

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

In the Matter of:

Indiana University  
107 S. Indiana Avenue  
Bloomington, Indiana 47405

Respondent.

ORDER RELATING TO  
INDIANA UNIVERSITY

The Bureau of Industry and Security, U.S. Department of Commerce (“BIS”), has notified The Trustees of Indiana University, (“IU”) of Bloomington, Indiana, of its intention to initiate an administrative proceeding against IU, with respect to conduct by its Bloomington *Drosophila* Stock Center, pursuant to Section 766.3 of the Export Administration Regulations (the “Regulations”),<sup>1</sup> through the issuance of a Proposed Charging Letter to IU that alleges that IU committed forty-two (42) violations of the Regulations.<sup>2</sup> Specifically:

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<sup>1</sup> The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. §§ 4601-4623 (Supp. III 2015) (“the EAA”), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. § 1701, et seq. (2012) (“IEEPA”). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. §§ 4801-4852 (“ECRA”). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA’s date of enactment (August 13, 2018), shall continue in effect until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

<sup>2</sup> The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2024). The charged violations occurred from 2017 through 2021. The Regulations governing the violations at issue are found in the 2017-2021 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774). The 2024 Regulations set forth the procedures that apply to this matter.

**Charges 1–42      15 C.F.R. § 764.2(a) – Engaging in Prohibited Conduct**

1. On 42 occasions between on or about November 27, 2017 and on or about April 29, 2021, IU, specifically the Bloomington Drosophila Stock Center, engaged in conduct prohibited by the Regulations when it exported 42 shipments of various strains of genetically modified fruit flies containing transgenes of the A subunit of the ricin toxin. These fruit fly strains were classified under Export Classification Control Number (“ECCN”) 1C353.b.2 until April 2, 2018, and 1C353.a.3 thereafter. These shipments, described in further detail in the attached schedule of violations, were valued at \$580.44.
2. Fruit flies modified to express *Ricin A* are used frequently in basic research of fruit fly development. The protein expressed by the *Ricin A* gene is not, by itself, a toxin, and does not pose a danger. Nevertheless, ricin and its subunits are controlled for export under the Australia Group, a multilateral group of countries dedicated to minimizing the risk of chemical and biological weapons proliferation, and for this reason is controlled under the Commerce Control List.
3. Pursuant to 15 C.F.R. § 742.2(a), a BIS license was required to export items with ECCN 1C353 to all destinations listed on the Commerce Country Chart in the CB1 (Chemical and Biological Weapons) category. *See* Supp. No. 1 to 15 C.F.R. Part 774 and Supp. No. 1 to 15 C.F.R. Part 738. The exports at issue went to 30 different institutions in 16 separate destinations. Although none of the 30 institutions were entities on BIS lists of parties of concern, all 16 destinations were listed under the CB1 category on the Commerce Country Chart, and therefore required a license for export. However, no license was sought or obtained for any of these exports.
4. IU’s Office of Research Compliance maintains an Export Control Office responsible for the university’s adherence to applicable export control laws and regulations. Upon discovering the unlicensed exports at issue, the IU Export Control Office submitted a voluntary self-disclosure to BIS in accordance with Section 764.5 of the Regulations.
5. By exporting the 1C353 fruit fly strains on 42 occasions without the required BIS licenses as described above, IU committed 42 violations of the Regulations.

WHEREAS, BIS and IU have 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;

WHEREAS, IU admits committing the alleged conduct described in the Proposed Charging Letter; and

WHEREAS, I have approved of the terms of such Settlement Agreement;

IT IS THEREFORE ORDERED:

FIRST, for a period of one (1) year from the date of the Order, Indiana University, with a last known address of 107 S. Indiana Avenue, Bloomington, Indiana 47405, shall be made subject to a suspended denial of its export privileges under the Regulations for all items designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations (“denial”). As authorized by Section 766.18(c) of the Regulations, such denial shall be fully suspended and shall thereafter be waived, provided that IU has not committed another violation of ECRA, the Regulations, or any order, license or authorization issued under ECRA or the Regulations, and has conducted export controls compliance training, and presented to the academic research community as described below. If IU commits another violation of ECRA, the Regulations, or any order, license or authorization issued under ECRA or the Regulations during the one-year suspension period under the Order, or fails to complete the compliance requirements specified in the below paragraphs, the suspension of the denial may be modified or revoked by BIS pursuant to Section 766.17(c) of the Regulations and a denial order (including a one-year denial period) activated against IU. If the suspension of the denial is modified or revoked, the activation order may also revoke any BIS licenses for any items designated as ECCN 1C351, 1C353, or 1C354 in which IU has an interest at the time of the activation order.<sup>3</sup>

SECOND, IU shall deliver export compliance training on the Regulations to relevant IU administrators across the university, including relevant research administrators and relevant fiscal officers, within twelve (12) months from the date of the Order. Before conducting such

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<sup>3</sup> Such a revocation would include licenses existing at the time of the activation order, whether the license had issued before or after ECRA’s enactment on August 13, 2018. *See* Note 1, *supra*.

training, IU shall notify the Office of Export Enforcement, Special Agent in Charge of the Chicago Field Office, of the IU administrators and offices it intends to train. No later than one month after completing such training, IU shall certify completion of the training, including by providing a list of participating offices and administrative groups and any training materials used, to the Office of Export Enforcement, One Oakbrook Terrace, Suite 804, Oakbrook Terrace IL 60181 (“BIS Chicago Field Office”).

THIRD, in order to raise awareness of the Regulations to others engaged in distributing transgenic organisms to the biomedical research community, IU shall deliver a presentation on the circumstances involved in the violations and related voluntary self-disclosure to a forum of stock center directors, such as the meeting of directors of National Institutes of Health-sponsored stock centers convened biennially. Before conducting such a presentation, IU shall notify the BIS Chicago Field Office of the date and intended audience of the presentation. No later than one month after the presentation, IU shall certify in writing to the BIS Chicago Field Office its completion of this presentation and provide a copy of any related presentation materials.

FOURTH, in order to raise awareness of the Regulations in the academic research community, IU shall deliver a presentation on the circumstances involved in the violations and related voluntary self-disclosure on export controls relating to biological materials at the Association of University Export Control Officers conference, or another appropriate forum, such as a conference for university legal counsel, research administrators, or research compliance or university export control officers. Before conducting such a presentation, IU shall notify the BIS Chicago Field Office of the date and intended audience of the presentation. No later than one month after presenting, IU shall certify in writing to the BIS Chicago Field Office its

completion of this presentation requirement and provide a copy of any related presentation materials.

FIFTH, compliance with the terms of the Settlement Agreement and the Order, including the timely completion and submission of verification of attendance at export compliance training, as set forth above, are hereby made conditions to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to IU.

SIXTH, should the suspension of the denial be modified or revoked pursuant to Section 766.17(c) of the Regulations, and a denial order (including a one-year denial period) be activated against IU, for the duration of such denial order, IU, and when acting for or on its behalf, its successors, assigns, directors, officers, employees, representatives, or agents (hereinafter collectively referred to as "Denied Person"), may not, directly or indirectly, participate in any way in any transaction involving any item designated as ECCN 1C351, 1C353, or 1C354 exported or to be exported from the United States that is subject to the Regulations, or in any other export-related activity involving any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations, including, but not limited to:

- A. Applying for, obtaining, or using any license, license exception, or export control document for items designated as ECCN 1C351, 1C353, or 1C354;
- B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item designated as ECCN 1C351, 1C353, or 1C354 exported or to be exported from the United States that is subject to the Regulations, or engaging in any other export-related

activity involving any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations; or

- C. Benefitting in any way from any transaction involving any item designated as ECCN 1C351, 1C353, or 1C354 exported or to be exported from the United States that is subject to the Regulations, or from any other export-related activity involving any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations.

SEVENTH, should the suspension of the denial be modified or revoked, and a denial order be activated against IU, for the duration of the denial order, no person may, directly or indirectly, do any of the following:

- A. Export or reexport to or on behalf of the Denied Person any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations;
- B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;
- C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations that has been exported from the United States;
- D. Obtain from the Denied Person in the United States any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations with knowledge or reason to

know that the item will be, or is intended to be, exported from the United States;

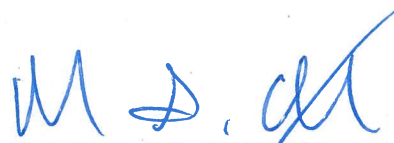
or

- E. Engage in any transaction to service any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item designated as ECCN 1C351, 1C353, or 1C354, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item designated as ECCN 1C351, 1C353, or 1C354 subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

EIGHTH, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to the Denied Person by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

NINTH, 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.



Matthew S. Axelrod  
Assistant Secretary of Commerce  
for Export Enforcement

Issued this 24<sup>th</sup> day of June, 2024.

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

In the Matter of:

Indiana University  
107 S. Indiana Avenue  
Bloomington, Indiana 47405

Respondent.

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made by and between The Trustees of Indiana University, (“IU”), with respect to conduct by its Bloomington Drosophila Stock Center in Bloomington, Indiana, and the Bureau of Industry and Security, U.S. Department of Commerce (“BIS”) (collectively, the “Parties”), pursuant to Section 766.18(a) of the Export Administration Regulations (the “Regulations”).<sup>1</sup>

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<sup>1</sup> The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. §§ 4601-4623 (Supp. III 2015) (“the EAA”), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. § 1701, et seq. (2012) (“IEEPA”). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, Title XVII, Subtitle B of Pub. L. 115-232, 132 Stat. 2208 (“ECRA”). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA’s date of enactment (August 13, 2018), shall continue in effect until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.



WHEREAS, IU filed a voluntary self-disclosure with BIS's Office of Export Enforcement in accordance with Section 764.5 of the Regulations concerning the transactions at issue herein;

WHEREAS, BIS has notified IU of its intentions to initiate an administrative proceeding against IU pursuant to the Regulations;<sup>2</sup>

WHEREAS, BIS has issued a Proposed Charging Letter to IU that alleges that IU committed forty-two (42) violations of the Regulations, specifically:

**Charges 1–42                      15 C.F.R. § 764.2(a) – Engaging in Prohibited Conduct**

1. On 42 occasions between on or about November 27, 2017, and on or about April 29, 2021, IU, specifically the Bloomington *Drosophila* Stock Center, engaged in conduct prohibited by the Regulations when it exported 42 shipments of various strains of genetically modified fruit flies containing transgenes of the A subunit of the ricin toxin. These fruit fly strains were classified under Export Classification Control Number (“ECCN”) 1C353.b.2 until April 2, 2018, and 1C353.a.3 thereafter. These shipments, described in further detail in the attached schedule of violations, were valued at \$580.44.
2. Fruit flies modified to express *Ricin A* are used frequently in basic research of fruit fly development. The protein expressed by the *Ricin A* gene is not, by itself, a toxin, and does not pose a danger. Nevertheless, Ricin and its subunits are controlled for export under the Australia Group, a multilateral group of countries dedicated to minimizing the risk of chemical and biological weapons proliferation, and for this reason is controlled under the Commerce Control List.
3. Pursuant to 15 C.F.R. § 742.2(a), a BIS license was required to export items with ECCN 1C353 to all destinations listed on the Commerce Country Chart in the CB1 (Chemical and Biological Weapons) category. *See* Supp. No. 1 to 15 C.F.R. Part 774 and Supp. No. 1 to 15 C.F.R. Part 738. The exports at issue went to 30 different institutions in 16 separate destinations. Although none of the 30 institutions were entities on BIS lists of parties of concern, all 16 destinations were listed under the CB1 category on the Commerce Country Chart, and therefore required a license for export. However, no license was sought or

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<sup>2</sup> The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2024). The charged violations occurred from 2017 through 2021. The Regulations governing the violations at issue are found in the 2017-2021 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774). The 2024 Regulations set forth the procedures that apply to this matter.

obtained for any of these exports.

4. IU's Office of Research Compliance maintains an Export Control Office responsible for the university's adherence to applicable export control laws and regulations. Upon discovering the unlicensed exports at issue, the IU Export Control Office submitted a voluntary self-disclosure to BIS in accordance with Section 764.5 of the Regulations.
5. By exporting the 1C353 fruit fly strains on 42 occasions without the required BIS licenses as described above, IU committed 42 violations of the Regulations.

WHEREAS, IU 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;

WHEREAS, IU has reviewed, with the assistance of counsel, the terms of this Agreement, the Order ("Order") that the Assistant Secretary of Commerce for Export Enforcement, or appropriate designee, will issue if he approves this Agreement as the final resolution of this matter, and the Proposed Charging Letter, and understands the terms of all three documents;

WHEREAS, IU enters into this Agreement voluntarily and with full knowledge of its rights, after having consulted with counsel;

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

WHEREAS, IU admits committing the alleged conduct described in the Proposed Charging Letter; and

WHEREAS, IU agrees to be bound by the Order, if issued;

NOW THEREFORE, the Parties hereby agree, for purposes of this Agreement, as follows:

1. BIS has jurisdiction over IU, under the Regulations, in connection with the matters alleged in the Proposed Charging Letter.

2. The following sanctions shall be imposed against IU:

a. For a period of one (1) year from the date of the Order, IU shall be made subject to a suspended denial of its export privileges under the Regulations for all items designated as ECCN 1C351, 1C353, or 1C354 and subject to the Regulations (“denial”). As authorized by Section 766.18(c) of the Regulations, such denial shall be fully suspended and shall thereafter be waived, provided that IU has not committed another violation of ECRA, the Regulations, or any order, license or authorization issued under ECRA or the Regulations, and has conducted export controls compliance training, and presented to the academic research community as described below. If IU commits another violation of ECRA, the Regulations, or any order, license or authorization issued under ECRA or the Regulations during the one-year suspension period under the Order, or fails to complete the requirements specified in Paragraphs 2.c - 2.e below, the suspension of the denial may be modified or revoked by BIS pursuant to Section 766.17(c) of the Regulations and a denial order (including a one-year denial period) activated against IU. If the suspension of the denial is modified or revoked, the activation order may also revoke any BIS licenses for any items designated as ECCN 1C351, 1C353, or 1C354 in which IU has an interest at the time of the activation order.<sup>3</sup>

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<sup>3</sup> Such a revocation would include licenses existing at the time of the activation order, whether the license had issued before or after ECRA’s enactment on August 13, 2018. *See* Note 1, *supra*.

b. Should the suspension of the denial be modified or revoked pursuant to Section 766.17(c) of the Regulations, and a denial order (including a one-year denial period) be activated against IU, for the duration of such denial order, IU, and when acting for or on its behalf, its successors, assigns, directors, officers, employees, representatives, or agents (hereinafter collectively referred to as “Denied Person”), may not, directly or indirectly, participate in any way in any transaction involving any items designated as ECCN 1C351, 1C353, or 1C354 exported or to be exported from the United States and subject to the Regulations, or in any other export-related activity involving items designated as ECCN 1C351, 1C353, or 1C354 and subject to the Regulations, including, but not limited to:

i. Applying for, obtaining, or using any license, license exception, or export control document for items designated as ECCN 1C351, 1C353, or 1C354;

ii. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving items designated as ECCN 1C351, 1C353, or 1C354 exported or to be exported from the United States and subject to the Regulations, or engaging in any other export-related activity involving items designated as ECCN 1C351, 1C353, or 1C354 and subject to the Regulations; or

iii. Benefitting in any way from any transaction involving items designated as ECCN 1C351, 1C353, or 1C354 exported or to be exported from the United States and subject to the Regulations, or from any other export-related

activity involving items designated as ECCN 1C351, 1C353, or 1C354 and subject to the Regulations.

c. IU shall deliver export compliance training on the Regulations to relevant IU administrators across the university, including relevant research administrators and relevant fiscal officers, within twelve (12) months from the date of the Order. Before conducting such training, IU shall notify the Office of Export Enforcement, Special Agent in Charge of the Chicago Field Office, of the IU administrators and offices it intends to train. No later than one month after completing such training, IU shall certify completion of the training, including by providing a list of participating offices and administrative groups and any training materials used, to the Office of Export Enforcement, One Oakbrook Terrace, Suite 804, Oakbrook Terrace IL 60181 (“BIS Chicago Field Office”).

d. In order to raise awareness of the Regulations to others engaged in distributing transgenic organisms to the biomedical research community, IU shall deliver a presentation on the circumstances involved in the violations and related voluntary self-disclosure to a forum of stock center directors, such as the meeting of directors of National Institutes of Health-sponsored stock centers convened biennially. Before conducting such a presentation, IU shall notify the BIS Chicago Field Office of the date and intended audience of the presentation. No later than one month after the presentation, IU shall certify in writing to the BIS Chicago Field Office its completion of this presentation and provide a copy of any related presentation materials.

e. In order to raise awareness of the Regulations in the academic research community, IU shall deliver a presentation on the circumstances involved in the violations and related voluntary self-disclosure on export controls relating to biological materials at the Association of University Export Control Officers conference, or another appropriate forum, such as a conference for university legal counsel, research administrators, or research compliance or university export control officers. Before conducting such a presentation, IU shall notify the BIS Chicago Field Office of the date and intended audience of the presentation. No later than one month after the presentation, IU shall certify in writing to the BIS Chicago Field Office its completion of this presentation requirement and provide a copy of any related presentation materials.

f. Compliance with the terms of this Agreement and the Order, including the timely completion of the requirements set forth in Paragraphs 2.c. - 2.e. above, are hereby made conditions to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to IU.

3. Subject to the approval of this Agreement pursuant to Paragraph 7 hereof, IU hereby waives all rights to further procedural steps in this matter including, without limitation, any right to: (a) an administrative hearing regarding the allegations in any charging letter; and (b) seek judicial review or otherwise contest the validity of this Agreement or the Order, if issued. IU also waives and will not assert any Statute of Limitations defense, and the Statute of Limitations will be tolled, in connection with any violation of the Act or the Regulations arising out of the transactions identified in the

Proposed Charging Letter or enforcement of this Agreement and the Order, if issued, from the date of the Order until the later of the date of (1) IU's completion of the requirements set forth in Paragraphs 2.c - 2.e. above, and (2) the expiration of the one-year suspension period under the Order.

4. BIS agrees that upon successful compliance in full with the terms of this Agreement and the Order, if issued, BIS will not initiate any further administrative proceeding against IU in connection with any violation of the Regulations arising out of the transactions specifically detailed in the Proposed Charging Letter.

5. 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.

6. 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, if issued; nor shall this Agreement serve to bind, constrain, or otherwise limit any action by any other agency or department of the U.S. Government with respect to the facts and circumstances addressed herein.

7. This Agreement shall become binding on the Parties only if the Assistant Secretary of Commerce for Export Enforcement, or appropriate designee, approves it by issuing the Order, which will have the same force and effect as a decision and order issued after a full administrative hearing on the record.

8. BIS will make the Proposed Charging Letter, this Agreement, and the Order, if issued, available to the public.

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

BUREAU OF INDUSTRY AND  
SECURITY  
U.S. DEPARTMENT OF COMMERCE  
JOHN  
SONDERMAN  
Digitally signed by JOHN  
SONDERMAN  
Date: 2024.06.22 14:14:01  
-04'00'

John Sonderman  
Director of Export Enforcement

Date: \_\_\_\_\_

THE TRUSTEES OF INDIANA  
UNIVERSITY

*Donald S. Lukes*  
Electronically signed by:  
Don Lukes  
Date: Jun 17, 2024 08:51  
EDT  
Donald S. Lukes  
University Treasurer  
Indiana University

Date: Jun 17, 2024

Reviewed by:

*Jeffrey Goetz*  
Electronically signed by:  
Jeffrey Goetz  
Date: Jun 17, 2024 09:50  
EDT  
Jeffrey Goetz  
Associate Vice President & Deputy General  
Counsel  
Indiana University

Date: Jun 17, 2024



PROPOSED CHARGING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Indiana University  
107 S. Indiana Avenue  
Bloomington, Indiana 47405

*Attention:* Donald S. Lukes, University Treasurer

Dear Mr. Lukes:

The Bureau of Industry and Security, U.S. Department of Commerce (“BIS”), has reason to believe that Indiana University of Bloomington, Indiana (“IU”), through the conduct of its Bloomington Drosophila Stock Center, has violated the Export Administration Regulations (“the Regulations” or “the EAR”).<sup>1</sup> Specifically, BIS alleges that IU committed the following violations:

**Charges 1-42            15 C.F.R. § 764.2(a) – Engaging in Prohibited Conduct**

1. On 42 occasions between on or about November 27, 2017 and on or about April 29, 2021, and as described in further detail in the attached schedule of violations, IU, specifically the Bloomington Drosophila Stock Center, engaged in conduct prohibited by the Regulations when it exported 42 shipments of various strains of genetically modified fruit flies containing transgenes of the A subunit of the ricin toxin. These fruit fly strains were classified under Export Classification Control Number (“ECCN”) 1C353.b.2 until April 2, 2018, and 1C353.a.3 thereafter. These shipments, described in further detail in the attached schedule of violations,

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<sup>1</sup> The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. §§ 4601-4623 (Supp. III 2015) (“the EAA”), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. § 1701, et seq. (2012) (“IEEPA”). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. 115-232, which includes the Export Control Reform Act of 2018, 50 U.S.C. §§ 4801-4852 (“ECRA”). Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA’s date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2024). The charged violations alleged occurred in 2017-2021. The Regulations governing the violations at issue are found in the 2017-2021 versions of the Code of Federal Regulations, 15 C.F.R. Parts 730-774. The 2024 Regulations govern the procedural aspects of this case.

were valued at \$580.44.

2. Fruit flies modified to express *Ricin A* are used frequently in basic research of fruit fly development. The protein expressed by the *Ricin A* gene is not, by itself, a toxin, and does not pose a danger. Nevertheless, ricin and its subunits are controlled for export under the Australia Group, a multilateral group of countries dedicated to minimizing the risk of chemical and biological weapons proliferation, and for this reason is controlled under the Commerce Control List.
3. Pursuant to 15 C.F.R. § 742.2(a), a BIS license was required to export items with ECCN 1C353 to all destinations listed on the Commerce Country Chart in the CB1 (Chemical and Biological Weapons) category. *See* Supp. No. 1 to 15 C.F.R. Part 774 and Supp. No. 1 to 15 C.F.R. Part 738. The exports at issue went to 30 different institutions in 16 separate destinations. Although none of the 30 institutions were entities on BIS lists of parties of concern, all 16 destinations were listed under the CB1 category on the Commerce Country Chart, and therefore required a license for export. However, no license was sought or obtained for any of these exports.
4. IU's Office of Research Compliance maintains an Export Control Office responsible for the university's adherence to applicable export control laws and regulations. Upon discovering the unlicensed exports at issue, the IU Export Control Office submitted a voluntary self-disclosure to BIS in accordance with Section 764.5 of the Regulations.
5. By exporting the 1C353 fruit fly strains on 42 occasions without the required BIS licenses as described above, IU committed 42 violations of the Regulations.

\* \* \* \* \*

Accordingly, IU 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, potentially including, but not limited to, any or all of the following:

- The maximum civil penalty allowed by law of up to the greater of \$368,136 per violation, or twice the value of the transaction that is the basis of the violation;<sup>2</sup>

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<sup>2</sup> For alleged violations that occurred prior to August 13, 2018, the applicable potential sanctions are provided for under IEEPA, rather than ECRA. *See* note 1, *supra*; *see* also 50 U.S.C. § 1705(b) (prescribing civil monetary penalty amount for IEEPA violation). This amount is subject to annual increases pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Sec. 701 of Public Law 114-74, enacted on November 2, 2015. *See* 88 Fed. Reg. 89300 (Dec. 27, 2023) (adjusting for inflation the maximum civil monetary penalty under IEEPA from \$356,979 to \$368,136, effective Jan. 15, 2024); *see also* 15 C.F.R. §§

- Denial of export privileges;
- Exclusion from practice before BIS; and/or
- Any other liability, sanction, or penalty available under law.

If IU fails to answer the charges 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 IU defaults, the Administrative Law Judge may find the charges alleged in this letter are true without a hearing or further notice to IU. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty for the charges in this letter.

IU is further notified that it is entitled to an agency hearing on the record if it files a written demand for one with its answer. *See* 15 C.F.R. § 766.6. IU is also entitled to be 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 IU have a proposal to settle this case, IU should transmit it to the attorneys 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, IU's answer must be filed in accordance with the instructions 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 IU's answer must be served on BIS at the following address:

Office of Chief Counsel for Industry and Security  
14th Street and Constitution Avenue, N.W.  
Room H-3839  
Washington, D.C. 20230  
Attention: Kimberly Hsu, Esq.

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6.3(c)(4), 6.3(c)(6), 6.4. For violations occurring on or after the enactment of ECRA on August 13, 2018, the maximum civil penalty is \$364,992. *See* 50 U.S.C. § 4819 (prescribing civil monetary penalty amount for ECRA violation); 15 C.F.R. §§ 6.3(c)(4), 6.4 (adjusting civil monetary penalty amount for inflation); Supp. No. 1 to 15 C.F.R. Part 766 (prescribing civil monetary penalty amount for ECRA violation).

Kimberly Hsu is the attorney representing BIS in this case; any communications that IU may wish to have concerning this matter should occur through her. Ms. Hsu may be contacted by phone at 202-482-5301.

Sincerely,

John D. Sonderman  
Director  
Office of Export Enforcement

Schedule of Violations

Charge No.	Export Date	Item Description	ECCN	Destination
1	11/27/2017	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	Japan
2	11/30/2017	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	United Kingdom
3	12/4/2017	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	Singapore
4	1/18/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	United Kingdom
5	2/1/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	France
6	2/1/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	Belgium
7	2/22/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	Portugal
8	3/29/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.b.2	United Kingdom
9	5/31/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	India
10	6/18/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Ireland
11	10/4/2018	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Canada
12	1/24/1019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Israel
13	2/14/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Taiwan

14	3/25/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Israel
15	4/4/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Germany
16	4/22/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Germany
17	4/22/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Portugal
18	4/22/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	France
19	7/4/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Germany
20	9/5/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	India
21	10/10/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Switzerland
22	10/21/2019	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	France
23	2/13/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Taiwan
24	3/23/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	China
25	5/28/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Portugal
26	6/11/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Germany
27	6/18/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Israel
28	6/29/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Canada

29	7/20/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Greece
30	7/23/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Israel
31	8/3/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Germany
32	8/17/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Portugal
33	8/20/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	United Kingdom
34	9/10/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Germany
35	10/22/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Portugal
36	11/5/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Japan
37	11/9/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Spain
38	12/7/2020	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Germany
39	1/11/2021	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Portugal
40	3/1/2021	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Portugal
41	3/4/2021	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Belgium
42	4/29/2021	Fruit flies Genetically Modified to Produce a Subunit of a Controlled Toxin	1C353.a.3	Japan