



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

SEP 21 2010

VIA EXPRESS MAIL

William Goodwine
Janssen PMP
1126 Trenton Harbourton Road
Office A32108
Titusville, New Jersey 08560-0200

Re: In the Matter of Janssen PMP, Docket No. FIFRA-02-2010-5108

Dear Mr. Goodwine:

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 ("EPA"), Region 2.

Please assure that your client makes arrangement for payment of the civil penalty in accordance with the timeframe specified in the CA/FO.

Thank you in advance for your cooperation in this matter. If you have any questions, please contact me at (212) 637-3224.

Sincerely yours,

Bruce H. Aber
Assistant Regional Counsel

Enclosure

cc: Karen Maples, Region 2 Regional Hearing Clerk
Marcedius Jameson, NJDEP
Edward Ruckert, Esq.

U.S. ENVIRONMENTAL
PROTECTION AGENCY
2010 SEP 21 P 2:27
REGIONAL HEARING
CLERK

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of

Janssen PMP,

Respondent.

Proceeding Under the Federal
Insecticide, Fungicide and
Rodenticide Act, as amended.

**CONSENT AGREEMENT
AND FINAL ORDER**

Docket No. FIFRA-02-2010-5108

U.S. ENVIRONMENTAL
PROTECTION AGENCY REGION 2
2010 SEP 21 P 2:27
FEDERAL HEARING
OFFICE

PRELIMINARY STATEMENT

This administrative proceeding for the assessment of a civil penalty is initiated pursuant to Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. Section 136l(a) (hereinafter referred to as "FIFRA" or the "Act"), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, 40 C.F.R. Part 22 (hereinafter "CROP"). Complainant in this proceeding is the Director of the Division of Enforcement and Compliance Assistance, United States Environmental Protection Agency, Region 2 ("EPA"). Pursuant to Section 22.13(b) of the CROP, where the parties agree to settlement of one or more causes of action before filing of an Administrative Complaint, a proceeding may be simultaneously commenced and concluded by issuance of a Consent Agreement and Final Order ("CA/FO") pursuant to 40 C.F.R. Sections 22.18(b)(2) and 22.18(b)(3). Complainant and Respondent agree that settling this matter by entering into this CA/FO pursuant to 40 C.F.R. Sections 22.13(b), 22.18(b)(2) and 22.18(b)(3) of the CROP, is an appropriate means of resolving this matter without litigation.

EPA'S FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Respondent is Janssen PMP (Preservation & Material Protection), a division of Janssen Pharmaceutica NV (hereinafter "Janssen" or "Respondent"), a subsidiary of Johnson & Johnson.
2. Janssen devises and formulates chemical compounds to: protect fresh fruit and vegetables; preserve wood and wood products; provide antifouling agents for shipping; and protect a wide range of fluids and materials in industrial applications.
3. Respondent is a "person" as that term is defined in FIFRA Section 2(s), 7 U.S.C. Section 136(s), and as such, is subject to FIFRA and the regulations promulgated thereunder.
4. Respondent maintains and/or operates an "establishment" as defined in Section 2 (dd) of FIFRA, 7 U.S.C. Section 136(dd), located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560-0200.
5. Respondent is a "producer" within the meaning of Section 2(w), 7 U.S.C. Section 136(w).

6. Section 2(u) of FIFRA, 7 U.S.C. Section 136(u), defines the term “pesticide” as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.
7. Section 2(t) of FIFRA, 7 U.S.C. Section 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.
8. Respondent is the registrant of the pesticide PENBOTEC 400 SC (EPA Reg. No. 43813-32).
9. PENBOTEC 400 SC is a post-harvest fungicide containing Pyrimethanil as an active ingredient and has an EPA approved tolerance level for applications on pome fruit, such as pears and apples.
10. Pursuant to Section 2 (c)(2) of FIFRA, 7 U.S.C. Section 136(c)(2), the term “adulterated” applies to any pesticide if “. . . (2) any substance has been substituted wholly or in part for the pesticide. . . .”
11. On February 16, 2010, the Respondent became aware that during the manufacturing process of PENBOTEC 400 SC, three batches of product became cross-contaminated with the chemical, Imazalil.

12. The batches of PENBOTEC 400 SC containing Imazalil are: Fill Lot No. GA215559EXA008; Fill Lot No. GA215559EXA009; and Fill Lot No. EA215559EXA007.
13. Imazalil is an active ingredient in other post-harvest fungicide products registered for use on citrus in the United States, but it is not an active ingredient in any pesticide registered for application on pome fruit and EPA has not established a tolerance level for Imazalil on pome fruit.
14. The pesticide, PENBOTEC 300 SC, was adulterated with the chemical Imazalil.
15. Pursuant to Section 6(a)(2) of FIFRA, if at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to EPA.
16. On February 22, 2010, Respondent filed a report to EPA headquarters under FIFRA Section 6(a)(2) about the possible unreasonable adverse effects of adulterated PENBOTEC 400 SC on the environment.
17. On February 23, 2010, Respondent voluntarily notified Complainant that on approximately Feb 16, 2010 the Respondent became aware of possible contamination for certain of its PENBOTEC 400 SC (EPA Reg. No. 43813-32) post-harvest fungicide batches with the Imazalil fungicide.

18. During February through June 2010, investigations were conducted by states and EPA regional offices to identify stocks of adulterated PENBOTEC 400 SC
19. On March 12, 2010, EPA issued an information request letter (“IRL”) pursuant to Sections 8 and 9 of FIFRA, requesting information and records regarding the sale or distribution of the pesticide PENBOTEC 400 SC.
20. On March 29, 2010, Respondent provided a response to the IRL documenting the sales or distributions of the cross-contaminated batches of PENBOTEC 400 SC.
21. Respondent has a contract manufacturing arrangement with Stahler Agrochemie GMBH & Co. KG (“Stahler”), a German company, for the manufacture of PENBOTEC 400 SC.
22. “To distribute or sell” is defined by Section 2(gg) of FIFRA, 7 U.S.C. Section 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.”
23. Respondent is a “distributor or seller” within the meaning of Section 2(gg) of FIFRA, 7 U.S.C. Section 136(gg).
24. Respondent distributed or sold the adulterated pesticide, PENBOTEC 400 SC, to various persons on fourteen occasions from July 2009 to February 2010.

25. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. Section 136j(a)(1)(E), states that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is adulterated within the meaning of Section 2(c) of FIFRA, 7 U.S.C. Section 136(c).
26. On April 7, 2010, Complainant issued a Stop Sale, Use or Removal Order (Docket No. 02-2010-5103) (hereinafter "SSURO") to Respondent.
27. The SSURO prohibited the sale, use or removal of all quantities and sizes of the adulterated pesticide PENBOTEC 400 SC (EPA Reg. No. 43813-32), including any supplementally registered products which are adulterated with the chemical Imazalil.
28. Pursuant to the SSURO Respondent reacquired ownership, control or custody of the PENBOTEC 400 SC covered by the SSURO and identified the amount within the company's ownership, control or custody at each product location.
29. On July 9, 2010, Respondent provided documentation to substantiate the disposition of the adulterated pesticide PENBOTEC 400 SC subject to the SSURO, such as evidence of removal, transport and disposal of the products off-site to a licensed RCRA treatment, storage and disposal (TSD) facility.
30. Respondent's sales or distributions during 2009 and 2010 of the adulterated pesticide, PENBOTEC 400 SC, to various persons on fourteen occasions,

constitutes unlawful acts under Section 12(a)(1)(E) of FIFRA, 7 U.S.C. Section 136j(a)(1)(E).

31. The Agency has conducted a risk assessment of the adulterated pesticide, PENBOTEC 400 SC and has determined that this adulterated pesticide did not result in any dietary risks of concern.

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 that:

1. Respondent shall hereafter maintain compliance with the statutory provisions of FIFRA, as amended, 7 U.S.C. Section 136 et seq., and its implementing regulations.
2. Respondent's signatory certifies on behalf of the Respondent that, as of the effective date of this Consent Agreement, the manufacturing problems associated with the production of PENBOTEC 400 SC (EPA Reg. No. 43813-32), whereby cross-contamination with the active ingredient Imazalil occurred, have been corrected and production procedures, including all necessary Quality

Assurance/Quality Control measures, have been implemented, in order to ensure that the manufacture of this pesticide is in compliance with FIFRA.

3. Additionally, Respondent's signatory certifies on behalf of the Respondent that, as of the effective date of this Consent Agreement, the Respondent is no longer producing and/or selling or distributing any adulterated PENBOTEC 400 SC pesticide products.
4. If in the future EPA believes that any information certified to, pursuant to paragraphs 2 or 3 above, of the Consent Agreement, is untrue or inaccurate, EPA will so advise the Respondent of its belief and basis, and will afford the Respondent thirty (30) days to submit comments to EPA or correct any alleged untrue or inaccurate certification. If, after consideration of Respondent's reply, EPA determines that the certification(s) is untrue or inaccurate, Respondent shall be liable to EPA for a stipulated penalty of \$25,000 for each certification that EPA determines was untrue or inaccurate. EPA may also initiate a separate criminal investigation pursuant to 18 U.S.C. Section 1001 et seq. or any other applicable law.
5. Respondent shall pay, by cashier's or certified check, or by electronic fund transfer, a civil penalty in the amount of One Hundred and Five Thousand Dollars (\$105,000) in settlement of this case. If payment is by cashier's or

certified check, such payment shall be payable to the "Treasurer, United States of America."

The check shall be identified with the notation of the name and docket number of this case as follows: In the Matter of Janssen PMP, Docket No. FIFRA-02-2010-5108.

The check shall be mailed to:

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

WIRE TRANSFER

If Respondent chooses to pay by electronic fund transfer ("EFT"), Respondent shall provide the following information to the remitter bank (Federal Reserve Bank of New York):

- A) Amount of Payment (\$105,000.00)
- B) SWIFT address = FRNYUS33
33 Liberty Street
New York, N.Y. 10045
- C) Account Code for Federal Reserve Bank of New York (receiving payment) = 68010727
- D) Federal Reserve Bank of New York ABA routing number = 021030004
- E) Field Tag 4200 of the Fedwire message should read "D 68010727 Environmental Protection Agency"

- F) Name of Respondent (Janssen PMP)
- G) Case Docket Number (FIFRA-02-2010-5108)

Respondent shall also send a proof of the payment to:

Bruce Aber
Assistant Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th Floor
New York, N.Y. 10007-1866; and

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

The check must be received at the above address, or the EFT must be received by the Federal Reserve Bank of New York, on or before 45 calendar days after the date of the Regional Administrator's signature on 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 or other appropriate action.
- b. Furthermore, if the 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 its due date. Any such non-payment penalty charge on the debt will accrue from the date the penalty payment becomes due and is not paid.
 - d. If Respondent fails to pay the civil penalty within thirty (30) days of its due date, Respondent shall also be liable to the United States for an additional stipulated penalty of Fifty Thousand Dollars (\$50,000) for such failure unless, on or before the due date, Respondent has submitted to EPA a writing that demonstrates to EPA's satisfaction good cause for such failure, as provided in paragraph 7 of this Consent Agreement.
 - e. Pursuant to 40 C.F.R. Section 22.31(b), the effective date of this Consent Agreement and Final Order shall be the date of filing with the Regional Hearing Clerk, U.S. E.P.A. Region 2, New York, New York.
6. All stipulated penalties are due and payable within forty-five (45) calendar days of Respondent's receipt from EPA of a written demand for payment. All

stipulated penalty payments shall be made in accordance with the payment instructions in paragraph 5. Penalties shall accrue as provided below regardless of whether EPA has notified the Respondent of the violation or made a demand for payment, but need only be paid upon demand. Any payment of stipulated penalties shall be in addition to any other payments required under any other paragraph of this CA/FO. Nothing in this CA/FO, including payment of penalties identified in this CA/FO, shall preclude EPA from initiating a separate criminal investigation pursuant to 18 U.S.C. Section 1001 et seq. or any other applicable law. Failure to pay any stipulated penalty in full will result in referral of this matter to the United States Department of Justice or the United States Department of Treasury for collection and/or appropriate action.

7. The Complainant may, in her sole discretion, reduce or eliminate any stipulated penalty due under this CA/FO if Respondent has, in writing, demonstrated to EPA's satisfaction good cause for such action by EPA. If, after review of Respondent's submission, Complainant determines that Respondent has failed to comply with the provisions of this Consent Agreement, and Complainant does not, in her sole discretion, eliminate the stipulated penalties demanded by EPA, Complainant will notify Respondent, in writing, that either the full stipulated penalty or a reduced stipulated penalty must be paid by Respondent. Respondent shall pay the stipulated penalty amount indicated in EPA's notice within

thirty (30) calendar days of its receipt of such written notice from EPA. Failure of Respondent to pay any stipulated penalty demanded by EPA pursuant to this Consent Agreement may result in further action by EPA.

8. Respondent has read the Consent Agreement, understands its terms, finds it to be reasonable and consents to the issuance and its terms. Respondent consents to the issuance of the accompanying Final Order. Respondent agrees that all terms of settlement are set forth herein.
9. For the purpose of this proceeding and in the interest of an expeditious resolution of this matter, Respondent (a) admits that EPA has jurisdiction pursuant to Section 14 of FIFRA, 7 U.S.C. Section 136l(a), to commence a civil administrative proceeding for the allegations in the EPA Findings of Fact and Conclusions of Law section above; and (b) neither admits nor denies any allegations in the EPA Findings of Fact and Conclusions of Law contained herein.
10. The civil penalty and any applicable stipulated penalties provided for 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.
11. This Consent Agreement is being voluntarily and knowingly entered into by the Complainant and Respondent to resolve (conditional upon full payment of the civil penalty herein, any applicable stipulated penalty that becomes due, the

performance of obligations set forth in the Consent Agreement, and the accuracy of the Respondent's representations in this proceeding) the civil and administrative claims alleged in this Consent Agreement. Nothing herein shall be read to preclude EPA or the United States, on behalf of EPA, however, from pursuing appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

12. Respondent explicitly and knowingly consents to the assessment of the civil penalty and any applicable stipulated penalties as set forth in this Consent Agreement and agrees to pay the civil penalty and any applicable stipulated penalties in accordance with the terms of this Consent Agreement.
13. Respondent explicitly and knowingly waives its right to request or to seek any Hearing on this Consent Agreement or on the Findings of Fact and Conclusions of Law herein, or on the accompanying Final Order.
14. The Respondent agrees not to contest the validity or any term of this CA/FO in any action brought: a) by the United States, including EPA, to enforce this CA/FO; or b) to enforce a judgment relating to this CA/FO.
15. Respondent waives its right to appeal this Consent Agreement and the accompanying Final Order.
16. This Consent Agreement and any provision herein shall not be construed as an admission of liability in any criminal or civil action or other administrative

proceeding, except in an action or proceeding to enforce or seek compliance with this Consent Agreement and its accompanying Final Order.

17. 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, Deputy Regional Administrator, or Regional Judicial Officer for Region 2, 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 Consent Agreement and issue the attached Final Order.
18. This Consent Agreement and Final Order does not relieve Respondent of its obligations to comply with all applicable provisions of federal, state or local law, nor shall it be construed to be a ruling on, or a determination of, any issue related to any federal, state or local permit. This Consent Agreement and Final Order does not waive, extinguish, or otherwise affect Respondent's obligation to comply with all applicable provisions of FIFRA and the regulations promulgated thereunder.
19. Nothing in this Consent Agreement and Final Order shall be construed as a release from any other action under any law and/or regulation administered by EPA.
20. 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 Final Order and all the terms and conditions set forth in this Consent Agreement and Final Order.

21. The provisions of this Consent Agreement and Final Order shall be binding upon both EPA and Respondent, its officers/officials, agents, authorized representatives and successors or assigns.
22. Any failure by Respondent to perform fully any requirement herein will be considered a violation of this CA/FO, and may subject Respondent to a civil judicial action by the United States to enforce the provisions of this CA/FO.
23. Each party hereto agrees to bear its own costs and fees in this matter.
24. Respondent consents to service upon itself of a copy of this Consent Agreement and Final Order by an EPA employee other than the Regional Hearing Clerk.

In the Matter of Janssen PMP FIFRA-02-2010-5108

RESPONDENT: Janssen PMP

BY: 
(Signature)

NAME: Thierry DEMONCHEAUX
(Please Print)

TITLE: VP Allied Business &
Sourcing

DATE: 14 / 09 / 2010



CHRIS VAES
VP Finance
14 / 09 / 2010

In the Matter of Janssen PMP, FIFRA-02-2010-5108

COMPLAINANT:

Dore F. LaPosta

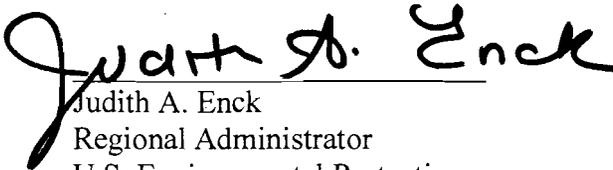
Dore F. LaPosta, Director
Division of Enforcement
and Compliance Assistance
U.S. Environmental Protection
Agency - Region 2

DATE: 9/15/10

In the Matter of Janssen PMP, FIFRA-02-2010-5108

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, United States Environmental Protection Agency, Region 2, New York, New York.



Judith A. Enck
Regional Administrator
U.S. Environmental Protection
Agency - Region 2
290 Broadway, 26th Floor
New York, New York 10007

DATE: 9/17/10

In the Matter of Janssen PMP, FIFRA-02-2010-5108

CERTIFICATE OF SERVICE

I certify that I have this day caused to be sent the foregoing fully executed Consent Agreement and Final Order ("CA/FO"), bearing the above-referenced docket number, in the following manner to the respective addressees listed below:

Original and Copy
By Hand Delivery:

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

Copy by Certified Mail/
Return Receipt Requested:

William Goodwine
Janssen PMP
1126 Trenton Harbourton Road
Office A32108
Titusville, NJ 08560-0200

Dated: Sep 21, 2010
New York, New York

