO Box 1999, Sudbury, Suffolk, UK, CO10 6FS. Tel: +44 1787 881165, Fax: +44 1787 313995

URL: http://europa.eu.int/eur-lex/en/lif/dat/2000/en_300D0608.html

Certain aspects of the regulatory regime for the contained use of GMOs are provided for by:

- Environmental Protection Act 1990, Part VI (c.43),

and associated Regulations made under the Act, namely:

- Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996
  SI 1996/1106; ISBN 0 11 054587 7
  URL: http://www.hmso.gov.uk/si/si1996/Uksi_19961106_en_1.htm

This is amended by:

- Genetically Modified Organisms (Deliberate Release and Risk Assessment) Regulations 1997
  SI 1997/1900; ISBN 0 11 064773 4
  URL: http://www.hmso.gov.uk/si/si1997/97190001.htm

All of the above legislation covers Great Britain (i.e., England, Wales and Scotland). Northern Ireland has legislation which corresponds to all of the foregoing except the Genetically Modified Organisms (Contained Use) Regulations 2000; Northern Ireland equivalents to those Regulations are in preparation.

Detail

As with Directives 90/219/EEC and 98/81/EC the GMO (Contained Use) Regulations 2000 have extensive requirements for the handling of genetically modified microorganisms (GMMs) in contained use activities. These requirements are linked to the level of risk posed by the GMM concerned.

AGCM

In the UK, the Advisory Committee on Genetic Modification (ACGM) advises the Competent Authorities on safety matters (which may include the handling, packaging, transport and identification of GMMs and GMOs for contained use). The committee provides only an advisory role. ACGM consists of between 13 and 15 members including employee and employer representatives, independent scientific experts and lay members.

ACGM advises on the production of detailed technical guidance, which is published as the ACGM Compendium of Guidance.6 Topics covered include risk assessment and containment and control measures.

Future changes to the UK Regulations

Directive 2001/18/EC requires the labelling of GMMs destined for contained use and GMOs other than GMMs destined for contained use. Implementing UK Regulations introduced later in 2001 will provide for this requirement. This document will be amended accordingly in due course.

6 The Compendium is available from HSE Books (see previous footnote). There is also a copy of the Compendium on the Internet at: http://www.hse.gov.uk/hthdir/noframes/acgmcomp/acgmcomp.htm

3. Transport and packaging of living modified organisms (LMOs) – Article 18.1, Article 18.2(b) and Article 18.2(c)

a) Transport of LMOs

Summary

The following Regulations apply in England, Scotland and Wales:

- The Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996
  SI 1996/2092; ISBN 0 11 062923 X
  URL: http://www.hmso.gov.uk/si/si1996/Uksi_19962092_en_1.htm
- The Carriage of Dangerous Goods by Road Regulations 1996
  SI 1996/2095; ISBN 0 11 062926 4
  URL: http://www.hmso.gov.uk/si/si1996/Uksi_19962095_en_1.htm
- The Carriage of Dangerous Goods by Rail Regulations 1996
  SI 1996/2089; ISBN 0 11 062919 1
  URL: http://www.hmso.gov.uk/si/si1996/Uksi_19962089_en_1.htm

The above Regulations are amended by:

- The Carriage of Dangerous Goods (Amendment) Regulations 1999
  SI 1999/303; ISBN 0 11 080470 8
  URL: http://www.hmso.gov.uk/si/si1999/19990303.htm

The above Regulations are made under:

- The Health and Safety at Work etc. Act 1974 (c.37)

The following Regulations apply in Northern Ireland:

- The Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations (Northern Ireland) 1997
  SR 1997/247; ISBN 0 33 792847 9
  URL: http://www.hmso.gov.uk/sr/sr1997/Nisr_19970247_en_1.htm
- The Carriage of Dangerous Goods by Road Regulation (Northern Ireland) 1997
  SR 1997/248; ISBN 0 33 792848 7
  URL: http://www.hmso.gov.uk/sr/sr1997/Nisr_19970248_en_1.htm
- The Carriage of Dangerous Goods by Rail Regulation (Northern Ireland) 1998
  SR 1998/131; ISBN 0 33 793145 3
  URL: http://www.hmso.gov.uk/sr/sr1998/19980131.htm

The above Regulations are amended by:

- The Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles (Amendment) Regulations (Northern Ireland)1997
  SR 1997/360; ISBN 0 33 792849 5

The above Regulations are made under:

- The Health and Safety at Work (Northern Ireland) Order 1978

The Regulations implement:

- Council Directive of the European Communities 94/55/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road [OJ No L 319, 12.12.1994, p7] as amended by Commission Directive 96/86/EC [OJ No L 335, 24.12.1996] and Commission Directive 1999/47/EC [OJ No L 169, 5.7.1999, p1]
  URLs:
  95/55/EC: http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394L0055.html
  96/86/EC: http://europa.eu.int/eur-lex/en/lif/dat/1996/en_396L0086.html
- Council Directive of the European Communities 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail [OJ No L 235, 17.9.1996, p25] as amended by Commission Directive 96/87/EC [OJ No L 335, 24.12.1996, p45] and Commission Directive 1999/48/EC [OJ No L 169, 5.7.1999, p58]
  URLs:
  96/49/EC: http://europa.eu.int/eur-lex/en/lif/dat/1996/en_396L0049.html
  96/87/EC: http://europa.eu.int/eur-lex/en/lif/dat/1996/en_396L0087.html

Detail

The Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996 (and the relevant Northern Ireland Regulations) impose requirements and prohibitions in relation to the classification, packaging and labelling of dangerous goods (including GMMs but excluding GMOs) for carriage by road or on a railway.

The Carriage of Dangerous Goods by Road Regulations 1996 (and the relevant Northern Ireland Regulations) impose prohibitions on and requirements for the carriage of dangerous goods by road in any container, tank or vehicle.

The Carriage of Dangerous Goods by Rail Regulations 1996 (and the relevant Northern Ireland Regulations) impose requirements and prohibitions in relation to the carriage of dangerous goods by rail in a container, package, tank, container, tank wagon or wagon.

Together these Regulations and their amendments (where applicable) implement EC Directives 94/55/EC, 96/49/EC and their amendments. The provisions (relating to the transport of GMMs) of these UK Regulations are the same as those of the EC Directives. These provisions are described in a separate submission from the European Community on its existing practices, rules and standards relevant to Article 18 of the CPB.

b) Packaging of LMOs

Summary

- See Section **2** (LMO-FFPs).

Detail

The UK Genetically Modified Organisms (Deliberate Release) Regulations require that applications for consent to market LMOs give specific instructions for the storage of the product. The Regulations also require that applicants provide "information regarding the proposed packaging for the product and its appropriateness so as to avoid the escape of GMOs during storage or at a later stage."

4. Cross-cutting UK advisory bodies

AEBC

The Agriculture and Environment Biotechnology Commission (AEBC) was established in June 2000 to offer the UK Government independent strategic advice on biotechnology issues. The AEBC consists of experts from a wide variety of backgrounds, including academia, non-governmental organisations, industry, journalism, healthcare and consumer organisations. The Commission considers primarily the impact of developments in biotechnology (including the development of LMOs) on agriculture and the environment.

For more information, please see: http://www.aebc.gov.uk

UNITED STATES OF AMERICA [20 April 2001]
[ORIGINAL: ENGLISH]

Table of Contents

Appendices

I. Introduction

This document provides an overview of relevant regulations, policies, and practices in the United States pertaining to handling, packaging, transport, and identification of genetically engineered organisms. In the United States, new varieties of plants, animals, or microbes produced using genetic engineering are subject to extensive review by the Federal Government to ensure these products are safe for the environment and to animal and human health. In general, once a product of genetic engineering has successfully completed the Federal review process, *it is handled, transported, packaged, and identified according to the same practices, regulations and standards that apply to its conventional counterpart.*

The agencies primarily responsible for regulating the products of biotechnology in the United States are the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Products are regulated according to their intended use, with most products being regulated under more than one agency (see Appendix I: Overview of U.S. Regulation of the Products of Modern Biotechnology). Guidelines of the National Institutes of Health (NIH) apply to the handling, transport and packaging of living modified organisms used in research that is conducted at or sponsored by an institution that receives any funding from NIH for recombinant DNA research. Further, transport of certain materials may also be subject to Department of Transportation regulations.

International commercial shipments involve an average of 46 separate documents (see Appendix III: Transport Documentation). The specific documents required for any given shipment to or from the U.S. depend on U.S. regulations, the country of destination's import regulations, importer requirements, terms of sale, method of payment, and mode of transportation.

The following describes U.S. practices, rules, and standards that relate specifically to genetically engineered organisms subject to intentional transboundary movement. The sections follow the divisions of Article 18.2. Information is also included that is relevant to such organisms regardless of the process by which they were developed.

Note: "CFR" stands for Code of Federal Regulations, which are referenced in this document by title number proceeding "CFR," and the part number immediately following. Any CFR reference may be obtained at the National Archives and Records Administration web site (relevant web addresses are listed in Appendix II).

II. Importation and Interstate Movement

A. Direct Use of Living Organisms as Food or Feed, or for Processing

Prior to commercialization for direct use as food or feed, or for processing, genetically engineered organisms are evaluated by each relevant Federal agency. Only those genetically engineered organisms that comply with Federal requirements may be sold commercially as food or feed, or for processing in the United States.

Food and Drug Administration (FDA)

FDA regulates foods and feed, including those imported and those developed through genetic engineering. Genetically engineered foods (both imported and domestic) must meet the same rigorous safety standards required of all other foods. In general, as is the case in most other countries, food in the United States does not have to receive approval before it may be sold. Thus, food from genetically

engineered plants in general does not have to be approved prior to sale. However, if a food were genetically engineered to contain a food additive, it would need to receive FDA approval before it could be sold. In any case, all of the biotech food products currently on the market in the U.S. have gone through a voluntary consultation process with FDA to ensure that the products are safe for human and animal consumption. FDA recently issued a proposal that, if finalized, would require companies to provide relevant scientific information to the agency in a notification at least 120 days prior to marketing. The notification requirement would supplement the consultation process.

U.S. Department of Agriculture (USDA) - Animal and Plant Health Inspection Service (APHIS)

Under the Plant Protection Act, APHIS regulates certain articles ("regulated articles") including organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Generally, prior to commercial use, these regulated articles are evaluated by APHIS through a petition process for their potential risk to agriculture and the environment to determine whether they can be released from APHIS oversight. A table of products that have been granted nonregulated status by APHIS is available on the APHIS web site. If an APHIS determination of non-regulated status has not been granted, then the agency should be consulted. If this status is granted, handling and identification requirements for the importation of genetically engineered organisms*do not differ from the usual plant protection requirements for any commodity subject to USDA regulation.*

Requirements for documentation accompanying commodities for import vary depending on the conditions in the exporting country and the nature of the commodity. Documents required to accompany a commodity shipment typically include a phytosanitary certificate and packing list. Specific requirements may be found on the APHIS web site.

Environmental Protection Agency (EPA)
EPA does not regulate food or feed labeling, packaging, or handling. If a living modified organism (as defined in the Cartagena Protocol on Biosafety) is being imported for processing purposes and is subject to regulation under the Toxic Substances Control Act (TSCA) or the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), then EPA imposes labeling and other requirements on a case by case basis, depending on the characteristics of the specific product, in the same way that conventional chemicals are regulated. There is no general requirement for the organism to be identified as a product of genetic engineering.

EPA generally requires importers to certify on the entry document or invoice that a shipment of a product (*e.g.*, microorganism) either complies with all applicable requirements under TSCA, or that the product is not subject to TSCA (19 CFR 12, 40 CFR 707). TSCA applies to organisms in all uses not specifically excluded by the statute (i.e., TSCA does not apply to foods, drugs, cosmetics, pesticides, or tobacco). This paper refers to TSCA uses as general commercial use.

Under TSCA and FIFRA, EPA has also established a few generic requirements (e.g. 40 CFR 156) which apply to a special class of products that share common characteristics. However, before the requirements are applied to an individual product, the Agency must determine that it meets the criteria or shares those common characteristics. EPA establishes specific handling, transport, and documentation or labeling requirements (if any) on a case-by-case assessment of the characteristics of the individual product. For example, regulations in 40 CFR 157, 170, 721, 725 detail a range of various label requirements for products meeting specified criteria. However, food and feed are not subject to these requirements because neither is considered to be

a pesticide. There is no general requirement for the product to be identified as product of genetic engineering.

B. Contained Use of Living Organisms

As originally negotiated, this category was intended to refer to living modified organisms intended for early stage research and development/laboratory research. Laboratory research involving living modified organisms containing recombinant DNA is subject to the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules if the research is conducted at or sponsored by an institution that receives any funding from NIH for recombinant DNA research. APHIS must grant permission to import or move interstate a genetically engineered organism that is considered a regulated article under APHIS regulations. In addition, certain genetically engineered organisms intended for certain specific uses (e.g., pesticidal, general commercial use) are subject to EPA jurisdiction over laboratory research.

National Institutes of Health (NIH)

The NIH Guidelines for recombinant DNA research require physical and biological containment of living modified organisms that contain recombinant DNA molecules. The level of containment increases based upon the risk that release of the organism would pose for humans and the environment. The Guidelines specify container requirements when living modified organisms are removed from physical containment in the course of an experiment (e.g., plants removed from physical containment in a greenhouse) but otherwise reference the applicable shipping requirements of the Centers for Disease Control and Prevention (etiologic agents), the Department of Transportation and the U.S. Department of Agriculture. There is no general requirement for the organism to be identified as a product of genetic engineering.

USDA - Animal and Plant Health Inspection Service (APHIS)

Regulated articles

The importation of genetically engineered organisms that are considered regulated articles requires application for permission from APHIS (see Appendix V). Plants and other organisms including bacteria, nematodes, viruses, and viroids are covered. In addition, APHIS regulations in 7 CFR 340 detail the marking, identification and container requirements for the movement of regulated articles into and through the U.S after such permission has been granted. Containers must be marked with: the general nature and quantity of contents; the country and locality where the organism was collected, developed and produced; the name and address of shipper, owner, or person shipping or forwarding the organism; the name address and telephone number of the consignee; and the number of the authorizing permit. The container used must ensure the secure containment of the article, as specified in 7 CFR340.8. There is no requirement for the organism to be identified as a product of genetic engineering.

Veterinary biologics

The importation of veterinary biologics for Research and Evaluation requires permission from APHIS (see Appendix VI). Labeling and identification must conform to regulations in 9 CFR 112, which do not distinguish between genetically engineered and non-engineered materials. A copy of the import permit must accompany the shipment.

Environmental Protection Agency (EPA)

The following discussion applies to contained use for research and development for eventual use commercially or as a pesticide.

Products intended for commercial uses
As is the case for products destined for direct use, EPA generally requires importers to certify on the entry document or invoice that a shipment of a product (*e.g.*, microorganism) either complies with all applicable requirements under TSCA, or that the product is not subject to TSCA (19 CFR 12, 40 CFR 707, 725). There is no general requirement for the organism to be identified as a product of genetic engineering.

In addition, for certain living microorganisms used for contained research and development, EPA has established the following requirements. (1) If the manufacturer, importer, or processor distributes the substance beyond its employees, it must provide written notification (*e.g.*, by labeling the container) to those receiving the microbe/chemical that it may only be used for research and development. (2) If the manufacturer, importer, or processor has any reason to believe that a health risk may be associated with the organism, it must provide written notification of the health risk to all employees, as well as anyone to whom the chemical has been directly distributed, through a container labeling system; conspicuous placement of written notices where exposure may occur; or some similar system (40 CFR 720, 725).

Products intended for use as pesticides
EPA generally requires pesticides to be labeled as such in order to be sold or distributed (including imported) domestically. If a substance is intended to be used as a pesticide, EPA has established a few generic requirements (40 CFR 156) which apply to a specific class of pesticidal products that share common characteristics. However, before the requirements are applied to an individual product, the Agency must determine that it meets the criteria or shares those common characteristics. EPA establishes specific handling, transport, and documentation or labeling requirements (if any) on a case-by-case assessment of the characteristics of the individual product. Regulations in 40 CFR 157 and 170 detail a range of various label requirements for products meeting specified criteria. EPA plans soon to establish a unique part of the CFR for pesticidal substances produced by plants, including pesticides that are a product of genetic engineering. There is no general requirement for the organism to be identified as a product of genetic engineering.

In order to import pesticidal organisms, the container must either bear a label demonstrating that the organisms are being transferred between registered (licensed) establishments operated by the same producer; or comply with any requirements that EPA establishes pursuant to a submitted Notification or Experimental Use Permit (EUP). There are a few narrow exceptions to the import labeling requirements, which apply equally to both conventional pesticides and pesticides that are products of genetic engineering.

C. Living Organisms Destined for Intentional Introduction into the Environment

As with genetically engineered organisms destined for direct use, only those genetically engineered organisms that have completed the Federal process are authorized for introduction into the environment for commercial use. Field release for field testing may take place with the supervision and approval of the relevant agencies. The authorizations, packaging, and identification required depend on the type and intended use of the organism.

USDA - Animal and Plant Health Inspection Service (APHIS)

Field testing – regulated articles

APHIS allows the conditional release of genetically engineered organisms considered regulated articles under 7 CFR 340 regulations for field testing, subject to APHIS approval, oversight, and performance standards in 7 CFR 340.3 (see Appendix V). Plants and other organisms including bacteria, nematodes, viruses, and viroids are covered. The performance standards may be met by protocols designed to meet the needs of the individual circumstances. Plant material may be shipped by methods given in the container requirements in 7 CFR 340.8. Plant materials shipped may include seeds, tubers, tissue cultures, plantlets, and leaves. For most plant material, any shipping container that consists of an inner container that is a sturdy bag, box, or other such structure, surrounded by an outer container that is also a sturdy bag, box, or other such structure would be acceptable under most circumstances. Both inner container and outer container should be independently capable of preventing seed or material loss. Containers for transport should be labeled as described in section III above. No indication of genetic engineering is required.

Experimental use of veterinary biologics

Shipment of any unlicensed or experimental veterinary biological product for studies outside of a laboratory is subject to APHIS approval in 9 CFR 101-118. The approval process involves inspection of recipient facilities and a risk assessment. Once approved, the materials must be transported in a container labeled with the name or identification of material, quantity, and the indication "Experimental use only–not for sale" as per 9 CFR 103 (see Appendix VI). No indication of genetic engineering is required, and no other documents are required for the shipment.

Commercial uses

Products of genetic engineering considered regulated articles by APHIS under its 7 CFR 340 regulations are generally evaluated and granted nonregulated status prior to introduction to the environment for commercial use. A table of products that have been granted nonregulated status by APHIS is available on the APHIS web page. If this status is granted, handling and identification requirements for the importation of genetically engineered organisms *do not differ from the plant pest requirements for any commodities subject to USDA regulation.*

Although requirements for documentation accompanying shipments for import vary depending on the nature of the organism and the conditions in the exporting country, documents required to accompany a commodity shipment typically include a phytosanitary certificate and packing list. Specific requirements may be found on the APHIS web site.

Environmental Protection Agency (EPA)

Products intended for commercial uses

EPA generally requires importers to certify on the entry document or invoice that a shipment of a product (*e.g.*, microorganism) either complies with all applicable requirements under TSCA, or that the product is not subject to TSCA (19 CFR 12, 40 CFR 707, 725). In addition, the product would need to comply with any handling, packaging, and identification requirements the Agency determined were necessary to protect human health and the environment, as part of its review process for field tests or full-scale commercialization.

Products intended for use as pesticides

Field testing

In general, for all field tests, except for those of extremely small-scale, EPA establishes requirements as part of the review and approval process for an Experimental Use Permit (EUP). All pesticides shipped under an EUP must bear labeling with directions for use/restrictions, and a label that includes the following additional information: (a) a statement the organism is only for experimental use; (b) the permit number; (c) the statement that this is not for sale to any person other than a participant or coordinator of the permitted test program; (d) name of the product; (e) name and address of the permittee; (f) net contents of the package; (g) an ingredient statement; and (h) the establishment registration number. No indication of genetic engineering is required.

Commercial scale uses

EPA generally requires pesticides to be labeled as such in order to be sold or distributed (including imported) domestically. If a substance is intended to be used as a pesticide, EPA has established a few generic requirements (40 CFR 156) which apply to a specific class of pesticidal products that share common characteristics. However, before the requirements are applied to an individual product, the Agency must determine that it meets the criteria or shares those common characteristics. EPA establishes specific handling, packaging, transport, documentation, and labeling requirements (if any) on a case-by-case assessment of the characteristics of the individual product. Regulations in 40 CFR 157, 170 detail a range of various label requirements for pesticide products meeting specified criteria.

For example, in the case of *Bt* Cry IA(b) corn seed sold to seed propagators, EPA required that the bags of seed bear labels specifying that it contained *Bacillus Thuringiensis* delta endotoxin, and the genetic material necessary for its production as expressed in corn cells; the percentages of the active and inert ingredients; the EPA registration number; directions for use and caution statements; and the name and address of the producer. Documents specifying requirements for insect resistance management refugia were required to be mailed separately to growers. However, the food or feed produced from the *Bt* corn was not required to be labeled because it is not a pesticide. (Note: the safety of any potential residue in food derived from the corn was thoroughly assessed by EPA prior to registration of the pesticide. Before permitting the use of any pesticide on food, EPA conducts a risk assessment of any potential residue on food, and establishes a tolerance or exemption from the requirement for a tolerance.)

III. EXPORT REQUIREMENTS AND INTERNATIONAL ORGANIZATIONS

U.S. EXPORT REQUIREMENTS

The United States Government requires export documentation for a number of different reasons including national security, control of products in short supply, compiling export statistics, administration of export laws, protection of endangered species, and to protect U.S. export markets by ensuring product quality of specific exports. The main document required by the United States government is the Shippers Export Declaration (see Appendix III). An overview of the steps of export shipment and responsible entities are provided in Appendix IV.

USDA - Animal and Plant Health Inspection Service (APHIS)

APHIS has mandatory minimal certifications and testing that must be performed on animals destined for export, due to animal welfare considerations (see Appendix VII). Importing countries generally have additional import requirements, which are certified by veterinary practitioners accredited by APHIS. The veterinarian performs the required inspections and tests and signs the export certificate, which is endorsed by an APHIS veterinarian. If the importing

country requires the identification of the animal as a product of genetic engineering, this information may be provided on the export health certificate (see Appendix III).

Environmental Protection Agency (EPA)

Pesticides destined for export
EPA has certain labeling requirements for exported products that are registered, and different requirements for exported products that are not registered. In general, exported registered products must bear the EPA approved label, with certain modifications permitted to accommodate the requirements of the importing country. For exported products that are unregistered for use in the United States, EPA requires all pesticides intended for export to be packaged and labeled in accordance with the specification of the foreign purchaser. In addition, a pesticide must bear a label containing the following information in both English, and the other appropriate language: (1) EPA producing establishment number; (2) appropriate warning or caution statements; (3) the statement that the pesticide is "Not Registered for Use in the US;" (4) an ingredient statement; and (5) the name and address of either the producer or purchaser. There is no general requirement for the product to be identified as a product of genetic engineering. Exported food and feed are not subject to these requirements because they are not considered to be pesticides.

IMPORTING COUNTRY REQUIREMENTS

Each country has different requirements regarding the documentation that accompanies any given import shipment. Importing countries require these documents for the administration of their import laws, assessment of taxes, and protection from hazardous pests and diseases. Some of the more frequently required documents include: commercial invoice, bill of lading, phytosanitary certificate (for plants or plant products), veterinary health certificate (for animals or animal products), packing list, and certificate of origin (see Appendix III). Other import regulations that may affect a shipment are packaging and labeling requirements, and recycling laws.

IMPORTER'S REQUIREMENTS

The buyer/importer may require documents in addition to the documents required by their government. An importer may need a specific document in order to receive an import permit from their government, or to obtain financing from their financial institution. Possible documents requested include: pro forma invoice, inspection certificate for grade and condition, or a statement of processing methodology (see Appendix III)).

ADDITIONAL DOCUMENTS

Additional documents are required based on the terms of sale, method of payment, and transportation mode. Such documents can include a letter of credit, shipper's letter of instruction, certificate of insurance, dock receipt, bill of lading, and air waybill (see Appendix III).

INTERNATIONAL STANDARDS

The U.S. follows multiple international standards, practices and rules regarding the import and export of biological materials. Domestic standards for movement of certain materials are based on international standards developed by multiple organizations, under regulations such as the International Maritime Dangerous Goods Code, the International Air Transport Association Dangerous Goods Regulations, and the International Civil Aviation Organization's Technical Instructions on the Safe Transport of Dangerous Goods. The U.S. also follows the rules of the

Office International des Epizoites (OIE), an international standard setting body for animals and animal products.

Private Contract Requirements

The importing country sets practices, standards, and rules regarding the export of seeds for planting, with additional requirements provided under contract provisions. A contract for seed export may specify "FIS," meaning that International Seed Trade Federation (FIS) Rules apply. FIS provisions for packaging include quality of packaging, the gross or net weight, ability to show clear evidence of tampering, and marking or labeling for identification based on the documentation. FIS Rules also specify several documents that are to be presented prior to arrival of the seeds at their destination. FIS recognizes the Association of Official Seed Analysts (AOSA) and the International Seed Testing Association (ISTA) as standard-setting bodies. ISTA rules contain provisions for identifying and sealing of seed in containers that would show evidence of tampering. In some cases, the Organization for Economic Cooperation and Development (OECD) Seed Schemes may apply. Seeds exported under these schemes must be certified for varietal purity. Laboratories may be accredited under ISTA to perform necessary certifications and supply Seed Analysis Certificates.

Disclaimer

The above information is a general description of the applicable statutes and regulations for the treatment of genetically engineered organisms. This information is not intended to be comprehensive nor does it imply any obligation. It is intended as an aid in sharing information about the system of regulatory oversight in the United States of certain products or articles. The primary emphasis is on genetically engineered organisms. However, the United States has extensive systems that cover many types and kinds of organisms and products independent of whether they have been genetically engineered. Many of these requirements are associated with accepted international agreements.

List of Appendices

I. Overview of U.S. Regulation of the Products of Biotechnology
II. Web Sites for Further Information
III. Transportation Documentation
IV. Overview of U.S. Export Shipment Steps and Responsibilities
V. Animal and Plant Health Inspection Service Import Permit Information
VI. Animal and Plant Health Inspection Service Oversight of Veterinary Biologicals
VII. Animal and Plant Health Inspection Service Animal Export Documentation
VIII. U.S. Grain Inspection and Weighing Requirements

Appendix I: Overview of U.S. Regulation of the Products of Modern Biotechology

The U.S. Federal Government has a well-coordinated, science-based system to ensure new biotechnology products are safe for the environment and to human and animal health. Following the "Coordinated Framework for the Regulation of Products of Biotechnology" of 1986, new biotechnology products are regulated under the existing web of Federal statutory authorities and regulations. In some cases, new regulations implementing these statutes were written. Laboratory research involving living modified

organisms containing recombinant DNA is subject to the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules if the research is conducted at or sponsored by an institution that receives any funding from NIH for recombinant DNA research.

Before commercialization, all organisms (including genetically engineered organisms) must conform with standards set by state and federal marketing statutes, such as state seed certification laws, the Federal Food, Drug, and Cosmetic Act, (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Food Quality Protection Act (FQPA), the Toxic Substances Control Act (TSCA), and the Federal Plant Pest Act (which was recently subsumed under the new Plant Protection Act).

ROLES OF FEDERAL AGENCIES

U.S. DEPARTMENT OF AGRICULTURE (USDA)

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. APHIS regulations (7 CFR 340) provide procedures for obtaining a permit or for providing notification, prior to "introducing" a regulated article in the United States (see Appendix V). Regulated articles are considered to be organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. The act of introducing includes any movement into (import) or through (interstate) the United States, or release into the environment outside an area of physical containment. Thus, USDA regulates the handling, interstate movement, containment, confinement, and disposal of regulated recombinant organisms, including organisms undergoing confined experimental use or field trials, until a determination of non-regulated status has been granted. Regulated articles are reviewed to ensure that, under the proposed conditions of use, they do not present a plant pest risk.

USDA-APHIS regulations provide a petition process for the determination of non-regulated status. The petitioner must supply information such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the genetically modified organism, and field test reports. A notice is filed in the Federal Register and public comments are considered in the decision on approval of the petition. A list of nonregulated products is available at *http://www.aphis.usda.gov/biotech/not_reg.html.*

APHIS Veterinary Services inspects biologics production establishments and licenses veterinary biological substances, including animal vaccines, that are products of biotechnology (see Appendix VI).

The Grain Inspection, Packers and Stockyards Administration (GIPSA) conducts mandatory inspection of grain shipments destined for international commerce (i.e. weighing of grain, inspection according to official U.S. Standards for Grain, and testing of corn for aflatoxin; see Appendix VIII). Plants that have received all the appropriate Federal approvals, including non-regulated status, may be commingled with other varieties.

U.S. Environmental Protection Agency (EPA)

EPA ensures the safety of pesticides for humans, animals, and the environment, both chemical pesticides and those that are produced biologically. The Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs regulates the distribution, sale, use and testing of pesticidal substances produced in plants and microbes producing pesticidal substances under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Food Quality Protection Act (FQPA). EPA sets tolerance limits for substances used as pesticides on and in food and feed, or establishes an exemption from the requirement

for a tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the Toxic Substances Control Act (TSCA), EPA's TSCA Biotechnology Program regulates microorganisms intended for general commercial or industrial uses. For example, it conducts a pre-market review of "new" microorganisms intended for such uses. (EPA has defined new microbes as "intergeneric microorganisms," i.e. those microbes formed by deliberate combinations of genetic material from different taxonomic genera.) A list of product approvals and tolerance exemptions is available at *http://www.epa.gov/pesticides/biopesticides*.

U.S. Food and Drug Administration (FDA)

FDA regulates foods and feed, including those imported and those developed through genetic engineering. Genetically engineered foods (both imported and domestic) must meet the same rigorous safety standards required of all other foods. In general, as is the case in most other countries, food in the U.S. does not have to receive approval before it may be sold. Thus, food from genetically engineered plants in general does not have to be approved prior to sale. However, if a food were genetically engineered to contain a food additive, it would need to receive FDA approval before it could be sold. In general, a food additive would be a new substance in food that is significantly different in structure, function, or amount from substances commonly and safely found in food, and for which there is not general recognition by the relevant scientific expert community of its safety for such use. To date, the bioengineered foods currently on the market in the U.S. do not contain substances that are significantly different from those already in the diet and thus have not needed premarket authorization before use. Nevertheless, all of the biotech food products currently on the market in the U.S. have gone through a voluntary consultation process with FDA to ensure the products are safe for human and animal consumption. FDA recently issued a proposal that, if finalized, would require companies to provide relevant scientific information to the agency in a notification at least 120 days prior to marketing. The notification requirement would supplement the consultation process. A list of final consultations is available at *http://vm.cfsan.fda.gov/~lrd/biocon.html*.

U.S. Fish and Wildlife Service (FWS)

The FWS regulates the interstate and international transport of wildlife. Containers and packages containing any fish or wildlife must be marked conspicuously on the outside with both the name and address of the shipper and consignee. An accurate and legible list of the contents by species scientific name and number of each species and whether or not the listed species are venomous must accompany the entire shipment.

U.S. National Marine Fisheries Service (NMFS)

The NMFS, an agency of the National Oceanic and Atmospheric Administration of the U.S. Department of Commerce, regulates the interstate and international transport of living marine mammals or their parts under the authority of the Marine Mammal Protection Act, Endangered Species Act, and Fur Seal Act. Marine mammals legally held for public display do not require a permit for export to a qualified foreign facility; however, NMFS must receive notification of all transports and transfers of marine mammals held in public display facilities. All other exports and imports of marine mammals or their parts including living cells and genetic material for scientific research, enhancement, or public display require a permit issued by the NMFS.

U.S. Customs Service

The U.S. Customs Service does not handle the products of modern biotechnology differently from other living organisms. At the time of release to the importer, selective inspections are conducted as part of the

regular clearance process. Shipments of any living organism will often involve special requirements from such Federal agencies as USDA or FWS.

U.S. Department of Transportation

The U.S. Department of Transportation does not currently regulate living modified organisms differently from other living organisms.

Appendix II: Web Sites for Further Information

National Archives and Records Administration (Code of Federal Regulations)
http://www.access.gpo.gov/nara/cfr/index.html

National Institutes of Health Guidelines for Recombinant DNA Use
http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

National Oceanic and Atmospheric Administration
National Marine Fisheries Service
http://www.nmfs.noaa.gov/index1.html

Regulatory Oversight in Biotechnology: With links to responsible agencies, relevant laws, regulations and rules, final decisions, approvals and consultations, etc.
http://www.aphis.usda.gov/biotech/OECD/usregs.htm

U.S. Customs Service
http://www.customs.gov

U.S. Department of Agriculture

Agricultural Research Service
National Agricultural Library Biotechnology Information Resource
http://www.nal.usda.gov/bic/

Animal and Plant Health Inspection Service (APHIS)
http://www.aphis.usda.gov/
APHIS regulations for regulated articles
http://www.aphis.usda.gov/biotech/7cfr340.html
APHIS Veterinary Services
http://www.aphis.usda.gov/vs/

Agricultural Marketing Service
http://www.ams.usda.gov/
Agricultural Export Transportation Handbook
http://www.ams.usda.gov/tmd/export/index.htm

Foreign Agricultural Service
http://www.fas.usda.gov/

Food Safety Inspection Service
http://www.fsis.usda.gov/index.htm

Grain Inspection, Packers and Stockyards Administration (GIPSA)
http://www.usda.gov/gipsa/
GIPSA Federal Grain Inspection Service: Laws and Regulations
http://www.usda.gov/gipsa/lawsandregs/lawsregs.htm

U.S. Department of Health and Human Services
Food and Drug Administration (FDA)
http://www.fda.gov
FDA Center for Food Safety and Applied Nutrition: Biotechnology
http://www.cfsan.fda.gov/~lrd/biotechm.html

U.S. Department of Transportation
http://www.dot.gov

U.S. Environmental Protection Agency (EPA)
http://www.epa.gov
EPA Office of Pesticide Programs: Biopesticides
http://www.epa.gov/pesticides/biopesticides/

Appendix III: Transportation Documentation

http://www.ams.usda.gov/tmd/export/documentation.htm
Printout of web page (11 pages) and 17 sample documents provided.*

Appendix IV: Overview of U.S. Export Shipment Steps and Responsibilities*

http://www.ams.usda.gov/tmd/export/overview.htm
Printout of web page (6 pages) provided.

Appendix V: Animal and Plant Health Inspection Service Import Permit Information

Common Document Name	**PURPOSE OF DOCUMENT**	*Needed Information*
Import Permit or notification	Application to import genetically engineered organisms that are considered regulated articles under APHIS regulations at 7 CFR 340, generally for purposes of use in contained facilities or for contained production or field release under these regulations. (Genetically engineered organisms that do not meet the definition of a regulated article under APHIS regulations at	APHIS Permit Form 2000 requires the following types of information as specified in 340.4 (c)(2) • Responsible person's name, address, and phone number. • Names of organisms used as donor, recipient, and vectors. • Means of movement and by whom.

* For technical reasons, the materials submitted by the United States relating to appendices III and IV are reproduced at the end of the present document, following the submission of the Global Industry Coalition.

	7 CFR 340 as determined by the APHIS Administrator, or which have been granted nonregulated status under 7 CFR 340.6, do not require a notification or permit under these regulations for importation for any purpose).	• Description of the molecular biology of the system/organism (transforming genetic material, its function, and the conferred phenotype). • Country and locality where organism was collected, developed, and produced. • Quantity, schedule and number of introductions. • Location and description of intended destination, uses, and distribution. • Safeguards used to prevent escape and dissemination at each destination. • Accompanying biological material or medium. • Method of final disposition or destruction. For notifications a subset of the above types of information as specified in 340.3 (d) (2) is required. 7 CFR 340.7 describes requirements for marking and identifying containers of regulated articles to be imported. e.g.: 1. Nature and quantity of contents. 2. Country and locality where organism was collected, developed, and produced 3. Name and address of shipper, owner, or person shipping or forwarding the organism. 4. Name, address, and telephone number of consignee 5. Number of permit (or notification) authorizing the importation. Container requirements are specified in 7 CFR 340.8.

Appendix VI: Animal and Plant Health Inspection Service Oversight of Veterinary Biologicals

Common document name	Purpose of document	Sampling of information contained therein.
VS Memo 800.50	"... gives guidance on the requirements for obtaining a U.S. Veterinary Biologics Establishment License and a U.S. Veterinary Biological Product License ... provides references to applicable sections of Title 9, Code of Federal Regulations."	Categories of information required for establishment and product licenses, general procedures for their submission, and CVB actions thereon.
VS Memo 800.84	"... define[s] the contents of ... submission packages, ...containing the information and documents needed by APHIS to complete applicable licensing actions."	Specific information regarding required data needed to support licensure of veterinary biologics.
APHIS - CVB Guidance document "Risk Analysis for Veterinary Biologics"	Describes documentation required for compliance with NEPA, to ensure safety of new veterinary biologicals, and support CVB action on requests to ship and/or release experimental biologics.	Procedures for submitting assessment, characterization, management, and communication of hazard/risk related to release of new veterinary biologic in the environment.
Virus – Serum – Toxin Act	Provides statutory authority for regulation of veterinary biologics in U.S.	Regulations on all aspects of regulation of veterinary biologics.
Draft VS Memo "Guidelines Concerning Permits for Sale and Distribution" (Unpublished CVB policy document)	Provides guidelines for submission of materials in support of the issuance of permits for importation for sale and distribution of products.	Procedures and data needed concerning pre- and post- permit inspections, product testing requirements, serial sample testing requirements.
9 CFR 104	Authority for regulation of imports of veterinary biologics.	Types of import permits and requirements for each.
Summary Information Format (CVB documents in several versions depending on nature of organism)	Provide characterization of biological properties of organism and related safety information.	Known previous use and biological properties of organism(s); if applicable, method of genetic manipulation, source of parent and inserted genes/ gene segments or organisms and relevant sequences.
Individual state/country authorizations (per 9 CFR 103)9	Compliance with 9 CFR 103.3(a)	Authorization by local regulatory authorities for use/ field testing of experimental veterinary biological product.

FDA-Export Reform and Enhancement Act of 1996 (FDA-EREA)	(This is an FDA document whose authority was subsequently found to extend to veterinary biologics normally regulated by CVB)	Mandates that production of unlicensed veterinary biologicals intended for export only be permitted in licensed facilities.
VS Memo 800.94	"... provides guidance ... concerning [APHIS] implementation of the FDA-EREA ... as it applies to veterinary biological products."	Describes those provisions of FDA-EREA regulation applicable to CVB regulated products.
Additional VS Memos	Provide guidance and/or interpretation of other regulations, describe formats for submission of information or data to CVB.	General or specific information on aspects of CVB policy, formats for submissions, required tests or data, etc.
VS Notices	Describe or interpret CVB policy related to particular issues.	Public (industry) announcements of new CVB policy or policy changes.
Internal CVB documents	Establish CVB policies and maintain consistency among CVB reviewers.	May cover any aspect of CVB policy.
9 CFR Sections 101-124	Statutory requirements for regulation of veterinary biologics.	Codified regulations which address all aspects of licensure, such as specific requirements for testing of seed stocks and/or products, labeling requirements, establishment requirements, record keeping requirements. Basis for CVB policies.

Appendix VII: Animal and Plant Health Inspection Service Animal Export Documentation

Common document name	*Purpose of document*	*Types of information in document*
Export animal health certificate (for live animals)	Shows that animals are healthy and meet requirementsfor export	-consignor name and address -consignee name and address -country of export -country of import -species, age, breed, sex of animal -date of inspection -tests performed on the animal -other tests and certifications as requested by the importing country
Export animal health certificate (for embryos and semen)	Shows that embryos and/or semen come from healthy animals and meet requirements for export	-same as above -also lists sires (for semen) and/or sires and dams (for embryos) -lists seal(s) used to prevent tampering with container
Final export inspection certificate	Shows that animals were inspected and found healthy within 24 hours of export, and had feed, water and rest immediately prior to export	-consignor name and address -consignee name and address -country of export -country of import -species, age, breed and sex of animal -date of inspection

APPENDIX VIII: U.S. GRAIN INSPECTION AND WEIGHING REQUIREMENTS

General under the U.S. Grain Standards Act — Regulations

Official Inspection and
Class X or Class Y Weighing Requirements

800.15 Services.

(a) General. These regulations implement requirements for a national inspection and weighing system. This system promotes the uniform and accurate application of the official grain standards and provides inspection and weighing services required by the Act and as requested by applicants for official services. The types and kinds of services available under the Act and regulations can be obtained at all specified service points in the United States and on U.S. grain in Canadian ports.

(b) Responsibilities for complying with the official inspection, aflatoxin testing, and weighing requirements-

(1) Export grain. Exporters are responsible for (i) complying with all inspection, Class X weighing, and other certification provisions and requirements of section 5(a)(1) of the Act and the regulations applicable to export grain and (ii) having all corn, as defined in 1A810.401, exported from the United States tested for aflatoxin contamination unless the buyer and seller agree not to have the corn tested. The Service shall perform the aflatoxin testing service unless the buyer and seller agree to have the corn tested by an entity other than the Service.

(2) Intercompany barges. Operators of export elevators at export port locations are responsible for complying with Class X weighing requirements and regulations covering intercompany grain shipments received by barge.

(3) Grain in marked containers. When grain is in a container that bears an official grade designation or mark, the person who places the designation or mark on the container or the person who places the grain in a container that bears the designation or mark shall be responsible for determining that the grain has been inspected or weighed by official personnel and qualifies for the official grade designation or mark.

(4) Grain for which representations have been made. Any person who makes a representation that (i) grain has been officially inspected or weighed; or (ii) grain has been officially inspected or weighed and found to be of a particular kind, class, quality, condition, or weight; or (iii) particular facts have been established with respect to the grain by official inspection or weighing, shall be responsible for determining that the representation is true and is not in violation of the Act and regulations.

[50 FR 49668, Dec. 4, 1985, as amended at 57 FR 2439, Jan. 22, 1992]

800.16 Certification requirements for export grain.

(a) General. Official Export Grain Inspection and Weight Certificates, Official Export Grain Inspection Certificates, and Official Export Grain Weight Certificates for bulk or sacked grain shall be issued according to _800.162 for export grain loaded by an export elevator. Only these types of export certificates showing the official grade, official aflatoxin test results if required under the Act and the regulations, and/or the Class X weight of the grain shall be considered to be in compliance with inspection and weighing requirements under the Act for export grain.

(b) Promptly furnished. Export certificates shall be considered promptly furnished if they are forwarded by the shipper or the shipper's agent to the consignee not later than 10 business days after issuance.

[50 FR 49668, Dec. 4, 1985, as amended at 57 FR 2439, Jan. 22, 1992]

800.17 Special inspection and weighing requirements for sacked export grain.

(a) General. Subject to the provisions of _800.18, sacked export grain shall be (1) officially inspected on the basis of official samples obtained with an approved sampling device and operated in accordance with instructions, (2) Class X weighed or checkweighed, and (3) officially checkloaded by official personnel at

/...

the time the grain is loaded aboard the export carrier, in accordance with the provisions of paragraphs (b) and (c) of this section.

(b) Services at time of loading. When official sampling, official inspection, Class X weighing or checkweighing, and checkloading of sacked export grain loaded aboard an export carrier is performed at one location and time, official export inspection and weight certificate(s) which identify the export carrier shall be issued.

(c) Services prior to loading. When official sampling, official inspection, and Class X weighing or checkweighing of sacked export grain is performed prior to the date of loading aboard an export carrier, official ``OUT'' certificates shall be issued. An examination by official personnel for condition and checkloading of the grain shall be made as the grain is loaded aboard the export carrier. If the examination for condition and the checkloading shows that the identity or quantity of the grain has not changed or the condition of the grain has not changed beyond expected variations prescribed in the instruction, official export inspection and weight certificates shall be issued on the basis of the official ``OUT'' certificates and the checkloading. If the identity, quantity, or the condition has changed, official export inspection and weight certificates shall be issued on the basis of the most representative samples, including weight samples, obtained at the time the grain is loaded aboard the export carrier. [50 FR 49668, Dec. 4, 1985]

800.18 Waivers of the official inspection and Class X weighing requirements.

(a) General. Wavers from the official inspection and Class X weighing requirements for export grain under section 5 of the Act shall be provided in accordance with this section and the Act.

(b) Waivers-(1) 15,000 metric-ton waiver. Official inspection and Class X weighing requirements apply only to exporters and individual elevator operators who (i) exported 15,000 metric tons or more of grain during the preceding calendar year, or (ii) have exported 15,000 metric tons or more of grain during the current calendar year. Exporters and elevator operators who are granted a waiver by reason of this paragraph shall, as a condition of the waiver, keep such accounts, records, and memorandum to fully and correctly disclose all transactions concerning lots of all export grain shipments. In addition, the exporters or elevator operators shall notify the Service in writing of the intention to export grain under this waiver. In the case of lots waived under this provision, if such lots are required by contract to be inspected or weighed, or if the lots are represented by official inspection or weight certificates, then such certificates shall meet the requirements of section 5 of the Act.

(2) Grain exported for seeding purposes. Official inspection and Class X weighing requirements do not apply to grain exported for seeding purposes, provided that (i) the grain is (A) sold or consigned for sale and invoiced as seed; and (B) identified as seed for seeding purposes on the Shipper's Export Declaration; and (ii) records pertaining to these shipments are made available, upon request by the Service, for review or copying purposes.

(3) Grain shipped in bond. Official inspection and weighing requirements do not apply to grain that is shipped from a foreign country to a foreign country through the United States in bond in accordance with applicable regulations of the United States Customs Service (19 CFR part 18).

(4) Grain exported by rail or truck to Canada or Mexico. Inspection and weighing requirements do not apply to grain exported by rail or truck from the United States to Canada or Mexico.

(5) Grain not sold by grade. Official inspection requirements may be waived by the Service on a shipment-by-shipment basis for export grain not sold, offered for sale, or consigned for sale by official grade if (i) the contract and any amendments clearly show that the buyer and seller mutually agree to ship the grain without official inspection and (ii) a copy of the contract and any amendments is furnished in advance of loading, along with a completed application on a form prescribed by the Service.

(6) Service not available. Upon request, any required official inspection or Class X weighing of grain may be waived on a shipment-by-shipment basis if (i) official personnel are not and will not be available within a 24-hour period to perform needed inspection or weighing services and (ii) both the buyer and seller of the grain are made aware that the grain has not been officially inspected or Class X weighed.

(7) Emergency waiver. Upon request, the requirements for official inspection or Class X weighing may be waived whenever the Service determines (i) that an emergency exists that precludes official inspection

or Class X weighing and (ii) that granting an emergency waiver will not impair the objectives ofthe Act. To qualify for an emergency waiver, the exporter or elevator operator shall make timely application and comply with all conditions which may be required by the Service.
(Approved by the Office of Management and Budget under control number 0580-0013) [50 FR 49669, Dec. 4, 1985]

UNITED NATIONS ENVIRONMENT PROGRAMME [22 February 2001]
[ORIGINAL: ENGLISH]

USE OF THE WORLD CUSTOMS ORGANIZATIONS' "HARMONIZED COMMODITY DESCRIPTION AND CODING SYSTEM" BY MULTILATERAL ENVIRONMENTAL AGREEMENTS: A DISCUSSION PAPER FOR THE NINTH MEETING ON COORDINATION OF CONVENTION SECRETARIATS, FEBRUARY 11-12, 2001, NAIROBI, KENYA

INTRODUCTION

The WCO's Harmonized Commodity Description and Coding System, commonly referred to as the Harmonized System or HS, is an applications-based international numerical coding system for commodities. The system has been in use for some time, and now comprises more than 5000 commodity groups and 200,000 commodities. Over 98% of the merchandise in international trade is classified in terms of the HS. The system is multi-purpose, and can be used for internal taxes, trade policies, monitoring controlled goods, monitoring rules of origin, freight tariffs, transport statistics, price monitoring, quota controls, national accounts, and economic research and analysis.

The system is governed by the "International Convention on the Harmonized Commodity Description and Coding System". The European Community and about 100 other countries are Parties to the Convention, and accept to use the HS. About 67 other countries also elect to apply the HS in whole or in part. The HS Committee, comprising Convention Parties, deals with policy, classification, disputes, and amendments. Amendments to the HS come into effect 2 months after approval by the Committee, which normally meets twice a year. The hard copy version of the HS is updated every 4-6 years, with the next updates scheduled for 2002 and 2007. The WCO Enforcement Committee monitors international efforts to eradicate illegal trade.

Originally the criteria for listing commodities under the HS system was the volume and monetary value in trade, but the criteria have now been expanded to include commodities of social or environmental concern. Therefore the following MEAs, by virtue of their controls on import and export of various commodities of environmental concern, have the option of applying to WCO to use the HS to further MEA objectives: Basel Convention, Montreal Protocol, Rotterdam Convention, proposed POPs Convention, Convention on International Trade in Endangered Species, Convention on Biological Diversity's Cartagena Protocol on Biosafety, Chemical Weapons Convention, and others.

There are important benefits to MEAs of using the HS to identify controlled commodities. Trade in these commodities can be monitored more reliably, and because controlled commodities are coded according to an internationally accepted system, customs officials are better positioned to control illegal trade, a major concern for many MEAs. The system is applicable not only to commodities in their pure form, but also to products and mixtures containing those commodities.

USE OF THE HARMONIZED SYSTEM UNDER MEAS

The use of the HS to further the implementation of an MEA entails a number of considerations.

A clear need to use the system must be established by MEAs. The HS will help to identify commodities in legitimate trade for customs inspectors, but will not prevent smuggling, since entities operating outside the law will not use a legitimate coding system. Therefore a determination must be made by MEAs that control of trade will be enhanced if the HS is implemented or its current use expanded.

Use of the HS system to suit MEA needs may require the use of longer codes than the current six-digit system, and therefore be more complex, in order to accommodate for example, products containing ozone-depleting substances, products derived from CITES-listed species, or living modified organisms. A more complex system may be more costly to countries to implement nationally, and a cost analysis may be warranted. Customs officials may need further training on the use of the codes, and on how to handle and dispose of certain seized products of environmental concern. Coding to suit MEA needs may present special problems, for example for multiple commodity groupings, multiple-use commodities, and mixtures where the application is not clearly defined. Finally, if the HS is to be used, MEA Parties may need to put in place or modify national legislation to mandate implementation. There will also be a need to monitor use and compliance, periodically improve implementation procedures, and determine and evaluate the benefits.

There are two options for implementing a harmonized system. The first is to request the WCO HS Committee to approve new codes, which will give them official and legal status. A second option is to have the WCO establish an interconnection system (an indicative list of HS codes) between the MEA-controlled commodities and the HS, without the benefit of legal or official status. The interconnection system allows customs officials to, for example, relate a given unofficial HS code number to the requirement for CITES documentation as a prerequisite to import or export. In this instance, the need for an "official" HS code is secondary from a CITES perspective, to the need to alert customs officials to the requirement for CITES documentation for certain commodities.

CURRENT EFFORTS BY MEAS

What have MEAs done already, and what further action are they proposing, to incorporate the HS into their commodity control regimes? A brief overview follows.

The *Basel Convention* has been informed about appropriate HS code numbers for a number of categories of waste controlled by the convention., and is now considering having WCO establish an indicative list of codes for wastes listed in Annexes VIII and IX.

The *Montreal Protocol* has had the HS coding applied to pure ozone-depleting substances, and is considering having it applied to products and mixtures containing ODS. An informal internet discussion group has also been formed to maintain dialogue between Parties interested in further application of the HS to ozone-depleting substances. A decision taken at the last meeting of the Parties to the Protocol on options for studying various aspects of the use of the HS is discussed below in the context of a proposed cooperative approach by MEAs on the HS.

The WCO has prepared a list of HS code numbers for various chemicals listed in Annex III to the *Rotterdam Convention.* Further clarification of the coding requirements for some products and mixtures containing chemicals to be controlled under the convention is required.

Regarding the proposed convention on *persistent organic pollutants (POPs);* which will control production, import, export and use of POPs, some POPs listed in its Annexes are candidates for HS classification. Although most of the listed POPs are also listed in the Rotterdam Convention, some are not, and consideration will have to be given to applying the HS to the latter.

The WCO has allocated HS codes to chemicals listed in the schedules to the *Chemical Weapons Convention.*

The *CITES* convention has had an interconnection system established by WCO between the HS and the Appendices to the convention. That system takes the form of a non-exhaustive indicative list of HS codes for commodities (species of wild flora and fauna, and their derivatives and parts) of high-risk for CITES. The HS codes indicate that any shipment of the commodities may require CITES documentation, and local CITES regulations should be consulted. As from January 1, 2002 a number of animal species covered by CITES will be separately identified at the HS level.

Certain tuna species falling under the *International Convention on the Conservation of Atlantic Tunas (ICCAT)* will be separately identified at the HS level.

Under the *Convention on Biological Diversity*; the CBD Secretariat is exploring means to identify, handle, package and transport Living Modified Organisms (LMOs) pursuant to the *Cartagena Protocol on Biosafety.* The HS is one potential means of identifying LMOs in trade.

In addition, the 3rd Intergovernmental Forum on Chemical Safety (IFCS) has requested the Interorganization Programme for the Sound Management of Chemicals (IOMC), which comprises UNEP, FAO, OECD, WHO, ILO, UNIDO and UNCTAD, to establish a working group on illegal traffic in chemicals, and report on this issue in 2003. IOMC is chaired by the Director of UNEP Chemicals.

Possible Collaboration among MEAs

UNEP is bringing the issue of the HS and its relevance to curbing illegal trade to the attention of MEA Secretariats at this meeting because it is a common concern for many MEAs, several of which are already working cooperatively with the WCO. What does UNEP recommend that MEA secretariats undertake as future cooperative work and how will this add value to the implementation of the MEAs? Three areas for possible collaboration among MEAs are suggested.

1. A Coordinated Approach to Dealing with the WCO.

It is possible to have broader cooperation and communication among MEAs, resulting in more efficient use of MEA Secretariat resources, and more focused interaction with the WCO. UNEP is willing to assume a facilitation role to bring together the individual efforts of MEAs on the HS and work with the WCO to achieve these efficiencies. UNEP recognizes that it can be argued that since MEAs generally deal with vastly different suites of commodities and chemicals, that there is little benefit from a coordinated approach to dealing with the WCO. UNEP is not convinced by this argument.

UNEP's Division of Environmental Conventions has already secured the agreement of seven international protocols and conventions (Basel, Montreal Protocol, PIC, POPs, CITES, CBD, Cartagena Convention) to explore further the potential of the harmonized system of customs codes. UNEP Chemicals is promoting sharing HS experiences among the chemicals-related MEAs.

2. A Workshop and Focussed Studies

UNEP recommends that a workshop be convened in 2001 to fulfil its commitment to conventions to further explore the HS system. The purpose of the workshop would be to identify those aspects of the use of the HS system by MEAs that warrant further study, and determine how best to address them. This could include requirements and procedures for working with WCO (e.g. MOUs), making joint submissions to WCO on coding needs, problems associated with coding products and mixtures, establishing an HS web site for MEAs to maintain dialogue and share experiences, and a common approach to promoting and evaluating the use of and compliance with the HS. Workshop participants may also wish to include in their deliberations those aspects of the use of the HS that the 12th Meeting of the Parties to the Montreal Protocol mandated the Ozone Secretariat to examine and report on, specifically options for studying:

current national legislation on labeling products and mixtures;

the need for, scope and cost of a comprehensive system that would include producer identifiers;

methods for sharing experiences among Parties on classification, labeling, compliance, and incidents of illegal trade;

the differences between products and mixtures, and the possibility of categorizing products and classifying them using the HS, and

guidance to customs authorities on how to proceed with seized, illegally traded ozone depleting substances.

The results of the workshop will benefit MEAs by providing a clearer understanding of the issues around and consequences of using the HS. MEAs will determine those aspects of the HS that warrant further study, including opportunities for cost sharing of studies, and lay the groundwork for the studies. MEAs may also decide that certain aspects of the HS are best approached unilaterally.

3. *Development of Training Programs*

UNEP is prepared to explore the possibility of developing a manual for customs officials on the use of HS codes relevant to MEAs. Such a manual could be used by countries to train their customs officials on the use of the HS. UNEP will also consider developing appropriate training programs for use at the national level and convening workshops on the use of the manual, i.e. "train the trainers".

GLOBAL INDUSTRY COALITION (GIC) [26 April 2001]
[ORIGINAL : ENGLISH]

EXISTING PRACTICES, RULES AND STANDARDS RELEVANT TO ARTICLE 18.2(a) OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Introduction

Article 18.2(a) requires transboundary shipments of LMOs intended for direct use as food or feed, or for processing (LMO FFPs) to be accompanied by documentation containing the following information: (1) clear identification that the shipment "may contain" LMOs; (2) a statement that the LMOs are not intended for intentional release into the environment (and, therefore, are not a threat to biological diversity); and (3) a contact point for further information.

There are no existing rules and standards for the documentary information described in Article 18.2(a) established at either the national or inter-governmental level. Nor, as far as we are aware, is such documentary information currently provided as a matter of normal commercial practice.

Commercial Documents

Attached as Annex A is a representative list of the documentation that accompanies international shipments of bulk commodities, whether they contain LMOs or not. For the majority of international shipments of bulk commodities, the commercial trade does not distinguish between those that may contain LMO FFPs and those that do not. Therefore, there is no indication on accompanying documentation that the shipment "may contain" LMO FFPs.

Most international sales of bulk commodities are made under standardized commercial contracts. In fact, certain trade organizations have created contract forms that contain many standardized items widely accepted in trade. For example, the North American Export Grain Association (NAEGA) has a four page, widely used contract for standard FOB (free on board) purchases of bulk grain and oilseeds called the "NAEGA Standard Contract No. 2" (see Annex B). It has 26 separate clauses delineating the various aspects of a grain purchase. Other forms have been developed, such as the Grain and Feed Trade Association of London (GAFTA) contract for C&F (cost and freight) and CIF (cost, insurance and freight) grain transactions, and the FOSFA standardized contract for CIF and C&F sales of soybeans.

The principal exception to the general practice concerns shipments of products under identity preservation (IP) systems. Examples of IP systems currently in use include certified seed, high erucic acid rapeseed, waxy corn (for starch production), flint corn (for cereal production), white corn (for tortilla and corn chip production), and soybeans for food use. All IP systems are regulated commercially rather than being controlled through government standards. The documentation accompanying products shipped under IP systems may contain greater detail about some characteristics of the product than the documentation accompanying a bulk commodity shipment. Furthermore, IP systems allow for some adventitious presence of products that differ from the specified characteristics of the IP product may also be present.

Mandatory Labeling Regulations

A number of countries have established, or are in the process of establishing, mandatory labeling requirements for food products developed through biotechnology. Article 18.2(a) is not designed to be

consistent with the labeling of food products; such labeling would differ greatly in content to documentation accompanying bulk commodity shipments.

- Most national labeling regulations apply to food products at the retail level; the indication of biotech food content appears on the food package label. Most national labeling regulations are significantly different, based on the country, and do not apply to bulk commodities. In fact, bulk commodity shipments are not packaged and do not have labels.

- The trigger for food labeling is usually the presence of specific DNA or protein. Therefore, the scope of labeling regulations is broader than just the LMOs that fall within the scope of the Cartagena Protocol.

- Most regulations have a threshold for biotech presence, below which labeling is not required. Article 18.2(a) has no threshold. A shipment containing any LMOs would have to comply with the documentation requirements in Article 18.

- To comply with labeling requirements, the biotech content of foods must be determined through testing. However, testing is not practical as a means of determining the adventitious presence of LMOs in bulk commodity shipments, as it is too costly and unreliable. More importantly, full implementation of the "may contain" provision does not require testing.

Specific Identification

Specific identification of the LMOs in a shipment is not required under the Protocol, would require extensive testing and control systems, and would bring no benefit to biological diversity. Testing can be used to identify the presence or absence of LMOs in general, or of specific LMOs. Control systems can involve various degrees of process control systems, including audits, documentation requirements, or markers.

Three types of tests are currently in use: one nucleic acid based technique (PCR) and two immunochemical approaches (ELISA and lateral flow strip). All three methods require appropriate, statistically valid sampling methodology to estimate the presence of LMOs in a lot of the product being tested. Neither the DNA nor the protein-based methods are able to definitively establish that a lot is LMO-free. Furthermore, the DNA and ELISA methods are not able to provide a reliable quantitative estimate of the quantity of LMOs in a lot because both methods only measure a specific nucleic acid or protein, the quantity of which is not easily related to the percentage of LMO in the lot. As the target threshold level of LMO material in a commodity shipment decreases, the cost of testing to that threshold increases. Costs and time requirements vary considerably among the three methods. An important factor to note is that no one test is available to detect the presence of each biotech event that may be present in a lot. This reality would make the testing of bulk shipments prohibitively costly and time consuming.

The objective of the bulk commodity system is to move large quantities of a homogenous product quickly and efficiently. Testing is used at various stages of the marketing chain to determine and control for grades and other readily-determined quality characteristics (e.g., moisture content or fungal contamination), all of which are subject to specified tolerance levels. Current tests for quality characteristics of bulk shipments employ standardized techniques and equipment that can provide reasonably accurate and consistent results in a timely and cost-effective fashion. However, testing to identify the presence or absence of LMOs is not routinely done for bulk shipments because of the limitations related to accuracy, cost and timeliness previously mentioned.

The obstacles to use of wide scale testing for LMOs in the bulk commodity system are numerous and substantial. Perhaps the most important consideration to the use of testing for bulk commodity shipments is the issue of a "zero tolerance" (i.e., no minimum threshold) for some LMOs -- the presence of which may result from adventitious commingling, false positives or other considerations. Tests can provide information about the contents of a lot at that point in time, but the tests are limited by sampling and testing error and can not be used as a tool to achieve a desired outcome. Any commingling that occurs before the test cannot be undone. Similarly, within a bulk commodity system commingling cannot be prevented after the test is performed to ensure the tested level of purity is maintained. It is also important to recognize that testing is subject to sampling and laboratory error and only provides an estimate of the quality and contents of a bulk shipment.

Annex A

Current data requirement of Transport Documents

The current transportation process typically requires more than 10 transport documents and over 200 data elements to complete a cross border transport process; e.g.

Documents	***Information Provided***
• Bills of lading	• who is the shipper and the receiver of the goods…
• Multi-modal Bills of Lading	• what specification the goods conform to…
• Marine Bills of Lading*	• where the goods originate…
• Air Waybills	• what are the goods insured for, who can claim for damage…
• Sea Waybills	• what the price is…
• Road, Rail and Waterways Waybills	• what are the terms of the sale…

It can require a great deal of time and effort to assemble, process and exchange the information, which represents a heavy burden for companies involved in international trade, and this exercise leads to the potential for errors and delays through copying and re-keying of data.

We have identified an initial set of data requirements for a full cross border transportation process using various modes of transport, which is set out in points 3.1, 3.2, 3.3, 3.4.

Data required for the full life cycle of transportation process using AIR TRANSPORT

We have identified that **Air *Waybill*** documents include the following data:

Air Waybill	the document issued by the carrier that serves for air transport
Name and address of carrier	*a* person who performs or holds himself out to perform, in whole or in part, the carriage of merchandise. This includes any representatives or agents of the carrier
Unique and verifiable reference number	a unique code that identifies the transport document

Name and address of the shipper/ consignor	the person who contracts with the carrier and who owns, or represents the owner of, the goods to be sent
Name and address of the consignee	The person or party named on the transport document that is to receive the goods at the point of delivery
Name of the issuing carrier's agent and location	an identification, name and address of the entity representing the carrier
Name and address of notify party	name and address of a party to be notified by the carrier of the arrival of a shipment
Airport of departure	name and location of the air terminal from which goods are sent
Airport of destination	name and location of the air terminal where goods are collected
Flight routing	flight details including flight numbers and date
Currency of declared value	a published value of the currency of the transaction
Name and details of insurer	name and address of the insurance agent
Amount of insurance	sum or price of insurance coverage
Handling information	any special handling information
Number of packages	specification of the quantity of parcels within which the goods are contained
Gross weight	total weight of the package
Brief description of goods	list of the details and condition of the goods when received by the carrier
Freight charges	a list of the freight charges for the transportation of goods
Amount of freight prepaid and/or collect and currency conversion rates	sum paid in advance for the transportation service and payment details.
Signature of shipper or agent	written endorsement of the person or party that contracts
Signature of issuing carrier or agent, date and place executed	written endorsement and details of the agreement by the person is in charge of the transportation of goods
Details of the transfer of title	place, time and requirements related to the transfer of title

Data required for the full life cycle of transportation process using OCEAN/MARITIME TRANSPORT

We have identified that ***Marine/Ocean Bill of Lading and Sea Waybills*** documents include the following data:

Marine/Ocean Bill of Lading and Sea Waybills	the document issued by the carrier that serves as transport document for ocean/marine transportation
The number of originals of the document	the number of originals of the transport document, if more than one
Name and address of carrier/or agent	a person who performs or holds himself out to perform, in whole or in part, the carriage of merchandise. This includes any representatives or agent of the carrier
Unique and verifiable reference number	a unique code that identifies the transport document
Name and address of the shipper/ consignor	the person who contracts with the carrier and who owns or represents the owner of the goods to be sent

Name and address of the consignee	the person or party named on the transport document that is to receive the goods at the point of delivery
Name of the issuing carrier's agent and location	an identification, name and address of the entity representing the carrier
Name and address of notify party	name and address of a party to be notified by the carrier of the arrival of a shipment
Name of the carrying vessel	vessel name
Place of receipt of goods	the location where the merchandise is picked-up.
Place of delivery of goods	the place which is the point of destination of the goods
Port of loading	name and location of the port where goods are taken in charge by the carrier
Port of discharge	name and location of the port where goods are discharged after shipment
Marks and numbers identifying the goods	identification numbers and codes found on the packages
Number and kind of packages; if shipped by container, the container number must be identified	specification of the quantity of packs or parcels that contain the goods
Name and details of insurer	name and address of the insurance agent or guarantor
Amount of insurance	sum or price of insurance coverage
Declared value of goods for customs	charges assessed by the customs authorities on cross-border sales/purchase of goods
Currency of declared value	a published value of the currency of the transaction
Gross weight and measurements	weight and dimensions of packages
Brief description of goods	list of the details and condition of the goods when received by carrier
Freight charges	a list of the freight charges for the transportation of goods
Amount of freight prepaid and/or collect	sum paid in advance for the transportation service and payment details.
Signature of issuing carrier or agent, date and place executed	writing endorsement and details of the agreement by the person who is in charge of the transportation of goods
Date received on board	date the merchandise is loaded on the vessel
Details of the transfer of title	place, time and requirements related to the transfer of title

Data required for the full life cycle of transportation process using for RAIL/ROAD TRANSPORT

We have identified that ***Road/Rail Waybills*** documents include the following data:

Road/Rail Waybills	the document issued by the carrier that serves as road /rail transport document
Name and address of carrier	a person who performs or holds himself out to perform, in whole or in part, the carriage of merchandise. This includes any representatives or agents of the carrier
Unique and verifiable reference number	a unique code that identifies the transport document
Name and address of the shipper/consignor	the person who contracts with the carrier and who owns or represents the owner of the goods to be sent

Name and address of the consignee	the person or party named on the transport document that is to receive the goods at the point of delivery
Name of the issuing carrier's agent and location	an identification, name and address of the entity representing the carrier
Name and address of notify party	name and address of a party to be notified by the carrier of the arrival of a shipment
Place of departure and date of taking over the goods	name and location of collection place
Place of destination	name and location of delivery place
Marks and numbers identifying the goods	identification numbers and codes found in the packages
Number of packages	number of parcels/packs that handle the goods
Gross weight	total weight of the goods or their quantity otherwise expressed
Railway wagon/trailer number	numerical identification or code on the rail wagon or trailer
Brief description of goods	list of the details and condition of the goods when received by carrier
Name and details of insurer	name and address of the insurance agent
Amount of insurance	sum or price of insurance coverage
Administrative data for customs	a list of information required by customs and other administrative authorities.
Reception stamp	date when the goods have been taken in charge by the carrier
Freight charges	list of the freight charges for the carriage of goods
Amount of freight prepaid and/or collect	sum paid in advance for the transportation service and payment details.
Signature of issuing carrier or agent, place and date of issue	writing endorsement and details of the agreement by the person is in charge of the transportation of goods
Details of the transfer of title	place, time and requirements related to the transfer of title

Existing International Law Covering Transport Documentation

Montreal Protocol No. 4- Air Transport

Hague-Visby Rules and the Hamburg Rules-Bill of Lading in international maritime, sea, ocean transport

Convention on the Contract for the International Carriage of Goods by Road

* *Note by the Secretariat.* For technical reasons, the materials that follow this part of annex A are reproduced at the end of the rest of the GIC submission (following page 71 below).

EXISTING PRACTICES, RULES AND STANDARDS RELEVANT TO ARTICLE 18.2(b) OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Introduction

Article 18.2(b) of the Cartagena Protocol *on* Biosafety (the "Protocol") requires documentation for living modified organisms (LMOs) destined for contained use which: (1) identifies them as LMOs; (2) specifies any requirements for their safe handling, storage, transport and use; and (3) lists the contact point for ftirther information.

The transboundary movement of LMOs destined for contained use is currently well-regulated through internationally-accepted processes that fulfill the requirements under Article 18.2(b) of the Protocol. For instance, the United Nations Recommendations on the Transport of Dangerous Goods (known as the "Orange Book"), perhaps the most widely-recognized reference on this subject, requires that LMOs be clearly identified. Various international industry and government modal transport organizations and agreements use these recommendations to set guidelines on packaging, handling, and transport procedures for their member countries. In addition, standard shipping documentation provides the requisite contact information.

As the level of potential risk associated with the LMO increases, the requirements for packaging and transport become more stringent. These established and transparent procedures allow for the movement of LMOs for contained use to be predictable, facilitating the thousands of exchanges (or movements) of LMOs for contained use that take place each year. This trade is crucial to research efforts underway in the field of biotechnology to improve crop varieties, develop new medicines, and protect biodiversity.

International Norms and Reeulations

Several international bodies provide definitions of biological materials and/or organisms based on risk or hazard levels, and recommendations on standards for the transport of these materials, including those that are considered LMOs for the purposes of the Protocol. These guidelines are broadly accepted, and help determine how LMOs destined for contained use should be categorized for purposes of transboundary movement. These bodies include:

- The United Nations Committee of Experts on the Transport of Dangerous Goods: Under the auspices of this committee, the Orange Book provides recommended classification, package testing, and marking standards for the transport of dangerous goods. It contains in an Annex a set of Model Regulations on the Transport of Dangerous Goods. It is updated and amended based on regular discussions of the Committee and Subcommiitees of Experts.
- The World Health Organization (WHO): The WHO defines biological materials in terms of four 'Risk Groups.'LMOs destined for contained use are likely to fall in one of the two lower-risk groups.[1]
- The World Organization for Animal Health (Office International des Epizooties,OIE) Falling under the UN umbrella, OIE provides more specific guidelines for the movement of animal organisms.
- The International Plant Protection Convention (IPPC) sets guidelines and regulates phytosanitary certification at the global level, as described in the accompanying paper on existing standards relevant to Article 18.2(c).

The recommendations and definitions provided by the organizations listed above form the basis for dangerous goods transport programs in countries and through international agencies responsible for setting guidelines on various modes of transport. These bodies include the Universal Postal Union (UPU), the International Maritime Organization (IMO), the International Civilian Aviation Organization (ICAO), and the International Air Transport Association (IATA). The Orange Book becomes binding on countries either through adoption as national laws and regulations, or through country membership in certain modal unions and organizations. Testing is conducted in certain situations to ensure compliance with these regulations.

Categorization of LMOs for Purposes of Transboundary Movement

All LMOs which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction are covered under UN Dangerous Goods Class 9 (Miscellaneous Dangerous Goods and Substances) and are assigned a UN Serial Number specific to LMOs (UN Number 3245). Shipments of such LMOs must include the corresponding Class 9 label and UN number for identification. In these cases, specific procedures for safe handling, labeling, and identification must be followed according to the guidelines set out by the relevant modal transportation scheme. A Shipper's Declaration of Dangerous Goods must also be completed.

If the LMOs meeting the definition above are also infectious,[2] they are subject to even more stringent regulation for transboundary movement. They must be classified in UN Dangerous Goods Class 6, Division 6.2 (Infectious Substances) and assigned UN Serial Number 2814 (for infectious substances potentially affecting humans) or 2900 (for infectious substances potentially affecting animals). It is worth pointing out that this categorization would be required for only a small portion of the LMOs destined for contained use.
A more complete explanation of the provisions and classification schemes contained in the Orange Book, including the Model Regulations themselves, is available on-line at : http://www.unece.org/trans/main/dgdemo/contents.htm.

In addition, a list of the 22 expert and 17 observer countries on the UN Committee of Experts on the Transport of Dangerous Goods is posted on the Internet at : http://www.unece.org/trans/main/dgdb/comite.html.

Conclusion

There are numerous well-defined proceures governing the transboundary movement of LMOs destined for contained use. The guidelines set forth by the UN and its affiliated bodies, and incorporated into national laws and guidlines of organizations like the UPU, IMO, ICAO, and IATA, have laid a foundation for international transport norms. Many UN member countries are members of the agreementst discussed above. Therefore, they have had exposure to and involvement in the development of handling, transport, and documentation processes designed to protect the environment and animal and plant health, while not unnecessarily impeding the movement of such goods. As the orange Book explains, this is the goal of having harmonized standards where possible : to promote the uniform development of national and international regulations governing the various modes of transport, while retaining enough flexibility to accommodate special requirements of various countries and modal agencies. These principles illustrate the extent of existing international standards, which meet the requirements under Article 18.2(b) of the Protocol.

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[1] Risk Group 1 is for microorganisms which are unlikely to cause human or animal disease, i.e., no, or very low, individual or community risk. Microorganisms falling into Risk Group I are not classified as infectious substances.

Risk Group 2 is for pathogens that can cause human or animal disease but are unlikely to be a serious hazard and, while capable of causing serious infection on exposure, there are effective treatments and preventive measures available and the risk of spread of infection is limited (i.e., moderate individual risk and low community risk).

[2] According to the UN Recommendations on the Transport of Dangerous Goods, an infectious substance is defined as "a substance containing a viable microorganism, such as a bacterium, virus, rickettsia, parasite, or fungus that is known or reasonable believed to cause disease in humans or animals. Infectious substances include:

1) all cultures containing or suspected of containing an agent which may cause infection;
2) human or animal samples that contain such an agent in quantities sufficient to cause infection, should an exposure to them occur due to a transport mishap;
3) sample(s) from a patient with a serious disease of unknown cause
4) other specimens not included above and designated as infectious by a qualified person, e.g. physicia, scientist, nurse, etc.

EXISTING PRACTICES, RULES AND STANDARDS RELEVANT TO ARTICLE 18.2(c) OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Introduction

Article 18.2(c) of the Cartagena Protocol on Biosafety (the "Protocol") requires transboundary shipments of LMOs intended for intentional introduction into the environment to be accompanied by documentation that clearly identifies them as LMOs and includes the following information: (1) the identity and relevant traits and/or characteristics; (2) any requirements for the safe handling, storage, transport and use; (3) the contact point for information and, as appropriate, the name and address of the importer and exporter; and (4) a declaration that the movement is in conformity with the requirements of the Protocol.

Existing standards and regulations guide the movement of seeds and satisfy the bulk of informational requirements referenced above. In this paper, the Global Industry Coalition provides a brief background on the world seed trade and an overview of existing practices and standards throughout the seed marketing process.

Overview of the International Seed Trade

The total value of seeds used worldwide is approximately $50 billion (USD). Of this $50 billion, more than $30 billion results from commercial transactions, of which almost $4 billion is comprised from the international seed trade. As reflected in the following table, the international seed trade has increased four-fold during the last 30 years, with much of that growth taking place from 1985 to the present.

Year	1970	1977	1980	1985	1994	1996	1998	2000
Int'l trade ($ million)	860	1,076	1,200	1,300	2,900	3,300	3,600	3,800
Comparative increase (1970 basis of 100)	100	125	140	151	337	383	418	442

The sale of seed of a plant variety to a farmer is the final step in a long scientific and industrial process, from the original cross in a greenhouse or the gene transfer made by a breeder to the final sale made by a seed distributor. The industry is very diversified and the market is divided among companies located throughout the world. It is comprised of, for example, vegetable, forage, flower, and field seed. The process of developing a new variety for marketing involves numerous steps, including quality assurance practices and regulatory oversight.

Standards and procedures are typically set at the national level, but are often coordinated by international agreements. The two primary systems of regulation are a certification scheme that pertains to phytosanitary requirements of importing countries and to the Organization for Economic Cooperation and Development (OECD) Seed Schemes. International trade in seed generally involves the exporter ensuring that each shipment of seed meets the phytosanitary requirements of the importing country. A number of international bodies regulate the genetic purity and ensure phytosanitary requirements are met. Testing may be performed by governmental authorities, accredited seed certification agencies, the developer of the variety, or by more than one of these groups. The groups

/...

and treaties involved, as discussed in detail below, include the Sanitary and Phytosanitary (SPS) Agreement under the World Trade Organization (WTO); the International Plant Protection Convention (IPPC); national plant protection organizations (NPPOs); regional plant protection organizations (RPPOs); the OECD; the Food and Agriculture Organization (FAO); the International Seed Testing Association (ISTA); the International Convention for the Protection of New Varieties of Plants (UPOV); and the Association of Official Seed Analysts (AOSA).

Plant Breeding

Plant breeding is conducted principally by:

- publicly supported state (or provincial) and national agricultural research agencies;
- privately owned seed companies or institutes; and
- international agricultural research institutes.

The strategy of plant breeding is relatively straightforward. The basic elements of this strategy are: to identify the needs and desires of customers to identify the morphological, physiological, and pathological traits in a cultivated plant species that contribute to its adaptation, health, productivity, and suitability for food, fiber, or industrial products; to search out new genes that encode for desired traits in different strains of the cultivated species and their close relatives-, to combine genes for the desired traits into an improved cultivar through traditional breeding or new biotechnology procedures; to assess performance of the improved breeding lines in the local environment in comparison with present cultivars; and to distribute as new cultivars those breeding lines that are superior to cultivars currently grown.

Breeding work calls for significant annual investments in land, equipment and skilled scientists. For instance, the length of time required for the development of a new variety typically ranges from 6 to 10 generations after the initial introduction of variation. After the discovery or creation of a desired genetic characteristic, observation and selection continues over several generations until sufficient stability of the new characteristic and a variety of commercial value is obtained. From the very large number of variants produced each year within one breeder's program, only one or two will eventually become successful varieties. Once it is decided that a variety will be commercialized, seed companies must increase a handful of "breeder seeds" to the levels needed for marketing by using strict production practices that maintain varietal quality and purity.

Plant breeding for agricultural crops consists of a recurrent cycle based upon growing seasons with a typical development time for new varieties of 5-12 years. For example, com and soybeans are 5-7 years; and wheat, 10-12 years. Three stages can be distinguished in the development process:

Years 1-2:
Creation of genetic variation by conventional plant breeding practices to give varying recombination.

Years 3-8:
Selection and stabilization of the optimal genetic combination, usually in inbred lines and testing of performance in experimental hybrids.

Years 9-12: Final selection, variety protection and registration for market release and start-up of commercial seed multiplication.

During all of these stages, large amounts of experimental material are shipped to countries in the world for:

- Optimal selection and adaptation under local conditions of soil, climate, disease conditions and agronomy followed by recombination with top-yielding material.
- Testing and verification of the resulting experimental varieties.
- Agronomy trials to determine optimum production with selected varieties.
- Seed production for which specific locations and isolation arc necessary for the required seed quality.
- Decrease in number of years per generation needed for development and secd increase by using "off-season" nurseries.

Counter Season Production

A short cut to reduce the time period for seed development is the counter season production where an extra generation is realized in warmer climates, such as the southern hemisphere during the northern winter time or vice versa. While expensive, the savings in development time can be very important. Countries involved in counter season production include Chile, Argentina, Mexico, Puerto Rico, Hawaii, and Brazil.

A typical large multinational breeding company for a crop like maize can send experimental varieties across countries in the following orders of magnitude:

Counter season production:	50,000 genotypes/year/5 countries
Testing:	50,000 genotypes/year/10 countries
Pre-commercial :	100 genotypes/year/20 countries

The above numbers are average figures per company for any one crop.

Pre-Commercial Seed Shipments

Plant breeding is a global process, Many companies exchange germplasm. between world areas with similar climates, and winter nurseries are used to reduce time from establishment of an initial variation to release of a variation. While thousands of breeding lines move globally each year, limited seed is available for any assessment. Breeding lines typically move with only a phytosanitary certificate. If the breeding line was developed using genetic modification, a planting clearance may be required.

Phytosanitary Clearance of Commercial Seed Shipments

Regulatory requirements for marketing seeds vary and include phytosanitary clearance. Phytosanitary certification generally ensures that the imported shipment is inspected and free of pests or diseases of significance to the importing country. The relevant phytosanitary agreement, the SPS Agreement, entered into force with the establishment of the WTO in 1995. The Agreement generally permits countries to develop their own phytosanitary standards, but also states that such regulations must be based on science. Member countries are encouraged to use international standards and guidelines where they exist. In general, nearly all countries have phytosanitary measures.

Phytosanitary measures regarding plants can include requirements that they come from a diseasefree area, inspection, and treatment or processing. Because of differences in climate, pests or diseases in other conditions, however, the same phytosanitary requirements sometime vary, depending on the

country of origin of the plant product, The WTO itself does not develop such standards, but encourages governments to establish national SPS measures that are consistent with international standards, guidelines, and recommendations.

Most of the 140 WTO member governments participate in the development of standards as part of other international bodies. The IPPC is a multilateral treaty of the FAO of the United Nations. One hundred and thirteen governments are currently contracting parties to the IPPC. The IPPC plays a critical role as it is recognized in the SPS Agreement as a source for international standards for phytosanitary measures related to trade. NPPOs carry out official inspections and tests, and issue phytosanitary certificates. Inspection and testing may be carried out by accredited agencies or companies.

RPPOs are key in establishing regional standards for phytosanitary measures and developing standardized procedures used to be applied to pest problems. There are roughly eight regional groupings: North America, Europe, Asia-Pacific, Caribbean, Central America, the Andean region, South America, and Africa.

Commercial Marketine of Seeds

In addition to the phytosanitary clearance, a variety of commercial criteria are in place that serve to enhance the scrutiny of seeds in international trade. These additional requirements may include:

- variety registration:
  - distinctness, uniformity and stability
  - value for commercialization and use
- varietal purity
- minimum germination

These requirements are described in more detail below, For a seed lot to move in international seed trade, additional controls and examinations may be required.

I . Registration

In some countries, varieties offered for sale must be registered in a national official catalogue of vancties. In the application form, information on the breeding scheme, parents and other relevant information, including confidential business information, is requested. Prior to the registration, technical examinations are carried out by bodies deemed competent by the different countries, where that information is controlled. Results of the examinations and the non-confidential information are publicly available.

To obtain registration, the variety must be judged as distinct from other varieties in the market and with sufficient uniformity and stability of characteristics. Additionally,authorities determine that the variety has value to growers,

> **Distinctness, Uniformity *and* Stability.** Specific standards for distinctness, uniformity and stability are not required by all countries. Many countries have their own guidelines for conducting the tests in order to assess these three conditions, but most of them use the guidelines for the conduct of tests developed by the UPOV. Article 12 of this Convention states that authorities (tests are conducted by governmental agencies) may carry out or take into account all the necessary tests and trials and may require the breeder to furnish all the

necessary information, documents or material. The test guidelines are regularly updated and include criteria such as: (1) material required; (2) minimum duration of tests; (3) number of places; (4) size of plots; (5) methods; and (6) the characteristics and their states to be observed. All participating countries have access to the tests already carried out in other countries.

Valuefor Commercialization and Use. Many countries include in their regulations special provisions requiring some commercial value for registering new varieties. These provisions are established only at national levels and require the development of comparative field trials controlled by public officers, for which the results -- in terms of commercial value for farmers (yield, agronomic behavior, etc.) -- are made publicly available.

2. Varietal Quality and Purity

If standards for varietal quality and purity exist, they are set at the national level but may be harmonized and internationally recognized through the OECD Schemes for the Varietal Certification of Seed Moving in International Trade. Additionally, the FAO established the Quality Declared Seed Scheme in 1993 to address issues of quality seed distribution in countries with scarce government resources.

OECD Seed Schemes. The purpose of the OECD Seed Schemes, which establish genetic purity certification standards, is to assure the genetic purity of seeds that move in international cormnerce. The Schemes facilitate a complete and long-expericnced set of rules that guarantee the fulfillment of these standards and the correct management of the documentation generated throughout the process. These Schemes are open to OECD members as well as members of the United Nations and/or its Specialized Agencies. They are legally binding on OECD members and those others that participate. Currently, approximately 48 countries (21 non-OECD members) participate in one or more OECD Seed Schemes (see attachment). The annual meeting of the national authorities of the participating countries ensures the review and update of the operation and development of the Schemes.

The OECD Schemes authorize the use of labels and certificates for seed produced and processed for international trade according to agreed-upon principles. There are seven Schemes pertaining to groups of species of cultivated plants: grasses and legumes; cereals; maize and sorghum; crucifers and other oil or fiber species; fodder beet and sugar beet; subterranean clover and similar species; and vegetables. Generally, each Scheme sets a series of rules and directions aiming at varietal certification of seed. The Schemes are based on the principle that only those varieties that are officially recognized as distinct and having acceptable value in at least one country can be included on official lists.

Also, all certified seed must achieve a certain varietal purity and therefore special tests are prescribed. Satisfactory conditions for production and processing of seed must be ensured and verified by field inspection and pest control tests. Pest control tests are conducted to ascertain that the schemes are operating appropriately. Most importantly, the tests are intended to determine that the characteristics of varieties have remained unchanged during the process of multiplication and to ensure that the varietal identity and purity of individual seed lots can be verified. OECD certification is given only to those shipments in which the buyer or the importing nation has requested such certification.

ISTA is an international organization comprised of representatives from governments worldwide. It develops seed testing procedures and accredits laboratories to conduct testing

regarding the quality, genetic purity, and health of seeds. Another organization involved in seed testing analysis is AOSA. AOSA is primarily concerned with seed testing procedures pertaining to germination, mechanical purity, and noxious weed content. OECD certification conforms to ISTA requirements for seed lots and uses testing procedures developed by AOSA. Both ISTA and AOSA are equally recognized under OECD.

In order to commercialize a certified variety, it must be multiplied from parental material -- the smallest unit used by breeders to maintain variety. Multiplication is made under technical conditions approved by the national authorities. The OECD Seed Schemes provide a set of rules and directions aiming at the harmonization and mutual recognition of these conditions for the international seed trade, Under the OECD Seed Schemes, each participating country publishes and annually revises an official national list of varieties that have been approved. Varieties are added to the list when a national authority has checked that its generation used for crop production has sufficiently uniform and stable characters. Depending on the species, satisfactory results by official tests (including comparative field tests) must be obtained and an adequate description, including essential morphological or physiological characters and in the case of hybrid varieties, of the parental constituents, must be available.

The national authorities of the participating countries must take all practicable steps to ensure that the identity and the varietal purity of the seed have been maintained between harvest and the fastening and labeling. These practicable steps include: (1) inspection of the plants at an appropriate stage, and (2) seed sampling and testing for analytical purity and germination. Finally, fastening and labeling are governed by the national authorities or, in some countries, by authorized personnel under official supervision.

Under the certification schemes, a percentage of the samples are checked in post-control tests conducted under the official supervision of the national authorities. Certification schemes also include minimum requirements for the production of certified seed concerning aspects (depending on the species) such as:

- previous cropping;
- minimum isolation distances;
- number of harvest years;
- presence of contaminant varieties;
- presence of weeds;
- field inspection;
- varietal purity and identity; and
- species purity.

The label of the certified seed, depending on the Scheme, provides the following basic information in either English or French:

- name and address of the national designated authority;
- species (Latin name);
- common name;
- variety name;
- category of seed (pre-basic, basic, certified, etc.);
- country and region of production;
- reference number: key for monitoring the entire production process and to distinguish the seed lot from others harvested in the same country; and

- reference to the OECD Seed Scheme.

FAO Quality Declared Seed System. The Quality Declared Seed System developed by FAO in 1993 is similar to the OECD Schemes, but has the added goal of ensuring *that* farmers and growers in less developed countries are purchasing good quality seed. Guidelines are provided for cereals, food legumes, oil crops, forage crops, forage legumes, industrial crops and vegetable crops.

The system is based in four main aspects:

- establishment of a list of varieties eligible for supplying "quality declared seeds;"
- registration of seed producers by the appropriate national authority;
- verification of 10% of all the seed crops by the national authority; and
- verification of 10% of the seed commercialized as "quality declared system" by the national authority.

The quality declared seeds are produced under the governmental supervision and must be labeled with the following minimum information:

- name and address of the national authority;
- name of the producer;
- species;
- variety name;
- reference number: key for monitoring the entire production process and to distinguish the seed lot from others harvested in the same country; and
- information on possible chemical treatment.

Conclusion

The Quality Declared Seed Scheme is designed to benefit the least developed countries. However, to-date it has not yet enjoyed large-scale implementation.

Existing systems of clearance, quality control and certification schemes in the seed industry provide regulation and control of seed moving in international trade significantly in excess of Protocol requirements. These systems, based on record collection and documentation by the operators in the chain, are an established part of the global seed business and should be recognized in the Protocol implementation process.

NORTH AMERICAN EXPORT GRAIN ASSOCIATION, INC.

FREE ON BOARD EXPORT CONTRACT U.S.A./CANADA

Revised as of May 1, 2000

NO. 2

Contract No. _____

New York, N.Y. _____ 20_____

1. **Sold by** _____

2. **Purchased by** _____

3. **Broker/Agent** _____

4. **Quantity** _____

in bulk, including dockage, 5% more or less at buyer's option, and at market price (per Clause 10) as follows: If the first delivery under this contract is for a quantity between contract minimum and contract maximum (both inclusive), no further deliveries shall be made. If this contract is to be executed by more than one vessel, the loading tolerance of 5% more or less shall apply on the difference between the mean contract quantity and the quantity that has been delivered on all prior vessels. Any delivery which falls within this difference, plus or minus 5%, shall complete the contract.

5. **Weight** Quantity to be final at port of loading in accordance with customary weight certificates. 1,016 kilos shall be equal to 2,240 lbs.

6. **Commodity** _____

_____

in accordance with the official grain standards of the United States or Canada, whichever applicable, in effect on the date of this contract.

7. **Quality** Quality and condition to be final at port of loading in accordance with official inspection certificates.

In case of delivery at St. Lawrence ports, quality and condition to be final in accordance with Lake and/or loading ports official inspection certificates; Lake inspection certificates to be properly identified at ports of shipment.

Each party hereby authorizes the other party to request in both parties' names an appeal inspection under the U.S. Grain Standards Act at any time prior to or during the loading of the vessel, and whether or not such request was filed before commencement of loading. The cost of such appeal inspection, unless otherwise stipulated in this contract, shall be borne by the party requesting it.

Delivery of higher grades of grain of the same type and description is permissible. The commodity is not warranted free from defect, rendering same unmerchantable, which would not be apparent on reasonable examination, any statute or rule of law to the contrary notwithstanding.

8. **Delivery** Delivery shall be made between _____ and _____, both inclusive (the "delivery period"), at discharge end of loading spout, to buyer's tonnage in readiness to load, in accordance with custom of the port and subject to the elevator tariff to the extent that it does not conflict with the terms of this contract. Incorporation of a loading rate guaranty in this contract shall not entitle seller to delay delivery.

Buyer shall give vessel nominations ("preadvice") in accordance with Clause 15, in time for seller to receive minimum _____ days notice of probable readiness of tonnage and quantities required (the "preadvice period"). Buyer to keep seller informed of changes in expected date of vessel readiness.

Time for the preadvice shall be deemed to commence to count at 1200 noon, local time at place of receipt, on the business day of receipt by seller and shall be counted in consecutive periods of 24 hours.

Seller shall, if applicable, declare port and berth of loading within a reasonable time (but not later than _____ days) after receipt by seller of the preadvice, except that seller shall not be obligated to make such declaration earlier than (a) the 8th day prior to commencement of the delivery period for port declaration and (b) the 5th day prior to commencement of the delivery period for berth declaration.

The vessel shall not be prevented from filing and from taking its place in the vessel line-up at the designated port/berth during the preadvice period or before commencement of the delivery period, notwithstanding which, seller shall not be obliged to effect delivery to the vessel before the expiration of the preadvice period or before commencement of the delivery period. For the purposes of this contract a vessel shall be considered filed when it (a) has tendered valid notice of readiness to load to the charterer or its agent, at the port of loading, (b) has given written advice of such tender to the loading elevator, complete with all customarily required documents, such advice having been presented between the hours of 0900 and 1600 local time on a business day or between the hours of 0900 and 1200 noon on Saturday (provided not a holiday) and (c) is ready to receive grain in the compartments required for loading under this contract.

Buyer shall be allowed to make one substitution of a vessel, provided the substituting vessel is of the same type and approximately the same size and position. If the original or the substituting vessel is unable to lift the commodity by reason of the vessel having sunk or having suffered incapacitating physical damage, an additional substitution shall be made of a vessel of the same type and approximately the same size, and with a position agreeable to buyer and seller. Such agreement shall not be unreasonably withheld. The nomination of the substituting vessel shall be subject to the preadvice requirements of this clause, regardless of any preadvice previously given, unless the estimated time of arrival of the substituting vessel is the same as the estimated time of arrival of the original vessel when nominated. No substitution of vessels other than as provided in this clause shall be made. If this is a "named vessel" contract, no substitution other than after a casualty as described above shall be permitted.

Bills of lading and/or mate's receipts to be considered proof of date of delivery in the absence of evidence to the contrary. Any delivery in part fulfillment of this contract shall be considered as if made under a separate contract.

9. **Days** In any month containing an odd number of days, the middle day shall be reckoned as belonging to both halves of the month.

10. Price _____ per _____

free on board buyer's tonnage at _____

_____

If this contract is for a flat price, any variance in quantity from the mean contract quantity shall be settled basis the FOB market value (as defined in paragraph (a) and (b) below).

If the contract price is to be established on an exchange of futures, futures shall be exchanged prior to delivery of the commodity or at least 5 calendar days prior to the last trading day of the applicable futures month, whichever is earlier, to the nearest 5,000 bushels of the mean contract quantity. If deliveries under this contract result in a variance from the mean contract quantity, there shall be another exchange of futures as soon as possible after the last date of loading to bring the resulting amount of futures exchanged to the nearest 5,000 bushels of the quantity delivered. All exchanges of futures shall be made within the range of prices prevailing on the futures market on the date of the exchange. The variance from the mean contract quantity shall be settled basis the market value of the premium (as defined in paragraph (a) and (b) below).

(a) The FOB (flat price) market value, or the market value of the premium, as the case may be, shall be that prevailing on the close of the appropriate market in the country of origin of the commodity on the last date of loading, if such be a business day, otherwise on the close of such market on the previous business day.

(b) In the event the parties do not agree on the market value by the time the shipping documents are ready to be transmitted to buyer, seller shall invoice the entire shipment provisionally at contract price. Thereafter, final invoice for the difference between contract price and market value shall be presented as soon as possible and payment shall be made immediately.

11. Payment

*(a) Net cash by irrevocable divisible letters of credit issued or confirmed by a prime U.S. bank in New York (or _____ by mutual agreement), available by sight drafts accompanied by shipping documents per Clause 12 (or warehouse receipts if option (c) of Clause 18 is exercised). Such letters of credit, in a form acceptable to seller, shall be established not later than 5 days prior to the beginning of the delivery period, and shall be valid at least until the 30th day after expiration of the delivery period. Should delivery be delayed beyond the delivery period, buyer, if requested by seller, shall amend letters of credit accordingly and buyer shall increase the amount of the letter of credit to provide for carrying charges, if applicable. All bank charges shall be for buyer's account.

—or—

*(b) Net cash in U.S. Dollars, by telegraphic transfer to the bank designated by seller, against presentation of and in exchange for shipping documents per Clause 12 (or warehouse receipts if option (c) of Clause 18 is exercised). Such presentation shall be made in the city of _____

_____

All bank charges in connection with payment shall be for buyer's account.

—or—

*(c) _____

_____

_____

*Delete paragraphs which are not applicable.

12. Shipping Documents Payment to be made against bills of lading or mate's receipts (at seller's option), and weight and inspection certificates. However, if practicable, seller shall follow instructions of buyer in establishing bills of lading containing such clauses as buyer's/vessel's agents or owners usually endorse or attach. Buyer shall accept such bills of lading but seller assumes no responsibility for their correctness.

13. Notice of Delivery Notice of delivery stating vessel's name, dates of bills of lading (or mate's receipts), quantities and qualities loaded (including percentage of dockage if applicable) shall be given or passed on by seller to buyer without undue delay. Notices of delivery shall be subject to correction of any errors.

14. Insurance Marine and war risk (plus strikes, riots, civil commotions and mine risk) insurance, covering seller's/buyer's interests as they may appear, is to be covered by buyer with first-class approved companies and/or underwriters and to be confirmed by such companies and/or underwriters to seller at least 5 days prior to the expected readiness of the vessel. If this confirmation is not received by seller by such time, seller may place such insurance for buyer's account and at buyer's risk and expense.

15. Communications All notices under this contract shall be given by letter, if delivered by hand on the day of writing, or by cable, telex or other method of rapid written communication. Any notice received after 1600 hours (local time at place of receipt) on a business day shall be deemed to have been received on the following business day, except that for notices given and received by parties which are both located in the Continental United States and/or Canada, the reference herein to 1600 hours shall signify 1600 hours New York City time (E.S.T. or E.D.T., as in effect on date of receipt of the notice).

16. Circles

(a) For the purposes of this clause, a circle shall consist of a series of contracts in which each seller is also a buyer of a commodity of the same description and quality, for delivery at the same ports and with compatible delivery periods.

(b) If this contract forms part of a circle, each party may agree with the other parties in the circle to forego actual delivery and to participate in a clearing agreement for the settlement of contract price differences. Monies due and owed to parties in the circle shall be payable on the middle day of the contract delivery period.

(c) If a circle can be shown to exist but no clearing agreement has been reached by the 10th calendar day following the last day of the delivery period, actual delivery shall not be made and payment shall be made by each buyer to its seller of the excess of seller's invoice amount over the lowest invoice amount in the circle. Such payments shall be made promptly after the 10th calendar day following the last day of the delivery period.

(d) Should any party in a circle fail to make payment on the due date as required under paragraph (b) or (c) above for reasons cited in Clause 23 or for any other reason, payment shall be made between each buyer and its seller of the difference between the seller's invoice amount at contract price and the market value of the commodity on date of insolvency or default, as the case may be. Such payment shall be made latest on the 2nd business day after the due date under paragraph (b) or (c) above.

Payments already made under paragraph (b) or (c) above shall be refunded.

(e) All circle settlements shall be based on the mean contract quantity.

If a circle under paragraph (b), (c) or (d) above exists, Clause 21 shall not apply and Clauses 18 and 20 shall not be invoked.

Payments due on a non-business day shall be made not later than the following business day.

All payments made after the delivery period shall include carrying charges from the day following the last day of the delivery period, to the date of payment, at the rates stipulated in this contract. These carrying charges shall be settled individually between each buyer and its seller.

(f) The parties agree that any dispute arising out of the voluntary clearing agreement entered into in accordance with paragraph (b) above shall be subject to arbitration as to any party thereto. Such arbitration shall be conducted in accordance with the provisions of Clause 30.

17. U.S./Canadian Government Rules and Regulations

Buyer and seller agree to comply with the U.S. and Canadian regulatory prerequisites applicable to this contract, including, but not limited to, those governing any export subsidy, destination controls, government financing of agricultural commodities and the monitoring of export purchases and sales. Any losses, fines, penalties, expenses, costs or damages incurred as a result of failure to perform in accordance with this provision shall be borne by the party responsible for such failure.

18. Failure to Take Delivery

If vessel fails to file before the end of the delivery period, buyer shall be in breach of contract and seller shall carry the grain for buyer's account and risk as provided in Clause 19. In the event that buyer has not given vessel nominations conforming to the applicable provisions of Clause 8 by the 15th calendar day following the last day of the delivery period, or if the vessels having been nominated within such time, fail to file by the 35th calendar day following the last day of the delivery period, seller may, in its discretion: (a) continue to carry the commodity for buyer's account and risk, (b) declare buyer in default, or (c) tender to buyer proper warehouse receipts in a quantity equal to the mean quantity open under this contract, in exchange for which buyer shall pay at contract price plus accrued carrying charges, but less out-elevation and outbound weighing and inspection charges. Such tender of warehouse receipts shall be deemed due performance of the contract by seller.

SPECIAL PROVISIONS FOR CONTRACTS PROVIDING FOR DELIVERY AT ST. LAWRENCE, GREAT LAKES OR HUDSON BAY PORTS:

(1) Seller shall be barred from declaring option (b) above while the navigation in the designated delivery area is officially closed for the ice season, and for 20 days thereafter.

(2) However, if options (a), (b) and (c) above become available to seller only while the navigation is officially closed, the seller may declare option (b) during the first 10 days it becomes available to him; thereafter, he shall be barred from declaring it, until the 21st day after the official opening of navigation.

(3) If seller carries the grain into the new season for buyer's account, buyer shall have the right to nominate vessels per Clause 8, regardless of whether vessels were already nominated during the delivery period.

19. Carrying Charges

If the commodity is being carried for buyer's account and risk as provided in Clause 18, it is mutually agreed that carrying charges, consisting of storage, insurance and interest, shall accrue as follows:

(a) Storage and insurance from the day following the last day of the delivery period up to and including the dates of delivery (or if seller exercises option (b) or (c) of Clause 18, the date applicable thereto), both dates inclusive, at the following rates:

_____ U.S. cents per bushel per day _____

_____ U.S. cents per bushel per day _____

(b) Interest from the day following the last day of the delivery period up to and including the last day of delivery (or if seller exercises option (b) or (c) of Clause 18, the date applicable thereto), both dates inclusive, at the following rates:

Carrying charges for the delivery completing this contract shall be computed on the mean contract quantity less the amounts previously delivered (if any), irrespective of whether or not buyer has availed himself of the loading tolerance option under Clause 4. It is further expressly agreed that carrying charges as provided herein are to be construed in the nature of liquidated damages and, as such, that no further proof of damages shall be required in substantiation thereof.

20. Strikes or Other Causes of Delay in Delivery

(a) This clause shall apply if delivery by seller of the commodity, or any part thereof, is prevented or delayed at the port(s) of delivery and/or elevator(s) of delivery or elsewhere, or if the forwarding of the commodity to such port(s) and/or elevator(s) is prevented, by reason of the causes enumerated in paragraph (b) below; PROVIDED that seller shall have sent notice to buyer not later than 2 business days after the date of commencement of the causes, or not later than 2 business days after the 1st day of the delivery period, whichever occurs later (except that subsequent sellers shall not be bound by these deadlines, provided they pass along the notice to their buyer, without delay); and PROVIDED further that seller shall, at buyer's request, furnish a certificate of the North American Export Grain Association, Inc., certifying the existence and the duration of the causes. Such certificate shall be final.

(b) The causes of delay and/or prevention ("causes") referred to in paragraph (a) above shall be:

(1) Riots, strikes, lockouts, interruptions in or stoppages of the normal course of labor,

(2) Embargoes or exceptional impediments to transportation,

(3) Action by Federal, State or local government or authority.

(c) The obligation of seller to make delivery shall be suspended while the causes are in effect, until the termination of the causes and/or the resumption of work after the termination of the causes, whichever is later. Seller shall not be responsible for further delays after resumption of work (whether such termination or resumption of work occurs prior to, during or after the delivery period) except that, if a vessel nominated under this contract is not loaded in the proper rotation but is bypassed by vessels (other than liners) which had filed after the vessel nominated under this contract, seller shall pay to buyer damages equal to the actual working time lost (weather working days, Saturdays, Sundays and holidays excluded) to buyer's vessel during the loading of the bypassing vessels, at the demurrage rate in the Charter Party for the vessel nominated under this contract.

If the Charter Party of the vessel under this contract does not indicate a demurrage rate, the damages are to be calculated at a reasonable demurrage rate predicated on the then current market, to be agreed upon amicably or to be determined by arbitration.

(d) (1) If the causes commence before or during the delivery period and terminate during or after delivery period, then the delivery period shall be deemed to be extended by a number of days equivalent to the period starting with the commencement of the causes or the commencement of the delivery period, whichever is later, and ending with the termination of the causes, and/or the resumption of work after the termination of the causes, whichever is later.

(2) If the causes commence during the additional time afforded to buyer under Clause 18 with respect to vessel nominations and filings, then the right of seller to exercise option (b) or (c) under Clause 18 shall be deemed to be delayed by a number of days equivalent to the period starting with the commencement of the causes and ending with the termination of the causes and/or the resumption of work after the termination of the causes, whichever is later.

(e) Carrying charges, if due under Clauses 18/19, shall begin to accrue on the day following the last day of the delivery period, as extended by paragraph (d)(1) above; however, if this clause becomes operative while carrying charges are already accruing, then such charges shall continue to accrue as they would in the absence of the causes.

21. Prohibition In case of prohibition of export, blockade or hostilities or in case of any executive or legislative act done by or on behalf of the government of the country of origin or of the territory where the ports of shipment named herein are situate, restricting export, whether partially or otherwise, any such restriction shall be deemed by both parties to apply to this contract and to the extent of such total or partial restriction to prevent fulfillment and to that extent this contract or any unfulfilled portion thereof shall be cancelled without prejudice to seller's entitlement to carrying charges. Seller shall advise buyer without delay of the reasons therefor, and if required by buyer, seller shall provide certification of the North American Export Grain Association, Inc., as sufficient evidence for cancellation under this clause.

22. Default In case of default by either party, the other party shall be at liberty, after giving notice, to resell or repurchase, as the case may be, without undue delay and the defaulting party shall make good the loss, if any, to the other party but the defaulting party shall not be entitled to any profit. If the non-defaulting party has not repurchased or resold the commodity by the 10th calendar day after the giving of notice of default, the market value on the said 10th day shall be used for settlement purposes. If such 10th day falls on a non-business day, the market value on the previous business day shall govern. In the event of a default by buyer, the sale price under this contract shall automatically be increased by the value of carrying charges calculated up to the date of resale, or the 10th calendar day after the giving of notice of default, whichever is applicable.

23. Insolvency Either party shall, at any time after sending notice, have the right to terminate this contract and to recover the loss (if any) in the event that:

(a) the other party suspends payment or commits an act of bankruptcy;

-or-

(b) reasonable grounds for insecurity having arisen with respect to the financial capacity of the other party to perform under this contract, and a written demand for adequate assurance of due performance having been made, such assurance is not received within a period of time not exceeding 5 days.

24. Construction For the purposes of this contract, except as otherwise expressly provided or unless the context otherwise requires, plural terms include the singular.

25. Passage of Title Anything in this contract to the contrary notwithstanding, seller shall retain title to the commodity until seller has been paid in full (per Clause 11), it being understood that risk of loss shall pass to buyer on delivery at discharge end of loading spout (per Clause 8).

26. Limitation of Liability The liability of the seller under the contract, except as expressly stated herein, shall be limited to its actions in delivering the commodity at discharge end of loading spout and to presentation of the contractually required documentation. Any claims, losses, costs, damages, etc. arising from events or actions thereafter shall be the responsibility of the buyer, who shall indemnify seller for all costs (including attorney fees) and damages thereby incurred.

27. International Conventions The following shall not apply to this contract:

(a) the Uniform Law on the International Sale of Goods and the Uniform Law on the Formation of Contracts for the International Sale of Goods;

(b) the United Nations Convention on Contracts for the International Sale of Goods of 1980; and

(c) the United Nations Convention on the Limitation Period in the International Sale of Goods, concluded at New York on 14 June 1974, and the Protocol Amending the Convention on the Limitation Period in the International Sale of Goods, concluded at Vienna on 11 April 1980.

28. Governing Law The parties agree that this contract shall be governed by the laws of the State of New York, notwithstanding any choice of law provision to the contrary.

29. Other Conditions

30. Arbitration Buyer and seller expressly agree that any controversy or claim arising out of, in connection with or relating to this contract, or the interpretation, performance or breach thereof, shall be settled by arbitration in the City of New York before the American Arbitration Association (AAA), or its successors, in accordance with the International Arbitration Rules of the American Arbitration Association, as those Rules may be in effect at the time of such arbitration proceeding, which Rules are hereby deemed incorporated herein and made a part hereof, and under the laws of the State of New York. The number of arbitrators shall be three. Each party shall designate one arbitrator, and those two shall name a third, with the AAA making appointments if the tribunal is not formed by this procedure. The arbitrator named by the party-appointed arbitrators shall be from the list of grain arbitrators maintained by the AAA. Any arbitrator appointed by the AAA may be from the list of grain arbitrators maintained by the AAA or the AAA Commercial Arbitration Panel. The language of the arbitration shall be English. In disputes involving a "string" of contracts, two or more arbitrations may be consolidated before the same tribunal, at the written request of any party. The tribunal in consolidated arbitrations shall be mindful of differences in terms between the various contracts and in the action of the parties, and vary the award from contract to contract, if indicated. The arbitration award shall be final and binding on the parties and judgment upon such arbitration award may be entered in the Supreme Court of the State of New York or any other court having jurisdiction thereof. Buyer and seller hereby recognize and expressly consent to the jurisdiction over each of them of the American Arbitration Association or its successors, and all of the courts of the State of New York. The parties agree that arbitration awards may be released by the AAA to the North American Export Grain Association, Inc., for distribution to the interested public. Buyer and seller agree that this contract shall be deemed to have been made in New York State and be deemed to be performed there, any reference herein or elsewhere to the contrary notwithstanding.

BUYER SELLER

NORTH AMERICAN EXPORT GRAIN ASSOCIATION, INC.

ADDENDUM NO. 1
TO NORTH AMERICAN EXPORT GRAIN ASSOCIATION, INC., F.O.B. CONTRACT NO. 2
(REVISED AS OF MAY 1, 2000)

LOADING RATE GUARANTY

This Addendum shall apply if the parties have agreed to be bound by a loading rate guaranty, and provided that lifting under this contract is by one self-trimming bulk carrier only.

1. Seller guarantees to deliver at an average rate of _____ long tons per weather working day of 24 consecutive hours, Saturdays, Sundays and holidays excepted, provided vessel can receive at such rate. Holidays shall be those listed as such in the BIMCO Holiday Calendar and/or in the elevator tariff.

   For this purpose, laytime shall commence to count:

   (a) at 0700 hours on the business day following filing of the vessel in accordance with Clause 8 of North American Export Grain Association, Inc., FOB Contract No. 2 ("NAEGA 2"),

   –or–

   (b) at 0700 hours on the business day following expiration of the preadvice period stipulated in Clause 8 of NAEGA 2, unless an earlier date is agreed to by both parties,

   –or–

   (c) at 0000 hours on the first business day of the contract delivery period, unless an earlier date is agreed to by both parties,

   whichever is the latest, whether vessel is in berth or not.

2. Should seller deliver at less than the stipulated rate, seller to pay buyer demurrage at $ _____ for each additional day (or pro-rata for part of day) used. Should seller deliver faster than at the stipulated rate, buyer to pay seller despatch money at half the demurrage rate, i.e., $ _____ per day, for each day (or pro-rata for part of day) of laytime saved.

3. Any overtime work performed by the elevator and/or grain inspection and weighing services and/or stevedores shall be for seller's account if ordered by the elevator or the Port Authority; otherwise, for account of the party ordering the overtime.

4. If Clause 20 of NAEGA 2 has been duly invoked, time shall not count for demurrage purposes while the causes are in effect, until the termination of the causes and/or the resumption of work after the termination of the causes, whichever is later, and for an additional period ("additional period") of equal duration, but such additional period not to exceed 30 days. However, for purposes of settling despatch accounts only, any time lost in delivering through any of the causes, and the additional period, shall be counted as time used in loading.

   If during the additional period the vessel nominated under this contract is not loaded in proper rotation but is bypassed by vessels (other than liners) which had filed after the vessel nominated under this contract, seller shall pay to buyer damages equal to the actual working time lost (i.e., weather working days, but Saturdays, Sundays and holidays excluded) to buyer's vessel during the loading of the bypassing vessels, at the demurrage rate stipulated in Clause 2 above. The provisions regarding payment of damages under paragraph (c) of Clause 20 of NAEGA 2 shall not apply to this Addendum.

   Notwithstanding the above, if time has started to count under Clause 1 above within the delivery period, and demurrage is already accruing under this Addendum when the causes of prevention or delay commence under Clause 20 of NAEGA 2, demurrage shall continue to accrue as if these causes did not exist. In such case, the preceding paragraph shall be deemed to be deleted.

5. Buyer's or seller's claim under this Addendum shall be accompanied by the statement of facts at loading, signed on behalf of the owner and the charterer or on behalf of the owner and by the supplier, and such other papers as may be necessary to process the claim. If payment is not made within 40 days from date of mailing of properly documented claim, interest shall accrue, starting on the 41st day after such mailing, and shall be computed on the final amount due, at the rate of interest stipulated elsewhere in this contract, up to the date of payment of the claim.

6. If vessel nominated under this contract also lifts additional commodities (grain and/or oilseeds), regardless of whether or not such commodities are covered by loading rate guaranties, the following shall apply:

   (a) For commodities delivered to vessel at the same berth:

   The "time allowed" shall be arrived at by dividing the tonnage loaded under this contract by the daily rate stipulated in Clause 1 above. A calculation of "total time used" for all the commodities loaded at the berth shall be made, in which any such time in excess of the "time allowed" shall be computed as time on demurrage. The "total time used" shall then be pro-rated to the tonnage loaded under this contract. The "time allowed" shall be deducted from this pro-rated figure to arrive at the time on demurrage or time saved under this contract.

   (b) If the commodities other than those under this contract are delivered at (an)other berth(s) in the same port:

   The waiting time ("waiting time") at the first berth shall be pro-rated among all the contracts for the commodities to be delivered to the vessel.

   The time spent getting to and used at the first berth ("berth time") shall be pro-rated among the contracts loaded at the first berth.

   The waiting time at the second berth shall be pro-rated among all remaining contracts for the commodities yet to be delivered to the vessel.

   The berth time at the second berth shall be pro-rated among the contracts loaded at the second berth.

Waiting time and berth time for berths subsequent to the second berth shall be treated in a similar manner as for the second berth.

Waiting time shall cease and berth time begin when pilot is on board and vessel lifts anchor in order to proceed to the loading berth.

Berth time shall cease when loading is completed at that berth and waiting time shall begin when vessel drops anchor in waiting area after having sailed from berth.

If no waiting time is involved between berths, berth time at the next berth shall begin when vessel sails from the previous berth.

If, between the time that the vessel is ordered into a berth and the time of completion of loading at that berth, the vessel is ordered into one or more other berths, subsequently incurred waiting time at this (these) other berth(s) shall not count.

(c) If the commodities other than those under this contract are delivered at (an)other port(s):

The laytime statement shall be prepared as if the vessel had not called at another port. If the commodities under this contract are loaded at the second or a subsequent port, the words "filing of the vessel in accordance with Clause 8 of the North American Export Grain Association, Inc., FOB Contract No. 2 ("NAEGA 2")" in Clause 1(a) above shall be deemed to read "presentation of the vessel's passes". If, however, the first and second or subsequent ports have been nominated by the seller of the grain under this contract, laytime for the second and/or subsequent port(s) shall commence upon vessel's arrival at that or the subsequent port(s); except that, if vessel fails inspection at such port(s), laytime shall cease to count until vessel passes.

7. If vessel fails reinspection at the loading berth, laytime shall cease to count until vessel passes.

8. Any trimming costs as well as overtime costs for performing trimming shall be for buyer's account. Any time used for trimming shall not count as laytime and/or shall be exempt from demurrage, unless loading operations are being carried on simultaneously in other holds.

9. Other Conditions:

10. Buyer and seller expressly agree that any controversy or claim arising out of, in connection with or relating to this contract, or the interpretation, performance or breach thereof, shall be settled by arbitration in the City of New York before the American Arbitration Association (AAA), or its successors, in accordance with the International Arbitration Rules of the American Arbitration Association, as those Rules may be in effect at the time of such arbitration proceeding, which Rules are hereby deemed incorporated herein and made a part hereof, and under the laws of the State of New York. The number of arbitrators shall be three. Each party shall designate one arbitrator, and those two shall name a third, with the AAA making appointments if the tribunal is not formed by this procedure. The arbitrator named by the party-appointed arbitrators shall be from the list of grain arbitrators maintained by the AAA. Any arbitrator appointed by the AAA may be from the list of grain arbitrators maintained by the AAA or the AAA Commercial Arbitration Panel. The language of the arbitration shall be English. In disputes involving a "string" of contracts, two or more arbitrations may be consolidated before the same tribunal, at the written request of any party. The tribunal in consolidated arbitrations shall be mindful of differences in terms between the various contracts and in the action of the parties, and vary the award from contract to contract, if indicated. The arbitration award shall be final and binding on the parties and judgment upon such arbitration award may be entered in the Supreme Court of the State of New York or any other court having jurisdiction thereof. Buyer and seller hereby recognize and expressly consent to the jurisdiction over each of them of the American Arbitration Association or its successors, and all of the courts of the State of New York. The parties agree that arbitration awards may be released by the AAA to the North American Export Grain Association, Inc., for distribution to the interested public. Buyer and seller agree that this contract shall be deemed to have been made in New York State and be deemed to be performed there, any reference herein or elsewhere to the contrary notwithstanding.

BUYER

SELLER

NORTH AMERICAN EXPORT GRAIN ASSOCIATION, INC.

ADDENDUM NO. 2
TO NORTH AMERICAN EXPORT GRAIN ASSOCIATION, INC., F.O.B. CONTRACT NO. 2
(REVISED AS OF AUGUST 1, 1988)

Effective as of March 15, 1993

The North American Export Grain Association, Inc., F.O.B. Contract No. 2 (revised as of August 1, 1988) ("NAEGA 2") is deemed to be amended as follows:

Clause 15. Communications

The word "preadvice" in the second sentence of Clause 15 is deleted and replaced by the word "notices", so that Clause 15 now reads:

> "All notices under this contract shall be given by letter, if delivered by hand on the day of writing, or by cable, telex or other method of rapid written communication. Any notice received after 1600 hours (local time at place of receipt) on a business day shall be deemed to have been received on the following business day, except that for notices given and received by parties which are both located in the Continental United States and/or Canada, the reference herein to 1600 hours shall signify 1600 hours New York City time (E.S.T. or E.D.T., as in effect on date of receipt of the notice)."

Otherwise, NAEGA 2 (including Addendum No. 1) remains unchanged.

Reference to NAEGA 2 in any contract shall be deemed to include this Addendum No. 2, unless otherwise specifically stated.

NORTH AMERICAN EXPORT GRAIN ASSOCIATION, INC.

ADDENDUM NO. 3
TO NORTH AMERICAN EXPORT GRAIN ASSOCIATION, INC.
F.O.B. CONTRACT NO. 2
(INCLUDING ADDENDUM NO. 1 [LOADING RATE GUARANTY])
(REVISED AS OF AUGUST 1, 1988)

Effective as of January 1, 2000

Clause 28 of the North American Export Grain Association, Inc., F.O.B. Contract No. 2 (revised as of August 1, 1988) ("NAEGA 2")

and

Clause 10 of Addendum 1 to NAEGA 2 - Loading Rate Guaranty (revised as of August 1, 1988) ("Addendum 1")

are deemed to be amended as follows:

"Buyer and seller expressly agree that any controversy or claim arising out of, in connection with or relating to this contract, or the interpretation, performance or breach thereof, shall be settled by arbitration in the City of New York before the American Arbitration Association (AAA), or its successors, in accordance with the International Arbitration Rules of the American Arbitration Association, as those Rules may be in effect at the time of such arbitration proceeding, which Rules are hereby deemed incorporated herein and made a part hereof, and under the laws of the State of New York. The number of arbitrators shall be three. Each party shall designate one arbitrator, and those two shall name a third, with the AAA making appointments if the tribunal is not formed by this procedure. The arbitrator named by the party-appointed arbitrators shall be from the list of grain arbitrators maintained by the AAA. Any arbitrator appointed by the AAA may be from the list of grain arbitrators maintained by the AAA or the AAA Commercial Arbitration Panel. The language of the arbitration shall be English. In disputes involving a "string" of contracts, two or more arbitrations may be consolidated before the same tribunal, at the written request of any party. The tribunal in consolidated arbitrations shall be mindful of differences in terms between the various contracts and in the action of the parties, and vary the award from contract to contract, if indicated. The arbitration award shall be final and binding on the parties and judgment upon such arbitration award may be entered in the Supreme Court of the State of New York or any other court having jurisdiction thereof. Buyer and seller hereby recognize and expressly consent to the jurisdiction over each of them of the American Arbitration Association or its successors, and all of the courts of the State of New York. The parties agree that arbitration awards may be released by the AAA to NAEGA for distribution to the interested public. Buyer and seller agree that this contract shall be deemed to have been made in New York State and be deemed to be performed there, any reference herein or elsewhere to the contrary notwithstanding."

Otherwise, NAEGA 2, including Addendum 1, remains unchanged. Reference to NAEGA 2 and Addendum 1 in any contract shall be deemed to include this Addendum 3, unless otherwise specifically stated.

Return to *Table of Contents*

Agricultural Export Transportation Handbook

Transport Documentation

U.S. Export Requirements | Importing Country Requirements
Importer's Requirements | Additional Documents

Pro Forma Invoice | Commercial Invoice | USDA Inspection Certificates | Weight Certification
Packing List | Shipper's Letter of Instruction | Dock Receipt | Certificate of Origin
Consular Invoice | Insurance Certificate | Shipper's Export Declaration | Bill of Lading | Air Waybill

Sample Transportation Documents

The average international shipment involves 46 separate documents. The specific documents required for any given shipment depend on U.S. Government regulations, destination country's import regulations, importer's requirements, terms of sale, method of payment, and mode of transportation.

U.S. Export Requirements--The United States Government requires export documentation for a number of different reasons including national security, control of products in short supply, compiling export statistics, administration of export laws, protection of endangered species, and to protect U.S. export markets by ensuring product quality of specific exports. The main document required by the United States government is the Shippers Export Declaration (SED).

Importing Country Requirements--Each country has different requirements regarding the documentation that accompanies any given import shipment. Importing countries require these documents for the administration of their import laws, assessment of taxes, and protection from hazardous pests and diseases. Some of the more frequently required documents are: commercial invoice, bill of lading, phytosanitary certificate (for plants or plant products), veterinary health certificate (for animals or animal products), packing list, and certificate of origin.

Other import regulations that may affect a shipment are packaging and labeling requirements, and recycling laws.

Importer's Requirements--The buyer/importer may require documents in addition to the documents required by their government. An importer may need a specific document in order to receive an

import permit from their government, or to obtain financing from their financial institution. Possible documents requested are: pro forma invoice, inspection certificate for grade and condition, or a statement of processing methodology (depending on the level of processing involved).

Additional Documents--Additional documents are required based on the terms of sale, method of payment, and transportation mode. These documents could include a letter of credit, shipper's letter of instruction, certificate of insurance, dock receipt, bill of lading, and air waybill.

Although only the most common documentation requirements will be addressed here, exporters must know all regulations that apply to their shipment.

An experienced freight forwarder can assist exporters in determining what documents are required and can complete much of the documentation on the shipper's behalf. Additional sources for determining documentation requirements for any given shipment are: importer, bank, destination country's consulate, and USDA's Foreign Agricultural Service, Animal and Plant Health Inspection Service, and Food Safety and Inspection Service. Publications like the *Official Export Guide*, Bureau of National Affairs' International Trade Reporter-Export Reference Manual, and Dun's Marketing Services' Exporters' Encyclopaedia also provide this type of information.

Slight discrepancies or omissions in documentation may prevent goods from being exported, may result in the shipper not getting paid, or may even result in seizure of the goods by U.S. or foreign customs agents. Completion of much of the documentation is routine for freight forwarders or customs brokers, but the exporter is ultimately responsible for accuracy of the documentation.

This section looks at the most commonly required documents and includes sample documents.

Pro Forma Invoice

(See Sample Document in PDF format)

Export transactions, particularly first-time transactions, may begin with an inquiry from abroad, followed by a request for a quotation or a pro forma invoice. The pro forma invoice is essentially a quotation in an invoice format. It is a form the buyer uses when applying for an import license or arranging for funds.

The following information should be included on the pro forma invoice:

- Seller's name, address, phone, telex, and FAX numbers
- Buyer's name and address
- Buyer's reference number and date of inquiry
- Listing of requested products and brief description
- Price of each item (preferably to quote in U.S. dollars in order to reduce foreign exchange risk)
- Whether the product is new or used
- Gross and net shipping weight (in metric units where appropriate)
- Total cubic volume and dimensions (in metric units where appropriate) when packed for export
- Trade discount (if applicable)
- Delivery point
- Terms of payment
- Insurance and shipping costs
- Validity period for quotation

- Total charges to be paid by customer
- Estimated shipping date from factory to U.S. port (it is preferable to give U.S. port)
- Estimated date of shipment arrival

In addition to the preceding items, a pro forma invoice should include a statement certifying that the invoice is true and correct and a statement naming the country of origin of the goods. The invoice also should be conspicuously marked "pro forma invoice."

Quotations should state explicitly that they are subject to change without notice. If a specific price has been agreed upon or guaranteed by the exporter, and must be upheld in the quotation, the precise period during which the offer remains valid should be specified.

Commercial Invoice

See sample document in PDF format

The commercial invoice is a bill for the goods. The buyer needs the invoice to prove ownership and to arrange payment. Some governments use the commercial invoice to assess customs duties. Although there is no standard form for a commercial invoice, the following information should be included:

- Seller's name and address
- Buyer's name and address
- Exact description of goods (kind, grade, quality, weight)
- Agreed-upon price (preferably in U.S. dollars in order to reduce foreign exchange risk)
- Type of container
- Description of packages (number, kind, markings)
- Delivery point
- Terms of payment
- Date and place of shipment
- Method of shipment
- Signature of shipper/seller

USDA Inspection Certificates

Agricultural exporters are frequently required to provide a certificate attesting to the condition of the goods shipped. Depending on the product, the USDA, or USDA-certified inspector, will inspect agricultural exports for specific insects and diseases, wholesomeness, and grade and condition, and issue certificates attesting to the product's condition at the time of inspection. Contact information for the USDA agencies that conduct these inspections is included in the Export Advice and Assistance section of this publication. Included among these certificates are:

Phytosanitary Certificate--The purpose of the phytosanitary certificate, Plant Protection and Quarantine (PPQ) form 577, is to expedite the entry of plants or plant products into a foreign country. This certificate certifies to a foreign country that the plants or plant products described were inspected by the U.S. Government and are free from quarantine pests and other injurious pests of specific concern to the importing country. This certificate is completed by USDA's Animal and Plant Health Inspection Service (APHIS). (Downloadable forms from the Animal and Plant Health Inspection Service)

See sample document in PDF format

Export Certificate-Processed Plant Products--The export certificate for processed plant products, PPQ form 578, was created for processed plant products that cannot be given a phytosanitary certificate but have been denied entry to one or more countries because no certification process existed. This certificate certifies to a foreign country that the processed plant product has been inspected by the U.S. Government and that the shipment was processed or manufactured to the extent that there is negligible risk of harboring injurious plant pest of specific concern to the importing country. Examples of products that fall under this category are:

1. Meal extracted from seeds by solvent
2. Bulk newsprint derived from wood pulp
3. Nuts in bulk that are salted, roasted, or vacuum-packed (in or out of their shells)
4. Oilseed cake of any kind
5. Pelletized plant material
6. Soy-fortified products
7. Soy protein, isolated
8. Thread waste from cotton milling
9. Wood products, molding, pressure-treated lumber, particle board, plywood, timber impregnated with creosote, tongue-in-groove flooring, paneling, ceiling, veneer, and furniture parts, either sanded or unsanded

The processed product certificate is also completed by APHIS. (Downloadable forms from the Animal and Plant Health Inspection Service) or See sample document in PDF format.

Federal-State Inspection Certificate-Export Apple Act--Apples exported from the United States must meet minimum quality and other requirements established by the Export Apple Act. This act also requires that USDA, through a Federal or Federal-State inspection service, officially inspects and certifies these fruits as being in compliance with the regulations. The Fruit and Vegetable Division of the USDA Agricultural Marketing Service administers this act. See sample document in PDF format.

Federal-State Inspection Certificate-Export Grape and Plum Act--Vinifera grapes exported from the United States must meet minimum quality and other requirements established by the Export Grape and Plum Act. Export shipments of vinifera grapes must be inspected and certified by the Federal or Federal-State inspection service. Exports of plums are not currently regulated under this act since other regulations already restrict exports of plums to better grades and sizes. The Fruit and Vegetable Division of the USDA Agricultural Marketing Service administers this act. See sample docuement in PDF format.

Voluntary Food Quality Certification--USDA's Agricultural Marketing Service (AMS) offers, for a fee, a voluntary food quality certification service. Quality certificates are offered by the Dairy Division, Fruit and Vegetable Division (for both fresh and processed products), Livestock and Seed Division, and Poultry Division.

Contract Certification--For a fee, AMS will review contracts and work with exporters to develop a written specification for the quality certification of food products.

Meat and Poultry Export Certificate of Wholesomeness--USDA's Food Safety and Inspection Service (FSIS) inspectors located in the U.S.-based, government approved processing/slaughter

facilities issue the meat and poultry export certificate of wholesomeness, FSIS form 9060-5. This certificate certifies that all meat and meat products for human consumption are safe, wholesome, and accurately labeled to meet both the U.S. standards and the receiving country's import requirements.

Additional export certificates issued by FSIS include horsemeat export certificate, inedible product export certificate, and animal casings export certificate. See sample document in PDF format.

Veterinary Health Certificate--USDA's Veterinary Services, a division in APHIS, inspects animals and animal by-products and provides certification that the specific health requirements of the importing country have been met. Downloadable forms from the Animal and Plant Health Inspection Service or See sample document in PDF format.

Organic Certification--With implementation of national organic standards and accreditation of private and State certifiers, foreign buyers will look to the USDA for assurances that the products are produced organically. All producers and handler/processors wishing to label their products as organic must have their production and handling systems certified by USDA-accredited certifiers. These certifiers will also be able to verify that any organic products meet specific additional requirements of foreign buyers. All imported organic products must be produced and certified under systems that are equivalent to the U.S. standards as determined by USDA. This includes imported products that may become ingredients in processed products for export from the United States.

Other Certification Programs--USDA-AMS's Science and Technology Division (STD provides export certification services. STD laboratories test for *Salmonella enteritidis* in poultry products intended for export to South Africa. They also test honey, dry whole milk, and butteroil, and certify that they meet the requirements of the importing countries. STD tests soybeans intended for export to Japan for pesticide residues.

In addition to the USDA agencies listed above, the Grain Inspection, Packers and Stockyards Administration (GIPSA) inspects grain shipments to ensure that they meet contract specifications. Contact information for the USDA agencies that provide these inspection services are listed in the Trade Assistance section of this handbook.

Weight Certification

The Intermodal Safe Container Act of 1992 was enacted to attempt to reduce the number of overweight loads on the Nation's highways. This legislation will affect all agricultural importers and exporters. Effective April 6, 1997, shippers are required to provide weight certifications for intermodal movements of containers or trailers. Shippers are required to provide accurate and complete information to the intermodal carrier, and the carrier will be responsible for transmitting this information to any subsequent carrier.

The following is a brief summary of the requirements, liability, and penalties.

Certification Requirements--All cargoes that are either loaded into trailers or ocean shipping containers that are part of an intermodal movement, that will travel by motor carrier on a U.S. public highway, and weigh more than 29,000 pounds will require certification.

The certificate must include:

- The identification number of the container or trailer.
- The actual gross weight, including all packaging material and pallets.
- A general description of the contents. Shippers should note that the FAK (Freight of all Kinds) cargo designation will not be acceptable after December 31, 2000, for shipments where any one commodity equals or exceeds 20 percent of the total weight. The certificate should note if the cargo is perishable, or likely to shift in transit.
- The identity of the certifying party. No signature is required.
- The date of certification.

Prior to tendering the cargo, the shipper must notify the carrier, either by telephone or electronic transmission, of the gross cargo weight and a general description of the cargo.

The certificate may be incorporated into other shipping documents as long as the document contains all of the required information. The date of transfer of the certificate, and the identity of the party performing the transfer, must be noted on the document. If a separate document is used, it must be conspicuously marked as "Intermodal Certification."

Each carrier transporting the cargo in the intermodal chain is responsible for forwarding the certification to the next carrier. If no certification is received by the subsequent carrier before, or when, the container or trailer is tendered, the subsequent carrier may presume that no certification is required.

Liability--The party tendering the cargo is liable for any false information on the certificate and for failure to provide a certificate. The party transferring the certification data is liable for inaccurately transferred data. The carrier is liable for failure to forward the certificate to the subsequent carrier.

Exceptions--Notification and certification requirements do not apply to intermodal containers or trailers containing consolidated shipments loaded by a motor carrier who performs the highway portion of the movement, or assumes responsibility for weight-related penalties for any other motor carrier.

Penalties--Federal law provides for penalties ranging from $500 to $1,000 per count for violations of the certification requirements. Violations of the act include: improper weight certification, failure to provide certification, failure to forward certification, inaccurate transfer of certification data. Failure to pay fines may result in a lien against the cargo until payment is received, but lien provisions do not apply to perishable agricultural commodities. Shippers should also note that highway weight requirements for State (non-Federal) roads may vary, and they should ensure that intermodal movements meet all local standards.

Contact--For further information regarding weight certification requirements, contact the Federal Highway Administration in Washington, DC, (202) 366-0650.

Packing List

See sample document in PDF format.

The export packing list is considerably more detailed and informative than a standard domestic packing list. An export packing list itemizes the material in each individual package and indicates the

type of package--box, crate, drum, carton, etc. It shows the individual net, legal, tare and gross weights, and measurements for each package (in both imperial and metric units).

- Net weight--Weight of the goods not including packaging.
- Legal weight--Weight of product plus paper, box, bottle, etc., contains the article as usually carried in stock.
- Tare weight--Weight of packaging, or weight of shipping container.
- Gross weight--Weight of goods and packaging.

Package markings should be shown along with the shipper's and buyer's references. The packing list should either be included in or attached to the outside of a package in a waterproof envelope marked "packing list enclosed." The list is used by the shipper or forwarding agent to ascertain the total shipment weight and volume in addition to determining whether the correct cargo is being shipped. In addition, customs officials (both U.S. and foreign) may use the list to check the cargo and assess import duties.

Shipper's Letter of Instruction

See sample document in PDF format.

This document is completed by the shipper and includes all of the information necessary for the freight forwarder or carrier to make transportation arrangements and complete the bill of lading and other related documents. The shipper's letter of instruction should include:

- Shipper's company name, address, phone, fax, and contact name
- Shipper employee identification number
- Shipper reference numbers (bill of lading, invoice, purchase order, etc.)
- Product information (description of goods, product quantity, number of packages, weight in pounds, cubic feet, marks)
- Consignee information
- Notify party
- Product invoice value
- Harmonized commodity code
- Freight and documentation billing information
- Special instructions
- Signature and date

Dock Receipt

See sample document in PDF file.

The dock receipt is used to transfer accountability when the export item is moved by the domestic carrier to the port of embarkation and left with the international carrier for export. There is no standard format for a dock receipt, but it should include a description of shipment and shipping information. This document is traditionally produced by the exporter or the exporter's freight forwarder and is signed by the receiving clerk for the carrier. With more and more ports utilizing electronic data interchange (EDI), this document is being transmitted electronically.

Certificate of Origin

See sample document in PDF file

Certain nations require a signed statement as to the origin of the export item. The certificate is usually obtained through a semi-official organization, such as a local Chamber of Commerce. It may be required even though the commercial invoice contains the information.

Consular Invoice

A consular invoice for imported goods may be required by certain nations. It is used as a means to control and identify imported goods. The invoice must be purchased from the consulate of the country where the goods are being shipped and usually must be prepared in the language of that country.

Insurance Certificate

See sample document in PDF file

If the seller is responsible for providing insurance, the insurance certificate should state the type and amount of coverage. This is a negotiable instrument.

Shipper's Export Declaration

See sample document in PDF file

The U.S. Government requires that exporters complete a Shipper's Export Declaration (SED) for international shipments. The SEDs, forms 7525-V, 7525-V-Alternate (Intermodal), and 7513 (In-Transit Goods), are joint Bureau of the Census/International Trade Administration documents. They include pertinent information on the export transaction such as parties to the transaction, transportation details, Schedule B classification, value of the goods, and export licensing information. The information collected is used for compiling official U.S. export statistics and administering the requirements of the Export Administration Act. SED forms and the Brochure *Correct Way To Fill Out The Shipper's Export Declaration* are available from the Bureau of the Census, Foreign Trade Division, Regulation Branch, Washington, DC 20233, phone (301) 457-2238.

Export Licensing

An export license may be required for filling out the shipper's export declaration. Determining which export authorization to use may appear complex. But in most cases, it is a straightforward process.

There are two types of export authorization: export license and license exception. Licenses are given for transactions, not for individuals or companies. Ninety-five percent of products exported from the United States do not require an export license.

To comply with export licensing regulations, the exporter needs to determine if the product being exported requires an export license. Determining which authorization is needed is based on three factors:

1. What product is being exported? The Government restricts exportation of some products for

reasons of national security, foreign policy, short supply, nuclear proliferation, or terrorist activity. For example, cedar logs require an export license because of short supply. But almost no other agricultural products require an export license for these reasons.

The Bureau of Export Administration (BXA), Department of Commerce, can provide information on how to determine if a product is restricted and requires an export license. The number to call at BXA is (202) 482-4811.

2. Where is the product's final destination? Are there any trade restrictions on products going to this destination? U.S. Government policy restricts trade with some countries. Exporting to a country with trade restrictions is either prohibited or requires an export license. At the time of publication, there are trade embargoes on exports to Iraq, Iran, Cuba, Libya, and North Korea.

To verify that there are no trade restrictions for exporting to any given country, contact the U.S. Department of the Treasury, Office of Foreign Assets Control, 1500 Pennsylvania Avenue NW., Washington, DC 20220, phone (202) 622-2480 or fax (202) 622-1657.

3. What will the product be used for? The Government restricts exportation of some products if they could be used for terrorist activities.

License Exception--If the exporter determines that there are no restrictions on exporting a product to the destination country, there is no need to formally apply for a license. Agricultural exporters ship under a license exception and type "NLR" (no license required) when requested for the license symbol on the shipper's export declaration. A license exception is a broad grant of authority by the U.S. Government to all exporters for certain categories of products. There is no application process for a license exception. Agricultural products usually qualify for this type of license.

Export License--If the exporter determines that the product being shipped is considered by the U.S. Government to be in short supply, or is being shipped to a country with which the U.S. Government has trade restrictions, or could be used for terrorist activities, an export license will be necessary. An export license is a specific grant of authority from the U.S. Government to a particular exporter to export a particular product. This license is granted on a case-by-case basis, either for a single transaction or for a specified period of time. An exporter must apply for an export license. For information on obtaining an export license contact BXA, Department of Commerce. The number to call at BXA is (202) 482-4811.

Although most agricultural shipments are exported using a license exception, exporters should know that violations of the Export Administration Regulations carry both civil and criminal penalties. It is recommended that exporters follow the above procedure to verify that they are using the correct export authorization.

Other U.S. Government agencies may have additional export regulations regarding a given commodity other than the licensing requirements. For instance, exporters of alcoholic beverages must obtain a permit from the Department of the Treasury's Bureau of Alcohol, Tobacco, and Firearms. The U.S. Department of the Interior, Fish and Wildlife Service restricts exportation of endangered wildlife and plants. (See Trade Assistance section of this handbook for contact information.) Many States also have rules and regulations governing exports. A State's department of agriculture can assist exporters in understanding State rules and regulations.

Schedule B Harmonized Commodity Description and Coding System

The United States has adopted the Harmonized Commodity Description and Coding System (HS) for classifying merchandise in international trade. Exporters, freight forwarders, and carriers must report export shipments in terms of the HS on their SEDs. The HS code for any given agricultural product can be obtained from the Department of Commerce publication: Schedule B--Statistical Classification of Domestic and Foreign Commodities Exported from the United States, or by contacting the Bureau of the Census, Foreign Trade Division, Nondurables Section, Washington, DC 20233, (301) 457-3492 or 457-2981.

When filling out the Schedule B commodity number on the SED, be sure to include the entire 10-digit code and the check digit. The Schedule B commodity number's corresponding quantities and shipping weights must be reported on the SED using the metric system. The following conversion factors can be used to convert English weights into metric units.

Approximate Metric Conversion Factors

When You Know Number Of	Multiply By	To Find The Number Of
pounds (lb)	0.4536	kilograms (kg)
long tons (lt)	1.016	metric tons (mt)
short tons (st)	0.907	metric tons (mt)

Bill of Lading

See sample document in PDF format

Ocean bills of lading (b/l) serve three purposes:

- They act as a contract between the owner of the goods and the carrier to deliver the goods, spelling out all legal responsibilities and liability limits for all parties to the shipment.
- They act as receipt from the ocean carrier, confirming that they have received the goods for shipment.
- They act as title to the shipment and can be used to transfer title to the goods to a party named in the document.

The b/l is issued by the steamship line. Bills of lading can be made out in two different ways, "to order" or "direct" (straight). When the b/l is made "to order" it offers protection to the shipper by making it absolutely necessary that the consignee present the original endorsed b/l before the goods will be released from the port of destination. An original endorsed b/l is called a negotiable b/l, and acts as title to the goods. A copy of an original endorsed bill of lading is non-negotiable and cannot act as title to the goods.

Air Waybill

See sample document in PDF format

The air waybill, like the bill of lading, is a contract of carriage between the air carrier and shipper. Due to the short transit times there are no negotiable air waybills. The air waybill is issued by the airline or consolidator.

Sample Transportation Documents

The files below are in Adobe Acrobat [PDF] format. Click on the icon if you need to download the adobe acrobat reader used to view PDF files. If you would like these documents sent to you via mail or facsimile please contact Heidi Reichert at (202) 690-2325. (**These documents are completed samples, not actual forms that can be used in the export process.**)

- Pro Forma Invoice
- Commercial Invoice
- Phytosanitary Certificate (Downloadable forms from the Animal and Plant Health Inspection Service)
- Export Certificate--Processed Plant Products (Downloadable forms from the Animal and Plant Health Inspection Service)
- Federal-State Inspection Certificate--Export Apple Act
- Federal-State Inspection Certificate--Export Grape and Plum Act
- Certificate of Quality and Condition
- Meat and Poultry Export Certificate of Wholesomeness
- Veterinary Health Certificate (Downloadable forms from the Animal and Plant Health Inspection Service)
- Packing List
- Shipper's Letter of Instruction
- Dock Receipt
- Certificate of Origin
- Insurance Certificate
- Shipper's Export Declaration
- Bill of Lading
- Air Waybill

Return to top of page

Pro Forma Invoice

FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A 10000

ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

CARRIER'S BOOKING NUMBER 123456
BILL OF LADING NUMBER APLU123456789
SHIPPER'S REFERENCE NUMBER FOE 001
J.E. REFERENCE NUMBER SF01060423
TRAFFIC MANAGER D. ENBERG
CARRIER'S AGENT AMERICAN PRESIDENT LINES
FORWARDING AGENT (415) 781-7040
J. E. LOWDEN & CO.
275 Battery Street, Ste 400
San Francisco CA 94111-3701
POINT & COUNTRY OF ORIGIN FAX 415-392-3790
CALIFORNIA USA
TLX/EMAIL 404235592

BERTH 223
V. 13
APL JAPAN
PORT OF LOADING
SAN PEDRO
PORT OF DISCHARGE
HONG KONG
FOR TRANSSHIPMENT TO
HONG KONG

PROFORMA INVOICE

100 CARTONS SIZE 88 USA BRAND NAVEL ORANGES AT USD15.70 USD 6280.00

550 CARTONS SIZE 72 USA BRAND NAVEL ORANGES AT USD16.20 USD 8910.00

950 CARTONS C.I.F. HONG KONG USD 15190.00

TERMS OF PAYMENT: CAD T/T TO OUR BANK ACCOUNT
WITHIN 10 DAYS OF SHIPMENT
DATE

THANK YOU
FRESH ORANGE EXPORTER

Source: *J.E. Lowden & Company*

Commercial Invoice

11 MAR 97 INVOICE FOE 001 11 MAR 97

SELLER:

FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U. S. A. 10000

CARRIER'S BOOKING NUMBER 123456
BILL OF LADING NUMBER APLU123456789
SHIPPER'S REFERENCE NUMBER FOE 001
JEL REFERENCE NUMBER SF01060423
TRAFFIC MANAGER D. ENBERG
CARRIER'S AGENT AMERICAN PRESIDENT LINES
FORWARDING AGENT (415)781-7040
J. E. LOWDEN & CO. FMC 87
275 Battery Street #400
San Francisco, CA 94111

POINT & COUNTRY OF ORIGIN
CALIFORNIA USA
CUSTOMER ORDER NO:
TERMS OF SALE:
C. I. F. HONG KONG

SOLD TO:
ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

SHIP TO:

PIER/TERMINAL
BERTH 223
SAN PEDRO

VESSEL VOYAGE # FLAG V. 13
APL JAPAN

PORT OF LOADING
SAN PEDRO

PORT OF DISCHARGE
HONG KONG

FOR TRANSHIPMENT TO
HONG KONG

DESCRIPTION	SIZE	PRICE	AMOUNT
400 CARTONS	88	15.70	6,280.00
550 CARTONS	72	16.20	8,910.00

TOTAL 950 CARTONS "USA BRAND" FRESH NAVEL ORANGES USD 15,190.00
C. I. F. HONG KONG

WE CERTITY THAT THIS INVOICE IS TRUE AND CORRECT. WE CERTIFY THAT THE MERCHANDISE IS ORIGIN OF THE U. S. A.

FRESH ORANGE EXPORTER
WE HEREBY CERTIFY THAT
THIS INVOICE IS TRUE
AND CORRECT

Source: *J.E. Lowden & Company*

Phytosanitary Certificate

No phytosanitary certificate can be issued until an application is completed (7 CFR 353). See reverse for additional OMB information. FORM APPROVED OMB NO. 0579-0052

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

PHYTOSANITARY CERTIFICATE

FOR OFFICIAL USE ONLY

PLACE OF ISSUE

NO. FPC 2000003

DATE INSPECTED

TO: THE PLANT PROTECTION ORGANIZATION(S) OF

CERTIFICATION

This is to certify that the plants, plant products described below have been inspected according to appropriate procedures and are considered to be free from quarantine pests, and practically free from other injurious pests; and that they are considered to conform with the current phytosanitary regulations of the importing country.

DISINFESTATION AND/OR DISINFECTION TREATMENT

1. DATE	2. TREATMENT
3. CHEMICAL (active ingredient)	4. DURATION AND TEMPERATURE
5. CONCENTRATION	6. ADDITIONAL INFORMATION

DESCRIPTION OF THE CONSIGNMENT

7. NAME AND ADDRESS OF THE EXPORTER	8. DECLARED NAME AND ADDRESS OF THE CONSIGNEE
9. NAME OF PRODUCE AND QUANTITY DECLARED	10. BOTANICAL NAME OF PLANTS
11. NUMBER AND DESCRIPTION OF PACKAGES	12. DISTINGUISHING MARKS
13. PLACE OF ORIGIN	14. DECLARED MEANS OF CONVEYANCE
	15. DECLARED POINT OF ENTRY

Any intentional false statement in this phytosanitary certificate or misrepresentation relative to this phytosanitary certificate is a violation of law, punishable by a fine of not more than $10,000, or imprisonment of not more than 5 years, or both. (18 U.S.C. 1001)

ADDITIONAL DECLARATION

NAPPO

16. DATE ISSUED	17. NAME OF AUTHORIZED OFFICER (Type or Print)	18. SIGNATURE OF AUTHORIZED OFFICER

No financial liability shall attach to the United States Department of Agriculture or to any officer or representative of the Department with respect to this certificate.

PPQ FORM 577
(JUN 98)

Previous editions of PPC series may be used.

PART 1 - SHIPPER'S ORIGINAL

Source: *USDA Animal and Plant Health Inspection Service*

Export Certificate—Processed Plant Products

FORM APPROVED
OMB NO. 0579-0052

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

FOR OFFICIAL USE ONLY

EXPORT CERTIFICATE
PROCESSED PLANT PRODUCTS

PLACE

DATE

NUMBER P 072608

NAME AND ADDRESS OF EXPORTER

NAME AND ADDRESS OF CONSIGNEE

MEANS OF CONVEYANCE

POINT OF ENTRY

DESCRIPTION OF CONSIGNMENT

PRODUCT (Botanical Quantity, and Weight)

IDENTIFICATION

ORIGIN

This is to affirm that, based upon inspection of submitted samples and/or by virtue of processing received, the plant products described above are believed to be free from injurious plant pests.

NAME OF AUTHORIZED OFFICER

SIGNATURE

No liability shall attach to the United States Department of Agriculture or to any officer or representative of the Department with respect to this certificate.

PPQ FORM 578
(OCT 91)

PART 1 - SHIPPER'S ORIGINAL

SAMPLE

Source: *USDA Agricultural Marketing Service*

Federal-State Inspection Certificate—Export Apple and Pear Act

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FRUIT AND VEGETABLE DIVISION

EXPORT FORM CERTIFICATE
FOR NON - CANADIAN DESTINATIONS

X — 021655-6

INSPECTION STARTED: 0 9 2 2 9 7
INSPECTION COMPLETED: 0 9 2 2 9 7

APPLICANT / SHIPPER: PAPA'S PEARS AND APPLES — CITY / STATE: COURTLAND, CA

RECEIVER: MAMA'S PEARS AND APPLES, LTD — CITY / COUNTRY: LONDON, ENGLAND

☐ CARRIER ID ☒ PLI No. CA FSL 922-SAC — CERT. / WORKSHEET NUMBER: N/A

APPLES	400 CTNS	"EXPORT" FUJI, 72 COUNT PRODUCE OF USA	US EXTRA FANCY
	ALL APPLES SHOW 50% TO 100%, MOSTLY 50% to 75% BLUSH OR RED SURFACE COLOR. MOSTLY HARD SOME FIRM. DEFECTS WELL WITHIN TOLERANCE, NO DECAY		
PEARS	400 CTNS	"EXPORT" BARTLETT, 110 COUNT PRODUCE OF USA	US NO. 1
	MOSTLY HARD, MANY FIRM, GROUND COLOR MOSTLY LIGHT GREEN, SOME GREEN. DEFECTS WITHIN TOLERANCE. NO DECAY		

THIS IS TO CERTIFY THAT THE ☒ APPLES, ☒ PEARS, ☐ TABLE GRAPES IN THE ABOVE IDENTIFIED LOT(S) HAVE BEEN INSPECTED AT THE PLACE AND DATE STATED ABOVE, AND FOUND TO MEET THE REQUIREMENTS OF THE:

☒ Export Apple and Pear Act ☐ Export Grape and Plum Act
☐ Export Grape and Plum Act except for export to destinations in Europe, Greenland, or Japan.

REMARKS: APPLICANT STATES ABOVE PRODUCTS TO BE AIR SHIPPED TO DESTINATION.

DATA BLOCK - FOR USDA USE ONLY

APPLICANT NO.: 21

C. M. Inspector — 9/22/97
INSPECTOR'S SIGNATURE — DATE ISSUED

FEE: $
OVERTIME:
EXPENSES:
ESTIMATED TOTAL: $

Issuing Office: WEST SACRAMENTO, CA

VESSEL: VOYAGE NO.: CONTAINER NO.:

OTHER RELEVANT SHIPPING INFORMATION:

AUTHORIZED REPRESENTATIVE:

FORM FV-207 (07/92)

ORIGINAL / APPLICANT

Source: *USDA Agricultural Marketing Service*

Federal-State Inspection Certificate—Export Grape and Plum Act

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FRUIT AND VEGETABLE DIVISION

EXPORT FORM CERTIFICATE

FOR NON - CANADIAN DESTINATIONS

X — 021653-1

DATE INSPECTED: 09 15 97
DATE ISSUED: 09 15 97

APPLICANT / SHIPPER: ABC TABLE GRAPES — CITY / STATE: DELANO, CA
RECEIVER: MONGOLIAN TRADING CO. — CITY / COUNTRY: BEJING, CHINA
☐ CARRIER ID ☒ PLI No. CA FSL 945 - DEL — CERT. / WORKSHEET NUMBER: N/A

TABLE GRAPES	540 LUGS	"CHINA GOLD" FLAME SEEDLESS PRODUCE OF USA	U.S. No. 1 TABLE
	BUNCHES	MOSTLY MEDIUM, SOME SMALL	
	BERRIES	MOSTLY MEDIUM, SOME SMALL	
	MOSTLY	WELL, MANY REASONABLY WELL COLORED	
	DEFECTS	AVERAGE WITHIN TOLERANCE	

SAMPLE

THIS IS TO CERTIFY THAT THE ☐ APPLES ☐ [illegible] ☒ GRAPES
IDENTIFIED LOT(S) HAVE BEEN INSPECTED AND FOUND TO
MEET THE REQUIREMENTS OF THE
☐ [illegible] ☐
☒ Export Control and Terms Agreement

REMARKS:

STATE BLOCK - FOR USDA USE ONLY
CONNECTION BY CERTIFICATE NO.:
APPLICANT NO.:
BOX #:
OVERTIME:
EXPENSES:

I. M. Inspector — 9/15/97
Issuing Office: DELANO, CA

FEE: $
OVERTIME:
EXPENSES:
$

VESSEL: VOYAGE NO.: CONTAINER NO.:
OTHER RELEVANT SHIPPING INFORMATION: BOOKING # A-1357-BC1-89
AUTHORIZED REPRESENTATIVE:

FORM FV-207 (07 / 92)

ORIGINAL / APPLICANT

Source: *USDA Agricultural Marketing Service*

Certificate of Quality and Condition

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

CERTIFICATE OF QUALITY AND CONDITION
(PROCESSED FOODS)

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained. It does not excuse failure to comply with any applicable Federal or State laws. WARNING: Any person who knowingly falsely make, issue, alter, forge, or counterfeit this certificate, or participate in any such action is subject to a fine of not more than $1,000 or imprisonment for not more than one year, or both (7 U.S.C. 1622 (h)).
The conduct of all services and the licensing of all personnel under the regulations governing such services shall be accomplished without discrimination as to race color, religion, sex or national origin.

Please refer to this certificate by number and inspection office

166-A-1
December 1996
EXHIBIT 3

DATE
March 5

APPLICANT ABC Frozen Foods	**ADDRESS** Portland, Oregon 97206
RECEIVER OR BUYER Trappe Trading Co.	**ADDRESS** London, England
SOURCE OF SAMPLES Submitted by Applicant	**PRODUCT INSPECTED** FROZEN WHOLE KERNEL CORN

CODE MARKS ON CONTAINERS

T34; and T36...

PRINCIPAL LABEL MARKS

"Frozen Cut Corn net weight 16 ounces. Distributed by Major, Inc. Sacramento, California 92210"

Net weights: 16.0 and 16.2 ounces
Color: Golden (or yellow)

SAMPLE

GRADE:

U. S. Grade C or U. S. Standard
Score: 75 points each
CERTIFICATE RESTRICTED: This certificate covers the examination of 2-16 ounce cartons submitted by applicant and does not officially represent any lot.

REMARKS:

Exporter declares this consignment is for 800 cases, 24/16 ounce containers, (19,200 pounc applicant's count and weight), and covered by loading manifest number A-3345.

Pursuant to the regulations issued by the Secretary of Agriculture under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621-1627), governing the inspection and certification of the product designated herein, I certify that the quality and condition of the product as shown by samples inspected on the above date were as shown, subject to any restrictions specified above.

ADDRESS OF INSPECTION OFFICE
340 High Street, NE
Salem, Oregon 97301-3631
(503) 399-5761

SIGNATURE OF INSPECTOR
John Doe

FORM FV-146-S (9-92)

Source: *USDA Agricultural Marketing Service*

Meat and Poultry Export Certificate of Wholesomeness

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
MEAT AND POULTRY INSPECTION OPERATIONS

MEAT AND POULTRY EXPORT CERTIFICATE OF WHOLESOMENESS

A knowingly false entry or false alteration of any entry on this certificate may result in a fine of not more than $10,000 or imprisonment for not more than five years or both. (18 USC 1001). Additional penalties exist under the Federal Meat Inspection Act (21 USC 617 (b) (1), (2), and (3), 21 USC 676) and the Poultry Products Inspection Act (21 USC 458 (b) (1), (2), and (3), 21 USC 461) for an unauthorized or false alteration or misuse of this certificate.

AREA OFFICE	COUNTRY OF DESTINATION	DATE ISSUED	MPC - 339824
Long Beach, CA	Singapore	June 9, 1997	

EXPORTED BY (Applicant's name and address including ZIP Code)

Columbia Trading Co.
33 Pacific View Ave.
Torrance, CA 90509

PRODUCT EXPORTED FROM:

EST. / PLANT NUMBER (If applicable)

Est. 3000X

CITY

Los Angeles, CA

CONSIGNED TO (Name and address, including ZIP Code)

Columbia Trading Co.
26 Harbor St.
Singapore

- ☐ @ SLAUGHTERING PLANT
- ☐ @ PROCESSING PLANT
- ☒ @ WAREHOUSE
- ☐ @ DOCKSIDE

TOTAL MARKED NET WEIGHT	TOTAL CONTAINERS
42,000 lbs.	1207

PRODUCT AS LABELED	MARKED WEIGHT OF LOT 1/	NUMBER OF PACKAGES (MARKS) 1/	SHIPPING MARKS 1/	EST. / PLANT NUMBER ON PRODUCT
Frozen Beef Tenderloins	3550 lbs.	50	6/336/Singapore	Est. 38
Frozen Beef Short Ribs	3700 lbs.	"	" "	Est. 38
Beef Stew 24 oz.	3200 lbs.	140	" "	Est. 38
Frozen Corned Beef Brisket	3900 lbs.	50	" "	Est. 00
Assorted beef Jerky 12-8 oz.	1200 lbs.	200	" "	Est. 00
Frozen Fryer Parts	6000 lbs.	150	" "	P-42
Frozen Chicken Wings	3200 lbs.	80	" "	P-42
White Turkey Rolls	9700 lbs.	235	" "	P-00
Raw Turkey Breast	6450 lbs.	150	" "	P-00
Cooked Boneless Diced Chicken Meat	6060 lbs.	202	" "	P-42X

1/ As stated by applicant or contractor

SAMPLE

REMARKS
The canned products have been manufactured and inspected in accordance with Section 318.11 of USDA regulations.

☒ I CERTIFY that the meat or meat food product specified hereon is from animals that received both antemortem and postmortem inspection and were found sound and healthy and that it has been inspected and passed as provided by law and regulations of the Department and is sound and wholesome.

☒ I CERTIFY that the poultry and poultry products specified above came from birds that were officially given an antemortem and postmortem inspection and passed in accordance with applicable laws and regulations of the United States Department of Agriculture and are wholesome and fit for human consumption.

NOT VALID UNLESS SIGNED BY AN INSPECTOR OF MEAT AND POULTRY INSPECTION PROGRAM

By order of the Secretary of Agriculture

INSPECTOR AND CIRCUIT NUMBER

James R. David, DVM 202-21

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained.
This certificate does not excuse failure to comply with any of the regulatory laws enforced by the United States Department of Agriculture.

FSIS FORM 9060-5 (9/92) REPLACES PSIC FORM 9060-5 (5/95), WHICH MAY BE USED UNTIL EXHAUSTED. REPLACES MP FORM 130 (2/45), WHICH IS OBSOLETE

ORIGINAL

Source: *USDA Food Safety and Inspection Service*

Veterinary Health Certificate

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

EXPORT CERTIFICATE
ANIMAL PRODUCTS

FOR OFFICIAL USE ONLY

Port:

Date and No. EXAMPLE ONLY

This is to certify that rinderpest, foot-and-mouth disease, and contagious bovine pleuropneumonia do not exist in the United States of America.

ADDITIONAL DECLARATION

THE PLANT OF ORIGIN CERTIFIES THAT THE MATERIALS USED IN THE MANUFACTURING OF THE DEGREASED BONE CHIPS TO BE SHIPPED WERE FROM ANIMALS SLAUGHTERED UNDER THE SUPERVISION OF USDA AND PROCESSED AT A FACILITY CAPABLE OF SUBJECTING THE RAW MATERIALS TO A TEMPERATURE OF 260 DEGREES FAHRENHEIT AND THAT THE DRY RENDERED PRODUCT HAS BEEN SUBJECTED TO A TREATMENT OF 210-250 DEGREES FAHRENHEIT FOR A PERIOD OF AT LEAST ONE AND ONE HALF HOURS.

USDA, APHIS, VETERINARY SERVICES HAS ON FILE A LETTER ATTESTING TO THE ABOVE.

(Signature)

APHIS OFFICER
(Title)

DESCRIPTION OF THE CONSIGNMENT

NAME AND ADDRESS OF EXPORTER

EXCEL CORPORATION
123 Main Street
Anywhere, MD 12345

NAME AND ADDRESS OF CONSIGNEE

Mr. Marolo Garcia
USDA/APHIS/VS/NCIE
4700 River Road, Unit 40
Riverdale, MD 20737

PRODUCT (Kind, quantity, weight)

4 CONTAINERS, BONES GROUND AND ARE CHIPS AT 178660.0 POUNDS

IDENTIFICATION

CONVEYANCE

No liability shall accrue to the United States Department of Agriculture or to any officer or representative of the Department with respect to this certificate

VS FORM 16-4
(NOV 72)

Source: *USDA Animal and Plant Health Inspection Service*

Packing List

PACKING LIST

SHIPPER:
FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A. 10000

CARRIER'S BOOKING NUMBER 123456 10 MAR 97
BILL OF LADING NUMBER APLU123456789
SHIPPER'S REFERENCE NUMBER FDE 001
J.E.L. REFERENCE NUMBER SF01060423
TRAFFIC MANAGER D. ENBERG
CARRIER'S AGENT AMERICAN PRESIDENT LINES
FORWARDING AGENT 415-781-7040
J. E. LOWDEN & CO. FMC 87
275 Battery Street, Ste 400
San Francisco CA 94111-3701
FAX (415)392-3970
POINT & COUNTRY OF ORIGIN CALIFORNIA USA

NOTIFY PARTY:

ORIENTAL FRESH FOODS
136 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

PIER/TERMINAL
BERTH 223
SAN PEDRO
VESSEL VOYAGE + FLAG V. 13
APL JAPAN
PORT OF LOADING
SAN PEDRO
PORT OF DISCHARGE
HONG KONG
FOR TRANSSHIPMENT TO
HONG KONG

MARKS & NOS.	NO. PKGS.	DESCRIPTION OF GOODS	GRS. WEIGHT	MEASUREMENT
CONTAINER APLU 596327-1	950	CARTONS FRESH ORANGES 1/BOX FL CY/CY CONTAINER SHIPPERS LOAD AND COUNT (NET WEIGHT 35,150 LBS.) CARGO UNDER REFRIGERATION MAINTAIN TEMPERATURE AT 42 DEGREE F VENTS 45 CFM	39900# 18098K	1140 ' 32.280M3
	950	TOTAL	39900# 18098K	1140 ' 32.280M3

WE HEREBY CERTIFY THAT THE ABOVE WEIGHTS ARE
TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE.

FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A. 10000

D. ENBERG

Source: *J.E. Lowden & Company*

Shipper's Letter of Instruction

SHIPPER'S INSTRUCTIONS & CONFIRMATION MEMO

J. E. LOWDEN & CO. - International Freight Forwarders 275 Battery Street, Suite 400, San Francisco, CA 94111
FMC#87 PHONE: (415) 781-7040 FAX: (415) 392-3970

SHIPPER / EXPORTER

SHIPPER TO ENTER INFO & SEND TO LOWDEN OR LOWDEN TO RECORD INFO FROM PHONE CALL THEN ADD INFO & SEND TO SHIPPER OR OTHERS

LOWDEN FILE NO. SF010

EXPORTER'S REFERENCE | SHIPPER'S REP

SERVICE CONTRACT | LOWDEN'S REP

CONSIGNEE

OCEAN CARRIER

BOOKING NUMBER | DATE BOOKED

POINT & COUNTRY ORIGIN

NOTIFY PARTY

SUPPLIER / LOCATION OF CARGO FOR PICK UP

LAST RECEIVING DATE & TIME | SAIL DATE | ARRIVAL DATE

PIER / TERMINAL

TERMINAL CHARGES PREPAID___ COLLECT___

OCEAN FREIGHT CHARGES PREPAID___ COLLECT___

TRUCK / RAIL CARRIER | PLACE OF RECEIPT

TEMPERATURE SETTINGS___ VENTS___

VESSEL / VOYAGE | PORT OF LOADING

RATES & COMMENTS

PORT OF DISCHARGE | PLACE OF DELIVERY

MARKS & NUMBERS	NUMBER OF PACKAGES	DESCRIPTION OF CARGO (SHOW SUFFICIENT DETAIL TO DETERMINE SCHEDULE B NUMBER)	GROSS WEIGHT & CUBIC MEASURE	NET QUANTITY, UNITS & FAS VALUE FOR SED

DECLARED VALUE FOR CUSTOMS: US$

HAZARDOUS: YES___ NO___ EXPORT LICENSE: YES___ NO___ NEED MARINE INSURANCE: YES___ NO___

(Additional details and documents required if hazardous or licensed)

POWER OF ATTORNEY - DESIGNATION OF FORWARDING AGENT

I hereby authorize J. E. Lowden & Co. to act as our forwarding agent for export control and customs purposes, and to perform other acts to facilitate this export shipment on our behalf. We also authorize J. E. Lowden & Co. to delegate this authority to their agents or representatives.

Name:_____ Date:_____

Title:_____ Shipper's EIN:_____

Required unless a separate power of attorney is on file at J. E. Lowden & Co.

TRANSMITTAL RECORD

DATE OF INSTRUCTIONS FROM SHIPPER_____

INSTRUCTIONS BY: PHONE___ FAX___ IN PERSON___

DATE MEMO SENT BY FORWARDER:___

SUBSEQUENT COMMUNICATIONS:

TO_____ FROM_____ DATE___

TO_____ FROM_____ DATE___

TO_____ FROM_____ DATE_____

Source: *J.E. Lowden & Company*

Dock Receipt

DOCK RECEIPT

SHIPPER/EXPORTER FRESH ORANGE EXPORTER 123 FIRST STREET AMERICAN CITY, U.S.A. 10000	DOCUMENT NO. BOOKING#:123456 APLU123456789 EXPORT REFERENCES SHIPPER'S REF NO: FOE 001 JEL REF NO: SF01060423 SC#
CONSIGNEE ORIENTAL FRESH FOODS 456 ORIENTAL BEND ROAD KOWLOON, HONG KONG	FORWARDING AGENT - REFERENCES J.E. LOWDEN & CO. FMC87 - CHB5118 275 Battery Street #400 San Francisco, CA 94111 POINT AND COUNTRY OF ORIGIN CALIFORNIA USA
NOTIFY PARTY ORIENTAL FRESH FOODS 456 ORIENTAL BEND ROAD KOWLOON, HONG KONG	DOMESTIC ROUTING/EXPORT INSTRUCTIONS
PIER OR AIRPORT SAN PEDRO	
EXPORTING CARRIER (Vessel/Air/Truck) APL JAPAN	PORT OF LOADING SAN PEDRO
FIRST PORT OF DISCHARGE HONG KONG	FOR TRANSHIPMENT TO HONG KONG
	ONWARD INLAND ROUTING BERTH 223

PARTICULARS FURNISHED BY SHIPPER

MARKS AND NUMBERS	NO. OF PKGS.	DESCRIPTION OF PACKAGES AND GOODS	GROSS WEIGHT	MEASUREMENT
FREIGHT PREPAID		TERMINAL CHARGES PREPAID		
CONTAINER APLU 596327-1	950	CARTONS FRESH ORANGES (1 X 40 FT. CY/CY CONTAINER SHIPPERS LOAD AND COUNT (NET WEIGHT 35,150 LBS.) CARGO UNDER REFRIGERATION MAINTAIN TEMPERATURE AT 42 DEGREE F VENTS 45 CFM	39900# 18098K	1140' 32.280M³
	950	TOTAL LADEN ON BOARD		
LICENSE EXCEPTION: NLR NO SED REQUIRED, SEC 30		29 FTSR, CAS-JL TOTAL	39900# 18098K	1140' 32.280M³

SAMPLE

DELIVERED BY:

LIGHTER .....
TRUCK

ARRIVED- DATE .....TIME .....

UNLOADED-DATE .....TIME .....

CHECKED BY.....

PLACED IN SHIP / ON DOCK LOCATION .....

902
WIRE NO. 0940
JOB NO. H 6648

RECEIVED THE ABOVE DESCRIBED GOODS OR PACKAGES SUBJECT TO ALL THE TERMS OF THE UNDERSIGNED'S REGULAR FORM OF DOCK RECEIPT AND BILL OF LADING WHICH SHALL CONSTITUTE THE CONTRACT UNDER WHICH THE GOODS ARE RECEIVED, COPIES OF WHICH ARE AVAILABLE FROM THE CARRIER ON REQUEST AND MAY BE INSPECTED AT ANY OF ITS OFFICES.

FOR THE MASTER

BY .....
RECEIVING CLERK

DATE .....

ONLY CLEAN DOCK RECEIPT ACCEPTED.

Source: *J.E. Lowden & Company*

Certificate of Origin

CERTIFICATE OF ORIGIN

SHIPPER:
FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A. 10000

CARRIER'S BOOKING NUMBER: 123456
B/L OR LADING NUMBER: APLU123456789
SHIPPER'S REFERENCE NUMBER: FOE 001
B/L REFERENCE NUMBER: SF01060423
TRAFFIC MANAGER: D. ENBERG
CARRIER'S AGENT: AMERICAN PRESIDENT LINES
FORWARDING AGENT:
J. E. LOWDEN & CO. FMC 87
275 Battery Street #400
San Francisco, CA 94111
PHONE (415) 781-7040
FAX (415) 392-3970
TLX/EMAIL 404235592

POINT & COUNTRY OF ORIGIN: CALIFORNIA USA

NOTIFY PARTY:
ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

ALSO NOTIFY:

PIER/TERMINAL: BERTH 223
SAN PEDRO
VESSEL/VOYAGE + FLAG: APL JAPAN V. 13
PORT OF LOADING: SAN PEDRO
PORT OF DISCHARGE: HONG KONG
FOR TRANSSHIPMENT TO: HONG KONG

SAMPLE

MARKS & NOS.	NO. PKGS	DESCRIPTION OF GOODS	GRS WEIGHT	MEASUREMENT
CONTAINER APLU 596327-1	950	CARTONS FRESH ORANGES 1/40 FT. CYWCY CONTAINER SHIPPER'S LOAD AND COUNT (NET WEIGHT 35,150 LBS.) CARGO UNDER REFRIGERATION MAINTAIN TEMPERATURE AT 42 DEGREE F VENTS 45 CFM	39900# 18098K	1140 ' 32.280M3
	950	TOTAL	39900# 18098K	1140 ' 32.280M3

LADEN ON BOARD 11 March 97

PREPAID

THE UNDERSIGNED, D. ENBERG (AGENT), DOES HEREBY DECLARE FOR THE ABOVE NAMED SHIPPER, THE GOODS DESCRIBED ABOVE WERE SHIPPED ON THE ABOVE DATE AND CONSIGNED AS INDICATED AND ARE PRODUCTS OF THE UNITED STATES OF AMERICA, DATED AT SAN FRANCISCO, CALIFORNIA ON 12 March 97

SIGNATURE OF OWNER OR AGENT

Source: *J.E. Lowden & Company*

Insurance Certificate

INSURANCE CERTIFICATE

AMERICAN NATIONAL
FIRE INSURANCE COMPANY
1350 Treat Blvd #470
Walnut Creek, CA 94596

CARRIER'S BOOKING NUMBER 123456
BILL OF LADING NUMBER APLU123456789
SHIPPER'S REFERENCE NUMBER FOE 001
JEL REFERENCE NUMBER SF01060423
TRAFFIC MANAGER D. ENBERG
CARRIER'S AGENT AMERICAN PRESIDENT LINES
FORWARDING AGENT
J. E. LOWDEN & CO.
275 BATTERY ST. #400
SAN FRANCISCO, CA 94111

We hereby certify that on , we the undersigned, insured under, and subject to the terms and conditions of Policy No. OMC-7567613 (terms, conditions, endorsements, riders attached) for
FRESH ORANGE EXPORTER
123 FIRBT STRFET
AMERICAN CITY, U.S.A. 10000

POINT & COUNTRY OF ORIGIN
CALIFORNIA, USA

__ FPAEC
__ With Average, irrespective of percentage
X All Risk Refrigeration Clause
__ Theft, P.D. Average & Non-delivery
__ Air Clauses

IN THE SUM OF: $16709.00 +US

This insurance is subject to the following Current American Institute Clauses: Amended F.C.&S. Warranty, S.R.&C.C. Endorsement, Marine Extension Clauses, WarRisk Insurance, 60 Day South American Clause, American Institute WAREHOUSE to WAREHOUSE Clause.

PIER/TERMINAL
BERTH 223

SAN PEDRO
PORT OF LOADING
SAN PEDRO

VESSEL VOYAGE + FLAG 13
APL JAPAN

PORT OF DISCHARGE
HONG KONG

FOR TRANSSHIPMENT TO
HONG KONG

SAMPLE

MARKS	PKGS	DESCRIPTION	GRS WEIGHT/MEASURE	
CONTAINER	950	CARTONS FRESH ORANGES	39900#	1140
APLU 596327-1		1/40 FT. CY/CY CONTAINER	18098K	32.280M3
		SHIPPERS LOAD AND COUNT		
		(NET WEIGHT 35,150 LBS.)		
		CARGO UNDER REFRIGERATION		
		MAINTAIN TEMPERATURE AT 42 DEGREE F		
		VENTS 45 CFM		
	950	TOTAL	39900#	1140
			18098K	32.280M3

In case of loss the same is payable to the order of the Assured.
This certificate invalid unless countersigned by an authorized representative of this Company or ASSURED.

D. ENBERG

Source: *J.E. Lowden & Company*

Source: J.E. Lowden & Company

Shipper's Export Declaration

U.S. DEPARTMENT OF COMMERCE - BUREAU OF THE CENSUS - INTERNATIONAL TRADE ADMINISTRATION

FORM 7525-V-ALT. (Intermodal) (1-1-88) **SHIPPER'S EXPORT DECLARATION**

CONFIDENTIAL - For use solely for official purposes authorized by the Secretary of Commerce (13 U.S.C. 301 (g)).

OMB No. 0607-0152

DO NOT USE THIS AREA

2. EXPORTER (Principal or seller licensee and address including ZIP Code)
FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A. 10000
ZIP CODE

3. CONSIGNED TO
ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

4. NOTIFY PARTY/INTERMEDIATE CONSIGNEE (Name and address)

5. DOCUMENT NUMBER
NAWB:618-4260-9732HAWBSR

5a. B/L OR AWB NUMBER
0-001974

6. EXPORT REFERENCES
SHIPPER'S REF NO: 11334
JEL REF NO: SF03001924

7. FORWARDING AGENT (Name and address - references)
J.E. LOWDEN & CO IATA 01-1-3839/024
510 MYRTLE AVE.,SUITE 210
S.SAN FRANCISCO,CA. 94080

8. POINT (STATE) OF ORIGIN OR FTZ NUMBER

9. DOMESTIC ROUTING/EXPORT INSTRUCTIONS

AUTHENTICATION (When required)

29. THE UNDERSIGNED HEREBY AUTHORIZES
TO ACT AS FORWARDING AGENT FOR EXPORT CONTROL AND CUSTOMS PURPOSES.
EXPORTER (BY DULY AUTHORIZED OFFICER OR EMPLOYEE)

30. METHOD OF TRANSPORTATION (Mark one)
☐ Vessel ☐ Other - Specify
☒ Air

31. ULTIMATE CONSIGNEE (Give name and address if other than item 3)
SAME AS ITEM 4

32. DATE OF EXPORTATION (Not required for vessel shipments)

33. COUNTRY OF ULTIMATE DESTINATION
HONG KONG

34. EXPORTER'S EIN (IRS) NUMBER

35. PARTIES TO TRANSACTION
☐ Related ☒ Non-Related

Export shipments are subject to inspection by U.S. Customs Service and/or Office of Export Enforcement.

12. PRE-CARRIAGE BY

13. PLACE OF RECEIPT BY PRE-CARRIER
SAN FRANCISCO /HONG KONG

14. EXPORTING CARRIER
SINGAPORE AIRLINES

15. PORT OF LOADING/EXPORT
SAN FRANCISCO AIRPORT

16. LOADING PIER (Vessel only)

16. FOREIGN PORT OF UNLOADING (Vessel and air only)
HONG KONG

17. PLACE OF DELIVERY BY ON-CARRIER

11. TYPE OF MOVE

11a. CONTAINERIZED (Vessel only)
☐ Yes ☒ No

MARKS AND NUMBERS (18)	NUMBER OF PACKAGES (19)	DESCRIPTION OF COMMODITIES (Schedule B Code) (20)	GROSS WEIGHT (KILOS) (21)	MEASUREMENT (22)	D OR F (23)
	400	ORANGES IN CARTONS 1.25 CU FT/CTN	7200K		D

24. SCHEDULE B NO. 0805.10 CD
25a. QUANTITY 1 6800 K
25b. QUANTITY 2
26. VALUE 4000

24. SCHEDULE B NO. CD
25a. QUANTITY 1
25b. QUANTITY 2
26. VALUE

24. SCHEDULE B NO. CD
25a. QUANTITY 1
25b. QUANTITY 2
26. VALUE

27. VALIDATED LICENSE NO./GENERAL LICENSE SYMBOL
NLR

28. ECCN (When required)

36. I certify that all statements made and all information contained herein are true and correct and that I have read and understand the instructions for preparation of this document, set forth in the "Correct Way to Fill Out the Shipper's Export Declaration." I understand that civil and criminal penalties, including forfeiture and sale, may be imposed for making false or fraudulent statements herein, failing to provide the requested information, or for violation of U.S. laws on exportation (13 U.S.C. Sec. 305; 22 U.S.C. Sec 401; 18 U.S.C. Sec 1001; 50 U.S.C. App. 24 10)

D. [illegible] JE LOWDEN & CO.

(Signature) (Title) (Date)

The "Correct Way to Fill Out the Shipper's Export Declaration" is available from the Bureau of the Census, Washington, D.C. 20233

SAMPLE

Bill of Lading

GLOBETRANS, INC.

BILL OF LADING
FOR COMBINED TRANSPORT AND PORT TO PORT SHIPMENT
NOT NEGOTIABLE UNLESS CONSIGNED "TO ORDER"

EXPORTER (NAME)
FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A. 10000

BILL OF LADING NUMBER: BOOKING#:123456
CONTAINER NUMBER: APLU123456789

EXPORT REFERENCES
SHIPPER'S REF NO: FOE 001
JEL REF NO: SF01060423
SC#

CONSIGNED TO
ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

FORWARDING AGENT
J.E. LOWDEN & CO. FMC87 - CHB5118
275 Battery Street #400
San Francisco, CA 94111

POINT (STATE) OF ORIGIN OR FTZ NUMBER
CALIFORNIA USA

NOTIFY PARTY (IF NOT SHOWN IN "CONSIGNED TO")
ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

DESTINATION AGENT

PRE-CARRIAGE BY

PLACE OF RECEIPT BY PRE-CARRIER
SAN PEDRO

VESSEL: V.13
PORT OF LOADING / EXPORT: SAN PEDRO
BERTH 223

APL JAPAN
FOREIGN PORT OF UNLOADING: HONG KONG
PLACE OF DELIVERY BY ON-CARRIER: HONG KONG

CARRIER'S RECEIPT		PARTICULARS FURNISHED BY SHIPPER		
MARKS AND NUMBERS	NO. OF PKGS	DESCRIPTION OF PACKAGES AND GOODS	GROSS WEIGHT	MEASUREMENT
FREIGHT PREPAID		TERMINAL CHARGES PREPAID		
CONTAINER	950	CARTONS FRESH ORANGES		
APLU 596327-1		1/40 FT. CY/CY CONTAINER	39900#	1140
		SHIPPERS LOAD AND COUNT		
		(NET WEIGHT 35,150 LBS.)	18098K	32.280M
		CARGO UNDER REFRIGERATION		
		MAINTAIN TEMPERATURE AT 42 DEGREE F		
		VENTS 45 CFM		
	950 TOTAL	LADEN ON BOARD		
LICENSE EXCEPTION: NLR			TOTAL 39900#	1140
NO SED REQUIRED, SEC 30.39 FTSR, CAS-JL			18098K	32.280M

* WHEN CARGO LEAVES THIS DOCUMENT USED AS A COMBINED TRANSPORT BILL OF LADING

DECLARED VALUE (For AD VALOREM purpose only)
(Refer to clause 6(b)(c) on reverse hereof.) in US $

In accepting this bill of lading, any local customs or privileges to the contrary notwithstanding, the shipper, consignee and owner of the goods and the holder of this bill of lading agree to be bound by all the stipulations, exceptions and conditions stated herein whether written, printed, stamped or incorporated on the front or reverse side hereof, as fully as if they were all signed by such shipper, consignee, owner or holder.

In witness whereof three (3) bills of lading, all of this tenor and date have been signed, one of which being accomplished, the others to stand void.

GLOBETRANS, INC.

BY: AGENT FOR THE CARRIER

DATED

FREIGHT AND CHARGES			
DESCRIPTION OF CHARGE	RATE	PREPAID	COLLECT
TOTAL PREPAID			
TOTAL COLLECT			

Source: *J.E. Lowden & Company*

Air Waybill

SG AIR SFO-001974

SG AIR SFO-001974

FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A. 10000

Air Waybill
Issued by SINGAPORE AIRLINES
P.O. BOX 8746
SAN FRANCISCO CA 94128

ORIENTAL FRESH FOODS
456 ORIENTAL BEND ROAD
KOWLOON, HONG KONG

J. E. LOWDEN & CO IATA 01-1-3839/024
510 MYRTLE AVE., SUITE 210
S. SAN FRANCISCO, CA. 94080

JEL REF#: SFO3001924
SHIPPER#: 11334
HAWB: SFO-001974
MAWB: 618-4260-9732

01-1 3839/024

SAN FRANCISCO AIRPORT

HKG | SG

US$ | PP | C | | NVD | NCV

HONG KONG | 173/13

PLEASE CONTACT CONSIGNEE UPON ARRIVAL. TP# 66-9932-4471

No. of Pieces RCP	Gross Weight	Rate Class / Commodity	Chargeable Weight	Rate / Charge	Total	Nature and Quantity of Goods (incl. Dimensions or Volume)
400	7200K	Q	7200	1.70	12240.00	ORANGES IN CARTONS 1.25 CU FT/CTN

Prepaid Weight Charge: 12240.00

Other Charges: ACT:

DUE CARR: $.10 FSCH 720.00

Total Other Charges Due Carrier: 720.00

FRESH ORANGE EXPORTER
123 FIRST STREET
AMERICAN CITY, U.S.A. 10000

J. E. LOWDEN & CO. AS AUTHORIZED AGENTS FOR, ISSUING CARRIER.

Total Prepaid: 12960.00

13 MAR 97 SAN FRANCISCO AIRPORT

D. ENGERS

For Carrier's Use only at Destination

SG AIRHAWB SFO-001974732

ORIGINAL 3 (FOR SHIPPER)

Source: *J.E. Lowden & Co.*

Return to *Table of Contents*

Agricultural Export Transportation Handbook

Overview

Overview

A typical export shipment from the United States involves approximately 40 steps that are carried out by 11 separate entities. The following is an outline of an export shipment going by sea using a confirmed irrevocable letter of credit as the method of payment. This is followed by a list of the entities involved and their individual responsibilities.

Forty Steps of an Export Shipment (2)

1. The buyer requests a quotation from the supplier/seller.

2. The seller responds by sending a pro forma invoice. The buyer uses the pro forma invoice to apply to its bank for a letter of credit.

3. The buyer/consignee's bank issues the letter of credit.

4. A purchase order and the letter of credit are sent to the shipper.

5. Shipper issues instructions to the freight forwarder for shipping the goods.

6. The freight forwarder books space with an ocean carrier (and inland carrier if requested by the shipper). When the booking is made, the carrier assigns a booking number which is used to identify the shipment.

7. The freight forwarder prepares and submits a bill of lading master and a shippers export declaration which are sent to the ocean carrier.

8. The shipper's freight forwarder transmits the inland bill of lading and delivery instructions to the selected inland carrier, a truck, rail, or barge line.

9. The inland carrier picks up the cargo at the specified location and issues a cargo receipt to the shipper.

10. The cargo is delivered, along with a set of prepared dock receipts, to the out-bound pier terminal.

11. After taking delivery of the cargo, the outbound terminal gives a signed copy of the dock receipt to the inland carrier.

12. A copy of the dock receipt is also sent to the ocean carrier's office.

13. The ocean carrier's office matches the dock receipt with the booking number; it prepares a loading stowage plan.

14. The cargo is lifted aboard and stowed on the vessel, according to the stowage plan.

15. After the cargo has been loaded, the terminal sends the bills for stevedoring and wharfage to the outbound carrier's office.

16. Outbound carrier's office issues an ocean bill of lading with on-board certification, when required, to the shipper's freight forwarder. This bill of lading is a negotiable instrument and acts as title to the goods.

17. Upon receipt of the due bills from the outbound carrier's office, the shipper's freight forwarder pays the amounts due (if prepaid).

18. If the terms of sale indicate that the shipper is responsible for all transportation costs, and the shipper has not already prepaid, then the freight forwarder collects payment from the shipper in exchange for the transportation documents.

19. Shipper submits a commercial set--the documents required for collection of payment as stated in the letter of credit--typically a negotiable bill of lading, an invoice and insurance certificate, and a customs invoice, if necessary--to the bank.

20. The bank carefully reviews the documents in the commercial set to guarantee that there are no discrepancies. After acceptance of the commercial set, the bank pays the shipper in accordance with the letter of credit issued by the buyer's bank.

21. The shipper's bank transmits the commercial set and a debit invoice to the consignee's bank.

22. A non-negotiable copy of the bill of lading is sent to the consignee as notification that the cargo has been shipped.

23. After the vessel has sailed, the manifest, freight bills (if sent freight due), delivery receipts, container list, and arrival notice are sent to the carrier's overseas office.

24. Within 4 working days of the vessel's clearance, U.S. Customs receives a non-negotiable bill of lading copy with the shipper's export declaration.

25. Copies of the manifest are provided to the inbound pier terminal.

26. The consignee's bank releases the commercial set to the consignee against payment of the invoice amount.

27. Before the ship's arrival, the carrier's overseas office issues an arrival notice and invoice covering the ocean freight and other charges due if freight charges are for the buyer's account.

28. The buyer sends the commercial set, arrival notice and invoice, and forwarding instructions to its customs broker.

29. The customs broker presents the endorsed negotiable bill of lading to the inbound carrier's office as proof of title to the goods, and pays the ocean freight (if freight charges are for the buyer's account).

30. Upon receipt of freight due (if a collect shipment) and the negotiable bill of lading, the carrier releases the cargo to the customs broker.

31. At the same time, the carrier's office notifies the inbound pier terminal that the consignee's cargo may be released.

32. The consignee's customs broker submits to the local customs office the proper documents and duties due for clearance in accord with local regulations.

33. The customs office reviews the documents and may elect to inspect the shipment. Once it is

satisfied that the shipment is in compliance with the laws, the customs office authorizes the release of the cargo to the customs broker.

34. In the case when the release is not effected at the berth, the customs office notifies its inspector at the inbound pier terminal that the cargo may be released.

35. Customs broker issues a delivery order to the inbound pier terminal authorizing delivery of the cargo to the designated inland carrier.

36. Consignee's customs broker issues an inland bill of lading to the selected inland carrier.

37. The inland carrier picks up the cargo at the inbound pier terminal.

38. Cargo is delivered to the buyer.

39. The inland carrier issues a freight bill to the consignee's customs broker.

40. With the shipment having been completed, the consignee's customs broker issues a bill to the consignee covering ocean freight, terminal charges (if these bills are charged to the buyer's account), inland freight, and fees for the customs broker's services.

USDA's Transportation and Marketing has produced a video,*A Business of Details--Exporting High Value U.S. Agricultural Products,* which follows an agricultural shipment from the farm to an overseas market. This video demonstrates the information covered in this section. (You can order a free copy of the video from T&M by calling (202) 690-1304.)

Responsibilities (3)

Shippers

- Contact freight forwarder with specifics of shipment including:
  - Number of packages
  - Marks and numbers
  - Description of cargo
  - Foreign destination
  - Gross weight of each package shipped
  - Foreign party to be notified
- Arrange inland freight *
- Prepare inland bill of lading *
- Prepare dock receipt *
- Prepare packing list
- Mark cargo for:
  - Gross and net weight
  - Cubic measurement
  - Foreign destination
  - Identification marks
  - Country of origin
- Check documents prepared by freight forwarder for accuracy

** Denotes tasks that can also be handled by the freight forwarder.*

Freight Forwarders

- Arrange inland transportation **
- Book space with steamship company or air carrier
- Prepare documents, including:
  - inland bill of lading **
  - Dock receipt **
  - Ocean bill of lading/air waybill master
  - Consular invoice
  - Delivery order
  - Shipper's export declaration
- Pay the ocean freight charges
- Secure the original documents for the shipper

** Denotes tasks that the shipper can also perform.

Inland Carriers

- Receive delivery instructions ***
- Pick up cargo from shipper
- Deliver cargo to export point
- Have dock receipt signed ***
- Notify exporter of arrival of cargo ***

*** This information can be supplied by either the shipper or the freight forwarder, whoever made the arrangements for inland transportation.

Commercial Banks

- Issue financial documents guaranteeing payment under specified terms and conditions

Terminal Operators

- Control truck traffic by issuance of pass to driver
- Check the delivery order or dock receipt
- Assign a checker for loading and unloading
- Stuff containers for breakbulk cargo
- Control parking of containers
- Assign stowage locations
- Coordinate movement of containers to the vessel
- Load and secure the vessel

Ocean Carriers

- Book cargo
- Dispatch containers

- Process the bill of lading
- Prepare:
  - Freight invoice
  - Manifest
  - Arrival notice
  - Delivery receipt
  - Stow plan

- File shippers export declaration (SED) with U.S. Customs
- Notify Consignee of arrival and availability of cargo
- Arrange inland transportation when required

Customs Inspectors

- Check import documents
- Inspect cargo
- Control release of cargo
- Assess duties where required
- Complete the processing of import permits

Customs Brokers

- Prepare required customs entry and files with customs
- Effect customs release, freight release
- Coordinate with inland carrier for pickup of import cargo
- Verify information on bill of lading and prepare delivery orders
- Guarantee loading charges with terminal operator

Conference Cargo Inspectors

- Spot-check exported cargo against submitted documents
- Check against commodity description, weight, and cube

Port Authorities

- Quasi-governmental organizations responsible for the control and movement of vessels and cargo in and out of the port

Insurance Surveyors

- Survey cargo damage as requested by shipper or carrier

2. *Source: Sea-Land Service, Inc.*

3. *Source: Sea-land Service, Inc., and the Port Authority of New York and New Jersey*

Return to top of page