

## A Legal Discussion of the FIFRA/ESA Consultation Process Over Time

### Introduction

As the Environmental Protection Agency (“EPA”) works to develop its new strategy for meeting its Endangered Species Act (“ESA”) responsibilities when regulating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), it is faced with the challenge of complying with the terms of both statutes. Both the ESA and FIFRA lay out certain obligations that EPA is required to comply with, and historically, the agency has struggled to satisfy both statutes simultaneously. This paper will examine the relevant provisions of both the ESA and FIFRA, provide an overview of EPA’s past attempts to meet its ESA responsibilities, and finally take a look at EPA’s most recent policy proposals while comparing them to previous efforts. Ultimately, many questions remain as to whether EPA’s current approach will satisfy its legal requirements.

### Endangered Species Act

When Congress passed the ESA in 1973, it declared that the purpose of the Act was “to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved,” and “to provide a program for the conservation of such endangered species and threatened species[.]”<sup>1</sup> The ESA is administered jointly by the U.S. Fish and Wildlife Service (“FWS”) and the National Marine Fisheries Service (“NMFS”) (collectively, “the Services”). FWS is responsible for all terrestrial and freshwater species, while NMFS is responsible for marine and anadromous fish.<sup>2</sup> While the Services are responsible for implementing the ESA, the Act states that “all Federal departments and agencies shall seek to conserve endangered species and threatened species[.]”<sup>3</sup> To that end, all federal agencies are responsible for carrying out its goals and priorities. The Services are responsible for identifying species and habitat for ESA protection, while all other federal agencies are required to consult with the Services to ensure that any agency actions they carry out will not jeopardize the existence of any protected species.<sup>4</sup>

Adding species to the Federal List of Endangered and Threatened Wildlife and Plants (an action known as “listing”) is a critical aspect of the ESA’s framework. A species will only receive ESA protection if it is formally listed as either “threatened” or “endangered.” A threatened species is defined as “any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range,” while an endangered species is defined as “any species which is in danger of extinction throughout all or a significant portion of its range.”<sup>5</sup>

The ESA provides listed species with a variety of different legal protections. Perhaps the most well-known of these protections is the prohibition on “take” of any listed species. Under the ESA, “take” is defined as “to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to

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engage in any such conduct.” 16 U.S.C. § 1532(19). The term “harass” is further defined as “an intentional or negligent act or omission which creates the likelihood of injury to wildlife by annoying to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding or sheltering.”<sup>6</sup>

Another protection offered to some listed species is the designation of critical habitat. The ESA describes critical habitat as:

(i) the specific areas within the geographical area occupied by the species at the time it is listed [...] on which are found those physical or biological features essential to the conservation of the species and which may require special management considerations or protection; and

(ii) specific areas outside the geographical area occupied by the species at the time it is listed [...] that are essential for the conservation of the species.<sup>7</sup>

Simply put, critical habitats are areas located either within or outside of the geographic range of a listed species that contain features necessary for conserving the species. While the ESA does not provide a definition for “habitat,” the United States Supreme Court has found that in order for an area to be designated as critical habitat for a species, the area must at the very least be capable of supporting the species.<sup>8</sup> The Services may designate critical habitat for either threatened or endangered species.<sup>9</sup>

Finally, another crucial protection the ESA grants to listed species is a process known as Section 7 consultation. Under Section 7 of the ESA, federal agencies are required to ensure that the actions they carry out will not jeopardize the existence of any listed species or destroy designated critical habitat.<sup>10</sup> If a federal agency determines that its action may jeopardize a listed species or destroy critical habitat, the agency is required to enter into Section 7 consultation with the Services to determine how the potential harm may be avoided.<sup>11</sup>

Prior to initiating Section 7 consultation, a federal agency must first determine if the process is even necessary. According to the ESA, Section 7 consultation is only required for actions an agency has “authorized, funded, or carried out[.]”<sup>12</sup> Examples of agency actions include, but are not limited to: promulgation of regulations; granting a license, contract, lease, or permit; or actions directly or indirectly causing modification to the environment.<sup>13</sup> If an agency is planning to carry out an activity that qualifies as an agency action, it must engage in Section 7 consultation. While there are a handful of exceptions to the ESA’s consultation requirements, the United States Supreme Court affirmed in *Nat’l Ass’n of Home Builders v. Defenders of Wildlife*,<sup>14</sup> that all “actions in which there is discretionary Federal involvement or control” are subject to Section 7 consultation.

Once an agency has determined that it is taking an action subject to Section 7 consultation, it can reach out to either FWS or NMFS to begin informal ESA consultation.<sup>15</sup> During informal consultation, the agency taking the proposed agency action (referred to as the “action agency”) will work with the Services to determine which listed species are present in the proposed action area, and the possible impacts the proposed action may have on those species.<sup>16</sup> It is during this phase of the consultation process that the action agency will determine whether its proposed action “may affect” any listed species or critical habitat.<sup>17</sup> A “may affect” finding can include actions that are either “likely to adversely affect” or “not likely to adversely affect” listed species or critical habitat.<sup>18</sup> If the action agency finds that its proposed action will have no effect on listed species or critical habitat, and the Service agrees, then consultation is at an end and no further action is needed.<sup>19</sup> Similarly, if the action agency makes a “may affect” determination, but concludes that the proposed action is not likely to adversely affect species or habitat and the Service agrees, then no further action is needed.<sup>20</sup> However, if the action agency finds that its proposed action is likely to adversely affect listed species or critical habitat, then it is required to proceed with formal consultation.<sup>21</sup>

The overall goal of formal consultation is to ensure that the proposed agency action will avoid either jeopardizing the continued existence of a listed species, or destroying or otherwise adversely modifying designated critical habitat.<sup>22</sup> Formal consultation begins when the action agency submits a written request to either FWS or NMFS and ends when the Service issues a Biological Opinion ("BiOp").<sup>23</sup> The BiOp is a detailed document that contains a discussion of the current status of the listed species or critical habitat at issue, and an analysis of the effects the proposed agency action will have on the species or habitat.<sup>24</sup>

Ultimately, the BiOp will result in either a "jeopardy" or "no jeopardy" / "adverse modification" or "no adverse modification" conclusion.<sup>25</sup> The Services will issue a "jeopardy" finding if they determine that the action agency's proposed action is expected to "reduce appreciably the likelihood of both the survival and recovery of a listed species[.]"<sup>26</sup> Similarly, an "adverse modification" finding is issued if the Services conclude that the proposed action will result in "a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species."<sup>27</sup> If a BiOp contains a jeopardy/adverse modification finding (often referred to as a "J/AM" finding), then the document will also include a selection of reasonable and prudent alternatives.<sup>28</sup>

Reasonable and prudent alternatives refer to alternative ways of carrying out the proposed agency action that would avoid, minimize, or offset the likelihood of jeopardy or adverse modification.<sup>29</sup> Reasonable and prudent alternatives are limited to: (1) alternatives the Service believes will avoid the likelihood of jeopardy or adverse modification; (2) alternatives that can be implemented in a manner consistent with the intended purpose of the action; (3) alternatives that can be implemented within the scope of the action agency's legal authority and jurisdiction; and (4) alternatives that are economically and technologically feasible.<sup>30</sup> The Service and action agency will work together to develop any reasonable and prudent alternatives included in the BiOp.<sup>31</sup>

Once the BiOp is issued, Section 7 consultation is at an end. If the BiOp determines that the agency action will not result in jeopardy or adverse modification, then the agency may proceed as initially planned. However, if the BiOp contains a finding of jeopardy or adverse modification, then the action agency may choose to adopt the reasonable and prudent measures proposed in the BiOp, decide not to carry out the proposed action, reinstate consultation with the Services, or take some other action that the agency believes would satisfy its ESA requirements.<sup>32</sup> Importantly, whatever the action agency chooses to do, it must still ensure that its action is not likely to jeopardize any listed species or result in the adverse modification of critical habitat.<sup>33</sup>

## Federal Insecticide, Rodenticide, and Fungicide Act

FIFRA is the primary federal statute regulating the sale and use of pesticide products in the United States. EPA is responsible for administering FIFRA and carrying out numerous agency actions pursuant to the statute.

One of the primary FIFRA actions that EPA carries out is the registration of new pesticide products. According to FIFRA, no pesticide product may be legally sold or used in the United States until the EPA has registered a label for that product.<sup>34</sup> The registration process requires the pesticide manufacturer to submit the complete formula of the pesticide, a copy of the label that will accompany the pesticide, and a significant amount of scientific data for EPA to review as part of the registration application.<sup>35</sup> FIFRA instructs EPA to register a pesticide for use if the agency determines that the product, when used as intended, will "perform its intended function without unreasonable adverse effects on the environment[.]"<sup>36</sup>

FIFRA defines "unreasonable adverse effects on the environment" to mean "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[.]"<sup>37</sup> The "unreasonable adverse effects" standard has been described as a risk-benefit analysis that requires EPA to balance the known risks and benefits to using the pesticide according to its proposed label.

If EPA determines that a pesticide product meets the “unreasonable adverse effects” standard, it will proceed with registration. When EPA registers a pesticide, it will specify the uses the pesticide is approved for, and the conditions of such use including safe methods of storage and disposal.<sup>38</sup> Such information will be included on the pesticide label, and it is considered a violation of FIFRA to use a pesticide contrary to its labeling requirements.<sup>39</sup>

Registering a pesticide under FIFRA is considered an agency action subject to ESA Section 7 consultation, but it is not the only agency action EPA carries out under FIFRA. After a pesticide product is first registered, FIFRA directs EPA to review its registration every fifteen years to ensure that the pesticide continues to meet the “unreasonable adverse effects” standard.<sup>40</sup> The process requires EPA to collect and review data, develop additional risk assessments, and hold focus meetings to address any areas of uncertainty or concern.<sup>41</sup> Registration review concludes with EPA issuing a final registration review decision.<sup>42</sup>

In some cases, EPA may issue an interim registration review decision during the review process. An interim decision may be issued when EPA would like to add new risk mitigation measures to the pesticide’s label or ask for additional data prior to completing registration review.<sup>43</sup> Although such interim decisions are part of the overall registration review process, courts have found that they constitute agency actions under the ESA and are subject to Section 7 consultation.<sup>44</sup> Therefore, in some circumstances, a pesticide’s registration review decision may be subject to two rounds of Section 7 consultation.

Finally, courts have also found that registering a new use for an already registered pesticide is an agency action that requires Section 7 consultation.<sup>45</sup> Much like registering a pesticide or conducting registration review, FIFRA instructs EPA to approve a proposed new use if it finds that doing so would not cause “unreasonable adverse effects” to the environment.<sup>46</sup>

## Previous Efforts to Comply with ESA and FIFRA

Prior to 1989, EPA did not have an organized approach to meet its ESA responsibilities when carrying out agency actions under FIFRA. During the early 1980s, EPA would review individual pesticide registrations, and consult with the Services on a case-by-case basis.<sup>47</sup> However, the process was time-consuming, and due to how many new registrations EPA issued each year, there was little time left to evaluate already registered pesticides.<sup>48</sup> In an attempt to make the consultation process more efficient, EPA moved to a new “cluster approach” in 1982.<sup>49</sup> Under the cluster approach, EPA would group together pesticides with the same use pattern (pesticides used on corn, on forests, or to target mosquitoes, for example) would be considered at the same time.<sup>50</sup> While the cluster approach seemed to speed up the Section 7 consultation process, it still proved inefficient and had a tendency to prioritize restrictions for major uses pesticides while failing to review the impacts of minor uses.<sup>51</sup> An independent review of EPA’s pesticide program revealed that the agency was not meeting its ESA requirements in roughly one third of all pesticide decisions.<sup>52</sup> In response to that review, EPA announced that it would work to come into compliance with the ESA by 1988.<sup>53</sup>

To reach full compliance, EPA intended to address the restrictions that had so far been recommended by the Services during the case-by-case consultations and the cluster consultations carried out during the 1980s.<sup>54</sup> The plan was to print restrictions on pesticide product labels and provide additional information bulletins that contained use instructions.<sup>55</sup> However, the program failed to get off the ground, and by 1989, EPA had gone back to the drawing board.

In July 1989, EPA published a Notice of Proposed Program in the Federal Register announcing the development of the Endangered Species Protection Program (“ESPP”).<sup>56</sup> The program had two objectives: first, to achieve the best protection for listed species, and second, to be responsive to the needs of agricultural production by not placing unnecessary burden on

pesticide users.<sup>57</sup> To accomplish those objectives, EPA proposed taking a species-based approach to ESA consultation wherein EPA would identify the listed species most vulnerable to pesticides, work with FWS to identify the counties where such species are located, and develop geographic-specific restrictions.<sup>58</sup> Once again, EPA proposed adding language to the pesticide labels that would direct users to county-specific bulletins which would provide specific information on use limitations.<sup>59</sup> Ultimately, this initial version of the ESPP had a variety of shortcomings. The program was voluntary and unfinalized, which made it unenforceable. Additionally, prior to widespread internet use it was difficult for users to access the county bulletins.<sup>60</sup>

In 2005, EPA released an updated version of the ESPP.<sup>61</sup> Under the updated program, EPA would address concerns to listed species while carrying out pesticide registration, reregistration, and registration review.<sup>62</sup> This shows a shift away from the species-first approach to the ESPP that EPA had proposed in 1989 and a return to evaluating risks to listed species on pesticide-by-pesticide basis. Under the new ESPP, EPA would develop an endangered species assessment when reviewing a pesticide registration.<sup>63</sup> The assessment would result in one of three conclusions: that the pesticide would have “no effect” on listed species; that the pesticide “may affect but is not likely to adversely affect” listed species; or that the pesticide is “likely to adversely affect” listed species.<sup>64</sup> According to EPA, each determination could relate to a specific use of a particular pesticide and a particular listed species.<sup>65</sup> If EPA reached either a “may affect but is not likely to adversely affect” conclusion or a “likely to adversely affect” conclusion, the agency would reach out to the Services to initiate Section 7 consultation.<sup>66</sup> As with previous iterations of the ESPP, any necessary pesticide use restrictions would be geographically specific.<sup>67</sup> Pesticide labels would contain language directing users to consult county bulletins that would contain species maps and information on any relevant restrictions.<sup>68</sup> While EPA noted that the ESPP itself is not a legally binding regulation and could be amended at any time, the agency noted that any bulletins issued pursuant to the ESPP would be “effective and enforceable upon reference to them on a product label.”<sup>69</sup> EPA created a website to host the bulletins, which the agency still uses today.<sup>70</sup>

Until recently, the 2005 ESPP has remained EPA's method for handling Section 7 consultation when registering pesticides or conducting registration review. However, like previous attempts, the method has not been perfect. The agency has continued to struggle with fulfilling its ESA responsibilities leading to mounting lawsuits, court orders, and settlement agreements that have caused EPA to once again revisit its process for Section 7 consultation when carrying out FIFRA actions.

## Recent Lawsuits

Over the last several years, EPA has been faced with various lawsuits filed by different environmental organizations alleging that EPA has violated the ESA by failing to engage in ESA consultation when taking agency actions under FIFRA. In some cases, plaintiffs have challenged the registration of a pesticide without prior ESA consultation.<sup>71</sup> In other cases, the plaintiffs challenged registration review decisions that were issued without consultation.<sup>72</sup> In yet more cases, plaintiffs have challenged EPA actions that amend a registered pesticide label by adding a new use without fulfilling Section 7 requirements.<sup>73</sup>

Many of these cases have ended either in court decisions favorable to the plaintiffs, or in settlement agreements with EPA committing to complete Section 7 consultation by a particular deadline<sup>74</sup>. For example, in *Farmworker Ass'n of FL v. Env'tl. Protection Agency*, the court found that EPA had failed to undergo ESA consultation when it amended the label for the pesticide aldicarb to allow for use on orange and grapefruit trees in Florida to combat citrus greening disease.<sup>75</sup> In a two-page order, the court vacated the label and sent it back to EPA for further ESA review.<sup>76</sup> Without the label amendment in place, aldicarb could not be used on citrus trees. In *Ctr. for Food Safety v. Regan*<sup>77</sup>, the court found that EPA had unlawfully registered the pesticide sulfoxaflor without undergoing ESA consultation. While in that instance the court chose to leave the registration in place, it remanded the decision to EPA with a court-ordered timeline to complete consultation.<sup>78</sup>

Between court orders and settlements, EPA estimates that it has court-enforceable deadlines to complete Section 7 consultation for eighteen pesticides.<sup>79</sup> Together with additional settlement discussions the agency was in at the time, EPA determined that completing the consultations would take until beyond 2030.<sup>80</sup> Acknowledging the uncertainty this creates for farmers, and the burden it presents to the agency, EPA began to develop a new approach to Section 7 consultation.

## Current Developments

In April 2022, EPA published a document titled “Balancing Wildlife Protection and Responsible Pesticide Use: How EPA’s Pesticide Program Will Meet its Endangered Species Act Obligations”.<sup>81</sup> That document, together with an update published the following November<sup>82</sup>, announced two primary strategies that EPA planned to pursue to bring its FIFRA actions into full ESA compliance. Both strategies share some similarities with methods EPA has tried in the past, but with several marked differences. The primary difference between EPA’s past approaches and its latest attempt is a focus on “early mitigation.”<sup>83</sup> While the 1980s attempts and ESPP methods relied on the traditional Section 7 consultation process of evaluating pesticide registrations, making effects determinations, and consulting with the Services to develop BiOps when appropriate, the new method EPA is focused on adopting early mitigation methods for pesticides that are predicted to be at risk of jeopardy or adverse modification findings during future consultations.<sup>84</sup> By adopting early mitigation measures, EPA hopes to avoid future findings of jeopardy/adverse modification and keep use restrictions to a minimum.

The first strategy identified in EPA’s work plan is similar to the cluster approach that EPA took in the 1980s. Under this strategy, EPA would group together pesticides with similar chemicals and then focus on identifying and incorporating early ESA mitigation measures across those groups.<sup>85</sup> At the moment, EPA appears to be sorting registered pesticides into three broad groups – herbicides, rodenticides, and insecticides.<sup>86</sup> The agency has chosen to address the herbicides group first, and released a document titled “Draft Herbicide Strategy Framework to Reduce Exposure of Federally Listed Endangered and Threatened Species and Designated Critical Habitats from the Use of Conventional Agricultural Herbicides” (“Draft Herbicide Strategy”) for public comment in July 2023. The comment period closed in October, and a finalized version of the Strategy is expected sometime in early 2024.<sup>87</sup>

Within the Draft Herbicide Strategy, EPA has identified two primary categories of mitigation measures that it expects to incorporate into existing herbicide labels. The first category of mitigation is focused on reducing pesticide spray drift, while the second category is aimed at reducing pesticide runoff and erosion.<sup>88</sup> According to EPA, those are the most common ways that listed species are exposed to herbicides.<sup>89</sup> To reduce spray drift, the Draft Herbicide Strategy proposes adding additional buffer requirements to herbicide labels in areas where the risk to listed species exceeds a certain threshold.<sup>90</sup> Depending on the expected level of risk, EPA may also require windbreaks, hedgerows, hooded sprayers, and application rate reductions.<sup>91</sup>

To reduce herbicide runoff with water or bound to soil (erosion), the Draft Herbicide Strategy has identified a variety of mitigation measures and organized them into what EPA calls a mitigation menu. Those measures include restrictions on applications when rain is in the forecast; restrictions based on field characteristics like soil type and field slope; methods of application; in-field management activities designed to reduce runoff such as terrace farming or mulch amendment; management activities adjacent to sprayed fields like establishing buffer strips; and other activities intended to increase water retention.<sup>92</sup> Importantly, EPA is proposing what appears to be a completely novel approach for implementing the runoff/erosion reduction measures. According to the Draft Herbicide Strategy, EPA is proposing a point-based system that the agency says would give farmers more control over which measures to implement.<sup>93</sup> The system would work by assigning a point value for each of the identified runoff/erosion mitigation measures based on the measure’s efficacy.<sup>94</sup> Herbicide labels would identify how many

mitigation points are needed for each of the product's intended uses.<sup>95</sup> From there, pesticide applicators can review the mitigation menu and choose the methods that would work best to achieve the necessary number of points.<sup>96</sup> The Draft Herbicide Strategy notes that activities farmers are already taking to reduce runoff or erosion may be used to satisfy the point system.<sup>97</sup> Currently, EPA does not appear to be recommending a similar system for implementing spray drift mitigation measures.

According to the Draft Herbicide Strategy, EPA will incorporate the proposed mitigation measures into pesticide labels in two primary ways. For those mitigation measures that EPA finds are necessary across the entire pesticide use area, the agency would add the restrictions to the product's general label.<sup>98</sup> However, for the mitigation measures that EPA identifies as necessary only in specific geographic areas, the agency would continue to rely on county bulletins which would be posted on its website Bulletins Live! Two ("BLT").<sup>99</sup> Pesticides with geographically specific restrictions would include language on their product labels directing users to check BLT for any relevant mitigation requirements.<sup>100</sup>

Finally, EPA notes that for impacts that cannot be avoided or minimized, the agency will work on identifying offsets to "compensate for remaining unavoidable impacts."<sup>101</sup> While the Draft Herbicide Strategy states that offsets "can include actions such as habitat preservation or restoration, invasive species control, and species reintroduction," no further information is currently available as to what, if any, offsets may be included in the final strategy.<sup>102</sup>

The Draft Herbicide Strategy is only the first of the three pesticide groups EPA will address under the new policy. While a draft strategy for insecticides is not expected until 2024, the Draft Herbicide Strategy gives some indication of how EPA will develop the insecticide strategy.

The second strategy identified in EPA's 2022 work plan is similar to the species-based approach that EPA developed in 1989. Under this second strategy, EPA would introduce early mitigation measures targeted at "vulnerable species," or species that EPA has identified as being at the greatest risk of pesticide exposure.<sup>103</sup> Following the publication of EPA's April 2022 work plan, the agency launched the Vulnerable Species Pilot Program ("VSPP"), which involved identifying mitigation measures for twenty-seven species with limited ranges.<sup>104</sup> The species included in the VSPP were selected based on a combination of factors that EPA has determined make the species particularly vulnerable to pesticides, including limited geographic range, small population size, and general susceptibility to environmental stressors.<sup>105</sup> To reduce pesticide exposure for these species, EPA has identified mitigations that would apply broadly to conventional pesticide active ingredients that are applied outdoors.<sup>106</sup> The mitigation measures fall into two general categories, avoidance and minimization.<sup>107</sup>

As its name suggests, avoidance mitigations refer to areas where the proposed mitigation measures involve prohibiting pesticide applications.<sup>108</sup> Such areas would be limited to places where the species is most likely to occur, and would be based on "specific and refined" information from FWS.<sup>109</sup> For areas where avoidance mitigations are required, EPA would direct pesticide applicators to coordinate with FWS at least three months prior to making a pesticide application in order to "determine appropriate measures to ensure the proposed application is likely to have no more than minor effects on the species."<sup>110</sup>

The minimization mitigations proposed in the VSPP are focused on measures that would reduce spray drift, runoff, and erosion during and following application.<sup>111</sup> Proposed mitigations for reducing spray drift include spray drift buffers, and the prohibition of certain application methods or droplet sizes.<sup>112</sup> Proposed measures for reducing runoff and erosion include prohibitions on applications when soil in the area is saturated, prohibition on applications when rain is in the forecast, and requiring applicators to adopt land use practices designed to reduce runoff or erosion such as contour farming, planting a cover crop, or mulching.<sup>113</sup> While the VSPP does not appear to employ the same point-based system for runoff/erosion mitigations presented in the Draft Herbicide Strategy, EPA would still allow farmers to select which of the land management mitigation measures work best on their fields.<sup>114</sup>

EPA notes that while most of the proposed mitigations identified in the VSPP would apply year-round, some would only be required during certain times of the year. For example, EPA proposes only requiring avoidance and mitigation measures for the American burying beetle when temperatures are forecasted to be above 60 degrees Fahrenheit for three or more nights in a row.<sup>115</sup>

Because all of the mitigations proposed in the VSPP are geographically specific, EPA will rely on BLT to inform applicators of any required restrictions.<sup>116</sup> Pesticide labels would contain language directing users to check BLT prior to application.<sup>117</sup> EPA notes that it expects “most, if not all” conventional pesticides registered for non-residential outdoor use would need a reference to BLT on their product labels.<sup>118</sup>

Moving forward, EPA plans to continue developing bulletins for the twenty-seven species used in the pilot program, while expanding the program to include other vulnerable species.<sup>119</sup> In an update on the VSPP that EPA issued in November 2023, the agency briefly summarized modifications it plans to make to the program as it moves ahead.<sup>120</sup> Those modifications include developing more precise species maps, clarifying the scope of the VSPP for non-agricultural uses, clarifying potential exemptions to the proposed mitigations, revising some of the already proposed mitigations, revisiting how vulnerable species are selected, and developing a “consistent approach” for the strategies used to reduce pesticide exposure to listed species.<sup>121</sup> EPA intends to provide further updates on the VSPP by fall of 2024.<sup>122</sup>

Importantly, many of the milestones identified in both the April and November 2022 work plans are now subject to a settlement agreement between EPA and two environmental organizations to resolve litigation involving over 1,000 pesticide products.<sup>123</sup> The agreement, which was issued on September 12, 2023, commits EPA to finalizing the Herbicide Strategy by no later than May 30, 2024, and to issuing a final insecticide strategy by no later than March 31, 2025.<sup>124</sup> The settlement also requires EPA to work towards expanding the VSPP by identifying additional species that would benefit from the mitigation measures developed under the program.<sup>125</sup> While these were goals EPA had already established in its April and November 2022 work plans, by including them in a settlement agreement, the deadlines have become court enforceable.<sup>126</sup>

## Final Thoughts

Overall, many questions remain as to the legality and practicality of EPA's policy proposals. Perhaps one of the most important questions to consider when reviewing EPA's new policy is whether the proposal actually fulfills the requirements of Section 7 consultation. In comparing EPA's current approach to its previous attempts, what appears to be missing is direct consultation with the Services. Both the Draft Herbicide Strategy and the VSPP focus on developing “early mitigations” that EPA hopes will result in fewer jeopardy or adverse modification findings during future Section 7 consultations. However, it is not clear whether these early mitigations were themselves developed through consultation with the Services. In a comment submitted during public comment for the VSPP, the United States Agriculture Department (“USDA”) expressed its disagreement with EPA's plans to require mitigation measures before completing Section 7 consultation.<sup>127</sup> USDA also expressed concern over the scope of the avoidance areas identified in the VSPP. Specifically, USDA pointed to avoidance areas recommended to protect the Taylor's checkerspot butterfly which could include large portions of Benton, Lane, Lincoln, Linn and Polk counties in Oregon which are responsible for 60% of the hazelnut production in the United States.<sup>128</sup> USDA further noted that in certain circumstances, Section 7 consultation could reveal that less restrictive mitigations than those proposed in the VSPP would be sufficient to prevent jeopardy or adverse modification.<sup>129</sup>

Although it is not clear where the early mitigation measures proposed by EPA fit into the Section 7 consultation scheme, at least some may be required pursuant EPA's authority under Section 7(d) of the ESA. Under this provision of the ESA, any agency that has initiated formal



consultation with the Services is prohibited from making any “irreversible or irretrievable commitment of resources [...] which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures[.]”<sup>130</sup> In other words, Section 7(d) provides that once an agency has initiated formal consultation, they must not take any action that would make it impossible to implement any reasonable and prudent measures that the Services identify in the final BiOp. Importantly, Section 7(d) is only relevant after an agency has initiated formal consultation, but before the Services have issued a final BiOp. In early 2022, EPA issued a decision to extend the current registrations for the pesticides Enlist One and Enlist Duo for an additional seven years.<sup>131</sup> Prior to issuing that decision, EPA had initiated formal consultation with the Services over its decision to extend the registration.<sup>132</sup> Because the Enlist registrations were set to expire well before formal consultation would conclude, EPA moved ahead with its decision to extend the registration while taking steps to comply with Section 7(d).<sup>133</sup> In order to ensure that extending the Enlist registrations would not cause an “irreversible or irretrievable commitment of resources,” EPA introduced a variety of new mitigation measures to the Enlist labels, including new limitations intended to reduce runoff and spray drift.<sup>134</sup> EPA justified the addition of these new restrictions by concluding that they were necessary to ensure compliance with Section 7(d). Critically, the addition of these mitigation measures to the Enlist labels could only be done during this time when Section 7 consultation had been initiated, but not completed. This may provide some insight to EPA’s timeline for introducing early mitigation measures to registered pesticide labels. The agency may need to initiate formal Section 7 consultation before it can add early mitigation measures to the label through its Section 7(d) authority.

While there are some concerns that introducing early mitigations to pesticide labels could dissuade the Services from consulting with EPA in the future, the text of the ESA makes it clear that once the action agency has initiated the consultation process, the Services have a duty to consult.<sup>135</sup> However, it is possible that by adding early mitigation measures to pesticide labels, EPA may choose to rely on informal consultation rather than formal consultation when taking future FIFRA actions. Informal consultation is less stringent than formal consultation. Formal consultation results in the development of a BiOp that thoroughly examines the impacts the proposed action is likely to have on listed species, and results in a jeopardy/adverse modification finding that includes any reasonable and prudent measures the Services believe necessary.<sup>136</sup> On the other hand, informal consultation has no such requirement. The informal consultation process concludes either when the Services provide written concurrence that the proposed agency action will have either no effects or will be unlikely to adversely affect listed species.<sup>137</sup> Because formal consultation can result in suggested reasonable and prudent measures that are less strict than early mitigations proposed by EPA, a reduction in formal consultations could ultimately lead to labels with more restrictions than necessary.

Questions also remain as to whether EPA’s policy proposal satisfies the legal requirements of FIFRA. When a pesticide registration is amended under FIFRA, EPA must ensure that the registration continues to meet FIFRA’s “unreasonable adverse effects” standard.<sup>138</sup> Changes to a registered pesticide’s label must also meet that standard.<sup>139</sup> As discussed, the “unreasonable adverse effects” standard is a balancing test that requires EPA to conduct a risk-benefit analysis to fully consider the costs and benefits of using a particular pesticide. When carrying out this risk-benefit analysis, FIFRA directs EPA to take multiple factors into consideration, including economic, social, and environmental costs.<sup>140</sup> Many commenters on EPA’s Draft Herbicide Strategy expressed concern that both the Strategy and the VSPP were proposing label changes that had not been evaluated pursuant to the “unreasonable adverse effects” standard.<sup>141</sup> In a comment submitted by the University of Arkansas Division of Agriculture, it was noted that the proposed mitigations in the Draft Herbicide Strategy were likely to result in economic costs to agricultural producers in the forms of yield loss, increased weed pressure, productivity costs as producers worked to come into compliance with the new requirements, and reduction of acres planted.<sup>142</sup> The comment also highlighted potential social costs that could occur as a result of the proposed label changes, including increased pressure on relationship between producers and landowners, applicators, lenders, regulators, and the public.<sup>143</sup> In 2020, the Ninth Circuit Court of Appeals issued a ruling to vacate the registration for the pesticide dicamba.<sup>144</sup> One of the reasons the court cited as grounds for overturning the registration was EPA’s failure to consider the economic and

social costs of registering the pesticide.<sup>145</sup> If EPA fails to ensure that labeling changes made pursuant to its new ESA-FIFRA policy do not meet the “unreasonable adverse effects” standard, it is possible that those labels could be at risk of judicial review.

Finally, EPA’s policy proposal presents confusion over what the impacts will be to state and federal laws that conflict with the proposal. While FIFRA does allow states to regulate the sale or use of any federally registered pesticide, it prohibits states from “impos[ing] or continu[ing] in effect” any labeling or packaging requirements that are “in addition to or different from” those required under FIFRA.<sup>146</sup> Therefore, if EPA added language to a pesticide label requiring additional mitigation measures pursuant to its new policy, no state would have the authority to alter that language. However, it remains unclear what would happen to state laws that conflict with the EPA’s policy but do not involve making changes to the pesticide’s label. It is generally the case that federal law will preempt state law when the laws conflict.<sup>147</sup> This is especially true if it is impossible to comply with both state and federal laws at once.<sup>148</sup> However, determining whether a state law is in fact preempted by federal law can be a challenge, and may require judicial review. This could result in a long period of confusion for pesticide applicators as regulators work to determine which law prevails. Such confusion could be even more pronounced if EPA’s new ESA-FIFRA policy puts federal law at odds with itself. A producer may be enrolled in an USDA program that requires them to carry out certain conservation measures on their farm. If those requirements are incompatible with mitigation measures added to pesticide labels under the new policy, it is unclear which law would prevail.

Currently, it remains uncertain whether EPA’s new policy for meeting its ESA responsibilities while carrying out FIFRA actions will be a success. Questions remain as to the policy’s legality and overall practicality.

## Endnotes

<sup>1</sup> 16 U.S.C. § 1531(b).

<sup>2</sup> Fish & Wildlife Service, *ESA Basics – 40 Years of Conserving Endangered Species*, USFWS (last visited Nov. 10, 2023), .  
<sup>3</sup> U.S. Congressional Research Service, *The Endangered Species Act: Overview and Implementation* (R46677; February 9, 2021). Text in: CRS Web; Accessed November 1, 2023; ; 16 U.S.C. § 1531(c)(1).

<sup>4</sup> 16 U.S.C. §§ 1533; 1535.

<sup>5</sup> 16 U.S.C. §§ 1532 (6), (20).

<sup>6</sup> 50 C.F.R. § 17.3.

<sup>7</sup> 16 U.S.C. § 1532(5).

<sup>8</sup> *Weyerhaeuser Co. v. U.S. Fish and Wildlife Serv.*, 139 S. Ct. 361 (2018).

<sup>9</sup> 16 U.S.C. § 1533(a)(3)(A)(i).

<sup>10</sup> 16 U.S.C. § 1536(a)(2).

<sup>11</sup> 50 C.F.R. § 402.14(g).

<sup>12</sup> 16 U.S.C. § 1536(a)(2).

<sup>13</sup> 50 C.F.R. § 402.02.

<sup>14</sup> 551 U.S. 644 (2007).

<sup>15</sup> 50 C.F.R. § 402.13(a).

<sup>16</sup> U.S. Fish & Wildlife Serv. & Nat’l Marine Fisheries Serv., *Endangered Species Consultation Handbook 3-1* (1998), .

<sup>17</sup> 50 C.F.R. § 402.14(a).

<sup>18</sup> Fish & Wildlife Service, *Section 7 Consultation Technical Assistance*, USFWS (last visited Nov. 2, 2023), .

<sup>19</sup> 50 C.F.R. § 402.13(c).

<sup>20</sup> *Id.*

<sup>21</sup> 50 C.F.R. § 402.14(a).

<sup>22</sup> 16 U.S.C. § 1536(a)(2).

<sup>23</sup> 50 C.F.R. §§ 402.14(c), (m)(1).

<sup>24</sup> 50 C.F.R. § 402.14(h)(1).

<sup>25</sup> 50 C.F.R. § 402.14(h)(1)(iv).

<sup>26</sup> 50 C.F.R. 402.02.

<sup>27</sup> *Id.*

<sup>28</sup> 50 C.F.R. § 402.14(h)(2).

<sup>29</sup> 50 C.F.R. §§ 402.02; 402.14(c)(1)(i)

<sup>30</sup> 50 C.F.R. § 402.02.

<sup>31</sup> 50 C.F.R. §§ 402.14(g)(5), (h)(2).

<sup>32</sup> 50 C.F.R. § 402.15.

<sup>33</sup> 16 U.S.C. § 1536(a)(2).

<sup>34</sup> 7 U.S.C. § 136a(a).

<sup>35</sup> 7 U.S.C. § 136a(c)(1); U.S. Congressional Research Service, *Pesticide Law: A Summary of the Statutes* (RL31921; November 14, 2012). Text in: CRS Web; Accessed November 3, 2023; .

<sup>36</sup> 7 U.S.C. § 136a(c)(5).  
<sup>37</sup> 7 U.S.C. § 136(bb).  
<sup>38</sup> Pesticide Law: A Summary of the Statutes.  
<sup>39</sup> Environmental Protection Agency, Introduction to Pesticide Labels, EPA (last visited Nov. 10, 2023), .  
<sup>40</sup> 7 U.S.C. § 136a(g)(1)(A)(iii).  
<sup>41</sup> 40 C.F.R. § 155.53.  
<sup>42</sup> 40 C.F.R. §§ 155.58(a), (c).  
<sup>43</sup> 40 C.F.R. § 155.56.  
<sup>44</sup> Nat. Res. Def. Council v. U.S. Env't Prot. Agency, 38 F.4th 34, 59 (9th Cir. 2022).  
<sup>45</sup> Farmworker Ass'n of FL v. Env'tl. Protection Agency, No. 21-1079 (D.C. Cir. 2021).  
<sup>46</sup> 7 U.S.C. § 136a(c)(5)(C).  
<sup>47</sup> Jim Serfis et al., *Balancing on the Brink of Extinction* 216 (Kathryn A. Kohm ed., 1991).  
<sup>48</sup> Id.  
<sup>49</sup> Id.  
<sup>50</sup> Id.  
<sup>51</sup> Id at 217.  
<sup>52</sup> Id; Mary Jane Angelo, *The Killing Fields: Reducing the Casualties in the Battle Between U.S. Species Protection Law and U.S. Pesticide Law*, 32 Harv. Env'tl. L. Rev. 95, 118 (2008).  
<sup>53</sup> Seris at 218.  
<sup>54</sup> Id.  
<sup>55</sup> Id.  
<sup>56</sup> Endangered Species Protection Program, 54 Fed. Reg. 27984 (July 3, 1989).  
<sup>57</sup> Id at 27988.  
<sup>58</sup> Id.  
<sup>59</sup> Id at 27990.  
<sup>60</sup> *The Killing Fields: Reducing the Casualties in the Battle Between U.S. Species Protection Law and U.S. Pesticide Law* at 118.  
<sup>61</sup> Endangered Species Protection Program Field Implementation, 70 Fed. Reg. 66392 (November 2, 2005).  
<sup>62</sup> Id at 66399.  
<sup>63</sup> Id.  
<sup>64</sup> Id.  
<sup>65</sup> Id.  
<sup>66</sup> Id.  
<sup>67</sup> Id at 66400.  
<sup>68</sup> Id.  
<sup>69</sup> Id at 66398, 66402.  
<sup>70</sup> United States Env'tl. Protection Agency, *Bulletins Live! Two – View the Bulletins, Endangered Species*, (last visited Nov. 10, 2023), <https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins>.  
<sup>71</sup> *Ctr. for Food Safety v. U.S. Env't'l Protection Agency*, No. 1:23-cv-01633 (D. D.C., June 6, 2023) (plaintiffs challenge registration of Enlist One and Enlist Duo without completing ESA consultation).  
<sup>72</sup> Nat. Res. Def. Council v. U.S. Env't'l Prot. Agency, 38 F.4th 34 (9th Cir. 2022) (plaintiffs allege that EPA approved an interim registration decision for glyphosate without conducting Section 7 consultation).  
<sup>73</sup> *Farmworker Ass'n of FL v. Env'tl. Protection Agency*, No. 21-1079 (D.C. Cir. 2021) (plaintiffs claim that EPA violated the ESA by approving a new use for the pesticide aldicarb without undergoing Section 7 consultation).  
<sup>74</sup> United States Env'tl. Protection Agency, *Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet its Endangered Species Act Obligations*, 4 (2022), [https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use\\_final.pdf](https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf).  
<sup>75</sup> No. 21-1079 (D.C. Cir. 2021).  
<sup>76</sup> Id.  
<sup>77</sup> 56 F.4th 648 (9th Cir. 2022).  
<sup>78</sup> Id at 669.  
<sup>79</sup> *Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet its Endangered Species Act Obligations* at 4.  
<sup>80</sup> Id.  
<sup>81</sup> Id.  
<sup>82</sup> United States Env'tl. Protection Agency, *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions*, 2 (2022), .  
<sup>83</sup> *Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet its Endangered Species Act Obligations* at 27.  
<sup>84</sup> Id at 41.  
<sup>85</sup> *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions* at 15.  
<sup>86</sup> United States Env'tl. Protection Agency, *Draft Herbicide Strategy Framework to Reduce Exposure of Federally Listed Endangered and Threatened Species and Designated Critical Habitats from the Use of Conventional Agricultural Herbicides*, 4 (2023) <https://downloads.regulations.gov/EPA-HQ-OPP-2023-0365-0009/content.pdf>.  
<sup>87</sup> Environmental Protection Agency, *Implementing EPA's Workplan to Protect Endangered and Threatened Species from Pesticides: Pilot Projects*, EPA (last visited Nov. 10, 2023), .  
<sup>88</sup> *Draft Herbicide Strategy* at 8.  
<sup>89</sup> Id.  
<sup>90</sup> Id at 18-19.  
<sup>91</sup> Id at 34-37.  
<sup>92</sup> Id at 41-42.  
<sup>93</sup> Id at 21.  
<sup>94</sup> Id at 47.  
<sup>95</sup> Id at 21-22.  
<sup>96</sup> Id.  
<sup>97</sup> Id at 43.

<sup>98</sup> Id at 55.  
<sup>99</sup> Id at 57.  
<sup>100</sup> Id.  
<sup>101</sup> Id at 78.  
<sup>102</sup> Id.  
<sup>103</sup> Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet its Endangered Species Act Obligations at 47.  
<sup>104</sup> ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions at 17; Implementing EPA's Workplan to Protect Endangered and Threatened Species from Pesticides: Pilot Projects.  
<sup>105</sup> United States Env'tl. Protection Agency, Vulnerable Listed (Endangered and Threatened) Species Pilot Project: Proposed Mitigations, Implementation Plan, and Possible Expansion, 3 (2023) <https://downloads.regulations.gov/EPA-HQ-OPP-2023-0327-0002/content.pdf>.  
<sup>106</sup> Id at 9.  
<sup>107</sup> Id.  
<sup>108</sup> Id at 15.  
<sup>109</sup> Id.  
<sup>110</sup> Id at 19.  
<sup>111</sup> Id at 9.  
<sup>112</sup> Id at 20 – 22.  
<sup>113</sup> Id at 23-24.  
<sup>114</sup> Id at 24-25.  
<sup>115</sup> Id at 25.  
<sup>116</sup> Id at 45.  
<sup>117</sup> Id at 46.  
<sup>118</sup> Id.  
<sup>119</sup> Id at 47, 49.  
<sup>120</sup> United States Env'tl. Protection Agency, Update on Vulnerable Species Pilot (November 2023), 1 (2023) <https://www.epa.gov/system/files/documents/2023-11/vsp-update-nov2023.pdf>.  
<sup>121</sup> Id at 1-2.  
<sup>122</sup> Id.  
<sup>123</sup> Settlement Agreement.1, Ctr. for Biological Diversity v. U.S. Env'tl. Protection Agency, No. 3:11-cv-00293 (N.D. Cal. Sept. 12, 2023); Environmental Protection Agency. (2023, September 14). EPA Resolves Longstanding Litigation to Protect Endangered Species, Ensure Pesticides That Feed and Fuel America Remain Available. [Press release].  
<sup>124</sup> Settlement Agreement.13, 16, Ctr. for Biological Diversity v. U.S. Env'tl. Protection Agency, No. 3:11-cv-00293 (N.D. Cal. Sept. 12, 2023).  
<sup>125</sup> Id at 20.  
<sup>126</sup> Id at 23.  
<sup>127</sup> United States Dep't of Agriculture, USDA Office of Pest Management Policy Comments on the Vulnerable Species Pilot Project, Docket ID EPA-HQ-OPP-2023-0337, 3 (2023), <https://www.regulations.gov/comment/EPA-HQ-OPP-2023-0327-0140>.  
<sup>128</sup> USDA Office of Pest Management Policy Comments on the Vulnerable Species Pilot Project at 13.  
<sup>129</sup> USDA Office of Pest Management Policy Comments on the Vulnerable Species Pilot Project at 16 (USDA notes that in a Biological Opinion developed for the organophosphate insecticide malathion, FWS concluded that use of the pesticide did not pose a risk of jeopardy to the rusty patched bumblebee. If the Draft Vulnerable Species Pilot Program were implemented as proposed, this could result in an outcome where malathion usage would be permitted in the rusty patched bumble bee range while almost all other pesticides would be prohibited.)  
<sup>130</sup> 16 U.S.C. § 1546(d).  
<sup>131</sup> Environmental Protection Agency. (2022, January 11). EPA Renews Enlist Product Registrations with New Control Measures, Providing Growers with Certainty for the 2022 Growing Season. [Press release]. <https://www.epa.gov/pesticides/epa-renews-enlist-product-registrations-new-control-measures-providing-growers-certainty>.  
<sup>132</sup> Environmental Protection Agency, Endangered Species Act Section 7(d) Consistency Determination with Respect to a Request to Amend the GF-3335 (Enlist One) Registration, Docket ID EPA-HQ-OPP-2021-0957-0013, 3 (2022), <https://www.regulations.gov/document/EPA-HQ-OPP-2021-0957-0013>.  
<sup>133</sup> Id at 4.  
<sup>134</sup> Id.  
<sup>135</sup> 16 U.S.C. § 1536.  
<sup>136</sup> 50 C.F.R. § 402.14(h), (m).  
<sup>137</sup> 50 C.F.R. § 402.13(c)(1).  
<sup>138</sup> 7 U.S.C. § 136a(c)(7).  
<sup>139</sup> 40 C.F.R. § 152.44 (a).  
<sup>140</sup> 7 U.S.C. § 136 (bb).  
<sup>141</sup> University of Arkansas Division of Agriculture, Comment submitted by University of Arkansas Division of Agriculture, Docket ID EPA-HQ-OPP-2023-0365-0242, 1-2 (2023), ; National Barley Growers Association, Comment submitted by National Barley Growers Association, Docket ID EPA-HQ-OPP-2023-0365-0104, 2 (2023), ; National Cotton Council, Comment submitted by National Cotton Council, Docket ID EPA-HQ-OPP-2023-0365-0092, 2-3 (2023), <https://www.regulations.gov/comment/EPA-HQ-OPP-2023-0365-0092>.  
<sup>142</sup> Comment submitted by University of Arkansas Division of Agriculture at 2-3.  
<sup>143</sup> Id.  
<sup>144</sup> Nat'l Family Farm Coal. v. U.S. Env'tl. Protection Agency, 960 F.3d 1120 (2020).  
<sup>145</sup> Id at 1124-1125.  
<sup>146</sup> 7 U.S.C. § 136v(a), (b).  
<sup>147</sup> Samantha Mikolajczyk, Procedures: Federal Preemption, NALC (last visited Nov. 17, 2023), <https://nationalaglawcenter.org/procedures-federal-preemption/>.  
<sup>148</sup> Id.