



American Type Culture Collection
10801 University Boulevard
Manassas, Virginia 20110-2209

Attention: Dr. Raymond Cypess
President and Chief Executive Officer

Dear Mr. Cypess:

The Office of Export Enforcement, Bureau of Export Administration, United States Department of Commerce (BXA), hereby charges that, as described below, American Type Culture Collection has violated the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (1999)) (the Regulations),¹ issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C.A. app. §§ 2401-2420 (1991 & Supp. 1999)) (the Act).²

Facts constituting violations:

Charges 1-58

On 58 separate occasions between on or about July 4, 1993 and on or about May 31, 1996, American Type Culture Collection exported U.S.-origin microorganisms to various destinations without obtaining the validated licenses required by Section 772.1(b) of

¹ The alleged violations occurred in 1993, 1994, 1995 and 1996. The Regulations governing the violations at issue are found in the 1993, 1994, 1995 and 1996 versions of the Code of Federal Regulations (15 C.F.R. Parts 768-799 (1993, 1994, and 1995) and 15 C.F.R. Parts 768-799 (1996), as amended (61 Fed. Reg. 12714, March 25, 1996) (hereinafter the former Regulations). In addition, the March 25, 1996 Federal Register publication redesignated, but did not republish, the then-existing Regulations, designating them as an interim rule at 15 C.F.R. Parts 730-774, effective April 24, 1996. The former Regulations and the Regulations define the violations that BXA alleges occurred. The Regulations establish the procedures that apply to this matter.

² The Act expired on August 20, 1994. Executive Order 12924 (3 C.F.R., 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 C.F.R., 1995 Comp. 501 (1996)), August 14, 1996 (3 C.F.R., 1996 Comp. 298 (1997)), August 13, 1997 (3 C.F.R., 1997 Comp. 306 (1998)), August 13, 1998 (3 C.F.R., 1998 Comp. 294 (1999)), and August 10, 1999 (64 Fed. Reg. 44101 (August 13, 1999)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C.A. §§ 1701-1706 (1991 & Supp. 1999)).



the former Regulations. Each of those exports is described more fully on the enclosed schedule, which is incorporated herein by this reference. BXA alleges that, by exporting U.S.-origin commodities to any person or destination or for any use in violation of or contrary to the terms of the Act, or any regulation, order, or license issued thereunder, American Type Culture Collection committed 56 violations of Section 787.6 and two violations of Section 787A.6 of the former Regulations, for a total of 58 violations.

Accordingly, American Type Culture Collection is hereby notified that an administrative proceeding is instituted against it pursuant to Section 13(c) of the Act and Part 766 of the Regulations for the purpose of obtaining an order imposing administrative sanctions, including any or all of the following:

The maximum civil penalty allowed by law of \$10,000 per violation (see Section 764.3(a)(1) of the Regulations);

Denial of export privileges (see Section 764.3(a)(2) of the Regulations); and/or

Exclusion from practice before BXA (see Section 764.3(a)(3) of the Regulations).

Copies of relevant Parts of the Regulations are enclosed.

If American Type Culture Collection fails to answer the charges contained in this letter within 30 days after being served with notice of issuance of this letter as provided in Section 766.6 of the Regulations, that failure will be treated as a default under Section 766.7 of the Regulations.

American Type Culture Collection is further notified that it is entitled to an agency hearing on the record as provided by Section 13(c) of the Act and Section 766.6 of the Regulations, if a written demand for one is filed with its answer. American Type Culture Collection is also entitled to be represented by counsel, and to seek a settlement of the charges.

Pursuant to an Interagency Agreement between BXA and the U.S. Coast Guard, the U.S. Coast Guard is providing administrative law judge services, to the extent that such services are required under the Regulations, in connection with the matters set forth in this letter. Accordingly, American Type Culture Collection's answer should be filed with the U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202-4022, in accordance with the instructions in Section 766.5(a) of the Regulations. In addition, a copy of American Type Culture Collection's answer should be served on BXA at the

address set forth in Section 766.5(b), adding "ATTENTION: Lorie B. Whitaker, Esq." below the address. Ms. Whitaker may be contacted by telephone at (202) 482-5311.

Sincerely,

Mark D. Menefee
Director
Office of Export Enforcement

Enclosures

**SCHEDULE OF VIOLATIONS
AMERICAN TYPE CULTURE COLLECTION**

CHARGE NUMBER	EXPORT DATE (on or about)	COMMODITIES	DESTINATION	INVOICE	AIR WAYBILL
1	07/04/93	Vesicular Stomatitis	South Korea	341984	180-3241-8330
2	07/25/93	Vesicular Stomatitis	South Korea	345213	180-3241-8374
3	08/02/93	Hantaan Virus	Germany	344745	400-3688-2230
4	08/10/93	Hog Cholera	Argentina	347600	042-8238-8272
5	08/17/93	Vesicular Stomatitis	Denmark	345584	220-8603-7556
6	08/31/93	Vesicular Stomatitis	Spain	348499	220-8629-4880
7	09/14/93	Vesicular Stomatitis	Italy	353245	220-8629-6766
8	10/22/93	Xanthomonas	South Africa	383549	Airmail
9	10/29/93	Vesicular Stomatitis	Switzerland	359983	400-6566-4550
10	11/15/93	Hog Cholera	Scotland	363805	400-6903-7964
11	11/19/93	Vesicular Stomatitis	Switzerland	363933	400-6905-8312
12	11/30/93	Bluetongue Virus	Brazil	365431	042-8348-5581
13	12/12/93	Vesicular Stomatitis	Taiwan	366311	933-6234-5220
14	01/06/94	Newcastle Disease	Indonesia	369512	933-6234-5835
15	01/11/94	Vesicular Stomatitis	Croatia	365480	220-8640-1582

E688-4

E698-5

CHARGE NUMBER	EXPORT DATE (on or about)	COMMODITIES	DESTINATION	INVOICE	AIR WAYBILL
16	01/23/94	Newcastle Disease	Singapore	372521	933-6241-0725
17	01/30/94	Newcastle Disease	Indonesia	373900	933-6241-0913
18	04/10/94	Vesicular Stomatitis	South Korea	385442	180-3474-1195
19	05/03/94	Vesicular Stomatitis New Castle Disease	Italy	372092	055-1107-7172
20	05/13/94	Vesicular Stomatitis New Castle Disease	South Korea	391082	180-3474-1302
21	06/07/94	Vesicular Stomatitis	India	382875	220-5834-2432
22	07/19/94	Vesicular Stomatitis	Italy	392894	220-4851-6263
23	07/24/94	Salmonella Choleraesuis	Singapore	396917	933-6255-6222
24	08/09/94	Francisella Tularensis	Portugal	393814	220-4851-9004
25	09/03/94	Vesicular Stomatitis	Israel	404714	220-4852-2272
26	09/09/94	Vesicular Stomatitis	Germany	408172	400-6282-2933
27	09/20/94	Vesicular Stomatitis	Italy	410784	220-4852-4766
28	09/20/94	Hantaan Virus	Germany	407296	400-6283-5286
29	09/26/94	Hantaan Virus	Scotland	411896	400-2105-9172
30	10/02/94	Shigella Dysenteriae	New Zealand	412244	933-6262-6296
31	10/11/94	Newcastle Disease	Sweden	413483	105-5350-1770

E638-6

CHARGE NUMBER	EXPORT DATE (on or about)	COMMODITIES	DESTINATION	INVOICE	AIR WAYBILL
32	10/25/94	Vesicular Stomatitis	Austria	413013	220-4880-3672
33	12/13/94	Hantaan Virus	Italy	423364	220-6615-3231
34	02/05/95	Vesicular Stomatitis	South Korea	430838	180-3999-3295
35	02/12/95	Hantaan Virus Bluetongue Virus	South Korea	433241	131-7492-1490
36	03/07/95	Vesicular Stomatitis	Belgium	433647	400-5790-4350
37	03/28/95	Newcastle Disease Avian Influenza	Italy	435653	125-4382-9111
38	04/03/95	Vesicular Stomatitis	France	442027	400-2401-6930
39	05/08/95	Vesicular Stomatitis	South Korea	447093	180-4146-7705
40	06/11/95	Vesicular Stomatitis	South Korea	452711	180-4146-7775
41	07/09/95	Hantaan Virus Burkholderia Solanacearum	South Korea	457033	180-4462-2970
42	08/06/95	Vesicular Stomatitis	South Korea	461681	131-7524-7756
43	09/11/95	Newcastle Disease	Brazil	464624	042-8507-1630
44	10/06/95	Bluetongue Virus	Scotland	471796	400-9206-6402
45	11/05/95	Vesicular Stomatitis	Thailand	461331	933-6287-2880
46	11/13/95	Newcastle Disease	Pakistan	477331	214-7268-9035
47	12/11/95	Vesicular Stomatitis	United Kingdom	481550	020-8263-5803

E638-17

CHARGE NUMBER	EXPORT DATE (on or about)	COMMODITIES	DESTINATION	INVOICE	AIR WAYBILL
48	12/15/95	Bluetongue Virus	Scotland	480617	400-6048-6650
49	01/21/96	Vesicular Stomatitis	South Korea	485503	131-7567-3743
50	01/26/96	Hantaan Virus	Scotland	487410	400-7710-0424
51	03/03/96	Vesicular Stomatitis	South Korea	493035	180-4280-0192
52	03/12/96	Vesicular Stomatitis	Mexico	494965	006-3805-3864
53	03/23/96	Mycoplasma Mycoides	Germany	496351	400-1177-9552
54	03/25/96	Newcastle Disease	Chile	496520	020-8961-0426
55	03/26/96	Vesicular Stomatitis	Mexico	497209	006-4778-5430
56	04/22/96	Vesicular Stomatitis	Czech Republic	500952	020-8980-1493
57	04/29/96	Newcastle Disease	Turkey	502763	020-8983-2466
58	05/31/96	Vesicular Stomatitis	South Korea	508319	180-4280-0590

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF EXPORT ADMINISTRATION
WASHINGTON, D.C. 20230

In the Matter of:)
)
AMERICAN TYPE CULTURE COLLECTION)
10801 University Boulevard)
Manassas, Virginia 20110-2209,)
)
Respondent)

SETTLEMENT AGREEMENT

This Agreement is made by and between American Type Culture Collection and the Bureau of Export Administration, United States Department of Commerce, pursuant to Section 766.18(a) of the Export Administration Regulations (15 C.F.R. Parts 730-774 (1999)) (the Regulations),¹ issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C.A. app. §§ 2401-2420 (1991 & Supp. 1999)) (the Act).²

¹ The alleged violations occurred in 1993, 1994, 1995 and 1996. The Regulations governing the violations at issue are found in the 1993, 1994, 1995 and 1996 versions of the Code of Federal Regulations (15 C.F.R. Parts 768-799 (1993, 1994, and 1995) and 15 C.F.R. Parts 768-799 (1996), as amended (61 Fed. Reg. 12714, March 25, 1996) (hereinafter the former Regulations). In addition, the March 25, 1996 Federal Register publication redesignated, but did not republish, the then-existing Regulations, designating them as an interim rule at 15 C.F.R. Parts 730-774, effective April 24, 1996. The former Regulations and the Regulations define the violations that BXA alleges occurred. The Regulations establish the procedures that apply to this matter.

² The Act expired on August 20, 1994. Executive Order 12924 (3 C.F.R., 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 C.F.R., 1995 Comp. 501 (1996)), August 14, 1996 (3 C.F.R., 1996 Comp. 298 (1997)), August 13, 1997 (3 C.F.R., 1997 Comp. 306 (1998)), August 13, 1998 (3 C.F.R., 1998 Comp. 294 (1999)), and August 10, 1999 (64 Fed. Reg. 44101 (August 13, 1999)), continued the Regulations in effect under the International Emergency Economic Powers Act (50

WHEREAS, the Office of Export Enforcement, Bureau of Export Administration (BXA), has notified American Type Culture Collection of its intention to initiate an administrative proceeding against it pursuant to the Act and the Regulations, based on allegations that, on 58 separate occasions between on or about July 4, 1993 and or about May 31, 1996, American Type Culture Collection exported U.S.-origin microorganisms to various destinations without obtaining the validated licenses required by Section 772.1(b) of the former Regulations, for a total of 56 violations of Section 787.6 and two violations of Section 787A.6 of the former Regulations;

WHEREAS, American Type Culture Collection has reviewed the proposed Charging Letter and is aware of the allegations made against it and the administrative sanctions that could be imposed against it if the allegations are found to be true; it fully understands the terms of this Settlement Agreement and the proposed Order; it enters into this Settlement Agreement voluntarily and with full knowledge of its rights, and it states that no promises or representations have been made to it other than the agreements and considerations herein expressed;

WHEREAS, American Type Culture Collection neither admits nor denies the allegations contained in the proposed Charging Letter;

WHEREAS, American Type Culture Collection and BXA have executed a Memorandum of Understanding, which is attached hereto, and is incorporated into this Settlement Agreement by this

U.S.C.A. §§ 1701-1706 (1991 & Supp. 1999)).

reference. The term Settlement Agreement as used herein means the Settlement Agreement and the Memorandum of Understanding.

WHEREAS, American Type Culture Collection and BXA wish to settle and dispose of all matters alleged in the proposed Charging Letter by entering into this Settlement Agreement; and

WHEREAS, American Type Culture Collection agrees to be bound by an appropriate Order giving effect to the terms of this Settlement Agreement, when entered (appropriate Order);

NOW THEREFORE, American Type Culture Collection and BXA agree as follows:

1. BXA has jurisdiction over American Type Culture Collection, under the Act and the Regulations, in connection with the matters alleged in the proposed Charging Letter.

2. BXA and American Type Culture Collection agree that the following sanction shall be imposed against American Type Culture Collection in complete settlement of the alleged violations of the Act and the former Regulations set forth in the proposed Charging Letter:

- a. American Type Culture Collection shall be assessed a civil penalty in the amount of \$290,000, payment of which shall be suspended for a period of two years from the date of entry of the appropriate Order and shall thereafter be waived, provided that, during the period of suspension, American Type Culture Collection has complied with the terms of the attached Memorandum of Understanding, and has committed no violation of the

Act, or any regulation, order, or license issued thereunder.

2. American Type Culture Collection agrees that, subject to the approval of this Settlement Agreement pursuant to paragraph 6 hereof, it hereby waives all rights to further procedural steps in this matter (except with respect to any alleged violations of this Settlement Agreement or the appropriate Order, when entered), including, without limitation, any right (a) to an administrative hearing regarding the allegations in the proposed Charging Letter; (b) to request a refund of any civil penalty paid pursuant to this Settlement Agreement and the appropriate Order, when entered; and (c) to seek judicial review or otherwise to contest the validity of this Settlement Agreement or the appropriate Order, when entered.

3. American Type Culture Collection understands that BXA will make the proposed Charging Letter, this Settlement Agreement and attached Memorandum of Understanding, and the appropriate Order, when entered, available to the public.

4. BXA and American Type Culture Collection agree that this Settlement Agreement is for settlement purposes only. Therefore, if this Settlement Agreement is not accepted and an appropriate Order is not issued by the Assistant Secretary for Export Enforcement pursuant to Section 766.18(a) of the Regulations, BXA and American Type Culture Collection agree that they may not use this Settlement Agreement in any administrative or judicial proceeding and that the parties shall not be bound by the terms

contained in this Settlement Agreement in any subsequent administrative or judicial proceeding.

5. No agreement, understanding, representation or interpretation not contained in this Settlement Agreement may be used to vary or otherwise affect the terms of this Settlement Agreement or the appropriate Order, when entered, nor shall this Settlement Agreement serve to bind, constrain, or otherwise limit any action by any other agency or department of the United States Government with respect to the facts and circumstances addressed herein.

6. This Settlement Agreement shall become binding on BXA only when the Assistant Secretary for Export Enforcement approves it by entering an appropriate Order, which will have the same force and effect as a decision and order issued after a full administrative hearing on the record.

BUREAU OF EXPORT ADMINISTRATION
U.S. DEPARTMENT OF COMMERCE

AMERICAN TYPE CULTURE
COLLECTION

Mark Menefee
Mark Menefee
Director
Office of Export Enforcement
Date: 9/27/99

Raymond Cypess
Raymond Cypess
President
and Chief Executive Officer
Date: 9/22/99

INSTRUCTIONS FOR PAYMENT OF CIVIL PENALTY

1. The civil penalty check should be made payable to:

U.S. Department of Commerce

2. The check should be mailed to:

U.S. Department of Commerce
Bureau of Export Administration
Export Enforcement Team
Room H-6877
14th & Constitution Avenue, N.W.
Washington, D.C. 20230
Attn: Zoraida Vazquez

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF EXPORT ADMINISTRATION
WASHINGTON, D.C. 20230

In the Matter of:)
)
AMERICAN TYPE CULTURE COLLECTION)
10801 University Boulevard)
Manassas, Virginia 20110-2209,)
)
)

Respondent)

ORDER

The Office of Export Enforcement, Bureau of Export Administration, United States Department of Commerce (BXA), having notified American Type Culture Collection of its intention to initiate an administrative proceeding against it pursuant to Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C.A. app. §§ 2401-2420 (1991 & Supp. 1999)) (the Act),¹ and the Export Administration Regulations (15 C.F.R. Parts 730-774 (1999)) (the Regulations),² based on allegations that, on

¹ The Act expired on August 20, 1994. Executive Order 12924 (3 C.F.R., 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 C.F.R., 1995 Comp. 501 (1996)), August 14, 1996 (3 C.F.R., 1996 Comp. 298 (1997)), August 13, 1997 (3 C.F.R., 1997 Comp. 306 (1998)), August 13, 1998 (3 C.F.R., 1998 Comp. 294 (1999)), and August 10, 1999 (64 Fed. Reg. 44101 (August 13, 1999)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C.A. §§ 1701-1706 (1991 & Supp. 1999)).

² The alleged violations occurred in 1993, 1994, 1995 and 1996. The Regulations governing the violations at issue are found in the 1993, 1994, 1995 and 1996 versions of the Code of Federal Regulations (15 C.F.R. Parts 768-799 (1993, 1994, and 1995) and 15 C.F.R. Parts 768-799 (1996), as amended (61 Fed. Reg. 12714, March 25, 1996) (hereinafter the former Regulations). In addition, the March 25, 1996 Federal Register publication redesignated, but did not republish, the then-existing

58 separate occasions between on or about July 4, 1993 and on or about May 31, 1996, American Type Culture Collection exported U.S.-origin microorganisms to various destinations without obtaining the validated licenses required by Section 772.1(b) of the former Regulations, for a total of 56 violations of Section 787.6 and two violations of 787A.6 of the former Regulations; and

BXA and American Type Culture Collection having entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations, which incorporates therein the terms of a Memorandum of Understanding between the parties, and whereby they agreed to settle this matter in accordance with the terms and conditions set forth in those documents, and the terms of the Settlement Agreement and Memorandum of Understanding having been approved by me;

IT IS THEREFORE ORDERED:

FIRST, that a civil penalty of \$290,000 is assessed against American Type Culture Collection, payment of which is hereby suspended for a period of two years from the date of entry of this Order and shall thereafter be waived, provided that, during the period of suspension American Type Culture Collection has

Regulations, designating them as an interim rule at 15 C.F.R. Parts 730-774, effective April 24, 1996. The former Regulations and the Regulations define the violations that BXA alleges occurred. The Regulations establish the procedures that apply to this matter.

complied with the terms of the attached Memorandum of Understanding, and has committed no violation of the Act, or any regulation, order or license issued thereunder.

SECOND, that the Charging Letter, the Settlement Agreement and attached Memorandum of Understanding, and this Order shall be made available to the public.

This Order, which constitutes the final agency action in this matter, is effective immediately.


E. Amanda DeBusk
Assistant Secretary
for Export Enforcement

Entered this 30th day of September, 1999.

Memorandum of Understanding
between
Bureau of Export Administration
and
American Type Culture Collection

This Memorandum of Understanding (MOU) sets forth an agreement between the Office of Export Enforcement, Bureau of Export Administration, Department of Commerce (BXA) and the American Type Culture Collection to collaborate on several educational efforts designed to improve compliance with U.S. export controls on biological agents, as set forth below.

WHEREAS, BXA is required to keep the public fully apprised of changes in export control policy and procedures pursuant to Section 4(f) of the Export Administration Act. The Mutual Educational and Cultural Exchange Act of 1961 (22 U.S.C. 2455(f) and 2458(c)) applies to BXA's activities in this regard, as provided in Title II of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1999, enacted as Section 101(b) of the Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 1999 (Public Law 105-277).

WHEREAS, American Type Culture Collection is a non-profit organization. Its mission is to acquire, authenticate, preserve, develop, and distribute biological materials, information, technology, intellectual property, and standards for the advancement, validation and application of scientific knowledge.

WHEREAS, American Type Culture Collection engages in extensive interaction and cooperation with the U.S. Government and international agencies, including the Centers for Disease Control, most of the Cabinet-level agencies (including the Commerce Department), the National Academy of Science and the National Institutes of Health.

NOW THEREFORE, American Type Culture Collection and BXA agree as follows:

1. American Type Culture Collection will develop and implement a training workshop for up to 150 BXA agents and other Government employees on or before September 30, 2001. The purpose of the workshop will be to provide in-depth information and training regarding the technical and business aspects of biological agents, and the production, marketing, sale and export control thereof. American Type Culture Collection will provide organizers and speakers for this workshop, will provide logistical support, and will pay all material and location costs. BXA will, as necessary, pay transportation and lodging costs for its attendees, will provide speakers, and will assist in planning and coordination for the workshop. At the request of American Type Culture Collection, the workshop may be divided into two sessions, with up to 75 Government

employees attending each session.

2. American Type Culture Collection will develop and implement an educational seminar for the U.S. biotechnology industry on or before September 30, 2001. The purpose of this seminar will be to provide industry-specific information and training on U.S. export control requirements applicable to biological agents and related products, including a discussion of American Type Culture Collection's internal compliance program. American Type Culture Collection will contact and recruit seminar participants, will provide logistical support, organizers and speakers, but may charge a registration fee to cover its costs. American Type Culture Collection and BXA will work together to develop the agenda for this seminar, and speakers will be drawn from both organizations, and potentially from others as well.
3. American Type Culture Collection will prepare a multi-use training videotape based on the seminar workshops referenced in paragraphs 1. and 2. above. Five copies of this videotape will be provided to BXA on or before October 31, 2001.

- 4. American Type Culture Collection will work to create awareness of the need to restrict access to dual-use biological agents in the international culture collection community, and will report the substance and results of its efforts to BXA on or before September 30, 2001.

This Memorandum of Understanding shall become binding on BXA and American Type Culture Collection once both parties have signed it and the Assistant Secretary for Export Enforcement approves the Settlement Agreement into which this Memorandum of Understanding is incorporated by entering an appropriate Order.

BUREAU OF EXPORT ADMINISTRATION
U.S. DEPARTMENT OF COMMERCE

AMERICAN TYPE CULTURE
COLLECTION

Mark Menefee
Mark Menefee
Director
Office of Export Enforcement

Raymond H. Cypess
Raymond Cypess
President
and Chief Executive Officer

Date: 9/27/99

Date: 9/22/99