

EPA IMPORT PROCEDURES OVERVIEW



Ensuring Compliant and Accountable
Distribution of Microbial Pesticides Across
U.S. Borders



Objective

Ensure that Microbial Pesticides imported into the U.S. comply with all regulatory requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Those microbial pesticides that are not in compliance with FIFRA will be refused entry and the shipment will need to be returned to its origin.



“Pesticide” means

- (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest,
- (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and
- (3) any nitrogen stabilizer.

**As defined by the Federal Environmental Pesticide Act ~
FIFRA [the Federal Insecticide, Fungicide, and Rodenticide Act]**



By Regulation - “A Pesticide” Includes

Certain Biological Control Agents

- (1) Eukaryotic microorganisms – protozoa, algae, fungi and nematodes
- (2) Prokaryotic microorganisms – eubacteria and archaeobacterial
- (3) Parasitically-replicating microscopic elements – viruses and prions



Microbial Pesticides

[currently registered under FIFRA]

Microbial Active Ingredients	Date of Registration
Typhula phacorrhiza (isolate 94671)	11/02/2010
Isaria fumosoroseus strain FE 9901	05/12/2011
Trichoderma asperellum, strain T34	10/20/2011
Bacillus subtilis strain CX-9060	12/15/2011
Bacillus amyloliquefaciens strain D747	12/16/2011
Phoma macrostoma strain 94-44B	01/13/2012
Trichoderma virens strain G-41 (12.1%) (ATCC 20906)	01/23/2012
Aureobasidium pullulans strain DSM 14941	01/31/2012
Pasteuria nishizawae Pn1	02/02/2012
Pseudomonas fluorescens CL 145 A	03/09/2012



Microbial Pesticides - continued

Bacillus pumilus, strain GHA 180	03/15/2012
Killed, non-viable Streptomyces acidiscabies strain RL-110 (ATCC 49003) cells and spent fermentation media	04/26/2012
Chromobacterium subtsugae strain PRAA4-1 cells and spent fermentation media	05/01/2012
Pasteuria spp. (Rotylenchulus reniformis nematode) - Pr3	06/13/2012
Bacillus thuringiensis subsp. kurstaki strain VBTS 2546	09/27/2012
QST 713 strain of bacillus subtilis	11/27/2012



Microbial Pesticides - continued

Cydia pomonella granulovirus isolate V22	01/08/2013
Pasteuria spp. (Hoplolaimus Galeatus Nematode)-Ph3	04/22/2013
Bacillus thuringiensis subsp. israelensis, Strain SUM-6218	05/13/2013
Bacillus pumilus, strain Bu F-33	05/31/2013
Bacillus thuringiensis subspecies galleriea, strain SDS-502, fermentation solids, spores and insecticidal toxins	07/11/2013
GS-omega/kappa-Hctx-Hv1a	02/03/2014
Heat-Killed Burkholderia sp strain A396 cells and spent fermentation media	02/28/2014
Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Helicoverpa zea (corn earworm)	03/05/2014
Clonostachys rosea strain 321U	06/20/2014



Microbial Pesticides - continued

Pseudomonas fluorescens strain D7	08/29/2014
Beauveria bassiana strain ANT-03	11/12/2014
Bacillus subtilis strain IAB/BS03	02/05/2015
Trichoderma asperelloides strain JM41R	05/06/2015
Helicoverpa armigera nucleopolyhedrovirus, strain BV-0003	11/03/2015
Polyhedral occlusion bodies of the beet armyworm nuclear polyhedrosis virus	12/02/2015



Approved Sites for Microbial Pesticide Use

- 2235 approved sites where registered microbial pesticides may be used

Aureobasidium pullulans strain DSM 14941	36
Bacillus amyloliquefaciens strain D747	457
Bacillus pumilus, strain Bu F-33	65
Bacillus pumilus, strain GHA 180	28
Bacillus subtilis strain IAB/BS03	323
Bacillus thuringiensis subsp. israelensis, Strain SUM-6218	39
Bacillus thuringiensis subsp. kurstaki strain VBTS 2546	530
Bacillus thuringiensis subspecies galleriea, strain SDS-502, fermentation solids, spores and insecticidal toxins	18
Beauveria bassiana strain ANT-03	1
Chromobacterium subtsugae strain PRAA4-1 cells and spent fermentation media	606
Clonostachys rosea strain 321U	6
Cydia pomonella granulovirus isolate V22	13
GS-omega/kappa-Hxtx-Hv1a	143
Heat-Killed Burkholderia sp strain A396 cells and spent fermentation media	310
Helicoverpa armigera nucleopolyhedrovirus, strain BV-0003	37
Killed, non-viable Streptomyces acidiscabies strain RL-110 (ATCC 49003) cells and spent fermentaion media	125
Pasteuria nishizawae Pn1	5
Pasteuria spp. (Hoplolaimus Galeatus Nematode)-Ph3	1
Pasteuria spp. (Rotylenchulus reniformis nematode) - Pr3	38
Phoma macrostoma strain 94-44B	51
Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Helicoverpa zea (corn earworm)	64
Polyhedral occlusion bodies of the beet armyworm nuclear polyhedrosis virus	93
Pseudomonas fluorescens CL 145 A	15
Pseudomonas fluorescens strain D7	11
QST 713 strain of bacillus subtilis	996
Trichoderma asperelloides strain JM41R	3
Trichoderma asperellum, strain T34	6
Trichoderma virens strain G-41 (12.1%) (ATCC 20906)	420



The act of “importing” is “distribution”

- Except as provided by FIFRA, no pesticide may be distributed unless it is registered under the Act.
- Biological Control Agents ~ Microbial Pesticides ~ must be registered under FIFRA before the biologicals can be distributed anywhere in the United States [including the District of Columbia, its Commonwealths and Trust Territories]
- By regulation, a Microbial Pesticide may be distributed [i.e. imported] for research and development without registration



Importation for the Purpose of Research and Development

- Import a registered Microbial Pesticide
- Import an unregistered Microbial Pesticide in accordance with the provisions that require an Experimental Use Permit [See 40 CFR § 172.6]
- Import an unregistered Microbial Pesticide in accordance with the provisions that do not require an experimental use permit [See 40 CFR § 172.3]



Labeling of Microbial Pesticides

- All pesticides – including Microbial Pesticides – whether registered or unregistered – must be labeled in accordance with the provisions of FIFRA and the regulations covering pesticide labeling
- The correct labeling of imported Microbial Pesticides is an absolute must for allowing EPA to advise CBP to release the shipment
- [See 40 CFR Part 156]



The Import Process

- Notice of Arrival
 - An importer desiring to import **pesticides** [including microbial pesticides] into the United States shall submit to EPA a complete Notice of Arrival [EPA Form 3540-1] **prior to the arrival** of the shipment in the United States.
 - Note the difference between prior to arrival and prior to entry the customs territory of the United States
 - Note the difference between “United States” versus the “customs territory of the United States.



Overview ~ Statutory and Regulatory Requirements

- Biological Control Agents ~ Microbial Pesticides must comply with U.S. pesticide law
- Microbial Pesticides must not be adulterated or otherwise violative
- Microbial Pesticides must be properly labeled regardless of registration status under FIFRA
- Microbial Pesticides must be “produced” in an EPA-registered establishment that is in compliance with U.S. pesticide law
- Note – there is no de minimus or dollar value exception for imports under FIFRA – the NOA informational data set has to be submitted to EPA



Tips to Expedite NOA Entry Review





Paper Process or Electronic Portal Process for Notices of Arrival

- Current regulations allow for the paper process and then the uploading of the reviewed and EPA signed NOA into ACE/ITDS for CBP action
- Current regulations allow for submission of the NOA data set through the ACE/ITDS single trade portal [the electronic submission through a broker-filer is the way to go!]
- The submission – either hard copy or electronic – must have the correct labels and labeling accompanying the NOA informational data set.




Paper NOA (EPA Form 3540-1)

- The current OMB approved Notice of Arrival form must be used
- The Notice of Arrival form can be obtained from EPA's website –
https://www.epa.gov/sites/production/files/2013-09/documents/noaform_1.pdf



Paper NOA (EPA Form 3540-1)

		United States ENVIRONMENTAL PROTECTION AGENCY Washington, DC 20460		OMB Control No. 2070-0020 Expires on 11/30/2016	
Notice of Arrival of Pesticides and Devices Send Completed Form to Appropriate Regional Office Listed in the Instructions for this Form. Note: Read Instructions before completing form.					
Part 1: To Be Completed by Importer of record or Licensed Customs Broker					
1. Name and Complete Address of Licenced Customs Broker			2. Name and Complete Address of Importer of Record		
<input type="checkbox"/> Return Form to this Address			<input type="checkbox"/> Return to this Address		
3. Name and Complete Address of Shipper		4. EPA Registration Number	5. EPA Producer Establishment No.		
7. Active Ingredients and Percentage of Each		6. Brand Name of Product			
8. Unit Size	9. Quantity	10. Total Net Weight	11. Country of Origin		



Paper NOA (EPA Form 3540-1)

12. Port of Entry		13. Name and Complete Address of Carrier	
14. Entry Number		15. Anticipated Entry Date	
17. Location of Goods for Examination after Importation		16. I assert that information constituting Confidential Business Information is shown in the above blocks numbered: (Note: Blocks 4, 5, 6 and 7 are not entitled to CBI treatment - see instructions.)	
18. [Optional] For pesticides without an EPA Registration No., select all that apply: (The following information may expedite the processing of the Notice of Arrival.)			
<input type="checkbox"/> 18a. A pesticide transferred between registered establishments operated by the same producer. Domestic Producer Establishment Number: _____			
<input type="checkbox"/> 18b. A pesticide transferred between registered establishments not operated by the same producer. Domestic Producer Establishment Number: _____ EPA Registration Number of Product being Formulated, if applicable: _____			
<input type="checkbox"/> 18c. A pesticide distributed under an Experimental Use Permit. Experimental Use Permit Number: _____			



Paper NOA (EPA Form 3540-1)

EPA Registration Number:	Product Name:
Total Net Weight:	Entry Number:

<input type="checkbox"/> 18d. A pesticide distributed for research and development purposes without an Experimental Use Permit.
<input type="checkbox"/> 18e. A pesticide transferred solely for export. Domestic Producer Establishment Number: _____
<input type="checkbox"/> 18f. A pesticide distributed under an emergency exemption. Emergency Exemption Number: _____
<input type="checkbox"/> 18g. A pesticide transferred for the purposes of disposal.
<input type="checkbox"/> 18h. Other. Provide an explanation including the intended use and a description of why the product is being imported into the United States in Block 19 -- Remarks.

19. Remarks. Provide additional information here. It is recommended that a copy of the label affixed to the product be submitted with the NOA.

Certification

I certify that the statements I made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

20. Printed Name of Importer of Record or Licensed Customs Broker	<input type="text"/>	Telephone No.:	<input type="text"/>
21. Signature of Importer of Record or Licensed Customs Broker:	<input type="text"/>	Date:	<input type="text"/>



Unregistered Microbial Pesticides for R&D That Do Not Trigger an EUP - Additional Information

- A true and correct copy of the label on the immediate container of the R&D pesticide. This label should include:
 - a) An ingredient statement,
 - b) The statement, “For Research and Development Purposes Only,”
 - c) The statement, “Not for Sale,”
 - d) The foreign manufacturer’s address and EPA Establishment Registration Number (if the foreign establishment of the manufacturer is registered),
 - e) The net contents of the R&D pesticide within



Unregistered Microbial Pesticides for R&D That Do Not Trigger an EUP - Additional Information (continued)

- additional information should be submitted as an addendum to Item #18 on the NOA and signed by a duly authorized individual of the importing company (**not the broker-filer**) specifying:
 - a) That the R&D pesticide is being imported to determine its value for pesticidal purposes or to determine its toxicity or other properties, and no benefit of pest control is expected to result
 - b) A brief description of the anticipated research and development activity with a projected date of completion,
 - c) The R&D pesticide's ultimate destination (U.S. address),
 - d) Provisions for disposing of leftover stocks of the R&D pesticide,
 - e) A statement that the label provided to EPA is a true and correct representation of the label that will accompany the R&D pesticide throughout its distribution and analysis in the U.S.



TSCA Certification

SUBJECT: TSCA Certification

I certify that all chemical substances in this shipment are not subject to TSCA.

A handwritten signature in black ink, appearing to read "E. J. [unclear]", is written above a horizontal line.

Importer of Record



Pulling the NOA Package Together for Registered Pesticides

- NOA (EPA Form 3540-1) – Part 1 Complete, True, Accurate and contains an Original Signature [if submission is by paper]
- Copy of the label purported to be affixed to the microbial pesticide (listed in box 4) that is to be distributed or sold in the US
- Supplemental documentation that supports the information listed in part 1 of the NOA
- Negative TSCA Certification Statement
- Return courier envelope and fully completed return airway bill



Pulling the NOA Package Together for Unregistered Pesticides for R&D

- NOA (EPA Form 3540-1) – Part 1 Complete, True, Accurate and Original Signature
- Copy of the label purported to be affixed to the pesticide product (listed in box 5) that is to be distributed or sold to the US
- Supplemental documentation supporting information listed in part 1 of the NOA
- Negative TSCA Certification Statement
- Return envelope and fully completed return airway bill



Joint EPA-CBP Regulatory Process

- May Proceed – Release the Shipment to the Importer of Record or Ultimate Consignee
- Enforcement Hold
 - Hold/Intensive - Physical Exam / Detain / Seize
 - Hold/Documents Required - Pesticide Product Label (Market Label)
 - Hold Intact/Examination Required at Consignee – Physical exam after release into customs territory of U.S.
- Request Redelivery
- Refuse the Shipment and Request Importer of Record to File for Immediate Export



Potential Enforcement for Violative Shipments

- Failure to file a Notice of Arrival [FIFRA § 12(a)(2)(N) – failure to file reports]
- Knowingly falsifying a Notice of Arrival [FIFRA § 12(a)(2)(M) – knowingly falsify any report]
- Import of an unregistered pesticide [FIFRA § 12(a)(1)(A) – distribute or sell any pesticide that is not registered]
- Import of a misbranded pesticide [FIFRA § 12(a)(1)(E) – distribute or sell any pesticide which is misbranded]
- Import of an adulterated pesticide or pesticide whose composition differs [FIFRA § 12(a)(1)(E) or § 12(a)(1)(C)]



Q & A



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Statutory and Regulatory Authority Reference

- Sections 17(c) and 17(e) of FIFRA
 - 19 CFR Sections 12.110 – 12.117
- Sections 3(a) and 25(a) of FIFRA
 - 40 CFR Parts 152, 156, 157, 166, 168, and 172
- Sections 7(a) and 25(a) of FIFRA
 - 40 CFR Part 167
- Sections 8 and 9 of FIFRA
 - 40 CFR Part 169
- Sections 12, 13 and 14 of FIFRA
 - 55 Federal Register 30032
 - FIFRA Enforcement Response Policy
 - 40 CFR Part 22



Statutory and Regulatory Authority References(continued)

“Put Simply ...”

- Pesticides or devices must comply with U.S. pesticide law
- Not be adulterated or otherwise violative
- Properly labeled
- Produced in an EPA-registered establishment that is in compliance with U.S. pesticide law
- International shipment of Biologicals will be regulated by numerous federal agencies