

Overview of EPA Authorities for Natural Resource Managers Developing Aquatic Invasive Species Rapid Response and Management Plans Overview of EPA Authorities for Natural Resource Managers Developing Aquatic Invasive Species Rapid Response and Management Plans

U.S. Environmental Protection Agency Office of Wetlands, Oceans, and Watersheds

Overview of EPA Authorities for Natural Resource Managers Developing Aquatic Invasive Species Rapid Response and Management Plans

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Foreword

The U.S. Environmental Protection Agency (EPA) has developed this document as a tool for state, tribal, regional, and local natural resource managers who are preparing or considering the preparation of rapid response action and/or management plans for aquatic invasive species (AIS). The document provides an overview of EPA authorities that might apply to state or local AIS rapid response and control actions. Note that development of new rapid response or control methods and/or new judicial rulings could alter the applicability of the EPA authorities described here and make other EPA authorities relevant.

This tool does not cover other Federal agencies' authorities (e.g. the Endangered Species Act and the Magnuson-Stevens Fishery Conservation and Management Act) or state authorities that might apply to AIS rapid response and control actions.

This document does not represent final EPA action, is not intended to supplant or replace regulations and/or guidance for the authorities described in this document, and is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States.

This document was developed in response to Executive Order 13112 on Invasive Species (EO), signed on February 3, 1999, which orders "each Federal agency whose actions may affect the status of invasive species ... to identify such actions [and] use relevant programs and authorities to detect and respond rapidly to and control populations in a cost-effective and environmentally sound manner." (For the complete text of the EO, see *www.epa.gov/owow/invasive_species/EO13112.pdf*.)



Water chestnut Trapa natans

Introduction

Aquatic invasive species (AIS) are organisms introduced to marine or freshwater ecosystems to which they are not native and whose introduction causes harm to human health, the environment, or the economy. AIS have negative impacts on aquatic ecosystems throughout the United States, costing the nation billions of dollars annually in economic and ecological damages. AIS are considered one of the greatest threats to coastal environments and can significantly affect public water supplies; recreational activities, such as boating; and valuable natural resources, such as fisheries. Major pathways for AIS include:

- discharge of ships' ballast water
- fouling, such as barnacle growth, on commercial and recreational vessels
- accidental or intentional release of marine organisms intended for human consumption, aquaculture, bait, horticulture, aquaria, and the pet trade
- escape or unintended spread of nonnative biocontrol species

Prevention of AIS introductions is generally the most effective means of avoiding their establishment and spread. If prevention measures fail, the following steps are critical to managing AIS establishment and spread:

- 1. routine monitoring of aquatic ecosystems to detect AIS before they become widespread
- 2. rapid assessment of potential management options
- 3. rapid response to eradicate or control AIS

In many cases, eradication ("rapid response") actions must occur quickly, possibly even within a few days of the AIS introduction, to be effective. For this reason, natural resource managers are advised to identify and evaluate potential rapid response actions before species introductions even occur and prepare detailed rapid response plans that can be carried out quickly. If both prevention and rapid response actions fail, natural resource managers may be able to prevent further proliferation and/or minimize harmful AIS impacts by ongoing control of established AIS populations.

Sea lamprey Petromyzon marinus

Examples of AIS Impacts:

- Nonnative fish in the Great Lakes, such as the round goby Negobius melanostomus, sea lamprey Petromyzon marinus, Eurasian ruffe Gymnocephalus cernuus, and alewife Alosa pseudoharengus, compete with native fish for food and habitat, significantly impacting Great Lakes food webs and sports fisheries.
- Nonnative plants, such as the common reed *Phragmites australis*, purple loosestrife *Lythrum salicaria*, and Eurasian milfoil *Myriophyllum spicatum*, have become established in the Great Lakes, displacing native plants that provide wildlife habitat and prevent erosion. Their prevalence in recreational waters also hinders swimming and boating.
- The nonnative infectious oyster disease MSX has devastated native oyster populations along the U.S. East Coast.
- The nonnative green crab *Carcinus maenas* competes with native fish and birds for food and preys on native bivalve populations along the U.S. West Coast, threatening Dungeness crab, clam, and oyster fisheries.
- The nonnative Chinese mitten crab *Eriocheir sinensis* burrows in intertidal stream banks and levies in California, undermining the structural integrity of the banks and causing severe erosion problems.
- The nonnative freshwater weed water hyacinth *Eichhornia crassipes* forms dense mats at the surface of water bodies throughout the United States, decreasing surface flow and preventing light and oxygen from reaching phytoplankton and submerged plants.



Caulerpa taxifolia is a highly invasive marine alga used to decorate saltwater aquaria. It is believed to have been introduced to several regions, including California, through aquaria releases. Once introduced, it spreads by fragmentation (even small fragments can form a new plant) and can form a dense carpet over rock, sand, and mud bottoms and native vegetation. It can also be transported between water bodies by boat anchors, fishing gear, and other equipment. In areas where it has become well-established, it has had a very detrimental impact on native marine communities, recreational boating and diving, and commercial fisheries.

Because *C. taxifolia* is easily spread and very difficult to eradicate, public education about safe disposal of aquaria contents and routine checking and cleaning of boat anchors, hulls, rudders, trailers, and fishing gear is critical to preventing invasions.

Caulerpa taxifolia



Zebra mussels Dreissena polymorpha

In 1988, zebra mussels *Dreissena polymorpha* were inadvertently introduced to Lake St. Clair near Detroit, Michigan, and quickly spread throughout the Great Lakes and into many inland lakes, rivers, and canals. Since then, they have caused severe problems at power plants and municipal water supplies, clogging intake screens, pipes, and cooling systems. They have also nearly eliminated native clam populations in the Great Lakes.

To prevent the westward spread of zebra mussels and other AIS, the 100th Meridian Initiative, a cooperative effort between Federal, state, and Canadian provincial agencies, was started. The Initiative works to prevent the spread of zebra mussels by:

- informing and educating the public about the biology and impacts of zebra mussels and pathways for spreading zebra mussels
- voluntary boat inspections and boater surveys
- establishing monitoring sites to detect the presence of zebra mussels
- eradicating or containing zebra mussels if they are detected

For more information about the 100th Meridian Initiative, see *www.100thmeridian.org*.



Types of Rapid Response and Control Actions

There are three types of methods to eradicate and/or control AIS.

- **Chemical** methods involve the application of chemicals to eradicate and/or control AIS.
- Mechanical and physical methods involve the eradication and/or control of AIS by hand or machine or the alteration of the physical environment. Examples of mechanical and physical rapid response and control actions for invasive plants include manual cutting or picking, mowing, dredging, and shading to prevent photosynthesis. Examples of mechanical and physical rapid response and control actions for invasive animals include netting or trapping, smothering, and changing ambient water temperature.
- Biological methods involve the introduction of parasites, predators, or pathogens to the environment to control AIS. Biological methods are not generally considered rapid response methods because they typically take considerable time to develop and achieve results and they generally reduce, rather than eradicate, target populations.

The three types of eradication and control methods are not mutually exclusive because sometimes they can be used in combination and because some actions might belong to multiple categories. For example, the application of a saline solution to water bodies to eradicate or control AIS could be considered both a chemical and a physical action.



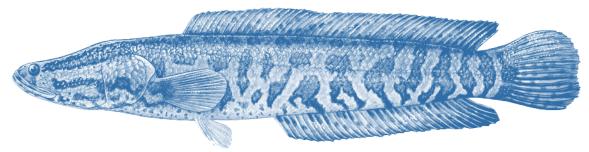
Eurasian watermilfoil Myriophyllum spicatum

Examples of Rapid Response and Control Actions

It can be very difficult to eradicate or control AIS because both AIS and control agents, such as pesticides, are relatively easily spread. Examples of successful rapid response and control actions in aquatic environments are:

- The marine alga *Caulerpa taxifolia*, which is highly invasive in the Mediterranean, was eradicated from two coastal locations in southern California. Natural resource managers covered the *C. taxifolia* infestations with tarps and then injected chlorine beneath the tarps to destroy the alga (Chemical control method).
- The marine mussel *Mytilopsis* sp., a close relative of the zebra mussel *Dreissena polymorpha*, was eradicated from Darwin Harbor in Australia. Chlorine and copper sulphate were added to the waters of three hydraulically and physically locked marinas, and fouled vessels that were inside the infested marinas were hauled out and cleaned (Chemical and mechanical/physical control methods).
- The northern snakehead *Channa argus*, a large, nonnative predatory fish, was eradicated from several small ponds in Maryland. Herbicides were applied to the ponds to remove potential fish refuges and then a piscicide was used to kill the snakeheads in the ponds (Chemical control method).

If rapid response actions are not initiated or do not result in AIS eradication, ongoing control of AIS could be very costly. While there is no credible, comprehensive estimate of what AIS cost the United States economy, it is estimated that control costs in the United States for the invasive marsh weed European purple loosestrife *Lythrum salicaria* are \$45 million annually, and fouling damages in the United States from the invasive shipworm *Teredo navalis* are \$1 billion annually.¹



Northern snakehead Channa argus

¹ For estimates of invasive species control costs, see Pimentel, D., L. Lach, R. Zuniga, D. Morrison (2000) *Environmental and economic costs of nonindigenous species in the United States*. BioScience 50(1): 53-65.



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A Tool for State and Local Natural Resource Managers

Because AIS can have substantial impacts on local environments and economies, and states and localities are often the first responders to aquatic invasions, EPA is providing this tool for state and local natural resource managers. The document provides an overview of EPA authorities that might apply to state or local AIS rapid response and control actions. The document:

- summarizes relevant Sections of the Clean Water Act (CWA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- summarizes how to apply for CWA Section 404 permits to discharge dredged or fill material
- summarizes how to apply for FIFRA Section 18 emergency exemptions and FIFRA Section 24(c) special local need registrations
- describes case studies in which state and local natural resource managers successfully obtained FIFRA emergency exemptions and special local need registrations for AIS eradication or control actions

This document can be found on EPA's website at *www.epa.gov/owow/ invasive_species*.



Giant salvinia Salvinia molesta

Clean Water Act

What is the Clean Water Act (CWA)?

CWA is the cornerstone of surface water quality protection in the United States. The statute employs regulatory and nonregulatory tools to achieve the broad goal of restoring and maintaining the chemical, physical, and biological integrity of the nation's waters so that they can support the protection and propagation of fish, shellfish, and wildlife and recreation in and on the water. CWA regulatory and nonregulatory tools are used to:

- reduce direct pollutant discharges into waterways
- finance municipal wastewater treatment facilities
- manage polluted runoff

Currently, many of the tools used for surface water quality protection employ the watershed approach, which focuses equally on protecting healthy waters and restoring impaired ones. (For the complete text of the Clean Water Act, see *www.epa.gov/region5/water/pdf/ecwa.pdf*.)

In particular, CWA Section 404 might apply to AIS rapid response or control activities. Section 404, which regulates the discharge of dredged or fill material, might apply to AIS eradication activities that involve moving dirt or placing materials into the waters of the United States.

"Waters of the United States" means:

- navigable-in-fact waters
- waters subject to the ebb and flow of the tide
- interstate waters and wetlands
- all other waters, such as interstate lakes and streams, the use, destruction, or degradation of which could affect interstate commerce
- impoundments of waters of the United States
- tributaries of above waters
- territorial seas
- wetlands adjacent to above waters

See 40 CFR 230.3(s) (*www.access.gpo.gov/nara/cfr/waisidx_04/40cfr230_04.html*) for precise regulatory definition. Updates and background information regarding the scope of "waters of the United States" protected under the CWA can be found at *www.epa.gov/owow/wetlands/guidance/SWANCC*.

"Pollutant" means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal, and agricultural waste discharged into water.

"Point source" means any discernible, confined, and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.

CWA Section 402—The National Pollutant Discharge Elimination System (NPDES)

What is CWA Section 402?

CWA Section 402 establishes the NPDES permit program to regulate point source discharges of pollutants into waters of the United States. An NPDES permit sets specific discharge limits for point sources discharging pollutants into waters of the United States and establishes monitoring and reporting requirements, as well as special conditions. (For more information about the NPDES permit program, see *http://cfpub.epa.gov/npdes*.)

EPA is charged with administering the NPDES permit program, but can authorize states to assume many of the permitting, administrative, and enforcement responsibilities of the NPDES permit program. Authorized states are prohibited from adopting standards that are less stringent than those established under the Federal NPDES permit program, but may adopt or enforce standards that are more stringent than the Federal standards if allowed under state law. At the time of publication, 45 states and the Virgin Islands have assumed NPDES authority.² (See *http://cfpub.epa.gov/npdes/ statestats.cfm* for a list of states with full or partial NPDES authority and *http://cfpub.epa.gov/npdes/contacts.cfm?program_id=45&type=STATE* for contact information for state NPDES authorities.)

Hydrilla verticillata

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Does CWA Section 402 apply to AIS rapid response or control actions?

An interpretive statement issued by EPA in January 2005 stated that the application of a pesticide to waters of the United States consistent with all relevant requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does **not** constitute the discharge of a pollutant (and consequently does **not** require a Federal NPDES permit) in the following two circumstances:

- the application of pesticides directly to waters of the United States to control pests. Examples of such applications include applications to control mosquito larvae, aquatic weeds, or other pests that are present in the waters of the United States.
- the application of pesticides to control pests that are present over waters of the United States, including near such waters; that results in a portion of the pesticides being deposited to those waters, for example, the aerial application of pesticides to waters of the United States. Examples include aerial applications of insecticides to a forest canopy where waters of the United States may be present below the

² At the time of publication, the only states that have not assumed either full or partial NPDES authority are Alaska, Idaho, Massachusetts, New Hampshire, and New Mexico.

canopy, or applications of pesticides over or near water for control of adult mosquitoes or other pests.

EPA notes that the application of a pesticide in violation of FIFRA is not covered by the interpretive statement, and the applicator is subject to enforcement actions under any and all appropriate authorities including, but not limited to, FIFRA and CWA. EPA has proposed incorporating the 2005 interpretive statement into regulations. Further information can be found at 70 Fed. Reg. 5093 (February 1, 2005) *www.epa.gov/fedrgstr/ EPA-PEST/2005/February/Day-01/p1868.htm*.

For more information about FIFRA and FIFRA compliance, see the FIFRA Section of this document, the EPA Pesticide Registration Program website *www.epa.gov/ pesticides/factsheets/registration.htm*, or the National Pesticide Information Center website *http://npic.orst.edu/brochure.pdf*.



CWA Section 404—Permits to Discharge Dredged or Fill Material

What is CWA Section 404?

CWA Section 404 establishes a program to regulate the discharge of dredged and fill material into waters of the United States, including wetlands. Responsibility for administering and enforcing Section 404 is shared by the U.S. Army Corps of Engineers (USACE) and EPA. USACE administers the day-to-day program, including individual permit decisions and jurisdictional determinations; develops policy and guidance; and enforces Section 404 provisions. EPA develops and interprets environmental criteria used in evaluating permit applications, identifies activities that are exempt from permitting, reviews/comments on individual permit applications, enforces Section 404 provisions, and has authority to veto USACE permit decisions. (See *www.epa.gov/owow/wetlands/facts/fact10.html* for additional information about CWA Section 404, and *www.usace.army.mil/inet/functions/cw/cecwo/reg/index.htm* for additional information about the USACE Regulatory Program.)

With EPA approval and oversight, states and tribes can assume administration of the Section 404 permit program in certain "nonnavigable" waters within their jurisdiction. At the time of publication, only Michigan and New Jersey have done this. In those two states, USACE retains jurisdiction in tidal and navigable waters and their adjacent wetlands.



When does CWA Section 404 apply to AIS rapid response or control actions?

It is possible that some mechanical/physical AIS rapid response and control methods, such as the mechanized clearing of riparian areas to remove AIS or dumping of fill material to smother AIS, might require Federal or state Section 404 permits. EPA and USACE have issued a rule stating that they regard the use of mechanized earth-moving equipment to conduct activities in waters of the United States (e.g. land clearing, ditching, channelization, and in-stream mining) as regulated discharge of dredged or fill material under Section 404 unless project-specific evidence shows otherwise.

USACE regulatory program management and administration is focused at the District office level, with policy oversight at higher levels. District Engineers are authorized to issue permits, including standard permits, letters of permission, and regional general permits. Division Engineers may also issue permits under certain circumstances. USACE also issues nationwide permits that authorize certain activities that result in minimal adverse environmental effects. Natural resource managers should consult the appropriate USACE District office when planning AIS rapid response or control actions to determine if these actions require a Federal Section 404 permit. (See *www.usace.army.mil/inet/functions/cw/cecwo/reg/district1.htm* for contact information for USACE District offices.) In Michigan and New Jersey, natural resource managers should also consult their state Section 404 authorities when planning AIS rapid response or control actions to determine if these actions for use offices.) In Michigan and New Jersey, natural resource managers should also consult their state Section 404 authorities when planning AIS rapid response or control actions to determine if these actions require a federal Section 404 authorities when planning AIS rapid response or control actions to determine if these actions require a state Section 404 permit.

How do I apply for a CWA Section 404 permit?

There are several ways in which activities requiring Section 404 permits can be authorized:

- Standard permits can be issued in situations where, after a public notice and comment period, the USACE District Engineer determines that the proposed activity is not contrary to the public interest. USACE issues a public notice within 15 days of receiving a completed permit application. The public notice describes the proposed activity, its location, and potential environmental impacts and invites comments within a specified time period, typically 15 to 30 days. The public at large, as well as interested Federal, state, and local agencies, have an opportunity to comment on the proposed activity.
- Letters of permission can be issued in situations where the USACE District Engineer determines the proposed work would be minor, would not have significant individual or cumulative impact on environmental values, and will not encounter appreciable opposition. Concerned fish and wildlife agencies and, typically, adjacent property owners who might be affected by the proposal are notified, but the public at



Round goby Negobius melanostomus



Purple loosestrife *Lythrum salicaria*

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large is not. Section 404 letters of permission can be issued only in cases where, after consulting with certain Federal and state agencies, the USACE District Engineer has previously approved categories of activities that can be authorized by letter of permission procedures. Requesting a letter of permission may be an appropriate and relatively expedient means of complying with Section 404 for many relatively localized and non-controversial AIS rapid response or control actions that require Section 404 compliance.

General permits are often issued by USACE for categories of activities that are similar in nature and would have only minimal individual or cumulative adverse environmental effects. General permits can be issued on a nationwide ("nationwide permit") or regional ("regional general permit") basis. A general permit can also be issued on a programmatic basis ("programmatic general permit") to avoid duplication of permits for state, local or other Federal agency programs. The mechanized clearing of riparian areas for the control of invasive species may be authorized by a nationwide permit, but the appropriate USACE District office should be contacted to determine if a nationwide permit can be used to authorize a specific activity. In some USACE Districts, nationwide permits, letters of permission, regional general permits, or programmatic general permits are used instead.

In general, to obtain a Section 404 permit, applicants must demonstrate that the discharge of dredged or fill material would not significantly degrade the nation's waters and there are no practicable alternatives less damaging to the aquatic environment. Applicants should also describe steps taken to minimize impacts to water bodies and wetlands and provide appropriate and practicable mitigation, such as restoring or creating wetlands, for any remaining, unavoidable impacts. Permits will not be granted for proposals that are found to be contrary to the public interest. In the case of AIS rapid response or control actions, the removal of AIS or mitigation of their harmful effects could be considered a benefit of the action. Compliance with the Endangered Species Act and/or Section 106 of the National Historic Preservation Act may also be required before a Section 404 permit can be issued.

On average, individual permit decisions (standard permits and letters of permission) are made within 2 to 6 months from receipt of a completed application. For activities authorized by general permits, decisions are usually made in less than 30 days. In emergencies, USACE may be able to expedite the permitting process. Natural resource managers considering AIS rapid response actions should contact their District Engineer to discuss the circumstances and request use of expedited procedures. Expedited procedures are authorized on a case-by-case basis. Permit applications that require the preparation of an Environmental Impact Statement take an average of 3 years to process.

Federal Insecticide, Fungicide, and Rodenticide Act

What is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)?

FIFRA is the principal law that authorizes EPA to regulate the manufacture, distribution, sale, and use of pesticides in the United States. EPA determines that a pesticide meets FIFRA health and safety requirements, and then approves a product label that identifies the terms for safe use of the pesticide. EPA has authority under FIFRA to regulate pesticide use through labeling, packaging, composition, and disposal. EPA also has authority to suspend or cancel pesticide registration if new information shows that continued use of the pesticide would pose unreasonable risks. (For the complete text of FIFRA, see *www.epa.gov/opp00001/regulating/fifra.pdf*.)

States are also authorized to regulate pesticides under FIFRA and state pesticide laws. (For the text of Federal regulations regarding state pesticide registrations, see 40 CFR Part 162 *www.access.gpo.gov/nara/cfr/waisidx_04/40cfr162_04.html*). States may place more restrictive requirements on pesticides than does EPA. Contact information for state pesticide regulatory agencies can be found at *http://npic.orst.edu/state1.htm*.

In particular, FIFRA Sections 18 and 24(c) might apply to AIS rapid response or control activities. Section 18 applies to use of a pesticide for an unregistered use, and Section 24(c) applies to new uses or new end use products. Parrot feather watermilfoil *Myriophyllum aquaticum*

Pesticides are often understood to be just bug sprays or weed killers, but they include almost all substances or mixtures intended to kill or repel pests, prevent their reproduction, or mitigate or control their behavior or life-patterns. They include repellents and bactericides, as well as insecticides, herbicides, and fungicides.



FIFRA Section 18—Emergency Exemptions

What is FIFRA Section 18?

FIFRA Section 18 authorizes EPA to allow states to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. (For more information about FIFRA Section 18 emergency exemptions, see *www.epa.gov/opprd001/Section18.* For the text of Federal regulations regarding emergency exemptions, see 40 CFR Part 166 *www.access.gpo.gov/nara/cfr/waisidx 04/40cfr166 04.html.*)

When does FIFRA Section 18 apply to AIS rapid response or control actions?

AlS rapid response or control methods using pesticides must comply with FIFRA and the regulations promulgated thereunder. If a pesticide is already registered for the rapid response or control use under FIFRA, the action does not require additional permitting from EPA. There are several pesticides registered for use in aquatic environments, and natural resource managers may be able to rely on these pesticides to eradicate or control AIS. If the rapid response or control action requires the use of an unregistered pesticide or a pesticide registered for a different end use or use pattern and an emergency situation exists, Federal or state agencies may be able to obtain approval to use an unregistered, i.e. nonlabeled, pesticide under FIFRA Section 18.

Emergency exemptions are subject to EPA's regulations at 40 CFR Part 166. A general summary follows.

An emergency condition is an urgent, nonroutine situation that requires the use of a pesticide or pesticides and meets the following criteria:

- no effective registered pesticides are available
- no feasible alternative control practices are available
- the situation involves the introduction of a new pest, will cause significant economic loss, or will present significant risks to human health, endangered species, or the environment

Detection of an AIS can qualify as an emergency condition. Natural resource managers considering use of an unregistered pesticide or a pesticide registered for a different end use or use pattern to eradicate or control AIS should consult their lead state agency for pesticides about the possibility of developing a Section 18 emergency exemption application. Contact information for state pesticide regulatory agencies can be found at *http://npic.orst.edu/state1.htm*.



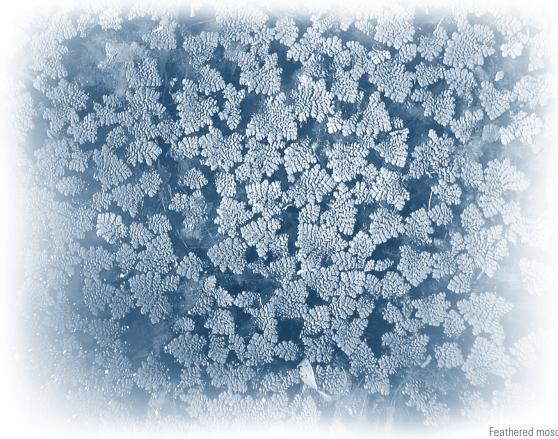
Water lettuce Pistia stratiotes

How do I apply for a FIFRA Section 18 Emergency Exemption?

Lead state agencies can develop applications for several categories of emergency exemptions:

- specific exemptions are issued to avert significant economic loss or a significant risk to endangered or threatened species, beneficial organisms, or the environment
- quarantine exemptions are issued to control the introduction or spread of a new or currently localized pest
- public health exemptions are issued to control a pest that poses a significant risk to human health
- crisis exemptions are issued in instances when the time between discovery of the emergency and the time when pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption

Quarantine exemptions are generally the most appropriate for AIS rapid response and control actions. Crisis exemptions may be appropriate when actions need to be taken extremely quickly (i.e. within a matter of days or weeks).



Feathered mosquitofern Azolla pinnata

Specific, Quarantine, or Public Health Emergency Exemptions

EPA has developed regulations and guidance documents that describe the data necessary to apply for a Section 18 exemption. A specific, quarantine, or public health emergency exemption application must provide the following information:

- 1. the type of exemption requested and the identity of contact persons
- 2. a description of the pesticide and complete labeling for proposed exemption use
- 3. a description of the proposed use
- 4. alternative methods of control
- 5. the effectiveness of the proposed use
- 6. residue in food or feed use
- 7. a discussion of risk information
- 8. coordination with other affected Federal or state agencies
- 9. notification of basic manufacturer or registrant
- 10. compliance and enforcement program for any special requirements
- 11. repeated uses
- 12. progress toward registration, if applicable

Quarantine exemption applications must provide the following additional information:

- 13. scientific and common name of the pest
- 14. origin of the pest and the means of its introduction, if known
- 15. anticipated impact of the pest
- 16. impact of the pest if uncontrolled
- 17. pertinent information about the potential economic impacts of the pest

EPA attempts to make decisions about the exemption within 50 days of receiving a completed application. During this period, EPA conducts dietary, occupational, and environmental risk assessments of the requested use. EPA also assesses the emergency situation and the progress toward permanent pesticide registration for the use in question, if applicable. Some emergency exemptions require public notification.

If EPA determines that the risks posed by the proposed use of the pesticide are acceptable and that the criteria for an emergency condition have been met, EPA approves the emergency exemption request. If the proposed



Brazilian waterweed Egeria densa



pesticide use may cause unreasonable adverse effects to health or the environment, or if the emergency exemption criteria are not met, EPA will deny the emergency exemption request. Section 18 emergency exemptions are typically utilized for pesticides that are already registered under FIFRA for other uses. Quarantine exemptions can be approved for up to 3 years, whereas other exemptions may only be approved for up to 1 year.

Crisis Exemptions

Crisis exemptions are used in dire situations when an emergency exists, the time period for pesticide application is critical, and there is insufficient time to request another type of exemption. A crisis exemption allows for the use of an unregistered pesticide for up to 15 days. If the Federal or state agency submits or has already submitted an application for a specific, quarantine, or public health exemption for the same use, use of the unregistered pesticide under the terms of a crisis exemption may be allowed to continue until EPA makes a decision on the exemption application.

A crisis exemption request may be issued by the head of a Federal or state agency, the Governor of a state, or their official designee. Whenever feasible, the Federal or state agency issuing the crisis exemption must notify EPA of this action at least 36 hours prior to using the crisis provisions. The notification provided to EPA must contain:

- 1. the name of the active ingredient and Chemical Abstract Service (CAS) number
- 2. the site or crop on which the pesticide is to be used
- 3. the use pattern
- 4. the approximate start and end date of application
- 5. an estimate of the expected pesticide residue level for food crops
- 6. a discussion of the emergency situation and any other pertinent information available at the time, including an explanation of why there was insufficient time to request another type of exemption

EPA reviews the notification package to ensure that all required information has been made available and that the use of the pesticide under the crisis exemption conditions will not pose an unreasonable risk to health or the environment. Notification must also be given to the registrant or the manufacturer of the pesticide. Crisis exemptions may not be utilized for pesticides that have been suspended under FIFRA Section 6(c), pesticides containing a new active ingredient, or the first food use of a pesticide. Neither are they issued to mitigate emergencies for which crisis exemptions or specific exemptions have been issued in previous years.



Old World climbing fern Lygodium microphyllum

FIFRA Section 18 Case Study: Eradicating Northern Snakeheads in Crofton, Maryland Ponds

On May 18, 2002, a recreational angler caught an 18-inch fish in a small pond in Crofton, Maryland, which is located between Baltimore, MD and Washington, DC. He photographed the fish and released it back into the pond. A month later, the Maryland Department of Natural Resources (MD DNR) identified the fish as a species of snakehead. In the following two months, a second adult snakehead (26 inches long) and over 100 juveniles were caught in the same pond and identified as northern snakehead Channa argus. Northern snakeheads are large, predatory fish native to China. They can grow to 3 feet in length and primarily eat other fish, including fish up to one-third their length. They can breathe air and survive out of water if kept moist and cool. They cannot walk, as is commonly reported, but are easily shipped alive or transported by people. MD DNR conducted an investigation to determine the source of the snakeheads in the Crofton pond and learned that in 2000, a local resident had released two 12- to 14-inch northern snakeheads into the pond.



Immediately after the fish were positively identified and determined to be a risk to local ecosystems, the Secretary of the MD DNR (Secretary) assembled the Snakehead Scientific Advisory Panel (Panel) to develop strategies for eradicating and controlling the fish in the Crofton pond. On July 29, 2002, the Panel presented the Secretary with a list of risks the northern



snakehead posed to natural resources. It recommended chemical eradication of the Crofton pond vegetation and fish populations, along with those of two small adjacent ponds, to prevent the spread of the fish to the Little Patuxent River. Chemical eradication of vegetation would remove potential refuges for the fish and facilitate application of the piscicide rotenone.

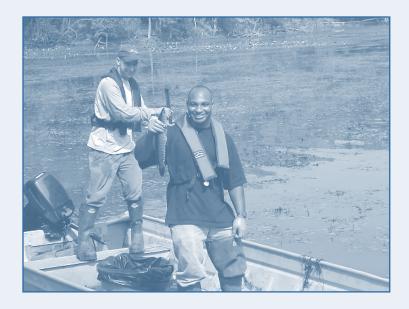
The herbicides glyphosate and diquat bromide were chosen to eliminate emergent and submerged pond vegetation. After removal of the vegetation, application of the piscicide rotenone would effectively eradicate

the northern snakeheads in the ponds. These chemicals were chosen for their effectiveness and relatively rapid decomposition after application. The Panel recommendation to control vegetation in the entire pond area in one application exceeded the manufacturer's label restriction for a maximum 50 percent areal application and therefore did not meet Maryland Department of Environment (MD DE) standards. Because the proposed diquat bromide application differed from allowable use patterns and the available label for diquat bromide, the MD DNR worked with the Maryland Department of Agriculture (MD DA), the lead state agency for pesticide registration, to submit a FIFRA Section 18 emergency exemption application.

Quarantine exemptions are generally the most appropriate exemptions for AIS rapid response actions requiring Section 18 emergency exemptions. However, the potential for spread of the northern snakehead to other water bodies and the potentially devastating environmental impacts of such a spread led the MD DNR and MD DA to apply for a crisis exemption because those programs can be initiated immediately after the lead state authority declares a crisis situation. EPA reviews the crisis on an expedited basis, but use of the pesticide may begin once the lead state agency has invoked its authority to initiate a crisis program.

In the Crofton ponds case, effective interagency collaboration and communication resulted in the timely and successful preparation of a Section 18 emergency exemption application. The application was prepared by the MD DA Pesticide Coordinator with support from the MD DNR and the EPA Section 18 program. MD DA submitted the application package to EPA on August 1. The following day, EPA requested confirmation of the pesticide registration number (EPA's records showed that two pesticides with the same active ingredient were registered) and additional information regarding steps that would be taken to ensure that fish from the treated ponds would not be used for human consumption. On August 6, EPA granted a Section 18 crisis exemption for the proposed use of diquat bromide in the three Crofton ponds for up to 15 days.

State officials faced an additional obstacle to herbicide application in the Crofton ponds, however, because the ponds were on private property and the State lacked the statutory authority to access the property. Permission to access the property was eventually obtained from the owners, and the diquat bromide was applied before the end of the 15-day crisis exemption period. After the application of herbicides and a piscicide took place, over 1000 juvenile and six adult northern snakeheads were recovered. Approximately 800 pounds of native fish were also removed from the three ponds.



In late September and November 2002, state biologists used electro-shock monitoring in all three ponds and determined that no northern snakeheads remained in the ponds. Vegetation returned the following spring, and MD DNR stocked the ponds with native fish. Turtles, frogs, snakes, ducks, and beavers appear to have been unaffected by the pesticides.

In 2004 and 2005, northern snakeheads were found in several other water bodies in the region. These fish are believed to be the result of separate introductions rather than the spread of the species from the Crofton ponds.

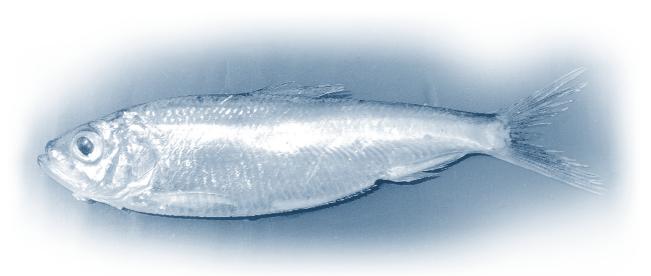
FIFRA Section 24(c)—Special Local Need Registrations

What is FIFRA Section 24(c)?

FIFRA Section 24(c) authorizes states to register an additional use of a Federally-registered pesticide product or a new end use product to meet a special local need. (For EPA guidance on FIFRA Section 24(c) registrations, see *www.epa.gov/opprd001/24c*.)

When does FIFRA Section 24(c) apply to AIS rapid response or control actions?

AlS rapid response or control methods using pesticides must comply with FIFRA and the regulations promulgated thereunder. If a pesticide is already registered for the rapid response or control use under FIFRA, the action does not require additional permitting from EPA. There are several pesticides registered for use in aquatic environments, and natural resource managers may be able to rely on these pesticides to eradicate or control AIS. If the rapid response or control action requires the use of an unregistered pesticide or a pesticide registered for a different end use or use pattern and a state can demonstrate a special local need, FIFRA Section 24(c) authorizes a state to register an additional use of a Federally-registered pesticide product. Section 24(c) registrations are also referred to as state labels or special local need registrations and are considered Federal registrations authorizing distribution and use within the granting state only.



Alewife Alosa pseudoharengus

State registrations under Section 24(c) are subject to EPA's regulations at 40 CFR Part 162. A general summary follows.

States may register a new use or use pattern of a Federally-registered pesticide if all of the following conditions exist:

- There is a special local need for the use within the state. A special local need is an existing or imminent pest problem within a state for which the state has determined that an appropriate Federally-registered pesticide is not sufficiently available.
- If the pesticide use is a food or feed use, there must exist appropriate tolerances (maximum amount of pesticide residue allowed in or on a food or feed commodity) or exemptions from the requirement of a tolerance under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). If these tolerances do not already exist, a Section 24(c) registration cannot be used, and a Section 18 emergency exemption may be more appropriate. Under FFDCA Section 408, EPA may establish a temporary tolerance or exemption from the tolerance requirement for a Section 18 emergency exemption.
- Registration for the same use has not previously been denied, disapproved, suspended or canceled by EPA, or voluntarily canceled by the registrant subsequent to EPA issuing a notice of intent to cancel that registration because of health or environmental concerns, unless such denial, disapproval, suspension or cancellation has been superseded by a subsequent EPA action.
- The registration is in accord with the purposes of FIFRA.



Nutria Myocastor coyous

How do I apply for a FIFRA Section 24(c) Registration?

Each state designs its own review process and timeline for state pesticide registration. As part of its review process, each state is required to conduct an ecological risk assessment (ERA) to determine if the pesticide will cause unreasonable adverse effects on humans or the environment under the following circumstances:

- the pesticide's composition is not similar to any Federally-registered pesticide
- the use of the pesticide is not similar to any Federally-registered use of the same pesticide or a pesticide of similar composition
- EPA has denied, disapproved, suspended, or canceled registration of other uses of the same pesticide or uses of pesticides of similar composition

All products registered by a state must meet all appropriate packaging standards and might need to be classified as restricted use if their toxicity exceeds EPA specific hazard criteria. Depending on the length of time needed to conduct an ERA, Section 24(c) pesticide registrations requiring an ERA may be more useful for ongoing control of AIS rather than for carrying out AIS rapid response actions.



Brazilian peppertree Schinus terebinthifolius

If a state decides to issue a Section 24(c) registration, it must send EPA a notification package within 10 days of issuing a registration containing the following:

- an application for the Section 24(c) registration
- verification of a special local need
- if required, a determination of no unreasonable adverse effects on humans or the environment
- verification of efficacy for public health uses
- the original registered labeling and the Section 24(c) labeling of the pesticide; and
- notification of state pesticide registration describing:
 - tolerances or clearances for food or feed use
 - type of registration, i.e. new pesticide or changed use pattern
 - history of previous Section 24(c) activity or registration for the pesticide
 - list of threatened or endangered species within use area of pesticide

EPA has 90 days to verify that the special local need registration meets FIFRA requirements. If EPA subsequently disapproves the registration, sales and distribution must stop immediately.



Parrot feather watermilfoil *Myriophyllum aquaticum*

FIFRA Section 24(c) Case Study: Controlling Old World Climbing Fern in Florida

Old World climbing fern *Lygodium microphyllum* is an aggressive perennial vine that has invaded cypress stands, pine flatwoods, wet prairies, sawgrass marshes, mangrove communities, and Everglade tree islands in Florida. The vine can reach 90 feet in length and form dense mats in tree canopies, on the ground, and over wetlands, killing native vegetation. The first reported occurrence of Old World climbing fern in Florida was a plant in cultivation at a Delray Beach nursery in 1958. In 1960, the vine was observed in the wild in Martin County. Old World climbing fern eventually became a severe threat to native Florida ecosystems, especially cypress-



dominated wetlands, and in the 1990s, the South Florida Water Management District (SFWMD) began evaluating methods of controlling the vine, including herbicides, fire, flooding, physical removal by hand or machinery, and biological controls.

Aerial spraying of herbicides is one of the most effective means of controlling invasive plants in remote or otherwise inaccessible areas, but may involve the application of herbicide directly to water. Old World climbing fern had invaded many remote and inaccessible areas in Florida, and aerial spraying was desired to control the vine in those areas. At the time, the most effective product for controlling the vine registered for direct application to water was the glyphosate-based herbicide Rodeo[™], a broad spectrum herbicide that injures or kills many nontarget species. To avoid harming other vegetation in Old World climbing fern-infested areas, SFWMD sought alternatives to Rodeo. The District found that application of the herbicide Escort XP[™], a metsulfuron methyl-based product, directly to water showed promise as an effective means to control the vine. The application of Escort XP directly to water was not a registered use for the product and was therefore not in compliance with FIFRA. To use Escort XP for vine control, the SFWMD pursued a Section 24(c) special local need registration for the herbicide.

Florida natural resource managers wishing to control invasive plants often informally consult weed management experts at the University of Florida Institute of Food and Agricultural Science (IFAS) to determine optimal control methods. The SFWMD contacted IFAS about the Old World climbing fern, and in April 2003, IFAS informally contacted the DuPont Corporation, the manufacturer of Escort XP, about using the herbicide to control Old World climbing fern in aquatic



ecosystems. In Florida, pesticide manufacturers generally begin the Section 24(c) special local need registration process on behalf of natural resource managers who want to use one of their pesticide products for a new use or use pattern. Consequently, in May 2003, DuPont submitted a Section 24(c) special local need registration application to the Florida Department of Agriculture and Consumer Services (DACS), the lead state agency for pesticide registration. Section 24(c) special local need registration applications in Florida must include verification of the product's efficacy under Florida or Florida-like conditions, as well as the information described in the FIFRA Section 24(c) section of this document.

After DACS received the Section 24(c) special local need registration application, it reviewed the application to verify the special local need justification. In June 2003, DACS forwarded the application

to the Florida Pesticide Registration Evaluation Committee (PREC), which is comprised of representatives from DACS and other state agencies. PREC reviewed the Section 24(c) special local need registration application to ensure that the proposed herbicide use would not have unreasonable adverse impacts on human health or the Florida environment and was in compliance with all applicable pesticide laws. PREC requested that DuPont make several revisions to the Escort XP Section 24(c) special local need label. After these revisions were made,

the application was submitted to IFAS for independent external review of whether product label efficacy claims were justified. Three IFAS weed management experts offered individual opinions on the Escort XP efficacy claims. On the basis of these opinions, IFAS responded to DACS that it supported the Section 24(c) special local need registration of the herbicide but also requested additional changes to the product label.

In Florida, the Section 24(c) special local need registration application review process can take anywhere from a few months to over a year. In this case, the process was completed quickly. DACS accepted DuPont's Section 24(c) special local need registration with the revised label and submitted a notification package to EPA in August 2003. EPA also requested revisions to the Escort XP Section 24(c) special local need label, including the addition of a section prohibiting the use of the herbicide in areas where specific endangered or threatened species are present. In December 2003, DACS accepted the revised product label. The herbicide is now available for controlling Old World climbing fern populations in aquatic environments in Florida.



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