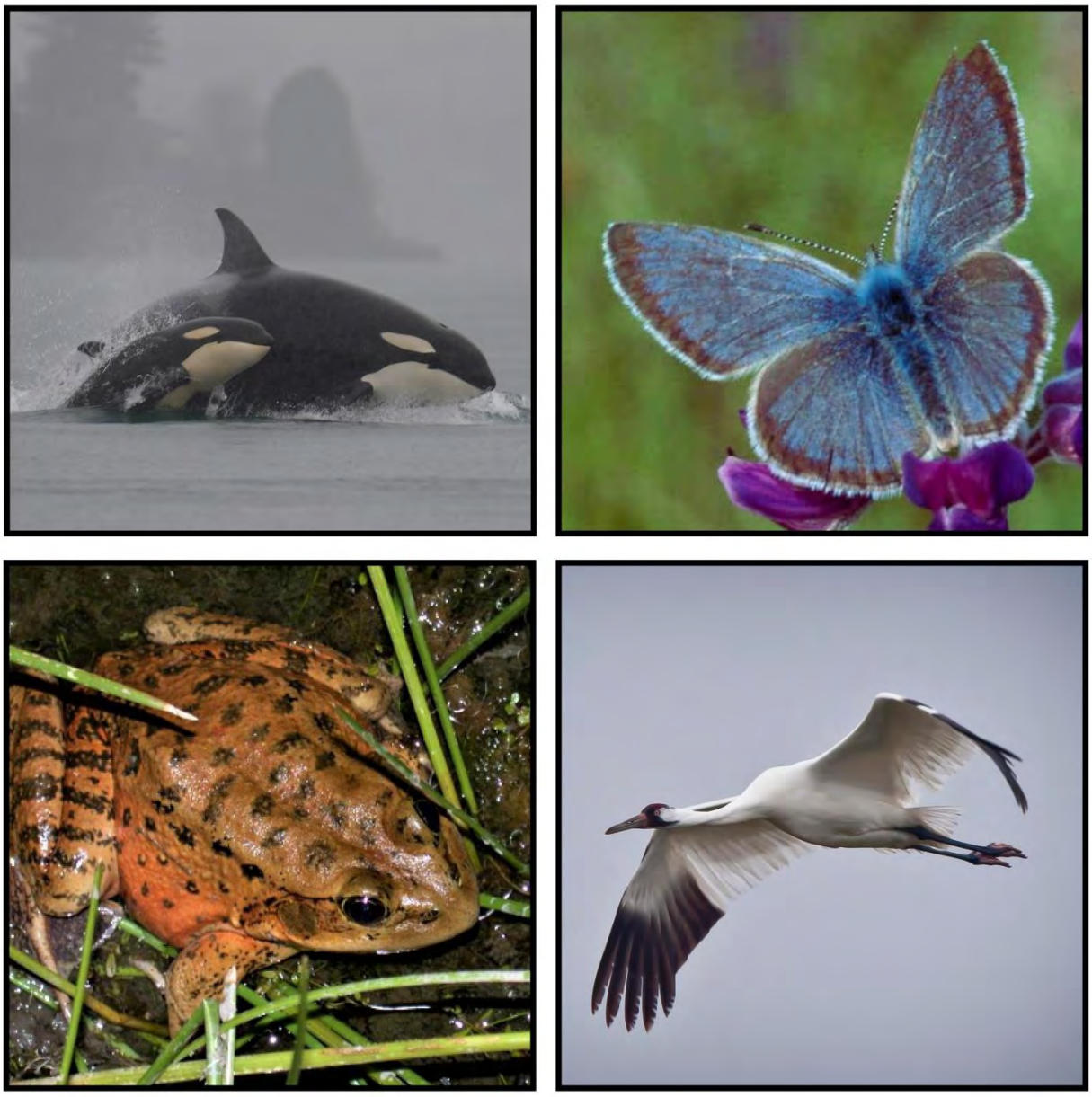
BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PETITION FOR RULEMAKING TO LIMIT SPECIFIC EMERGENCY EXEMPTIONS FOR PESTICIDE USE TO TWO YEARS UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT



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CENTER FOR BIOLOGICAL DIVERSITY
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Via Electronic and Certified Mail

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Re: Petition for Rulemaking to Limit Specific Emergency Exemptions to Two Years under the Federal Insecticide, Fungicide, and Rodenticide Act

Dear Administrator Wheeler,

This Petition for Rulemaking seeks to end ongoing, significant abuses of Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S. C. § 136p, by limiting approvals of specific emergency exemptions for pesticides to a period of no more than two years in any ten year period. Adopting an explicit regulatory term of no more than two years will provide pesticide users with flexibility during urgent, emergency events while protecting public health and the environment against abuses of FIFRA's narrow emergency exemption provision.

Section 18 —which allows for the emergency use of pesticides that have not gone through FIFRA's Section 3 registration process—is included in FIFRA for the limited purpose of addressing "urgent, non-routine" pest management situations.[1] It is not intended to substitute or act as an alternative to a pesticide going through a full registration review under Section 3 prior to that pesticide being used. Indeed, as the United States Environmental Protection Agency ("EPA"), the federal agency that administers FIFRA, has further clarified, "[t]he phrase 'urgent, non-routine situation' has been used to emphasize that the situation must be other than an ordinary one. . . . A chronic or continually occurring problem does not represent an 'urgent, non-

[1] 40 C.F.R. § 166.3.

routine situation.'"[2] EPA's training materials provide that emergency conditions are "new" circumstances "in which the status quo has changed in an unusual way that was unforeseen."[3] EPA further warns that Section 18 exemptions should not be used to address predictable conditions or offer "revenue enhancement" to compensate for "decisions made with knowledge of the risks of agriculture."[4]

Yet, despite the clearly limited scope of Section 18, EPA continues to provide emergency exemptions for chronic, long-term uses of pesticide products, and has been doing so since at least the 1970's. This practice undermines FIFRA's Section 3 new use registration process by allowing for long-term uses without first demonstrating that the use can meet statutory safety standards. Further, without having any measures in place to monitor or describe the human health or environmental impacts of its emergency exemptions, EPA cannot be sure that its Section 18 approvals result in minimal negative impact to public health and the environment.[5]

Pursuant to the right to petition the government as provided in the First Amendment to the United States Constitution[6]and the Administrative Procedure Act,[7] the Center thus hereby formally petitions EPA to promptly initiate rulemaking to limit specific emergency exemptions for pesticide use under Section 18 of FIFRA to a period of not more than two years in any ten year period. This rulemaking is necessary because the facts and history overwhelmingly demonstrate that Section 18 is being grossly abused by state agencies and EPA to approve pesticides for long-term use without having to comply with the FIFRA's proper use requirements.

I. PETITIONER

The Center for Biological Diversity is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. The Center has more than 1.7 million members and online activists dedicated to the protection and restoration of endangered species and wild places. For over 30 years, the Center has worked to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of

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[2] 50 Fed. Reg. 13,944, 13,946 (Apr. 8, 1985); *see also* 51 Fed. Reg. 1,896, 1,896 (Jan. 15, 1986) (finalizing rule and reaffirming choice to exclude "chronic or continually occurring problem[s]" from the definition of an emergency condition).

[3] EPA, Pesticide Regulatory Education Program's (PREP) FIFRA Section 18 Emergency Exemption Program Training Resource, Module 2, at 1-2 (June 2013), https://www3.epa.gov/pesticides/regulating/section18_training/sec18-training-modules.html [hereinafter "EPA Section 18 Training"].

[4] *Id*. at 4.

[5] *See generally* Office of Inspector General ("OIG"), EPA, *Measures and Management Controls Needed to Improve EPA's Pesticide Emergency Exemption Process*, Report No. 18-P-0281 (Sept. 25, 2018), https://www.epa.gov/sites/production/files/2018-09/documents/_epaoig_20180925-18-p-0281_0.pdf [hereinafter "2018 OIG Report"] (Enclosure A).

[6] *See* U.S. Const. Amend. I. The right to "petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights." *United Mine Workers v. Ill. State Bar Assn*, 389 U.S. 217, 222 (1967).

[7] The Center and its members are "interested persons" within the meaning of the Administrative Procedure Act. *See* 5 U.S.C. § 553(e) (granting any "interested person the right to petition for the issuance, amendment, or repeal of a rule"). Should EPA fail to respond to this petition in a timely manner, the Center may pursue relief in federal court.

life. The Center's Environmental Health Program and Pesticides Reduction Campaign aim to improve pesticide regulation in order to reduce the harms of pesticides to the environment as a whole, and threatened and endangered species in particular.

II. ACTION REQUESTED

Petitioner requests the following action:

1. Amend 40 C.F.R. § 166.3 definition of "*Emergency condition*" by inserting the following bold and underlined language in subsection (3)(iv):

Emergency condition means an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:

(3) The situation:

> (iv) Will cause significant economic loss**, which is limited to two years within any ten year period,** due to:
>
> > (A) an outbreak or an expected outbreak of a pest**, limited to two years within any ten year period**; or
> >
> > (B) A change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).

2. Amend 40 C.F.R. § 166.3 definition of "*Significant economic loss*" by inserting the following bold and underlined language:

Significant economic loss **is limited to two years within any ten year period, and** means that, compared to the situation without the pest emergency . . . .

3. Amend 40 C.F.R. § 166.20(a)(11) concerning "Repeated uses" by inserting the following bold and underlined language:

(11) Repeated uses. **Specific exemptions are limited to a maximum of two years within any ten year period.** Applications for the use of a pesticide at the site for which the applicant has previously been exempted….

4. Amend 40 C.F.R. §166.20(b) by deleting subsection (5) in its entirety:

~~**(5) *Re-certification of an emergency condition.*** Applicants for specific exemptions may submit re-certification applications relying on previously submitted information to satisfy the~~

~~information requirements of paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this section, where all of the following conditions are met:~~
~~**(i)** An exemption was granted for the same pesticide at the same site to the same applicant the previous year;~~
~~**(ii)** The emergency condition could reasonably be expected to continue for longer than 1 year;~~
~~**(iii)** EPA has not declared the use ineligible for re-certification;~~
~~**(iv)** The use is not subject to public notice pursuant to § 166.24(a)(1) through (a)(6);~~
~~**(v)** The applicant certifies that all of the following are true:~~
~~**(A)** The emergency condition described in the preceding year's application continues to exist;~~
~~**(B)** Except as expressly identified, all information submitted in the preceding year's application is still accurate;~~
~~**(C)** Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year;~~
~~**(D)** Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied;~~
~~**(E)** The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or has provided documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible.~~

5. Amend 40 C.F.R. § 166.24 by inserting the following bold and underlined language:

40 C.F.R. § 166.24(a) Publication requirement. . . . .

(7) The application proposes use of a pesticide for a specific or public health exemption, if:

(i) An emergency exemption **for a specific exemption has been requested or approved for that use in the previous year, or for a public health exemption** for that use in any 3 previous years, or any 5 previous years if the use is supported by the IR-4 program, and

6. Amend 40 C.F.R. § 166.25 by inserting the bold and underlined language and deleting the strikethrough language:

(b) Criteria for approval. The Administrator may authorize a specific, public health, or quarantine exemption, based on the information available to the Agency, after:

(1) ~~He~~ **They** determine~~s~~ that:

(iv) A specific exemption has not been approved for any two of the prior ten years;

~~(2) Giving due consideration to:~~

~~(i)~~ **(v)** ~~Whether t~~**T**he pesticide is reasonably likely to be used in compliance with the requirements imposed by the Agency under the exemption; and

~~(ii)~~ **(vi)** ~~The~~ **Reasonable** progress ~~which~~ has been made toward registration of the proposed use, if a repeated or public health exemption is sought. It shall be presumed that if a complete application for registration of a use, which has been under a specific **exemption the previous year,** or public health exemption for any 3 previous years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not been submitted, reasonable progress towards registration has not been made.

III. RELEVANT LEGAL BACKGROUND

a. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA is the primary statute under which EPA regulates the distribution, sale, and use of pesticides. FIFRA defines a "pesticide" as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest[.]"[8] When a pesticide is sold or distributed, it is generally referred to as a "pesticide product." FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been "registered" under FIFRA Section 3 by EPA.[9]

EPA "issues a license, referred to as a 'registration,' for each specific pesticide product allowed to be marketed; the registration approves sale of a product with a specific formulation, in a specific type of package, and with specific labeling limiting application to specific uses."[10] FIFRA Section 3(c)(5), "Approval of Registration," provides that EPA can "register a pesticide if [the agency] determines that[:]

> (A) its composition is such as to warrant the proposed claims for it;
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.[11]

In limited emergency conditions—*e.g.*, "urgent, non-routine situation[s]"[12]—EPA may grant an "emergency" exemption from Section 3's registration requirement pursuant to FIFRA Section 18.[13] As applied, "[t]he phrase 'urgent, non-routine situation' has been used to emphasize that the situation must be other than an ordinary one . . . . A chronic or continually occurring problem

[8] 7 U.S.C. § 136(u).
[9] *Id*. § 136a(a).
[10] 69 Fed. Reg. 47,732, 47,733 (Aug. 5, 2004).
[11] 7 U.S.C. § 136a(c)(5).
[12] 40 C.F.R. § 166.3.
[13] 7 U.S.C. § 136p.

does not represent an 'urgent, non-routine situation.'"[14] "Chronic or continually occurring pest problems are specifically excluded from the definition of emergency condition."[15]

b. Pesticide Emergency Exemptions

There are four different types of emergency exemptions defined in EPA's FIFRA regulations. These categories are defined by the circumstances that give rise to the request, and each type of emergency exemption has slightly different conditions associated with it.[16] The four types of emergency exemptions are (1) specific, (2) quarantine, (3) public health, and (4) crisis.[17]

A specific exemption is granted to avert either a "significant economic loss" or a "significant risk" to wildlife resources or the environment.[18] A quarantine exemption is meant to "control the introduction or spread of any pest that is an invasive species" or new to the United States.[19] A public health exemption "control[s] a pest that will cause a significant risk to human health."[20] A "crisis" exemption is a very short-term exemption that "may be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption;" a crisis exemption generally expires after a period of fifteen days.[21]

Specific exemptions are the most common of the four exemptions.[22] There are two bases for requesting a specific exemption: (1) risk of significant economic loss; or (2) significant risk to endangered species, threatened species, beneficial organisms, or the environment.[23] Specific exemptions, unlike the other emergency exemptions, are currently eligible for re-certification, a process that "streamline[s]" the application process and enables "quicker determinations by EPA" on applications requesting the same use and to address the same conditions as an exemption granted in the prior year.[24]

IV. STATEMENT OF LEGAL GROUNDS

EPA's failure to limit the number of Section 18 pesticide approvals that can be granted for specific emergencies has enabled routine and unlawful abuses of FIFRA's emergency exemption provision. Limiting specific emergency exemptions to a period of no more than two years in any

[14] 50 Fed. Reg. 13,944, 13,946 (Apr. 8, 1985); *see also* 51 Fed. Reg. 1,896, 1,896 (Jan. 15, 1986) (finalizing rule and reaffirming choice to exclude "chronic or continually occurring problem[s]" from the definition of an emergency condition).
[15] Office of Pesticide Programs, EPA, *Emergency Exemptions Under Section 18 of the Federal Insecticide Fungicide and Rodenticide Act: Guidance for State and Federal Agencies*, Part I at ii (June 2, 1992).
[16] *See, e.g.,* 40 C.F.R. § 166.28 (differing duration of the different types of emergency exemptions).
[17] *Id*. § 166.2.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.* §§ 166.2, 166.40, 166.45(b).
[22] *See, e.g.*, 81 Fed. Reg. 90,836, 90,837 (Dec. 15, 2016) (noting that "[m]ost emergency exemptions are specific exemptions" and that quarantine and public health exemptions are "rarely requested").
[23] 40 C.F.R. § 166.2(a).
[24] 71 Fed. Reg. 4,495, 4,502 (Jan. 27, 2006).

ten year period will support lawful compliance with the emergency exemption provisions of FIFRA and better serve to protect public health and the environment.

a. History of Emergency Exemption Abuses, as Detailed by the Government Accountability Office, Shows that a Prescribed Time Limitation on Emergency Uses is Necessary

An accounting of EPA's improper, routine use of emergency exemptions is detailed in three Government Accountability Office ("GAO") analyses that span a period of 13 years.

The first GAO report, in 1978, provided a general analysis of the emergency permitting process as a whole. This investigation found that EPA was granting emergency exemptions for "continuing, predictable pest outbreaks."[25] When digging further into specific exemptions that were granted, the GAO concluded that "[s]everal of these exemptions were granted repeatedly to the same agency," and that "[i]f valid emergencies exist and are likely to recure [sic] periodically, EPA should register a pesticide to control such emergencies."[26] In light of these findings, GAO concluded that "it appears that some of these situations were not true emergencies and EPA should not have granted exemptions in these instances."[27]

A follow-up GAO investigation in 1981 found that no progress had been made by EPA in preventing repeated Section 18 "emergency" exemption approvals for predictable pest outbreaks.[28] As GAO determined,

> [review of] 167 randomly selected emergency exemptions . . . disclosed that 45, or 27 percent, were repeatedly approved for 2 or more consecutive years and 15, or 9 percent, were for 3 or more consecutive years. For example: In New York, 7 of 30 emergency requests we reviewed were approved by EPA for the same use in successive years. In two cases, emergency exemptions were approved in Washington for 5 and 6 consecutive years, respectively.[29]

In 1991, GAO testified before the U.S. House of Representatives Subcommittee on the Environment about EPA's continued approval of chronic, repeat emergency exemptions, and provided the strongest rebuke yet of the agency's persistent failure to comply with its regulations.[30] Based on its third investigation, GAO testified that,

> Although it recognizes that repeat emergency exemptions may circumvent, or at least give the appearance of circumventing, registration as well as cause other

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[25] GAO, *Report to the Congress by the Comptroller General of the United States: Special Pesticide Registration By The Environmental Protection Agency Should Be Improved*, CED-78-9, at 30 (Jan. 9, 1978) (Enclosure B).
[26] *Id.* at 31.
[27] *Id*.
[28] GAO, *Report to the Congress by the Comptroller General of the United States: Stronger Enforcement Needed Against Misuse Of Pesticides*, CED-82-5 (Oct. 15, 1981) (excerpts in Enclosure C).
[29] *Id*. at 32.
[30] GAO, *Testimony before the U.S. House of Representatives Subcommittee on Environment Committee on Science, Space, and Technology: EPA's Repeat Emergency Exemptions May Provide Potential for Abuse*, GAO/T-RCED-91-83 (July 23, 1991) (Enclosure D).

> problems, EPA regularly grants such emergency exemptions. In fiscal year 1990, EPA granted almost 80 percent of the requests for exemptions for chemicals that had already received exemptions for that particular use for at least 3 years.[31]

The GAO goes on to add that despite regulations requiring that reasonable progress be made towards Section 3 registration within three years, "66 of the fiscal year 1990 emergency use requests have received exemptions for more than 3 years (attachment III)," and "[o]f these 66 repeat requests, EPA denied only one."[32]

b. <u>Congressional Investigation into Abuses of the Emergency Exemption Process Shows that a Prescribed Time Limitation on Emergency Uses is Necessary</u>

Related to GAO's 1991 testimony, in 1992 the U.S. House of Representatives Subcommittee on the Environment ("Subcommittee") reviewed abuses to the use of FIFRA Section 18 exemptions.[33] As part of its investigation, the Subcommittee found multiple cases of repetitive, long-term exemptions being granted—some lasting for *more than 10 years*. For example, the Subcommittee established as "examples of repetitive exemptions:"

- The "emergency" use of Botran on Peanut for a 14 year period;
- The "emergency" use of sodium chlorate on wheat for 10 years;
- The "emergency" use of glyphosate on wheat for 9 years;
- The "emergency" use of cryolite on potatoes for 10 years;
- The "emergency" use of Vinclozin on snap beans for 8 years;
- The "emergency" use of triadimefon on tomatoes for 8 years;
- The "emergency" use of hydrogen cyanamide on grapes for 6 years;
- The "emergency" use of cryomazine on peppers for 7 years;
- The "emergency" use of cypermethrin on onions for 5 years;
- The "emergency" use of bromoxinil on rice for 5 years;
- The "emergency" use of chlorothalonil on mushrooms for 5 years;
- The "emergency" use of mancozeb on ginseng for 4 years;
- The "emergency" use of thiobencarb on assorted vegetables for 5 years; and
- The "emergency" use of triflumizole on spathiphyllum for 5 years.[34]

In analyzing these results, the Subcommittee considered that "[o]ftentimes, Section 18 requests are made for the use of older chemicals on crops for which they are not registered," and that "[t]hese older chemicals receive repetitive exemptions for use on such crops despite the fact that many of these substances may have difficulty obtaining reregistration since many have been identified as being potentially carcinogenic."[35]The Subcommittee ultimately determined that "by

[31] *Id*. at 6.
[32] *Id*. at 10.
[33] *See* U.S. House of Representatives, Subcommittee on Environment, Committee on Science, Space, and Technology, Section 18 (Emergency Exemptions) to the Federal Insecticide, Fungicide, and Rodenticide Act, 102nd Cong. (Oct. 1992) https://babel.hathitrust.org/cgi/pt?id=umn.31951d009898984;view=1up;seq=4, (excerpts in Enclosure E).
[34] *Id*. at 2.
[35] *Id*. at 3.

liberally and repetitively granting exemptions to potentially carcinogenic substances, little incentive is provided to encourage companies to invest in the development of newer safer pesticides or alternative agricultural practices."[36]

In wrapping up its investigation, the Subcommittee further concluded that "[t]he findings of this report show that misuse will continue to plague the emergency exemption program, *unless a final limit defines the length of time* beyond which an unregistered substance cannot qualify for an exemption."[37] EPA, therefore, was directed to both "follow its own adopted regulations, especially regarding limiting the number of years for which exemptions can be granted" and "rewrite the regulations to create an absolute time limit beyond which repetitive requests for an exemption will not be granted."[38]

The reasoning for this conclusion, which likewise applies to Petitioner's request here, is simple: "a maximum time limit will prevent a manufacturer from using the Section 18 program to gain temporary access to the market for limited use of a chemical" and "will also ensure that modern and long-term health and environmental tests are conducted" for the majority of chemicals that are used on crops.[39]

c. History of Emergency Exemption Abuses, as Detailed by EPA's Office of Inspector General, Shows that a Prescribed Time Limitation on Emergency Uses is Necessary

In 2018, EPA's Office of Inspector General ("OIG") conducted a further audit to determine whether the EPA has a comprehensive pesticide emergency exemption approval process that maintains environmental and human health safeguards.[40] While OIG's audit did not specifically look at abuses related to repeated annual approvals of pesticide uses for emergency purposes, it did generally review the ability of the program to maintain human health and environment safeguards, and determined that EPA "does not have outcome measures in place to determine whether the emergency exemption process protects human health and the environment."[41] In further establishing that "measures and management controls [are] needed to improve EPA's pesticide emergency exemption process," OIG additionally identified that EPA is: "missing key data management controls that would support its ability to manage its emergency exemption process," and that the "emergency exemption process also faces challenges regarding the collection and dissemination of reliable emergency exemption information."[42]

In arriving at this conclusion, OIG used emergency exemption applications related to the use of medically important antibiotics (streptomycin and oxytetracycline) as pesticides to combat a disease known as "citrus greening disease," a bacterial disease in citrus plants.[43] As OIG identified there, while the economic harm of revenue loss due to citrus greening disease is

[36] *Id*.
[37] *Id.* at 19 (emphasis added).
[38] *Id*. at 3.
[39] *Id.*
[40] *See generally* 2018 OIG Report.
[41] *Id*. at 10.
[42] *Id*.
[43] *Id*. at 4.

measurable, the "misuse and overuse of antibiotics can result in the spread of bacteria that are resistant to them, triggering concern about the continuing long-term ability of these drugs to tackle disease."[44] Critical consideration of the potential harms to human health and the environment from the use of medically important antibiotics as a pesticide is undermined by EPA's numerous emergency approvals of these antibiotics, especially streptomycin, for specific uses.

d. Because Abuses of FIFRA's Specific Emergency Exemption Provisions Persist Unabated, a Prescribed Time Limitation on Emergency Uses is Necessary

Despite the critical conclusions of three GAO reports, one OIG report, and one congressional investigation, EPA has not imposed a maximum time limit for recurring emergency exemptions. For example, a 2017 analysis by the Center found that between 2012 and 2017 fourteen states were granted specific emergency exemptions for uses of the pesticide sulfoxaflor for at least three consecutive years to respond to the same "emergency."[45] In a 2019 analysis of sulfoxaflor, the Center additionally determined that "[o]f the 18 states where the approvals were granted for sorghum and cotton crops, 12 have been given the approvals for at least four consecutive years for the same 'emergency.'"[46]

According to analysis conducted by the Center in 2019 of EPA's Emergency Exemption Database,[47] chronic, long-term emergency exemptions remain common. For example,

1) From 2010 to mid-2019, every single one of the 170 emergency exemptions granted for the pesticide bifenthrin was for an "emergency" that lasted at least 3 years, and 163 out of the 170 were for an "emergency" that lasted at least 6 years;
2) From 2010 to mid-2019, all but two of the 118 emergency exemptions granted for the pesticide dinotefuran were for an "emergency" that lasted at least 3 years, and 105 out of the 118 were for an "emergency" that lasted at least 7 years;
3) The State of Washington received a recurring exemption for at least nine years for "emergency" uses of the pesticide lambda-cyhalothrin; and
4) The State of Florida received a recurring exemption for at least seven years for "emergency" uses of the pesticide clothianidin.

As with the pesticides the Subcommittee reviewed in 1992, pesticides that EPA continues to chronically approve for long-term use under Section 18 are harmful to human health and the environment, and would likely have difficulty receiving Section 3 approval. Bifenthrin, for

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[44] *Id*. at 5.
[45] Center for Biological Diversity, *Poisonous Process: How the EPA's Chronic Misuse of 'Emergency' Pesticide Exemptions Increases Risks to Wildlife* (Dec. 2017) (Enclosure F). https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/Poisonous_Process.pdf.
[46] Center for Biological Diversity, *Trump EPA OKs 'Emergency' to Dump Bee-killing Pesticide on 16 Million Acres*, Press Release (Feb. 15, 2019), https://www.biologicaldiversity.org/news/press_releases/2019/sulfoxaflor-02-15-2019.php.
[47] EPA, Emergency Exemption Database, https://iaspub.epa.gov/apex/pesticides/f?p=124:2::::::.

example, is classified as a Group C possible human carcinogen by the EPA.[48] Dinotefuran and clothianidin are neonicotinoid pesticides that have been banned for outdoor use in the European Union and are widely implicated in pollinator declines throughout the world.[49,50]

Further, "emergency" exemption approvals of medically important antibiotics for use as pesticides, as earlier identified by OIG in 2018, has continued into 2020 and remains of concern to human health and the environment. Specifically, in 2020 EPA again, and for the *fifth* year in a row, approved the antibiotic streptomycin for "emergency" pesticide use in the State of Florida.[51] Streptomycin is identified by the World Health Organization as being "critically" important to human medicine due to its ability to treat tuberculous and the plague, and is identified as at risk for antibiotic resistance and affiliated concerns.[52]

In sum, not only does EPA continue to grant emergency exemptions year-after-year for extended periods of time, but the agency is granting these exemptions for uses that are dangerous to human health and the environment. As the Subcommittee properly summarized in 1992, "EPA's review of chemicals under the exemption program entails significantly less complete and rigorous data requirements and analyses than undergone to obtain Section 3 registrations. Emergency exemptions, therefore, increase risks to human health and also increase the chances of adverse environmental and wildlife impacts."[53]

e. A Two Year Time Limitation on Specific Emergency Exemptions is Practical, Necessary, and Reasonable

In the past, EPA has recognized the value of limiting the number of years an emergency exemption is granted, historically telling state agencies that "Section 18 of FIFRA was not intended to be a substitute for section 3 of FIFRA."[54] However, more recently EPA has regressed in that positon. In 2006, the agency amended its regulations to add "re-certification" to its Section 18 program, which makes it easier to show EPA that an "emergency" condition exists if it granted a specific exemption for that same situation in the previous year.[55] Originally the re-certification process, as proposed by EPA, limited re-certification to three years,[56] but EPA

[48] National Pesticide Information Center, Bifenthrin – Technical Fact Sheet (Mar. 2011), http://npic.orst.edu/factsheets/archive/biftech.html#references.
[49] Pisa, L., *et al,* An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 2: impacts on organisms and ecosystems, *Environmental Science and Pollution Research*, doi:10.1007/s11356-017-0341-3 (2017), https://www.ncbi.nlm.nih.gov/pubmed/29124633.
[50] Stokstad, E., European Union expands ban of three neonicotinoid pesticides, *Science* (Apr. 27, 2018), https://www.sciencemag.org/news/2018/04/european-union-expands-ban-three-neonicotinoid-pesticides.
[51] Center for Biological Diversity, *EPA Extends 'Emergency' Antibiotic Use on California, Florida Citrus Crops*, Press Release (Feb. 11, 2020), https://biologicaldiversity.org/w/news/press-releases/epa-extends-emergency-antibiotic-use-on-california-florida-citrus-crops-2020-02-11/.
[52] World Health Organization, Critically Important Antimicrobials for Human Medicine, 5th Revision (2016), https://www.who.int/foodsafety/publications/antimicrobials-fifth/en/.
[53] *See* U.S. House of Representatives, Subcommittee on Environment, Committee on Science, Space, and Technology, Section 18 (Emergency Exemptions) to the Federal Insecticide, Fungicide, and Rodenticide Act, 102nd Cong., at 2 (Oct. 1992), https://babel.hathitrust.org/cgi/pt?id=umn.31951d009898984;view=1up;seq=4.
[54] GAO, *Report to the Congress by the Comptroller General of the United States: Stronger Enforcement Needed Against Misuse Of Pesticides*, CED-82-5, at 32 (Oct. 15, 1981).
[55] 71 Fed. Reg. at 4,495; 40 C.F.R. § 166.20(b)(5).
[56] *See* 69 Fed. Reg. 53,866, 53,871 (Sept. 3, 2004).

revoked its proposed time limit in response to push back from grower groups, state agencies, and pesticide registrants.[57] This has facilitated EPA's abuse of the Section 18 exemption process and allowed many emergency exemptions to essentially drag on open-ended.

The Section 18 provision of FIFRA exists in order to quickly make a pesticide available for an emergency until an alternative is found or the pesticide can be reviewed under Section 3. EPA's most recent report on its Section 3 pesticide registration decisions, submitted pursuant to the Pesticide Registration Improvement Act, indicate that the agency moves very quickly with Section 3 registration review, with average decision times ranging from a couple of months to around three years.[58] Further, according to the EPA "most section 18 chemicals are already registered for use on some crops but are not completely tested for use on the crops for which emergency exemptions are requested."[59] Indeed, the pesticides identified in the previous section (clothianidin, dinotefuran, bifenthrin, lambda-cyhalothrin, and the antibiotic streptomycin) are pesticides already registered for other food crops. Therefore, in order for the registrant to apply for Section 3 registrations for many of these pesticides, it would only need to submit new use applications.

With the average time for an EPA decision on a new, additional food uses ranging from about 16 to 18 months, and the average decision time for almost all new uses sitting at well under two years, in the event an "emergency" event is expected to continue for longer than two years, then the Section 3 registration process provides a viable alternative to the agency's current practice of approving specific emergency exemptions for periods of five and ten years .[60] Thus, adopting a two-year time limitation on specific emergency exemptions is not only practical, it is reasonable and necessary for protecting public health and the environment.

V. CONCLUSION

Given the recent, long-term specific emergency exemptions granted by EPA, it appears that Section 18 currently functions as a means to facilitate the widespread use of pesticides that have not completed the Section 3 registration review. This establishes a system in which pesticides that are "indefinitely stalled" in the registration process can be sold and distributed freely without any incentive to make progress towards registration.[61] By establishing a finite amount of time that Section 18 specific exemptions will be granted, EPA will be giving greater regulatory certainty to growers and state agencies. The agency will also cut down on abuse of the

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[57] 71 Fed. Reg. at 4,497-98.

[58] *See* EPA, *Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017; Fourteenth Annual Report* (Mar. 1, 2018), https://www.epa.gov/sites/production/files/2018-02/documents/fy17-pria-annualrpt-table3.opp_.pdf.

[59] GAO, *Testimony before the U.S. House of Representatives Subcommittee on Environment Committee on Science, Space, and Technology: EPA's Repeat Emergency Exemptions May Provide Potential for Abuse*, GAO/T-RCED-91-83, at 6 (July 23, 1991).

[60] *See* EPA, *Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017; Fourteenth Annual Report* (Mar. 1, 2018), https://www.epa.gov/sites/production/files/2018-02/documents/fy17-pria-annualrpt-table3.opp_.pdf.

[61] *See* U.S. House of Representatives, Subcommittee on Environment, Committee on Science, Space, and Technology, Section 18 (Emergency Exemptions) to the Federal Insecticide, Fungicide, and Rodenticide Act, 102nd Cong., at 16 (Oct. 1992), https://babel.hathitrust.org/cgi/pt?id=umn.31951d009898984;view=1up;seq=4.

emergency exemption process and ensure a greater number of pesticides are being used in accordance with the safety standards outlined in Section 3 of FIFRA.
Petitioner the Center for Biological Diversity therefore requests for EPA to end the significant, ongoing abuses of Section 18 of FIFRA by limiting specific emergency exemptions for pesticides to a period of no more than two years in any ten year period.

Sincerely,

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Enclosures

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Enclosure A

U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Ensuring the safety of chemicals

Measures and Management Controls Needed to Improve EPA's Pesticide Emergency Exemption Process

Report No. 18-P-0281 **September 25, 2018**

Report Contributors:

Ming Chang
Jeffrey Harris
Lauretta Joseph
Thane Thompson

Abbreviations

CFR	Code of Federal Regulations
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPP	Office of Pesticide Programs
SLA	State Lead Agency
SOP	Standard Operating Procedure
U.S.C.	United States Code

Cover Photo: Citrus greening (a bacterial disease) occurring on a Florida citrus tree. (U.S. Department of Agriculture)

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U.S. Environmental Protection Agency
Office of Inspector General

18-P-0281
September 25, 2018

At a Glance

Why We Did This Project

We conducted this audit to determine whether the U.S. Environmental Protection Agency (EPA) has a comprehensive pesticide emergency exemption approval process that maintains environmental and human health safeguards.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), all pesticides distributed and sold in the United States must be registered by the EPA for each specific use. Per Section 18 of FIFRA, the EPA can grant federal and state lead agencies the authority to approve—in certain emergency situations—the limited application of a pesticide not registered for that particular use. These short-term pesticide use approvals are called *emergency exemptions*.

This report addresses the following:

- *Ensuring the safety of chemicals.*

Send all inquiries to our public affairs office at (202) 566-2391 or visit www.epa.gov/oig.

Listing of OIG reports.

Measures and Management Controls Needed to Improve EPA's Pesticide Emergency Exemption Process

What We Found

The EPA needs outcome measures to demonstrate the benefits or risks of pesticide emergency exemptions on human health and the environment.

The EPA's Office of Pesticide Programs (OPP) does not have outcome measures in place to determine how well the emergency exemption process maintains human health and environmental safeguards. The program office also does not have comprehensive internal controls to manage the emergency exemption data it collects. Finally, the OPP does not consistently communicate emergency exemption information with its stakeholders.

Specifically, we found that the OPP collects human health and environmental data through its emergency exemption application process, including the total acres affected, the proposed and actual quantities of the exempted pesticide applied, and the estimated economic losses. Yet, we found that the OPP does not use these data to support outcome-based performance measures that capture the scope of each exemption or to measure the potential benefits or risks of each exemption.

We also found significant deficiencies in the OPP's online database management, in its draft Section 18 emergency exemption standard operating procedure and application checklist, and in its reports to Congress and the Office of Management and Budget. Some state lead agencies and extension agents that we interviewed also reported that additional guidance is needed to support the preparation of emergency exemption applications, including whether data can be used from applications submitted by other state lead agencies.

Furthermore, we found that the OPP previously sent a "year in review" letter to states that summarized the emergency exemption activity for that year and provided additional information regarding the emergency exemption process. However, the OPP has not sent this letter since 2015.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention develop outcome-based performance measures; develop or update procedures on data collection, database management and the re-use of data submitted by state lead agencies; and communicate changes to the emergency exemption processes in a timely manner. Of our eight recommendations, the EPA agreed with four, neither agreed nor disagreed with two, and disagreed with two. For three recommendations, the agency proposed corrective actions that meet the intent of the recommendations. The remaining five recommendations are unresolved.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

September 25, 2018

MEMORANDUM

SUBJECT: Measures and Management Controls Needed to Improve EPA's Emergency Pesticide Exemption Process
Report No. 18-P-0281

FROM: Arthur A. Elkins Jr.

TO: Charlotte Bertrand, Acting Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject audit conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this evaluation was OPE-FY17-0024. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The office responsible for issues evaluated in this report is the EPA's Office of Pesticide Programs within the Office of Chemical Safety and Pollution Prevention.

In accordance with EPA Manual 2750, your office provided acceptable corrective actions and milestone dates in response to Recommendations 2, 3 and 4. These recommendations are resolved and no final response is required.

Action Required

Recommendations 1, 5, 6, 7 and 8 are unresolved. In accordance with EPA Manual 2750, the resolution process begins immediately with the issuance of this report. We are requesting a meeting within 30 days between the acting Principal Deputy Assistant Administrator for Chemical Safety and Pollution Prevention and the OIG's Assistant Inspector General for Audit and Evaluation. If resolution is still not reached, the EPA is required to complete and submit a dispute resolution request to the Chief Financial Officer to continue resolution.

We will post this report to our website at www.epa.gov/oig.

Table of Contents

Appendices

Purpose

The U.S. Environmental Protection Agency's (EPA's) Office of Inspector General (OIG) conducted this audit to determine whether the EPA has a comprehensive emergency exemption process that maintains environmental and human health safeguards.

Background

Pesticides are chemicals used to curb unwanted vegetation, insects, animals or bacteria. Pesticide use has contributed to increased agricultural production and improved public health through control of disease-ridden pests. However, pesticides are poisons. Acute and chronic issues affecting human health and causing environmental harm can be associated with exposure to many pesticides.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was enacted in part to reduce the negative impacts of pesticides on human health and the environment. All pesticides distributed or sold in the United States must be registered (licensed) by the EPA. Before the EPA may register a pesticide under FIFRA, the manufacturer or formulator (also known as the *registrant*) must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment."[1] Under the normal, nonemergency registration requirements of FIFRA, a registrant of a pesticide must register that product for each specific use. Registrants must submit a new application each time they register a new pesticide active ingredient, register a new product for an existing pesticide active ingredient, or add a new use to an existing product registration.

Emergency Exemptions

Unexpected pests, invasive species or resistant strains of insect, weed, microbe or other type of pests that cannot be eliminated or controlled with registered pesticide products are periodically identified. Section 18 of FIFRA allows the EPA to grant federal and state agencies the authority to approve the limited application of a pesticide not currently registered for that use. These short-term pesticide use approvals are called *emergency exemptions*.

Regulations that govern the implementation of Section 18 of FIFRA are found at 40 CFR Part 166. These regulations identify four types of emergency exemptions: specific, quarantine, public health and crisis. As shown in Table 1, each type addresses a different emergency situation, and each has a corresponding allowable time frame for the emergency exemption.

[1] EPA, "Summary of the Federal Insecticide, Fungicide, and Rodenticide Act" webpage, and 7 U.S.C. § 136a(c)(5)(D).

Table 1: Types of emergency exemptions

Type	Maximum duration	Description of emergency exemption
Specific	1 year	The most common emergency exemption. May be authorized in an emergency condition to avert a significant economic loss or a significant risk to endangered species, threatened species, beneficial organisms or the environment.
Quarantine	3 years	May be authorized in an emergency condition to control the introduction or spread of any pest that is an invasive species or not known to be widely prevalent or distributed within the United States and its territories.
Public health	1 year	May be authorized in an emergency condition to control a pest that will cause a significant risk to human health.
Crisis	15 days	May be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine or public health exemption.

Source: 40 CFR § 166.2(a–d).

The purpose of an emergency exemption is to allow the application of a pesticide not currently registered for the requested use. Most emergency exemption applications are *specific* types, and nearly all of those applications address impacts to agricultural crops.

Emergency Exemption Process

State and federal agencies can apply for emergency exemptions when a serious pest problem jeopardizes public health or the production of agricultural goods. If the emergency exemption is based on current crop loss, applicants must demonstrate that a significant economic loss will or has occurred and that the pest cannot be countered by a pesticide currently approved for that use. In conjunction with growers and extension agents, a state lead agency (SLA) submits an emergency exemption application to the EPA.[2] The application specifies the estimated significant economic loss without the expanded use, the total requested application acreage, the requested application rate and other parameters of use, and numerous other information points.

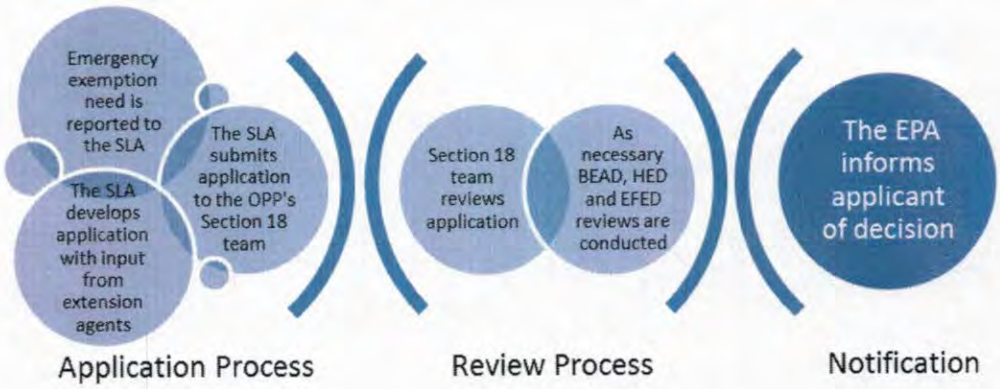
In most instances, an emergency exemption applicant requests approval for the expanded use of a pesticide that has already been registered by the EPA for other uses. Because of the existing registration, the review time for the short-term emergency use is significantly reduced compared to the full registration process under Section 3 of FIFRA. In addition, as shown in Table 1, crisis exemptions can only be approved for 15 days, requiring the EPA's Office of Pesticide Programs

[2] *Extension agents* are employed by land-grant universities and serve the citizens of that state as experts or teachers on topics related to economics, community development, agriculture, family, animal production, diet or nutrition. An example of an *SLA* that would apply for an emergency pesticide exemption is a state department of agriculture.

(OPP) to review those applications as quickly as possible. The other types of emergency exemptions have different review time frames. OPP staff informed us that their goal is to review and approve most emergency exemption applications (other than *crisis* types) within 50 calendar days of receipt. Reviews can take longer if the OPP needs to request more information from the SLA.

Once the OPP receives an emergency exemption application, the office's Section 18 team starts the review process (Figure 1). As a part of the review, the Section 18 team determines whether the emergency exemption request requires public notice in the Federal Register.[3] Then the Section 18 team forwards the applicant's request to the OPP's Biological and Economic Analysis Division, Health Effects Division, and Environmental Fate and Effects Division for economic, health effect and/or ecological risk assessments.[4] The OPP uses these assessments to determine whether the situation is a valid emergency and the efficacy of the requested use. At the end of the review process, the Section 18 team recommends to OPP management whether an emergency exemption should be approved or denied, and the applicant is informed of the final decision. According to the OPP, the agency processes an average of 140 emergency exemption applications annually. The OPP publishes information regarding approved emergency exemptions in a database publicly available on its Section 18 website.

Figure 1: Section 18 emergency exemption process



Acronyms: *BEAD*—Biological and Economic Analysis Division; *EFED*—Environmental Fate and Effects Division; *HED*—Health Effects Division; *SLA*—State Lead Agency

Source: OIG-generated image.

When an emergency exemption is granted, the OPP issues an approval to the SLA that contains general use instructions, use limitations and the emergency

[3] When an exemption request meets the following criteria outlined in 40 CFR § 166.24(1–8), the EPA is required to publish a notice of that request in the Federal Register: the proposed use of a new (unregistered) chemical, the first food use of a chemical, if the chemical's use is currently suspended or cancelled, and other instances where the public can provide comments on the requested exemption.

[4] When an exemption request is for an antimicrobial or biological pesticide, after the Biological and Economic Analysis Division completes its initial evaluation of the emergency economic-loss claim, the request will then be forwarded to the Antimicrobial Division and/or the Biopesticides Pollution Prevention Division.

exemption expiration date. Because FIFRA provides states with primary enforcement authority for pesticide violations, the EPA does not usually conduct oversight of approved emergency exemptions. Instead, approved exemptions require the SLA to conduct implementation and oversight and to submit an end-of-use report to the OPP 6 months after the exemption expires. This end-of-use report details the amount of pesticide used, the total acres treated, any adverse effects reported and other information required by the EPA.

As long as the situation continues to meet the emergency exemption criteria, SLAs have the option of reapplying for a repeat emergency exemption. Based on the regulations governing emergency exemptions, to repeatedly gain approval for a specific or public health emergency exemption use, the registrant must demonstrate progress toward permanent registration of that pesticide use under Section 3 of FIFRA. If after 3 years (or 5 years for some small volume uses) the manufacturer has not made an effort to register the exempted use, the OPP may deny a repeat specific or public health emergency exemption.

Potential Human Health and Environmental Risks

Emergency exemptions to address urgent and nonroutine pest situations can create human health and environmental risks. Issues such as herbicide resistance, the Zika virus and citrus greening (Figure 2) have required emergency exemptions to protect public health and help prevent significant economic loss. However, environmental groups have argued that emergency exemptions have become a mechanism for protecting growers' profit margins while placing human health and the environment at risk.

Figure 2: Examples of emergency exemption situations

Herbicide resistance, Zika virus concerns and citrus greening have required emergency exemptions. Sources *(from left to right)*: the OIG, Centers for Disease Control and Prevention, and U.S. Department of Agriculture.

For example, citrus greening is a bacterial disease spread by the Asian Citrus Psyllid, for which there is no known cure. A 2012 study by the University of Florida estimated that approximately 80 percent of Florida citrus trees are currently infected, and some affected groves no longer produce any fruit. The study further estimated the direct revenue loss to citrus growers to be $1.66 billion over 5 years, or $331 million annually, representing 19 percent of the average grower revenues. Emergency exemption applications related to citrus greening have requested approval to treat the problem by applying antibiotics. However,

misuse and overuse of antibiotics can result in the spread of bacteria that are resistant to them, triggering concern about the continuing long-term ability of these drugs to tackle disease. The Centers for Disease Control and Prevention estimates that more than 2 million people in the United States are infected with antibiotic-resistant organisms each year, leading to 23,000 deaths. Some environmental groups have also expressed concern that exposure to antibiotics can have serious unintended side effects for wildlife, including adverse drug reactions. They further claim that antibiotics used in the environment can cause changes in the chemical composition and pH of waters and soils, with potentially serious consequences.

Responsible Office

The OPP, within the Office of Chemical Safety and Pollution Prevention (OCSPP), is responsible for administering FIFRA and for all regulatory activities associated with the emergency exemption issues evaluated in this report. The OPP's Section 18 team manages the emergency exemption process.

Scope and Methodology

We conducted our work from September 2017 through July 2018. We conducted this audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

The scope of this audit focused on the emergency exemption management process and the internal controls necessary to consistently implement and administer it. We did not evaluate the science used to review emergency exemptions or the subsequent emergency exemption application decisions.

During our interviews, we obtained information about the EPA's emergency exemption process, including the application, review, approval, implementation and oversight of emergency exemptions. We reviewed the universe of emergency exemption applications[5] that were received by the EPA between January 1, 2010, and September 5, 2017. We also determined the five states with the highest percentage of emergency exemption applications between those dates and interviewed SLA representatives regarding their emergency exemption experiences. In addition, we performed the following steps:

[5] According to the Section 18 database, there were 1,033 applications from SLAs during this period. Federal agencies requested 71 emergency exemptions during this period, bringing the total application number to 1,104.

- Reviewed and analyzed relevant EPA regulations, as well as statutory and policy requirements governing the agency's measurement and internal management controls environment.
- Conducted a review of emergency exemption-related reports and articles.
- Interviewed extension agents from three states to discuss their roles, responsibilities and experiences regarding emergency exemptions.
- Interviewed nongovernmental organization stakeholders with interests in pesticides (e.g., Pesticide Action Network, Center for Biological Diversity, Beyond Pesticides and Crop Life America).

Results

The OPP's emergency exemption process provides flexibility to growers and other pesticide applicators during emergency situations. However, the OPP does not have outcome measures in place to determine how well the emergency exemption process maintains human health and environmental safeguards. The program office also does not have comprehensive internal controls to manage the emergency exemptions data it collects. Finally, the OPP does not consistently communicate emergency exemption information to its stakeholders. Without outcome measures, better data management and consistent communication, the EPA cannot demonstrate the benefits or risks of emergency pesticide exemptions on human health and the environment.

Poor Data Use Prevents OPP from Developing Meaningful Performance Measures

The OPP currently has no measures in place to demonstrate how human health or environmental safeguards for the emergency exemption process are being maintained. The OPP informed us that the annual number of emergency exemption applications has fallen over the years. OPP staff said that they believe this reduction shows improved outcomes.

The GPRA Modernization Act of 2010 requires federal programs and activities to develop measures to attain outcome-oriented goals and collect data that support outcome measures.[6] However, as of March 2018, the only official measure for the emergency exemption process was the average number of days to review applications. Information on progress toward the full registration of the pesticide's expanded use is not required to be collected, and the OPP does not

[6] GPRA stands for *Government Performance and Results Act*. The GPRA Modernization Act of 2010 requires every federal agency to have performance measures that "reflect the highest priorities of the agency." Outcome-oriented goals are identified as more impactful than output goals, and output goals are identified as more impactful than customer service goals.

currently report on whether the exempted uses approved under the emergency exemption process later obtain full approval for use under FIFRA.
We found that the OPP collects outcome data through its emergency exemption application process that are not used to describe the human health and environmental impacts of the process, nor are these data reported in the Section 18 public database. Only the following application data are available on the EPA Section 18 database public website:

• Chemical	• Site	• Pest	• Applicant
• Status	• Received Date	• Response Date	• Expiration Date

However, none of these reported data allow the OPP or the public to track any potential risks or benefits to human health or the environment, or even to track and understand the scope of any individual exempted use.

The OPP collects outcome data through its emergency exemption process, but it is not using these data or making these data publicly available on its website. For example, emergency exemption applicants are required to calculate the potential significant economic loss that the exemption will prevent or reduce. The OPP also requires applicants to submit the number of affected acres that the pest is impacting, as well as the number of acres that the exempted pesticide could potentially be applied to. In addition, at the end of the exemption period, applicants must report the number of acres that the exempted pesticide was applied to during the exemption period.

Yet the OPP does not use these data to measure the impacts or potential risks of the pesticides it exempts, nor does it report the total application acres of those pesticides in its emergency exemption database to inform the public of the scope of their risks. As a result, the public is currently unable to determine whether an exempted pesticide was applied to 1,000 acres or 1,000,000 acres because the Section 18 database does not report or measure outputs or outcomes.

Case Study

- In 2014, the EPA denied a pesticide emergency exemption request for the use of a potential endocrine disruptor on a major field crop.
- This decision prevented the environmental and human health exposure to a higher-risk pesticide across as many as 3 million acres of cropland.
- This benefit could be more transparent to the public in the Section 18 database if potential application acreage data were available.

The OPP should use its data to measure outputs and outcomes to determine whether its decisions are protective of human health and the environment. In discussing program outcomes, OPP staff indicated that one factor that suggests that the emergency exemption program has been successful is a decrease in the number of emergency exemption applications over the years. However, the decline in the number of applications does not measure whether there were reductions in risks or increases in benefits to human health or the environment. Without meaningful outcome-based measures in place, the OPP does not know whether a decline in applications also resulted in changes to human health and environmental impacts.

OPP Lacks Internal Controls to Manage Emergency Exemption Data

The OPP does not have comprehensive internal controls to manage the emergency exemption data it collects. We found deficiencies within its online public database, internal guidance documents, and annual progress reports to the Office of Management and Budget (OMB) and Congress.

During our review, we found that the OPP's Section 18 database webpage stated, "Our Emergency Exemption Database provides information about actions received since October 1997. This database is updated approximately every two weeks." We found that neither of these statements was accurate. During interviews, OPP staff confirmed that data collected before 2010 were not included in the version of the Section 18 database that we reviewed and that the database was only updated quarterly.[7] During our interviews with the OPP and SLAs, we were also told that there can be significant lags in data entry. Several SLAs said they did not use the database at all or did not find it useful.

Internal guidance documents that address the emergency exemption process lack controls to require accurate and consistent data collection. We found numerous steps in the OPP's internal guidance documents that mention data collection, but these steps lack sufficient specificity to demonstrate consistent control of either data entry or data management. We also found that the OPP does not have a formal method of ensuring consistency in the review process, such as a process flowchart or application checklist. When asked, the OPP did provide an informal Section 18 Application Checklist that was developed by a member of the Section 18 team, but that document is incomplete and not consistently used. For example, there are nine specific line items in the Section 18 Application Checklist that identify data management actions. However, each of those steps has a note stating "TBA, directions," "TBA specific directions" or "TBA Process." Based on our review of the document, we determined that "TBA" indicates a process that is "To Be Announced" and has not yet been developed. These gaps leave staff with incomplete direction and guidance regarding data collection and database management.

We found that these gaps are mirrored in the draft Section 18 standard operating procedure (SOP) document, with numerous steps that expect data to be collected but that do not provide any procedures or specific descriptions regarding what, how and when data points are to be recorded. Based on our discussions with the OPP, we determined that these deficiencies have existed for nearly a decade. Specifically, we identified these gaps in a still-draft SOP document first developed 10 years ago, which was written to update procedures based on regulatory changes made in January 2006, over 12 years ago. Without a finalized

[7] In response to our concerns, the OPP changed the language on its website in March 2018 to reflect that the database only contains information starting from 2010 and that updates are made quarterly rather than biweekly.

SOP document or specific data points defined, the OPP is at risk of not collecting or reporting consistent and accurate data.

Lastly, we found inconsistencies in the way the OPP's emergency exemption implementation is reported to the OMB and Congress. The OPP's 2017 Annual Performance Goal, which was submitted to OMB and Congress as part of the EPA's annual performance plan, states that the OPP's goal is to process emergency exemption applications in an average of 45 days. During our interviews, OPP staff indicated that they strive to achieve a 50-day maximum application processing time frame. This 50-day approval time frame is further reinforced by the EPA's Pesticide Emergency Exemption website. However, this performance target is not mentioned in the emergency exemption draft SOP or Section 18 Application Checklist documents.

In fiscal year 2016, the OPP reported an average application review time of 48 days to the OMB and Congress. This level of performance meets the OPP's internal goal of 50 days but fails to meet the Annual Performance Goal commitment of 45 days. Since emergency exemption requests are based on the urgent need for a solution, this discrepancy could result in SLAs and growers waiting longer to obtain solutions to emergencies than if the OPP worked to meet the Annual Performance Goal reported to the OMB and Congress. It also means that OPP staff are working to meet an internal goal (50 days) that is not consistent with the performance target (45 days) that the OMB and Congress are expecting them to achieve.

EPA Needs to Improve Communication Regarding Its Emergency Exemption Process

The OIG has previously reported on the value of increased communication to stakeholders and the public regarding the EPA's management of chemicals and pesticides.[8] OPP staff stated that the Section 18 team communicates often with emergency exemption applicants. However, SLAs and extension agents with whom we spoke stated that communication could be further improved with better guidance and timely emergency exemption updates.

Pesticide efficacy data and potential economic loss calculations are a required part of emergency exemption applications. Invasive species and diseases can migrate from state to state, and SLAs may try to proactively address an emergency that they expect to impact their state. For example, once trees contract citrus greening,

[8] The OIG previously issued three reports related to this topic:

- EPA OIG, *EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities,* Report No. 10-P-0066, February 17, 2010.
- EPA OIG, *Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act,* Report No. 2006-P-00003, October 19, 2005.
- EPA OIG, *EPA Needs Policies and Procedures to Manage Public Pesticide Petitions in a Transparent and Efficient Manner,* Report No. 16-P-0019, October 27, 2015.

there is no cure, so SLAs may look to prevent the disease from even reaching their state. However, because the "emergency" does not yet exist in their state, these SLAs do not have access to state-specific pesticide efficacy data. One stakeholder was concerned that the lack of state-specific data would prevent an SLA from proactively requesting an emergency exemption. In addition, one extension agent we interviewed said that it is unclear whether the OPP allows applicants to use data for the same pest and same pesticide use from another SLA's application. The OPP needs to clarify the guidance regarding whether states must use efficacy data only from their state to justify an emergency exemption request.

Staff within the OPP stated that the office's online training module is its main tool for communicating with applicants about the emergency exemption process. Yet, some of the various stakeholders with whom we spoke were unfamiliar with the training module. One SLA that was aware of the module stated that it would prefer shorter guidance. However, the OPP does not provide concise emergency exemption guidance for applicants. Applicants are directed to either use the online training module, which contains 174 slides, or contact the Section 18 team with any questions. We also found that the emergency exemption training module provides general information about the entire emergency exemption process but does not provide specific data requirements or answers to frequently asked questions. Conversely, on another OPP-managed pesticide website focused on FIFRA Section 24(c) registrations, there are quick links to relevant information and specific examples of how to submit applications. In addition, this OPP website has links to general policies and a question-and-answer webpage.

Lastly, the SLAs we spoke with indicated that communication from the Section 18 team regarding the status of the emergency exemption applications could be improved. The OPP previously sent an annual "year in review" letter that summarized the emergency exemption activity for that year. The letter also provided additional information from the Section 18 team regarding the emergency exemption process. According to the OPP, the most recent letter was sent in 2015. Some SLAs with whom we spoke requested that the OPP reinstate this end-of-the-year letter.

Conclusion

Emergency exemptions represent a necessary element in a grower's toolbox to handle nonroutine and urgent situations caused by unexpected pests, invasive species or pesticide resistance. However, we found that the OPP does not have outcome measures in place to determine whether the emergency exemption process protects human health and the environment. The OPP is missing key data management controls that would support its ability to manage its emergency exemption process. The OPP's emergency exemption process also faces challenges regarding the collection and dissemination of reliable emergency exemption information. To mitigate these challenges, the OPP needs meaningful

measures, better data management and consistent communication to increase the agency's ability to manage its emergency exemption process.

Recommendations

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention:

1. Develop and implement applicable outcome-based performance measures to demonstrate the human health and environmental effects of the EPA's emergency exemption decisions.

2. Determine which application review performance target for emergency exemption applications the Office of Pesticide Programs plans to meet, and make that target consistent between its Annual Performance Goal and its internal controls governing the emergency exemption process.

3. Update and finalize the draft standard operating procedure that the Office of Pesticide Programs uses to guide the emergency exemption process.

4. Develop formal emergency exemption application review procedures that detail specific data collection, management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the Office of Pesticide Programs Section 18 database.

5. Develop concise emergency exemption application guidance that specifies the minimum requirements of an application submission and is available on the Office of Pesticide Programs Section 18 website.

6. Provide clear guidance to state lead agencies on how and when they can use efficacy data from other state lead agencies to satisfy the emergency exemption application criteria.

7. Expand the data presented in the Office of Pesticide Programs Section 18 database by considering additional data points, such as application acreage requested, actual acreage applied and registration status of each exempted pesticide.

8. Provide an annual update and information summary to state lead agencies to better inform them about any changes to the emergency exemption application-and-review process.

Agency Response and OIG Evaluation

In the EPA's official comments regarding the draft report, the agency agreed with Recommendations 3, 4, 7 and 8; neither agreed nor disagreed with Recommendations 2 and 5; and disagreed with Recommendations 1 and 6. The OIG accepts the proposed corrective actions and scheduled completion dates for Recommendations 2, 3 and 4. During our exit conference and other discussions with OCSPP staff, the OIG tried to reach resolution on sufficient corrective actions for Recommendations 1, 5, 6, 7 and 8; however, no resolution was reached, and these recommendations remain unresolved. The following list summarizes the status of our recommendations:

- The OCSPP concurred with Recommendations 3 and 4, and it provided acceptable planned corrective actions and completion dates. Although the agency did not agree or disagree with Recommendation 2, it provided an acceptable corrective action "to avoid future confusion." This corrective action meets the intent of the recommendation. These three recommendations are therefore resolved with corrective actions pending.

- The EPA disagreed with Recommendations 1 and 6. Regarding Recommendation 1, the OCSPP stated that the development of an outcome-based performance measure for the Section 18 emergency exemption process was neither appropriate nor feasible. Although we attempted to reach resolution on Recommendations 1 and 6, the EPA did not formally propose corrective actions. Recommendations 1 and 6 remain unresolved.

- The OCSPP neither agreed nor disagreed with Recommendation 5. Based on our analysis of the emergency exemption application guidance, as well as stakeholder comments regarding that guidance, we believe that a corrective action is warranted. The agency did propose corrective action for this recommendation, but it was insufficient to meet the intent of the recommendation. This recommendation remains unresolved.

- Although the EPA agreed with Recommendations 7 and 8, the proposed corrective actions were insufficient to meet the intent of the recommendations. For Recommendation 7, the OCSPP proposed only that it "will consider additional data points" and did not commit to expanding the data presented in the Section 18 database. For Recommendation 8, the EPA proposed to "develop a strategy which details the activities that might be conducted to provide periodic and useful program updates to applicants." However, the agency needs to clarify the term "periodic" before we can determine whether the proposed corrective action is acceptable. Therefore, both recommendations remain unresolved.

The agency provided technical comments on the draft report, which we incorporated into our final report as appropriate. Appendix A includes the agency's official response to the draft report.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	11	Develop and implement applicable outcome-based performance measures to demonstrate the human health and environmental effects of the EPA's emergency exemption decisions.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
2	11	Determine which application review performance target for emergency exemption applications the Office of Pesticide Programs plans to meet, and make that target consistent between its Annual Performance Goal and its internal controls governing the emergency exemption process.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/19	
3	11	Update and finalize the draft standard operating procedure that the Office of Pesticide Programs uses to guide the emergency exemption process.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/19	
4	11	Develop formal emergency exemption application review procedures that detail specific data collection, management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the Office of Pesticide Programs Section 18 database.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/19	
5	11	Develop concise emergency exemption application guidance that specifies the minimum requirements of an application submission and is available on the Office of Pesticide Programs Section 18 website.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
6	11	Provide clear guidance to state lead agencies on how and when they can use efficacy data from other state lead agencies to satisfy the emergency exemption application criteria.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
7	11	Expand the data presented in the Office of Pesticide Programs Section 18 database by considering additional data points, such as application acreage requested, actual acreage applied and registration status of each exempted pesticide.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
8	11	Provide an annual update and information summary to state lead agencies to better inform them about any changes to the emergency exemption application-and-review process.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Agency Response to Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL - 3 2018

MEMORANDUM

SUBJECT: Response to Draft Report entitled "Measures and Management Controls Needed to Improve EPA's Emergency Pesticide Exemption Process."

FROM: Charlotte Bertrand
Acting Principal Deputy Assistant Administrator

TO: Arthur A. Elkins
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG's) June 5, 2018 Draft Report entitled "Measures and Management Controls Needed to Improve EPA's Emergency Pesticide Exemption Process," Project No. OPE-FY17-0024.

OCSPP's Responses to OIG's Recommendations:

The Draft Report contains eight recommendations for the Office of Chemical Safety and Pollution Prevention's (OCSPP's) Office of Pesticide Programs (OPP):

Recommendation 1. Develop and implement applicable outcome-based performance measures to demonstrate the human health and environmental effects of the EPA's emergency exemption decisions.

> **OCSPP Response:** OCSPP does not agree that outcome-based performance measures to demonstrate the human health and environmental impacts of EPA's emergency exemption decisions are appropriate or feasible. Requests for FIFRA Section 18 emergency exemptions are reviewed in accordance with the specific statutory criteria of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). OPP assesses all emergency exemptions for human and environmental safeguards consistent with these statutory requirements. In addition, each emergency exemption decision details the conclusions of OPP's

assessment and the public safety requirements necessary to support the approved use. As a result, the decision to authorize an emergency exemption under FIFRA Section 18 ensures that the pesticide can be used safely, in accordance with Federal law. The human health and environmental risk assessments that are done for all Section 18 exemptions are based on the best available data and assessment procedures, and must ensure the same safety findings are made as for uses covered by Section 3 registrations. As such, OPP believes that emergency exemption decisions, which are scientifically supported by risk assessments, show that EPA has adequately met its obligations under our regulatory statutes.

Proposed Corrective Action and Timeframe for Completion: OCSPP disagrees with this recommendation and is not providing a timeframe for completion.

Recommendation 2. Determine which application review performance target for emergency exemption applications the Office of Pesticide Programs plans to meet, and make that target consistent between its Annual Performance Goal and its internal controls governing the emergency exemption process.

OCSPP Response: EPA's Annual Performance Plan has a performance metric of 45 days for completing emergency exemption applications. OCSPP has historically advised applicants to allow 50 days for EPA to render a decision on an emergency exemption request, but to avoid future confusion, OCSPP will state 45 days as the timeframe for completion whether referring to estimated processing time, target completion, or performance goals.

Proposed Corrective Action and Timeframe for Completion: By July 2019, OCSPP will consistently reference the 45-day decision period, as is reflected in EPA's Annual Performance Assessment (https://www.epa.gov.sites.production/files/2018-03/documents/fy19-cj-14-program-performance.pdf). In particular, internal control documents and public-facing discussion of the processing timelines will cite 45 days.

Recommendation 3. Update and finalize the draft standard operating procedure that the Office of Pesticide Programs uses to guide the emergency exemption process.

OCSPP Response: OCSPP agrees with OIG's recommendation that the standard operating procedure (SOP) guidance for emergency exemptions needs to be updated and finalized.

Proposed Corrective Action and Timeframe for Completion: OCSPP will update and finalize the standard operating procedures and/or guidance for emergency exemptions by July 2019.

Recommendation 4. Develop formal emergency exemption application review procedures that detail specific data collection, management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the Office of Pesticide Programs Section 18 database.

OCSPP Response: OCSPP agrees with OIG's recommendation to develop formal emergency exemption application review procedures that detail specific data collection,

management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the OPP Section 18 database. As part of the updates to the standard operating procedures guidance cited in recommendation 3, OCSPP will also incorporate recommendation 4.

Proposed Corrective Action and Timeframe for Completion: OCSPP will update and finalize the standard operating procedures and/or guidance for emergency exemptions by July 2019.

Recommendation 5. Develop concise emergency exemption application guidance that specifies the minimum requirements of an application submission and is available on the Office of Pesticide Programs Section 18 website.

OCSPP Response: Section 18 application and training materials are currently available through several sources, including the EPA Section 18 website, periodic and regular group training sessions with State Lead Agency personnel, and one-on-one sessions between EPA staff and the State Lead Agencies. The most recent update to the EPA Section 18 website was on March 22, 2018. The updated site provides links to Section 18 training materials, and links to the regulatory language in 40 CFR 166.20, which provide a precise description of the requirements for a specific, quarantine, crisis, or public health exemption. The website also provides an EPA program contact to assist the State Lead Agencies with the application process.

Although OPP believes that emergency exemption applicants currently have reliable and useful resources for this information, EPA staff will evaluate how its web resources can be enhanced to respond to this recommendation.

Proposed Corrective Action and Timeframe for Completion: If, after evaluating our current web resources, OCSPP determines that enhancements to the Section 18 website are necessary, OCSPP will implement any needed web updates by December 2019.

Recommendation 6. Provide clear guidance to State Lead Agencies on how and when they can use efficacy data from other State Lead Agencies to satisfy the emergency exemption application criteria.

OCSPP Response: As a routine matter, state applications can readily address the expected efficacy of a proposed use, and data do not need to be state-specific.

The sole example cited by the OIG to support this recommendation represents an extremely rare situation. In this particular situation, the California Department of Pesticide Regulation (DPR) requested use of the same antibiotic materials as authorized under exemptions for use in Florida citrus (where widespread establishment of the disease has devastated commercial citrus). However, citrus greening had not (at the time) been detected in California's commercial citrus, with only very limited occurrence in residential trees in several areas of the state. To support their request, California cited data from Florida researchers that examined antibiotic use to improve health and production **of already-diseased trees.** In contrast to the Florida research and uses, California intended to make "prophylactic" treatments to healthy trees to protect them

from infection. However, the Florida data did not, in fact, analyze or demonstrate the prophylactic effect on healthy trees that California was seeking. **In other words, the data submitted to support the emergency exemption in Florida represented very different conditions from those being experienced in California.**

Notwithstanding the challenges in trying to apply the Florida data to the circumstances in California, OCSPP worked collaboratively with California DPR to find a path forward for California growers to be able to use the requested antibiotics to meet their pest control needs. Ultimately, EPA authorized **quarantine** exemptions to California for the requested antibiotics. The uses allowed in California are for treatment of healthy trees in specified perimeters around positive detects of citrus greening, with the goal of preventing the spread, particularly into commercial citrus.

Proposed Corrective Action and Timeframe for Completion: OCSPP disagrees with this recommendation and is not providing a timeframe for completion.

Recommendation 7: Expand the data presented in the Office of Pesticide Programs Section 18 database by considering additional data points, such as application acreage requested, actual acreage applied and registration status of each exempted pesticide.

OCSPP Response: OCSPP agrees with OIG's recommendation and will consider additional data points, such as application acreage requested, decision documents, and registration status of each exempted pesticide, as OCSPP explores ways to improve the website database and its overall content.

Proposed Corrective Action and Timeframe for Completion: By December 2019, the Registration Division will make recommendations to the Director of the Office of Pesticide Programs for enhancing the Section 18 database. The recommendations will consider the additional data points suggested in Recommendation 7. By December 31, 2019, the Director of the Office of Pesticide Programs will provide a memorandum to the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention with a plan for updating the Section 18 database addressing these recommendations.

Recommendation 8. Provide an annual update and information summary to State Lead Agencies to better inform them about any changes to the emergency exemption application and review process.

OCSPP Response: OCSPP agrees with OIG's recommendation and will explore how to provide periodic and useful program updates to applicants. To accomplish this, OCSPP will work with State Lead Agencies to identify the types of information they may find helpful for periodic updates.

Proposed Corrective Action and Timeframe for Completion: By December 2019, OCSPP will develop a strategy which details the activities that might be conducted to provide periodic and useful program updates to applicants.

Distribution

The Administrator
Deputy Administrator
Chief of Staff
Chief of Operations
Special Advisor, Office of the Administrator
Assistant Administrator for Chemical Safety and Pollution Prevention
Agency Follow-Up Official (the CFO)
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Audit Follow-Up Coordinator, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention

Enclosure B

REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Special Pesticide Registration By The Environmental Protection Agency Should Be Improved

Environmental Protection Agency administration of special pesticide registration activities has not always been effective. Agency processing of requests for emergency and experimental uses of pesticides often takes too long. The Agency often approves requests for emergency use of canceled pesticides in non-emergency situations.

Some participating Federal and State agencies have violated their authority by using unregistered, canceled, or suspended pesticides. As a result, the public may not be protected from potentially harmful and dangerous pesticides used under this program.

CED-78-9

JANUARY 9, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-133192

To the President of the Senate and the
Speaker of the House of Representatives

This report discusses the Environmental Protection Agency's program to regulate pesticides that are used for experimental and emergency purposes or that are registered by the States to meet special local needs. The Agency's administration of the program has not always been effective, and as a result, the American public may not be adequately protected from potentially harmful and dangerous pesticides used under this program.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), the Accounting and Auditing Act of 1950 (31 U.S.C. 67), and the Legislative Reorganization Act of 1970 (31 U.S.C. 1152). Our review was prompted by deficiencies that we noted in other aspects of the Agency's pesticide registration program and increasing congressional interest in controlling pesticide use.

Copies of this report are being sent to the Acting Director, Office of Management and Budget; the Administrator, Environmental Protection Agency; the Secretary of Agriculture; interested congressional committees; Members of Congress; and other interested parties.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

SPECIAL PESTICIDE REGISTRATION BY THE ENVIRONMENTAL PROTECTION AGENCY SHOULD BE IMPROVED

D I G E S T

Each year in the United States over a billion pounds of pesticides are knowingly released into the environment to control insects, rodents, weeds, bacteria, diseases, and other pests that attack man's food and fiber supplies and threaten his health and welfare.

The Environmental Protection Agency regulates these pesticides, registering for use only those that will not cause unreasonable adverse effects on man and the environment. The Agency permits exceptions, allowing limited use of unregistered and previously canceled or suspended pesticides to

--control pest infestations that present health or economic emergencies,

--gather experimental data to register the pesticide, and

--meet a State's special local needs. (See p. 2.)

However, the Agency has not always been effective in administering these special registration activities because:

--Requests for emergency and experimental pesticide uses take too long to process. (See pp. 6 and 22.)

--Program requirements are not always met by the Agency and other Federal and State agencies. (See pp. 25, 28, 30, 46, 49, 57, and 61.)

--States are permitted to register pesticides that the Agency would not register. (See p. 42.)

--Some activities are not coordinated effectively with the Agency's regional offices or responsible State agencies, and many pesticide uses are not monitored adequately. (See pp. 10, 34, and 35.)

Often the Agency has been slow in approving pesticides for both emergency and experimental uses--an average of 40 and 105 days, respectively.

Some requestors, however, have used pesticides illegally to

--protect human health or crops in emergencies or

--avoid losing a growing season in their experimental programs.

One manufacturer, for example, used three products before the experimental permits were approved to avoid missing a season. Thus, the Agency did not assure that man and the environment were protected from inappropriate use of potentially dangerous or harmful pesticides. (See pp. 6 and 22.)

The Environmental Protection Agency and other Federal and State agencies have not complied with regulatory requirements. The Agency has permitted unauthorized agencies to participate in special registration activities and some pesticides to be used inappropriately.

Other Federal and State agencies have violated their pesticide authority. In addition, the Agency has not, as required, issued final regulations governing State registration of pesticides to meet special local needs. (See pp. 25, 28, 30, 46, 49, 57, and 61.)

The Agency has permitted States to register pesticide products on which it has placed registration moratoriums and would not register. In effect, the Agency has given States greater registration authority than it has for such chemicals. (See p. 42.)

The Agency has not always notified its regional offices or State agencies when experimental permits or emergency exemptions were granted. Consequently, these offices and agencies could not monitor program activities. State agencies normally have personnel whose responsibilities include pesticide monitoring

and who could monitor activities if necessary. (See pp. 10, 34, and 35.)

GAO has made over a dozen recommendations to improve the Agency's administration of special registration activities. (See pp. 14, 37, and 51.)

AGENCY COMMENTS

The Agency agrees that its special registration activities should be improved. However, many of its views sharply conflict with GAO's conclusions and recommendations. The Agency's comments are discussed at length in the report. (See pp. 14, 38, and 51.)

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Contents

ABBREVIATIONS

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
TVA	Tennessee Valley Authority

CHAPTER 1

INTRODUCTION

Pesticides are substances used to control harmful insects, rodents, weeds, bacteria, diseases, and other pests that attack man's food and fiber supplies and threaten his health and welfare. Over 1 billion pounds of pesticides are used domestically each year--55 percent for agriculture; 30 percent for industrial, institutional, and governmental use; and 15 percent for home and garden use. Approximately 34,000 pesticide products--including insecticides, rodenticides, herbicides, fungicides, and disinfectants--made from 1 or more of about 1,800 chemicals were registered with the Environmental Protection Agency (EPA) as of March 1977.

The basic authority for regulating pesticides is (1) the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C 135 et seq. (Supp. V, 1975)) as amended by the Federal Environmental Pesticide Control Act of 1972 (7 U.S.C 136 et seq. (Supp. V, 1975)), referred to in this report as the Pesticide Act, and (2) the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 301 et seq. (Supp. V, 1975)), referred to as the Food and Drug Act. Authority for administering the Pesticide Act was transferred from the Department of Agriculture along with the responsible organization elements to EPA on December 2, 1970, pursuant to Reorganization Plan No. 3 of 1970 which established EPA.

PESTICIDE REGISTRATION AND TOLERANCES

Pesticides are regulated by the Federal Government to insure that quality products are available to the public and that, when properly used, these products will provide effective pest control without unreasonable adverse effects on man or the environment. EPA has the primary responsibility for regulating pesticides.

EPA registers a pesticide under the Pesticide Act when it determines that the pesticide

--meets its proposed claims (product performance),

--complies with labeling and other requirements,

--performs its intended function without unreasonable, adverse effects on the environment (including man safety), and

--will not generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

The act defines unreasonable adverse effects as any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

If a pesticide remains in or on food or feed, the Food and Drug Act requires that a tolerance--the maximum pesticide residue allowed in food--be established. EPA's Office of Pesticide Programs establishes all tolerances for pesticide residues remaining in or on raw agricultural commodities and for pesticide food additives.

Before EPA's existence, tolerances were established by the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare. FDA is still responsible for enforcing established tolerances. FDA tests samples of food to determine if any residues exceeding tolerance levels remain on the food, rendering the food adulterated. Adulterated foods may not be sold in interstate commerce.

SPECIAL REGISTRATION ACTIVITIES

While a pesticide generally must be registered by EPA before it can be used in the United States, the Pesticide Act and its implementing regulations allow certain exceptions for using unregistered and previously canceled or suspended pesticides under specified conditions. These exceptions include:

--Experimental Use Permits--permits to use pesticides for accumulating information necessary to (1) register a product not previously registered with EPA or (2) modify the use, application, crop, amount, or pest involved with a currently registered product. Permits are normally granted for 1-year periods.

--Emergency Exemptions--exemptions granted to Federal or State agencies to use suspended, canceled, or unregistered pesticides in emergency situations where (1) pest outbreaks have or are about to occur and effective registered pesticides are not available, (2) significant economic or health problems will occur without the use of pesticides, and (3) there is insufficient time available from discovery of a pest outbreak to register pesticides to control the pest.

--State Registrations--pesticide registrations by States, certified by EPA as capable of registering pesticides, for use and distribution only within the registering State to meet special local needs.

The special registration activities are administered by the special registration section at EPA headquarters in Washington, D.C. EPA regional office staffs monitor the various special registrations within their jurisdictions.

SCOPE OF REVIEW

We reviewed EPA's policies and practices and examined pertinent legislation, documents, reports, and records on special registration activities.

We interviewed responsible agency officials at EPA headquarters in Washington, D.C., and at EPA regional offices in Atlanta, Chicago, Dallas, Denver, and Kansas City. We also obtained information from a number of State officials and major pesticide manufacturers on their special registration activities and on their views on EPA's handling of special registration activities.

CHAPTER 2

EXPERIMENTAL USE PERMIT PROGRAM IS NOT EFFECTIVE

EPA's experimental use permit program has not been fully effective because (1) the types of data that must be submitted with a permit application have not been clearly defined, (2) permits were not processed in a timely manner, (3) headquarters did not notify regions of approved permits in a timely manner or notifications were not made at all, and (4) pesticide applications under permits were not adequately monitored. Delays in approving such permits cause corresponding delays in marketing new pesticides, resulting in increased costs to the manufacturer. Ultimately, the consumer must pay higher prices for pesticides.

Under Section 5 of the Pesticide Act, EPA issues experimental use permits to enable manufacturers to develop certain data--primarily efficacy data and environmental chemistry data--needed for product registration. The permits are issued subject to a number of conditions which generally specify (1) who may apply the pesticide, (2) the location, total acreage, and crops that may be treated, and (3) any reporting requirements. As part of its program, EPA requires monitoring to assure that permit requirements are followed and to identify the extent of adverse effects as they become known.

The permit program provides an important link between the "birth" of a pesticide and its registration and subsequent introduction into commerce. During this phase a pesticide is tested to determine whether it is effective and whether it will adversely affect man or the environment. Of necessity, the experimental use program must be efficient and effective to encourage the development of new pesticides.

Pesticide product development has declined in recent years. A 1975 National Agricultrual Chemicals Association report pointed out that while pesticide sales have increased, research and development expenditures have decreased each year since 1972--from 8.5 percent in 1972 to 6.5 percent in 1975--in terms of total domestic sales. A followup 1976 report said that research and development expenditures increased to about 7.9 percent of domestic sales but that the total number of new products screened for development was about 6,000 less in 1976 than 1975. This deemphasis in developing pesticides will not be felt for several years because of the long lead time required to register pesticides--products registered by EPA in 1974 and 1975 were actually discovered an average of 8 years previously.

The reasons for industry's growing reluctance to develop new pesticides were discussed in an August 1975 report of the Entomological Society of America which stated that:

> "The pesticide industry has substantially reduced its efforts in this field * * * [because of] shrinking profits, increased costs of discovering effective compounds and obtaining the data required to establish tolerances and obtain registration, the relatively short effective life of many compounds and the widespread antipathy of society at large to the use of pesticides * * *."

Another report (William Blair & Company, July 1975) stated that the number of active researchers and funds available for research and development of innovative approaches to pest management has been reduced, creating a tendency to concentrate research efforts on developing variations on existing chemical controls. We did not attempt to determine what economic, social, political or other factors, such as pesticide registration requirements, have caused the decline in pesticide product development. Although EPA's experimental permit is only one of many factors that may affect pesticide development, this program must be as effective and efficient as possible to encourage development of innovative products that will be less hazardous to man and the environment. This chapter discusses our recommendations for improving EPA's experimental program.

GUIDELINES NEEDED

EPA has not issued guidelines setting out the (1) minimum data required for permit approvals and (2) type of data required to be developed while the pesticide is being used experimentally. As a result, EPA is using registration data requirements and the manufacturer may be required to begin all tests, including laboratory animal feeding studies which are required for full EPA registration but are not necessary to determine environmental safety and efficacy. For example, a permit requestor may be required to begin expensive laboratory tests, such as 2-year chronic feeding studies costing $250,000, before it is known whether the experimental pesticide is sufficiently safe and effective in the environment to warrant EPA registration.

EPA's regulations for experimental use permits require among other things available data on the

--rate of decline of residues on the treated crop or environmental site or other information regarding entry of persons into treated areas and

--results of toxicity tests and other data concerning products' potential for causing injury to users or other exposed persons, including any available epidemiological information.

These requirements are not specific and EPA has not issued appropriate guidelines to implement them. Both EPA reviewers and permit applicants told us that they are not sure what data is required for permit approval or what data must be obtained during the experimental use period.

Representatives of eight major pesticide manufacturers we visited said that lack of guidelines was a common problem. They also said that some EPA reviewers are more stringent and require more data than other reviewers for similar products. EPA officials agreed with these comments and added that it was primarily a problem of not having guidelines on which to base data requirements.

Another problem is that data required by EPA reviewers may be inconsistent with the purpose of an experimental use permit. For example, EPA denied one permit application because the EPA reviewer said he was unable to determine if the product would be effective. This does not appear to be appropriate because the primary intent of the experimental permit program is to determine the pesticide's effectiveness.

Development of guidelines implementing EPA regulations should reduce delays in permit processing because requestors can conform applications to specific requirements and various EPA reviewers can act on applications more consistently than was done in the past. In developing specific guidelines for granting experimental permits before toxicity tests are completed, EPA should include a standard condition that treated crops with detectable residues of the experimental pesticide could not be marketed without EPA waiver. The guidelines should be sufficiently flexible to allow different requirements for new uses of registered pesticides and new pesticides which have not been previously registered.

PROCESSING TIMES ARE EXCESSIVE

EPA's processing of original permits, extensions, and renewals has not been timely. EPA regulations state only

that EPA will act on permit applications as quickly as possible. In its proposed permit regulations, EPA set its processing time at 90 days; however, public and industry comments on the proposed regulations advocated 30- or 60-day processing periods as more reasonable. As a result, EPA's regulations do not specify processing periods for applications. EPA records show that an average of 105 days--ranging from 3 to 547--elapsed between the dates of application and approval. The following table shows the processing times, where available, for permits issued between July 1974 and March 1976.

	Number	Average number of days from application to approval
New permits	196	114
Extensions	77	86
Renewals	7	58
Total	280	105

EPA delays in acting on permit applications have had detrimental effects on some manufacturers' pesticide development programs because frequently the permits are approved too late in the season for the pesticide to be used effectively. Also, there have been instances where manufacturers illegally applied pesticides before EPA acted rather than lose an entire year. These points are illustrated in the following examples.

Example 1

On August 5, 1975, a manufacturer requested an experimental permit for testing an herbicide on peanuts and soybeans that were to be destroyed after testing. EPA issued the permit 210 days later on March 2, 1976--2 months after the manufacturer was to begin his experimental program. As a result, the manufacturer may have found it difficult to find farmers willing to test the pesticide because the crops were already planted or were being planted and the farmers would likely already have purchased other pesticides to alleviate potential pest problems. This example is especially significant because EPA received the request during a "slack period" when permit submissions were relatively light.

Example 2

On May 20 and 27, and July 29, 1975, EPA issued three experimental use permits to one manufacturer. These permits were requested on January 28 and February 25, 1975, and November 30, 1974, respectively. On July 22 and August 6, 1975, an EPA investigator visited two of the manufacturer's

test sites and found that one of the products had been used in May 1975 before the permit was approved. Further, in October 1975 an EPA inspector in the Kansas City region found that all three products were used at different sites before the permits were approved. A company representative told EPA that he had been instructed by his headquarters office to proceed with testing the three products even though the permits had not been approved.

The Pesticide Act provides for civil or criminal penalties for such illegal use after the Agency's final regulations have been in effect for 60 days. EPA's experimental use permit regulations were not published in the Federal Register until April 30, 1975; consequently, EPA could not take punitive actions until after June 30, 1975. Because these violations occurred in May 1975, EPA was unable to act. However, EPA did include the company on a list of "potential violators" so that the company's pesticide activities could be closely monitored in the future.

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Before the House Subcommittee on HUD--Independent Agencies, Committee on Appropriations, one pesticide industry official testified:

> "The main difficulties that both the industry groups and the regulatory agencies are not aware of is the fact that there are certain fields of pesticides where a year cannot be divided into 12 months.
>
> "The year consists of 4 months because insects and plants mature and grow during very limited amounts of time. The EPA also has to approve large scale field research that can only be done in the summer. If you apply in February for experimental permits and ask for them to be granted in May and the agency gives it to you in June, you have lost an entire year."

Other pesticide manufacturers told us that many pesticide products must be applied at certain stages of plant growth or during a specific phase of pest infestation to be effective. Therefore, permits must be approved before that time or the experimental program is delayed until the required test conditions recur, often 6 months or a year later.

The untimely approval of experimental use permits, in addition to causing delays for as much as a year, also affects other aspects of an experimental program. For example, a pesticide product legally cannot be used until an EPA-approved

label is available; however, printing labels and shipping products may require 3 or 4 weeks after permit approval. If permits are not approved until just before the testing season, the manufacturer may have trouble starting his experimental program on time.

Manufacturers told us that the interest and commitment of farmers who are willing to test the product also may be adversely affected without some assurance of timely EPA approval. Prospective farmers participating in the experimental program must have sufficient lead time to obtain other products to alleviate pest problems in the event a permit is not approved when needed.

Longer experimental periods needed

EPA normally issues experimental use permits for 1-year periods; however, many permits must be extended or renewed beyond that period to develop data necessary to support registration. A total of 84 of the 286--or 30 percent--approved permit actions during the period July 1974 through March 1976 were extensions or renewals. In addition, 47 permits originally issued during this period were later extended, and 9 permits previously extended were reextended. The burden of processing extensions and renewals contributes, at least in part, to the excessive time required to approve permits.

We could not readily determine from EPA records how many extensions were requested by manufacturers because (1) additional data was needed or (2) the original permit was approved too late. However, EPA officials and industry representatives told us most extensions were requested to develop additional data. During our review we met with 13 pesticide manufacturers who had received 112 permits for which 35 extensions or renewals were granted. Thirty of these extensions or renewals were requested to develop additional data. If the original permits had been issued for sufficient periods to allow manufacturers to complete their experimental program, EPA's processing workload would have been reduced by about 30 percent.

Approximately 45 percent of EPA's permit workload is received between December and March. Manufacturers normally evaluate experimental test results at the end of a growing season, completing this work about the end of the calendar year. Extensions or renewals are usually requested immediately thereafter, resulting in a flood of applications that EPA cannot handle promptly. Apparently, alternatives to

alleviate this seasonal surge do not exist, but as much as 30 percent of the workload could be eliminated if EPA made permits effective for 2 years rather than 1. Manufacturers we visited said that they generally need at least 2 years to develop the data needed to register pesticide products.

Manufacturing officials told us that they had submitted permit applications during the "off season" to miss the seasonal surge. These officals said, however, that their experiences show that EPA does not act on extension applications until about 30 days before they are needed. For example, one official said that although it was known in July 1976 that an extension was needed in April 1977, the company would not apply for the extension until shortly before April because EPA would not act on it before that time.

An EPA official explained that permits are not approved in advance because EPA wants to review all pertinent data before a decision is made. He said it is harder to cancel an issued permit than not to issue one in the first place.

We see no compelling reasons why permits should not be processed and either approved or disapproved as they are received. We believe this would benefit both EPA and the manufacturer. Manufacturers would be able to plan their programs and line up farmers who are willing to test their product. This would also help spread EPA's workload throughout the year, allowing it to review applications more thoroughly and in shorter turnaround time.

EPA DOES NOT ADEQUATELY MONITOR EXPERIMENTAL PRODUCTS

In the five EPA regions we visited, 116 of the 201 (58 percent) experimental use permits applicable to those regions were identified by EPA as having been monitored. However, EPA visited the application sites of only 41 permits and most of these visits were made after the pesticides had been used; thus, EPA inspectors could not readily determine if permit conditions were met. At least seven permits were monitored by telephone contacts only. We could not determine how or the extent to which the remaining 68 were monitored because EPA's records were inadequate. The remaining 85 permits were not monitored because the regions either were unaware that they existed or did not believe that monitoring was warranted.

Each EPA region is responsible for monitoring selected experimental pesticide uses within its region. This responsibility includes developing monitoring schedules and assigning personnel to visit sites and determine whether

--the product was effective;

--the product was applied in accordance with label directions and the terms of the permit;

--the permittee supervised testing activities, evaluated results, and reported adverse effects to EPA;

--food or feed not covered by tolerances were disposed of properly;

--unused pesticides were disposed of in accordance with permit instructions; and

--there were adverse reactions or side effects, such as accidents and undesirable effects, on beneficial plants and animals.

The following table shows EPA's monitoring efforts in each of the five regions included in our review.

EPA region	Number of permits (note a) Applicable to each region	Region was aware of Number	Region was aware of Percent	Considered as monitored	Number of site visits
Atlanta	168	135	81	81	(b)
Chicago	143	129	90	33	26
Dallas	162	143	88	4	4
Kansas City	122	110	90	16	16
Denver	113	74	65	21	(b)

a/A permit may be issued for use in one or more regions; thus each permit may be listed as many as five times, once for each region.

b/The quality of the monitoring reports was such that we could not determine whether site visits were made. However, it appears that 70 to 80 percent of the monitoring actions were telephone contacts.

The objectives of EPA's monitoring activities are to determine whether experimental products are used in accordance with permit conditions and whether significant adverse effects occur. These objectives generally were not achieved

because (1) monitoring visits were made after experimental products were applied and (2) monitoring was done by telephone.

EPA monitoring consisted of 46 site visits on 41 permits in the Chicago, Dallas, and Kansas City regions. Although some regions monitored considerably more than others, most monitoring was done after the product was applied. It is important to visit testing sites when the pesticide is applied to assure that EPA restrictions are met and that significant adverse effects do not occur. Only through first-hand observation can EPA investigators make these determinations; to do so after the fact requires reliance on written records or the memory of participants. This procedure is not the most effective way to achieve EPA's mission. Telephone monitoring is not the most effective form of monitoring and should be used only to monitor permits that (1) would not be monitored otherwise because sufficient staff is not available or (2) do not warrant onsite monitoring.

In EPA's Denver and Atlanta regions we could not determine the quality of monitoring because the records were inadequate. Although Atlanta regional officials told us that their monitoring consisted of site visits rather than telephone contacts, we were unable to verify or confirm this information. A Denver regional official said that telephone calls were treated the same as site visits. The type of monitoring performed and any deviations from procedures prescribed in the experimental use permit should be adequately documented.

Factors contributing to inadequate monitoring included headquarters failure to (1) notify regional offices or to notify them in a timely manner about permit approvals and (2) place monitoring on a high priority. For example, the Dallas region was aware of only 88 percent of the permits issued for use in the region; notification of the issuance of 105 experimental permits came an average of 41 days after approval.

A region usually learns of experimental permits when EPA headquarters forwards a package containing the (1) original permit or applicable extension or renewal letters, (2) product label, and (3) manufacturer's experimental program. As shown in the table on page 11, the regions were not aware of all permits issued for use within the region.

EPA regional officials said that monitoring plans could be affected if the region was not aware of all experimental permits especially if the permit was (1) issued to a manufacturer who was being monitored closely because of past violations or (2) for a new chemical. However, a Dallas regional official said that it did not matter whether EPA was aware of all permits because it did not have the resources to monitor them anyway, and permit monitoring was given low priority.

An EPA official told us that monitoring is limited because regions have very limited staff resources and travel funds available for pesticide investigations. For example, EPA's Denver region had only three inspectors to cover the entire region--six States. As a result, regional officials apply these limited resources to those areas where they have found the most violations--establishment inspections and pesticide misuse investigations rather than monitoring experimental products.

CONCLUSIONS

The experimental use permit program has not been fully effective because EPA has not promulgated guidelines to implement its rather general regulations particularly concerning the specific data which should be (1) required as a basis for permit approvals and (2) developed while the pesticide is being used experimentally. Such guidelines should reduce delays in processing because requestors will be able to conform applications to specific requirements and various EPA reviewers will be able to act on applications more consistently than was done in the past.

Permits should be processed and either approved or disapproved within a reasonable time after being received. This would enable manufacturers to better plan their programs and line up farmers willing to test experimental products. By processing the applications as received rather than creating a backlog to be processed shortly before the growing season, EPA would benefit by spreading its workload more evenly throughout the year, permitting it to review applications more thoroughly, and in shorter turnaround time.

Monitoring of unregistered pesticide products, the safety of which has not been established, should be given high priority as a basis for insuring that permit restrictions are followed and that the public is not unnecessarily exposed to harmful pesticides. EPA has not adequately monitored permits to assure that terms and conditions are met. Of the 201

experimental use permits applicable to the five EPA regions we visited, only 58 percent were identified as being monitored by EPA and only 20 percent were monitored onsite. Most of the site visits were made after the pesticides were used; thus, EPA inspectors could not readily determine if permit conditions were met.

In addition, EPA headquarters' communication with regions has not been good--notifications of permit approvals either have been untimely (after pesticide applications were made) or have not been made at all.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Promulgate guidelines specifying data requirements that are necessary for permit approvals and the type and extent of data to be developed under permits.

--Require reviewers to act on--approve or disapprove--properly prepared permits within a specified period.

--Furnish prompt information on permit approvals to applicable regions so that site visits can be programed when experimental pesticides are applied.

--Set priorities for the permit-monitoring program to assure proper control of experimental products the safety of which has not been established.

--Authorize experimental use permits for the reasonable duration of an experimental program rather than limiting them to 1 year as is now done.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our proposed report EPA said that we concluded that the experimental use permit program was having a direct adverse impact on research and development in the pesticide industry. In rebuttal EPA cites

--a report by William Blair and Company in which the pesticide industry is characterized as one of "extraordinary profitability;"

--an EPA report titled "FIFRA: Impact on the Industry"1/ which points out that (1) in recent years about an equal number of firms have entered and left the pesticide research field, (2) high profits and profit potentials have kept the industry interested, and (3) although pesticide innovations may be fewer than in the past, the industry has and will continue to build on its existing research and development base; and

--a purported 300-percent increase in experimental permits since FIFRA was amended in 1972.

We concluded that EPA's experimental use permit program is not fully effective, not that the program is having a direct adverse impact on research efforts in the pesticide industry. There is solid evidence that pesticide product development as a percentage of sales has declined in recent years. In line with congressional intent when it amended the Pesticide Act, we believe that the experimental permit program, only one of many factors affecting pesticide development, should be as effective and efficient as possible to encourage development of innovative pesticide products.

Several clarifications must be made regarding EPA's specific comments. First, EPA's statements on the Blair report were taken out of context without appropriate qualifiers. Blair's conclusion that the industry was "extremely profitable" is based on hard evidence for only one company which Blair cites as being "somewhat atypical." The report further says that profits from pesticide operations are not reported separately by virtually all major manufacturers, "thus obscuring the facts." Other statements concerning profits from pesticide operations are estimates which the report says "seem likely." More importantly, other pertinent conclusions of the report are not addressed, including:

--A number of manufacturers were driven out of the industry or their efforts were greatly reduced because of (1) uncertainty before and after the Pesticide Act and (2) the law's general result to boost research and development expenditures substantially on both existing and new products. It is an "ironic consequence" that the law's objective of encouraging innovative pesticide approaches instead reduced the

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1/FIFRA--Federal Insecticide, Fungicide and Rodenticide Act.

number of active researchers and the funds available for new research and concentrated research and development efforts on developing variations of existing "safe" chemical approaches.

--Research and development efforts generally are (1) concentrated toward developing existing pesticide products and (2) directed primarily to the highest volume potential market with the exclusion of smaller, more specialized markets, i.e., concentration on a few major pests and crops, while many others are neglected.

--Expeditious processing of experimental permit applications is essential for the timely development of a product, since a minor delay often pushes testing back a full year until the next growing season. Further, EPA's process is especially slow for radical products that may provide major advances in pesticide safety and has contributed to delays of as long as 8 years in the registration of some chemicals.

We find the foregoing arguments supportive of the conclusions and recommendations we made on EPA's experimental permit program.

The statements to which EPA refers in its report entitled "FIFRA: Impact on the Industry" were taken from the Blair report just discussed. Consequently, no further discussion of these statements is necessary.

We found EPA's statement that experimental permits have increased 300 percent since amendment of the Pesticide Act to be erroneous. For a 21-month period preceding enactment of the 1972 amendments, EPA issued 174 permits as compared to 286 permits for a similar 21-month period ended March 1976 (the period of our sample). This is a 65-percent increase, not a 300-percent increase as EPA states. Also, a review of the permits in our sample shows that 52 percent of the increase was not due to added interest in research and development on the part of the pesticide manufacturers, rather to changes in the regulations requiring permits for testing which were not previously required. Under EPA's new regulations (1) pesticide manufacturers are now required to obtain permits to conduct additional testing of previously registered pesticides, for example, extending use of the pesticide to other pests, or changing the dosage rate or the method of application and (2) Federal and State agencies previously

authorized to experiment without permits are now required to obtain permits.

EPA agreed with our recommendation that guidelines specifying data requirements for experimental permit approvals are needed, but felt that defining data to be developed under an experimental permit would be repetitious of its general registration guidelines. EPA also said that it does not plan to develop permit guidelines until after its general registration guidelines are finalized.

While EPA may be correct in stating that defining data to be developed under an experimental permit would be repetitious, it does not address the very real problem that neither pesticide manufacturers nor EPA permit reviewers really know what should be included in the experimental permit application or what data is required to be developed under the approved permit. (See p. 6.) Such guidelines should eliminate these uncertainties, thereby facilitating the applicants' preparation of acceptable packages as well as EPA's review and approval process. Also, it appears that it would be advantageous to EPA to develop permit guidelines now, in view of the time-consuming process needed to obtain approval. For example, EPA published proposed registration guidelines in the Federal Register in June 1975; they have as yet not been finalized and are now scheduled to be reproposed in the Federal Register in various sections from November 1977 through May 1978. To delay the permit guidelines until the registration guidelines are finalized could delay them for up to 2 years or longer which we believe is unacceptable.

EPA also disagreed with our argument that manufacturers should not be required to start chronic feeding studies as a condition of permit approval. EPA said that long-term feeding studies are an important part of the safety data required for registration and when the manufacturer enters the final stages of testing under a permit, it is in his best economic interest to conduct such studies concurrently to be fully prepared for registration when the experimental program is finished.

Generally this is true; however, there are exceptions where the manufacturer may not yet have determined that the chemical is sufficiently effective under actual use conditions to be worth pursuing. To require that manufacturers commit themselves to studies in excess of one quarter of a million dollars at such time may result in no-go decisions for beneficial pesticides. We see no problem in approving

such permits provided (1) the manufacturer is aware that registration will not proceed until all appropriate test data is provided and (2) appropriate safeguards are established for the experimental uses.

EPA agreed that permits should be submitted, processed, and either approved or disapproved as they are received. However, EPA said that applicants, not EPA, control the submission of permit applications and that they are not submitted far enough in advance of the testing date to be processed. Concerning processing applications more effectively, EPA concluded that the report contained conflicting statements regarding (1) the processing of applications as received to spread EPA's workload throughout the year and (2) that there do not appear to be alternatives in alleviating seasonal surge of applications.

Office of Pesticide Program officials may believe that permits are processed and either approved or disapproved as they are received; however, permit reviewers tell a different story. One reviewer told us that permits are not approved in advance because EPA wants to insure that all pertinent data is reviewed before a permit is approved and that, as a result, permit applications are set aside until just before they are needed. This is consistent with information obtained from pesticide manufacturers presented on page 10.

Had EPA considered this in its comments, it would have found no conflict in our statements because permits submitted during slack periods were being held until shortly before they were needed, thereby creating a backlog that was affecting the seasonal surge that we had characterized as being unavoidable. Thus, contrary to its statement, EPA was exercising a great deal of control on permit submissions. If EPA implements our recommendation, which it states is its policy, we believe that permit-processing time can be improved substantially.

Furthermore, if EPA implements our recommendation that experimental permits be issued for the duration of an experimental program rather than limiting it to 1 year as is done now, it appears that up to 30 percent--the percentage of permit extensions and renewals in our sample--of experimental applications could be eliminated, allowing EPA to concentrate on new applications.

EPA agreed with this recommendation but did not believe it necessary because EPA's experimental use permit regulations already have such a policy which was reaffirmed March 28 and

29, 1977, when EPA met with the American Association of Pesticide Control Officials. This meeting occurred almost 2 months after we first discussed this recommendation with EPA officials on February 1, 1977. We believed it necessary to document the recommendation because, as EPA pointed out, experimental programs of longer than 1 year were permitted by EPA's regulations. However, EPA reviewers told us that 1-year permits were the in-house rule and, in fact, none of the 286 permits in our sample were for more than 1-year programs.

In commenting on the timing of its approval of experimental permits, EPA stated that for fiscal year 1977 it projected that its resources would allow experimental permits to be processed in the following time frames:

20 percent within 90 days,
50 percent within 120 days, and
30 percent within 180 days.

We believe that such time frames do not reflect EPA's stated policy of processing permits as expeditiously as possible and that this could delay development of new products unnecessarily. The House Subcommittee on Department Investigations, Oversight, and Research, Committee on Agriculture, also does not agree with such lengthy time frames and as of December 1977 had proposed an amendment to the Pesticide Act to require EPA to approve or disapprove all permits within 90 days as compared to EPA's 120- to 180-day time frame for up to 80 percent of permit applications.

In commenting on our recommendations concerning the notification of EPA regional offices of experimental permit approvals and monitoring of experimental uses, EPA's Office of Enforcement stated that the following corrective actions had been taken:

--A procedure was established to insure that regions are promptly notified when permits are issued.

--Procedures setting priorities for permit monitoring were being developed.

--To insure that priority permits are being monitored and to adequately cover those permits a comprehensive review of regional policies and procedures concerning experimental permit monitoring, inspecting, reporting, and recordkeeping was being initiated. The results of the review will be used to assist the regions in

planning, conducting, and reporting permit monitoring and in revising EPA guidance and manuals.

We believe that these actions, if properly followed through, will substantially correct the problems noted.

The Office of Pesticide Programs, on the other hand, agreed that prompt regional notification of experimental permits was necessary but did not agree that monitoring had been inadequate. However, the Office of Pesticide Programs is only indirectly involved in the monitoring process.

CHAPTER 3

INEFFICIENCIES IN ADMINISTERING EMERGENCY EXEMPTIONS

Certain State and Federal agencies have misused emergency exemptions by (1) illegally taking crisis exemptions on suspended or canceled pesticides, (2) taking crisis exemptions when a crisis did not exist, and (3) not always complying with EPA restrictions and requirements under the exemption.

EPA's administration of the emergency exemption program has been hampered by a number of problems, including

--untimely action on requested emergency exemptions;

--granting exemptions to unauthorized organizations;

--granting exemptions repeatedly to certain requestors for pest problems not meeting EPA criteria for emergencies;

--poor communication between EPA's headquarters and regional offices in evaluating, approving, and reporting exemption actions; and

--monitoring emergency exemptions inadequately.

Predictably, these problems have adversely affected EPA's relations with some States.

Section 18 of the Pesticide Act permits EPA to grant Federal and State agencies exemptions to use suspended, canceled, or unregistered pesticides in emergency situations. By EPA definition, an emergency exists when (1) a pest outbreak has or is about to occur and no registered pesticide is available, (2) significant health or economic problems will occur without the use of a pesticide, and (3) there is insufficient time to register a pesticide to control the pest outbreak.

In December 1973 EPA established regulations for three types of emergency exemptions: quarantine-public health, specific, and crisis. Quarantine-public health exemptions are granted to prevent the spread of a foreign pest into or throughout the United States. Such exemptions may be requested by Governors or their designees, usually State lead pesticide agencies, and by Federal agencies.

Specific exemptions are granted to control pest outbreaks for which registered pesticides are not readily available and significant economic or health problems will occur unless the pest is controlled. These exemptions are also requested by State Governors or their designees and by Federal agencies.

Crisis exemptions may be taken for unpredictable pest outbreaks in the United States where registered pesticides are not readily available and the time element is too critical to request a specific exemption. In contrast to specific and quarantine-public health exemptions, State or Federal agencies, upon determining that a crisis exists, may apply the pesticide before notifying EPA. EPA can, if deemed necessary, stop further applications of the pesticide. Pesticides that EPA has suspended or canceled cannot be used legally under crisis exemptions.

A total of 128 emergency exemptions were requested or taken during the period December 3, 1973, to June 30, 1976. The disposition of these exemptions is shown in the following table.

Disposition of Exemption Actions

Specific exemptions granted	58
Quarantine-public health exemptions granted	1
Crisis exemptions taken	19
Specific exemption requests denied	36
Specific exemption requests withdrawn	14
Total	128

PROCESSING TIMES ARE EXCESSIVE

Emergency exemptions provide Federal and State agencies a means to control unexpected pest outbreaks when registered pesticides are not available. Such "emergencies" may require the use of registered pesticides for unregistered uses or the use of unregistered, suspended, or canceled pesticides.

Federal or State agency requests for specific exemptions must be reviewed and acted on quickly to prevent the destruction of important commercial crops or to protect the public from harmful pests. The following table shows processing times for emergency exemptions requested between December 3, 1973, and June 30, 1976.

Type of exemption	Number of exemptions	Processing time	
		Average	Range
		(days)	
Specific	108	88	1 to 395
Quarantine-Public Health	1	129	

Between July 1, 1975, and June 30, 1976, EPA's average processing time dropped from 155 days for the preceding year to 40 days. Following is a table showing the range of days for processing exemptions during this period.

Days	Number of exemptions
1 to 10	18
11 to 20	8
21 to 30	12
31 to 50	2
51 to 100	4
101 to 200	1
201 to 335	3
Total	48

EPA's processing of emergency exemptions is obviously too long to be effective. If emergencies existed, an average 40-day delay before EPA acted on the request could be catastrophic. At any rate, the emergency would generally have run its course and any probable harm to people or the environment would already have resulted. The following examples illustrate the potential for harm resulting from delays in EPA's actions on exemption requests.

Example 1

On March 7, 1975, Wyoming requested a specific exemption to use strychnine-treated eggs against rabid skunks because five rabid skunks and a rabid cow were found in Campbell and Crook Counties between January 6 and February 20, 1975. This request was similar to a February 17, 1974, request EPA approved on March 14, 1974, and extended on three separate occasions--May 30, 1974; August 23, 1974; and October 5, 1974--and to five requests previously approved for Montana and Texas.

Two weeks later, on March 21, 1975, a skunk attacked children playing on the school grounds in Campbell County. The skunk was shot and, when tested, was found to be rabid.

Because EPA had not acted on the request, State officials on March 24, 1975, declared the situation to be a crisis and decided to use strychnine to eradicate the skunks. Wyoming placed 26 strychnine-treated eggs in abandoned buildings within one-quarter mile of the school. By April 7, 1975, three dead skunks were recovered and diagnosed as being rabid.

The use of strychnine under a crisis exemption is illegal; but, because the time element was critical, Wyoming could not wait for EPA to act on its specific exemption request. EPA later approved the request on June 17, 1975--more than 3 months after the original request and more than 2 months after Wyoming illegally used the strychnine. An EPA official said the lengthy approval process for this particular request resulted because Wyoming did not provide sufficient information for EPA to make a decision. Wyoming provided this information to EPA on April 3, 1975.

Example 2

On April 29, 1976, the Government of Guam requested a specific exemption to use compound 1080--a pesticide canceled by EPA in 1972--to control a large population of wild and stray dogs threatening public health and safety. Guam used compound 1080 initially between 1967 and 1969 to control rabies epidemics and had used it since to control the expanding dog population. Guam officials said the dogs presented a rabies threat as well as a serious nuisance, attacking humans and livestock and destroying property. In 1975 the Government of Guam recorded over 750 unprovoked attacks on humans by dogs.

A decision was finally issued on the request on March 9, 1977--over 10 months later. An EPA official said it took so long to make a decision on the request because the San Francisco Regional Office had to determine if an emergency existed. He said that EPA ultimately decided the request was not an emergency because the incidence of dogs attacking humans in Guam was no greater than in the continental United States.

EPA officials said that EPA generally requires lengthy time frames for approving exemption requests because (1) the requestor may not provide sufficient information for EPA to make a decision, (2) there is a lack of manpower (only one person is available to review emergency exemption requests), and (3) red tape slows down the review process. The Deputy Assistant Administrator or Administrator signs

approvals or denials of specific exemptions depending on the scope of the problem. This process may take from 1 day to 2 weeks. EPA officials said that some delays in acting on requests resulted because some were denied, but formal denial letters were not issued until later because of higher priority work.

It is obvious that EPA's 40-day average for processing emergency exemption requests is too long to best serve the public. In one of the examples cited, Wyoming illegally used a canceled pesticide to protect its citizens. Exemption requestors should not have to make decisions such as to illegally use a pesticide; rather they should be able to rely on EPA making a reasoned, judicious decision on their requests. EPA should take steps to insure each response, whether it is by making its information-gathering process more effective, providing additional staff, or streamlining its red tape review/approval process, or all three.

SPECIFIC EXEMPTIONS GRANTED TO ORGANIZATIONS NOT AUTHORIZED TO RECEIVE THEM

EPA's regulations state that specific exemptions may be granted only to Governors or their designees, usually the lead agency for coordinating pesticide use within the State, and to Federal agencies. However, EPA granted seven emergency exemptions to unauthorized organizations without notifying responsible State officials. Consequently, the State was unable to monitor the applications, some pesticide applications were apparently improperly made, and EPA-State relations were adversely affected.

EPA requires that specific exemptions be requested in writing by the head of the Federal agency or the Governor of the State involved or other official designee. EPA regional personnel are to be notified of requests immediately to provide them the opportunity to contact relevant State agencies and to evaluate the need for the exemptions. When specific exemptions are granted, EPA (1) may restrict the quantity and conditions under which the pesticide is used and (2) require monitoring of the application.

During 1974 and 1975 EPA granted seven specific exemptions for the use of toxaphene on sunflowers and rangeland to three universities which were not authorized to request exemptions. Toxaphene is a chlorinated hydrocarbon which may persist in the soil for more than 10 years and in lakes and ponds for up to 9 years.

The seven toxaphene exemptions are shown in the following table.

Date of Exemption	Granted to	Applied to	Pest
May 1974	South Dakota State University	Rangeland	Sod webworm
June 1974	North Dakota State University	Sunflowers	Sunflower beetles
June 1974	South Dakota State University	Sunflowers	Cutworms and thistle caterpillars
June 1975	University of Minnesota	Sunflowers	Army cutworms and sunflower beetles
June 1975	South Dakota State University	Sunflowers	Cutworms
July 1975	North Dakota State University	Sunflowers	Army cutworms and sunflower beetles
July 1975	South Dakota State University	Sunflowers	Grasshoppers

The South Dakota Department of Agriculture, the North Dakota Department of Labs and Agriculture, and the Minnesota Department of Agriculture were the only designated agencies authorized to request exemptions in their respective States.

Because of EPA's limited review and monitoring of exemptions (see p. 34), it is important to have State lead agency involvement in approving and monitoring. In our review of the files at EPA headquarters and the Denver region, we found that only one of the exemptions had been reviewed/monitored by EPA. EPA's National Enforcement Investigations Center, which assists the regions and headquarters through compliance inspections, reviewed this exemption at the request of the Denver region. This investigation included determining the effects and efficacy of using toxaphene but did not determine the extent to which the requestor adhered to all toxaphene use restrictions. There is no assurance that the grantees adhered to exemption restrictions. For example, the Center

did not determine if sunflower seeds harvested from treated areas were used for oil only, as specified in the exemption.

As a result of the Center's review, EPA stated in an October 10, 1975, letter to a South Dakota State University extension entomologist that the University had "* * *failed to adequately implement significant portions of the restrictions specified in the (1975) specific exemption * * *" to insure adequate protection of public health and to minimize any adverse environmental effects resulting from the toxaphene. Recognized problems included

--failure to notify EPA regional personnel of the times and places of toxaphene use,

--failure to properly supervise aerial use of toxaphene, and

--publishing in a newsletter that toxaphene use had been approved without adequately describing the use restrictions.

We also noted unresolved discrepancies between the information submitted by the University to EPA on the exemption spraying and that contained in the Center's report. For example, the University's report stated that 2,500 acres of sunflowers were sprayed in one county, whereas the Center's report indicated that less than 500 acres were planted in sunflowers. This could indicate that crops not included in the permit were sprayed or that fields were sprayed a number of times, thereby resulting in excessive toxaphene residues in certain crops. An EPA official said that obviously there is a discrepancy; however, available documentation is not sufficient to resolve the discrepancy.

The South Dakota Department of Agriculture, the State lead agency, was not advised of the 1975 exemption until after it had been approved. The Department was not aware of a cutworm problem, and an emergency condition may not have existed. EPA regional officials told us that failure to coordinate this exemption had detrimentally affected EPA's working relations with the Department of Agriculture.

A similar deterioration in cooperation resulted when EPA failed to coordinate a 1975 toxaphene exemption with the Minnesota Department of Agriculture. In a July 1975 letter to EPA, the Department of Agriculture stated:

"We also suggest that it is gross neglect on the part of your agency and staff not to also notify

the State regulatory agency with regard to this particular situation."

* * * * *

"* * * the actions of your agency again indicate to the Department of Agriculture in Minnesota your intent to completely disregard the State regulatory agency in the implementation of any types of programs. Had you had any intent of cooperation, you would have been in contact with the State regulatory agency to determine whether or not it could provide assistance in implementing this program. Instead, you have chosen to completely ignore us, therefore, we see no reason for spending any effort in providing you with assistance in implementing the program."

The practice of granting specific exemptions to unauthorized organizations may result in the misuse of potentially hazardous pesticides and may adversely affect man and the environment. Although we did not note any instances where specific exemptions were granted to unauthorized organizations in 1976, this situation could recur because EPA's procedures have not been changed. Also, the exclusion of responsible State agencies from participation in the decisionmaking and monitoring of exemptions is not consistent with EPA's policy of obtaining greater State participation in its pesticide programs. Alienation of State agencies, as occurred in South Dakota and Minnesota, could adversely affect EPA State cooperation in all pesticide regulatory activities.

NONCOMPLIANCE WITH EXEMPTION PROGRAM REQUIREMENTS

A common problem in EPA's emergency exemption program is that Federal and State agencies often do not comply with EPA's regulations and with specific exemption requirements. EPA may approve emergency exemptions with restrictions on (1) the quantity of pesticide used, (2) who may apply the pesticide, and (3) the conditions under which the pesticide may be applied. The exemption may also require certain monitoring activities. Restrictions and monitoring reduce potential adverse effects created by use of the pesticide.

The following two examples illustrate cases where requirements were not met.

Example 1

The DDT emergency exemption to control the Douglas-fir tussock moth in the Pacific Northwest is probably the most controversial exemption ever granted as well as the best monitored. Yet, despite (1) elaborate precautions taken to control DDT use and minimize its adverse effects on man or the environment and (2) constant onsite monitoring by EPA personnel, major restrictions imposed when the exemption was granted were not met. While evaluating various reports on the exemption, we noted the following problem areas.

--DDT apparently was used unnecessarily on 332,000 of the 421,000 acres sprayed because moth populations were near or below the U.S. Forest Service's action level at the time of spraying or within 4 days of spraying.

--Data sufficient to register DDT alternatives were not developed because the moth population was collapsing and testing had not progressed to the stage where reliable evaluations could be made.

--The U.S. Forest Service overestimated benefits derived from using DDT.

--Approximately 18,000 cattle and 900 sheep were contaminated with excessive DDT residues in their tissues from the spraying. Consequently, about 6,500 cattle scheduled for sale could not be marketed as scheduled, resulting in economic losses to the owners.

Appendix I is a case history of the DDT emergency exemption which details some of EPA's problems in administering emergency exemptions.

Example 2

The Department of Agriculture's Animal and Plant Health Inspection Service requested a specific exemption to use carbaryl and dieldrin on citrus fruit to combat the West Indian sugar cane root borer. EPA denied this request in February 1975 because the insect had been a continual problem since 1968 and data could have been developed and used to register the pesticides requested. EPA offered to grant the

Service an experimental use permit to test carbaryl on a fairly large scale, provided the Service could assure EPA that illegal residues would not result. However, in March 1975 the Service declared a crisis exemption and used the pesticides on 250 acres. In April 1975 the Service again requested a specific exemption for carbaryl but withdrew the application when EPA reiterated its previous objection.

In June 1975 the Service again bypassed EPA and declared a crisis exemption for carbaryl to control the West Indian sugar cane root borer. In July 1975 the Service requested for the third time a specific exemption for carbaryl; it too was withdrawn when EPA objected.

The exemptions just discussed indicate that EPA is not effectively administering emergency exemptions and that the American public may be unnecessarily exposed to pesticides known to be harmful.

The regulations provide that an agency's right to take crisis exemptions can be revoked if EPA determines the agency is not complying with exemption requirements. However, EPA has not been enforcing this provision. EPA should actively enforce this provision to prevent violations similar to those discussed and revoke an agency's crisis exemption authority for appropriate periods--probably 1 year.

EMERGENCY EXEMPTIONS REPEATEDLY GRANTED FOR SIMILAR USE

EPA repeatedly has granted Federal and State agencies emergency exemptions to control continuing, predictable pest outbreaks. Essentially, repeated pesticide exemptions for the same use have the same effect as pesticide registrations, indicating that the pesticide or a substitute should be registered for the use and that exemptions were granted for nonemergency situations. The following table lists repeated exemptions granted by EPA between May 1973 and June 30, 1976.

Pesticide	Pest	Number of exemptions
Strychnine	Control rabid skunks	a/12
2,4-D	Water hyacinth	3
	Eurasian watermilfoil	a/ 3
	Alligator weed	3
DDT	Rabid bats	5
Toxaphene	Army cutworm (in sunflowers)	4
	Sunflower beetle (in sunflowers)	4

a/One 2,4-D and two strychnine exemptions were granted before EPA issued final emergency exemption regulations in December 1973.

Several of these exemptions were granted repeatedly to the same agency. If valid emergencies exist and are likely to recure periodically, EPA should register a pesticide to control such emergencies. On the other hand, it appears that some of these situations were not true emergencies and EPA should not have granted exemptions in these instances. The following examples illustrate these points.

Example 1

All strychnine registrations for animal control were canceled and suspended on March 9, 1972. However, substitutes have not been registered to control animals, particularly rabid animals, that present a real danger to people. Consequently, EPA has granted certain States specific exemptions to use strychnine for controlling rabid skunks almost continuously since June 1973. Following is a chronology of actions relating to Montana's efforts to control rabid skunks.

Date	Action
June 1973	EPA granted specific exemption effective June 6, 1973, through October 31, 1973.
December 1973	EPA granted exemption effective December 20, 1973, through May 31, 1974.
June 1974	Above exemption extended through October 1, 1974
December 1974	Montana registers strychnine for intrastate control of rabid skunks. Registration effective January 1, 1975, through December 31, 1975.
March 1975	Montana requests Federal registration of strychnine.
August 1975	Montana submits application for Federal registration of two strychnine products to be used intrastate.
September 1975	EPA informs Montana that Federal registration is not possible.
October 1975	Montana informs EPA that State registration was canceled effective October 4 1975.
November 1975	EPA grants specific exemption effective November 17, 1975, through March 31, 1976.
April 1976	Above exemption extended through November 16, 1976.

A total of nine exemptions was also granted to Wyoming and Texas for almost continuous use of strychnine to control rabid skunks.

Requests similar to Montana's were made during the same period by HEW's Center for Disease Control and other States to register strychnine for rabid skunk control. In September 1975 EPA denied such registrations because the cancellation and suspension order would have to be reconsidered and public hearings held before it could register strychnine.

It is readily apparent from the number and nature of strychnine exemptions granted that there is a definite need to register either strychnine or another pesticide to control rabid skunks.

EPA has a precedent for registering a canceled pesticide for health-related use. In May 1976, at the request of the Center for Disease Control, EPA registered a DDT product for controlling rabid bats. EPA delegated authority to the Center to approve use of the product in situations the Center determined to be bona fide health emergencies.

EPA should establish a rational policy for controlling recurring infestations of rabid animals which are a threat to people. If it determines that strychnine is the only available pesticide for such control, it should register such products for use by an agency such as the Center for Disease Control in bona fide emergencies, as it did in registering DDT to control rabid bats.

Example 2

Since 1958 the Tennessee Valley Authority (TVA) has used 2,4-D extensively to control Eurasian watermilfoil (aquatic plants) in eight TVA reservoirs on the Tennessee River and its tributaries. Between calendar years 1973 and 1976, EPA granted TVA four emergency exemptions for unregistered use of 2,4-D. In granting the exemption, EPA recognized that the use did not constitute an emergency. For example, in its 1975 letter to TVA approving the exemption, EPA stated:

> "It should be emphasized that additional specific exemption requests by the TVA for the use of 2,4-D in moving water beyond calendar year 1975 will not be granted since, in our estimation, there will have been adequate time to gather the necessary data to register 2,4-D for this use by then."

Despite this and similar warnings in previous years, EPA did grant TVA an additional exemption in 1976.

In commenting on this example, TVA said

> "In a very real sense the emergency with Eurasian watermilfoil which confronted TVA and that required the unregistered use of 2,4-D, was the result, not of the pest outbreak itself, but of EPA's failure to act in a timely fashion on TVA's April 1973 petition to establish tolerances for 2,4-D residues in fish and potable water. EPA did not establish these tolerances until June 10, 1976--more than three years after the petition was submitted. (This tardy action is continuing to cost the taxpayers money; only one manufacturer of 2,4-D was able to obtain an appropriate label from EPA in the short time between the establishment of tolerances and TVA's request for bids for our 1977 supply of 2,4-D, forcing us to pay a substantial premium.)"

Granting of exemptions in recurring, predictable situations does not conform to EPA's policy and has not been consistently applied to exemption requestors. For example, in March 1974, the Department of Agriculture's Animal and Plant Health Inspection Service requested a specific exemption to use carbaryl and dieldrin on citrus fruit to combat the West Indian sugar cane root borer. EPA denied this request in February 1975 because the insect had been a continual problem since 1968 and data could have been developed and used to register the pesticides requested. EPA should discontinue the practice of granting exemptions for non-emergency uses. This would result in more consistent application of its emergency exemption procedures.

COORDINATION OF EXEMPTION ACTIONS AND MONITORING IS NOT GOOD

EPA headquarters has not done a good job of keeping its regional offices advised of exemption requests and, consequently, the regional offices could not fulfill requirements for obtaining data needed to make informed decisions on requests and monitoring. Even when regional offices were notified of requests, the time provided was often too short or regional offices' efforts were too limited to have significant impact on decisions.

This lack of communication hampers EPA's ability to insure that highly toxic pesticides, some of which have been banned because of their persistence in the environment or their ability to produce cancers, are used in accordance with exemption restrictions.

A December 3, 1974, memo directed regional pesticide branch chiefs to determine for specific and quarantine-public health exemption requests

--whether an emergency exists,

--the economic benefits and losses that could be anticipated with and without the exemption,

--alternatives to the requested pesticide, and

--whether the proposed use will adversely affect man and/or the environment.

EPA headquarters recognized that all relevant facts must be considered before making decisions on exemption requests and that regional personnel, being closer to the

scene of proposed application, were in a better position to assess exemption requests. Regional staffs were to contact all relevant State agencies which could be affected by or which had expertise in pesticide use. The information obtained was to be submitted to EPA headquarters by phone as soon as possible and was to be followed by a written report.

Despite the obvious benefits that could be derived from proper implementation of this memo, the exchange of information between EPA headquarters and regional staffs during the decisionmaking process has continued to be extremely limited. For example, in the five regions we visited, 46 exemptions were requested after the memo was issued. However, the regions (1) were aware of only 24 requests, (2) provided oral comments on only 20, and (3) provided no written comments.

EPA regional officials told us that their efforts were generally limited to commenting on whether emergencies actually existed and whether data provided in the request was accurate. They stated that the regions did not have the expertise or access to sufficient information to render opinions on anticipated economic benefits and losses likely to result from the approval or denial of the request. The officials said that written reports were not provided to headquarters because they had not had significant adverse comments warranting written documentation.

The absence of adequate communication between EPA headquarters, the regions, and State agencies also affected the extent of monitoring performed as evidenced by the number of inadequately monitored exemptions. Regional staffs were aware of only 40 and monitored only 8 emergency exemptions approved for the five EPA regions we visited. Regional monitoring was done after the pesticide was applied rather than at the time of application for six of the eight exemptions monitored. Therefore, EPA could not insure that exemption requirements were followed. There were benefits to EPA's monitoring--the assurance that no obvious, lasting detrimental environmental effects occurred and that the soil did not contain excessive pesticide residues where products were applied.

Some State lead agencies were also unaware that certain exemptions had been granted, and therefore, could not monitor these emergency exemptions. (See discussion of toxaphene exemptions on pp. 25 to 28.) A State lead agency is responsible for knowing what pesticides are being used in the State and assuring that they are properly applied. Normally it has

personnel whose responsibilities include pesticide monitoring who could monitor emergency exemptions if deemed appropriate.

EPA headquarters should communicate in a timely manner with regional staffs to enable them to assess exemption requests through contacts with appropriate agencies in the States. We believe that the objectives of the 1974 memo are laudable and that every encouragement should be provided to the regional staffs to comply with its requirements. EPA should also field monitor as many emergency exemption pesticide applications as possible, particularly those involving suspended or canceled pesticides. We believe that the presence of EPA personnel during applications would greatly reduce the possibility of exemption restrictions being violated. EPA should also keep State lead agencies appropriately advised of approved exemptions and encourage them to monitor applications which EPA personnel cannot.

CONCLUSIONS

EPA's 40-day average for processing exemption requests is obviously too long to best serve the public when true emergencies exist. Exemption requestors should not have to illegally use pesticides in such cases, rather they should be able to rely on EPA making timely decisions to meet the emergency. EPA could insure more timely responses by making its information-gathering process more effective, providing additional staff, and streamlining its review and approval process.

EPA's practice of granting specific exemptions to unauthorized organizations may result in misuse of potentially hazardous pesticides and adversely affect man and the environment. This has resulted in excluding responsible State agencies from participation in decisionmaking and monitoring of such exemptions and has adversely affected EPA's relationship with some States.

EPA has repeatedly granted Federal and State agencies emergency exemptions to control continuing, predictable pest outbreaks of which many are not emergencies under EPA criteria. Exemptions should not be granted in nonemergency situations. In controlling recurring infestations that are true emergencies, such as rabid animals that are a threat to man, EPA should register a suitable pesticide which can be used by appropriate State or Federal agencies without going through the exemption process; or, if sufficient data is not available, EPA should require that the user collect data needed for registration as a condition of the exemption.

If the only available alternative is to use a suspended or canceled pesticide, such as strychnine for control of rabid skunks, EPA should consider registering the pesticide for restricted use under supervision of a responsible agency such as the Center for Disease Control; this has already been done for DDT use to control rabid bats.

EPA headquarters has not done a good job of informing its regional offices or State lead agencies about requests for or approval of exemptions. Consequently, the regions could not fulfill requirements for obtaining data needed to make informed decisions on the need for exemptions and neither regional nor State lead agencies monitored many exemptions to assure that man and the environment were not adversely affected. To compound the problem, when EPA's regional offices did monitor exemptions, it was usually after the pesticide was applied and EPA could not assure that exemption requirements were followed.

RECOMMENDATIONS

To strengthen controls over emergency exemptions and avoid unnecessary use and exposure of the environment to known harmful pesticides, we recommend that the Administrator, EPA, take action to see that:

--Specific exemptions are granted only to authorized State and Federal agencies.

--State and Federal agencies are prevented from taking illegal crisis exemptions for suspended or canceled pesticides.

--Applications under specific and crisis exemptions are monitored, particularly those involving canceled or suspended pesticides.

--Flagrant or repeated violators of exemption requirements are prosecuted or their authority to request specific exemptions or to take crisis exemptions is suspended.

In addition, we recommend that priority be given to improving program operations to make sure that

--timely review and action is taken on emergency requests,

--pesticides necessary to control continuing, predictable pest outbreaks are registered, and

--communications between headquarters and regions on exemption requests are improved and regional input into the decisionmaking process is obtained.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on the draft report, EPA said that there are overriding philosophical inconsistencies and a basic misunderstanding of the intent of the emergency exemption program. EPA pointed out that we had consistently criticized it for actions of States or other agencies in taking exemptions illegally when EPA had not approved or had actually disapproved them.

As with other EPA comments, we discussed this matter repeatedly with EPA officials. We pointed out that, with the exception of those instances where States were forced to act illegally because of EPA's failure to take timely action, the examples cited were not a criticism of EPA that States or other agencies took illegal exemptions, but rather a criticism of EPA's failure to take corrective action so that such illegal actions would not recur.

In this regard, EPA said it considered our recommendation to revoke emergency exemption authority of flagrant or repeated violations to be rather ill-considered in light of our emphasis on good Federal/State/regional relations, especially when it has found only a very few organizations that have a pattern of repeated violations.

It seems obvious to us that our recommendation to revoke exemption authority would apply only to the very few organizations which had a pattern of repeated violations, thereby conforming to our terminology of "flagrant or repeated violators." Organizations which "react favorably to EPA's constructive criticism" in our opinion could not be characterized as flagrant or repeated violators and therefore would not be subject to revocation sanctions. On the other hand, violators who take exemptions disapproved by EPA or who show a pattern of repeated violations do fall into this characterization and should, in our opinion, be penalized. Further, we do not believe that revoking the crisis exemption authority of an agency that has repeatedly ignored EPA's decisions and circumvented them through apparently illegal means could damage EPA's relations with that agency, and remedial actions against such violators would tend to deter other agencies from acting similarly.

In commenting on our recommendations to improve the timeliness of actions to approve emergency exemptions, EPA did not comment on the adequacy of its average time to process emergency exemptions, rather it focused on its improvement in average processing time to 40 days for the period July 1, 1975, to June 30, 1976. Although this is a laudable improvement, much still remains to be done as 22 of the total 48 emergency exemptions required from 21 to 335 days to process.

We believe that the nature of an emergency exemption request makes it imperative that more timely actions be taken. As we have shown in the rabid skunk example on page 23, the State had to act illegally to protect the public because EPA did not respond promptly to its request. Further, although we agree with EPA that only reasoned judgments should be made, we do not concur that the Guam example on page 24 represents effective EPA action in disapproving a requested exemption. We see no valid reason why EPA took 10 months to ascertain that an emergency did not exist. In emergency situations time is of the essence, and we believe that EPA must act quickly on exemption requests--whether the decision is to approve or deny--in order for the program to be effective.

In commenting on our recommendation that exemptions are granted only to authorized State and Federal agencies, EPA said that it has taken measures to insure that the State lead agency and the EPA regional office are always involved in exemption requests. EPA also said that its policy has been to work with the State agency responsible for the area in which the emergency exists, not to solicit single designations of authorized agencies within each State. EPA asked for our guidance on the desirability of requesting that Governors designate a single authorized agency or organization to request emergency exemptions. We do not object to EPA's working with the State agency responsible for abating an emergency or to the concept of State Governors appointing multiple designees to request exemptions. We do suggest that if multiple designees are named, all exemption actions for the State be coordinated with each of the designees. Coordination of all actions should preclude the type of adverse relations that occurred with certain States.

In commenting on our recommendation that EPA register effective pesticides to control continuing, predictable pest outbreaks, EPA agreed that such registrations are needed, but disagreed that it had approved exemptions that

were not emergencies within the terms of its regulations. EPA attributed the need to grant exemptions in these situations to problems in implementing its 1975 registration requirements. We do not concur that the examples cited on pages 31 to 33 met EPA's criteria for emergencies because the pest outbreaks were predictable. EPA's criteria provides that an "emergency" is not predictable. We do not believe that EPA should use its emergency exemption authority as a substitute for registration of safe, effective pesticides which the Congress intended when it passed the Pesticide Act.

EPA told us that currently it receives regional input on every emergency exemption requested, informs the regions and State agencies of all exemption approvals, and makes monitoring requirements a part of those exemptions deemed hazardous enough to warrant monitoring. We believe the foregoing procedures, if followed, generally will correct the problems we noted during our review of the program. However, it is not apparent that it would correct the low priority placed on monitoring in the past. We strongly urge that EPA adequately consider the monitoring of pesticides under its emergency exemptions, particularly those pesticides which have been canceled or suspended.

CHAPTER 4

NEED TO IMPROVE STATE PESTICIDE REGISTRATION PROGRAM

States have misused their registration authority by registering pesticide ingredients EPA had

--previously suspended or canceled and

--ordered the State not to register because of unreasonable environmental effects or lack of safety/efficacy data.

In addition, States were permitted to register pesticide products that EPA had placed under registration moratoriums.

EPA has given low priority to promulgating the regulations for State registrations that were mandated by the 1972 Pesticide Act amendments. EPA does not expect final regulations to be printed in the Federal Register for some time. The timing is not known because of uncertainty about congressional action on proposed amendments to the Pesticide Act. Delays in implementing these regulations and requiring States to be certified as capable of registering pesticides under EPA's interim regulations caused relations between EPA and some States to deteriorate.

State-registered pesticides are limited to distribution and use within the State of registration for special local needs, particularly on minor pests or speciality crops for which effective EPA-registered pesticides are not available. Upon approval, State registrations have the same force and effect as EPA registrations.

Senate Report No. 92-838, dated June 7, 1972, stated that the purpose of State registration is

> "* * *to give a State the opportunity to meet expeditiously and with less cost and administrative burden on the registrant the problem of registering for local use a pesticide needed to treat a pest infestation which is a problem in such State but is not sufficiently widespread to warrant the expense and difficulties of Federal registration."

Clearly then, State pesticide registrations were intended to deal with localized problems that arise because of gaps in EPA registrations.

As of April 11, 1977, 45 States and 1 territory had been approved to register pesticides and had registered 646 products containing 142 active ingredients for special local needs. Of the 646 State registrations, EPA approved 592 and disapproved 44, and the States withdrew 10.

STATES REGISTER PESTICIDES THAT EPA WOULD NOT REGISTER

Under Section 24(c) of the Pesticide Act, States have registered pesticide products that EPA would not register. Of the 646 State pesticide registrations, 131 contained active pesticide ingredients that EPA would not register at the time because EPA had determined that these ingredients may have an unreasonable adverse effect on man or the environment.

EPA's pesticide registration policy concerning data requirements, which was published in the Federal Register on May 27, 1976, states that pesticide chemicals meeting or exceeding the criteria for risk would not be registered or reregistered until safety and environmental studies had been reevaluated, or until appropriate studies not currently available were done. This means that these pesticides and others with potentially dangerous characteristics are subject to intensive scientific review and public comment before a decision is made on whether to allow continued use or begin the process of removing them from commerce. This process is called "rebuttable presumption against registration." As of April 11, 1977, the States had registered 131 products (20 percent of total State registrations) containing 20 of these pesticide ingredients, 8 of which were potential carcinogens. Following is a table listing pesticide ingredients that were registered by the States but which EPA would not currently register.

Pesticide	Reason on list	Suspected carcinogen	Number of State registrations
BHC	a/potential oncogen	yes	1
Lindane	a/potential oncogen	no	30
Arsenic compounds	a/potential oncogen	yes	1
Carbaryl	b/potential teratogen a/potential oncogen	no	17
Benomyl	population reduction in nontarget species	no	13
EBDC compounds	carcinogen, causes thyroid cancer	yes	3
Strychnine	lack of emergency treatment; population reduction in nontarget species	no	c/14
DDVP	d/potential mutagen	no	2
Paraquat	lack of emergency treatment; population reduction in nontarget species	no	6
Dimethoate	a/potential oncogen	yes	4
Monuron	a/potential oncogen	yes	1
Ethylene Dibromide	a/potential oncogen	yes	e/4
Ethylene Oxide	b/potential oncogen	no	1
2, 4, 5-T	potential teratogen, contains dioxin contaminent	no	10
Trichlorfon	a/potential oncogen	yes	5

Pesticide	Reason on list	Suspected carcinogen	Number of State registrations
1080	lack of emergency treatment; population reduction in nontarget species	no	c/10
PCNB	a/potential oncogen	no	1
Rotenone	a/potential oncogen	no	2
Pronomide	a/potential oncogen	yes	2
Piperonyl butoxide	a/potential oncogen	no	4
Total			131

a/Potential to cause tumors, both benign and malignant.

b/Potential to cause birth defects.

c/Registrations disapproved by EPA.

d/Potential to cause permanent genetic changes.

e/Two registrations disapproved by EPA.

Following are two examples in which a State registered pesticides after EPA determined that they exceeded risk criteria and may cause unreasonable adverse health effects.

Example 1

EBDC compounds--EBDC (ethylene bisdiothiocarbamate) pesticides have been used extensively as agricultural fungicides for the past 30 years. At present there are six EBDC pesticide compounds having registered uses for approximately 80 crops. Ethylene thiourea (ETU), a potential carcinogen, is a degradation product of the EBDC compounds and may be a residue on certain food crops, such as spinach or lettuce. Repeated dietary exposures to EBDC's or ETU causes changes in the thyroid gland, including cancer, and depression of blood cholinesterase in warm-blooded animals.

Example 2

PCNB--PCNB (pentachloronitrobenzene) is registered primarily for use as a soil fungicide and as a seed treatment. In December 1969 the Mrak Commission 1/ recommended that human exposure to PCNB be minimized because laboratory tests showed it to be both a carcinogen and a teratogen. Also, an April 1976 EPA scientific review reported that PCNB could cause birth defects and tumors in test animals.

It is obvious that pesticides with such serious unresolved health questions should not be more widely dispersed into the environment until the questions of safety are resolved.

We gave an EPA official a list of these pesticides and asked why EPA was allowing States to register products containing pesticides that EPA would not register under its policy. This official said that EPA does not approve State registrations and only acknowledges receipt of the registration from the State. EPA officials also stated that pesticides identified by EPA as meeting or exceeding the risk criteria were not considered when evaluating State registrations and that EPA did not believe it could restrict the States from registering these pesticides. In addition, EPA does not plan to deal with such pesticides in the regulations for State registrations.

1/A commission established in 1969 by the Secretary of HEW to study pesticides and their relationship to environmental health.

We totally disagree with this reasoning because under the Pesticide Act EPA has 90 days in which to disapprove State pesticide registrations and has done so in 44 instances. Perhaps even more significant, the Pesticide Act gives State registrations the same status as EPA registrations if not disapproved within 90 days. Thus, by not disapproving State registrations, EPA is approving them (contrary to its statement) by allowing them to become Federal registrations at the end of the 90-day period. This means that State registrations would then be subject to the complex suspension and cancellation provisions should EPA later find it necessary to cancel such registrations. Such actions by EPA have taken 2 or more years for cancellation of such pesticides as DDT, aldrin/dieldrin, and chlordane/heptachlor.

Further, it does not seem logical that the Congress intended the States to register pesticides on which EPA had placed registration moratoriums. We believe that EPA should immediately notify the States that such pesticides may not be registered until they have been cleared. Such a provision should be included in EPA's State registration regulations.

STATE REGISTRATION AUTHORITY MISUSED

EPA disapproved 44 of 646 State registrations because the registrations violated provisions of the Pesticide Act and the implementing interim regulations. The following table shows the reasons registrations were disapproved.

State Registrations Disapproved

Numbers	Reasons
24 (note a)	Contained a suspended or canceled pesticide
13	Lacked tolerances
5	Product not previously registered by EPA
2	Use not efficacious
44	

a/These registrations appear to be only technical violations of the Pesticide Act. The use for which State registrations were made was not considered in the cancellation action, and it was believed that these registrations would not be affected by that action.

States with registration authority have been certified by EPA as capable of exercising adequate controls to assure that State registrations comply with the provisions of the Pesticide Act and EPA's regulations. It appears that those States that violated provisions of the law or regulations either do not have this capability or have done so intentially. EPA should take remedial action to insure that States are aware of their registration authority limitations. If States then fail to comply, EPA should take stronger action, such as rescinding States' authority to register pesticides.

The following example illustrates a situation that we believe warranted stronger EPA action. Tennessee registered two products--one containing fenthion and one containing methyl parathion--to control infestations of an estimated 5 million blackbirds in a State park. Before registering either product, the State asked EPA to recommend pesticides to control the bird infestation. EPA documents state that the State was advised to use TEPP or Tergitol. EPA also advised the State not to register (1) fenthion because it was not efficacious for this use and would create unreasonable adverse effects and (2) methyl parathion because its efficacy had not been determined.

In defending the registration of fenthion and methyl parathion, a Tennessee official wrote us that:

> "At that time, litigation pending with reference to a proposed use of Tergitol in a military installation located partly in Tennessee and partly in Kentucky prevented us from securing this material. We had reservations about the use of TEPP because of its very high toxicity, and we were not at all sure that we could use the material safely. We did, however, get in touch with the manufacturers of this compound to determine what data, if any, the manufacturers had as to the efficacy of the material for killing birds. We were told by the company that they had no data of a positive nature, and, as a matter of fact, the only data that they had was negative in that when securing a registration for the material in control of insects affecting hops, birds were caged in the hop fields prior to spraying with the material, and none of the caged birds were injured."

EPA officials told us that TEPP is an efficacious product for controlling birds. We also found that methyl parathion was neither registered or used by Tennessee until February 8 and 9, 1976, respectively--5 days after the President signed a bill into law authorizing the emergency use of Tergitol in both Kentucky and Tennessee.

Kentucky, which was also affected by the litigation, sprayed Tergitol on February 5, 1976--4 days before Tennessee sprayed methyl parathion. Tennessee officials also said that they were not able to obtain Tergitol for spraying; however, EPA and Department of the Interior officials said that stocks were available and could have been obtained.

During the course of these events, EPA on several occasions recommended that Tennessee obtain an experimental permit or an emergency exemption rather than register unproven products under State authority. EPA also contacted Tennessee State employees several times to determine what Tennessee was doing about the bird problem. According to EPA documents, these inquiries were ignored or evaded; after Tennessee began spraying, only one individual was available to EPA and he stated he was "not allowed" to discuss the spraying. The documents also say that after Tennessee's registration and use of fenthion, a Tennessee Department of Agriculture employee admitted that if EPA had been aware of the State's intent to register fenthion, EPA would have disapproved the registration.

Subsequent surveys of the sprayed area by an EPA inspector and a Tennessee State employee showed that the fenthion killed only 88 birds in an estimated 10,800-square-foot area where bird mortality should have been heaviest. Methyl parathion was similarly ineffective, and the State canceled both registrations.

Tennessee actions during this situation appear to be violations of its State registration authority, warranting action stronger than EPA's warning the State that similar violations would result in suspension of its registration authority.

The foregoing example demonstrates shortcomings in pesticide registrations of certain States. EPA should take action to insure that States do not register pesticides prohibited by the act or take action to limit or remove the States' registration authority for intentional violations.

REGULATIONS FOR CERTIFYING STATES NOT FINALIZED

The 1972 amendments to the Pesticide Act provided limited State registration authority under Section 24(c) for pesticides to meet special local needs that were not sufficient to justify Federal registrations. Regulations were to be finalized by October 21, 1974; however, EPA's interim regulations did not appear in the Federal Register for public comment until September 3, 1975--about 11 months after the mandated deadline for completing them. EPA is required to solicit public comment on the interim regulations before they are finalized because such regulations have the same legal effect as laws.

As of December 1977 EPA was still reviewing and evaluating public comments. An EPA official said that final regulations are being held in abeyance until the Congress acts on EPA's proposed amendments to the Pesticide Act. The official added that if the amendments are passed, issuance of final section 24(c) regulations would be delayed until new section 3 regulations are issued in accordance with the amendments. According to the official, the additional delay would be necessary to assure compatability between both sets of regulations. The regulations could be delayed as long as 2 or 3 years.

An EPA official said that the interim regulations were not completed in time to meet the legislative deadline because EPA gave low priority to these regulations while concentrating on Federal regulations for registering, reregistering, and classifying pesticides in accordance with section 3 of the act. This created no problems before the effective date of the new section 3 regulations on August 4, 1975. However, after that date, the States could no longer register pesticides except under the limited section 24(c) authority. Consequently, the need for section 24(c) regulations became critical for States with special local needs which were not being met under Federal registrations.

Because of delays in finalizing section 3 regulations, EPA elected to certify each State under the interim 24(c) regulations published in the September 3, 1975, Federal Register. An EPA official said that EPA would thus gain experience under the interim regulations to determine what changes were needed.

Delays in implementing the State registration regulations have further deteriorated relations between EPA and

certain States. Officials in one State we visited said that the State would not seek certification until after the final regulations were issued because requirements in the interim regulations may be substantially changed in the final regulations. Consequently, they said that the State did not want to expend funds, possibly needlessly, until the final requirements were firmed up. These officials explained that their reservations stemmed from previous experiences in which EPA had assured them that final regulations would be similar to interim regulations but, when finalized, the regulations were substantially different, resulting in wasted efforts and funds. Officials in two other States expressed similar sentiments, but told us that their States had elected to seek certification anyway.

CONCLUSIONS

States have obviously misused their registration authority granted under section 24(c) of the Pesticide Act by registering pesticides that:

--EPA had previously suspended or canceled.

--Required food tolerances but for which EPA had not set tolerances.

--EPA had directed the State not to register because the use caused unreasonable adverse environmental effects or was not efficacious for the intended use.

Because the foregoing are violations of the Pesticide Act, it appears that (1) certain States either intentionally violated their registration authority or (2) EPA has certified States that are incapable of assuring that registrations are in accord with the purposes of the Pesticide Act. In any case, EPA should take appropriate action against those States which have had intentional or repeated violations of the type noted. It is also apparent that EPA has permitted some States to continue using pesticides (for 90 days starting from the date of State registration) after EPA disapproved the State registrations. Use of pesticides that violate provisions of the act should be discontinued immediately.

EPA has allowed States to register pesticides that EPA has determined exceed established risk criteria and which must undergo additional scientific review before EPA may register any additional pesticides containing such chemicals. Thus, in effect, EPA has given the States greater registration authority than EPA has for such chemicals.

This gives us great concern because State registrations have the same legal status as Federal registrations if EPA does not disapprove them within 90 days of State approval. If EPA decides to cancel or suspend such State registrations after that date, they are subject to the same lengthy suspension and cancellation proceedings accorded Federal registrations--some Federal proceedings have taken well over 2 years to complete. We believe that State registrations of such chemicals should be subject to the same constraints as are EPA registrations and that such constraints should be spelled out in EPA's State registration regulations.

EPA has not promulgated State registration regulations in a timely manner and does not intend to do so in the near future. The importance of State registrations and EPA's delay in finalizing its regulations for such registrations have caused friction between EPA and some States. We believe that EPA's experience--in operating under its interim regulations and in certifying 45 States and 1 territory as capable of performing State registrations--provides sufficient expertise for EPA to finalize the mandated regulations. We believe such effort should be given priority attention and should incorporate the matters discussed in the preceding paragraphs.

RECOMMENDATIONS

We recommend that the Administrator, EPA, promulgate final regulations for State registrations and incorporate the following:

--States that intentionally or repeatedly violate their authority should be penalized immediately either by fines or suspension of their registration authority.

--States should not be permitted to register pesticides that EPA will not register.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our recommendation that States should not be permitted to register pesticides that EPA will not register, EPA agreed that there is some inconsistency between actions taken under section 24(c) and the lack of action taken under section 3 regulations regarding registration of rebuttable presumption against registration candidate chemicals or compounds under such review (registration moratoriums). EPA said that it is working to clarify this issue and that it

has proposed amendments to the Pesticide Act, which are being considered by the Congress, to resolve the issue. EPA said that the amendments include a concept designed to allow "conditional registration" of candidate chemicals for old uses or new uses where significant additional exposure is not anticipated. The primary criteria for such registrations would be clear evidence that it would not cause incremental, unreasonable adverse effects. We do not feel that pesticides under the rebuttable presumption against registration process should be registered by either States or EPA if other safe, effective pesticides are already registered.

In this regard, EPA also said that the Congress never intended that EPA devote extensive resources to reviewing State registrations and that EPA intends its review to serve solely as an audit function. We would like to emphasize that the Congress also made it illegal for States to take certain registration actions--such as registering canceled pesticides--however, as noted on page 46, several such State registrations did occur. We believe that EPA's audit role must be sufficient to preclude such illegal or irresponsible actions and that the Congress intended this by providing the 90-day period for EPA disapproval.

Concerning our recommendation that States which intentionally or repeatedly violate their registration authority be penalized, EPA did not believe that curtailing or suspending State authority under section 24(c) as a penalty for infractions of this authority is warranted, because deliberate misuse of this authority is not a prevalent or pervasive problem. While the problem may be neither prevalent nor pervasive at present, we believe that the examples noted indicate that certain States either violated their authority or are not capable of insuring that their registrations are in accordance with the intent of the Pesticide Act. Effective EPA sanctions on a case-by-case basis would aid in insuring compliance with the provisions of the Pesticide Act.

Finally, EPA commented on our observations that it had not promulgated State registration regulations in a timely manner with negative impact on some State/EPA relations by stating that although finalization of the regulations was important, operations under the interim regulations had (1) been effective, (2) been valuable in providing information to modify the proposed regulations and make them more workable, and (3) not caused a deterioration in its relations with the States. However, as pointed out in the report,

some State officials told us that they were unhappy that regulations had not been finalized and that they believed State/EPA relations had suffered as a result. We believe that these assertions cannot be ignored and that it is in the best interest of all concerned for EPA to begin finalizing the regulations at once.

APPENDIX I

THE DDT EMERGENCY EXEMPTION FOR DOUGLAS-FIR TUSSOCK MOTH CONTROL: A CASE HISTORY

The DDT emergency exemption to control the Douglas-fir tussock moth in the Pacific Northwest was perhaps the most controversial exemption EPA has ever granted. For this reason and because of many reports that the exemption was not warranted, we evaluated it to determine whether (1) DDT use was in fact necessary and (2) EPA requirements were met. We noted the following problem areas.

--DDT was used unnecessarily on 52,000 acres because the moth populations were near or below the U.S. Forest Service's action level. Also, moth populations within 4 days of spraying were at or below the action level on an additional 280,000 acres, raising the total to 332,000 acres where spraying apparently was not necessary.

--Data sufficient to register DDT alternatives was not developed during the 1974 program because the moth population was collapsing and testing had not progressed to the stage where reliable evaluations could be made.

--The U.S. Forest Service overestimated benefits derived from DDT use.

--Approximately 18,000 cattle and 900 sheep were contaminated with excessive DDT residues in their tissues from the spraying. Consequently, about 6,500 cattle scheduled for sale could not be marketed as scheduled, resulting in economic losses to the owners.

BACKGROUND

DDT (Dichloro-diphenyl-trichloroethane), a chlorinated hydrocarbon, is a broad spectrum insecticide acutely toxic to many invertebrates. Before 1972 DDT was the most widely used pesticide in the United States because of its effectiveness in controlling a large number of pests, its low cost, and its persistence. A 1975 EPA review of DDT literature identified several studies that showed that DDT could persist in the environment for decades.

During the 30 years before its cancellation, approximately 1,350 million pounds of DDT were used domestically.

When it was canceled, major uses included cotton (86 percent), soybeans (5 percent), peanuts (8 percent), and miscellaneous crops (1 percent). On June 14, 1972, EPA canceled DDT use in the United States effective December 31, 1972. The cancellation was based on DDT's persistence, transport, biomagnification, toxicological effects, and absence of benefits in relation to availability of effective and less environmentally harmful substitutes.

Tussock moth larvae defoliate true firs and Douglas-firs in forest lands of the western United States. Many trees are partially or completely killed either directly by the defoliation or because they are vulnerable to attack by other insects in their weakened state.

Usually the moth is present in the environment at relatively low concentrations; however, at periodic intervals (usually 8 to 10 years), the population increases to epidemic proportions. Major buildups and outbreaks occur in 3-year cycles. Epidemic-level moth outbreaks are usually not discovered until the second year of the cycle when defoliation is noticeable. For example, in parts of the Blue Mountains, Oregon, the moth population increased rapidly in 1971; defoliation became noticeable in 1972; and the outbreak in those areas collasped in 1973. A natural virus appears to have been the major factor in the collapse of moth populations in the past.

1973 EXEMPTION REQUEST

On March 20, 1973, the U.S. Forest Service requested a specific exemption to use DDT on 449,000 acres in the Blue Mountain area (Pacific Northwest) to control the moth. Additional requests for DDT exemptions were also received from several municipalities in Washington and Oregon in April 1973 and the Boise Cascade Corporation of Idaho in May and June 1973.

EPA inspection teams made onsite surveys to assess the situation in March and May 1973. The teams found that moth larvae in the area were infected by the natural virus. The EPA teams believed that the moth population would collapse in 1973, following its normal 3-year cycle. The U.S. Forest Service and Washington and Oregon State officials agreed that the populations would collapse in those areas noticeably defoliated during 1972.

On the basis of inspection team reports and other information available, EPA denied the exemption request because benefits derived from protecting immediate and future forest resources and recreational areas from moth damage were outweighed by such risks as reduced bird and fish populations, accumulated DDT residues in cattle and sheep grazing in sprayed areas, contaminated water supplies, and unknown effects on human health and the environment.

The moth population collapsed as expected in the Blue Mountain area in 1973; however, Forest Service officials said significant damage had already occurred as they forecasted before the collapse.

1974 EXEMPTION

On January 3, 1974, the U.S. Forest Service again requested an emergency exemption to use DDT to control several distinct outbreaks of the moth in the Pacific Northwest.

On February 28, 1974, EPA granted the emergency exemption authorizing application on 650,000 acres of Federal, State, and private land in Oregon, Idaho, and Washington at a rate of 3/4 pounds per acre (total of 490,000 pounds). The exemption was granted subject to certain spray restrictions and research and monitoring requirements. One of the major conditions in allowing the exemption was to develop alternatives to DDT that could be registered.

EPA approved the exemption request on the basis of the following findings.

--A moth outbreak had or was about to occur and there were no alternative pesticides or methods to control the pest.

--Significant economic problems would occur without DDT use.

--There was insufficient time for a pesticide to be registered.

--The benefits of DDT use outweighed the risks involved.

In the order announcing the decision, the EPA Administrator stated that EPA lacked considerable data which, ideally, should be assessed before a decision was made. In this case, however, EPA did not believe it had this option. EPA was uncertain about the (1) relationship between the

intensity of larval populations and tree damage, (2) economic and social impact of a decision not to control the infestation, and (3) virus concentration in moth larvae and its potential to cause a collapse of some or all the infestations.

Exemption restrictions

Although EPA granted the exemption, it cautioned the U.S. Forest Service that the exemption was not a directive from EPA to use DDT against the moth. EPA directed the U.S. Forest Service to survey and assess the viability of the moth egg masses and the virus concentration as a basis to insure that unnecessary DDT applications were not made.

Specifically, EPA stipulated that the U.S. Forest Service not spray acreage where larval incidence was too low to justify DDT use or where viral incidence would control the outbreak without DDT use. Lab hatches of egg masses were to be done and verified by field surveys at the time of natural hatch.

EPA also required that livestock and other domestic animals be removed from the treatment area to the extent possible and that hunters be informed that DDT residues may be present in game animals taken from the sprayed area.

Under the exemption, the U.S. Forest Service was to perform sufficient research to register other pesticides as alternatives to DDT control of the moth. EPA required the U.S. Forest Service to test resmethrin, bioethanomethrin, carbaryl, and trichlorfon as a followup to a 1973 test when these chemicals were used in attempts to develop DDT alternatives. In addition, the U.S. Forest Service was instructed to conduct statistical evaluations of DDT efficacy in preventing tree damage and mortality and to determine if DDT was efficacious at lower application rates. A final requirement was to better define the correlation between egg masses and larval populations, virus incidence, and tree damage and/or mortality. This research was to be completed and submitted to EPA by December 1, 1974.

DDT APPLIED UNNECESSARILY

The U.S. Forest Service did not comply with EPA's directive that unnecessary DDT applications not be made. In fact, up to 52,000 acres may have been sprayed unnecessarily, based on the U.S. Forest Service's own criteria.

In setting up parameters for its DDT spraying program, the U.S. Forest Service determined that areas should be sprayed only if larvae infestations exceeded 20 larvae in a 1,000-square-inch area. The following table shows moth populations for various areas before spraying and at 4- and 21-day intervals after spraying.

Moth Populations by Test Area and Sampling Periods

Test Area	Acreage	Prespray level (note a)	Postspray levels 4 days (note a)	Postspray levels 21 days (note a)
Colville, Wash.:				
treated	167,200	55.3- 78.9	0.6- 1.4	0.1- 0.3
untreated	872	17.8- 49.6	8.7-18	6.8-11.9
Pomeroy, Wash.:				
treated	17,200	17.7- 25.5	0.04-0.3	0.03-0.1
untreated	32,826	3.8- 8.3	1.3- 3.1	0.7- 1.3
Halfway, Oreg.:				
treated	33,700	15.6- 24.8	0.2- 0.5	0.1- 0.5
untreated	6,985	10.3- 18.8	7.3- 14.9	3.1- 6.4
LaGrande, Oreg.:				
treated	38,100	22.0- 29.2	0.2- 0.4	0.01-0.02
untreated	54,623	16.0- 33.2	6.2- 12.8	0.6- 2.2
Wallowa, Oreg.:				
treated	88,400	31.5- 48.2	0.3- 1.0	0.03-0.2
untreated	19,083	58.3-100.3	24.3- 39.2	10.5-23.2
St. Joe, Idaho:				
treated	75,300	23.0- 33.4	0.04- 1.1	0.1- 1.2
untreated	7,928	9.0- 12.4	7.8- 11.0	3.6- 6.6
Sawtooth, Idaho:				
treated	1,100	8.0- 12.2	0.3- 0.6	0.3- 0.6
untreated	100	5.1- 10.8	2.2- 4.8	2.4- 5.8

a/Number of larvae per 1,000 square inches.

The table shows that DDT was effective in reducing moth populations. However, it also shows that the populations were declining significantly in untreated areas, probably due to a naturally occurring virus and such other factors as egg infertility, overwintering stress, and egg predation. For example, moth population in the unsprayed LaGrande, Oregon, and Colville, Washington, areas, within 4 days of the spraying of the remaining acreage, had declined to about one-third of their prespray levels--both below the U.S. Forest Service's action level.

The table also shows that three sprayed areas totaling 52,000 acres were below or very near the action levels. The spraying was questionable in view of the declining moth populations. The questionable areas included Sawtooth, Idaho, (1,100 acres); Pomeroy, Washington, (17,200 acres); and Halfway, Oregon, (33,700 acres). Also, moth populations within 4 days of spraying were at or below the action level on an additional 280,000 acres, raising the total to 332,000 acres where spraying apparently was not necessary.

Agency comments and our evaluation

In commenting on our draft report the U.S. Forest Service disagreed with our conclusion that DDT was used unnecessarily. The Service said that:

--The need for treatment was determined by its 1973 fall egg mass survey and subsequent virus level determinations as indicated in its environmental impact statement.

--Prespray moth population data could not be used as indications of actual population levels, and there was not sufficient time to measure precise population levels before treatment in the spring of 1974.

--Serious damage would have occurred had DDT not been used.

In analyzing the data on egg mass density and viral incidence presented in the Forest Service's environmental impact statement, we found that the data was not sufficient to support the Service's claim that DDT was not sprayed unnecessarily. An analysis of the data follows.

Unit	DDT-treated acreage	Total acreage meeting treatment criteria A (note a)	B (note b)	Total	withheld (note c)	available	DDT-treated acreage not meeting criteria
Colville	167,200	83,840	2,560	[illegible]	500	85,900	81,300
Pomeroy	17,200	39,680	3,200	42,880	500	42,380	-
Wallowa	88,400	71,680	640	72,320	9,200	63,120	25,280
LaGrande	38,100	48,000	-	48,000	1,100	46,900	-
Halfway	33,700	40,960	2,560	43,520	16,200	27,320	6,380
Total	344,600	284,160	8,960	293,120	27,500	265,620	112,960

a/Recommended for control.
b/Treatment optional pending further evaluations, such as aerial surveys.
c/Acreage set aside as control plots and for research and testing of other chemicals.

About 284,160 acres were recommended for control on the basis of the 1973 fall egg mass survey and subsequent virus level determinations, and treatment was optional on an additional 8,960 acres (a total of about 293,120 acres). Some 27,500 of these acres were set aside for research and testing of other chemicals. Thus, only about 265,620 acres met the treatment criteria and should have been treated with DDT; about 112,690 of the 344,600 acres treated did not meet treatment criteria. A prime example of unnecessary spraying occurred in the Colville unit. The fall egg mass survey and subsequent virus level determinations showed that a section of land totaling about 23,040 acres should not be treated, and the U.S. Forest Service indicated it its environmental impact statement that this area was not to be treated. However, at least 16,640 of these acres were treated with DDT during the program.

We could not make reliable evaluations for the St. Joe and Sawtooth units because of incomplete information. The U.S. Forest Service said in its 1974 environmental impact statement that about 46,100 acres needed treatment and treatment was optional on another 97,500 acres; however, an analysis of the 1973 fall egg mass survey and egg viability data included in the statement indicates that only 12,160 acres may have needed treatment. Specific data pertaining to the Sawtooth unit was not included and we could not determine whether the unit was included in the 1973 fall egg mass survey.

While the prespray population data may not accurately reflect the true moth population, it was certainly an indication that populations were not as heavy as originally believed. More importantly, the 4-day and 21-day postspray data collected by the Forest Service showed clearly that the moth was declining at an extraordinary rate and that only a small portion of the moth populations would reach the fifth to seventh instars, the stages of development that the Forest Service states causes significant defoliation. At 21 days

postspray, the bulk of the moth population was only in the third or fourth instar--still too early to do significant damage.

A U.S. Forest Service researcher involved in the spraying told us that in retrospect it was a "given" that the spraying was unnecessary. Another U.S. Forest Service official stated that the population trends should have raised a "red flag" and spraying should have been discontinued until true populations were determined in the unsprayed areas. This position is further supported in an article published by a U.S. Forest Service researcher in September 1976 issue of the "Annals of the Entomological Society of America" which indicates that moth populations may not have been sufficient to justify treatment. The researcher found:

> "Egg masses for the 1973-74 generation were difficult to find on most plots and none was collected from heavy areas. Nevertheless, samples were available to estimate egg mortality independently for the other classes * * *. Expected egg densities were low on heavy and moderate plots but relatively high on light and very light plots. However, 90 percent or more of the eggs in all class samples failed to hatch. This mortality was fairly equally divided among three natural causes: hymenopterous parasites, infertility, and losses presumably due to overwintering stress and egg predation." (Underscoring added.)

The researcher also said that moth populations, after hatch, declined sharply. For example, moth populations in the first stage of development dropped by 92 percent (from 14 to 1.1 larvae per 100 square inches) because of virus, predators, parasites, and dispersion. One-half of the surviving population died for the same reasons within 21 days.

Based on the foregoing, we conclude that the U.S. Forest Service's argument is not convincing that all spraying was necessary and that significant damage would have occurred without the spraying.

U.S. FOREST SERVICE DID NOT IDENTIFY EFFICACIOUS DDT ALTERNATIVES

A major condition of the exemption was to develop registerable DDT alternatives for controlling the tussock moth. Field experiments were carried out, but some were scaled back or canceled because of low insect population in study areas. For example, proposed testing in Idaho of two of the most

promising pesticides, bacillus thuringiensis and the nuclear polyhedrosis virus, was canceled because of inadequate moth populations to provide satisfactory tests. Because of low populations in the test areas, no alternative pesticides were registered as a result of the exemption testing. The results of some of the alternative testing is discussed in the following sections.

In a November 1974 draft interim report on the program, the U.S. Forest Service said that in a field experiment using Sevin-4-Oil and Dylox, moth populations were the lowest of any used for testing in 1974. Because of the low insect populations, an additional test of Dylox was conducted in Wallowa, Oregon, and Seven-4-Oil in St. Joe, Idaho (high insect population areas). The additional test of Dylox on two 300-acre plots resulted in moth population reductions of 68 and 79 percent 4 days after spraying. The U.S. Forest Service draft stated that

> "Although some larvae were killed, the density of the surviving larvae was still at a level high enough to cause serious defoliation. Sometime between the 4-day and 21-day sampling periods a virus caused the moth population to collapse before the evaluation was completed."

The same situation occurred during the Sevin-4-Oil test. Population reductions on two 600-acre plots were 83 and 88 percent after 7 days and 97 and 96 percent after 14 days. Again, prespray larval populations were high, but a 60-percent reduction due to natural factors (virus) occurred in an untreated check plot after 14 days. Because the moth population collapsed before the tests could be completely evaluated, no analysis was made to determine the effectiveness of these pesticides.

Several EPA and U.S. Forest Service memos state that alternative pesticides could not be tested because of a natural decline in moth populations due to a combination of factors including virus and other natural predators. Two researchers who studied the project told us that the moth population was declining naturally in the entire area. One of these officials said that by 1975 moth populations had collapsed entirely and, consequently, additional studies of alternative pesticides could not be made.

U.S. Forest Service officials said that DDT alternatives were not developed because the tests had not progressed sufficiently to make a reliable evaluation when the population

collapsed. One official said DDT alternatives could not be tested in DDT-treated areas because treatment had already begun, and therefore, it was too late to switch.

Agency comments and our evaluation

With regard to development of DDT alternatives, the U.S. Forest Service said:

> "The reasons for not being able to register alternative pesticides are many, the least of which was the declining moth population in some areas * * *. One season's testing under the best of circumstances would usually not be sufficient to generate enough data to satisfy registration needs."
>
> * * * * *
>
> "It is true that the populations collapsed on some of the DDT alternative test areas before an effective test could be carried out. Because of the detailed planning and preparation work required to set up an adequate study area, it was not possible to move some of these tests to high insect population areas at the last minute. Although unfortunate from an experimental standpoint, it is completely erroneous to conclude that the insect population declines experienced in some of these areas were general in nature. It should be noted that some of these tests were quite successful, e.g., Acephate, Dimilin, and Sevin-4 Oil."

We agree that one season's testing may not be sufficient to generate enough data to satisfy registration needs; however, most of the chemicals tested by the Forest Service were also tested in 1973. Collection of data from 2 years of spraying is generally more than adequate to establish efficacy, which EPA believed appropriate in this instance because it made the registration of viable DDT alternatives a major condition in approving the spraying exemption. Also important is the fact that the Forest Service accepted this condition as reasonable when it agreed to the EPA conditions of the exemption.

To the Forest Service's credit, the follow-on program which was conducted in New Mexico, Colorado, and Canada beginning in December 1974 has resulted in the registration of two biological pesticides--bacillus thuringiensis and the polyhedrosis virus--and development of data to support the registration of three other chemical pesticides--orthene,

dimilin, and Sevin-4-Oil. However, the major portion of the data used to support the registration actions appears to have been developed since 1975, not during 1974 (the year of the DDT programs). Some data on the pesticides was collected in 1974 as well as 1973, but the tests merely indicated that the pesticides were promising alternatives and that additional testing would be needed, the same conclusions reached after the 1973 sprayings. Data used to support the registration of Sevin-4-Oil was developed in 1974 in Montana, an area not included in the DDT spraying area approved by EPA. Some Sevin-4-Oil tests were conducted in Idaho in 1974, but again the data developed was not adequate to make reliable determinations of its effectiveness.

Consequently, we must conclude that the 1974 DDT exemption had little or no effect on the registration of viable alternative pesticides to control the tussock moth and that this important condition of the DDT exemption was not complied with.

U.S. FOREST SERVICE OVERESTIMATED BENEFITS OF DDT USE

The U.S. Forest Service began using DDT on June 9, 1974, in the Colville unit in Washington and concluded the program on July 25, 1974, on the LaGrande unit in Oregon. A total of 420,944 acres were treated with 315,708 pounds of DDT (three-quarter pounds per acre). An additional 5,615 acres were sprayed at rates of one quarter and one-half pounds of DDT an acre. Only 6,060 acres were sprayed with DDT substitute pesticides.

The U.S. Forest Service stated in its report on the project that the program was highly successful in accomplishing its objectives of reducing moth populations and reducing timber losses. The Service reported that the effect of DDT on the moth population was immediate and dramatic, resulting in 98.8-percent reductions in the populations. The U.S. Forest Service estimated that treating the 420,944 acres prevented an additional loss of 411 million board feet of timber with a value of $11.6 million and prevented a loss of $23.8 million in damage to immature trees, growth losses, reforestation expenses, recreation losses, and increased fire protection costs. These estimates assume treatments prevented about 90 percent of the 1974 damage that otherwise would have occurred had the areas not been treated.

The U.S. Forest Service's benefit estimates did not consider the effects of the natural virus and other predators

on moth population declines. The Service recognized that significant natural declines in populations were occurring and in fact used these declines to justify terminating efficacy studies of DDT alternatives during the 1974 program. For example, the Service canceled proposed tests of bacillus thuringiensis and the nuclear polyhedrosis virus because adequate moth populations were not available to provide satisfactory tests. Using the U.S. Forest Service's rationale, all but one of the DDT-treated areas likewise would be unsuitable for determining the efficacy, and hence the resulting benefits, of the DDT applications because of similar declines in moth populations in adjoining untreated areas.

The extent of moth population declines in treated and untreated areas is shown in the following table.

Test area	Acreage	Percentage of prespray population reductions after 4 days	21 days
Colville, Wash.:			
treated	167,200	98.2	99.6
untreated	872	63.7	76.0
Pomeroy, Wash.:			
treated	17,200	98.8	99.6
untreated	32,826	62.6	84.3
Halfway, Oreg.:			
treated	33,700	98.0	98.0
untreated	6,985	20.7	66.0
LaGrande, Oreg.:			
treated	38,100	98.6	99.9
untreated	54,623	61.4	93.4
Wallowa, Oreg.:			
treated	88,400	97.9	99.6
untreated	19,083	60.9	76.9
St. Joe, Idaho:			
treated	75,300	96.7	96.4
untreated	7,928	11.3	46.7
Sawtooth, Idaho:			
treated	1,100	95.1	95.1
untreated	100	55.6	46.3

In five of seven test areas, moth populations in the untreated areas declined by 55 percent or more because of natural causes within 7 days (or 4 days after treated areas were sprayed). After 21 days populations in all untreated areas had declined to a minimum of 54 percent of the pre-treatment populations; 5 untreated areas adjacent to sprayed areas totaling 344,600 acres experienced declines ranging from 66 to 93 percent.

The foregoing is supported in EPA's August 20, 1974, monitoring report. In the report EPA stated:

> "The Forest Service sampled and collected egg masses in fall 1973; they also determined the viral incidence of larvae hatched from these eggs. These data were used to estimate the 1974 larval populations and to decide what areas required treatment. The inaccuracy of these estimates is clearly illustrated by the fact that 106,000 acres, of approximately 460,000 acres scheduled for treatment on the basis of egg surveys, had insufficient larvae to warrant spraying. Also, approximately 45 percent of the 79,161 acres sprayed due to visible defoliation had been included in the fall egg mass surveys and judged not to require treatment. More reliable measurements of larval populations are possible from direct field larval counts. The Forest Service did some prespray larval sampling in its "cluster plot" analysis. However, this analysis was primarily intended to evaluate DDT efficacy over the entire project. This prespray larval survey did not adequately ensure an accurate count of larvae in each spray block because:
>
> 1) an insufficient number of samples was included.
>
> 2) all spray blocks were not sampled.
>
> 3) sampling occurred before an established first instar larval population was present. Thus, a varying proportion of the eggs had not yet hatched and adequate larval dispersion had not yet occurred.
>
> 4) established and declining tussock moth populations were inappropriately sampled using methods and assumtions designed to measure incipient populations.

"In addition to the inadequacies of the survey, the Forest Service workplan did not guarantee that if the larval populations fell below the threshold density of 20 larvae/1000 $in.^2$, a spray block would be re-evaluated or eliminated from treatment. This and the inadequacies of the larval survey could lead to the unnecessary spraying of areas which did not have tussock moth populations large enough to warrant treatment."

In disagreeing with EPA's report, the Forest Service said:

--The report ignores the fact that EPA was told a complete prespray larval survey was not possible due to the short interval between moth egg hatch and the need to treat.

--Item 4 above is completely in error because a predetermined number of plots were surveyed, much of which were in the incipient stage--before visible defoliation had occurred.

--It was not feasible to carry out more than one type of survey because of the intermingled nature of the different outbreaks.

Notwithstanding the Forest Service's comments that it had insufficient time to carry out the type of indepth sampling EPA believed necessary, apparently EPA expected the Service to do this sampling, without which it would not be possible to insure that only necessary spraying was done and that DDT benefits were accurately measured.

On the basis of the foregoing, it appears that at best U.S. Forest Service estimates of benefits were very optimistic and at worst that benefits were nonexistent. It is true that moth populations experienced large declines in the DDT-treated areas; however, it is not apparent whether these declines resulted because the larvae were in a weakened state because of the natural virus and other factors or whether the DDT was truly efficacious. The Service, on the other hand, did not estimate the cost of detrimental environmental and economic effects resulting from the DDT applications. For example, an estimated 18,000 cattle and 900 sheep, found to have excessive DDT residues in their tissues from the spraying, were restricted from being marketed for up to 1 year. Consequently, about 6,500 cattle scheduled for sale during that year could not be marketed, resulting in economic losses to the owners.

Agency comments and our evaluation

In commenting on our proposed report on the benefits of DDT use, the U.S. Forest Service said

> "If any error was made in estimating benefits from using DDT, we believe, it was an underestimation. Because there was no existing data based on how much subsequent loss to bark beetles could be expected if tussock moth damage was not prevented, an estimate of this benefit was not included in the calculations. Salvage logging is now being conducted on an emergency basis in most of the untreated areas in an attempt to recover trees first defoliated by the tussock moth and subsequently killed by Douglas-fir bark beetles. In many cases this is the second logging entry, as the first efforts were limited in most cases to picking up only trees killed or severely damaged by the tussock moth alone. The difference between treated and untreated areas in this regard is striking and plainly visible at this time, particularly from low-flying aircraft."

We do not believe the U.S. Forest Service-claimed benefits from DDT use is warranted because Service estimates do not make allowance for the decline in moth populations resulting from natural causes. For example, the U.S. Forest Service assumes that about 90 percent of the 1974 damage that would have occurred was prevented by using DDT. As stated previously in a published report by the Forest Service researcher, moth populations failed to hatch as anticipated and those that hatched declined so rapidly that spraying was questionable. This coupled with the Forest Service's failure to recognize the adverse effects to grazing animals and to the environment, in our opinion, results in a significant overestimation of spraying benefits.

CONCLUSIONS

Contrary to U.S. Forest Service assessments, the DDT exemption for controlling the moth was, at best, of limited success. In fact, it appears that DDT treatment of over 330,000 of the 420,944 acres sprayed was questionable because (1) populations were at or below levels the U.S. Forest Service deemed harmful or (2) populations were declining so rapidly that spraying was not necessary. Consequently, the Service did not comply with EPA's directive that only

necessary DDT applications be made, and over 315,000 pounds of DDT were applied in the Pacific Northwest, much of it unnecessarily. This is environmentally significant because DDT will not degrade significantly for decades and, in the absence of offsetting benefits, was not justified.

Because of declines in moth populations, the U.S. Forest Service was unable to fulfill a major consideration--to identify efficacious, registerable pesticides to use in place of DDT in future moth infestations--in EPA's approval of the exemption. We believe that the U.S. Forest Service should have terminated all DDT applications when it found that moth populations were in substantial decline and that it could not test the efficacy of DDT alternatives.

We also believe that had sufficient monitoring been conducted, EPA early on would have detected that moth populations were declining and that additional DDT should be applied only after additional counts of moth populations and virus incidence had been made. Areas where the moths were declining rapidly or where the virus incidence was high should not have been treated.

APPENDIX II

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 26, 1977

OFFICE OF
PLANNING AND MANAGEMENT

Mr. Henry Eschwege
Director, Community and Economic
Development Division
U. S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Eschwege:

Enclosed are EPA's comments from the Offices of Pesticide Programs and Pesticide Enforcement on your draft report entitled "Opportunities for Improving EPA's Special Pesticide Registration Activities". I am sorry for the delay in relaying these comments.

Preparation of this report has been a difficult exercise for both your audit group and EPA staff. Strong and differing views are held by both parties on the state and health of the special pesticide review activity. The result in this case is a set of straightforward and frank comments.

Be assured that they were not prepared and are not intended to reflect a hostile attitude on the part of EPA. They are intended, however, to forcefully and factually state the Agency's position on both the special registration activity and your draft report. I hope these comments will further a constructive dialogue between us that will improve both the special registration activity and the GAO report on it.

Sincerely yours,

Bill Drayton

William Drayton, Jr.
Assistant Administrator
for Planning and Management

Enclosure

APPENDIX II

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Comments on the GAO Report, "Opportunities for Improving EPA's Special Registration Activities"

SUMMARY

The GAO began examining the work of the Office of Pesticide Program's special registration early in February 1976, looking specifically at the Agency's handling of experimental use permits, emergency exemptions, and State registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Agency staff cooperated fully with the GAO investigators, and all files were made available for inspection.

An original draft report was completed by GAO late May 1977 on which the Agency informally commented, with the present draft following in August. The Agency's comments on the latest draft are attached.

Overall, EPA is disappointed in GAO's seemingly contradictory recommendations and regulatory philosophy. Major flaws are that isolated instances are interpreted as trends, conclusions are not supported by the facts cited, and advice in specific areas would work to the detriment of program objectives in others; the GAO also seems intent on not giving credit where it is due, and ignores the positive aspects of the special registration reviews and improvements.

Agency comments on each of the three major parts of the report, i.e., Experimental Use Permits, Emergency Exemptions, and State Special Local Need Registrations, follow in order.

Edwin L. Johnson
Deputy Assistant Administrator
for Pesticide Programs

I. EXPERIMENTAL USE PERMITS

GAO concludes that EPA's experimental use permit program is not fully effective, and, as a result, new pesticide product development has declined in recent years.

In support of GAO's conclusion that EPA's experimental use permit program is having a direct, adverse impact on research and development efforts in the pesticides industry, the report cites a 1975 report by the National Agricultural Chemicals Association (NACA). EPA has addressed such concerns in a paper presented to the Senate Committee on Agriculture, Nutrition, and Forestry during recent deliberations on the amendment of FIFRA. This paper was included in the Committee report published on July 6, 1977. We provided GAO a copy of the Committee report and called attention to the study conducted by William Blair and Company in which the pesticide industry is characterized as one with "extraordinary profitability" (p. 63). According to a NACA survey, the categories of research and development most heavily impacted by EPA requirements amount to only about one third of total research and development expenditures.

EPA also directed GAO to our recent study, "FIFRA: Impact on the Industry", also included in the Senate Committee Report. This impact paper points out that in recent years about an equal number of firms have entered and left the pesticide research field. High profits and profit potentials have kept the industry interested. Although more stringent and extensive registration data requirements may result in innovations in the pesticide industry being fewer in number than in the past, the industry has and will continue to build on its existing research and development base with changes in use patterns and formulations of previously-registered products, and new chemicals within already successful classes of compounds. Partial evidence of this trend is the fact that issuance of experimental use permits has increased by 300% since FIFRA was amended in 1972. While this increase in the issuance of EUP's is due in part to the fact that Federal and State Agencies previously authorized to experiment without permits now are required to obtain EUP's, the majority of this increase, however, represents permits issued to industry.

In light of this radical increase in the number of permit applications and EUP's issued, and the continued high profit realization by pesticide industries, we feel that GAO's initial contention that the EUP program has led to a decline in research and development was unsubstantiated. The report has, however been revised to reflect that the Experimental Use Permit program is only one of several factors impacting on research and development activities. Since the Agency has not seen any information to substantiate the contention that EPA is driving firms from the pesticide field, we must take issue with the GAO's conclusions on this point.

There are several areas investigated by GAO discussed in the present draft report and an earlier version which bear close attention:

A. Guidelines

GAO RECOMMENDATION: promulgate guidelines specifying data requirements that are necessary for permit approvals and the type and extent of data to be developed under permits.

AGENCY COMMENT: The Agency does intend to promulgate general data requirements for the approval of experimental use permits. These requirements will be included as a section in the general registration Guidelines. Until, however, the Guidelines for full registration are finalized, the formulation of the EUP Guidelines would be ineffective. As the data requirements for full registration change, so do the requirements for EUP approval. It is necessary to first establish the full registration Guidelines before codifying the general data requirements for EUP approval.

The Agency is at a loss to understand GAO's implication that manufacturers should not be required to begin Section 3 registration data development, in particular long term animal feeding studies prior to the application for an EUP. The intent of the EUP program is to allow the development of efficacy data as well as field, fish, and wildlife, and environmental safety data necessary for full registration. Long term feeding studies are an important part of the safety data required, from EPA's standpoint. And surely, when the manufacturer enters the final stages of testing under the EUP, it is in his best economic interest to run such time consuming studies concurrently, to expedite compliance with full registration requirements and thus be fully prepared to apply for registration when the EUP is concluded.

The definition of data to be developed specifically under an EUP (as opposed to data to obtain an EUP) would be repetitious of the Section 3 registration guidelines. It would create additional time-consuming administrative problems to repeat this information in EUP guidelines.

B. Excessive Processing Times

GAO RECOMMMENDATION: Require reviewers to act on--approve or disapprove--properly prepared permits within a specified period.

AGENCY COMMENT: GAO sees no compelling reasons why permits should not be submitted, processed and either approved or disapproved as they are received. We fully concur with this observation. Unfortunately, however, EPA does not control the submission of permit applications. Applicants do not, in fact, submit their applications far enough in advance of the date they wish to begin testing.

[See GAO note 1, p. 85.]

The preamble to our Section 5 regulations states that EPA will generally require at least 90 days (not 60 days) to complete our review and issue the permit. The regulations themselves state that:

"An application or request for amendment to an existing permit shall be submitted...as far as possible in advance of the intended date of shipment or use. Applications will be processed as expeditiously as possible." (40FR 18783)

[See GAO note 1, p. 85.]

For Fiscal Year 1977 we projected that our resources and manpower would allow experimental use permit processing within the following time frames, depending on the chemical and testing situation involved:

20% within 90 days
50% within 120 days
30% within 180 days.

The report contains a number of conflicting statements on how to accomplish processing more efficiently. On the one hand, the report recommends that applications be processed "as they are received" and says that this will help to "spread EPA's workload throughout the year." On the other hand the report states that "there do not appear to be alternatives in alleviating this seasonal surge [of applications]." We fail to see how processing a "flood

of applications", as they are received will spread the workload throughout the year. We agree that all applications should be processed as they are received and in fact, we currently process and have in the past processed applications "as received." When possible, we attempt to prioritize submissions by the date needed. However, this is not always possible during the peak workload period With severely limited manpower, the final action on "seasonal surge" applications may not always be timely. The only ones who can spread the workload over the year while maintaining timely processing are the applicants. They can do this by submitting their permit applications as far in advance as possible.

C. Notification & Monitoring

GAO RECOMMENDATIONS: Furnish prompt information on permit approvals to applicable regions so that site visits can be programed when the experimental pesticides are being applied. Prioritize the permit monitoring program to assure proper control of experimental products whose safety has not been established.

AGENCY COMMENTS: The establishment of a good monitoring program is wholly dependent on knowing the basic properties of the chemical in question and its likely potential problems in the environment. EPA attempts to ensure that the "American public is not unncessarily exposed to harmful pesticides" (p. 18) before we issue an experimental use permit. There seems to be a discrepancy in the GAO findings in that on one hand, it implies that the Agency is requiring too much data to support an experimental use permit, and. on the other, the Agency is not adequately monitoring experimental products "whose safety has not been established

[See GAO note 2, p. 85.]

Regardless of this philosophical discrepancy, we do not agree that the 58% rate of experimental use permit monitoring is not adequate. We do not feel that extensive monitoring is necessary in many cases. The majority of EUP's are issued for "old" chemicals for which changes in use patterns, e.g , changed dosage, mode of application, or a different pest are sought. Acreage is often small and exposure to man and the environment is minimal Within the experimental use permit category, Regions prioritize monitoring so that the more dangerous chemicals, or those about which little is known, are monitored. In short, we feel that 58% is entirely adequate and appropriate for Agency monitoring of EUP's.

We agree with GAO that prompt notification of Regions on approval of experimental use permits is necessary, but we do not agree that the lack of notification of permit approvals causes "inadequate" monitoring. GAO would instruct EPA to "furnish prompt information on permit approvals to applicable regions so that site visits can be programmed when the experimental pesticides are being applied." It does not necessarily follow that an inspector must be on site at the time of pesticide application to determine if permit conditions have been met. While communications may not always have been optimal,

we try to furnish information on permit approval to Regions on a timely basis. As of June 1 1977, we were current on all permit approval notifications.

D. Extension of Permit Period

GAO RECOMMENDATION: Authorize experimental use permits for the reasonable duration of an experimental program rather than limiting them to 1 year as is now done.

AGENCY COMMENT: We agree with this recommendation, but not with the necessity for making the recommendation. We presently do consider the issuance of permits for more than one year on a case-by-case basis. The Section 5 regulations, when finalized, included such a policy, which was reaffirmed March 28 & 29, 1977, meeting of American Association of Pesticide Control Officials (AAPCO). We must, of course, require a two year program for a two year permit.

II. EMERGENCY EXEMPTIONS

As is the case with GAO's comments on the Experimental Use Permit Program EPA feels that there are overriding philosophical inconsistencies and basic misunderstanding of the intent of the Emergency Exemption Program, which must be addressed before considering the specific allegations made by GAO. GAO consistently cites examples of States or other agencies taking crisis exemptions illegally in the face of EPA lack of approval or actual disapproval of exemption requests. It does not seem to follow logically that, in the case of Agency failure to approve a request, or when the Agency rejects a request, the Agency can then be held liable for illegal use of the product in question. No one is compelled or has to use a pesticide illegally. The Agency cannot see the logic in criticizing the decision making because some Agencies are circumventing unfavorable decisions.

There are several aspects of emergency exemption processing singled out by GAO for particular discussion:

A. Untimely Action

GAO RECOMMENDATION: Timely review and action should be taken on emergency requests.

AGENCY COMMENTS: GAO originally used figures in support of its contention that emergency exemption processing takes too long which were biased by the statistical method employed. In response to Agency concerns on this biased methodology, we understand that GAO has performed a median analysis. This analysis shows a median processing time of 18 days, as opposed to an average processing time of 88 days. In the final draft of their report GAO revised the processing time figure on the basis of averaged processing times for 48 exemptions issued between July 1, 1977, and June 30, 1976. The average processing time for exemptions issued during this period was 40 days, less than half the time indicated by the original statistical methodology.

The meaningful consideration in issuing emergency exemptions is not the number of days it takes to process a request, but how close the Agency comes to meeting the date of anticipated need. The purpose of the emergency exemption program has been served if the exemption is granted in time to allow effective resolution of the emergency situation. We believe that this program is effective.

[See GAO note 1, p. 85.]

We believe that the Guam example supports the notion that the Agency should indeed take sufficient time to ensure a fully informed decision, which avoids unjustified exemptions. After the "delay" period necessary to acquire all pertinent information, EPA, in conjunction with the Center for Disease Control, could not determine that an emergency existed within the terms of the regulations. Therefore, the Agency did not grant an unnecessary exemption, and did not allow the proliferation of 1080, a compound with potential for causing secondary poisoning and other adverse effects.

B. Unauthorized Agencies

GAO RECOMMENDATION: Specific exemptions should be granted only to authorized State and Federal agencies.

AGENCY COMMENTS: While the regulations governing the issuance of emergency exemptions specify that these exemptions are to be requested by the Governor or his designee, we have never solicited single designations of authorized agencies. While we generally assume that the State lead agency is a Governor's designee, the lead agency may not necessarily be the sole designee. In cases where an emergency actually existed, we have not quibbled over jurisdictions, but have worked with responsible State agencies to remedy the emergency situation. We feel that this policy has been effective and, in fact, in some circumstances works better than insisting on a single Governor s designee. For example, should the lead agency be the State Department of Agriculture or Pesticides Agency, and the emergency be a threat to public health, certain public health organizations would possess the expertise necessary to properly identify and judge the extent of the emergency condition. We are open to suggestions on this point and solicit GAO's guidance on the desirability of requesting that Governors designate a single agency or organization as authorized to request emergency exemptions.

We agree that, in the case of the toxaphene exemptions, the recipients may not have been "authorized" organizations. It was assumed at the time of issuance that these State organizations were authorized to receive exemptions. Since the time of those exemptions, measures have been taken to ensure that the State lead agency and the Regional office are always involved in applications for exemptions.

[See GAO note 1, p. 85.]

[See GAO note 1, p. 85.]

C. Noncompliance

GAO RECOMMENDATION: State and Federal agencies should be prevented from taking illegal crisis exemptions for suspended or canceled pesticides.

AGENCY COMMENT: Again, it does not seem sensible that EPA should be criticized for illegal use of pesticides under crisis exemptions taken by other agencies, as in the APHIS/carbaryl example. It is not immediately apparent exactly how this example illustrates GAO's allegation that EPA is not effectively administering emergency exemptions and that the American public may be unnecessarily exposed to pesticides known to be harmful. EPA denied the exemption in question. We agree with GAO that agencies taking illegal crisis exemptions should be censured, but question the remedial measures GAO has suggested. Revocation of crisis exemption authority would place in serious jeopardy the Federal/State relations that we and GAO are most concerned about.

D. Repeated Exemptions

GAO RECOMMENDATIONS: Pesticides necessary to control continuing predictable pest outbreaks should be registered.

AGENCY COMMENT: EPA has not "repeatedly" granted Federal and State agencies emergency exemptions to control continuing, predictable pest outbreaks unless those outbreaks constitute emergency situations within the terms of the regulations, and subject to the availability of and the opportunity to make available registered alternatives. Determination of the necessity for issuing an emergency exemption pursuant to Section 18 is based on the question of whether or not emergency conditions within the terms of the regulations exist. Such a determination is not predicated upon previous issuance of Section 18's in the same or similar circumstances, although that factor may be taken into account. If there has been the opportunity to register an alternative for the use for which an emergency exemption is requested, the exemption request will probably be denied. It must be recognized, however, that the opportunity to register alternative pesticides has been limited for some time due to problems being encountered in implementation of the 1975 Section 3 registration requirements. These difficulties have resulted in an escalation in the number of Section 18's being granted, a trend not likely to halt in the near future.

GAO recommends that pesticides necessary to control continuing predictable pest outbreaks be registered. We agree, and the registration to CDC for DDT for control of rabid bats is evidence that we are moving in that direction. We are willing to consider applications for pesticide use in similar situations.

E. Monitoring and Communications

GAO RECOMMENDATION: Applications under specific and crisis exemptions should be monitored, particularly those involving canceled or suspended pesticides; and communications between headquarters and Regions on exemption requests should be improved and regional input into the decision-making process should be obtained.

AGENCY COMMENTS: In situations where the emergency exemption application is deemed hazardous enough to warrant monitoring. monitoring is included as part of the emergency exemption order and assigned to a responsible State agency or other organization.

"Absence of adequate communication" has not affected the extent of monitoring. The number of permits monitored is a function of staffing, resources, and the need to monitor, not communication. Several Regions have commented on this point to the effect that they monitored what they originally intended to monitor; additional monitoring was not possible given resource constraints.

At this point in time, headquarters receives Regional input on every emergency exemption requested and informs the Regions and State agencies of all emergency exemption approvals. Although this intercourse may not be as well documented as GAO would like, the essential information exchange has and does take place. Undoubtedly, filing and documentation problems do exist, and could conceivably be perceived as lack of communication. We do have significant verbal, one-to-one communication; however, we recognize the need for better documentation of exchanges between headquarters and Regional offices.

F. Discipline

GAO RECOMMENDATION: Flagrant or repeated violators of exemption requirements should be prosecuted or their authority to request specific exemptions or to take crisis exemptions revoked.

AGENCY COMMENTS: GAO's recommendation to revoke certain agencies' authority to take crisis exemptions seems rather ill-considered in light of their emphasis on good Federal/State/Regional relations. First of all, revocation of crisis exemption authority is an extremely strong measure and could irreparably damage those relations.

We consider a better solution to be actions designed to inform the State of their obligations under law and regulations. EPA has no desire to penalize entire States due to poor judgment on the part of one of its agencies. We have found in the past that States and other agencies react favorably to constructive criticism and we do not see the pattern of repeated violations, except in the case of a very few organizations.

III. SECTION 24(c)

The purpose of a State registration is to allow registrations to meet a "special local need"; this may or may not involve a minor or specialty crop. Frequently the special local need is for a pesticide dosage rate change, a change in dilution rate, use of different application equipment or techniques, change in timing of applications, or many other minor changes necessitated by local conditions. These changes preclude using an EPA registered product as currently labeled.

A. Pesticides Which EPA Would Not Register

GAO RECOMMENDATION: States should not be permitted to register pesticides that EPA will not register.

AGENCY COMMENTS:

[See GAO note 1, p. 85.]

There is, as GAO points out, some inconsistency between actions taken under Section 24(c) and the lack of action taken under Section 3 in the case of applications involving rebuttable presumption against registration (RPAR) candidate chemicals or compounds under RPAR review (registration "moratoriums"). We are actively working to clarify the issue of registration of chemicals which are candidates

for, or are under, RPAR review. The concept of "conditional registration" included in the most recent proposed amendments to FIFRA is designed to deal with registration inconsistencies arising from failure to register products containing RPAR candidate chemicals, while previously registered products containing RPAR candidate chemicals may continue to be sold and used. Chemicals which are candidates for RPAR action would be eligible for conditional registration on an old chemical, new use basis if the new use is minor, a new pest for an old site for example, or a specialty crop use, and if significant additional exposure is not anticipated. The primary criterion for conditional registration would be clear evidence that such use would not result in incremental unreasonable adverse effects. Under such a conditional registration scheme, States would likewise be able to register RPAR candidates upon demonstrating that no incremental hazard would result. Section 3(c)(7)(C) of the proposed amendments to the FIFRA, recently passed by the Senate, reflect such a conditional registration scheme. Similar measures are to be considered by the House when Congress reconvenes.

B. Registration Authority Misused

GAO RECOMMENDATION: Upon EPA disapproval, use of State-registered pesticides violating provisions of the Pesticide Act should be discontinued immediately.

AGENCY COMMENTS:

[See GAO note 1, p. 85.]

APPENDIX II

It should be noted that there was never any intention to devote extensive resources to reviewing individual State registrations, and, in fact, such review would seem to go against the Congressional intent of the 24(c) provisions. Once a State has submitted and has had approved a State Plan for making 24(c) registrations, that State is regarded as being capable, within the terms of the approved plan, of making such registrations. EPA intends, within the next few months, to review the State plans and identify areas where the State review process may need upgrading. Once this increased review capability is established, our review of State registrations will serve solely an audit function.

C. Federal-State Relations

GAO RECOMMENDATION: States that intentionally or repeatedly violate their authority should be immediately penalized either by fines or suspension of their registration authority.

AGENCY COMMENTS: GAO asserts that the 24(c) regulations governing the issuance of special local needs registrations should be finalized, and that States which violate their 24(c) authority should be severely penalized. We agree that the finalization of 24(c) regulations is important. However, GAO's assertion that the lack of these regulations has resulted in a deterioration of Federal State relations is not, in our opinion, a sound one. States are naturally unhappy about being regulated by EPA at all. We feel that the interim certification program has been effective not only in permitting the States to register products in the absence of finalized regulations, but also in providing valuable information in modifying the proposed regulations to make them more workable.

On the one hand GAO recommends that we improve Federal/State relations; at the same time they sanction the severe measure of curtailing or suspending State authority under Section 24(c) as a penalty for infractions of that authority. We do not perceive deliberate State misuse of 24(c) to be a prevalent or pervasive problem. The sole precedent of this type of behavior available for scrutiny, the situation involving Tennessee, clearly indicates that such severe penalties are not advisable. Suspension of Tennessee's Section 24(c) authority was contemplated. The decision not to take such action has been vindicated by the subsequent exceptional operation of the Tennessee State program.

APPENDIX II

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

11 JUN 1977

OFFICE OF ENFORCEMENT

To: Malcolm S. Stringer
Director, Office of Audit PM-209

Subject: GAO Draft Report - "Opportunities for Improving EPA's Special Pesticide Registration Activities - EPA DOES NOT ADEQUATELY MONITOR EXPERIMENTAL PRODUCTS" (Page 14)

The principal findings in the report concerning pesticides enforcement are, (1) regions are not aware of all permits issued for experimental use within the region, (2) regions are not notified of the issuance of permits in time to inspect the use of the experimental pesticide, (3) priority for monitoring and inspection of experimental pesticides is not established, (4) regions do not have adequate plans for monitoring permits issued for use in several regions, and (5) regions do not maintain adequate records of experimental permit monitoring and inspection activities.

The Special Registration Section, Registration Division, Office of Pesticide Programs, is responsible for notifying regions of the issuance of permits and for establishing priorities for inspection of experimental pesticides where safety has not been established. The Office of Enforcement's Pesticides and Toxic Substances Enforcement Division personnel have met with personnel of the Special Registration Section and established a review procedure that should ensure that regions are promptly notified by them when permits are issued. The Pesticides and Toxic Substances Enforcement Division is working with the Special Registration Section in the development of procedures for setting priorities for permit monitoring.

Section 5 of the Pesticides Inspection Manual provides instructions for the regional offices to follow in deciding which permits to monitor when the experimental pesticide is being used in several regions. It also provides guidance on conducting inspections and submitting reports to the regional offices when permits are monitored. All records concerning experimental permit monitoring should be maintained in the regional offices.

Information received by the Office of Enforcement through the Agency formal reporting system did not reveal the deficiencies noted in the draft GAO report. Therefore, in order to ensure that priority permits are being monitored and that adequate coverage is given those permits we are initiating a comprehensive review of regional policies and procedures for experimental use monitoring, inspection, reporting and record keeping. Results of the review will be used to (1) assist the regions in planning, conducting and reporting permit monitoring and (2) in revising Agency guidance and manuals.

Stanley W. Legro

GAO note:

1. Deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

2. Page references in this appendix refer to our draft report and do not necessarily agree with this final report.

APPENDIX III

UNITED STATES DEPARTMENT OF AGRICULTURE
FOREST SERVICE
P.O. Box 2417
Washington, DC 20013

5200
Sep 15, 1977

Mr. Henry Eschwege
Director, Community and
Economic Development Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Eschwege:

We have reviewed your proposed report, "Opportunities for Improving EPA's Special Pesticide Registration Activities," including the review draft of Appendix I enclosed with Robert G. Chambers' August 12 letter to James L. Stewart. Comments prepared by the Animal and Plant Health Inspection Service were forwarded to you on July 14. Because they covered most of the important concerns in the main body of the report, we will confine our remarks to Chapter 3, the section on "Noncompliance with Exemption Program Requirement," and Appendix I.

Although the review draft of Appendix I does not reflect all the facts we have been attempting to point out to you in earlier discussions, we are glad to see the material on pages 61A and 64A. [See GAO note 1, p. 90.]
We are concerned about the "problem areas" (page 54) and the "Conclusions" (page 66). We believe your comments are due primarily to misunderstandings of how Douglas-fir tussock moth outbreaks occur and the rapidity of damage suffered when moth levels reach epidemic levels.

In our opinion, the report is wrong in implying or concluding that:

1. DDT was used unnecessarily.

2. Survey methods used to measure Douglas-fir tussock moth populations were inadequate.

3. Serious damage would not have occurred if the DDT treatments had not been applied because 1974 insect populations were declining at an unusually rapid rate.

4. It is possible to draw some inference about the insect population level in the total treatment area from the prespray efficacy plot data.

APPENDIX III

5. It was possible in some way to remeasure the precise insect population levels in the spring of 1974, just prior to treatment (within 3 days of treatment).

6. The 1974 effort towards development of DDT alternatives was inadequate.

Consequently, we believe the following information should be recognized in preparing the final report.

Individual outbreaks normally go through a 3-year cycle starting with a release phase the first year in which populations build up to epidemic proportions. Considerable damage is caused the second year when defoliation first becomes noticeable. Severe tree mortality is caused the third year just before the populations collapse from natural causes. Occasionally this collapse occurs in the second year. During 1973 and 1974, we had outbreaks in all three stages of development. The most ideal time to treat an outbreak with insecticides is early in the second year prior to heavy defoliation. Most of the area treated during 1974 was treated at the most opportune time. Only about 127,000 acres of the 482,000 acres treated had been defoliated to any noticeable degree in 1973. All areas were treated early enough in 1974 to prevent serious defoliation. Serious defoliation would have occurred if DDT had not been sprayed.

We do not concur that DDT was used unnecessarily. The implication that some areas were treated with DDT unnecessarily occurs on page 54, first "problem area" and the first paragraph under "Conclusions" on page 66. This same implication appears to be the basis for a number of other incorrect or misleading statements (third "problem area" on page 54, the entire section, "DDT Applied Unnecessarily," starting on page 58, the last paragraph on page 62, all of the material on page 63, the first three lines on page 64, and the first sentence on page 65). The objective of the control program was to protect the timber resource. Again, we believe that had DDT not been sprayed, serious damage would have occurred prior to natural collapse of the tussock moth population.

[See GAO note 2, p. 90.]

[See GAO note 2, p. 90.]

The last paragraph on page 59 also relates to the timing of insect population collapse. Although conclusions are not made in this paragraph, it could be inferred that a decline "to about 1/3 of their prespray levels--both below the U.S. Forest Service's action level" is significant. This type of decline is quite normal and was fully anticipated. The point again here is that in order to prevent serious damage, even during this short period of time, it was necessary to treat the areas with DDT.

Everyone predicted that the insect population would collapse on the areas to be treated in 1974. This usually occurs and it happened in the earlier outbreak areas during 1972 and 1973. Studies of earlier outbreaks also verified this prediction--at least in areas where visible damage has occurred during 1973 and in previous years. However, the timing of the collapse is the important element of concern. An insect population collapse does little good if most of the affected trees end up as severely damaged as they would have been without a collapse. Tussock moths can completely defoliate and kill trees in a few weeks' time. Population collapse usually occurs in the late larval development stages after this kind of damage has been done. Laboratory studies on egg viability and virus incidence indicated the collapse would not occur soon enough to prevent serious tree damage on a large number of areas recommended for control. This is why treatment was applied early in the year (when 70 percent of the egg masses had hatched).

We do not concur that our efforts in determining population levels were inadequate. The basis for most of the statements on population levels and decline are taken from Table 5 (page 24) of the "1974 Cooperative Douglas-Fir Tussock Moth Control Project" report.

We believe the authors of the proposed report should review the Entomological Evaluation, Section B, in the Appendix (page B-1 to B-200) of the USDA Forest Service 1974 Environmental Statement Cooperative Douglas-fir Tussock Moth Pest Management Plan. This document which was provided to you earlier explains in detail how decisions to treat individual areas were made. During the summer of 1973, Douglas-fir tussock moth damage was detected on 799,000 acres. An egg mass survey was made in the fall of 1973 to predict tussock moth population levels in 1974 and the need for treatment. This survey showed that tussock moth populations would be high enough in 1974 to cause additional serious damage on about 649,000 acres. Continuing evaluations during the winter and early spring months including a laboratory examination of insect egg viability and the presence of a natural virus disease reduced the area needing control to about 455,000 acres. Some 77,000 acres of this

APPENDIX III

were set aside for determining efficacy of the proposed treatments, research, and testing of other chemicals. During the on-the-ground insect population evaluations in early 1974, it was possible to delete another 106,000 acres from the recommended treatment program because of apparent low insect populations. However, it was necessary to treat an additional 155,000 acres because of new insect populations and defoliation that were discovered just prior to and during spray operations. The total area that was finally treated with DDT was just slightly more than the Environmental Statement estimate (408,000 acres).

At best, any attempt to use the prespray population data as an indication of actual population levels throughout the entire unit must take into account that these data were collected at the time of only 70 percent egg hatch.

[See GAO note 2, p. 90.]

We do not concur that benefits of using DDT were overestimated. The last outbreak collapsed at the end of the 1974 growing season. Most areas treated with DDT remained green and relatively undamaged as compared to affected areas that were not treated. If any error was made in estimating benefits from using DDT, we believe it was an underestimation. Because there was no existing data base on how much subsequent loss to bark beetles could be expected if tussock moth damage was not prevented, an estimate of this benefit was not included in the calculations. Salvage logging is now being conducted on an emergency basis in most of the untreated areas in an attempt to recover trees first defoliated by the tussock moth and subsequently killed by Douglas-fir bark beetles. In many cases this is the second logging entry, as the first efforts were limited in most cases to salvaging only trees killed or severely damaged by the tussock moth alone. The difference between treated and untreated areas in this regard is striking and plainly visible at this time,

APPENDIX III

particularly from low-flying aircraft. This was the first time in the history of treating tussock moth outbreaks that comparable untreated "check" areas were established to answer the question, "What will happen if the areas are not treated?" The massive damage in these areas exceeded all expectations.

Congress provided EPA with $250,000 to determine the impact of not being able to use DDT to control Douglas-fir tussock moth. We are currently engaged in a cooperative effort with them to make this determination. We tentatively plan to do this under contract with an organization that has the capability of pulling together all existing information into a composite package. The target date for completion is early 1979.

We do not concur that our effort to find alternatives to DDT were inadequate. The reasons for not being able to register alternative pesticides are many, the least of which was the declining moth population in some areas as stated in the second paragraph on page 60. One season's testing under the best circumstances would usually not be sufficient to generate enough data to satisfy registration needs. We suggest changing the sentence to read: "Because of declines in moth populations and the usual requirement of more than one year's data for registration, the U.S. Forest Service . . . ."

It is true that the population collapsed on some of the DDT alternative test areas before an effective test could be carried out. Because of the detailed planning and preparation work required to set up an adequate study area, it was not possible to move some of these tests to high insect population areas at the last minute. Although unfortunate from an experimental standpoint, it is completely erroneous to conclude that the insect population declines experienced in some of these areas were general in nature. It should be noted that some of these tests were quite successful; e.g., Acephate, Dimilin, and Sevin 4 Oil. A copy of a December 1976 article reprint from the Journal of Economic Entomology, "Field Evaluations of Acephate and Dimilin Against the Douglas-fir Tussock Moth" is enclosed. The high insect population levels present at the time in this area should be acknowledged. A copy of the Sevin 4 Oil test report, as it appeared in the April 1976 issue of the Journal of Economic Entomology, was sent to you earlier.

[See GAO note 2.]

Sincerely,

for JOHN R. MCGUIRE
Chief

Enclosure [See GAO note 3.]

GAO note:

1. Page references in this appendix refer to our draft report and do not necessarily agree with this final report.

2. Deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

3. The enclosure of this letter was considered in the preparation of our final report but has not been included.

APPENDIX IV

State of Tennessee
DEPARTMENT OF AGRICULTURE

ELLINGTON AGRICULTURAL CENTER
Box 40627, Melrose Station
Nashville, Tenn. 37204

Ray Blanton, *Governor*
Edward S. Porter, *Commissioner*

June 8, 1977

Mr. Henry Eschwege, Director
Community & Economic Development Division
U. S. General Accounting Office
Room 2434, Waterside Mall
401 M Street, S. W.
Washington, D. C. 20460

Dear Mr. Eschwege:

This letter is in response to your letter to Governor Ray Blanton as per his request.

We have the following comments on your draft, which was furnished us on May 20, of a proposed report to the Congress entitled "Opportunities for Improving EPA Special Pesticide Registration Activities." We note your comment that the parts of this draft which effect Tennessee are on pages 47-49 of this draft.

[See GAO note 1, p. 93.]

The following comments relate to Example 2, on page 48, where you are discussing a state, obviously Tennessee. EPA did not advise this State not to register Methyl Parathion for use in bird control, quite possibly for the reason that the possibility for registering this material was never discussed with EPA. When we appealed to EPA for help in an emergency situation that was causing a great deal of concern in this State, they did suggest the use of Tepp as well as Tergitol. At that time, litigation pending with reference to a proposed use of Tergitol in a military installation located partly in Tennessee and partly in Kentucky prevented us from securing this material. We had reservations about the use of Tepp because of its very high toxicity, and we were not at all sure that we could use the material safely. We did however, get in touch with the manufacturers of this compound to determine what data, if any, the manufacturers had as to the efficacy of the material for killing birds. We were told by the company that they had no data of a positive nature, and, as a matter of fact, the only data that they had was negative in that when securing a registration for the material in control of insects affecting hops, birds were caged in the hop fields prior to spraying with the material, and none of the cated birds were injured. This was hardly encouraging, and we decided to pursue other means.

Fenthion is used for bird control in some sections of the world, notably in Africa, and this Department had, together with the Fish and Wildlife Service of the Interior Department and the University of Tennessee, been a party to an experimental use

of Fenthion some ten years or so ago, in which the material showed some promise. It therefore was registered in conformity with the established laws and regulations but failed to perform, and the registration was cancelled. In this connection we strongly object to the use of the word "ultimately" in the sentence at the top of Page 49, of the draft, "the State Ultimately cancelled the registrations." The State registered Fenthion on January 28, and cancelled this registration on February 18. The registration for the product containing parathion was registered on February 9, and cancelled on February 23. In both cases the State cancelled the registrations, just as soon as the applications could be evaluated. We believe that this does not represent "ultimate" cancellation, but it does indicate about as prompt action as could reasonably be taken with any evaluation made of the treatment.

With reference to evaluation, we notice reference in the final paragraph on page 48, of the draft in which "subsequent surveys" are quoted to the effect that only 88 birds were killed in an "estimated" 10,800 square foot area. No information is furnished as to who may have made these surveys, whether or not it was an agency which was capable of making an evaluation, and certainly it does not represent an official evaluation of any of the agencys that were concerned in this application.

[See GAO note 2, p. 93.]

Further along on the same page, you comment that it is your belief that EPA's action in this case was insufficient for "what appears to be deliberate violations of state registration authority." I think that if you will consult EPA's legal staff they will also assure you that they tried very hard to find a violation under which they could proceed against this State, and they could find none. In other words, the actions of the agencies of this State were in accordance with the Law.

I would like to comment on one further factor with reference to 24-C. At the present time, the chemical manufacturers and formulators are finding that an application for a change in registration in addition of a use, or a site, or a crop requires so much time that they

APPENDIX IV

are putting intense pressure for the use of 24-C to satisfy very real needs involving in most instances several contiguous states. It was never intended that 24-C should serve as a vehicle for registrations of this nature and the states would not receive these requests if such requests were handled promptly by the Environmental Protection Agency. As it is, the companies and groups involved are turning to requests of this nature in desperation to get some kind of action.

Yours very truly,

Edward S. Porter

ESP:ma

GAO notes:

1. Page references in this appendix refer to our draft report and do not necessarily agree with this final report.

2. Deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

APPENDIX V

PRINCIPAL ENVIRONMENTAL PROTECTION AGENCY

OFFICIALS RESPONSIBLE FOR ACTIVITIES

DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
ADMINISTRATOR:		
Douglas M. Costle	Mar. 1977	Present
John R. Quarles, Jr. (acting)	Jan. 1977	Mar. 1977
Russell E. Train	Sept. 1973	Jan. 1977
John R. Quarles, Jr. (acting)	Aug. 1973	Sept. 1973
Robert W. Fri (acting)	Apr. 1973	Aug. 1973
William D. Ruckelshaus	Dec. 1970	Apr. 1973
ASSISTANT ADMINISTRATOR FOR WATER AND HAZARDOUS MATERIALS:		
Thomas C. Jorling	June 1977	Present
Andrew Briedenbach	Dec. 1975	June 1977
Andrew Briedenbach	Sept. 1975	Dec. 1975
James L. Agee	Aug. 1974	Sept. 1975
James L. Agee (acting)	Apr. 1974	Aug. 1974
ASSISTANT ADMINISTRATOR FOR HAZARDOUS MATERIALS CONTROL (note a):		
Charles L. Elkins (acting)	Oct. 1973	Apr. 1974
David D. Dominick	June 1971	Sept. 1973
DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDES PROGRAMS:		
Edwin L. Johnson	Mar. 1975	Present
Edwin L. Johnson (acting)	Dec. 1974	Mar. 1975
Henry J. Korp (acting)	Oct. 1974	Dec. 1974
Henry J. Korp	Dec. 1972	Oct. 1974

a/Before July 24, 1973, the title of this position was Assistant Administrator for Categorical Programs.

(087800)

Enclosure C

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

Stronger Enforcement Needed Against Misuse Of Pesticides

Programs enforcing Federal pesticide laws are key factors in making sure that the public and the environment are not unnecessarily exposed to hazardous pesticides. But these programs have not always been adequate. For example, the Environmental Protection Agency and the States do not always properly investigate cases and sometimes take questionable enforcement actions.

EPA and States also have problems with the special registration program. In some cases, State agencies may be circumventing pesticide laws.

EPA and States need to alleviate the problems that continue to plague the enforcement programs and improve their management to help ensure the public's protection.

CED-82-5
OCTOBER 15, 1981

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

B-200588

To the President of the Senate and the
Speaker of the House of Representatives

This report summarizes the results of our review of the Environmental Protection Agency (EPA) and State programs to enforce pesticide laws and suggest ways to improve program activities. Because of enforcement, management, and special registration problems, the public and the environment may not be fully protected from potentially harmful pesticides.

We reviewed EPA and State pesticide enforcement programs because pesticide enforcement is a key factor in assuring that the public and the environment are not unnecessarily exposed to hazardous pesticides. We also reviewed special pesticide registrations to determine if some of the problems we identified in an earlier report had been corrected.

Copies of this report are being sent to the Director, Office of Management and Budget; the Administrator, Environmental Protection Agency; the Secretary of Agriculture; the Secretary of Health and Human Services; interested congressional committees; Members of Congress; and other interested parties.

Milton J. Socolar

Acting Comptroller General
of the United States

D I G E S T

The benefits of pesticides to maintain and improve food and fiber production and protect the public health and welfare could be outweighed by their dangers if used improperly. (See p. 1.)

GAO reviewed Environmental Protection Agency (EPA) and State pesticide enforcement programs because they are the key factors in assuring that the public and the environment are not unnecessarily exposed to hazards. GAO also reviewed special pesticide registrations to determine if some of the problems identified in an earlier GAO report had been corrected.

Prior to 1978 EPA was responsible for enforcing the Federal Insecticide, Fungicide and Rodenticide Act by conducting investigations and taking enforcement actions. However, in that year the act was amended to give the States this lead responsibility. EPA still retains authority for enforcement action when States do not act expeditiously. EPA is also responsible for establishing enforcement guidelines, monitoring and evaluating the quality of State enforcement programs, and providing funding through State grants. GAO reviewed both EPA and State enforcement programs to determine the impact of increased State responsibility on program effectiveness. Although improvements have been made in recent years, GAO found that the public may not always be protected from pesticide misuse because EPA and the States

--sometimes take questionable enforcement actions against violators,

--have not implemented adequate program administration and monitoring, and

--are approving the use of pesticides for special local needs and emergency purposes which may be circumventing EPA's normal pesticide registration procedures.

LACK OF ADEQUATE ENFORCEMENT ACTIONS

EPA and State enforcement programs do not always protect the public and the environment because:

--Many enforcement actions are questionable or inconsistent. (See p. 9.)

--Some cases are poorly investigated. (See p. 12.)

--State lead agencies often do not share EPA's enforcement philosophy. (See p. 14.)

--Most States lack the ability to impose civil penalties. (See p. 15.)

GAO's review of 2,855 randomly selected cases for the period 1975 to 1980 at 6 EPA regions and 11 States disclosed questionable enforcement actions in 491 cases, or 17 percent (10 percent for EPA and 19 percent for the States). The extent of questionable actions ranged from 5 to 80 percent for the States visited. In these cases, States either took no action or chose enforcement actions which were minimal when compared to the severity of the violation. Furthermore, GAO noted instances of inconsistent enforcement actions among the States for similar violations. State enforcement actions improved, however, during the period 1978 to 1980. (See pp. 9 and 10.)

GAO's review also disclosed that 704 of the 2,855 cases, or 25 percent (8 percent for EPA and 29 percent for States), were not investigated according to generally accepted EPA and State criteria. The extent of inadequate investigations ranged from 3 to 90 percent for the States visited. However, during the period 1978 to 1980 the percentage of inadequate investigations was reduced. (See p. 12.)

Differences between EPA and the States regarding their enforcement approach may account for the less stringent actions taken by State inspectors. In most cases, Federal pesticide environmental laws are enforced by State departments of agriculture which have broad responsibility to promote increased farm productivity. Generally, States are more likely to resolve misuse cases by negotiating settlements between parties involved, rather than by taking enforcement action against violators. According to EPA officials, inspectors

should not consider negotiated settlements as substitutes for enforcement actions against violators because of their limited deterent impact on future misuse. (See p. 9.)

Most States are unable to assess civil penalties against violators, another reason deterring them from taking stronger enforcement action. While EPA has this option, few State agencies can administratively fine those who misuse pesticides. (See p. 15.)

While problems exist regarding the enforcement actions, some program benefits have been achieved. Most States have improved their pesticide laws, purchased new equipment to upgrade laboratories, hired additional staff, and conducted more inspections. (See p. 16.)

NEED TO IMPROVE PROGRAM ADMINISTRATION

EPA and the States have not developed adequate management information to document pesticide enforcement activities. In 8 of the 11 States visited, GAO found serious recordkeeping and reporting problems, such as incomplete identification and documentation of investigation files, inaccurate and inconsistent reporting of program accomplishments, and untimely submission of reports. GAO also noted similar recordkeeping problems at five of the six EPA regional offices visited. (See p. 20.)

EPA's monitoring of State programs to measure accomplishments has been limited and generally directed at administrative aspects rather than evaluations of the adequacy of enforcement actions. Without these evaluations EPA cannot determine whether State programs are adequately protecting the public from the dangers of pesticide misuse. (See p. 21.)

Need for better management controls over the pesticide enforcement program is illustrated by the lack of quick and effective processing of misuse cases referred between EPA and the States and between EPA and the Food and Drug Administration. Successful resolution of referral cases has been hindered by

--inadequate recordkeeping systems which have prevented identification of referral cases and evaluation of appropriateness of actions taken,

--the lack of followup actions by the referring agency to determine the status of investigations, and

--untimely enforcement actions. (See p. 22.)

According to EPA's Director of Pesticide Enforcement, the cause of many administrative problems is that EPA started the program with very little control and guidance.

In December 1980, however, EPA took action to require States to submit consistent information on program accomplishments. These new reporting requirements are a first step in providing a basis for evaluating the quality of enforcement actions. (See p. 24.)

CONTINUED PROBLEMS WITH SPECIAL PESTICIDE REGISTRATIONS

While pesticides must generally be registered by EPA before they can be used, Federal regulations allow the exemptions for (1) State registrations for special local needs, (2) experimental-use permits to develop new products or modify existing products, and (3) using unregistered pesticides for emergency use, such as for pest outbreaks. (See p. 3.)

However, pesticide manufacturers are submitting and EPA and the States are approving State pesticide registrations which may circumvent EPA's normal registration procedures and congressional intent. The Congress intended that these special registrations be limited to local problems. However, GAO identified four pesticides that were registered by 20 or more States for the same or very similar uses. Since the number of State registrations has increased significantly since 1975 and since EPA does not monitor this practice, the potential for adverse effects on the environment and human health and safety is increased. (See p. 28.)

EPA also continues to approve emergency pesticide exemptions to control repeated and predictable pest outbreaks in violation of EPA's own program guidance. The lack of an adequate

management system has prevented EPA from identifying repetitive requests for exemptions. (See p. 31.)

EPA and the States have not adequately monitored experimental use permits to ensure that experiments are conducted correctly and that the public is not unnecessarily exposed to potentially harmful pesticides. (See p. 32.)

RECOMMENDATIONS

The Administrator, EPA, should:

--Direct EPA regional office inspectors to emphasize the importance of conducting proper investigations and taking appropriate enforcement actions.

--Take action to help the States improve the quality of investigations and enforcement actions. This could include providing additional inspection and enforcement guidelines.

--Encourage passage of State laws to provide authority for assessing civil penalties.

The Commissioner, FDA, should:

--Improve management controls over referrals and strengthen coordination with EPA to help assure that investigations and enforcement actions are properly carried out. This could include requiring FDA to document pesticide misuse cases it refers to EPA and establishing a system to monitor the status of cases referred.

Additional recommendations are in chapter 3 (see p. 26) and chapter 4 (see p. 34).

AGENCY COMMENTS

EPA perceived that GAO was emphasizing the increased use of civil penalties as an enforcement tool. EPA stated that given the small size of available penalties, it is doubtful that increased emphasis on fines alone would materially alter the rate of compliance. Also, EPA stated that an effective enforcement program should not be merely punitive, but should emphasize compliance and voluntary corrective action.

GAO is not emphasizing the increased use of civil penalties but recommends that this enforcement option be available to States and used when appropriate. GAO agrees with EPA that an effective enforcement program should emphasize voluntary compliance and enforcement actions.

In general EPA and FDA agreed with the recommendations addressed to them. (See apps. III and IV.) Each state agency reviewed and generally agreed with the GAO summary of its program. (See app. II.)

Contents

ABBREVIATIONS

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
OMB	Office of Management and Budget
USDA	U.S. Department of Agriculture

CHAPTER 1

PESTICIDE USE AND REGULATION

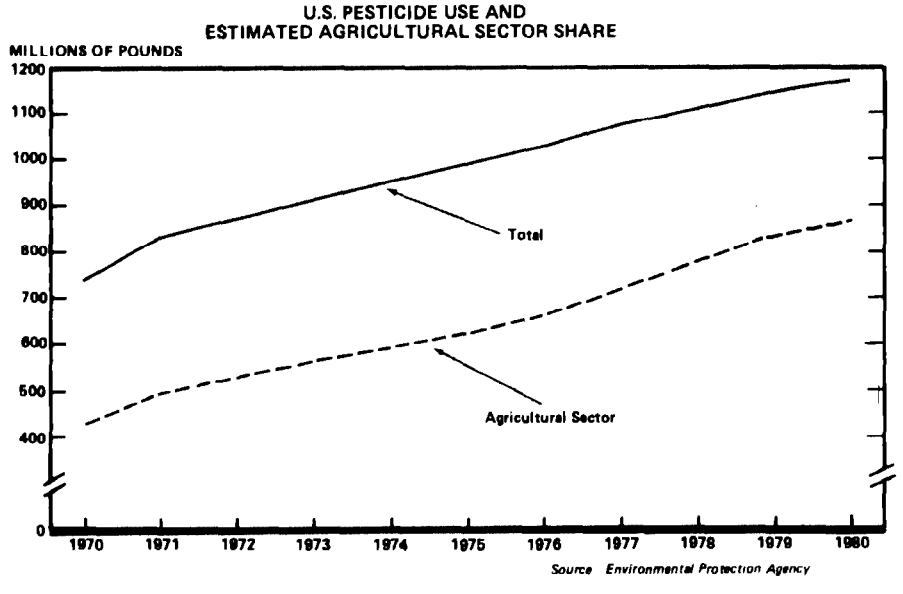
IN THE UNITED STATES

Pesticides have been used for many years to control insects, diseases, rodents, weeds, bacteria, and other pests that attack food and fiber supplies and threaten people's health and welfare. Although pesticides benefit agricultural production, public health, sanitation, and natural resources, they are a mixed blessing. If used improperly or without knowledge of their side effects, pesticides, like other chemicals, can poison, cause cancer and birth defects, and harm wildlife and the environment.

A major problem facing decisionmakers and the public is determining a balance between the damage pests do and the health and environmental problems and unknown risks pesticide use causes. 1/

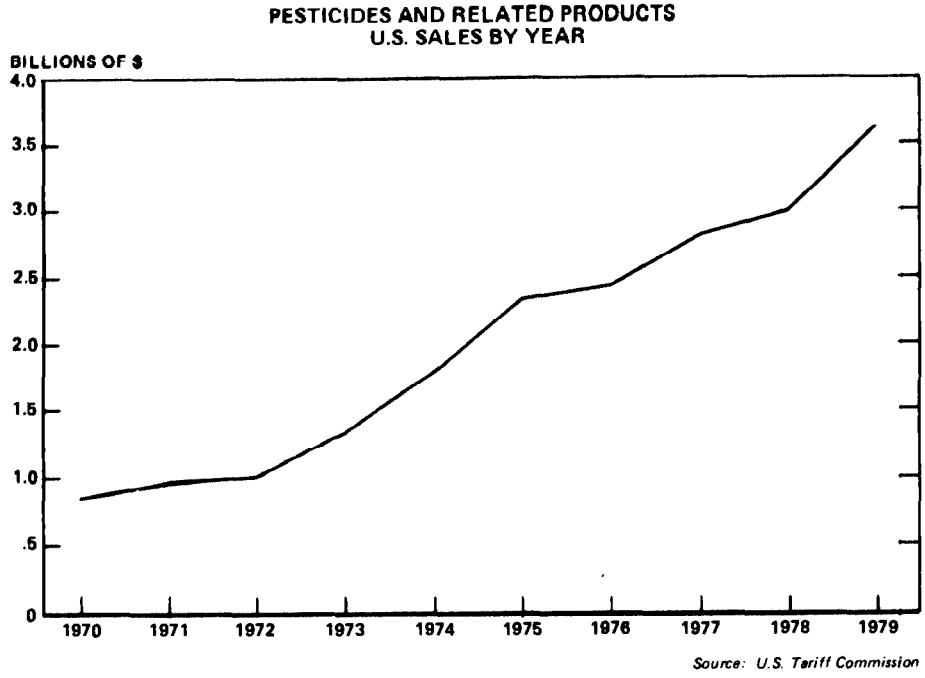
PESTICIDE USAGE

The domestic market for pesticides has increased dramatically as the Nation's agricultural sector increasingly depends on chemical pesticides to control crop damage. Although more than 1,200 chemicals are labeled for pesticide use and thousands for registered pesticide formulations, farmers currently use only a few. According to an October 1979 Office of Technology Assessment report, 43 major pesticides--17 herbicides, 20 insecticides, and 6 fungicides--account for more than 80 percent of all pesticides used. The following chart shows U.S. pesticide use and the agricultural sector's share.



1/GAO Report "Delays and Unresolved Issues Plague New Pesticide Protection Programs" (CED-80-32, Feb. 15, 1980)

The use of pesticides to control pests in homes, health facilities, food processing and service institutions, and other structures has also increased, according to the National Pest Control Association. Pesticides are also big business and, like pesticide usage, pesticide sales have increased dramatically.



PESTICIDE REGULATION

Pesticide regulation has been at the forefront of environmental concerns since the mid-1960's and has always involved much controversy and emotion. Pesticide regulation is particularly controversial because it affects many sectors of society. The agricultural community is very concerned about the potential impact of pesticide use cancellation and restriction on food and fiber production. Other user groups, particularly professional pest control operators, are concerned about removing tools they use to combat structural and disease-carrying pests. The pesticide-producing industry is concerned about the impact of registration requirements, cancellation actions, and expensive and time-consuming data requirements. Environmental groups are concerned about the adverse effects of pesticides in the environment, not only the potential human health effects but also the long-term, subtle residual effects. All groups are interested in enforcement and each has its own "enforcement philosophy" based on its concerns.

The Environmental Protection Agency (EPA) is the primary regulator of pesticides. Its authority is given in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.), and the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended (21 U.S. 301 et seq.). Under FIFRA, a

pesticide can generally not be sold, shipped, or delivered unless EPA has registered it. FIFRA further provides that EPA can unconditionally register a pesticide only if it determines, among other things, that the pesticide will perform its intended function without causing "* * * any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA also contains provisions which govern pesticide inspections, unlawful actions, and penalties.

While a pesticide generally must be registered by EPA before it can be used in the United States, FIFRA and its implementing regulations allow certain exceptions for using unregistered and previously canceled or suspended pesticides under specified conditions. These exceptions include:

--State registrations: Pesticides are registered by States for use and distribution only within the State to meet special local needs. State pesticide registrations have the same force and effect as EPA registrations.

--Experimental-use permits: Permits are granted to use pesticides for accumulating information necessary to (1) register a product not previously registered with EPA or (2) modify the use, application, crop, amount, or pest involved with a currently registered product. Permits are normally granted for 1-year periods.

--Emergency exemptions: Exemptions are granted to Federal or State agencies to use suspended, canceled, or unregistered pesticides in emergency situations where (1) pest outbreaks have occurred, or are about to occur, and effective registered pesticides are not available, (2) significant economic or health problems will occur without the use of pesticides, and (3) insufficient time exists from the discovery of a pest outbreak to register a pesticide to control the pest.

If a pesticide remains in or on food, FFDCA requires that pesticide manufacturers, or other petitioners, apply to EPA for a tolerance--the maximum residue allowed in or on food. EPA sets tolerances on the basis of data the petitioner submits on the nature, level, and toxicity of a pesticide's residue. This data, including the results of tests of the pesticide's effect on laboratory animals, such as mice, is similar to the types of data pesticide manufacturers must submit to EPA to register a pesticide.

The task of enforcing tolerances--generally by sampling food--belongs to the Food and Drug Administration (FDA) and the Department of Agriculture (USDA). FDA enforces tolerances on general food commodities while USDA handles meat and poultry tolerances.

Prior to EPA's creation in December 1970, USDA regulated pesticides and FDA granted tolerances. The shift in 1970 reflected, in part, congressional dissatisfaction with USDA's lack of enforcement because of its conflicting roles--promoting increased food production using pesticides while regulating and enforcing pesticides. However, as discussed in chapter 2 (see p. 14), State departments of agriculture are generally now responsible for pesticide enforcement.

STATES' ROLES

In recent years primary responsibility for pesticides enforcement has shifted from the Federal Government to the States, although most States have had pesticide laws and regulations for many years. In 1974 and 1975, EPA's Office of Enforcement started pilot State enforcement grant programs with six States to determine the feasibility of implementing an enforcement program in each State. States were required to conduct inspection activities that were previously handled by EPA investigators, and in return the State received a grant. Also, from 1975 through 1978, EPA pesticide enforcement budget requests were modified by the Office of Management and Budget (OMB) to increase funding levels and decrease authorized agency personnel. By curtailing EPA's capability to take direct actions, OMB created a strong incentive for EPA to enter into more State cooperative enforcement agreements.

In 1978, while the pilot program was ongoing, the Congress further amended FIFRA to give States lead responsibility for enforcing pesticide-use violations and legislatively created provisions for a State enforcement grant program. The law provides that the EPA Administrator may rescind the State's primary enforcement responsibility for pesticide use violations if the Administrator determines the program to be inadequate.

As of March 1981, most States were participating in the enforcement program. During fiscal year 1980, EPA gave these States about $8.7 million in grants to run their pesticide enforcement programs and estimates that it will give $7.9 million for 1981 and $8.7 million for 1982.

The following table shows the States 1/ that do not fully participate in the pesticide enforcement grant program.

1/The Trust Territories, Mariana Islands, Guam, and American Samoa do not receive specific enforcement grants. Instead they receive about $25,000 each year for general pesticide activity.

No primary enforcement authority 1/	Enforcement primacy but no EPA enforcement grant
Nebraska	Alabama
Colorado	South Carolina
Wyoming	Alaska
	Ohio

OBJECTIVE, SCOPE, AND METHODOLOGY

We reviewed the EPA Federal/State Pesticide Enforcement Grant Program because pesticide enforcement is a key factor in assuring that the public and the environment are not unnecessarily exposed to hazardous pesticides. While laws governing pesticides are important, the public and the environment will be protected from pesticides only if these laws are enforced. The assumption is that an energetic and strong enforcement program, fairly but firmly administered, is the best guarantee. An effective enforcement program will also generate a deterrent impact and contribute to less pesticide misuse.

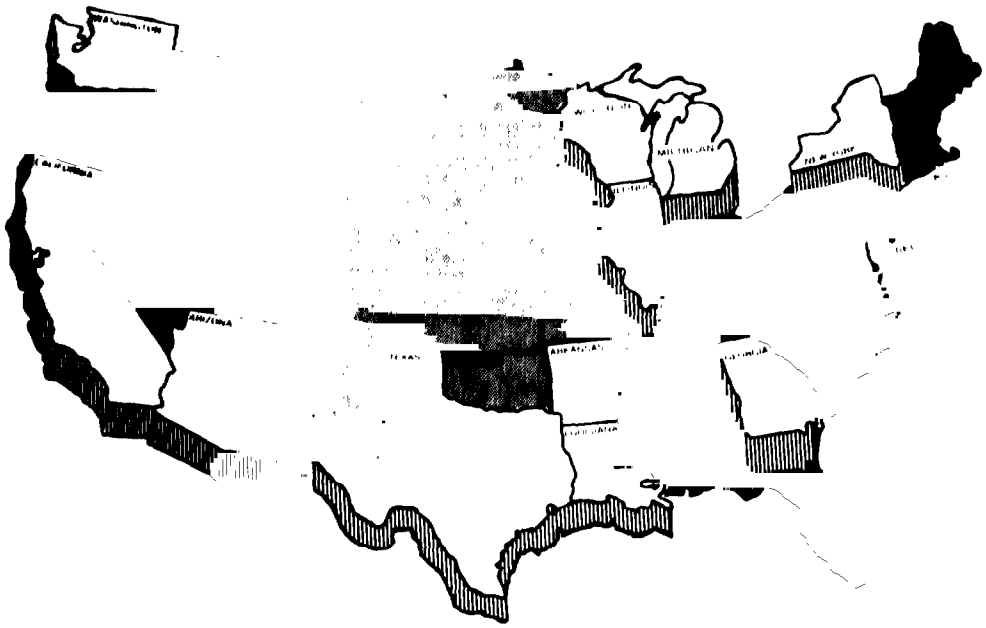
Since many State enforcement programs have been in existence for several years, we believed it was time to examine how well EPA and the States have adjusted to their new responsibilities. The basic objective of our work was to evaluate how well EPA and the States enforce pesticide laws. We also reviewed special pesticide registrations to determine if some of the problems we identified in our 1978 report 2/ had been corrected.

Our principal fieldwork was performed between August 1980 and February 1981. In making our selection of 11 States and six corresponding EPA regional offices, we included a representative mix of States participating in the enforcement grant program. The selection criteria included geographical dispersion and diversity in population, amount of pesticide usage, number of pesticide-producing establishments, number of farms, number of private and commercial applicators, amount of grants funds, size of migrant worker population, and lengths of time States participated in the enforcement program. EPA enforcement division officials agreed that our selection provided a representative sample of the program administration on the national level.

We performed our fieldwork at EPA headquarters; the 11 States shown below; and EPA regions 2, 4, 5, 6, 9, and 10:

1/In these States EPA is responsible for enforcing Federal pesticide laws.

2/"Special Pesticide Registration by the Environmental Protection Agency Should Be Improved" (CED-78-9, Jan. 9, 1978).



We also contacted officials at the Food and Drug Administration, Washington, D.C., to discuss their role in pesticide enforcement. We interviewed State and EPA program officials and reviewed and analyzed records covering enforcement actions, inspection correspondence, staffing, and grant expenditures. We also accompanied State inspectors during four pesticide use and misuse investigations and visited State laboratories that test for pesticide residues.

We reviewed and analyzed 2,855 randomly selected agricultural and nonagricultural enforcement cases out of 17,542 1/ for the 11 States 2/ and six EPA regions covering pesticide use, misuse, and complaints generally from fiscal year 1975 through September 1980. We also randomly selected and reviewed 207 of 239 EPA and State case referrals, plus 15 of 65 FDA referrals to EPA. We also reviewed a random sample of special pesticide registrations at the 11 States and selected cases at EPA headquarters. We did not review case files covering marketplace, producer, import/export, dealer, and applicator license inspections because violations for these categories generally represent a less serious threat and would have involved an inordinate amount of additional time.

1/Many records at EPA and the States were so poorly controlled and maintained that we were unable to be completely sure that our file counts were complete. However, these counts reflect the best available information at the time of our review.

2/In California and Texas, enforcement cases were decentralized to county and district levels, respectively. In California we reviewed cases in Los Angeles, Fresno, and Sutter Counties representing both agricultural and nonagricultural use and misuse cases. In Texas we reviewed cases in the Austin and Houston districts which represented most of the State's use/misuse cases.

Finally, we contacted numerous organizations, such as the American Farm Bureau Federation, the Environmental Defense Fund, the States FIFRA Issues Research and Evaluation Group, the National Agricultural Aviation Association, the National Agricultural Chemicals Association, the Chemical Manufacturers Association, and the National Pest Control Association, Inc., for their opinions regarding the pesticide enforcement program and special registrations.

Since the early 1970's we have issued several reports on pesticides. Appendix I lists these reports. Appendix II contains a brief overview of the State programs and activities we reviewed as well as State officials' comments on the sections.

CHAPTER 2

EPA AND STATE PESTICIDE ENFORCEMENT PROGRAMS DO NOT FULLY PROTECT THE PUBLIC AND THE ENVIRONMENT

EPA and State pesticide enforcement programs do not always ensure that adequate enforcement actions are taken against pesticide violators. While laws governing pesticide use are important, they must be enforced to ensure that the public and the environment are protected from pesticides misuse. Although improvements have been made in recent years to enforce the laws, EPA and State enforcement programs have not always fully protected the public and the environment because

--many EPA and State pesticide enforcement actions are questionable or inconsistent,

--some cases are poorly investigated,

--State lead agencies often do not share EPA's enforcement philosophy, and

--most States lack the ability to impose civil penalties.

However, some pesticide enforcement program benefits have been achieved, such as strengthening State pesticide laws, purchasing new equipment, hiring additional staff, and increasing the total number of pesticide inspections and enforcement actions.

PESTICIDE INSPECTIONS--OBJECTIVES, CRITERIA, AND ENFORCEMENT OPTIONS

Generally, pesticide inspections are initiated as a result of complaints from the public or as part of the State's normal responsibility to monitor pesticide use. The objectives of inspections may include one or more of the following:

--To investigate and document an alleged pesticide misuse.

--To develop information on pesticide application practices.

--To determine whether pesticides are used according to label directions.

--To determine whether applicators properly maintain, store, and dispose of pesticides.

According to EPA and State officials, pesticide violations are generally analyzed on a case-by-case basis. However, officials identified both formal and informal criteria which are used in reviewing cases to ensure that proper enforcement is taken. For example, guidelines on investigations are contained in EPA's inspector and pesticide policy manuals. Also, the

following informal criteria include some important factors in deciding how severe enforcement actions should be:

--Exposure to humans, animals, and the environment.

--Toxicity and persistence of the pesticide.

--Intent of the pesticide applicator (for example, deliberate versus accidental misuse).

--Amount of evidence developed by the inspector.

--Economic impact of the damages sustained.

--Prior offenses.

If the inspector determines through an investigation that a violation has occurred and that an enforcement action is justified, the following civil and criminal options (ranked from the least to most severe) are generally available to State agencies.

--Informal verbal warning.

--Warning letter.

--Informal or formal hearing with State officials.

--Assessment of fines (not available in many States).

--Suspension or revocation of license or certification.

--Criminal prosecution.

EPA has basically the same options but is also able to administratively fine violators.

As part of their investigations, inspectors may identify the extent of damages sustained by the injured party as a result of pesticide misuse, and the parties involved may agree to a damage settlement. States are more likely to negotiate settlements than take enforcement actions against violators. According to EPA headquarters officials, inspectors should not generally consider negotiated settlements as substitutes for enforcement actions against violators because the settlements have limited deterrent impact on future misuse.

MANY PESTICIDE ENFORCEMENT ACTIONS ARE QUESTIONABLE OR INCONSISTENT

Our analysis of 2,855 randomly selected cases showed that EPA and State officials took questionable enforcement actions in 491, or 17 percent, of the cases reviewed for the period 1975 to 1980.

We considered an enforcement action to be questionable if no action was taken in response to a violation or if only a warning letter was issued in a case involving a serious violation. We discussed examples of these questionable actions with State and EPA regional officials, and they generally agreed with our results.

The number of questionable actions varied between the EPA regions and the States; EPA had 10 percent and the States 19 percent. Questionable actions also varied among the States, ranging from a high of 80 percent to a low of 5 percent.

We noted that State enforcement actions improved during the period 1978 to 1980 when compared to the period 1975 through 1977. The percentage of questionable enforcement actions was reduced to 16 percent compared to 32 percent in the earlier period. However, percentages varied among States.

The following cases describe some examples of EPA and State enforcement actions we believe were questionable.

--In May 1979 a person filed a damage report in Washington, contending that 25 acres of his pea field had been damaged by an aerial application of 2,4-D pesticide to an adjacent wheat field. The State inspector gathered samples of the damaged pea vines and pods, which after laboratory analysis showed symptoms of 2,4-D damage. In addition, he observed the damage to the pea field in relation to the adjacent wheat field and concluded that the 2,4-D had drifted. The inspector reported that an economic loss would result. He determined that the aerial application company should be responsible for the damages. The inspector indicated that no regulatory action was necessary and none was taken because the complainant and the company were going to work it out. We question whether getting the parties together without any enforcement action is an effective deterrent to future misuse. State enforcement officials agreed that some type of enforcement action should have been taken.

--During an October 1979 inspection of an aerial applicator's pesticide operation, Georgia inspectors noted improper pesticide loading and storage procedures that could cause serious human and environmental problems. In addition, drainage from the operation was going into a ditch next to a school and playground. At the time of the inspection the owner indicated that he would take measures to correct the problems. State officials issued a warning letter. In June 1980, during a followup investigation, a State inspector found the same serious problems. Again the State issued a warning letter. We question whether a second warning letter was appropriate based on the seriousness of the violation. State enforcement officials agreed

but said that instead of taking a stronger enforcement action, they requested the Georgia Department of Natural Resources to help the operator correct the problem.

--In March 1976 a person complained to EPA region 5 that the wells on his property were contaminated after a termite treatment. EPA conducted an investigation and determined that chlordane and other pesticides were applied beneath the basement floor and foundation walls of his house, but the applicators did not notice the wells on the property. Subsequent water sample analysis showed pesticide residues in the well water. No enforcement action was taken by EPA. We believe that the applicator could have been more careful in applying the pesticides and that an enforcement action should have been taken. EPA regional officials agreed.

During our analysis, we observed inconsistent enforcement actions on similar cases.

--In Arizona an aircraft performing an aerial spray application allegedly flew over the parking lot of a school in October 1979. Despite the allegation, we found no evidence that an investigation had been performed. In California a similar incident of pesticide spray drifting onto school grounds in January 1979 resulted in a full investigation and a subsequent administrative hearing in which the applicator pleaded guilty to several violations. The enforcement action required the applicator to obtain a job permit for each application of restricted material, as well as requiring each application to be under the direct supervision of county agricultural commission personnel.

--In May 1979 a homeowner complained to Texas officials that his house was contaminated and that he and his wife had become ill with headaches, lung problems, and rashes after a pest control operator had drilled a hole in their heating unit and pumped in a pesticide. The State's investigation disclosed that the hole had penetrated the air duct, which allowed the pesticide to be dispersed throughout the complainant's house. Discussions with the operator revealed that he had used 20 to 30 gallons of chlordane, which is not to be used inside homes. The State took no enforcement action against the operator for pesticide misuse because it considered this situation an honest mistake. It did advise the operator to report the incident to his insurance company.

--In a similar case, a homeowner complained to Louisiana officials in August 1979 that a pest control operator had treated her attic with a chemical to kill swarming termites. The chemical had soaked through the ceiling onto the floor

and made the homeowner ill. The agency took several samples and all showed the presence of chlordane and heptachlor. The application occurred in late April 1979, and the homeowner complained about her health problems to the operator in May 1979. The operator obtained accommodations for the homeowner at a local motel for 4 weeks while the operator completely renovated the interior of her house to remove pesticide contamination. The State's investigation documented that the operator had used the pesticides inconsistently with the label and the operator's termite control license was suspended for 45 days.

The above inconsistent and questionable enforcement actions did not create an effective deterrent impact to ensure that the public and the environment were adequately protected from pesticide misuse. Also, according to EPA's Deputy Assistant Administrator for pesticide programs, weak State enforcement programs could mean that EPA might be forced to cancel certain pesticide uses to ensure that products are not causing problems.

IMPROVEMENTS ARE NEEDED IN INVESTIGATING PESTICIDE MISUSE CASES

According to EPA and State officials, inspectors should take certain basic steps when investigating pesticide complaints, including

--interviewing all parties involved,

--visually inspecting the damage,

--taking samples for laboratory analysis if needed,

--reviewing pesticide application records, and

--completing an investigation report documenting the pertinent facts of the case.

These basic inspector activities--questioning, observing, and sampling--take on great importance with respect to their value as elements of proof, admission as evidence, and the eventual enforcement action. Yet, some cases we reviewed had been poorly conducted according to the above criteria. For example, inspectors failed to cover the basic requirements of a proper investigation in 44 cases, or 8 percent, of the 543 EPA investigations we reviewed from 1975 to 1980, compared with 660 cases, or 29 percent, of the 2,312 State investigations. The extent of inadequate investigations for the States ranged from 3 to 90 percent.

When a case is not properly investigated, necessary evidence is lacking and enforcement officials may not be able to take the appropriate enforcement action.

However, State investigations improved during the period 1978 to 1980 when compared to the period 1975 through 1977. The percentage of inadequate investigations was reduced to 24 percent compared to 46 percent in the earlier period. However, percentages varied among States.

In responding to our findings, EPA and State officials stated that in some cases adequate investigations were conducted and enforcement actions were taken, but the supporting documentation was not always prepared and placed in the case files. Chapter 3 discusses case file documentation and reporting problems.

The following cases show examples of poorly conducted EPA and State investigations.

--On September 26, 1979, Texas officials received a complaint from a schoolteacher stating that school personnel had been exposed to a pesticide in several classrooms. The teacher had cleaned the rooms before the students arrived but was concerned about the pesticide's possible effects on the students. State investigators conducted a 1-day investigation which consisted of interviewing the school principal. The principal assured the inspector that the situation had been taken care of and would not happen again. The principal told the inspector that other agencies (not identified) had investigated the matter 2 weeks before and that there was no need for further investigation. The inspector took no samples or photographs and took no enforcement action. The file contained no evidence that the inspector had contacted the other agencies to determine the extent of their investigations and plans for enforcement action.

--In June 1979 EPA region 5 officials conducted an inspection to ensure that a pesticide was used properly. The EPA inspector examined the site and talked to the landowner. However, the use inspection was conducted 2 months after the pesticide was applied. According to EPA policy, inspections of pesticide uses should be made during or immediately following the actual application.

--In August 1977 tenants complained of becoming ill after their apartment complex had been sprayed with a pesticide. EPA region 4 inspectors determined that the apartment owner's son had applied pesticides to dishes and food in the apartments. The case file included no inspector's report and no evidence of whether the applicator was certified or whether samples had been taken to determine what pesticide had been used. No enforcement action was taken.

--In May 1980 a farmer complained to Louisiana officials that his crops had been damaged by herbicides. The State investigated and found pesticide damage. The investigation appeared to center around estimating the value of the pesticide damage, rather than on determining who had caused the damage.

The State concluded its investigation in November 1980 with a report valuing the damage at $702.50. No evidence in the State's records showed that the investigators had taken samples for laboratory analysis or had contacted any suspected violators. The State took no enforcement action.

STATE LEAD AGENCIES OFTEN DO NOT SHARE EPA's PESTICIDE ENFORCEMENT PHILOSOPHY

Pesticide enforcement responsibility appears to have come full circle. It has shifted from USDA to EPA to State departments of agriculture. 1/ FIFRA and its legislative history do not indicate which State agencies the Congress intended would enforce Federal pesticide law. However, since the Congress was aware that most State pesticide regulation was exercised by State departments of agriculture, the Congress' silence on the issue suggests it did not object to Federal environmental law being enforced by State agricultural agencies.

Philosophical differences and occasional conflicts exist among EPA and State lead agencies in their approach to pest management and pesticide enforcement. Like USDA, State departments of agriculture have broad responsibility to promote increased farm production. As State lead agencies for agriculture, departments of agriculture are concerned with the ability of farmers and growers to produce adequate supplies of food and fiber in the most efficient and economical manner. While State departments of agriculture are also concerned with the environment, their top priority in pest management is to ensure that their programs offer farmers and growers adequate protection against pest damage at a reasonable cost.

EPA's involvement in pest management, on the other hand, stems from its overall responsibility to protect the quality of the environment by regulating environmental and public health hazards. EPA officials believe strong enforcement is a deterrent to future misuse while States prefer to handle violations through voluntary compliance and education. According to State officials,

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1/The following States are those where the lead agency is not the State department of agriculture:

--Connecticut, Department of Environmental Protection.
--District of Columbia, Department of Environmental Services.
--Indiana, State Chemist.
--New Jersey, Department of Environmental Protection.
--New York, Department of Environmental Conservation.
--Virgin Islands, Department of Conservation and Cultural Affairs.
--Kentucky, Department of Natural Resources and Environmental Protection.
--Rhode Island, Department of Environmental Management.

they must be more sensitive to local politics than EPA would be if it were the principal enforcement authority. Both EPA and State officials stated that the biggest issue in pesticide regulation is their different enforcement philosophies.

STATES LACK ABILITY TO IMPOSE CIVIL PENALTIES FOR PESTICIDE MISUSE

One of the primary distinctions between Federal and State enforcement options is the ability of EPA to assess civil penalties. 1/ Unlike EPA, few States are able to administratively fine pesticide violators. Only 2 of the 11 States in our review are able to assess civil penalties for pesticide misuse.

In the legislative history of FIFRA that granted EPA civil penalty authority, the Congress recognized the benefits of this enforcement option. According to Senate Report 92-838,

> "Civil penalty provisions are considered a necessary part of a regulatory program such as pesticides control. While the criminal provisions may be used where circumstances warrant, the flexibility of having civil remedies available provides an appropriate means of enforcement without subjecting a person to criminal sanctions".

Although most States have had pesticide laws for many years and have amended their legislation to conform to FIFRA, few have added provisions to assess civil penalties. According to EPA officials, the inability to assess civil penalties places States in a dilemma. States are faced with either issuing warning letters (a relatively weak action) or initiating criminal proceedings (a very serious approach). According to most State officials, local district attorneys are reluctant to initiate criminal actions since they consider pesticide prosecutions to be a low priority and, in many cases, not in their political reelection interests.

While many States lack civil penalty authority and are reluctant to initiate criminal actions, many are able to suspend or revoke applicator and dealer licenses. However, State officials consider these enforcement options more stringent than assessing a civil penalty and are sometimes reluctant to take these actions. In New York and Georgia--two States where civil fines are issued for pesticide misuse--State enforcement officials told us that the use of civil penalties is an effective enforcement tool because it gives them flexibility in choosing the appropriate enforcement option. Civil penalties also help the State gain compliance with pesticide laws.

1/Civil penalties are administrative fines assessed by an agency without involving the court system.

According to a December 1979 EPA consultant's report, 1/ EPA regional personnel felt that while some States were beginning to take more enforcement actions, on the whole, such actions were not stringent enough and were at least one or two levels lower than Federal actions would have been for comparable pesticide violations.

SOME PROGRAM BENEFITS HAVE BEEN ACHIEVED

While problems exist regarding the quality of investigations and enforcement actions, EPA grants to States have resulted in the following improvements.

--Better pesticide laws. In order to obtain enforcement grants, most States had to pass legislation to make their laws conform to FIFRA. This resulted in additional and stronger enforcement authority over pesticide use. For example, new laws provided States with the authority to inspect producer establishments and pesticide products sold in the marketplace.

--Purchase of new equipment. Most States have used a large portion of their grants to purchase equipment to improve inspection capabilities and administrative controls. Capital items acquired included laboratory analysis equipment, computers and related programs, office equipment, and automobiles.

--Hiring of additional staff. Many States hired new staff to increase the capacity of their inspection and laboratory and administrative staffs. New hires included field inspectors (not all work full time on the pesticide program), chemists, and clerical support staff.

--Increased enforcement activities. The 1978 shift in pesticide enforcement responsibility to the States has contributed to the increase in investigations and enforcement actions. From 1977 to 1979, State pesticide investigations increased from 1,131 to 7,390, while enforcement actions increased from 561 to 2,650. For some States with ongoing enforcement programs, only a portion of this increase is attributable to the shift to the States, while in other States enforcement programs were virtually nonexistent before enforcement grants were initiated. Furthermore, the grants have allowed States to cover a much larger pesticide user population.

1/"Field Survey of EPA's Federal/State Cooperative Pesticide Enforcement Grant Program." Messer Associates, Inc., December 7, 1979.

--Improved EPA and State relations. An outgrowth of the grant program has been the establishment of the States FIFRA Issues Research and Evaluation Group, which provides a means for EPA and State officials to freely exchange ideas on proposed FIFRA regulations and other issues affecting the States.

CONCLUSIONS

The U.S. population is exposed to a wide variety of chemical contaminamts, including pesticides, for which the long-term health effects and possible chemical interactions are unknown. The Congress has passed legislation to provide protection against pesticide misuse. An energetic and strong enforcement program, fairly but firmly administered, is the best guarantee that the public and the environment are protected from pesticide misuse.

Our evaluation of EPA and State pesticide enforcement programs disclosed that although improvements have been made in recent years, these programs do not always ensure that adequate enforcement actions are taken against pesticide violators. In many cases, EPA and State officials either took no action or took minimum action when compared with the severity of the violation. Furthermore, we noted instances where enforcement actions lacked consistency.

Various factors have contributed to the number of questionable enforcement actions, including

--instances of poorly investigated cases,

--the fact that State agencies often do not share EPA's enforcement philosophy, and

--the inability of States to assess civil penalties against violators.

Program benefits have been achieved as a result of EPA grants to the States. Generally, States have improved their programs by passing new laws and strengthening existing ones, purchasing new equipment, and hiring additional staff. Furthermore, the shift in pesticide enforcement responsibility to the States has contributed to increased investigations and enforcement actions.

RECOMMENDATIONS

To improve the effectiveness of the pesticide enforcement program, we recommend that the Administrator, EPA:

--Direct EPA regional office inspectors to emphasize the importance of conducting proper investigations and taking appropriate enforcement actions.

--Take action to help the States improve the quality of investigations and enforcement actions. This could include providing additional inspection and enforcement guidelines.

--Encourage the passage of State laws which provide authority for assessing civil penalties. This could include an outreach effort through the EPA regions with letters to State Governors and key legislators.

AGENCY COMMENTS AND OUR EVALUATION

EPA agreed with our recommendation to emphasize the importance of conducting proper investigations and taking appropriate enforcement actions. It said its recent reviews of regional program operations support our recommendation for more thorough investigations in a number of the regions and States. EPA has made specific recommendations to the regions to improve deficiencies in implementing the EPA and State pesticide enforcement program. These recommendations include

--the need to follow all required inspection procedures,

--more thorough documentation of suspected violations, and

--the need for more immediate and thorough supervisory review of inspection reports to ensure completeness.

EPA said that it had taken efforts to improve training and would provide each State with specific additional training designed to solve any problems identified during scheduled program evaluations.

In commenting on our recommendation to encourage the passage of State laws, EPA noted that before entering into an enforcement agreement, EPA determined that the State appeared to have adequate legal authority to ensure a successful enforcement program. Some States, it said, may find after several years that they need additional authority to assess civil penalties. EPA would assist any State in preparing a request to its legislature; however, it is not EPA's policy to dictate the need for such authority to the States. EPA perceived that we are emphasizing the increased use of civil penalties as an enforcement tool. EPA stated that, given the small size of available penalties, it is doubtful that increased emphasis on fines alone would materially alter the rate of compliance. Compliance rate, not dollars collected, is the measure of the success of any regulatory program, according to EPA. EPA also stated that an effective enforcement program should not be merely punitive, but should emphasize baseline compliance and voluntary corrective actions. Awareness on the part of regulated parties that EPA can and will monitor them will encourage good faith efforts to voluntarily comply with the law.

Our recommendation neither stated nor intended that EPA should dictate to the States the need for civil penalty authority. EPA should, however, inform the States that it is ready to assist

them. Also, we are not advocating the increased use of civil penalties but think this enforcement option should be available to the States and used when appropriate. We agree with EPA that an effective enforcement program should emphasize voluntary compliance and enforcement action.

CHAPTER 3

EPA AND STATES NEED TO IMPROVE PESTICIDE ENFORCEMENT PROGRAM ADMINISTRATION

EPA and the States have not developed adequate management information to document the results of the pesticide enforcement program. Program records and reports lack data on the quality of enforcement activities and are plagued with inaccurate, incomplete, and inconsistent information. EPA has recognized the need for better management information and has recently implemented new reporting requirements. EPA's monitoring of State programs to measure accomplishments has been limited. Finally, EPA, the States, and FDA have not established adequate management controls over pesticide enforcement cases referred between the agencies. As a result, EPA cannot readily evaluate the effectiveness of the program in meeting its main goal of protecting the public and the environment from improper pesticide use.

PESTICIDE ENFORCEMENT RECORDS AND REPORTING SYSTEMS NEED IMPROVEMENT

EPA has established various reporting mechanisms in an attempt to provide some indication of State program effectiveness. However, much of the data required by EPA provides only a quantitative rather than qualitative measure. For example, in most States information was not organized or maintained to document the quality of enforcement activites and actions or to report such efforts to EPA.

Compounding the problem, EPA had not established uniform reporting requirements for the States, and many States had not provided reliable, timely, and consistent input. In 8 of the 11 States we visited, we found recordkeeping and reporting problems, including the lack of filing systems to identify case files, incomplete documentation in investigative files, untimely submission of reports, and inaccurate and inconsistent reporting of program accomplishments. According to EPA's Director of Pesticides and Toxic Substances Enforcement Division, the cause of many of the pesticide enforcement program's administrative problems is that EPA started the program with very little control and guidance. EPA is now starting to establish more controls and procedures to better administer the program.

The following examples highlight the extent of the record and reporting problems.

--In Illinois, agency officials had no filing system before 1980 to identify pesticide misuse investigations.

--In Wisconsin, some case files consisted only of a warning letter issued by an inspector and had no documentation of the inspection itself.

--New York was submitting monthly reports to the EPA regional office about 60 to 80 days late. In EPA region 5, late State submission of reports required EPA officials to obtain State monthly information over the telephone and prepare the report forms themselves.

--Arkansas' grant activities for fiscal years 1979 and 1980 were inaccurately reported to the EPA regional office. Only 461 inspections of the 580 reported could be documented from State records.

--Louisiana reported the number of aerial applicators certified and the number of aircraft inspected as the number of certified applicator records inspected in fiscal year 1980.

--Texas overstated the number of agricultural pesticide misuse investigations reported during fiscal years 1978 to 1980 because it counted the number of different site visits or trips investigators made during their investigations rather than the number of separate and distinct complaint investigations conducted.

--EPA regional requirements to review State pesticide misuse cases varied considerably depending on the EPA regional office involved. For example, all State enforcement case files were submitted to EPA region 2 for review; only selected files were submitted to region 10; and in region 5, States provided no files at all.

We also identified similar recordkeeping problems at five of the six EPA regional offices we visited. For example, records in region 2 were haphazard and disorganized. Pesticide enforcement files received from the States were bound together and randomly stacked on tables and desks, which prevented orderly retrieval of needed case files. In region 6, enforcement files were in disarray and many did not adquately document the final disposition of a case.

INDEPTH MONITORING IS NEEDED

EPA headquarters guidance requires that regional staffs meet with State personnel at least twice a year to review and evaluate the grant programs. More specifically, the guidelines require both a midyear evaluation (during the seventh month of each grant year) to assess program accomplishments and identify problem areas and areas needing improvement, and an end-of-year review within 30 days after the end of the grant year to review accomplishments and establish future goals. The regional offices are required to prepare a written report documenting each visit.

Given the inaccurate, incomplete, and inconsistent program information, EPA must rely heavily on onsite monitoring to evaluate State programs. However, this monitoring has not provided the type of information needed to evaluate whether State programs

are adequately protecting the public from the dangers associated with pesticide use. In a June 1980 program study, EPA headquarters concluded that while onsite monitoring was a potentially excellent management tool, improvements were needed because

--the lack of uniform standards for conducting these evaluations resulted in a lack of consistency between the regional offices,

--monitoring consisted primarily of comparisons of projected grant activities with activities actually performed, and

--evaluation of the quality of the programs was minimal.

Our review of monitoring activities conducted by EPA staff in the six regions generally confirmed EPA's observations. The midyear reviews usually took about 1 day, whereas the end-of-year evaluations required 2 to 3 days. The scope of these visits varied but was generally directed at administrative aspects and comparisons of grant commitments and accomplishments. There was little emphasis on evaluating the adequacy of State enforcement actions. Furthermore, EPA staff in three of six regional offices did not prepare written reports of their onsite visits as required by headquarters guidance.

NEED FOR IMPROVED MANAGEMENT CONTROLS OVER REFERRED CASES

Section 27(a) of FIFRA requires EPA to refer to the States any information regarding significant violations of pesticide use laws. If a State has not started an appropriate enforcement action within 30 days, EPA may investigate the matter. States may also refer cases to EPA when enforcement action at the Federal level would be more appropriate or effective.

In addition to referrals between EPA and the States, information on potential violations may also be referred to EPA from FDA, which is responsible for monitoring pesticide residues on general food commodities.

EPA, the States, and FDA need to establish management controls over referred pesticide enforcement cases to ensure that investigations are timely and that adequate enforcement actions are taken. Successful resolution of referral cases has been hindered by

--poor agency recordkeeping systems which have prevented the identification of referral cases and the evaluation of the appropriateness of actions taken,

--the lack of followup actions by the referring agency to determine the status of the investigations, and

--the lack of timely enforcement actions.

Referrals between EPA and the States

Documentation of referral cases in 9 of the 11 States and five of the six EPA regional offices was so inadequate that it was difficult, and sometimes impossible, to identify the cases involved and the extent of enforcement actions taken. For example, in region 6, referrals to States were made over the telephone and not recorded. In region 5, EPA officials could only identify cases referred from the States based on their memory since the cases were not otherwise identified in the records.

To further complicate matters, neither EPA nor State officials routinely followed up on the status of referred cases. Without such followup the referring agency has no idea whether the alleged violation was being expeditiously and appropriately investigated. Furthermore, State enforcement actions for 45 of 157 referral cases we reviewed were not begun within the 30-day time period specified in FIFRA.

Our analysis of a random sample of 36 cases referred by States to EPA also shows the need for better documentation by EPA and more timely enforcement action. For 31 cases the documentation was so limited that we could not make any judgments regarding the appropriateness or timeliness of the enforcement activities. EPA enforcement actions were delayed for over a year for three of five remaining cases, thereby reducing the actions' deterrent impact.

Referrals from FDA to EPA

EPA, FDA, and other regulatory agencies are members of the Interagency Regulatory Liaison Group 1/ which is designed to expeditiously identify and correct serious violations and hazards to the public. One goal of the group is to refer potential violations between agencies to expedite reviews and maximize the limited investigative resources.

Our review of referrals by FDA to EPA disclosed a lack of coordination and management control by both agencies. Neither agency maintained records of referrals or had any idea of the number of cases referred. Also, followup action to determine the status of investigations was practically nonexistent and some enforcement actions were questionable. Our analysis of 26 of the 65 referral cases between January 1978 and December 1980 which FDA could identify, based on its field staffs' memories, showed instances of poor investigations and questionable enforcement actions. For example, FDA referred a case to EPA

1/In March 1980, EPA, the Consumer Product Safety Commission, FDA, and USDA agreed to formalize a national referral inspection program. FDA and EPA also refer cases based on a June 12, 1975, Memorandum of Understanding.

based on an analysis of popcorn grain which showed very high pesticide levels. EPA officials did not conduct an investigation because FDA was unable to clearly identify the person who may have misused the pesticide. That identification, however, is EPA's responsibility.

EPA INITIATIVES TO IMPROVE PESTICIDE ENFORCEMENT REPORTING

In a June 1980 study, EPA recognized the need for more and better information to evaluate the success of the program. The study concluded that "without accurate, reliable, and timely information, it will be impossible to determine the status of enforcement activities, perform program evaluations, or make appropriate program adjustments." A subsequent February 1981 program overview noted that EPA needed to modify its reporting system to require States to report enforcement actions by type of investigation. This would allow EPA to evaluate the appropriateness of enforcement actions taken by States in response to the violations identified.

In November 1980 EPA published regulations which expanded State reporting requirements. These regulations, effective December 1980, require States to submit quarterly reports on grant outputs, such as number of establishment and marketplace inspections, use observations, enforcement actions, and detailed explanations of all use investigations. The regulations also require States to submit a chronological log showing the

--source of information indicating a violation;

--nature of the violation, including the name and EPA registration number of the pesticide involved and the certification category of the applicator; and

--status of the actions taken in investigating the alleged violation.

As of June 1981, EPA had not provided the States with additional instructions or a report format to be used in transmitting the requested information. Since our fieldwork was completed before the implementation of this regulation, we did not have the opportunity to evaluate the impact of the new reporting requirements. However, the effect of this reporting will be diminished unless the States develop better recordkeeping systems to assure reliable and accurate input.

On February 10, 1981, EPA published for comment a proposed interpretive rule which, among other things, provides that EPA will implement a tracking system to determine whether a State is expeditiously and appropriately responding to pesticide use violation referrals. As of June 1981, this rule had not been finalized.

FUTURE TRENDS FOR PESTICIDE ENFORCEMENT PROGRAMS

Since the current administration perceives that less Federal and more State controls over environmental programs are needed, environmental programs such as pesticide enforcement have an uncertain future. Some EPA enforcement officials would like to see the States eventually have self-supporting programs, but little progress toward that goal has been made. An OMB official responsible for EPA's budget told us that in the short run the enforcement program will probably be fully funded, perhaps slightly increased. However, the administration is considering providing State environmental agencies with consolidated block grants to fund Federal and State environmental programs. Under these consolidated block grants, State environmental agencies would have wide discretion over how the money is spent to address State environmental problems. Yet, the OMB official recognizes that the pesticide programs represent a problem, since these environmental programs are administered generally by State departments of agriculture. A final decision by the administration has not yet been made.

According to State officials, the impact of not having federally funded State pesticide enforcement programs varies from little or no effect to major reductions in resources.

CONCLUSIONS

EPA needs to improve administration of the pesticide enforcement program by instituting better recordkeeping and reporting systems and conducting more frequent and indepth onsite monitoring. The lack of effective investigation techniques, inconsistent and questionable enforcement actions, and lack of controls over referral cases attest to the need for such action to provide information necessary for better program evaluation.

As part of this effort, EPA could improve its system for program evaluation by

--requiring EPA regional offices and States to maintain consistent, accurate, and complete program information so that EPA can readily evaluate State programs and

--increasing the frequency and comprehensiveness of onsite program reviews to include evaluations of the quality of investigations and enforcement actions.

The need for better management controls over the pesticide enforcement program is best shown in regard to the processing of referral cases. Since these cases involve some of the most potentially serious violations, care must be exercised to assure adequate documentation, cooperation, and followup among EPA, States, and FDA so that enforcement actions are appropriate and timely.

EPA has recognized the need for better information to evaluate the program's success. Recent changes in reporting requirements are a first step in improving the consistency of data reporting and providing some basis for evaluating the quality of enforcement actions.

The administration's plans to use block grants to fund environmental programs raise questions regarding the future funding of the pesticide enforcement program.

RECOMMENDATIONS

We recommend that the EPA Administrator:

--Require EPA regional offices and States to improve recordkeeping and reporting systems so that accurate, complete, and timely data is generated and information on program results is provided.

--Establish standards for increasing the frequency and scope of onsite monitoring to assure State compliance with regulations and to evaluate the quality of investigations and enforcement actions.

--Strengthen coordination with FDA and improve management controls over referrals to assure appropriate and expeditious investigations and enforcement actions.

We recommend that the Secretary of Health and Human Services, through the Commissioner, FDA, improve management controls over referrals and strengthen coordination with EPA to help assure that investigations and enforcement actions are properly carried out. This could include requiring FDA to document pesticide misuse cases it refers to EPA and establishing a system to monitor the status of cases referred.

AGENCY COMMENTS AND OUR EVALUATION

EPA agreed that existing recordkeeping and reporting systems at the Federal and State levels need improvement. EPA has made recommendations to its regions regarding specific recordkeeping improvements, and according to EPA regional officials, changes are being made.

EPA is also working with the States to modify existing investigation forms to include such additional data as

--the circumstances of each pesticide misuse violation and

--the final disposition of the case.

EPA anticipates this additional information will enable the States and EPA to identify the causes of recurrent pesticide problems and to assess the appropriateness of the enforcement actions taken to address them.

Also, EPA has developed a ranking procedure to assist the States in establishing pesticide enforcement priorities and allocating enforcement resources. EPA stated that while the States are free to adopt or modify this procedure, it expects that all States will apply an objective ranking procedure to allocate their enforcement resources.

In commenting on our recommendation to increase the frequency and scope of onsite monitoring, EPA stated that it is working with the States FIFRA Issues Research and Evaluation Group to ensure more intensive and uniform qualitative and quantitative evaluations of the pesticide enforcement program. While EPA does not intend to increase the frequency of program evaluations, it does expect more thorough and qualitative program oversight.

We agree that the major factor should be improved quality of onsite visits. However, the frequency of these visits should be increased until program improvements are achieved.

FDA, responding for HHS, and EPA agreed that improvements are needed in controlling pesticide misuse referrals between their agencies. For example, EPA will work with FDA to ensure that existing referral procedures are followed. FDA plans to more formally and systematically document its referrals to EPA. It also plans to discuss with EPA the need to establish better management controls on the way FDA is notified on the outcomes of the pesticide misuse cases it refers to EPA.

CHAPTER 4

PROBLEMS CONTINUE TO PLAGUE

EPA AND STATE SPECIAL PESTICIDE REGISTRATIONS

Pesticide producers are submitting and EPA and numerous States are approving identical or similar State registrations for special local needs in conflict with what the Congress intended. Also, some problems continue with EPA approving emergency exemptions year after year. Finally, experimental-use permits are being approved by EPA with little or no monitoring by EPA or State officials. In our prior report 1/ we discussed how EPA was not always effective in administering special pesticide registrations and, as a result, the American public may not be adequately protected from potentially harmful and dangerous pesticides used under these programs.

MANY STATES HAVE APPROVED IDENTICAL OR VERY SIMILAR SPECIAL LOCAL NEED REGISTRATIONS

The Congress substantially broadened the States' authority to register pesticides for additional uses to meet special local needs and correspondingly limited EPA's authority over the States' pesticide registration process. Because of EPA's reduced role and its lack of monitoring special local need registration, pesticide producers are submitting and EPA and the States are approving similar pesticide registrations for special local needs which may be circumventing EPA's normal registration procedures.

The Congress was concerned about this potential problem and did not intend that States register additional pesticide uses to avoid Federal registration requirements. Senate Report 92-838 stated that the purpose of State registration is

> "* * * to give a State the opportunity to meet expeditiously and with less cost and administrative burden on the registrant the problem of registering for local use a pesticide needed to treat a pest infestation which is a problem in such State but is not sufficiently widespread to warrant the expense and difficulties of Federal registration."

Therefore, State pesticide registrations were intended to deal with localized problems that arise because of gaps in EPA's registration process.

1/"Special Pesticide Registration by the Environmental Protection Agency Should Be Improved" (CED-78-9, Jan. 9, 1978).

In addition, according to the Chairman, Subcommittee on Agricultural Research and General Legislation, Senate Committee on Agriculture, Nutrition and Forestry, in 1978,

> "* * * [State registration] is not intended to permit an end run around Federal registration requirements. States must be cognizant of the potential problems in extending pesticide uses and Congress is no less determined today than it was in 1972 to protect U.S. citizens and their environment from unreasonable pesticide hazards regardless of State boundries.
>
> "Thus, while the provision is designed to ease the administrative burden for all involved and facilitate availability of pesticides, it is not intended to limit the Administrator's ultimate authority to enforce FIFRA and protect the environment and human health and safety. We expect 'each similar' use question to be carefully assessed by EPA."

Also, the 1978 amendments to FIFRA removed the requirement that EPA determine if a special local need exists. According to EPA's Director of Registration, the 1978 amendments limited EPA's scrutiny over special local need registrations because EPA must now rely solely on the States to determine whether a need exists. Therefore, EPA now examines only (1) whether the pesticide has a residue tolerance and (2) if the pesticide registration for such a use has been previously canceled or denied. The following table shows the increase in special local need registrations from 1975 through 1980.

Special Local Need Registrations
Submitted and Approved from 1975 through 1980

Year	Number submitted to EPA	Number EPA approved	Not approved by EPA
1975	13	12	1
1976	465	425	40
1977	1,227	1,200	27
1978	1,281	1,275	6
1979	1,431	1,409	22
1980	1,381	1,377	4

EPA Registration Division officials further stated that the number of special local need registrations varies significantly from State to State, as the following table shows.

Special Local Need
Registrations for Selected States
Calendar Years 1978 through 1980

State	1978	1979	1980
Arizona	28	44	34
Arkansas	32	24	27
California	225	336	183
Georgia	38	22	28
Illinois	11	17	12
Louisiana	30	30	33
Michigan	19	31	31
New York	29	17	6
Texas	58	39	43
Washington	70	90	100
Wisconsin	-	4	-

According to officials in EPA's Registration Division, EPA does not regularly determine how many other States have requested a registration for the same or similar pesticide use because the 1978 FIFRA amendments limited EPA's review of special local need registration. However, because of the significant increase in special local need registrations and the lack of EPA review, the same pesticides with the same or very similar uses are being approved in many States. For example, we reviewed special local need registrations for 1980 from EPA headquarters records and noted several cases where a large number of States had approved the same or similar registration, as shown below.

Examples of Multiple State Registrations

Pest	Chemical	Used on	Number of States with same or similar special local need
Leafminers	Pramex 13.3%	Chrysanthemums	28
Flies	Atruban WP	Livestock and poultry	23
Flies	Ectiban EC	Livestock premises	23
Leafminers	Permectrin 10% EC	Chrysanthemums	20
Beetles	Lindane/xylene	Wood structures	14
Grasshoppers	Acephate	Pasture grass	13
Seed diseases	Thiram/carboxin	Soybeans	11
Leafminers	Pounce 3.2 EC	Chrysanthemums	8

Furthermore, many pesticides were registered for special local needs for more than one use or pest. For example:

--One pesticide was registered in Arkansas for 32 pests and 448 different uses. It was also registered for 118 different uses in at least 10 other States.

--Another pesticide was registered by Connecticut for 2,990 different uses--23 different pests on 130 different crops. The same product was registered in Maine and New Jersey for 2,967 uses and 2,960 uses, respectively.

--Another pesticide was registered in Oregon for 31 sites with 13 pests--403 different uses.

Some State registrations have caused problems. For example:

--In May 1980 EPA officials in region 6 received a complaint that four workers had been hospitalized because of pesticide misuse on a farm. The region referred the complaint to Texas officials to conduct an investigation. The State investigated and learned that a private applicator had used a pesticide for a State-registered use without having the special local need label. As a result, farmworkers had been allowed to enter the fields too soon after the pesticide was applied and therefore had become ill. The State filed charges of misuse against the applicator. In June 1980 a local court ordered the applicator to pay a $50.00 fine and $3.50 court costs.

--In 1975 New York approved a special registration for increasing a pesticide's application rate. Four years later company officials observed pesticide residues in drinking wells.

According to EPA officials, EPA must assume that the States are more aware and have a better understanding of their own special geographic situations. EPA noted, however, that only a few States have the capability to assess the environmental hazards associated with special local need registrations. Furthermore, many State cooperative extension services and State agriculture departments review proposed registrations based on how the pesticides will improve agriculture production and may discount potential environmental problems.

A limited EPA analysis in March 1980 showed that 29 products had special local need registrations in 10 or more States. One product that had numerous special local need registrations was not even federally registered.

SOME PROBLEMS CONTINUE WITH EPA AND STATES REPEATEDLY APPROVING EMERGENCY EXEMPTIONS

Problems continue with EPA and the States repeatedly approving emergency pesticide exemptions. In our 1978 report to the Congress, we disclosed that EPA had repeatedly granted Federal and State agencies emergency exemptions to control continuing and predictable pest outbreaks. We questioned whether some situations involved were true emergencies and whether EPA should continue to grant emergency exemptions in these situations or should

register the pesticides necessary to control these continuing and predictable pest outbreaks.

Section 18 of FIFRA permits EPA to grant Federal and State agencies exemptions to use suspended, canceled, or unregistered pesticides in emergency situations. By EPA definition an emergency exists when (1) a pest outbreak has occurred or is about to occur and no registered pesticide is available, (2) significant health or economic problems will occur without the use of a pesticide, and (3) insufficient time exists to register a pesticide to control the pest outbreak.

We analyzed 167 randomly selected emergency exemptions which disclosed that 45, or 27 percent, were repeatedly approved for 2 or more consecutive years and 15, or 9 percent, were for 3 or more consecutive years. For example:

--In New York, 7 of 30 emergency requests we reviewed were approved by EPA for the same use in successive years.

--In two cases, emergency exemptions were approved in Washington for 5 and 6 consecutive years, respectively.

--In Arizona, the same emergency request was approved twice in 1979 and again in 1980.

According to EPA's Director of Registration, emergency exemptions should not be repeated year after year. However, EPA does not maintain information on emergency exemptions which would allow it to analyze those chemicals used repeatedly. The absence of this basic information makes it difficult for EPA to control emergency exemption requests.

In a December 1979 letter EPA did, however, notify State agencies that some emergency exemption requests were being submitted year after year:

> "Section 18 of FIFRA was not intended to be a substitute for section 3 of FIFRA. While we are aware that the States are not in a position to gather much of the data necessary to register a pesticide, we cannot sanction the continued use of a pesticide under section 18 year after year. States must either solicit help from companies producing the product to ensure that data is gathered and submitted in support of registration or search for alternative pesticides which can be registered."

MONITORING OF EXPERIMENTAL PERMITS NEEDS IMPROVEMENT

In our 1978 study of special pesticide registrations, we reported that experimental-use permits were not being adequately

monitored by EPA to ensure that special permit terms and conditions were being met. Problems continue between EPA and the States in adequately monitoring experimental-use permits.

--In New York we reviewed 25 permits; of those, 11 experiments were conducted, but none were monitored.

--In Texas and Louisiana, EPA regional officials required the States to monitor permits. However, according to State officials, they gave only token attention to this requirement. As a result, no records were available at each State to disclose which permits were monitored.

--In Georgia, no permits were monitored in 1980 because State officials were not sure how many permits were approved or how many experiments were actually conducted.

According to EPA and State officials, experimental-use permits are not being adequately monitored because

--they have a low priority,

--the experiments do not always take place,

--more information is needed to let officials know when the experiments are going to be conducted, and

--limited staff is available to conduct the needed onsite monitoring.

According to EPA officials, experimental-use permits need to be monitored to ensure that the experiments are conducted correctly. Monitoring of these unregistered products whose safety has not been established is important to ensure that permit restrictions are followed and that the public is not unnecessarily exposed to harmful pesticides.

CONCLUSIONS

Problems continue to plague EPA and State special pesticide registrations. EPA and the States are approving

--State registrations of pesticides for similar or identical needs in numerous States,

--repetitive emergency exemptions, and

--experimental-use permits with little or no monitoring.

Without ongoing monitoring of State registrations, EPA cannot determine the frequency with which States are registering the same

pesticides for the same or similar special local needs. Since these registrations are occurring, as our review disclosed, Federal registration procedures to ensure the safety of pesticides may be circumvented.

Similarly, because of the lack of information on emergency exemptions by the States, EPA is not in a position to identify which pesticides are being used repetitively for continuing and predictable pest outbreaks. In these situations, EPA should reject requests for emergency exemptions and require Federal registration.

Furthermore, the monitoring of unregistered, experimental pesticide products, whose safety has not been established, needs to be given high priority as a basis for ensuring that permit restrictions are followed and that the public is not unnecessarily exposed to harmful pesticides.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Review each similar special local need registration to ensure that products or additional uses are being properly registered by the States.

--Develop an information system which identifies emergency exemptions by State so that repetitive requests can be analyzed and reviewed for conformance with FIFRA guidelines.

--Notify States that repetitive emergency exemptions will not be approved unless their justifications are fully documented.

--Require EPA Registration Division, regional offices, and State offices to better coordinate experimental-use monitoring. This could include a requirement that requestors of experimental-use permits notify EPA region and State officials when they actually plan to conduct their experiments.

AGENCY COMMENTS AND OUR EVALUATION

Notwithstanding EPA's philosophy of giving States more responsibility over approving special local need registrations, EPA agreed that it needs to do a better job of attempting to get applicants to apply for a Federal registration where there are clearly multiple special local need registrations which circumvent the Federal registration process.

EPA agreed to notify States that repetitive emergency exemptions will not be approved unless their justifications are fully documented.

EPA agreed that better coordination over experimental-use monitoring is needed. EPA is implementing coordination requirements to ensure that all parties are informed about the issuance of experimental use permits and associated monitoring requirements. Specifically, operating procedures require EPA to (a) publish the experimental-use permit in the Federal Register, (b) send a copy of the label, formal letter authorizing the permit, and a description of the program to regional offices for forwarding to the States, (c) encourage the applicant to notify State officials of the issuance and conditions of the permit, and (d) comply with applicable State laws as well. In those cases where the region has reduced its level of effort in the pesticide area due to resource constraints, States will be contacted directly.

PRIOR GAO REPORTS ON PESTICIDES

"Better Data Needed to Determine the Extent to Which Herbicides Should be Used on Forest Land" (CED-81-46, April 17, 1981).

"Need for Comprehensive Pesticide Use Data" (CED-80-145, September 30, 1980).

"Federal-State Environmental Programs--The State Perspective" (CED-80-106, August 22, 1980).

"Need for a Formal Risk/Benefit Review of the Pesticide Chlordane" (CED-80-116, August 5, 1980).

"Delays and Unresolved Issues Plague New Pesticide Protection Programs" (CED-80-32, February 15, 1980).

"Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential" (CED-79-43, June 22, 1979).

"Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues" (HRD-79-10, April 17, 1979).

"Need for EPA To Improve Foreign Nation Notifications" (CED-78-103, April 20, 1978).

"Special Pesticide Registration by the Environmental Protection Agency Should Be Improved" (CED-78-9, January 29, 1978).

"Adequacy of Safety and Efficacy Data Provided to EPA by Nongovernmental Laboratories" (RED-76-63, January 26, 1976).

"Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards?" (RED-76-42, December 4, 1975).

"Questions on the Safety of the Pesticide Maleic Hydrazide Used on Potatoes and Other Crops Have Not Been Answered" (B-133192, October 23, 1974).

"Pesticides: Actions Needed To Protect the Consumer from Defective Products" (B-133192, May 23, 1974).

"Environmental Protection Agency Efforts To Remove Hazardous Pesticides from the Channels of Trade" (B-133192, April 26, 1973).

Enclosure D

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Testimony

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PESTICIDES

EPA's Repeat Emergency Exemptions May Provide Potential for Abuse

Statement of
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Environmental Protection Issues
Resources, Community, and Economic
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Before the
Subcommittee on Environment
Committee on Science, Space, and Technology
U.S. House of Representatives

GAO/T-RCED-91-83

GAO Form 160 (12/87)

Dear Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to discuss the Environmental Protection Agency's (EPA) administration of the emergency use exemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This provision gives states and federal agencies a mechanism for using unregistered pesticides in an emergency without having to go through EPA's registration process.

Because of concerns that EPA has allowed states to use unregistered pesticides for increasing lengths of time under the emergency exemption program, you asked us to provide information on EPA's granting of pesticide emergency exemptions, including the number of exemptions granted, the extent of repeat exemptions, and the potential impact of the exemptions. While we are providing summary statistics and information on EPA's emergency exemptions program--also known as section 18 requests--we did not determine whether any individual exemptions should have been granted or denied. This testimony presents the final results of our review.

In summary, a large number of emergency exemptions have been granted for unregistered pesticides since the regulations were promulgated for the program in 1973. Furthermore, we found that EPA has repeatedly granted emergency exemptions for the same uses for several years. In one case, these exemptions have been granted for as many as 12 years. By granting repeat exemptions, EPA may put companies that register pesticides and incur the associated costs at an economic disadvantage compared with companies that are able to sell their chemicals for uses for which they are not registered. In addition, since these pesticides have not gone through EPA's registration process, the extent of their effects on human health and the environment for these uses are unknown.

According to the section 18 regulations, EPA must give due consideration to whether "reasonable progress" has been made in registering pesticides for repeat requests. A basic problem, in our view, that has contributed to extended exemptions is EPA's lack of guidance on what constitutes a complete application for registration to determine "reasonable progress towards registration" for exemptions exceeding 3 years. Furthermore, EPA's definition of emergency does not exclude chronic or continually occurring problems and therefore allows EPA to grant long-term emergency exemptions.

Our recent work illustrates that problems with the exemption program we described in 1978 and 1981 still exist today. Our 1978 report concluded that EPA repeatedly granted federal and state agencies emergency exemptions to control continuing and predictable pest outbreaks.[1] We questioned in these prior reports whether some situations involved were true emergencies and whether EPA should continue to grant emergency exemptions for repeat requests or should register the pesticide necessary to control continuing and predictable pest outbreaks. Our 1981 report stated that these repetitive exemptions continued to plague EPA.[2]

Before I discuss our findings in more detail, let me provide the Subcommittee with some background on section 18.

Background

FIFRA authorizes EPA to register pesticides for specific uses and to take regulatory action--such as denying, canceling, or restricting a pesticide's use--if the pesticide presents a

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[1]Special Pesticide Registration By the Environmental Protection Agency Should Be Improved (CED-78-9, Jan. 9 1978).

[2]Stronger Enforcement Needed Against Misuse of Pesticides (CED-82-5, Oct. 15, 1981).

significant health or environmental risk. Section 18 of FIFRA states,

> "The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this [Act] if he determines that emergency conditions exist which require such exemption."

Section 18 regulations divide emergency exemptions into four categories: specific, quarantine, public health, and crisis. Most emergency exemptions are "specific" exemptions, which a state or federal agency can request when it believes a particular pest will cause a significant economic loss, or when a state seeks to avert significant risk to an endangered species, a threatened species, beneficial organisms, or the environment. For example, the voluntary cancellation of a registered chemical used to control a fungus on mushrooms threatened to reduce the yields of mushroom crops in California and Pennsylvania by 30 to 40 percent. To control the fungus, which EPA determined would cause a "significant economic loss" under section 18 regulations, these states requested specific exemptions from EPA for chlorothalonil.

"Quarantine" exemptions are intended to limit the spread of a pest not previously known in the United States, such as the emergency exemptions granted for the Med Fly.

The third type of exemption, "public health" exemption, is granted by EPA when a pest presents a significant health risk. We did not find any public health exemptions requested by states.

Finally, states may declare "crisis" exemptions under emergency conditions when there is not sufficient time to request or for EPA to review an emergency exemption. Crisis exemptions can have the characteristics of specific, quarantine, or public health exemptions--the difference being that crisis exemptions do not require prior approval by EPA. However, a crisis exemption may be

authorized only for 15 days, unless an application requesting a specific, quarantine, or public health exemption has been filed with EPA. Also, EPA may revoke a particular crisis exemption or a state's authority to issue any crisis exemption.

As I will explain, the federal regulations which support section 18 require EPA to judge, among other things, whether a pest creates an emergency situation and whether the pesticide for which the emergency exemption request was filed will result in adverse health and environmental effects, and for repeat exemptions, whether reasonable progress has been made towards registration.

The regulations define an emergency condition as an "urgent, non-routine" situation that requires the use of a pesticide, when no effective registered pesticides or alternative practices exist to control the pest. In addition, an emergency situation must involve the introduction of a new pest, present a significant risk to human health, a threatened or endangered species, beneficial organisms or the environment, and/or cause significant economic loss. EPA's Chief of the Emergency Response and Minor Use Section, who is in charge of evaluating emergency exemption requests, estimated that over 90 percent of the specific exemption requests states submit cite "significant economic loss" as a result of the emergency. Briefly, EPA considers "significant economic loss" to exist if a grower experiences losses outside the range of profits earned for the previous 5 years.

The pesticide cited in an application for an emergency exemption must meet several additional criteria. By examining test data submitted by the states as well as EPA's own data bases, EPA must determine that the pesticide will not cause unreasonable adverse effects to the environment and that the pesticide has not been registered and then canceled or suspended by EPA. In addition, EPA must give due consideration to whether "reasonable" progress has been made in registering pesticides in repeat

requests. If the registrant for a section 18 chemical has not submitted to EPA a complete application for registration after 3 years of emergency exemptions, the regulations state that EPA will assume that reasonable progress has not been made.

LARGE NUMBER OF EXEMPTIONS HAVE BEEN GRANTED

Since 1978, over 4,000 specific and crisis exemptions have been granted for unregistered pesticides. Our first chart shows the number of emergency exemption requests granted, denied, and withdrawn since 1978 (attachment I). As you see, 149 exemptions were granted in 1978, increasing to a high of 698 in 1982, and then dropping to a low of 143 in 1985. In fiscal year 1990, 226 exemptions were granted, or 72 percent of the exemptions requested. The EPA official responsible for emergency exemptions said that the sudden increase in exemptions in the early 1980s was due to invalid data provided for the registration process. Registration for a large number of chemicals was held up until EPA received valid data, and as a result, many states filed for emergency exemptions for these chemicals.

Our second chart provides a break down on emergency exemptions requested in fiscal year 1990 (attachment II). The vast majority, 71 percent, were for "specific" exemptions, 11 percent of the requests were for quarantine exemptions, and none were for public health exemptions. Crisis exemptions declared by states comprised 18 percent of the section 18 exemptions. EPA granted about 70 percent of the applications for quarantine and specific exemptions it received, denied about 16 percent, and the remainder were withdrawn either by the agency or the state. EPA revoked none of the state crisis exemptions.

REPEAT EXEMPTIONS ARE GRANTED

Although it recognizes that repeat emergency exemptions may circumvent, or at least give the appearance of circumventing, registration as well as cause other problems, EPA regularly grants such emergency exemptions. In fiscal year 1990, EPA granted almost 80 percent of the requests for exemptions for chemicals that had already received exemptions for that particular use for at least 3 years, and EPA tacitly approved another 18 percent of the repeat requests by not revoking crisis exemptions.

EPA is required to review repeat requests for specific and public health exemptions, giving due consideration to whether or not the chemical is making reasonable progress towards registration. If the manufacturer of a section 18 chemical has not submitted a complete application for registration to EPA after any 3 years of emergency exemptions, the regulations state that EPA will assume that the registrant has not made reasonable progress. In addition, the Federal Register preamble to the section 18 regulations state that "a chronic or continually occurring problem does not represent an 'urgent, non-routine' situation", but the regulations themselves give EPA broad discretion to decide if the repeat requests can be classified as "non-routine". Consequently, EPA often considers repeat requests to be urgent and non-routine even when the emergency situation has lasted for over 3 years.

As I noted, EPA's long-term grants of emergency exemptions from FIFRA for unregistered pesticides may be putting companies that register pesticides at an economic disadvantage. According to EPA, most section 18 chemicals are already registered for use on some crops but are not completely tested for use on the crops for which emergency exemptions are requested. Because of the many health and safety tests required, registration is a costly process--even for chemicals already registered for some uses. A company that is not required to register a chemical or that can delay the

registration of a chemical through section 18 exemptions will save money compared with a company that registers chemicals for uses that do not receive section 18 exemptions.

Repeat exemptions can also skew the economic data EPA uses to determine if an emergency situation exists. For example, EPA analysts ideally examine 5 years of crop cost, value, and yield data to determine whether or not a pest will cause significant economic damage. However, data from a crop that has been treated for several years with section 18 chemicals precludes EPA from examining and comparing data from untreated crops to determine if the pest would, in fact, cause significant economic loss. Therefore, although EPA may determine that a situation is non-routine, it may not be able to calculate the economic loss that would be suffered if the growers used a registered alternative chemical. EPA cited this difficulty in a number of fiscal year 1990 repeat exemption request analyses and in each case was forced to rely on old crop profit and cost data.

The repeat emergency exemptions granted for the chemical DCNA illustrate some of the problems caused by how EPA handles repeat requests. Virginia first requested an emergency exemption for use of DCNA on peanuts in 1977 to combat scerlotina blight, and Oklahoma followed suit in 1978. Scerlotina blight is a fungus that attacks the roots of the peanut plant and is exacerbated by cool, humid weather. Recognizing that these states could lose upwards of $12 million--a loss that DCNA could prevent--EPA granted emergency use exemptions for the chemical for 6 years. However, in 1984, the Director of EPA's Office of Pesticide Programs wrote: "It is very doubtful that I will authorize use again under an emergency exemption" because of a lack of key test data and the chronic nature of the problem.

Consequently, in 1985 EPA denied Oklahoma's request for an emergency exemption for DCNA. EPA said that a registered

alternative, Rovral, could be used to prevent the fungus. EPA wrote that the reasons for the exemption request appeared to be chiefly economic: that the growers were not willing to pay the higher cost of Rovral, and EPA noted that DCNA was not making reasonable progress towards registration.

But, in 1986, Oklahoma cited the significant economic loss sustained by peanut growers who used Rovral and was again granted an exemption for DCNA on peanuts. EPA conceded that Rovral was not effective alone, but it stated that it would not grant another section 18 exemption for DCNA unless several key tests, such as those for carcinogenicity, were submitted for the registration process. Without these tests, EPA would not consider that the manufacturers of DCNA had submitted a complete application for registration, and would assume that DCNA had not made reasonable progress towards registration.

In 1987, EPA first denied Oklahoma's requests for DCNA on the basis that there were too many data gaps for DCNA to be certain of its safety, and because 9 years of emergency exemptions had already been granted, saying that granting another section 18 exemption was "tantamount to or at least gives the appearance of" circumvention of EPA's registration process. However, Oklahoma resubmitted its request the same year, and this time EPA granted it. Although EPA's decision memo presented no new information, its conclusions were different. This time EPA justified granting an emergency exemption for DCNA by saying that (1) if weather conditions did not change, an emergency would continue to exist, (2) although critical studies had not been submitted other data did not indicate that DCNA would harm the environment, (3) exemptions had been granted for 8 years without reports to EPA of adverse effects to the environment, and (4) the company producing DCNA was genuinely committed to registering the chemical. Although the registrant for DCNA had submitted some test results, EPA's Health Effects Division concluded that there were "insufficient data to support the

proposed use." Serious data gaps existed for DCNA, including a mouse oncogenicity study and appropriate mutagenicity studies to assure that the public and the environment are not exposed to a mutagen and a potential carcinogen.

EPA continued to grant exemptions for DCNA in 1988 and 1989 for the same reasons, each time warning the states that adequate progress toward registration must be made, but not stating what would constitute "reasonable progress". In 1990, EPA finally concluded that the manufacturers of DCNA were not making a "good faith" effort to register the chemical, but the agency granted an emergency exemption to Oklahoma and Texas, concluding that without the chemical peanut growers would suffer a substantial financial loss. As of mid-July of this year, EPA has not decided whether to grant or deny Oklahoma and Texas's 1991 requests for the thirteenth year of emergency use exemptions for DCNA.

In addition, although many chemicals are granted repeat exemptions for the same use, most section 18 chemicals are granted exemptions for more than one crop. For example, the chemical avermectin, which has not been granted an exemption for any one crop for more than 3 years, nevertheless has received 31 emergency exemptions in the past 5 years, on celery, lettuce, pears, strawberries, tomatoes, and ornamental plants.

EPA recognizes the problems caused by repeat exemptions, and 1987 and 1988 reports prepared by EPA's Registration Division summarizing emergency exemptions (the latest reports EPA has available) state that "continued use under section 18 represents or at least gives the appearance of circumvention" of EPA's registration process. EPA's 1987 and 1988 reports also note that repeat emergency exemptions drive up the number of exemption requests as the exemptions become permanent fixtures in the section 18 program. The reports concluded that EPA should take a hard stance on emergency exemption requests entering their fourth year,

and noted that firm commitments and time schedules for registration should be in place, and there should not be any allowance for slippage on the part of the registrant.

In spite of what EPA stated in these reports, the situation has not improved. Our third chart shows that although EPA generally considers 3 years to be the maximum number of times it will grant an exemption for the same chemical and crop unless the chemical has a complete application for registration on file at EPA, 66 of the fiscal year 1990 emergency use requests have received exemptions for more than 3 years (attachment III). Of these 66 repeat requests, EPA denied only one.

The 1990 figures are not an anomaly. EPA's 1987 and 1988 section 18 reports showed similarly high numbers. Although the reports did not list exemptions granted by EPA for more than 3 years, in fiscal year 1987 the report showed that 22 chemicals which had been granted exemptions for 5 or more years, and in fiscal year 1988 EPA's list had grown to 29 chemicals.

EPA's 1988 report also cautioned that more and more pesticides will be voluntarily cancelled for small crops as companies do not find it economically feasible to reregister them for minor crops. According to officials in EPA's Office of Pesticide Programs, many growers of these small crops will apply for emergency use exemptions for the cancelled pesticides, and if effective registered alternatives are not found--which is likely--these requests will become repeat exemptions.

EPA'S CRITERIA FOR DEFINING EMERGENCIES AND REASONABLE PROGRESS TOWARDS REGISTRATION

In our opinion, an underlying cause of the high number of repeat exemptions stems from a lack of specific criteria defining a "complete application for registration", and the failure of the

regulations to preclude routine situations from being defined as emergencies. According to EPA officials, EPA uses section 18 regulations to decide whether to grant emergency use exemptions but has no other internal guidance other than that used to calculate significant economic loss. Where the regulations are broad, EPA relies on the experience and expertise of its staff. EPA's Registration Division Director agreed that such guidance is needed and has discussed its usefulness with the states.

With regard to repeat requests, the regulations state that after 3 years of emergency exemptions, if a complete application for registration has not been submitted to EPA, EPA will assume that reasonable progress towards registration has not been made. Neither "reasonable progress" nor "complete application for registration" are further defined. Without guidance, decisions are made on a case-by-case basis on whether a pesticide is making enough progress to be granted another emergency exemption.

The regulations supporting section 18 define an emergency in such a way that a recurring situation, even if it has existed for several years, can still be considered an emergency and granted an emergency exemption. Although the regulatory definition of emergency is an "urgent, non-routine" situation, the regulations do not require EPA to consider the duration or predictability of the situation.

Conclusions

The sheer volume of emergency exemptions granted casts a shadow over the emergency exemption program. EPA's reluctance to deny repeat requests opens the door to potential abuse of the section 18 program by causing companies that do register their pesticides to be placed at a competitive disadvantage. EPA currently lacks criteria to explain what a "complete application" is when determining progress towards registration and therefore may

frequently grant section 18 requests for more than 3 years. As our review suggests states will request more emergency exemptions as companies voluntarily cancel registration, especially for pesticides applied to minor use crops. Developing criteria to define a complete application for registration and distributing this information to the states and registrants of emergency use pesticides, would help EPA identify which registrants are making adequate progress towards registration.

In addition, currently EPA's regulatory definition of an emergency does not exclude chronic or continually occurring problems, and therefore allows EPA to grant long term emergency exemptions. Establishing criteria for excluding these chronic situations from being considered emergencies and revising its regulations accordingly would help EPA separate true emergencies from chronic situations.

RECOMMENDATIONS

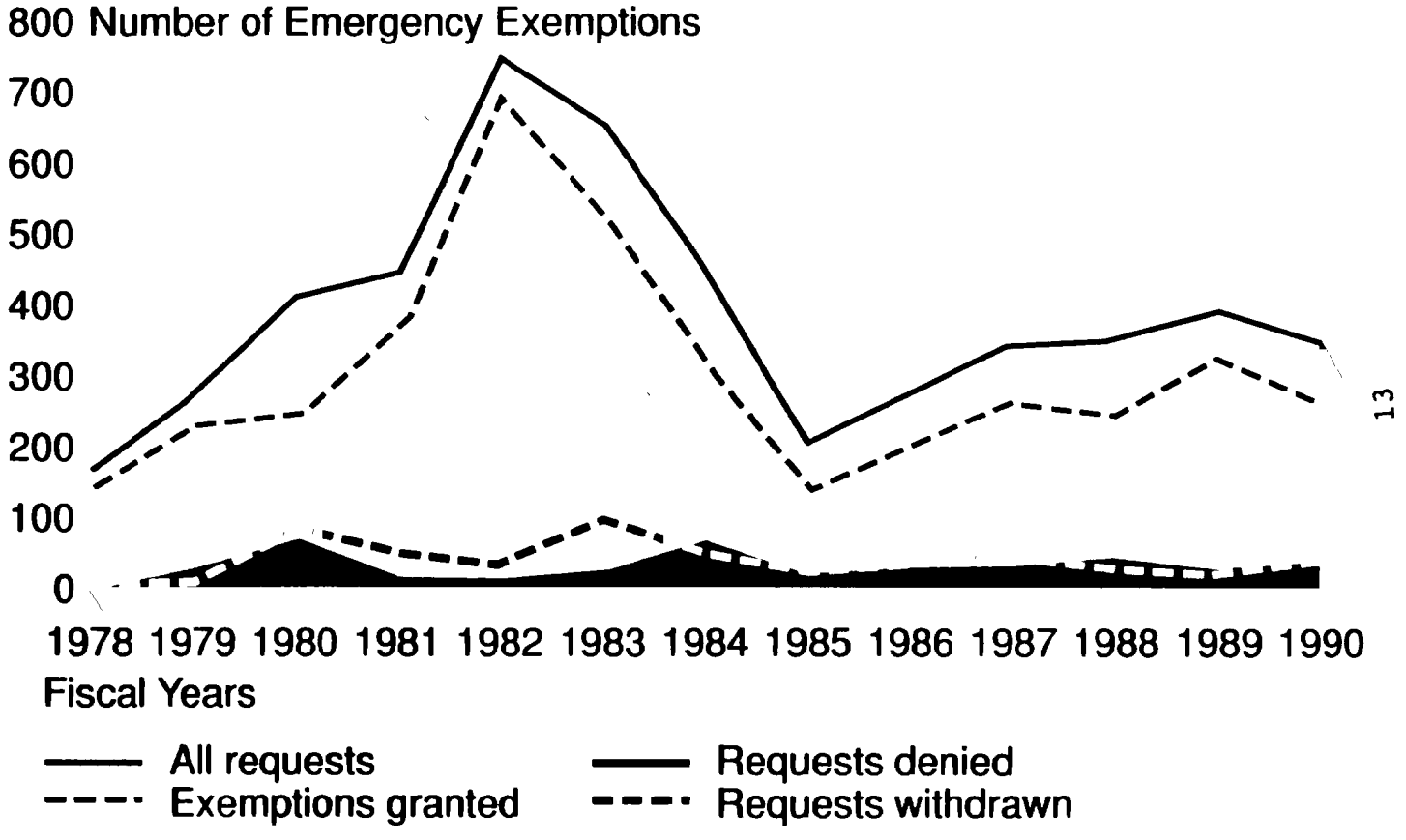
To help ensure that section 18 exemptions do not become routine, particularly as some pesticides are discontinued, we recommend that EPA develop criteria to measure a chemical's progress towards registration and that these criteria be distributed to the states and registrants of emergency use pesticides. We also recommend that EPA establish criteria that differentiate a chronic from an emergency situation and that EPA revise its regulations accordingly.

- - - -

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions you or members of the subcommittee might have.

ATTACHMENT I

GAO Emergency Exemptions for Fiscal Years 1978-90



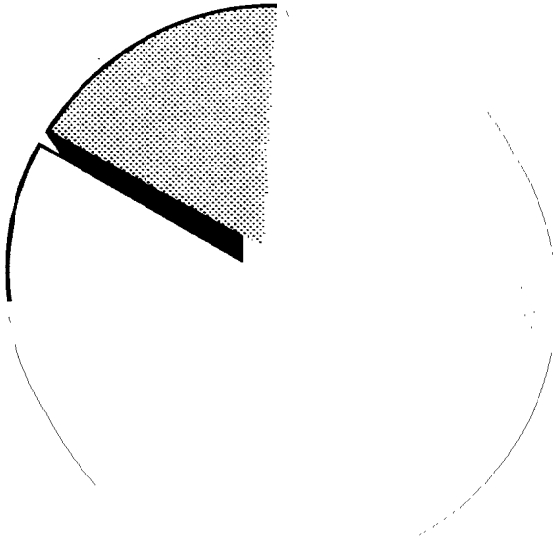
GAO analysis of EPA data

13

ATTACHMENT I

ATTACHMENT II

GAO Types of Emergency Exemptions in Fiscal Year 1990



Quarantine (39) 11%
Crisis (62) 17.6%
Specific (252) 71.4%

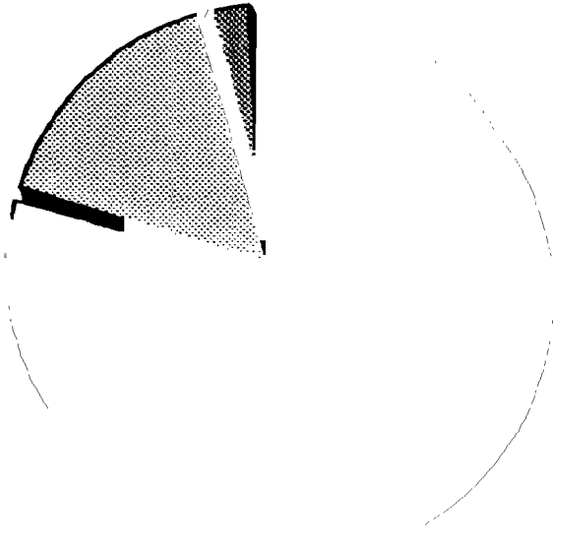
No public health exemptions were requested in fiscal year 1990.

GAO analysis of EPA data.

ATTACHMENT II

ATTACHMENT III

GAO Disposition of Fiscal Year 1990 Repeat Exemption Requests



Denied by EPA (1) 1.5%
Crisis Exemptions by States (11) 16.7%
Withdrawn (2) 3%
Approved by EPA (52) 78.8%

GAO analysis of EPA data.

ATTACHMENT III

Enclosure E

[COMMITTEE PRINT]

SECTION 18 (EMERGENCY EXEMPTIONS) TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

REPORT

PREPARED BY THE

SUBCOMMITTEE ON ENVIRONMENT

TRANSMITTED TO THE

COMMITTEE ON
SCIENCE, SPACE, AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

SECOND SESSION

Serial V

[This document has been printed for informational purposes only and does not represent either findings or recommendations adopted by this Committee]

OCTOBER 1992

Printed for the use of the Committee on Science, Space, and Technology

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*Ranking Republican Member.

LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, DC, October 1992.

Members, Committee on Science, Space, and Technology:

There is transmitted herewith a Subcommittee report together with dissenting views on the emergency exemption section, Section 18, of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Subcommittee oversees all of the research, development and demonstration programs of the Environmental Protection Agency (EPA) including the agricultural research programs as a means of ensuring that such programs are well managed and supportive of the Agency's primary role of protecting public health and the environment. The report was circulated to Members of the Subcommittee on Environment for review and approval. The Members were notified of the opportunity to file separate or dissenting remarks. The dissenting remarks are appended to the Subcommittee Report.

I commend the report to your attention.

Sincerely,

GEORGE E. BROWN, Jr.,
Chairman.

CONTENTS

APPENDICES

Appendix A

APPENDIX B

I. FORWARD

This report contains the findings, conclusions and recommendations from an investigation of the U.S. Environmental Protection Agency's ("EPA's") administration of Section 18, the emergency exemption section, of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). The investigation was authorized by the Honorable James H. Scheuer, Chairman of the Subcommittee on Environment of the House Science, Space, and Technology Committee.

In the Spring of 1990, under direction from Chairman Scheuer, the Environment Subcommittee began this investigation in order to provide continued oversight of the EPA's implementation of the Section 18 program and to ensure that prior mismanagement of the Section 18 program had been rectified. Specifically, in the early 1980's, the House Agriculture Committee [1] and the General Accounting Office [2] both identified that serious inconsistencies and other abuses permeated the EPA's administration of Section 18 of FIFRA. The Subcommittee undertook this investigation to determine if abuses had ceased to permeate the administration of the Section 18 program.

The Subcommittee began its investigation with a hearing held on July 23, 1991. During the hearing, the General Accounting Office released a study revealing that abuses continued in the administration of the Section 18 emergency exemption program. The Subcommittee then proceeded to conduct its own analysis of the Section 18 program by reviewing certain Section 18 approval documents dating from 1989 through 1991 which had been submitted to the Subcommittee by the EPA. These repetitive Section 18 approval documents are included in this report together with the Section 18 regulations and the EPA's Guidance document to Section 18 as Appendix A. The correspondence between Chairman Scheuer and the EPA regarding Chairman Scheuer's request for documents and information to conduct this investigation is also included in this report as Appendix B. An index to these documents is also included with the Appendices.

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[1] The Agriculture Committee found an increase in the diversity and volume of pesticides exempted under Section 18 and criticized exemptions for entailing "significantly less complete and rigorous data requirements and analyses than undergone to obtain federal registrations." See. "Regulatory Procedures and Public Health Issues in the EPA's Office of Pesticide Programs", p. 11, Staff Report Prepared for the Department Operations, Research, and Foreign Agriculture Subcommittee, contained in Appendix to Hearings of the Committee on Agriculture, 98th Cong., 1st Sess., 22 (1983) Vol. III, [hereinafter cited as "DORFA Report"].

[2] "The Agency often approves requests for emergency use of canceled pesticides in non-emergency situations". U.S. General Accounting Office. 1978. "Special Pesticide Registration By the Environmental Protection Agency Should be Improved". GAO/CED-78-9. Washington, D.C.; *see also*, U.S. General Accounting Office. 1981. "Stronger Enforcement Needed Against Misuse Of Pesticides". GAO/CED-82-5. Washington, D.C.

II. SUMMARY

The Environmental Protection Agency (the "EPA") is the primary regulatory of pesticides. Its authority is given in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended (7 U.S.C. 136 et seq.), and the Federal Food, Drug, and Cosmetic Act ("FFDCA") as amended (21 U.S. 301 et seq.).

The principle method of regulating the use of pesticides is through the registration requirement. In general, all pesticides must be registered, which requires the manufacturer of pesticides to submit certain health and safety data to establish that use of the pesticide will not generally cause unreasonable adverse effects. Section 18 of FIFRA allows, however, for the use of unregistered pesticides in certain emergency situations.[3] This report and its accompanying documents demonstrate a large increase in the volume and the diversity of pesticides that are issued as Section 18 exemptions. Specifically, since 1973 more than 4,000 emergency exemptions have been granted for the use of pesticide on crops for which they carry no registration. A large number of these emergency exemptions have been repeatedly granted for the same uses for many years.[4]

The report finds that the continuing reliance on Section 18 is harmful to public health and the environment and is also detrimental to the development of innovative, less toxic pesticides. First, EPA's review of chemicals under the exemption program entails significantly less complete and rigorous data requirements and analyses than undergone to obtain Section 3 registrations. Emergency exemptions, therefore, increase risks to human health and also increase the chances of adverse environmental and wildlife impacts. Further, by granting repeated exemptions for unregistered pesticides, EPA is putting at a disadvantage the companies that incur the expense of fully registering products for similar uses.

The Subcommittee found that the existence of such large numbers of emergency exemptions is primarily caused by the EPA's failure to implement its own regulations. For instance, numerous exemptions are granted despite the fact that the applicant has not made the requisite showing, as provided by regulation, that "significant economic loss" will occur without the use of the unregistered pesticide. Similarly, the EPA often grants exemptions despite the fact that the applicant has not shown, in accordance with the regulations, that the chemical substance is making "reasonable progress towards registration" for that crop. Further, the EPA frequently fails to examine whether or not "effective [registered] al-

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[3] Section 18 provides, "(t)he Administrator may, at his discretion, exempt any Federal or State agency from any provisions of this subchapter if he determines that emergency conditions exist which requires such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination." 7 U.S.C. 136p.

[4] Examples of repetitive exemptions include exemptions granted for Botran on Peanut for a 14 year period; sodium chlorate on wheat for 10 years; glyphosate on wheat for 9 years; cryolite on potatoes for 10 years; Vinclozin on snap beans for 8 years; triadimefon on tomatoes for 8 years; hydrogen cyanamide on grapes for 6 years; cryomazine on peppers for 7 years; cypermethrin on onions for 5 years; bromoxinil on rice for 5 years; chlorothalonil on mushrooms for 5 years; mancozeb on ginseng for 4 years; thiobencarb on assorted vegetables for 5 years, and triflumizole on spathiphyllum for 5 years. See, Appendix A.

ternatives" are available, although the regulations specify that the existence of effective registered substitutes should prevent the use of Section 18.

Additionally, the Subcommittee investigation found that the EPA's reliance on Section 18 may be related to the Agency's difficulty in reregistering older chemical substances. Oftentimes, Section 18 requests are made for the use of older chemicals on crops for which they are not registered. These older chemicals receive repetitive exemptions for use on such crops despite the fact that many of these substances may have difficulty obtaining reregistration since many have been identified as being potentially carcinogenic.[5] The Subcommittee found that by liberally and repetitively granting exemptions to potentially carcinogenic substances, little incentive is provided to encourage companies to invest in the development of newer safer pesticides or alternative agricultural practices.

The Subcommittee concludes this report with the following recommendations:

- The Subcommittee recommends that the EPA follow its own adopted regulations, especially regarding limiting the number of years for which exemptions can be granted.
- The Subcommittee recommends that the EPA rewrite the regulations to create an absolute time limit beyond which repetitive requests for an exemption will not be granted.
- The Subcommittee recommends the establishment of economic standards in the form a regulation that will define what qualifies as "significant economic loss" to a crop justifying the use of an unregistered chemical under Section 18.
- The Subcommittee recommends the establishment of a new a regulation that will provide for evidence to be taken by the EPA to determine whether a registered chemical should be deemed an alternative to be used instead of an unregistered substance that is the subject of an exemption request. The regulation should provide for an open comment period or a hearing allowing for the public submission of data regarding the effectiveness of registered alternatives versus the effectiveness of the requested exempted substance. The regulation should provide clear procedures for the EPA to follow in its review of competing data regarding the effectiveness and the environmental or health benefits of registered alternative substances versus the effectiveness and environmental impacts of the unregistered substance which is the subject of the exemption application.

III. Requirements of Registration

To understand the causes underlying the overabundance of Section 18 exemptions, it is necessary to examine the basic provisions

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[5] The report also associates the overuse of Section 18 with the EPA's lack of success in dealing with pesticide minor-use problems. Essentially, the minor crops are considered all crops other than cotton, corn, rice, soybeans, and wheat. Minor crops are grown in relatively smaller amounts compared to the major crops, and pesticide manufacturers are frequently unwilling to make the needed investment to register these minor use products under FIFRA. Manufacturers are even more unwilling to go to the expense of registering pesticides for minor crops if Section 18 exemptions are liberally granted.

of the registration sections of FIFRA. In general, FIFRA regulates which chemicals can safely be utilized on certain crops by requiring every chemical to be registered for each specific use. Thus, FIFRA mandates that a pesticide cannot be sold for use on a given crop, shipped, or delivered until it is registered for use on that crop by the EPA. See 7 U.S.C. 136(a). The use of a pesticide in a manner inconsistent with the terms and conditions of its registration is unlawful.

Section 3 of FIFRA, which provides for the registration of pesticides, mandates that the EPA must first determine that the product "will perform its intended function without unreasonable adverse effects on the environment * * * taking into account the economic, social, and environmental costs and benefits of the [use] of the pesticide." 7 U.S.C 136(a)(5). To grant registration, the EPA must conclude that the food production benefits of a pesticide outweigh any risks.

To make the cost-benefit determination required to register a pesticide as usable, the EPA requires manufacturers to submit detailed tests on the chemical's health and environmental effects. The burden rests on the manufacturer to provide the data needed to support registration for use on the particular crop. The adopted regulations to implement Section 3 of FIFRA spell out in detail the data required to be submitted to register a substance on a particular crop. See 40 C.F.R. Parts 158 and 162. Required data include disclosure of the substance's chemical and toxicological properties, likely distribution in the environment, and possible effects on wildlife, plants and other elements in the environment. After the data is submitted, the EPA may grant the registration if it determines the substance's use poses "no unreasonable adverse effects on the environment".

Substances that are registered for use on food crops must also be granted tolerances in addition to being registered generally. The Federal Food, Drug, and Cosmetic Act ("FFDCA) requires that the manufacturer of such substances apply to the EPA for a tolerance or a maximum residue level to be allowed in or on food.[6] Because of the way pesticide residues are defined and incorporated into the food additive provisions of the FFDCA, there are actually several kinds of tolerances, each subject to different decisional criteria. A given pesticide can thus have many tolerances, both for use on difference crops and for any one crop. For instance, for each crop for which it is registered a pesticide may need a raw commodity tolerance, a food additive tolerance, and an animal feed tolerance, each of which will be subject to particular decisional criteria.[7]

The EPA sets tolerances on the basis of data the manufacturer is required to submit on the nature, level, and toxicity of a substance's residue. Tolerances are initially calculated by measuring the amount of pesticide that remains in or on a crop after it is treated with the pesticide at the proposed maximum allowable

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[6] See. 21 U.S.C. Sections 321, 346, and 348.

[7] For details regarding the establishment of tolerances, See generally, The National Research Council, Board on Agriculture, "Regulating Pesticides in Food—The Delaney Paradox, National Academy Press, Washington, D.C. 1987, [hereinafter referred to as the "National Academy Report"].

rate. EPA then calculates the possible risk posed by that proposed tolerance to determine if it is acceptable.

In calculating risk, EPA estimates exposure based on the "theoretical maximum residue concentration" (TMRC), normally assuming three factors: that all of the crop is treated, that residues on the crop are all at the maximum level, and that all consumers eat a certain fixed percent of the commodity in their diet. This exposure calculation is then compared to an "allowable daily intake" (ADI) calculated on the basis of the pesticide's inherent toxicity. The ADI represents the level of exposure in animal tests at which there appears to be no significant toxicological effect. If the residue level for that crop, the "TMRC", exceeds the "allowable daily intake" then the tolerance will not granted as the residue level of the pesticide on that crop is presumed unsafe. On the other hand, if the residue level is lower than the "allowable daily intake" than the tolerance would normally be approved. Exposure rates are based on assumptions regarding the amount of treated commodities that an "average" adult person, weighing 60 kilograms, eating an "average" diet would consume.

Although the law requires a thorough tolerance review for chemical pesticides prior to registration for health and environmental impacts, the majority of pesticides currently on the market and in use today were registered before modern testing requirements were established. Thus, many older pesticides do not have an adequate data base, as judged by current standards, particularly data about potential chronic health effects.[8]

The 1972 amendments to FIFRA required a review (called "reregistration") of all then-registered products according to contemporary standards. Originally, the EPA was to complete the review of all registered products within 3 years, but this process broke down completely. The 1978 amendments to FIFRA authorized EPA to group together individual substances by active ingredient for an initial "generic" review of similar chemicals in order to identify data gaps and assessment needs. The amendments mandate that after this generic review, EPA is to establish a "registration standard" for the active ingredient basis. Then, the EPA must wait for additional data in order to establish specific requirements for each substance's specific use on differing crops.[9]

The 1988 amendments extended the deadline for reregistration until 1997. To date, however, the EPA only has complete residue chemistry data on less than 25 percent of pesticides used on foods, and only 2 products, as yet, have been reregistered. Thus, the backlog of substances awaiting reregistration is now on the order of 16,000 to 20,000 compounds, including over 650 active ingredients.[10] Most of these chemical are temporarily retaining their registration status under the former testing requirements.

Once tested in accordance with contemporary standards, many of the older pesticides are likely to be identified as potentially carcinogenic. In fact, the National Academy of Sciences estimates that

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[8] Id. National Academy Report, pp. 83-86.
[9] Id. at pp. 33-35.
[10] See U.S. General Accounting Office. 1991. "Pesticides, EPA COULD Do More To Minimize Groundwater Contamination". GAO/RCED 91-75. Washington, D.C.

25-33 percent of the pesticides to undergo reregistration procedures are likely to be found to be oncogenic (an "oncogen" causes tumors in laboratory animals and is considered potentially cancerous to humans). In general, such older pesticides, registered prior to 1972, have not been tested adequately for oncogenicity.[11] For a substance to be used on a new crop, however, current data must be submitted in order to obtain a tolerance.

IV. Exemption From Registration

SECTION 18 OF FIFRA

A. The Statute

Section 18 of FIFRA provides:

> "the Administrator of the EPA may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination." 7 U.S.C. 136(p).

B. Section 18 Regulations

The regulations implemented to Section 18 of FIFRA give states and federal agencies the right to request emergency exemptions. The regulations allow for exemptions of pesticides from the requirements of registration in pest "emergency" situations and "crisis" situations. An overview of the language of the regulations follows:

> *Emergency Exemptions: Section 18:* Exemptions are granted by EPA to Federal or State agencies to use suspended, cancelled, or unregistered pesticides in emergency situations where: (1) pest outbreaks have occurred, or are about to occur, and effective registered pesticides are not available; (2) significant economic or health problems will occur without the use of pesticides; and (3) insufficient time exists from the discovery of a pest outbreak to register a pesticide to control the pest.
>
> *Crisis Exemptions: Section 18:* Exemptions are granted by a State agency where (1) an unpredictable emergency situation exists, and (2) the time element with respect to the pest outbreak does not allow for sufficient time to obtain an emergency or a public health or quarantine exemption. Crisis exemptions must be submitted for review to the EPA and the EPA can prevent an exemption from being issued and can also withdraw such an exemption once issued if the EPA later decides it is improper. Also, the EPA can withdraw a State's authority to issue such exemptions if a State abuses its exemption authority. Crisis exemptions are limited to 15 days unless extended by the

[11] National Academy Report at pp. 40-41.

EPA as an emergency, public health or quarantine exemption.[12]

In 1985, the EPA initiated a negotiated rulemaking process to develop detailed regulations for Section 18. As part of the negotiated rulemaking procedure, a committee was established consisting of representatives of commodity groups, state regulators, the chemical industry, environmentalists, and the EPA. The Committee's purpose was to assist the EPA in the drafting of the regulations. The Committee held a series of meetings during the year it was convened. The consensus reached by the Committee was adopted as final regulations to Section 18 of FIFRA on January 15, 1986. (See 40 C.F.R. Part 166).

The regulations clarify what types of situations qualify as an emergency. These regulations attempt to limit the number of emergency exemptions and to ensure that the same chemical products are not consistently granted exemptions year after year providing a *de facto* registration or "backdoor" market access for a chemical.

According to the regulations, an emergency is defined as an "*urgent nonroutine situation*". 40 C.F.R. Part 166.2(d). The emergency is to be caused by either "*the introduction or dissemination of a pest new*" to the area or by "*significant economic loss*" caused by a new pest or by "*a change in plant growth or development caused by natural environmental conditions.*" 40 C.F.R. Part 166.3. [Emphasis Added]. The regulations specify further that the term "*significant economic loss*" refers to a substantial reduction in normal, historical profitability resulting "*only from losses caused by the emergency conditions specific to the impacted site,* not from "*normal fluctuations*" in the market. Id. [Emphasis Added]."

The regulations also specify that for an emergency to exist there must be: "(i) *no effective [registered] pesticides available * * * and,* (ii) *no economically or environmentally feasible alternative practices which provide adequate control * * **" 40 C.F.R. 166.3. [Emphasis Added].

The rulemaking committee workpaper (published with the regulations) states that the typical emergency situation should involve a new pest for the region or a pest outbreak that will present a significant risk to human health for which there is no available registered pesticide. It further specifies that the regulations require an "*urgent nonroutine situation*" in order "*to emphasize that the situation must be other than an ordinary one * * * a chronic or continually occurring problem does not represent an urgent nonroutine situation*". See 50 Fed. Reg. No. 67. [Emphasis Added].

Finally, the regulations state that the applicant must also show that the pesticide which is the subject of the exemption request is making "*reasonable progress towards registration*" for the proposed use. *See* 40 C.F.R. 166.25. According to the regulations, "*it shall be presumed that if a complete application for the previous 3 years, has not been submitted, reasonable progress towards registration has not been made.*" Id. [Emphasis Added].

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[12] 40 C.F.R. Part 166.

C. The EPA's Section 18 Guidance Manual

In 1990, the EPA's Registration Division issued a guidance document interpreting Section 18. According to this guidance manual, the applicant for an emergency must "conduct a thorough search to identify all registered pesticides and cultural practices currently available for control of the emergency situation" in order to show that there are no alternatives to the requested exemption.[13]

The EPA guidance manual goes on to clarify how EPA will make a determination regarding *"significant economic loss."* The manual states *"a proposal based solely on using a pesticide (not registered for use on the subject crop) to improve the growers yields/income because the new pesticide is significantly more effective or less expensive than any of the existing control measures, is not an acceptable basis for a Section 18 request for an ongoing pest problem which has not intensified in recent years."* [Emphasis added].[14]

According to the guidance manual, the applicant is to submit five years of yield and price data and five years of data regarding the cost of production for the crop using alternative pesticides other than the substance for which the exemption is sought. *"Significant economic loss"* is then to be determined by analyzing the average net review for a five year period, if the expected loss figure without the exemption falls outside of average net profit, then the Agency determines the significant economic loss will result.[15]

Even if *"significant economic loss"* is demonstrated, the applicant still must be able to demonstrate that the pesticide in question is making *"reasonable progress towards registration."* The guidance manual states that the Agency will follow the regulatory definition which finds that *"reasonable progress towards registration"* is *not in effect where a complete registration application has not been submitted for the requested pesticide and the pesticide has been the subject of exemption requests during the past three years.* [Emphasis added].[16]

The guidance manual recognizes that a problem may arise when an application and supporting studies to register a chemical are submitted within the three year period yet the EPA decides that different or additional studies are required. In such a situation, the Manual states, the EPA will examine whether the applicant should have known that the submitted registration data had obvious deficiencies or whether the applicant in fact had submitted a "good faith" application in an attempt to obtain registration.[17] It is important to note that the guidance manual also specifies that a bright line presumption against a determination of *"reasonable progress"* will arise where an application has been pending but not deemed complete for a period of five years.[18]

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[13] Appendix A, Number 2 [hereinafter referred to as the "guidance manual"].
[14] Id. at 4-7.
[15] Id.
[16] Id. p. 3.
[17] Id.
[18] Id. at 13.

V. Prior Committee and GAO Investigations

A. The Agriculture Committee Report

From 1978 to 1983, the GAO and the Subcommittee on Department Operations, Research and Foreign Agriculture of the Committee on Agriculture (the "DORFA Subcommittee") thoroughly examined the EPA's implementation of the Section 18, emergency exemption program. Under the auspices of Chairman George E. Brown Jr., the DORFA Subcommittee held a series of hearings which revealed that numerous abuses plagued the EPA's administration of Section 18. To culminate the hearings, the Subcommittee prepared a report entitled *"Regulatory Procedures and Public Health Issues In the EPA's Office of Pesticide Programs"* which was issued in 1982 and reprinted as part of the Committee's 1983 Hearings.

The Subcommittee report found that "the rapid increase in the number and volume of pesticides applied under Section 18" was "clearly the most pronounced trend in the EPA's pesticide regulatory program." [19] According to the Subcommittee report, a primary cause of the increase in the number of Section 18 exemptions derived from the difficulty the Agency had in registering chemicals, under Section 3 of FIFRA, in a timely manner. In this regard, the DORFA Subcommittee report stated:

> Regulatory actions involving suspect human carcinogens which meet or exceed the statute's "unreasonable adverse effects" criterion for chronic toxicity often become stalled in the Section 3 review process for several years. The risk assessment procedures required by States requesting Section 18 and 24(c) actions, and by the EPA in approving them, are generally less strict. For example, a relatively new insecticide, first widely used in 1977, was granted some 140 Section 18 emergency exemptions and over 300 Section 24(c) Special Local Needs registrations in the next four years while the Agency debated the significance to man of positive evidence of oncogenicity in laboratory animals.[20]

The DORFA Subcommittee expressed concern that the EPA was not making decisions on registration applications in a timely manner but was granting exemptions year after year to the same chemicals which were unable to meet the health and safety concerns of registration. Section 18 authority was thus being used to circumvent the more stringent data and risk control requirements that apply to registration. The report found that emergency exemptions entail significantly less complete and rigorous data requirements and scientific review than is required for actual chemical registration. The act of granting such numerous Section 18 exemptions could thus, according to the Subcommittee, result in possibly serious adverse effects on human health, the environment, and on wildlife.[21]

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[19] DORFA Report, p. 59.
[20] Id.
[21] Id. pp. 39-59.

B. The GAO's 1978 and 1981 Investigations

In 1978 and again in 1981, at the request of the DORFA Subcommittee, the U.S. General Accounting Office conducted an investigation of the EPA's administration of the emergency exemption sections of FIFRA. The GAO found, in both investigations, that the EPA repeatedly granted emergency exemptions in situations of continuing and predictable pest outbreaks. In 1978, the GAO stated,

> *Repeated pesticide exemptions for the same use have the same effect as pesticide registrations,* indicating that the pesticide or a substitute should be registered for the use and *that exemptions have been granted for nonemergency situations.* [Emphasis added].[22]

The GAO investigations specifically revealed that from 1972 to the end of 1981 the number of granted exemptions rose dramatically and a large percentage of these exemptions were repeatedly granted for the same pest and the same crop in nonemergency situations. In 1981, the GAO found that of 167 randomly selected requests for emergency use of unregistered chemicals, 45, or 27 percent, had been repeatedly approved for 2 or more consecutive years and 15, or 9 percent, were approved for 3 or more consecutive years.[23]

At that time, the EPA's own policy statements acknowledged that emergency exemptions should not be repeated year after year; however, the EPA did not maintain a data base allowing it to analyze what substances were continually exempted as emergencies. The GAO in its 1981 report concluded from such data that severe problems plagued the EPA's administration of the exemption program.[24]

The GAO investigations further revealed poor compliance with specific requirements written into exemption grants. Under the exemption program, the EPA may approve an exemption with requirements regarding: (1) the quantity of pesticide used; (2) who may apply the pesticide; and (3) the conditions under which the pesticide should be applied and monitored. In its 1981 report, the GAO noted a severe lack of any monitoring for compliance with exemption grants resulted in a lack of compliance by state and local agencies with specific requirements attached to many Section 18 exemptions.[25]

Further, the GAO investigation revealed that as a result of an average 40 day processing delay, many requests for emergency exemptions were neither approved nor rejected in a timely manner. Consequently, the GAO found that the states frequently would grant a "crisis exemption" for a pesticide while a decision on an emergency exemption was still pending before the EPA. To preclude the inappropriate designation of a "crisis," the GAO, in its

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[22] GAO, p. 30, "Special Pesticide Registration By the Environmental Protection Agency Should Be Improved" GAO/CED-78-9. Washington, DC, 1978.
[23] GAO, 1981. pp. 28-34. "Stronger Enforcement Needed Against the Misuse of Pesticides". GAO/CED-82-5. Washington, DC.
[24] Id. at 31.
[25] Id.

1981 report, strongly recommended that the EPA ensure more timely responses to Section 18 requests.[26]

In addition to recommending that requests be processed speedily, the GAO also listed the following recommendations to the EPA:

- Develop an information system which identifies emergency exemptions by state so that repetitive requests can be analyzed and reviewed for conformance with FIFRA guidelines.
- Notify states that repetitive emergency exemptions will not be approved unless their justifications are fully documented.
- Ensure that specific exemptions are monitored for compliance with any specific requirements.[27]

To date, the EPA has only implemented one of the recommendations found in the 1982 GAO report. Specifically, the EPA has developed an information system with the stated goal of identifying emergency exemptions by both chemical compound and by state. In response to the other GAO recommendations, however, the EPA has taken no action.

VI. Findings of the GAO's 1991 Investigation

In the fall of 1990, Chairman of the Subcommittee on Environment, The Honorable James Scheuer, requested that the GAO conduct a follow-up investigation of Section 18 of FIFRA. The Subcommittee on Environment specifically requested that the GAO examine whether Section 18 was still allowing for the repetitive use of unregistered pesticides in nonemergency situations.

As a result of Chairman Scheuer's request, the GAO conducted a specific follow-up investigation to determine if repetitive exemptions continued to be granted by the EPA. The findings of the GAO investigation were released at a Subcommittee hearing held by the Subcommittee on Environment on July 23, 1991.[28] In its testimony during the hearing, the GAO concluded that the same problems identified in 1978 and in 1981 continued to plague the Section 18 program. Specifically, the GAO found that the EPA improperly continues to grant exemptions for the same use for several years or in nonemergency situations of predictable pest outbreaks.[29]

As for total numbers of exemption grants, the GAO found that roughly 400 emergency exemptions were issued annually. The large numbers of chemicals continually being used under Section 18 clearly represents the circumvention of EPA's registration process by many companies. The GAO also found that repetitious use of Section 18 for the same product creates "permanent fixtures" in the Section 18 program.[30]

Further, the 1991 GAO investigation found a continuing pattern of repeat emergency exemptions. The investigation revealed that:

- Of the 353 specific exemptions that were requested during 1990, 66, or roughly 20%, were for pesticides that had already been exempted at least three times over the last five years.

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[26] Id.
[27] Id. at 34.
[28] See U.S. Congress, Hearing before the Committee on Science, Space, and Technology, Subcommittee on Environment, Committee Publication Number 102-68 (hereinafter referred to as Hearing Record), Testimony of the General Accounting Office.
[29] Id.
[30] Id.

- Of the 66 three year repetitive requests made to EPA in 1990, 53 were granted as emergencies, 11 were granted as crisis exemptions, 2 were withdrawn, and only 1 request was rejected.
- Thus, EPA approved outright 53 of the group of 66 repetitive requests, granted tacit approval to 11, and rejected only 1.[31]

According to the GAO, such figures indicate that EPA is not adequately enforcing the requirement that repetitive emergency approvals be made only if the pesticide can demonstrate *"reasonable progress towards* registration."[32]

The GAO also found that the same pesticides are often granted exemptions in a number of States for a variety of uses, despite the fact that the EPA has not thoroughly examined the cumulative effects to human health or the environment from such use. For instance, the GAO found that from 1986 to 1991, the chemical compound Avermectin was granted 31 exemptions for use on various crops, yet no cumulative assessment of the health or environmental impact of such cumulative use was conducted.[33]

As part of its 1991 investigation, the GAO also determined that emergency exemptions are often granted by the EPA although effective alternative pesticides could be utilized to prevent the emergency situation.[34] The investigation revealed that the EPA frequently decides that the affordability of an unregistered product versus the higher cost of using a registered alternative pesticide sufficient to show *"significant economic loss"*. Thus, although the regulations require a determination by the EPA as to whether *"significant economic loss"* will occur without the exemption but with the use of an alternative chemical, this regulation is rarely followed. Instead, the EPA frequently grants the emergency exemption if the requested substance will cost less than the alternative registered chemical.[35]

In regard to recommendations, the GAO asserted that the EPA should follow its own stated policy of establishing time schedules for FIFRA registration and not allowing any exemptions for substances which are not in compliance with such time schedules. Thus, to ensure against repetitive exemptions, the GAO strongly recommended that the EPA adopt a firm rule flatly excluding from the definition of an "emergency" chronic or repetitive requests that continue for over three or four years".[36]

VII. Subcommittee Findings

The Subcommittee on Environment of the Science, Space, and Technology Committee also conducted an investigation and analysis of the Section 18 program. This investigation utilized documents that were produced to the Subcommittee from EPA as well as testimony submitted for the record of the July 23, 1991 subcommittee hearing.[37]

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[31] Id.
[32] Id.
[33] Id.
[34] Id.
[35] Id.
[36] Id.
[37] See. Hearing Record and Appendix A.

The Subcommittee on Environment's findings are similar to the findings of the GAO. After analyzing the documents produced by the EPA and examining the testimony submitted for the hearing, the Subcommittee determined that the EPA often fails to enforce its own regulations to Section 18 of FIFRA. In this regard, the Subcommittee found that repetitive requests are often granted for periods of 10 or 11 consecutive years.[38] Such repetitive exemptions violate the EPA's own regulatory guidance, as such guidance states that after three years a legal presumption should be raised that the requested substance is not making *"reasonable progress towards registration."* [39]

A. EPA Fails to Examine Significant Economic Loss

Further, the Subcommittee found that, in the majority of Section 18 decisions, the EPA ignores the requirement that an exemption should only be granted upon a finding of *"significant economic loss"*. The regulations state that a *"significant economic loss"* exists when *"losses caused by the emergency conditions, specific to the impacted site, and specific to the geographic area * * * exceed what would be expected as a result of normal fluctuations (in profitability) over a number of years."* See, 40 C.F.R. Part 166. The EPA's guidance document states that the Agency is to examine "five years of yield and price data along with cost of production data" to complete an historical economic analysis of crop losses without the use of the requested unregistered substance to determine if significant economic losses will occur.[40] An analysis of the EPA documents in Appendix B clearly indicates that, in reality, the EPA rarely makes such a historical finding of *"significant economic loss"* based upon an analysis of losses during prior years. Instead, the EPA generally ignores this requirement by accepting the applicants assertion that without the requested exemption the crop will suffer from *"significant economic losses"*.

B. EPA Fails To Examine of The Effectiveness of Alternatives As Required By Regulation

The Subcommittee also found that the EPA has no criteria to identify whether or not any *"alternative"* effective chemicals could be utilized instead of the requested exempted substance. The regulations clearly specify that an emergency only exists where *"no effective {registered} pesticides are available,"* and where there are no *"environmentally feasible alternative practices"*. 40 C.F.R. Part 166.20(4). The approval documents submitted to the Subcommittee show however, that the EPA follows no criteria to identify whether an "alternative" substance to the requested Section 18 chemical may be "effective".

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[38] Examples of repetitive exemptions include exemptions granted for Botran on Peanuts for a 14 year period; sodium chlorate on wheat for 10 years; glyphosate on wheat for 9 years; cryolite on potatoes for 9 years; Vinclozin on snap beans for 8 years; triadimefon on tomatoes for 8 years; hydrogen cyanamide on grapes for 6 years; cryomazine on peppers for 7 years; cypermethrin on onions for 5 years; bromoxinil on rice for 5 years; chlorothalonil on mushrooms for 5 years; mancozeb on ginseng for 4 years; thiobencarb on assorted vegetables for 5 years, and triflumizole on spathiphyllum for 5 years.

[39] Appendix A, Number 2.

[40] Id.

Testimony received by the Subcommittee during the hearing emphasized that new effective alternatives to the exempted substance often exist yet farmers are reluctant to give up the use of the older, often more toxic substances to experiment with the use of newer products.[41] For instance, according to the National Coalition Against the Misuse of Pesticides, reliable data from the University of Kansas indicated "that yields not significantly different from those using Capture (the subject of exemption requests) could be achieved by using Dipel * * *" to control spider mites on corn in Kansas, Nebraska, Oklahoma and Texas.[42] Notably, Section 18 has been utilized for the last 11 years for mite control of corn in a number of these States. Despite the existence in 1991 of an alternative, the EPA continued to grant the exemption apparently because of farmers reluctance to use the new substance.

Detailed below are additional examples, gathered from the submitted documents, which illustrate that the EPA frequently fails to examine the actual "effectiveness" of alternatives or whether *"significant economic loss"* would result even with the use of an alternative substance. The first example is bromoxynil. In 1990, the EPA—for the fourth consecutive year—granted exemptions to various states for the use of the herbicide bromoxynil and triclopyr on rice. The EPA noted, in one of its own Section 18 approval documents, that "the economic losses are probably overstated" since the economic analysis had been conducted without figuring in the use of alternatives. Despite this acknowledgment, the EPA failed to independently analyze *"significant economic loss"* with the use of alternative herbicides and granted the request for the exemption.[43]

Exemptions were also granted by the EPA for the use of the substance permethrin. Permethrin is known to be acutely toxic to fish and bees, and, according to the National Academy of Sciences, is a known oncogen.[44] Exemptions continue to be requested for the use of permethrin on wheat and other crops although Dipel 2x is registered on wheat and the Bacillus thuringiensis ("Bt")[45] product Javelin is also an available alternative. EPA continues to grant the permethrin exemptions although no analysis is done to examine the effectiveness of the alternatives.

Also, Section 18 exemptions were granted to many States for the use of Avermectin on pears, despite the fact that the EPA's own

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[41] See. Hearing Record. Testimony of Dr. Jerry Caulder.

[42] Id.

[43] Appendix A, No. 61. Section 18 Action Memorandum for Bromoxynil on rice.

[44] Appendix A, No. 13. Section 18 Memorandum for Permethrin. An oncogenic chemical substance is defined by the EPA as a substance capable of producing benign or malignant tumors in laboratory animals. Such substances have the potential to cause cancer in humans. To indicate the relative hazard of animal oncogens to humans, the EPA has developed a classifications system which was adapted from the approach of the International Agency for Research on Cancer. The system contains five basic categories: a group A oncogen is classified as a human carcinogen; a group B oncogen is classified as a probable human carcinogen; a group C oncogen is classified as a possible human carcinogen; a group D oncogen is not classifiable due to inadequate data; and a group E oncogen indicated no evidence of carcinogenicity in at least two adequate animal tests in difference species. The classification for group E is based on available evidence and does not mean that the agent will not be a carcinogen under any circumstances. See National Academy Report. Chapter 3 for general information on oncogens, p. 68 on EPA's classifications, and p. 75 for information on permethrin.

[45] A Bacillus thuringiensis ("Bt") product utilizes a natural plant bacteria to selectively control pests on crops. Genetic engineering technology recently has created new uses for Bt's by allowing the encapsulation of natural pest toxins into parts of the crop. See National Research Council, "Alternative Agriculture," 1989. p. 182.

1989 approval document for this exemption admits that the registered substance Apollo may be an effective alternative.[46] Similarly, the EPA in 1991 granted exemptions for the 10th consecutive year for the use of cryolite on potatoes to Delaware, Rhode Island, and Virginia despite the fact that these States did not even claim that the alternative pesticide would not be effective. Problematically, no real analysis was ever conducted by the EPA at to the effectiveness of the alternative Bt pesticides as compared to the use of cryolite and, similarly, no real analysis was undertaken of the effectiveness of the Bt substance, Apollo, as an alternative to Avermectin.[47]

From the above examples, the Subcommittee concluded that exemptions are repetitively granted despite the fact that alternative registered chemicals could prove effective. The EPA fails to require the submission of independent data upon which to consider the effectivencss of alternatives. Instead, the EPA relies on whatever bare information is submitted in applications for a Section 18 exemption. Thus, many effective alternatives are not being utilized in place of Section 18 chemicals. The EPA's permissiveness in granting exemptions in routine situations, in fact, delays the acceptance of environmentally benign pesticides and alternatives while encouraging farmers to rely on older, established chemical solutions.

C. Routine Predicted Pest Outbreaks And Foreign Competition Qualify As An Emergency

Not only does the EPA fail to examine alternatives, the Subcommittee determined further that the EPA, in fact, follows no criteria regarding what types of situations qualify as emergencies. The language of the Statute and regulations refer to a new pest outbreak or a change in plant growth caused by unusual environmental conditions as the requisite causes of an emergency. See 40 C.F.R. Part 166.[48]

Unfortunately, it is evident that, in many instances, Section 18 is being utilized to salvage poor business decisions instead of to control unexpected pest emergencies. For instance, foreign competition has sufficed as the cause of a six year emergency allowing the use of the substance hydrogen cyanamide on grapes. Hydrogen cyanamide works to speed the growing season so that U.S. grapes can be marketed prior to the less expensively grown grapes from outside of the U.S. From 1984 to 1990, California farmers were permitted to use the Section 18 exemption program to apply hydrogen cyanamide and speed the natural growing season thereby providing for higher prices and early market access of such locally grown grapes. Problematically, hydrogen cyanamide is not registered at all for use on any crop. Moreover, it is considered a hazardous substance which cannot be shipped by plane, and studies indicate that meta-

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[46] Appendix A, Nos. 13 and 14. Section 18 Memorandum for Permethrin and for Avermectin.

[47] Appendix A, No. 14 and 19. In 1992, a number of States received their 10th annual exemption for Cryolite.

[48] The negotiated rulemaking committee, that assisted in drafting the regulations, noted a danger of Section 18 evolving away from an emergency exemption clause and into a form of insurance by which growers could salvage unsuccessful business decisions by obtaining end-runs around the expensive requirements of FIFRA registration. See 40 C.F.R. Part 166. The EPA's guidance document to implement Section 18 of FIFRA states that the emergency exemption "was not intended to help growers maximize yields or profits." Appendix B. Guidance Manual. p. i.

bolities of hydrogen cyanamide can be traced in the blood and urine of workers even in regions that are not directly involved in the chemical's application.[49]

The Subcommittee's view is that if enhancing the growing season of U.S. grapes should only occur if the chemical can be proven safe through full registration. Granting exemptions for the use of hydrogen cyanamide thus represents an example of a clear abuse in the administration of Section 18. Testimony given to the Subcommittee also revealed that in recent years the substances Harmony and Propicaonazole were granted under Section 18 despite the fact that the problems causing the proclaimed emergency were other than pest problems and despite the potential harm to human health and the environment from these unregistered substances.[50]

D. Possible Human Carcinogen Are Repetitively Granted Exemptions

The Subcommittee also found that many of the exempted chemicals are indefinitely stalled in their progress toward Section 3 registration because of concerns of carcinogenicity or mutagenicity. Companies attempting to register new uses of substances known to cause tumors in laboratory animals or "oncogens" often engage in lengthy debates with the EPA over the data needed to satisfy the Agency's toxicity standards. These companies attempt to show that the chemical does not meet the statutory definition of "unreasonable adverse effects" warranting rescission of all registered uses. Such debates can extend for well over 10 years.

These chronic toxicity studies, usually the most complex requirement of a FIFRA registration, take an average of three to four years to complete. The Assistant Administrator, Office of Pesticides and Toxic Substances, Ms. Linda Fisher stated at the Subcommittee hearing "[i]t generally takes three years to conduct a chronic toxicity test on a chemical and an additional year to analyze the results and report to EPA".[51] Despite this mean time period and despite the three year time limit in the EPA's guidelines, the Subcommittee found that, in practice, EPA follows no procedures to establish whether a chemical is making *"reasonable progress towards registration"*. In fact, the EPA often grants repeat emergency exemptions for much longer than a period of three or four years. The GAO investigation found that many recent exemptions have been repetitively granted for 9 or so years, such as for cryolite on potatoes and vinclozin on snap beans. These exemptions are for new uses of chemicals for which chronic toxicity data has never been submitted.

Although such chemicals review are stalled in terms of full registration for many years, they are still able to repeatedly obtain exemptions. Exemptions can be granted because Section 18 review procedures entail significantly less complete and less rigorous data and analyses. Thus, if a chemical is a probable or suspected oncogen it may already be registered under old standards and testing procedures, but it likely will have difficulty being registered for use

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[49] Appendix A, Number 26. Section 18 memorandum for Hydrogen Cyanamide.
[50] Hearing Record. Testimony of Mr. Jay Feldman.
[51] Hearing Record. Testimony of the Environmental Protection Agency.

on new crops or crops with higher residue levels due to carcinogenicity concerns which arise when these substances are tested according to the current, modern standards and procedures. Section 18 exemptions, however, allow for temporary market access even though the chronic toxicity studies for crops with high residue levels will be almost impossible to complete.

The GAO in its testimony during the hearing, used the example of Botran, also called DCNA, which has been repetitively granted Section 18 exemptions for use on peanuts from 1978 through 1992. The exemptions for Botran were granted despite the fact that significant mutagenicity and carcinogenicity concerns existed and despite the existence of an alternative registered substance. In fact, the EPA granted the exemption for Botran in 1990 although in the EPA's own documents from a prior year it had admitted that Botran was not making reasonable progress towards registration since the manufacturer was unable to complete the required toxicity residue studies.[52]

The Subcommittee found additional instances of repetitive Section 18 exemptions being granted for substances that are classified by the EPA and the National Academy of Sciences as probable and suspected carcinogens. For example, repetitive requests were granted during the period from 1988 to 1991 for linuron, cypermethrin, permethrin, mancozeb, metachlor, parathion, and fosetyl-al. Each of these is ranked by the EPA as a Group B or Group C probable or suspected carcinogen.[53]

Generally, chemicals that were registered for any uses prior to current standards and testing requirements are the most dangerous or potentially carcinogenic. In large part, they comprise the list of chemicals classified by the EPA and the National Academy of Sciences as probable and suspect oncogens. In fact, the National Academy of Sciences has found that the older chemicals (those registered prior to 1978 and prior to modern testing requirements) now comprise more than 90 percent of all estimated dietary oncogenic risk.[54] Unfortunately, many of these substances are still utilized under the emergency exemption procedures.

Another example of a questionable exemption are the exemptions for the use of chlorothalonil, which is classified as a group B oncogen. The EPA itself acknowledges that chlorothalonil is oncogenic, highly toxic to fish, persistent in water, has the potential to reach groundwater, and requires extreme care in handling.[55] Nevertheless, the State of Pennsylvania was granted an exemption by the EPA to use chlorothalonil on mushrooms even though the same exemption in the proceeding year had resulted in improper spraying practices and human health concerns.[56] The regulations require the EPA to find that the pesticide is reasonably likely to be used in compliance with the conditions imposed by the exemption grant. 40 C.F.R. Part 166.25. The EPA, however, decided to grant a

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[52] Hearing Record. Testimony of the General Accounting Office.
[53] National Academy Report, p. 68.
[54] Id. at 85-87.
[55] Appendix A, No. 12. Section 18 Memorandum for Chlorothalonil.
[56] Id.

repetitive exemption for use of a highly oncogenic substance even when past violations of the grant conditions were evident.[57]

From the above examples, it is evident that EPA's failure to determine what constitutes *"reasonable progress toward registration"* as required in the regulations may have quite serious consequences for human health and the environment. Besides the grants of exemptions for known or suspected oncogens, it is also troubling that by certain exemptions have been granted by the EPA despite the fact that the use of the exemption will place the allowable daily intake ("ADI") amounts for such chemicals above the permissible level of 100 percent. For instance, repetitive exemptions for the substances Poast and Lorsban were recently granted although, in each case, the exemption placed the current ADI over present human safety levels.[58]

VIII. Subcommittee Conclusions

From its review of Section 18 decisional memorandum and testimony received during the hearing, the Subcommittee concluded that almost any degree of expected economic loss will suffice for the EPA to make a determination of *"significant economic loss"*. The Subcommittee review also showed that no procedures are in place for the EPA to assess the effectiveness of alternatives, or to what extent such alternatives could be more beneficial to human health or the environment. Finally, the Subcommittee found that many of the Section 18 exemptions which are repetitively granted year after year could individually, and in the aggregate, result in adverse impacts to both human health and the environment.

As for the problem of repeat emergency exemptions, Ms. Linda Fisher, the Assistant Administrator of EPA's Office of Pesticide and Toxic Substances, suggested that the statute be amended to allow for exemptions in "routine" pest situations. She claimed, during the hearing, that a pest outbreak can stretch on for 10, 11, or 12 years, be quite predictable, and still be an emergency situation warranting the use of unregistered substances.[59]

Both she and other witnesses, however, admitted that Section 18 is frequently used by a company to gain market access for use of a pesticide on a new crop, although the company often never intends (or will never be able) to submit adequate data to register the chemical for the use.[60]

Because Section 18 provides such temporary market access, only half of all Section 18 substances ever become registered for their exempted use.[61] From such data, the Subcommittee concluded that the EPA's current practice of allowing exemptions year after year in predictable situations provides "back-door" pre-registration market access to potentially dangerous chemicals.

Further, the Subcommittee concluded that improper and repetitive grants of Section 18 exemptions over the long term serve to

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[57] Id.

[58] Appendix A, No. 11. Section 18 Memorandum for Poast.

[59] Hearing Record, Testimony of the EPA. p. 82, Ms. Fisher states, referring to the Section 18 regulations, "we need to take a look at whether nonroutine is an appropriate term".

[60] ID. Testimony of Dr. Jerry Caulder and Mr. Jay Feldman.

[61] Id. Testimony of the EPA.

"discourage the use or the development of alternatives to chemical pesticides that can be just as effective when used properly." [62] The Subcommittee's view is that it is of the utmost importance to encourage growers to move toward a more sustainable method of pest control. Further, this investigation clearly shows that a move toward sustainable pest control will only occur when such prevalent misuse of Section 18 ceases.

IX. The Subcommittee's Recommendations

To rectify the problems identified in this report, the Subcommittee recommends the adoption of a number of changes to the Section 18 program. First, the Subcommittee concurs in the GAO's recommendation of the establishment of a firm rule by which chronic, repetitive requests would be flatly excluded from the definition of an "emergency". The findings of this report show that misuse will continue to plague the emergency exemption program, unless a final limit defines the length of time beyond which an unregistered substance cannot qualify for an exemption.

On occasion, such a rule could prevent the use of a desired substance. More importantly, however, a maximum time limit will serve to expedite registration for new uses where the manufacturer is serious about pursuing registration. Establishing a maximum time limit will prevent a manufacturer from using the Section 18 program to gain temporary access to the market for limited use of a chemical. Finally, a maximum time limit will also ensure that modern and long-term health and environmental tests are conducted for the majority of chemical's that are used on our crops.

In addition, the Subcommittee recommends that the term "significant economic loss" be defined as a specific percentage ~~of~~ loss of yield. Such a definition will prevent the current practice whereby minor losses or normal fluctuations in profits are categorized as significant or where the applicant could use an effective alternative but wishes to obtain an exemption for use of an unregistered substance which would maximize profits.

To rectify the usage of unregistered chemicals simply to maximize yield, the Subcommittee recommends the adoption of a percentage limit not only to define "significant economic loss" but also to define when an alternative is to be deemed an "effective alternative" that prevents the granting of the exemption. To review alternative substances, the Subcommittee recommends the adoption of a number of new procedures to be followed by the EPA. First, any efficacy data on alternative chemicals that accompanies proposed Section 18 requests should be examined to determine whether such data is consistent among the States requesting Section 18's. Further, procedures should be implemented to mandate that the EPA consider public efficacy data on alternatives other than the data that may have been submitted with the Section 18 request.

As mentioned above, the EPA should further adopt a percentage limit to define how much more effective an unregistered substance must be for it to be allowed over a substantially effective alterna-

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[62] Hearing Record. Testimony of the General Accounting Office, Testimony of Dr. Jerry Caulder, Testimony of Mr. Jay Feldman.

tive. This type of regulation will clarify that the health and safety benefits to be derived from the use of an alternative registered substance clearly outweighs a slight reduction in crop yield.

The Subcommittee investigation of Section 18 of FIFRA shows that innovation in the field of pest control or agricultural systems will always lag far behind beneficial innovations as long as the regulatory scheme fails to define how one weighs and balances the costs of chemical inputs to human health and environment versus increases in crop yield. Neither Section 18, nor FIFRA nor the FFDCA prescribes the nature of the benefits analysis that should be done prior to authorizing use of an agricultural chemical.[63] For example, nowhere in either statute is there a legal requirement for a cost-benefit analysis to be done for use of the chemical as compared with alternatives. This policy exists in spite of the fact that a small number of currently used pesticides appear to present the vast majority of health and environmental risks associated with pesticides, and this policy, moreover, inhibits the marketing of newer, safer pesticides and alternative practices.[64]

The Subcommittee thus recommends that standards be established to show the efficacy of a substance versus its harmful health and environmental impacts prior to either its registration or its exemption under Section 18. These standards should include an analysis of the environmental benefits as well as potential human health benefits to be derived from alternatives including alternative agricultural policies. To foster development of alternative agriculture, the Subcommittee further recommends that the EPA review alternative pest controls still under development prior to granting a Section 18 exemption. According to the National Academy of Sciences, the efficacy data on experimental compounds available in the reports of professional associations provide evidence of possible replacements for presently used chemicals.[65]

In conclusion, the Subcommittee strongly recommends that EPA follow its own regulations and refrain from allowing exemptions to be used where the emergency is due to foreign marketing or a situation that is not related to a pest problem or to allow for the same emergency exemption for over three years in a row. Finally, the Subcommittee's view is that it is imperative that strict procedures be established to review Section 18 requests for substances that have been identified as oncogenic or substances for which the registration of new uses is stalled due to environmental concerns or human health concerns. Extended delays in completing the health or environmental data set of older chemicals substances should raise a presumption, on the part of the EPA, that the chemical is not making reasonable progress towards full registration or re-registration.

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[63] U.S.C. 136 and 21 U.S.C. 346.

[64] National Research Council, "Alternative Agriculture," p. 13.

[65] National Academy Report, p. 227. If the EPA were to emphasize the prospects for new pest control technologies in its benefits analyses, such a shift to a wider range of alternatives would decrease the long-run benefits of the pesticide under consideration and would encourage use of alternatives in general. According to the National Academy, "the broadened scope of benefit analysis would increase the risk/benefit ratio and the probability of cancellation of a registered pesticide or the rejection of an unregistered pesticide. If this expanded benefit analysis by the EPA is perceived by industry to be reasonably stable, pesticide manufacturers may be expected to respond by increasing production of registered substitutes and developing new pesticides for a changing market.

X. Dissenting Views

We disagree with our colleagues who approved the publication of this report, Messrs. Brown, Scheuer, Nowak, Swett, Olver, Wolpe, Mrs. Horn and Mrs. Morella. We believe Section 18 provides a vital mechanism to ensure that appropriate tools are available for emergency situations that threaten public welfare, the environment and agricultural production or distribution.

Under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), pesticides must be registered with the Environmental Protection Agency (EPA). Under the registration process, EPA must be certain that the use of a chemical will not result in unreasonable adverse effects on human health or the environment, which calls explicitly for balancing adverse impacts on public welfare and environment against economic impacts of disruption of agricultural production or distribution. To reach this determination, EPA requires a large number of scientific studies that can cost $20 to $40 million, and generally take 7 years or more to complete. In addition, manufacturers are required to reregister older chemicals.

The burden on EPA in reevaluating existing agricultural pesticides and reviewing new ones for registration is increasing. While the registration and reregistration processes provide a valuable safety benefit to society, the result has been and will continue to be, that many manufacturers are forced to reduce the number of pesticides available for specific uses. The problem is particularly acute for emergency pest introductions and import quarantine uses because there is little or no economic benefit to a manufacturer for incurring registration or reregistration costs for a pesticide that will have a limited market.

Since Section 3 pesticide registrations are costly and time consuming to complete, emergency pest control situations can require the immediate use of a pesticide to prevent significant crop losses and retard the growth of pest populations. In 1972, Congress amended FIFRA by adding Section 18, which gives EPA the authority to allow emergency use of a chemical that has not yet completed the Section 3 registration. Current EPA regulations governing Section 18 are much more restrictive than required by broad authority provided by Congress.

We have identified six general conclusions and recommendations contained in this Report, and outline our objections to them.

1. Section 18 emergency exemption approvals do not require as much data to be provided to EPA as would otherwise be required to obtain a complete Section 3 registration. Therefore, humans, wildlife, and the environment are subjected to increased risk.

EPA does not allow the Section 18 process to be used to bypass the full health and safety review required for the registration of a pesticide under Section 3 of FIFRA. Although

the full range of data required for a Section 3 registration may not be available, EPA evaluates each request for potential risks to human health and the environment. This includes a toxicology evaluation, a residue evaluation, an ecological effects review, and an environmental fate review. EPA does not approve the use of a pesticide under Section 18 that will cause an unreasonable adverse effect on the environment.

2. EPA is failing to implement its own regulations by granting repeat exemptions, failing to show that significant economic losses would occur, or failing to substantiate that the potential registrant is making adequate progress towards obtaining a full Section 3 registration.

EPA requires that the state or federal agency requesting the Section 18 exemption prove that an emergency situation, in fact, exists. EPA typically requests five years of yield and price data to calculate potential economic losses while states provide the best possible production expense and revenue data. EPA does not approve requests unless shown to affect a farmer's long-term financial viability.

In the case of public health emergencies, EPA requires information on the potential disease which may be transmitted, the magnitude of health problems which can be expected to occur and the medical treatment available for the health problems.

EPA presumes that reasonable progress has not been made if a complete registration application has not been submitted for a pesticide use which has been under an emergency exemption for 3 years. However, EPA does not have the flexibility to determine if overriding factors would allow the exemption beyond 3 years. Several kinds of circumstances can occur to legitimately delay the submission of the data necessary for Section 3. For example, chronic toxicity tests required as for registration generally take more than 3 years to conduct. States rely on EPA's ability to provide flexibility in this area in order to control pest outbreaks which can threaten public health, the environment and the livelihood of farmers.

It is also illustrative that EPA's request for increased appropriations to improve their responsiveness on reregistration have been denied consistently.

3. Older chemicals are provided Section 18 approvals on crops for which they are not registered, even though the chemical may be identified as potentially carcinogenic.

EPA will not approve a Section 18 request without sufficient toxicology and residue data necessary to address human dietary concerns. If EPA finds that approval of additional uses of a particular chemical could cause an unwarranted increase in cancer risk, the emergency request will be denied.

4. EPA should put into law an absolute time limit beyond which repetitive exemption requests would not be granted.

EPA should be able to maintain the flexibility necessary to deal with special circumstances. It is important to remember that Section 18 requests are put forward based on the many factors: the need to control a public health hazard; to protect the environment; eradicate foreign pests coming into the United States from abroad; and farmers' need to produce a crop. Public health professionals and farmers have no control over the Section 3 registration process. Ultimately, an inflexible EPA statute will bring significantly greater public health concerns, interruptions in the free flow of trade and financial devastation to farmers.

Because of a shortfall of approximately $15 million in the EPA's appropriations for this function, many manufacturers are failing to reregister certain chemicals. This has placed additional strain on the Section 18 program, and has led EPA to seek increases in registration fees.

5. Economic standards should be established to define what constitutes a "significant economic loss."

Under existing EPA regulations, a significant economic loss only occurs when a farmer's financial losses will exceed those that could be normally expected over several years or would significantly impact the long-term viability of the farm. It would be extremely difficult, if not counterproductive, to more precisely define "significant economic loss" since financial conditions can vary greatly from farm to farm, crop to crop, and region to region. If anything, EPA criteria should be changed to provide for careful evaluation of smaller groups of affected farmers. Under current procedures where EPA evaluates quests on a state-by-state basis, small groups of producers find it extremely difficult to convince EPA that an emergency situation exists even though they stand to suffer irreparable financial damage. Basing "significant economic loss" on lost yield fails to take into consideration other economic factors such as international trade, social and environmental consequences.

6. Section 18 requests should follow a complete regulatory process including comment periods and public hearings to provide for greater public input and submission of competing data.

EPA is already hard pressed to complete all of its reviews of Section 18 requests quickly enough to provide states with a decision before the pesticide is needed for timely application. Although they attempt to issue decisions on Section 18 requests within 50 days, in some cases EPA has been unable to complete an adequate review in time for the pesticide to be used effectively.

Given the repeated failure to provide EPA the appropriations necessary to administer the existing program, imposing the costs of a complete regulatory process on the agency would result in greater delays in the program.

A more realistic, cost-effective approach would be to direct EPA to streamline the Section 18 process to provide quicker

reviews so that the most appropriate applications of the needed chemical can be make.

The recommendations in this Report fail to recognize the real need to combat emergency outbreaks of pests which, if left untreated, could have a long-term economic impact on the environment, agriculture, consumers and trade. The Section 18 program can be assisted by appropriating funds necessary to conduct the current program and by maintaining enough flexibility in the program to ensure that decisions on pesticide use are based on solid risk-benefit analyses.

DON RITTER.
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Enclosure F

POISONOUS PROCESS

How the EPA's Chronic Misuse of 'Emergency' Pesticide Exemptions Increases Risks to Wildlife

Stephanie M. Parent and Nathan Donley
Center for Biological Diversity • December 2017

Poisonous Process: How the EPA's Chronic Misuse of 'Emergency' Pesticide Exemptions Increases Risks to Wildlife

Stephanie M. Parent and Nathan Donley[1]

EXECUTIVE SUMMARY

For years the U.S. Environmental Protection Agency has routinely issued "emergency" exemptions for the use of certain pesticides across millions of acres in the United States, in ways that are known to be harmful to wildlife and in cases where the potential harmful effects haven't been properly investigated. These exemptions allow pesticide manufacturers to bypass the established pesticide-approval process intended to protect people, wildlife and the environment.

For this analysis the Center for Biological Diversity examined those types of exemptions for use of the bee-killing pesticide sulfoxaflor.

Our examination of EPA records reveals a chronic misuse of emergency exemptions for this pesticide. At least 78 emergency exceptions have been granted for sulfoxaflor over the past six years on just two crops: cotton and sorghum. The ongoing exemptions are notable because previous approval of the pesticide's use on cotton was cancelled in 2015 due to its potential harm to pollinators; it has *never* been approved for use on sorghum, which is attractive to bees.

Our analysis also found that:

- The 78 emergency exemptions issued for sulfoxaflor since 2012 allowed its use on more than 17.5 million acres of U.S. farmland.
- Only eight of the 78 exemptions went through a public review process that allowed for comment and review by citizens and independent researchers.
- The emergency uses of the pesticide approved for cotton were in response to an insect that has been a chronic problem for at least a decade and has already developed resistance to four different classes of pesticides.
- The emergency uses on sorghum were granted in at least 18 states in response to an insect that has been a problem for the past five years.
- Fourteen states were given emergency exemptions for sulfoxaflor for at least three consecutive years for the same "emergency."

These emergency exemptions have essentially allowed its use on millions of acres of crops where exposure to pollinators through contaminated pollen is high, for scenarios

[1] The Center appreciates and acknowledges the work of Purba Mukerjee in drafting this report.

that are routine and foreseeable. In effect this facilitates widespread use of pesticides that are not eligible for approval on certain crops because of well-documented risks to the environment.

Conclusion: The EPA's routine misuse of these exemptions for sulfoxaflor poses significant risks to pollinators such as bees, small birds and butterflies. Our analysis also reveals a larger, systemic problem that has gone largely unrecognized at the EPA with regards to widespread application of "emergency" exemptions.

Recommendation: The EPA should only grant emergency exemptions for a true emergency on a temporary basis and not as a way of continually insulating growers from the normal risks of agriculture. If a pesticide cannot gain approval under the normal pesticide-approval process, then agricultural practices must change to reflect that reality.

Emergency Exemption Review

More than 1 billion pounds of pesticides are used each year in the United States, the bulk of which are applied to farmland. U.S. pesticide use is regulated under the Federal Insecticide Fungicide and Rodenticide Act, or FIFRA, which gives the Environmental Protection Agency authority to approve or ban pesticides based on their effects on human and environmental health.

Sometimes emergency pest infestations arise, and farmers or state agencies request quick access to a pesticide that is not approved for a particular use. For this reason FIFRA contains an emergency exemption provision that allows the EPA to temporarily approve a pesticide based on a demonstrated emergency so that an unexpected outbreak can be contained and not spread to other areas.

But the EPA has facilitated routine abuse of the exemption provision by: 1) allowing emergency use of a pesticide for predictable situations instead of unpredictable emergencies; 2) allowing emergency use in situations that are chronic and occur over many consecutive years; 3) rarely providing for public notice and comment, and; 4) relying on the applicants as the primary — and sometimes only — source of information.

FIFRA is intended to protect the public and the environment by requiring that before any pesticide product can be sold or distributed in the United States the EPA must first register that product by granting administrative approval. The FIFRA standard for pesticide registration is that a proposed use of a product will not cause "unreasonable

adverse effects on the environment." But Section 18 of FIFRA — the emergency exemption provision — allows use of pesticides that have not met this safety standard.

Congress intended use of Section 18 to address urgent pest conditions such as severe and unexpected insect outbreaks. But since its inception, the EPA has administered the emergency exemption program so that it functions as a shortcut, allowing pesticide manufacturers to bypass the registration process. Despite repeated findings that the agency improperly grants these exemptions for the same uses over many years, the EPA has made it easier to obtain "emergency" exemptions by "streamlining" the application process, expediting its application-review procedures and providing for indefinite renewals (without public notice) of emergency exemptions.

The EPA's repeated authorization of emergency exemptions of the use of sulfoxaflor on cotton and sorghum demonstrates that the agency continues to act outside its Section 18 authority and contrary to congressional intent.

I. Section 18 Only Applies to "Emergency Conditions" for "Unexpected Pest Situations"

Section 18 permits the EPA to "exempt any Federal or State agency from any provision of this Act if the [EPA] determines that emergency conditions exist which require such exemption."[2] In the EPA's words, the "practical meaning" of Section 18 is that a state or federal agency can "request EPA to authorize . . . a temporar[y] use [of] a pesticide that is not registered for the proposed use."[3] The EPA's approach is not consistent with the plain language of Section 18 and is outside the discretion Congress gave it to provide exemptions only in emergency conditions.

Section 18 was added to FIFRA as part of the 1971 amendments to the Act.[4] The House Committee Report reviewing this amendment explained that the purpose of the emergency exemption was to allow "the President [to] enable farmers and ranchers to cope with emergency conditions before they spread to other areas" by "facilitat[ing] temporary registration of restricted use of pesticides for meeting emergency outbreaks of plant or animal diseases."[5] Although the legislative history is slim, there is ample

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[2] 7 U.S.C. § 136p (2012).

[3] Pesticide Regulatory Education Program, EPA, *FIFRA Section 18 Emergency Exemption Training Resource*, Module 2 at 1 (June 2013), https://www3.epa.gov/pesticides/regulating/section18_training/sec18-training-modules.html [hereinafter *EPA Section 18 Training*].

[4] H.R. 10729, 92nd Cong. § 18 (1971); *see* Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (1947) (original enactment of FIFRA, lacking an emergency exemption).

[5] H.R. Rep. No. 92-511, at 27 (1971). The amendment as originally proposed only authorized exemptions for federal agencies and not for states. H.R. Rep. 92-511, at 63. States, meanwhile, were authorized under Section 24(c) to "certify" certain registered pesticides "formulated for intrastate distribution" for uses

guidance in Congress's reports on its investigations into the EPA's implementation of the program. Congress has been concerned that "serious inconsistencies and other abuses permeated the EPA's administration of Section 18."[6] The most recent of these was completed in 1992 by the House Committee on Science, Space, and Technology (House Committee).[7]

In its 1992 report, the House Committee found that EPA was "repeatedly" granting emergency exemptions "for the same uses for many years," and the Section 18 program was being used to address "nonemergency situations of predictable pest outbreak."[8] The House Committee observed that these routine grants of emergency exemptions had turned Section 18 into a tool for "salvag[ing] poor business decisions instead of to control unexpected pest emergencies."[9]

Not only was the EPA granting emergency exemptions for the same use year after year, but the agency was not pressuring pesticide manufacturers to pursue registration. In so doing the EPA was disregarding its own regulation requiring "consideration" of a pesticide product's "reasonable progress towards registration," before granting emergency exemptions.[10] This "reasonable progress" requirement, the House Committee explained, is an important safeguard preventing "*de facto* registration or 'backdoor' market access."[11]

The House Committee was especially concerned that the EPA's abuse of Section 18 had created a registration workaround that was putting human health and the

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that were not registered, in order to "allow States the opportunity to . . . meet expeditiously and with less cost and administrative burden on the registrant the problem of registering for limited local use a pesticide needed to treat sudden pest infestation." *Id.* at 28; *see id.* at 64. After review in the Senate, the bill as amended made exemptions available to states in addition to federal agencies. S.R. Rep. 92-838 at 11, 28. The bill after Senate amendments—and the current version of FIFRA—still retained the authorization for states to certify pesticides "to meet specific local needs." *Id.* at 30; *see* 7 U.S.C. § 136v (c)(1).

One additional change to the amendment after Senate review: It authorized emergency exemptions by EPA action, rather than by executive orders of the president, as originally proposed in the House bill. *Compare* H.R. Rep. 92-511 at 27, *with S*.R. Rep. 92-838 at 11, 28.

[6] S. Comm. on Environment, Comm. on Science, Space, and Technology, 102nd Cong., *Section 18 (Emergency Exemptions) to the Federal Insecticide, Fungicide, and Rodenticide Act*, at 1 (Oct. 1992) [hereinafter *1992 Investigation*].

[7] *1992 Investigation*. During the course of the House Committee's investigation, the Congressional Government Accounting Office (GAO) released a study finding that, at the time, EPA was "continu[ing] to grant exemptions for the same use for several years or in nonemergency situations of predictable pest outbreaks." *Id.* at 11.

[8] *Id.* at 2, 11.

[9] *Id.* at 15.

[10] *Id.* at 11-12; *see* 40 C.F.R. § 166.25(b)(2)(ii) (2016).

[11] *1992 Investigation* at 7.

environment at risk.[12] The EPA was granting emergency exemptions for products without having "thoroughly examined the cumulative effects to human health or the environment from such use." [13] This is because Section 18 applications require "significantly less complete and less rigorous data and analyses."[14] The House Committee discovered that many pesticides receiving repeated exemptions were "indefinitely stalled" in the Section 3 registration process "because of concerns of carcinogenicity or mutagenicity."[15] "[B]y liberally and repetitively granting exemptions to potentially carcinogenic substances, little incentive is provided to encourage companies to invest in the development of newer safer pesticides or alternative agricultural practices."[16]

To rein in this abuse of the Section 18 program, the Committee recommended that the EPA adopt a rule categorically excluding grants of emergency exemptions for any "chronic or repetitive requests" made beyond a fixed length of time, such as a period of three or four years.[17] The EPA has not done so. Instead, in 2006, the agency created a streamlined process for granting repeat exemptions called "re-certification,"[18] discussed below.

In sum, the 1992 House Committee investigation makes exceedingly clear that Congress intended Section 18 to be applied sparingly, for limited periods of time, and to address "unexpected pest situations."

II. EPA Implementation of Section 18

A. Emergency Conditions

For the EPA to grant a Section 18 exemption, it must make a threshold finding that an "emergency condition" exists. FIFRA regulations state that emergency conditions must be "urgent, non-routine situation[s]" and that there must be no "economically or environmentally feasible alternatives" that can provide adequate control of the pest situation.[19]

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[12] *Id.* at 1, 18.

[13] *1992 Investigation* at 12. *But c.f.* 40 C.F.R. § 166.25(b)(1)(ii) (requiring that EPA determine that pesticide use under exemption "will not cause unreasonable adverse effects on the environment").

[14] *1992 Investigation* at 16.

[15] *Id.*

[16] *Id.* at 3.

[17] *1992 Investigation* at 12, 19.

[18] *See* 40 C.F.R. § 166.20(b)(5).

[19] 40 C.F.R. § 166.3.

1. Urgent and Non-routine Situations

The EPA defines an emergency condition as an "urgent, non-routine situation that requires use of a pesticide(s)."[20] EPA clarified: "The phrase 'urgent, non-routine situation' has been used to emphasize that the situation must be other than an ordinary one. . . . A chronic or continually occurring problem does not represent an 'urgent, non-routine situation.'"[21] The EPA's training materials provide that emergency conditions are "new" circumstances "in which the status quo has changed in an unusual way that was unforeseen."[22] The EPA warns that Section 18 exemptions should not be used to address predictable conditions or offer "revenue enhancement" to compensate for "decisions made with knowledge of the risks of agriculture." [23] FIFRA regulations also provide that "in no case" should exemptions granted to avert risk of significant economic loss last for longer than one year.[24]

In application, however, the EPA treats long persisting conditions as "emergency" conditions. For example, the EPA's Section 18 training materials list "loss of a pesticide," either due to pest resistance or "because of regulatory action" such as cancellation of registration, as conditions that commonly warrant emergency exemptions.[25] The EPA notes that emergency exemptions could be repeatedly granted for several consecutive years, because some "events usually continue into subsequent years and represent a *permanent* change to the system."[26] Examples of such continuing events, according to the EPA, are "pest resistance, the cancellation of a pesticide, or restrictions on a pesticide's use."[27] The EPA adds that "it is likely that the emergency will continue until a permanent solution, such as registration of an effective pesticide, is found."[28]

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[20] *Id*.

[21] 50 Fed. Reg. 13,944, 13,946 (Apr. 8, 1985); *see* 51 Fed. Reg. 1,896, 1,896 (Jan. 15, 1986) (finalizing rule and reaffirming choice to exclude "chronic or continually occurring problem[s]" from the definition of an emergency condition).

[22] *EPA Section 18 Training*, Module 2 at 1-2.

[23] *Id.* at 4.

[24] *See* 40 C.F.R. § 166.28(a).

[25] *EPA Section 18 Training*, Module 2 at 3; Module 1 at 1.

[26] *Id.* Module 7 at 1 (emphasis added).

[27] *Id.*

[28] *Id.*

2. Economically or Environmentally Feasible Alternatives

The EPA must also find there is a lack of economically or environmentally feasible alternatives for addressing the pest situation.[29] The report from the 1992 House Committee investigation found that the "EPA follows no criteria to identify whether an 'alternative' substance to the requested Section 18 chemical may be 'effective.' "[30] The EPA has not promulgated any hard criteria to define "economically or environmentally feasible alternative practices."[31] Instead it seems to continue its practice of "rel[ying] on whatever bare information is submitted in applications" and routinely granting these exemptions.[32] The agency's current Section 18 guidance document merely recommends that applicants support "claims of ineffectiveness" with "field data *when possible*," and if supporting data is not available "statements from qualified experts" may suffice.[33]

B. "Specific" Exemptions

There are four different types of emergency exemptions defined in EPA regulations.[34] The most common are "specific" exemptions, which are granted to avert either a "significant economic loss" or a "significant risk" to wildlife resources or the environment.[35] The EPA notes that the "typical" specific exemption request is made based on a claim of "significant economic loss."[36] Specific exemptions are eligible for re-certification, a process that "streamline[s]" the application process and enables "quicker determinations by EPA" on applications requesting the same use and to address the same conditions as an exemption granted in the prior year.[37]

1. Significant Economic Loss

FIFRA regulations offer two approaches for showing significant economic loss. One is an output-based approach, while the other is a discretionary catch-all that permits the EPA to find there was a significant economic loss when the output-based approach "would not adequately describe the expected loss."[38] Under the output-based approach,

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[29] 40 C.F.R. § 166.3.

[30] *1992 Investigation* at 13.

[31] *See* 40 C.F.R. § 166.7.

[32] *See id.* at 15.

[33] *EPA Section 18 Training*, Module 4 at 5-6.

[34] 40 C.F.R. § 166.2.

[35] *Id.*

[36] *EPA Section 18 Training*, Module 3 at 1.

[37] 71 Fed. Reg. 4,495, 4,502 (Jan. 27, 2006).

[38] *See* 40 C.F.R. § 166.3; *see also EPA Section 18 Training*, Module 3 at 1.

an applicant can show significant economic loss by demonstrating any of the following: "(i) Yield loss greater than or equal to 20%; (ii) Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues; [or] (iii) Economic loss, including revenue losses and cost increases greater than or equal to 50% of net revenues."[39]

Alternatively, under the discretionary approach, the EPA may make a determination of significant economic loss when a pest situation might impact "long-term financial viability" of growing operations.[40] The EPA explains that these are situations such as damage to buildings or other infrastructure like irrigation systems or capital assets like trees or vines.[41] The discretionary approach to significant economic loss is broad; for example, it encompasses reduction in "aesthetic value of an urban landscape" or "attractive[ness]" of "recreational activities."[42] As a rough rule, the EPA considers this second option appropriate for assessing longer term impacts, while the output-based approach is more appropriate for short-term economic impacts.[43]

The EPA calls this output-based framework a "tiered approach," because the three different loss metrics defined in the regulation serve as "[s]uccessive screening levels."[44] Starting with Tier 1, or yield loss of 20% or more, "[e]ach additional tier requires more data and involves more analysis."[45] Next is intermediate Tier 2, gross revenue loss of 20% or more, and last is Tier 3, net revenue loss of 50% or more, which is the most difficult to prove and requires the most data.[46] The EPA explains, "[i]f the pest situation does not appear likely to result in a significant economic loss based on the first tier analysis, it might qualify based on further analysis in succeeding tiers."[47] The EPA clarifies that in analyzing significant economic loss, "*the comparison . . . between the typical or 'routine' situation and the 'non-routine' situation . . . is not with or without [use of] the requested chemical*."[48]

Under the tiered framework, as currently applied by the EPA, there are at least two ways in which Section 18 applicants can present data and facts to skew in favor of a

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[39] 40 C.F.R. § 166.3.

[40] *Id.*

[41] *EPA Section 18 Training*, Module 3 at 1.

[42] *Id.* at 2.

[43] *Id.* at 3.

[44] 71 Fed. Reg. at 4,504.

[45] *See id.*; 40 C.F.R. § 166.3.

[46] *See* 71 Fed. Reg. at 4,504; 40 C.F.R. § 166.3.

[47] *See* 71 Fed. Reg. at 4,504.

[48] *EPA Section 18 Training*, Module 3 at 2 (emphasis in original).

finding of significant economic loss. First, the Section 18 training materials reveal that the EPA does not have any standardized formulas for calculating the output metrics, which means that Section 18 applicants can cherry-pick data — indeed the EPA encourages applicants to do so — to inflate reported yields anticipated in the absence of emergency conditions. The tiered approach works by comparing the anticipated yield or revenue under the emergency pest conditions and the yield or revenue in the absence of these conditions, or under non-emergency circumstances. In order to calculate the non-emergency outputs, the EPA recommends that Section 18 applicants use an average of outputs from "several years of data, say three to five."[49] The EPA does not standardize or set any minimum span of years from which data must be used to establish the non-emergency output baseline. Instead each Section 18 application can calculate non-emergency outputs using data from whatever span of years best suits its application. In fact, the output data need not even be from consecutive years; the EPA recommends that in calculating the non-emergency output, applicants exclude outputs from years that the applicant determines "would not be representative of typical conditions," such as a year in which there was "an untimely freeze."[50]

The second apparent way in which the EPA applies the tiered approach to favor a finding of significant economic loss is that it considers the higher cost of currently available registered pesticides in determining that there is a pest emergency situation. Specifically, this would occur in Tier 3 screening, which involves examining anticipated gross revenue minus "operating costs"; operating costs include the cost of registered pesticides.[51] Thus, the higher price of registered pesticide products can be used to demonstrate increased costs that warrant an emergency unregistered use.[52]

The EPA's assertions during the rulemaking process for the tiered approach indicate that it intended to create an analytical framework that disregards natural market fluctuations in analysis of significant economic loss. Prior to the adoption of the tiered approach, the EPA's significant economic loss analysis involved examining yields and revenues from the five years immediately preceding the Section 18 request.[53] But in

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[49] *Id.* at 6.

[50] *Id.*

[51] *Id.* at 3.

[52] In its 1992 investigation, the GAO expressed concern that "EPA frequently decides that the affordability of an unregistered product versus the higher cost of using a registered alternative pesticide [is] sufficient to show '*significant economic loss*.'" *See 1992 Investigation* at 11-12.

[53] EPA would examine "whether the expected reduction in profitability exceeds what would be expected as a result of normal fluctuations over a number of years"—five years specifically. 51 Fed. Reg. at 1,903; 69 Fed. Reg. 53,866, 53,871 (Sept. 3, 2004). If the revenues anticipated under the emergency conditions were less than the lowest revenue recorded in the previous five years, EPA would conclude there was a risk of significant economic loss. 69 Fed. Reg. at 53,871.

2006, citing the need for a "less burdensome methodology" for demonstrating significant economic loss, the EPA adopted the tiered approach.[54] The agency explained that the "burden" of demonstrating significant economic loss was lower under the tiered approach because "the analysis focuses on the current year rather than historical data."[55] The old approach, focused on historical data, was purportedly an inadequate yardstick with which to determine significance of economic loss because profit variations over several years "often reflect[] market forces entirely unrelated to pest pressure."[56]

Thus the EPA seems to favor significant economic loss determinations that disregard natural market fluctuations and "historical data." It explained that the tiered approach was adopted to "streamline the data and analytical requirements for emergency exemption requests, and allow for potentially quicker decisions by EPA."[57] As it is currently applied, the tiered approach facilitates very "quick" decisions indeed, because it allows — even encourages — inflated economic loss values, achieved by accounting for higher costs of registered pesticides and permitting applicants to cherry-pick data.

In sum, the EPA's approach to significant economic loss analysis seems to be propelled by a goal of insulating growers from normal risks of agriculture and enhancing agricultural revenues.

2. Re-certification

The re-certification process modifies the Section 18 application process by reducing the burden of showing to the EPA that an emergency condition exists if the EPA granted a specific exemption for that same situation in the year prior.[58] More specifically, a re-certification application "rel[ies] on previously submitted information," including the "discussion of the events which brought about the emergency condition," and "data and other information" showing, *inter alia*, "anticipated significant economic loss."[59]

The EPA promulgated regulations adding re-certification to its Section 18 program, citing goals of "sav[ing] applicants time and effort in gathering data and preparing their submissions" and "sav[ing] [EPA] time and resources by not having to annually repeat each administrative step of its review of the documents supporting the exemption

[54] 69 Fed. Reg. at 53,871.

[55] 71 Fed. Reg. at 4,505.

[56] 69 Fed. Reg. at 53,872; *see* 71 Fed. Reg. at 4,505 (reiterating this rationale in the final rule).

[57] 71 Fed. Reg. at 4,505.

[58] 40 C.F.R. § 166.20(b)(5);71 Fed. Reg. at 4,504 (noting that "[r]e-certification only alters the process for an emergency finding").

[59] 40 C.F.R. § 166.20(b)(5).

requests."[60] Re-certification surely does save the EPA time and resources, especially because the EPA streamlines this already-abbreviated process by making re-certification determinations before applicants even make such requests. When the agency issues a decision on a specific exemption application, it simultaneously "make[s] an initial assessment regarding potential eligibility for a streamlined re-certification application the following year, in the event that the applicant reapplies the next year."[61] And the EPA shares this initial assessment with the Section 18 applicant: "EPA will advise the successful applicant that, should it reapply the following year, they appear eligible to use a re-certification application."[62] The re-certification process was directed to certain uses that the EPA predicted are likely to persist beyond the year-long limit intended for specific exemptions,[63] for example pesticide resistance to a registered product or when a previously registered product "becomes permanently unavailable," presumably referring to situations in which a product does not survive re-registration review.[64]

Certain uses are not eligible for re-certification. These include specific exemptions granted for use of a new chemical or for a use that has been previously registered but is now suspended[65] or cancelled.[66] Notably, all uses that are ineligible for re-certification require public notice when an exemption is granted. In other words, there is no public notice requirement when the EPA grants a specific exemption that is eligible for re-certification, and re-certification itself does not require public notice. This means that there can ongoing unregistered uses of pesticides for years without any public notice.

Re-certification without public notice is especially troubling when coupled with the fact that "[t]here is no established limit on the number of years an exemption is eligible for recertification."[67] The original re-certification process, as proposed by the EPA, limited re-certification to three years.[68] However, in finalizing the rule, the agency was persuaded by comments that re-certification should not be time limited, and it made

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[60] 71 Fed. Reg. at 4,504.

[61] *Id.* at 4,503.

[62] *Id.*

[63] *See* 40 C.F.R. § 166.28(a).

[64] *See* 71 Fed. Reg. at 4,503. As a point of contrast, EPA cites the following situations as those that would not be eligible for re-certification: "temporary supply problem of a registered product, an isolated weather event, or a sporadic pest outbreak." 71 Fed. Reg. at 4,503. These suddenly arising and temporary situations seem to align more with congressional intention behind the Section 18 program.

[65] 7 U.S.C. § 136d(c).

[66] 40 C.F.R. § 166.20(b)(5)(iv); 7 U.S.C. § 136d(b).

[67] *EPA Section 18 Training*, Module 7 at 4.

[68] *See* 69 Fed. Reg. 53,866, 53,871 (Sept. 3, 2004).

streamlined re-certification available indefinitely.[69] It reasoned that "[a]ny specific limit to the number of years of eligibility [for re-certification] would be arbitrary."[70]

But a three-year cutoff is hardly arbitrary in the context of the Section 18 regulatory scheme. The longest duration for any emergency exemption, set forth in the Section 18 regulations, is "in no case for longer than 3 years."[71] And a three-year limit makes sense, because during the 1992 House Committee investigation of the Section 18 program, the EPA explained that "[i]t generally takes three years to conduct a chronic toxicity test on a chemical."[72] Accordingly, Section 18 regulations presume that three years is the approximate time required to complete an application for unconditional registration.[73] Finally, both the House Committee and the GAO, concerned about repeat exemptions granting backdoor access to the pesticide market, "strongly recommended" that the EPA "adopt a firm rule flatly excluding from the definition of an 'emergency' chronic or repetitive requests that continue for over *three* or four years."[74]

Thus, a three-year limit on re-certification is not arbitrary within the context of the EPA's administration of the Section 18 program, and by declining to cap the number of years re-certification is available, the EPA created a workaround for the one-year limit on specific exemptions.[75] This establishes a system in which pesticides that are "indefinitely stalled" in the registration review process — perhaps due to lack of toxicological data or concerns about carcinogenicity — can be sold and distributed freely without any incentive to make progress towards registration.[76] Re-certification seems to offer the same market access as unconditional registration, but the former offers manufacturers the added benefits of lower application cost (due to less rigorous data requirements) and less public scrutiny.

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[69] 71 Fed. Reg. at 4,497-98.

[70] *Id.* at 4,497.

[71] 40 C.F.R. § 166.28(b) (setting duration for quarantine exemptions).

[72] *1992 Investigation* at 16.

[73] *See* 40 C.F.R. § 166.25(b)(2)(ii) ("It shall be presumed that if a complete application for registration for registration of a use, which has been under a specific . . . exemption for any 3 previous years, . . . has not been submitted, reasonable progress towards registration has not been made.").

[74] *1992 Investigation* at 12, 19 (emphasis added).

[75] 40 C.F.R. § 166.28(a).

[76] *See 1992 Investigation* at 16.

III. Sulfoxaflor

A. Sulfoxaflor Registration

Sulfoxaflor is an insecticide used to control sap-feeding insects like aphids, which are rapidly becoming resistant to neonicotinoids — currently "the mainstay for [insect] control in a wide range of crops."[77] Sulfoxaflor and neonicotinoids share the same mode of action, targeting the same receptor in insects' central nervous system.[78] But sulfoxaflor's structure-activity relationship is distinct from that of neonicotinoids; this means that the piece of the sulfoxaflor molecule that most closely correlates with its biological activity is chemically different from that of neonicotinoids.[79] Growers are increasingly relying on sulfoxaflor to control neonicotinoid-resistant insects.[80]

In 2010 Dow Agrosciences applied to the EPA for registration of three pesticide products containing sulfoxaflor, which was a new active ingredient at the time.[81] Dow applied for uses on several crops, one of which was cotton. Determining that data in Dow's application raised toxicity concerns for bees, the EPA concluded that additional studies and data on impacts on bees were necessary before it could grant unconditional registration and proposed to conditionally register sulfoxaflor in January 2013.[82] Then, a few months later and apparently without receiving any additional data or studies from Dow, the EPA unconditionally registered sulfoxaflor in May 2013.[83] Several commercial beekeepers and beekeeping organizations, concerned that the EPA had registered sulfoxaflor after concluding that it was "very highly toxic" to bees, challenged the approval in court.[84] The Ninth Circuit vacated the original sulfoxaflor registration, effective November 2015.[85]

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[77] Thomas C. Sparks, et al. *Sulfoxaflor and the Sulfoximine Insecticides: Chemistry, Mode of Action and Basis for Efficacy on Resistant Insects*, 107 PESTICIDE BIOCHEM. & PHYSIOLOGY 1, 1 (2013).

[78] *Id.*

[79] *See* Sparks, et al. at 2-3.

[80] *See* Christopher Longhurst, et al., *Cross-Resistance Relationships of the Sulfoximine Insecticide Sulfoxaflor with Neonicotinoids and Other Insecticides in the Whiteflies* Bemisia tabaci *and* Trialedurodes vaporariorum, 69 PEST MANAGEMENT SCIENCE 809, 809 (2013).

[81] 75 Fed. Reg. 80,490, 80,491-93 (Dec. 22, 2010).

[82] EPA Docket # EPA-HQ-OPP-2010-0889-0031 (posted Jan. 14, 2013) found at regulations.gov.

[83] EPA Docket # EPA-HQ-OPP-2010-0889-0396 (posted May 6, 2013) found at regulations.gov.

[84] *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 522, 527-28 (9th Cir. 2015).

[85] *Id.* at 528.

In October 2016 the EPA issued a new unconditional registration.[86] This decision — like the 2013 unconditional registration — was not a product of evaluating any new or additional data supplementing Dow's initial submission. But the EPA explained that it did not need further studies on sufloxaflor's toxicity to bees because the new registration limited the crops and timing of sulfoxaflor uses "resulting . . . in essentially no exposure to bees."[87] Dow had amended its application, purportedly to reduce risks to pollinators, by limiting sulfoxaflor application to only post-bloom uses for crops that are attractive to bees.[88] Crops that are indeterminate bloomers, such as cotton, were not included in the amended proposed registration.[89]

B. Emergency Exemptions for Use of Sulfoxaflor on Cotton and Sorghum

As of November 30, 2017, the EPA had issued at least *78* Section 18 specific exemptions for use of sulfoxaflor (Appendix A).[90] Every single one of these granted exemptions were for uses either on cotton, which was retracted from Dow's 2015 amended registration application, or on sorghum, which was never included in the registration application at all. The few publicly available Section 18 applications for sulfoxaflor indicate that the most common (possibly only) basis for requesting a specific exemption is the risk of significant economic loss. These applications also reveal that states are claiming anticipated economic losses by comparing yields and revenues expected with, and without, use of this pesticide, rather than comparing yields and revenues with, and without, the "pest emergency" required by the Section 18 regulations. And despite its own regulations, the EPA is granting these requests, thereby permitting unregistered uses of sulfoxaflor for the purpose of revenue enhancement.

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[86] Office of Pesticide Programs, EPA, *Registration of Sulfoxaflor for Use on Agricultural Crops, Ornamentals, and Turf* (Oct. 14, 2016) [hereinafter *Sulfoxaflor Reg.*].

[87] *Id.* at 3-4.

[88] *Id.* at 2, 4.

[89] *Id.* at 2-3.

[90] *See* appended spreadsheet downloaded from EPA's Section 18 Emergency Exemption Database, https://www.epa.gov/pesticide-registration/emergency-exemption-database (last visited Nov. 30, 2017). Note that at least four emergency exemptions reported in the Federal Register do not appear in the EPA's Section 18 Emergency Exemption Database. *See* 81 Fed. Reg. 90,836 (Dec. 15, 2016) (Use on cotton in AR to control tarnished plant bug June 7 to Oct. 31, 2016); 77 Fed. Reg. 66,834 (Nov. 7, 2012) (Use on cotton in AR and LA to control tarnished plant bug June 1 to Sept. 30, 2012); 82 Fed. Reg. 14,715 (March 22, 2017) (Use on sorghum in MS to control sugarcane aphid May 1 to Oct. 31, 2017. *See also* 82 Fed. Reg. 31,056 (July 5, 2017); 80 Fed.Reg. 76,481 (Dec. 9, 2015); 80 Fed. Reg. 60,669 (Oct. 7, 2015); 80 Fed. Reg. 26,555 (May 8, 2015); 80 Fed. Reg. 6,515 (Feb. 5, 2015); 79 Fed. Reg. 57,081 (Sept. 24, 2014); 82 Fed. Reg. 56,821 (Nov. 30, 2017); 81 Fed. Reg. 4,623 (Jan. 27, 2016); 81 Fed. Reg. 27,129 (May 5, 2016); 76 Fed. Reg. 33,276 (June 8, 2011).

1. Cotton

Although Dow amended its sulfoxaflor registration application to exclude cotton, the EPA granted specific exemptions for this use to at least six states in 2016 and in at least 10 states in 2017. All of these exemptions are directed to controlling tarnished plant bug, *Lygus lineolaris*.[91] Five of the applications for use in 2017 were submitted before cotton was even planted.[92] There are presently only seven publicly available applications requesting use of sulfoxaflor on cotton: four requests in 2012 for use on 1.4 million acres and three requests made in 2016 for use on 826,250 acres.[93] These indicate that in Section 18 applications seeking use of sulfoxaflor on cotton (1) the underlying "emergency" condition is a pest problem that has been around for at least a decade; (2) the claims of "significant economic loss" are based on comparing yields and revenues with and without the use of sulfoxaflor; and (3) despite its demonstrated toxicity to bees, sulfoxaflor has become a cornerstone of many states' cotton pest-management programs.

The three 2016 publicly available Section 18 applications use the same boilerplate language to characterize the "pest emergency" warranting use of sulfoxaflor on cotton.[94] They state that the pest problem, "economic damage from tarnished plant bugs," is one that cotton growers in these states have been actively battling since the mid-1990s.[95] In response growers turned to chemical control for tarnished plant bugs, "relying heavily" on neonicotinoids, along with organophosphates, pyrethroids and carbamates; tarnished plant bugs predictably developed resistance to all of these pesticides. This resistance to other insecticide classes is the "pest emergency" for which states are requesting use of sulfoxaflor, and all three applications cite to the same 2007 study to support the insecticide resistance claim. So these robust tarnished plant bug populations, resistant to neonicotinoids, pyrethroids, organophosphates and carbamates, are a problem that cotton growers have been actively combatting since at

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[91] These exemptions are not eligible for re-certification because registration was cancelled "[p]ursuant to section 6 of FIFRA," after the Ninth Circuit vacated EPA's first unconditional registration. *See* Office of Pesticide Programs, EPA, *Sulfoxaflor – Final Cancellation Order*, at 5 (Nov. 12, 2015); 40 C.F.R. § 166.20(b)(5)(iv); § 166.24(a)(4).

[92] *See* Appendix A.

[93] 77 Fed. Reg. 66,834 (Nov. 7, 2012) and 81 Fed. Reg. 27,129 (May 5, 2016).

[94] Tennessee Dep't of Agriculture, *Section 18 Application – Sufloxaflor (Transform WG Insecticide) Tennessee Cotton*, at 29-30 (April 4, 2016) [hereinafter *TN App.*]; Arkansas State Plant Board, *Section 18 Application – Sulfoxaflor (Transform TM) Arkansas Cotton*, at 24-25 (March 1, 2016) [hereinafter *AR App.*]; Mississippi Dep't of Agriculture & Commerce, *Request for Section 18 Emergency Use of Sulfoxaflor (Transform WG Insecticide) to Control Tarnished Plant Bug*, at 27-28 (March 1, 2016) [hereinafter *MS App.*].

[95] *TN App.* at 29-30; *AR App.* at 24-25; *MS App.* at 27-28.

least 2007, or possibly earlier. It does not meet the EPA's definition of a "non-routine"[96] situation, "in which the status quo has changed in an unusual way that was unforeseen."[97]

The 2016 Section 18 applications nevertheless frame the tarnished plant bug problem as one that is new and unforeseen because of the anticipated loss of sulfoxaflor, which the states claim "would result in the collapse of the existing pest management system for Mid-South cotton."[98] Arkansas, Mississippi and Tennessee explained that growers "have come to rely on [sulfoxaflor] since 2012 when Transform [EPA Reg. No. 62719-625] was first introduced as a Section 18 [sic]."[99] In fact, Tennessee explained, "Transform has become one of the foundation products" of the states' management of tarnished plant bug on cotton.[100] Loss of the use of sulfoxaflor, these states claimed, would "result in a collapse of the existing pest management system for cotton growth in the Mid-South."[101]

These Section 18 applications also reveal that states' claims for specific exemptions for sulfoxaflor on cotton are based on risk of significant economic loss due to unavailability of the use of sulfoxaflor. The applications compare yields and revenues from years in which sulfoxaflor was available to cotton growers with yields and revenues from years in which sulfoxaflor was not available.[102] In fact, both Arkansas's and Mississippi's applications describe the "emergency period" as "Pre Transform" and the "non-emergency period" as "Post Transform."[103] This directly contradicts the EPA's warning that when demonstrating significant economic loss, "*the comparison . . . between the typical or 'routine' situation and the 'non-routine' situation . . . is not with or without [use of] the requested chemical*."[104] Regardless, the EPA granted emergency exemptions to Mississippi, Tennessee, and Arkansas (and likely other states) on precisely this basis.[105]

These Section 18 exemptions to maintain yields and revenues possible only through unregistered use of sulfoxaflor shows that the EPA and states are using this program to

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[96] 40 C.F.R. § 166.3.

[97] *EPA Section 18 Training*, Module 2 at 1-2.

[98] *AR App.* at 35; *MS App.* at 28.

[99] *MS App.* at 28.

[100] *TN App.* at 31.

[101] *TN App.* at 30; *AR App.* at 25; *MS App.* at 28.

[102] *AR App.* 26-28; *MS App.*at 29-30; *TN App.*at 31-32.

[103] *AR App.* at 26; *MS App.*at 29.

[104] *EPA Section 18 Training*, Module 3 at 2 (emphasis in original).

[105] 81 Fed. Reg. 90,838 (Dec. 15, 2016).

"salvage poor business decisions"[106] and offer "revenue enhancement" to compensate for "decisions made with knowledge of the risks of agriculture."[107] Indeed, Tennessee's application explained that until sulfoxaflor was available to cotton growers, they were "facing an economic crisis . . . because control costs and yield loss ha[d] nearly tripled in the last decade" and "poor commodity prices" were "[e]xacerbating" the economic risks.[108] But "since Transform has become available for use in cotton, producers have benefitted greatly both in terms of revenue and increased yield protection."[109] Similarly, Arkansas's application notes that "since Transform has become available for use in cotton, Arkansas producers have benefited greatly both in terms of gross revenue and increased yield protection."[110]

In sum, the EPA is routinely authorizing use of sulfoxaflor to insulate cotton growers from the normal risks of agriculture, even though the agency presently lacks data to adequately understand, and accordingly mitigate, the toxicity of sulfoxaflor to bees.[111] The data deficiencies on impacts to bees are precisely the reason cotton is not a registered use of sulfoxaflor. Despite this, states are able to utilize Section 18 to maintain continuing availability of this unregistered use of sulfoxaflor, which cotton growers now consider "foundation[al]" to pest control on cotton.[112]

2. Sorghum

Use on sorghum is directed to controlling sugarcane aphids, *Melanaphis sacchari*. In the fall of 2013, "huge populations" of sugarcane aphids were discovered in Texas and reportedly spread to 10 states.[113] Dow did not include sorghum among the uses requested in its sulfoxaflor registration application, but today, this use is widespread — authorized in at least 18 states, many by repeat emergency exemptions. There is no public record, in the Federal Register or otherwise, disclosing the total sorghum acreage covered by sulfoxaflor emergency exemptions, but in 2016 Texas's specific exemption alone applied to 3 million acres of sorghum and in 2017 jumped to 5.5 million acres.[114]

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[106] *1992 Investigation* at 15.

[107] *EPA Section 18 Training*, Module 2 at 4.

[108] *TN App.* at 30.

[109] *Id.* at 30, 31.

[110] *AR App.* at 28.

[111] *See Pollinator Stewardship Council*, 806 F.3d at 531-32.

[112] *See TN App.*at 31.

[113] Texas Department of Agriculture, *Section 18 Emergency Specific Exemption: Transform WG Insecticide Sulfoxaflor, EPA Reg. No. 62719-625*, *For the Control of the Sugarcane Aphid*, Melanaphis Sacchari, *in Sorghum in Texas*, at 16 (2016) [hereinafter *TX App.*]

[114] *TX App.* at 4 and 82 Fed. Reg. 56,821 (Nov. 30, 2017).

Texas's 2016 application is, at present, the only publicly available Section 18 application requesting this use. The information in this application reveals that, like in the case of cotton, states and growers are relying on Section 18 use of sulfoxaflor for revenue enhancement and to salvage poor business decisions. Texas's application claims risk of significant economic loss for sorghum growers due to the rise of the sugarcane aphid. But it appears that even before the sugarcane aphid infestation in 2013, sorghum cultivation was a risky venture with razor-thin (if any) profit margins. Texas reported average yields and sorghum prices from before the aphid problem, in 2010, 2011 and 2012, and sorghum netted losses for all three of those years.[115] Texas's application offers no point of comparison with yield data from years in which the purported sugarcane aphid emergency arose or was ongoing; the application contains no sorghum yield or revenue data from 2013 through the present. Instead, to demonstrate significant economic loss at Tier 1, Texas offers only the following naked assertion: "Dr. Michael Brewer, Texas A&M AgriLife Research Specialist in Corpus Christi, has reported losses rangeing [sic] from 25-75% along the Gulf Coast."[116] This unsubstantiated assertion was sufficient for Texas to gain an emergency exemption for use of sulfoxaflor on sorghum.

Offering sorghum growers revenue enhancement for their risky investment by widespread Section 18 sufloxaflor exemptions puts bees at risk.[117] The U.S. Department of Agriculture's 2015 Bee Pollinator Attractive Crops List identified sorghum as a crop that is attractive to honey bees and solitary bees.[118] The Ninth Circuit vacated the EPA's initial registration of sulfoxaflor because, despite its conclusion that sulfoxaflor triggered risk concerns for bees, the EPA failed to require further studies and data to fully evaluate the risk.[119] Nevertheless, the EPA re-registered sulfoxaflor using

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[115] Texas's application states:

> the avg yield of grain sorghum in Texas in 2010, 2011 and 2012 was 70, 49 and 59 bu/acre, respectively, for a 3-year avg of approximately 59 bu/acre (56 lb/bu for grain sorghum) which is about 3300 lb/acre. The avg price for grain sorghum in Texas in 2010, 2011 and 2012 was approximately $7.26, $10.40 and $11.20/cwt. The current price for grain sorghum is about $7.50/cwt.

TX App. at 18. These figures correspond to the following monetary yields for 2010, 2011 and 2012, respectively: $284/acre, $285/acre and $370/acre. Texas also reports "cost of production for grain sorghum is approximately $325-375 per acre." *Id.* This means that sorghum growers netted losses in 2010 and 2011, and likely in 2012, but Texas characterizes these as a "slim profit margin" that would be "devastat[ed]" by "unexpected and uncontrolled pest infestations, like the sugarcane aphid." *Id.*

[116] *TX App.* at 17.

[117] EPA asserts that it is controlling risk to pollinators by issuing Section 18 labels that "preclude[] application of sulfoxaflor three days before bloom or before seed set" for sorghum, since "bees are typically only present when plants are in bloom." EPA response to TX, at 2.

[118] USDA, *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*, at 19 (2015).

[119] *Pollinator Stewardship Council*, 806 F.3d at 531-32.

the initial data submission — without demanding or reviewing any additional studies or data on impacts to pollinators — because Dow had amended its application to "reduce/eliminate exposure to pollinators."[120] At the time of the amended application, sulfoxaflor was already being widely used on sorghum; so Dow's decision not to include sorghum in its amended application is notable, indicating that sorghum would be one of the crops that would trigger need for further study because triggered the EPA's risk concerns for pollinators. This means that use of sulfoxaflor on sorghum exposes bees to risks[121] that have not been adequately reviewed by the EPA.

Conclusion

The EPA's administration of sulfoxaflor under Section 18 reveals that this provision is effectively utilized as a workaround for FIFRA registration. As demonstrated in the case of sulfoxaflor emergency exemptions for use on cotton and sorghum, Section 18 facilitates widespread use of pesticides that are not eligible for registration because of possible risks to human health and the environment. Repeated Section 18 authorizations create dependency on unregistered pesticide uses by authorizing these for several years on end. Once that dependency arises, states can make a case that growers need continuing use of the unregistered pesticide because it is an essential component of that state's growers' pest management program. And without the unregistered use, states claim a risk of significant economic loss that rises to the level of an emergency condition. This is contrary to congressional purpose for Section 18, which was supposed to be a temporary fix to address unanticipated, urgent and short-lived pest situations. Instead, Section 18 has become a mechanism for protecting growers' profit margins while placing human health and the environment at risk.

Cover photo of bumblebee from Pixabay`

[120] *Sulfoxaflor Reg.* at 2-3.

[121] To reduce risks to pollinators, Dow eliminated indeterminate blooming crops like cotton and strawberry from its registration application, *Sulfoxaflor Reg.* at 2-3, but sorghum is a determinate crop. Pummy Kumary, et al. *Sorghum*, BROADENING THE GENETIC BASE OF GRAIN CEREALS, at 177, Mohar Singh & Sandeep Kumar Eds., 2016.

Appendix A -- Emergency Exemptions for Sulfoxaflor

Applicant	Site	Pest	Status	Received Date	Response Date	Expire Date	Approved Acreage	Fed Reg Notice
Alabama	Cotton	Tarnished Plant Bugs	Issued	2/2/2017	3/6/2017	10/31/2017	75,000	A
Alabama	Sorghum	Sugarcane Aphid	Issued	2/2/2017	2/23/2017	10/31/2017	45,000	A
Alabama	Cotton	Tarnished Plant Bugs	Issued	4/20/2016	6/7/2016	10/31/2016	unknown	C
Alabama	Sorghum	Sugarcane Aphid	Issued	3/28/2016	5/5/2016	4/8/2017	unknown	C
Alabama	Sorghum	Sugarcane Aphid	Issued	2/2/2015	2/26/2015	11/30/2015	unknown	F
Arizona	Sorghum	Sugarcane Aphid	Issued	4/26/2017	5/1/2017	11/30/2017	26,000	J
Arizona	Cotton	Tarnished Plant Bugs	Issued	4/21/2017	5/4/2017	10/31/2017	150,000	J
Arizona	Cotton	Tarnished Plant Bug	Issued	4/7/2017	4/21/2017	10/31/2017	unknown	
Arizona	Sorghum	Sugarcane Aphid	Issued	9/16/2016	9/22/2016	4/8/2017	unknown	C
Arizona	Alfalfa	Blue Aphid	Withdrawn	3/18/2015	7/16/2015	-	N/A	
Arkansas	Sorghum	Sugarcane Aphid	Issued	3/2/2017	3/16/2017	9/15/2017	50,000	A
Arkansas	Cotton	Tarnished Plant Bugs	Issued	2/27/2017	3/16/2017	10/31/2017	420,000	A, J
Arkansas	Sorghum	Sugarcane Aphid	Issued	4/8/2016	5/5/2016	4/8/2017	unknown	C
Arkansas	Cotton	Tarnished Plant Bug	Issued*	-	6/7/2016	10/31/2016	320,000	C, L
Arkansas	Sorghum	Sugarcane Aphid	Issued	1/8/2015	2/26/2015	10/31/2015	unknown	F
Arkansas	Sorghum	Sugarcane Aphid	Issued	7/1/2014	7/2/2014	10/31/2014	unknown	G
Arkansas	Cotton	Tarnished Plant Bug	Issued*	-	6/1/2012	9/30/2012	387,000	I, M
Arkansas	Cotton	Tarnished Plant Bug	Withdrawn	1/18/2011	7/21/2011	-	N/A	
Colorado	Sorghum	Sugarcane Aphid	Issued	3/14/2017	4/3/2017	11/30/2017	500,000	J
Colorado	Sorghum	Sugarcane Aphid	Issued	7/5/2016	7/11/2016	4/8/2017	unknown	C
Florida	Sorghum	Sugarcane Aphid	Issued	9/18/2014	9/24/2014	12/31/2014	unknown	G
Georgia	Sorghum	Sugarcane Aphid	Issued	1/30/2017	5/1/2017	11/30/2017	50,000	J
Georgia	Sorghum	Sugarcane Aphid	Issued	3/3/2016	5/5/2016	4/8/2017	unknown	C
Georgia	Sorghum	Sugarcane Aphid	Issued	1/26/2015	2/26/2015	11/30/2015	unknown	F
Georgia	Sorghum	Sugarcane Aphid	Issued	9/4/2014	9/11/2014	11/30/2014	unknown	G
Idaho	Alfalfa Seed	Lygus Bug	Withdrawn	3/18/2016	6/16/2016	-	N/A	
Idaho	Alfalfa Seed	Lygus Bug	Withdrawn	4/17/2015	5/21/2015	-	N/A	
Illinois	Sorghum	Sugarcane Aphid	Issued	7/18/2016	7/19/2016	4/8/2017	unknown	C
Illinois	Sorghum	Sugarcane Aphid	Withdrawn	9/10/2015	10/29/2015	-	N/A	
Kansas	Sorghum	Sugarcane Aphid	Issued	3/20/2017	4/3/2017	11/30/2017	2,850,000	J
Kansas	Sorghum	Sugarcane Aphid	Issued	4/12/2016	5/5/2016	4/8/2017	unknown	C
Kansas	Sorghum	Sugarcane Aphid	Issued	3/26/2015	3/31/2015	11/30/2015	unknown	F
Kentucky	Sorghum	Sugarcane Aphid	Issued	6/22/2016	7/19/2016	4/8/2017	unknown	C
Kentucky	Sorghum	Sugarcane Aphid	Issued	8/4/2015	8/10/2015	11/30/2015	unknown	D
Louisiana	Cotton	Tarnished Plant Bugs	Issued	1/27/2017	3/6/2017	10/31/2017	175,000	A
Louisiana	Sorghum	Sugarcane Aphid	Issued	1/27/2017	2/17/2017	11/30/2017	180,000	A
Louisiana	Cotton	Tarnished Plant Bugs	Issued	4/20/2016	6/7/2016	10/31/2016	unknown	C
Louisiana	Sorghum	Sugarcane Aphid	Issued	1/15/2016	5/5/2016	4/8/2017	unknown	C
Louisiana	Sorghum	Sugarcane Aphid	Issued	2/9/2015	3/12/2015	10/31/2015	unknown	F
Louisiana	Sugarcane	Sugarcane Aphid	Withdrawn	7/28/2014	10/1/2014	-	N/A	
Louisiana	Sorghum	Sugarcane Aphid	Issued	3/18/2014	4/30/2014	10/31/2014	unknown	H
Louisiana	Cotton	Tarnished Plant Bugs	Issued*	-	6/1/2012	9/30/2012	230,000	I, M
Louisiana	Cotton	Tarnished Plant Bugs	Withdrawn	2/17/2011	7/25/2011	-	N/A	

Applicant	Site	Pest	Status	Received Date	Response Date	Expire Date	Approved Acreage	Fed Reg Notice
Louisiana	Cotton	Tarnished Plant Bugs	Withdrawn	2/17/2011	7/25/2011	-	N/A	
Minnesota	Soybean	Soybean Aphid	Withdrawn	4/6/2017	5/9/2017	-	N/A	
Mississippi	Cotton	Tarnished Plant Bugs	Issued	4/20/2017	4/21/2017	10/31/2017	337,500	B
Mississippi	Cotton	Tarnished Plant Bug	Issued	11/21/2016	12/23/2016	10/31/2017	750,000	J
Mississippi	Sorghum	Sugarcane Aphid	Issued*	-	5/1/2017	10/31/2017	115,000	B
Mississippi	Cotton	Tarnished Plant Bugs	Issued	3/10/2016	6/7/2016	10/31/2016	337,500	C, L
Mississippi	Sorghum	Sugarcane Aphid	Issued	3/3/2016	5/5/2016	4/8/2017	unknown	C
Mississippi	Sorghum	Sugarcane Aphid	Issued	12/29/2014	2/26/2015	10/31/2015	unknown	F
Mississippi	Sorghum	Sugarcane Aphid	Issued	5/28/2014	6/12/2014	10/31/2014	unknown	H
Mississippi	Cotton	Tarnished Plant Bugs	Issued	2/3/2012	6/1/2012	9/30/2012	467,500	I, M
Mississippi	Cotton	Tarnished Plant Bugs	Withdrawn	12/15/2010	7/25/2011	-	N/A	
Missouri	Sorghum	Sugarcane Aphid	Issued	4/12/2017	4/20/2017	11/30/2017	85,000	J
Missouri	Cotton	Tarnished Plant Bugs	Issued	4/12/2017	4/21/2017	10/31/2017	241,500	J
Missouri	Cotton	Tarnished Plant Bugs	Issued	5/16/2016	6/7/2016	10/31/2016	unknown	C
Missouri	Sorghum	Sugarcane Aphid	Issued	5/6/2016	5/11/2016	4/8/2017	unknown	C
Missouri	Sorghum	Sugarcane Aphid	Issued	3/13/2015	3/27/2015	10/31/2015	unknown	F
Missouri	Sorghum	Sugarcane Aphid	Issued	9/5/2014	9/11/2014	11/30/2014	unknown	G
Nebraska	Sorghum	Sugarcane Aphid	Issued	5/26/2016	6/2/2016	4/8/2017	unknown	C
New Mexico	Sorghum	Sugarcane Aphid	Issued	4/24/2017	5/5/2017	11/30/2017	140,000	J
New Mexico	Pecans	Black Pecan Aphid	Withdrawn	6/24/2016	9/21/2016	-	N/A	
New Mexico	Sorghum	Sugarcane Aphid	Issued	6/24/2016	6/28/2016	4/8/2017	unknown	C
New Mexico	Sorghum	Sugarcane Aphid	Issued	8/28/2015	8/28/2015	11/30/2015	unknown	D
North Carolina	Sorghum	Sugarcane Aphid	Issued	4/20/2017	5/5/2017	11/30/2017	50,000	J
North Carolina	Sorghum	Sugarcane Aphid	Issued	4/14/2016	5/5/2016	4/8/2017	unknown	C
North Carolina	Sorghum	Sugarcane Aphid	Issued	7/13/2015	7/16/2015	11/30/2015	unknown	D
Oklahoma	Sorghum	Sugarcane Aphid	Issued	3/14/2017	4/3/2017	11/30/2017	300,000	J
Oklahoma	Sorghum	Sugarcane Aphid	Issued	2/22/2016	5/5/2016	4/8/2017	unknown	C
Oklahoma	Sorghum	Sugarcane Aphid	Issued	3/17/2015	3/27/2015	10/31/2015	unknown	F
Oklahoma	Sorghum	Sugarcane Aphid	Issued	4/16/2014	4/30/2014	10/31/2014	unknown	H
South Carolina	Sorghum	Sugarcane Aphid	Issued	3/1/2017	4/3/2017	11/30/2017	19,600	J
South Carolina	Sorghum	Sugarcane Aphid	Issued	4/21/2016	5/25/2016	4/8/2017	unknown	C
South Carolina	Sorghum	Sugarcane Aphid	Issued	3/4/2015	3/27/2015	11/30/2015	unknown	F
Tennessee	Cotton	Tarnished Plant Bugs	Issued	2/16/2017	4/13/2017	9/30/2017	240,000	J
Tennessee	Sorghum	Sugarcane Aphid	Issued	4/18/2016	5/5/2016	4/8/2017	unknown	C
Tennessee	Cotton	Tarnished Plant Bugs	Issued	4/4/2016	6/7/2016	10/31/2016	168,750	C, L
Tennessee	Sorghum	Sugarcane Aphid	Issued	4/13/2015	6/8/2015	11/30/2015	unknown	E
Tennessee	Sorghum	Sugarcane Aphid	Issued	8/11/2014	8/18/2014	10/31/2014	unknown	G
Tennessee	Cotton	Tarnished Plant Bug	Issued	5/1/2012	6/1/2012	9/30/2012	325,000	I, M
Tennessee	Cotton	Tarnished Plant Bug	Withdrawn	12/27/2010	6/15/2011	-	N/A	
Texas	Cotton	Tarnished Plant Bugs	Issued	5/10/2017	5/12/2017	10/31/2017	5,500,000	J
Texas	Cotton	Tarnished Plant Bugs	Issued	4/20/2017	5/1/2017	10/31/2017	unknown	
Texas	Citrus Trees	Asian Citrus Psyllid	Pending	4/4/2017	-	-	N/A	
Texas	Sorghum	Sugarcane Aphid	Issued	1/17/2017	2/7/2017	11/30/2017	3,000,000	A, K
Texas	Sorghum	Sugarcane Aphid	Issued	12/7/2015	4/8/2016	4/8/2017	unknown	C
Texas	Sorghum	Sugarcane Aphid	Issued	11/20/2014	2/26/2015	10/31/2015	unknown	F

Applicant	Site	Pest	Status	Received Date	Response Date	Expire Date	Approved Acreage	Fed Reg Notice
Texas	Sorghum	Sugarcane Aphid	Issued	1/21/2014	4/24/2014	10/31/2014	unknown	H
Virginia	Sorghum	Sugarcane Aphid	Issued	3/23/2017	4/3/2017	11/30/2017	16,591	J
Virginia	Sorghum	Sugarcane Aphid	Issued	5/10/2016	5/16/2016	4/8/2017	unknown	C
Virginia	Sorghum	Sugarcane Aphid	Withdrawn	9/3/2015	10/28/2015	-	N/A	
Washington	Alfalfa Seed	Lygus Bugs	Withdrawn	4/27/2016	6/16/2016	-	N/A	
Wyoming	Alfalfa Seed	Lygus Bug	Withdrawn	5/24/2016	6/15/2016	-	N/A	
							17,551,941	

* emergency exemptions that are not listed in the Section 18 Emergency Exemption Database

Fed Reg Notice

A	82 Fed. Reg. 31,056 (July 5, 2017)	link
B	82 Fed. Reg. 14,715 (March 22, 2017)	link
C	81 Fed. Reg. 90,836 (Dec. 15, 2016)	link
D	80 Fed. Reg. 76,481 (Dec. 9, 2015)	link
E	80 Fed. Reg. 60,669 (Oct. 7, 2015)	link
F	80 Fed. Reg. 26,555 (May 8, 2015)	link
G	80 Fed. Reg. 6,515 (Feb. 5, 2015)	link
H	79 Fed. Reg. 57,081 (Sept. 24, 2014)	link
I	77 Fed. Reg. 66,834 (Nov. 7, 2012)	link
J	82 Fed. Reg. 56,821 (Nov. 30, 2017)	link
K	81 Fed. Reg. 4,623 (Jan. 27, 2016)	link
L	81 Fed. Reg. 27,129 (May 5, 2016)	link
M	76 Fed. Reg. 33,276 (June 8, 2011)	link