

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

Andrew R. Wheeler, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Mail Code: 1101A
Washington, DC 20460
Wheeler.andrew@epa.gov

Rick Keigwin, Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Mail Code: 7501P
Washington, DC 20460
keigwin.richard@epa.gov

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 Constitution⁶ 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

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/epa_oig_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** determines 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~~ The 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 recur [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

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

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.31951d00989884;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

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 tuberculosis 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 position. 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

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,



Hannah M.M. Connor
Center for Biological Diversity
P.O. Box 2155
St. Petersburg, FL 33731
Phone: (202) 681-1676
hconnor@biologicaldiversity.org



Stephanie M. Parent
Center for Biological Diversity
P.O. Box 11374
Portland, OR 97211
Phone: (971) 717-6404
sparent@biologicaldiversity.org

Enclosures

cc: Matthew Z. Leopold
General Counsel
Environmental Protection Agency
Office of General Counsel, MC 2310A
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Leopold.Matthew@epa.gov