

**UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 4  
ATLANTA, GEORGIA**

In the Matter of:

Medentech Limited

Respondent.

Docket No. FIFRA-04-2020-0710(b)

**CONSENT AGREEMENT**

**I. NATURE OF ACTION**

1. This is an administrative penalty assessment proceeding brought under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. § 136l(a) (FIFRA or the Act), and Sections 22.13(b) and 22.18 of the Consolidated Rules of Practice Governing Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules), as codified at Title 40 of the Code of Federal Regulations (C.F.R.) Part 22.
2. This Consent Agreement and the attached Final Order shall collectively be referred to as the CAFO.
3. Having found that settlement is consistent with the provisions of FIFRA and applicable regulations, the Parties have agreed to settle this action pursuant to 40 C.F.R. § 22.18 and consent to the entry of this CAFO without adjudication of any issues of law or fact herein.

**II. PARTIES**

4. Complainant is the Director, Enforcement and Compliance Assurance Division, Region 4, who has been delegated the authority on behalf of the Administrator of the United States Environmental Protection Agency (EPA) to enter into this CAFO pursuant to 40 C.F.R. Part 22 and Section 14(a) of FIFRA, 7 U.S.C. § 136l(a).

5. Respondent is Medentech Limited, a company doing business in the Whitemill Industrial Estate, Clonard Road, Wexford, Y35Y7WY, Ireland, which imports products into the United States.

### III. GOVERNING LAW

6. Respondent is a "person" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and as such is subject to FIFRA and the regulations promulgated thereunder.
7. Pursuant to 40 C.F.R. § 167.20(a)(1), any establishment where a pesticide is produced must be registered with the Administrator of the EPA. Registration of an establishment with the Agency activates a unique, site specific registration number known as the EPA Establishment Number (EPA Est. No.) which is issued to the applicant pursuant to 40 C.F.R. § 167.20(d).
8. Pursuant to Section 7(a) of FIFRA, 7 U.S.C. § 136e(a), no person shall produce any pesticide in any State unless the establishment in which it is produced is registered with the Administrator of the EPA.
9. Pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), it is unlawful for any person to distribute or sell to any person any pesticide that is misbranded.
10. Pursuant to Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), a pesticide is "misbranded" if its labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false or misleading in any particular.
11. A "pest" is defined in Section 2(t) of FIFRA, 7 U.S.C. § 136(t), as 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 microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1).
12. The term "pesticide" is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u), to mean, any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.
13. The term "establishment" is defined at Section 2(dd) of FIFRA, 7 U.S.C. § 136(dd) and 40 C.F.R. § 167.3, to mean, any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.
14. The term "produce" is defined by Section 2(w) of FIFRA, 7 U.S.C. § 136(b), to mean in part, to manufacture, prepare, compound, propagate, or process any pesticide or active ingredient used in producing a pesticide.
15. The term "to distribute or sell" as defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), includes to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, or to release for shipment.

16. Pursuant to Section 17(c) FIFRA, 7 U.S.C. § 136o(c) and the regulations at 19 C.F.R. § 12.112, an importer (or its agent) desiring to import pesticides into the United States is required to submit to the EPA Administrator a Notice of Arrival of Pesticides and Devices (NOA) [EPA Form 3540-1] prior to the arrival of the shipment(s) into the United States, or, as an alternative to submitting an NOA, the importer or its agent may file an entry via the U.S. Customs and Border Protection's (CBP) Automated Commercial Environment (ACE) Data Processing System.
17. Pesticides that are sold and distributed in the United States are required to be registered with the EPA, pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a.
18. Civil penalties under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a) may be assessed by administrative order.

#### **IV. FINDINGS OF FACTS**

19. On or around April 30, 2018, the licensed customs broker American Cargo Express, Inc. (American) submitted entry documents via the CBP ACE Data Processing System on behalf of Medentech for the importation of one shipment, under Entry Number U16-10064192, of the pesticide product Inovotabs (EPA Reg. No. 71847-3-1007) which contained a total of 1,200 cases, each case weighing 23.2 pounds. The information provided to the EPA Region 4 through the CBP ACE System indicated that the shipment of Inovotabs was scheduled to arrive at the Port of Charleston, South Carolina on April 27, 2018.
20. After reviewing the label that was provided in the ACE System, the EPA determined that the label included incorrect information that did not match the EPA master label for the product. Specifically, the statement under the Brand Name of Product on the import label "Inovotabs Effervescent Tablets Only for use with Embrex in ovo vaccination devices" was not on the EPA approved-master label.
21. On August 3, 2018, the licensed customs broker American submitted entry documents via the CBP's ACE Data Processing System on behalf of Medentech for the importation of one shipment, under Entry U16-10084042, of the pesticide product Inovotabs which contained a total of 1,200 cases, each case weighing 4.81 kilograms. The information provided to the EPA Region 4 through the CBP ACE System indicated that the shipment of Inovotabs was scheduled to arrive at the Port of Charleston, South Carolina on July 29, 2018.
22. After reviewing the label that was provided in the ACE System, the EPA determined that the label included incorrect information that did not match the EPA master label for the product. Specifically, under the Step by Step Mixing Directions, the label did not contain step number 11, "Twist close plastic bag and close lid firmly after withdrawing tablets from container". In addition, the outer carton label did not reference the full tub label and added the sentence "Contains: Anhydrous Sodium Dichloroisocyanurate...CAS NO. 2893-78-9".
23. On July 2, 2018, Zoetis, the consignee who had purchased the Inovotabs, emailed the EPA advising the EPA that the Inovotabs cases had been transported to Zoetis's facility in Marietta, Georgia, on May 15, 2018, and that 48 of the 1,200 cases had been shipped out to

an end-use customer. Zoetis further advised that the remainder of the product cases, totaling 1,152 cases, were currently being held at the Zoetis Marietta Logistics Center located at 1950 West Oak Circle, Marietta, Georgia. Zoetis requested that it be allowed to relabel the 1,152 cases through the issuance of a SSURO, and that the relabeling would be conducted at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, Georgia 30036 (EPA Establishment Number 52270-GA-3). On August 13, 2018, the EPA Region 4, issued a Stop Sale, Use, or Removal Order (SSURO) to Zoetis prohibiting the sale, use, or removal of the shipments listed above.

24. On September 28, 2018, the EPA issued an amendment to the SSURO which corrected the address and the establishment number of the facility where the product was to be relabeled. On October 22, 2018, Zoetis notified the EPA that the cases of the pesticide product were relabeled incorrectly. Zoetis advised the EPA that Medentech had requested to export the cases, under Entry Numbers U16-10064192 and U16-10084042 back to its facility in Ireland. On December 28, 2018, the EPA issued a letter to Zoetis which stated that the two shipments could be exported back to the Medentech facility in Ireland. On April 3, 2019, the EPA received a letter from Zoetis stating that the two shipments had been exported and received by Medentech in Ireland. On May 15, 2019, the SSURO was terminated.

#### **V. ALLEGED VIOLATIONS**

25. The EPA alleges that Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), on at least two occasions and is therefore subject to the assessment of a civil penalty under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a).
26. Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), in conjunction with 40 C.F.R. Part 19, Adjustments of Civil Monetary Penalties for Inflation, authorizes the assessment of a civil penalty.

#### **VI. STIPULATIONS**

27. The issuance of this CAFO simultaneously commences and concludes this proceeding. 40 C.F.R. § 22.13(b).
28. For the purpose of this proceeding, as required by 40 C.F.R. § 22.18(b)(2), Respondent:
  - (a) admits that the EPA has jurisdiction over the subject matter alleged in this CAFO;
  - (b) neither admits nor denies the factual allegations set forth in Section IV (Findings of Facts) of this CAFO;
  - (c) consents to the assessment of a civil penalty as stated below;
  - (d) consents to the conditions specified in this CAFO;
  - (e) waives any right to contest the alleged violations of law set forth in Section V (Alleged Violations) of this CAFO; and

(f) waives its rights to appeal the Final Order accompanying this CAFO.

29. For the purpose of this proceeding, Respondent:

- (a) agrees that this CAFO states a claim upon which relief may be granted against Respondent;
- (b) acknowledges that this CAFO constitutes an enforcement action for purposes of considering Respondent's compliance history in any subsequent enforcement actions;
- (c) waives any right it may possess at law or in equity to challenge the authority of the EPA to bring a civil action in a United States District Court to compel compliance with the CAFO, and to seek an additional penalty for such noncompliance, and agrees that federal law shall govern in any such civil action;
- (d) by executing this CAFO, certifies to the best of its knowledge that Respondent is currently in compliance with all relevant requirements of FIFRA and its implementing regulations, and that all violations alleged herein, which are neither admitted nor denied, have been corrected;
- (e) waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during any discussions with, or to be served with and reply to, any memorandum or communication addressed to the EPA officials where the purpose of such discussion, memorandum, or communication is to persuade such official to accept or issue this CAFO; and
- (f) agrees comply with the terms of the CAFO.

30. In accordance with 40 C.F.R. § 22.5, the individuals named in the certificate of service are authorized to receive service related to this proceeding.

## **VII. TERMS OF PAYMENT**

- 31. Based on the Respondent's substantiated ability to pay claim, Respondent consents to the payment of a civil penalty, which was calculated in accordance with the Act, in the amount of **\$10,260.00**, which is to be paid within thirty (30) calendar days of the Effective Date of this CAFO.
- 32. Payment(s) shall be made by cashier's check, certified check, by electronic funds transfer (EFT), or by Automated Clearing House (ACH) (also known as REX or remittance express). If paying by check, the check shall be payable to: Treasurer, United States of America, and the Facility name and docket number for this matter shall be referenced on the face of the check. If Respondent sends payment by the U.S. Postal Service, the payment shall be addressed to:

United States Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
P.O. Box 979077  
St. Louis, Missouri 63197-9000

If Respondent sends payment by non-U.S. Postal express mail delivery, the payment shall be sent to:

U.S. Bank  
Government Lockbox 979077  
U.S. EPA Fines & Penalties  
1005 Convention Plaza  
Mail Station: SL-MO-C2-GL  
St. Louis, Missouri 63101  
Contact Number: (314) 425-1819

If paying by EFT, Respondent shall transfer the payment to:

Federal Reserve Bank of New York  
ABA: 021030004  
Account Number: 68010727  
SWIFT address: FRNYUS33  
33 Liberty Street  
New York, New York 10045  
Field Tag 4200 of the Fedwire message should read:  
"D 68010727 Environmental Protection Agency"

If paying by ACH, Respondent shall remit payment to:

US Treasury REX / Cashlink ACH Receiver  
ABA: 051036706  
Account Number: 310006, Environmental Protection Agency  
CTX Format Transaction Code 22 – checking  
Physical location of US Treasury facility:  
5700 Rivertech Court  
Riverdale, Maryland 20737  
Contact: Craig Steffen (513) 487-2091  
REX (Remittance Express): 1-866-234-5681

33. Respondent shall send proof of **payment**, within 24 hours of payment of the civil penalty, to:

Regional Hearing Clerk  
U.S. EPA Region 4  
61 Forsyth Street, S.W.  
Atlanta, Georgia 30303-8960  
bullock.patricia@epa.gov

and

Kimberly Tomczak  
Chemical Safety Section  
Enforcement and Compliance Assurance Division]  
U.S. EPA Region 4  
61 Forsyth Street, S.W.  
Atlanta, Georgia 30303-8960  
Tomczak.kimberly@epa.gov

34. "Proof of payment" means, as applicable, a copy of the check, confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer, and any other information required to demonstrate that payment has been made according to the EPA requirements, in the amount due, and identified with the Facility name and Docket No. FIFRA-04-2020-0710(b).
35. Pursuant to 31 U.S.C. § 3717, 31 C.F.R. § 901.9, and 40 C.F.R. § 13.11, if Respondent fails to remit the civil penalty as agreed to herein, the EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the costs of processing and handling the delinquent claim. Accordingly, the EPA may require the Respondent to pay the following amounts on any amount overdue:
- (a) Interest. Interest will begin to accrue on the civil penalty from the Effective Date of this CAFO [If the civil penalty is paid within 30 days of the Effective Date of this CAFO, Interest is waived. However, if the civil penalty is not paid in full within 30 days of the Effective Date of this CAFO from the date that the EPA first mails notice to the Respondent that a stipulated penalty is due], Interest will continue to accrue on any unpaid portion until the unpaid portion of the penalty and accrued Interest is paid. Interest will be assessed at the rate of the United States Treasury tax and loan rate, as established by the Secretary of the Treasury, in accordance with 31 U.S.C. § 3717(a)(1), 31 C.F.R. § 901.9(b), and 40 C.F.R. § 13.11(a).
  - (b) Non-Payment Penalty. On any portion of a civil penalty more than ninety (90) calendar days past due, Respondent must pay a non-payment penalty of not more than six percent (6%) per annum, which will accrue from the date the penalty payment became due and is not paid, as provided in 31 U.S.C. § 3717(e)(2) and 31 C.F.R. § 901.9(d). This non-payment penalty is in addition to charges which accrue or may accrue under subparagraphs (a) and (c) and will be assessed monthly. 40 C.F.R. § 13.11(c).
  - (c) Monthly Handling Charge. Respondent must pay a late payment handling charge to cover the administrative costs of processing and handling the delinquent claim, based on either actual or average cost incurred. 31 C.F.R. § 901.9(c), and 40 C.F.R. § 13.11(b). Administrative costs will be assessed monthly throughout the period the debt is overdue except as provided by 40 C.F.R. § 13.12.

36. If Respondent fails to timely pay any portion of the penalty assessed under this CAFO, pursuant to Section 14(a)(5) of FIFRA 7 U.S.C. § 136l(a)(5), the EPA may:
- (a) refer the debt to a credit reporting agency or a collection agency pursuant to Section 14(a) of FIFRA 7 U.S.C. § 136l(a), 40 C.F.R. §§ 13.13 and 13.14;
  - (b) collect the debt by administrative offset (i.e., the withholding of money payable by the United States to, or held by the United States for, a person to satisfy the debt the person owes the Government), which includes, but is not limited to, referral to the Internal Revenue Service for offset against income tax refunds, 40 C.F.R. Part 13, Subparts C and H;
  - (c) suspend or revoke Respondent's licenses or other privileges, or suspend or disqualify Respondent from doing business with the EPA or engaging in programs the EPA sponsors or funds, 40 C.F.R. § 13.17; and/or
  - (d) request that the Attorney General bring a civil action in the appropriate district court to recover the amount assessed pursuant to Section 14(a)(5) of FIFRA, 7 U.S.C. § 136l(a)(5).
37. Penalties paid pursuant to this CAFO shall not be deductible for purposes of federal taxes.

#### **VIII. EFFECT OF CAFO**

38. In accordance with 40 C.F.R. § 22.18(c), Respondent's full compliance with this CAFO shall only resolve Respondent's liability for federal civil penalties for the violations and facts specifically alleged above.
39. Full payment of the civil penalty, as provided in Section VII (Terms of Payment), shall not in any case affect the right of the EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. 40 C.F.R. § 22.18(c),
40. Any violation of this CAFO may result in a civil judicial action for civil penalties as provided in Section 14(a) of the Act, 42 U.S.C. § 136l(a), as well as criminal sanctions as provided in Section 14(b) of the Act, 42 U.S.C. § 136l(b). The EPA may use any information submitted under this CAFO in an administrative, civil judicial, or criminal action.
41. Nothing in this CAFO shall relieve Respondent of the duty to comply with all applicable provisions of FIFRA and other federal, state, or local laws or statutes, nor shall it restrict the EPA's authority to seek compliance with any applicable laws or regulations, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state, or local permit, except as expressly provided herein.
42. Nothing herein shall be construed to limit the power of the EPA to undertake any action against Respondent or any person in response to conditions that may present an imminent and substantial endangerment as provided under the Act.



43. The terms, conditions, and compliance requirements of this CAFO may not be modified or amended except upon the written agreement of both Parties, and approval of the Regional Judicial Officer.
44. The provisions of this CAFO shall apply to and be binding upon Respondent and its officers, directors, employees, agents, trustees, servants, authorized representatives, successors, and assigns.
45. Any change in the legal status of the Respondent, or change in ownership, partnership, corporate or legal status relating to the Facility, will not in any way alter Respondent's obligations and responsibilities under this CAFO.
46. By signing this Consent Agreement, Respondent acknowledges that this CAFO will be available to the public and agrees that this CAFO does not contain any confidential business information or personally identifiable information.
47. By signing this Consent Agreement, the Complainant and the undersigned representative of Respondent each certify that he or she is fully authorized to execute and enter into the terms and conditions of this CAFO and has the legal capacity to bind the party he or she represents to this CAFO.
48. By signing this Consent Agreement, both Parties agree that each party's obligations under this CAFO constitute sufficient consideration for the other party's obligations.
49. By signing this Consent Agreement, Respondent certifies that the information it has supplied concerning this matter was at the time of submission, and continues to be, true, accurate, and complete for each such submission, response, and statement. Respondent acknowledges that there are significant penalties for submitting false or misleading information, including the possibility of fines and imprisonment for knowing submission of such information, under 18 U.S.C. § 1001.
50. The EPA also reserves the right to revoke this CAFO and settlement penalty if and to the extent that the EPA finds, after signing this CAFO, that any information provided by Respondent was materially false or inaccurate at the time such information was provided to the EPA. If such false or inaccurate material was provided, the EPA reserves the right to assess and collect any and all civil penalties for any violation described herein. The EPA shall give Respondent notice of its intent to revoke, which shall not be effective until received by Respondent in writing.
51. It is the intent of the parties that the provisions of this CAFO are severable. If any provision or authority of this CAFO or the application of this CAFO to any party or circumstances is held by any judicial or administrative authority to be invalid or unenforceable, the application of such provisions to other parties or circumstances and the remainder of the CAFO shall remain in force and shall not be affected thereby.
52. Unless specifically stated otherwise in this CAFO, each party shall bear its own attorney's fees, costs, and disbursements incurred in this proceeding.

## **IX. EFFECTIVE DATE**

53. This CAFO shall become effective upon execution of the Final Order by the Regional Judicial Officer on the date of filing with the Hearing Clerk.

**Remainder of Page Intentionally Left Blank**

**Complainant and Respondent will Each Sign on Separate Pages**

The foregoing Consent Agreement In the Matter of Medentech Limited Docket Number FIFRA-04-2020-0710(b) Is Hereby Stipulated, Agreed and Approved for Entry.

FOR RESPONDENT:

Julie Lambert  
Signature

23 April 2020  
Date

Printed Name: Julie Lambert

Title: HEAD OF TECHNICAL AND QUALITY.

Address: White Hill, Dunsmuir Estate, Clonsilla Rd,  
Wexford Ireland

The foregoing Consent Agreement In the Matter of Medentech Limited, Docket Number **FIFRA-04-2020-0710(b)** Is Hereby Stipulated, Agreed and Approved for Entry.

FOR COMPLAINANT:

---

Carol L. Kemker  
Director  
Enforcement and Compliance Assurance Division  
U.S. Environmental Protection Agency, Region 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4

In the Matter of:

**Medentech Limited,**

Respondent.

Docket No. **FIFRA-04-2020-0710(b)**

FINAL ORDER

The Regional Judicial Officer is authorized to ratify this Consent Agreement which memorializes a settlement between Complainant and Respondent. 40 C.F.R. §§ 22.4(b) and 22.18(b)(3). The foregoing Consent Agreement is, therefore, hereby approved, ratified and incorporated by reference into this Final Order in accordance with the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits*, 40 C.F.R. Part 22.

The Respondent is hereby ORDERED to comply with all of the terms of the foregoing Consent Agreement effective immediately upon filing of this Consent Agreement and Final Order with the Regional Hearing Clerk. This Final Order disposes of this matter pursuant to 40 C.F.R. §§ 22.18 and 22.31.

**BEING AGREED, IT IS SO ORDERED**

---

Tanya Floyd  
Regional Judicial Officer

## CERTIFICATE OF SERVICE

I certify that the foregoing “Consent Agreement” and “Final Order,” in the Matter of **Medentech Limited**, Docket No. **FIFRA-04-2020-0710(b)**, were filed and copies of the same were emailed to the parties as indicated below.

**Via email to all parties at the following email addresses:**

To Respondent:      Mr. Telisport Putsavage  
                                 Attorney at Law  
                                 Putsavage PLLC  
                                 17 Elk Street, 5<sup>th</sup> Floor  
                                 Albany, New York 12207  
                                 putsavage@environmentallaw.us  
                                 (202) 466-3700

To EPA:                      Kimberly Tomczak, Life Scientist  
                                 tomczak.kimberly@epa.gov  
                                 (404) 562-8987

                                 Robert Caplan, Senior Attorney  
                                 caplan.robert@epa.gov  
                                 (404) 562-9520

                                 U.S. EPA Region 4  
                                 61 Forsyth Street, S.W.  
                                 Atlanta, Georgia 30303-8960

---

                                 Patricia A. Bullock, Regional Hearing Clerk  
                                 U.S. Environmental Protection Agency, Region 4  
                                 61 Forsyth Street, SW  
                                 Atlanta, Georgia 30303-8960  
                                 (404) 562-9511