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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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Before the
Subcommittee on Environment
Committee on Science, Space, and Technology
U.S. House of Representatives



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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

¹Special Pesticide Registration By the Environmental Protection Agency Should Be Improved (CED-78-9, Jan. 9 1978).

²Stronger 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.

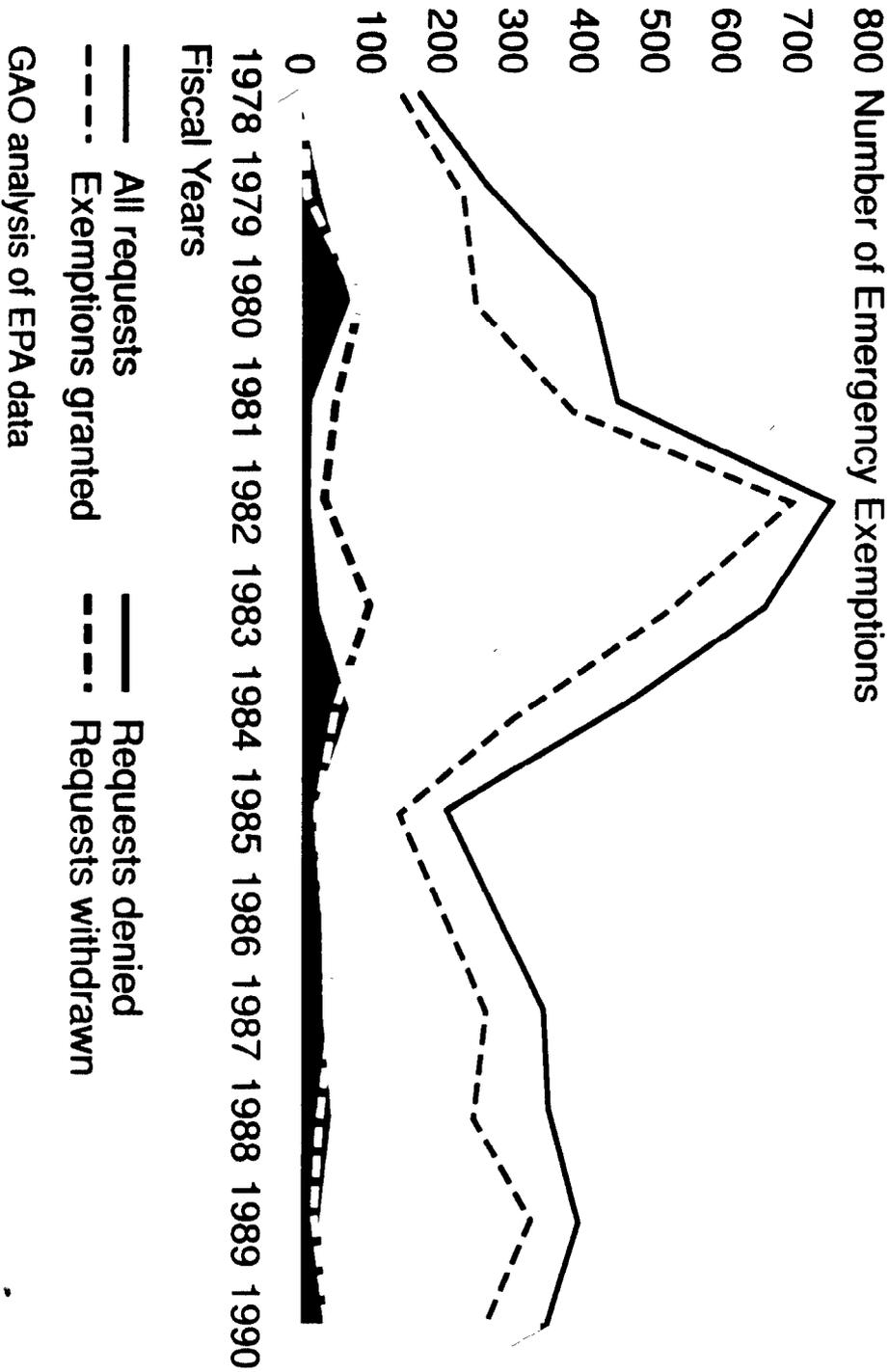
RECOMMENDATIONS

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.

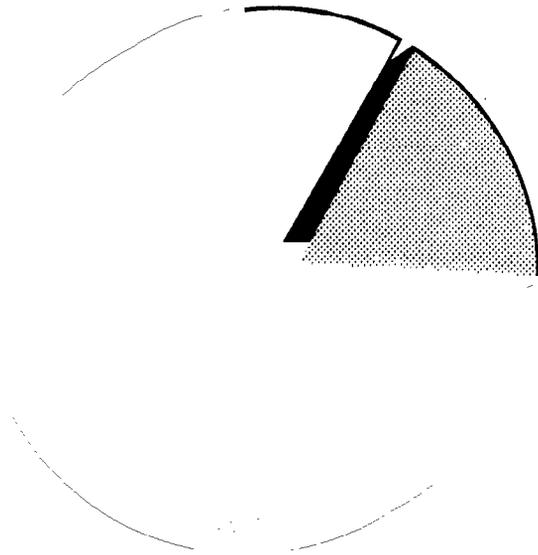
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Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions you or members of the subcommittee might have.

GAO Emergency Exemptions for Fiscal Years 1978-90



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.

GAO Disposition of Fiscal Year 1990 Repeat Exemption Requests

