UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NEW YORK 10007-1866

JUL - 9 2008

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cynthia L. Taub, Esq.
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

Re: In the Matter of Lonza Inc.
Docket No. FIFRA-02-2007-5116

Dear Ms. Taub:

Please find enclosed a copy of the Consent Agreement and Final Order ("CA/FO") in the above-referenced matter, signed by the Regional Administrator of the United States Environmental Protection Agency, Region 2.

Please have your client, Lonza Inc., arrange payment of the civil penalty and implementation of the Supplemental Environmental Project in accordance with the terms of the CA/FO.

Thank you in advance for your cooperation in this matter. If you have any questions, I may reached by phone at (212) 637-3637, by facsimile at (212) 637-3199, or by e-mail at Taylor.Karen@epa.gov.

Sincerely,

KLTaylor

Karen L. Taylor, Esq.
Office of Regional Counsel

Enclosure

cc: Marcedius Jameson
Administrator, Pesticides Control Program
New Jersey Department of Environmental Protection
P.O. Box 411
Trenton, NJ 08625-0411

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of Lonza Inc., Respondent. Proceeding Under the Federal Insecticide, Fungicide and Rodenticide Act, as amended.	**CONSENT AGREEMENT AND FINAL ORDER** Docket No. FIFRA-02-2007-5116

PRELIMINARY STATEMENT

This administrative proceeding for the assessment of a civil penalty was initiated pursuant to Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), as amended, 7 U.S.C. Section 136*l*(a). On March 30, 2007, Complainant in this proceeding, the Director of the Division of Enforcement and Compliance Assistance, United States Environmental Protection Agency, Region 2 ("EPA"), issued a Complaint and Notice of Opportunity for Hearing (the "Complaint") to Respondent, Lonza Inc., located at 90 Boroline Road, Allendale, New Jersey. The Complaint alleged that, through its supplemental registrants, Respondent committed thirty-three (33) violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. Section 136j(a)(1)(E), involving the distribution or sale of a misbranded pesticide. Subsequent to the issuance of the Complaint, EPA Region 2 received allegations of an additional twenty-five (25) violations. Complainant and Respondent have included the additional allegations in this Consent Agreement and Final Order in lieu of amending the Complaint. Complainant and Respondent agree that settling this matter by entering into this Consent Agreement and Final Order

("CA/FO"), pursuant to Title 40 of the Code of Federal Regulations ("C.F.R.") Sections 22.13(b), 22.18(b)(2) and (3) of the revised Consolidated Rules of Practice, is an appropriate means of resolving this matter without further litigation.

EPA's FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Respondent is Lonza Inc., a Delaware corporation.
2. Respondent is a "person" as defined by FIFRA Section 2(s), 7 U.S.C. § 136(s), and as such, is subject to FIFRA and the regulations promulgated thereunder.
3. Respondent maintains an "establishment," as defined in Section 2(dd) of FIFRA, 7 U.S.C. § 136(dd), located at 90 Boroline Road, Allendale, New Jersey 07401.
4. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines a "pest" as any insect, rodent, nematode, fungus, weed, or any form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism.
5. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term "pesticide" as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.
6. Respondent is a "distributor or seller" within the meaning of Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg).
7. "To distribute or sell" is defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), as "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."

8. Section 2(q) of FIFRA, 7 U.S.C. § 136(q), states that 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.

9. 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 a pesticide which is adulterated or misbranded.

10. Under 40 C.F.R. § 152.132, the distributor is considered an agent of the registrant for all intents and purposes under FIFRA, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product.

Formula 158 Lemon Disinfectant

11. On twelve (12) occasions between July 2, 2003 and September 5, 2003, Respondent, through its supplemental registrant Banner Chemical Corp., distributed or sold the antimicrobial pesticide Formula 158 Lemon Disinfectant, the label of which bore the claim that the pesticide was effective in controlling the microorganism *Pseudomonas aeruginosa.*

12. Efficacy test results of Formula 158 Lemon Disinfectant showed the product to be ineffective in controlling *Pseudomonas aeruginosa*, thus the label of the product when offered for sale was false and misleading regarding its control of *Pseudomonas aeruginosa.*

13. Therefore, Respondent, through its supplemental registrant, committed twelve (12) violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.

hTh Brominating Tablets

14. On or about November 30, 2004, Respondent, through its supplemental registrant Arch Chemicals, Inc., distributed or sold the antimicrobial pesticide hTh Brominating Tablets (Dantobrom S), the label of which bore the claim, "Kills bacteria, controls algae destroys organic contaminants," while the EPA-Approved label for Dantobrom S contained no such statement.

15. Therefore, Respondent, through its supplemental registrant, committed one (1) violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.

Fresh and Clean

16. On ten (10) occasions between February 24, 2005 and March 10, 2005, Respondent, through its supplemental registrant ABC Corp., distributed or sold the antimicrobial pesticide Fresh and Clean, the label of which bore the claim that the pesticide was effective in controlling the microorganism *Pseudomonas aeruginosa.*

17. Efficacy test results of Fresh and Clean showed the product to be ineffective in controlling *Pseudomonas aeruginosa*, thus the label of the product when offered for sale was false and misleading regarding its control of *Pseudomonas aeruginosa.*

18. Therefore, Respondent, through its supplemental registrant, committed ten (10) violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.

REV

19. On ten (10) occasions between February 3, 2005 and March 30, 2005, Respondent, through its supplemental registrant U.N.X. Incorporated, distributed or sold the antimicrobial pesticide REV, the label of which bore the claim that the pesticide was effective in controlling the microorganisms *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

20. Efficacy test results of REV showed the product to be effective in controlling neither *Pseudomonas aeruginosa* nor *Staphylococcus aureus*, thus the label of the product when offered for sale was false and misleading regarding its control of *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

21. Therefore, Respondent committed ten (10) violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.

Germicidal Cleaner 426

22. Respondent was the primary registrant of the antimicrobial pesticide Germicidal Cleaner 426 (Lonza Formulation Y-59, EPA Reg. No. 6836-71).

23. Indusco Ltd. was authorized to distribute the Germicidal Cleaner 426 product as a supplemental registrant (EPA Reg. No. 6836-71-53053).

24. On or about March 17, 2005, an authorized inspector from EPA's Region 4 office inspected Indusco Ltd., located at 2319 Joe Brown Drive, Greensboro, North Carolina 27405, in order to examine and collect samples of pesticides formulated, packaged, labeled and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

25. During the aforementioned inspection, the inspector collected a physical sample of the Germicidal Cleaner 426 product and assigned the sample no. 03170547220101.

26. During the aforementioned inspection, the inspector also collected sales invoices documenting distribution or sale of Germicidal Cleaner 426 by Indusco Ltd. on seven (7) occasions as follows:

Distribution/Sale	Date
1	12/16/2002
2	3/11/2003
3	3/10/2004
4	10/8/2004
5	1/20/2005
6	3/4/2005
7	3/11/2005

27. Germicidal Cleaner 426 was an antimicrobial pesticide as defined in Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), in that the product was intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.

28. The Germicidal Cleaner 426 antimicrobial pesticide product was registered as a hospital disinfectant; the label of which bore the claim that the pesticide was effective in controlling the microorganisms *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

29. Efficacy test results of Germicidal Cleaner 426 showed the product to be effective in controlling neither *Pseudomonas aeruginosa* nor *Staphylococcus aureus*, thus the label of the product when offered for sale was false and misleading regarding its control of *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

30. Therefore, Respondent, through its supplemental registrant, committed seven (7) violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.

Sanifil Lemon Quat

31. Respondent is the primary registrant of the antimicrobial pesticide Sanifil Lemon Quat (Lonza Formulation HWS-64, EPA Reg. No. 47371-131).

32. Bortek Industries was authorized to distribute the Sanifil Lemon Quat product as a supplemental registrant (EPA Reg. No. 47371-131-68541).

33. On or about April 6, 2005, an authorized inspector from EPA's Region 3 office inspected Bortek Industries, located at 4713 Old Gettysburg Road, Mechanicsburg, PA, in order to examine and collect samples of pesticides formulated, packaged, labeled and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

34. During the aforementioned inspection, the inspector collected a physical sample of the Sanifil Lemon Quat product and assigned the sample number 05-6-ALEC-1.

35. During the aforementioned inspection, the inspector also collected sales invoices documenting distribution or sale of the Sanifil Lemon Quat product by Bortek Industries on eleven (11) occasions as follows:

Distribution/Sale	Date
1	12/2/2004
2	12/6/2004
3	12/8/2004
4	12/13/2004
5	12/14/2004
6	12/17/2004
7	12/20/2004

8	12/21/2004
9	1/13/2005
10	3/24/2005
11	4/5/2005

36. Sanifil Lemon Quat was an antimicrobial pesticide as defined in Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), in that the product was intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.

37. The Sanifil Lemon Quat antimicrobial pesticide product was registered as a hospital disinfectant; the label of the product bore a claim that the product was effective against *Pseudomonas aeruginosa* and *Staphylococcus aureus.*

38. Efficacy test results of Sanifil Lemon Quat showed the product to be ineffective in controlling *Pseudomonas aeruginosa*, thus the label of the product when offered for sale was false and misleading regarding its control of *Pseudomonas aeruginosa.*

39. Therefore, Respondent, through its supplemental registrant, committed eleven (11) violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.

Quatracide PV-15

40. Respondent is the primary registrant of the antimicrobial pesticide Quatricide PV-15 (Lonza Formulation HWS-256, EPA Reg. No. 47371-129).

41. Pharmacal Research Labs, Inc. was authorized to distribute the Quatricide PV-15 product as a supplemental registrant (EPA Reg. No. 47371-129-08714).

42. On or about March 24, 2006, an authorized inspector from EPA's Region 1 office inspected Pharmacal Research Labs, Inc., located at 562 Captain Neville Drive, Waterbury, CT 06705, in order to examine and collect samples of pesticides

formulated, packaged, labeled and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

43. During the aforementioned inspection, the inspector collected a physical sample of the Quatricide PV-15 product and assigned the sample no. 032406-KT-01.

44. During the aforementioned inspection, the inspector documented distribution or sale by Pharmacal Research Labs, Inc. of the Quatricide PV-15 product on seven (7) occasions as follows:

Distribution/Sale	Date
1	12/22/2005
2	2/1/2006
3	2/6/2006
4	3/28/2006
5	3/10/2006
6	3/13/2006
7	3/23/2006

45. Quatricide PV-15 was an antimicrobial pesticide as defined in Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), in that the product was intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.

46. The Quatricide PV-15 antimicrobial pesticide product was registered as a hospital disinfectant; the label of the product bore a claim that the product was effective against *Pseudomonas aeruginosa* and *Staphylococcus aureus.*

47. Efficacy test results of Quatricide PV-15 showed the product to be ineffective in controlling *Pseudomonas aeruginosa*, thus the label of the product when offered for sale was false and misleading regarding its control of *Pseudomonas aeruginosa.*

48. Therefore, Respondent, through its supplemental registrant, committed seven (7) violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.

CONSENT AGREEMENT

Based upon the foregoing, and pursuant to Sections 22.13(b) and 22.18 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 C.F.R. §§ 22.13(b) and 22.18, it is hereby agreed, and accepted by Respondent that it shall hereafter the date of execution of this Consent Agreement comply with the following terms:

1. For the purposes of this proceeding, Respondent: (i) admits all jurisdictional allegations of the Complaint; and (ii) neither admits nor denies the above Findings of Fact and Conclusions of Law.

2. Respondent shall pay a civil penalty in the amount of **Ninety Thousand Five Hundred Dollars ($90,500)**. Such payment shall be made by cashier's or certified check or by Electronic Fund Transfer (EFT). If the payment is made by check, then the check shall be made payable to the **"Treasurer, United States of America,"** and shall be identified with a notation of the name and docket number of this case as follows: In the Matter of Lonza Inc., Docket No. FIFRA-02-2007-5116

   The check shall be mailed to:

   U.S. Environmental Protection Agency
   Fines and Penalties
   Cincinnati Finance Center
   P.O. Box 979077
   St. Louis, MO 63197-9000

If Respondent chooses to make the payment by EFT, then Respondent shall provide the following information to its remitter bank:

1) Amount of Payment
2) SWIFT address: FRNYUS33, 33 Liberty Street, New York, NY 10045.
3) Account Code for Federal Reserve Bank of New York receiving payment: 68010727.
4) Federal Reserve Bank of New York ABA routing number: 021030004.
5) Field Tag 4200 of the Fedwire message should read "D 68010727 Environmental Protection Agency."
6) Name of Respondent: Lonza Inc.
7) Case Number: FIFRA-02-2007-5116.

Respondent shall also send copies of the check or furnish reasonable proof that electronic payment has been made to each of the following:

Karen L. Taylor, Esq.
Assistant Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th Floor
New York, NY 10007-1866

and

Ms. Karen Maples, Regional Hearing Clerk
Office of the Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th Floor
New York, NY 10007-1866

The payment must be received on or before 45 calendar days after the date of signature of the Final Order, which is located at the end of this CA/FO (the date by which payment must be received shall hereafter be referred to as the "due date").

a. Failure to pay the penalty in full according to the above provisions will result in referral of this matter to the United States Department of Justice or the United States Department of the Treasury for collection.

b. Furthermore, if payment is not received on or before its due date, interest will be assessed at the annual rate established by the Secretary of the Treasury pursuant to the Debt Collection Act, 31 U.S.C. § 3717, on the overdue amount from the due date through the date of payment. In addition, a late payment handling charge of fifteen dollars ($15.00) will be assessed for each thirty (30) day period (or any portion thereof) following the due date in which the balance remains unpaid.

c. A 6% per annum penalty also will be applied on any principal amount not paid within 90 days of the due date.

Supplemental Environmental Project

3. Respondent agrees to begin implementation of the following Supplemental Environmental Project ("SEP") within six (6) months after the date of signature of the Final Order, which the parties agree is intended to secure significant environmental or public health protection and improvements:

Quality Assurance Project: Respondent will evaluate existing formulators of its products to determine whether they satisfy their regulatory obligations, disallowing those that do not from formulating Respondent's products in the future. Of the remaining formulators, Respondent will (a) inspect their physical plants, (b) interview their key personnel to ensure they fully understand the technical and regulatory requirements involved in manufacturing Respondent's products, and (c) review their required documentation. Only those formulators that meet Respondent's established criteria of regulatory, quality assurance, and manufacturing compliance will be permitted to formulate Respondent's products. New

customers requesting the right to formulate Respondent's products under supplemental registration will undergo the same review as existing formulators, including a site visit.

4. Respondent agrees that the SEP shall be implemented (i.e., all formulator reviews, evaluations and inspections), and all the work described in paragraph 3, above, completed within eighteen (18) calendar months from the date of signature of the Final Order at the end of this document or by such later deadline as EPA may in its discretion later establish in writing.

5. Respondent hereby certifies that, as of the date of this CA/FO, Respondent is not required to perform or develop the SEP by any federal, state, or local law or regulation; nor is Respondent required to perform or develop the SEP by agreement, grant, or as injunctive relief in this or any other case or in compliance with state or local requirements. Respondent further certifies that Respondent has not received, and is not presently negotiating to receive, credit in any other enforcement action for the SEP.

6. The total expenditure for the SEP shall be not less than **Three Hundred Ninety Thousand Dollars ($390,000)** in allowable and appropriate SEP-related costs. Respondent shall provide EPA with documentation of the expenditures made in connection with the SEP in a SEP Completion Report on or by 2 years after the date of signature of the Final Order. Said documentation shall be mailed to:

Dr. Adrian J. Enache, Ph.D., MPH,
Leader, Pesticides Team
U.S. Environmental Protection Agency, Region 2
2890 Woodbridge Avenue – MS-500
Edison, NJ 08837

7. The SEP Completion Report shall include at a minimum: (i) a detailed description of the SEP as implemented; (ii) itemized costs, documented by copies of purchase orders and receipts or canceled checks for purchases and monies expended on the SEP (if documentation has been previously provided with a Progress Report, it will suffice to refer to the prior submittal); (iii) outcomes in numeric format and if problems were found, list the specific corrective actions taken by Respondent, without identifying the companies; (iv) a description of any logistical problems encountered and the solutions thereto; and (v) a description of the environmental and public health benefits resulting from implementation of the SEP (with quantification of the benefits, if feasible).

8. Respondent shall provide EPA with semiannual Progress Reports, on the form in Attachment A, the Lonza Supplemental Environmental Project Semiannual Progress Report, starting 6 months after the date of signature of the Final Order, until the reviews, inspections and evaluations and remaining aspects of the SEP is completed. The Progress Reports shall inform EPA of Respondent's efforts to achieve milestones for the SEP and shall document the expenditures that Respondent has made in connection with the SEP. All invoices and documents related to the SEP and created or paid or received by Respondent during the reporting period shall be enclosed with the Progress Reports when transmitted to EPA. Respondent shall send each Progress Report to the addressee specified in paragraph 6 above.

9. Respondent shall maintain in one central location legible copies of non-confidential documentation concerning the development, implementation and financing of the

SEP and non-confidential documentation supporting information in any and all documents or reports submitted to EPA pursuant to this CA/FO, including the Progress Reports and SEP Completion Report. Respondent shall grant EPA access to such documentation. Respondent shall provide a copy of such documentation to EPA within seven (7) days of a request for such information.

10. In all documents or reports, including, without limitation, the Progress Reports and the SEP Completion Report, submitted to EPA pursuant to this CA/FO, Respondent shall, by its authorized representative, sign and certify under penalty of law that the information contained in such document or report is true, accurate, and not misleading by signing the following statement:

> I certify under penalty of law that I have examined and am familiar with the information submitted in this document and all attachments and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment.

11. Following receipt of each Progress Report and the SEP Completion Report, EPA will either (i) accept the report, or (ii) reject the report, notify Respondent in writing of deficiencies in the report and grant Respondent an additional thirty (30) days in which to answer EPA's questions and/or to correct any deficiencies in the implementation of the SEP or the reports; or (iii) reject the report and find Respondent in violation of this CA/FO.

12. If EPA elects to exercise option (ii) or (iii) in paragraph 11, above, EPA shall permit Respondent the opportunity to object in writing to the notification of deficiency or disapproval given pursuant to that paragraph within ten (10) days of receipt of such

notification. EPA and Respondent shall have an additional 30 days from the due date of Respondent's notification of objection to reach agreement. If agreement cannot be reached on any such issue within this 30-day period, EPA shall provide a written statement of its decision to Respondent, which decision shall be final and binding upon Respondent. Respondent agrees to comply with any requirements imposed by EPA as a result of any such deficiency or failure to comply with the terms of this Consent Agreement and Final Order. In the event the SEP is not completed as contemplated herein, stipulated penalties shall be due and payable by Respondent to EPA in accordance with paragraph 15 below.

13. If in the future EPA believes that any of the information certified to, pursuant to paragraphs 5 and 10, above, was inaccurate, EPA will so advise the Respondent of its belief and its basis for such, and will afford Respondent an opportunity to respond to EPA. If EPA determines that the certification is inaccurate, Respondent shall pay a stipulated penalty in the amount of two hundred and seventy-one thousand five hundred dollars ($271,500) within sixty (60) days of receipt of EPA's determination, using the same procedure specified in paragraph 2, above, and shall include a statement noting the payment is a stipulated penalty pursuant to this provision. This payment shall not preclude EPA from initiating a separate criminal investigation pursuant to 18 U.S.C. § 1001 et seq., or any other applicable law.

14. The determination of whether the SEP has been satisfactorily completed, whether the Respondent has made good faith, timely effort to implement the SEP and whether costs are creditable to the SEP shall be in the sole determination of EPA.

15. In the event that Respondent fails to comply with any of the terms or provisions of this CA/FO relating to the performance of the SEP described in paragraph 3, above, and/or to the extent that the actual expenditures for the SEP do not equal or exceed the cost of the SEP described in paragraph 6, above, Respondent shall be liable for stipulated penalties according to the provisions set forth below:

(i) Except as provided in subparagraphs (ii) and (iii) immediately below, if the SEP has not been completed satisfactorily, Respondent shall pay a stipulated penalty in the amount of **Two Hundred Seventy One Thousand Five Hundred Dollars ($271,500)**. Payment shall be transmitted using the same procedure specified in paragraph 2, above.

(ii) If the SEP is not completed satisfactorily, but Respondent: a) made good faith and timely efforts to complete the project; and b) certifies, with supporting documentation, that at least ninety (90) percent of the amount of money which was required to be spent was expended on the SEP, Respondent shall not pay any stipulated penalty.

(iii) If the SEP is satisfactorily completed, but Respondent spent less than ninety (90) percent of the amount of money required to be spent for the project, Respondent shall pay a stipulated penalty in the amount determined as follows:

$$\text{Stipulated penalty} = \left[1 - \frac{\$ \text{ allowable SEP costs expended}}{\$390{,}000} \right] \times \$271{,}500$$

(iv) For failure to submit any Progress Report and/or SEP Completion Report required by paragraphs 6, 7, and 8, above, Respondent shall pay a stipulated

penalty in the amount of $50 for each day after the due date until the report is submitted.

16. Stipulated penalties described above shall begin to accrue on the day after performance is due, and shall continue to accrue through the final day of the completion of the activity.

17. Respondent shall pay stipulated penalties within 30 days of receipt of written demand by EPA for such penalties. The method of payment and applicable interest and late charges shall be in accordance with the provisions of paragraph 2, above.

18. The Director of the Division of Enforcement and Compliance Assistance may, in his or her discretion, reduce or eliminate any stipulated penalties specified above, if Respondent has in writing demonstrated to EPA's satisfaction good cause for such action.

19. If any event occurs which causes or may cause delays in the completion of the SEP as required under this Consent Agreement, Respondent shall notify EPA in writing within 10 days of the delay or Respondent's knowledge of the anticipated delay, whichever is earlier.

a. The notice shall describe in detail the anticipated length of delay, the precise cause of delay, the measures taken by Respondent to prevent or minimize delay, and the timetable by which those measures will be implemented. Respondent shall adopt all reasonable measures to avoid or minimize any such delay. Failure by Respondent to comply with the notice requirements of this paragraph shall render this paragraph void and of no effect as to the particular

incident involved and constitute a waiver of Respondent's right to request an extension of its obligation under this Consent Agreement based on such incident.

b. If the parties agree that the delay or anticipated delay in compliance with this Consent Agreement has been or will be caused by circumstances entirely beyond the control of Respondent, the time for performance hereunder may be extended for a period no longer than the delay resulting from such circumstances. In such event, the parties shall stipulate to such extension of time.

c. In the event that EPA does not agree that a delay in achieving compliance with the requirements of this Consent Agreement has been or will be caused by circumstances beyond the control of Respondent, EPA will notify Respondent in writing of its decision and any delays in completion of the SEP shall not be excused.

d. The burden of proving that any delay is caused by circumstances entirely beyond the control of Respondent shall rest with Respondent. Increased cost or expenses associated with the implementation of actions called for by this Consent Agreement shall not, in any event, be a basis for changes in this Consent Agreement or extensions of time under section b. of this paragraph. Delay in achievement of one interim step shall not necessarily justify or excuse delay in achievement of subsequent steps.

20. Any public statement, oral or written, made by Respondent making reference to the SEP shall include the following language: "This project was undertaken in connection with the settlement of an enforcement action taken by the U.S.

Environmental Protection Agency for violations of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. Section 136j(a)(1)(E)."

21. This CA/FO is being voluntarily and knowingly entered into by the parties to resolve (conditional upon full payment of the civil penalty herein and upon the accuracy of Respondent's certifications in this proceeding) the civil and administrative claims alleged in the Complaint. Nothing herein shall be read to preclude the EPA or the United States, however, from pursuing appropriate injunctive or other equitable relief or criminal sanctions for any violation of law. Respondent has read the Consent Agreement, understands its terms, and consents to its issuance and its terms. Respondent consents to the issuance of the accompanying Final Order. Respondent agrees that all terms of the settlement are set forth herein.

22. This CA/FO does not waive, extinguish, or otherwise affect Respondent's obligation to comply with all applicable provisions of FIFRA and the regulations promulgated thereunder.

23. Respondent explicitly and knowingly consents to the assessment of the civil penalty and stipulated penalties as set forth in this Consent Agreement, and agrees to pay these penalties in accordance with the terms of this Consent Agreement.

24. The civil penalties and stipulated penalties provided herein are penalties within the meaning of Title 26, Section 162(f) of the United States Code, 26 U.S.C. § 162(f), and are not deductible expenditures for purposes of federal, state or local law.

25. For Federal Income Tax purposes, Respondent agrees that it will neither capitalize into inventory or basis nor deduct any costs or expenditures included in the SEP expenditures reported to EPA under this CAFO.

26. Respondent explicitly and knowingly waives its right to request or to seek any Administrative Hearing in the above captioned matter, on the Complaint or on any of the allegations therein asserted, on the Findings of Fact and Conclusions of Law herein, or on the accompanying Final Order.

27. Respondent explicitly waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during discussions with or to be served with and to reply to any memorandum or communication addressed to the Regional Administrator or the Deputy Regional Administrator where the purpose of such discussion, memorandum, or communication is to discuss a proposed settlement of this matter or to recommend that such official accept this CA/FO.

28. Each undersigned signatory to this Consent Agreement certifies that he or she is duly and fully authorized to enter into and ratify this Consent Agreement and all the terms and conditions set forth in this Consent Agreement.

29. The provisions of this CA/FO shall be binding upon Respondent, its officers, directors, agents, servants, authorized representatives and successors, or assigns.

30. Each party hereto agrees to bear its own costs and fees in this matter.

31. Respondent consents to service upon Respondent by a copy of this CA/FO by an EPA employee other than the Regional Hearing Clerk.

32. Pursuant to 40 C.F.R. § 22.31(b), the effective date of the Final Order herein shall be the date when filed with the Regional Hearing Clerk of the United States Environmental Protection Agency, Region 2.

RESPONDENT: **Lonza Inc.**

BY: _____
(Authorized Signature)

NAME: **Joseph R. Robinson**
(PLEASE PRINT)

TITLE: **Vice President Regulatory Services**

DATE: **6/25/08**

COMPLAINANT:

_____
Dore LaPosta, Director
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency - Region 2
290 Broadway
New York, NY 10007-1866

DATE: JUNE 26, 2008

In the Matter of Lonza Inc.
Docket No. FIFRA-02-2007-5116

FINAL ORDER

The Regional Administrator of the U.S. Environmental Protection Agency, Region 2, ratifies the foregoing Consent Agreement. The Consent Agreement, entered into by the parties to this matter, is hereby approved, incorporated herein, and issued as an Order. The effective date of this Order shall be the date of filing with the Regional Hearing Clerk, U.S. EPA, Region 2, New York, New York.

for

Alan J. Steinberg
Regional Administrator
U.S. Environmental Protection Agency - Region 2
290 Broadway
New York, NY 10007-1866

DATE: 6/27/08

In the Matter of Lonza Inc.
Docket No. FIFRA-02-2007-5116

CERTIFICATE OF SERVICE

I certify that I have this day caused to be sent the foregoing fully executed CONSENT AGREEMENT and FINAL ORDER, bearing the above-referenced docket number, in the following manner to the respective addressees below:

Original and One Copy
by Hand:

Office of the Regional Hearing Clerk
U.S. Environmental Protection Agency - Region 2
290 Broadway, 16th floor
New York, NY 10007-1866

Copy by Certified Mail,
Return Receipt Requested:

Cynthia L. Taub, Esq.
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

Dated: JUL - 9 2008
New York, NY

Millicent N. Bae

Attachment A

Lonza Supplemental Environmental Project Semiannual Progress Report

Lonza Supplemental Environmental Project Semiannual Progress Report

I. SEP Milestones

A. Qualification questionnaire (copy attached as Attachment 1).

1. Dates sent

2. Response rate

3. Description of issues raised by questionnaire responses

B. Follow up to Questionnaires

1. Number of formulators who were denied right to formulate due to nonresponsiveness

2. Actions taken based on questionnaire responses

a. Number of formulators who were denied right to formulate due to issues raised by the "paper audit"

b. Other actions based on questionnaire responses

C. Site visits

1. Dates

2. Summary of site visit results: 1) number of formulators who passed review, 2) outcomes in numeric format and if problems were found, list the specific corrective actions taken by Lonza, without identifying the companies, or 3) number of formulators who were denied right to formulate based on site visit.

D. Follow up to site visits

II. SEP Expenditures to Date

The total cost of this program to date has been $_____. Please see the spreadsheet at Attachment 2 for a detailed breakdown of the SEP expenditures and supporting documentation.