U.S. Department
of Transportation

**Research and
Special Programs
Administration**

MAR 4 1998

400 Seventh Street, S.W.
Washington, D.C. 20590

DOT-E 11980

EXPIRATION DATE: **June 30, 1998**

1. GRANTEE: American Type Culture Collection (ATCC)
Rockville, Maryland

2. PURPOSE AND LIMITATION: This exemption authorizes the transportation in commerce of certain infectious substances in special packagings, and provides no relief from any regulation other than as specifically stated herein.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR Part 172, Subpart C; 172.301(a); 172.301(b); 172.301(c); 173.196(a); 173.196(b), and 173.196(d).

5. BASIS: This exemption is based on the application of American Type Culture Collection (ATCC), dated October 1, 1997, and supplemental information, dated January 23, February 3, February 11, and February 25, 1998, submitted in accordance with 49 CFR 107.105.

6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous materials description -- proper shipping name	**Hazard Class/ Division**	**Identi-fication Number**	**Packing Group**
Infectious substances, affecting humans, (*Risk Group 1, 2, and 3 materials as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Ninth revised edition*)	6.2	UN2814	(n/a)

7. PACKAGING AND SAFETY CONTROL MEASURES:

a. PACKAGING

(1) Infectious substances in the form of freeze-dried material (stored in cold rooms), as listed in Paragraph 6, must be packed in sealed vials and ampules (primary receptacles) and over-packed in small boxes. The volume of culture material in each vial or ampule may not exceed 1.0 ml. Five or less boxes must be banded together and packed in a plastic bag and sealed. The filled and sealed plastic bags must be packed and secured in a one cubic yard 11G fiberboard intermediate bulk container (IBC) that has a seven (7) mil polyethylene, bag-style, liner. Each IBC must be secured to a pallet. IBCs may not be stacked in the transport vehicle.

(2) Infectious substances in the form of freeze-dried or frozen material, as listed in Paragraph 6, that are stored in mechanical or nitrogen freezers must be packed in watertight vials and ampules (primary receptacles). The volume of material in any vial or ampule may not exceed 1.0 ml. Vials and ampules must be tightly secured and packed with bubble wrap within the freezer to prevent the contents from shifting. Freezers serve as outer packagings.

(3) High risk agents (i.e., those listed in the CDC list of select agents in 42 CFR Part 72) must be packaged in a single, double-locked, liquid nitrogen freezer that serves as the outer packaging.

(4) The mechanical freezers are constructed of double-walled steel with insulation material between the walls, and the liquid nitrogen freezers are constructed of double-wall stainless steel with vacuum insulation. Nitrogen freezers must be filled with approximately four inches of liquid nitrogen prior to movement.

(5) The contents of each IBC or freezer must be secured against movement, and each IBC or freezer must be secured against movement in the transport vehicle. All freezer doors must be secured with locks or belts to prevent opening during transportation.

b. OPERATIONAL CONTROLS -

(1) This exemption authorizes the transport of packages containing infectious substances from ATCC's current facilities in Rockville, Maryland to their new facility in Manassas, Virginia. Packages must be prepared, and transported by contract carrier personnel under ATCC supervision, as outlined in the application for exemption. The freeze-dried materials from the cold room must be delivered to the Manassas location within four (4) hours of its removal from the cold room in the Rockville facility. The materials in the mechanical and nitrogen freezers must be delivered to the Manassas location within four (4) hours of departure from the Rockville facility.

(2) An itemized list of contents must be securely attached to the outside of each IBC or freezer.

(3) Emergency responders and equipment necessary to mitigate a spill must accompany each transport vehicle.

8. SPECIAL PROVISIONS:

a. The shipping paper requirements of 49 CFR Part 172 Subpart C and the marking requirements of 49 CFR 172.301(a), (b) and (c) are waived.

b. Emergency responders and escorts must have a copy of packing lists for each IBC and freezer.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

10. MODAL REQUIREMENTS:

a. The contract carrier used to transport packagings covered by the exemption must have a "Satisfactory" safety rating assigned by the Office of Motor Carrier Safety Field Operations, Federal Highway Administration.

b. A copy of this exemption must be carried aboard each motor vehicle used to transport packages covered by this exemption.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. Section 5101 *et seq*:

- All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

- Registration required by 49 CFR 107.601 et seq., when applicable.

Each "hazmat employee", as defined in 49 CFR 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by 49 CFR 172.700 through 172.704.

No person may use or apply this exemption, including display of its number, when the exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: The carrier is required to report any incident involving loss of packaging contents or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable. (49 CFR 171.15 and 171.16 apply to any activity undertaken under the authority of this exemption.) In addition, the holder(s) of this exemption must inform the AAHMS, in writing, of any incident involving the package and shipments made under the terms of this exemption.

Issued at Washington, D.C.:

MAR 4 1998

Alan I. Roberts
Associate Administrator
for Hazardous Materials Safety

(DATE)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590-0001. Attention: DHM-31.

The original of this exemption is on file at the above office. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

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