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The Ground View of Navigating FIFRA and the ESA: One Pesticide Registrant's Perspective

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ABSTRACT: The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), enacted in 1947 and amended in 1972, 1978, and 1988, established federal regulation of pesticides in order to protect human and environmental health. FIFRA has been under the jurisdiction of the U.S. Environmental Protection Agency (EPA) since the EPA's inception in 1970. Although FIFRA requires EPA to consider the benefits of a pesticide's use, EPA must ensure that the pesticide is used without posing unreasonable adverse effects to human health or the environment. Furthermore, the Endangered Species Act (ESA), enacted in 1973, requires federal agencies to protect species vulnerable to extinction without consideration of costs. The amendments to FIFRA in 1972, 1978, 1988, and 1996 mandated the EPA review and reevaluate the eligibility of older pesticide products for reregistration under the updated FIFRA standard, while also complying with the new environmental laws of the 1970s. Today EPA's goal is to review existing pesticide product registrations at least every 15 years under "Registration Review." To meet their responsibilities under the ESA, EPA is initiating consultations with the U.S. Fish and Wildlife Service (USFWS) during the Registration Review process. The first pesticide active ingredients to advance to consultations under Registration Review are those in gas cartridge products. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) holds two gas cartridge product registrations. As a federal agency, APHIS also must comply with the ESA and consults with the USFWS on wildlife damage management activities, including tools such as pesticide products. This discussion presents APHIS' unique ground view as a federal agency navigating the EPA's ESA consultations during the Registration Review process, and describes the mitigation measures and their impacts on APHIS Wildlife Services' activities.

KEY WORDS: Bulletins Live, Endangered Species Act, ESA, Federal Insecticide Fungicide and Rodenticide Act (FIFRA), gas cartridge, pesticide, registration, registration review

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REGULATORY FRAMEWORK - PESTICIDES AND ENVIRONMENTAL PROTECTION

The regulation of pesticides in the United States (U.S.) at the federal level is accomplished through a number of laws, rules, and executive orders, but primarily falls under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) under the authority of the U.S. Environmental Protection Agency (EPA). The focus of this paper is on EPA's additional regulatory responsibilities under the Endangered Species Act (ESA) to protect endangered and threatened species (hereafter, "listed species"; 16 USC § 1531(a)(5)) from harm from the pesticide products they authorize or register, and to provide an example of EPA's current process for meeting these requirements from the perspective of a registrant.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 USC § 136 et seq.)

FIFRA was enacted in 1947 primarily to protect consumers against fraudulent pesticide product claims by requiring product registration. Today, FIFRA requires that pesticides are first evaluated and authorized by EPA through registration before they are sold, distributed, or used in the U.S. FIFRA also gives states the authority to enforce pesticide sale, use, and distribution within their boundaries. The FIFRA definition of a pesticide is "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" (7 U.S.C. § 136(u)). A pesticide active ingredient is "... any substance (or group of structurally similar substances if

specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant ..." (40 C.F.R. § 152.3). A pest is defined under FIFRA as "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other animals)" (7 U.S.C. § 136(t)). FIFRA was significantly amended in 1972 to include environmental and human health protections; amended in 1978 and 1988 to enhance periodic review of existing pesticide products; amended in 1996 to improve food safety, and amended in 2004, 2007, and 2012 to authorize registration fees and establish timelines for specific registration reviews and actions by EPA (Eisemann et al. *In Press*, Schierow and Esworthy 2012).

In 2006, EPA initiated a process called "Registration Review" in order to reevaluate the risk posed by existing pesticide active ingredients on a 15-year cycle. EPA's goal for Registration Review is to ensure that human and environmental safety is maintained by assessing the risks of current pesticide use using the most current risk assessment methodologies. The Registration Review process is initiated for a given active ingredient by opening a public docket at Regulations.gov (<https://www.regulations.gov/>) and announcing the availability of the docket in the Federal Register. The docket contains relevant public notices and information including science reviews, the work plan outlining EPA's assessment of the chemical and strategy to address gaps in data, other supporting documents, rules

and decisions, announcements of public comment periods, and public comments. More information on the Registration Review process is available on EPA's website at <https://www.epa.gov/pesticide-reevaluation/registration-review-process>.

Endangered Species Act (ESA, 16 USC § 1531 et seq.)

The ESA was enacted in 1973 "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of such endangered species and threatened species." The ESA is implemented by the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Services (NMFS), collectively known as "the Services." Federal entities must work with the Services, and state and local governments to ensure their activities will not "take" a listed species, populations, or their habitat. Under the ESA, "take" means "...to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (ESA; 16 U.S.C § 1532(19)).

The ESA requires federal entities to assess the risk of their proposed actions (e.g., the approval of a use of a pesticide) to listed species, and to consult with the Services when adverse effects from those actions may occur. The decision process by the agency decides if a specific listed species may be at risk (taken) is mandated by the ESA. In brief, the agency must make a determination about whether or not the action will have "no effect" or "may affect" the listed species. Both of these terms also have regulatory definitions. A no effect determination can be made if an action will not directly or indirectly affect a listed species or its critical habitat either negatively or beneficially. A may affect determination means the action could potentially impact a species in some manner. May affect determinations then fall into 2 categories:

- "May affect, but is not likely to adversely affect" (NLAA) the species or designated critical habitat may mean the likely effects are considered to be entirely discountable, insignificant, or beneficial.
- "May affect and is likely to adversely affect" (LAA) the species or designated critical habitat means the likely effects are deemed to be negative and to result in take of one or more individuals.

If an agency makes a may affect determination (NLAA or LAA), they are required to seek a section 7 consultation with the Services (usually the USFWS). Formal consultations are initiated for LAA determinations, and usually informal consultations are initiated for NLAA determinations (<https://www.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act>).

Comparison of FIFRA and ESA Implementation Approaches

Both FIFRA and the ESA require an assessment of risk to the environment. However, how these risks are weighed may differ due to the differing legislative goals and priorities. The National Academy of Sciences (NRC 2013) evaluated EPA's ESA compliance during FIFRA registration actions, and in the process, identified three pesticide regulatory challenges for the Agency:

- Pesticides are applied with the intent to kill, control,

repel, or otherwise mitigate populations of target pest organisms by a variety of means that includes environmental release. Consequently, there is potential for these products to also cause harm to nontarget species including species listed under the ESA.

- The registration of pesticides under FIFRA is regulated on a national in scale, whereas the ESA requires that risk be assessed and mitigated for listed species and their habitats at smaller geographic and temporal scales.
- FIFRA requires that pesticides do not cause unreasonable risk to man or the environment, but still directs EPA to take into account the economic and social benefits associated with their use when making registration decisions (7 USC § 136(bb)). In contrast, the ESA does not allow agencies to consider the economic or social benefits of a proposed action if it will adversely affect individuals of a listed species or protected habitat, such as the approval or use of a pesticide within the species range.

In addition, the intersection of these laws during the regulation of pesticides reveals two different approaches for handling uncertainty in assessment of pesticide risk (Leggert 2013). These philosophical differences may result in disparate risk findings, create real or perceived failures to comply with these mandates, and contribute to legal challenges. For example, in one of the larger suits regarding the registration of pesticides, the Center for Biological Diversity sued the EPA in 2010, charging that EPA failed to comply with the ESA by not assessing and consulting on the impacts of 395 registered pesticide active ingredients on 887 listed species (Center for Biological Diversity 2010). This and other legal actions brought against EPA demonstrate the pressure placed on EPA to enhance protection of endangered species under the ESA when implementing FIFRA.

DEVELOPING A CONSISTENT APPROACH TO PESTICIDE REGULATION UNDER FIFRA AND THE ESA

In 1988, EPA created an Endangered Species Protection Program for pesticide registrations. One feature of this earlier program was a non-regulatory county bulletin system designed to inform pesticide users of listed species distribution. These bulletins were intended to facilitate the protection of listed species, but were not an enforcement tool. Also, due to the lack of a standardized framework to assess the risk of pesticides to endangered species, the Services, and the U.S. Department of Agriculture (USDA) asked the National Research Council of the National Academy of Sciences to evaluate the issues affecting the assessment of pesticide risks to listed species. In response, the "Committee on Ecological Risk Assessment under FIFRA and ESA," was formed in 2011, with EPA, the Services, and USDA as sponsors. The committee's charge was to examine the scientific and technical risk assessment approaches used to prevent harm to listed species by the registration of pesticides under FIFRA. The National Research Council of the National Sciences Academy published the committee's findings in 2013, "Assessing Risks

to Endangered Species from Pesticides” (NRC 2013). In summary, the NRC concluded that after the 1972 amendment of FIFRA, the EPA had made progress in their registration processes for considering risk to listed species and their habitats from the use of pesticides, and using current risk assessment techniques and environmental models. But until recent years, a consistent process for EPA and the Services to consult on pesticide registration actions had been slow to develop. Improvements to EPA’s approaches for assessing direct, indirect, sublethal, and cumulative effects of pesticide use, including the interaction of chemical mixtures, on individuals and populations, and for integrating uncertainty into analyses were also needed (Racke et al. 2012).

In recent years, the EPA has made progress in its efforts to protect endangered species by mitigating risk with additional use restrictions on pesticide labels. EPA reinvented their bulletin system, and it is now working to populate an on-line system. The bulletins are considered an extension of the pesticide labels, and thus enforceable under FIFRA. This system designates areas for listed species as determined by the Services in which specific pesticides cannot be used at all or can only be used seasonally or under specific conditions. The current version of this new system is known as “Bulletins Live! Two” (hereafter, “Bulletins Live”); <https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins>). Before application, pesticide applicators must access Bulletins Live as required by the pesticide label directions, to determine if there are any use restrictions at their proposed use site. Pesticide applicators identify pesticide use prohibitions in their use site by inputting the specific products or active ingredients, and the location and time of year of the proposed application into the mapping program. If use restrictions have been put into place, the resulting map will show restricted areas called Pesticide Use Limitation Areas (PULAs) where the pesticide may not be used, or only used under additional restrictions such as seasonal restrictions.

Bulletins Live fits into EPA’s overall strategy to prevent take of a listed species as a result of a pesticide application. By prohibiting the use of a pesticide within the range of a listed species and represented by a PULA in Bulletins Live, take of that species is prevented, which allows EPA to make a no effect determination for listed species, because the species will not be exposed to the pesticide. When such restrictions on the use of a pesticide within the range of a listed species is protested by the registrant or other stakeholders, EPA must make a may affect determination for that species and proceeds to consultation with the Services. For those listed species that EPA forwards to the USFWS for consultation, there may be additional PULAs designated for those specific pesticides if USFWS agrees with EPA’s effects determinations.

GAS CARTRIDGE REGISTRATION REVIEW - THE APHIS EXPERIENCE

The time required to complete Registration Review of a pesticide varies greatly due to the complexity of the required EPA risk assessments, which are shaped by potential hazards of the active ingredients in the context of their pesticide use pattern; the development of the necessary data by registrants, if required; and the development

of mitigation measures. The EPA selected gas cartridge products as the first pesticide products to implement Bulletins Live during a Registration Review process. It was EPA’s thought that the gas cartridge products would provide a relatively straightforward test of the process (EPA Office of Pesticide Programs, personal commun.). Although the first active ingredient with use restrictions implemented using Bulletins Live was for a single product containing chlorophacinone, this occurred outside of the Registration Review process.

Small gas cartridge products are used to control specific rodent pests, and larger products are for control of certain predator mammal species, including coyotes, red foxes, and striped skunks. Depending upon the formulation of each specific product, gas cartridges contain the active ingredients carbon (charcoal), and sodium nitrate or potassium nitrate, and in some products, also sulfur. For the purposes of Registration Review, EPA has grouped these active ingredients into the three dockets. The carbon and carbon dioxide docket (EPA-HQ-OPP-2007-0705), and the inorganic nitrites and nitrates docket (EPA-HQ-OPP-2007-1118) were opened in 2007. The sulfur docket (EPA-HQ-OPP-2008-0176) was opened in 2008. At that time, USDA’s Animal and Plant Health Inspection Service (APHIS) held two gas cartridge registrations, a small gas cartridge product called Gas Cartridge (EPA Registration Number 56228-2) and a large gas cartridge product called Large Gas Cartridge (EPA Registration Number 56228-21).

EPA’s risk assessments and ESA effects determinations for the active ingredients were based on the use of these chemicals in registered gas cartridges, and thus the eventual regulatory actions are applied to these products as a group. The Registration Review process and outcomes of the three active ingredients were identical with respect to gas cartridge products. The inorganic nitrites and nitrates Registration Review docket was selected here to represent the gas cartridge regulatory actions. The following excerpt from the Inorganic Nitrate Interim Registration Review Decision (EPA 2015) summarized the regulatory milestones through to the publication of the Registration Review Interim Decision in 2015 (Excerpt Source: Inorganic Nitrate Interim Registration Review Decision (EPA 2015))

- March 26, 2008 – The Agency published the *Inorganic Nitrate/Nitrite Summary Document*, dated March 19, 2008 in docket number EPA-HQ-OPP-2007-1118 for a 60-day public comment period. The *Summary Document* included the Agency’s *Preliminary Work Plan for Inorganic Nitrate/Nitrite*, an *Inorganic Nitrates Fact Sheet*, the *Problem Formulation for Ecological Risk Assessment, for Carbon Dioxide and Gas Fumigant Producing Cartridges: Carbon, Sawdust, Sodium Nitrate, Potassium Nitrate, and Sulfur*, dated March 17, 2008 and the *Sodium Nitrate (076104) and Potassium Nitrate (076103). Human Health Assessment Problem Formulation Document in Support of Registration Review*, dated March 6, 2008. The Agency received no comments concerning the *Inorganic Nitrate/Nitrite Summary Document*.

- August 21, 2008 – The Agency published the *Inorganic Nitrate/Nitrite Final Work Plan*, dated August 19, 2008 which stated that the Agency would conduct a comprehensive ecological risk assessment that included an endangered species risk assessment, and that EPA would not conduct a human health risk assessment for registration review. The *Inorganic Nitrate/Nitrite Final Work Plan* also concluded that the Agency would not require additional human health or environmental fate and effects data.

- April 8, 2010 – The Agency initiated informal consultation under the Endangered Species Act (ESA) section 7(a)(2) with the U.S. Fish and Wildlife Service (FWS) for the gas cartridge uses of sulfur, carbon and inorganic nitrate.

- May 26, 2010 – The Agency published the draft *Registration Review Ecological Risk Assessment and Effects Determinations, Carbon, Carbon Dioxide, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur Gas Cartridges*, dated March 30, 2010 for a 60-day public comment period. During that time, one comment was received from U.S. Fish and Wildlife Service (FWS) Region 4. EPA made a “May Affect and Likely to Adversely Affect (LAA)” determination for federally listed terrestrial mammals, terrestrial birds, and terrestrial invertebrates and a likely to modify determination for designated critical habitats. EPA also concluded “No Effect” for aquatic species given the expected lack of exposure to non-target taxa (EPA-HQ-2010-0434; FRL–8826–6).

- December 17, 2010 – The Agency published the *EFED Response to Comments for Registration Review for Carbon, Nitrates, and Sulfur Gas Cartridges*, dated October 20, 2010 and *Input for Mitigation Options for Endangered and Threatened Species Identified in EFED’s Carbon, Nitrates, and Sulfur Gas Cartridges Registration Review Ecological Risk Assessment and Effects Determination*, dated November 16, 2010. This document responded to comments received concerning the draft ecological risk assessment.

- July 16, 2012 – The Agency provided an *Addendum to the environmental fate and Ecological Risk Assessment for Carbon Dioxide and for Carbon, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur Containing Cartridges*. This document updated EPA’s list of threatened and endangered species with “LAA” determinations as a result of direct effects from gas cartridge use. The document also outlined potential mitigation that, if adopted by the registrants, would result in changing the determination to “No Effect” for certain species.

- June 28, 2013 – The Agency finalized the *Revision to the Environmental Fate and Ecological Risk Assessment for Carbon Dioxide and for Carbon, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur Containing Cartridges*. This document provides an

updated list of potentially affected species and additional mitigation options.

- June 4, 2014 – The Agency published the *Inorganic Nitrate/Nitrite Proposed Interim Registration Review Decision*, dated May 30, 2014 in docket number EPA-HQ-OPP-2007-1118 for a 60-day public comment period. Comments were received from the Center for Biological Diversity, Defenders of Wildlife, the California Department of Pesticide Regulation, the USDA Animal and Plant Health Inspection Service (APHIS), and the Agricultural Commissioner of San Luis Obispo County, California.

- September 2015 – The Agency is publishing the *Inorganic Nitrate/Nitrite Interim Registration Review Decision and the Response to Public Comments on the Registration Review Proposed Interim Decisions for Gas Cartridges*.

As the initial 2008 work plan indicated, EPA did not require additional data to be submitted to support the continued registration of gas cartridge products. EPA’s focus was on protecting listed species pursuant to the ESA. The list of listed species for which EPA made LAA determinations was refined over the course of Registration Review. In the Proposed Interim Decision, the EPA recommended that 11 of these species effect determinations be changed to no effect through the issuance of PULAs in Bulletins Live. However, in response to comments from APHIS and California state and local government entities, and after dialogue with USFWS, EPA issued bulletins for just four species. For one of the four species, the Utah prairie dog (*Cynomys parvidens*), EPA issued a no effect determination using a PULA for all gas cartridge products used to control burrowing rodents (small gas cartridge products). However, EPA made a may effect determination for the APHIS Large Gas Cartridge, and initiated consultation with USFWS for this product and species, because APHIS argued that the risk profile of large gas cartridge product is likely very different for the Utah prairie dog than for the other smaller gas cartridge products. Thus, APHIS requested that EPA consult with FWS on the Utah prairie dog for the Large Gas Cartridge rather than simply restricting use of this product in the range of the Utah prairie dog in order to reach a no effect determination. In total, EPA requested consultations for 52 listed species for which EPA made may affect determinations for the gas cartridge products.

EPA had initially determined that hundreds of listed animal and plant species may be impacted indirectly by the use of gas cartridges. Indirect effects are impacts that are caused by an action, in this case the use of gas cartridges, but the impacts occur later in time and possibly further from the site of a particular action. These effects may result from activities associated with the pesticide application such as trampling vegetation in the course of applying a pesticide, and the resulting downstream impacts. The group of listed species potentially indirectly affected by gas cartridge use was removed by EPA prior to the Interim Decision in 2015.

USDA APHIS INTERESTS

EPA's consultations with USFWS on gas cartridge products will require considerable resources and time to complete. APHIS expects that additional PULAs will be added to Bulletins Live as a result of these consultations. In the meantime, EPA has mandated that gas cartridge pesticide labels contain language requiring that pesticide applicators obtain bulletins (via Bulletins Live) for their proposed use areas no more than six months in advance of a pesticide application. This ensures that applicators will be made aware of PULA changes or the addition of new PULAs in a timely manner. In APHIS' letter to EPA dated August 1, 2014 in response to EPA's request for comments on the Proposed Interim Registration Review Decision, APHIS expressed support of the use of Bulletins Live to protect listed species, given that it provides more precise guidance on locations where pesticides can be used to avoid harming listed species than previous mitigation measures implemented to date.

However, although APHIS stated support for the general approach, the application of EPA's mitigation measures via Bulletins Live required changes to the label language of gas cartridge products that, if implemented as originally proposed, would have adversely impacted APHIS Wildlife Service's (WS) activities for managing human wildlife conflicts in two important ways. First, EPA's proposed pesticide label language in the Proposed Interim Decision, which directed pesticide applicators to Bulletins Live, made no allowance for the routine consultations that APHIS WS already must complete with the USFWS for APHIS WS' activities and field use of wildlife damage tools, including pesticides. As originally proposed, the gas cartridge label language requirement, and by extension Bulletins Live, would have in affect rendered APHIS' consultations with the Services on use of these products moot. However, APHIS WS' uses of gas cartridges and other pesticide products are often unique from other users. For example, in certain circumstances, APHIS WS may use pesticides within the range of listed species to protect listed species and other species of concern, such as the protection of shore bird nests from predation. APHIS WS sometimes works in collaboration with state and federal agencies, including the USFWS, on these and similar projects. For this reason, APHIS argued that APHIS' gas cartridge product pesticide labels continue to allow for APHIS WS to continue to consult with USFWS on their use of these products within PULAs.

Second, APHIS wanted to preserve the ability to target pest species not specifically listed on the product labels as allowed under FIFRA section 2(ee) when the use site and application rate and methods are allowed on the label. Section 2(ee) allows "applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling..." (7 USC §136(2)(ee)). The provision continues with this qualifier, "...unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment..." When a pesticide label states that a product "may only" be used against specific target pests means that

section 2(ee) uses are prohibited. Even if section 2(ee) uses are allowed by EPA, many state pesticide agencies already have more restrictive requirements, and may require written directions describing which 2(ee) applications are allowed within their state boundaries. For the gas cartridge products, EPA required in the Interim Decision that the following label language be added: "This product may only be used to control (species name(s))."

The eventual agreement reached between APHIS and EPA to resolve these two concerns was to split each of the two APHIS product registrations into two registrations, a general consumer use product and an APHIS-only use product. APHIS agreed to amend the labels of the existing registrations, Gas Cartridge and Large Gas Cartridge, to make them the APHIS-only use. The names of these products was changed to APHIS-Only Gas Cartridge and APHIS-Only Large Gas Cartridge. Two new registrations were granted by EPA for the general consumer use products, and these two products were given the same names as the original products; Gas Cartridge (EPA Registration Number 56228-61) and Large Gas Cartridge (EPA Registration Number 56228-62). All four APHIS gas cartridge labels now contain language directing the applicator to Bulletins Live to determine if their proposed application is prohibited to avoid exposure to listed species. The two general consumer use labels also limit use of the pesticide to only those target pests listed the label, prohibiting all section 2(ee) uses. The two APHIS-only labels do not contain this language, meaning that APHIS may use the product as allowed under section 2(ee) of FIFRA.

The four PULAs instated by EPA's Interim Decision were implemented in Bulletins Live and effective June 2017. Now, when an applicator has queried Bulletins Live for a specific gas cartridge product, application site, and time period, they will learn if their proposed use falls within a PULA and is prohibited. If prohibited, language for the APHIS general consumer use products is as follows: "Use of gas cartridges (containing some or all of the following active ingredients: carbon dioxide, carbon, sodium nitrate, potassium nitrate, and sulfur) is prohibited in this area." For the APHIS-Only gas cartridge products, which may be used by APHIS employees only, the language is as follows: "Use of the gas cartridge products by USDA/APHIS personnel is prohibited in this area, unless USDA/APHIS has consulted with the USFWS on the use of these products within the specified area and follows all USFWS specifications for use."

APHIS PERSPECTIVE

APHIS' concerns thus far have been largely resolved by the approach taken by EPA in the Interim Decision. However, it is still unclear how the USFWS will respond to future APHIS WS requests for consultations once a national-level consultation with EPA for a given product and species is complete. APHIS WS requests for consultations must be specific for the listed species and their critical habitats that would otherwise be prohibited in Bulletins Live. Also, EPA's Final Registration Review Decisions for the three active ingredients in gas cartridges are still pending for two reasons. First, the consultations for those listed species where EPA made may affect determinations are not yet completed. It is anticipated that a final

decision will take several years to complete due to the 52 species section 7 consultations required. The final decision is also still pending due to other regulatory requirements of the Federal Food, Drug and Cosmetic Act (FFDCA), specifically how to addressing the Endocrine Disruptor Screening Program (EDSP) requirements. Additional information on the EDSP is found at <https://www.google.com/#q=Endocrine+Disruptor+Screening+Program&spf=1>.

APHIS anticipates that the APHIS-only label approach will serve as the template for other APHIS registrations as EPA works its way through Registration Review. Consequently, APHIS needed to consider the impacts of the new mitigation measures on all of the APHIS pesticide products as EPA strove to comply with the ESA and prevent potential take of listed species due to pesticide use. Some of the APHIS products have labeled uses specifically to protect listed species, and may require the pesticide be used within the critical habitat of such species. Thus, the final outcome of the gas cartridge Registration Review process will have significant implications for APHIS' products and APHIS WS' use of pesticides beyond the gas cartridge products alone. The agreement reached by APHIS and EPA that led to the APHIS-only label approach took time to accomplish. But ultimately, this approach allows both agencies to fulfill their respective responsibilities regarding the protection of the environment and listed species under FIFRA and the ESA.

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