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VIA FEDEX

May 5, 2015

Regional Hearing Clerk  
U.S. EPA, Region 4  
61 Forsyth Street  
Atlanta, GA 30303

**Re: MTJ American, LLC's Response to Complaint; Docket No.:  
FIFRA-04-2014-3009.**

Dear Sir or Madam:

Enclosed is **MTJ American, LLC's Motion to Dismiss, Affirmative Defenses and Answer to the Civil Administrative Complaint and Request for Hearing** for Docket No.: FIFRA-04-2014-3009.

Please file stamp the original and provide us with a file stamped copy for our files. I have enclosed a self-addressed postage paid envelope for this purpose.

Sincerely,

Law Offices of Matthew K. Rogers, PLLC



Patrick Miller

Legal Assistant to Matthew K. Rogers

Cc: Michiko Kono

Encl.

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 4  
ATLANTA, GEORGIA

RECEIVED  
EPA REGION IV  
2015 MAY -6 PM 4:28  
HEATHER O'LEARY

**IN THE MATTER OF:**

MTJ AMERICAN, LLC

Respondent.

**RESPONDENT MTJ AMERICAN,  
LLC'S MOTION TO DISMISS,  
AFFIRMATIVE DEFENSES AND  
ANSWER TO THE CIVIL  
ADMINISTRATIVE COMPLAINT  
AND REQUEST FOR HEARING**

**Docket No.: FIFRA-04-2014-3009**

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Respondent, MTJ American, LLC ("Respondent"), responds to the Complaint as follows by admitting, denying and asserting:

**MOTION TO DISMISS**

The plain reading of materials referenced by the EPA Complaint shows that (a) the EPA does not have authority pursuant to FIFRA and no standing to bring action against Respondent; and (2) there is no violation of FIFRA, including without limitation that MTJ does not nor has made any pesticidal or "public health claim" in violation of FIFRA and (3) the statements cited in the Complaint support nothing more than MTJ's products being inclusive in express exceptions of FIFRA. The Complaint should be dismissed pursuant to Rule 12(b)(6) and all similar rules set forth in the Administrative Procedure Act.

**I. Answer to Complaint**

**A. Jurisdiction**

1. The allegation contains legal conclusions to which Respondent which do not relate to the facts specific to Respondent. Respondent's products referenced herein are not intended to be a pesticide regulated by FIFRA and FIFRA does not expressly confer

the EPA authority relating to Respondent's products herein. Respondent does not consent to jurisdiction and denies that the EPA has jurisdiction to issue the Complaint pursuant to FIFRA.

2. The allegation is a legal conclusion which do not relate to the facts specific to Respondent. Respondent is not able to respond to an allegation appearing to characterize the authorization of filing a Complaint pursuant to FIFRA. Respondent specifically denies that the EPA or the Administrator is expressly authorized by FIFRA to file any Complaint to enforce FIFRA against non-pesticide products sold without pesticide claims. If and to the extent the Administrator is able to delegate authority to the Regional Administrator, and that authority can be delegated to the Director of Air, Pesticides, and Toxics Management and Regional Administrator to issue a Complaint for non-pesticide products, that authority must be strictly construed and delegation considered pursuant to specific authority, including without limitation the referenced delegation documents, which are referenced but not supplied, must be evaluated. Respondent is without sufficient information to admit or deny the allegation, and until the referenced documents can be provided, Respondent must deny that the Region 4 Director has the authority to issue a Complaint under these specific circumstances.
3. It is admitted that the captioned Respondent is MTJ American, LLC.
4. Respondent denies that Respondent has violated any provision of FIFRA nor that violation of 7 U.S.C. §136j provides standing for the EPA to initiate a Complaint for products not subject to FIFRA. Further, the allegation states nothing more than the EPA "has reason to believe that Respondent has violated" an unspecified section of

FIFRA. This is a legal conclusion to which no response is required, however, to the extent an answer is required, Respondent denies that Respondent violated any section of FIFRA.

**B. Preliminary**

5. The allegation takes a portion of Section 2(u) out of context legal conclusion to which no response is required. Respondent asserts that the section cited is incomplete. It is admitted that Section 2(u) of FIFRA, 7 U.S.C.§136(u) defines “pesticide” in part as “any substance or mixture of substance intended for preventing, destroying, repelling, or mitigating any pest.” Respondent denies manufacturing any substance or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest. Respondent refers to 40 CFR 152.10 which states in part “[A] product that is not intended to prevent, destroy or repel or mitigate a pest, or to defoliate, dessicate or regulate the growth of plants, is not intended to be a pesticide. The following types of products or articles are not considered to be pesticides.....(c) Products that are intended to exclude pests only by providing a physical barrier against pest access,”. Except as expressly admitted, denied.
6. Admit that pest is defined in FIFRA Section 2(t) which speaks for itself and that Federal Regulations relating thereto speak for themselves. If and to the extent the allegation implies that the definition is broader than as written, such as application to virus’s on a living man), Respondent expressly denies any interpretation broader than the definition as written. Except as expressly admitted.
7. It is admitted that Section 2(mm)(1)(A)(i) of FIFRA, 7 U.S.C.§136(mm), defines the term “antimicrobial pesticide”, which definition speaks for itself. The allegation

appears to take only parts of the definition in order to make further allegations which are inconsistent with the entire allegation and purposes of FIFRA. MTJ expressly denies that MTJ products are pesticides. Except as expressly admitted, denied.

8. It is admitted that Section 3(a) of FIFRA, 7 U.S.C. §136a(a) states in part "...no person in any State may distribute or sell to any person any pesticide that is not registered under this Act...". Respondent denies distributing or selling any pesticide, and further denies selling or distributing any pesticide that is not registered under the Act. Except as expressly admitted, denied.
9. Section 12(a)(1)(A) states "(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person... (A) any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;". Respondent denies distributing or selling any pesticide, and further denies selling or distributing any pesticide that is not registered under the Act. Except as expressly admitted, denied.
10. It is admitted that Section 2(w) of FIFRA, 7 U.S.C. §136(w) defines "producer" which definition speaks for itself. "The term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide....". Respondent denies it is a producer as contemplated by or defined by Section 2(w). Except as expressly admitted, denied.
11. Section 7 of FIFRA including specifically subsection (a) therein speaks for itself and states: "(a) REQUIREMENT. – No person shall produce any pesticide subject to this

Act or active ingredient used in producing a pesticide subject to this Act in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment and of the producer who operates such establishment.” Respondent denies that it produces any pesticide or any active ingredient used in producing a pesticide and Respondent denies that its facility was required to be registered. Except as expressly admitted, denied.

12. Section 12(a)(2)(L) of FIFRA speaks for itself, and applies to producers and violations of Section 7 only. Respondent denies that Respondent’s products are subject to regulation by FIFRA or that Respondent was required to register pursuant to Section 7. Further, Respondent denies that Respondent violated any provision of FIFRA. Except as expressly admitted, denied.

13. Respondent admits that 40 CFR §152.25 speaks for itself, and exempts certain pesticides from FIFRA. Respondent denies that Respondent manufactures or sells products that are pesticides. Respondent’s product includes a cover material acting as a barrier made with material using EPA registered “Ultra-Fresh DM-50”, registered under EPA Reg. No. 10466-28. Respondent denies that Respondent or its products are pesticides subject to FIFRA. The “treated articles exemption” of 40 C.F.R. §152.25 appears to describe an exemption for pesticides similar to the manner Respondent’s products use an EPA registered product as a barrier in Respondent’s non-pesticide product.

14. The referenced EPA publication speaks for itself and in no way broadens FIFRA or regulations promulgated pursuant thereto. The referenced publication does not bring Respondent’s products within the jurisdiction of FIFRA, and may be limited in its

interpretation to the “treated articles exemption”. Accordingly, neither Respondent nor the products subject to this Complaint are or should be subject to EPA regulation.

15. The referenced EPA publication speaks for itself and in no way broadens FIFRA or regulations promulgated pursuant thereto. The referenced publication does not bring Respondent’s products within the jurisdiction of FIFRA, and may be limited in its interpretation to the “treated articles exemption”. Accordingly, neither Respondent nor the products subject to this Complaint are or should be subject to EPA regulation.
16. The referenced EPA publication speaks for itself and in no way broadens FIFRA or regulations promulgated pursuant thereto. The referenced publication does not bring Respondent’s products within the jurisdiction of FIFRA, and may be limited in its interpretation to the “treated articles exemption”. Accordingly, neither Respondent nor the products subject to this Complaint are or should be subject to EPA regulation. Further, Respondent denies that it made or implied any “public health-related protection” or that the allegations herein relate to anything other than protection of the product. Except as expressly admitted, denied.
17. The referenced EPA publication speaks for itself and in no way broadens FIFRA or regulations promulgated pursuant thereto. The referenced publication does not bring Respondent’s products within the jurisdiction of FIFRA, and may be limited in its interpretation to the “treated articles exemption”. Accordingly, neither Respondent nor the products subject to this Complaint are or should be subject to EPA regulation. Further, Respondent denies that it made or implied any “public health-related protection” or that the allegations herein relate to anything other than protection of the product. If and to the extent the use of examples is broader than the authority or

FIFRA then reference to examples is inappropriate and such be stricken. Further, if and to the extent the allegation intends to imply that Respondent made any statements which are contrary to FIFRA, Respondent denies the same. Except as expressly admitted, denied.

18. The referenced EPA publication speaks for itself and in no way broadens FIFRA or regulations promulgated pursuant thereto. The referenced publication does not bring Respondent's products within the jurisdiction of FIFRA, and may be limited in its interpretation to the "treated articles exemption". Respondent denies that it sells or distributes a pesticide that becomes subject to the "treated articles exemption". Accordingly, neither Respondent nor the products subject to this Complaint are or should be subject to EPA regulation. Further, Respondent denies that it made or implied any "public health-related protection" or that the allegations herein relate to anything other than protection of the product. Except as expressly admitted, denied.

**C. Complainant's Allegations of Violations**

**COUNT 1**

19. No response is necessary for this allegation. Provided, however, all Respondent's responses are incorporated herein by reference.
20. Admitted
21. The definition of Person does not specifically reference Limited Liability Companies, and as such, Respondent cannot admit nor deny.
22. Respondent admits that on July 22, 2010, a person representing they were authorized by the EPA inspected the facility located at 4276 Helena Street, Granite Falls, North Carolina 28630, and notified Respondent there were no violations of FIFRA.



23. Admitted.
24. Respondent does not maintain records sufficient to admit or deny the content of Respondent's website at the time of inspection. Respondent denies that Respondent advertised included the language set forth in the allegation. Respondent's website may have contained, at one time or another, product specification sheets, which product specification sheets contain a section entitled "Cover Specifications", which section contained a sub-section entitled "Bacteria Resistant" and within that section heading, the product specification identified passing tests which relate to "anti-microbial, anti-fungal, bacteriostatic, virus barrier" properties. Except as expressly admitted, denied. Respondent denies that said statements are public health claims Respondent understands and intended that the language comport with the 40 CFR 152.10 which supports that the quoted language shows Respondent's products and statements are not subject to FIFRA regulation.
25. Respondent believes that Respondent provided EPA Inspector Bowman a brochure that contained the quoted language. Respondent denies that the quoted language is a public health claim or brings Respondent's products within the purview of FIFRA or jurisdiction conferred to the EPA by FIFRA. Respondent understands and intended that the language comport with the language of 40 CFR 152.10, therefore, Respondent's products are not pesticides. Except as expressly admitted, denied.
26. To the extent the allegation refers to "pests" within the framework and subject to FIFRA, the definition of pests is set forth in Section 2(t), which speaks for itself. The definition does not include "microbes" and contains exceptions to the allegation with

regard to viruses, bacteria and other micro-organisms. Except as expressly admitted, denied.

27. Respondent is not microbiologist and there is relevance of alleging that microbes, fungus, bacteria and viruses to be “microbiological organism” with regard to FIFRA. FIFRA does not define microbiological organisms, and Respondent is without sufficient information or specialize knowledge to admit or deny. Respondent refers to the definitions of FIFRA, and to the extent the allegation is inconsistent therewith, denies the same.
28. To the extent the allegation refers to the use of those words by Respondent, denied.
29. Denied.
30. Denied.
31. Denied. MTJ specifically denies any intent for the product to be a pesticide, any intent to make pesticidal claims or any intent to make public health claims. To the best of MTJ’s knowledge, the sale was made to meet the customer’s specifications which did not include “public health” or “pesticidal” claims.
32. Admitted that Respondent shipped the Fusion Advantage University Mattress pursuant to an order placed pursuant to a successful bid after customer submitted product specification. Respondent does not believe the customers requested nor received the brochures nor reviewed the website. Respondent is not able to admit or deny if the brochures or specification sheets were provided in relation to the invoice referenced. Except as expressly admitted, denied.

33. Respondent admits that Respondent sold the Fusion University Mattress as the term “To Distribute or Sell” appears to be defined by definition (gg). Respondent denies that the sale was regulated by or subject to FIFRA. Except as admitted, denied.
34. Respondent denies the Fusion Advantage University Mattress is or was a pesticide subject to FIFRA. Respondent denies that FIFRA requires the registration of the Fusion Advantage University Mattress pursuant to Section 3 of FIFRA.
35. If and only to the extent that the Fusion Advantage University Mattress was a pesticide subject to FIFRA (which Respondent denies), then the Fusion Advantage Mattress would fit within the “Treated Articles Exemption.” Except as expressly admitted, denied.
36. Denied.

## COUNT 2

37. No response is necessary for this allegation. Provided, however, all Respondent’s responses are incorporated herein by reference.
38. Respondent does not maintain records sufficient to admit or deny the content of Respondent’s website at the time of inspection. Respondent denies that Respondent advertisements included the language set forth in the allegation. Respondent’s website may have contained, at one time or another, product specification sheets, which product specification sheets contain a section entitled “Cover Specs”, which section contained a sub-section entitled “Bacteria Resistant” and within that section heading, the product specification identified passing tests which evaluate to anti-microbial, anti-fungal, bacteriostatic, virus barrier” properties. Respondent denies that said statements are public health claims and specifically identify that the

language 40 CFR 152.10 supports that the quoted language shows Respondent's products and statements are not subject to FIFRA regulation. Except as expressly admitted, denied.

39. Respondent does not have or maintain records showing that Respondent possessed brochures for the Clear Safe Detention Mattress at the time of inspection. Response to MTJ's Freedom of Information Act request do not include any "brochures" for the "Clear Safe Detention Mattress" referenced in the allegation. At this time, Respondent does not have information sufficient to admit or deny, and therefore denies the allegation.
40. To the extent the allegation refers to "pests" within the framework and subject to FIFRA, the definition of pests is set forth in Section 2(t), which speaks for itself. The definition does not include "microbes" and contains exceptions to the allegation with regard to viruses, bacteria and other micro-organisms. Except as expressly admitted, denied.
41. Respondent is not a microbiologist and there is relevance of alleging that microbes, fungus, bacteria and viruses to be "microbiological organism" with regard to FIFRA. FIFRA does not define microbiological organisms, and Respondent is without sufficient information or specialize knowledge to admit or deny. Respondent refers to the definitions of FIFRA, and to the extent the allegation is inconsistent therewith, denies the same.
42. To the extent the allegation refers to the use of those words by Respondent, denied.
43. Denied.
44. Denied.

45. Denied.
46. Admitted that Respondent supplied Inspector Bowman an invoice which speaks for itself. Respondent admits it shipped the Clear Safe Detention Mattress pursuant to an order placed pursuant to a successful bid after and responding to the product specification requested by the customer. Respondent does not believe the customer requested nor received brochures nor reviewed the website. Respondent is not able to admit or deny if the specification sheets were provided in relation to the invoice referenced. Except as expressly admitted, denied.
47. Respondent admits that Respondent sold the Clear Safe Detention Mattress as the term "To Distribute or Sell" appears to be defined by definition (gg). Respondent denies that the sale was regulated by or subject to FIFRA. Except as admitted, denied.
48. Respondent denies the Clear Safe Detention Mattress is or was a pesticide subject to FIFRA. Respondent admits the Respondent denies that FIFRA requires the registration of the Clear Safe Detention Mattress pursuant to Section 3 of FIFRA. Respondent admits that the Clear Safe Detention Mattress was not registered under Section 3 of FIFRA, but denies that FIFRA Section 3 requires that the Clear Safe Detention Mattress be registered. Respondent's use of the words "Bacteria Resistant and Anti-Microbial, Anti-Fungal, Bacteristatic/Virus Barrier" on specification sheets are not pesticidal claims, and if they are, the use is subject to appropriate registration and/or treated articles exemption. Respondent denies that Respondent made pesticidal claims or that Respondent sold or distributed an unregistered pesticide.

49. If and only to the extent that the Fusion Advantage University Mattress was a pesticide subject to FIFRA (which Respondent denies), then the Fusion Advantage Mattress would fit within the “Treated Articles Exemption.” Except as expressly admitted, denied.
50. Denied.

### **COUNT 3**

51. No response is necessary for this allegation. Provided, however, all Respondent’s responses are incorporated herein by reference.
52. With regard to the definitions set forth at Section 2(w) of FIFRA, 40 C.F.R. §167.3 and 40 C.F.R. §169.1, denied. Respondent denies that it produced (or produces) a pesticide or active ingredient used in producing a pesticide.
53. Denied.
54. Section 7(a) of FIFRA speaks for itself. If and to the extent the allegation implies that Respondent is either subject to FIFRA or violating FIFRA, the allegation is denied.
55. Respondent denies that Respondent is required to register any establishment with pursuant to FIFRA, and Respondent denies it produced or held any pesticide for distribution or sale as required by the FIFRA definition of establishment. Subject to the foregoing, Respondent admits that it did not register any establishment as contemplated by FIFRA.
56. Denied.

#### **D. Proposed Penalty**

57. Subject to Respondents denials set forth above, including without limitation that neither Respondent nor the products sold by Respondent are subject to FIFRA, Respondent denies that the EPA has followed the EPA's Enforcement Guidelines or Section 14(a)(4) of FIFRA. After telling Respondent that there were no violations of FIFRA, and without notifying Respondent that Respondent made a pesticide or issuing any Notice of Warning to Respondent, contrary to FIFRA and the EPA Enforcement Guidelines, the EPA issued Stop Sale, Use or Removal Order ("SSURO"). Although Respondent does not believe the EPA had authority to issue such SSURO to Respondent and without waiving Respondent's rights, Respondent complied with SSURO until Written Vacatur was issued. Thereafter, the EPA notified Respondent that the EPA intended to pursue penalties of at least \$7,500.00 for three alleged violations of FIFRA, representing penalties in excess of EPA Enforcement Guidelines or Section 14 of FIFRA as amended by the statutes referenced in the allegation. At no time prior to notifying Respondent that the EPA could penalize Respondent more the \$20,000.00 or proposing Respondent pay \$20,000.00 did the EPA "take into consideration the size of Respondent's business, the effect on Respondent's ability to continue in business and the gravity of the violations." Respondent denies that the EPA has at any time taken "into consideration the size of Respondent's business, the effect on Respondent's ability to continue in business and the gravity of the violations." Neither the Complaint nor the specific allegation provide sufficient factual basis pursuant to which any penalty can be imposed, and the Complaint lacks allegation that Respondent was notified of any potential FIFRA violation before the issuance of the SSURO. The Complaint reveals

that the EPA failed to follow its own guidelines and that no administrative penalty may be awarded.

## **II. NOTICE OF OPPORTUNITY FOR HEARING**

### **A. Answer And Request For Hearing**

58. If and to the extent Respondent or Respondents Products are subject to FIFRA, and to the extent that the Complaint is not dismissed, then Respondent requests a formal hearing to contest all issues raised herein, including without limitation that Respondent violated FIFRA and the proposed penalty herein. Nothing in this Answer or the counterclaims raised herein shall be deemed as a waiver of Respondent's objection to the jurisdiction of the Administrative Courts or EPA regulatory authority or application of FIFRA, all of which Respondents reserve and hereby object.

59. Subject to Respondents objection to being subject to the provisions of 40 C.F.R. Part 22 and FIFRA, which objection Respondent hereby re-asserts, this Answer is filed within 30 days of service upon Respondent.

60. Subject to Respondents objection to being subject to the provisions of 40 C.F.R. Part 22 and FIFRA, and subject to the rules governing responses to allegations which speak for themselves and to which the allegation shall not be deemed to broaden, Respondent acknowledges the Answer and responses to each allegation comport with the allegation.

### **B. Informal Settlement Conference**

61. This numbered allegation refers to "informal" settlement discussions and no response is required. Respondent's responses are incorporated herein by reference and



Respondent's willingness to discuss settlement is not to be considered any admission that Respondent is subject to FIFRA or that Respondent has violated FIFRA.

62. Respondent denies that settlement must be embodied in a CAFO. Rules of procedure and the authority of parties speak for themselves. If and to the extent the EPA requires signature of the EPA Regional Judicial Officer, then Respondent is without sufficient information to admit or deny said portion.
63. Respondent is without sufficient information to admit or deny this allegation which appears to make specific references to barring discussions between either the EPA or the Respondent with the Administrator, Regional Administrator, Judicial Officer, Regional Judicial Officer, and/or Presiding Officer. Respondent is unaware of the identity of the foregoing, or "any person likely to advise these officials in the case" and the EPA has not identified any such person. Respondent does not believe any response to this allegation is required. If and to the extent response is required, Respondent reserves its rights to amend this response.

### **SECOND AFFIRMATIVE DEFENSE**

(Waiver)

When the EPA inspected MTJ's facility in July 2010, the EPA inspector notified MTJ that there were no violations of FIFRA, and filed report indicating that there were no FIFRA violations thereby waiving any potential violations. The Stop Sale Order issued more than nine (9) months later contradicted the inspection report and representations made to MTJ.

### **THIRD AFFIRMATIVE DEFENSE**

(Estoppel)

The EPA inspectors representations to MTJ, the Inspection Report, and the passage of more than six (6) months before any notice of purported violation of FIFRA estops the EPA from now seeking penalty.

### **FOURTH AFFIRMATIVE DEFENSE**

(OFF-SET)

The EPA's conduct of (1) first notifying MTJ that there were not FIFRA violations; (2) in failing to notify MTJ of potential violations before issuance of a Stop Sale Order; and (3) issuances of a Stop Sale Order causing MTJ's operations to be shut-down violated the EPA's enforcement guidelines and caused MTJ substantial damages which should off-set and be credited against any actual award to the EPA.

**FIFTH AFFIRMATIVE DEFENSE**  
(Unclean Hands)

The doctrine of unclean hands, including without limitation the EPA issuing a SSURO without any risk to public health or the environment bars any penalty assessment.

**COUNTERCLAIMS**

Now comes MTJ American, LLC ("MTJ"), and to the extent permissible including pursuant to the Administrative Procedures Act and other basis for jurisdiction, alleging the following counterclaims against the Environmental Protection Agency and to the extent permitted by law, those persons within the EPA that may be individually responsible for the claims herein set forth and identified herein below:

1. MTJ sells institutional mattresses including mattresses made to meet or exceed customer specifications, including institutional mattresses for the criminal detention industry and universities.
2. In most cases, MTJ is required by customer specifications to use particular fabrics supplied to MTJ by Spec-Text, Inc.
3. EPA inspector Thomas C. Bowman ("Inspector Bowman") inspected MTJ American, LLC on July 22, 2010.
4. MTJ provided Inspector Bowman all materials requested including copies of brochures in MTJ's possession.
5. At his request, MTJ provided Inspector Bowman invoices including those attached hereto as **Exhibits 1 and 2**.
6. Exhibits 1 and 2 reflect products sold pursuant to and in response to customer bid specifications and/or response to request for quotation submitted by the particular customer requiring products meet specific criteria identified by the customer.
7. MTJ does not maintain records to determine whether MTJ's Specification Sheet was sent to the customers referenced in the invoices.

8. MTJ does not believe that the customers referenced in the invoices were supplied a brochure provided to Inspector Bowman.
9. Pursuant to request, MTJ supplied Inspector Bowman with the Spec-Tex Specification sheets attached hereto as **Exhibit 3** (provided however, MTJ makes no representation regarding the handwriting on one of the specification sheets).
10. Pursuant to request, MTJ supplied Inspector Bowman with the Ultra-Fresh Data Sheets reflecting registration of Ultra-Fresh with the EPA attached as **Exhibit 4**.
11. After performing the inspection and at the time of departing MTJ, Inspector Bowman notified Rick Detter that there were no violations of FIFRA.
12. Inspector Bowman told Detter that MTJ should receive an “all clear” letter stating that MTJ practices met EPA standards.
13. Upon information and belief, Inspector Bowman then prepared the “Inspection Summary Narrative” attached hereto at **Exhibit 5** (“Inspection Summary”).
14. Inspector Bowman then submitted the Inspection Report to EPA Region IV attached hereto as **Exhibit 6** (“Inspection Report”).
15. The Inspection Report reflects that product packaging are not subject to FIFRA.
16. The Inspection Report found that review of the labels for false or misleading claims was not applicable.
17. The Inspection Report identifies the shipments to the Chester County, Tennessee Sheriff Department and East Kentucky University reflected in Exhibits 1 and 2.
18. The Inspection Report identifies that maintaining pesticide sale and shipment records is not applicable.
19. The Inspection Report notes that there were no corrective actions taken during the visit.
20. The Inspection Report does not identify any suspected violations of FIFRA or identify any pesticide subject to FIFRA.
21. Inspector Bowman signed the Inspection Report.
22. Without warning or opportunity to be heard, on or about March 31, 2011, MTJ received the Stop Sale, Use or Removal Order attached at **Exhibit 7** (“Stop Sale Order” or “SSURO”).

23. MTJ denies that MTJ made any “public health claims” and the SSURO identifies numerous MTJ products for which the EPA alleges MTJ made any purported “public health claims”.
24. The Stop Sale Order ordered and forced MTJ to shut down its operations, send workers home and miss shipments of products then being manufactured, whether subject to purported “public health claims” or otherwise.
25. Upon receiving the Stop Sale Order, MTJ’s representative Rick Detter contacted the EPA and spoke with either Kimberly Bingham or Melba Table, and stated that MTJ used the Ultra-Fresh product as a mattress cover material and that he was unaware of any claims that could violate FIFRA.
26. Either Kimberly Bingham or Melba Table represented to Mr. Detter that MTJ must have received the Stop Sale Order by mistake.
27. MTJ contacted legal counsel Matthew K. Rogers to investigate the SSURO and Rogers contacted EPA, and was directed to speak with attorney Michiko Kono (“Kono”).
28. EPA Attorney Kono represented that sections from MTJ’s Specification Sheets made “public health claims” in the section entitled “Bacteria Resistant” and that upon removal of those sections the EPA would vacate the Stop Sale Order.
29. Attorney Rogers asked why a SSURO was issued without warning.
30. Attorney Kono represented that MTJ would not have complied with a warning and the SSURO was issued to force MTJ to comply with EPA demands.
31. MTJ disputed that the Specification Sheet Section header “Bacteria Resistant” which cited testing methods that MTJ passed made public health claims.
32. Attorney Kono initially represented that the EPA would vacate the SSURO upon changing the language; however, the EPA did not notify MTJ that it was vacating the SSURO as promised.
33. More than one week after issuing the SSURO, the EPA finally issued Vacatur of the SSURO on April 8, 2011 as reflected at **Exhibit 8**.
34. Thereafter, the EPA demanded that MTJ pay penalties of \$20,000 for alleged violations of FIFRA.
35. MTJ notified the EPA on May 13, 2011 that MTJ’s products are not pesticides and statements made by MTJ are specifically made pursuant to FIFRA Section 152.10 as being non-pesticidal products.

36. MTJ provided the EPA with MTJ's then understanding of FIFRA, including that MTJ's mattresses were not subject to FIFRA.
37. The EPA did not assert that language referenced in the Complaint make MTJ's a product subject to or similar products subject to FIFRA.
38. On or about May 16, 2011, the EPA provided MTJ with copies of the "Pesticide Registration (PR) Notice 2000-1".
39. On or about May 16, 2011, the EPA provided MTJ with a copy of the EPA's Enforcement Response Policy.
40. The EPA's "FIFRA ENFORCEMENT RESPONSE POLICY" is attached hereto as **Exhibit 10** (hereinafter "Enforcement Policy").
41. MTJ reviewed the Enforcement Policy and notified the EPA that the EPA did not follow the Enforcement Policy by, among other actions, failing to notify MTJ of any purported violation of FIFRA and failing to consider that there was no threat to the public health or the environment before the EPA issued the SSURO.
42. Attorney Rogers requested that the EPA provide evidence which the EPA used to determine that MTJ was subject to FIFRA and evidence of purported violations.
43. The EPA refused to identify evidence or provide MTJ or Rogers evidence upon which the EPA determined that MTJ was subject to FIFRA or purporting to prove MTJ violated FIFRA.
44. MTJ also requested that the EPA provide MTJ with the evidence and other information upon which the EPA decided to issue the SSURO.
45. The EPA refused to cite any evidence or provide MTJ with evidence or other information upon which it decided to issue SSURO.
46. On June 11, 2011, the EPA represented that it issued the SSURO because the EPA considered MTJ may not comport with the EPA's belief that MTJ's products were pesticides and that the SSURO forced MTJ to comply with the EPA's assertions that the mattresses were pesticides.
47. MTJ made a request pursuant to the Freedom of Information Act for information within the EPA's possession relating to MTJ.
48. After MTJ's Freedom of Information Act Request, and pursuant to that request, Respondent received the report attached at **Exhibit 6** hereto ("Inspection Report") and **Exhibit 5** "Inspection Summary".

49. Neither the Inspection Report nor the Inspection Summary identify any purported or potential violations of FIFRA.
50. On or about April 30, 2014, the EPA provided MTJ with a CAFO relating to Bob Barker, a company that MTJ estimates is at least five-times larger than MTJ.
51. On May 29, 2014, Melba Table stated that no Stop Sale Order was issued to Bob Barker.
52. The CAFO cited a consent penalty of \$7,000.00 for one alleged violation of FIFRA which Bob Barker does not admit or deny was a pesticide at the time.
53. In discussions thereafter, including on or about May 29, 2014, MTJ notified the EPA that MTJ was financially distressed and that Bob Barker was substantially larger than MTJ.
54. MTJ expressed that MTJ did nothing in violation of FIFRA but that MTJ would enter into a fair and reasonable agreement reflecting the facts to avoid further legal expenses.
55. Despite size differences, the EPA insisted that MTJ pay more than Bob Barker.
56. MTJ requested explanation regarding how the EPA could (i) issue a SSURO and (ii) disregard its own published Enforcement Policy and demand payment of more than Bob Barker under the circumstances.
57. Melba Table told MTJ that MTJ's "public health claims" were more egregious than Bob Barkers'.
58. MTJ requested Ms. Table identify what "public health claims" she referred to and which she considered more egregious than those identified by Bob Barker in the Consent CAFO.
59. Ms. Table represented that MTJ's made claims relating to preventing HIV and AIDS.
60. MTJ denied that it made such claims and requested the EPA provide the basis for such assertions.
61. Ms. Table promised to provide information proving that MTJ made claims relating to HIV and hepatitis within twenty four hours.
62. On May 30, 2015, the EPA provided copies of MTJ's specification sheets which do not include any reference to HIV or hepatitis.
63. To date, MTJ has received no evidence that MTJ made any claims relating to HIV and hepatitis.
64. MTJ provided comments to a proposed CAFO provided by the EPA.

65. MTJ objected to certain language as not being representative of the facts or events.
66. EPA officials insisted that MTJ sign the CAFO proposed by the EPA, even with facts that MTJ believes were not accurate.
67. MTJ refused to sign documents that did not reflect the facts known and believed by MTJ to be true and accurate.
68. On June 6, 2014, MTJ notified the EPA that it was not following the EPA's Enforcement Policy.
69. To avoid further allegation of wrong-doing by the EPA, and mitigate MTJ's damages by including further attorney fees, on June 6, 2014 MTJ offered to pay a total of \$2,500.
70. The EPA rejected MTJ's offer.

**FIRST AND SECOND COUNTERCLAIMS FOR RELIEF**  
**(DECLARATORY RELIEF AND RECOVERY FOR INTENTIONAL, BAD FAITH AND WANTON DECISIONS BEYOND DISCRETIONARY INTERPRETATION AND/OR APPLICATION OF FIFRA, AS WELL AS BAD FAITH ATTEMPTS TO PENALIZE MTJ BEYOND THE SCOPE OF THE EPA'S FIFRA ENFORCEMENT POLICIES CAUSING DIRECT, CONSEQUENTIAL DAMAGES AND SPECIAL DAMAGES INCLUDING ATTORNEY FEES)**

71. MTJ incorporates by reference each of the numbered allegations above and the responses to the Complaint allegations by reference and as if set forth fully herein.
72. Upon information and belief, the EPA has interpreted FIFRA in a manner that is inconsistent with the intent, purposes and scope of FIFRA, including regulations promulgated relating thereto, and so as to cause parties to pay penalties even though there are no violations of FIFRA.
73. The EPA has consciously disregarded FIFRA and its FIFRA Enforcement policy attempting to extort a settlement and settlement payments from MTJ.
74. Section III.A of the Enforcement Policy states in part "all persons not covered by the exception in section 14(a)(2), EPA should issue a Notice of Warning for a first-time violation."
75. Section III.A of the Enforcement Policy also states in part "FIFRA §14(a)(4) provides the EPA may choose to issue a Notice of Warning in lieu of a penalty action if EPA determines that the violation occurred despite the exercise of due care or the violation does not cause significant harm to the health or environment."

76. Section III.C of the Enforcement Policy states in part “FIFRA §13 provides EPA the authority to issue a Stop Sale, Use, or Removal Order (SSURO) to any person who owns, controls, or has custody of a pesticide or device, whenever the EPA has reason to believe on the basis of inspection or tests that: (1) a pesticide or device is in violation of any provision of the Act; (2) a pesticide or device has been, or is intended to be, distributed in violation of the Act; or (3) the registration of a pesticide has been cancelled by a final order or has been suspended.”
77. At no point did MTJ fit the criteria for Section III.C and there was no reasonable basis to believe a SSURO should issue.
78. Section III.C.1 of the Enforcement Policy identifies that the EPA should issue a SSURO for (1) pesticides for which there is reason to believe there is a hazard to human health or the environment; (2) pesticides or devices with materially misleading for fraudulent labeling if followed by a use is likely to cause a significant health hazard or serious adverse environmental effect; (3) pesticides or devices that are the subject of a recall and the party refuses to remove or is recalcitrant or unable to remove; (4) pesticides in violation of FIFRA for which a civil penalty has already issued; and (5) pesticides that have been suspended.
79. The EPA alleges only purported violations resulting in a Gravity of Level of 3 or less, which appendices attached to the Enforcement Policy establish warrant either “No action or Notice of Warning”.
80. On May 16, 2011, Attorney Kono represented that the Enforcement Policy was used to calculate a Civil Penalty, which the facts establish was not true and likely was an intentional misrepresentation.
81. At no time has the EPA asserted in good faith or with factual basis that MTJ’s mattresses pose any risk to public health or the environment.
82. The SSURO caused MTJ compensatory and consequential damages, including without limitation shipping delays, employee overtime, damaged customer relationship due to delayed shipments, and other special damages for which MTJ is entitled recover.
83. The EPA has made intentional misrepresentations and consciously disregarded truth attempting to convince MTJ to pay improperly assessed penalties.
84. The EPA and individuals cited herein have acted beyond the scope of any discretionary authority and acted in bad faith in shutting down MTJ’s mattress business, in attempting to force MTJ to pay unwarranted penalty and in filing the Complaint at issue.
85. The EPA’s continued pursuit of damages against MTJ is contrary to the authority of the EPA, not pursuant to FIFRA, and even if it were, has been and continues to be inconsistent with the EPA’s own enforcement policies.



86. MTJ incurred damages in such amount as to be determined at hearing and has incurred attorney fees relating to the EPA's conduct all of which MTJ seeks to recover.

NOW THEREFORE, MTJ American, LLC requesting and demanding one or more of the following relief:

87. Declaratory finding, relief and order that MTJ American, LLC does not manufacture, sale or distribute a pesticide subject to and regulated by FIFRA,
88. Declaratory finding, relief and order that stating the words "Bacteria Resistant", "Anti-microbial", "Bacteriostatic" and/or "virus" in conjunction with "barrier" as used by MTJ are not public health claims contemplated by or subject to FIFRA.
89. If and only to the extent relief number 1 or 2 are not granted, in the alternative a declaratory finding and relief via order that stating the words "Bacteria Resistant", "Anti-microbial", "Bacteriostatic" and/or "virus" in conjunction with "barrier" are within the "treated articles exemption".
90. Declaratory finding, relief and order that the EPA intentionally and in bad faith disregarded FIFRA's express terms, Federal Regulations adopted pursuant thereto and/or the EPA's Enforcement Policy in attempting to enforce a civil penalty against MTJ.
91. Declaratory finding, relief and order that MTJ is not subject to any civil penalty and that the EPA erroneously issued a SSURO causing damages to MTJ.
92. Award of such compensatory, consequential, special and punitive damages as the law and circumstances allow, including without attorney fees incurred by MTJ in responding to an improvidently entered SSURO which was contrary to the EPA policies and beyond any discretion granted by or pursuant to FIFRA or the Enforcement Policy, as well as attorney's fees incurred in responding to the Complaint as may be authorized by law, and proved hereafter.
93. Hearing on these matters after reasonable opportunity to conduct discovery of and from the EPA.
94. Such other relief as is permitted and appropriate.
95. MTJ expressly reserves the right to trial by jury, to the extent necessary and available, requests all matters to be determined by jury.

This the 5<sup>th</sup> day of May, 2015.



Matthew K. Rogers

NC State Bar No.: 26992

*Attorney for MTJ American, LLC*

OF COUNSEL:

LAW OFFICES OF MATTHEW K. ROGERS, PLLC

P.O. Box 9096

Hickory, North Carolina 28603

Phone: (828) 327-2005

Fax: (828) 327-7009

Email: [rogersmk@mrbizlaw.com](mailto:rogersmk@mrbizlaw.com)

UNITED STATES  
ENVIROMENTAL PROTECTION AGENCY  
REGION 4  
ATLANTA, GEORGIA

**IN THE MATTER OF:**

MTJ AMERICAN, LLC

Respondent.

**CERTIFICATE OF SERVICE**

**Docket No.:** FIFRA-04-2014-3009

**THIS IS TO CERTIFY** that a copy of **Respondent MTJ American, LLC's Motion To Dismiss, Affirmative Defenses And Answer To The Civil Administrative Complaint And Request For Hearing** was served on the parties listed below by mailing a true copy thereof to each party's counsel of record in an envelope addressed as indicated below with proper postage attached and deposited in an official depository under the exclusive care and custody of Federal Express.

TO: Regional Hearing Clerk  
U.S. EPA, Region 4  
61 Forsyth Street  
Atlanta, GA 30303

Michiko Kono  
U.S. EPA, Region 4  
61 Forsyth St.  
Atlanta, GA 30303

This the 5<sup>th</sup> day of May, 2015.



Matthew K. Rogers  
N.C. State Bar No.: 26992  
*Attorney for MTJ American, LLC*

OF COUNSEL:  
LAW OFFICES OF MATTHEW K. ROGERS, PLLC  
P.O. Box 9096  
Hickory, North Carolina 28603  
Phone: (828) 327-2005  
Fax: (828) 327-7009  
Email: rogersmk@mrbizlaw.com

# **EXHIBIT 1**



Remit To: MTJ AMERICAN, LLC  
 PO BOX 826  
 GRANITE FALLS NC 28630  
 PHONE #: 828-396-6700  
 FAX #: 828-313-0612

I N V O I C E

Bill To: EAST KENTUCKY UNIVERSITY  
 DIV OF ACC, CPO 3A, JONES 213  
 521 LANCASTER AVE  
 RICHMOND KY 40475

Ship To: EKU-HOUSING & RESIDENTIAL SVC  
 SSB CPO 51, ROOM 552  
 521 LANCASTER AVENUE  
 RICKMOND KY 40475

Invoice/Dt	Order#/Dt	Ship/Prom	DCust#/Sales	Rep	P.O./Ship Via	Pmt/Frght	Terms
07/07/10	5617	07/05/10	5986	EKU	P0018107	NET 30	
Ln#	Quantity	U/M	Item / Description		Unit Price		Amount

SCHEDULE DATE: 06/21/10

1	72.00	EA	UFA063674		143.13		10,305.36
	Back Ord	B/O	6X36X74 UNIV. ADVANTAGE				
			CUSTOMER PART #:				

FIRST CITIZENS BANK	Sub Total	10,305.36
WORKING CAPITAL FINANCE		.00
PO BOX 4715		.00
GREENSBORO		.00
NC 27404	Pay This Amt	10,305.36

# **EXHIBIT 2**

TB

07221022130101TB



Remit To: MTJ AMERICAN, LLC  
 PO BOX 826  
 GRANITE FALLS NC 28630  
 PHONE #: 828-396-6700  
 FAX #: 828-313-0612

I N V O I C E

Bill To: TN-CHESTER COUNTY SHERIFF DEPT Ship To: CHESTER COUNTY JAIL  
 ATTN: ANDREA HOLLAND 333 ERIC BELL DR.  
 P O BOX 19 HENDERSON TN 38340  
 HENDERSON TN 38340

Invoice/Dt	Order#/Dt	Ship/Prom	DCust#/Sales Rep	P.O./Ship Via	Pmt/Frght Terms
	5590	6145	06/25/10 TN-CHESTER	RUSH	NET 30
06/23/10	06/21/10	06/25/10	DLH	WILL ADVISE	PREPAID
Ln#	Quantity	U/M	Item / Description	Unit Price	Amount

SCHEDULE DATE: 06/21/10

1	50.00	EA	DCS452775P 4.5X27X75 CLEAR SAFE W/PILLOW CUSTOMER PART #:	64.95	3,247.50
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Sub Total	3,247.50
FREIGHT	221.59
Pay This Amt	3,469.09

Emad

# **EXHIBIT 3**



0722102213 0101 15



PO Box 8636 • Coral Springs, FL 33075  
Telephone: Toll Free 866-477-3289 • Fax: Toll Free 877-577-3289  
Email: info@spectexinc.com • Website: www.spectexinc.com

Econo  
+  
Value  
+  
Clear

### PVC INSTITUTIONAL MATTRESS/PILLOW SURFACE FABRIC - Pigmented or Clear

<u>Typical Physical Properties:</u>	<u>Typical Test Results:</u>	<u>Test Method:</u>
Total Weight (oz/yd <sup>2</sup> ):	10.5 (+/- .5)	ASTM D3776
Fabric Weight (oz/yd <sup>2</sup> ):	1.6	ASTM D3776
Substrate Description:	Circular knit	
Coating:	<b>EXTRUDED PVC</b>	
Coating weight (oz/yd <sup>2</sup> ):	8.9	ASTM D3776
Trapezoid Tear (lbs):	21 (w) x 19 (f)	ASTM D751
Tongue Tear	7 (w) x 9 (f)	ASTM D2261
Grab Tensile (lb/inch):	116 (w) x 71 (f)	ASTM D751
Adhesion (lb/inch):	4.0 (w) x 6.7 (f)	ASTM D751
Flame Resistance:	Pass	NFPA 701-2004 TM2
	Pass	Cal 117 Section E
	Pass	CFR 1633 in proper composite
Standard Antimicrobial*:	ULTRA FRESH® EPA Registration No. 10466-28	
	Pass	AATCC 30-1988
	Pass	AATCC 100-1999
	Pass	AATCC 147-1998
	Pass	NY State 1241.1985
Foam Compatible:	Pass - Loss < 3.0%	HTM
Draize Dermal Toxicity:	No irritation	
Heat-sealability:	Seam strength 67 lbs with 1 inch RF weld	

ClearView will pass Cal TB 121, Cal TB 129, Cal TB 117, Cal TB 133, Cal TB 603, as well as, CFR 1633 when used as a component in a properly constructed composite.

PVC mattress covering must be produced in a certified ISO 9000 manufacturing facility. The product must not contain phthlates, mercury, lead, or cadmium. The manufacturing under ISO 9000 certification will allow a raw material supply chain verification to certify that none of the mentioned toxins (phthlates, mercury, lead, or cadmium) are contained in the production of the finished product. A third party independent certification employed by the manufacturing facility must be supplied with each shipment confirming the manufacturing has taken place without the introduction of phthlates, mercury, lead, or cadmium in the base PVC formulation, the pigmenting system as well as the antimicrobial.



PO Box 8636 • Coral Springs, FL 33075  
Telephone: 954-796-7641 • Fax: 954-796-7643  
Email: info@spectexinc.com • Website: www.spectexinc.com

## PROTECT 210 DPU SPECIFICATIONS

Protect 210 DPU is 210 denier nylon, oxford construction, with a polyurethane back coating. It has been developed specifically for use as a mattress and/or pillow covering. The solvent based polyurethane coating is applied so it can be built up to meet liquid resistance, fire retardant, and antimicrobial requirements. The coating process also prevents the coating from becoming brittle. This combination of fabric coating and processing produces a high quality, long wearing, and cost effective institutional mattress ticking.

### TESTING RESULTS:

Weight:	4.34 ounces per sq yd.	
Antimicrobial:	Ultra Fresh	EPA registered
Bacteria Resistance:	AATCC Method 14-1988	99% reduction
Antifungal:	AATCC Method 30-1988	99% reduction
Flame Resistance:	NFPA 701	pass
	Cal 117	pass
	CFR 1632	Class A
Hydrostatic Resistance:	Mullen/burst	150+
Draize Dermal Toxicity:		pass
FR/HR Foam compatibility:	HTM test.	no advanced aging

Protect 210 DPU is the perfect alternative to vinyl mattress ticking. It has greater tear and durability compared to 70 denier nylon and yet remains softer than most vinyl products in the market. The polyurethane coating used in Protect 210DPU and Protect 70DPU have proven to withstand the test of time. Both of these coated textile constructions have been in use on healthcare mattresses for the past ten years.

*Ultra Fresh is a trademark of Thomson Research, Toronto, Canada.  
Please address all inquiries to Spec-tex Inc.  
Rev.08/09*



PO Box 8636 • Coral Springs, FL 33075  
Telephone: Toll Free 866-477-3289 • Fax: Toll Free 877-577-3289  
Email: info@spectexinc.com • Website: www.spectexinc.com

## CORRECT-TICK PRO TPU

Thermal Plastic Urethane

Correct-tick Pro TPU has been developed as a cost effective, heat sealable mattress covering material. It is highly resistant to abrasion and chemical breakdown while showing extended durability. It is also extremely resistant to cracking.

<u>Typical Physical Properties:</u>	<u>Typical Test Results:</u>	<u>Test Method:</u>
Substrate:	2.9 ounce circular knit Specially constructed to accomplish a strong mechanical bond.	
Coating:	5.5 ounces TPU	
Total weight:	8.5 oz/yd <sup>2</sup>	ASTM D3776
Trapezoid Tear (lb):	35 (w) x 24 (f)	ASTM D751
Grab Tensile (lb/inch):	160 (w) x 69 (f)	ASTM D751
Adhesion (lb/inch):	STF	ASTM D751
Moisture Vapor Transmission:	62 g/m <sup>2</sup> /24hrs	ASTM E96 Proc B per T-2016
Antibacterial:	Pass	AATCC TM 147 2004
Antifungal:	Pass	AATCC TM 30-2004
Abrasion:	190 cycles	ASTM D3389 taber, H18 wheel, 1,000 g load
Flame Resistance:	Pass Pass	NFPA 701-2004 TM 2 Cal. Bull. 117 Sec. E. Part 1
Heat Sealed Seam Strength:	48.1 lbs./Sq. In.	ASTM D1683-07A (Modified to test heat sealed seams)

*Please address all inquiries to Spec-tex Inc.*

# **EXHIBIT 4**

# Ultra-Fresh\* DM-50

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use as a bacteriostatic and fungistatic preservative for textiles, such as wool, polyester and tenting; aqueous/non-aqueous emulsions and adhesives such as adhesive films, polyvinyl acetate emulsions and starch based adhesives; polyurethane foams; synthetic and cellulose sponges; plastics and polymers such as latex, rubber, polypropylene and polyolefins; medium density fiber and particulate board. For a more detailed list see the Technical Data Sheet for *Ultra-Fresh\*DM-50*.

*Ultra-Fresh\*DM-50* also eliminates house dust mites from treated materials.

Finished products containing *Ultra-Fresh\*DM-50* cannot make public health claims relating to antimicrobial activity. When incorporated into treated articles, this product does not protect users or others against food borne or disease causing bacteria, viruses, germs, or other disease causing organisms. Do not use for any applications involving direct or indirect food contact, or human or animal drinking water contact applications.

*Ultra-Fresh\*DM-50* is to be used as directed in the accompanying Technical Data Sheet.

## ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge.

Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## BACTERIOSTAT & FUNGISTAT

### ACTIVE INGREDIENTS

tri-n-butyltin maleate.....25.0 %

**INERT INGREDIENTS**.....75.0 %

Total .....100.0%

**KEEP OUT OF REACH OF CHILDREN  
DANGER!**

### PRECAUTIONARY STATEMENT:

**Danger.** Hazard to humans and domestic animals. Corrosive, causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. May be fatal if swallowed or absorbed through the skin. Wear protective eye wear (goggles, face shield, or safety glasses) and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

### FIRST AID

<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call poison control center or doctor for treatment advice.</li> </ul>
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call your local poison control center.

Manufactured for:

Thomson Research Associates  
95 King Street East, Suite 400  
Toronto, Ontario  
Canada M5C 1G4

## STORAGE AND DISPOSAL

**Prohibitions:** Do not store or transport in unlined metal containers. Do not contaminate with strong oxidizing or reducing agents. Do not contaminate water, food or feed by storage or disposal or cleaning of equipment.

**Pesticide Disposal:** Pesticides are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

### Container Disposal

**Metal Containers:** Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

**Plastic containers:** Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**General:** Consult Federal, state, or local disposal authorities for approved alternative procedures.

E.P.A. Reg. No. 10466-28

E.P.A. Est. No. 34310-RI-01

70653-TX-001

Net Contents:

U.S. Gallons

ACCEPTED

SEP 27 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under 10466-28

trademark of Thomson Research Associates  
220903

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# TECHNICAL DATA SHEET

## Ultra-Fresh\* DM-50

E.P.A. Registration No. 10466-28

### PRODUCT DESCRIPTION

Ultra-Fresh\*DM-50 is a colorless liquid used for rendering fabrics, water-based emulsions, polyurethane foams, synthetic/cellulosic sponges, plastics and polymers resistant to attack by microorganisms such as bacteria, fungi and house dust mites.

### PHYSICAL PROPERTIES

Boiling Point.....198-200C / 388-392F  
 Freezing Point.....-13C / 8.6F  
 Specific Gravity .....1.048 at 25C / 77F  
 Solubility.....Soluble or miscible in water and most organic solvents

### BIOLOGICAL ACTIVITY

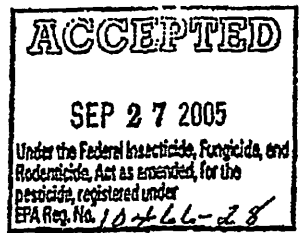
The following table lists the minimum concentrations of Ultra-Fresh\*DM-50, dispersed in aqueous media, required to inhibit the growth of various microorganisms in test tube cultures. This table is intended to provide an indication of the broad-spectrum activity of Ultra-Fresh\*DM-50 in aqueous solution and is neither intended as a claim for recommended use concentrations under practical conditions, nor as a list of micro-organisms involved in specific end-use conditions.

ORGANISM	Minimum Concentration (ppm) Required for Complete Inhibition of Growth
<b>A. Gram positive bacteria</b>	
<i>Bacillus cereus</i>	10
<i>Bacillus mycoides</i>	5
<i>Bacillus megaterium</i>	37
<i>Bacillus subtilis</i>	26
<i>Brevibacterium ammoniagenes</i>	8
<i>Clostridium oroticum</i>	150
<i>Corynebacterium pseudodiphtheriticum</i>	4
<i>Nocardia asteroides</i>	2
<i>Staphylococcus aureus</i>	2
<i>Streptovercillium reticulum</i>	25
<b>B. Gram negative bacteria</b>	
<i>Acinetobacter calcoaceticus</i>	5
<i>Enterobacter aerogenes</i>	722
<i>Enterobacter cloacae</i>	656
<i>Escherichia coli</i>	334
<i>Klebsiella pneumoniae</i>	24

**ACCEPTED**  
 SEP 27 2005  
 Under the Federal Insecticide, Fungicide, and  
 Rodenticide Act as amended, for the  
 pesticide, registered under  
 EPA Reg. No. 10466-28

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ORGANISM	Minimum Concentration (ppm) Required for Complete Inhibition of Growth
<i>Morganella morgani</i>	26
<i>Proteus mirabilis</i>	36
<i>Pseudomonas aeruginosa</i>	200
<i>Salmonella schottmuelleri</i>	620
<i>Salmonella typhimurium</i>	30
<b>C. Fungi</b>	
<i>Alternaria alternata</i>	5
<i>Aspergillus flavus</i>	30
<i>Aspergillus fumigatus</i>	30
<i>Aspergillus niger</i>	15
<i>Aureobasidium pullulans</i>	31
<i>Candida albicans</i>	2
<i>Chaetomium globosum</i>	less than 1
<i>Curvularia genticulata</i>	9
<i>Epidermophyton floccosum</i>	1
<i>Fusarium oxysporum</i>	25
<i>Gloeophyllum trabeum</i>	5
<i>Lentinus lepideus</i>	5
<i>Mucor racemosus</i>	15
<i>Penicillium funiculosum</i>	15
<i>Penicillium variabile</i>	15
<i>Poria placenta</i>	5
<i>Rhizopus sp.</i>	10
<i>Schizophyllum commune</i>	15
<i>Serpula lacrymans</i>	15
<i>Stachybotrys chartarum</i>	31
<i>Trichoderma viride</i>	5
<i>Trichophyton mentagrophytes</i>	7
<i>Trichophyton rubrum</i>	1



**APPLICATION PROCEDURES**

The application levels given below are representative of those found necessary in practice. For each specific use, a trial run is recommended in order to determine the application level and method of addition for the particular product being treated.

**1. Fabrics**

Ultra-Fresh\*DM-50 can be padded on to fabrics from either an aqueous or solvent dispersion. Sufficient Ultra-Fresh\*DM-50 should be added to the pad bath to give a fabric pick-up of 0.2% to 0.4%. This product, when applied according to recommendations, will last through at least 25 conventional launderings.

DI: mu Ec fo ag ad be ce la de de F: L fr F cu m a af B k C a 7 a K J C e v E E

**2. Water-Based Emulsion/Adhesives**

Water-based adhesives and related emulsion systems can be rendered resistant to biologically induced instability and degradation by the addition of *Ultra-Fresh\*DM-50*. An application level of 0.08% w/w based on total emulsion weight is recommended. *Ultra-Fresh\*DM-50* should be treated as one of the components and added prior to mixing. In the case of hot-melt adhesives, temperature should not exceed 200C / 392F. The in-can and in-use protection conferred by *Ultra-Fresh\*DM-50* will last indefinitely in the undiluted adhesive or emulsion.

**3. Polymer Systems**

Polymeric materials such as vinyl and polyolefins can be rendered resistant to the growth of mildew by the incorporation of *Ultra-Fresh\*DM-50*. Add 0.1% to 0.25% by weight of *Ultra-Fresh\*DM-50* to the resin mix. The exact amount required for a specific usage can be readily determined by means of a preliminary trial.

**TOXICITY****A. Animals**

Dermal-Acute Cutaneous LD <sub>50</sub> (rabbits)	=	>2.0 g/kg
Oral-Acute Oral LD <sub>50</sub> (rats)	=	330 mg/kg
Inhalation-Acute Inhalation LCT <sub>50</sub>	=	2.7 mg/L of air

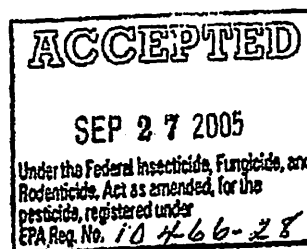
Eyes (rabbits) *Ultra-Fresh\*DM-50* is corrosive to eye tissue.

**B. Birds**

Acute Oral LD <sub>50</sub> (Mallard Duck)	=	1,631 mg/kg
Dietary LD <sub>50</sub> 8-day - Mallard Duck	=	3,401 ppm
- Bobwhite Quail	=	4,601 ppm

**C. Fish**

Fish Bioassay, 96-hour Static TL <sub>50</sub>	=	
-Rainbow Trout	=	54.6 ppb

**D. Invertebrate**

Acute Toxicity LC<sub>50</sub> 24-48 hours (*Daphnia magna*) = 250 ppb

**E. Human Skin Tests**

With *Ultra-Fresh\*DM-50* impregnated fabrics, primary sensitization patch tests indicated no sensitization at the highest level tested: i.e., 0.416% by weight of *Ultra-Fresh\*DM-50* on the fabric.

**PRECAUTIONS**

*Ultra-Fresh\*DM-50*, as received in its concentrated form, is a potentially dangerous material and should be handled with the care and common sense that be accorded to all biologically active



March 1998

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chemicals. *Ultra-Fresh\*DM-50* is corrosive to eyes and exposure can cause skin irritation. May be fatal if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or faces shield and rubber gloves when handling. Avoid contamination of food. Treated effluent should not be discharged where it will drain into lakes, streams, ponds, or public water.

#### FIRST AID

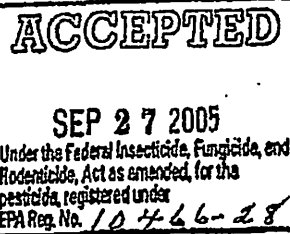
In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

#### NOTE TO PHYSICIAN

Probable mucosal damage contraindicates the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

#### NOTICE

The technical information and suggestions for use made herein are based on TRA's research and experience and are believed to be reliable, but such information and suggestions do not constitute a warranty, and no patent liability can be assumed. Since TRA has no control over the conditions under which this product is transported, stored, handled, used or applied, it is TRA's intent that its liability on any basis be limited to the price of the product used.



# **EXHIBIT 5**

# INSPECTION SUMMARY NARRATIVE

## Producer Establishment

**Company Name & Address:** MTJ American  
PO Box 826  
4276 Helena Street  
Granite Falls, NC 28630  
**EPA Establishment Number & Reg. Number:** none  
**Product Brand Name:** Econo, Value and Clear, Fusion Advantage and Sealed Safe, Denier nylon  
**Date of Inspection:** 07-22-10

### Narrative:

On Thursday July 22, 2010 Charles Clark and I conducted an EPA Referral Inspection at MTJ American, Granite Falls, NC. At this time EPA credentials were shown to and a Notice of Inspection was issued to Rick Detter, Vice-President of Sales and Operations.

I explained to Mr. Detter that our purpose for being there was because of a referral from Region 4 EPA concerning public health claims being made on MTJ American's website (one claim list several public health claims, including one for killing MSRA) I then told him what information and items we would need. He was very cooperative and supplied us with all items asked for.

Mr. Detter explained that MTJ American manufactures bedding products (mattresses and mattresses with pillows attached) for four different categories. College, Health Care, Military and Detention. He stated that not all products contain the material that provides protection for microorganisms. Mr. Detter said they purchase fabric from another manufacturer, Spec-Tex Inc. PO Box 8636, Coral Springs, Fl. 33075, 954-796-7641. This company is the one that treats the fabric with silver or some other product to give it antimicrobial properties. Mr. Detter stated that the information and claims on their web site (<http://www.mtjamerican.com>) and in their brochures are from the information listed on the specification sheets provided by Spec-Tex Inc. This is also standard industry lingo according to Mr. Detter.

Mr. Detter stated that these claims were standard in the industry and that many of his competitors make similar claims. Two such companies are Bob Barker (<https://www.bobbarker.com>) and Derby (<http://www.derbyindustries.com>). He also stated that when his company or a competitor bids on a contract that antimicrobial claims are required.

I then asked Mr. Detter if they used the antimicrobial fabric in all the products and he said no. He said there are three treated fabrics that they purchase from Spec-Tex Inc and that MTJ American uses it in certain lines for all four categories which are College, Health Care, Military and Detention. Within each category they offer different lines with each having different features. Mr. Deter stated that products are produced only when they receive orders for that item.

Documentary samples were taken of two different mattresses with the different treated fabrics. There was no product package, labeled and ready for shipment for the third fabric called the denier nylon used in all lines for University Category. The following is a list of samples and the lines they are used in: 07221022130101TB- Fabric-PVC Institutional Mattress/Pillow Surface


Fabric, used in the Econo, Value and Clear line. This line would be available in each of the categories, College, Health Care, Military and Detention, 07221022130102TB- Fabric-Correct-Tick Pro TPU (Thermal Plastic Urethane), used in the Fusion Advantage and Sealed Safe line. This line would be available in each of the categories, College, Health Care, Military and Detention.

Mr. Deter then allowed us to photograph products that were packaged and ready for shipment. It was noted that none of the products are labeled by MTJ American. Only the law tag is sewn to the mattress and a small shipping tag (showing the purchaser and their address) is on the outside of the plastic wrapper.

Mr. Deter provided us with specification sheets on each material and invoices showing when and what company they received it from. He also provided shipping invoices for two of the different lines of material. He was unable to provide a shipping invoice for the third material. A receipt for samples was issued.

I left Mr. Deter a business card and instructions to contact me if he had any questions.

**Name of Inspector:** Thomas C. Bowman

**Signature of Inspector:** 

**Date:** July 22, 2010

# **EXHIBIT 6**



**North Carolina Department of Agriculture and Consumer Services  
Structural Pest Control and Pesticides Division  
Producer Establishment Inspection Report  
Region IV**

Steve Troxler  
Commissioner

Inspector Number	2213	Date of Visit	07-22-2010	County	Caldwell Co.
EPA Establishment Number	None				
Credentials Presented?	Yes	Notice of inspection issued?	Yes		

**Establishment Information**

Establishment Name	MTJ American				
Mailing Address	PO Box 826	City	Granite Falls	Zip	28630
Physical Address	4276 Helena Street	City	Granite Falls	Zip	28630
Telephone Number	828-396-6700	Fax Number	828-313-0612		

**Name of Principal Officers and Partners or Owners**

Mark Kiser-owner
------------------

**Names and Address of Related Establishment(s)**

none
------

Person(s) Interviewed	Rick Detter	Title	VP-Sales & Operations	Phone Number	828-396-6700
		Title		Phone Number	

History of Business	Started manufacturing Aug. 2005 in High Point, NC. Moved to current location in Feb. 2009.
---------------------	--

**Product Information**

How many products are manufactured and marketed by establishment?	3
---	---

Do labels of products packaged, labeled, and released for shipment comply with the provisions of the Federal Insecticide Fungicide and Rodenticide Act?	YES	NO	x
			N/A

3. Do they manufacture or sell restricted use pesticides (40 CFR part 169.2)?		x	
	YES	NO	N/A

4. Are RUPs in compliance?(If no, give explanation on page 4)			x
	YES	NO	N/A

5. Are manufacturing/batch/lot codes on its products?		x	
	YES	NO	N/A

Example and explanation	DFA042575, (DFA model), (04, thickness)(25"x75" Size), Date of manufact. On Law Tag attached to mattress.
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6. Was an EPA accepted label on file?			x
	YES	NO	N/A

7. Was the label(s) compared for discrepancies?			x
	YES	NO	N/A

8. Are all applicable productions packaged in child resistant packaging (40 CRP Part 157/157.36)?			x
	YES	NO	N/A

9. Was the label reviewed for false & misleading claims as outlined in PR notice 93-6?			x
	YES	NO	N/A

10. Are record production of devices kept (40 CRF part 169.2(b))?		x	
	YES	NO	N/A

Comments	
----------	--

(List all label discrepancies and inventory notes)

**Product Samples - Pesticides, Packaged, Labeled & Released for Shipment**

Physical Sample(s)		Document Sample(s)		Labels reviewed w/out sample "FYI"
EPA Reg. #	Sample #	EPA Reg. #	Sample #	EPA Reg. #
		none	07221022130101TB	
		none	07221022130102TB	

**Worker Protection Standard Review**

Are any product labels required to meet WPS? <i>(If yes, complete WPS checklist)</i>			x
	YES	NO	N/A

**Bulk**

1. Is the container designed and constructed to accommodate the return and refill of greater than 55 gallons liquid or 100 pounds of dry material?	N/A	
	YES	NO
2. Are the containers dedicated to and refilled with one specific active ingredient in a compatible formulation?	YES	NO
3. Are the containers cleaned according to written instruction provided by the registrant to the bulk repackager?	YES	NO
4. Are all repackaged pesticides sold or distributed, labeled with current EPA registered end-use product label?	YES	NO
5. Is the end site of repacking EPA establishment number on labels or container?	YES	NO
6. Are net contents on label?	YES	NO
7. Does the repackaged pesticide meet product integrity of registrant?	YES	NO
8. Is the bulk storage holding tank labeled with the registrant's current EPA registrant label and registrant establishment number?	YES	NO
9. Does user get a complete label?	YES	NO
10. Does the repackaging facility keep records as required by Section 8 of FIFRA?	YES	NO

Comments <i>(If your answer to any of the above questions is no, explain discrepancy.)</i>	
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**Cancelled / Suspended Pesticides**

List and give status on any products that have been cancelled or suspended

Brand Name	EPA Reg #	Status
	N/A	

**Cosignee(s)**

Buyer Name & Address	TN Chester Co. Sheriff Dept., PO Box 19, Henderson, TN 38340		
Product	Clear Safe with Pillow, DCS452775P	EPA Reg#	none
Buyer Name & Address	East Kentucky Univ., 521 Lancaster Ave, Richmond KY 40475		
Product	Univ. Advantage, UFA063674	EPA Reg#	none
Buyer Name & Address			
Product		EPA Reg#	

**Label Improvement Program**

Endangered Species, Ground Water (list products discussed)	
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**Guarantees and labeling agreements**

1. Does establishment have manufacturing or distributing contract agreement? (If yes, list name and address below)			X
	YES	NO	
	EPA Reg. #		
	EPA Reg. #		
2. Does establishment have supplemental label written agreements with other firms? (If yes, list name and address below)			X
	YES	NO	
	EPA Reg. #		
	EPA Reg. #		
3. Does establishment have repackaging written agreements with other firms? (If yes, list name and address below)			X
	YES	NO	
	EPA Reg. #		
	EPA Reg. #		

**Books and Records**

1. AS DETAILED IN 40 CFR PART 169 was a Section 7 affidavit explained to and signed by management?			X
	YES	NO	N/A
2. Does establishment maintain pesticide sale and shipment records?			X
	YES	NO	N/A
3. Does establishment maintain the required file on all complaints it receives on its pesticides products?			X
	YES	NO	N/A
4. Are the required pesticide disposal records complete and container disposal statements file?			X
	YES	NO	N/A
5. Are records being maintained for 2 years?			X
	YES	NO	N/A
Are batch records being maintained?			X
	YES	NO	N/A
7. Is establishment filing annual production reports?			X
	YES	NO	N/A

Comments	
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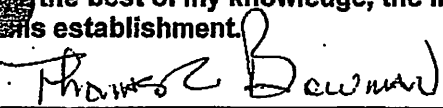
**Import, Export & Experimental Use Permit Activities**

1. Does establishment meet FIFRA provisions (sec. 17) on imported pesticides?			X
	YES	NO	N/A
2. Does establishment meet FIFRA provisions (sec. 17) on exported pesticides? (If yes, follow chapter fourteen of EPA inspection manual.)			X
	YES	NO	N/A
3. Does establishment meet FIFRA provisions (sec. 5) on Experimental Use Permits?			X
	YES	NO	N/A

**Discussion**

Any corrective action taken during this visit?	none
--	------

**Signatures**

I, the undersigned, certify that, to the best of my knowledge, the information recorded on this report accurately portrays the activities at this establishment.	
	
Signature of Inspector	Other Inspector Present



**If any violations are suspected, Here is the checklist of documentation**

- 1. Brand name of pesticide
- 2. Common chemical name of active ingredients
- 3. Name and address of shipper
- 4. Name of delivery carrier
- 5. Date received by establishment
- 6. Quantities received
- 7. Retention records

**Additional Comments**

Please note in provided boxes additional comments on sections where needed.

Page Number	Header / Section	Question Number
Comments		

Page Number	Header / Section	Question Number
Comments		

Page Number	Header / Section	Question Number
Comments		

# **EXHIBIT 7**

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
ATLANTA, GEORGIA

IN THE MATTER OF:	)	STOP SALE, USE, OR REMOVAL ORDER (SSURO)
MTJ American, LLC	)	
Respondent.	)	FIFRA-04-2011-3261

**I. AUTHORITIES AND BACKGROUND**

1. Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (FIFRA), 7 U.S.C. § 136k(a), authorizes the Administrator of the U.S. Environmental Protection Agency (EPA) to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that, *inter alia*, the pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA. This authority has been delegated from the Administrator of EPA to the Regional Administrator, Region 4, to the Director, Air, Pesticides and Toxics Management Division, Region 4, and to the Chief, Pesticides and Toxic Substances Branch.
2. The Respondent in this matter is MTJ American, LLC. Respondent's facility is located at 4276 Helena Street, Granite Falls, North Carolina 28630. Respondent also sells and advertises its products via the internet at [www.mtjamerican.com](http://www.mtjamerican.com).
3. On or about May 23, 2010, Respondent's mattress products, Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention

Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress were offered for sale and advertised on Respondent's website.

4. On or about July 22, 2010, an inspector, duly appointed by the EPA Administrator, inspected Respondent's facility located at 4276 Helena Street, Granite Falls, North Carolina 28630.
5. The aforementioned inspection revealed that the Respondent sold and distributed mattress products with antimicrobial pesticidal claims including public health claims.
6. Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress, are pesticides as defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), in that they are substances or a mixture of substances intended for preventing, destroying, repelling, or mitigating a pest.
7. Further, the MTJ American, LLC, products identified in paragraph 3 and 6 are antimicrobial pesticides as defined in Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), in

that they are intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.

8. A pest is defined in Section 2(t) of FIFRA, 7 U.S.C. § 136(t) to include any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under Section 25(c)(1).
9. The Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress, offered for sale at the Respondent's facility and over the internet website are not registered as pesticides with the EPA.
10. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136(a)(1)(A), states that it shall be unlawful for any person in any state to distribute or sell to any person a pesticide that is not registered by EPA.
11. As offered for sale on Respondent's website and facility, Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress,

Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress, were misbranded in that they failed to bear information required by EPA including, but not limited to, an EPA Establishment Number, an ingredient statement and an EPA Registration Number.

12. According to Section 2(q) of FIFRA, 7 U.S.C. § 136(q) a pesticide is misbranded if its label fails to bear the registration number assigned under Section 7 to each establishment in which it was produced, an ingredient statement, and an EPA registration number.
13. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide which is adulterated or misbranded.
14. At the time of the inspection, Respondent's facility was not registered as a pesticide producing establishment with EPA and Respondent produced the above-named pesticides at its facility.
15. Pursuant to Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), it is unlawful to produce a pesticide in an unregistered establishment.

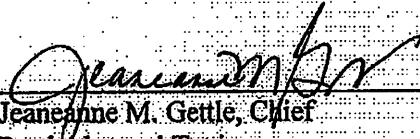
## II. ORDER

16. Pursuant to Section 13 of FIFRA, 7 U.S.C. § 136k(a), whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis on the inspection that such a pesticide is in violation of any provisions of the Act, the Administrator may issue a written printed "stop sale, use, removal" order to any person who owns, controls, or has custody of such pesticide device described in the order.

17. Respondent is hereby ordered to STOP any further distribution, sale, use, or removal of the following pesticide products: Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress or any other unregistered pesticide, within the ownership, control, or custody of Respondent, wherever located. These unregistered pesticides or any other unregistered pesticide shall not be sold; offered for sale; held for sale; shipped; delivered for shipment; received; or, having been so received, delivered, offered for delivery, moved, or removed from the premises, for any reason.
18. Respondent shall not commence any sale or distribution of: Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress, or any other unregistered pesticide, without prior written approval from EPA.
19. Violation of the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 136l.

20. The issuance of this Order shall not act as a waiver by EPA of any enforcement or other authority available to EPA under FIFRA.
21. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by Respondent.

03-31-11  
DATE

  
\_\_\_\_\_  
Jeanne M. Gettle, Chief  
Pesticides and Toxic  
Substances Branch  
U.S. Environmental Protection Agency, Region 4  
61 Forsyth Street  
Atlanta, Georgia 30303-8960



# **EXHIBIT 8**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 4  
ATLANTA FEDERAL CENTER  
61 FORSYTH STREET  
ATLANTA, GEORGIA 30303-8960

UNITED PARCEL SERVICE

Mr. Rick Detter  
Vice President  
MTJ American, LLC  
4276 Helena Street  
Granit Falls, North Carolina 28630

Re: Case No.: FIFRA-04-2011-3261  
Vacatur Stop Sale, Use, or Removal Order

Dear Mr. Detter:

Enclosed is a Vacatur of the Stop Sale, Use, or Removal Order (SSURO) that the U.S. Environmental Protection Agency (EPA) issued to MTJ American, LLC, on March 31, 2011, pursuant to the authority set forth in Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. § 136k. This Vacatur is effective immediately.

Please contact Melba Table at (404) 562-9086 or Michi Kono at (404) 562-9558 if you have any further questions regarding this Vacatur.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeaneanne M. Gettle".

Jeaneanne M. Gettle  
Chief  
Pesticides & Toxic  
Substances Branch

Enclosures

cc: Shannon Joyner  
EPA Pesticides Liaison  
NC Department of Agriculture  
& Consumer Services

**UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY**

IN THE MATTER OF:	)	
	)	
MTJ American, LLC	)	<b>RELEASE OF</b>
	)	<b>STOP SALE, USE, OR</b>
	)	<b>REMOVAL ORDER</b>
	)	
Respondent	)	FIFRA-04-2011-3261
	)	
	)	

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**VACATUR of STOP SALE, USE or REMOVAL ORDER  
DOCKET NO. FIFRA-04-2011-3261**

**1. AUTHORITIES AND BACKGROUND**

1. On March 31, 2011, the U.S. Environmental Protection Agency (EPA), Region 4, issued Stop Sale, Use, or Removal Order (SSURO) FIFRA-04-2011-3261, to MTJ American, LLC, (Respondent) prohibiting the sale, use or removal of the pesticides Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress.
2. The fabric used to make the mattress coverings for the Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress products contain Ultra Fresh,

EPA Registration Number 10466-28, which is registered by EPA for use as a bacteriostatic and fungistatic preservative for textiles.

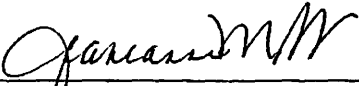
3. In response to the SSURO, Respondent has taken down its website and will no longer distribute MTJ brochures with claims that would require registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), Section 3. As a result, the products are no longer under the purview of FIFRA.
4. The SSURO is hereby terminated to allow the sale and distribution of Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress products which bear no pesticidal claims requiring registration under FIFRA, and in accordance with 40 C.F.R. 152.25(a).
5. Respondent will sell or distribute the Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress products without claiming, stating, or implying, on its website, promotional materials or anywhere else, that the products protect anything but the articles themselves, in accordance with paragraphs 2 and 4 above.

## **II. ORDER**

6. The SSURO, FIFRA-04-2011-3261 issued March 31, 2011, is hereby terminated to allow Respondent to sell and distribute all quantities and sizes of Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress within the ownership, control, or custody of Respondent, wherever located.
7. The MTJ American, LLC products may then be sold or distributed by Respondent, provided Respondent does not claim, state, or imply on its labels, website or anywhere else, that the Fusion Advantage Pressure Relief Medical Mattress, Fusion Advantage University Mattress, Fusion Detention Mattress with Silver, Econo Safe Detention Mattress, Clear Safe Detention Mattress, Summit Sealed Safe Behavioral Health Mattress, Silver Sewn Safe University Mattress, Sealed Safe Detention Mattress with Silver, Sealed Safe University Mattress, Value Safe Detention Mattress and Value Safe University Mattress should be used to control public health organisms; and Respondent does not have actual or constructive knowledge that the products will be used, or are intended to be used, for such purpose.
8. Violation of the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 136l.

9. The issuance of this Order shall not act as a waiver by EPA of any future enforcement actions or other authority available to EPA under FIFRA.
10. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by Respondent.

04/08/11  
DATE

  
\_\_\_\_\_  
Jeannette Gettle, Chief  
Pesticides & Toxic  
Substances Branch  
Air, Pesticides & Toxics  
Management Division  
EPA, Region 4

# **EXHIBIT 9**

March 6, 2000

PESTICIDE REGISTRATION (PR) NOTICE 2000 - 1\*

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS  
AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Applicability of the Treated Articles Exemption to Antimicrobial Pesticides

This notice clarifies current EPA policy with respect to the scope of the "treated articles exemption" in 40 CFR 152.25(a). This exemption covers qualifying treated articles and substances bearing claims to protect the article or substance itself. EPA does not regard this exemption as including articles or substances bearing implied or explicit public health claims against human pathogens. This notice addresses the types of claims which are not permitted for antimicrobial pesticide products exempt from registration under this provision and gathers together in one place guidance the Agency has offered in recent years on labeling statements which it believes would or would not be covered under this provision. This notice also explains the requirement that the pesticide in a treated article be "registered for such use."

This notice provides guidance to producers and distributors of pesticide treated articles and substances, and to producers and distributors of pesticides used as preservatives to protect treated articles from microbial deterioration.

**I. BACKGROUND**

EPA regulations in 40 CFR 152.25(a) exempt certain treated articles and substances from regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if specific conditions are met. The specific regulatory language is:

**Section 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation**

*"(a) Treated articles or substances.* An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect

\* This version makes corrections to the February 3, 2000 PR Notice 2000-1. Corrections in bold/italics or editorial deletions were made on pages 3, 4, 7, and 9.



the paint coating, or wood products treated to protect the wood against insect or fungus infestation),  
if the pesticide is registered for such use."

Known as the "Treated Articles Exemption," section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if:

- (1) the incorporated pesticide is registered for use in or on the article or substance, and;
- (2) the sole purpose of the treatment is to protect the article or substance itself.

The exemption gives two examples of treatments that are intended to protect only the treated article or substance itself. In the first case, paint is being protected from deterioration of the paint film or coating. In the second case, wood is being protected from fungus or insect infestations which may originate on the surface of the wood. Pesticides used in this manner are generally classified as preservatives. Other pesticides are incorporated into treated articles because of their ability to inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew. Because of this treatment, it is claimed that a fresher and more pleasing surface can be maintained.

To qualify for the treated articles exemption, both conditions stated above must be met. If both are not met, the article or substance does not qualify for the exemption and is subject to regulation under FIFRA.

In recent years, the marketplace has experienced a proliferation of products that are treated with pesticides and bear implied or explicit public health claims for protection against bacteria, fungi and viruses, as well as specific claims against pathogenic organisms which may cause food poisoning, infectious diseases or respiratory disorders. Examples of such articles include toothbrushes, denture cleansers, children's toys, kitchen accessories such as cutting boards, sponges, mops, shower curtains, cat litter, vacuum cleaner bags, pillows, mattresses and various types of finished consumer textiles. In many cases, these products have made public health claims that extend beyond the protection of the article itself, and thus, they do not qualify for the treated articles exemption.

## **II. TYPES OF ANTIMICROBIAL CLAIMS**

### **A. Public Health Claims**

Because consumers have long associated the following widely used claims and references to microorganisms harmful to humans with products providing public health protection, EPA considers an article or substance to make a public health claim if any of the following claims are made either explicitly or implicitly:

1. A claim for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *E. coli*, *HIV*,

*Streptococcus* and *Staphylococcus aureus*.

2. A claim for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site of use of the product, and regardless of whether specific microorganisms are identified.

3. A claim of "antibacterial," "bactericidal," or "germicidal" activity or references in any context to activity against germs or human pathogenic organisms implying public health related protection is made.

4. A claim for the product as a fungicide against fungi infections or fungi pathogenic to man, or the product does not clearly indicate it is intended for use against non-public health fungi.

5. A claim to control the spread of allergens through the inhibition or removal of microorganisms such as mold or mildew.

6. A non-specific claim that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.

7. An unqualified claim of "antimicrobial" activity. Refer to Unit IV.C.

#### **B. Non-Public Health Claims**

EPA considers a product to make a non-public health claim if any of the following applies:

1. A claim to inhibit the growth of mildew on the surface of a dried paint film or paint coating.

2. A claim to inhibit microorganisms which may cause spoilage or fouling of the treated article or substance.

3. A claim to inhibit offensive odors in the treated article or substance.

4. EPA considers terms such as "antimicrobial," "fungistatic," "mildew-resistant," and "preservative," as being acceptable for exempted treated articles or substances provided that they are properly, and very clearly, qualified as to their intended non-public health use. Refer to Unit IV.C. Use of these terms in product names or elsewhere in the labeling in bolder text than accompanying information may render such qualifications inadequate.

### **III. PAST EPA LABELING CLAIMS INTERPRETATIONS**

#### **A. Odor and Mildew-Resistant Properties May Be Claimed**

Over the past twenty-five years the Agency has issued several interpretations concerning the

exemption from FIFRA regulations *of* certain types of antimicrobial treated article claims associated with mildew-resistant paint, films and coatings. In the same period, EPA has also issued other interpretations concerning certain types of odor-resistant antimicrobial treated article claims.

During this period there has been widespread dissemination and adoption by the antimicrobial pesticide product community of these EPA interpretations regarding mildew-resistant and odor-resistant claims under the “treated articles exemption.” Furthermore, the Agency continues to treat these general types of claims as covered by the term “to protect the treated article or substance itself” because mitigation of these non-public health related organisms can contribute to the protection of the appearance and maintenance of the intended useful life of the treated article or substance. Because during this period, there has also been widespread misinterpretation of EPA’s guidance, the Agency has developed a representative set of statements designed to clarify its position in this area. Consequently, if they otherwise qualify for the exemption, properly labeled treated articles and substances bearing claims such as those described under Unit IV.B. continue to be eligible for the treated articles exemption.

#### **B. Product Names May Not Contain Public Health Claims**

The Agency regards trademarked product names of treated articles or substances [or references to trademarked names of registered pesticides] as potential sources of public health claims that could render a product ineligible for the “treated articles exemption” just as could other direct or indirect public health claims on or in a product’s packaging or in its labeling or advertising literature. The Agency has maintained this position in enforcement actions against pesticide-treated articles, such as pesticide-treated cutting boards and other items, which bore names suggesting health or other benefits beyond mere preservation of the treated article itself. In determining the eligibility of a treated article or substance for the exemption, the Agency will examine the product name, its context, labeling claims and other related elements on a case-by-case basis

### **IV. TREATED ARTICLE LABELING CLAIMS**

Products treated with antimicrobial pesticides with claims such as those described in Section A below are likely to not be acceptable under the “treated articles exemption” because they imply or express protection that extends beyond the treated article or substance itself. Products treated with antimicrobial pesticides registered for such use and which only bear claims for protection of the article or substance itself such as those described in Section B below are likely to be acceptable and eligible for the “treated articles exemption”, assuming all other conditions have been met. Section C below contains examples of appropriate qualifying and prominence statements which have been extracted from multiple enforcement proceedings dealing with claims that can be made for treated articles without obtaining registration.

#### **A. Examples of Labeling Claims That the Agency is Likely to Consider Unacceptable Under the Exemption**

The following examples are not intended to be an all-inclusive listing of unacceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the Antimicrobials Division at one of the addresses listed under Unit VII.

These examples represent claims or types of claims for a treated article that would lead to a requirement to register the article as a pesticide product.

- o Antibacterial
- o Bactericidal
- o Germicidal
- o Kills pathogenic bacteria.
- o Effective against E. coli and Staphylococcus.
- o Reduces the risk of food-borne illness from bacteria.
- o Provides a germ-resistant surface.
- o Provides a bacteria-resistant surface.
- o Surface kills common gram positive and negative bacteria.
- o Surface controls both gram positive and negative bacteria.
- o Surface minimizes the growth of both gram positive and negative bacteria.
- o Reduces risk of cross-contamination from bacteria.
- o Controls allergy causing microorganisms.
- o Improves indoor air quality through the reduction of microorganisms.

**B. Examples of Labeling Claims the Agency is Likely to Consider Acceptable Under the Exemption**

The following examples are not intended to be an all-inclusive listing of acceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the

Antimicrobials Division at one of the addresses listed under Unit VII.

1. Mold and Mildew Resistant Claims

- o This article has been treated with a fungistatic agent to protect the product from fungal growth.
- o Mildew Resistant - treated with a fungistatic agent to protect the paint itself from the growth of mildew.
- o Mildew Resistant - This paint contains a preservative which inhibits the growth of mildew on the surface of this paint film.
- o Mildew Resistant - Extends useful life of article by controlling deterioration caused by mildew.
- o Algae Resistant - This article contains a preservative to prevent discoloration by algae.
- o A fungistatic agent has been incorporated into the article to make it resistant to stain caused by mildew.
- o Article treated to resist deterioration by mold fungus.
- o Article treated to resist deterioration from mildew.
- o The fungistatic agent in this article makes it especially useful for resisting deterioration caused by mildew.
- o Dry coating of this paint mildew resistant.
- o Dried paint film resists mold fungus.
- o Dry enamel coating resists discoloration from mildew.
- o Cured sealant is mildew resistant.
- o Dried film resists stains by mold.
- o A mold or mildew resisting component has been incorporated in this article to make its dry film mildew resistant.
- o Specially formulated to resist mildew growth on the paint film.
- o Gives mildew-resistant coating.

- o The mildew resistance of this outside house paint film makes it especially useful in high humidity areas.
- o Retards paint film spoilage.
- o Resists film attack by mildew.

## 2. Odor Resistant Claims

- o This product contains an antimicrobial agent to control odors.
- o This product contains an antimicrobial agent to prevent microorganisms from degrading the product.
- o Resists Odors - This product has been treated to resist bacterial odors.
- o Inhibits the growth of bacterial odors.
- o Resists microbial odor development.
- o Retards the growth and action of bacterial odors.
- o Guards against the growth of odors from microbial causes.
- o Guards against degradation from microorganisms.
- o Reduces odors from microorganisms.
- o Odor-resistant.
- o Acts to mitigate the development of odors.

## C. Antimicrobial Qualifying and Prominence Considerations

EPA does not believe that claims such as “antimicrobial,” “fungistatic,” “mildew-resistant,” and “preservative” or related terms are consistent with the intent of 40 CFR 152.25(a) if they are: (1) part of the name of the product; or (2) not properly qualified as to their intended non-public health use. Examples of *permissible* statements would include, but not be limited to: “Antimicrobial properties built in to protect the product” and “Provides mildew-resistant dried paint coating.” All references to the pesticidal properties and the required qualifying statements should be located together, should be printed in type of the same size, style, and color, and should be given equal prominence. Moreover, such references should not be given any greater prominence than any other described product feature.

incorporating an antimicrobial pesticide which is registered for treating the specific article or substance.

Because of the wide range of exposure scenarios associated with the use of treated articles such as cutting boards and conveyor belts used in the food processing industry, and the wide range of household consumer uses, the Agency has interpreted 40 CFR 152.25(a) to mean that the registration and the labeling of the antimicrobial pesticide intended for incorporation into the treated article or substance needs to include specific listings of the articles or substances that may be treated. Accordingly, in registration actions over the past several years, EPA has not permitted broad general use patterns, such as the preservation of hard surfaces, plastics, adhesives or coatings for the registered pesticide. Instead, it has required that specific listings such as toys, kitchen accessories and clothing articles be reflected in the product registration and labeling as a prerequisite for incorporation of the pesticide into an article or substance under 40 CFR 152.25(a).

## VI. EFFECTIVE DATE AND PROCEDURES

In order to remain in compliance with FIFRA and avoid regulatory or enforcement consequences as described here and below, it is the Agency's position that producers, distributors, and any other person selling or distributing pesticide treated articles and substances not in compliance with the Agency's interpretation of 40 CFR 152.25(a), as clarified by this notice, need to bring their products, labeling and packaging, any collateral literature, advertisements or statements made or distributed in association with the marketing (*sale or distribution*) of the treated article or substance into full compliance with the regulation as clarified by this notice as soon as possible.

Because some of the elements of this interpretation may not have been well understood by the regulated community, the Agency expects that some companies may need up to a year in order to comply with those elements that have been clarified by this notice. Therefore, for the present, the Agency is following the approach set forth in the April 17, 1998 **Federal Register** (63 FR 19256). Although non-public health claims for microbial odor control and mold and mildew claims associated with deterioration, discoloration, and staining were not specifically mentioned in the April 17, 1998 **Federal Register**, such claims are also consistent with the enforcement approach set forth in that notice, as well as with this guidance, provided that they are properly, and very clearly, qualified as to their non-public health use. The Agency will begin to rely on the guidance provided in this Notice on February 11, 2001. Products in commerce after that date *which make statements, etc. that do not reflect the clarification offered in this notice* would risk being considered out of compliance with 40 CFR 152.25(a).

## VII. ADDRESSES

By mail:

Antimicrobials Division (7510C)  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, D. C. 20460-0001

By courier:

Antimicrobials Division (7510C)  
U. S. Environmental Protection Agency  
Room 300, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

**VIII. FOR FURTHER INFORMATION CONTACT**

If you have questions about the content of this notice, you should contact Debra Edwards at (703) 308-7891.

/signed/

Marcia E. Mulkey, Director  
Office of Pesticide Programs



# **EXHIBIT 10**

**FIFRA ENFORCEMENT RESPONSE POLICY**  
**FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT**

**Waste and Chemical Enforcement Division**  
**Office of Civil Enforcement**  
**Office of Enforcement and Compliance Assurance**  
**United States Environmental Protection Agency**

**December 2009**

# FIFRA ENFORCEMENT RESPONSE POLICY

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## I. INTRODUCTION

This document sets forth guidance for the U.S. Environmental Protection Agency (EPA or the Agency) to use in determining the appropriate enforcement response and penalty amount for violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).<sup>1</sup> The goal of this Enforcement Response Policy (ERP) is to provide fair and equitable treatment of the regulated community, predictable enforcement responses, and comparable penalty assessments for comparable violations. The policy is designed to allow swift resolution of environmental problems and to deter future violations of FIFRA by respondents, as well as other members of the regulated community.

This policy supersedes the “Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)” issued on July 2, 1990 and other FIFRA penalty policies, except for the following policies, which remain in effect: the June 2007 “Enforcement Response Policy for FIFRA Section 7(c), Pesticide Producing Establishment Reporting Requirement”; the September 1997 “FIFRA: Worker Protection Standard (WPS) Penalty Policy – Interim Final”; and the September 1991 “Enforcement Response Policy for the FIFRA Good Laboratory Practices (GLP) Regulations.” These policies are to be used as supplements to this policy to determine the appropriate enforcement response for the referenced programs. We have attached these policies as appendices to this document for ease of use.

This guidance applies only to violations of EPA’s civil regulatory programs. It does not apply to enforcement pursuant to criminal provisions of laws or regulations that are enforced by EPA. The procedures set forth in this document are intended solely for the guidance of government professionals. They are not intended and cannot be relied on to create rights, substantive or procedural, enforceable by any party in litigation with the United States. The Agency reserves the right to act at variance with this policy and to change it at any time without public notice.

## II. OVERVIEW OF THE POLICY

This Enforcement Response Policy is divided into three main sections. The first section, “Determining the Level of Action,” describes the Agency’s options for responding to violations of FIFRA. The second section, “Assessing Civil Administrative Penalties,” elaborates on EPA’s policy and procedures for calculating civil penalties to be assessed in administrative cases against persons who violate FIFRA. The third section, the appendices, contains tables to be used in calculating civil penalties for this ERP and the other FIFRA penalty policies that remain in effect. The appendices to this ERP are: (1) Appendix A - FIFRA Violations and Gravity Levels; (2) Appendix B - Gravity Adjustment Criteria; (3) Appendix C - The Summary of Tables; (4) Appendix D - The FIFRA Civil Penalty Calculation Worksheet; (5) Appendix E - “Enforcement Response Policy for FIFRA Section 7(c), Pesticide Producing Establishment Reporting Requirement” (June 2007); (6) Appendix F – “FIFRA: Worker Protection Standard (WPS) Penalty Policy – Interim Final” (September 1997); and Appendix G – Enforcement Response Policy for the FIFRA Good Laboratory Practices (GLP) Regulations.

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<sup>1</sup> For purposes of this Policy and its Appendices, the terms “pesticide” and “pesticide product” include, as applicable, “pesticide,” “antimicrobial pesticide,” “device,” “pesticide product,” “pesticidal substance,” and/or “plant incorporated protectant” as these terms are defined and used in FIFRA § 2(u), (mm), and (h), and 40 C.F.R. Parts 152 - 174.

### III. DETERMINING THE LEVEL OF ACTION

Once the Agency finds that a FIFRA violation has occurred, EPA will need to determine the appropriate level of enforcement response for the violation. FIFRA provides EPA with a range of enforcement options. These options include:

- Notices of Warning under sections 9(c)(3), 14(a)(2), and 14(a)(4);
- Notices of Detention under section 17(c);
- Stop Sale, Use, or Removal Orders under section 13(a);
- Seizures under section 13(b);
- Injunctions under section 16(c);
- Civil administrative penalties under section 14(a);
- Denials, suspensions, modifications, or revocations of applicator certifications under 40 C.F.R. Part 171;
- Referral for criminal proceedings under section 14(b); and
- Recalls.

To ensure national consistency in FIFRA enforcement actions, EPA enforcement professionals should use this ERP as a guide in considering the facts and circumstances of each case and the company's compliance history to ensure an enforcement response appropriate for the particular violations. Each of the potential enforcement responses is discussed below.

#### A. Notices of Warning

FIFRA §§ 14(a)(2), 14(a)(4), and 9(c)(3) provide EPA with the authority to respond to certain violations of FIFRA with a Notice of Warning (NOW) to the violator. Under FIFRA § 14(a)(2), EPA may not assess a penalty for violations by a private applicator or other person not covered by section 14(a)(1) without having issued a written warning or citation for a prior violation of FIFRA by that person, "except that any applicator not included [in paragraph 14(a)(1)] who holds or applies registered pesticides, or uses dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served . . . may be assessed a civil penalty . . . of not more than \$500 for the first offense nor more than \$1,000 for each subsequent offense." For all persons not covered by the exception in section 14(a)(2), EPA should issue a Notice of Warning for a first-time violation.

A state citation for a violation that would also be considered a violation under FIFRA, can be used to meet the requirement of a citation for a prior violation under FIFRA § 14(a)(2). For this purpose, the prior citation may be a notice of warning and does not have to include a penalty. The prior citation does not have to be related to the current violation; it may be for any FIFRA violation.

Regions may issue a NOW or assess a penalty of up to \$500<sup>2</sup> for the first offense by any applicator within the scope of the exception set forth in section 14(a)(2). Section 9(c)(3) permits EPA to issue a written Notice of Warning for minor violations of FIFRA in lieu of instituting a penalty action if the Administrator believes that the public interest will be adequately served by this course of action. Generally, a violation will be considered minor under this section if the total "gravity adjustment value," as determined from Appendix B of this ERP, is three or less. A Notice of Warning may also be appropriate for certain first-time recordkeeping violations as listed in Appendix A (for example, late Section 7 reports that meet the guidelines of the FIFRA Section 7 ERP). FIFRA § 14(a)(4) provides that EPA may choose to issue a Notice of Warning in lieu of a penalty action if EPA determines that the violation occurred despite the exercise of due care or the violation did not cause significant harm to health or the environment.

## **B. Notices of Detention**

A shipment of a pesticide or device may not be imported into the United States until EPA makes a determination of the admissibility of that shipment. FIFRA § 17 authorizes EPA to refuse admission of a pesticide or device into the United States if EPA determines that the pesticide or device violates any provisions of the Act. EPA may deny entry of a pesticide or device by refusing to accept the Notice of Arrival or by issuing a Notice of Detention and Hearing. Upon receiving a copy of the Notice of Detention, the Department of Homeland Security, through the U.S. Customs and Border Protection (Customs), will refuse delivery to the consignee. If the consignee has neither requested a hearing nor exported the pesticide or device within 90 days from the date of the notice, Customs will oversee destruction of the pesticide or device.

Customs regulations for enforcement of FIFRA § 17(c) (19 C.F.R. Part 12.110 - 12.117) allow Customs to release a shipment to the importer or the importer's agent before EPA inspects the shipment only if (1) the Customs District Director receives a completed Notice of Arrival signed by EPA indicating the shipment may be released and (2) the importer executes a bond in the amount of the value of the pesticide or device, plus duty. When a shipment of pesticides is released under bond, the shipment may not be used or otherwise disposed of until the Administrator has determined the admissibility of that shipment. Should the shipment subsequently be refused entry and the importer or agent fails to return the pesticide or device, the bond is forfeited.

## **C. Stop Sale, Use, or Removal Orders (SSURO)**

FIFRA § 13 provides EPA the authority to issue a Stop Sale, Use, or Removal Order (SSURO) to any person who owns, controls, or has custody of a pesticide or device, whenever EPA has reason to believe on the basis of inspection or tests that:

- (1) a pesticide or device is in violation of any provision of the Act;
- (2) a pesticide or device has been, or is intended to be, distributed in violation of the Act;
- or
- (3) the registration of a pesticide has been cancelled by a final order or has been suspended.

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<sup>2</sup> Each of the FIFRA penalty amounts referenced in this document has been increased pursuant to the Debt Collection Improvement Act of 1996, which requires federal agencies to periodically adjust the statutory maximum penalties to account for inflation. The inflation adjustment is based on the date of the violation. See 40 C.F.R. Part 19.

EPA should generally seek a civil penalty in addition to the SSURO when EPA confirms that a violation of FIFRA has occurred. EPA has established criteria to ensure judicious use of the authority to stop the sale or use of a pesticide and to order its removal. SSUROs can be a useful enforcement response, particularly for more serious violations and situations that pose a significant risk, as described further below.

#### 1. Issuance of a SSURO

A SSURO is among the most expedient and effective remedies available to EPA in its efforts to prevent illegal sale, distribution, and use of pesticides. Unlike a seizure, EPA does not need to bring action in federal court and does not need to take custody of the materials. The advantages of a SSURO over other responses are that: (1) it may be issued whenever EPA has *reason to believe* that the product is in violation of the Act; (2) it is easier to prepare and issue than a seizure; (3) it governs all of the product under the ownership, custody, or control of the individual receiving the SSURO regardless of where the product is located; (4) it can be written to include future amounts of the product that may come into custody of the respondent; and (5) it can easily be adapted to particular circumstances.

EPA should issue a SSURO against persons who own, control, or have custody of pesticides in the following categories:

- Pesticides for which there is reason to believe that there is a potential hazard to human health or the environment because they are either not registered or are over-formulated, under-formulated, or adulterated as to present a potentially serious health hazard.<sup>3</sup>
- Pesticides or devices with labeling that is materially misleading or fraudulent and, if followed by a user, is likely to cause a significant health hazard or serious adverse environmental effect. For example, a pesticide lacking a required restricted use label is an especially serious labeling violation. A SSURO should be issued for labeling on products that: (1) are ineffective for the purposes claimed; (2) are so chemically deficient as to affect the product's efficacy; or (3) bear false or misleading safety claims.
- Pesticides or devices that are the subject of a recall in instances where the responsible party refuses to remove, is recalcitrant in removing, or is unable to remove the product from the channels of trade.
- Pesticides or devices that are in violation of FIFRA and for which a civil penalty has been issued but the registrant has not brought the product into compliance.
- Pesticides that have been suspended under FIFRA § 6.

EPA may also issue a SSURO if a product has been cancelled under any section of FIFRA or suspended under FIFRA §§ 4 or 3(c)(2)(B) and the existing stock deadlines have expired at that level of sale, distribution, or use. In addition, EPA may issue a SSURO to address serious violations that present a threat of harm where there has also been a large volume of sales.

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<sup>3</sup> This may include pesticides packaged in improper or damaged containers, or pesticides that are so inadequately labeled as to make their safe or effective use unlikely or impossible.



When a SSURO is issued to a basic registrant for a registered pesticide product, the issuing office should ensure that the terms of the SSURO are equally applicable to the supplemental registrations of the product, as appropriate. In those cases, the SSURO should separately cite the supplemental registrations and copies should be sent to all known supplemental registrants.

#### **D. Seizures**

FIFRA § 13(b) gives EPA the authority to initiate *in rem* condemnation proceedings in U.S. District Court. Once a court grants EPA's request for authority to conduct a seizure, FIFRA § 9(b)(3) authorizes officers or employees designated by the Administrator to obtain and execute warrants for the purpose of seizing any pesticide or device that is in violation of the Act. Seizures may be executed with the assistance of the U.S. Marshals Service.

Under FIFRA § 13(b), EPA may initiate seizure actions in District Court against any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any state, or that is imported from a foreign country, if:

- (1) a pesticide is adulterated or misbranded;
- (2) a pesticide is unregistered;
- (3) a pesticide has labeling that does not bear the information required by the Act;
- (4) a pesticide is not colored or discolored as required;
- (5) a pesticide bears claims or directions for use that differ from those made in connection with its registration;
- (6) a device is misbranded; or
- (7) a pesticide or device causes unreasonable adverse effects on the environment even when used in accordance with FIFRA requirements.

These circumstances are similar to the circumstances under which EPA would issue a SSURO. Because a SSURO is an administrative action, it can be issued more quickly than a seizure, which requires judicial action. The SSURO is therefore the more expedient enforcement response. Nevertheless, the Agency should consider initiating a seizure in the following circumstances:

- EPA has issued a SSURO but the recipient of the order has not complied with it;
- EPA has reason to believe that a person, if issued a SSURO, would not comply with it;
- The pesticide at issue is so hazardous that it should be removed from the marketplace, place of storage, or place of use to prevent any chance of harm to human health or the environment;
- The seizure will be used to support a recall; or
- It is necessary to dispose of products being held under a SSURO for which the responsible party has indicated it will not take corrective action.

## **E. Injunctive Relief**

FIFRA § 16(c) gives EPA the authority to initiate actions in U.S. District Court seeking permanent injunction, preliminary injunction, or temporary restraining order. Because an injunction is an extraordinary form of relief, the Agency's arguments supporting injunction must be clear and compelling. As a party seeking permanent injunction, EPA would need to demonstrate one of the following: (1) other remedies would be inadequate or not available administratively either in restraining the violation or in preventing unreasonable risk to human health or the environment; (2) the Agency has already diligently exercised all appropriate administrative remedies (such as SSUROs and civil penalties) yet the violation or threat of violation continues unabated; or (3) irreparable injury, loss, or damage will result if the relief sought is not granted.

When seeking a preliminary injunction or temporary restraining order, the U.S. must demonstrate that: (1) immediate and irreparable injury, loss, or damage will result if the requested relief is not granted; and (2) EPA is likely to prevail at trial, based on the facts before the court.

Under FIFRA, a number of specific circumstances may justify injunctive relief. These include:

- Violation of a Section 6 suspension or cancellation order;
- Violation of a SSURO where a civil penalty or criminal prosecution would not provide a timely or effective remedy to deter further violations;
- Continued production, shipment, sale, distribution, or use of an unregistered pesticide after the Agency has taken civil or criminal action;
- A person continues to sell, distribute, or make available for use a restricted use pesticide (RUP) other than in accordance with FIFRA § 3(d), after the Agency has taken an enforcement response;
- A person continues to violate the FIFRA § 17 import or export requirements after the Agency has taken an enforcement response;
- A person continues to use a pesticide in a manner inconsistent with its labeling, in a manner contrary to an experimental use permit, or repeats any violation of FIFRA, after EPA has taken an enforcement response.

## **F. Civil Administrative Penalties**

A civil penalty is the preferred enforcement response for most violations. A civil penalty is appropriate where the violation:

(1) presents an actual or potential risk of harm to humans or the environment,<sup>4</sup> or would impede EPA's ability to fulfill the goals of the statute; and

(2) was apparently committed as a result of ordinary negligence (as opposed to criminal negligence), inadvertence, or mistake; and the violation either:

(a) involves a violation by any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor, or any applicator within the scope of the exception set forth in FIFRA § 14(a)(2) (no prior warning is required by FIFRA for violators in this category); or

(b) involves a private applicator or other person not listed above who has received a prior Notice of Warning or citation for a FIFRA violation (as described in section III.A).

FIFRA § 14(a)(1) provides that a registrant, commercial applicator, wholesaler, dealer, or other distributor may be assessed a civil penalty of up to \$5,000 for each violation. FIFRA § 14(a)(2) authorizes the Administrator to assess a private applicator or other person a penalty of up to \$1,000 for each violation occurring after the issuance of a Notice of Warning or a citation for a prior FIFRA violation. Additionally, any applicator within the scope of the exception set forth in FIFRA § 14(a)(2) may be assessed a civil penalty of up to \$500 for the first offense, and up to \$1,000 for each subsequent offense.

Each of these penalty amounts has been increased pursuant to the Debt Collection Improvement Act of 1996, which requires federal agencies to periodically adjust the statutory maximum penalties to account for inflation. EPA has thus increased the maximum penalty amounts for FIFRA violations. For violations of FIFRA § 14(a)(1) that occur on or after January 12, 2009, the maximum civil penalty has increased to \$7,500 for each violation. Violations prior to that date may be assessed up to \$6,500 for each violation. For violations of FIFRA § 14(a)(2) that occur on or after January 12, 2009, the maximum civil penalty has increased to \$1,100 for each violation following the first offense by both private applicators and any applicator within the scope of the exception set forth in FIFRA § 14(a)(2). Additional penalty inflation increases are expected to occur periodically and such increases are incorporated by reference into this ERP.

As the statutory definitions of "distribute or sell" and "commercial applicator" indicate, and as the conference report for the Federal Pesticide Act of 1978<sup>5</sup> confirms, any applicator, including a "for hire" applicator, who holds or applies an unregistered pesticide to provide a service of controlling pests without delivering any unapplied pesticide, will be considered a distributor of pesticides and will be subject to the higher penalties set forth in FIFRA § 14(a)(1) and 14(b)(1). Any applicator, other than a private applicator, who uses or supervises the use of a restricted use pesticide (RUP), whether or not that applicator is certified, is a commercial applicator and is subject to the higher penalties set forth in section 14(a)(1) and 14(b)(1). Any applicator, including a certified applicator, who holds or applies a general use pesticide (GUP) or an unclassified pesticide in violation of FIFRA will be subject to the lower penalties set forth in section 14(a)(2) and 14(b)(2).

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<sup>4</sup> In such cases, the Agency should consider issuing a SSURO or other injunctive relief in addition to a civil penalty.

<sup>5</sup> Senate Report No. 95-1188, September 12, 1978, pp. 44 and 45.

**G. Denials, Suspensions, Modifications, or Revocations of Applicator Certifications**

Regulations governing certification of pesticide applicators (40 C.F.R. Part 171) authorize EPA to deny, suspend, or revoke a federally issued applicator certification if the holder of the certification violates FIFRA or its regulations. The Agency views enforcement actions affecting certification status as a very strong measure, to be taken only when the “public health, interest, or welfare warrants immediate action,” 40 C.F.R. § 171.11(f)(5)(i). Therefore, EPA will deny, suspend, modify, or revoke a federal certification only in response to serious violations or against persons with a history of noncompliance.

**1. Suspension**

In response to violations by applicators that have previously received a civil complaint for FIFRA violations and where none of the factors for revocation (discussed in paragraph G.2. below) are present, EPA will seek suspension of the individual applicator’s federal certification, as well as assess a civil penalty against the employer. EPA may also suspend certifications of commercial applicators who violate restricted use pesticides recordkeeping requirements, 40 C.F.R. § 171.11(c)(7); 40 C.F.R. § 171.11(f)(1)(iii). For purposes of this section of the policy, EPA will not distinguish between commercial and private applicators. A suspension has a more substantial impact on commercial applicators because it affects their primary business activity. Recommended suspension periods are set forth on the chart below.

**Recommended Suspension Periods**

	<b>First enforcement action</b>	<b>Second enforcement action<sup>6</sup></b>	<b>Third enforcement action</b>
<b>Enforcement remedy</b>	Penalty action	Penalty action	Penalty action
<b>Base suspension period</b>	N/A	4 months	6 months
<b>Additional suspension time for multiple violations</b>	N/A	2 months for each additional violation (up to a limit of 8 months total)	2 months for each additional violation (up to a limit of 12 months total)

If EPA decides to suspend certification, it must notify the applicator of the grounds upon which the suspension is based and the time period during which the suspension will be in effect. In order for the suspension to function as a deterrent, the suspension should take effect during the time when the applicator is most likely to be applying restricted use pesticides. In cases where the violation involved keeping fraudulent records (*i.e.*, where the violator intentionally concealed or misrepresented the true circumstances and the extent of the use of restricted use pesticides), EPA may revoke the violator’s certification in response to the initial infraction.

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<sup>6</sup> For purposes of this section, the second and third enforcement actions must occur within five years of the original civil administrative complaint.

## **2. Denial/Revocation**

The denial or revocation of a certification deprives an applicator of the authority to apply restricted use pesticides and forces the applicator to acquire or re-acquire certification. EPA will not consider an application to acquire or re-acquire certification for at least six months following a denial or revocation. Therefore, EPA will deny or revoke a certification only where:

- (1) a violation resulted in a human fatality or created an imminent danger of a fatality;
  - (2) a violation resulted in severe damage to the environment or created an imminent danger of severe damage to the environment;
  - (3) a misuse violation has resulted in significant contamination of food and water;
  - (4) the violator's certification has been suspended as a result of a previous serious violation;
  - (5) the violator's certification has been suspended three times within the past five years;
- or
- (6) a person has maintained or submitted fraudulent records or reports.

If EPA pursues an action to deny, revoke, or modify an applicator's certification, EPA will notify the applicant or federal certificate holder of:

- (1) the ground(s) upon which the denial, revocation, or modification is based;
  - (2) the time period during which the denial, revocation, or modification is effective, whether permanent or otherwise;
  - (3) the conditions, if any, under which the individual may become certified or recertified;
- and
- (4) any additional conditions EPA may impose.

EPA must also provide the federally certified applicator an opportunity to request a hearing prior to final Agency action to deny, revoke, or modify the certificate.

## **H. Recalls**

### **1. Suspended or Cancelled Products**

FIFRA § 19(b) gives EPA the authority to recall pesticide products if the registration of a pesticide has been suspended and cancelled and EPA finds that a recall is necessary to protect public health or the environment. Where the product registration has been suspended or cancelled, EPA will request either a voluntary or mandatory recall. When EPA believes that a recall is necessary to protect public health or the environment and the product registration has not been suspended or cancelled, EPA may request an informal recall, which is also voluntary.

EPA should only request a recall where the evidence clearly supports the need for such action. EPA will base the decision that a product should be withdrawn from the market on information in the sample file, including laboratory analyses, staff evaluations and opinions, and other available information. All information supporting a recall decision should be included in the official file.

#### **a. Mandatory Recalls**

If a product is suspended and cancelled, a voluntary recall by the registrant and others in the chain of distribution may be sufficient. However, if the Agency believes that a voluntary recall will not ensure protection of human health or the environment, mandatory recall procedures under FIFRA §§ 19(b)(3) and (4) can be used to require registrants, distributors, or

sellers of a cancelled pesticide to:

- (1) recall the pesticide;
- (2) make available storage facilities to accept and store existing stocks of the suspended and cancelled pesticide;
- (3) inform the EPA of the location of the storage facility;
- (4) inform the EPA of the progress of the recall;
- (5) provide transportation of the pesticide on request; and
- (6) take reasonable steps to inform holders of the recall and transportation provisions.

Persons conducting the recall must comply with transportation, storage, and disposal requirements set forth in the recall plan developed and approved under FIFRA § 19(b).

#### **b. Voluntary Recalls**

Recalls other than those described in section 1.a., above, are voluntary. A voluntary recall is appropriate if EPA finds that it can be "as safe and effective as a mandatory recall." Voluntary recalls can be used where the cancelled product is either potentially hazardous when used as directed, ineffective for the purposes claimed, or significantly violative in nature. For a voluntary recall, EPA will ask the registrant to develop a recall plan. The effectiveness of these recalls depends on the cooperation of the company involved. The company may seek EPA's assistance in developing or implementing a recall plan, but it is not required to do so.

#### **2. Other Recalls**

A product does not have to be suspended or cancelled for EPA to request a recall. The Agency should consider asking the company to do an informal recall of a product when its use as directed by the label is likely to result in:

- (1) injury to the user or handler of the product;
- (2) injury to domestic animals, fish, wildlife, or plant life;
- (3) physical or economic injury because of ineffectiveness or due to the presence of actionable residues; or
- (4) identifiable adverse effects on the environment.

For example, EPA may issue an informal recall for an antimicrobial product that fails efficacy testing for a public health organism when the product is distributed to hospitals or other health care facilities.

In cases posing more serious threats, the Agency may monitor the progress of an informal recall and may ask the company to submit progress reports and to notify state officials to ensure that the recall occurs. These informal recalls are generally accompanied by a civil penalty action or a SSURO. In cases where a recall is necessary but the level of potential hazard is not great or when it is unlikely that significant amounts of the defective product remain in the marketplace, the recall may be conducted entirely by the company with no monitoring by EPA or state officials.

### **I. Criminal Proceedings**

FIFRA § 12 specifically lists the unlawful acts that are subject not only to civil and administrative enforcement but also to criminal enforcement. (For further information on criminal enforcement investigations see Chapter 18 of the Pesticides Inspection Manual, "FIFRA

Criminal Enforcement.”) Section 14(b) provides the authority to proceed with criminal sanctions against violators, as follows.

- A registrant, applicant for a registration, or producer who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$50,000 or imprisonment for up to one year, or both.
- A commercial applicator of a restricted use pesticide, or any other person not described above who distributes or sells pesticides or devices, who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$25,000 or imprisonment for up to one year, or both.
- A private applicator or other person not included above who knowingly violates the Act is subject, upon conviction, to a fine of not more than \$1,000, or imprisonment for not more than 30 days, or both.

FIFRA § 14(b)(1) and (2) include the requirement that the violation be committed “knowingly.” An act is committed “knowingly” by a person who has the general intent to do the action(s) constituting the violation. A specific intent to violate FIFRA or knowledge of its regulations is not a necessary element of the crime. Thus, the government must generally prove that the defendant knew of the conduct that constituted the violation and that the person’s action(s) was voluntary and intentional and not the result of an accident or mistake of fact.

In addition, pursuant to the Alternative Fines Act (18 U.S.C. § 3571), the FIFRA criminal fine amounts for an individual or an organization<sup>7</sup> may be substantially increased if the violation results in death. All acts of the regulated community exhibiting actual or suspected criminal conduct should be discussed with EPA’s regional or Headquarters Criminal Enforcement Counsel or brought to the attention of the Criminal Investigation Division (CID) for possible investigation.

### **1. Parallel Criminal and Civil Proceedings**

Although the majority of EPA’s enforcement actions are brought as either a civil action or a criminal action, there are instances when it is appropriate to bring both a civil and a criminal enforcement response. These include situations where the violations merit the deterrent and retributive effects of criminal enforcement, yet a civil action is also necessary to obtain an appropriate remedial result, and where the magnitude or range of the environmental violations and the available sanctions make both criminal and civil enforcement appropriate.

Active consultation and cooperation between EPA’s civil and criminal programs, in conformance with all legal requirements including OECA’s Parallel Proceedings Policy (September 24, 2007), is critical to the success of EPA’s overall enforcement program. The success of any parallel proceedings depends upon coordinated decisions by the civil and criminal programs as to the timing and scope of their activities. For example, it will often be important for the criminal program to notify civil enforcement managers that an investigation is about to become overt or known to the subject. Similarly, the civil program should notify the criminal

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<sup>7</sup> As used in Title 18 of the United States Code, the term “organization” means a person other than an individual.

program when there are significant developments that might change the scope of the relief. In every parallel proceeding, communication and coordination should be initiated at both the staff and manager levels and should continue until resolution of all parallel matters.

#### **J. State and Federal Roles in Enforcement of FIFRA**

State governments have primary enforcement authority for both civil and criminal pesticide use violations under FIFRA §§ 26 and 27. States are allowed 30 days to commence appropriate enforcement actions for such violations. While Congress delegated to the states primary enforcement authority for pesticide use violations, FIFRA does not create exclusive enforcement jurisdiction in the states. A state may waive its primary enforcement responsibility or make a referral to the United States for federal action.

EPA has primary enforcement authority over violations concerning the sale or distribution of pesticides. Examples of such violations include failure to report a pesticide's unreasonable adverse effects on the environment, distribution of an unregistered pesticide, violations of a cancellation order or an EPA SSURO, and fraudulent labeling, advertising, or registration of a pesticide. FIFRA violations that are not use violations may be investigated and prosecuted on the federal level without waiting for state authorities to exercise their enforcement responsibility. Under most circumstances EPA will inform the state of an EPA investigation being conducted within its borders.

#### **K. Press Releases and Advisories**

EPA may, at its discretion, issue a press release or advisory to notify the public of the filing of an enforcement action, settlement, or adjudication concerning a person's violation of FIFRA. A press release can be a useful tool to notify the public of Agency actions for FIFRA noncompliance and to educate the public on the requirements of FIFRA. Some regions routinely issue press releases to inform the public of FIFRA settlements. Issuance of a press release or advisory must not be an item of negotiation during settlement.

### **IV. ASSESSING CIVIL ADMINISTRATIVE PENALTIES**

#### **A. Computation of the Penalty**

In determining the amount of a civil penalty, FIFRA § 14(a)(4) requires EPA to consider the appropriateness of the penalty to the size of respondent's business, the effect of the penalty on respondent's ability to continue in business, and the gravity of the violation.

For each type of violation associated with a particular product, the penalty amount is determined in a seven-step process considering the Section 14(a)(4) criteria listed above. These steps are:

(1) determine the number of independently assessable violations [Section IV.A.1. Independently Assessable Violations];

(2) determine the size of business category for the violator, using Table 1 [Section IV.A.2. Size of Business];



- (3) determine the gravity of the violation for each independently assessable violation using Appendix A [Section IV.A.3. Gravity of Violation];
- (4) determine the “base” penalty amount associated with the size of business (Step 2) and the gravity of violation (Step 3) for each independently assessable violation, using the matrices in Table 2 [Section IV.A.4. Base Penalty Amount];
- (5) determine the “adjusted” penalty amount based on case-specific factors using the Gravity Adjustment Criteria in Appendix B and Table 3 [Section IV.A.5. Adjustment for Case-Specific Factors];
- (6) calculate the economic benefit of noncompliance [Sections IV.A.6. Economic Benefit of Noncompliance]; and
- (7) consider the effect that payment of the total penalty amount plus economic benefit of noncompliance derived from the above calculation will have on the violator’s ability to continue in business [Section IV.A.7 Ability to Continue in Business/Ability to Pay].

A civil penalty may be further modified in accordance with Section IV.B.1. Graduated Penalty Calculations, Section IV.B.2. Voluntary Disclosure, and Section IV.B.3. Adjusting the Proposed Civil Penalty in Settlement.

#### **1. Independently Assessable Violations**

A separate civil penalty, up to the statutory maximum, will be assessed for each independent violation of the Act. A violation is considered independent if it results from an act (or failure to act) which is not the result of any other violation for which a civil penalty is to be assessed or if at least one of the elements of proof is different from any other violation.

Consistent with the above criteria, the Agency considers violations that occur from each sale or shipment of a product (by product registration number, not individual containers) or each sale of a product to be independent violations.<sup>8</sup> There may also be situations where two unlawful acts arise out of one sale or shipment, such as the sale of a product that is both a misbranded pesticide and an unregistered pesticide. Similarly, under the pesticide use regulations, one application of a pesticide may lead to multiple misuse violations. For example, if an applicator mixes pesticides over the rate prescribed by the label and during the same application allows pesticide to drift onto non-target areas, each of those acts would be a separately assessable violation of FIFRA § 12(a)(2)(G).

Each of these independent violations of FIFRA is subject to civil penalties up to the statutory maximum. For example, when EPA can document that a registrant has distributed a misbranded product (one single EPA product registration number) in four separate shipments, EPA will allege four counts of selling or distributing a misbranded product. Similarly, when EPA can document that a registrant has shipped four separate misbranded products (four separate EPA product registration numbers) in a single shipment, EPA will plead four counts of selling or

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<sup>8</sup> Independent violations which can be documented as both per sale and per shipment are to be calculated only as either per sale or per shipment, whichever is more appropriate based on the supporting documentation.

distributing a misbranded product. In use cases that EPA handles, the Agency will allege three misuse violations when a commercial applicator who misuses a restricted use product on three occasions (either three distinct applications or three separate sites). If a dealer sells a restricted use pesticide (RUP) to six uncertified persons, other than in accordance with FIFRA § 3(d), EPA will plead six violations of FIFRA.

On the other hand, the Agency will assess a penalty for one violation arising from a single event or action (or lack of action) that is an unlawful act under FIFRA for multiple reasons unless the event or action results in two unlawful acts for which at least one element of proof differs. For instance, a person can be assessed a civil penalty of up to the statutory maximum for the sale and/or distribution of an unregistered, cancelled or suspended pesticide under FIFRA § 12(a)(1)(A). If the unregistered pesticide is actually a product whose registration had been cancelled, EPA cannot allege two separate violations of FIFRA § 12(a)(1)(A) since the sale or distribution related to a single event or transaction. However, the Agency could separately allege a violation of a cancellation order under FIFRA § 12(a)(2)(K). In this example, the violation of the cancellation order is independent of the sale and distribution of the unregistered product.

Another example of a dependent violation is multiple misbrandings on a single product label. EPA may assess a count of misbranding each time that a misbranded product is sold or distributed. For example, a registrant who sells or distributes four distinct shipments of a misbranded pesticide product generally may be assessed four counts of misbranding. If a single product label is misbranded in one way or ten ways, as defined by FIFRA § 2(q), it is still misbranding on a single product label and is considered a single violation of FIFRA § 12(a)(1)(E). Note, however, for pesticide use regulations, where the applicator fails to follow two label requirements, for example, does not follow the prescribed application rate and does not provide the prescribed personal protective equipment, there are two separate violations.

When a product label is grossly misbranded such that two or more misbrandings assigned Level 2 in Appendix A are present, the gravity level is adjusted upward to a Level 1 to address the seriousness of the misbranding.

## **2. Size of Business**

In order to provide equitable penalties, civil penalties that will be assessed for violations of FIFRA will generally decrease as the size of the business decreases. Size of business is determined based on an individual's or a company's gross revenues from all revenue sources during the prior calendar year. If revenue data for the previous year appears to be unrepresentative of the general performance of the business or the income of the individual, an average of the gross revenues for the three previous years may be used. Further, the size of business and gross revenue figures are based on the corporate family rather than a specific subsidiary or division of the company which is involved with the violation (including all sites owned or controlled by the foreign or domestic parent company) unless the subsidiary or division is independently owned.

As shown in the FIFRA Civil Penalty Matrices in Table 2, the appropriateness of the penalty to the size of the respondent's business is based on three distinct size of business categories. Further, because gross revenues of persons listed in FIFRA § 14(a)(1) [registrants, commercial applicators, wholesalers, dealers, retailers, or other distributors] will generally be higher than gross incomes of persons listed in FIFRA § 14(a)(2) [private applicators and other

persons not listed in 14(a)(1)], the policy has separate size of business categories for Section 14(a)(1) persons and Section 14(a)(2) persons. The size of business categories for FIFRA § 14(a)(1) and Section 14(a)(2) violators are listed in Table 1. Revenue includes all revenue from an entity and all of the entity's affiliates. When no information of any kind is available concerning a respondent's size of business, the penalty should be calculated using the Category I size of business.

**TABLE 1**

**For section 14(a)(1) violators, the size of business categories are:**

- I - over \$10,000,000 a year
- II - \$1,000,000 - \$10,000,000 a year
- III - under \$1,000,000 a year

**For section 14(a)(2) violators, the size of business categories are:**

- I - over \$1,000,000 a year
- II - \$300,000 - \$1,000,000 a year
- III - under \$300,000 a year.

**3. Gravity of the Violation**

The "gravity level" established for each violation of FIFRA is listed in Appendix A of this ERP. The level assigned to each violation of FIFRA represents an assessment of the relative severity of each violation. The relative severity of each violation considers the actual or potential harm to human health and the environment which could result from the violation and the importance of the requirement to achieving the goals of the statute. The gravity level, which is determined from the chart in Appendix A, is then used to determine a base penalty figure from the FIFRA Civil Penalty Matrices in Step 4 below. In Step 5, the dollar amount derived from the matrix can be adjusted upward or downward depending on the actual circumstances of each violation.

**4. Base Penalty Amount**

The size of business categories and gravity levels are broken out in the FIFRA Civil Penalty Matrices shown in Table 2. Each cell of the matrix represents the Agency's assessment of the appropriate civil penalty, within the statutory maximum, for each gravity level of a violation and for each size of business category. Because FIFRA imposes different statutory ceilings on the maximum civil penalty that may be assessed against persons listed in FIFRA Section 14(a)(1) and persons listed in Section 14(a)(2), this policy has separate penalty matrices for Section 14(a)(1) violators and Section 14(a)(2) violators.

With the exception of any applicator within the scope of the exception set forth in FIFRA § 14(a)(2), EPA will only use the Section 14(a)(2) penalty matrix for persons falling under FIFRA § 14(a)(2) who have previously been issued a Notice of Warning or prior citation.<sup>9</sup>

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<sup>9</sup> FIFRA § 14(a)(2) states that private applicators are only subject to civil penalties after receiving a notice of warning or following a citation for a prior violation. A notice of warning or citation for a prior

When a civil penalty is the appropriate response for a first-time violation by any applicator within the scope of the exception set forth in FIFRA § 14(a)(2), EPA will seek the statutory maximum civil penalty. Subsequent violations will be assessed using the FIFRA § 14(a)(2) civil penalty matrix below.

**TABLE 2**

**Civil Penalty Matrix for FIFRA § 14(a)(1)**

LEVEL OF VIOLATION	SIZE OF BUSINESS		
	I – over \$10,000,000	II -- \$1,000,000 - \$10,000,000	III – under \$1,000,000
Level 1	\$7,500	7,150	7,150
Level 2	7,150	5,670	4,250
Level 3	5,670	4,250	2,830
Level 4	4,250	2,830	1,420

**Civil Penalty Matrix for FIFRA § 14(a)(2) <sup>10</sup>**

LEVEL OF VIOLATION	SIZE OF BUSINESS		
	I – over \$1,000,000	II -- \$300,000 - \$1,000,000	III – under \$300,000
Level 1	\$1,100	1,100	1,100
Level 2	1,100	1,030	770
Levels 3 & 4	1,030	770	650

**5. Adjustments for Case-Specific Factors**

The Agency has assigned adjustments, based on the gravity adjustment criteria listed in Appendix B, for each violation relative to the specific characteristics of the pesticide involved, the harm to human health and/or harm to the environment, compliance history of the violator,

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violation may include an action by either EPA or a delegated state if the prior violation would be a violation of federal law.

<sup>10</sup> This 14(a)(2) matrix is only for use in determining civil penalties issued subsequent to a notice of warning or following a citation for a prior violation, or in the case of a “for hire” applicator using a registered general use pesticide, subsequent to the issuance of a prior civil penalty.

and the culpability of the violator. Then the gravity adjustment values from each gravity category listed in Appendix B are to be totaled. The dollar amount found in the matrix will be raised or lowered, not to exceed the statutory maximum, based on the total gravity values in Table 3. Once this base penalty amount is calculated, it should be rounded to the nearest \$100, in accordance with Amendments to Penalty Policies to Implement Penalty Inflation Rule 2008 - (Nakayama, 2008).<sup>11</sup>

**TABLE 3**

<b>Total Gravity Value from Appendix B</b>	<b>Enforcement Remedy</b>
3 or below	No action or Notice of Warning (60% reduction of matrix value recommended where multiple count violations exist)
4	Reduce matrix value 50%
5	Reduce matrix value 40%
6	Reduce matrix value 30%
7	Reduce matrix value 20%
8	Reduce matrix value 10%
9 to 11	Assess matrix value
12	Increase matrix value 10% **
13	Increase matrix value 20% **
14	Increase matrix value 30% **
15	Increase matrix value 40% **
16	Increase matrix value 50% **
17 or above	Increase matrix value 60% **
** Matrix value can only be increased to the statutory maximum.	

## 6. Economic Benefit of Noncompliance

The Agency's Policy on Civil Penalties (EPA General Enforcement Policy #GM-21), dated February 16, 1984, mandates the recapture of any significant economic benefit of noncompliance (EBN) that accrues to a violator from noncompliance with the law. Economic benefit can result from a violator delaying or avoiding compliance costs or when the violator realizes illegal profits through its noncompliance. A fundamental premise of the 1984 Policy is that economic incentives for noncompliance are to be eliminated. If, after the penalty is paid, violators still profit by violating the law, there is little incentive to comply. Therefore, enforcement professionals should always evaluate the economic benefit of noncompliance in calculating penalties. Note that economic benefit can only be added to the proposed penalty up to the statutory maximum penalty.

An economic benefit component should be calculated and added to the gravity-based penalty component when a violation results in "significant" economic benefit to the violator. "Significant" is defined as an economic benefit that totals more than \$10,000 for all violations alleged in the complaint. In the interest of simplifying and expediting an enforcement action, enforcement professionals may use the "rules of thumb" (discussed in section 6.b below) to

<sup>11</sup> <http://www.epa.gov/compliance/resources/policies/civil/penalty/amendmentstopenaltypolicies-implementationpenaltyinflationrule08.pdf>

determine if the economic benefit will be significant. Distribution and sale of unregistered and misbranded pesticides are examples of violations that are likely to result in significant economic benefits. For certain FIFRA requirements, the economic benefit of noncompliance may be relatively insignificant (e.g., failure to submit a report on time).

EPA generally will not settle cases for an amount less than the economic benefit of noncompliance. However, the Agency's 1984 Policy on Civil Penalties explicitly sets out three general areas where settling for less than the economic benefit may be appropriate. Since the issuance of the 1984 Policy, the Agency has added a fourth exception for cases where ability to pay is a factor. The four exceptions are:

- The economic benefit component is an insignificant amount (defined for purposes of this policy as less than \$10,000);
- There are compelling public concerns that would not be served by taking a case to trial;
- It is unlikely, based on the facts of the particular case as a whole, that EPA will be able to recover the economic benefit in litigation; and
- The company has documented an inability to pay the total proposed penalty.

**a. Economic Benefit from Delayed Costs and Avoided Costs**

Delayed costs are expenditures that have been deferred by the violator's failure to comply with the requirements. The violator eventually will spend the money to achieve compliance. Delayed costs are either capital costs (i.e. equipment), if any, or one-time non-depreciable costs (e.g., registration fees for pesticides that are eventually registered).

Avoided costs are expenditures that will never be incurred, as in the case of an unlawfully distributed unregistered pesticide that is subsequently removed from commerce and never registered by the Agency. In this example, avoided costs include all the costs associated with product registration because the product was never registered. Those costs were never and will never be incurred. Those avoided costs might include the registration fees, annual maintenance fees, and costs associated with the testing that would have been required to support a pesticide registration or to support specific claims about the product.

**b. Calculation of Economic Benefit from Delayed and Avoided Costs**

Since 1984, it has been Agency policy to use either the BEN computer model or "rules of thumb" to calculate the economic benefit of noncompliance. The "rules of thumb" are straightforward methods to calculate economic savings from delayed and avoided compliance expenditures. They are discussed more fully in the Agency's General Enforcement Policy #GM-22, entitled "A Framework for Statute-Specific Approaches to Penalty Assessments," issued on February 16, 1984, at pages 7-9. The "rule of thumb" methodology is available in a Lotus spreadsheet available to EPA enforcement professionals from the Special Litigation and Projects Division of the Office of Civil Enforcement. Enforcement professionals may use the "rules of thumb" whenever the economic benefit penalty is not substantial (generally under \$10,000) and use of an expert financial witness may not be warranted. If the "rules of thumb" yield an amount

over \$10,000, the case developer should use the BEN model and/or an expert financial witness to calculate the higher economic benefit penalty. Using the “rules of thumb,” the economic benefit of delayed compliance may be estimated at: 5% per year of the delayed one-time capital costs, if any, and/or one-time non-depreciable costs for the period from the date the violation began until compliance was or is expected to be achieved. For avoided annual costs, the “rule of thumb” is the annual expenses avoided until the date compliance is achieved less any tax savings. These rules of thumb do not apply to avoided one-time or avoided capital costs. Enforcement professionals should calculate the economic benefit of avoided one-time and avoided capital costs, if any, by using the BEN model.

The primary purpose of the BEN model is to calculate economic savings for settlement purposes. The model can perform a calculation of economic benefit from delayed or avoided costs based on data inputs, including optional data items and standard values already contained in the program. Enforcement professionals wishing to use the BEN model should take the Basic BEN training course offered by the Special Litigation and Projects Division in cooperation with NETI. Enforcement professionals who have questions while running the model can access the model’s help system which contains information on how to: use BEN, understand the data needed, and understand the model’s outputs.

The economic benefit component should be calculated for the entire period for which there is evidence of noncompliance, i.e., all time periods for which there is evidence to support the conclusions that the respondent was violating FIFRA and thereby gained an economic benefit. Such evidence should be considered in the assessment of the penalty assessed for the violations alleged or proven, up to the statutory maximum for those violations. In certain cases, credible evidence may demonstrate that a respondent received an economic benefit for noncompliance for a period longer than the period of the violations for which a penalty is sought. In such cases, it may be appropriate to consider all of the economic benefit evidence in determining the appropriate penalty for the violations for which the respondent is liable. For example, in a case where credible evidence demonstrates that a respondent sold an unregistered pesticide during the past four years but the specific violations for which EPA has chosen to seek a penalty all occurred within the past two years, the economic benefit should be calculated for the four-year period. In such a case, the economic benefit component of the penalty for the specific sales transactions during the past two years should be based on a consideration of the economic benefit gained for the four-year period, but the total penalty is limited to the statutory maximum for the specific violations alleged and proven.<sup>12</sup>

In most cases, the violator will have the funds gained through non-compliance available for its continued use and/or competitive advantage until it pays the penalty. Therefore, for cases in which economic benefit is calculated by using BEN or by a financial expert, the economic benefit should be calculated through the anticipated date a consent agreement would be entered. If the matter goes to hearing, this calculation should be based on a penalty payment date corresponding with the relevant hearing date. It should be noted that the respondent will continue to accrue additional economic benefits after the hearing date, until the assessed penalty is paid. However, there are exceptions for determining the period of economic benefit when

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<sup>12</sup>When considering the economic benefit of noncompliance that accrued to the respondent more than five years prior to the filing of a complaint or a pre-filing Consent Agreement, the litigation team should consult with the Waste and Chemical Enforcement Division.

using a “rule of thumb.” In those instances, the economic benefit is calculated in the manner described in the first paragraph of this subsection.

**c. Economic Benefit Gained from Illegal Sales of Unregistered Pesticides**

In addition to delayed and avoided costs, an economic benefit may accrue to a violator of FIFRA from the sale of unregistered or misbranded pesticides. The economic benefit derived from sales of unregistered or misbranded pesticides is sometimes referred to as “illegal profits” or “illegal competitive advantage.” Illegal profits economic benefit is fundamentally different from the economic benefit calculated by using the BEN model. Unlike the delayed/avoided benefits addressed through BEN, this type of economic benefit is based on the profits generated by violating the law. Care should be taken to insure that any calculation of a benefit derived from illegal profits does not include profits attributable to lawful operations of the facility or delayed or avoided costs already accounted for in the BEN calculation. In most cases, a violator will realize either benefits from delayed/avoided costs or from illegal profits; however, whenever the facts and circumstances of the case provide a sufficient basis to calculate illegal profits and the Region is able to obtain sufficient information, the Region should calculate the benefits due to illegal profits and add it to any other type of economic benefit that has been calculated.

**7. Ability to Continue in Business/Ability to Pay**

FIFRA § 14(a)(4) requires the Agency to consider the effect of the penalty on the respondent’s ability to continue in business when determining the amount of the civil penalty. There are several sources available to assist enforcement professionals in determining a respondent’s ability to pay. Enforcement professionals considering a respondent’s ability to continue in business should consult “A Framework for Statute-Specific Approaches to Penalty Assessments,” (cited above) and EPA General Enforcement Policy PT.2-1 (previously codified as GM-#56), entitled “Guidance on Determining a Violator’s Ability to Pay a Civil Penalty” (December 16, 1986). In addition, the Agency has three computer models available to help assess whether violators can afford compliance costs and/or civil penalties: ABEL, INDIPAY and MUNIPAY. INDIPAY analyzes individual taxpayers’ claims about inability to pay. MUNIPAY analyzes cities, towns, and villages’ ability to pay. These models are designed for settlement purposes only.

ABEL is an EPA computer model that is designed to assess inability to pay claims from corporations and partnerships. The evaluation is based on the firm’s excess cash flow. ABEL looks at the money coming into the entity, and the money going out. It then looks at whether the excess cash flow is sufficient to cover the firm’s environmental responsibilities (i.e., compliance costs) and the proposed civil penalty. Because the program only focuses on a violator’s cash flow, there are other sources of revenue that should also be considered to determine if a firm is unable to pay the full penalty. These include:

- Certificates of deposit, money market funds, or other liquid assets;
- Reduction in business expenses such as advertising, entertainment, or compensation of corporate officers;
- Sale or mortgage of non-liquid assets such as company cars, aircraft, or land;



- Related entities (e.g., the violator is a wholly owned subsidiary of Fortune 500 company).

The complaint will notify the respondent of its right under the statute to have EPA consider its ability to continue in business in determining the amount of the penalty. Any respondent may raise the issue of ability to pay/ability to continue in business in its answer to the complaint or during the course of settlement negotiations. If a respondent raises the inability to pay as a defense in its answer or in the course of settlement negotiations, the Agency should ask the respondent to present appropriate documentation, such as tax returns and financial statements. The respondent must provide records that conform to generally accepted accounting principles and procedures at its expense. If the proposed penalty exceeds the respondent's ability to pay, the penalty may be reduced to a level consistent with FIFRA § 14(a)(4). If a respondent does not provide sufficient information to substantiate its claim of inability to pay the calculated penalty, then EPA may draw an inference from available information that the respondent has the ability to pay the calculated penalty.<sup>13</sup>

A respondent may argue that it cannot afford to pay the proposed penalty even though the penalty as adjusted does not exceed EPA's assessment of its ability to pay. In such cases, EPA may consider a delayed payment schedule calculated in accordance with Agency installment payment guidance and regulations.<sup>14</sup> In exceptional circumstances, EPA may also consider further adjustment below the calculated ability to pay.

Finally, EPA will generally not collect a civil penalty that exceeds a violator's ability to pay as evidenced by a detailed tax, accounting, and financial analysis. However, it is important that the regulated community not choose noncompliance as a way of aiding financially troubled businesses. Therefore, EPA reserves the option, in appropriate circumstances, of seeking a penalty that might exceed the respondent's ability to pay, cause bankruptcy, or result in a respondent's inability to continue in business. Such circumstances may exist where the violations are egregious or the violator refuses to pay the penalty. However, if the case is generated out of an EPA regional office, the case file must contain a written explanation, signed by the regional authority duly delegated to issue and settle administrative penalty orders under FIFRA, which explains the reasons for exceeding the "ability to pay" guidelines. To ensure full and consistent consideration of penalties that may cause bankruptcy or closure of a business, the regions should consult with the Waste and Chemical Enforcement Division (WCED).<sup>15</sup>

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<sup>13</sup> Note that under the Environmental Appeals Board ruling in *In re: New Waterbury, LTD*, 5 E.A.D. 529 (EAB 1994), in administrative enforcement actions for violations under statutes that specify ability to pay (which is analogous to ability to continue in business) as a factor to be considered in determining the penalty amount, EPA must prove it adequately considered the appropriateness of the penalty in light of all of the statutory factors. Accordingly, enforcement professionals should be prepared to demonstrate that they considered the respondent's ability to continue in business as well as the other statutory penalty factors and that their recommended penalty is supported by their analysis of those factors. EPA may obtain information regarding a respondent's ability to continue in business from the respondent, independent commercial financial reports, or other credible sources.

<sup>14</sup> See, 40 C.F.R. § 13.18.

<sup>15</sup> In accordance with the November 1, 1994 memorandum entitled, "Final List of Nationally Significant Issues and Process for Raising Issues to TPED." This final implementation guidance was developed in follow-up to Steve Herman's July 11, 1994 memorandum on "Redelegation of Authority and Guidance on Headquarters' Involvement in Regulatory Enforcement Cases."

## **B. Modifications of the Penalty**

### **1. Graduated Penalty Calculations**

In instances where inspectors or case developers obtain records which evidence multiple sales or distributions for the same violations, the Region may apply a “graduated” penalty calculation. The graduated method should only be applied after a consideration of the actual or potential serious or widespread harm caused by the violations, the toxicity of the pesticides involved, and the culpability of the violator. The graduated penalty method should not be used in cases involving highly culpable violators or violations that caused an actual serious or widespread harm to human health or the environment. In cases involving violations that present *potential* serious or widespread harm to human health or the environment, the Region should decide whether application of the graduated penalty method is appropriate based on the circumstances of the individual case.

In no case is the graduated penalty method mandated and the Agency maintains its statutory right to assess penalties of up to the statutory maximum for each violation, when appropriate. For highly culpable parties the penalty should be calculated at the full value for all violations. After considering the factors described above and determining that a graduated penalty method is appropriate, the Region may calculate the penalty in accordance with Table 4 below. Table 4 provides for three separate graduated systems based on the three “size of business” categories.

**TABLE 4**

#### **Graduated Penalty Tables**

<b>Number of Distributions</b>	<b>CATEGORY I “SIZE OF BUSINESS” RESPONDENTS</b>
1 – 100	100% of calculated per violation penalty
101 – 400	25% of per violation penalty
> 400	10% of per violation penalty

<b>Number of Distributions</b>	<b>CATEGORY II “SIZE OF BUSINESS” RESPONDENTS</b>
1 – 20	100% of calculated per violation penalty
21 – 40	25% of per violation penalty
> 40	10% of per violation penalty

<b>Number of Distributions</b>	<b>CATEGORY III “SIZE OF BUSINESS” RESPONDENTS</b>
1 – 5	100% of calculated per violation penalty
6 – 20	10 % of per violation penalty
> 20	5% of per violation penalty

Graduated penalties should generally be calculated separately for each type of violation and for each product (in other words, on a “per product violation” basis). In cases involving similar product violations (for example, violations involving products that contain the same

active ingredient and the same violative conduct on the part of the respondent), the Agency has the discretion to group together similar product violations for the graduated penalty calculation.

To calculate penalties using the graduated penalty method, the “adjusted” penalty amount must first be determined in accordance with Steps 1-5 of section IV.A Computation of the Penalty, above. The next step is to apply the graduated penalty calculation separately for each product violation, beginning with the first sale/distribution at 100% and proceeding to calculate the reduced penalty depending on the size of business. After the graduated penalty amount is calculated for each separate product violation, the Agency should add together the graduated penalty amounts for all of the product violations.

For example, a Category II business distributes two products with a total of three violations. For Product 1, the Agency is alleging misbranding (a Level 3 violation) and distribution of an unregistered pesticide (a Level 1 violation), each for 61 shipments. For Product 2, the Agency is alleging distribution of an unregistered pesticide (a Level 1 violation) for 90 shipments. After applying the case-specific factors, no adjustments to the base penalties were made. The graduated penalty calculation would proceed as follows:

**Product 1, Misbranding (Level 3):**

Violations 1-20 @ 100% =	20 violations @ \$ 4,250 =	\$ 85,000
Violations 21- 40 @ 25% =	20 violations @ \$ 1,063 =	\$ 21,260
Violations 41- 61 @ 10% =	21 violations @ \$ 425 =	\$ 8,925

**Product 1, Unregistered (Level 2):**

Violations 1-20 @ 100% =	20 violations @ \$ 5,670 =	\$113,400
Violations 21- 40 @ 25% =	20 violations @ \$ 1,418 =	\$ 28,360
Violations 41- 61 @ 10% =	21 violations @ \$ 567 =	\$ 11,907

**Product 2, Unregistered (Level 2):**

Violations 1-20 @ 100% =	20 violations @ \$ 5,670 =	\$113,400
Violations 21- 40 @ 25% =	20 violations @ \$ 1,418 =	\$ 28,360
Violations 41- 90 @ 10% =	50 violations @ \$ 567 =	\$ 28,350

When the graduated penalty method is applied to the example case, the penalty is \$438,962, which is significantly lower than the \$1,115,420 [(61 x 4,250) + (61 x 5,670) + (90 x 5,670)] penalty that would be calculated without applying the graduated penalty.

## **2. Voluntary Disclosure**

Facilities that conduct an environmental audit or implement a compliance management system and promptly self-disclose any violations may be eligible for a significant reduction in the gravity-based penalty if they meet the nine criteria established in EPA’s Audit Policy (Incentives for Self-Policing: Disclosure, Correction and Prevention of Violations: Final Policy Statement, April 11, 2000). A facility may also be eligible for penalty reductions if they meet the specific criteria outlined in the “Small Business Compliance Policy” (May 11, 2000). If a facility self-discloses violations that do not qualify under the Audit Policy or Small Business Compliance Policy, the Agency may consider a company’s willingness to disclose as good faith (see Section IV.B.3.b.i. Good Faith Adjustments).

### **3. Adjusting the Proposed Civil Penalty in Settlement**

Certain circumstances may justify adjustment of the proposed penalty. These circumstances may come to EPA's attention when a respondent files an answer to a civil complaint or during pre-filing settlement discussions under the *Consolidated Rules of Practice Governing Administrative Assessment of Civil Penalties*, 40 C.F.R. Part 22.

#### **a. Factual Changes**

EPA will recalculate the proposed penalty if the respondent can demonstrate that the size of business category, the gravity level, or the gravity adjustment criteria (Appendix B) used to derive the penalty is inaccurate. Adjustments to the proposed civil penalty may also be appropriate if the respondent can demonstrate an inability to pay the civil penalty (see Section IV.A.7. Ability to Continue in Business/Ability to Pay). Where additional facts indicate that the original penalty is not appropriate, EPA will calculate a new penalty consistent with the new facts. The burden is on the respondent to raise those factors which may justify the recalculation.

#### **b. Negotiations Involving Only the Amount of the Penalty**

In some cases the respondent may admit to all jurisdictional and factual allegations alleged in the complaint and may desire a settlement conference limited to the amount of the proposed penalty. The following sections describe adjustments that EPA may consider during settlement negotiations if the specific case meets the criteria set forth below.

##### **i. Good Faith Adjustments**

During the course of settlement negotiations, EPA may consider evidence of significant good faith efforts by the respondent to comply with FIFRA prior to the discovery of the violation(s) by EPA or a state as well as the respondent's good faith efforts to comply with FIFRA expeditiously after the discovery of the violation(s) by EPA or a state. In such instances, EPA may reduce the penalty by as much as 20 percent below the proposed penalty, if such a reduction would serve the public interest. A reduction for good faith efforts to comply is not mandated in any case. Such a reduction in penalty should only occur where there is an appropriate showing by respondent and finding by the Agency. Additionally, no reduction based on good faith efforts of the respondent should extend beyond a total of 20 percent of the proposed penalty without a showing of "special circumstances," as discussed below. No downward adjustment should be made if the Respondent fails to correct the violation(s) promptly after EPA or a state discovers the violation(s). Moreover, no downward adjustment should be made because respondent lacks knowledge concerning either applicable requirements or violations committed by respondent.

##### **ii. Special Circumstances/Extraordinary Adjustments**

Should EPA determine in a particular case that equity would not be served by adjusting the proposed penalty by only the allowable 20 percent adjustment for good faith, the FIFRA program manager may approve an adjustment to the proposed penalty for up to an additional 20 percent. In such cases, the case file must include substantive reasons why the extraordinary reduction of the civil penalty was appropriate, including: (1) setting forth the facts of the case; (2) why the penalty derived from the FIFRA civil penalty matrices and gravity adjustment was

inequitable; (3) how all other methods for adjusting or revising the proposed penalty would not adequately resolve the inequity; and (4) the manner in which the adjustment of the penalty effectuated the purposes of the Act. The FIFRA program manager's concurrence in the extraordinary reduction must be included in the case file.

### **iii. Supplemental Environmental Projects (SEPs)**

To further EPA's goals to protect and enhance public health and the environment, certain environmentally beneficial projects, or Supplemental Environmental Projects (SEPs), may be included in the settlement. SEPs are environmentally beneficial projects which a respondent agrees to undertake in settlement of an environmental enforcement action, but which the respondent is not otherwise legally required to perform. In return, some percentage of the cost of the SEP is considered as a factor in establishing the final penalty to be paid by the respondent. EPA has broad discretion to settle cases with appropriate penalties. Evidence of a violator's commitment and ability to perform a SEP is a relevant factor for EPA to consider in establishing an appropriate settlement penalty. While SEPs may not be appropriate in settlement of all cases, they are an important part of EPA's enforcement program. Whether to include a SEP as part of a settlement of an enforcement action is within the sole discretion of EPA. EPA will ensure that the inclusion of a SEP in settlement is consistent with "EPA Supplemental Environmental Projects Policy," effective May 1, 1998, or as revised.

## **APPENDICES**

Appendix A - FIFRA Violations and Gravity Levels

Appendix B - Gravity Adjustment Criteria

Appendix C - Summary of Tables

Appendix D - FIFRA Civil Penalty Calculation Worksheet

Appendix E – Enforcement Response Policy for FIFRA Section 7(c) – Pesticide Producing Establishment Reporting Requirements

Appendix F – FIFRA: Worker Protection Standard (WPS) Penalty Policy – Interim Final

Appendix G – Enforcement Response Policy for the FIFRA Good Laboratory Practices (GLP) Regulations