



Defending the Planet One Beat at a Time

**102 Dogwood Lane
Pittsburgh, Pennsylvania 15237**

March 29, 2004

VIA OVERNIGHT MAIL & ELECTRONIC MAIL

Assistant Director for Endangered Species
U.S. Fish and Wildlife Service
4401 North Fairfax Drive, Room 420
Arlington, VA 22203

Re: Joint Counterpart Endangered Species Act Section 7 Consultation Regulations; Docket No. 021223326-4022-02.

Dear Sir or Madam:

The members of Rock the Earth, a national, nonprofit corporation, hereby submit comments on the proposed Joint Counterpart Endangered Species Act Section 7 Consultation Regulations, Docket No. 021223326-4022-02 (69 FR 4465, January 30, 2004) (“Proposed Rulemaking”). In the Proposed Rulemaking, the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (jointly “the Services”), after consultation with the U.S. Environmental Protection Agency (“EPA”), proposed joint counterpart regulations for consultation under Section 7 of the Endangered Species Act, 16 U.S.C. §§1531 *et seq.*, as amended (“ESA”) for regulatory actions under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*, as amended (“FIFRA”). The counterpart regulations provide two optional alternatives for completing Section 7 consultation for FIFRA regulatory actions. As stated in the Federal Register, the purposes of this rulemaking include:

- Eliminate the need for the EPA to conduct informal consultation and obtain written concurrence from the Services for those FIFRA actions that EPA determines are “not likely to adversely affect” any listed species or critical habitat; and
- Permit the Services to conduct formal consultation in a manner that more effectively takes advantage of EPA’s substantial expertise in evaluating ecological effects of FIFRA regulatory actions on federally-protected threatened and endangered species and critical habitats.

69 FR 4465-4466.

It is our opinion that the Proposed Rulemaking severely undermines the Congressionally mandated requirements of Section 7 of the ESA. As is demonstrated herein, EPA is neither legally permitted to bypass Section 7 ESA consultations with the Services when endangered species may be impacted by FIFRA determinations, nor is EPA technically qualified to conduct such evaluations themselves.

I. Rock the Earth.

Rock the Earth (“RtE”) is a Pennsylvania nonprofit corporation with a national membership of concerned citizens who believe that wildlife species in the United States are an integral part of a sustainable and healthy environment. Our membership believes that the protection and propagation of wildlife species, especially threatened and endangered species and their associated critical habitats are essential and that detrimental threats to their survival (especially through the misapplication of the ESA) are intolerable. The Proposed Rulemaking will directly affect RtE’s members as many of our membership find great value in the enjoyment of natural and wild areas for recreational activities, such as hiking, camping, photography, and meditation. These recreational activities are enhanced when one knows that wildlife species are present and when one has the opportunity to view those species and their habitats. In fact, one assumes that natural and wild areas should, by definition, include the presence of wildlife species. Since wildlife species, especially threatened and endangered species, provide RtE members with significant recreational experiences, these species, therefore, are deserving of the most stringent regulatory protections available.

II. The Proposed Rulemaking.

In the Proposed Rulemaking, the Services conclude that the EPA, through its FIFRA ecological risk assessment process, is qualified to conduct Section 7 consultations and that in many cases, consultation with the Services by the EPA will be unnecessary or greatly reduced. The Services contend that the EPA has significant expertise in conducting risk assessments, and that, after a careful review of EPA’s ecological risk assessment methodology, “the Services have determined that the approach used by EPA...will produce effects determinations that reliably assess the impact of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations.” 69 FR 4469. In particular, the Proposed Rulemaking will establish the following:

1. Two additional methods for EPA to utilize to meet Section 7 consultation requirements;
2. Allow EPA to make a No Likely Adverse Affects (“NLAA”) determination for a FIFRA action without formal or informal consultation with the Services;
3. Provide for optional formal consultations with the Services should EPA choose to initiate them; and

4. Require an annual review of the program by the Services.

It is the Services' position that authorizing the EPA to conduct Section 7 reviews will provide for greater efficiency and effectiveness in the FIFRA process. The rationale for these regulatory changes is two-fold: First, EPA anticipates that the number of consultation requests will substantially increase in the coming years requiring a significant level of resources due to the large number of consultations and their complexity. Second, the Services assert that many new active ingredients are being formulated that have been developed to have less impact than currently registered products. As such, any improvement in the process will benefit species, as these new products will be registered quicker.

As will be demonstrated throughout this comment letter, Rock the Earth strongly disagrees that EPA has either the technical expertise or the legal authority to make such assessments.

III. The Ecological Impacts of Pesticides

Pesticides pose a tremendous threat to all organisms—endangered species and otherwise. In order for an assessment procedure to be adequate, one must first understand the threat that pesticides pose to endangered species and the complex analysis that must be conducted to ensure their safety.

A. The Ecological Impacts of Pesticides on Wildlife Species

Due to their multitude of uses, locations, and application types, pesticides, as a class of chemicals, may be considered to have the single greatest potential negative impact to threatened and endangered species. Lappé and Bailey, citing the Center for Biological Diversity, indicated that during the period 1993 to 2001, the listing of approximately 17% of the 1,088 endangered species on average was due to pesticide-related impacts. Furthermore, in that same time period, approximately 14% of Federal Register notices discussing critical habitat actions identified pesticides as a major issue (Lappé and Bailey, 2002).¹

Pesticides may impact wildlife, including endangered and threatened species directly when a species comes in contact with a pesticide during the application of the pesticide, or indirectly, long after a pesticide is applied. One author notes, “pesticides may impact wildlife indirectly when a part of its habitat or food supply is modified.”² (Whitford, *et al.*, 2001). Studies have documented the direct and indirect effects of pesticides on wildlife, including threatened and endangered species. Several are summarized as follows:

¹ Lappé, Marc and Britt Bailey, *New Considerations for Evaluating Pesticide Impacts to Endangered/Threatened Species*. Report to the Environmental Protection Agency, U.S Fish and Wildlife Service, and National Marine Fisheries Service, Case No. C00-3150 CW (2002) .

² Whitford, F., B. Miller, R. Bennett, M. Jones, and L. Bledsoe, *Pesticides and Wildlife*, Indiana: Purdue University Cooperative Extension Service (2001).

- Atrazine, one of the most widely used herbicides in the United States, has been shown to cause negative effects in frogs, including sexual deformities, and destroy sea turtle habitat and food sources.³
- Carbofuran has been shown to have extremely toxic effects to numerous species of birds.⁴
- Pesticides may have a deleterious effect on salmon.⁵
- Diazinon poses unacceptable risks to agricultural workers and to birds and other wildlife species.⁶
- Chlorpyrifos, a pesticide that by EPA's own estimates has been responsible for more than 1000 pesticide poisonings a year, is highly toxic to freshwater fish, aquatic invertebrates, estuarine and marine organisms, and has the potential for acute and chronic human, avian, and aquatic toxicity.⁷
- Pyrethrins are extremely toxic to aquatic life, and have reportedly killed thousands of fish, lobsters, birds and beneficial insects (e.g. butterflies and bees) by spraying.⁸

³ Hayes, T., K. Haston, M. Tsui, A. Hoang, C. Haeffele, and A. Vonk. *Atrazine-Induced Hermaphroditism at 0.1 PPB in American Frogs (Rana pipiens): Laboratory and Field Evidence*. On the web: <http://www.mindfully.org/Pesticide/2002/Atrazine-Induced-Hermaphroditism23oct02.htm>; Letter from Cascade Resources Advocacy Group to Marianne Horinko. *Notice of Intent to Sue for Violations of the Endangered Species Act Concerning EPA Registration of the Pesticides Diazinon, Atrazine, Prometon, Simazine, Carbaryl, and Metolachlor*, September 22, 2003; Rabert, W., J. Lin, M. Frankenberry, H. Nelson, and D. Urban, *Reregistration Eligibility Science Chapter For Atrazine Environmental Fate and Effects Chapter* (2001). On the web: http://www.epa.gov/oppsrd1/reregistration/atrazine/atrazine_eco_assessment.pdf

⁴ EXTTOXNET Pesticide Information Profiles - Carbofuran. On the <http://exttoxnet.orst.edu/pips/carbofur.htm>

⁵ NAOO National Marine Fisheries Service. On the web: <http://www.nwfsc.noaa.gov/publications/issuepapers/Pdfs/EC6505.pdf>

⁶ Diazinon IRED Facts. http://www.epa.gov/REDS/factsheets/diazinon_ired_fs.htm

⁷ On June 8, 2003, under increasing pressure from state officials along with environmental and concerned citizens groups, EPA cancelled all consumer product registrations for the chlorpyrifos product Dursban, yet EPA retained the use of chlorpyrifos products for aerial application in public health mosquito control programs. Reference: Comments of New York State Attorney General Eliot Spitzer. In re: United States Environmental Protection Agency's Preliminary Risk Assessment For the Chlorpyrifos Reregistration Eligibility Decision Docket Control Number OPP-34203 December 27, 1999, amended January 3, 2000; EPA Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs ("OPP"). Chlorpyrifos incident review update, U.S. EPA Office of Pesticides Programs memorandum. DP barcode 259617. (1999). On the web: <http://www.epa.gov/pesticides/op/chlorpyrifos/incidentsreview.pdf>; American Bird Conservancy. <http://www.abcbirds.org/pesticides/Profiles/chlorpyrifos.htm>; EPA Restricted Use Products Report, June 2003. <http://www.epa.gov/opprd001/rup/rupjun03.htm>. ATSDR. Toxicological Profile for Chlorpyrifos, Agency for Toxic Substances and Disease Registry, United States Public Health Service (1996).

⁸ EXTTOXNET Pesticide Information Profiles - Pyrethrins and Pyrethroids. On the web: <http://ace.ace.orst.edu/info/exttoxnet/pips/pyrethri.htm>; Brown, Mariangail, "Lobster die-off linked to pesticides. Fishermen applaud scientific finding" The Connecticut Post: Saturday, March 08, 2003; <http://www.safe2use.com/poisons-pesticides/pesticides/pyrethroids/resmethrin.htm>.

Regardless of the fact that pesticides are registered under FIFRA for the targeted application and control of specific organisms, pesticides are by their very nature non-specific biological toxins. As such, non-target organisms (plants, terrestrial and aquatic wildlife, and other organisms that are not the intended target of the pesticide) are often inadvertently impacted through their use. Pesticides are likely to be transported away from the target treatment area into water bodies that were not intended or permitted to receive pesticides, and which may be used by sensitive ecological or human receptors. Growing scientific evidence points to the complexity of performing comprehensive assessments of the human and ecological risks associated with non-target pesticide exposures.⁹

B. The Ecological Impact of Pesticides on Water Quality

Recent water quality studies raise the concern that pesticide contamination is occurring and may contribute to direct and indirect impacts to water quality and aquatic life, resulting from non-target exposure, in particular. The first phase of the USGS's National Water Quality Assessment ("NAWQA") Program indicates "that pesticides are widespread in stream and groundwater, occurring in geographic and seasonal patterns that follow land use and related pesticide use."¹⁰ (Gilliom, *et al.*, 1999). Of the 65 surface waters designated for study, approximately 95 percent (approximately 62 surface waters) contained at least one detectable pesticide.¹¹ With regard to groundwater, at least one pesticide was detected in approximately 50 percent of the wells sampled. Seventy-four of the 83 pesticide compounds analyzed were detected at least once in these same waters (streams or groundwater). (Gilliom, *et al.*, 1999).

The authors noted that of the 76 pesticides analyzed during the study, only 43 have established Maximum Contaminant Levels ("MCLs"), Health Advisory Levels ("HALs"), or Risk-Specific Doses ("RSD"). Although annual average concentrations of pesticides rarely exceeded regulatory standards (MCLs or HALs), the peak concentrations of several herbicides exceeded regulatory levels in several surface waters. Furthermore, because of the typically punctuated usage of pesticides (rather than continual applications), a recent EPA report concluded that peak pesticide concentrations are not statistically likely to be measured by

⁹ Example factors that complicate such assessments include:

- variations in pesticide persistence and mobility;
- lack of established risk assessment criteria for many pesticides;
- inadequate research on the toxicity of chemical mixtures;
- inadequate research and consideration of transformation products;
- non-disclosure of the composition of "inert" materials in pesticide formulations that may have toxicity, and/or increase the cumulative health risk of the final product;
- cumulative and acute effects of seasonal exposures; and
- the unique effects on sensitive populations, including disorders related to endocrine, reproductive, or nervous system disruption.

The EPA Office of Pesticides explicitly acknowledges such complexities in their attempt to address this in recent studies such as EPA OPP, *Revised Cumulative Risk Assessment of Organophosphate Pesticides* (2002).

¹⁰ Gilliom, R.J., J.E. Barbash, D. W. Kolpin, and S. J. Larson, *Testing Water Quality for Pesticide Pollution*, Environmental Science and Technology 33(7): 164A-169A (1999).

¹¹ Samples were collected from 40 agricultural streams, 11 urban streams, and 14 larger rivers. *Id.*

periodic sampling events such as those conducted in their study, and therefore it must be concluded that pesticide concentrations in periodically monitored waters are likely to have peak concentrations *significantly higher* than those measured in the sampling events.¹² Potential impacts to aquatic life were considered high in surface waters, “particularly those in which concentrations of more than one pesticide approach or exceed aquatic-life criteria for an extended period of time” (Gillom, *et al.*, 1999).

Another key finding of this study was the fact that the most commonly occurring form of pesticides observed in watercourses were low-level pesticide mixtures. As a result, the authors postulated that “long-term exposure to low-level mixtures of pesticide compounds, punctuated with seasonal pulses of high concentrations, is an exposure pattern that may not be adequately accounted for in present criteria.” (Gillom, *et al.*, 1999). As such, the cumulative effects (or risk) of pesticide mixtures is unknown. Furthermore, the cumulative effects of pesticide transformation products (of which there is no criteria established) or the cumulative effects of mixtures of transformation products are also unknown and considered to be potentially significant.¹³

IV. The FIFRA Risk Assessment Process

Under FIFRA, the EPA is required to evaluate and determine that the use of a pesticide will not cause “unreasonable adverse effects on the environment.” *See* 69 FR 4467. Adverse effects on the environment are defined to include “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.” 69 FR 4467. The EPA uses an ecological risk assessment approach to evaluate the impacts of pesticides on ecological systems during the registration process. (OPP, 2004)¹⁴ A brief description of the ecological risk assessment approach, as conducted by the OPP, is presented below and follows the information provided in a recent Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs (“Office of Pesticide Programs” or “OPP”) publication¹⁵.

Two divisions within the Office of Pesticide Programs conduct ecological risk assessments: the Environmental Fate and Effects Division (“EFED”); and the Field and External Affairs Division (“FEAD”). EFED is responsible for conducting screening level assessments. Data sources for EFED analyses include registrants as well as other published materials (OPP, 2004). The screening level assessment, through the use of computer modeling and other tools, provides an initial review of the environmental fate of the proposed pesticide. If the assessment indicates that use of the pesticide will not impact wildlife species, the risk assessment is concluded.

¹² EPA OPP, *Revised Cumulative Risk Assessment of Organophosphate Pesticides*, (2002)

¹³ EPA OPP, *Revised Cumulative Risk Assessment of Organophosphate Pesticides* (2002).

¹⁴ Office of Prevention, Pesticides, and Toxic Substances, Office of Pesticide Programs. 2004. *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency, Endangered and Threatened Species Effect Determinations*. Washington, D.C.

¹⁵ *Id.*

If the results of the screening level assessment exceed Levels of Concern for a listed species, FEAD conducts a species-specific review. Typically, the FEAD analysis attempts to reflect actual conditions (e.g. research whether listed species are actually located in the area where the proposed pesticide may be applied). If species are known to exist in the area, FEAD investigates if exposure levels will directly or indirectly impact listed species (OPP, 2004). FEAD prepares an effects determination which is used to document if the pesticide may or may not effect a listed species.

Once completed, risk assessment results(e.g. the effects determination) are used by the risk management division of the OPP for final regulatory determination. As stated in its 2004 publication, OPP risk managers evaluate the ecological effects of a pesticide along with socio-economic benefits, legal requirements, and the effect of mitigation measures. “Trade-offs between different regulatory actions are evaluated, and value judgements applied to reach a decision.” (OPP, 2004, pg 11).

V. Rock the Earth’s Position

As outlined above, pesticides pose a serious threat to endangered species. It is also clear that the FIFRA registration process alone is not sufficient to protect wildlife species or the waters of the United States from the deliberate application or inadvertent discharge of pesticides to the Nation’s lands and/or waters, nor is it sufficient to protect human and ecological health. It is Rock the Earth’s position that the EPA is not legally permitted to bypass the Services’ statutorily mandated duty to conduct evaluations required under Section 7 of the ESA. Furthermore, based on the shortcomings contained within the EPA FIFRA risk assessment process described herein, EPA is not competent to undertake such evaluations alone.

A. The EPA may not legally make NLAA determinations without consulting with the Services.

The EPA is legally required to consult with the Services when evaluating the impact that FIFRA determinations may have on endangered species. As detailed in Section IV above, EPA’s FIFRA risk assessment process is rather limited and has several shortcomings and biases.¹⁶ Further, as is also demonstrated above, most pesticides have an ability to impact species and since pesticide usage is not geographically limited. At any given time endangered species could be impacted by any given pesticide—even if used properly. Therefore, there is a statutory requirement that the EPA consult with the services in making their decisions. Finally, the ESA *already* contains an exception and process to the requisite consultation, negating the need for the new alternative consultation process.

¹⁶ See also, Section V.B., *infra*.

1. The Services have a statutory duty to conduct risk assessments.

Section 7 of the ESA provides the statutory mandate that the Services be consulted whenever a federal decision or action may impact endangered species. Specifically, Section 7(a)(2) provides as follows:

Each Federal agency *shall, in consultation with and with the assistance of the Secretary*, insure that any action authorized, funded, or carried out by such agency...is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with the affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of this section. In fulfilling the requirements of this paragraph each agency *shall* use the best scientific and commercial data available.

16 U.S.C. §1536(a)(2) (emphasis added); see Natural Resources Defense Council v. Houston, 146 F.3d 1118, 1125-1126 (9th Cir. 1998). The import of this language has been read by the United States Supreme Court as “indicat[ing] beyond doubt that Congress intended endangered species to be afforded the highest of priorities.” TVA v. Hill, 437 U.S. 153, 174 (1978). In Congress’ view, actions that jeopardize the continued existence of endangered species threaten an incalculable harm. Accordingly, in the balance of hardships in complying with the ESA and the public interest, the scales tip heavily in favor of endangered species. Sierra Club v. Marsh, 816 F.2d 1376, 1383 (9th Cir. 1987) citing TVA v. Hill, at 187-88, 194-95.

Other subsections of Section 7 contain similar language regarding the mandatory nature of consultations with the Services.¹⁷ The only exemptions are defined in the statute in subsection (h), which exemptions go towards a waiver of the obligation to protect said species—*not* a waiver of the consultation process itself.¹⁸ In fact, in light of the allowance of a waiver of protection or ability to mitigate a taking under certain, specific conditions, consultation with the Services *must* occur. Therefore, if an agency determines that its proposed action “may affect” an endangered or threatened species, the agency must formally consult with the Services and this “duty” of consultation is required of all federal agencies. See NRDC v. Houston, at 1125; Marsh, at 1386.

¹⁷ Section 7(b)(1)(A) states, “Consultation under subsection (a)(2) of this section with respect to any agency action *shall* be concluded within the 90-day period...” 16 U.S.C. §1536(b)(1)(A). See also, Section 7(c)(1): “To facilitate compliance with the requirements of subsection (a)(2) of this section, each Federal agency *shall*, with respect to any agency action...request of the Secretary information whether any species which is listed or proposed to be listed may be present in the area of such proposed action. 16 U.S.C. §1536(c)(1) (emphasis added)

¹⁸ See 16 U.S.C. §1636(h).

This mandatory consultation requirement contained within the ESA if reaffirmed in the regulations promulgated in Part 402 of Title 50 of the Code of Federal Regulations, 50 CFR §402.01(a), wherein the Scope of the ESA is defined. Contained within that section, it states:

Section 7(a)(2) of the Act *requires* every Federal Agency, *in consultation with and with the assistance of the Secretary*, to insure that *any action* it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or results in the destruction or adverse modification of critical habitat.

50 CFR §401.01(a) (emphasis added). Furthermore, the regulations go on to state that this responsibility for administering the ESA is one that is shared between the U.S. Fish and Wildlife Service and the National Marine Fisheries Service. See 50 CFR §402.01 (b). According to the plain language of the regulations, the responsibility for conducting these evaluations is that of the Services and the Services alone. Formal consultation is only excused where: “(1) an agency determines that its action is unlikely to adversely affect the protected species or habitat; **and (2) the relevant Service (FWS or NMFS) concurs with that determination.**” NRDC v. Houston, at 1126 citing 50 CFR §402.14(b); Pacific Rivers Council v. Thomas, 30 F.3d 1050, 1054, n. 8 (9th Cir. 1994) (emphasis added).¹⁹

In terms of defining what “agency actions” are subject to this review, Congress, in promulgation of the regulations in furtherance of the ESA, defined “action” as:

Action means all activities or programs or any kind authorized, funded, or carried out, in whole or in part, by Federal agencies.... Examples include, but are not limited to: ...the promulgation of regulations...the granting of licenses...permits; or...actions directly or indirectly causing modifications to the land, water, or air.

50 CFR § 402.02. The courts have also examined what Congress meant by “agency actions” subject to the mandatory review. In TVA v. Hill, the Supreme Court stated:

One would be hard pressed to find a statutory provision whose terms were any plainer than those in § 7 of the Endangered Species Act. Its very words affirmatively command all federal agencies ‘to insure that actions authorized, funded, or carried out by them do not jeopardize the continued existence’ of an endangered species or ‘result in the destruction or modification of habitat or such species...’

¹⁹ Even in circumstances where the Services’ position is that a formal consultation is unnecessary, the 9th Circuit has held that there is still a clear obligation on the part of the agency to at least request a formal consultation. NRDC v. Houston, at 1127 citing 50 CFR §§402.13, 402.14.

TVA v. Hill, at 173. Clearly, the registration of pesticides pursuant to the labeling requirements of FIFRA would be an agency action subject to the mandatory requirement that EPA consult with the Services and that the Services undertake their mandatory duty to review any potential impacts that the particular pesticides may have on endangered species and/or critical habitat.

The Proposed Rulemaking attempts to undermine that Congressionally mandated statutory requirement contained within the ESA, as well as within the regulations promulgated thereunder and the wealth of caselaw that has interpreted these provisions. It is simply improper and contrary to law to attempt to modify a clear, well-established statutory requirement through regulations. Whenever Congress by statute authorizes an agency to carry out or execute certain environmental duties, it delegates its micro-level legislative authority to the executive branch through grants of power to the appropriate agencies. However, Congress cannot delegate legislative authority to the President. Field v. Clark, 143 U.S. 649, 692 (1892). An agency only receives the authority that it legislatively is delegated and it must not venture outside the substantive “tent” erected by Congress. Ferry, Environmental Law: Examples and Explanations, 1997, at 32-33. When reviewing a delegation problem, one must look at the face of the enabling act to find that authority. While it is presumed that the agency is functioning within its statutory authority, one may dispute this presumption by showing that the agency action is not authorized under the enabling act. Id. The Supreme Court described this principal in Stark v. Wickard, 321 U.S. 288, 309 (1944) stating, “[w]hen Congress passes an Act empowering agencies to carry on governmental activities, the power of those agencies is circumscribed by the authority granted.” Furthermore, “[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress,” Chevron, U.S.A. v. National Resource Defense Council, 467 U.S. 837, 842-43 (1984)²⁰; National Resource Defense Council v. Costle, 568 F.2d 1369, 1374 (D.C. Cir. 1977).

All pesticides have the potential to impact a variety of endangered species. Since there is a Congressionally mandated statutory duty assigned to the Services to make assessments and a duty on the part of the EPA to consult with the Services when taking an action under FIFRA with regards to a given pesticide. Since the Proposed Regulations provide EPA with the ability to bypass these Congressionally mandated statutory requirements resulting in deleterious impacts to endangered species, the Proposed Regulations are legally deficient and in direct contravention to the mandates of the ESA. Therefore, the Proposed Regulations may not be legally adopted.

2. EPA’s authority to make risk assessments is limited.

EPA has not been delegated the authority by Congress to conduct risk analysis under FIFRA to determine whether or not endangered species may be impacted by a particular pesticide. As such, EPA lacks the authority to conduct such risk assessments and must consult with the Services.

²⁰ Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837 (1984), holding that where a statute is silent on a precise issue in question, weight shall be given to an agency’s interpretation.

EPA, as a federal agency, is a creature of statute, whose authority is limited to that bestowed upon it by Congress. EPA has no constitutional or common law existence or authority, but only those authorities conferred upon it by Congress. An administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress. See Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988). Simply stated, nowhere within the ESA or FIFRA has EPA been delegated the authority to conduct risk assessments of pesticides without consultation with the Services. Furthermore, there is no implied delegation to EPA and delegation cannot be presumed. "Were courts to presume delegation of power absent an express withholding of such power, agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with Chevron and quite likely the Constitution as well." Ethyl Corporation v. EPA, 51 F.3d 1053, 1060 (D.C. Cir. 1995). Mere ambiguity in a statute is not evidence of a congressionally delegation of authority. Sea-Land Servs., Inc. v. Department of Transportation, 137 F.3d 640, 645 (D.C. Cir. 1998).

In this case, EPA is not entitled to Chevron deference in its interpretation that it has the authority to conduct endangered species risk assessments. The authority to conduct risk assessments under the ESA for actions taken pursuant to FIFRA have clearly and unambiguously been granted to the Services.

3. Exceptions to consultations with the Services already exist.

The Proposed Rulemaking would, in effect, create an exception to Section 7(a)(2) of the ESA for EPA's FIFRA actions. The ESA already sets forth a procedure for granting such exceptions and gives that authority to the Endangered Species Committee ("ESC") in Section 7(e) of the ESA. The ESC is the **only** established body under the ESA with the power to grant exceptions from the requirements of subsection (a)(2). It is comprised of seven members²¹ and may, based on a vote of no less than five members, grant such exceptions and/or require mitigation measures. Grants of exemption may be made when:

- There are no reasonable and prudent alternatives to the agency action;
- The benefits of such action clearly outweigh the benefits of alternative courses of action consistent with conserving the species or its critical habitat, and such action is in the public interest;
- The action is of regional or national significance; and
- Neither the Federal agency concerned nor the exemption applicant made any irreversible or irretrievable commitment of resources prohibited by subsection (d) of this section.

16 U.S.C. §1526(h). Since Congress, in their infinite wisdom in enacting the ESA has already created an statutory avenue for exemptions under the ESA, to allow EPA to bypass the Services

²¹ The seven members of the ESC are the: Secretary of Agriculture; Secretary of the Army; Chairman of the Council of Economic Advisors; the Administrator of the EPA; the Secretary of the Interior; the Administrator of the National Oceanic and Atmospheric Administration; and one representative from each affected State, as chosen by the President. 16 U.S.C. §1536 (e).

review through promulgation of the Proposed Rulemaking would be contrary to the intent of Congress.

In light of the above analysis, EPA is not legally permitted to bypass the consultation requirements of the ESA. All decisions regarding the potential impact of pesticides registered under FIFRA on endangered species are entitled and, in fact, must be subject to review by the Services. Not only does the plain language of the statute require it, but EPA's legal authority to conduct risk analysis of FIFRA actions under the ESA is limited. Finally, the only exemptions to Section 7 ESA reviews are contained within the statutory confines of the ESA itself.

B. The EPA is not qualified to conduct evaluations required under Section 7 of the ESA.

Even assuming that EPA was legally permitted to conduct endangered species risk evaluations, the assessments conducted pursuant to FIFRA would be insufficient to fulfill the requirements of the ESA. EPA's reregistration and risk assessment review processes under FIFRA has been previously alleged to be deficient in a number of notable ways. Lingering questions exist over the timeliness, effectiveness, and unbiased nature of EPA's reregistration and risk assessment review processes. Not only has EPA been forced to comply with court-imposed settlement agreements to undertake extensive evaluations beyond a normal FIFRA assessment, but EPA's method of assessment is also deficient due to its reliance on biased Science Advisory Boards, its failure to prevent water quality and wildlife species impacts, and its failure to consider inert ingredients when making an assessment determination.

1. EPA's risk assessment review process under FIFRA has been demonstrated to be deficient in litigation.

On August 3, 1999, NRDC and the other farmworker/environmental plaintiffs filed a lawsuit in federal district court in California alleging that EPA had failed to carry out mandatory duties imposed by the tolerance reassessment requirements of the Federal Food, Drug and Cosmetic Act, section 408(q), 21 U.S.C. § 346a(q). NRDC v. Whitman, Case No. C-99-3701 CAL (N.D. CA. 1999). This lawsuit also included claims regarding EPA's implementation of the estrogenic substances screening program ("ESSP") under FFDCA section 408(p), 21 U.S.C. § 346a(p). At the same time, NRDC filed a second suit in the federal court of appeals for the Ninth Circuit challenging EPA's compliance with the reregistration schedules in section 4 of FIFRA. United Farm Workers of America, et al. ("UFW") v. Whitman, No. 99-70496 (filed, Aug. 3, 1999).²²

EPA entered into a consent decree with NRDC in September 2001, which required the Agency to issue annual progress report addressing the risks identified in certain previously issued Reregistration Eligibility Decisions ("REDs") and Interim Reregistration Eligibility Decisions ("IREDs"). "With respect to each covered RED and IRED, EPA is to identify any risks from pesticide use and/or any pesticide tolerances that the Agency has determined do not

²² On the web: http://www.epa.gov/oppfead1/cb/csb_page/updates/nrdc-comt.htm.

meet applicable statutory standards and to describe its plans for addressing the risk or tolerance. For REDs and IREDs discussed in the first annual report, EPA must describe its steps toward completing its plan to address identified risks or tolerances.”²³ NRDC has since sued the Agency, again, for failing to comply with said consent decree. Specifically, the NRDC lawsuit charges that EPA has violated the law by: failing to use a tenfold infant and child protection safety factor; failing to protect highly vulnerable or highly exposed people, including farmworkers' children and other children living on or near farms who are more heavily exposed to pesticides than average children; and relying on a confidential, proprietary, industry-developed computer model to determine pesticide risks.²⁴

In light of the apparent need for citizens to continue to seek court relief and enforcement of agreements into which EPA has entered to ensure adequate evaluation of risks, it is apparent that EPA's risk evaluation process is deficient and insufficient.

2. EPA's risk assessment review process is biased due to its use of Science Advisory Boards.

In addition to a deficiency in EPA's review of pesticide impacts, EPA's reliance on Science Advisory Boards in the process calls into question the veracity, the robustness and unbiased nature of the assessments. At the direction of Congress, the General Accounting Office ("GAO") was asked to investigate the selection of scientific advisory boards that are used in EPA risk assessments and policy decisions.²⁵ The General Accounting Office report found serious deficiencies in the EPA's procedures to prevent conflicts of interest within Science Advisory Boards. According to GAO, EPA fails to provide for adequate determinations of conflicts of interest when panels are formed, does not obtain sufficient information to evaluate conflicts of interest, fails to obtain appropriate information on financial disclosure forms, fails to review disclosure forms in a timely fashion, and fails to adequately disclose potential conflicts of interest to the public.²⁶ The GAO found such problems as: four of the thirteen panel members studying cancer risks of the chemical 1,3-butadiene (an intermediate in the production of the fungicides captan and captfol) in 1998 had worked for chemical companies or industry-affiliated research organizations, including one who had worked for the company that had manufactured the chemical; seven of 17 advisory board members on a cancer-risk assessment panel had worked for chemical companies or for industry-affiliated research organizations, and five other panelists had received consulting or other fees from chemical manufacturers.²⁷

²³ EPA Actions Implementing Regulatory Determinations Required under the NRDC Consent Decree – Second Annual Report. On the web: <http://www.epa.gov/oppsrrd1/nrdc2.htm>.

²⁴ NRDC Sues EPA (Again) for Failing to Carry Out Pesticide Control Law. Press release. September 15, 2003. On the web: <http://www.nrdc.org/media/pressreleases/030915a.asp>

²⁵ Key Findings of the GAO Report "EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance" July 16, 2001. On the web: http://www.house.gov/reform/min/pdfs/pdf_inves/pdf_enviro_gao_epa_sum.pdf.

²⁶ Id.

²⁷ Id.

Therefore, since EPA relies on potentially biased Science Advisory Boards in conducting risk assessments, EPA's evaluation of potential impacts of FIFRA registered pesticides is inadequate.

3. EPA's risk assessment review process is deficient as evidenced by resulting water quality and wildlife species impacts.

The results of the GAO study present uncertainty as to the effectiveness of the FIFRA program in evaluating the risks of pesticides on water quality. As stated above, the chemical effects of mixtures and transformation products are unknown. Matthiessen²⁸ questioned the ability of risk assessment to adequately predict the impacts of chemical mixtures in the environment. He noted that risk assessment is providing a tool in "screening out some undesirable chemicals, or at least their risky uses". However, the author noted, "few environmental investigations and monitoring programs are explicitly designed to test whether chemical risk assessments are working as intended". Furthermore, current risk assessment models appear to not be able to account for the significance of cumulative health risk from environmental mixtures.

The California Regional Water Quality Control Board ("CRWQCB"), in a March 7, 2003 letter to the EPA, stated that, a number of studies have shown that some pesticides registered by the OPP may cause lethal or serious non-lethal effects on aquatic species.²⁹ Furthermore, CRWQCB indicated that many water bodies under its jurisdiction are impaired due to discharges of registered pesticides. As a result, expensive programs must be undertaken to address these water quality issues.

With respect to EPA's risk assessment program and its review of threatened and endangered species, Lappé and Bailey state, "EPA's current pesticide risk assessment systems suffer from at least the following deficiencies:

1. They inadequately consider best available scientific evidence;
2. They fail to incorporate the effects of complete pesticide formulations and multiple pesticide components including diluents, adjuvants and degradation products;
3. They exclude synergistic effects (e.g. none of the existing models include formulae or risk estimation procedures that quantify the harm caused by indirect pesticide effects that may degrade food sources or environmental quality generally);
4. They fail to use field monitoring to validate transport and persistence models; and
5. They inadequately assess the chronic and sublethal effects of pesticides on all life stages of each species."

(Lappé and Bailey, 2002, at 2, 15)

²⁸ Matthiessen, P. 1998. Aquatic risk assessment of chemicals: Is it working? *Environmental Science and Technology*. 32(19), 460A-461A.

²⁹ California Regional Water Quality Control Board. March 7, 2003 letter to U.S. EPA Public Information and Records Integrity Branch and Arthur-Jean B. Williams, Branch Chief of FEAD.

Furthermore, the authors proposed a new reference dose, the Endangered Species Reference Dose (“RfDes”), for measuring the impact of pesticides on listed species based on reproductive toxicity. The intent of the proposed reference dose is to aid the EPA’s mandate to determine a pesticide’s adverse effects. The ability for a listed species to reproduce is crucial for survival. Therefore, it is apparent the EPA’s current system is inadequate in addressing this critical issue.

4. EPA’s risk assessment review process is deficient in its failure to consider inert ingredients.

Aquatic, wildlife, sediment, and human health guidelines applied during the FIFRA pesticide registration process are often based on single-species, single-chemical toxicity tests – tests that are generally performed solely on the listed active ingredient, not on the pesticide’s final formulation. The final chemical formulations of most pesticides include one or more active ingredients and inert materials. Inert ingredients are typically added to dilute, dissolve, or preserve the active ingredients and to make the pesticide easier to apply. The final chemical formulation of the entire product (active ingredient plus inert ingredients) is not reviewed for toxicity. Neither are potential breakdown products, or the possible cumulative impacts of multiple products reviewed.

FIFRA requires that the active ingredients of pesticides be disclosed on product labels along with their associated precautions. Inert ingredients, however, are exempt from such labeling requirements under FIFRA. In 1996, The New York State Attorney General’s Office (“NY AG”) released a report on the hidden hazards associated with the so-called “inert” ingredients in pesticides. (NYS AGO, 1996)³⁰ In its report, the NY AG points out that although EPA has categorized inert ingredients into four groups (substances known to cause long-term health damage and harm the environment, chemicals suspected of causing such health or environmental damage, chemicals of unknown toxicity, and those of minimal concern), EPA has been historically slow to assess the potential hazards that inert ingredients in pesticides may pose under FIFRA” (NYS AGO, 1996). The report concludes that the FIFRA labeling requirements are inadequate in protecting both human health and the environment, as many of the known “inert” ingredients in pesticides are regulated as toxins under other federal statutes, including TSCA, RCRA, and CWA, and that many more “inerts” are of unknown composition or have inadequate toxicological documentation (NYS AGO, 1996).

In light of both the legal rationale and scientific reasons set forth above, as well as the apparent inadequacies and potential conflicts of interest associated with EPA review processes, the EPA is not qualified to conduct risk assessment evaluations under Section 7 of the ESA.

³⁰ NYS AGO. 1996. The Secret Hazards of Pesticides: Inert Ingredients. Office of New York State Attorney General Elliot Spitzer. On the web at: <http://www.oag.state.ny.us/environment/inerts96.html>

VI. Conclusion

The draft regulations contained within the Proposed Rulemaking allowing EPA to make risk assessments of endangered species in conjunction with decisions under FIFRA without engaging the Services in consultation is in violation of Congressionally mandated statutory duties required under the ESA. Furthermore, even assuming that EPA had the authority to undertake endangered species assessments required by Section 7 of the ESA, EPA simply is not capable of conducting adequate, unbiased and comprehensive assessments that are necessary to ensure that pesticides do not present threats to endangered species. Therefore, the members of Rock the Earth request that the Proposed Rulemaking be abandoned.

Sincerely,

Marc A. Ross
President
Rock the Earth