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FORM APPROVED
OMB NUMBER 0579-0054/0088/0129/0198/0238/0257/0306/0310

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

COMPLIANCE AGREEMENT

1. NAME AND MAILING ADDRESS OF PERSON OR FIRM

Heidi Hickes
MDOA – Agriculture Sciences Division
Laboratory Bureau, McCall Hall – Room 10
Montana State University
Bozeman, Montana 59717-3620

Phone: 406-994-3383 Fax: 406-994-4494
Email: hhickes@mt.gov

2. LOCATION

Heidi Hickes
MDOA – Agriculture Sciences Division
Laboratory Bureau, McCall Hall – Room 10
Montana State University
Bozeman, Montana 59717-3620

3. REGULATED ARTICLE(S)

Regulated Domestic soil; or Domestic soil (HI and/or U.S. territories) - ANALYSIS

4. APPLICABLE FEDERAL QUARANTINE(S) OR REGULATIONS

7 CFR Part 330 and 7 CFR 301

5. I/WE AGREE TO THE FOLLOWING:

I. Transfer and Noncompliance

A. This agreement may be immediately cancelled or revoked for noncompliance.

B. This compliance agreement is non-transferable.

C. Any person who knowingly violates the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.) and/or the Animal Health Protection Act (AHPA) (7 U.S.C. 8301 et. seq.) may be criminally prosecuted and found guilty of a misdemeanor which can result in penalties, a one-year prison term or both. Additionally, any person violating the PPA and/or the AHPA may be assessed civil penalties of up to $250,000 per violation or twice the gross gain or gross loss for any violation that results in the person deriving pecuniary gain or causing pecuniary loss to another, whichever is greater.

II. Procedures, protocols and limitations established in 'General Stipulations' (attached).

6. SIGNATURE	7. TITLE	8. DATE SIGNED
	Chief, Laboratory Bureau	6.16.11

The affixing of the signatures below will validate this agreement which shall remain in effect until cancelled, but may be revised as necessary or revoked for noncompliance.

9. AGREEMENT NO.
MT-SL-11-03

10. DATE OF AGREEMENT
06/16/2011

11. PPQ/CBP OFFICIAL (NAME AND TITLE)	12. ADDRESS
Shayne Galford, Plant Health Safeguarding Specialist	**USDA APHIS PPQ** **1629 Avenue D, Suite A-5** **Billings, MT 59102**
13. SIGNATURE	
14. U.S. GOVERNMENT/STATE AGENCY OFFICIAL (NAME AND TITLE)	**15. ADDRESS**
16. SIGNATURE	Montana Department of Agriculture Agriculture Sciences Division 303 North Roberts P.O. Box 200201 Helena, MT 59620-0201

Form Approved
OMB Number 0579-0054

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE PROGRAMS

Compliance Agreement

This Compliance Agreement (CA) supplements the PPQ 525 Soil Permit; and Heidi Hickes, MDOA (hereinafter referred to as Permittee), must meet all the terms and conditions as stated on the CA and Permit documents. Although Permittee is signing the Compliance Agreement today, authorization to receive foreign soil is not granted until an official PPQ 525 soil permit from the USDA-APHIS-PPQ, Permit Services, Riverdale, Maryland, is issued to Permittee. By signing this compliance agreement you agree to adhere to the conditions hereby stipulated to receive regulated soil.

Authorization:

This Compliance Agreement authorizes Permittee of Heidi Hickes, MDOA, Laboratory Bureau, McCall Hall, Room 10, Montana State University, Bozeman, MT 59717-3620 to receive untreated regulated DOMESTIC soil for _____ **[chemical/geological/physical/DNA-RNA extraction/analysis/growing medium]**

NOTE: Neither this CA nor a PPQ 525 permit authorizes receipt of untreated regulated soil that has been imported and/or moved domestically across state lines for the purpose of isolation of a living organism, or for extracting and concentrating organisms from the soil. Further it is not authorized for use in field research or release into the environment before treatment. Authorization to receive soil for biological purposes requires a separate PPQ 526 permit (application can be submitted via ePermits and your local USDA-APHIS-PPQ office can provide assistance and direction regarding the application process – see the Supplementary Information Attachment).

Standard Conditions:

1. Activation of this CA requires the signature of Permittee. However, authorization to receive regulated soil is not granted until: 1) notification is received that the State Plant Regulatory Official or designee from the **Montana** Department of Agriculture and the USDA-APHIS-PPQ State Plant Health Director (SPHD) or designee have approved and signed the CA; and 2) the official PPQ 525 permit has been received from the USDA-APHIS-PPQ, Pest Permit Services, Riverdale, Maryland.

2. Compliance Agreements and Soil Permits are non-transferable. Permittee must maintain an official permanent work assignment at the address identified on this CA.

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If Permittee ceases assignment/affiliation at the address identified on this CA, then the local PPQ office must be notified immediately (that is, within one business day) by either (a) **hhickes@mt.gov** (b) **local fax 406-994-4494** (c) MDOA, Laboratory Bureau, McCall Hall, Room 10, Montana State University, Bozeman, MT 59717-3620 . Permittee must also contact the USDA-APHIS-PPQ permitting office at 1866-524-5421. Should Permittee depart from the organization/facility, Permittee will either (a) request cancellation of both the CA and the permit, and comply with all permit-specific termination conditions, (b) apply for and receive a permit to move the soil to a new facility, or (c) relinquish control of the regulated soil to a qualified individual who obtained a permit and CA for the continued use of this regulated soil prior to this permit holder's departure. Go to the Permits website at: (http://www.aphis.usda.gov/plant_health/permits/index.shtml) to apply for an ePermits account to initiate the process. Your local USDA-APHIS-PPQ office can provide direction – (see the Supplementary Information Attachment).

3. This compliance agreement MT-SL-11-03 is valid for the life of the permit issued by APHIS-PPQ.

4. If the regulated soil is to be used by other persons within the same organization, those persons must be under Permittee's supervision or they must apply for their own permit. Notification to this office may help facilitate such circumstance(s).

5. Transfers of untreated regulated soil require prior written authorization from the local PPQ and/or state office. This approval comes in the form of written authorization from the local PPQ office of the State Plant Health Director (SPHD) and/or the State Plant Regulatory Official (SPRO) of the Montana Department of Agriculture (**MDA**). Such transfer must be done at a facility that is inspected and authorized by USDA-APHIS-PPQ.

6. Without prior notice and during reasonable hours, authorized PPQ and/or State regulatory officials shall be allowed to inspect the conditions associated with the regulated soil authorized under this compliance agreement/permit.

7. Prior to preparing soil for shipment, Permittee must inform shippers to address the soil shipment exactly as it is written on the soil permit and Compliance Agreement and supply a copy of the soil permit to be included with the shipment.

8. All shipments of foreign soil must be shipped by bonded carrier from the port of arrival or Hand-Carried* from the port of arrival directly to Permittee at MDOA, Laboratory Bureau, McCall Hall, Room 10, Montana State University, Bozeman, MT 59717-3620. All shipments of regulated domestic soil must be shipped by bonded carrier to Heidi Hickes at [MDOA, Laboratory Bureau, McCall Hall, Room 10, Montana State University, Bozeman, MT 59717-3620 *NOTE: APHIS PPQ may authorize hand-carry of imported soil under the PPQ 525 Soil import permit process on a case by case basis. This change will ensure APHIS policy pertaining to soil importations are consistent with the unique and most recent sanitary/phytosanitary requirements to mitigate risks involved in regulating soil movement. Denial of a hand carry request will not be reason to deny issuance of a permit to move soil by other approved means.

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Hand carry event is granted only if it is specifically provided for by permit. **However, hand carry is not allowed for bulk shipment of soil intended for decontamination or landfill disposal.** If hand carry authorization is granted, you must adhere to all specific permit conditions including special label requirements pertaining to the hand carry event. You can find additional information on hand carry on the USDA-APHIS website at: http://www.aphis.usda.gov/plant_health/permits/organism/soil/handcarry.shtml

9. Permittee must attach a PPQ Form 550 Black/White label to the exterior of each shipment being imported under the permit or, in the case of bulk shipment, include the label in the shipping manifest. USDA-APHIS-PPQ, Pest Permit Services, Riverdale, Maryland will send you the PPQ Form 550 Black/White labels upon issuance of the permit (i.e., a signed PPQ permit) by bonded courier. Permittee may request additional labels by email at: BlackWhiteGreenYellow.labelrequest@aphis.usda.gov. Permittee must specify the type of label being requested- PPQ Form 550 Black/White labels, and the number of labels needed.

10. For all shipments/transfers, the integrity of the sample identification must be preserved from the shipper's inventory records to the recipient. Shipper and recipient must maintain records that provide a traceable link with the shipper's sample identification system in order to preserve the integrity of the sample identification from the shipper to eventual sample destruction.

    For example, if the shipper transfers a sample designated ABC and the recipient logs it in to his/her inventory system as sample 123, the recipient must maintain and provide to the shipper a record that cross references the sample identifications. An inspector must be able to review the recipient's records and be able to trace them back to the shipper's sample numbers. If the recipient ultimately transfers the regulated material to an alternate USDA approved facility, the integrity of the sample identification must be maintained throughout the transfer process and any subsequent transfers.

    Records for each shipment should include the weight, general composition, shipper, shipment origin; and final disposition. Upon request, records of all untreated regulated soil shipments (soil received, soil disposed, and soil transferred) must be available to USDA-APHIS-PPQ and/or the **MDA**.

Safeguarding Conditions:

1. Soil shall be shipped in a securely closed, watertight container (primary container, test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container).

2. All regulated soil must be safeguarded through all storage/processing/ decontamination procedures in the authorized facility (and during the transfer from processing point to a detached room for

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sterilization if this method is used) until sterilized by one of the treatment methods specified (See #5 below). The same applies if the soil is to be transferred to another facility that is inspected and authorized by USDA-APHIS to receive soil. A list of facilities inspected by USDA-APHIS to receive foreign and interstate (domestic) soil samples can be accessed at: https://web01.aphis.usda.gov/PPQ/AuthSoilLabs.nsf/web?openform

3. Upon arrival at the authorized facility the regulated material will be stored at all times in secured containment until transferred or decontaminated. Each stored sample must be labeled as regulated material under USDA Permit. The secured containment must be used to store only regulated material or, if the secured containment area also houses unregulated material, the regulated material must be clearly segregated from the unregulated material as well as being appropriately labeled. A sign must be placed on the outside of the containment: "Contents: Foreign soil and/or regulated domestic soil to be handled in accordance with USDA-APHIS-PPQ Soil Permit and/or Compliance Agreement". As long as untreated regulated soil is present, the containment and all other affected area(s) of the facility must be restricted to access by authorized personnel only. Labeling must be sufficient to readily provide for recognition of the regulated material by emergency response personnel who have the potential to affect the security of the containment as a result of their activities. Permittee is encouraged to interact with local emergency response personnel to acquaint them with all pertinent information relative to the materials regulated under this CA and associated soil permit.

4. Shipping containers and other materials associated with the shipment must be decontaminated by one of the approved treatment methods for soil (see #5 below) or destroyed by incineration.

5. All soil residues must be dry-heated, incinerated, hydroclaved or autoclaved or any other procedure approved by the Deputy Administrator.

   A. For Dry Heat Treatment: use one of the following schedules:

   110- 120.5 degrees C (230-249 F) for 16 hours
   121-154 degrees C (250-309 F) for 2 hours
   154.4 - 192.5 degrees C (310-379 F) for 30 minutes
   193-220 degrees C (380-429 F) for 4 minutes
   221-232 degrees C (430-450 F) for 2 minutes

   Time starts when the entire sample reaches the required temperature, and a suitable temperature probe must be used for verification.

   B. Autoclave soil and other material using the following conditions:

   i. Soil must be autoclaved at 121 degrees Centigrade (250 degrees Fahrenheit) for a minimum of

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30 minutes at 15 psi.

ii. Autoclave tape or other indicators must be placed on each bag or sharps container prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.

iii. The autoclave log must be completed by each user for each autoclave cycle. All parameters must be noted as listed on the log for each autoclave load.

iv. If the autoclave does not attain the minimum time and/or temperature or the autoclave tape does not change color, a notation must be made in the comment section of the autoclave log. The load must then be re-autoclaved after placing new tape on the material. If minimum time and temperature is not attained on the second cycle, the user must contact the person responsible for maintaining the unit to initiate repairs. Waste should then be treated with a functional autoclave at another facility that is approved by USDA; or contact your local PPQ office.

v. Thermometers on the autoclave must be calibrated annually, and a written record must be maintained. This should be done by an authorized autoclave service company during routine servicing.

vi. Every 6 months, you should use a commercially available test indicator kit that uses bacterial spores Bacillus stearothermophilus that are rendered unviable at 250 degrees F or 121 degrees C. For the test, ampules of B. stearothermophilus are autoclaved along with a load of waste. Upon completion of the cycle, the ampules are incubated for 48 hours and then observed for any sign of growth, which indicates insufficient sterilization. If any growth is observed, you must have the autoclave serviced and retested.

C. Hydroclave soil and other material using the following conditions:

I. Soil must be hydroclaved at 121 degrees Centigrade (250 degrees Fahrenheit) for a minimum of 30 minutes, or at 132 degrees Centigrade (267 degrees Fahrenheit) for a minimum of 15 minutes.

ii. Hydroclaves vary; therefore, the manufacturer's recommendations for hydroclave usage and maintenance must be followed, and these instructions must be readily available for review by PPQ.

iii. The hydroclave log must be completed by each user for each hydroclave cycle. All parameters must be noted as listed on the log for each hydroclave load.

iv. Observe the temperature sensor to ensure that the hydroclave maintains its required temperature. If the required temperature is not attained, you must contact the person responsible for maintaining the unit to initiate repairs. In the interim, waste must be treated either by an alternate treatment method, or at a PPQ inspected facility.

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D. Incineration: With the exception of metal and glass containers, all regulated and associated material must be reduced completely to ash at the end of the incineration cycle.

E. Any other procedure approved by the Deputy Administrator.

6. All water residues (effluent) from the processing of soil samples must be treated by an approved treatment/sterilization procedure such as those listed in #5 above.

7. Equipment and supplies used to conduct operations or that have contacted the soil must be decontaminated using one of the following methods:

   (a) Material can be soaked in a fresh household bleach solution of 10 percent (1:10) for at least 30 minutes
   (b) Material can be soaked in a minimum of 70 percent ethanol
   (c) Flamed with ethanol
   (d) Treated with quaternary ammonium compounds.

   Note that autoclave, hydroclave, incineration, and dry heat sterilization are also acceptable sterilization/decontamination methods.

8. When the laboratory has control over the collection of soil samples, they must inform the collectors that equipment and hand tools used for collecting soil samples in areas subject to Federal and/or State cooperative domestic plant quarantines must be thoroughly cleaned of all soil residues at the collection site.

9. In the event Permittee receives foreign soil or regulated domestic soil with a contaminant (e.g. heavy metals like lead, mercury etc.) that prevents the regulated soil from being decontaminated by dry heat, hydroclave or autoclave and requires a disposal site such as an incinerator or landfill, such site must have a valid USDA, APHIS, PPQ Soil Permit and Compliance Agreement for foreign soil or a valid Compliance Agreement for regulated domestic soil, respectively. Prior written approval from the local USDA, APHIS, PPQ office is required before movement of the soil samples to an approved disposal site.

10. All unconsumed soil, containers and effluent are to be autoclaved, incinerated or properly sterilized by Permittee at the conclusion of the project as approved and prescribed by the CA and permit conditions.

11. Permittee must maintain a valid Soil Permit and/or Compliance Agreement for soil samples to be retained for permanent study or research collections. For continuous possession a soil permit can be renew by reapplying at least three months before the current permit expires.

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To reapply for permit, see "**Soil Permit application/renewal procedure and the transition to ePermits"** from the Supplemental information attachment.

12. Exact records must be kept and made available upon each visit that USDA, APHIS, PPQ or the Montana State Department of Agriculture makes to MDOA regarding:

    (1) Date of arrival of each shipment,
    (2) Origin of the soil
    (3) Total amount of soil in each shipment
    (4) Date and amount of soil used for testing purposes
    (5) Date and amount of disposed soil and amount of any remainder
    (6) For transfers of foreign soil - date, amount of soil, and copies of permit and compliance agreement of other party.
    (7) For transfers of regulated domestic soil - date, amount of soil, and copy of compliance agreement of other party.

Standard Operating Procedure (SOP):

1. Permittee at **MDOA** must prepare a standard operating procedure (SOP) demonstrating compliance with the USDA, APHIS PPQ regulations in terms of handling, storing, safeguarding, transporting, and disposing of foreign soil or effluent, regulated domestic soil or effluent, used shipping containers, equipment and other contact waste. The SOP must contain instructions regarding the cleanup of potential spillage of regulated soil, the subsequent decontamination of affected surfaces, and the sterilization of glassware and equipment. The SOP must be posted in areas where soil is stored and where soil is processed. The SOP may be required at the time of inspection.

2. Permittee at MDOA must present a training program to all employees involved in the process of handling, storing, safeguarding, transporting, and disposing of the regulated soil in accordance with USDA APHIS PPQ regulations. Training must include policy/instructions detailed in the stipulation and conditions in your PPQ 525, the compliance agreement, and the SOP; each employee must know where the SOP is posted. Training must be completed before employees are permitted access to the regulated soil in order to process, safeguard, treat, or dispose. All employees handling regulated soil must be trained annually. Records of all training administered to employees (name and dates) shall be made available to USDA, APHIS, PPQ or **Montana State** Regulatory personnel upon request.

3. Records relating to a sample must be retained and made available for inspection upon request by USDA-APHIS-PPQ and/or the **MDA** for a period of 3 years following the

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decontamination/sterilization or transfer to another permitted establishment/individual. Records related to training must be retained for 3 years from the date of the records.

4. With **Heidi Hickes'** signature, Permittee is responsible for compliance with all conditions on the Soil Permit and the Compliance Agreement. This also includes all personnel he/she directly supervises who may be involved with the regulated domestic and/or foreign soil. In the event Permittee is no longer working in this capacity for MDOA, Laboratory Bureau, McCall Hall, Room 10, Montana State University, Bozeman, MT 59717-3620 either Permittee or MDOA must immediately notify USDA, APHIS, PPQ of this change.

This agreement may be immediately canceled or revoked for noncompliance. Violation of these Federal regulations can result in a criminal penalty of up to a $5,000 fine, one year in jail, or both, or a civil penalty of up to $1,000 per violation.

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