



VIA CERTIFIED AND ELECTRONIC MAIL  
RETURN RECEIPT REQUESTED

June 12, 2020

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Environmental Protection Agency  
Office of the Administrator, 1101A  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Wilbur Ross, Secretary  
Department of Commerce  
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Chris Oliver, Assistant Administrator for Fisheries  
National Oceanic and Atmospheric Administration  
1401 Constitution Avenue NW, Room 5128  
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David Bernhardt, Secretary of the Interior  
Department of the Interior  
1849 C Street, N.W.  
Washington, DC 20240

Aurelia Skipwith, Director  
Fish and Wildlife Service  
1849 C St., NW  
Washington, DC 20240

**Re: Notice of Intent to Sue for Violations of the Endangered Species Act Regarding the Environmental Protection Agency's May 1, 2020 Agency Action Approving the Experimental Use Permit (EUP) for the OX5034 *Aedes aegypti* Mosquitoes Expressing Tetracycline Trans-Activator Variant (tTAV-OX5034) Protein in Florida and Texas**

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Administrator Wheeler,

The U.S. Environmental Protection Agency (EPA) is hereby notified, unless the violations described herein are remedied within sixty days, that the organizations listed below intend to sue EPA and its Administrator Andrew Wheeler (collectively, EPA), for violations of the Endangered Species Act (ESA), 16 U.S.C. § 1531 *et seq.*, associated with EPA's May 1, 2020 approval of the experimental use permit to test genetically engineered (GE) OX5034 *Aedes aegypti* mosquitoes expressing tetracycline Trans-Activator Variant (tTAV-OX5034) protein (hereafter the OX5034 GE Mosquitoes or OX5034) in Monroe County, Florida, and Harris County, Texas. EPA has violated and remains in violation of Section 7 of the ESA by, *inter alia*, failing to insure, through consultation with the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS) (collectively, the Services), that its approval of the release of the OX5034 GE Mosquitoes is not likely to jeopardize the continued existence of any threatened or endangered species and/or result in the destruction or adverse modification of the critical habitat of any listed species. Center for Food Safety (CFS) provides this letter pursuant to Section 11(g) of the ESA, 16 U.S.C. § 1540(g), on behalf of itself, Florida Keys Environmental Coalition, GMO Free USA, Foundation Earth, Friends of the Earth, and the International Center for Technology Assessment (ICTA) (collectively, the concerned parties).

#### **I. IDENTITY OF THE PARTIES GIVING NOTICE**

The name and location of the concerned parties giving notice of intent to sue under the ESA are:

**Center for Food Safety  
660 Pennsylvania Avenue SE, Suite #402  
Washington, D.C. 20003**

**Florida Keys Environmental Coalition  
PO Box 205  
Key West, FL 33041**

**Foundation Earth  
660 Pennsylvania Avenue SE, Suite #302  
Washington, D.C. 20003**

**Friends of the Earth  
1101 15th Street NW, 11th Floor  
Washington, D.C. 20005**

**GMO Free USA  
P.O. Box 458  
Unionville, CT 06085**

**International Center for Technology Assessment  
303 Sacramento Street, 2nd Floor  
San Francisco, CA 94111**

## **II. COUNSEL FOR THE CONCERNED PARTIES**

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Center for Food Safety  
303 Sacramento Street, 2nd Floor  
San Francisco, CA 94111  
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## **III. REQUIREMENTS OF THE ESA**

Section 7 of the ESA requires federal agencies such as EPA, in consultation with the expert wildlife agencies, to insure that any action authorized, funded, or carried out by the agency is not likely to jeopardize the continued existence of any threatened or endangered species, or result in the destruction or adverse modification of the critical habitat of such species.<sup>1</sup> An action is considered to result in jeopardy where it would reasonably be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.<sup>2</sup> “Action” is broadly defined to include all activities or programs of any kind authorized, funded, or carried out by federal agencies, including actions directly or indirectly causing modifications to the land, water, or air.<sup>3</sup>

To carry out this substantive mandate, the ESA and its implementing regulations require all federal agencies to consult with the Services on the effects of their proposed actions.<sup>4</sup> This process begins with the requirement that the “action” agency, such as EPA here, ask the Services whether any listed or proposed species may be present in the area of the agency action.<sup>5</sup> If listed or proposed species may be present, the action agency must prepare a “biological assessment” to determine whether the listed species is likely to be affected by the proposed action.<sup>6</sup> The biological assessment generally must be completed within 180 days.<sup>7</sup>

If the action agency determines the action “may affect” a listed species or critical habitat, the action agency must formally consult with NMFS and/or FWS to “insure” that the action is “not likely to jeopardize the continued existence” of that species, or “result in the destruction or

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<sup>1</sup> 16 U.S.C. § 1536(a)(2).

<sup>2</sup> 50 C.F.R. § 402.02.

<sup>3</sup> *Id.*

<sup>4</sup> 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.12-402.16.

<sup>5</sup> 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12.

<sup>6</sup> *Id.*

<sup>7</sup> 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12(i).

adverse modification of habitat ... determined ... to be critical....”<sup>8,9</sup> The threshold for a finding of “may affect” is extremely low. A triggering effect need not be significant; rather “any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement....”<sup>10</sup>

If a proposed action “may affect” a listed species or designated critical habitat, formal consultation is required unless the Service(s) concur in writing with an action agency’s finding that the proposed action “is not likely to adversely affect” listed species or designated critical habitat.<sup>11</sup> This “informal consultation” process consists of discussions and correspondence between the Services and the action agency and is designed to assist the action agency in determining whether formal consultation is required.<sup>12</sup> An action is “likely to adversely affect” protected species and formal consultation is required if: “any adverse effect to listed species may occur as a direct or indirect result of the proposed action or its interrelated or interdependent actions, and the effect is not discountable, insignificant, or beneficial.”<sup>13</sup>

To complete formal consultation, NMFS and/or FWS must provide EPA with a “biological opinion” explaining how the proposed action will affect the listed species or habitat.<sup>14</sup> In fulfilling Section 7 consultation duties, agencies are required to use the best scientific and commercial data available.<sup>15</sup> Until the expert wildlife agency issues a comprehensive biological opinion, the action agency may not commence the action.<sup>16</sup> Further, during consultation, EPA is prohibited from making any irreversible or irretrievable commitment of resources with respect to the agency action which may foreclose the formulation or implementation of any reasonable and prudent alternative measures.<sup>17</sup>

If the expert wildlife agency concludes that the proposed action “will jeopardize the continued existence” of a listed species, the biological opinion must outline “reasonable and

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<sup>8</sup> 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a).

<sup>9</sup> “Jeopardize” means taking action that “reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.” 50 C.F.R. § 402.02. A species’ “critical habitat” includes those areas identified as “essential to the conservation of the species” and “which may require special management considerations or protection.” 16 U.S.C. § 1532(5)(A).

<sup>10</sup> Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule, 51 Fed. Reg. 19,926, 19,949 (June 3, 1986); Final ESA Section 7 Consultation Handbook at xvi (Mar. 1998) (defining “may affect” as “the appropriate conclusion when a proposed action may pose any effects on listed species....”).

<sup>11</sup> 50 C.F.R. §§ 402.02, 402.13(a), 402.14 (a).

<sup>12</sup> 50 C.F.R. § 402.13(a).

<sup>13</sup> *Endangered Species Consultation Handbook*, March 1998, p. xv.

<sup>14</sup> 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14.

<sup>15</sup> 16 U.S.C. § 1536(a)(2).

<sup>16</sup> *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1056-57 (9th Cir. 1994); *see also* 16 U.S.C. § 1536(d).

<sup>17</sup> 16 U.S.C. § 1536(d).

prudent alternatives,” if any exist.<sup>18</sup> If the biological opinion concludes that the action is not likely to jeopardize the continued existence of a listed species, and will not result in the destruction or adverse modification of critical habitat, NMFS and/or FWS must provide an “incidental take statement,” specifying the amount or extent of such incidental taking on the listed species, any “reasonable and prudent measures” that they consider necessary or appropriate to minimize such impact, and setting forth the “terms and conditions” that must be complied with by EPA to implement those measures.<sup>19</sup> In order to monitor the impacts of incidental take, EPA must monitor and report the impact of its action on the listed species to the Services as specified in the incidental take statement.<sup>20</sup> If during the course of the action the amount or extent of incidental taking is exceeded, EPA must immediately re-initiate consultation with the Services.<sup>21</sup>

Federal agencies have an independent and substantive obligation to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or adversely modify critical habitat. Indeed, Section 7(a)(1) of the ESA requires EPA, in consultation with and with the assistance of the Services, to utilize its authorities in furtherance of the purposes of the ESA by carrying out programs for the conservation of endangered and threatened species.<sup>22</sup>

Federal agencies also have a continuing duty under Section 7 of the ESA to re-initiate consultation whenever “new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered,” where the action in question is “subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion,” or where “a new species is listed or critical habitat designated that may be affected by the identified action.”<sup>23</sup>

Finally, Section 9(a) of the ESA prohibits the “take” of an endangered species by any person.<sup>24</sup> This prohibition has generally been applied to many species listed as “threatened” through the issuance of regulations under Section 4(d) of the ESA.<sup>25</sup> “Take” includes actions that kill, harass, or harm a protected species.<sup>26</sup> “Harass” is defined to include acts that create the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns.<sup>27</sup> “Harm” includes significant habitat modification or degradation that actually kills or injures wildlife by significantly impairing essential behavioral patterns.<sup>28</sup>

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<sup>18</sup> 16 U.S.C. § 1536(b)(3)(A).

<sup>19</sup> 16 U.S.C. § 1536(b)(4); 50 C.F.R. § 402.14(i).

<sup>20</sup> 16 U.S.C. § 1536(b)(4); 50 C.F.R. § 402.14(i)(1)(iv), (i)(3).

<sup>21</sup> 50 C.F.R. § 402.14(i)(4).

<sup>22</sup> 16 U.S.C. § 1536(a)(1).

<sup>23</sup> 50 C.F.R. § 402.16(b)-(d).

<sup>24</sup> 16 U.S.C. § 1538(a).

<sup>25</sup> 16 U.S.C. § 1533(d); 50 C.F.R. § 17.31(a).

<sup>26</sup> 16 U.S.C. § 1532(19).

<sup>27</sup> 50 C.F.R. § 17.3.

<sup>28</sup> *Id.*; 50 C.F.R. § 222.102.

#### IV. FACTUAL BACKGROUND AND LEGAL VIOLATIONS

At issue is the first-ever genetically engineered (GE) mosquito release into the wild in the United States, totaling billions of GE mosquitos.

In 2016, Oxitec, Ltd. (Oxitec) applied for an investigational new animal drug (INAD) with the FDA to allow the field release of GE *Aedes aegypti* mosquito strain OX513A in Key Haven, Monroe County, Florida. The OX513A mosquito strain was genetically engineered to contain a conditional lethality trait and a fluorescent marker.<sup>29</sup> Oxitec prepared a draft Environmental Assessment pursuant to the National Environmental Policy Act (NEPA) and the Center for Veterinary Medicine (CVM) of the FDA published a preliminary Finding of No Significant Impact (FONSI) for public comment, concluding that the GE *Aedes aegypti* mosquito is unlikely to impact the physical, biological, and human environment; that no cumulative impacts are anticipated; and without consulting the expert wildlife agencies, that the release will have no effect on threatened and endangered species or their designated habitat, CFS objected to this application, which has since been withdrawn.<sup>30</sup> CFS had sent a similar sixty-day notice of intent to sue letter to FDA concerning the agency's inadequate assessment of the effect Oxitec's OX513A GE mosquitoes would have on threatened and endangered species in the Florida Keys.<sup>31</sup> That proposal was subsequently withdrawn.

Jurisdiction between FDA and EPA was subsequently changed by the agencies. Oxitec then submitted an application to EPA to release the OX513A strain of *Aedes aegypti* mosquito in 2018. CFS also objected to this application and it was later withdrawn by Oxitec.<sup>32</sup> Oxitec's OX513A GE mosquitoes were genetically engineered to in theory die at the larval stage in the absence of the antibiotic tetracycline, which acts as a chemical switch to allow breeding in the laboratory. While never released in the U.S., OX513A GE mosquitoes were released internationally in other countries.

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<sup>29</sup> Phuc, H. K., Andreasen, M. H., Burton, R. S., Vass, C., Epton, M. J., Pape, G., ... Alphey, L. (2007). Late-acting dominant lethal genetic systems and mosquito control. *BMC Biology*, 5, 11.

<sup>30</sup> Ctr. for Food Safety et al., Comment on FDA Notice: Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning Investigational Use of Oxitec OX513A Mosquitoes; Extension of Comment Period, ID: FDA-2014-N-2235-2585 (May 13, 2016), *available at* <https://www.regulations.gov/document?D=FDA-2014-N-2235-2585>.

<sup>31</sup> *Available at* [http://www.centerforfoodsafety.org/files/60-day-notice-of-intent-for-mosquito-suit\\_38745.pdf](http://www.centerforfoodsafety.org/files/60-day-notice-of-intent-for-mosquito-suit_38745.pdf).

<sup>32</sup> Ctr. for Food Safety et al., Comment on EPA Notice: Pesticide Experimental Use Permits; Applications: Oxitec Ltd., ID: EPA-HQ-OPP-2017-0756-0356 (Apr. 19 2018), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2017-0756-0356>; Ctr. for Food Safety et al., Comment on EPA Notice: Pesticide Experimental Use Permits; Applications: Oxitec, Ltd., ID: EPA-HQ-OPP-2017-0756-0775 (June 7, 2018), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2017-0756-0775>.

Oxitec states that this prior GE mosquito has now been superseded by a new GE mosquito, OX5034, and thus the previous applications to release OX513A have been withdrawn. Oxitec submitted the most recent application to EPA requesting a permit for experimental releases of its GE *Aedes aegypti* OX5034 mosquitoes expressing tTAV-OX5034 protein in Monroe County, Florida, and Harris County, Texas on May 20, 2019. Very limited information regarding the newer OX5034 strain has been provided by the applicant in a published letter to the EPA.<sup>33</sup>

The main substantive difference, compared to the earlier OX513A strain, is that the genetically engineered killing mechanism in OX5034 GE Mosquitoes is intended to kill the female GE mosquitoes only, with GE males surviving for multiple generations. Although there are some differences between the OX513A strain and the second-generation OX5034 strain, many of the issues raised regarding the first-generation releases remain of concern and have not been addressed. In addition, because the OX5034 strain is female-killing only, GE males are expected to survive for multiple generations and this will considerably increase the spread of genes from the introduced strain into the wild population. In an online presentation, Oxitec presents this as a benefit because it argues that the released laboratory-derived strain will spread insecticide susceptibility genes into the wild mosquito population:<sup>34</sup> however, there is no guarantee that only beneficial and no harmful traits will be spread in this way.

This GE mosquito release is the first that EPA has approved, and will be the first-ever GE mosquito experiment in the United States. With EPA's approval, Oxitec plans to make open releases of the OX5034 GE Mosquitoes on up to 6,600 total acres at a maximum rate of 20,000 male OX5034 GE Mosquitoes, per acre per week.<sup>35</sup> The GE Mosquitoes that EPA approved Oxitec to release are of the *Aedes aegypti* species, which transmit viruses that cause diseases including dengue fever, zika, and chikungunya. CFS submitted comments to EPA objecting to Oxitec's application and to the release of OX5034 mosquitoes in Florida and Texas.<sup>36</sup>

EPA has approved the unprecedented release of more than a billion GE mosquitoes over two years in Monroe County, Florida, beginning in summer 2020, and in Harris County, Texas, beginning in 2021, as a field test of a "pesticide" under development, pursuant to its authority it purports under section 5 of the Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C.

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<sup>33</sup> See Oxitec Ltd., Description of OX5034 *Aedes aegypti* Mosquito, including Active and Inert Ingredients, ID: EPA-HQ-OPP-2019-0274-0002 (May 20, 2019), available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0002>.

<sup>34</sup> Enca Martin-Rendon, Introduction to Oxitec 2nd Generation Mosquitoes Technology Summary - Roll Back Malaria Vector Control Working Group – Geneva, 30th Jan - 1st Feb, 2019 (2019), available at <https://endmalaria.org/sites/default/files/Enca%20Martin-Rendon.pdf>.

<sup>35</sup> See 84 Fed. Reg. 47947 (Sept. 11, 2019), available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0001>.

<sup>36</sup> See Ctr. for Food Safety, Comment on EPA Notice: Pesticide Experimental Use Permit; Application, ID: EPA-HQ-OPP-2019-0274-0344 (Oct. 11, 2019), available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0344>.

136c. Specifically, these experiments have been approved to evaluate the efficacy of Oxitec’s alternative second-generation OX5034 GE mosquitoes as a tool for suppression of wild *Aedes aegypti* mosquito populations.<sup>37</sup>

Contrary to Oxitec’s claims, the release of its first-generation OX513A GE mosquitoes has not been successful, as has been documented extensively: the company has no evidence of any impact on disease transmission and has made repeated, exaggerated claims about the impact of its experimental releases on wild mosquito populations.<sup>38,39</sup> As a result of this poor performance, international trials of OX513A have ceased, with a single trial of OX5034 GE mosquitoes being undertaken solely in Brazil. However, Oxitec’s claim<sup>40</sup> that “effective mosquito control, with built-in biosafety” has been demonstrated in field trials of its second-generation OX5034 GE mosquitoes in Brazil is not supported by any published evidence.

In approving the release of Oxitec’s OX5034 GE mosquitoes, EPA has made erroneous and unilateral assumptions that its approval action will have “no effect” on protected species and/or their critical habitat.<sup>41</sup> Yet dozens of protected species that live or occur in the area of the release may be affected by the approval.<sup>42</sup> See *infra* Section IV.A. EPA’s “no effect” decision for these species was contrary to law. Pursuant to its duties under the ESA, EPA was required to consult with the expert wildlife agencies before reaching any decision on the unprecedented GE mosquito.

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<sup>37</sup> 84 Fed. Reg. 47947.

<sup>38</sup> GeneWatch UK, Briefing: Oxitec’s GM insects: Failed in the Field? (May 2018), *available at* [http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Failed\\_in\\_the\\_field\\_in.pdf](http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Failed_in_the_field_in.pdf).

<sup>39</sup> GeneWatch UK et al., Oxitec’s Failed GM Mosquito Releases Worldwide: Forewarnings for Africa and the Target Malaria Project (Apr. 30, 2019), *available at* [http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitec\\_failed\\_GM\\_mosquito\\_releases\\_worldwide\\_Forewarnings\\_for\\_Africa\\_and\\_the\\_Target\\_Malaria\\_project.pdf](http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitec_failed_GM_mosquito_releases_worldwide_Forewarnings_for_Africa_and_the_Target_Malaria_project.pdf).

<sup>40</sup> Oxitec Ltd., Description of OX5034 *Aedes aegypti* Mosquito, including Active and Inert Ingredients, ID: EPA-HQ-OPP-2019-0274-0002 (May 20, 2019), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0002>.

<sup>41</sup> See EPA, Response to Comments to the Notice of Receipt of an Application for an Experimental Use Permit Number 93167-EUP-E, ID: EPA-HQ-OPP-2019-0274-0355, 139 (May 1, 2020) (hereinafter Response to Comments), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0355>; *see also id.* at 73-74.

<sup>42</sup> See FWS, Species By County Report: Monroe, Florida, <https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=12087> (last visited May 16, 2020). See FWS, Species By County Report: Harris, Texas, <https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=48201> (last visited May 16, 2020) (Note that not all federally threatened and endangered species are listed for Harris County); Texas Parks & Wildlife, Rare, Threatened, and Endangered Species by County Map, Harris County Report, <https://tpwd.texas.gov/gis/rtest/> (last visited May 16, 2020) (This report includes all federally listed threatened and endangered species in Harris County, including listed species not included in FWS’s species by county report for Harris County, Texas.).



## A. Affected Threatened and Endangered Species.

### Monroe County, Florida

The species' habitat that may be affected in Florida by EPA's approval action includes, but is not limited to, Monroe County, Florida.

- The protected species of birds include, but are not limited to, the Everglade snail kite (*Rostrhamus sociabilis plumbeus*), Cape Sable seaside sparrow (*Ammodramus maritimus mirabilis*), Wood stork (*Mycteria americana*), Audubon's crested caracara (*Polyborus plancus audubonii*) Piping plover (*Charadrius melodus*), Roseate tern (*Sterna dougallii dougallii*), Red knot (*Calidris canutus rufa*), Florida grasshopper sparrow (*Ammodramus savannarum floridanus*), and Florida scrub-jay (*Aphelocoma coerulescens*).
- The protected species of insects include, but are not limited to, Schaus swallowtail butterfly (*Heraclides aristodemus ponceanus*), Miami blue butterfly (*Cyclargus thomasi bethunebakeri*), Bartram's hairstreak butterfly (*Strymon acis bartrami*), and Florida leafwing Butterfly (*Anaea troglodyte floridalis*).
- The protected species of mammals include, but are not limited to, Key deer (*Odocoileus virginianus clavium*), Florida panther (*Puma concolor coryi*), Silver rice rat (*Oryzomys palustris natator*), Key Largo cotton mouse (*Peromyscus gossypinus allapaticoloa*), Key Largo woodrat (*Neotoma floridana smalli*), Lower Keys marsh rabbit (*Sylvilagus palustris hefneri*), Puma (*Puma concolor*), and Florida bonneted bat (*Eumops floridanus*).
- The protected species of reptiles include, but are not limited to, American alligator (*Alligator mississippiensis*), Hawksbill sea turtle (*Eretmochelys imbricata*), Leatherback sea turtle (*Demochelys coriacea*), Loggerhead sea turtle (*Caretta caretta*), Eastern indigo snake (*Drymarchon coarais couperi*), American crocodile (*Crocodylus acutus*), and Gopher tortoise (*Gopherus polyphemus*).
- The protected species of fish include, but is not limited to, Atlantic sturgeon (*Acipenser oxyrinchus*).
- The protected species of snail include, but is not limited to, Stock Island tree snail (*Orthalicus reses*).
- The protected species of flowering plants include, but are not limited to, Blodgett's silverbush (*Argytheamnia blodgetti*), Big Pine partridge pea (*Chamaecrista lineata keyensis*), Wedge spurge (*Chamaesyce deltoidea serpyllum*), Sand flax (*Linum arenicola*), Garber's spurge (*Chamaesyce garberi*), Florida pineland crabgrass (*Digitaria pauciflora*), Key tree cactus (*Pilosocereus robinii*), Cape Sable Thoroughwort (*Chromolaena frustrata*), Florida prairie-clover (*Dalea carthagenensis*

*floridana*), Florida semaphore Cactus (*Consolea corallicola*), and Everglades bully (*Sideroxylon reclinatum ssp. sustrofloridense*).

As examples of these species, the Cape Sable seaside sparrow is a non-migratory bird that lives only in Florida and inhabits freshwater to brackish marshes.<sup>43</sup> Its restricted range is what led to its initial listing in 1967, and threats to its habitat posed by large-scale conversion of land to agricultural uses and changes in the distribution, timing, and quantity of water flows in South Florida continue to threaten the subspecies with extinction.<sup>44</sup> The bird is a dietary generalist meaning that it forages for a variety of insects and is opportunistic in nature.<sup>45</sup> Accordingly, the sparrow shifts the importance of prey items in its diet in direct response to their availability.<sup>46</sup>

For piping plovers, food availability may be one of the reasons the species is in decline.<sup>47</sup> Piping plovers likely eat invertebrates and their diets vary depending on habitat type.<sup>48</sup> If piping plovers are unable to obtain a sufficient food source, it impacts their weight, which makes it more likely that they will not be able to avoid predators.<sup>49</sup> The other greatest threat to piping plovers is human disturbance.<sup>50</sup> The wintering locations of the plovers in South Florida are plagued by pedestrian recreationists, their pets, and off-road vehicle enthusiasts.<sup>51</sup>

The Red Knot was recently listed by FWS in January 2015.<sup>52</sup> It is a migratory bird that travels as far north as the Canadian Arctic.<sup>53</sup> Red knots winter in Southern Florida where they forage for mollusks, insects, green vegetation, and seeds.<sup>54</sup> The knot's life history depends on suitable habitat, food, and weather conditions at far-flung sites across the Western Hemisphere.<sup>55</sup>

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<sup>43</sup> FWS, Cape Sable Seaside Sparrow Multi-Species Recovery Plan for South Florida, at 4-345, available at <https://www.fws.gov/verobeach/MSRPPDFs/CapeSableSeasideSparrow.pdf>.

<sup>44</sup> *Id.* at 4-352.

<sup>45</sup> *Id.* at 4-351.

<sup>46</sup> *Id.*

<sup>47</sup> FWS, Piping Plover (*Charadrius melodus*) 5-Year Review: Summary and Evaluation 100 (Sept. 2009), available at [https://www.fws.gov/northeast/endangered/PDF/Piping\\_Plover\\_five\\_year\\_review\\_and\\_summary.pdf](https://www.fws.gov/northeast/endangered/PDF/Piping_Plover_five_year_review_and_summary.pdf).

<sup>48</sup> *Id.* at 101.

<sup>49</sup> *Id.*

<sup>50</sup> FWS, Piping Plover Multi-Species Recovery Plan for South Florida, at 4-331, available at <https://www.fws.gov/verobeach/MSRPPDFs/PipingPlover.pdf>.

<sup>51</sup> *Id.*

<sup>52</sup> FWS, Species Profile for Red Knot, ECOS Environmental Conservation Online System, <https://ecos.fws.gov/ecp0/profile/speciesProfile?spscode=B0DM> (last visited May 17, 2020).

<sup>53</sup> Audubon, Guide to North American Birds: Red Knot (*Calidarus canutus*), available at <http://www.audubon.org/field-guide/bird/red-knot>.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

If the birds do not encounter favorable habitat, food, and weather conditions within narrow seasonal windows during migration stops, it could further exacerbate their decline.<sup>56</sup>

Rice rats, or silver rice rats as they are commonly called, are unique to the Lower Keys.<sup>57</sup> Similar to the birds listed above, Rice rats are opportunistic when it comes to foraging for food. They are predominantly omnivorous, but preferably carnivorous, feeding mainly on insects, snails, and crabs.<sup>58</sup> Rice rats were listed as endangered in 1991 due to severe habitat loss from residential and commercial destruction, as well as the introduction or increase of non-native predators and competitors.<sup>59</sup>

The Florida bonneted bat is the largest bat in Florida and was listed as endangered in October 2013.<sup>60</sup> While the species breeds year-round, with peak activity occurring in April, the Florida bonneted bat also has a fairly extensive breeding season during summer months.<sup>61</sup> It is active-year round and therefore likely dependent upon a constant and sufficient food supply, consisting of insects, to maintain its generally high metabolism.<sup>62</sup> Certain characteristics of the Florida bonneted bat's life history and ecology, including slow reproduction, low fecundity, high-altitude aerial-hawking, foraging, and roosting habits, make it especially susceptible to current threats.<sup>63</sup> According to FWS, "[c]limate change, pesticide use, and environmental stochasticity" could further contribute to the Florida bonneted bat's imperilment.<sup>64</sup>

In addition to the species listed above, GE mosquitoes may migrate beyond the test trial sites of Monroe County, Florida, to neighboring counties by car, boat, or other conveyance, thereby potentially impacting other threatened and endangered species.

#### *Harris County, Texas*

The species' habitat that may be affected in Texas by EPA's approval action includes, but is not limited to, Harris County, Texas.

- The protected species of birds include, but are not limited to, the whooping crane (*Grus americana*), Red knot (*Calidris canutus rufa*), red-cockaded woodpecker (*Picoides borealis*), piping plover (*Charadrius melodus*), Attwater's greater prairie-chicken (*Tympanuchus cupido attwater*), and Brown pelican (*Pelecanus occidentalis*).

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<sup>56</sup> *Id.*

<sup>57</sup> FWS, Rice Rat Multi-Species Recovery Plan for South Florida, at 4-173, available at <https://www.fws.gov/verobeach/MSRPPDFs/RiceRat.pdf>.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 4-182.

<sup>60</sup> FWS, Recovery Outline for Florida Bonneted Bat (*Eumops floridanus*) 1 (Oct. 2018), [https://ecos.fws.gov/docs/recovery\\_plan/Final%20FLBB%20recovery%20outline.pdf](https://ecos.fws.gov/docs/recovery_plan/Final%20FLBB%20recovery%20outline.pdf).

<sup>61</sup> *Id.* at 2.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

- The protected species of mammals include, but are not limited to, the West Indian Manatee (*Trichechus manatus*), humpback whale (*Megaptera novaeangliae*), Gulf of Mexico Bryde's Whale (*Balaenoptera edeni*), blue whale (*Balaenoptera musculus*), Sei Whale (*Balaenoptera borealis*), and sperm whale (*Physeter macrocephalus*).
- The protected species of reptiles include, but are not limited to, the loggerhead sea turtle (*Caretta caretta*), and Western Chicken turtle (*Deirochelys reticularia ssp. Miarua*).
- The protected species of amphibian include, but are not limited to, the Houston toad (*Bufo houstonensis*).
- The protected species of flowering plants include, but are not limited to, the Texas prairie dawn-flower (*Hymenoxys texana*).

Examples of these threatened and endangered species in Harris County, Texas, include the whooping crane, which is a migratory bird that resides only in North America.<sup>65</sup> The whooping crane is North America's tallest bird, with males approaching 1.5 m (5 ft) when standing erect.<sup>66</sup> Whooping cranes currently exist in the wild at three locations and in captivity at twelve sites, with only one self-sustaining wild population, the Aransas-Wood Buffalo National Park population, which nests in Wood Buffalo National Park and adjacent areas in Canada, and winters in coastal marshes in Texas at Aransas.<sup>67</sup> The whooping crane's summer diet includes "large nymphal or larval forms of insects, frogs, rodents, small birds, minnows, and berries."<sup>68</sup> Foods consumed by the cranes during migration "include frogs, fish, plant tubers, crayfish, insects, and agricultural grains."<sup>69</sup> The cranes have a winter diet that consists predominately of animal foods, including blue crabs, clams, and the plant wolfberry.<sup>70</sup> Foraging occurs mostly in the brackish bays, marshes, and salt flats on the edge of the mainland and on barrier islands.<sup>71</sup> Whooping cranes are occasionally attracted "by fresh water to drink or by foods such as acorns, snails, crayfish and insects," and therefore fly to upland sites and then return to the marshes to roost.<sup>72</sup> The threats that are currently affecting whooping cranes include "limited genetics of the

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<sup>65</sup> FWS, Species Profile for Whooping Crane, ECOS Environmental Conservation Online System, <https://ecos.fws.gov/ecp0/profile/speciesProfile?sPCODE=B003> (last visited May 13, 2020).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> FWS, International Recovery Plan: Whooping Crane (*Grus americana*) (Third Revision) 8 (Mar. 2007), available at [https://ecos.fws.gov/docs/recovery\\_plan/070604\\_v4.pdf](https://ecos.fws.gov/docs/recovery_plan/070604_v4.pdf).

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

population, loss and degradation of migration stopover habitat, construction of additional power lines, degradation of coastal ecosystems, and threat of chemical spills in Texas.”<sup>73</sup>

The red-cockaded woodpecker is listed as an endangered species endemic to open, mature and old growth pine ecosystems in the southeastern United States.<sup>74</sup> In 2003, there was “an estimated 14,068 red-cockaded woodpeckers living in 5,627 known active clusters across eleven states, which “is less than 3 percent of estimated abundance at the time of European settlement.”<sup>75</sup> Over 75 percent of the red-cockaded woodpecker’s diet consists of arthropods.<sup>76</sup> Threats to red-cockaded woodpeckers include, but are not limited, insufficient numbers of natural cavities and continuing net loss of cavity trees, habitat fragmentation, and lack of foraging habitat of adequate quality.<sup>77</sup>

Houston toads have experienced considerable declines since its listing in 1970.<sup>78</sup> The last Houston toad seen in Harris County, Texas, was in 1976.<sup>79</sup> Regardless of extensive range-wide survey attempts, only twelve Houston toads and no reproductive events were observed during the 2011 breeding season.<sup>80</sup> It is presumed that Houston toads feed on small arthropods.<sup>81</sup> With ongoing threats of habitat loss and persistent drought conditions, extinction of this species could be likely in the near future.<sup>82</sup>

In addition to the species listed above, GE mosquitoes may migrate beyond the test trial sites of Harris County, Texas, to neighboring counties by car, boat, or other conveyance, thereby potentially impacting other threatened and endangered species.

**B. EPA Has Taken Action that “May Affect” Listed Species and Their Designated Critical Habitat Without Consulting with the Expert Services.**

Oxitec requested an Experimental Use Permit (EUP) under FIFRA section 5 for a new end-use product containing the new active ingredient tetracycline-repressible transactivator protein variant (tTAV-OX5034) protein, the new inert ingredient DsRed2-OX5034 protein, and the genetic material (vector pOX5034) necessary for their production in OX5034 *Aedes aegypti* (Yellow Fever mosquito). Oxitec requested this EUP to evaluate whether the product is effective

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<sup>73</sup> *Id.* at xi.

<sup>74</sup> FWS, Recovery Plan for the Red-cockaded Woodpecker (*Picoides borealis*) (Second Revision) ix (Jan. 2003), available at [https://ecos.fws.gov/docs/recovery\\_plan/030320\\_2.pdf](https://ecos.fws.gov/docs/recovery_plan/030320_2.pdf).

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 42.

<sup>77</sup> FWS, Red-cockaded Woodpecker (*Picoides borealis*) 5-Year Review: Summary and Evaluation 12 (Oct. 2006), available at [https://ecos.fws.gov/docs/five\\_year\\_review/doc787.pdf](https://ecos.fws.gov/docs/five_year_review/doc787.pdf).

<sup>78</sup> FWS, Houston toad (*Bufo houstonensis*) 5-Year Review: Summary and Evaluation 13 (Nov. 2011), available at [https://ecos.fws.gov/docs/five\\_year\\_review/doc3958.pdf](https://ecos.fws.gov/docs/five_year_review/doc3958.pdf).

<sup>79</sup> FWS, Houston Toad Recovery Plan 11 (Aug. 1984), available at [https://ecos.fws.gov/docs/recovery\\_plan/840917.pdf](https://ecos.fws.gov/docs/recovery_plan/840917.pdf)

<sup>80</sup> FWS, Houston toad 5-Year Review at 13.

<sup>81</sup> FWS, Houston Toad Recovery Plan at 21; FWS, Houston toad 5-Year Review at 3.

<sup>82</sup> FWS, Houston toad 5-Year Review at 13.

in suppressing naturally-occurring *Aedes aegypti* populations under field conditions. EPA regulates products meant to reduce the population of mosquitoes as pesticides, such as OX5034.<sup>83</sup>

Pursuant to the EPA EUP approval, Oxitec plans to test the efficacy of the product by deploying eggs, pupae, and adults homozygous for the OX5034 trait.<sup>84</sup> According to Oxitec, the OX5034 is intended to act as a species-specific female larvicide, or “male-selecting” larvicide, resulting in “all-male progeny in the absence of tetracycline in the larval diet due to a female-specific self-limiting gene.”<sup>85</sup> Oxitec intends to only release male mosquitoes because they do not bite; however, it is impossible to assess Oxitec’s claim that no biting GE female mosquitoes will be released or survive to adulthood.

The GE mosquitoes are to be released over a time period of up to twenty-four months. In total, Oxitec requested 6,600 acres for conducting tests from April 2021 through the end of April 2022.<sup>86</sup> Over this twenty-four-month period, Oxitec and EPA projected that as many as **1,266,720,000** male OX5034 mosquitoes will be released in two different types of trials in Monroe County, Florida, and in one trial in Harris County, Texas.<sup>87</sup> Like its approval decision, EPA’s conclusion concerning threatened and endangered species rests on an extremely limited inquiry that failed to adequately consider the significant risks of harm to listed species related to releasing more than a billion GE mosquitoes into the environment at the test trial sites in Monroe County and Harris County.

Because of this approval decision, for the first time ever in the United States, hundreds of millions of GE mosquitoes will be released into the environment, which may potentially harm threatened and endangered species. The ESA requires EPA to consult on these potential impacts.

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<sup>83</sup> EPA, Memorandum: Summary of the Data and Information Related to Vectorial Capacity Presented for the New Product OX5034 (EPA File Symbol: 93167-EUP-E) Containing the Tetracycline-Repressible Transactivator Protein Variant (tTAV-OX5034), a Variant of the Modified *Discosoma* spp. DsRed2 Protein, and the Genetic Material (Vector pOX5034) Necessary for Their Production in OX5034 *Aedes aegypti*. Data and Information Were Provided in Support of a FIFRA Section 5 Application., ID: EPA-HQ-OPP-2019-0274-035, at 3 (May 1, 2020) (hereinafter Memorandum on Vectorial Capacity), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0351>.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> EPA, Review of the Updated Section G Dated April 30, 2020 for an Experimental Use Permit 93167-EUP-E to Test OX5034 *Aedes aegypti* Mosquitoes Decision #549240, ID: EPA-HQ-OPP-2019-0274-0352, at 4 (May 1, 2020), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0352>.

<sup>87</sup> *See id.* at 5; *see also id.* at 4-5 (explaining that EPA has approved Oxitec’s EUP for a Trial A study (i.e., life stage assessed = eggs or adults (one life stage only)) in Monroe County, Florida only, and Trial B studies (i.e., life stage assessed = eggs only) in Monroe County, Florida, and Harris County, Texas).

These threats are detailed in numerous comments to EPA, as well as in previous comments from FWS to FDA about the earlier application for the similar OX513A strain that was withdrawn. In FWS's comments to FDA regarding the release of OX513A GE mosquitoes, FWS said:

We [] recognize a possibility for conflicts with the conservation of native species (especially those that are listed as threatened or endangered under the Endangered Species Act (ESA)), and the potential negative consequences of releasing non-native (including some GE) organisms into the environment.<sup>88</sup>

Based on this conclusion, FWS had recommended that FDA require Oxitec, as a condition of the permit, to: (1) when possible and appropriate, conduct field studies on the potential effects of the release to non-target organisms and the local native environment; (2) make the data available to regulatory agencies; and (3) whenever possible, publish the results in a peer reviewed journal.<sup>89</sup> EPA has not required Oxitec to implement any type of mitigation measures similar to these recommendations as a condition of the permit for OX5034 GE mosquitoes.

EPA even recognizes that the release of more than a billion Oxitec GE mosquitoes could adversely impact threatened and endangered species in Monroe County and Harris County in stating that “[p]ossible adverse effects to non-target organisms from OX5034 releases are two-pronged: direct effects from oral consumption of OX5034 mosquitoes and indirect effects on ecosystem processes from reduced *Ae. Aegypti* populations.”<sup>90</sup> EPA's Human Health and Environmental Risk Assessment also clearly states that “mosquitoes make up part of the diet of some insect-eating animals, such as birds, bats, adult dragonflies, or spiders.”<sup>91</sup> Moreover, EPA in its response to public comments on the EUP, specifically acknowledges that birds, dragonflies, bats, amphibians (frogs), and lizards eat mosquitoes.<sup>92</sup> For example, EPA found:

With regard to birds, several types of birds including most varieties of swallows, warblers and other songbirds consume mosquitoes among other flying insects.

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<sup>88</sup> FWS, Comment on FDA's Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning Investigational Use of Oxitec OX513A Mosquitoes; Extension of Comment Period, ID: FDA-2014-N-2235-1317, at 1 (Apr. 20, 2016), *available at* <https://www.regulations.gov/document?D=FDA-2014-N-2235-1317>.

<sup>89</sup> *Id.* at 2.

<sup>90</sup> EPA, Human Health and Environmental Risk Assessment for the New Product OX5034 Containing the Tetracycline-Repressible Transactivator Protein Variant (tTAV-OX5034; New Active Ingredient) Protein, a DsRed2 Protein Variant (DsRed2-OX5034; New Inert Ingredient), and the Generic Material (Vector pOX5034) Necessary for Their Production in OX5034 *Aedes aegypti*; Data and Information Were Provided in Support of a FIFRA Section 5 Application, ID: EPA-HQ-OPP-2019-0274-0359, at 44 (Apr. 30, 2020) (hereinafter Human Health and Environmental Risk Assessment), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0359>.

<sup>91</sup> EPA, Human Health and Environmental Risk Assessment at 45.

<sup>92</sup> *See* EPA, Response to Comments at 73-74.

In terms of lizards and frogs, lizards and frogs are vertebrates and while it is not known that any vertebrates have evolved to specifically target *Ae. aegypti* mosquitoes as a major portion of their diet, in some instances, mosquitoes can constitute a source of prey. Mosquitoes do not form a large part of the lizard diet, although these reptiles may consume mosquitoes they capture opportunistically. Frogs, tadpoles and toads are amphibians and can all eat mosquitoes....

With regard to bats, insectivorous bats are often anecdotally regarded to be a significant predator of mosquitoes and are thought to eat large quantities of mosquitoes.<sup>93</sup>

Thus, it is highly foreseeable that threatened and endangered species that maintain habitat in Monroe County, Florida, and Harris County, Texas, may come into contact with and orally ingest GE mosquitoes. Moreover, many predators that consume mosquitoes are opportunistic, meaning that increasing the amount of mosquitoes in the area by over a billion may change behavioral patterns of species that have access to an augmented food supply.<sup>94</sup> It is unknown what negative impacts there may be on these endangered species from ingesting these novel GE organisms.

Further, if the trial is successful over the course of two years and the wild mosquito population is eventually suppressed by the introduction of non-native GE mosquitoes, it could also result in a reduction of food supply for many predatory species, including threatened and endangered species.

EPA claims that no adverse impacts on threatened or endangered species will occur from the release of more than a billion GE mosquitoes in Monroe County and Harris County.<sup>95</sup> Specifically, the agency's Human Health and Environmental Risk Assessment states:

EPA has determined that *no adverse effects are anticipated* for nontarget organisms as a result of the experimental permit to release OX5034 mosquitoes. Therefore, since adverse effects are not anticipated to nontarget organisms, a "No Effect" determination is also made for direct and indirect effects to federally listed endangered and threatened species, and for their designated critical habitats.<sup>96</sup>

EPA fails to apply the correct legal standard for assessing the impacts of GE mosquitoes on threatened and endangered species in Monroe County and Harris County. Here, the test is whether the release of more than a billion GE mosquitoes "*may affect*" threatened or endangered species in the area, not whether "*adverse effects are anticipated.*"<sup>97</sup> "Adverse effect" is the

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<sup>93</sup> *Id.*

<sup>94</sup> *See, e.g., id.* at 73 (EPA admitting that certain "reptiles may consume mosquitoes they capture opportunistically.").

<sup>95</sup> *See id.* at 139.

<sup>96</sup> EPA, Human Health and Environmental Risk Assessment at 49 (emphasis added).

<sup>97</sup> *See id.*



wrong legal standard; the only way the agency can avoid consultation is if the action will have absolutely no effect.

Moreover, the agency provides no reasoned explanation for why threatened or endangered species in these areas will not be impacted by the release of hundreds of millions of GE mosquitoes, while these listed species are present. Rather, EPA merely concludes that it has made a “no effect” finding.<sup>98</sup>

However, there is no factual or legal support for this finding. EPA cannot claim there is “no effect,” especially when answering the question it is statutorily required to ask under the ESA, which is simply whether the species “may be present.” FWS habitat maps for nearly all the species listed in Monroe County and Harris County indicate that these species “may be present.” Any assumption that protected species do not share the same habitat as *Aedes aegypti* mosquitoes in these two counties is erroneous. The applicant acknowledges that the *Aedes aegypti* habitat is not confined to human habitat or urbanized areas, but is rather diverse and includes “septic tanks, disused tires, flowerpots, planters, trivets [ ] and plastic buckets, trash cans, and discarded plastic containers,”<sup>99</sup> as well as “tree holes” and “clean, still water.”<sup>100</sup> EPA further acknowledged in its Human Health and Environmental Risk Assessment that *Aedes aegypti* “usually uses man-made containers such as gutters, water containers, cans, and tires as breeding sites.”<sup>101</sup> EPA’s Memorandum on Vectorial Capacity also recognizes that the “natural immigration of *Ae. aegypti* happens frequently as the species is known to hitchhike on human modes of transportation such as cars, trucks, and boats.”<sup>102</sup> Considering the natural habitats of many of the species listed in Monroe County, Florida, and Harris County, Texas—particularly coastal and wetland habitats—it is clear that the *Aedes aegypti* habitat overlaps with many listed species. *See supra* Section IV.A.

Indeed, even FDA’s environmental assessment with respect to Oxitec’s initial application to release the similar OX513A mosquitoes in Monroe County, Florida, found that the threatened Stock Island tree snail “may be present” in physical vicinity of that proposed trial site.<sup>103</sup> However, FDA unilaterally and arbitrarily determined that the field trial was “not likely to adversely affect” the species as no removal or modification of habitat was proposed.

Additionally, the ESA requires EPA to assess all effects of its action, including indirect, interrelated, and interconnected ones. If population suppression of *Aedes aegypti* is successful, a decline in *Aedes aegypti* could create an ecological niche which other, possibly more harmful pests could fill, including other invasive mosquito species which carry dengue and other

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<sup>98</sup> EPA, Response to Comments at 139.

<sup>99</sup> Oxitec, Section G OX5034 *Aedes aegypti*: Proposed Field Trial Protocol for an Experimental Use Permit, ID: EPA-HQ-OPP-2019-0274-0358, at 29 (Apr. 30, 2020), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0358>.

<sup>100</sup> EPA, Response to Comments at 40.

<sup>101</sup> EPA, Human Health and Environmental Risk Assessment at 44.

<sup>102</sup> EPA, Memorandum on Vectorial Capacity at 4.

<sup>103</sup> FDA, Environmental Assessment for Investigational Use of *Aedes aegypti* OX13A 46 (Aug. 5, 2016), *available at* <https://www.fda.gov/media/133804/download>.

diseases. For example, *Aedes albopictus* (Asian Tiger) mosquitoes, which also transmit dengue and other viruses (including chikungunya), will increase in numbers and perhaps establish in new areas as a result of competitive displacement of one species by another. *Aedes albopictus* is widespread in the United States, including in Florida and Texas.<sup>104</sup> The *Aedes albopictus* mosquito is known to be a better vector for the West Nile virus compared to the *Aedes aegypti* mosquito, meaning that a decline in *Aedes aegypti* and resulting increase in *Aedes albopictus* could lead to increased adverse effects from West Nile virus on threatened and endangered birds.<sup>105</sup>

The release of more than a billion GE OX5034 mosquitoes will also lead to an increase in the use of traditional control methods for mosquitoes, including adulticides and larvicides. Adulticides and larvicides are toxic insecticides that are known to have negative impacts on threatened and endangered species. EPA has not evaluated the effects of releasing hundreds of millions of GE mosquitoes in Monroe County and Harris County while using current methods of vector control on threatened and endangered species found in or surrounding these counties.

Moreover, EPA has failed to consider that the increase in tropical cyclones and hurricanes in the Gulf of Mexico this year will cause a wide dispersal of Oxitec's GE mosquitoes across various counties in Florida and Texas. This is particularly concerning given that scientists have predicted that this hurricane season is supposed to be a record high.<sup>106</sup>

These likely impacts far exceed the low threshold for actions that "may affect" listed species and trigger EPA's duty to consult with FWS and/or NMFS regarding its approval of Oxitec's EUP application. EPA's failure to complete consultation with the expert fish and wildlife agencies violates the ESA. For the same reasons, EPA also violated its independent duty to consult on the potential effects to any habitat designated as "critical" pursuant to ESA § 4(a)(3)(A).<sup>107</sup>

### **C. EPA's "No Effect" Determinations are Arbitrary and Did Not Use the Best Scientific and Commercial Data Available.**

In EPA's published response to comments on Oxitec's application, EPA ambiguously stated that EPA "has made a 'no effect' finding as to threatened or endangered species under the Endangered Species Act with regard to the present EUP."<sup>108</sup> EPA provides no explanation for its

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<sup>104</sup> CDC, Estimated potential range of *Aedes aegypti* and *Aedes albopictus* in the United States, 2017, available at <https://www.cdc.gov/zika/vector/range.html> (last visited May 20, 2020).

<sup>105</sup> See, e.g., Oxitec, Ltd., Application to Conduct Scientific Study in the Cayman Islands (Nov. 14, 2020), available at [http://www.centerforfoodsafety.org/files/2014-application-to-doe-3\\_97611.pdf](http://www.centerforfoodsafety.org/files/2014-application-to-doe-3_97611.pdf).

<sup>106</sup> See Morgan McFall-Johnson, *We're Only 3 Days Into Hurricane Season, And It's Already a Record-Breaker*, SCIENCE ALERT (June 4, 2020), available at <https://www.sciencealert.com/three-days-into-hurricane-season-and-already-we-have-a-new-storm-record>.

<sup>107</sup> 16 U.S.C. § 1533(a)(3)(A).

<sup>108</sup> EPA, Response to Comments at 139.

arbitrary “no effect” determination, and fails to make any adequate environmental review regarding the EUP application to release millions of GE mosquitoes in Monroe County and Harris County public. Instead EPA merely refers to a recently published “Human Health and Environmental Risk Assessment” in its response to public comments.<sup>109</sup> EPA makes no adequate environmental assessment publicly available, nor does it provide an environmental assessment to the Service(s) or any documentation that shows that EPA sought informal or formal consultation as required under the ESA.

Rather than consult with NMFS and/or FWS after a “may affect” determination, EPA instead relied entirely on its own internal assessments of the risks to conclude that its approval of releasing GE mosquitoes into the environment will have “no effect” on any listed species or designated critical habitat.<sup>110</sup> EPA’s “no effect” conclusion—and the process by which it reached that conclusion—violates the ESA. At a minimum, EPA was required under the ESA to make its determination using the best available science, meaning that it should have consulted the FWS recovery plans for the threatened and endangered species found in Monroe County and Harris County, as well as listed species in surrounding counties. Nothing in the existing public record demonstrates that EPA did so. It was also contrary to the ESA’s mandates to hide whatever EPA did rely upon and any of the agency’s conclusions or findings with regards to endangered species from any public scrutiny, either at the draft stage or even now after approval.

EPA based its conclusions on its own inexpert—and fatally flawed—assumptions that GE mosquitoes released into the environment will not share the same habitat as threatened and endangered species, despite evidence that nearly all the protected species “may be present” where the planned test trials are located at in Monroe County and Harris County. EPA argues that “testing under the EUP would have no adverse effects on organisms specifically mentioned in the comments, i.e., on birds, dragonflies, bats, amphibians (frogs) or lizards.”<sup>111</sup> EPA also states that “[i]t is highly unlikely that any of these species would be reliant on *Ae. aegypti* because, as a non-native species, the mosquito has not been present in the North American ecosystem for sufficient time to develop an essential ecosystem function.”<sup>112</sup> However, EPA even appears to doubt its own assumption by stating in its Human Health and Environmental Risk Assessment that “mosquitoes can play a number of roles in the environment such as pollinator, detritivore, or food source.”<sup>113</sup> EPA also recognizes that the larvae that lives in the water “can act as food for other aquatic organisms.”<sup>114</sup>

Additionally, EPA’s response to public comments continues to doubt its own assumption by stating:

[T]he mosquito is likely to form only a small part of the bird diet.

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<sup>109</sup> See *id.* Note that the Human Health and Environmental Risk Assessment was not published until May 28, 2020, after CFS requested that EPA publish the assessment for public review.

<sup>110</sup> EPA, Response to Comments at 139.

<sup>111</sup> *Id.* at 73.

<sup>112</sup> *Id.*

<sup>113</sup> EPA, Human Health and Environmental Risk Assessment at 44.

<sup>114</sup> *Id.* at 44-45.

[D]ragonflies are known to eat adult mosquitoes; however, they also consume butterflies, moths and smaller dragonflies which serve as significant energy sources, thus mosquitoes are likely not an essential part of their diet.

Mosquitoes do not form a large part of the lizard diet.... Frogs, tadpoles and toads ... do not rely on mosquitoes for a substantial part of their diet. Given the limited time during which OX5034 testing is to occur and given that the area of testing is human habitat, it is unlikely that OX5034 releases would adversely affect reptile or amphibian populations.

*Ae. aegypti* is not known to have any direct interaction with pollinators, nor to be an effective pollinator itself; thus testing of OX5034 is not expected to adversely impact pollinators or plant populations.

[I]n areas where larger, more nutritious insect prey are available, bats do not consume large numbers of mosquitoes as they do not constitute significant calories or nutrients relative to the task of preying upon them. Bats therefore are rarely if ever reliant on *Ae. aegypti* mosquito populations as a sole food source, and the limited OX5034 numbers involved in the EUP testing indicate that the mosquito releases associated with the test will have no effect on bats.<sup>115</sup>

EPA's reasoning shows that it contemplates that releasing over a billion GE mosquitoes could affect threatened or endangered species, and yet EPA failed to consult the expert agencies. It is immaterial whether the amount of GE mosquitoes consumed by threatened or endangered species is "significant" or "substantial." The question is whether releasing and ingesting GE mosquitoes "may affect" a listed species. EPA's conclusion that the impact would not be adverse should a protected species come into contact with a GE mosquito or that it is unlikely a listed species would be reliant on GE mosquitoes in the future for their diet utilizes the wrong standard, and is thus arbitrary and capricious. EPA also improperly relied on inaccurate information to determine the potential effects on listed species.<sup>116</sup>

EPA's "no effect" determinations are arbitrary and contrary to law because EPA did not consider impacts to threatened or endangered species and their habitats, including the Stock Island tree snail (*see supra* Section IV.B). EPA's erroneous conclusion that *Aedes aegypti* habitat does not overlap with the habitat of various protected species in Monroe County, Florida, and Harris County, Texas, or that the listed species found at these trial sites will not be affected by ingesting these GE mosquitoes is not supported by the evidence. Thus, EPA is required to consult FWS and/or NMFS prior to approving the release of more than a billion GE mosquitoes in the states of Florida and Texas.

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<sup>115</sup> EPA, Response to Comments at 73-74.

<sup>116</sup> 16 U.S.C. § 1536(a)(2) (requiring agencies to use only the best scientific and commercial data available).

## VI. CONCLUSION

In sum, EPA's "no effect" findings and failure to consult are arbitrary and capricious and violate the ESA because they fail to follow the ESA's mandated procedures, fail to use the best scientific and commercial data available, fail to consider significant aspects of the issue, and offer an explanation that runs counter to the evidence before the agency. For the above stated reasons, EPA has violated, and remains in ongoing violation of, Section 7 of the ESA. EPA is hereby notified that it has violated Section 7 of the ESA, 16 U.S.C. § 1536(a)(2), in at least the following ways:

Prior to approving the GE mosquito release, EPA failed to request from the expert agencies whether any threatened or endangered species, or designated critical habitat, may be present within or near the areas of the proposed actions.<sup>117</sup>

Prior to approving the GE mosquito release, EPA failed to prepare a "biological assessment" to determine whether any threatened and endangered species that may be present within or near the areas of the proposed actions may be affected.<sup>118</sup>

Prior to approving the GE mosquito release, EPA failed to consult with the expert Services regarding the potential adverse effects of the GE mosquito on dozens of threatened and endangered species, and/or their critical habitat.<sup>119</sup>

EPA has failed to insure, in consultation with the expert agencies, that its action is not likely to jeopardize the continued existence of any threatened or endangered species or result in the destruction or adverse modification of the critical habitat of such species.<sup>120</sup>

EPA has failed to insure that the agency or Oxitec will not make any irreversible or irretrievable commitment of resources with respect to the GE mosquitos prior to initiating and completing consultation with the Services.<sup>121</sup>

EPA has failed, in consultation with the expert agencies, to utilize its authorities in furtherance of the purposes of the ESA by carrying out programs for the conservation of endangered and threatened species, in violation of the ESA.<sup>122</sup> More specifically, EPA has failed to utilize its authorities to carry out programs for the conservation of the threatened and endangered species located in areas where GE mosquitoes will be released, in violation of the ESA.<sup>123</sup>

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<sup>117</sup> 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12.

<sup>118</sup> 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12.

<sup>119</sup> 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.13-14.

<sup>120</sup> 16 U.S.C. § 1536(a)(2).

<sup>121</sup> 16 U.S.C. § 1536(d).

<sup>122</sup> 16 U.S.C. § 1536(a)(1).

<sup>123</sup> 16 U.S.C. § 1536(a)(1).

EPA's determination that its approval of Oxitec's EUP will have "no effect" on listed species is arbitrary and fails to use the best available science.

For the above stated reasons, EPA has violated and remains in ongoing violation of Section 7 of the ESA. If these violations of law are not cured within sixty days, the listed organizations intend to file suit against the responsible agency/agencies and officials to enforce the ESA, seeking declaratory and injunctive relief, as well as attorney and expert witness fees and costs.<sup>124</sup> This notice letter was prepared based on good faith information and belief after reasonably diligent investigation. If you believe that any of the foregoing is factually erroneous or inaccurate, please notify us promptly. Further, during the notice period we are available to discuss effective remedies and actions that will assure future compliance with the ESA.

Sincerely,



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<sup>124</sup> 16 U.S.C. § 1540(g)(4).