UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

In the Matter of: **Astec Bio USA Inc.** **10 Keith Way, Suite 3** **Hingham, MA 02043** Respondent	**CONSENT AGREEMENT AND FINAL ORDER** **EPA Docket No.** **FIFRA-01-2023-0001**

CONSENT AGREEMENT

I. PRELIMINARY STATEMENT AND JURISDICTION

1. The issuance of this Consent Agreement and attached Final Order, in accordance with 40 C.F.R. § 22.13(b), simultaneously commences and concludes an administrative penalty assessment proceeding brought under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136*l*(a), and Sections 22.13 and 22.18 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules of Practice), as codified at 40 C.F.R. Part 22.

2. Complainant is the United States Environmental Protection Agency, Region 1 (EPA). On EPA's behalf, the Director of the Enforcement and Compliance Assurance Division, EPA Region 1, is delegated the authority to settle civil administrative penalty proceedings under Section 14(a) of FIFRA.

3. Respondent is Astec Bio USA Inc. (Astec Bio), a company incorporated in the state of Delaware, with its principal place of business located in Hingham, Massachusetts.

4. Complainant and Respondent (collectively, the Parties), having agreed that settlement of this matter is in the public interest, agree to settle this action before any hearing or the taking of any testimony and without the filing of a complaint or the adjudication of any issue of fact or law, agree to comply with the terms of this Consent Agreement, and consent to the issuance of a final order ratifying this Consent Agreement.

5. This Consent Agreement and Final Order (CAFO) is entered into under Section 14(a) of FIFRA, 7 U.S.C. § 136*l*(a), and the Consolidated Rules of Practice, 40 C.F.R. Part 22.

6. The Consent Agreement informs Respondent of Complainant's intention to assess a penalty against Respondent for alleged violations of Section 12 of FIFRA, as amended, 7 U.S.C. § 136j, and implementing regulations at 40 C.F.R. Parts 150 - 180 and at 19 C.F.R §§ 12.110 - 12.117 (collectively, the FIFRA regulations). The Consent Agreement also informs Respondent of its right to request a hearing.

7. 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), 22.18(b).

II. GOVERNING LAW

8. FIFRA, 7 U.S.C. § 136 et seq., and the FIFRA regulations govern the import, sale, distribution and use of pesticides in the United States.

9. Section 3(a) of FIFRA, 7 U.S.C. § 136a(a), states that no person in any state may distribute or sell to any person any pesticide that is not registered under FIFRA, except as provided for by FIFRA.

10. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."

11. Section 2(gg) of FIFRA, 7 U.S.C § 136(gg), states that the term "to distribute or sell" means "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."

12. The regulation set forth at 40 C.F.R. § 152.3 further explains that "[d]istribute or sell" and other grammatical variations of the term such as "distributed or sold" and "distribution or sale," means "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State."

13. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a "pesticide," in part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."

14. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines a "pest," in pertinent part, as "any insect, rodent, nematode, fungus, weed, or [ ] 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 EPA Administrator declares to be a pest under section [25(c)(1) of FIFRA]."

15. The regulation set forth at 40 C.F.R. § 152.15 provides that "[a] substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

a. The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
    i. That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or
    ii. That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or
b. The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or
c. The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose."

16. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers," and "labeling" as "all labels and all other written, printed, or graphic matter— (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device …".

17. The regulation set forth at 40 C.F.R. § 152.5 provides that "[a]n organism is declared to be a pest under circumstances that make it deleterious to man or the environment," including if the organism is "[a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs [ ] and cosmetics [ ]."

18. The regulations at 40 C.F.R. part 152 set forth "procedures, requirements, and criteria concerning the registration of pesticide products under FIFRA Section 3." 40 C.F.R. § 152.1(a).

19. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that "[i]t shall be unlawful for any person in any State to sell or distribute to any person any pesticide that is not registered under Section 3 [of FIFRA] …".

20. The importation of pesticides into the United States is governed by sections 17(c) and (e) of FIFRA, 7 U.S.C. §§ 136o(c) and 136o(e), and the regulations promulgated thereunder in consultation with the Administrator of the EPA, set forth at 19 C.F.R. §§ 12.110 – 12.117. 19 C.F.R. § 12.1(b).

21. The regulation at 19 C.F.R. § 12.111 states, in pertinent part, that certain imported pesticides are required to be registered under Section 3 of FIFRA and the regulations promulgated thereunder (40 C.F.R. Part 152) before being permitted entry into the United States.

22. The regulation at 40 C.F.R. § 152.3 defines "pesticide product" as "a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide."

23. Section 17(c) of FIFRA, 7 U.S.C. § 136o(c), and the regulations implementing that provision set forth at 19 C.F.R. §§ 12.110 – 12.117, establish that an importer or the importer's agent desiring to import pesticides or devices into the United States shall submit to EPA, prior to the arrival of the shipment in the United States, a Notice of Arrival of Pesticides and Devices ("Notice of Arrival") on EPA Form 3540-1, or, in the alternative, file the electronic version of Form 3540-1, with the filing of entry documentation, via any electronic data interchange system authorized by the U.S. Customs and Border Protection ("CBP"). (Herein, both the physical Form 3540-1 and its electronic alternative are referred to as a "NOA").

24. The term "importer" is defined at 19 C.F.R. § 101.1 as the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his behalf. The importer may be the consignee, importer of record, the actual owner of the merchandise or the transferee of the merchandise.

25. Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), provides that "[i]t shall be unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by [FIFRA]." Such reports include, but are not limited to, NOAs submitted to EPA for each shipment of pesticides that are imported into the United States under Section 17 of FIFRA and 19 C.F.R. § 12.112(a).

26. The FIFRA requirement to submit NOAs prior to importing pesticides into the United States protects against unreasonable risks to human health or the environment by providing EPA with vital information about pesticides or devices before their arrival into the United States for distribution or sale. NOAs provide information – including active ingredients, quantities, countries of origin, identity of producing establishments, carriers, and ports of entry – that enables EPA to make informed decisions about whether importation will pose unreasonable adverse risks to public health or the environment and, also, provide critical contact information in the event of an emergency related to the movement of potentially harmful pesticides.

27. Section 14(a)(1) of FIFRA, 7 U.S.C. § 136*l*(a)(1), states that any registrant, commercial applicator, wholesaler, dealer, retailer or other distributor who violates any provision of FIFRA may be assessed a civil penalty by the EPA of not more than $5,000 for each offense. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended through 2015, 28 U.S.C. § 2461, and its implementing regulations set forth at 40 C.F.R. Part 19, increased the

amount that can be assessed to $23,494 for each offense occurring after November 2, 2015, when assessed on or after January 6, 2023. See 88 Fed. Reg. 988 (Jan. 6, 2023).

28. Section 14(a)(4) of FIFRA, 7 U.S.C. § 136*l*(a)(4), provides that the Administrator, in determining the amount of the penalty, shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation.

III. COMPLAINANT'S FINDINGS OF FACT AND LAW

29. Between March 25, 2020 and October 27, 2022, Respondent imported into the United States numerous shipments of Oosafe brand disinfectant products, which were labeled and marketed with pesticidal claims (hereinafter, the "Oosafe disinfectant products").

30. The Oosafe disinfectant products that Respondent imported represent five distinct "pesticide products," as that term is defined in FIFRA, and 40 C.F.R. 152.3, as follows (the information below includes the description of the pesticide product and associated model number):

a. Oosafe Disinfectant for CO2 Incubators and Laminar Flow Hoods (1 Liter w/ Spray) (OODIH-1000);
b. Oosafe Disinfectant for CO2 Incubators and Laminar Flow Hoods (Disinfectant Wipes - 70 Wipes/Container) (OODW-70);
c. Oosafe Disinfectant for CO2 Incubators and Laminar Flow Hoods (5 Liters Refill) (OODIH-5000);
d. Oosafe Surface Disinfectant (2 Liters w/ Dose Cup) (OODSF-02000); and
e. Oosafe Surface Disinfectant (10 Liter Refill) (OODSF-10000).

31. Respondent imported the Oosafe disinfectant products through the United States Port of Entry at Boston, MA with the unique CBP Port of Entry number 0401.

32. On December 13, 2022, two duly-authorized EPA Region 1 FIFRA inspectors conducted an inspection (the "Inspection") of Respondent's facility at 10 Keith Way, Suite 3, Hingham, Massachusetts (the "Facility"). At the Inspection, the inspectors observed quantities of Oosafe disinfectant products packed, labeled, and ready for distribution.

33. At all times relevant to the allegations herein, Respondent made the following pesticidal claims on the labels of the five Oosafe types of disinfectant products, in marketing materials for the Oosafe disinfectant products on Respondent's website, https://astecbiousa.com/, or both:

a. Oosafe Disinfectant for CO2 Incubators and Laminar Flow Hoods (1 Liter w/ Spray) (OODIH-1000):
    i. "Safe disinfection for CO_2 incubators and laminar flow hoods"
    ii. "Scientifically Proven Safety: Human sperm survival bioassay to

examine toxicity of a new clinical laboratory equipment disinfectant (Poster at ASRM, 2010). Changing old trends in IVF laboratory cleaning and disinfection (Study from MONASH University Australia, 2012)."

iii. "Fast Disinfection: Complete disinfection 15 minutes after application."

iv. "Effective against bacteria, fungi (Candida), mycobacteria, enveloped viruses including HIV, Hepatitis B and C, Herpes, simplex, Influenza A (H5N1/H1N1), Ebola, also Adenovirus and Poliovirus."

v. "Microbiological Efficacy: Effective against hepatitis B, HIV, rotavirus within 1 minute, mycobacterium within 5 minutes, bacteria, fungi (Candida), influenza A virus (H5N1/H1N1) within 15 minutes."

vi. "Usage: Can even be used in laboratories with suboptimal ventilation, as disinfectant releases no VOCs after application."

vii. "Application: Apply evenly to desired surface using spray or wipes; wait 15 minutes for the surface to dry for best results. For best results, wipe the surface with a humid sterile sponge or cloth after 15 minutes to remove dead organisms and other debris."

viii. "Active ingredients: Quaternary ammonium compound: Benzyl-alkyldimethyl chloride 2.6 mg/g."

b. Oosafe Disinfectant for CO2 Incubators and Laminar Flow Hoods (Disinfectant Wipes - 70 Wipes/Container) (OODW-70):

i. "Multipurpose ready to use disinfection wipes for CO_2 incubators, laminar flow hoods."

ii. "Scientifically Proven Safety: Human sperm survival bioassay to examine toxicity of a new clinical laboratory equipment disinfectant (Poster at ASRM, 2010). Changing old trends in IVF laboratory cleaning and disinfection (Study from MONASH University Australia, 2012)."

iii. "Fast Disinfection: Complete disinfection 15 minutes after application."

iv. "Microbiological Efficacy: Effective against hepatitis B, HIV, rotavirus within 1 minute, mycobacterium within 5 minutes, bacteria, fungi (Candida), influenza A virus (H5N1/H1N1) within 15 minutes."

v. "Bactericidal, Yeasticidal, Mycobactericidal, Tuberculocidal, Virucidal on Poliovirus, Adenovirus and Vaccinia virus (all enveloped viruses from Annex Z, EN14476:2013+A1:2015 including HBV, HCV, HDV, HIV, Coronavirus, Influenza, Rabies, Measles virus)."

vi. "Designed and tested for IVF Laboratory professional use."

vii. "Usage: Can even be used in laboratories with suboptimal ventilation, as disinfectant releases no VOCs after application."
viii. "Application: Apply evenly to desired surface using spray or wipes; wait 15 minutes for the surface to dry for best results. For best results, wipe the surface with a humid sterile sponge or cloth after 15 minutes to remove dead organisms and other debris."
ix. "Active ingredients: Quaternary ammonium compound: Benzyl-alkyldimethyl chloride 2.6 mg/g."

c. Oosafe Disinfectant for CO2 Incubators and Laminar Flow Hoods (5 Liters Refill) (OODIH-5000):
i. "For safe disinfection of CO2 incubators, laminar flow hoods, glass, plastic, metal, Hi-Macs surfaces, equipment, ultrasound probes and hospital furniture."
ii. "Scientifically Proven Safety: Human sperm survival bioassay to examine toxicity of a new clinical laboratory equipment disinfectant (Poster at ASRM, 2010). Changing old trends in IVF laboratory cleaning and disinfection (Study from MONASH University Australia, 2012)."
iii. "Fast Disinfection: Complete disinfection 15 minutes after application."
iv. "Microbiological Efficacy: Effective against hepatitis B, HIV, rotavirus within 1 minute, mycobacterium within 5 minutes, bacteria, fungi (Candida), influenza A virus (H5N1/H1N1) within 15 minutes."
v. "Bactericidal, Yeasticidal, Mycobactericidal, Tuberculocidal, Virucidal on Poliovirus, Adenovirus and Vaccinia virus (all enveloped viruses from Annex Z, EN14476:2013+A1:2015 including HBV, HCV, HDV, HIV, Coronavirus, Influenza, Rabies, Measles virus)."
vi. "Designed and tested for IVF Laboratory professional use."
vii. "Usage: Can even be used in laboratories with suboptimal ventilation, as disinfectant releases no VOCs after application."
viii. "Application: Apply evenly to desired surface using spray or wipes; wait 15 minutes for the surface to dry for best results. For best results, wipe the surface with a humid sterile sponge or cloth after 15 minutes to remove dead organisms and other debris."
ix. "Active ingredients: Quaternary ammonium compound: Benzyl-alkyldimethyl chloride 2.6 mg/g."

d. Oosafe Surface Disinfectant (2 Liters w/ Dose Cup) (OODSF-02000):
i. "Economical: A 1:100 dilution of Oosafe disinfectant in water is sufficient, while many other disinfectants require 1:10 water dilution."
ii. "MEA and HSSA Tested: This disinfectant comes with MEA and

HSSA Test Results for each lot."

iii. "Cleaning and Disinfection: Thanks to non-ionic soap content, Oosafe Surface Disinfectant can clean and disinfect at the same time. Product is effective on bloodstains and suitable for use in operating rooms as well."

iv. "Fast Disinfection: Treated surface completely disinfected 30 minutes after application."

v. "Scientist Approved: Our disinfectant has been used by leading IVF clinics in more than 100 countries."

vi. "Microbiological Efficacy: Bactericide, fungicide (Candida), algicide and selective viricide."

vii. "Bactericidal, Yeasticidal, Mycobactericidal, Tuberculocidal, Virucidal on Poliovirus, Adenovirus and Vaccinia virus (all enveloped viruses from Annex Z, EN14476:2013+A1:2015 including HBV, HCV, HDV, HIV, Coronavirus, Influenza, Rabies, Measles virus)."

viii. "Designed and tested for IVF Laboratory professional use."

ix. "Usage: Can even be used in laboratories with suboptimal ventilation, as disinfectant releases no VOCs after application."

x. "Dilution: For efficacy against specified microorganisms dilute with water and wait as follows:

(1) Bactericidal, Yeasticidal and Vaccinia virus . . . 1:50, 15 min;

(2) Adenovirus Type 5 . . . 1:25, 10 min

(3) Mycobactericidal, Tuberculocidal and Poliovirus Type 1 . . . 1:25, 30 min"

xi. "Active Ingredients: Quaternary ammonium compound (propionate): 6.3 mg/g."

e. Oosafe Surface Disinfectant (10 Liter Refill) (OODSF-10000):

i. "Economical: A 1:100 dilution of Oosafe disinfectant in water is sufficient, while many other disinfectants require 1:10 water dilution."

ii. "MEA and HSSA Tested: This disinfectant comes with MEA and HSSA Test Results for each lot."

iii. "Bactericidal, Yeasticidal, Mycobactericidal, Tuberculocidal, Virucidal on Poliovirus, Adenovirus and Vaccinia virus (all enveloped viruses from Annex Z, EN14476:2013+A1:2015 including HBV, HCV, HDV, HIV, Coronavirus, Influenza, Rabies, Measles virus)."

iv. "Cleaning and Disinfection: Thanks to non-ionic soap content, Oosafe Surface Disinfectant can clean and disinfect at the same time. Product is effective on bloodstains and suitable for use in operating rooms as well."

v. "Fast Disinfection: Treated surface completely disinfected 30 minutes after application."
vi. "Scientist Approved: Our disinfectant has been used by leading IVF clinics in more than 100 countries."
vii. "Microbiological Efficacy: Bactericide, fungicide (Candida), algicide and selective viricide."
viii. "Designed and tested for IVF Laboratory professional use."
ix. "Usage: Can even be used in laboratories with suboptimal ventilation, as disinfectant releases no VOCs after application."
x. "Dilution: For efficacy against specified microorganisms dilute with water and wait as follows:
(1) Bactericidal, Yeasticidal and Vaccinia virus . . . 1:50, 15 min;
(2) Adenovirus Type 5 . . . 1:25, 10 min
(3) Mycobactericidal, Tuberculocidal and Poliovirus Type 1 . . . 1:25, 30 min"
xi. "Active Ingredients: Quaternary ammonium compound (propionate): 6.3 mg/g."

34. Respondent provided information to EPA about the Oosafe disinfectant products and Respondent's sale of the Oosafe disinfectant products.

35. During the Inspection, EPA obtained sales records from Respondent, which included sales of the Oosafe disinfectant products between January 7, 2022 and December 9, 2022. Between January 7, 2022 and December 9, 2022, Respondent distributed or sold the 5 pesticide product types of Oosafe disinfectant products on numerous occasions.

36. At no time relevant to the allegations herein were the Oosafe disinfectant products registered with the EPA.

37. EPA determined that the Oosafe disinfectant products, as manufactured and marketed, were intended to provide an antibacterial benefit to the user.

38. The Oosafe disinfectant products are "pesticides" as defined by FIFRA.

39. The Oosafe disinfectant products were required to be registered with EPA before being distributed or sold, including imported, in the United States.

40. At no time has Respondent possessed an EPA registration that would authorize it to distribute or sell, including import, the Oosafe disinfectant products in the United States.

41. Between March 25, 2020 and October 27, 2022, Respondent imported the 5 pesticide product types of Oosafe disinfectant products on numerous occasions.

42. Between March 25, 2020 and October 27, 2022, Respondent failed to file a NOA in accordance with 19 C.F.R. § 12.112(a) for the import of the Oosafe disinfectant products on numerous occasions.

43. On January 23, 2023, based on its reason to believe that Respondent had distributed, by import and sale, unregistered pesticides in violation of section 12(a)(1)(A) of FIFRA, EPA issued a Stop Sale, Use or Removal Order (SSURO) to Respondent under the authority of section 13(a) of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A), 136k(a).

44. The SSURO required Respondent to cease importing, selling and distributing all Oosafe disinfectant products that were under its ownership, custody or control, wherever such products were located.

45. The SSURO provided that should Respondent seek an exception to the SSURO's prohibitions, Respondent may seek prior written approval from EPA to move the Oosafe disinfectant products for purposes including disposal.

46. Respondent obtained EPA approval for a plan to dispose of its existing inventory of Oosafe disinfectant products, and disposed of the existing inventory in accordance with such approval.

47. Respondent is and was at all times relevant to the allegations herein, a corporation, and therefore, is a "person" as that term is defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

48. Respondent's importation and sale of the Oosafe disinfectant products constitutes an act within the definition of "to distribute or sell" in section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3. Respondent was a distributor of the Oosafe disinfectant products at all times relevant to the allegations herein.

49. Respondent is and was at all times relevant to the allegations herein, an "importer" as that term is defined in 19 C.F.R. § 101.1 and was the importer of record for all of the unlawful imports alleged herein.

50. Respondent was responsible for submitting a NOA in accordance with section 17(c)(1) of FIFRA, 7 U.S.C. § 136o(c)(1), and 19 C.F.R. § 12.112(a), for its imports of the Oosafe disinfectant products.

Liability for the Distribution of Unregistered Pesticides

51. Each of Respondent's numerous unlawful sales or distributions of the Oosafe disinfectant products between January 7, 2022 and December 9, 2022 constitutes a distribution of unregistered pesticides and is therefore a violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

52. Respondent may be assessed a civil penalty under the authority in section 14(a)(1) of FIFRA for each violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A). 7 U.S.C. § 136*l*(a)(1).

Liability for Failure to File Reports Required by FIFRA

53. Each of Respondent's numerous failures to submit a NOA in accordance with 19 C.F.R. 12.112(a) for the import of the Oosafe disinfectant products to the United States between March 25, 2020 and October 27, 2022 constitutes a failure to file reports required by section 17(c)(1) of FIFRA, 7 U.S.C. § 136o(c)(1), and is therefore a violation of section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N). 7 U.S.C. § 136l(a)(1).

54. Respondent may be assessed a civil penalty under the authority in section 14(a)(1) of FIFRA for each violation of section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N). 7 U.S.C. § 136*l*(a)(1).

IV. CIVIL PENALTY

55. Based on an evaluation of the facts alleged in this Consent Agreement, the factors enumerated in section 14(a)(4) of FIFRA, and the EPA's Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (December 2009), Complainant has determined the appropriate penalty to settle this action is $74,594 (Civil Penalty).

56. This Civil Penalty includes a 20% reduction of the gravity-based penalty amount, for purposes of settlement, in acknowledgement of Respondent's good faith efforts to bring the Oosafe disinfectant products into compliance with FIFRA after the discovery of the violations by EPA.

V. TERMS OF AGREEMENT

57. For the purpose of this proceeding, as required by 40 C.F.R. § 22.18(b)(2), Respondent:

a. Admits the jurisdictional allegations in this CAFO;
b. Neither admits nor denies the specific factual allegations contained in this CAFO;
c. Consents to the assessment of a civil penalty as stated below;

d. Consents to the issuance of any specified compliance or corrective action order;
e. Consents to the conditions specified in this CAFO;
f. Consents to any stated Permit Action;
g. Waives any right to contest the allegations forth in section III of this Consent Agreement; and
h. Waives its right to appeal the Final Order ratifying this Consent Agreement.

58. For the purposes of this proceeding, Respondent also:
a. Acknowledges that it has been informed of its right to request a hearing to contest the allegations set forth in this CAFO;
b. Agrees that this CAFO states a claim upon which relief can be granted against Respondent;
c. Acknowledges that this CAFO constitutes an enforcement action for purposes of considering Respondent's compliance history in any subsequent enforcement actions;
d. Waives any and all remedies, claims for relief, and otherwise available rights to judicial or administrative review that Respondent may have with respect to any issue of fact or law set forth in this CAFO.
e. Consents to personal jurisdiction in any action to enforce this Consent Agreement or Final Order, or both, in the United States District Court for the District of Massachusetts; and
f. Waives any rights it may possess at law or in equity to challenge the authority of EPA to bring a civil action in a United States District Court to compel compliance with the Consent Agreement or Final Order, or both, and to seek an additional penalty for such noncompliance, and agree that federal law shall govern in any such civil action.

59. The parties agree to submit this Consent Agreement to the Region 1 Regional Judicial Officer with a request that it be incorporated into a Final Order.

60. Respondent consents to the assessment of the Civil Penalty in the amount specified in section IV of this Consent Agreement and agrees to pay such penalty to the United States within 30 calendar days following the effective date of the Final Order.

61. Respondent agrees to pay the Civil Penalty in the manner specified below:
a. Using any method, or combination of methods, provided on the website: http://www2.epa.gov/financial/additional-instructions-making-payments-epa, and identify every payment with "*In the Matter of Astec Bio USA Inc.*, Docket No. FIFRA-01-2023-0001"; and

b. Within 24 hours of payment of the Civil Penalty, Respondent shall send proof

of payment by e-mail to the Regional Hearing Clerk and Kevin Pechulis at:

Wanda I. Santiago
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 1
Santiago.Wanda@epa.gov
and
R1_Hearing_Clerk_Filings@epa.gov

and to:

Kevin Pechulis, Senior Enforcement Counsel, Office of Regional Counsel
United States Environmental Protection Agency – Region 1
Pechulis.Kevin@epa.gov

"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 EPA requirements, in the amount due, and identified with "*In the Matter of Astec Bio USA Inc.*, Docket No. FIFRA-01-2023-0001."

62. Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. In the event that any portion of the civil penalty is not paid when due, the penalty shall be payable, plus accrued interest, without demand. Interest shall be payable at the rate of the United States Treasury tax and loan rate in accordance with 31 C.F.R. § 901.9(b)(2) and shall accrue from the original date on which the penalty was due to the date of payment. In addition, a penalty charge of six (6) percent per year will be assessed on any portion of the debt which remains delinquent more than ninety (90) days after payment is due. However, should assessment of the penalty charge on the debt be required, it will be assessed as of the first day payment is due under 31 C.F.R. § 901.9(d).

63. The provisions of this Consent Agreement shall apply to and be binding upon Respondent and its officers, directors, employees, agents, trustees, authorized representatives, successors, and assigns.

64. By signing this CAFO, 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.

65. By signing this CAFO, the undersigned representative of 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.

66. By signing this CAFO, the parties agree that each party's obligations under this CAFO and EPA's compromise of statutory maximum penalties constitute sufficient consideration for the other party's obligations.

67. By signing this CAFO, Respondent certifies that the information it has supplied concerning this matter was at the time of submission 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.

68. By signing this CAFO, Respondent certifies that, to the best of its knowledge and belief, it is presently complying with FIFRA, 7 U.S.C. §§ 136 to 136y, and the FIFRA regulations promulgated thereunder, that it has fully addressed the violations alleged by EPA herein, and that the information it has provided to EPA during the course of the EPA investigation of this matter and up to the present is true and complete.

69. Complainant and Respondent, by entering into this CAFO, each consent to accept digital signatures hereupon. Respondent further consents to accept electronic service of the fully executed CAFO, by e-mail at: don@astec-bio.com. Respondent understands that this e-mail address may be made public when the CAFO and Certificate of Service are electronically filed and uploaded to a searchable database. Complainant has provided Respondent with a copy of the EPA Region 1 Regional Judicial Officer's Authorization of EPA Region 1 Part 22 Electronic Filing System for Electronic Filing and Service of Documents Standing Order, dated June 19, 2020. Electronic signatures shall comply with, and be maintained in accordance with, that Standing Order.

VI. EFFECT OF CONSENT AGREEMENT ATTACHED FINAL ORDER

70. In accordance with 40 C.F.R. § 22.18(c), Respondent's full compliance with this Consent Agreement shall only resolve liability for federal civil penalties for the violations specifically alleged in section III above.

71. This CAFO constitutes a settlement by EPA of all claims for civil penalties pursuant to Section 12 of FIFRA, for the specific violations alleged in section III of this CAFO. Compliance with this CAFO shall not be a defense to any other actions subsequently commenced pursuant to federal laws and regulations administered by EPA for matters not addressed in this CAFO, and it is the responsibility of Respondent to comply with all applicable provisions of federal, state or local law.

72. The civil penalty due under this CAFO, and any interest, non-payment penalties,

and charges described in this CAFO, shall represent penalties assessed by EPA within the meaning of 26 U.S.C. § 162(f) and are not tax deductible for purposes of federal, state, or local law. Accordingly, Respondent agrees to treat all payments made pursuant to this CAFO as penalties within the meaning of Internal Revenue Service regulations, including 26 C.F.R. § 1.162-21, and further agrees not to use these payments in any way as, or in furtherance of, a tax deduction under federal, state or local law.

73. This CAFO constitutes the entire agreement and understanding of the parties and supersedes any prior agreements or understandings, whether written or oral, among the parties with respect to the subject matter hereof.

74. 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 ability to seek compliance with any applicable laws or regulations, or be construed to be a ruling on, or determination of, any issue related to any federal, state, or local permit.

75. EPA reserves the right to revoke this CAFO and settlement penalty if and to the extent that 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 EPA, and EPA reserves the right to assess and collect any and all civil penalties for any violation described herein. EPA shall give Respondent notice of its intent to revoke, which shall not be effective until received by Respondent in writing.

76. This CAFO in no way relieves Respondent or its employees of any criminal liability, and EPA reserves all its other criminal and civil enforcement authorities, including the authority to seek injunctive relief and the authority to undertake any action against Respondent in response to conditions which may present an imminent and substantial endangerment to the public health, welfare, or the environment.

77. Except as qualified by paragraph 62 (overdue penalty), each party shall bear its own costs and fees in this proceeding including attorney's fees. Respondent specifically waives any right to seek such costs and fees from EPA pursuant to the Equal Access to Justice Act, 5 U.S.C. § 504, or other applicable laws.

VII. EFFECTIVE DATE

78. Respondent and Complainant agree to issuance of the attached Final Order. Upon filing, EPA will electronically transmit a copy of the filed CAFO to Respondent. This CAFO shall become effective after execution of the Final Order by the Regional Judicial Officer, on the date of filing with the Regional Hearing Clerk.

The foregoing Consent Agreement, in the *In the Matter of Astec Bio USA Inc.*, Docket No. FIFRA-01-2023-0001, is hereby stipulated, agreed, and approved for entry.

For Respondent, ASTEC BIO USA INC.:

Donald J Luongo Jr

Digitally signed by Donald J Luongo Jr
Date: 2023.07.26 05:47:20 -04'00'

The foregoing Consent Agreement, in the *In the Matter of Astec Bio USA Inc.*, Docket No. FIFRA-01-2023-0001, is hereby stipulated, agreed, and approved for entry.

For Complainant, U. S. ENVIRONMENTAL PROTECTION AGENCY, REGION 1:

JAMES CHOW

Digitally signed by JAMES CHOW
Date: 2023.08.04 15:34:38 -04'00'

James Chow, Acting Director
Office of Enforcement and Compliance Assurance
U.S. EPA, Region 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

In the Matter of: **Astec Bio USA Inc.** **10 Keith Way, Suite 3** **Hingham, MA 02043** Respondent	**CONSENT AGREEMENT AND FINAL ORDER** **EPA Docket No.** **FIFRA-01-2023-0001**

FINAL ORDER

In accordance with 40 C.F.R. § 22.18(b) of the United States Environmental Protection Agency's Consolidated Rules of Practice found at 40 C.F.R. Part 22, the parties to the above-captioned matter have forwarded an executed Consent Agreement to the undersigned for final approval. In accordance with 40 C.F.R. § 22.13(b) of the Consolidated Rules of Practice, the parties have simultaneously commenced and settled the above-captioned action.

The foregoing Consent Agreement is hereby ratified and incorporated by reference into this Final Order. Respondent, Astec Bio USA Inc., is ordered to comply with the terms of the Consent Agreement, which will become effective on the date it is filed with the Regional Hearing Clerk.

So ordered.

LEANN JENSEN Digitally signed by LEANN JENSEN
Date: 2023.08.10 15:59:51 -04'00'

LeAnn W. Jensen, Regional Judicial Officer
EPA-Region 1