DOC #:	EHS-0041	**Revision #:**	2.0
DOC Type:	SOP	**Implementation Date:**	9/16/2005
Page #:	1 of 28	**Last Reviewed/Update Date:**	03/20/2023
Owner:	Iraj Aalaei	**Approval:**	Jim Doughty

Toxic Substances Control Act (TSCA): Procedures for Core Program Compliance

1. Purpose / Background

The US Environmental Protection Agency (EPA), as part of its mandate to protect human health and the environment, is authorized to evaluate and control the entry and circulation of hazardous substances in the marketplace. Through the Toxic Substances Control Act (TSCA), EPA regulates the import, production (manufacture), and export of new chemicals and can also restrict the production and use of existing chemicals. EPA may also require MIT to supply data on adverse health and environmental effects of chemicals used for research and development.

Because of the broad powers granted to EPA through TSCA, the law and its codified regulations (40 CFR 700-799) are extensive. However, only a few key sections of TSCA potentially affect the day-to-day research activities and operations of the DLCs. These key sections, which comprise the "Core TSCA" program, are as follows:

- Section 5, Pre-Manufacture Notice Requirements for New Chemicals
- Section 8, Chemical Data Reporting (new and existing chemicals)
- Section 12, Exports (new and existing chemicals)
- Section 13, Imports (new and existing chemicals)

This Standard Operating Procedure (SOP) outlines the steps DLCs must take to ensure that MIT complies with "Core TSCA" requirements. Violations of the TSCA can subject MIT to fines of up to $27,500 per day.

This SOP supports MIT's Environmental, Health, and Safety Policy which calls for minimizing, as feasible, the adverse environmental, health, and safety impacts of our facilities, activities, and operations to protect human health and the environment and "achieving and maintaining compliance with federal, state and local environmental, health and safety laws and good practices in all of our departments, laboratories, research centers, facilities, and operations."

2. Scope

Research activities involving chemicals, both "new" and "existing," are covered under this SOP. The import and export of chemicals across all DLCs are also covered, as is evidence of health or environmental harm resulting from a chemical. This SOP does not address research activities involving the engineering of new microorganisms[1]. However,

[1] Although microorganisms are considered chemical substances under TSCA, the definition of "small quantities" is complicated by the ability of microorganisms to reproduce quickly. Contact the EHS Office if your research involves importing or producing new microorganisms.

nanomaterials regarded as "chemical substances" under TSCA are covered under this SOP. A nanomaterial is defined as a substance or particle with dimensions or diameter of 1-100 nanometers (where a nanometer is one billionth, or 10^{-9}, of a meter).

The TSCA Inventory is a listing of over 70,000 chemicals that are known to be broadly circulating in commerce, and is updated semi-annually. For TSCA, a chemical is considered "new" if it is not listed on the TSCA Inventory. DLCs may be more familiar with the Chemical Abstract Service (CAS), a far more comprehensive listing of chemicals, only a fraction of which are broadly circulating in commerce.

3. Prerequisites

Researchers and laboratory staff should know their DLC's Chemical Hygiene Plan and receive General and Lab Specific Chemical Hygiene training. Specific attention shall be paid to labeling requirements, procedures for working with hazardous substances (i.e., chemicals for which little or no information on health effects is known), medical surveillance, and exposure monitoring.

Sponsored Research: Scope of Research and Development (R&D) activity

MIT's ability to document that laboratory activity involving chemicals is for research and development (R&D) purposes only (even if it is considered "commercial" R&D) is critical to comply with certain exemptions in the TSCA regulations (R&D exemptions). R&D exemptions provide a streamlined method for MIT to comply with the law; however, MIT must demonstrate that its activities are eligible for this exemption. Regarding the Core TSCA program, the R&D exemption exists for Pre-Manufacture Notification requirements (section 5). Appendix A guides the scope of activities that the EPA considers "research and development" under TSCA.

Much of MIT research is funded (sponsored) by a government, non-government, or private sector organization. The Office of Sponsored Programs (OSP) and the Industrial Liaison Program (ILP) are the two central offices on the MIT campus through which grant applications and funding paperwork/contracts are processed. Grant documents submitted to the OSP, particularly the Standard Agreements, and contracts coordinated through the Industrial Liaison Program, will likely describe the nature of the research activity and any intellectual property rights. Both documents prove that the research activity is conducted for R&D purposes only. Researchers or their Administrative Officers (AOs) or Administrative Assistants should have these documents. Additionally, each Department is assigned to a contact at OSP and ILP.

Researchers are encouraged to review any Material Transfer Agreements (MTAs) that may have been executed through MIT for using or transferring new chemicals. MTAs serve as supporting documentation that the material will be used for R&D only. The Technology Licensing Office issues MTAs for outgoing materials; the Office of Intellectual Property Counsel issues MTAs for incoming materials.

A Standard Agreement issued through OSP and a sample MTA appear as Appendix B-1 and Appendix B-2 to this SOP.

4. Procedures

4.1. Summary of General Procedures

4.1.1. A TSCA Import Certification must be completed if a researcher imports a chemical substance. The certification must be completed regardless of whether the substance is regulated under TSCA. Refer to Section 4.2, "Import Requirements." **Note: Microorganisms and nanomaterials are considered chemical substances under TSCA.**

4.1.2. If a researcher is **exporting** a chemical substance, a TSCA Export Notice may be required in certain circumstances. Refer to Section 4.3, "Export Requirements."

4.1.3. All laboratory research that involves synthesis, processing, or analysis of new chemicals must comply with the requirements outlined in Section 4.4, "R&D Exemption from Pre-Manufacture Notification."

4.1.4. Transfers of a new chemical (including export) for which little environmental, health, and safety data is known to a lab outside of the one where it is synthesized require risk notification to the users. Section 4.5, "Handling and Transfer of Chemicals for Which Little Environment, Health, and Safety Data are Known," outlines risk notification requirements.

4.1.5. Incidents and exposures (including environmental exposures) involving a new or existing chemical must be reported to the EHS Office. Section 4.6, "Allegations of Adverse Reactions and Substantial Risk Notification," contains requirements for reporting chemical exposures.

4.2. Import Requirements

4.2.1. Section 13 of TSCA requires a Chemical Import Certification Form (see Appendix C) to be completed for any new or existing chemical imported into the United States. A chemical is imported if it is:

- hand carried into the US on the person or in personal baggage;
- formally brought into the US through Customs; or
- shipped through a method other than Customs (e.g., airmail or FedEx).

4.2.2. The importer must make either a positive TSCA declaration or a negative TSCA declaration.

4.2.3. A chemical receives a negative TSCA declaration if its intended use falls under one of the following categories:

- food, drugs, cosmetics, medical devices, or other materials regulated by the Food and Drug Administration (FDA) or chemicals (e.g., intermediates) that are manufactured exclusively for these uses;

- firearms, ammunition, and other materials regulated under the Bureau of Alcohol, Tobacco, and Firearms (ATF);
- nuclear or other radioactive material that is regulated by the Nuclear Regulatory Commission (NRC); or
- pesticides (registered under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act); pesticide intermediates and individual components of a pesticide, however, are covered.

The negative certification statement wording is as follows: *"I certify that all chemicals in this shipment are not subject to TSCA."*

4.2.4. Tobacco/tobacco products and articles do not require a TSCA import certification. A chemical or substance is considered part of an article if the substance or mixture is not intended to be removed from that article and has no end use or commercial purpose separate from the article of which it is a part. Fluids and particles are not considered articles. Refer to Section 10, "Definitions," for a complete definition of "article."

4.2.5. All other chemicals require a positive certification. The positive certification statement wording is as follows: "I certify that all chemical substances in the shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable order under TSCA."

4.2.6. The EHS Office must be contacted if the DLC intends to import microorganisms, as their potential risks may require review/registration through the Biosafety Program.

4.2.7. Before the chemical is imported, it is important to check that it is not banned or restricted under TSCA.[2] The EHS Office shall provide DLCs with an updated list of import restrictions compiled from EPA's Federal Register. The EHS Office may also be contacted at x2-3477 to verify the status of a chemical before importation.

4.2.8. The researcher must complete the import certification form if the researcher intends to import the chemical independently (i.e., arranges to have a colleague send a sample from outside the US).

4.2.9. They will complete the import certification if the chemical is ordered through VWR.

[2] Examples of chemical restrictions include:
a) EPA has issued a consent order under Section 5
b) EPA has restricted the circulation of the chemical under Section 6
c) EPA has deemed the chemical imminently hazardous under Section 7, and is authorized under this Section to seize chemicals.
EPA can also take action against the importers of such chemicals.

4.2.10. If the chemical is ordered directly through a foreign vendor (i.e., a vendor outside the U.S.), the completed Import Certification Form shall be submitted with the purchase order to the foreign vendor. The purchase order must include the language "This chemical substance will be used for research and development purposes only" and shall include the identity of the substance, including CAS number if available, and the quantity (mass or volume) of the substance ordered. The vendor must be instructed to return the certification form with the shipment to be available to the customs officer when it enters the country. When the shipment is received, keep the import certification attached to the copy of the purchase order.

4.2.11. When ordering a chemical or microorganism through a foreign vendor, researchers are advised to contact the EHS Office. MIT's Customs Broker, Carmichael International Service, will check to ensure that Customs paperwork has been completed. They do not, however, physically complete the certification forms for the importer.

4.2.12. The DLC shall keep one copy of the Import Certification Statement and shall forward a copy of the Import Certification Statement to the EHS Office.

4.2.13. Copies of the Import Certification Forms shall be kept for three years.

4.3. Export Requirements

4.3.1. TSCA requires EPA to notify importing countries of the export of chemicals or mixtures subject to certain rules and orders. The EHS Office shall maintain and provide DLCs with an updated listing of chemicals subject to export notification (link below).

Chemicals Subject to TSCA Section 12(b) Export Notification Requirements (March 30, 2018)

No export notification is required if the chemical does not appear on the Export Notification list.

4.3.2. A TSCA Export Notification Form must be completed and submitted to EPA if the chemical appears on the Export Notification list. The TSCA Export Notification appears as Appendix D to this SOP.

4.3.3. The researcher shall contact the EHS Office before shipping the chemical to ensure the Export Notification is completed and documented with the remaining standard shipping documents.

4.3.4. The Export Notification to EPA shall consist of:

- A letter to EPA indicating that it is about the TSCA Section 12(b) Notice

- A notification statement reads: *"In accordance with the requirements of 40 CFR 707, Subpart D, notice is hereby given that MIT is exporting the following chemical(s), which is regulated under the Toxic Substances Control Act. This export notification is triggered by (TSCA Section 4) or (TSCA Section 5, 6, or 7)."*[23]
- Export information: the chemical name; CAS number; name and address of exporter, country of import, name and address of the recipient, and date of export.

4.3.5. If the chemical is designated under Section 5(f), 6, or 7, a notification to EPA is required for the first export of each calendar year.

4.3.6. If the chemical is designated under Section 4 or subparts of Section 5 other than Section 5(f), then only a one-time export notification is required to EPA.

4.3.7. De minimis concentrations for export notification exemption. No notice of export is required for the following:

- Chemical substances or mixtures for which notification is normally required under 4.3.5 or 4.3.6 IF the chemical IS NOT a known or potential human carcinogen AND the substance or mixture is present in concentrations less than 1% by weight or volume.

- A chemical substance or mixture that IS a known or potential human carcinogen IF the chemical substance or mixture is present in a concentration of less than 0.1% (by weight or volume); and/or

- PCBs or PCB-containing materials where the concentration of PCBs is less than or equal to 50 ppm (parts per million).

4.3.8. The Export Notification must be postmarked within seven days after accepting a definite contractual obligation or reaching a final decision to export. When the actual export occurs less than seven days after the export obligation or agreement has been executed, the notice must be submitted to EPA no later than the same day as the export.

4.3.9. DLCs receiving funding through the Office of Sponsored Programs shall check the Policy on Export Control of Chemicals (see "Do I Need to be Concerned About Export Controls?) to ensure compliance with said Policy.

4.3.10. The DLC shall keep one copy of the Export Notification and submit a second copy to the EHS Office.

4.3.11. Copies of all export notifications shall be kept for three years.

[2]Section 4 of TSCA allows EPA to require manufacturers or processors to conduct testing of chemicals for health effects and submit data. Entities such as MIT that are engaged in non-commercial and commercial research and development are not primarily targeted to conduct testing. If, however, after publishing a notice in the Federal Register announcing a test rule EPA does not receive feedback from industry, EPA may require R&D facilities to conduct testing.

4.4. R&D Exemption from Pre-Manufacture Notification

4.4.1. All chemicals considered “new”(i.e., any chemical not on the TSCA inventory), regardless of whether they were imported, obtained domestically, or synthesized in an MIT laboratory, shall be handled using the prudent laboratory practices established in the Chemical Hygiene Plan for that DLC. This includes general procedures for the handling of hazardous substances and risk evaluation.

4.4.2. Research must be performed under the direction of a technically qualified individual. Principal investigators (PIs) and the Chemical Hygiene Officer (CHO) are technically qualified individuals.

4.4.3. A new chemical for which little or no environmental, health, or safety data exists shall be presumed a hazardous substance. All lab members expected to come in contact with the chemical shall be notified of its risks. The notification is not required to be written but must be done in a manner to communicate risks that may be present sufficiently.

4.4.4. An SDS must accompany new chemicals provided by a vendor. Where a lab has developed hazard sheets, these and any vendor sheets shall be submitted to the EHS Office.

4.4.5. If a chemical for which little or no environmental, health, or safety data exists will be transferred to a lab outside (of MIT Campus) the one where it has been developed, risk notification shall be done per Section 4.5, “Handling and Transfer of Chemicals for which Little or No Environmental, Health, or Safety Data Exists.”

4.4.6. If the new chemical is sent to another laboratory (out of MIT campus), advise that use of the chemical is to be conducted for R&D purposes only and under the supervision of a technically qualified individual. Shipping papers and/or transmittal letters must reflect this statement.

4.5. Handling and Transfer of Chemicals for which Little or No Environmental, Health, or Safety Data Exists

4.5.1. Transfers/shipments of the new chemical to the recipient outside of the MIT Campus shall include documentation stating that the chemical substance is to be used for research and development purposes only and that the risks of the chemical are not completely known. Appendix E contains a sample notification.

4.5.2. Keep records of chemical substances transferred to facilities outside of MIT.

4.5.3. Inform the recipient of the chemical of any known or potential health, safety, and environmental risks associated with the substance. This information has to be in writing. Containers shall be appropriately labeled with known or suspected hazard warnings. Copies of such communication shall be maintained on file. The EHS Office has developed a risk notification template for DLC use.

4.5.4. Shipping Labels: DOT and IATA regulations provide guidelines on the proper packaging and labeling of new chemicals under 49 CFR 172-173. DLCs shall follow DOT/IATA requirements for proper labeling and packaging. Refer to the SOP "Shipping and Handling of Hazardous Chemicals" (SOP EHS-0065). Contact the EHS Office at 452-3477 (x2-EHSS) for assistance in preparing chemicals for shipment.

4.5.5. Label Language. All chemical containers shall be labeled with the following: "The hazards associated with this chemical have not been fully evaluated. This chemical is to be used for research and development purposes only under the supervision of a technically qualified individual."

4.5.6. If the material is shipped outside of the United States, review the Export Notification listing to determine if EPA regulates the chemical; if so, complete the Export Notification form.

4.6. Allegations of Adverse Reactions and Substantial Risk Notification

4.6.1. Laboratory personnel should forward all allegations of adverse environmental or health effects of chemicals (both on the TSCA Inventory and new chemicals) handled in the laboratory and report data or anecdotal information generated during research that suggests a chemical substance may present a significant risk to human health and the environment. Alleged adverse reactions in animals should also be reported to EHS.

4.6.2. Alleged significant adverse reactions to health that must be recorded include but are not limited to:

- Long-lasting or irreversible damage, such as cancer or congenital disabilities
- Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders, or blood disorders
- An impairment of normal activities is experienced each time an individual is exposed or is experienced by all or most of the persons exposed at one time.

4.6.3. Alleged significant reactions to the environment include but are not limited to:

- Gradual or sudden changes in the composition of animal or plant life, including fungal or microbial organisms in an area
- An abnormal number of deaths of organisms, e.g., fish kills
- Reduction of the reproductive success or vigor of a species

- Reduction in agricultural productivity, whether crops or livestock
- Alterations in the behavior or distribution of a species
- Long-lasting or irreversible contamination of components of the physical environment

4.6.4. There is no requirement to record allegations of significant adverse reactions to health that are known human effects, i.e., a commonly recognized health effect.

4.6.5. There is no requirement to record a significant adverse reaction to the environment if the alleged cause of that reaction can be directly attributable to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incidents of environmental contamination that has been reported to the federal government under any applicable authority.

4.6.6. A Chemical Hygiene Plan developed per 29 CFR 1910.1450 should provide a basic procedure for reporting adverse health effects, using the Supervisor's Report of Illness or Injury as the basis.

4.6.7. The EPA must be notified if information reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.

4.6.8. EPA defines a substantial risk as a risk that is of considerable concern because of the following:

- the seriousness of the effect and
- the fact or probability of its occurrence.

The more serious the effect, the less weight should be placed on the actual or potential exposure and vice versa.

4.6.9. The report must be received by EPA no later than the 30th calendar day after the date the person obtains the information.

4.6.10. It is necessary for the person that makes the allegation of a significant adverse reaction to put it in writing and sign it.

4.6.11. Allegations concerning the health of any employee arising from any employment-related exposure must be maintained for 30 years.

4.6.12. All other allegations must be maintained for five years.

Laboratory personnel is not required to evaluate risk if the DLC has a Chemical Hygiene Plan. However, personnel is expected to use their knowledge to convey information to others and, in the case of an unexpected

or previously unknown effect, to convey this information to the EHS Office. The EHS Office will then decide whether EPA should be notified.

4.7. Corrective Action

Suppose the Principal Investigator, researcher, or EHS Coordinator/Chemical Hygiene Officer (since in many DLCs, one individual assumes both roles) discovers that one or more of the R&D exemption requirements are potentially not being met. In that case, the possible noncompliance shall be reported to the EHS Office as soon as practicable. The EHS Office will then determine the appropriate corrective action and coordinate with the DLC.

5. Roles & Responsibilities

The DLC Chemical Hygiene Plan outlines the roles and responsibilities of the PI, Chemical Hygiene Officer/EHS Coordinator (in those DLCs where one individual assumes both roles), the EHS Coordinator, the EHS Representative, and the EHS Office. Thus, the Chemical Hygiene Plan outlines the roles and responsibilities of the individuals with respect to meeting the "prudent practices" requirement of TSCA.

5.1. PI/Researchers/Laboratory Staff- are responsible for:

- Reviewing the Chemical Hygiene Plan and complying with the management practices;
- completing documentation for chemicals brought into or out of the United States or delivered to another organization domestically;
- in the event of an adverse health effect, reporting the incident and seeking medical treatment/opinion; and
- notifying the EHS Office in the event noncompliance is discovered.

5.2. Chemical Hygiene Officer/EHS Coordinator *(in the case where one individual fulfills both roles)*

Will act as the TSCA Coordinator for the DLC. A condition for the R&D exemption is that "the chemical substance is used by, or directly under the supervision of, a technically qualified individual" (40 CFR 720.36(a)(3)). OSHA defines the Chemical Hygiene Officer (CHO) as *"an employee whom the employer designates, and qualified by training and experience, to provide technical guidance in the development and implementation of the provisions of the Chemical Hygiene Plan."*. The CHO is therefore responsible for ensuring that:

- the prudent practices requirement of the R&D exemption is satisfied through the Chemical Hygiene Plan;
- required documentation for chemical use and transfer is maintained. The EHS Office may assist, and
- corrective action is taken when the need is identified.

5.3. EHS Coordinator (*for DLCs where the Chemical Hygiene Officer and EHS Coordinator are two different people*)

- Will assist CHOs with developing and maintaining a TSCA compliance file and will work with DLCs to ensure that TSCA awareness training is received.
- EHS Coordinators are responsible for ensuring corrective action is taken and communicating this to the EHS Office.

5.4. EHS Office shall:

- Provide TSCA awareness training for PIs, Chemical Hygiene Officers, EHS Coordinators, and other staff whom the R&D exemption requirements may impact;
- Develop and maintain updated information on the TSCA program, including the TSCA Inventory and the Export Notification listing;
- ensure that Chemical Hygiene Plans demonstrate prudent laboratory practices by complying with the requirements of 29 CFR 1910.1450;
- Secure documents necessary for injury reporting and follow-up on accident investigations involving exposures from chemical substances for which little/no health effects data are available;
- Assist DLCs and EHS Coordinators in making decisions about chemical imports/exports;
- Review allegations of adverse health and/or environmental effects and decide as to whether EPA should be notified; and
- Provide recommendations to DLCs for corrective actions to be taken.

5.5. EHS Representatives (EHS Reps) and Researchers shall:

- Ensure that the DLC's EHS Coordinator and the EHS Office are notified if new chemicals are imported, exported, or transferred outside the laboratory.
- EHS Reps and Researchers shall also ensure that the Coordinator and EHS Office are notified where an exposure involving a new chemical occurs, an injury results, or if it comes to their attention that a chemical generates a substantial risk of harm not previously noted in the general scientific literature.

5.6. Medical Department/Clinician shall:

- Provide a written medical opinion in response to a reported adverse health effect. The medical opinion shall be made available to the Supervisor per the SOP "Reporting Illness and Injuries for OSHA-Covered Personnel" so that follow-up illness/injury reporting as required by OSHA may occur on time.

5.7. Supervisor:

- Completes Supervisor's report of an accident/illness in the event of an exposure that requires medical follow-up.
- The Supervisor also ensures that medical paperwork is received from the Medical Center and forwarded to the TSCA Coordinator and EHS Office.

6. Training

Training on Chemical Hygiene is offered online and as a classroom session. DLCs may register at http://ehs.mit.edu/training. At the DLC's request, the EHS Office may also provide tailored TSCA training via Laboratory Specific Chemical Hygiene training.

7. Monitoring Requirements

The EHS Office shall review a DLC's compliance with TSCA when:

- The EHS Office is directly contacted by a third party conducting business with the DLC. Examples include shipping companies and chemical suppliers;
- A Supervisor's report of illness/injury involving a new chemical is received; or
- An allegation of a significant adverse health or environmental effect is reported.

8. Records Management

8.1. General TSCA Compliance Documentation

8.1.1. DLCs shall maintain a TSCA compliance file to demonstrate compliance with the R&D exemption. The file shall include the following documentation:

- Material Transfer Agreements
- Import certifications
- Container labels, DOT/IATA/IMDG shipping papers (if certified through the EHS Office to perform chemical shipments)
- Purchase Orders (or Requisitions)
- Transmittal Letters (e.g., interdepartmental, from MIT to another university)
- Export Certifications
- For distribution of materials outside of MIT --- name and address of the person who received the substance; amount distributed; copies of written notification of hazard information; and labels
- Supervisor Report of Injury/Illness (for Adverse Health Effects)
- Physician's Written Opinion, per the Chemical Hygiene Plan

8.1.2. The Chemical Hygiene Plan serves as documentation of prudent laboratory practices. Chemical Hygiene Plans are typically updated annually.

8.1.3. Import and Export notifications shall be retained for three years.

8.1.4. Grant documentation, requisition forms, shipping papers, transmittal letters, material transfer agreements, or any other documentation indicating that the chemical is being used for research and development (non-commercial and commercial) purposes only shall be retained for five years.

8.2. Allegations of Adverse Effects

8.2.1. Allegations concerning the health of any employee arising from any employment-related exposure must be retained for 30 years.

8.2.2. Other allegations must be maintained for five years.

8.2.3. The EHS Office will maintain all records of allegations of adverse effects.

9. References

9.1. Standards

- 40 CFR 707: Chemical Imports and Exports
- 40 CFR 716: Health and Safety Data Reporting
- 40 CFR 717: Records/Reports of Allegations of Significant Adverse Reactions to Health/Environment
- 40 CFR 720: PreManufacture Notification
  - 40 CFR 720.3: Definitions
  - 40 CFR 720.36: Exemption for Research and Development
  - 40 CFR 720.78: Recordkeeping
- 40 CFR 725: Reporting Requirements and Review Processes for Microorganisms

9.2. Other SOP/ SOGs

- "Reporting Injuries and Illnesses of OSHA-Covered Personnel" (EHS-0008)
- "Shipping and Handling Hazardous Chemicals" (EHS-0065)
- "Shipping Biological Materials" (EHS-0062)

9.3. Supplementary Documents

- DLC Chemical Hygiene Plan
- Prudent Practices in the Laboratory, National Research Council.
- Research Administration Services, https://ras.mit.edu/

10. Definitions (as extracted from the TSCA regulations)

- **Article** – means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has an end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in [40 CFR 720.36(g)(5)], except that fluids and particles are not considered articles regardless of shape or design.

- **Byproduct** – means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

- **Chemical substance** – any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that "chemical substance" does not include:
  (1) Any mixture
  (2) Any pesticide, when manufactured, processed or distributed in commerce for use as a pesticide
  (3) Tobacco or any tobacco product
  (4) Any source material, special nuclear material, or byproduct material
  (5) Any pistol, firearm, revolver, shells, or cartridges
  (6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed or distributed in commerce for use as a food additive, drug, cosmetic, or device.

- **Importer -** any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. "Importer" includes the person primarily liable for paying any duties on the merchandise or an authorized agent acting on their behalf. The term also includes, as appropriate:

  (1) The consignee.
  (2) The importer of record.
  (3) The actual owner if an actual owner's declaration and superseding bond has been filed per 19 CFR 141.20; or
  (4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred per subpart C of 19 CFR part 144. (See "principal importer.")

- **An impurity** is a chemical substance unintentionally present with another chemical substance.

- **Intermediate -** any chemical substance consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present to alter the rates of such chemical reactions.

- **Laboratory** – contained research facility where relatively small quantities of chemical substances are used non-production and where activities involve containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.

- **Manufacture** – means to produce or manufacture in the United States or import into the customs territory of the United States.

- **Manufacture or Import for Commercial Purposes** – to import, produce, or manufacture to obtain an immediate or eventual commercial advantage for the manufacturer or importer, and includes, among other things, "manufacture" of any

amount of a chemical substance or mixture (1) for commercial distribution, including for test marketing (2) for use by the manufacturer, including use for product research and development or as an intermediate. The term also applies to substances produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are produced to obtain a commercial advantage since they are part of manufacturing a chemical substance for commercial purposes.

- **Material Transfer Agreement –** a document that outlines the conditions under which a product, including a chemical substance, may be used with permission of the provider. The MTA may specify when intellectual property rights may be triggered upon discovering commercialized results from the research.

- **Mixture** – any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction, except "mixture" does include:
  (1) Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and

  (2) Hydrates of a chemical substance or hydrated ions are formed by associating a chemical substance with water, so long as the non-hydrated form is not a new chemical substance.

- **New Chemical Substance** – means any chemical substance not included in the Inventory.

- **Significant Adverse Reactions** – are reactions that may indicate a substantial impairment of normal activities or long-lasting or irreversible damage to health or the environment.

- **Small Quantities Solely for Research and Development**- (or, *"small quantities solely for scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product"*) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

- **Technically Qualified Individual**- means a person or persons (1) who, because of education, training, experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical

substance which is used under their supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

- **Test Marketing** - means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period before the broader distribution of that chemical substance, mixture, or article in commerce.

Appendix A: Activities Considered "Research and Development" under TSCA

R&D encompasses a wide range of activities, which may occur in a laboratory, pilot plant, commercial plant outside the research facility, or at other sites appropriate for R&D. The following activities, which test the physical, chemical, production, and performance characteristics of a substance may be considered R&D:

- Chemical synthesis and physical/chemical properties testing in the laboratory,
- Health and environmental effects testing,
- Tests or demonstrations of equipment or production processes, which typically take place in pilot facilities, but may also involve production in full-scale commercial runs (e.g., testing a new chemical to ascertain whether it can be produced in commercial scale equipment or testing a new or modified process to determine process capabilities such as yield, uniformity, or process scale-ups),
- Efficacy and performance tests (e.g., testing of color fastness of a dye or the efficiency or lifetime of a new catalyst in a chemical manufacturing process), and
- Consumer panel testing of the performance characteristics of a new chemical substance. (EPA encourages manufacturers and importers to check with the Office of Pollution Prevention and Toxics to determine whether their consumer panel testing activities comply with the rule's requirements.)

Because consumer panel testing could involve broad exposures to new chemical substances, manufacturers and importers using a consumer panel should be sure that to meet the requirements of the R&D exemption, they:

(1) Consider the activities of the consumer panel in any assessment of risk,

(2) Notify panel members of the potential for risks in a manner that adequately informs them, and

(3) Provide the services of a technically qualified individual who will supervise the tests directly, offering panelists no less protection than would be provided to workers engaged in R&D in a laboratory.

Appendix B-1:
MIT Office of Sponsored Programs (OSP) Standard Agreement

RESEARCH AGREEMENT (the "Agreement") between the Massachusetts Institute of Technology, hereinafter referred to as "M.I.T.," and _____, hereinafter referred to as the "Sponsor."

This Agreement is entered into as of_____, the "Effective Date."

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to M.I.T. and to the Sponsor, *and will further the instructional and research objectives of M.I.T. in a manner consistent with its status as a non-profit, tax-exempt, educational institution.*

NOW, THEREFORE, the parties hereto agree as follows:

1. STATEMENT OF WORK. M.I.T. agrees to use reasonable efforts to perform the research program as set forth in Attachment A (the "Research").

2. PRINCIPAL INVESTIGATOR. *The Research will be supervised by _____, the "Principal Investigator."* If, for any reason, s (he) is unable to continue to serve as Principal Investigator, and a successor acceptable to both M.I.T. and the Sponsor is not available, this Agreement shall be terminated as provided in Article 6.

3. PERIOD OF PERFORMANCE. The Research shall be conducted during the period _____ (the "Starting Date") through _____ (the "Completion Date"). The Completion Date will be subject to extension only by mutual written agreement of the parties.

4. REIMBURSEMENT OF COSTS. In consideration of the foregoing, the Sponsor will reimburse M.I.T. for all direct and F&A (Facilities & Administrative or indirect) costs incurred in the performance of the Research, which shall not exceed the total estimated project cost of $ _____ without written authorization from the Sponsor.

5. PAYMENT. Payments shall be made to M.I.T. by the Sponsor in advance in U.S. dollars, net of taxes or impost of any kind on the following basis:

A final financial accounting of all costs incurred and all funds received by M.I.T. hereunder, together with a check for the amount of the unexpended balance, if any, shall be submitted to the Sponsor within ninety days following the Completion Date.

6. TERMINATION. Performance under this Agreement may be terminated by the Sponsor upon sixty (60) days prior written notice. Performance may be terminated by M.I.T. (1) if the Sponsor fails to make payment to M.I.T. in accordance with the payment schedule stated in Article 5 above and does not remedy the non-payment within thirty (30) days' written notice from M.I.T., or (2) if circumstances beyond M.I.T.'s reasonable control preclude continuation of the Research. Upon termination by either party for any of these reasons, M.I.T. will be reimbursed as specified in Article 4 for all costs and non-cancelable commitments incurred in the performance of the Research, such reimbursement not to exceed the total estimated project cost specified in Article 4.

7. PUBLICATIONS. M.I.T. will be free to publish the results of the Research after providing the Sponsor with a thirty (30) day period in which to review each publication to identify patentable subject matter and to identify any inadvertent disclosure of the Sponsor's proprietary information. If necessary to permit the preparation and filing of U.S. patent applications, the Principal Investigator may agree to an additional review period not to exceed sixty (60) days. Any further extension will require subsequent agreement between the Sponsor and M.I.T.

8. PROPRIETARY INFORMATION. If, in the performance of the Research, the Principal Investigator and members of the M.I.T. research team require and accept access to Sponsor's information that the Sponsor considers proprietary, the rights and obligations of the parties with respect to such information shall be governed by the terms and conditions set forth in Attachment B.

9. INTELLECTUAL PROPERTY.

A. TITLE TO INVENTIONS. Title to any invention conceived or first reduced to practice in the performance of the Research shall remain with M.I.T. Sponsor shall be notified of any such invention promptly after a disclosure is received by the M.I.T. Technology Licensing Office. M.I.T. (i) may file a patent application at its own discretion or (ii) shall do so at the request of Sponsor and at Sponsor's expense.

B. LICENSING OPTIONS. In the event that a patent application on such an invention is filed by M.I.T., for each such invention, M.I.T. hereby grants the Sponsor a non-exclusive, non-transferable, royalty-free license for internal research purposes. The Sponsor shall further be entitled to elect one of the following alternatives by notice in writing to M.I.T. within six (6) months after notification to the Sponsor that a patent application has been filed:

1. a non-exclusive, non-transferable, world-wide, royalty-free license without the right to sublicense (in a designated field of use, where appropriate) to the Sponsor to make, have made, use, lease, sell and import products embodying or produced through the use of such invention, *provided that the Sponsor agrees to (a) demonstrate reasonable efforts to commercialize the technology in the public interest and* (b) pay all patent prosecution and maintenance costs in all countries, including the United States, in which the Sponsor is granted a non-exclusive license right under this paragraph; or

2. a royalty-bearing, limited-term, exclusive license (subject to third party rights, if any) to the Sponsor, including the right to sublicense in the United States and/or any foreign country elected by the Sponsor (subject to (D) below) to make, have made, use, lease, sell and import (in a designated field of use, where appropriate) products embodying or produced through the use of such invention, provided that the Sponsor agrees to reimburse M.I.T. for the costs of patent prosecution and maintenance in the United States and any elected foreign country and further agrees that any products produced pursuant to this license, and that are sold in the United States, shall be substantially manufactured in the United States. This alternative is subject to M.I.T. concurrence and the negotiation of commercially reasonable terms and conditions within three (3) months after selection of this alternative.

C. FOREIGN FILING ELECTION. If the Sponsor elects alternative 2., the Sponsor shall notify M.I.T. of those foreign countries in which it desires a license in sufficient time for M.I.T. to satisfy the patent law requirements of those countries. The Sponsor will reimburse M.I.T. for the out-of-pocket costs, including patent filing, prosecution and maintenance fees related to those foreign filings.

D. CONFIDENTIALITY OF INVENTION DISCLOSURES. The Sponsor shall retain all invention disclosures submitted to Sponsor by M.I.T. in confidence and use its best efforts to prevent their disclosure to third parties. The Sponsor shall be relieved of this obligation only when this information becomes publicly available through no fault of the Sponsor.

E. COPYRIGHT OWNERSHIP AND LICENSES. Title to and the right to determine the disposition of any copyrights or copyrightable material first produced or composed in the performance of the Research shall remain with M.I.T. The Sponsor shall be entitled to elect license rights from the following license alternatives by notice in writing to M.I.T. within six (6) months after M.I.T.'s notification or delivery to the Sponsor of copyrightable material that is required to be delivered to the Sponsor in accordance with Attachment A.

1. Sponsor shall be entitled to elect an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, distribute and perform all such copyrightable materials other than computer software and its documentation and/or informational databases for the Sponsor's internal research purposes.

2. Sponsor shall be entitled to elect an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display and perform computer software and its documentation and/or databases specified to be developed and delivered under the Statement of Work for the Sponsor's internal research use.

3. Sponsor shall be entitled to elect a royalty-bearing license to use, reproduce, display, distribute and perform such computer software and its documentation and/or databases for commercial purposes. Computer software for which a patent application is filed shall be subject to paragraph B. above.

F. RIGHTS IN TRP. In the event that M.I.T. elects to establish property rights other than patents to any tangible research property (TRP), including but not limited to biological materials, developed during the course of the Research, M.I.T. and the Sponsor will determine the disposition of rights to such property by separate agreement. *M.I.T. will, at a minimum, reserve the right to use and distribute TRP for non-commercial research purposes.*

G. LICENSE EFFECTIVE DATE. All licenses elected by the Sponsor pursuant to Sections B.1., B.2., E. and F. of Article 9 become effective as of the date the parties sign a subsequent license agreement.

10. USE OF NAMES. Neither party will use the name of the other in any advertising or other form of publicity without the written permission of the other. As an example for M.I.T., the Sponsor shall not use the name of "Massachusetts Institute of Technology," "Lincoln Laboratory" or any variation, adaptation or abbreviation thereof, or that of any of its trustees, officers, faculty, students, employees, or agents, or any trademark owned by M.I.T. For M.I.T., the Director of the M.I.T. News Office has authority to grant to Sponsor any approved use of the M.I.T. name.

11. REPRESENTATIONS AND WARRANTIES. M.I.T. MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE RESEARCH OR ANY INTELLECTUAL PROPERTY RIGHTS, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, VALIDITY OF ANY INTELLECTUAL PROPERTY RIGHTS OR CLAIMS, WHETHER ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE. Specifically, and not to limit the foregoing, M.I.T. makes no warranty or representation (i) regarding the validity or scope of the Research or any intellectual property rights optioned or granted hereunder and (ii) that the exploitation of the Research or any intellectual property rights will not infringe any patents or other intellectual property rights of M.I.T. or of a third party.

IN NO EVENT SHALL M.I.T., ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, STUDENTS AND AFFILIATES, BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGES OR INJURY TO PERSONS OR PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER M.I.T. SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING. THIS ARTICLE 11 SHALL SURVIVE THE EXPIRATION OR ANY EARLIER TERMINATION OF THIS AGREEMENT.

12. NOTICES. Any notices required to be given or which shall be given under this Agreement shall be in writing and be addressed to the parties as shown below. Notices shall be delivered by certified or registered first class mail (air mail if not domestic) or by commercial courier service and shall be deemed to have been given or made as of the date received.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY	**SPONSOR**
(name)	(name)
(address)	(address)
(phone)	(phone)
(fax)	(fax)
(email address)	(email address)

Inquiries related to billing and payment under this Agreement shall be addressed to the parties as shown below.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY	**SPONSOR**
(name)	(name)
(address)	(address)
(phone)	(phone)
(fax)	(fax)
(email address)	(email address)

13. ASSIGNMENT. This Agreement shall be binding upon and inure to the benefit of the parties hereto and the successors to substantially the entire business and assets of the respective parties hereto. This Agreement shall not be assignable by either party without the prior written consent of the other party; any attempted assignment is void.

14. GOVERNING LAW. The validity and interpretation of this Agreement and the legal relationship of the parties to it shall be governed by the laws of the Commonwealth of Massachusetts and the applicable U.S. Federal law.

15. FORCE MAJEURE. Neither party shall be responsible to the other for failure to perform any of the obligations imposed by this Agreement, provided such failure shall be occasioned by fire, flood, explosion, lightning, windstorm, earthquake, subsidence of soil, failure or destruction, in whole or in part, of machinery or equipment, or failure of supply of materials, discontinuity in the supply of power, governmental interference, civil commotion, riot, war, strikes, labor disturbance, transportation difficulties, labor shortage or any cause beyond its reasonable control.

16. EXPORT CONTROLS. It is understood that M.I.T. is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, and that its obligations hereunder are contingent on compliance with applicable U.S. export laws and regulations (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979). *The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by the Sponsor that the Sponsor will not re-export data or commodities to certain foreign countries without prior approval of the cognizant government agency.* While M.I.T. agrees to cooperate in securing any license, which the cognizant agency deems necessary in connection with this Agreement, M.I.T. cannot guarantee that such licenses will be granted.

17. ENTIRE AGREEMENT. Unless otherwise specified, this Agreement and its Attachments embody the entire understanding between M.I.T. and the Sponsor for the Research, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or changes to this Agreement, including without limitation, changes in the statement of work, total estimated cost, and period of performance, shall be effective unless made in writing and signed by authorized representatives of the parties.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY **SPONSOR**

By _____ By _____

Title _____ Title _____

Date _____ Date _____

ATTACHMENT A
M.I.T. STATEMENT OF WORK

ATTACHMENT B
SPONSOR PROPRIETARY INFORMATION

If, in the performance of the Research, the Principal Investigator and members of the M.I.T. research team designated by him/her require and accept access offered by Sponsor to certain information that the Sponsor considers proprietary, the rights and obligations of the parties with respect to such information are as follows:

1. PROPRIETARY INFORMATION. For the purposes of this Agreement, "Proprietary Information" refers to information of any kind which is disclosed by Sponsor to M.I.T. and which, by appropriate marking, is identified as confidential and proprietary at the time of disclosure. In the event that proprietary information is provided visually or orally, obligations of confidentiality shall attach only to that information which is identified as confidential and proprietary at the time of disclosure and is confirmed by Sponsor in writing within ten (10) working days as being confidential.

2. LIMITATIONS ON USE. *M.I.T. shall use the Sponsor's Proprietary Information solely for the purposes of the Research.* It is agreed by Sponsor and M.I.T. that the disclosure of Proprietary Information shall not be construed as a grant of any right or license with respect to such information except as set forth herein or in a duly executed license agreement.

3. CARE OF PROPRIETARY INFORMATION. The Sponsor and M.I.T. agree that all Proprietary Information communicated by Sponsor and accepted by M.I.T. in connection with this Agreement shall be kept confidential by M.I.T. as provided herein unless specific written release is obtained from Sponsor. M.I.T. agrees to make Proprietary Information available only to those employees and students who require access to it in the performance of this Agreement and to inform them of the confidential nature of such information. M.I.T. shall exert reasonable efforts to maintain such information in confidence.

M.I.T. shall be deemed to have discharged its obligations hereunder provided M.I.T. has exercised the foregoing degree of care and provided further that M.I.T. shall immediately, upon discovery of any disclosure not authorized hereunder, notify Sponsor and take reasonable steps to prevent any further disclosure or unauthorized use.

When the Proprietary Information is no longer required for the purpose of this Agreement, M.I.T. shall return it or dispose of it as directed by the Sponsor. M.I.T.'s obligations of confidentiality with respect to Proprietary Information provided under this Agreement will expire five (5) years after the Effective Date of this Agreement.

4. INFORMATION NOT COVERED. It is agreed by Sponsor and M.I.T. that the above obligations of confidentiality shall not attach to information which:

(a) is publicly available prior to the date of the Agreement or becomes publicly available thereafter through no wrongful act of M.I.T.;
(b) was known to M.I.T. prior to the date of disclosure or becomes known to M.I.T. thereafter from a third party having an apparent bona fide right to disclose the information;
(c) is disclosed by M.I.T. in accordance with the terms of the Sponsor's prior written approval;
(d) is disclosed by Sponsor without restriction on further disclosure;
(e) is independently developed by M.I.T.;
(f) M.I.T. is obligated to produce pursuant to an order of a court of competent jurisdiction or a valid administrative or Congressional subpoena, provided that M.I.T. (i) promptly notifies the Sponsor and (ii) cooperates reasonably with the Sponsor's efforts to contest or limit the scope of such order.

Appendix B-2: Material Transfer Agreement

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

_____
(Recipient Institution)

MATERIAL TRANSFER AGREEMENT

The Massachusetts Institute of Technology ("Provider") and _____ ("Investigator") agree to provide _____ (Recipient Institution hereinafter "Recipient") with material as described below as requested by _____ ("Scientist") *for use in a research project*, subject to the terms and conditions set forth in this Agreement.

1. This Agreement applies to _____, any additional progeny or derivatives, which could not have been made, but for the _____ and any related information and know-how which is received by Recipient under this Agreement (collectively, the "Material") for use in Scientist's research relating to _____ _____ *("Research").*

2. Legal title to the Material will remain with Provider. Except as otherwise provided in Paragraph 6 of this Agreement, Recipient and Scientist will maintain the confidentiality of proprietary information relating to the Material.

3. Provider grants Recipient a nonexclusive license to use the Material *solely for the noncommercial scientific research of Recipient.* The Material is provided to Recipient for use only in laboratory animals or in vitro experiments. THE MATERIAL WILL NOT BE USED IN HUMANS.

4. *The Material will be used only in Scientist's laboratory and only by Scientist and laboratory personnel under Scientist's immediate and direct control*.

5. *The Material is experimental in nature and will be used with prudence and appropriate caution, since not all of its characteristics are known*. THE MATERIAL IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. Provider makes no representation or warranty that the use of the Material will not infringe any patent or other proprietary right.

6. Scientist will inform Investigator in confidence of Research results related to the Material, by personal communication or by providing Investigator with copies of manuscripts describing the results of such Research at the time the manuscripts are submitted for publication.
7. Scientist and Recipient will acknowledge Provider and Investigator as the source of the Material in any publication of Research results.

8. The transfer of the Material grants to Recipient no rights in the Material other than those specifically set forth in this Agreement. Recipient will, at the request of Provider, return or destroy all unused Material.

9. Recipient will at all times during the term of this Agreement and thereafter, indemnify, defend and hold Provider, its trustees, directors, officers, employees, agents, students, investigators and affiliates, harmless against all claims, proceedings, demands and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys' fees, arising out of the death of or injury to any person or persons or out of any damage to property, resulting from the use, handling, storage or disposition of the Material or arising from any obligation of Recipient or Scientist hereunder. In no event will Provider be liable for any use of the Material by Scientist, or laboratory personnel under Scientist's immediate and direct control, or Recipient, or for any loss, claim, damage, or liability, of any kind or nature, that may arise from or in connection with this Agreement or the use, handling, storage, or disposition of the Material.

10. *Scientist and Recipient will use the Material in compliance with all laws, governmental regulations and guidelines*, including current National Institutes of Health guidelines and any regulations or guidelines pertaining to research with animals or recombinant DNA, *which may be applicable to the Material*.

11. This Agreement is not assignable, whether by operation of law or otherwise, without the prior written consent of Provider.

If you agree to accept the Material under the above conditions, please have this Agreement signed by an authorized representative of Recipient and return one original to:

Material Transfer Coordinator
Technology Licensing Office
Massachusetts Institute of Technology
77 Massachusetts Ave., Room NE25-230
Cambridge, MA 02139

The Material will be sent to you as soon as possible after the receipt of the signed Agreement.

Agreed to for:

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

By: _____
Name: _____
Title: _____
Date: _____

_____
(Recipient Institution)

By: _____
Name: _____
Title: _____
Date: _____

_____
(Scientist)
By: _____
Name: _____
Title: _____
Date: _____

Appendix C: TSCA Import Certification Form

TSCA Import Certification Form

Complete this form if you intend to import a new chemical into the U.S. "Importing" includes:

- Carrying the chemical on your person or carrying it in your baggage;
- Shipping the chemical through the mail or express service (FedEx, UPS, DHL, etc.); or
- Ordering the chemical through a foreign vendor.

If you are importing the chemical through VWR, Sigma Aldrich or another domestic vendor, they will take responsibility for submitting the import certification.

You must make either a positive certification or a negative certification.

Retain one copy of this form in your TSCA file and send one copy to iraj@mit.edu or EHS Office at N52-496. Be sure to retain import certifications and accompanying shipping papers for 3 years.

I am importing the chemicals listed on this form into the United States by:

☐ Personal conveyance (on self or in baggage)

☐ Mail or express service

☐ Foreign vendor/Customs broker

and

☐ will be using the chemicals listed below for **research and development purposes only.**

In accordance with the Toxic Substance Control Act (TSCA) Section 13, Import Certification, and 40 CFR 707, I hereby certify that:

POSITIVE CERTIFICATION

☐ All chemical substances in this shipment comply with all applicable rules and orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order hereunder*.

NEGATIVE CERTIFICATION

☐ All chemical substances in this shipment are not subject to TSCA**.

Chemical Name	CAS Number	Quantity	Units	Import Date

Importer Information		Exporter Information	
Name		Company	
Title		Address	
DLC		Phone	
Address		Contact	
Phone		Date	
Email			
Signature			

*Microorganisms and nanomaterials are considered chemical substances under TSCA.
**The Negative certification is for:

- Food, drugs, cosmetics, medical devices, or other materials regulated by the FDA
- Firearms, ammunition, and other materials regulated under ATF
- Nuclear or other radioactive material that is regulated by NRC
- Pesticides, pesticide intermediates and individual components of a pesticide under FIFRA

Appendix D: TSCA Export Notification Form

TSCA Export Notification Form

This form must be completed if you intend to export a chemical outside of the United States

that meets the conditions outlined below. "Exporting" includes:

- Carrying the chemical on your person or carrying it in your baggage; or
- Shipping the chemical through the mail or express service (FedEx, UPS, DHL, etc.).

TSCA Section 12(b) Export Notifications must be submitted to EPA if the chemical you intend to export has been regulated under TSCA Sections 4, 5, 6, or 7*. Refer to the Export Restriction List. Complete this form if your chemical appears on this list. Send the completed form to the address below. Retain one copy of this form and send one copy to the EHS Office, N52-496. Retain export certifications and accompanying shipping papers for 3 years. Contact the EHS Office (x2-3477) to verify proper packaging or for assistance.

Document Control Office (7407M)

Office of Pollution Prevention and Toxics (OPPT)

U. S. Environmental Protection Agency

1200 Pennsylvania Ave., NW., Washington, DC 20460-0001

Re: TSCA Section 12(b) Export Notification

In accordance with 40 CFR 707 Subpart D, I am providing notification of MIT's intent to export the following chemical(s) as regulated under the Toxic Substances Control Act:

Chemical Name	CAS Number	Quantity	Units	Export Date

The chemical named above has been regulated under:

☐ TSCA Section 4, and Section 5 (other than 5(f)). This form serves as one-time notification for the destination country.

☐ TSCA Sections 5(f), 6, or 7. This form serves as the required once per calendar year notification for the destination country.

EPA has taken the following action on the chemical:

Exporter Information		Receiver Information	
Name		Name	
Title		Title	
DLC		Institution	
Address		Address	
Phone		Phone	
Email		Contact	
Signature		Date	

* No export certification is required IF:

• the chemical substance or mixture IS NOT a known or potential human carcinogen AND is present in concentrations less than 1% by weight or volume;

• the chemical substance or mixture IS a known or potential human carcinogen AND is present in concentrations less than 0.1% by weight or volume; or

• the chemical substance or mixture contains PCBs (polychlorinated biphenyls) in concentrations less than or equal to 50 ppm (parts per million) by weight or volume

Appendix E: TSCA Transmittal Form for New Chemical Transfers/Shipments to Outside Laboratories

TSCA Transmittal form for New Chemical Transfers/Shipments to Outside Laboratories

CAUTION: The chemical, physical, or toxicological data for this chemical are not fully known or fully investigated. Handling or use of the chemical described below may be hazardous. Please follow prudent practices as for all hazardous chemicals, including those with unknown health effects. **THIS FORM SHALL ACCOMPANY ALL TRANSFERS OF THE CHEMICAL(S) BELOW TO OTHER LABS OUT OF MIT CAMPUS. Both the initiating lab and the receiving lab agree that the chemical(s) listed below will be used for research and development purposes only.** The initiating lab shall retain a copy of this form in its TSCA file and shall forward 1 copy to the EHS Office, N52-496 (x2- 3477).

Initiating Lab Information

Researcher	
Email	
MIT Department	
Building and Room Number	
Shipping Address	
Date	
Researcher signature	

Receiving Lab Information*

Shipped to	
Phone	
Title	
Laboratory Name	
Street Address	
City, State, Zip	
Province/Country**	

*a receiving laboratory located outside of MIT may be subject to other TSCA requirements. It is the responsibility of the receiving laboratory to comply with its institution's policies concerning new chemical shipments.

**shipments outside the US Customs Territory may require a TSCA Export Notification Form.

Chemical Name or description	CAS Number (if available)	Quantity	Units