Information Collection Request:
Concentrated Aquatic Animal Production Effluent Guidelines (Renewal)
ICR No. 2087.03, OMB No. 2040-0258

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U.S. Environmental Protection Agency
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Content

Tables

1. Identification of the Information Collection

1.a. Title of the Information Collection

Title: Concentrated Aquatic Animal Production Effluent Guidelines (Renewal)
EPA ICR Number 2087.03
OMB Control Number 2040-0258

1.b. Short Characterization/Abstract

This Information Collection Request (ICR) requests OMB renewal of the approval for the Concentrated Aquatic Animal Production (CAAP) Effluent Guidelines. The rule establishes specific reporting requirements for a segment of CAAP facilities through NPDES permits. The rule covers facilities which are defined as CAAP facilities (see 40 CFR 122.24 and 40 CFR Part 122 Appendix C) and produce at least 100,000 pounds per year in flow through, recirculating and net pen systems.

The rule includes special reporting and recordkeeping requirements which are the subject of this ICR. CAAP facility owners or operators are also required to file reports with the permitting authority when drugs with special approvals are applied to the production units or a failure in the structural integrity occurs in the aquatic animal containment system.

When CAAP facilities apply either an Investigational New Animal Drug (INAD) or a drug that has been prescribed extra-label by a veterinarian to treat the aquatic animals at their facility, the owner or operator must report this use to the permitting authority. In addition, the owner or operator of a CAAP facility must notify the permitting authority upon agreeing to participate in an INAD study.

Whenever a structural failure occurs in the aquatic animal containment system, the owner or operator must report this to the permitting authority. For the purposes of this requirement, the aquatic animal containment system is defined as the unit(s) that contain(s) the aquatic animals and in which their culture takes place, as well as the wastewater handling and treatment units associated with aquatic animal production.

CAAP facilities subject to this regulation are also required to develop and implement a Best Management Practices (BMP) plan that ensures that the regulatory requirements will be met. Upon completion of this BMP plan the owner or operator must certify to the permitting authority that the plan has been developed.

CAAP facilities are also expected to keep records on the feed inputs along with an estimate of the number and weight of the animals being raised. These records are to be used to calculate the feed conversion ratios for the facility. Records must also be kept documenting the frequency of facility inspections, maintenance and repairs, along with the cleaning of the rearing units at flow through and recirculating facilities or changing the nets at net pen facilities.

2. Need for and Use of the Collection

2.a. Need and Authority for the Collection

The purpose of the Clean Water Act (CWA) is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters. To meet that end, the CWA establishes the NPDES program to regulate the discharge of any pollutant or combination of pollutants from point sources into waters of the United States.

EPA promulgated technology-based effluent limitation guidelines and standards (ELGs) for a subset of CAAP facilities required to obtain NPDES permits. The requirements in the ELGs are incorporated into the NPDES permits issued by EPA and states.

Section 308(a) of the CWA authorizes the Administrator to require the owner or operator of any point source to file reports as required to carry out the objectives of the Act. The Concentrated Aquatic Animal Production ELG requires reporting in the event that drugs are used which are either under a conditional approval as Investigative New Animal Drugs (INADs) or are prescribed by a licensed veterinarian for treatment of a disease or a species that is outside the approved use of the specific drug, referred to as extra-label use. This reporting requirement is appropriate for these classes of drugs, because they have not undergone the same degree of review with respect to their environmental impact as approved drugs. Reporting is also required when the facility has a failure in the structural integrity of the aquatic animal containment systems. This reporting is necessary to alert the permitting authority to the release of large quantities of material from these facilities.

Any CAAP facility that agrees to participate in an INAD program is required to notify the permitting authority within 7 days of its agreement. Facilities are to report the identity of the INAD, the method of application, the dosage and the disease or condition it is intended to treat. This reporting provides the permitting authority with the opportunity to require some monitoring or even controls on the discharge of the wastewater containing these drugs if they believe there is any reason for concern. It can also serve to identify multiple applications of a specific extra-label drug or INAD in the same watershed which could contribute to an unacceptable loading to that watershed. This has been raised as a concern where there are several CAAP facilities located in the same watershed.

Facilities are required to file two reports to the permitting authority whenever an INAD or extra-label drug is used at their facility. The first report must be made orally within 7 days of initiating the use of an INAD or extra-label drug. The owner or operator shall notify the permitting authority of the drug active ingredient being applied and the reason for using it. The second is a written report which must be filed within 30 days of the conclusion of application of the drug. This report must identify the drug added, the reason for treatment, the date(s), time(s) and duration of addition, the total amount of active ingredient added, the total amount of medicated feed added (if that is the application method) and the estimated number of aquatic animals treated with the additions.

Reporting a failure in the structural integrity of the aquatic animal containment system also involves making two reports to the permitting authority. The first report is to be made orally

within 24 hours of discovery of the system failure, and must provide the likely cause of the failure and an estimate of the material released. Seven days following the discovery of the failure, the facility owner or operator must file a written report which includes all the same information that was included in the initial report as well an estimate of the time elapsed until the failure was repaired and steps being taken to prevent a reoccurrence.

Failures tend to be rare, especially at flow through and recirculating facilities. However, when they do occur, they can have significant environmental impacts including the discharge of large quantities of solids, fish carcasses and live fish.

2.b. Practical Utility and Users of the Information

The information on the use of INAD and extra-label drugs may lead to permit requirements to prevent or minimize further discharges of the drug. Advance notice of a CAAP facility's participation in an INAD program can provide the permitting authority an opportunity to obtain information concerning the effects of the drug and determine if any controls on the discharge of the INAD is warranted. If a determination is made to limit the discharge when the INAD is being used in accordance with 40 CFR §125.3, and 122.44, the facility can subsequently determine how the limits can be achieved. Furthermore, in the event that adverse environmental impacts are noted from the use of an investigational drug, the permitting authority could share the information with the Food and Drug Administration (FDA). Based on this information, FDA could determine whether to withdraw the investigational approval.

The information on the failure of structural integrity can provide the permitting authority with some indication of pollutant slugs discharged to the receiving streams. These slugs may include solids, carcasses, and fish. The impact on the receiving water can be severe although in most cases brief. In addition to the solids loading, the release of fish from the CAAP facility may pose concerns if the fish being produced are non-native. The permitting authority may need to alert state fish and game authorities when non-native species have been released. Early intervention can minimize the establishment of a species and thus avoid the negative economic and environmental impacts associated with establishment of a non-native species.

3. Nonduplication, Consultations, and Other Collection Criteria

3.a. Nonduplication

During the rulemaking process prior to 2004, EPA examined all other reporting requirements contained in the CWA and 40 CFR Parts 122, 123, 124, 125, 501, and 503. The Agency also met with other Federal Agencies including the Food and Drug Administration (FDA), National Marine Fisheries Service (NMFA) of the Department of Commerce, the National Invasive Species Council, and the Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture (USDA). The Agency also consulted with the following sources of information to determine if similar or duplicate information were available elsewhere:

- the EPA Information Systems Inventory
- the EPA Inventory of Information Collection Requests, and
- the Federal Information Locator System.

Examination of these databases and discussions with other Federal Agencies did not identify any reporting requirements that were duplicative with existing requirements.

3.b. Public Notice Required Prior to ICR Submission to OMB

In compliance with the 1995 Paperwork Reduction Act (PRA), any agency developing a non-rule-related ICR must solicit public comments before submitting the ICR to OMB. These comments, which are used partly to determine realistic burden estimates for respondents, must be considered when completing the Supporting Statement that is submitted to OMB.

This ICR was published in the Federal Register on June 27, 2007 (72 FR 35227-35230). The notice included a request for comments on the content and impact of these information collection requirements on the regulated community. EPA received no comments on this ICR.

3.c. Consultations

During the rule development process, EPA met with several other Federal Agencies to better understand their programs and how they relate to EPA's development and implementation of this ELG. EPA met with representatives of FDA, the APHIS in USDA, U.S. Fish and Wildlife Service (USFWS) in the Department of Interior, and the National Marine Fisheries Service of the National Oceanic & Atmospheric Administration (NOAA) in the Department of Commerce. Each of these Agencies has some authority over issues related to aquatic animal production and has some ability to address environmental concerns related to this sector.

FDA indicated that they do not have authority to control the drug residues present in the wastewater discharges from CAAP facilities that have used a drug. The FDA does conduct an environmental assessment to evaluate the potential environmental impacts that could be associated with the use and release of the drug into the environment, but they don't necessarily have the authority to withhold a drug's approval solely on the basis of potential environmental impacts. Further, the environmental assessment does not account for all the various site-specific conditions or the possible cumulative effects when several facilities use the same drug and discharge wastewater into the same watershed. FDA did not have any objections to EPA including the reporting requirements for INADs and extra-label drugs in the regulation.

APHIS is responsible for tracking, reporting and taking action when there are disease outbreaks at aquatic animal production facilities. Diseases that require action by APHIS include those identified by the World Organization for Animal Health (formerly known as *Office International des Epizooties)*. APHIS works with State Departments of Agriculture which typically have the responsibility to take action when a reportable disease is identified at a facility. Action can include confiscating and destroying the animals and shutting the facility down for a period of time or until the facility can demonstrate that they are disease free. APHIS also has responsibility for preventing the entry of invasive species and controlling the spread of established populations of invasive species. APHIS is responsible for implementing several Acts related to the control of invasive species including disease. Since APHIS in conjunction with

State Departments of Agriculture have considerable authority to take action to prevent the spread of diseases from aquaculture facilities, EPA is not establishing any additional requirements specific to this concern.

EPA also had discussions with NOAA's National Marine Fisheries Service to discuss their program to develop off-shore aquaculture. Some of the concerns related to this topic include the control of pollutants at open water systems and the potential for system failure. NOAA believes that many concerns related to the development of aquaculture off-shore will be dealt with when suitable sites are identified and indicated that new off-shore sites would be subject to an Environment Impact Statement under NEPA.

3.d. Effects of Less Frequent Collection

EPA requires minimal reporting in this regulation. Facilities are expected to certify to the permitting authority that they have developed a BMP plan only once over the course of the permit cycle (usually 5 years). The certification itself is expected to consist of a letter that states that the BMP plan has been developed in accordance with the requirements of the regulation.

The other reporting associated with the use of drugs or failure in the structural integrity are only required in the event one of these activities occurs. The reporting itself for either of these situations is minimal. EPA requires an oral report to be made initially, followed by a more detailed written report. EPA has determined less frequent reporting would impede the ability of the permitting authority to take action to minimize harm to the environment when warranted.

3.e. General Guidelines

This information collection complies with Paperwork Reduction Act guidelines at 5 CFR 1320.5(d)(2). Requests for supplemental information for the purposes of emergency response of enforcement activities are exempt from Paperwork Reduction Act requirements.

3.f. Confidentiality

This information collection may contain Confidential Business Information (CBI), especially the reporting requirements associated with investigational drug use. If this is the case, the respondent may request that such information be treated as confidential. All confidential data will be handled in accordance with 40 CFR 122.7, 40 CFR part 2. However, CWA sec. 308(b) specifically states that effluent data may not be treated as confidential.

3.g. Sensitive Questions

This information collection does not include sensitive questions.

4. Respondents and Information Requested

4.a. Respondents/NAICS Codes

The NAICS codes that apply to the CAAP facilities included in EPA's regulation are listed on Table 4.1.

Table 4-1 NAICS Codes

Examples of regulated entities include facilities engaged in aquatic animal production	Primary NAICS codes
Finfish Farming and Fish Hatcheries	112511
Other Animal Aquaculture	112519

Not all facilities classified in these two NAICS codes will be subject to the reporting requirements included in this request. Other rules established a subset of facilities engaged in aquatic animal production as concentrated aquatic animal production facilities and by definition these facilities must obtain an NPDES permit. The definition of CAAP can be found at 40 CFR 122.24 and Appendix C of 40 CFR Part 122. The regulations covered by this ICR in turn only apply to a subset of CAAP facilities. These facilities are defined in the applicability of the final rule at 40 CFR 451. EPA estimates that 242 facilities will be subject to these requirements.

Not all of the 242 regulated facilities will be subject to all of the reporting requirements included in the final rule. Many of the reporting requirements apply only when certain events or conditions exist at the facility. EPA does not expect all facilities will experience these conditions or events annually and thus will not incur the burden or cost associated with the reporting requirements.

4.b. Information Requested

This section presents the data items, including recordkeeping requirements and required respondent activities in preparing and submitting those data items.

4.b.i. Data Items, Including Reporting and Recordkeeping Requirements

EPA established reporting and recordkeeping requirements to ensure that the facilities are implementing BMPs and reporting on the use of certain classes of drugs and any failures to the structural integrity of the rearing units, net pens or wastewater treatment structures. EPA also established requirements for facilities to perform feed monitoring at net pen facilities which can include the use of real-time monitoring systems such as video monitoring, the use of sediment sampling, benthic monitoring or devices designed to capture solids that have fallen beneath the nets. Finally, EPA required facilities to maintain records on the feed added, the number and weight of the animals being raised as well as records on the frequency of inspections, maintenance and repairs to the facility aquatic animal containment system. Also the regulation required facilities to keep records on the frequency that the rearing units at flow through and recirculating facilities are cleaned or nets are changed at net pen facilities.

EPA established reporting requirements associated with the application of INAD and extra-label drugs. When a CAAP facility agrees to participate in an INAD program EPA requires the owner or operator to notify the permitting authority in writing within 7 days of the date that the facility signed up to participate in this program. The report would include the name of the INAD, the method of application, the dosage and the disease or condition it is intended to treat. Reporting is not required if the INAD or extra label drug use does not exceed the approved dosage for the same drug in use under similar conditions. When an INAD or extra-label drug that does not

meet the exception is used at a CAAP facility, the owner or operator must file two reports with the permitting authority concerning this use. The first report is made orally and must be made no later than 7 days after initiating treatment. The facility owner or operator must notify the permitting authority that either an INAD or extra-label drug application is occurring at the facility. The report must identify the drug and the reason for its addition.

The second report is a written report which must be provided to the permitting authority within 30 days of concluding treatment. The written report must include the identity of the drug, the reason for treatment, the date(s), time(s) and duration of the treatment, the total amount of active ingredient added, or the total amount of medicated feed added when this is the method of application and the estimated number of animals treated.

FDA's Center for Veterinary Medicine (CVM) under the authority of the Federal Food, Drug and Cosmetic Act (FFDCA) approves drugs to treat specific diseases in specific species of aquatic animals. FDA also issues exemptions of approval for Investigative New Animal Drugs that can be used to treat specific diseases in specific species. As part of the evaluation of a drug for its approval, FDA is required to conduct an environmental assessment. Thus, approved drugs have been studied for the potential effect their use would have on the environment. Although FFDCA does not provide FDA the authority to disapprove a drug solely on the basis of environmental concerns, the environmental assessment information is publicly available. This information can be accessed by permit writers or producers so they can take action on a case-by-case basis to protect the environment should residual drug active ingredients be discharged from the facility in levels which pose environmental concern.

The FFDCA authorizes veterinarians to prescribe drugs which have been approved for treating humans or animals of a different species or to treat a different condition. Veterinarians prescribe extra-label drugs when the animals' health is suffering or threatened; however, the treatment may not result in a violative food residue.

INADs and extra-label drugs used at dosages which exceed approved dosage and under different conditions have not undergone the same degree of scrutiny for their environmental effects. Therefore, EPA believed it was appropriate to establish requirements for CAAP facility owners or operators to report to the permitting authority when these classes of drugs are being used at their facilities.

EPA required facilities to report to the permitting authority any time the facility experiences a failure or damage to the aquatic animal containment system resulting in a material discharge to waters of the United States. The aquatic animal containment system is defined as the culture or rearing unit including raceways, ponds, tanks or nets used to contain, hold or produce aquatic animals. The containment system also includes structures designed to hold sediments and other materials as part of the wastewater treatment system. For net pen systems, failures include physical damage to the predator control nets or the nets containing the aquatic animals, which result in a discharge of the contents of the nets. Physical damage includes abrasion, cutting or tearing of the nets and breakdown of the netting due to rot or ultra violet exposure. For flow through and recirculating systems, a failure includes a collapse or damage of a rearing unit or wastewater treatment structure; damage to pipes, valves, and other plumbing fixtures; and

damage or malfunction to screens or physical barriers in the system, which would prevent the unit from containing water, sediment, and the aquatic animals. Because the determination of what constitutes damage resulting in a "material" discharge varies from one facility to the next, permitting authorities are encouraged to include more specific reporting requirements defining these terms in the permit. Such conditions might recognize variations in production system type and environmental vulnerability of the receiving waters. A failure of the containment system that results in a material discharge must be reported within 24 hours of discovery of the failure. This report would be made orally to the permitting authority and would describe the cause of the failure in the containment system and identify materials that may have likely been released to the environment as a result of this failure. The facility would also be required to provide a written report within seven days of discovery of the failure documenting the cause, the estimated time elapsed until the failure was repaired, an estimate of the material released as a result of the failure, and steps being taken to prevent a reoccurrence.

EPA required reporting of failures and damage that lead to a material discharge to ensure that permitting authorities are alerted to the release of significant pollutant loads over a relatively short time frame. EPA did not expect this type of failure to occur very frequently at flow through and recirculating facilities. EPA anticipated that there will be a greater number of these events occurring at net pen facilities. The location of these facilities in open water makes them vulnerable to damage from predators and accidents. Failures at net pen facilities have the potential to release the contents of the nets including fish and fish carcasses.

EPA included requirements that address the structural maintenance of the aquatic animal containment system and a requirement that facilities keep records on the frequency of inspections, maintenance and repairs to the facility to avoid structural failures. The type of records this requirement might include would be a log of dates when inspections occur and brief notations when something is found. Also records would be kept on maintenance and repair activities, including the date and the actions taken.

EPA required reporting of any spills of drugs, pesticides or feed that result in a discharge to waters of the United States. The regulation requires CAAP facilities to ensure proper storage of these materials and to implement procedures for properly containing, cleaning and disposing of any spilled material. Therefore, the occurrence of spills should be minimal. Since the facility is operating in an aquatic environment, it would not be difficult for any spill to result in a pollutant discharge. Therefore, EPA believed this reporting requirement was important to notify permit writers of the potential for environmental effects in the receiving stream.

The ELG for the CAAP category is based on requirements to reduce the discharge of solids, avoid spills of materials, and ensure the facility is being properly operated and maintained through implementing BMPs. Each of these requirements is based on the presumption that the CAAP facilities will achieve compliance by implementing BMPs. EPA required CAAP facilities to develop a BMP plan which identifies the BMPs and documents any associated activities such as recordkeeping, and training associated with the BMPs. The Plan will be maintained at the CAAP facility, but must be made available to the permitting authority upon request. EPA also required that CAAP facilities certify in writing to the permitting authority once upon issuance of a permit that the BMP plan has been developed.

In addition to the recordkeeping described above related to the inspections, maintenance and repair of the facility, EPA also required CAAP facilities to keep records on the amount of feed added to each rearing unit along with an estimate of the number of animals contained in the unit and the weight of the animals. From these records the facility should calculate a representative feed conversion ratio for the animals produced at the facility. EPA also required CAAP facilities to keep records on the frequency of cleaning the rearing units and changing the nets at net pen facilities.

4.b.ii. Respondent Activities

All facilities subject to this regulation will be required to develop, and implement BMPs which address a variety of aspects of their facility. These BMPs must also be documented in a BMP plan, and a letter certifying that the Plan has been developed must be sent to the permitting authority. EPA estimates that these activities will require 40 hours to accomplish. This activity is expected to be done once over the term of the permit which is typically five years. Thus the annual estimated burden pro-rated across the five year permit term is 8 hours per year.

The number of facilities that reported participating in INAD programs in response to EPA's detailed survey indicates that there would likely be less than 20 facilities annually affected by EPA's INAD or extra-label reporting requirement. The rule specifies that facilities report when an INAD and extralabel drug is used and they would file less than 40 reports on the use of an INAD or extra-label drug in any given year. All of the facilities that reported participation in an INAD study were non-commercial facilities that were either State or Federal hatcheries. EPA's data do not provide the details on the use of extra-label drugs at CAAP facilities. Thus, EPA is making an assumption that facilities will use either extra-label or INAD drugs in any given year, and the number of applications requiring reporting will be less than 40. EPA is assuming that the facilities that will apply extra-label drugs will not be just non-commercial facilities. The number of commercial facilities is likely to be substantially smaller than non-commercial facilities in part due to withdrawal concerns.

The burden associated with reporting for INADs and extra-label drugs will include an hour of a manager's time to prepare and mail a letter notifying the permitting authority that the facility is participating in an INAD study. EPA estimates that a manager will spend half an hour filing the oral report on either INAD or extra-label drug use and subsequently an additional hour writing the letter that notifies the permitting authority when the treatment is concluded. EPA also anticipates that unskilled labor will spend some time keeping records throughout the application of the drug. This data will be used by the manager in the written report. However, EPA expects that this staff will also be doing these activities to respond to requirements of the INAD agreement or simply for the purposes of good husbandry in the case of extra-label drug applications.

EPA assumes that few flow through and recirculating facilities will experience structural failures in their aquatic animal containment systems. This is in part based on the very small number of facilities that EPA is aware of that have experienced such failures in the past. EPA is estimating that 22 facilities will experience a reportable failure each year. Failures are unlikely to affect only non-commercial or commercial facilities; thus, EPA is assuming that the failures will be

distributed between non-commercial and commercial facilities. Net pen facilities are expected to experience reportable failures at a much higher rate due to the inherent vulnerabilities of the system. EPA is assuming that each net pen facility will have one reportable failure each year.

Failures can be minimized through frequent inspection of the rearing units and wastewater treatment system and prompt repair of any damage identified. EPA is requiring that facilities keep records on the frequency of the inspections and any repairs and maintenance activities performed. EPA assumes the inspections will be performed by each facility once per week while production is occurring. For the flow through and recirculating facilities, EPA believes that inspections would occur on each rearing unit and wastewater treatment structure taking approximately 5 minutes per unit. Net pen inspections require divers to inspect the facility underwater. Based on available information, all net pen facilities are believed to be currently conducting these inspections on a regular basis, and these inspections are assumed to continue at the same frequency.

Reporting of spilled drugs, pesticides or feed that result in a discharge to waters of the United States, must be reported orally to the permitting authority within 24 hours of occurrence, followed by a written report within 7 days. The report must identify the material spilled and an estimated amount. EPA does not expect spills will occur very often, since facilities are required to implement proper storage and implement procedures for proper cleaning, containing and disposing of the spilled material. Again for the purpose of estimating the burden, EPA is assuming that more net pen facilities will experience a spill in any given year, and noncommercial flow through and recirculating facilities may experience a slightly higher rate of spills, since they tend to report a higher rate of drug and pesticide use.

Other recordkeeping required by the CAAP regulation involves recording the amount of feed added to each rearing unit and tracking the number of animals and the weight of the animals contained in the rearing unit. The feed inputs are assumed to be tracked on a weekly basis during periods when feeding occurs. The number of animals and weight of the animals will be tracked less frequently. Animal numbers can be estimated using the approximate number added to the unit when stocking occurred less the mortalities removed from the unit over time. The weight can be measured at the time of harvest. These values in aggregate by facility or by species shall be used to calculate a representative feed conversion ratio. The feed conversion ratio represents the proportion of feed provided in relation to the amount of weight gained. These records shall be maintained at the facility and provided to the permitting authority when requested or made available to inspectors. The facility owner or operator should also use this data to evaluate whether the feeding regime is achieving the intended results.

EPA also included a requirement that all net pen facilities conduct some form of feed monitoring. This monitoring can be in the form of real-time monitoring such as video monitoring to observe feed passing beneath the net, sediment or benthic sampling, and physical devices designed to capture uneaten feed that passes below the net or other good husbandry practice that is approved by the permit authority. The objective of this requirement is to minimize the discharge of uneaten feed from the net pen system. Based on available information and existing permits, all existing net pen facilities are currently using one of these techniques to minimize the discharge of uneaten feed.

5. Information Collected: Agency Activities, Collection Methodology, and Information Management

5.a. Agency Activities

The Agency's activities as the NPDES permitting authority for five States and all U.S. territories except the Virgin Islands are exactly the same for the 45 NPDES authorized States and the Virgin Islands and consist of processing and reviewing permit applications and Notices of Intent (NOIs). Permit authorities will also process certifications that BMP plans have been developed and document receipt of oral and written reports filed by the permittees concerning INAD and extra-label drugs, and the failure of aquatic animal containment structures.

5.b. Collection Methodology and Management

Each of the NPDES permitting authorities will have the ability to access the information kept by the owners or operators at the CAAP facilities. In addition, the permitting authorities will maintain records of reports made under the Special Reporting Requirements described above. This data may be made available to the public consistent with EPA's regulations concerning the protection of Confidential Business Information (CBI), (40 CFR part 2).

INADs can be considered CBI during the investigative studies. Reports required to be filed with the permitting authority under this regulation that contain CBI should be clearly marked and should be handled by the permitting authority in accordance with 40 CFR 122.7, 40 CFR part 2 and EPA's Security Manual, Part III, chapter 9.

5.c. Small Entity Flexibility

For the CAAP ELG rule, EPA conducted analyses required by the Regulatory Flexibility Act of 1980 (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). See section XIII.B of the preamble in the proposed rule for a summary of these analyses.

EPA believes the burden on small facilities is minimal since reporting is only linked with specific conditions or occurrences at the facility.

5.d. Collection Schedule

The regulation requires the development of a BMP plan to assist in compliance with the requirements along with a certification that a BMP plan has been developed. These activities will occur upon coverage under an NPDES permit that incorporates the ELG requirements. This BMP plan must be completed and certification filed once during the term of the NPDES permit. Reporting requirements associated with INAD and extra-label drugs are related to specific events. Likewise the reporting associated with an aquatic animal containment system failure is linked to a specific event. The reporting requirements do have a related time frame on which the report must be filed. INAD study participation must be reported within 7 days after agreeing to participate in an INAD study or initiating the use of an INAD or extra-label drug chemical. In conjunction with the use of the INAD or extra-label drug, a written report must follow the initial

oral report within 30 days of initiation the use. Likewise reporting associated with a failure damage resulting in a material discharge must be made orally within 24 hours of discovery followed by a written report within 7 days of the event. EPA considers this collection schedule to be reasonable. The certification of the BMP plan should be a straightforward document, most likely taking the form of a letter from the owner or operator at the CAAP facility addressed to the permitting authority. This letter need only be submitted once for each permit cycle which is typically 5 years. Likewise the effort associated with developing the BMP plan is expected to be expended once during the permit cycle.

The reporting of participation in an INAD program is required to occur within 7 days of agreeing to participate in the program. This time lapse provides the CAAP owner or operator ample time to assemble the required information and prepare a letter that will serve to notify the permitting authority. Facilities are generally not expected to require the application of the INAD immediately, however, if agreeing to participate in the INAD program coincides with use of the INAD, the facility would report consistent with the use reporting requirements. INAD and extra-label drug use reporting requires that an oral report be filed as soon as possible, but no later than 7 days after beginning treatment. EPA recognizes that facility owners and operators will be focusing on the health and welfare of the aquatic animals being treated and thus may not be able to file a report immediately, however, within the first 7 days of treatment, the owner or operator can provide an oral report.

The written report related to the use of INAD or extra-label drugs must be filed within 30 days following completion of the treatment. EPA does not expect this time period will impose any hardship on facilities to compile the required information into a letter that can be sent to the permitting authority.

The occurrence of a failure in the aquatic animal containment system must be reported orally through a phone call to the permitting authority within 24 hours of discovery. The urgency associated with this reporting is to allow the permitting authority to take rapid action to mitigate any harmful effects that could occur as a result of the failure's releasing pollutant slugs into the receiving stream. The subsequent written report describing the failure and steps taken to prevent its reoccurrence among other things, is due within 7 days of discovering the failure. EPA expects that operators will be busy taking steps to address the failure, but also believes filing a prompt report will ensure that the facility is actively addressing the causes and looking for ways to prevent reoccurrences to the extent possible.

Spills of drugs, pesticides and feed that result in a discharge to waters of the United States, must be reported orally to the permitting authority within 24 hours of occurrence. A written report must be submitted within 7 days. The report must identify the material that spilled and an estimated amount.

5.e. Information Management

Permitting Authorities will keep the written reports received through this regulation in the permit file. The information may be made available to the public unless it is subject to a claim of CBI. EPA anticipates that there may be such claims attached to reports related to the participation or use of INADs.

The permitting authority may refer to these reports in the event that subsequent reports are filed. For example, previous reports of failures may be reviewed upon oral notification of a failure. If the permitting authority determines that sufficient steps may not have been taken to avoid further failures from occurring, the authority may require the facility to take specific actions.

Upon receipt of a notification report of participation in an INAD program, the permitting authority may choose to gather information on the potential environmental effects of the INAD. EPA anticipates that this could involve some combination of web searching, contacts with the FDA and academics and contacts with the EPA regional office or Headquarters. Based on findings from this research, the permitting authority may choose to establish site-specific controls for the discharge when the INAD is being used.

Upon receipt of the oral notification of the use of an INAD or extra-label drug, the permitting authority may gather the same type of information described above from the same sources. It is unlikely that this information would be used to control the occurrence of the drug's use, but it could lead to discharge requirements for any following use of that drug.

6. Estimating the Burden and Cost of the Collection

In this section EPA presents estimated burden on the CAAP facilities and NPDES Authorized States based on the requirements included in the final regulation. In most cases the total burden per activity is estimated on an annual basis and then multiplied by three to derive the total burden associated with this ICR. There are some requirements in the effluent guidelines regulation that are expected to occur only once during the permit cycle which is typically five years long. The burden estimate for these requirements is estimated based on the time required to accomplish the activity divided by five to provide an annual estimated burden.

6.a. Estimating Respondent Burden

There are requirements which will affect all 242 CAAP facilities estimated to be subject to this effluent guidelines regulation. The requirements include the identification of best management practices, their incorporation into BMP plans and certifications to the permitting authority that the plans have been developed and are being implemented.

Other requirements will affect CAAP facilities dependent on circumstances or the conditions at the facility. CAAP facilities are required to report a failure or damage to the aquatic animal containment system which result in a material discharge of pollutants to waters of the U.S. Permit authorities should specify what constitutes damage resulting in a material discharge to waters of the United States when they issue the permits. These determinations should take into consideration factors such as the production system type, sensitivity of the receiving waters and other relevant factors. For example, the requirement to report a failure or damage in the containment system is more likely to affect facilities which are located in open water such as net pens systems. These facilities are more vulnerable to containment system failure due to weather related events, man-made accidents, or predator activity. Therefore, EPA has distinguished the burden imposed on this category of facilities separately from land-based facilities.

The tables presented below under section 6.d provide the burden and cost associated with the regulation. The tables present the information over three tables, Tables 6-2 through 6-4. EPA has estimated a separate burden and cost associated with the two subcategories, the flow through and recirculating subcategory and the net pen subcategory. Although both subcategories have essentially the same requirements under the rule, the frequency of reporting for some of the requirements is likely to be different. EPA is also subdividing the estimated burden for the flow through and recirculating facilities into two tables. One table (Table 6-2) presents the burden and costs for commercial flow through and recirculating facilities. The second (Table 6-3) presents the burden and costs for non-commercial facilities. Commercial facilities are those which raise aquatic animals for sale; the non-commercial facilities are mostly state or federal facilities and are raising the animals for the purpose of stocking and enhancement of wild populations. The two types of facilities are presented separately because the frequency of reporting is likely to be different for some of the reporting and because the labor rates of the two types of facilities is very different. Non-commercial facilities are actively engaged in the INAD programs through the USFWS which is has been a sponsor of INAD drug products. Other non-commercial facilities are invited to participate in these INAD programs, and several facilities reported to EPA in the detailed surveys that they have used INADs at their facilities. This appears to be much less prevalent at commercial facilities although there have been INAD programs that have been focused on commercial producers.

6.b. Estimating Respondent Costs

EPA has estimated costs associated with the time required to comply with this regulation. Since the regulation is based on the compliance with narrative effluent standards which are based on the implementation of BMPs rather than wastewater treatment technologies, there are no capital and operation and maintenance costs associated with this rulemaking. EPA used the annual estimated hours required to respond to the various requirements and multiplied these costs by a national average labor rate according to labor classification, management or unskilled labor. EPA also distinguishes between commercial facilities and public facilities in the estimation of the costs associated with the information collection. Public facilities are subject to public sector wage schedules; the costs to private, commercial facilities were estimated based on the information reported by respondents to the detailed surveys and data included in the comments on the proposed regulation. The costs presented in this document are calculated using national average hourly rates; however, the costs estimated for the purpose of assessing economic impact were based on more regionally appropriate wages when available. EPA received wage information from CAAP facilities in the detailed surveys and updated them to December 2006 dollars. Table 6.1 presents the labor rates used in this ICR.

In two instances EPA has estimated the costs associated with the requirements based on a more regionally specific labor rate. As described above, net pen facilities are more vulnerable to system failures resulting in the release of large numbers of fish which are potentially non-native species. Thus for net pen facilities a different reporting frequency is assumed for the reporting of the failure of the aquatic animal containment system. Net pen facilities are presently located in the Northeast and Northwest coastal waters. Thus an average labor rates reported in survey responses for these two regions were used to estimate the costs associated with this requirement. The same average labor rate used to calculate costs for reporting non-native releases was also used to estimate the costs for the burden associated with active feed monitoring.

Table 6-1 Hourly rates used in this ICR

Labor category	$/hr
Flow-through and Recirculating (Commercial)	
Facility Management	$24.13
Facility Unskilled Labor	$13.94
Flow-through and Recirculating (Non-commercial)	
Facility Management	$32.48
Facility Unskilled Labor	$23.08
Net Pens	
Facility Management	$31.62
Facility Unskilled Labor	$15.10

Source: 2004 ICR (EPA ICR No. 2087.02) updated to December 2006 dollars using the BLS Employer Costs for Employee Compensation Index.

The costs associated with the structural failure reporting at flow through and recirculating CAAP facilities are derived using a national average hourly rate which excludes the rate associated with net pen facilities.

6.c. Estimating Agency Burden and Cost

6.c.i. Burden on NPDES Authorized States

EPA estimated the burden for State permit writers for the specific actions related to the Alternate Compliance Provision provided in the final regulation.

All CAAP facilities subject to the Effluent Guidelines Regulations are required to develop and implement a BMP plan that addresses specific aspects of the facility. Facility owners or operators are required to certify to the permitting authority that the BMP plan has been developed and is being implemented. As described elsewhere in this document, EPA assumes this certification will take the form of a letter addressed to the permitting authority. EPA estimates that the permitting authorities will spend approximately 15 minutes per certification, reading over the letter and filing it with the facility's permit file. This certification will be filed once in the permit term of five years. Thus the annual burden on the permitting authority per permitted facility is less than one tenth of an hour.

CAAP facilities are required to file reports in conjunction with specific events at their facilities. When animals are treated with a drug or chemical either under an investigative approval from FDA (Investigative New Animal Drug) or at the direction of a licensed veterinarian, the facility owner or operator is required to report it to the permitting authority. Related to the use of an INAD or extra-label drug, the owner or operator must provide an oral report and a written report. The intended purpose of these reports is to provide the permitting authority with the necessary information to make decisions on the potential impact these drugs and chemicals may have on the receiving stream and to determine the need for effluent monitoring or controls associated with the use of these drugs or chemicals. Based on the reports of INAD or extra-label drug use reported in the responses to the detailed survey of CAAP facilities, EPA assumes that most of the INAD applications will be of the same drug for repeated treatments or will be extra-label treatments with drugs which are already widely used for other applications. EPA anticipates that permitting authorities will spend a minimum of two hours researching the potential

environmental effects of the drugs being reported. If there is some concern that warrants further research and the establishment of some effluent controls, the permitting authority may spend as much as an additional 8 hours. For the purpose of this ICR, EPA is assuming an average of 3 hours to conduct research and an additional 3 hours to determine limits or restrictions on the discharge of the drug. This is considered a reasonable estimate, since not all reports will require this much effort while others will require more.

Reporting requirements associated with a failure in the aquatic animal containment system will provide the permitting authority with information concerning the release of large quantities of pollutants over a short span of time. It can provide the permitting authority with the ability to anticipate possible stream impacts that could result from this release and if possible take steps to mitigate them. A release of live fish that are not native to the region may pose a threat to native species. EPA anticipates that the permitting authority will notify the State Department of Fish and Wildlife so that appropriate action may be taken to mitigate this release in a timely manner. Any subsequent failures at the same facilities should also be reviewed in light of the previous reports to determine whether the facility's BMP plan may need to be updated.

6.c.ii. Costs to NPDES Authorized States

The cost to NPDES authorized States is calculated by multiplying the estimated total burden for each respondent by the labor rate of $ $38.28 (December 2006 dollars). This labor rate was based on the average hourly rate for state and municipal employees as determined by the U.S. Department of Labor, Bureau of Labor Statistics (BLS), updated to December 2006 dollars using the BLS Employer Costs for Employee Compensation Index. EPA estimates that there are 204 CAAP facilities in NPDES authorized States. Of these 204 CAAP facilities, an estimated 176 facilities use flow-through system, 9 facilities use recirculating systems and 19 facilities use net pens to produce aquatic animals. The cost for authorized states is presented in Table 6-5.

The estimated burden to EPA per permit is estimated to be the same as the burden associated with state permitting authorities. EPA is the permitting authority in five states. There are an estimated 39 regulated CAAP facilities in these 5 states. The estimated burden associated with the proposed BMP and reporting requirements that would be included in the permits issued to the 39 facilities in these 5 states is shown below in Table 6-6. The State of Idaho has the largest population of CAAP facilities. CAAP facilities in Idaho are already subject to permits that require them to establish a BMP plan and keep records on feed; thus, this ICR does not account for that burden.

6.d. Estimating the Respondent Universe and Total Burden and Costs

The following tables present the estimated annual burden and cost for regulated facilities aggregated by subcategory (e.g., net pen subcategory and the flow through and recirculating subcategory). EPA has not estimated any capital start-up or operational costs. The regulation does not require any specific wastewater treatment be installed and focuses on implementation of practices rather than operation of technologies as the means to ensure compliance with these requirements. EPA's estimated costs are based on the burden and associated labor rates. The labor rates shown on the following tables are averages of the labor rates reported in EPA's detailed survey. These are loaded labor rates as reported by respondents to the detailed survey and updated to December 2006 dollars.

Facilities in the flow through and recirculating subcategory are subdivided by commercial facilities and noncommercial facilities. The majority of noncommercial facilities are publicly owned State or Federal hatcheries that are producing fish for stocking or restoration purposes. The burden and costs estimates for these two types of facilities are presented separately because of the different wages paid to employees of these two types of facilities which has a significant effect on the overall estimated costs of the reporting requirements.

As discussed above in Section 4.b., there are some different assumptions made in the frequency of reporting at noncommercial flow through and recirculating facilities as well. Based on data provided by CAAP facilities in response to EPA's detailed survey, noncommercial facilities have a higher use of INAD drugs. Survey responses from commercial facilities give no indication that INAD or extra-label drugs are used at these facilities; however, EPA is assuming that one facility each year will use an INAD and will incur the burden of reporting for that drug.

EPA's final CAAP regulation requires all facilities to develop a BMP plan and to certify to the permitting authority that this plan has been developed. EPA is including the burden for the plan development for all CAAP facilities subject to this regulation except for flow through and recirculating facilities located in the States of Washington and Idaho. Facilities in these two States are already required to develop BMP plans under existing NPDES permits. Likewise facilities in these two States are already required to perform the feed management practices and associated recordkeeping.

All of the existing net pen facilities indicated that they currently keep records on the feed inputs and inspections, net changes and maintenance and repairs.

Table 6-2 Annual Burden for Flow Through and Recirculating Commercial Facilities

Activity	Management hours (hrs/facility/yr)	Unskilled labor hours (hrs/facility/yr)	Management cost	Unskilled labor cost	No. of facilities	Total hours	Total dollars
BMP Plan Development	8	0	$193.04	$-	59	472	$11,389
BMP Plan Certification	0.25	0	$6.03	$-	59	15	$356
Training for BMPs	2	4	$48.26	$55.76	59	354	$6,137
INAD Program Sign-up Report	1	0	$24.13	$-	1	1	$24
INAD or Extra-Label Use Report	1.5	0	$36.20	$-	1	2	$36
Spill Report	2	0	$48.26	$-	2	4	$97
Structural Failure Report	5	0	$120.65	$-	8	40	$965
Feed Management Records	13	90	$313.69	$1,254.60	59	6,077	$92,529
Inspection, Cleaning, Maintenance & Repair Records	13	90	$313.69	$1,254.60	59	6,077	$92,529

Table 6-3 Annual Burden for Flow Through and Recirculating Non-Commercial Facilities

Activity	Management hours (hrs/facility/yr)	Unskilled labor hours (hrs/facility/yr)	Management cost	Unskilled labor cost	No. of facilities	Total hours	Total dollars
BMP Plan Development	8	0	$259.84	$-	122	976	$31,700
BMP Plan Certification	0.25	0	$8.12	$-	122	31	$991
Training for BMPs	2	4	$64.96	$92.32	122	732	$19,188
INAD Program Sign-up Report	1	0	$32.48	$-	15	15	$487
INAD or Extra-Label Use Report	1.5	0	$48.72	$-	15	23	$731
Spill Report	2	0	$64.96	$-	3	6	$195
Structural Failure Report	5	0	$162.40	$-	14	70	$2,274
Feed Management Records	13	105	$422.24	$2,423.40	122	14,396	$347,168
Inspection, Cleaning, Maintenance & Repair Records	13	105	$422.24	$2,423.40	122	14,396	$347,168

Table 6-4 Annual Burden for Net Pen Facilities

Activity	Management hours (hrs/facility/yr)	Unskilled labor hours (hrs/facility/yr)	Management cost	Unskilled labor cost	No. of facilities	Total hours	Total dollars
BMP Plan Development	8	0	$252.96	$-	19	152	$4,806
BMP Plan Certification	0.25	0	$7.91	$-	19	5	$150
BMP Training	2	4	$63.24	$153.11	19	114	$4,111
INAD Program Sign-up Report	1	0	$31.62	$-	1	1	$32
INAD or Extra-Label Use Report	1.5	0	$47.43	$-	1	2	$47
Spill Report	2	0	$63.24	$-	4	8	$253
Structural Failure Report	5	0	$158.10	$-	19	95	$3,004
Feed Management Records	0	0	$-	$-	0	-	$-
Inspection, Net Replacement, Maintenance & Repair Records	0	0	$-	$-	0	-	$-

Table 6-5 Annual Burden Estimate for State Permitting Authorities

Activity	Hours (hrs/permit/yr)	$/permit	No. of permits	Total hours	Total dollars
BMP Plan Certification Receipt	0.05	$1.91	202	10.1	$386
INAD Program Sign-up Report Receipt	0.5	$19.14	13	6.5	$249
Research on Environmental Affects of INAD	3	$114.84	13	39	$1,493
Determination of Site Specific Limits for INAD	3	$114.84	7	21	$804
INAD or Extra-Label Drug Report Receipt	0.5	$19.14	13	6.5	$249
Spill Report Receipt	0.5	$19.14	7	3.5	$134
Structural Failure Report Receipt	0.5	$19.14	31	15.5	$593
Notify State Fish & Wildlife Department	0.5	$19.14	24	12	$459
Review cause of failure and past reports to evaluate effectiveness of practices	1	$38.28	20	20	$766

Table 6-6 Annual Burden Estimate for Federal Permitting Authorities

Activity	Hours (hrs/permit/yr)	$/permit	No. of permits	Total hours	Total dollars
BMP Plan Certification Receipt	0.05	$1.91	8	0.4	$15
INAD Program Sign-up Report Receipt	0.5	$19.14	4	2	$77
Research on Environmental Affects of INAD	3	$114.84	4	12	$459
Determination of Site Specific Limits for INAD	3	$114.84	1	3	$115
INAD or Extra-Label Drug Report Receipt	0.5	$19.14	4	2	$77
Spill Report Receipt	0.5	$19.14	2	1	$38
Structural Failure Report Receipt	0.5	$19.14	10	5	$191
Notify State Fish & Wildlife Department	0.5	$19.14	5	2.5	$96
Review cause of failure and past reports to evaluate effectiveness of practices	1	$38.28	3	3	$115

6.e. Bottom Line Burden Hours and Cost Tables

The following table presents the total estimated burden and cost for the three year term of this ICR.

Table 6-7 Total Estimated Burden for Facilities for the CAAP Effluent Guidelines Regulation

Activity	Flow through & Recirculating		Net pen	
	Total hours	Total cost	Total hours	Total cost
BMP Plan Development	4,344	$129,270	456	$14,419
BMP Plan Certification	136	$4,039	14	$451
Training for BMPs	3,258	$75,976	342	$12,333
INAD Program Sign-up Report	48	$1,534	3	$95
INAD or Extra-Label Use Report	72	$2,301	5	$142
Spill Report	30	$874	24	$759
Structural Failure Report	330	$9,716	285	$9,012
Feed Management Records	61,419	$1,319,092	0	$-
Inspection, Cleaning, Maintenance & Repair Records	61,419	$1,319,092	0	$-
Subtotal by Subcategory	131,056	$2,861,894	1,129	$37,210
TOTAL RESPONDENT BURDEN & COST	132,185 hours		$2,899,103	
Annual Respondent Burden & Cost	44,062 hours/year		$966,368/year	

Table 6-8 Total Estimated Burden for Permitting Authorities

Activity	State permitting authorities		Federal permitting authorities	
	Total hours	Total cost	Total hours	Total cost
BMP Plan Certification Receipt	30.3	$1,157	1.2	$46
INAD Program Sign-up Report Receipt	19.5	$746	6	$230
Research on Environmental Affects of INAD	117	$4,479	36	$1,378
Determination of Site Specific Limits for INAD	63	$2,412	9	$345
INAD or Extra-Label Drug Report Receipt	19.5	$746	6	$230
Spill Report Receipt	10.5	$402	3	$115
Structural Failure Report Receipt	46.5	$1,780	15	$574
Notify State Fish & Wildlife Department	36	$1,378	7.5	$287
Review cause of failure and past reports to evaluate effectiveness of practices	60	$2,297	9	$345
Subtotal by Subcategory	402.3	$15,398	92.7	$3,548
Annual Burden & Cost	134	$5,133	31	$1,183

Table 6-9 Annual Facilities and States Respondents Tally

Respondent	Respondents	Responses	Burden	Cost
Facilities	200	566	44,062	$966,368
States	45	168	134	$5,133
Total	245	734	44,196	$971,500

The total estimated annual burden for the CAAP Effluent Guidelines Regulation is 44,196 hours and the estimated cost is $971,500. The total burden over the three year ICR approval would be 132,587 hours and $2,914,501.

6.f. Reasons for Change in Burden

There is a decrease of 804 hours (1.8%) in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease reflects EPA's corrections to the 2004 ICR and is not the result of changes to the requirements covered by this ICR. These corrections were made for three types of errors detected:

- Precision errors when approximations were incorrectly done (e.g., 52 hours approximated to 50 hours)
- Assumption error: when assumptions were incorrectly used in the calculations (e.g., 30 minutes entered as 0.3 hours as opposed to 0.5 hours)
- Mathematical errors: clear arithmetic problems (e.g., 8x122=1,720)

6.g. Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 180 hours per respondent per year. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions, develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

To comment on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, the Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OW-2007-0142, which is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202-566-1744, and the telephone number for the Water Docket is 202-566-2426. An electronic version of the public docket is available through the Federal Docket Management System (FDMS) at http://www.regulations.gov/. Use FDMS to submit or view public comments, to access the index listing of the contents of the public docket, and to access documents in the public docket that are available electronically. Once in the system, key in the docket ID number identified above. You can also send comments to the Office of Information and

Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. EPA-HQ-OW-2007-0142 and OMB control number 2040-0258 in any correspondence.