



UNITED STATES DEPARTMENT OF COMMERCE
Office of the General Counsel
OFFICE OF CHIEF COUNSEL FOR INDUSTRY AND SECURITY
Washington, D.C. 20230

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dr. John Chen
Chairman and Chief Executive Officer
Bio Check, Inc.
8 3 7 Cowan Road
Burlingame, California 940 10

Dear Dr. Chen:

The Bureau of Industry and Security, United States Department of Commerce (“BIS”), has reason to believe that Bio Check, Inc. (“Bio Check”) of Burlingame, California, has committed 30 violations of the Export Administration Regulations (the “Regulations”),¹ which are issued under the authority of the Export Administration Act of 1979 (the “Act”).² Specifically, BIS charges that Bio Check committed the following violations:

**Charges 1-15 15 C.F.R. § 764.2(h) - Conduct Prohibited by or Contrary to the
Regulations - Unlicensed Exports of Items**

As described in greater detail in Schedule A, which is enclosed herewith and incorporated herein by reference, on 15 occasions between on or about May 27, 1998, and on or about May 6, 2002, Bio

¹ The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2003). The violations charged occurred from 1998 to 2002. The Regulations governing the violation at issue are found in the 1998 and 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1998-2002)). The Regulations define the violations that BIS alleges occurred and establish the procedures that apply to this matter.

² From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1707 (2000)) (“IEEPA”). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended by the Notice of August 14, 2002 (67 *Fed Reg.* 53721 (August 16, 2002)), has continued the Regulations in effect under IEEPA. The Act and Regulations are available on the Government Printing Office website at: <http://w3.access.gpo.gov/bis/>.

Check exported items subject to both the Regulations (EAR99),³ and the Iranian Transactions Regulations of the Treasury Department's Office of Foreign Assets Control ("OFAC"), through Italy or the United Arab Emirates, to Iran without obtaining authorization from OFAC as required by Section 746.7 of the Regulations. In doing so, Bio Check committed 15 violations of Section 764.2(a) of the Regulations.

Charges 16-30 15 C.F.R. § 764.2(a) - Conduct Prohibited by or Contrary to the Regulations - Failing to File Shipper's Export Declarations

In connection with the exports referenced above; on 15 occasions on or about May 27, 1998, and on or about May 6, 2002, Bio Check exported items subject to the Regulations to Iran without filing a Shipper's Export Declaration as required by Section 758 of the Regulations. In so doing, Bio Check committed 15 violations of Section 764.2(a) of the Regulations.

Accordingly, Bio Check is hereby notified that an administrative proceeding is instituted against it pursuant to 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 \$11,000 per violation;⁴

Denial of export privileges; and/or

Exclusion from practice before BIS.

If Bio Check fails to answer the charge contained in this letter within 30 days after being served with notice of issuance of this letter, that failure will be treated as a default. See 15 C.F.R. §§ 766.6 and 766.7. If Bio Check defaults, the Administrative Law Judge may find the charge alleged in this letter are true without a hearing or further notice to Bio Check. The Under Secretary for Industry and Security may then impose up to the maximum penalty on the charges in this letter.

Bio Check is further notified that it is entitled to an agency hearing on the record if Bio Check files a written demand for one with its answer. See 15 C.F.R. § 766.6. Bio Check is also entitled to be

³ The term "EAR99" refers to items subject to the Regulations which are not listed on the Commerce Control List. See 15 C.F.R. § 734.3(c). The term "ECCN" is an Export Control Classification Number. See Supp. 1 to 15 C.F.R. § 774.

⁴ See 15 C.F.R. § 6.4(a)(2).

Bio Check
Charging Letter
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represented by counsel or other authorized representative who has power of attorney to represent it.
See 15 C.F.R. §§ 766.3(a) and 766.4.

The Regulations provide for settlement without a hearing. See 15 C.F.R. § 766.18. Should you have a proposal to settle this case, your or your representative should transmit it to me through the attorney representing BIS named below.

The U.S. Coast Guard is providing administrative law judge services in connection with the matters set forth in this letter. Accordingly, Bio Check's answer must be filed in accordance with the instructions set forth in Section 766.5(a) of the Regulations with:

U.S. Coast Guard ALJ Docketing Center
40 S. Gay Street, Baltimore, Maryland 21202-4022

In addition, a copy of Bio Check's answer must be served on BIS at the following address:

Office of the Chief Counsel for Industry and Security
Attention: David C. Recker, Esq.
Room H-3839
United States Department of Commerce
14th Street and Constitution Avenue, N.W.
Washington, D.C. 20230

David C. Recker is the attorney representing BIS in this case. Any communications that you may wish to have concerning this matter should occur through him. He may be contacted by telephone at (202) 482-5301.

Sincerely,

Mark D. Menefee
Director
Office of Export Enforcement

Attachment: Schedule A

**BIO CHECK, INC.
SCHEDULE A
SCHEDULE OF VIOLATIONS**

DATE (on or about)	EXPORTER	COMMODITY	ECCN	DESTINATION	VALUE
5/27/98	Bio Check, Inc.	150 pregnancy tests (hCG) 80 thyroid function (T4) tests 20 thyroid function (TSH) tests 40 thyroid function (T3) tests 15 anemia @ man ferritin tests 15 infertility (prolactin) tests 15 fertility (FSH) tests 15 ovulation (LH) tests 10 prostate cancer (PSA) tests	EAR99	Iran	\$17,249.82
10/21/98	Bio Check, Inc.	10 pregnancy test (hCG) components 1 thyroid function (T4) test component 1 thyroid function (T3) test	EAR99	Iran	\$0 (replacement components)
12/23/98	Bio Check, Inc.	10 thyroid function (TSH) tests 25 thyroid function (T3) tests 50 thyroid function (T4) tests	EAR99	Iran	\$4,093.88
2/12/99	Bio Check, Inc.	30 thyroid function (TSH) tests 50 thyroid function (T3) tests 70 thyroid function (T4) tests 50 pregnancy tests (hCG) 10 liver function (HbsAg ELISA) test components	EAR99	Iran	\$10,178.00

DATE (on or about)	EXPORTER	COMMODITY	ECCN	DESTINATION	VALUE
4/30/99	Bio Check, Inc.	30 thyroid function (TSH) tests 50 thyroid function (T3) tests 70 thyroid function (T4) tests 50 pregnancy tests (hCG) 5 color reagent A (for determining test results) 5 color reagent B (for determining test results) 2.5 stop solution	EAR99	Iran	\$7,748.84
5/3/99	Bio Check, Inc.	30 thyroid function (TSH) tests 50 thyroid function (T3) tests 70 thyroid function (T4) tests 50 pregnancy tests (hCG)	EAR99	Iran	\$9,844.08

DATE (on or about)	EXPORTER	COMMODITY	ECCN	DESTINATION	VALUE
7/2/99	Bio Check, Inc.	40 thyroid function (TSH) tests 60 thyroid function (T3) tests 40 thyroid function (T4) tests 70 pregnancy tests (hCG) 20 ovulation (LH) tests 20 infertility (prolactin) tests 20 fertility (FSH) tests 10 anemia (human fenitin) tests 20 colon cancer (CEA) tests 20 liver cancer (AFP) tests 10 prostate cancer (PSA) tests 30 liver function (HbsAg ELISA) test components 60 thyroid function (T3) test components 40 thyroid function (TSH) test components 40 thyroid function (T4) test components 70 pregnancy test (hCG) components 3 5 thyroid function (T4) standards sets, replacement in plastic vials 3 ziploc bags 2 sets Avery labels 1 control serum (bio-rad) to monitor accuracy of tests 1 computer disk containing kit labels	EAR99	Iran	\$23,949.60

DATE (on or about)	EXPORTER	COMMODITY	ECCN	DESTINATION	VALUE
10/1/99	Bio Check, Inc.	52 liver function (HbsAg ELISA) test components 6 stomach ulcer (H. Pylori IgG) tests 6 fetus infection (toxoplasma IgG) tests 6 rubella tests 7 prostate cancer (PSA) tests 9 anemia (human fenitin) tests 1 anti-hyperthyroid chemical 1 each replacement component for pregnancy test, liver function test, and thyroid test	EAR99	Iran	\$0 (replacement kits and free samples)
10/9/01	Bio Check, Inc.	3 anemia (human ferritin) tests 3 heart disease (troponin) tests 3 fetus growth (estradiol level) tests 3 fetus growth (progesterone level) tests 3 fetus growth (testosterone level) tests	EAR99	Iran	\$600.00
12/17/01	Bio Check, Inc.	50 anemia (human ferritin) tests 5 fetus growth (estradiol level) tests 5 fetus growth (progesterone level) tests 20 fetus growth (testosterone level) tests 3 heart disease (troponin) tests	EAR99	Iran	\$3,3 10.00
1/23/02	Bio Check, Inc.	20 heart disease (troponin) tests	EAR99	Iran	\$2,200.00
3/12/02	Bio Check, Inc.	30 anemia (human fenitin) tests 30 fetus growth (testosterone level) tests 10 fetus growth (progesterone level) tests 10 fetus growth (estradiol level) tests	EAR99	Iran	\$3,210.00

DATE (on or about)	EXPORTER	COMMODITY	ECCN	DESTINATION	VALUE
4/23/02	Bio Check, Inc.	4 thyroid function (T3) tests 4 thyroid function (T4) tests 4 thyroid function (TSH) tests	EAR99	Iran	\$176.85
5/1/02	Bio Check, Inc.	5 thyroid function (T4) tests 5 thyroid function (free T4) tests 5 fetus growth (estradiol level) tests 5 fetus growth (progesterone level) tests 5 fetus growth (testosterone level) tests 5 pregnancy (hCG) tests 5 fertility (FSH) tests 5 ovulation (LH) tests 5 infertility (prolactin) tests 5 anemia (human ferritin) tests 5 growth hormone (hGH) tests 5 allergy (immunoglobulin E (IgE)) tests	EAR99	Iran	\$0 (free samples)
5/6/02	Bio Check, Inc.	5 liver function (AFP) tests 5 colon cancer (CEA) tests 5 ovarian cancer (CA 125) tests 5 breast cancer (CA 15-3) tests 5 gastrointestinal cancer (CA 19-9) tests 5 prostate cancer (PSA) tests 5 prostate cancer (f-PSA) tests 5 kidney function (B-2 microglobulin) tests 5 thyroid function (TSH) tests 5 thyroid function (U-TSH) tests 5 thyroid function (T3) tests 5 thyroid function (free T3) tests	EAR99	Iran	\$0 (free samples)

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY
WASHINGTON, D.C. 20230

In the Matter of:)
)
BIO CHECK, INC.)
837 Cowan Road)
Burlingame, California 94010,)
)
Respondent.)

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made by and between Respondent, Bio Check, Inc. (“Bio Check”), and the Bureau of Industry and Security, United States Department of Commerce (“BIS”) (collectively referred to as “Parties”), pursuant to Section 766.1 S(a) of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2003)) (“Regulations”),¹ issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (“Act”),²

¹ The violations charged occurred from 1998 to 2002. The Regulations governing the violation at issue are found in the 1998 to 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1998-2002)). The Regulations define the violations that BIS alleges occurred and establish the procedures that apply to this matter.

² From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1707 (2000)) (“IEEPA”). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended by the Notice of August 14, 2002 (67 Fed. Reg. 53721 (August 16, 2002)), has continued the Regulations in effect under IEEPA. The Act and Regulations are available on the Government Printing Office website at: <http://w3.access.gpo.gov/bis/>.

WHEREAS, BIS has notified Bio Check of its intention to initiate an administrative proceeding against Bio Check pursuant to the Act and the Regulations;

WHEREAS, BIS has issued a proposed charging letter to Bio Check that alleged that Bio Check committed 30 violations of the Regulations, specifically:

1. *1.5 Violations of 15 C.F.R. § 764.2(a) - Conduct Prohibited by or Contrary to the Regulations - Unlicensed Exports of Items:* Between on or about May 27, 1998, and on or about May 6, 2002, Bio Check exported items subject to both the Regulations (EAR99),³ and the Iranian Transactions Regulations of the Treasury Department's Office of Foreign Assets Control ("OFAC"), through Italy or the United Arab Emirates, to Iran without obtaining authorization from OFAC as required by Section 746.7 of the Regulations.
2. *15 Violations of 15 C.F.R. § 764.2(a) - Conduct Prohibited by or Contrary to the Regulations - Failing to File Shipper's Export Declarations:* In connection with the exports made on or about May 27, 1998, and on or about May 6, 2002, Bio Check exported items subject to the Regulations to Iran without filing a Shipper's Export Declaration as required by Section 758 of the Regulations.

WHEREAS, Bio Check has reviewed the proposed charging letter and is aware of the allegations made against it and the administrative sanctions which could be imposed against it if the allegations are found to be true;

³ The term "EAR99" refers to items subject to the Regulations which are not listed on the Commerce Control List. See 15 C.F.R. § 734.3(c). The term "ECCN" is an Export Control Classification Number. See Supp. 1 to 15 C.F.R. § 774.

WHEREAS, Bio Check fully understands the terms of this Agreement and the Order (“Order”) that the Assistant Secretary of Commerce for Export Enforcement will issue if she approves this Agreement as the final resolution of this matter;

WHEREAS, Bio Check enters into this Agreement voluntarily and with full knowledge of its rights;

WHEREAS, Bio Check states that no promises or representations have been made to it other than the agreements and considerations herein expressed;

WHEREAS, Bio Check neither admits nor denies the allegations contained in the proposed charging letter;

WHEREAS, Bio Check wishes to settle and dispose of all matters alleged in the proposed charging letter by entering into this Agreement; and

WHEREAS, Bio Check agrees to be bound by the Order, if entered;

NOW THEREFORE, the Parties hereby agree as follows:

1. BIS has jurisdiction over Bio Check, under the Regulations, in connection with the matters alleged in the proposed charging letter.

2. The following sanction shall be imposed against Bio Check in complete settlement of the violations of the Regulations set forth in the proposed charging letter:

- a. Bio Check shall be assessed a civil penalty in the amount of \$22,500 which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of the Order.

- b. The timely payment of the civil penalty agreed to in paragraph 2.a. is hereby made a condition to the granting, restoration, or continuing validity of any export license, permission, or privilege granted, or to be granted, to Bio Check. Failure to make timely payment of the civil penalty set forth above shall result in the denial of all of Bio Check's export privileges for a period of one year from the date of imposition of the penalty.

3. Subject to the approval of this Agreement pursuant to paragraph 8 hereof, Bio Check hereby waives all rights to further procedural steps in this matter (except with respect to any alleged violations of this Agreement or the Order, when entered), including, without limitation, any right to: (a) an administrative hearing regarding the allegations in the proposed charging letter; (b) request a refund of any civil penalty paid pursuant to this Agreement and the Order, when entered; and (c) seek judicial review or otherwise contest the validity of this Agreement or the Order, when entered.

4. Upon entry of the Order, BIS will not initiate any further administrative proceeding against Bio Check in connection with any violation of the Act or the Regulations arising out of the transactions identified in the proposed charging letter.

5. BIS will make the proposed charging letter, this Agreement, and the Order, when entered, available to the public.

6. This Agreement is for settlement purposes only. Therefore, if this Agreement is not accepted and the Order is not issued by the Assistant Secretary of Commerce for Export Enforcement pursuant to Section 766.18(a) of the Regulations, no Party may use this Agreement

in any administrative or judicial proceeding and the Parties shall not be bound by the terms contained in this Agreement in any subsequent administrative or judicial proceeding.

7. No agreement, understanding, representation or interpretation not contained in this Agreement may be used to vary or otherwise affect the terms of this Agreement or the Order, when entered, nor shall this 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.

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

9. Each signatory affirms that he has authority to enter into this Settlement Agreement and to bind his respective party to the terms and conditions set forth herein.

BUREAU OF INDUSTRY AND SECURITY
U.S. DEPARTMENT OF COMMERCE

BIO CHECK, INC.



Mark D. Menefee ³
Director
Office of Export Enforcement



Dr. John Chen
Chairman and Chief Executive Officer

Date: 5/23/03

Date: May 22, 2003

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY
WASHINGTON, D.C. 20230

In the Matter of:)
)
BIO CHECK, INC.)
837 Cowan Road)
Burlingame, California 940 10,)
)
Respondent.)
_____)

ORDER

The Bureau of Industry and Security, United States Department of Commerce (“BIS”) having notified Bio Check, Inc. (“Bio Check”) of its intention to initiate an administrative proceeding against Bio Check pursuant to Section 766.3 of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2003)) (“Regulations”),’ and Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (“Act”),* based on the proposed charging letter issued to Bio Check that alleged Bio Check committed 30 violations of the Regulations. Specifically, the charges are:

¹The violations charged occurred from 1998 to 2002. The Regulations governing the violation at issue are found in the 1998 to 2002 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774 (1998-2002)). The Regulations define the violations that BIS alleges occurred and establish the procedures that apply to this matter.

²From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1707 (2000)) (“IEEPA”). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), as extended by the Notice of August 14, 2002 (67 *Fed. Reg.* 53721 (August 16, 2002)), has continued the Regulations in effect under IEEPA. The Act and Regulations are available on the Government Printing Office website at: <http://w3.access.gpo.gov/bis/>.

1. *15 Violations of 15 C. F.R. § 764.2(a) - Conduct Prohibited by or Contrary to the Regulations - Unlicensed Exports of Items:* Between on or about May 27, 1998, and on or about May 6, 2002, Bio Check exported items subject to both the Regulations (EAR99),³ and the Iranian Transactions Regulations of the Treasury Department's Office of Foreign Assets Control ("OFAC"), through Italy or the United Arab Emirates, to Iran without obtaining authorization from OFAC as required by Section 746.7 of the Regulations.
2. *15 Violations of 15 C.F.R. § 764.2(a) - Conduct Prohibited by or Contrary to the Regulations - Failing to File Shipper's Export Declarations:* In connection with the exports made on or about May 27, 1998, and on or about May 6, 2002, Bio Check exported items subject to the Regulations to Iran without filing a Shipper's Export Declaration as required by Section 758 of the Regulations.

BIS and Bio Check having entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein, and the terms of the Settlement Agreement having been approved by me;

IT IS THEREFORE ORDERED:

FIRST, that a civil penalty of \$22,500 is assessed against Bio Check, which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of this Order.

Payment shall be made in the manner specified in the attached instructions.

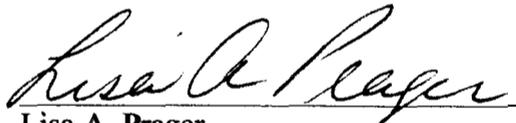
³ The term "EAR99" refers to items subject to the Regulations which are not listed on the Commerce Control List. See 15 C.F.R. § 734.3(c). The term "ECCN" is an Export Control Classification Number. See Supp. 1 to 15 C.F.R. § 774.

SECOND, that, pursuant to the Debt Collection Act of 1982, as amended (31 U.S.C. §§ 3701-3720E (2000)), the civil penalty owed under this Order accrues interest as more fully described in the attached Notice, and, if payment is not made by the due date specified herein, Bio Check will be assessed, in addition to the full amount of the civil penalty and interest, a penalty charge and an administrative charge, as more fully described in the attached Notice.

THIRD, that the timely payment of the civil penalty set forth above is hereby made a condition to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to Bio Check. Accordingly, if Bio Check should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of Bio Check's export privileges for a period of one year from the date of entry of this Order.

FOURTH, that the proposed charging letter, the Settlement Agreement, and this Order shall be made available to the public.

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



Lisa A. Prager
Acting Assistant Secretary of Commerce
for Export Enforcement

Entered this 24th day of June 3 .