

Compliance Guide for the Concentrated Aquatic Animal Production Point Source Category

Chapter 6: General Reporting Requirements for Flow- through, Recirculating, and Net Pen Facilities

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EPA established general reporting requirements for the use of certain types of drugs (i.e., Investigational New Animal Drugs (INADs), extralabel prescriptions). EPA also established general reporting requirements for failure in or damage to the structure of an aquatic animal containment system, resulting in an unanticipated material discharge of pollutant to waters of the United States.

What is an INAD drug?

An INAD is a drug for which there is a valid exemption in effect under 512(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360b(j). More specifically, INADs are those drugs for which FDA has authorized use on a case-by-case basis to allow a way of gathering data for the approval process. Quantities and conditions of use are specified. FDA, however, sometimes relies on the NPDES permitting process to establish limitations on pollutant discharges to prevent environmental harm. Most NPDES permits, which mention drugs and pesticides, to date have required only reporting of the use of drugs and pesticides.

FDA may grant INAD exemptions from approved use for establishing data to base drug approval. Through the investigative approval process, the sponsor agrees to conduct laboratory and field tests with the drug under the conditions and on the animals proposed for approval. These data are collected in the INAD and eventually submitted to a new animal drug application (NADA) to form the basis for the Center for Veterinary Medicine's (CVM's) approval or disapproval of the drug. Data collection for

the drug approval includes data on the observed or anticipated environmental effects associated with the drug's use. In the case of drugs used on aquatic animals the most significant environmental effect associated with the drug's usage is the effect on the aquatic environment.

What is extralabel use of a drug?

Extralabel use is when a drug is not used according to label requirements. Extralabel drug use is restricted to use of approved animal and human drugs by, or on the order of, a licensed veterinarian and must be within the context of a valid veterinarian-patient relationship.

An example of an extralabel use is injecting erythromycin into adult fish to treat bacterial infections. Since there are no current labeled uses of erythromycin in aquatic animals, this use would require a veterinarian to provide an extralabel prescription. Note, although erythromycin is under an INAD exemption to control bacterial kidney disease in salmonids, any uses other than those associated with the INAD study are only allowed as an extralabel use.

Your veterinarian prescribes oxytetracycline (Terramycin) medicated feed at a dose of 3.0 g of drug per 100 lb of feed for your yellow perch (grown in a flow-through system) that have been diagnosed with Aeromonas liquefaciens. Since Terramycin is approved for as a feed additive to treat salmonids and catfish for Aeromonas liquefaciens, when used according to the veterinarian's prescribed instructions, you do not have to report the use. Remember, you still are required to keep records of the treatment conditions as a requirement of the extralabel provisions developed by FDA.

What am I required to do if I use an INAD drug?

Unless you are exempt, under the general reporting requirements, you must first report your intention to use INAD(s). You must provide a written report to the permitting authority of an INAD's impending use within 7 days of agreeing or signing up to participate in an INAD study. The written report must identify the:

- INAD to be used.
- Method of application.
- Dosage.
- Disease or condition the INAD is intended to treat.

Second, you must provide the permitting authority with an oral report that you are using INAD(s). You must provide an oral report to the permitting authority as soon as possible (preferably in advance of use), but no later than 7 days after initiating use of the drug. The oral report must identify the:

- Drugs used.
- Method of application.
- Reason for using the drug.

Finally, you must also provide a written report to your permitting authority that you are using INAD(s). You must provide a written report to the permitting authority

INAD Reporting Exemption

Remember: you do not need to report an INAD use of a drug previously approved by FDA for a different aquatic animal species or disease if:

- The dosage of the drug is used at less than or equal to the approved dosage **and**
- The use is done under similar conditions.

within 30 days after initiating use of the drug. The written report must identify the:

- Drugs used.
- Reason for treatment.
- Date(s) and time(s) of the addition (including duration).
- Method of application.
- Amount added.

If using an INAD drug, you must provide the following to your permitting authority:

1. A written report within 7 days of agreeing to use an INAD.
2. An oral report no later than 7 days of initiating use of the drug.
3. A written report within 30 days after initiating use of the drug.

Refer to Appendix M for example forms that may be used to submit this information to your permitting authority.

 Regulation: 40 CFR 451.3

What am I required to do if there is extralabel drug use at my CAAP facility?

Unless you are exempt, you must provide the permitting authority with an oral report of extralabel drug use. You must provide an oral report to the permitting authority as soon as possible (preferably in advance of use), but no later

Extralabel Drug Use Reporting Exemption

Remember: you do not need to report an extralabel use of a drug previously approved by FDA for a different aquatic animal species or disease if:

- The dosage of the drug is used at less than or equal to the approved dosage **and**
- The use is done under similar conditions

than 7 days after initiating use of the drug.
The oral report must identify the:

- Drugs used.
- Method of application.
- Reason for using the drug.

You must also provide a written report to your permitting authority of extralabel drug use. You must provide a written report to the permitting authority within 30 days after initiating use of the drug. The written report must identify the:

- Drugs used.
- Reason for treatment.
- Date(s) and time(s) of the addition (including duration).
- Method of application.
- Amount added.

*With **extralabel drug use**, you must provide the following to your permitting authority:*

1. *An oral report no later than 7 days of initiating use of the drug.*
2. *A written report within 30 days after initiating use of the drug.*

Refer to Appendix M for example forms that may be used to submit this information to your permitting authority.

 Regulation: 40 CFR 451.3

What am I required to do if there is a failure in, or damage to, the structure of an aquatic animal containment system?

You will need to notify your permitting authority if:

- There is any failure in, or damage to, the structure of an aquatic animal

containment system resulting in an unanticipated material discharge of pollutants to waters of the United States **and/or**

- If there is a spill of drugs, pesticides, or feed that results in a discharge to waters of the United States.

*Upon discovery of a **structural failure or damage to a containment system or spill of drugs, pesticides, or feed**, you must provide the following to your permitting authority:*

1. *An oral report within 24 hours of discovery.*
2. *A written report within 7 days of discovery.*

The permitting authority may specify in the permit what constitutes reportable damage and/or material discharge of pollutants, based on consideration of production system type, sensitivity of the receiving waters, and other relevant factors.

You must provide an oral report to your permitting authority within 24 hours of the discovery of any reportable failure or damage that results in a material discharge of pollutants. This report must:

- Describe the cause of the failure or damage in the containment system.
- Identify materials that have been released to the environment as a result of the failure.

You must also provide a written report to your permitting authority within 7 days structural failure or damage. This report must:

- Document the cause of the failure or damage.

- Estimate the time elapsed until the failure or damage was repaired.
- Estimate the materials released to the environment as a result of the failure or damage.
- Describe steps being taken to prevent recurrence.

In the event of a spill of drugs, pesticides or feed that results in a discharge to waters of the United States, you must provide an oral report of the spill to your permitting authority within 24 hours of occurrence and a written report in 7 days. The report must include:

- The identity of the material.
- The quantity spilled.

Refer to Appendix M for example forms that may be used to submit information about failure or damage to the structure of containment systems and spills of drugs, pesticides, or feed to your permitting authority.

 Regulation: 40 CFR 451.3

Examples of Information to Include When Reporting Structural Failure

- *Cause of the structural failure – storm broke a hole in 2 nets; raceway screens clogged and caused overflow.*
- *Time that elapsed until the failure was repaired – 2 hours until the nets were repaired; 30 minutes until the screen was unclogged.*
- *Amount and composition of the spill – 2 tons of feed were washed overboard in heavy seas; 1,200 1.8 pound steelhead escaped; or 150 pounds of medicated feed containing Terramycin (0.55% oxytetracycline) spilled into a raceway and discharged.*
- *Steps being taken to prevent recurrence: routinely inspect and perform maintenance on nets; clean screens regularly to prevent clogging.*