Endangered Species Act Policy for New Active Ingredients: Q&A

General Questions

When does this policy take effect?

The policy takes effect immediately. EPA will include Endangered Species Act (ESA) analysis in all new conventional active ingredient (AI) applications already submitted for consideration (in house) as well as incoming applications.

What information should registrants provide to EPA when submitting a new active ingredient (AI) registration application?

EPA is determining whether any new information would be useful for assessing the potential impacts on listed species from a new active ingredient. EPA will contact registrants that have a new AI application currently under consideration to discuss whether additional information is necessary for EPA's ESA assessment for their new chemical.

How will EPA apply this policy to new AIs already submitted to EPA for consideration that have not completed registration?

EPA will apply this new policy to all new conventional active ingredient applications already submitted to EPA that have not been completed. In the coming weeks, EPA will contact these registrants about AI applications currently under consideration. EPA is considering how it may apply this policy to antimicrobials and biopesticides in the future.

What determinations may EPA make after assessing the potential effects of a pesticide's registration on listed species and their designated critical habitats?

Under the ESA, EPA must ensure that agency actions are not likely to result in jeopardy or adverse modification of designated critical habitat for species federally listed as endangered or threatened (listed species). To determine whether the action "may effect" listed species or designated critical habitat, EPA makes species-specific effects determinations. There are three types of effects determinations: No Effect (NE), Not Likely to Adversely Affect (NLAA), and Likely to Adversely Affect (LAA). If EPA makes an NLAA determination, then EPA seeks concurrence on that determination from the Fish and Wildlife Service, the National Marine Fisheries Service, or both (collectively, the Services). If EPA makes an LAA determination, EPA initiates formal consultation and, concurrently, determines if (and to what extent) measures to further reduce exposure are warranted.

The Agency will also determine whether the registration of a pesticide with an LAA determination is likely to jeopardize the continued existence of listed species or destroy or adversely modify their designated critical habitat, using existing biological opinions and other analyses the Services have issued as a guide. While EPA may predict jeopardy/adverse modification (J/AM), the final J/AM determinations are made by the Services through consultation that evaluates any effects of the pesticides on entire species. The purpose of EPA's J/AM analysis is to address potential J/AM issues earlier in the registration

process through mitigation, to help EPA focus its time and resources on the most significant effects to listed species, and to make the entire consultation process more efficient. In some circumstances, EPA may be able to identify sufficient mitigation measures to allow the Agency to revise preliminary effects determinations.

Will EPA not register a pesticide until consultation with the Services is complete?

In general, EPA expects that applicants for most new active ingredient applications will need to incorporate some degree of ESA mitigation prior to EPA issuing a new registration decision. This is true even if EPA has not begun to formally consult with the Services on that new active ingredient.

Prior to registering a new active ingredient, EPA will complete assessments for all new pesticides, their proposed uses, and any mitigation to make an NE, NLAA, or LAA determination. If EPA makes a NE determination for the action, there is no need to consult. If EPA makes only NLAA determinations for a pesticide, then the Agency will seek Service(s) concurrence, adopt any mitigations necessary to support the NLAA determinations, and, assuming the Services concur, move toward registration for the new active ingredient.

When EPA makes an LAA determination, the Agency will consider whether the registration action is likely to cause J/AM based on the Services' data and EPA's experience with previous and ongoing consultations. EPA will initiate formal consultation if it makes an LAA determination. Where appropriate, EPA will also identify mitigations necessary to avoid or minimize exposure to listed species and/or offset potential impacts on listed species, thereby avoiding or minimizing the likelihood of J/AM and in turn potentially reducing the effects of incidental take. EPA expects to include these mitigation measures in the registration and/or on the labeling before the pesticide can be used. The registration may also include mechanisms to allow EPA to readily amend the registration/labels if additional mitigation measures are identified as necessary through formal consultation. Such mechanisms will generally include labeling language requiring pesticide users to follow mitigation measures in *Bulletins Live! Two* (additional details below under Mitigation).

In phasing in this new policy, EPA may issue some registrations before completing any necessary formal consultation with the Service(s). This phased-in approach is designed to provide regulatory predictability to registrants, growers, and other pesticide users. Under ESA section 7(d), EPA may issue registrations before completing formal consultation so long as issuing the registration will not result in irretrievable or irreversible commitment of resources that would foreclose the Services' development and EPA's implementation of any ESA reasonable and prudent alternatives (RPAs). To facilitate this approach, EPA expects to discuss with applicants the adoption of early mitigation to avoid J/AM. As consultations become more efficient and Agency resources allow, EPA expects to complete formal consultation, where necessary, before issuing registration decisions for new active ingredients.

How will EPA address Pesticide Registration Improvement Act (PRIA) timelines when registering new active ingredients?

EPA strives to complete new AI applications within PRIA timelines. If EPA expects to need additional time to complete a new AI registration, based on additional work that may be needed including development of a streamlined approach to conduct ESA effects determinations for new active ingredients and to consult with the Services (particularly for applications that are already in house), EPA will work with

affected registrants to renegotiate the PRIA deadline, as necessary. Even if some PRIA deadlines need to be extended, EPA believes that the long-term benefits of today's policy are significant. This includes reducing litigation risk for new AI registrations.

New Uses and Other Active Ingredients

How will EPA address ESA for new uses?

EPA is developing a comprehensive strategy to address ESA for pesticides at all stages of the registration process. Due to resource constraints, EPA will implement this strategy in phases. EPA is beginning a phased approach where effects determinations are first incorporated into the registration process for new conventional active ingredients. Accordingly, in FY22, the Agency will prioritize ESA analyses and consultations for new active ingredient applications in the registration process. The Agency will continue to incorporate ESA analyses for new uses on GMO, pesticide-resistant crops. Further, in any new use applications where there are significant environmental concerns, including for listed species, EPA may wait to consider whether to approve a new use until the requisite ESA analysis can be completed, based on available resources. EPA will ultimately work to incorporate pending new uses into any in-progress consultations or consider whether completed consultations can be updated to address any pending uses.

What about implementing ESA for antimicrobials and biopesticides?

EPA is prioritizing conventional chemicals at this time, as this category of pesticides has a comparatively greater potential for effects on listed species. Many listed species have a very limited likelihood of coming in contact or being affected by many antimicrobials due to the limited, and often indoor, use of those pesticides. Biopesticides generally have a non-toxic mode of action and are derived from certain natural materials. Thus, many of them may be less likely to impact listed species than conventional chemicals. As part of EPA's long-term plan to address its ESA obligations, the Agency will work on methods and processes to further its approach to ESA assessments for antimicrobials and biopesticides.

Registration Review/ Old Chemicals

Will the additional steps required to address ESA in the registration process disadvantage new AIs, which often have lower human health and ecological risks than older pesticides?

EPA understands that, as registered, new AIs often have fewer human health and ecological risks than older pesticides. EPA believes it is important that these tools be available to growers with the appropriate measures to protect listed species and their designated critical habitats. To this end, this policy will help support the legal defensibility of new AI registrations.

EPA has increasingly faced litigation on registrations of new active ingredients issued without adequate compliance with the ESA. In general, ESA section 7 obligations apply to most EPA pesticide actions, including registering new active ingredients. EPA believes that improving ESA compliance in this area will help redirect EPA's resources away from defending new registration decisions and towards a systematic approach that helps ensure all new AIs are equally defensible and avoids undue effects on listed species.

At the same time, EPA acknowledges that there are several ongoing lawsuits focused on new AIs; using its best efforts, the Agency will continue to meet all deadlines that result from those lawsuits and, as appropriate, to prioritize its response to the cases.

In addition to this policy for new active ingredients, EPA is also developing several efforts to protect listed species from the potential effects of already-registered pesticides through the registration review process. In the coming months, EPA will release its ESA-FIFRA workplan, which will provide additional information on these efforts.

Mitigation

How will EPA ensure that the registrants adopt mitigations, including ones resulting from formal consultations of new AIs with the Services?

EPA expects that ESA protections will be included on pesticide labels or in the registration decisions. For new AI submissions that EPA expects will need mitigation for listed species, the Agency will work with the applicants to include additional label directions to reduce exposure to listed species and/or that direct users to *Bulletins Live! Two,* an online system that describes geographically specific pesticide use limitations. *Bulletins Live! Two* will be updated as needed with use limitations and mitigation measures that result from formal consultation. Additionally, new active ingredient registration notices may contain a term of registration that requires the registrant to implement changes to the pesticide label in accordance with the outcomes of formal consultation with the Services. Registrants who fail to comply with their terms and conditions on their registrations may face a cancellation proceeding brought by EPA. Further, users should also be aware of their obligation to avoid unauthorized "take," which is a violation of ESA.

What type of mitigations will EPA implement in new AIs to protect listed species from pesticide related effects?

EPA expects to address effects to listed species from pesticides using the following strategies in the order preferred by the Services: avoid and minimize effects, and where avoidance and minimization are not possible then consider compensatory mitigation (offsets). The Services prefer that EPA first limit potential pesticide effects by avoiding pesticide use where they might impact listed species and designated critical habitat. Where avoidance is not feasible, then EPA looks to minimize exposure and/or impacts from pesticides. Finally, where neither avoidance nor minimization are feasible, or adequate to reduce impacts to listed species, EPA may consider offsets. If EPA determines that offsets are appropriate, these measures will benefit listed species to counteract the negative effects of pesticide exposure. Offsets can include creating or restoring species habitat or helping to implement other actions to recover the species. EPA is currently working with the Services to determine how best to in corporate offsets into the ESA-FIFRA process. Where the EPA cannot avoid, minimize, or offset effects to listed species or such measures do not provide sufficient protection, EPA may decide not to register a pesticide.

Where appropriate, EPA anticipates starting with existing mitigation options to address effects to listed species from new active ingredients, including measures to reduce spray drift and runoff, geographic

restrictions, and timing restrictions for pesticide application. In the interests of maximizing efficiency and protections to species, EPA is also developing new mitigation options that can be applied to an entire class of pesticide rather than only an individual pesticide (e.g., herbicides), or to a specific manner in which species are exposed (e.g., aerial spraying). EPA will also continue to apply tailored mitigations for each pesticide's particular use pattern and chemical properties.

Consultations

How will EPA determine if a formal or informal consultation is required with the Services?

When EPA makes a LAA determination for any listed species, EPA formally consults with the appropriate Service(s). When EPA makes a NLAA determination, EPA intends to continue informally consulting with the appropriate Service and request concurrence on those determinations. EPA does not need to consult with the Services if it makes a NE determination.

What is the relationship between "likely to adversely affect" and "jeopardy" findings?

The "likely to adversely affect" (LAA) determination means that EPA reasonably expects that at least one individual animal or plant, among a variety of listed species, may be exposed to the pesticide at a sufficient level to have an effect, which will be adverse. The LAA threshold for a BE is very sensitive because the likely "take" of even one individual of a species, which includes unintentional harm or death, triggers an LAA determination. As a result, there are often a high number of "may effect" and LAA determinations in a BE. An LAA determination, however, does not necessarily mean that a pesticide is putting a species in jeopardy. Final jeopardy determinations are made by the Services during formal consultation, which evaluates any effects of the pesticides on the entire species. EPA is determining jeopardy/adverse modification to develop more meaningful mitigation measures prior to formal consultation.