



violations of the Pennsylvania Fish and Boat Code, Act of October 16, 1980, P.L. 996, *as amended*, 30 Pa. C.S.A. §§ 101-7314 ("Fish and Boat Code");

WHEREAS, Merck owns and operates a pharmaceutical and vaccine research and manufacturing facility located in West Point, Montgomery County, Pennsylvania as defined in paragraph 6(f) below and discharges wastewater containing pollutants from the facility to the Publicly Owned Treatment Works ("POTW") owned and operated by Upper Gwynedd Township ("UGT POTW") located in West Point, Pennsylvania, and to the POTW owned and operated by Upper Gwynedd Towamencin Municipal Authority ("UGTMA") located in Towamencin Township, PA;

WHEREAS, Merck is regulated as a significant industrial user and source of "Indirect Discharge" of non-domestic wastewater and pollutants under Section 307 of the CWA and the implementing regulations covering the Pharmaceutical Manufacturing Point Source Category, of the National Categorical Pretreatment Standards as set forth in 40 C.F.R. Part 439, Subparts B, D and E;

WHEREAS, pursuant to Section 402 of the CWA, 33 U.S.C. § 1342, EPA has authorized the Commonwealth to administer the National Pollutant Discharge Elimination System ("NPDES") in Pennsylvania;

WHEREAS, PADEP has issued an NPDES permit to Upper Gwynedd Township authorizing the discharge of pollutants pursuant to the terms and conditions set forth in National Pollutant Discharge Elimination System (NPDES) permit PA0023256;

WHEREAS, the United States alleges that on certain occasions between June 1, 2006 and August 31, 2006 as described in the Complaint, Defendant has violated Section 307 of the CWA, 33 U.S.C. § 1317, by discharging pollutants causing pass through and interference at UGT POTW as well as other requirements of the applicable pretreatment program;

WHEREAS, PADEP alleges that on certain occasions between June 1, 2006 and August 31, 2006 as described in its Complaint, Defendant has violated Sections 301, 307, and 401 of the Clean Streams Law, 35 P.S. §§ 691.301, 691.307, 691.401, by discharging pollutants

to the waters of the Commonwealth; 25 Pa. Code § 91.34(a), by failing to take necessary measures to prevent pollutants from reaching the waters of the Commonwealth, and that these violations constitute unlawful conduct under Section 611 of the Clean Streams Law, 35 P.S. § 691.611;

WHEREAS, PADEP alleges that on one or more occasions between June 1, 2006 and August 31, 2006 as described in its Complaint, Defendant has violated Sections 301, 302(a) and 302(b) of the Solid Waste Management Act, 35 P.S. §§ 6018.301, 6018.302(a) and 6018.302(b), by disposing of waste in an unauthorized manner, and that these violations constitute unlawful conduct pursuant to Section 610(4) of the Solid Waste Management Act, 35 P.S. § 6018.610(4);

WHEREAS, PADEP alleges that on certain occasions between June 1, 2006 and August 31, 2006 as described in its Complaint, Defendant has violated Section 721.13(j)(3) of the Safe Drinking Water Act, 35 P.S. 721.13(j)(3), by introducing a contaminant into the source water which directly supplies two of the City of Philadelphia Water Department's surface water treatment plants;

WHEREAS, PFBC alleges that on one or more occasions between June 1, 2006 and August 31, 2006 as described in its Complaint, Defendant has violated Section 2504 of the Fish and Boat Code, 30 Pa. C.S.A. § 2504, by allowing a substance deleterious to fish to be allowed to flow into water within the Commonwealth;

WHEREAS, Defendant denies the allegations set forth in the Complaints;

WHEREAS, the Parties have negotiated in good faith and without an admission of liability have reached a settlement of the issues raised in the Complaints; and

WHEREAS, the Parties agree, and the Court finds, that settlement of the claims alleged in the Complaints without further litigation or trial of any issues is fair, reasonable and in the public interest and that the entry of this Consent Decree is the most appropriate way of resolving the claims alleged in the Complaints.

NOW THEREFORE, it is hereby ORDERED, ADJUDGED and DECREED as follows:

## **I. JURISDICTION AND VENUE**

1. This Court has jurisdiction over the subject matter of this action and over the Parties to this action pursuant to Section 309(b) of the Clean Water Act, 33 U.S.C. § 1319(b), and 28 U.S.C. § 1331. The Complaints state claims upon which relief may be granted against the Defendant for injunctive relief and civil penalties under Section 309 of the Clean Water Act, 33 U.S.C. § 1319; Sections 601 and 605 of the Clean Streams Law, 35 P.S. §§ 691.601 and 691.605; Sections 604 and 605 of the Solid Waste Management Act, 35 P.S. §§ 6018.604 and 6018.605; Section 721.13(g) of the Safe Drinking Water Act, 35 P.S. § 721.13(g) and Section 2506 of the Fish & Boat Code, 30 Pa. C.S.A. § 2506. Venue is proper in this District pursuant to Section 309(b) of the Clean Water Act, 33 U.S.C. § 1319(b), and 28 U.S.C. §§ 1391(b) and 1395(a), because Defendant is doing business in this district and because the violations alleged herein occurred in this judicial district. Defendant waives any and all objections or defenses that it might have to the Court's jurisdiction to enter and enforce this Consent Decree or to venue in this District.

## **II. BINDING EFFECT**

2. The provisions of this Consent Decree shall apply to and be binding on the United States, the Commonwealth of Pennsylvania and on Merck and its successors, and assigns.

3. Within thirty (30 ) days from the Date of Entry of this Consent Decree and until its termination, Defendant shall give written notice of and provide a copy of this Consent Decree to any person or entity to whom Defendant may transfer ownership or operation of any portion of the Facility as defined herein. In addition to any provisions for notification of transfer under Merck's industrial user permit, the Defendant shall notify EPA, PADEP and the United States Department of Justice in writing of any successor in interest at least twenty-one (21) days prior to any such transfer. No transfer of ownership or operation of the Facility shall relieve Defendant of its obligations to ensure that the terms of this Consent Decree are implemented. No transfer of ownership or operation of the Facility shall relieve Defendant from liability for

any violation of this Consent Decree prior to the date of such transfer. Defendant shall condition any transfer of ownership or operation of the Facility upon the execution by the transferee of a modification to this Consent Decree, which makes the terms and conditions of this Decree that apply to Defendant apply to the transferee. Defendant shall remain liable for any and all assessed civil penalties and stipulated penalties that are assessed prior to the effective date of the transfer but not for any that are assessed thereafter if they relate to the transferee's operations. Until Defendant has paid any and all outstanding civil and/or stipulated penalties demanded by Plaintiffs, Defendant shall remain subject to the jurisdiction of the Court for such payment as provided in this Decree.

4. Except as provided in paragraph 3 above, Defendant shall be solely responsible for ensuring that performance of the obligations that Defendant is required to perform under this Consent Decree is undertaken in accordance with the deadlines and requirements contained in this Consent Decree, and the Appendices hereto. Any action taken by any contractor or consultant retained to implement Defendant's duties under this Consent Decree shall be considered an action of Defendant for purposes of determining compliance with this Consent Decree. In an action to enforce this Consent Decree, except as provided in Section XIII (Force Majeure) of this Consent Decree, Defendant shall not assert as a defense against Plaintiffs any act or failure to act by any of its officers, managers, employees, agents, contractors, successors and assigns; however, this Consent Decree shall not limit Defendant's right to take all appropriate action against any person or entity that causes or contributes to Defendant's failure to perform.

### **III. PURPOSE**

5. The express purposes of the Parties entering into this Consent Decree are (1) to further the objectives of the Clean Water Act, the Clean Streams Law, the Solid Waste Management Act, the Safe Drinking Water Act and the Fish and Boat Code (the "Statutes"); (2) to settle the civil claims of Plaintiffs against Defendant for the incidents alleged in the Complaints; and (3) to implement specific actions that will enhance Defendant's compliance

with the specific provisions of the Statutes and the regulations promulgated thereunder as described in the Complaints. The Decree as described in detail below accomplishes these purposes through the requirements for Defendant to pay civil penalties to the United States and the Commonwealth of Pennsylvania, perform supplemental environmental projects, and implement certain injunctive relief.

#### **IV. DEFINITIONS**

6. Unless otherwise defined herein, the terms used in this Consent Decree will have the meaning given to those terms in the Clean Water Act, 33 U.S.C. §§ 1251 et seq., and the regulations promulgated thereunder or, if not defined in the Clean Water Act or its regulations, then as defined in the Clean Streams Law, 35 P.S. §§ 691.1-691.1001; the Solid Waste Management Act, 35 P.S. §§ 6018.101-6018.1003; the Safe Drinking Water Act, 35 P.S. §§ 721.1-721.17, or the Fish and Boat Code, 30 Pa. C.S.A. §§ 101-7314, and the regulations promulgated thereunder. Any other words shall be given their ordinary meaning.

The following terms used in this Consent Decree, its Appendices, and studies and plans submitted by Defendant and approved by EPA and PADEP are defined as follows:

(a) “Collection System” shall mean the collection and transmission system (including all pipes, force mains, sanitary sewer lines, overflow structures, regulators, lift stations, pump stations, manholes, and appurtenances thereto) owned by Defendant and designed to convey sewage and industrial waste, and not storm water, from the Facility buildings, for treatment at UGT POTW and/or UGTMA POTW.

(b) “Collection System Components” shall mean those components of the Collection System defined above.

(c) “Date of Entry” or “Entry Date” shall mean the date on which the Consent Decree is approved and entered by the United States District Court for the Eastern District of Pennsylvania.

(d) "Date of Lodging" shall mean the date on which the Consent Decree is lodged with the United States District Court for the Eastern District of Pennsylvania.

(e) "Day" or "days" shall mean a calendar day or calendar days. When the day a report or other deliverable is due under this Consent Decree falls on a Saturday, Sunday or any Federal or Commonwealth of Pennsylvania legal holiday, Defendant shall have until the next calendar day that is not one of the aforementioned days for submittal of such report or other deliverable.

(f) "Facility" or "West Point Facility" shall mean the area in West Point, Pennsylvania within the fenceline located on the property bounded on the west by South Broad St., on the north by Sumneytown Pike, on the east by West Point Pike (a/k/a County Line Road) and on the south by Garfield Ave. and Jones Ave., together with the area within the fenceline encompassing Building 24 and associated equalization tanks located immediately east of West Point Pike.

(g) "Parties" shall mean the United States of America, the Commonwealth of Pennsylvania and Defendant Merck.

(h) "Permit" shall mean the currently effective industrial user permit No. M-101 issued by UGT to Defendant authorizing the discharge of certain pollutants to the UGT POTW, and all subsequent modifications or renewals.

(i) "Pretreatment Program" shall mean the currently effective pretreatment program(s) that relate to the Facility under 40 C.F.R. Part 403.

(j) "Significant Industrial User" has the meaning as set forth at 40 C.F.R. § 403.3(v) and as used in UGT's pretreatment program. The regulatory definition at 403.3(v) is controlling in the case of any conflict.

(k) "UGT" shall mean Upper Gwynedd Township located in Montgomery County, Pennsylvania.

(l) "UGT POTW" shall mean the publicly owned treatment works operated by UGT.

(m) "United States" shall mean the United States of America, acting on behalf of EPA.

## **V. REMEDIAL MEASURES**

### **A. General Duties**

7. **Duty to Comply.** Defendant has the duty to comply with all terms, conditions and requirements of the currently effective federal Pretreatment Program and the Permit issued to the Facility:

8. **Operation and Maintenance of the Facility.** Defendant has the duty to maintain in good working order and properly operate and maintain the components of the Collection System as necessary to comply with the Facility's Permit and the currently effective federal Pretreatment Program requirements applicable to UGT POTW and/or Merck, including that which is necessary to prevent pass through and/or interference at UGT POTW:

### **B. Specific Measures**

#### **9. Initial Phase Responses**

a. In response to discharges from the Facility to UGT POTW that occurred on certain occasions in the period June 1, 2006 to August 31, 2006, Merck took interim corrective measures including (i) imposition of a requirement beginning on June 22, 2006 that the discard of any material from the Building 17 Biologics Support Operation ("BSO") be approved by the BSO director, (ii) development of a material discard form and subsequent development of a Standard Operating Procedure (SOP) for waste handling within BSO that includes use of the discard request form, (iii) imposition of an interim requirement prohibiting the sewerage of non-rinsate material from BSO, (iv) issuance of a Facility-wide prohibition on sewerage any wastestream without a mandatory prior review and approval of the Site Environmental Engineering Group, and prior consideration of the relationship of the potential for excessive foaming and the timing of discharges beginning on August 14, 2006, (v) formation of a Facility wastewater task force that has identified each discharged wastestream from all major operating areas and pilot plants and confirmed its volume, constituents, frequency and variability, beginning on



September 1, 2006, (vi) establishment of a program to test waste streams and influent to the Facility's wastewater equalization tanks for foaming beginning on August 14, 2006, (vii) commencement of a study by the wastewater task force of systems, infrastructure, operations, best practices and infrastructure improvements, the result of which is reflected in certain of the remedial measures required by this Consent Decree beginning on September 1, 2006, (viii) formation of a materials accountability task force to recommend improvements to the Facility's incident response capabilities, the result of which is reflected in certain of the remedial measures required by this Consent Decree beginning on September 8, 2006, and (ix) periodic presentations of information and status reports to the United States and the Commonwealth of Pennsylvania on November 1, 2006, November 13, 2006 and June 6, 2007 to apprise them of remedial measures implemented and additional measures proposed. Some of these interim corrective measures have changed since they were first implemented, and will and must change in the future to meet changing conditions including but not limited to implementation of long range remedial measures.

b. **Long-range Phase Responses**

Merck has committed to undertake long-range remedial measures at the Facility including a prevention program, enhanced wastewater management program and chemical management accountability system as described more fully below.

10. **Prevention Program – Predictive Tool**

Merck has developed an enhanced management program, more fully described below, to further assist Merck in evaluating whether cumulative discharges from production waste streams generated at the Facility, which includes the wastestreams generated in pharmaceutical and vaccine manufacturing and in pilot plant and laboratory operations, would

violate the Facility's Permit, currently effective federal Pretreatment Program or applicable Clean Streams Law and Solid Waste Management Act requirements. This prevention program consists of a predictive tool, an associated users manual to be followed by Merck employees, consultants and contractors, and training of appropriate Merck employees, consultants and contractors, in the use of the predictive tool and users manual.

a. Merck has developed and demonstrated a predictive tool designed to enhance Merck's capability to evaluate, prior to sewerage, the cumulative amounts of certain waste stream materials sewerage simultaneously or in close temporal proximity as compared to relevant thresholds including the Facility's industrial user Permit, currently effective federal Pretreatment Program or applicable Clean Streams Law requirements. The tool does not evaluate chemical interactions of sewerage materials.

b. EPA and PADEP have approved the predictive tool, in accordance with the description attached hereto as Appendix A, the Users Manual dated August 13, 2007 previously submitted to and approved by EPA and PADEP, and a prior demonstration by Merck of the predictive tool to EPA and PADEP.

c. This predictive tool has already been piloted by Merck and within 60 days following the Date of Entry of the Consent Decree shall be fully implemented and used by Merck in making sewerage evaluations during the life of this Decree.

d. Merck will also submit a certification within 60 days following the Date of Entry of the Decree to the effect that all persons responsible for sewer evaluations have been fully trained in the use of the predictive tool and the Users Manual.

e. Merck has submitted to EPA and PADEP, and EPA and PADEP have

approved, a plan for evaluation of the effectiveness of the implementation of the predictive tool.

f. Within one year of the Date of Entry of this Consent Decree, Merck shall commence an evaluation of the implementation of the predictive tool using the approved plan and provide EPA and PADEP the results of the evaluation within 90 days after the completion of the evaluation, including recommendations for improvement of the prevention program.

g. EPA or PADEP may require reasonable modification of the prevention program, consistent with the scope of the predictive tool set forth in Appendix A and the User Manual, based on their review of Merck's evaluation. Subject to Merck's right to invoke the Dispute Resolution procedures set forth in Section XIV of this Decree, within 60 days following receipt of any EPA or PADEP comments on the results of the evaluation, Merck shall incorporate any required modifications in the prevention program or provide a plan with milestones for incorporating modifications in accordance with Section VIII of this Decree.

h. Except for its obligation under subparagraph 10.c of this Consent Decree, Merck's obligation under paragraph 10 of this Consent Decree shall be complete upon Merck's incorporation of any required modification in the prevention program.

i. The Parties understand and agree that the predictive tool may be enhanced, supplemented and changed over the life of this Consent Decree to meet changing conditions at the Facility and that this tool, while consistent with Appendix A and the Users Manual approved by EPA and PADEP, will reflect and must reflect those changing conditions. Such enhancements, supplements and/or changes to the Users Manual must be reported to EPA and PADEP pursuant to paragraph 13 below.

11. **Enhanced Wastewater Management Program**

Merck's existing Wastewater Management Program includes controls such as at source equalization, at source neutralization, at source interception and off site disposal, at source treatment, and end of pipe equalization and neutralization.

Merck shall develop and implement an enhanced Wastewater Management Program designed to expand to buildings 17, 24, 28 and 38 Merck's ability to intercept non-routine wastewater discharged from the Facility that would cause violation of the Facility's Permit, currently effective federal Pretreatment Program or applicable Clean Streams Law and Solid Waste Management Act requirements.

a. Merck shall expand its existing wastewater tank infrastructure in accordance with the description attached hereto as Appendix B and the operating plans for the interceptor tank/s detailed in Appendix B, all of which documents have been previously submitted to and approved by EPA and PADEP, and in accordance with the following schedule:

i. Within six months after entry of this Consent Decree, Merck shall submit the following documents to EPA and PADEP for their approval in accordance with Section VIII of this Decree: (1) a Wastewater Management Program work plan in accordance with Appendix B consisting of the following components required by EPA and PADEP: Scope and description, construction schedule with major milestones, site plot plan, tank sizing, flow diagrams and operating mode; and (2) an operating plan for the Building 28/38 tank(s) similar to the operating plan dated August 10, 2007 that EPA and PADEP have previously approved for the building 17 tank(s). EPA and PADEP shall promptly review the operating plan and the work plan.

ii. Within 180 days after EPA and PADEP approval of the work plan submitted under this Decree, and all federal, state and local approvals or permits have been obtained, Merck shall commence construction of the interceptor tank/s in accordance with the work plan.

iii. Merck shall complete construction within 18 months after commencement of construction.

iv. Within 90 days after completion of construction, Merck shall place the interceptor tank/s in operation and shall operate the program during the life of this Consent Decree in accordance with the operating plans previously approved by EPA and PADEP.

b. Merck has submitted to EPA and PADEP, and EPA and PADEP have approved, a plan for evaluation of the effectiveness of the Enhanced Wastewater Management Program for intercepting materials that would cause a violation of the Facility's Permit, currently effective federal Pretreatment Program or applicable Clean Streams Law and Solid Waste Management Act requirements.

c. Within one year after placing the interceptor tank/s detailed in the work plan in operation, Merck shall commence an evaluation of the effectiveness of the program of preventing the discharge of materials from the Facility that would cause a violation of the Facility's Permit, currently effective federal Pretreatment Program or applicable Clean Streams Law and Solid Waste Management Act requirements. Merck shall use the approved evaluation plan and provide EPA and PADEP the results of the evaluation within 90 days after the completion of the evaluation, including recommendation for improvement of the Enhanced Wastewater Management Program.

d. EPA or PADEP may require reasonable modification of the operation of the Enhanced Wastewater Management Program, consistent with the scope of the program set forth in Appendix B and the operating plans, based on their review of Merck's evaluation. Subject to Merck's right to invoke the Dispute Resolution procedures set forth in Section XIV of this Decree, within 60 days following receipt of any EPA or PADEP comments on the results of the evaluation, Merck shall incorporate any required modifications or provide a schedule of milestones to complete modifications in the operation of the Enhanced Wastewater Management Program in accordance with Section VIII of this Decree.

e. Except for the obligation under subparagraph 11(a)(iv) of this Consent Decree, Merck's obligation under paragraph 11 of this Decree shall be complete upon Merck's incorporation of any required modification in the operation of the Enhanced Wastewater Management Program.

f. The Parties understand and agree that the Wastewater Management Program may be enhanced, supplemented and changed over the life of this Consent Decree to meet changing conditions at the Facility and that the program, while consistent with Appendix B and the operating plans approved by EPA and PADEP, will reflect and must reflect those changing conditions. Such enhancements, supplements and/or changes to the operating plans must be reported to EPA and PADEP pursuant to paragraph 13 below.

## 12. **Chemical Management Accountability System**

Merck has developed a Chemical Management Accountability System (CMAS), more fully described below, to enable more effective incident management response at the Facility. The CMAS is a centralized electronic system that provides information on chemical identity, location and indication of quantity (but not precise inventory) at each location, thereby

allowing the user to prioritize an incident investigation/response on the areas of highest probability as described in Appendix C. Merck will be making enhancements to the CMAS as described further below and in Appendix C, to improve its use as an investigation and response tool.

a. The CMAS is being used by Merck in accordance with the description attached as Appendix C and the Users Manual previously provided to and approved by EPA and PADEP, and in accordance with the demonstration of the tool previously made by Merck to EPA and PADEP. Merck hereby certifies that all employees, consultants and contractors responsible for the use of the tool in incident investigation/response have been fully trained in the use of the tool and the Manual.

b. Merck is currently developing an enhancement to CMAS to include certain transaction information from the principal on-site systems, as described in Appendix C and in the Users Manual dated August 13, 2007 previously provided to and approved by EPA and PADEP, in the CMAS database. This phase's development and implementation will be complete by March 1, 2008. Within 30 days after completion and implementation, Merck will provide a demonstration of the enhanced version of CMAS to EPA and PADEP.

c. Merck will submit a certification within 30 days after completion and implementation of the transaction information to the effect that all employees, consultants and contractors responsible for the use of CMAS in incident investigation/response have been fully trained in the use of the enhanced tool and the Users Manual.

d. Merck will further enhance CMAS by including information from a baseline research laboratory inventory, as described in Appendix C and in the Users Manual previously provided to and approved by EPA and PADEP. As an alternative to performing the

baseline research laboratory inventory referenced above, within one year after the Date of Entry of this Consent Decree Merck may submit information to EPA and PADEP demonstrating that this enhancement would not materially improve the ability of CMAS to function as an investigation and response tool or that a more limited enhancement would do so. Unless EPA and PADEP determine that Merck has made the demonstration that no enhancement would materially improve the ability of CMAS to function as an investigation and response tool, or in the event that EPA or PADEP determine that a more limited enhancement would do so, Merck shall perform the enhancement or the more limited enhancement or it shall invoke the dispute resolution provisions of Section XIV (Dispute Resolution). If an enhancement is required to be performed, Merck shall complete and implement it within one year after (i) the Date of Entry of this Consent Decree, (ii) a submission by Merck and the determination by EPA and PADEP that Merck has not demonstrated that an enhancement would not materially improve CMAS, (iii) a submission by Merck and a determination by EPA and PADEP on whether a more limited enhancement would be sufficient to materially improve CMAS or (iv) the conclusion of the Dispute Resolution process and any appeals, whichever is later. Within 30 days after completion and implementation, or at such later date as EPA's and PADEP's schedules may allow, Merck will provide a demonstration of the enhanced version of CMAS to EPA and PADEP upon request.

e. Merck will submit a certification within 30 days after completion and implementation of the baseline research laboratory information to the effect that all employees, consultants and contractors responsible for the use of CMAS in incident investigation/response have been fully trained in the use of the enhanced tool and the Manual.



f. Merck has submitted to EPA and PADEP, and EPA and PADEP have approved a plan for evaluation of the effectiveness of the implementation of the CMAS.

g. Within two years after the Date of Entry of this Consent Decree, Merck shall commence an evaluation of the implementation of the fully enhanced or the currently effective CMAS using the approved plan and provide EPA and PADEP the results of the evaluation within 90 days after the completion of the evaluation, including recommendation for improvement of CMAS.

h. EPA or PADEP may require reasonable modification of CMAS, consistent with the scope of the tool set forth in Appendix C and the User Manual, based on their review of Merck's evaluation. Subject to Merck's right to invoke the Dispute Resolution procedures set forth in Section XIV of this Decree, and to the time period provided in paragraph 12(d) above, within 60 days following receipt of any EPA or PADEP comments on the results of the evaluation, Merck shall incorporate any required modification or provide a schedule of milestones to complete modifications in CMAS in accordance with Section VIII of this Decree.

i. Except for the obligation to continue to use the currently effective CMAS during the life of this Consent Decree, Merck's obligation under paragraph 12 of this Consent Decree shall be complete upon Merck's incorporation of any required modification in CMAS as required in paragraph 12(h) above.

j. The Parties understand and agree that CMAS may be enhanced, supplemented and changed over the life of this Consent Decree to meet changing conditions at the Facility and that CMAS, while consistent with Appendix C and the Users Manual approved by EPA and PADEP, will reflect and must reflect those changing conditions. Such enhancements, supplements and/or changes to the Users Manual must be reported to EPA and

PADEP pursuant to paragraph 13 below.

## **VI. REPORTING REQUIREMENTS**

13. Beginning with the one year anniversary of the Date of Entry of the Consent Decree, Defendant shall submit to EPA and PADEP within ninety (90) days after each anniversary of the Date of Entry until termination of this Consent Decree an Annual Report which shall contain the following:

(a) Progress reports on the implementation of the requirements of Section V. B (Specific Remedial Measures) as described in paragraphs 9 through 12, including without limitation a description of any substantive enhancements, supplements or changes made in accordance with paragraph 10(i), 11(f), and 12(j) of this Consent Decree.

(b) A description of any problems and/or delays anticipated with respect to meeting the requirements of Section V. B (Specific Remedial Measures) of this Consent Decree; and

(c) Any such additional matters as Defendant believes should be brought to the attention of EPA and PADEP.

(d) The Annual Report shall be certified by a duly designated Merck employee responsible for compliance or responsible for overseeing implementation of this Consent Decree, which shall state:

“I certify under penalty of law that this information was prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my directions and my inquiry of the person(s) who manage the system, or the person(s) directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete.”

## **VII. RIGHT OF ENTRY**

14. (a) EPA and PADEP, and their authorized representatives and contractors, shall each have authority at all reasonable times, upon the presentation of credentials, to enter the Facility in order to:

1. Monitor the progress of activities required by this Consent Decree;
2. Verify any data or information submitted by Merck to the United States and/or Pennsylvania pursuant to this Consent Decree;
3. Obtain samples to verify compliance with this Consent Decree;
4. Observe performance tests that Merck may from time to time conduct on the system improvements described herein;
5. Inspect and evaluate the Facility in order to verify Defendant's implementation of and compliance with the terms of this Decree; and
6. Review and copy any record required to be kept under the terms and conditions of this Consent Decree.

(b) Upon request, Defendant shall provide EPA or PADEP or their authorized representatives splits of any samples collected by Defendant or its consultants and/or contractors pursuant to this Consent Decree. Upon request, EPA or PADEP shall provide Defendant splits of any samples collected by EPA or PADEP or their respective representatives, consultants and/or contractors.

(c) These inspection rights are in addition to, and in no way limit or otherwise affect, EPA's and PADEP's statutory authorities to conduct inspections, to require monitoring and to obtain information from Defendant as authorized by law; however, such inspections by EPA and PADEP shall be conducted in compliance with the requirements of the U.S. Food and Drug Administration where applicable pertaining to good manufacturing practices and good laboratory practices. Following EPA or PADEP's entry of the Facility and their informing Merck of the scope of their intended activities at the Facility, Merck shall, within a reasonable time frame, make EPA or PADEP aware of such applicable requirements and provide any

required training. In the event of the need for an emergency response by EPA or PADEP, Merck shall have procedures in place which shall insure that inspectors are granted access within the shortest time frame reasonably possible and within a time frame that allows the agencies to respond promptly to the emergency.

### **VIII. REVIEW AND APPROVAL PROCEDURES**

15. (a) After receipt and review of any plan, program or other document which is required to be submitted for approval pursuant to this Consent Decree, EPA and PADEP may (1) approve, in whole or in part, the submission; (2) approve the complete submission or portions of the submission upon specified conditions; (3) disapprove the submission, in whole or in part, and direct that Defendant modify the submission as described further in paragraph 16 below; or (4) any combination of the above.

(b) In the event of approval of the complete submission, Defendant shall proceed to take any actions required by the plan, program or other approved document, as approved by EPA and PADEP in accordance with paragraph 19.

(c) In the event of approval of portions of the submission or approval upon specified conditions, and provided that implementation of approved portions are not dependent on unapproved portions, Defendant shall proceed to take the actions identified in the approved portion of the plan, program, other document, or portion thereof, in accordance with any applicable conditions specified by EPA and PADEP, subject only to Defendant's right to invoke the Dispute Resolution procedures set forth in Section XIV with respect to the conditions imposed. Implementation of any approved portions of the submission shall not eliminate the potential liability of Defendant for stipulated penalties pursuant to Section XII with respect to unapproved portions.

16. Upon receipt of a notice of disapproval of all or part of a submission from EPA and PADEP, Defendant shall, within thirty (30) days (or such greater time frame as specified by EPA and PADEP in writing), modify as necessary the submission to resolve the deficiency as identified in the written disapproval of EPA and PADEP, and resubmit the plan, program or

other document for approval, subject only to Defendant's right to invoke the Dispute Resolution procedures set forth in Section XIV. Any stipulated penalties applicable to the submission, as provided in Section XII, shall accrue during the 30-day period (or any such more extended time as is provided herein), but shall not be payable unless the resubmission is disapproved due to a material defect as provided in paragraph 17.

17. In the event that a resubmitted plan, program or other document, or portion thereof, is disapproved by EPA and PADEP due to a material defect, EPA and PADEP may again require the Defendant to respond to the deficiencies in accordance with paragraph 16, or EPA and PADEP may modify the submission. Unless Defendant invokes the Dispute Resolution Procedures set forth in Section XIV, and the disapproval by EPA and PADEP of the Defendant's resubmission is overturned pursuant to that Section, Defendant shall be deemed to have failed to submit such program, plan or other document timely and adequately, and stipulated penalties shall accrue for such violation from the date on which the resubmission was originally due.

18. Notwithstanding the foregoing, stipulated penalties shall not accrue for any submission or resubmission during the period the submission is under review by EPA or PADEP, i.e., from the date a submission or resubmission is made until and including the date EPA and PADEP notified Defendant of its adequacy or inadequacy.

19. All programs, plans or other documents required to be submitted pursuant to this Consent Decree shall become incorporated into and enforceable under this Consent Decree, upon EPA and PADEP approval, subject only to Defendant's right to invoke the Dispute Resolution procedures set forth in Section XIV. In the event EPA and PADEP approve a portion of any program, plan or other document pursuant to this Section, then the approved portion shall become incorporated into and enforceable under this Consent Decree, subject only to Defendant's right to invoke the Dispute Resolution procedures set forth in Section XIV.

## IX. CIVIL PENALTY

20. Defendant shall pay a total civil penalty in the amount of \$1,575,000.00 to the United States, PADEP and PFBC for violations as alleged by the United States and PADEP in the Complaints. Defendant shall pay \$750,000 to the United States within thirty (30) days following the Date of Entry of this Consent Decree, \$750,000 to PADEP within thirty (30) days following the Date of Entry and \$75,000 to PFBC within thirty (30) days following the Date of Entry in accordance with the procedures described in paragraphs 22, 23 and 24, below.

21. The United States, PADEP and PFBC shall be deemed judgment creditors for purposes of collection of this penalty.

22. Payment of the civil penalty to the United States shall be made by Electronic Funds Transfer ("EFT") to the U.S. Department of Justice ("DOJ") lockbox bank, referencing USAO NO 2006V00820. Payment shall be made in accordance with instructions provided by the United States to Defendant following execution of this Consent Decree. Any EFT received at the DOJ lockbox bank after 11:00 A.M. Eastern Time will be credited on the next business day. Notice of the EFT shall simultaneously be mailed to the following:

Docket Clerk (3RC00)  
U.S. EPA - Region III  
1650 Arch Street  
Philadelphia, PA 19103-2029

Christopher A. Day (3RC20)  
U.S. EPA - Region III  
1650 Arch Street  
Philadelphia, PA 19103-2029; and

Margaret L. Hutchinson  
Assistant United States Attorney  
Civil Division Eastern District of Pennsylvania  
615 Chestnut Street, Suite 1250  
Philadelphia, PA 19106-4476  
Re: USAO No. 2003V00437

The transmittal letter forwarding such notice shall include the caption, civil action number and judicial district of this action.

23. Payments of the civil penalty to PADEP shall be made by tendering to the Pennsylvania Department of Environmental Protection checks made payable as follows. A check in the amount of \$533,000.00 shall be made payable to the Clean Water Fund; a check in the amount of \$194,000.00 shall be made payable to Commonwealth of Pennsylvania, Safe Drinking Water Account, and a check in the amount of \$23,000.00 shall be made payable to the Solid Waste Abatement Fund, and these checks shall be sent to:

Steve O'Neil  
Operations Chief, Water Management  
Pennsylvania Department of Environmental Protection  
2 East Main Street  
Norristown, PA 19401

24. Payment of the civil damages to PFBC shall be made by tendering to the Pennsylvania Fish and Boat Commission a check in the amount of \$75,000 made payable to Pennsylvania Fish and Boat Commission and sent to:

Jason Oyler, Assistant Counsel  
Pennsylvania Fish and Boat Commission  
1601 Elmerton Ave.  
P.O. Box 67000  
Harrisburg, PA 17106-7000

25. If Defendant fails to tender all or any portion of the civil penalty payment owed to the United States, PADEP and/or PFBC within thirty (30) days of the Date of Entry of this Consent Decree, interest on the unpaid amount shall accrue in accordance with the provisions of 28 U.S.C. § 1961, and be paid from the date said payment is due until all amounts owed are paid.

#### **X. STATE COMMUNITY ENVIRONMENTAL PROJECT**

26. **Angus Tract at Erdenheim Farm Purchase and Protection SCEP**

Within sixty days following the Entry Date of this Consent Decree, and as described in Appendix D to this Decree, Merck shall establish an escrow account and fund it with \$4.5 million as a State Community Environmental Project ("SCEP"). The escrowed monies shall be made available for a period of one year following the Entry Date of the Consent Decree

to provide financial assistance to the Whitemarsh Foundation for its purchase of the tract of land known as the “Angus Tract” at Erdenheim Farm. The Angus Tract is an approximately 100 acre portion of Erdenheim Farm that is currently used principally for cattle grazing and other agricultural purposes. The purchase of the Angus Tract will enable the Whitemarsh Foundation or other parties to the sales transaction to place conservation easements on the property to protect the Angus Tract from development and to offer public access. This SCEP is a component of a larger watershed and preservation restoration plan. The Angus Tract is located adjacent to and upgradient from the Natural Lands Trust Tract through which the Wissahickon Creek flows. This segment of the Creek will be the subject of the restoration project described in paragraph 27 of this Decree. The water resources values and services of the Creek and its watershed will be enhanced through preservation of the upgradient Angus Tract pursuant to this SCEP and the creation or enhancement of environmentally protective features pursuant to the Angus Tract restoration project described in paragraph 28 of this Decree. Merck shall require that any purchase of the Angus Tract utilizing the funds established by this SCEP include the establishment of easement(s) and/or restrictive covenant(s) in substantially the form submitted to EPA and PADEP on September 5, 2007 as revised on September 13, 2007, or as are otherwise reasonably acceptable to EPA and PADEP on the Angus Tract, providing public access; designating certain portions of the Angus Tract comprising approximately ten (10) acres for use as wetlands, wet meadow, open water or similar uses; and protecting the entire tract from development, exclusive of farming, environmental and educational uses.

#### **XI. SUPPLEMENTAL ENVIRONMENTAL PROJECTS**

##### **27. Wissahickon Creek Restoration SEP at NLT Tract at Erdenheim Farm**

As described in this paragraph and in accordance with all provisions of Appendix E to this Decree, Merck shall implement a Supplemental Environmental Project (“SEP”) designed to improve water quality on a segment of the Wissahickon Creek located on property owned by the Natural Lands Trust (“NLT”) at the Erdenheim Farm known as the “NLT Tract” in Montgomery County, Pennsylvania. The portion of the Wissahickon Creek flowing through



Erdenheim Farm is impaired due to nutrients and siltation. This segment of the Creek would substantially benefit from restoration work within the Creek and on adjacent land. Merck shall complete this SEP within four years of the date of Entry as further described in Appendix E. This project is estimated to cost \$1.7 million and shall preserve and enhance the water resource values and services of the mainstem Wissahickon on the NLT Tract by, among other things, improving water quality, and shall include one or more of the following: (1) installation of a vegetated riparian buffer and a canopy tree layer near the Creek; (2) restoration of eroded stream bank and portions of the streambed to improve ecological habitat; (3) stabilization or reduction of water temperature; (4) reduction of stream turbidity; and (5) restoration of indigenous riparian and aquatic habitat.

**28. Angus Tract at Erdenheim Farm Environmental Restoration SEP**

Merck shall implement an environmental restoration project on the Angus Tract at Erdenheim Farm, as set forth in Appendix F to this Decree. This SEP, estimated to cost \$400,000, shall provide for the creation, enhancement and maintenance of certain environmental features and public access on the Angus Tract, including the creation of up to approximately ten (10) acres of wetlands, wet meadow, open water and/or other environmentally protective features of the Angus Tract. This SEP shall be completed within four (4) years of the Date of Entry as further described in Appendix F.

**29. Drinking Water Protection Early Warning System SEP**

Merck shall work with the City of Philadelphia Water Department (“PWD”) in the manner set forth in Appendix G to this Decree to purchase and install an intelligent aquatic biomonitoring system that monitors fish activity to provide advance notice to the PWD of the presence of materials in Wissahickon Creek that may constitute a threat to the drinking water. The system is expected to be installed and operated by PWD in the PWD Queen Lane Water Treatment Plant. The drinking water intake for the Queen Lane Plant is situated on the Schuylkill River immediately downstream of the confluence with Wissahickon Creek. This SEP is estimated to cost \$350,000 and shall be completed within two years from the Date of Entry as

further described in Appendix G.

**30. Automated Dissolved Oxygen ("DO") Control SEP at Upper Gwynedd Township POTW** - Merck shall work with Upper Gwynedd Township ("UGT") in the manner set forth in Appendix H to purchase and install an Automated Dissolved Oxygen ("DO") Control at the UGT POTW. The UGT POTW discharges to the headwaters of the Wissahickon Creek. This SEP, estimated to cost \$850,000, is designed to improve performance and reliability for DO, and reduce energy usage. This SEP shall be completed within three years from the Date of Entry as further described in Appendix H.

**31. Wissahickon Creek Restoration SEPs** - As set forth in Appendix I to this Decree, Merck shall implement SEPs designed to improve the water quality of the Wissahickon Creek and/or protect the Wissahickon Creek as a source of drinking water. The SEPs to improve the water quality of the Wissahickon may include streambank restoration, sediment reduction, habitat restoration, wetland restoration/creation and/or the other activities identified in Appendix I. The SEPs to protect the Wissahickon as a source of drinking water may include projects to reduce or eliminate pathogens or provide additional early warning projections. These projects, estimated to cost \$1.2 million, shall be completed within four years of the Date of Entry as further described in Appendix I.

**32. Implementation of State Community Environmental Project and Supplemental Environmental Projects.**

(a) **Defendant Certification.** With regard to the SCEP and SEPs, Defendant certifies the truth and accuracy of each of the following:

1. That all cost information provided to EPA or PADEP by Defendant in connection with EPA's or PADEP's approval of the respective SCEP or SEP represents a fair estimate of the costs necessary to implement the SCEP or SEP;
2. That, as of the date of lodging of this Decree, Defendant is not required to perform or develop this SCEP or any of these SEPs by any federal,

Commonwealth, or local law or regulation, or as injunctive relief awarded in any other action in any forum;

3. That Defendant has not received, and is not negotiating to receive, credit for any of this SCEP or any of these SEPs in any other enforcement action; and

4. That Defendant will not receive any reimbursement for any portion of the SCEP or SEPs from any other person, but for certain projects other persons may contribute monies or other resources to the SCEP or SEP.

**(b) Completion Report for SCEP or SEP**

1. No later than 90 days after the date set for completion of each SCEP or SEP as described above in paragraphs 27-30, Defendant shall submit a SCEP Completion Report to PADEP or a SEP Completion Report to EPA. The SCEP/SEP

Completion Report shall contain the following information:

- a) A detailed description of the SCEP/SEP as implemented;
- b) A description of any problems encountered in completing the SCEP/SEP and the solutions thereto;
- c) An itemized list of all eligible SCEP/SEP costs;
- d) Certification that the SCEP/SEP has been fully implemented pursuant to the provisions of this Decree; and
- e) A description of the environmental and public benefits resulting from implementation of the SCEP/SEP (with a quantification of the benefits and pollutant reductions, if feasible).

2. EPA and/or PADEP may, in the exercise of each agency's reasonable discretion, require information in addition to that described in the preceding

paragraph, in order to determine the adequacy of SCEP/SEP completion or eligibility of SCEP/SEP costs.

3. After receiving the SCEP/SEP Completion Report, EPA or PADEP shall notify Defendant whether or not Defendant has satisfactorily completed the SEP/SCEP. If Defendant's obligations with respect to the SEP/SCEP have not been satisfactorily completed, subject to paragraph 4 below, Defendant shall correct the deficiencies within 90 days of receipt of notice from EPA or PADEP, or within the remaining period provided in this Decree for completion of the SCEP/SEP, whichever is longer. If the deficiencies are not corrected within this time period, stipulated penalties may be assessed in accordance with paragraph 36 or 37 of this Consent Decree.

4. Disputes concerning the satisfactory performance of the SCEP/SEP and the amount of eligible SCEP/SEP costs shall be resolved under Section XIV of this Decree (Dispute Resolution).

5. Each submission required under this Section shall be signed by an official with knowledge of the SCEP/SEP and shall bear the certification language set forth in paragraph 13(d) of this Decree. Any public statement, oral or written, in print, film, or other media, made by Defendant making reference to the SCEP/SEP under this Decree shall include substantially the following language, "This project was undertaken in connection with the settlement of an enforcement action, United States & PADEP v. Defendant Merck & Co., Inc." If Merck in the exercise of its sole discretion elects to donate monies for the purchase, improvement or maintenance of land, programs or activities at Erdenheim Farm

beyond its obligations under this Consent Decree, the requirements of this paragraph shall not apply to any public statement concerning such additional donation.

## **XII. STIPULATED PENALTIES**

33. Upon written demand by EPA and/or PADEP, Defendant shall pay stipulated penalties for each failure to comply with the terms of this Consent Decree, including the terms of any plans or schedules developed pursuant to and incorporated into this Consent Decree. The stipulated penalties shall be assessed as follows and paid as set forth in paragraphs 34 through 43 of this Decree.

### 34. Stipulated Penalties for Remedial Measures

(a) Following its receipt of written demand by EPA and/or PADEP, Defendant shall pay stipulated penalties in the amount set forth below for each day it fails to submit deliverables (including proposed plans, progress reports or evaluation reports) required under Section V.B. Remedial Measures, paragraphs 9-12 of this Consent Decree, to timely correct deficiencies in deliverables for remedial measures identified by EPA and/or PADEP, or to commence or complete construction and/or commence operation of specific remedial measures in accordance with the schedules set forth in this Consent Decree or approved by EPA and PADEP and incorporated into this Consent Decree:

<u>Period of Non-Compliance</u>	<u>Penalty per Deliverable Due Date per day of Violation</u>
1 <sup>st</sup> to 15 <sup>th</sup> Day	\$500
16 <sup>th</sup> to 30 <sup>th</sup> Day	\$1,000
31 <sup>st</sup> to 60 <sup>th</sup> Day	\$2,000
After 60 Days	\$5,000

35. Stipulated Penalties for Pretreatment Effluent Limitations.

Following written demand by EPA and PADEP, for a period ending upon Defendant's notice to EPA and PADEP that the interceptor tanks required by the enhanced wastewater management program described in paragraph 11 above have been placed into operation: (a) Defendant shall pay stipulated penalties as described herein for all exceedances of the currently effective federal Pretreatment Program effluent limits including any more stringent local permit effluent limits:

\$5000 per parameter for the first calendar month of violation (per calendar month and not per day) \$7,500 per parameter for the 2<sup>nd</sup> and subsequent consecutive calendar month of violation (per calendar month and not per day); and

(b) Defendant shall pay stipulated penalties as described herein for all of its exceedances that cause interference or pass through within the meaning of 40 C.F.R. §§ 403.3(k) and (p) at the UGT POTW as governed by applicable principles of law:

\$5000 per day per violation.

36. Stipulated Penalties for SEPs.

If Defendant fails to implement the specific SEP or abandons work on the SEP, Defendant shall pay a stipulated penalty upon written demand of EPA as provided in this paragraph. If Defendant has performed its obligations in whole or in part related to an individual SEP, the costs that Defendant has incurred for that obligation shall provide a credit and/or offset against any calculation of a stipulated penalty for failure to implement the SEP or for abandoning work on the SEP. If EPA determines that Defendant has not performed its obligations in whole or in part in accordance with the requirements of this Decree, it shall notify Defendant. If Defendant cures the deficiency within thirty (30) days of its receipt of notice, stipulated penalties shall not accrue. If EPA elects to seek stipulated penalties for any of the SEPs listed below, the obligations of Defendant pursuant to that individual SEP shall terminate

upon payment of the stipulated penalties.

- a. **Wissahickon Creek Restoration SEP at NLT Tract at Erdenheim Farm –**  
\$1.7 million
- b. **Angus Tract at Erdenheim Farm Environmental Restoration SEP -**  
\$400,000
- c. **Drinking Water Protection Early Warning System SEP - \$350,000**
- d. **Automated Dissolved Oxygen Control SEP - \$850,000**
- e. **Wissahickon Creek Restoration SEPs - \$ 1.2 million**

37. Stipulated Penalties for SCEP

If Defendant fails to establish and fund the escrow account as described in paragraph 26 and Appendix D, and fails to cure any deficiency within thirty (30) days of its receipt of notice of the deficiency from PADEP, Defendant shall, upon written demand from PADEP, pay to PADEP as stipulated penalties \$4.5 million less any amount placed in escrow.

38. Stipulated civil penalties pursuant to paragraphs 34 and 35 shall automatically begin to accrue on the first day Defendant fails to satisfy any obligation or requirement of this Consent Decree and shall continue to accrue until the violation or deficiency is corrected, and subject only to Defendant's right to invoke the Dispute Resolution procedures set forth in Section XIV. Stipulated penalties with respect to the disputed matter shall continue to accrue from the first day of non compliance, but payment shall be stayed pending resolution of the dispute. Stipulated penalties shall not accrue during the period EPA and PADEP are reviewing any report or other submission or resubmission by Defendant nor during any period of formal dispute resolution as provided in paragraphs 51 through 54, inclusive, herein.

39. Following written demand by EPA and PADEP, and subject only to Defendant's right to invoke the Dispute Resolution procedures set forth in Section XIV, stipulated penalties incurred by Defendant under this Consent Decree pursuant to paragraphs 34 and 35 shall be paid

fifty percent (50%) to the United States and fifty percent (50%) to the PADEP; all stipulated penalties payable to the United States including those pursuant to paragraphs 34, 35 and 36 shall be paid in accordance with the procedures set forth in paragraph 22, and all stipulated penalties payable to the PADEP including those pursuant to paragraphs 34, 35 and 37 shall be made payable to the Clean Water Fund in accordance with the procedures set forth in paragraph 23, and sent to:

Steve O'Neil  
Operations Chief, Water Management  
Pennsylvania Department of Environmental Protection  
2 East Main Street  
Norristown, PA 19401

40. Stipulated penalties incurred under this Consent Decree shall be tendered within thirty (30) days of Defendant's receipt of a demand for payment of such penalties by EPA or PADEP unless Defendant contests the demand in accordance with the dispute resolution provisions of this Consent Decree.

41. The stipulated civil penalties as set forth above shall be in addition to any other rights or remedies which may be available to the United States and the Commonwealth of Pennsylvania or their agencies by reason of Defendant's failure to comply with the requirements of this Consent Decree, and all applicable federal, Commonwealth or local laws, regulations, or permits. Provided, however, that for any particular violation of this Consent Decree, in the event that the United States and/or the Commonwealth of Pennsylvania and their agencies shall pursue the collection of a statutory penalty, such statutory penalty shall be offset by the amount of any stipulated penalty collected for such violation.

42. In the event that a stipulated civil penalty is not paid when due, the stipulated civil penalty owed to the United States and/or PADEP shall be payable with interest from the original due date to the date of payment at the statutory judgment rate set forth at 28 U.S.C. § 1961(a).



43. The United States and/or PADEP may, in the unreviewable exercise of discretion, reduce or waive stipulated penalties otherwise due to the United States and/or PADEP under this Consent Decree.

### **XIII. FORCE MAJEURE**

44. "Force Majeure" for the purposes of this Consent Decree is defined as an event arising from causes beyond the control of Defendant or the control of any entity controlled by Defendant, including its agents, consultants and contractors, which delays or prevents the performance of any obligation under this Consent Decree. Unanticipated or increased costs or expenses associated with implementation of this Consent Decree and changed financial circumstances, shall not, alone, be considered "force majeure" events. In addition, failure to apply for a required permit or approval or to provide in a timely manner all information required to obtain a permit or approval that is necessary to meet the requirements of this Consent Decree, or failure of Defendant to approve contracts, shall not be considered "force majeure" events. Defendant may seek relief under the provisions of this Section XIII for any delay in the performance of any obligation resulting from a failure to obtain, or a delay in obtaining, any permit or approval required to fulfill such obligation if Defendant has submitted timely and complete applications to obtain all such permits and approvals. Defendant shall adopt all reasonable measures to avoid or minimize such delay.

45. When Defendant knows or if Defendant should have known, by the exercise of due diligence, of an event that might delay completion of any requirement of this Consent Decree, whether or not the event is a "force majeure" event, Defendant shall notify EPA and PADEP, in writing, within twenty (20) business days after Defendant first knew, or in the exercise of reasonable diligence under the circumstances, should have known of such event. The notice shall provide a description of the event and an explanation of the reasons for the delay, the anticipated duration of the delay, all actions taken or to be taken to prevent or mitigate the delay or the effect of the delay, the timetable by which those measures will be implemented, whether Defendant claims that the delay should be excused as a "force majeure" event, and its rationale

for attributing such delay to a "force majeure" event if it intends to assert such a claim. Defendant shall include available documentation supporting its claim that the delay was attributable to a "force majeure" event. Further, where a contractor or subcontractor has not completed a construction project on time, Defendant shall state what steps it is taking to ensure performance by the contractor or subcontractor in question, and shall supply any documentation available to show the steps it has taken.

46. Failure to provide the required written notice to EPA and PADEP shall render this Section void and of no effect as to the event in question, and shall be a waiver of Defendant's right to obtain an extension of time for its obligations based on such event, unless EPA or PADEP had actual knowledge of the event. Defendant shall be deemed to have notice of any circumstance of which its contractors, or subcontractors had notice.

47. If EPA and PADEP find that a delay in performance is, or was, caused by a "force majeure" event, the time for performance of the specific obligation(s) under this Consent Decree that are caused by the "force majeure" event shall be extended for a period to compensate for the delay resulting from such event, and stipulated penalties shall not be due for such period. EPA and PADEP will notify Defendant in writing of the length of the extension for performance of the obligation(s) caused by the "force majeure" event. An extension of time for performance of the obligation(s) caused by the "force majeure" event shall not, of itself, extend the time for performance of any other obligation unless Defendants demonstrate to EPA and PADEP's reasonable satisfaction that the performance of the other obligation is dependent upon the performance to which the force majeure event applies. Defendant shall make an individual showing of proof regarding the cause of each delayed incremental step or other requirement for which an extension is sought.

48. In the event of a dispute regarding application of these provisions to a delay in performance, the dispute resolution provisions of Section XIV (Dispute Resolution) shall apply, and Defendant shall have the burden of proving that the delay is, or was, caused by a "force majeure" event, and that the amount of additional time requested is necessary to compensate for

that event. Defendant shall not be liable for stipulated penalties for any period of delay which was excused by the Court or EPA and PADEP pursuant to this "Force Majeure" Section. However, pending resolution of a "force majeure" dispute, stipulated penalties will continue to accrue except during any period of formal dispute resolution, and shall be due and payable if the Court determines that the event in question was not a "force majeure" event, that the Defendant did not undertake reasonable measures to limit the effect of the event, or that the "force majeure" event occurred for a shorter period of time than that alleged by Defendant. If the Court determines that the "force majeure" event occurred for a shorter period of time than that alleged by Defendant, stipulated penalties will accrue only on the unexcused portion of the delay.

#### **XIV. DISPUTE RESOLUTION**

49. Unless otherwise expressly provided for in this Consent Decree, the dispute resolution procedures of this Section shall be the exclusive mechanism to resolve disputes between Defendant and Plaintiff(s) arising under or with respect to this Consent Decree. However, the procedures set forth in this Section shall not apply to actions by the United States and the Commonwealth of Pennsylvania to enforce obligations of Defendant that have not been disputed in accordance with this Section.

50. **Informal Dispute Resolution.** Any dispute which arises under or with respect to this Consent Decree shall in the first instance be the subject of informal negotiations between Defendant and Plaintiffs. The period for informal negotiations shall not exceed twenty (20) days from the time Defendant sends Plaintiffs a written Notice of Dispute, unless that period is modified by written agreement of Defendant and Plaintiffs. The Notice of Dispute shall clearly describe the matter in dispute. In the event the Parties cannot resolve their dispute within the informal negotiation period, then the position advanced by Plaintiffs shall be considered binding unless, within 30 days of the conclusion of the informal negotiation period, Defendant invokes the formal dispute resolution procedures as set forth below. Defendant is required to notify

PFBC only if the dispute involves an obligation of Defendant to PFBC under this Consent Decree.

51. **Formal Dispute Resolution.** Defendant shall invoke formal dispute resolution procedures, within the time period provided in the preceding paragraph, by filing with the Court and serving on Plaintiffs a motion requesting judicial resolution of the dispute. The motion shall contain a written statement of Defendant's position on the matter in dispute, including any supporting factual data, analysis, opinion or documentation, and shall set forth the relief requested and any schedule within which the dispute must be resolved for orderly implementation of the Consent Decree.

52. The Plaintiffs shall respond to Defendant's motion within the time period provided in the Local Rules of this Court, unless the Parties stipulate otherwise. Defendant may file a reply memorandum, to the extent permitted by the Local Rules or the Parties' stipulation, or with leave of court as applicable.

53. In any dispute under this paragraph, Defendant shall bear the burden of demonstrating by a preponderance of the evidence that Defendant's position best complies with the terms and conditions of, and furthers the objectives of this Consent Decree. In resolving any dispute the Plaintiffs reserve the right to argue that their position is reviewable only on the administrative record and must be upheld unless arbitrary and capricious or otherwise not in accordance with law and Defendant reserves the right to argue that the Court may receive and consider evidence outside the administrative record and that the Court may conduct de novo or other review.

54. Submission of any matter to the Court for resolution shall not extend any of the deadlines set forth in this Consent Decree unless the Parties agree to such extension in writing or the Court grants an order extending such deadline. Stipulated penalties with respect to the disputed matter shall continue to accrue only as provided in this Consent Decree and payment shall be stayed pending resolution of the dispute as provided in Section XII. Notwithstanding the stay of payment, stipulated penalties shall accrue from the first day of noncompliance with any

applicable provision of this Consent Decree, or in the cases of a required resubmission, from the date of the resubmission except as otherwise provided herein. In the event that Defendant does not prevail on the disputed issue, stipulated penalties shall be assessed and paid as provided in Section XII (Stipulated Penalties) and consistent with the Court's ruling.

#### **XV. EFFECT OF SETTLEMENT**

55. Compliance with this Consent Decree, including the payment of all civil and stipulated penalties demanded by Plaintiffs and interest accrued thereon, and the completion of the SCEP and all SEPs and injunctive relief, shall resolve the United States' and the Commonwealth of Pennsylvania's (including without limitation PADEP's and PFBC's) civil claims for violations alleged in the Complaints filed in this matter, through the Date of Lodging of this Consent Decree and for certain discharges from the Facility to the UGT POTW sewer system for the period June 1, 2006 through August 31, 2006 as alleged in the Complaints.

#### **XVI. NON-WAIVER PROVISIONS**

56. The Parties agree that Defendant is responsible for achieving and maintaining complete compliance with all applicable federal and Commonwealth laws, regulations, and permits, and that compliance with this Consent Decree shall be no defense to any actions commenced pursuant to said laws, regulations, or permits, except as otherwise expressly specified in the Consent Decree.

57. The United States and the Commonwealth of Pennsylvania, do not, by their consent to the entry of this Consent Decree, warrant or aver in any manner that Defendant's complete compliance with this Consent Decree will result in compliance with the provisions of the Clean Water Act, 33 U.S.C. §§ 1251 et seq., the Clean Streams Law, the Solid Waste Management Act, the Safe Drinking Water Act or the Fish and Boat Code. Notwithstanding EPA's and PADEP's review or approval of any plans, reports, policies, or procedures formulated pursuant to this Consent Decree, Defendant shall remain solely responsible for any non-compliance with the terms of this Consent Decree, the Clean Water Act and regulations

promulgated under that Act, and Pennsylvania's pollution control statutes and implementing regulations.

58. The Parties reserve any and all legal and equitable remedies available to enforce the provisions of this Consent Decree, and all defenses thereto.

59. This Consent Decree shall not limit any authority of EPA, PADEP and PFBC under the Clean Water Act, the Clean Streams Law, the Solid Waste Management Act, the Safe Drinking Water Act or the Fish & Boat Code or any applicable statute, including the authority to seek information from Defendant or to seek access to the property of Defendant nor shall it limit Defendant's rights or defenses.

60. Performance of the terms of this Consent Decree by Defendant is not conditioned on the receipt by Defendant of any federal, Commonwealth or local funds.

61. It is the intent of the Parties hereto that the clauses hereof are severable, and should any clause(s) other than paragraph 55 be declared by a court of competent jurisdiction to be invalid and unenforceable, the remaining clauses shall remain in full force and effect.

62. The United States and the Commonwealth of Pennsylvania reserve all remedies available to them for violations by Defendant which are not alleged in the Complaints or which occur after the Date of Lodging of this Consent Decree.

63. This Consent Decree does not resolve criminal liability, if any, that any person might have for violations of the Clean Water Act, the Clean Streams Law, the Solid Waste Management Act or the Safe Drinking Water Act.

64. Nothing in this Consent Decree shall be construed to limit the authority of the United States or the Commonwealth of Pennsylvania to undertake any action against any person, including Defendant, in response to conditions that may present an imminent and substantial endangerment to the environment or to the public health or welfare.

#### **XVII. NOT A PERMIT/COMPLIANCE WITH OTHER STATUTES/REGULATIONS**

65. This Consent Decree is not and shall not be construed as a permit issued pursuant to Section 402 of the Clean Water Act, 33 U.S.C. § 1342, nor as a modification of any existing

permit so issued, nor as a permit issued pursuant to the Clean Streams Law, the Solid Waste Management Act or the regulations implementing those Acts, nor as a modification of any existing permit so issued, nor shall it in any way relieve Defendant of its obligations to comply with permits, if any, otherwise required for any portion of its Collection System or related wastewater facilities, and with any other applicable federal or Commonwealth permit, law or regulation. Nothing herein shall relieve Defendant of its obligation to comply with any new permit, or modification of existing permits, issued to Defendant in accordance with applicable federal and Commonwealth laws and regulations.

66. Nothing herein shall be construed as relieving Defendant of the duty to comply with the Clean Water Act, the Clean Streams Law, the Solid Waste Management Act or the Safe Drinking Water Act, or the Fish & Boat Code, the regulations promulgated under those acts, and all applicable permits issued to Defendant under those acts and regulations.

#### **XVIII. COSTS OF SUIT**

67. Each party shall bear its own costs and attorney's fees with respect to matters resolved by this Consent Decree.

#### **XIX. RECORD KEEPING**

68. (a) Defendant shall maintain copies of any reports, plans, permits and documents, submitted to EPA and PADEP pursuant to this Consent Decree, including any underlying research and data, for a period of five (5) years from date of submission. Defendant shall require any independent contractor operating any portion of the Collection System or implementing any portion of this Consent Decree to also retain such materials for a period of five (5) years from date of submission. Defendant shall submit such supporting documents to EPA and PADEP upon request.

(b) In addition to the reports and documentation required to be provided by Defendant under the terms of this Consent Decree, Defendant shall also provide, upon demand, any analytical data or any other non privileged documents requested by the United States or

PADEP to review work done, or to be done, by Defendant pursuant to this Consent Decree or to determine Defendant's compliance with the terms of this Consent Decree.

(c) Defendant may assert business confidentiality claims covering part or all of the documents or information submitted to Plaintiffs under this Consent Decree to the extent permitted by 40 C.F.R. Part 2. Documents or information determined to be confidential by Plaintiffs shall be afforded the protection specified in 40 C.F.R. Part 2, Subpart B. Plaintiffs shall not provide public access to documents or information during any period of time during which EPA is making a determination regarding any such claim pursuant 40 C.F.R. Part 2, including all appeals of any such decision. Notwithstanding the language of this paragraph, Defendant may assert that certain documents, records or other information is protected because it contains or constitutes formulae or information from which formulae can be derived. If Defendant asserts such protection, it shall make the documents available for on site review and upon request of the Plaintiffs provide the following: (1) the title of the document, record, or information; (2) the date of the document, record, or information; (3) the name and title of the author of the document, record, or information; (4) the name and title of each addressee and recipient; and (5) a description of the subject of the document, record or information. If following their onsite review of the documents Plaintiffs require Defendant to produce one or more of the documents or the proprietary information therein, Defendant shall do so either pursuant to Defendant's invocation of Dispute Resolution pursuant to Section XIV of this Decree or upon the Court's entry of a protective order. Nothing herein shall constitute a waiver of any privilege; however, no documents, reports or other information created or generated pursuant to the requirements of this Consent Decree shall be withheld on the grounds that they are privileged.

69. Defendant shall notify EPA and PADEP thirty (30) days prior to the disposal or destruction of the records created or generated pursuant to the requirements of this Consent Decree at the end of this five year period and shall, upon EPA's and PADEP's request, make such records available to EPA and PADEP prior to such disposal or destruction.



## **XX. FORM OF NOTICE**

70. Unless otherwise specified, all reports, notices, or any other written communications required to be submitted under this Consent Decree shall be sent to the respective Parties at the following addresses:

### **As to the United States:**

Margaret L. Hutchinson  
Assistant United States Attorney  
Civil Division Eastern District of Pennsylvania  
615 Chestnut Street, Suite 1250  
Philadelphia, PA 19106-4476  
Re: USAO No. 2003V00437

### **As to EPA:**

Christopher A. Day (3RC20)  
Senior Assistant Regional Counsel  
United States Environmental Protection Agency  
Region III  
1650 Arch Street  
Philadelphia, PA 19103

Chief, NPDES Enforcement Branch (3WP42)  
Water Protection Division  
United States Environmental Protection Agency  
Region III  
1650 Arch Street  
Philadelphia, PA 19103

### **As to Commonwealth of Pennsylvania or Commonwealth of Pennsylvania Department of Environmental Protection:**

Martha E. Blasberg  
Supervisory Counsel  
Office of Chief Counsel  
Pennsylvania Department of Environmental Protection  
2 East Main Street  
Norristown, PA 19401

Steve O'Neil  
Operations Chief, Water Management  
Pennsylvania Department of Environmental Protection  
2 East Main Street  
Norristown, PA 19401

### **As to Commonwealth of Pennsylvania Fish and Boat Commission:**

Jason Oyler, Assistant Counsel  
Pennsylvania Fish and Boat Commission  
1601 Elmerton Avenue  
P. O. Box 67000  
Harrisburg, PA 17106-7000

**As to Defendant:**

**John T. McCubbins**

Vice President Global Vaccine Manufacturing  
and West Point Operations  
Merck & Co., Inc.  
P. O. Box 4 WP 36M-4  
West Point, PA 19486

Mark Benevenia, Esquire

Merck & Co., Inc.  
WS3W16D  
Two Merck Drive  
P.O. Box 200  
Whitehouse Station, NJ 08889-0200

Kenneth J. Warren, Esquire

Wolf, Block, Schorr and Solis-Cohen LLP  
1650 Arch Street, 22nd Floor  
Philadelphia, PA 19103

Notifications to or communications with EPA, PADEP, PFBC and the United States Department of Justice ("DOJ") and Defendant shall be deemed submitted on the date they are received.

**XXI. MODIFICATION**

71. This Consent Decree contains the entire agreement of the Parties and shall not be modified by any prior written agreement, representation or understanding. The Consent Decree may be modified by written consent of all of the Parties and notice to the Court or, if the Parties cannot agree, by written Order of this Court. All modifications, with the exception of modifications deemed non-material by mutual agreement of EPA, PADEP, and Defendant, shall be in writing and must be filed with the Court before such modification will be deemed effective.

**XXII. LODGING AND OPPORTUNITY FOR PUBLIC COMMENT**

72. This Consent Decree shall be lodged with the Court for a period of thirty (30) days for public notice and comment, pursuant to the requirements of 28 C.F.R. § 50.7. The United States and the Commonwealth reserve the right to withdraw or withhold their consent if the comments regarding the Consent Decree disclose facts or considerations which indicate that

this Consent Decree is inappropriate, improper, or inadequate. Defendant consents to the entry of this Consent Decree without further notice.

73. If for any reason this Court should decline to approve this Consent Decree in the form presented, this agreement is voidable at the sole discretion of any party and the terms of the agreement may not be used as evidence in any litigation including, without limitation, litigation between the Parties or with any third-party.

74. This Consent Decree shall not be construed to create rights in, or grant any cause of action to, any third party not party to this Consent Decree. This Consent Decree may not be used in any civil proceeding of any type as evidence or proof of any fact or as evidence of the violation of any law, rule, regulation, or Court decision, except in a proceeding to enforce the provisions of this Decree.

### **XXIII. RETENTION OF JURISDICTION**

75. This Court shall retain jurisdiction of this matter for the purposes of implementing and enforcing the terms and conditions of this Consent Decree and for the purpose of adjudicating all disputes among the Parties that may arise under the provisions of this Consent Decree, to the extent that this Consent Decree provides for resolution of disputes by the Court. Such jurisdiction shall not terminate until all requirements of this Consent Decree have been fulfilled and all disputes arising under this Consent Decree have been resolved.

### **XXIV. TERMINATION**

76. The Consent Decree shall terminate when all of the following events have occurred:

(a) Defendant certifies that it has completed all obligations under this Consent Decree, including without limitation under Section V (Remedial Measures), Section X (SCEP), Section XI (Supplemental Environmental Projects), and Section IX (Civil Penalties) of this Consent Decree, and that any obligations have been satisfied through the applicable completion dates specified above and has paid any applicable stipulated penalties demanded by Plaintiffs under Section XII of this Consent Decree.

(b) the Parties file a Joint Motion to Terminate the Consent Decree with the Court and the Court grants the Motion. If Defendant requests Plaintiffs to file a joint motion to terminate the Consent Decree, but one or more of the Plaintiffs do not agree that the Consent Decree may be terminated, Defendant may invoke Dispute Resolution under Section XIV of this Decree.

77. The Consent Decree shall not terminate if, following certification by Defendant of compliance pursuant to paragraph 76 (a) above, the United States or the Commonwealth of Pennsylvania assert in writing that full compliance has not been achieved. If the United States or the Commonwealth of Pennsylvania dispute Defendant's full compliance with this Consent Decree, this Consent Decree shall remain in effect pending resolution of the dispute by the Parties or the Court in accordance with the Dispute Resolution provisions of this Consent Decree. If Defendant invokes Dispute Resolution, Defendant shall have the burden of proof by a preponderance of the evidence that it has satisfactorily complied with the requirements of the Consent Decree.

#### **XXV. SIGNATORIES/SERVICE**

78. The Assistant Attorney General of the Environment and Natural Resources Division of the U.S. Department of Justice together with the United States Attorney for the Eastern District of Pennsylvania on behalf of the United States and the undersigned representatives of Defendant and the Commonwealth of Pennsylvania certify that they are fully authorized to enter into the terms and conditions of this Consent Decree and to execute and legally bind such party to this document.

79. Defendant agrees to accept service of process by mail with respect to all matters arising under or relating to this Consent Decree and to waive the formal service requirements set forth in Rule 4 of the Federal Rules of Civil Procedure and any applicable Local Rules of this Court including, but not limited to, service of a summons.

## **XXVI. INTEGRATION/APPENDICES**

80. This Consent Decree and its Appendices constitute the final, complete, and exclusive agreement and understanding among the Parties with respect to the settlement embodied in the Decree and supersede all prior agreements and understandings, whether oral or written. Other than the Appendices, which are attached to and hereby incorporated into this Decree, and the Users Manuals, operating plans and evaluation plans referenced herein, no other document, nor any representation, inducement, agreement, understanding, or promise, constitutes any part of this Decree or the settlement it represents, nor shall it be used in construing the terms of this Decree.

The following Appendices are attached to and incorporated into this Consent Decree:

“Appendix A” is the description of the Enhanced Management Program  
(Predictive Tool)

“Appendix B” is the description of the Enhanced Wastewater Management  
Program

“Appendix C” is the description of the Chemical Management Accountability  
System

“Appendix D” is the description of the Angus Tract at Erdenheim Farm Purchase  
and Protection SCEP

“Appendix E” is the description of the Wissahickon Creek Restoration SEP at  
NLT Tract at Erdenheim Farm

“Appendix F” is the description of the Angus Tract at Erdenheim Farm  
Environmental Restoration SEP

“Appendix G” is the description of the Drinking Water Protection Early Warning  
System SEP

“Appendix H” is the description of the Automated Dissolved Oxygen Control  
SEP at UGT POTW

“Appendix I” is the description of the Wissahickon Creek Restoration SEPs

Dated and entered this \_\_\_\_\_ day of \_\_\_\_\_ 2007.

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Judge

FOR THE UNITED STATES OF AMERICA:

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RONALD J. TENPAS  
Acting Assistant Attorney General  
U.S. Department of Justice  
Environment and Natural Resources Division  
Washington, DC 20530

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DATE

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NANCY FLICKINGER  
Senior Attorney  
Environmental Enforcement Section  
Environment and Natural Resources Division  
U.S. Department of Justice  
Post Office Box 7611  
Ben Franklin Station  
Washington, DC 20044  
(202) 514-5258

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DATE

FOR THE UNITED STATES OF AMERICA:

\_\_\_\_\_  
PATRICK L. MEEHAN  
United States Attorney

\_\_\_\_\_  
DATE

\_\_\_\_\_  
VIRGINIA A. GIBSON  
Assistant United States Attorney  
Chief, Civil Division

\_\_\_\_\_  
DATE

\_\_\_\_\_  
MARGARET L. HUTCHINSON  
Assistant United States Attorney  
U.S. Attorney's Office  
615 Chestnut Street, Suite 1250  
Philadelphia, PA 19106  
(215) 861-8282

\_\_\_\_\_  
DATE



FOR THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY:

\_\_\_\_\_  
GRANTA Y. NAKAYAMA

\_\_\_\_\_  
DATE

Assistant Administrator  
Office of Enforcement and Compliance Assurance  
U.S. Environmental Protection Agency  
Ariel Rios Building, 2201A  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

FOR THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY:

\_\_\_\_\_  
DONALD S. WELSH  
Regional Administrator  
U.S. Environmental Protection Agency  
Region III  
1650 Arch Street  
Philadelphia, PA 19103

\_\_\_\_\_  
DATE

\_\_\_\_\_  
WILLIAM C. EARLY  
Regional Counsel  
U.S. Environmental Protection Agency  
Region III  
1650 Arch Street  
Philadelphia, PA 19103

\_\_\_\_\_  
DATE

\_\_\_\_\_  
CHRISTOPHER A. DAY  
Senior Assistant Regional Counsel  
U.S. Environmental Protection Agency  
Region III  
1650 Arch Street  
Philadelphia, PA 19103

\_\_\_\_\_  
DATE



FOR THE COMMONWEALTH OF PENNSYLVANIA, FISH AND BOAT COMMISSION:

\_\_\_\_\_  
Douglas J. Austen, Ph.D.  
Executive Director  
Pennsylvania Fish and Boat Commission

\_\_\_\_\_  
DATE

FOR MERCK & CO., INC.:

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John T. McCubbins	DATE
Vice President Global Vaccine Manufacturing and West Point Operations	
Merck & Co., Inc.	
P. O. Box WP 36M-4	
West Point, PA 19486	