NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

November 2, 2004

VIA EMAIL AND HAND DELIVERY

Public Information and Records Integrity Branch
Office of Pesticide Programs
Environmental Protection Agency
Rm. 119, Crystal Mall #2
1801 S. Bell Street
Arlington, VA
email: opp-docket@epa.gov
ATTN: Docket ID No. OPP-2004-0038

Re: Emergency Exemption Process Revisions, 69 Fed. Reg. 53,866 (September 3, 2004).

Dear Sir or Madam,

These comments are being submitted on behalf of the Natural Resources Defense Council, Defenders of Wildlife, Beyond Pesticides, and [insert others] in response to the Environmental Protection Agency's Emergency Exemption Process Revisions Proposed Rule, published for comment at 69 Fed. Reg. 53,866 (September 3, 2004).

1. EPA's focus on "streamlining" comes at the expense of its obligations to protect public health and the environment.

We are wary of EPA's main objective of "streamlining" the emergency exemption process. 69 Fed. Reg. at 53,867. Original concerns that the passage of the Food Quality Protection Act (FQPA) might impose an undue burden on Section 18 applicants have proven to be unfounded. In fact, the number of exemption requests has increased sharply since passage of the FQPA, as has the number of exemptions granted. An analysis by the Environmental Working Group shows that the number of emergency exemptions granted had already doubled within two years of the passage of the FQPA. *See* EWG, *Attack of the Killer Weeds*, at 2 (Dec. 1999) (available online at http://www.ewg.org/pub/home/reports/killerweeds/killerweeds.pdf).

EPA's narrow-minded focus on speedy approvals of emergency exemptions is misguided. EPA's paramount obligations are to ensure that there is "a reasonable certainty that no harm will result" from aggregate pesticide exposure, 21 U.S.C. § 346a(b)(2), and to guarantee that pesticide use does not cause "unreasonable adverse effects on the environment," 7 U.S.C. § 136(bb). In the context of the Section 18 program, EPA appears to have lost sight of these

objectives, and instead focuses on faster and faster reviews of emergency exemption requests. It is hard to ignore the striking contrast between the speed with which EPA approves emergency requests on the one hand, and the glacial pace at which EPA takes any steps that might restrict pesticide use on the other hand. For example, under any fair reading of the FQPA, 21 U.S.C. § 346a(q), EPA should have completed tolerance reassessments for all organophosphates in August 1999, and is now five years overdue. In this light, EPA seems to have the precautionary principle backwards: the Agency hurries to get Section 18 pesticide uses approved on the basis of minimal information, but requires mountains of evidence and years (or decades) of review to impose restrictions on currently approved pesticides.

Notably, EPA does not assert that faster approvals of Section 18 applications will ultimately benefit public health. At most, EPA states that it believes these rule changes can be accomplished "without *compromising* protections for human health." 69 Fed. Reg. at 53,866 (emphasis added). EPA's wording betrays that the agency has pushed aside its primary responsibility of protecting public health in favor of unnecessary administrative changes.

2. EPA should not permit applicants to "re-certify" emergencies in repeated requests for subsequent years.

EPA proposes to allow emergency exemption applications to re-certify an asserted emergency with no new data or documentation for second-year and third-year requests. 69 Fed. Reg. at 53,869-70. This is a bad idea.

EPA's regulations define an "emergency" in part as "an urgent, non-routine situation." 40 C.F.R. 166.3(d). By definition, then, recurrence of a certain condition for several years in a row means that it is routine – and therefore not an emergency. Rather than making it *easier* to obtain permission for these repeated emergencies, EPA should make it more challenging, consistent with the applicant's obligation to demonstrate that the asserted emergency is indeed urgent and non-routine. EPA's regulations also define an emergency as a situation that "*requires* the use of a pesticide." 40 C.F.R. 166.3(d). Applicants should therefore be obligated to demonstrate, especially for repeat requests, that use of a pesticide is *necessary* and not just preferred. As the current regulations make clear, an emergency only exists when "[n]o economically or environmentally feasible alternative practices which provide adequate control are available." 40 C.F.R. 166.3(d)(2). Repeat applicants should be required to document at least (a) what effect the approved pesticide use had on the emergency condition in the first year of use; (b) why the requested pesticide use continues to be necessary; (c) that there are no feasible non-chemical alternatives; and (d) that the original predictions of economic harm are legitimate.

EPA's proposal would make it dramatically easier for an applicant to re-apply for a repeat exemption and for EPA to approve it. Testimony by the U.S. General Accounting Office more than ten years ago warned of the potential for abuse inherent in EPA's approval of repeat emergency exemptions. *See* GAO, *Testimony: EPA's Repeat Emergency Exemptions May Provide Potential for Abuse*, at 1-2, 6-9 (July 23, 1991). In one of the most flagrant recent examples of this abuse, EPA approved 14 consecutive emergency exemptions sought by the Oregon Department of Agriculture for vinclozolin on snap beans. The manufacturer of vinclozolin did not seek Section 3 registration for this obviously routine use until farmworker

and environmental groups threatened legal action in 1997 to stop the 15th consecutive emergency exemption request. EPA's current proposals to facilitate rather than restrict these repeat exemptions are a step in the wrong direction.

EPA lacks any meaningful backstop to continued emergency exemptions even when there is no progress towards FIFRA section 3 registration. First, the Agency states that "lack of progress towards registration *would not cause* denials during the first 3 years of exemptions for a chemical-crop combination." 69 Fed. Reg. at 53,871 (emphasis added). Registrants and growers therefore have a three-year free pass despite taking no steps at all towards registration. Even after that, however, lack of progress towards registration is simply listed as a factor that EPA "considers" in determining whether to approve an exemption, with no explanation of how. *Id.* at 53868. The most that EPA proffers in terms of preventing unlimited emergency exemptions is that "the Agency does not expect to re-approve emergency exemptions indefinitely." *Id.* at 53871. To be blunt, this is a feeble standard, and a completely ineffective safeguard against an acknowledged problem.

EPA notes several categories of pesticides that may warrant "heightened review" before additional use is approved, including the first food use of an active ingredient, or use of a pesticide that is under Special Review or has been cancelled. 69 Fed. Reg. at 53,870. Pesticide uses that have been voluntarily cancelled by the registrant should be added to this list. A registrant, in re-registration negotiations with EPA, will often voluntarily cancel certain high-risk pesticide uses in order to preserve the market for other uses and not overfill the re-registration "risk cup." EPA should not permit regulatory gamesmanship by allowing these cancelled uses back on the market through a Section 18 loophole.

3. The proposed alternative definitions of "significant economic loss" would expand the definition of emergency beyond reasonable limits.

EPA proposes several alternative measures – Tiers 1 through 3 – to document "significant economic loss," in order to make it easier to find that an emergency exists. These alternatives would unreasonably expand the definition of emergency.

EPA's Tier 1 would find significant economic loss on the basis of a 20% yield loss, regardless of actual economic effects. *Id.* at 53,871. But this standard is set without apparent reference to any historical data or benchmark. 20% yield loss compared to what? There is no way to know if a 20% yield loss standard is an appropriate proxy for actual economic loss, as EPA intends it to be.

EPA's Tier 2 and Tier 3 proposals make little sense in terms of EPA's twin statutory obligations to protect public health and the environment under FIFRA and the FFDCA. Tier 2 proposes that an emergency be declared if an applicant predicts economic losses of 20% of gross revenue for all crops. These losses could include "quality losses" or "changes in production costs, such as pest control costs and harvesting costs." *Id.* at 53,871-72. Tier 3 looks at the applicant's profit margins and will authorize an emergency if there is a 50% reduction in profits. *Id.* at 53,872. Tier 3 would therefore find that an economic emergency exists *even if the affected operations are still profitable* – just not as much so. "Even if economic loss seems small in comparison to gross revenues, the situation could still be determined to be a significant economic loss if the

profit margin is narrow." *Id.* While a 20% gross revenue loss or 50% profit reduction may be undesirable for the applicant, EPA's Section 18 process is not the appropriate mechanism to turn to for a remedy. Pesticide registration and tolerance decisions – including Section 18 decisions – must be made with a focus on public health and environmental protection, not profits. The fact that one pest control tool may be deemed "too expensive" because it reduces profits does not justify EPA declaring an emergency to authorize an otherwise-prohibited pesticide use. EPA's proposed redefinition of significant economic loss is unlawful, arbitrary and capricious, and contrary to clear congressional intent.

4. EPA's Section 18 activities violate the Endangered Species Act.

EPA routinely ignores its Endangered Species Act (ESA) obligations in the emergency exemption review and approval process. Any regulatory changes must attempt to improve EPA's abysmal record in this regard. The recommendations for streamlining in this Federal Register notice would be another step backwards on endangered species protection. EPA declares in this proposed rulemaking that "the Agency protects endangered and threatened species, and ensures compliance with the Endangered Species Act, through its implementation of the emergency exemption program." 69 Fed. Reg. at 53,867. However, EPA does not list a single example of agency consultation with federal wildlife services to ensure no jeopardy to endangered species in the course of a Section 18 exemption approval.

EPA concedes that Section 18 emergency exemptions must comply with the Agency's ESA obligations. 69 Fed. Reg. at 53,875. As currently implemented, the Section 18 program as a whole appears to be run with little concern for EPA's duty to prevent jeopardy to endangered species. 16 U.S.C. § 1536(a)(2). The U.S. Fish and Wildlife Service recently sent a letter to EPA's Region 2 to protest program-wide disregard for Endangered Species Act requirements. According to FWS, "the current process for granting FIFRA Section 18 emergency exemptions insufficiently addresses the EPA's consultation obligations under Section 7 of the ESA, and may result in the unintended consequence of adverse impacts to federally listed species." *See* Letter from Clifford G. Day to William J. Muszynski at p.3 (July 23, 2001). EPA's proposal for even faster review of Section 18 exemptions means giving even shorter shrift to endangered species considerations.

5. The Section 18 Pilot Process Already Underway Violates the Administrative Procedure Act.

EPA has already implemented all of the proposed changes in this Notice of Proposed Rulemaking on a pilot scale for reduced risk pesticides. EPA solicited public comment on this pilot program after it was already implemented, 68 Fed. Reg. 20,145 (April 24, 2003), and has not responded to any of the public comment submitted in response to that Federal Register notice. EPA's implementation of the Section 18 pilot process constitutes a binding regulation promulgated without public notice and comment, in violation of the Administrative Procedure Act. *See, e.g., CropLife America v. EPA*, 329 F.3d 876 (D.C. Cir. 2003).

6. EPA Should Use Section 18 to Promote, Not Discourage, Integrated Pest Management.

Section 18 unnecessarily enables the dependence on toxic chemicals to aid farmers. It is imperative that all changes proposed to this program require significant attention be paid to the possibility of non-chemical alternatives. With the rise of the organics industry, significant advances have been made in non-chemical pesticide alternatives and the use of physical and biological options to help control pests. EPA should use Section 18 to confirm the efficacy and economics of using new and old non-chemical alternatives in large-scale conventional agriculture. The use of non-chemical alternatives in addition to or in place of traditional pest management strategies can be successfully implemented to reduce pest resistance and slow the progress of existing resistance problems.

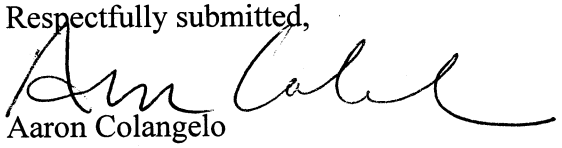
Pest resistance studies must be carried out in a scientific manner. If the Section 18 program is to be used to study pest resistance, it must do so under the guidance of trained professionals and monitored under the current extension service. Also, there must be an emphasis on non-chemical alternatives in the fight against resistance.

7. Conclusion.

EPA's proposed rulemaking will exacerbate one disturbing result of the Section 18 program as it is currently implemented – the authorization of extremely dangerous chemicals for an otherwise-prohibited use for years at a time. Recent Section 18 approvals include carbofuran and 2,4-D – two of the most toxic, harmful, and dangerous pesticides still in use.

With its focus on speed and streamlining, EPA appears to have lost sight of its fundamental obligations to protect public health and the environment. FIFRA Section 18 could be a useful safety valve to prevent a true pest emergency if the program were administered properly. But since passage of the FQPA, Section 18 exemptions have increased dramatically, and many of the approved exemptions respond to circumstances that clearly are not emergencies under any reasonable interpretation. For example, EPA established a tolerance for use of imidacloprid on blueberries pursuant to a Section 18 emergency exemption, 67 Fed. Reg. 2580 (Jan. 18, 2002), even though the pest at issue has not had and is not expected to have any effect on crop production or crop yield, and despite the existence of effective non-chemical alternatives. EPA's paramount objective should not be to ease the regulatory burden on Section 18 applicants. EPA must renew its focus on protecting public health from pesticide exposure, preventing widespread chemical contamination in the environment, and assessing the endangered species impacts of its Section 18 authorizations. These goals are being undermined in the name of greater speed, streamlining, and profits for a few growers.

Respectfully submitted,



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