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ONLINE FORUM ON PARAGRAPH 3 OF ARTICLE 18
REGARDING THE NEED FOR AND MODALITIES OF
DEVELOPING STANDARDS FOR THE HANDLING,
TRANSPORT, PACKAGING AND IDENTIFICATION OF
LIVING MODIFIED ORGANISMS
Online, 18-29 May 2009

SUMMARY OF INFORMATION ON STANDARDS AND STANDARD-SETTING BODIES RELEVANT TO THE HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

Addendum

ADDITIONAL INFORMATION ON THE UNITED NATIONS RECOMMENDATIONS ON THE TRANSPORT OF DANGEROUS GOODS, MODEL REGULATIONS

Note by the Executive Secretary

1. In response to a request from the Secretariat, the Dangerous Goods and Special Cargoes Section of the Transport Division of the United Nations Economic Commission for Europe submitted the information herein on the *United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations.* The information contains sections from the United Nations Model Regulations that are deemed to be relevant to the specific theme of the Forum. These sections should be considered in conjunction with section V of document UNEP/CBD/BS/ONLINECONF-HTPI/2/1.

2. Annex 1 below contains the provisions from the 14th revised edition of the United Nations Model Regulations that concern the transport of genetically modified organisms (GMOs) and genetically modified micro-organisms (GMMOs). This includes both the criteria for classifying GMOs and GMMOs under either division 6.2 ("Infectious Substances") or class 9 ("Miscellaneous Dangerous Substances and Articles") as well as the corresponding packing instructions. Annex 2 contains the revised provision on GMOs and GMMOs from the 16th revised edition of the Model Regulations to be published later this year.

Annex I

TRANSPORT OF GMOs and GMMOs

according to the 14th revised edition of the UN Model Regulations

NOTE 1: *For additional transport conditions applicable to international carriage by specific modes of transport (e.g. ADR (road); RID (rail); IMDG Code (sea); ICAO Technical Instructions (air)) it is necessary to consider the legal instrument.*

NOTE 2: *The full text of the 14th revised edition of the UN Model Regulations is available on the UNECE Transport Division website http://www.unece.org/trans/danger/publi/unrec/rev14/14files_e.html)*

1. General

1.1 For the purposes of the UN Model Regulations,

Genetically modified micro-organisms (GMMOs) and organisms (GMOs) are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

1.2 *GMMOs and GMOs* shall be classified under Class 6, Division 6.2 (and be assigned UN 2814, UN 2900 or UN 3373, as appropriate) if they meet the definition of infectious substances given in 1.1 of this Annex.

If they do not meet the definition of infectious substance in 1.1 of this Annex, but are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction, they shall be classified under Class 9 and assigned UN 3245.

1.3 GMMOs and GMOs are not subject to the Model Regulations when authorized for use by the competent authorities of the Governments of the countries of origin, transit and destination.

2. GMMOs and GMOs under Class 9

Class 9 (Miscellaneous dangerous substances and articles)

UN3245 GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS

* FOR DANGEROUS GOODS: you must specify: proper shipping name, hazard class, UN No., packing group (where assigned) and any other element of information required under applicable national and international regulations

Packing Instructions: P904 and IBC99

P904	**PACKING INSTRUCTION**	**P904**

This instruction applies to UN 3245.

The following packagings are authorized, provided the general provisions of **4.1.1** and **4.1.3** are met:

(1) Packagings according to P001 or P002 conforming to the packing group III performance level.

(2) Packagings, which need not conform to the packaging test requirements of Part 6, but conforming to the following:

(a) An inner packaging comprising:

(i) a watertight primary receptacle(s);

(ii) a watertight secondary packaging which is leakproof;

(iii) absorbent material placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in a quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;

(iv) if multiple fragile primary receptacles are placed in a single secondary packaging they shall be individually wrapped or separated to prevent contact between them;

(b) An outer packaging which shall be strong enough for its capacity, mass and intended use and the smallest external dimension shall be at least 100 mm.

Additional requirement:

Dry ice and liquid nitrogen

When carbon dioxide, solid, (dry ice) is used as a refrigerant, the packaging shall be designed and constructed to permit the release of the gaseous carbon dioxide to prevent the build up of pressure that could rupture the packaging.

Substances consigned in liquid nitrogen or dry ice shall be packed in primary receptacles that are capable of withstanding very low temperatures. The secondary packaging shall also be capable of withstanding very low temperatures and, in most cases, will need to be fitted over the primary receptacle individually.

IBC99	PACKING INSTRUCTION	**IBC99**

Only IBCs which are approved by the competent authority may be used (see 4.1.3.7).

Note: *Packagings or IBCs not specifically authorized in the packing instructions above shall not be used for the transport of GMMOs and GMOs of Class 9 unless specifically approved by the competent authority and provided that the alternative packaging complies with the general requirements of Part 4 and 6 of the Model Regulations and when the competent authority determines that the alternative packaging provides at least the same level of safety as if the substance were packed in accordance with a method specified in P904.*

Each consignment shall be accompanied by a copy of the competent authority approval or an indication that alternative packaging was approved by the competent authority. The competent authorities granting such approvals should take action to amend the Model Regulations to include the provisions covered by the approval, as appropriate.

3. GMMOs and GMOs under Class 6, Division 6.2

3.1 Class 6, Division 6.2 (Infectious substances)

UN 2814 INFECTIOUS SUBSTANCE, AFFECTING HUMANS
UN 2900 INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only
UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B

(No. 6.2)
Infectious substances
The lower half of the label may bear the inscriptions: "INFECTIOUS SUBSTANCE" and "In the case of damage or leakage immediately notify Public Health Authority";
Symbol (three crescents superimposed on a circle) and inscriptions: black;
Background: white; Figure '6' in bottom corner

GMMOs and GMOs meeting the definition of infectious substances, which are transported in a form that, when exposure to them occurs, are capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals shall be classified as Category A infectious substances and assigned to UN 2418 or UN 2900, as appropriate.

GMMOs and GMOs meeting the definition of infectious substances, which do not meet the criteria for inclusion in Category A shall be assigned to UN 3373.

3.1.1 UN Nos. 2814 and UN 2900

Special provision 318

For the purposes of documentation, the proper shipping name shall be supplemented with the technical name (see 3.1.2.8). Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A and assignment to UN 2814 or UN 2900, the words “suspected category A infectious substance” shall be shown, in parentheses, following the proper shipping name on the transport document, but not on the outer packagings.

Packing Instruction: P620

P620	***I.***	***PACKING INSTRUCTION***	**P620**

This instruction applies to UN Nos. 2814 and 2900.

The following packagings are authorized provided the special packing provisions of **4.1.8** are met:

Packagings meeting the requirements of Chapter 6.3 and approved accordingly consisting of:

(a) Inner packagings comprising:

(i) watertight primary receptacle(s);

(ii) a watertight secondary packaging;

(iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them;

(b) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension shall be not less than 100 mm.

Additional requirements:

1. Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2: such an overpack may contain dry ice.

2. Other than for exceptional consignments, e.g. whole organs which require special packaging, the following additional requirements shall apply:

(a) Substances consigned at ambient temperatures or at a higher temperature. Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure;

(b) Substances consigned refrigerated or frozen. Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.1.1. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;

(c) Substances consigned in liquid nitrogen. Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen;

(d) Lyophilized substances may also be transported in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

3. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40 °C to +55 °C.

Bulk waste goods of UN Nos. 2814 and 2900 (animal carcasses only) may also be transported in closed or sheeted bulk containers meeting the requirements for the design, construction, inspection and testing specified in chapter 6.8 of the Model Regulations and the additional provisions listed in 4.3.2.4.1.

3.1.2 UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B

Special provision 319

Substances packed and marked in accordance with packing instruction P650 are **not subject to any other requirements** in the Model Regulations.

Packing Instruction: P650

P650	PACKING INSTRUCTION	**P650**

This packing instruction applies to UN 3373.

(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transhipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.

(2) The packaging shall consist of at least three components:

(a) a primary receptacle;

(b) a secondary packaging; and

(c) an outer packaging

of which either the secondary or the outer packaging shall be rigid.

(3) Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.

(4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm; the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high. The proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" in letters at least 6 mm high shall be marked on the outer package adjacent to the diamond-shaped mark.

(5) At least one surface of the outer packaging shall have a minimum dimension of 100 mm × 100 mm.

(6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3 as specified in 6.3.5.2 of these Regulations at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.

(7) For liquid substances

(a) The primary receptacle(s) shall be leakproof;

(b) The secondary packaging shall be leakproof;

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;

(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;

(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

(8) For solid substances

(a) The primary receptacle(s) shall be siftproof;

(b) The secondary packaging shall be siftproof;

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;

(d) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, shall be used.

(9) Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen

(a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and the package (the outer packaging or the overpack) shall be marked "Carbon dioxide, solid" or "Dry ice";

(b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

(10) When packages are placed in an overpack, the package markings required by this packing instruction shall either be clearly visible or be reproduced on the outside of the overpack.

(11) Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.

(12) Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

(13) Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these Regulations need be met.

UN3373 may also be transported in portable tanks provided that the specific requirements of portable tank instruction T1 (concerning the applicable minimum test pressure, the minimum shell thickness and the pressure-relief and bottom-opening requirements) and portable tank special provision TP1 are met.

4 Conditions of transport and consignment procedures

4.1 Except as otherwise provided in the Model Regulations, no person may offer dangerous goods for transport unless those goods are properly marked, labelled, placarded, described and certified on a transport document, and otherwise in a condition for transport as required by Part 5 of the Model Regulations.

Transport of GMMOs and GMOs is subject to the following conditions:

(a) Packing:

For UN Nos. 2814 and 2900 according to P620;
For UN 3373, according to P650; and
For UN 3245, according to P904 and IBC99;

(b) Labelling of packages : Infectious substances packages shall bear, in addition to the primary risk label (model No.6.2, see 3.1 of this Annex), any other label required by the nature of the contents.

(c) Marking of UN number on packages;

(d) Placarding of cargo transport units

(The term "transport unit" comprise road transport tank and freight vehicles, railway transport tank and freight wagons and multimodal freight containers and portable tanks)

4.2 *Information required on the dangerous goods transport document*

The dangerous goods transport document shall contain the following information for each dangerous substance, material or article offered for transport:

(a) The UN number preceded by the letters "UN";

(b) The proper shipping name, as determined according to 3.1.2, including the technical name enclosed in parenthesis, as applicable (see 3.1.2.8);

(c) Class or Division of the goods. The words "Class" or "Division" may be included preceding the primary hazard class or division numbers;

(d) Subsidiary hazard class or division number(s) corresponding to the subsidiary risk label(s) required to be applied, when assigned, shall be entered following the primary hazard class or division and shall be enclosed in parenthesis. The words "Class" or "Division" may be included preceding the subsidiary hazard class or division numbers;

(e) Packing group, when assigned, which may be preceded by "PG" (e.g."PG II").

The five elements of the dangerous goods description above shall be shown in the order (a), (b), (c), (d), (e)) with no information interspersed, except as provided in the Model Regulations.

In addition to the description below and, for infectious substances, the full address of the consignee shall be shown on the document, together with the name of a responsible person and his telephone number.

An example of a multimodal dangerous goods transport document is given at the end of this Annex.

4.3 S*pecial provisions concerning transport operations and consignment of infectious substances*

Live vertebrate or invertebrate animals shall not be used to consign infectious substances unless such substances cannot be consigned by any other means. Infected animals shall be consigned in accordance with conditions specified by the competent authority.

It is the responsibility of the carriers and their staff to ensure that all applicable regulations for the packing, labelling, transport and documentation of consignments of infectious substances are fully understood and that the transport is made conforming to the rules in force. If the carrier finds any error in the labelling or documentation, he shall immediately notify the consignor or consignee so that the appropriate corrective measures may be taken.

Any person responsible for the carriage of packages containing infectious substances who becomes aware of damage to or leakage from such packages shall avoid handling the package or keep handling to a minimum, inspect adjacent packages for contamination and put aside any that may have been contaminated, inform the appropriate public health authority or veterinary authority, and provide information on any other countries of transit where persons may have been exposed to danger and notify the consignor and/or the consignee.

A railway wagon, road vehicle, cargo space of a ship, compartment of an aircraft or other transport unit which has been used to transport infectious substances shall be inspected for release of the substance before re-use. If the infectious substances were released during transport, the transport unit shall be decontaminated before it is re-used. Decontamination may be achieved by any means which effectively inactivates the released infectious substance.

Transport documents associated with the transport of units that have been fumigated shall show the date of fumigation and the type and amount of the fumigant used. In addition, instructions for disposal of any residual fumigant including fumigation devices (if used) shall be provided.

A warning sign as specified in 5.5.2.3 of the Model Regulations shall be placed on each fumigated unit.

MULTIMODAL DANGEROUS GOODS FORM

1. Shipper / Consignor /Sender	2. Transport document number
	3. Page 1 of Pages | 4. Shipper's reference
	5. Freight Forwarder's reference
6. Consignee	7. Carrier (to be completed by the carrier)

SHIPPER'S DECLARATION

I hereby declare that the contents of this consignment are fully and accurately described below by the proper shipping name, and are classified, packaged, marked and labelled /placarded and are in all respects in proper condition for transport according to the applicable international and national governmental regulations.

8. This shipment is within the limitations prescribed for: (Delete non-applicable) PASSENGER AND CARGO AIRCRAFT CARGO		9. Additional handling information
10. Vessel / flight no. and date	11. Port / place of loading	
12. Port / place of discharge	13. Destination	

14. Shipping marks	* Number and kind of packages; description of goods	Gross mass (kg)	Net mass	Cube (m^3)

15. Container identification No./ vehicle registration No.	16. Seal number (s)	17. Container/vehicle size & type	18. Tare (kg)	19. Total gross mass (including tare) (kg)

CONTAINER/VEHICLE PACKING CERTIFICATE
I hereby declare that the goods described above have been packed/loaded into the container/vehicle identified above in accordance with the applicable provisions **
MUST BE COMPLETED AND SIGNED FOR ALL CONTAINER/VEHICLE LOADS BY PERSON RESPONSIBLE FOR PACKING/LOADING

21.RECEIVING ORGANISATION RECEIPT
Received the above number of packages/containers/trailers in apparent good order and condition unless stated hereon: RECEIVING ORGANISATION REMARKS:

20. Name of company	Haulier's name	22. Name of company (OF SHIPPER PREPARING THIS NOTE)
Name / Status of declarant	Vehicle reg. no.	Name / Status of declarant
Place and date	Signature and date	Place and date
Signature of declarant	DRIVER'S SIGNATURE	Signature of declarant

BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS BLACK HATCHINGS

MULTIMODAL DANGEROUS GOODS FORM

Continuation Sheet

1. Shipper / Consignor /Sender	2. Transport document number	
	3. Page 1 of Pages	4. Shipper's reference
		5. Freight Forwarder's reference

14. Shipping marks	* Number and kind of packages; description of goods	Gross mass (kg)	Net mass	Cube (m^3)

/…

Annex II

REVISED PROVISION OF THE UN MODEL REGULATIONS (16TH REVISED EDITION)

(Expected date of application through international legal instruments: 1 January 2011)

219 Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs) packed and marked in accordance with packing instruction P904 are not subject to any other requirements in these Regulations.

If GMMOs or GMOs meet the definition in Chapter 2.6 of a toxic substance or an infectious substance and the criteria for inclusion in Division 6.1 or 6.2 the requirements in these Regulations for transporting toxic substances or infectious substances apply.

P904	PACKING INSTRUCTION	P904

This instruction applies to UN No. 3245.

The following packagings are authorized:

(1) Packagings meeting the provisions of 4.1.1.1, 4.1.1.2, 4.1.1.4, 4.1.1.8 and 4.1.3 and so designed that they meet the construction requirements of 6.1.4. Outer packagings constructed of suitable material of adequate strength and designed in relation to the packaging capacity and its intended use shall be used. Where this packing instruction is used for the transport of inner packagings of combination packagings the packaging shall be designed and constructed to prevent inadvertent discharge during normal conditions of transport.

(2) Packagings, which need not conform to the packaging test requirements of Part 6, but conforming to the following:

(a) An inner packaging comprising:
  (i) primary receptacle(s) and a secondary packaging, the primary receptacle(s) or the secondary packaging shall be leakproof for liquids or siftproof for solids;
  (ii) for liquids, absorbent material placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in a quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
  (iii) if multiple fragile primary receptacles are placed in a single secondary packaging they shall be individually wrapped or separated to prevent contact between them;

(b) An outer packaging shall be strong enough for its capacity, mass and intended use, and with a smallest external dimension of at least 100 mm.

For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm; the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high.

Additional requirement:

Ice, dry ice and liquid nitrogen

When dry ice or liquid nitrogen is used, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and the package (the outer packaging or the overpack) shall be marked "Carbon dioxide, solid" or "Dry ice".
The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.
