

Response to Comment to the Notice of Receipt of a Section 18 Application, 24HI01, for a renewal of the Specific Emergency Exemption to use DQB males in the State of Hawaii

Docket EPA-HQ-OPP-2024-0035

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1. Background

In a Federal Register Notice¹ published on February 8, 2024, the Environmental Protection Agency (EPA) announced the receipt of an application for renewal of the specific emergency exemption from the Hawaii Department of Agriculture (HDOA) for use of the pesticide DQB Males (*Wolbachia pipientis*, DQB strain (wAlbB), contained in live adult *Culex quinquefasciatus* males), to control *Culex quinquefasciatus* mosquitoes, a vector of avian malaria, on up to 20,000 acres of State, Federal, and private wildlife conservation areas throughout the State of Hawaii. The applicant proposes use of a microbial pesticide which has not been registered by EPA.

The applicant states that avian malaria was introduced into the Hawaiian Islands in the 19th century and spread by a non-native mosquito. Hawaii is experiencing increased mosquito populations that have significantly reduced Hawaiian bird populations. According to the applicant, without mosquito control, the survival and recovery of Hawaii's few remaining forest birds are at imminent risk. Several organizations including the US Fish and Wildlife Service, the National Park Service, University of Hawaii, and HDOA have spent the past 7 years reviewing various vector control options and methods for direct control of avian malaria. None of the currently available methods meet the requirements of potential efficacy, operational feasibility, and appropriateness for use in a conservation area.

The proposed continued releases of DQB Males aim to suppress wild-type populations of *Cx. quinquefasciatus* that are transmitting avian malaria to birds throughout the Hawaiian Islands, including federally listed threatened and endangered bird species. When male *Cx. quinquefasciatus* mosquitoes infected with the wAlbB strain of *Wolbachia pipientis* (DQB males) mate with wild-type *Cx. quinquefasciatus* female mosquitoes not infected with the same *Wolbachia* strain, the resulting eggs do not produce offspring. With continued releases of the DQB Males, the local mosquito populations are expected to decrease.

Similar to last year's emergency exemption request, the applicant proposes to make 156 maximum applications of DQB male mosquitoes per release site per year based on an anticipated maximum of 3 releases per week. The total amount of DQB Males to be applied per year to treat conservation lands throughout Hawaii is up to 3,000,000 male mosquitoes per week or 156,000,000 males per year. The maximum amount of *Wolbachia pipientis*, DQB strain, to be applied per year is up to ~1.83g/week or 95g/year.

The regulations governing FIFRA section 18 require publication of a notice of receipt of an application for a specific exemption proposing a new use of a microbial pesticide (i.e., an active ingredient) which has not been registered by EPA. The notice published February 8, 2024, provided an opportunity for public comment on the application. The Agency reviewed, considered, and in this document responds to all comments received during the comment

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period in determining whether to renew the specific exemption requested by the Hawaii Department of Agriculture.

2. Overview of Comments Received on the Notice of Receipt

This document summarizes comments that EPA received in response to the February 8, 2024 Federal Register Notice. Eighty-nine comments were received in response to the Federal Register Notice. Eighty-seven comments were posted for public view at <https://www.regulations.gov/>. Two comments contained inappropriate language, and therefore were not posted for public view.

Of the comments posted for public view, 80 comments opposed the renewal of the specific emergency exemption. However, 5 comments supported the renewal of the emergency exemption. Several comments contained the same content; therefore, this Response to Comment document will summarize the points offered by the commenters and consolidate the Agency responses to address the comments.

Specific comments will be cited in this document. A citation to “0013” refers to Document ID No. EPA-HQ-OPP-2024-0035-0013 (i.e., the last four digits of the Document ID Number) in Docket No. EPA-HQ-OPP-2024-0035, available at <https://www.regulations.gov/>. Citations to documents in the regulations.gov docket will hereinafter use the same citation form. Comments quoted in this Response to Comment document were chosen to illustrate points made in comments relevant to issues directly related to determining whether to renew the emergency exemption for DQB males. Many comments received simply express an opinion without providing sufficient information to allow the Agency to formulate a response. Where pertinent, commenters are quoted to illustrate a point that EPA addresses in the Response to Comment document.

Two comments neither opposed nor supported the renewal of the emergency exemption request. Comment 0044 is non-substantive, and Comment 0098 is a comment on the consultation process, which will be quoted later in this document.

Comments were received from professional associations, public interest groups, and private citizens. EPA thanks all commenters for their participation in the public process.

3. Comments in support of authorizing the renewal request for emergency exemption

3.1 Comments supporting the renewal request for emergency exemption indicated that the continued release of DQB males to Hawaii’s conservation areas may suppress the mosquito population and aid in controlling avian malaria transmission. [Comments 0046, 0050, 0077, 0079]

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Comment 0046 is a letter of support from the Center for Biological Diversity. The letter reads:

“Please accept the following comments from the Center for Biological Diversity (“Center”) on the Environmental Protection Agency’s receipt of a specific exemption renewal request from the Hawaii Department of Agriculture for use of the pesticide DQB Males (*Wolbachia pipientis*, DQB strain, contained in live adult *Culex quinquefasciatus* males), to treat up to 20,000 acres of State, Federal, and private wildlife conservation areas throughout the State of Hawaii to control *Culex quinquefasciatus* mosquitoes, a vector of avian malaria. The Center would like to offer its support for this application.

First, the Center strongly supports efforts to address the threat of non-native mosquitos and avian malaria in the Hawaiian Islands. Without landscape-level efforts to control, and then eventually eliminate mosquitos, Hawaii’s endangered songbirds face an extraordinarily high risk of extinction in the coming years. Direct mosquito control technologies – including *Wolbachia* – are promising alternatives to conventional pesticides, which although can be utilized to control mosquitos on Hawaii, present a substantial risk to the island’s native insect species.

The Department of Interior recently released its Strategy for Preventing the Extinction of Hawaiian Forest Birds, which outlines a number of action steps that will be taken in the coming years to address the impacts of avian malaria on Hawaii forest birds. While this document represents a substantial improvement from the years of inaction and indifference from the U.S. Fish and Wildlife Service to the plight of Hawaii’s birds, the Strategy remains woefully short on addressing the urgent need to remove feral pigs and other non-native mammalian species from Hawaii and aggressively fence all remaining native habitats. Removing pigs from the landscape would have a substantial positive conversation benefit in efforts to reduce malaria transmission, as feral pigs create standing water pools through their behaviors that allow mosquitos to breed.

Thus, while we are supportive of efforts to use *Wolbachia* to control mosquitos, this one mosquito-control technique should not be adopted to the exclusion of other technologies or approaches to control mosquitos. Instead, multiple and overlapping strategies for mosquito control may — and indeed should — be employed concurrently to reduce the impacts of avian malaria on Hawaii’s birds. If *Wolbachia* proves only to have limited benefits, conservation agencies should be able to adapt and nimbly respond to that without being committed to just one strategy indefinitely.

We want to highlight that EPA conducted a biological evaluation for this release in 2022 and obtained concurrence from FWS on its no effect (NE) and may affect but not likely to adversely affect (NLAA) findings. We concur with these findings and acknowledge

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that EPA has complied with its duties under the ESA for the purpose of this potential action.

It is also worth noting the unique circumstances of this action and of Hawaii itself. Mosquitos are endemic and native species that are parts of normal, functioning ecosystems across the world — but not in Hawaii itself, which was free of mosquitos until the arrival of European colonizers. The release of Wolbachia mosquitos into other ecosystems in other parts of the United States may have negative impacts on endangered species and should be carefully evaluated outside the context of an emergency application. However, in Hawaii itself, the elimination of non-native mosquitos is a paramount conservation priority that will not have impacts on Hawaii's native ecosystem communities. It is important that EPA recognizes this very important distinction.

We also recognize that this is a novel technology and essentially an experiment occurring out in the field. However, given the extinction-level threats it seeks to assuage, we believe the risk is acceptable. However, we urge the EPA to implement measures to both closely monitor events on the ground as they unfold and be prepared to take action if the experiment does not go as planned and unintended harmful impacts occur.

It is for these reasons that the Center supports this emergency application.”

Comment 0050 states:

“I appreciate the opportunity to comment on the proposed exemption, and the detailed information provided to the public.

I support the use of DQB male mosquitoes to reduce Hawai'i's mosquito population.

Native birds face many challenges in Hawai'i, and avian malaria transmitted by mosquitoes is a major issue for them. According to the American Bird Conservancy, 95 of Hawai'i's 142 endemic bird species have gone extinct since the arrival of humans, and 8 of those were declared extinct in 2023. Action must be taken to protect the remaining birds, and reducing avian malaria carrying mosquito numbers is a step in the right direction.

The DQB mosquito technique will allow for the controlled reduction of mosquito populations, and is a good alternative to a chemical insecticide, which could have negative impacts on non-target insects and other species on the islands. Both the mosquito species and the Wolbachia species that will be used in the technique are

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already present in Hawai'i, so nothing new is being introduced. Detailed information about this Incompatible Insect Technique can be found on the Birds, Not Mosquitoes website.

Hawai'i's birds are facing pressure from many factors: climate change, habitat loss, non-native predators, and more. This technique will grant them some relief from disease, and hopefully give them room to recover.

Thank you for taking the time to read public comments."

Comment 0077 is a letter of support from The Nature Conservancy. The letter reads:

"The Nature Conservancy (TNC) Hawai'i and Palmyra strongly supports the exemption renewal request from the Hawaii Department of Agriculture for use of the pesticide DQB Males (*Wolbachia pipientis*, DQB strain, contained in live adult *Culex quinquefasciatus* males), to treat up to 20,000 acres of State, Federal, and private wildlife conservation areas throughout the State of Hawaii to control *Culex quinquefasciatus* mosquitoes, a vector of avian malaria (Docket ID EPA-HQ-OPP-2024-0035).

Hawai'i's native forest birds highlight the extraordinary biodiversity of our islands. However, these species are facing extreme threats from the spread of avian malaria transmitted by introduced invasive mosquitoes. Due to the increased temperatures as a result of climate change, these mosquitoes are now expanding into higher elevations where the birds had previously been safe from disease transmission. The expansion of mosquitoes is causing rapid declines in native forest bird populations. Our partners, through the Birds, Not Mosquitoes project, a collaboration of state, federal, private, and non-profit organizations, are currently collecting data from the initial release of the DQB Males which will help inform the EPA Section 3 registration package. Renewal of the Section 18 authorization is a critical step allowing continued implementation and data collection for conservation focused mosquito suppression. This technology has been used to control mosquito populations for the protection of public health in other parts of the United States and around the world and renewal of this proposed emergency exemption will offer our critically endangered Hawaiian forest birds a fighting chance against avian malaria, which threatens them with imminent extinction, and allows time for more permanent solutions to be pursued.

Thank you for your consideration of our strong support for the approval of the Section 18 Emergency Exemption renewal package and vital effort to protect our native birds."

Comment 0079 is a letter of support from the American Bird Conservancy. The letter reads:

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“American Bird Conservancy (ABC) strongly supports the Hawai’i Department of Agriculture’s (HDOA) renewal of the Section 18 Emergency Exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of Wolbachia pipientis DQB strain (wAlbB) contained in live adult Culex quinquefasciatus (Cq) male mosquitos to suppress wild populations of the invasive Culex mosquitos in natural areas in Hawai’i. Native Hawaiian forest birds are imperiled by the spread of avian malaria which is transmitted to the birds by these invasive wild mosquitoes.

American Bird Conservancy’s mission is to protect wild birds and their habitats. We have been active in Hawai’i for over 15 years, working to protect and restore bird populations across the state, nearly all of which are on the US Endangered Species list. We work on endangered birds across the western hemisphere and the situation in Hawai’i presents the most significant bird extinction threat we have encountered. If action is not taken quickly to suppress invasive Cq mosquitoes, several species will go extinct in the next few years and a total of 12 species are likely to follow in the coming decade or two. This is a true extinction emergency.

Wolbachia-based IIT mosquito control for human health have recently been approved by the EPA for Ae. albopictus (EPA docket number EPA-HQ-OPP-2016-0205) in California and Kentucky, Ae. aegypti (EPA EUP docket number EPA-HQ-OPP-2017-0392) in California, Texas, and Florida, with amendments to add Puerto Rico and the U.S. Virgin Islands, and Ae. polynesiensis (EPA docket number EPA-HQ-OPP-2012-0181) in American Samoa. The extensive testing and safe implementation of this technique provides a foundation and invaluable opportunity to develop a similar solution for a conservation purpose.

The Birds, Not Mosquitoes project, a collaboration of state, federal, private, and non-profit organizations, are currently collecting data from the initial release of the DQB mosquitoes on east Maui. That data will help inform the EPA Section 3 registration package. Renewal of the Section 18 authorization is a critical step allowing continued implementation and data collection for conservation focused mosquito suppression.

ABC has been a leader in the Birds, Not Mosquitoes partnership, actively engaging community leaders, elected officials, and other stakeholders; there is both broad support and strong demand that we find and implement a solution quickly to prevent the loss of these biologically and culturally important species. We are racing time to deploy this technique to protect the last mountaintop refuges for the Hawaiian honeycreepers from invasion by Cq mosquitoes. Successful application of this tool will prevent the extinction of multiple species.”

EPA response to Comments 0046, 0050, 0077, and 0079 – EPA acknowledges the comments in support of the renewal request to authorize the emergency exemption for use of DQB Males.

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EPA has taken these comments into consideration in its deliberations on whether to authorize this renewal request for an emergency exemption under FIFRA Section 18. For this emergency exemption renewal request, EPA conducted a Human Health Risk Assessment and an Environmental Risk Assessment including a Biological Evaluation to determine effects for Federally Listed Endangered and Threatened Species and Designated Critical Habitats to evaluate the use of DQB males in Hawaii. In the Biological evaluation, EPA made May Affect but Not Likely to Adversely Affect (NLAA) determinations for 24 listed species, with effects expected to be wholly beneficial. All species for which NLAA determinations are made are under the authority of the US Fish and Wildlife Service (FWS). Based on these conclusions, EPA informally consulted with FWS pursuant to Section 7 of the Endangered Species Act (ESA) 16 U.S.C. § 1536 on those species and critical habitats with NLAA determinations.

In 40 CFR 166.2(a)(2)(i) and 40 CFR 166.2(a)(2)(ii), it states that the Agency may consider a specific exemption under Section 18 of FIFRA “to avert significant risks to endangered and threatened species.” Under this definition, in 40 CFR 166.3, an “emergency condition” is deemed to exist when: 1) no registered and effective pesticides (conventional and biopesticides) are available to adequately address the conditions of the emergency; 2) there are no economically or environmentally feasible alternative management practices (e.g., non-pesticidal controls) available to adequately address the conditions of the emergency; and 3) the situation will present significant risks to threatened or endangered species. In EPA’s initial analysis of the emergency condition, the Agency determined that the transmission of avian malaria by *Cx. quinquefasciatus* mosquitoes within populations of endangered honeycreeper bird species in the state of Hawaii constitutes an emergency situation. EPA found that 1) *Cx. quinquefasciatus* and avian malaria are significant risks to at least 11 federally listed honeycreeper species, 2) current registered mosquito control options are inadequate or inappropriate to suppress populations of *Cx. quinquefasciatus* and avian malaria below levels that threaten these bird species, and 3) the urgent and non-routine situation is likely to remain in effect, beyond a year, unless *Cx. quinquefasciatus* and/or avian malaria are controlled or continuously suppressed at a landscape-level. Therefore, the Agency is relying on the initial analysis by the Biological and Economic Analysis Division to satisfy the criteria for an emergency condition as the previously submitted information remains accurate.

The proposed use rates and application methods remain the same as the initial authorized use. The efficacy determination from last year’s assessment of the emergency exemption (23HI01) applies to this renewal request.

The Agency concluded that the submitted application supports the continued use of DQB males in Hawaii to address the threat of avian malaria on Hawaii forest birds. These review documents can be found in the public docket established for this action (EPA-HQ-OPP-2024-0035).

The review documents consist of:

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- An evaluation of whether EPA's approval of the submitted application may affect Federally listed threatened and endangered species and their designated critical habitats, titled "Biological Evaluation for Section 18 Specific Exemption Renewal Request for the use of DQB males (*Wolbachia pipiens* wAlbB, contained in live adult *Culex quinquefasciatus* males) in conservation areas throughout the State of Hawaii: Effects Determination for Federally Listed Endangered and Threatened Species and Designated Critical Habitats."
- A human health risk assessment titled "*Wolbachia* DQB strain (wAlbB) in *Culex quinquefasciatus* (DQB Males): Human Health Risk Assessment for the Section 18 Specific Emergency Exemption Renewal Request for DQB Male Use to Suppress *Culex quinquefasciatus* mosquitoes in Hawaii."
- An Agency analysis that determined emergency conditions exist titled "Review of Hawai'i Department of Agriculture's Specific Emergency Exemption Request (23-HI-01) to Release *Wolbachia pipiens* strain KLP-Infected *Culex quinquefasciatus* Mosquitoes to Suppress Populations of *Cx. quinquefasciatus* Vectoring Avian Malaria to Federally Listed Bird Species."
- An efficacy review titled "Efficacy assessment for use of DQB males in Hawaii under a Section 18 specific exemption."

3.2 One comment express support for the use of DQB Males under the condition that the frequency of releases be increased to three times a week. Comment 0042 states:

"Concern about Frequency of Releases

New information on longevity of the DQB males is presented in the Request for Renewal that warrants increasing the frequency of release on the current label. The Request for Renewal says "healthy released males" have a "minimum 2 days median longevity of males at point of release." (Further noting that "the lab longevity of *Cx. quinquefasciatus* is lower than *Aedes aegypti*.") The current label specifies an application rate as follows: 'Releases of male mosquitoes are to be performed at least once per week at a release rate adequate to maintain an overflooding ratio of DQB:Wild type male *Cx. q* > 10:1 or, in the absence of trapping data, a minimum of 150 males/acre/week.' Given the 2 days median longevity of DQB males, allowing a release of "at least once per week" is not enough to maintain overflooding pressure. In other words, releasing all your males on Monday is not going to lead to overflooding on Wednesday through Sunday because most of your males will be dead. Overflooding pressure must be consistent or else the program is ineffective.

Snod and Vorsino cite the study by Beebe et al 2021 as an example of how to achieve a strong suppression with ~10:1 overflooding ratio (See Attachment B: Estimated minimum effective treatment rate estimate for Hawaii DQB males). Beebe et al achieved these rates by conducting releases, not once a week, but 3 times a week. Given the short lifespan of the DQB male mosquitoes, the Maui project will be unable to

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demonstrate success in suppressing the mosquito population unless the frequency of releases is at least 3 times a week.

Here is a pertinent excerpt from Beebe et al 2021.

‘Males were delivered to the treatment sites on Monday, Wednesday, and Friday mornings each week. The frequency of releases was used to maintain overflooding pressure in light of the short lifespan of male *Ae. aegypti* in the field - estimated at an average lifespan of 1.6 or 1 to 3 days as observed through our own mark-release-recapture studies and other studies.’

We [rely] upon the EPA to make sure the application rate in the label is effective. Increase the releases to thrice weekly on the label to ensure compliance and product effectiveness.”

EPA response to 3.2 - EPA reviewed the application and confirms that the label rate allows for “up to three releases per week” to achieve and maintain the overflooding ratio, as suggested by Comment 0042.

4. Comments in opposition of authorizing the renewal request for emergency exemption

Eighty comments oppose EPA authorizing the emergency exemption renewal request submitted by the Hawaii Department of Agriculture. Comments offered in opposition covered a range of topics. A number of comments were generic in nature, offering no substantive explanation for opposition, and not enough information for the Agency to formulate a response. Several comments contained the same content; the section below summarizes the points offered by the commenters and consolidates the Agency responses to address the main concerns identified.

[Comments 0013, 0014, 0015, 0016, 0017, 0018, 0019, 0020, 0021, 0022, 0023, 0024, 0025, 0026, 0027, 0028, 0029, 0030, 0031, 0032, 0033, 0034, 0035, 0036, 0037, 0038, 0039, 0040, 0041, 0043, 0045, 0047, 0048, 0049, 0051, 0052, 0053, 0054, 0055, 0056, 0057, 0058, 0059, 0060, 0061, 0062, 0063, 0064, 0065, 0066, 0067, 0068, 0069, 0070, 0071, 0072, 0073, 0074, 0075, 0076, 0078, 0080, 0081, 0082, 0083, 0084, 0085, 0086, 0087, 0088, 0089, 0090, 0091, 0092, 0093, 0094, 0095, 0096, 0097, 0099]

4.1 Concerns that DQB males will carry and transmit West Nile virus, elephantiasis, encephalitis, or potentially Zika virus to humans were offered. [Comments 0022, 0025, 0030, 0032, 0033, 0040, 0052, 0067, 0076, 0080, 0081, 0082, 0083, 0084, 0085, 0086, 0087, 0088, 0089, 0090, 0091, 0092, 0093, 0094, 0095, 0096, 0097]

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EPA response to 4.1 – The EPA rigorously reviewed the data and information submitted to the Agency in support of the emergency exemption renewal request. The details of the human health risk assessment can be found in the document titled “*Wolbachia* DQB strain (wAlbB) in *Culex quinquefasciatus* (DQB Males): Human Health Risk Assessment for the Section 18 Specific Emergency Exemption Renewal Request for DQB Male Use to Suppress *Culex quinquefasciatus* mosquitoes in Hawaii”. This document can be found in the docket established for this action (EPA-HQ-OPP-2024-0035). The human health risk assessment refers back to the previously conducted risk assessment for DQB Males. This document can be found in the public docket, EPA-HQ-OPP-2022-0896, titled “*Wolbachia* DQB strain (wAlbB) in *Culex quinquefasciatus* (DQB Males): Human Health Risk Assessment for a Section 18 Specific Emergency Exemption Request for Use to Suppress *Culex quinquefasciatus* mosquitoes in Hawaii.”

In the previous risk assessment for the initial Section 18 request, the EPA made a determination that releases of DQB Male mosquitoes would not result in adverse effects for humans as a result of the approved emergency exemption (USEPA, 2023). This decision was based on several key factors which were:

- Humans have a history of safe exposure to the *Wolbachia* wAlbB strain. This strain naturally occurs in both female and male *Ae. albopictus* and, as *Ae. albopictus* is found in many parts of the world (including Hawai’i). Humans have likely been exposed to this strain of *Wolbachia* through female mosquitoes.
- As an invertebrate endosymbiont, *Wolbachia* has not been reported to infect mammals.
- The wAlbB strain is not considered toxic or pathogenic to humans.
- Exposure of the wAlbB strain to humans could conceivably occur through a mosquito bite. Since male mosquitoes do not bite humans, DQB Males cannot expose humans to either wAlbB or mosquito-borne pathogens.
- Releases are to occur on federal, state, and private conservation areas with minimal human habitation.
- The manufacturing process describes adequate quality control procedures, such as those that ensure the efficacy of the gender separation process and those testing for the presence of mosquito-borne pathogens.

Based on the above factors and additional analyses discussed in the Agency’s human health risk assessment, the EPA has determined that the information submitted for the current request continues to support the human health risk conclusion previously made for the original emergency exemption for DQB Males, i.e., that there is no adverse effect from DQB Males to human health, as neither a relevant human health hazard nor significant exposure was identified.

Important to the comment regarding concerns over pathogen transmission it is first important to note that only male mosquitoes (who do not bite humans and thus cannot

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transmit any pathogens) are to be released in the environment. As discussed in 4.2, the gender separation process that removes any female mosquitoes from the DQB Males release batches results in an exceedingly small number of plausible females (1 female : 70,000,000 males). For context, 156 million DQB Males are the maximum allowable amount to be released throughout the duration of the Section 18. That means that only about 2 females could theoretically be released during that time. Nevertheless, to account for the exceedingly small possibility of females being released that, in addition, are infected with pathogens, Verily has specific quality control procedures integrated into the manufacturing process of the DQB Males. The agency has previously reviewed these procedures, which are followed for each released batch of DQB Males, and found that they ensure the absence of any pathogens for which *Cx. quinquefasciatus* is a known vector. Details of this assessment were not provided in the human health risk assessment for the original Section 18 request or the risk assessment of the renewal as these details have been claimed as confidential business information.

- 4.2 Commenters offered concerns about the inadvertent release of female mosquitoes into the natural environment. The commenters assert that there is potential risk associated with the accidental release of female mosquitoes that bite humans which may transmit mosquito-borne diseases. [Comments 0025, 0030, 0032, 0033, 0040, 0052]

EPA response to 4.2 – The application of DQB Males proposes to only release male *Cx. quinquefasciatus* mosquitoes, which only feed on nectar and do not seek out blood meals. Male mosquitoes do not bite humans and therefore DQB Males cannot expose humans to either wAlbB or mosquito-borne pathogens. Adequate quality control procedures to ensure that female mosquitoes are not released into the action area are outlined in the manufacturing process submitted to the Agency. The EPA has previously established a maximum allowable contamination rate of 1 female per 250,000 males to result in negligible levels of exposure. The manufacturing process of DQB males indicates that the female contamination rate is expected to be significantly lower, i.e., less than 1 female per 250,000 males (more specifically, approximately 1 female : 70,000,000 males)

Upon Agency review, the renewal request for the use of DQB males is authorized for up to one year, with monitoring requirements imposed by the EPA. As a result of this monitoring, cessation of releases within 3km of the positive site must occur if $\geq 10\%$ of *Cx. quinquefasciatus* eggs or larvae sampled from a site are confirmed positive for wAlbB in two consecutive visits. Releases may resume if an additional sterilization method is used (i.e., irradiation of DQB Males) or once $< 10\%$ of *Cx. quinquefasciatus* eggs or larvae are positive for wAlbB during subsequent monitoring.

- 4.3 Several comments asserted that *Wolbachia* can enhance pathogen infection in mosquitoes, stating “Peer-reviewed studies have shown *Wolbachia* bacteria in mosquitoes to cause

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increased pathogen infection and to cause mosquitoes to become more capable of spreading diseases such as avian malaria and West Nile virus. West Nile virus can infect birds and humans. This project has the potential to cause the extinction of endangered native birds, and it could impact human health.” The comments also state that “pathogen screenings for these lab-altered mosquitoes are unknown, and that information is being withheld from the public.”

[Comments 0013, 0025, 0030, 0032, 0033, 0040, 0052, 0067, 0076, 0080, 0081, 0082, 0083, 0084, 0085, 0086, 0087, 0088, 0089, 0090, 0091, 0092, 0093, 0094, 0095, 0096, 0097]

EPA response to 4.3 – The symbiotic relationship of *Wolbachia* and its host is species-specific, and varying factors (e.g., arthropod host species, strain of *Wolbachia*) contribute to the effects (e.g., disrupted host reproduction, enhanced pathogen infection) of the bacterium to the host. There is no current published study of enhanced pathogen infection in *Cx. quinquefasciatus* transfected with *Wolbachia*, wAlbB strain, which is the mosquito-*Wolbachia* combination of DQB males. The findings of a recent preprint indicate that wAlbB-infected *Cx. quinquefasciatus* do not have enhanced vector competence for Hawaiian avian malaria (*Plasmodium relictum* GRW4) relative to wild type wPip-infected females (Kilpatrick et al., 2024). Further, as discussed in EPA’s response to comments 4.1 and 4.2 above, only female mosquitoes can transmit pathogens (because only females bite) and the manufacturing process for the DQB Males has quality control procedures in place that limit both the number of potential females in the release batches and ensures the absence of any pathogens that are known to be vectored by *Cx. quinquefasciatus* in the DQB Males. Spread of the bacterium in *Cx. quinquefasciatus* populations is severely limited by the inability of the male mosquitoes to pass the *Wolbachia* bacterium to their offspring (*Wolbachia* is maternally inherited) and to produce viable offspring with wild-type females (due to cytoplasmic incompatibility). For additional discussion regarding the likelihood for establishment of the DQB strain in the environment, see EPA’s response to comment to 4.4.

The DQB Males manufacturing process reviewed by the Agency provided adequate quality control procedures, including testing for relevant pathogens prior to the release of DQB male mosquitoes. As previously mentioned, the EPA determined that for the use of DQB Males, neither a relevant human health hazard, nor significant exposures were identified, which resulted in the overall risk assessment conclusion of no unreasonable adverse effects to humans from the proposed emergency exemption to release DQB Males. The Biological Evaluation and the Human Health Risk Assessment, which includes a review of the manufacturing process, are available to the public and can be found in the docket established for this action (EPA-HQ-OPP-2024-0035).

4.4 Commenters offered concerns about horizontal transmission of introduced bacteria, stating that “the evidence of horizontal spread of *Wolbachia* bacteria (documented in peer-

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reviewed studies) shows that the bacteria go not only to sexual cells, but also to somatic cells (nonsexual cells of the body). *Wolbachia* can also live outside of intra-cellular systems for several months. Horizontal transmission of the *Wolbachia* bacteria can occur through mating, shared feeding sites, and serial predation of larva in standing water breeding sites. Studies that downplay the possibility of horizontal transmission based on *aedes aegypti* mosquitoes are flawed references because *aedes aegypti* are resistant to *Wolbachia*.”

The comments also state that “These lab-altered southern house mosquitoes, and the *Wolbachia* bacteria they’re infected with, are life forms, and there is no way for this experimental project to be self-contained. The release of these mosquitoes could cause the extinction of endangered native birds, and it may impact human health. With new life forms coming to the islands, there is too much potential for unexpected, dangerous, irreversible ‘evolutionary’ events. This is especially true when the new organisms cannot be contained to their target ecosystem”.

[Comments 0013, 0025, 0030, 0032, 0033, 0040, 0052, 0054, 0069, 0070, 0071, 0074, 0076, 0080, 0081, 0082, 0083, 0084, 0085, 0086, 0087, 0088, 0089, 0090, 0091, 0092, 0093, 0094, 0095, 0096, 0097]

EPA response to 4.4 – For this emergency exemption renewal request, the EPA conducted a Biological Evaluation to evaluate the direct and indirect effects of the continued use of DQB Males to the environment. The details of the biological evaluation can be found in the “Biological Evaluation for Section 18 Specific Exemption Renewal Request for the use of DBQ males (*Wolbachia pipientis* wAlbB, contained in live adult *Culex quinquefasciatus* males) in conservation areas throughout the State of Hawaii: Effects Determination for Federally Listed Endangered and Threatened Species and Designated Critical Habitats.” review document. This document can be found in the docket established for this action (EPA-HQ-OPP-2024-0035).

EPA concluded that there are no hazards identified from the use of DQB Males, and no adverse effects are anticipated to federally listed species or their critical habitats with respect to consumption of wAlbB. EPA also concluded that there is negligible likelihood of horizontal transmission of wAlbB (i.e., movement of wAlbB to another species).

As *Wolbachia* is maternally inherited, it is possible for incidental female release to result in vertical transmission of *Wolbachia* in the environment; however, EPA has deemed the maximum allowable level of female contamination to result in negligible levels of exposure (US EPA, 2017a). This finding is consistent with modeling indicating a very low probability (< 0.01) of establishment with a female contamination probability of 0.000001 (Pagendam et al, 2020). Additionally, while 1 female per 250,000 males is EPA’s maximum allowable female contamination rate, a review of the manufacturing process associated with the human health risk assessment for this action indicates that it is expected to be significantly

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lower, approximately 1 female: 70,000,000 males. Whether exposure to wAlbB occurs from a released DQB Male or an established mosquito, the conclusions that no discernible effects are anticipated for nontarget organisms from the consumption of wAlbB and a negligible likelihood of transmission of wAlbB from *Cx. quinquefasciatus* to any other insect species, do not change and are equally applicable.

Further, it should be noted that *Ae. aegypti* are not “resistant” to infection with *Wolbachia*, as this species has been successfully infected with *Wolbachia* under laboratory conditions and studies have identified *Ae. aegypti* with naturally occurring *Wolbachia* infections (Ross et al., 2020). As such, the use of studies referencing *Ae. aegypti* remain valid for the purposes of human health and ecological risk assessment.

EPA is also aware of a preprint study which used a different mosquito species in an urban environment in Singapore and found transient establishment of *Wolbachia* in the nearly eliminated wild population from low levels of inadvertent female release (The Project *Wolbachia* – Singapore Consortium, 2021 preprint). EPA therefore evaluated the likelihood of establishment. Modeling, laboratory, and field studies indicate that in order for *Wolbachia* to establish in a population, a population prevalence threshold of 20-30% must be met (Hoffmann et al., 2011; Hoffmann et al., 2014; Jiggins 2017; Turelli et al., 2017). *Wolbachia*-infected females suffer a fitness cost due to a reduction in their fecundity (Almeida et al., 2011) and if *Wolbachia* prevalence stays below the 20-30% threshold, the infection is expected to be naturally selected against and lost from the population. The very low maximum allowable female contamination rate for DQB Male releases coupled with the use of population monitoring and cessation of releases if wAlbB prevalence reaches a conservative threshold (e.g., 10%) would result in a low likelihood of establishment of the wAlbB strain. As an additional risk mitigation measure, EPA is requiring monitoring for the presence of *Wolbachia* (wAlbB) in *Cx. quinquefasciatus* populations for the duration of the authorized period of use. As a result of this monitoring, cessation of releases within 3 km of the positive site must occur if $\geq 10\%$ of *Cx. quinquefasciatus* eggs or larvae sampled from a site are confirmed positive for wAlbB in two consecutive visits. Releases may resume if an additional sterilization method is used or once $< 10\%$ of *Cx. quinquefasciatus* eggs or larvae are positive for wAlbB during subsequent monthly monitoring. Once no wAlbB-infected *Cx. quinquefasciatus* eggs or larvae are detected at the positive site during monthly monitoring, or if unable to collect any samples after three consecutive monthly monitoring events, then quarterly monitoring may resume.

Although the likelihood of establishment is low, EPA also evaluated the potential risk to nontarget organisms should the wAlbB strain establish should establishment of the wAlbB strain occur. No direct hazard is associated with exposure to the wAlbB strain, but establishment of the wAlbB strain would result in reduced efficacy of DQB Males and the potential for increased dermal exposure to wAlbB infected female mosquitoes. The March 2023 Biological Evaluation noted uncertainty related to the potential indirect hazard of

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disease transmission should establishment of the wAlbB strain occur, as *Wolbachia* infection in mosquitoes has the potential to impact disease transmission capabilities (Bourtzis et al., 2014; Dutra et al., 2016) with different effects on transmission found with various *Wolbachia* strain/mosquito species/pathogen combinations; however, a recent preprint found that wAlbB-infected *Cx. quinquefasciatus* females do not have increased vector competence relative to wild type wPip-infected females (Kilpatrick et al., 2024). Therefore, the potential establishment of the wAlbB strain would not impact transmission rates of avian malaria in Hawaii and therefore is unlikely to present a hazard.

Regarding the ability of *Wolbachia* to survive outside the host, *Wolbachia* are a known obligate intracellular organism, specifically within arthropod hosts. *Wolbachia* are not pathogenic to humans and have also never been identified in mammals, birds, fish, or reptiles (Anderson and Karr, 2001; Dunning Hotopp et al., 2008; Araújo et al., 2022). There have been no publications indicating that the bacterium can survive outside its host and only limited studies are available that show that the bacterium can be cultured for a short period of time under controlled laboratory conditions. In one instance, *Wolbachia* were isolated in the laboratory and held in a high aminoacid environment for 1 week, with no replication of the bacteria observed (Rasgon et al., 2006). In another instance, infection and maintenance of an *in vitro* murine cell line with *Wolbachia* was observed (Noda et al., 2002). The infected cell line was required to be maintained below human body temperature (28°C) and remains the only documented observation of successful artificial infection of mammalian cells with *Wolbachia* to date (Masson and Lemaitre, 2020). Because of the conditions required, the results from these studies are unlikely to be relevant to human health. The commenter has not provided any evidence indicating survival of *Wolbachia* outside its host environment.

4.5 Comment 0013 states the following:

“The math model for this project does not seem to account for choke points. If only a certain number of larvae from compatible mosquitoes will survive due to availability of, say, food sources in standing water breeding sites, then any reduction in viable offspring due to incompatibility may not significantly affect the number of surviving larvae. The viable larvae will compete for microbes to eat, and only a specific number of larvae will have enough food to survive (rate determining step). That number may remain relatively constant based on volume of food-source microbes, and the non-viable offspring of incompatible mosquitoes may have no effect, or limited effect, on the survival rate of larvae in the breeding site overall.

Determination of efficacy of the biopesticide might be based on a flawed set up of the math model. The question is, do things affecting a population occur in sequence or in parallel; and if we treat them like resistors on an electrical circuit, isn't the rate limiting step like a capacitor somewhere in the circuitry? A very restrictive rate limiting step such as the paucity of microbial food in breeding water severely limiting the number of larvae reaching the

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adult stage would cause the reproduction/sterility interventions to be ineffective. Even if the proportions of X infected male mosquitoes released were increased, there would be very little impact.”

EPA response to 4.5 – The EPA believes the commenter is referring to a general phenomenon known as competitive release, whereby the removal of a species (or in the case of DQB Males, the reduction in competing larvae due to inviable matings) facilitates the survival of other species/individuals. In this specific case, the commenter has suggested that the overall population size of *Cx. quinquefasciatus* mosquitoes may remain constant despite the non-viable eggs from the matings between DQB males and wild-type females because the eggs/larvae produced by the matings of wild-type mosquitoes would have a higher likelihood of surviving to adulthood due to reduced intraspecific competition of resources. The EPA acknowledges the concern of the commenter; however, the EPA notes that measurements of efficacy are typically based on the size of the adult population of the mosquito (the life stage responsible for disease transmission) subsequent to release, thus any potential confounding factors (including competitive release) based on the immature life stages (i.e., eggs or larvae) would be accounted for in efficacy evaluations.

4.6 Comment 0013 states “Mosquitoes and other insects can be infected with more than one strain of *Wolbachia* bacteria at the same time. This is called ‘superinfection.’ *Culex q.* mosquitoes are very susceptible to many strains of *Wolbachia*. Superinfection in *Culex q.* has not been studied for this project. Superinfection could affect cytoplasmic incompatibility, horizontal transmission, evolutionary events, and population replacement.” The comment cites the article “*Wolbachia* transinfections in *Culex quinquefasciatus* generate cytoplasmic incompatibility”
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7027843/>

EPA response to 4.6 –Superinfection has not been proposed for the DQB Males product. The released DQB Males (*Culex q.*) will be infected with only the *Wolbachia* wAlbB strain and will not contain additional *Wolbachia* strains. The commenter did not provide enough information regarding the circumstances which would result in *Wolbachia* “superinfection” of mosquitoes in the wild, particularly *Cx. quinquefasciatus*. As it pertains to *Cx. quinquefasciatus*, samples collected from the field are often infected with only a single strain of *Wolbachia* (Atkinson et al 2016; da Moura et al 2023; Goindin et al 2018). As mentioned above, in the case of DQB Males, *Cx. quinquefasciatus* males are only infected with the *Wolbachia* wAlbB strain in the laboratory, under controlled conditions. The manufacturing process for DQB Males has been previously reviewed by EPA and found to contain adequate quality assurance measures (EPA-HQ-OPP-2024-0035). To add to this, in the preprint mentioned above in EPA’s response in Section 4.3, when *Cx. quinquefasciatus* infected with wAlbB are crossed with *Cx. quinquefasciatus* females infected with wPip, the females do not produce viable offspring (Kilpatrick et al., 2024).

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Further, regarding the scientific article cited in the comment, “superinfection” of *Cx. quinquefasciatus* was established under controlled laboratory conditions which resulted in a *Cx. quinquefasciatus* line infected with both *wPip* (*Wolbachia* strain native to *Cx. quinquefasciatus*) and *wAlbA* (*Wolbachia* strain commonly found in *Aedes aegypti*). This study found that *Cx. quinquefasciatus* males carrying both *Wolbachia* strains (i.e., the “superinfected” mosquito line) resulted in fully penetrant cytoplasmic incompatibility when crossed with wild type *Cx. quinquefasciatus* females.

Therefore, considering that superinfection of *Cx. quinquefasciatus* in the wild has not been documented, DQB Males are infected with a single strain of *Wolbachia* (*wAlbB*), *wAlbB*-infected *Cx. quinquefasciatus* males mated with *wPip*-infected *Cx. quinquefasciatus* females do not produce viable offspring, and that *Wolbachia* is a maternally inherited symbiont, it remains unlikely that DQB Males would encounter or result in a superinfection scenario.

4.7 Comment 0013 also states that “Alternative approaches to mitigating avian malaria have not been considered, including treatment of avian malaria in the mosquito phase through antimalarial drug feeding (i.e., primaquine and ivermectin) in rabbits and/or battery-powered warm artificial blood packs containing the antimalarial drugs. The range of blood-feeding females is a lot wider than extrapolated from sugar feedings of males.”

EPA response to 4.7 – The EPA supports the development and use of other mosquito control methods as part of an integrated pest management program. The EPA analyzed the current state of control options and found that current registered mosquito control options, including conventional and biopesticides, as well as non-pesticidal control methods, are inadequate or infeasible to suppress populations of *Cx. quinquefasciatus* and avian malaria below levels that threaten federally listed species. The analysis conducted by the Biological and Economic Analysis Division can be found in the docket established for this action (EPA-HQ-OPP-2024-0035) titled “Review of Hawai‘i Department of Agriculture’s Specific Emergency Exemption Request to Release *Wolbachia pipientis* strain KLP-Infected *Culex quinquefasciatus* Mosquitoes to Suppress Populations of *Cx. quinquefasciatus* Vectoring Avian Malaria to Federally Listed Bird Species.”

4.8 Comment 0013 asserts that “The final EA for the action failed to address biopesticide wind drift – the movement of biopesticide mosquitoes through wind to unintended areas. Mosquitoes carried on the wind into and out of the release sites of the project area have not been factored into the math model or the overall plan.”

EPA response to 4.8 – As EPA stated in its March 2023 biological evaluation, EPA conservatively included the entire state of Hawaii in the action area (the area included in the evaluation). In the biological evaluation for the renewal, EPA again considered the entire state of Hawaii to be the action area. As Hawaii is a geographically isolated island chain, there is a negligible likelihood that DQB Males would leave the action area. The use of DQB

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Males is a targeted approach to suppress *Cx. quinquefasciatus* populations in the action area. The biological evaluation did not identify any risks of concern and determined that no discernible effects are anticipated for nontarget organisms. EPA concludes that there are no risks of concern associated with the release of DQB Males to human health and the environment in the action area.

- 4.9 Several commenters opposed the release of “genetically-modified”, or “genetically-engineered” mosquitoes. [Comments 0018, 0036, 0064, 0065]

EPA response to 4.9 – The DQB males product consists of *Cx. quinquefasciatus* male mosquitoes which have been infected with *Wolbachia pipientis*, wAlbB strain. The *Wolbachia* strain was not created using genetic modification and the mosquitoes are not genetically modified organisms.

- 4.10 Several comments asserted that the use of DQB males in Hawaii is an “experiment” and that the commenters do not consent to the release of DQB male mosquitoes. [Comments 0027, 0039, 0053, 0069, 0070, 0071, 0078]

Comment 0027 states “This mosquito experiment needs to be ended immediately because it is not working. We live in Hana Hawaii and now have 100's more mosquitoes than we've ever had before - and yes, they do bite. Dropping these mosquitoes and parasites over our watershed is anything but safe. We are already infested with rat lungworm disease from plants imported from China - we don't need more parasites to contend with. East Maui is a tropical jungle - not a place to "experiment" with an unproven test. We are not test rats. This is a popular tourist destination and longtime residents. Dropping these tainted mosquitoes is a crime against humanity and anyone in government that allows such actions, along with companies and agencies serving under the color of government are and should individually be subject to a Title 42 § 1983 lawsuit - with loads of discovery.”

Comment 0039 asserts that “This is a very dangerous untested and no consent live experiment putting the eco system of Hawaii and its inhabitants at severe risk. No consent was given from the public. Expert testimony to stop this reckless experiment was provided in court. There’s no emergency as prerequisite for renewal.”

Comment 0069 states that “these mosquitoes are an experiment with unknown outcome that could harm the health of the people, wildlife, and ecosystems of Hawai’i. This is a National Security issue and a trespass against non-consenting citizens.”. [Comments 0069, 0070, 0071 are triplicate copies]

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EPA response to 4.10 – In response to comments suggesting that the use of DQB males is an experiment on the people of Hawaii and informed consent is required, the EPA does not find that the use of DQB males under this emergency exemption meets the regulatory definition of research involving human subjects under the applicable regulatory standard, 40 CFR 26, Subparts K-L. Because the research does not include “human subjects” as defined in the regulation, the threshold of “research involving intentional exposure of human subjects” is not met, and therefore the requirements of EPA’s human studies rule do not apply to the proposed continued use of DQB males in Hawaii.

The Hawaii Department of Agriculture and Verily Life Sciences plan to collect data during the period of use of DQB Males, with the intention of submitting the results to EPA in support of a pesticide registration decision. For collecting data, the relevant standards are found in EPA’s Rule for the Protection of Human Subjects of Research (40 CFR 26, Subparts K-L). This regulation is based on the federal Common Rule and consistent with the Nuremberg Code (*see* 70 FR 53838, 53858-9; September 12, 2005). Subpart K requires that study sponsors conducting research involving intentional exposure of human subjects to any substance with the intention of submitting the results to EPA comply with protections for human subjects. These protections include obtaining informed consent of subjects, balancing risks and benefits of the research, and obtaining review of the proposed study by an independent institutional review board prior to initiating research. Subpart L prohibits conducting research subject to Subpart K if it involves pregnant or nursing women, or children.

Under 40 CFR §26.1102(l), “research involving intentional exposure of a human subject means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject’s participation in the study.” There are three elements to this definition that all must be satisfied for the research to be subject to the requirements of 40 CFR 26, Subparts K-L:

1. Research. According to the rule, “*Research* means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this subpart, whether or not they are considered research for other purposes. For example, some demonstration and service programs may include research activities.”
2. Human subjects. “Human subject” is defined as “a living individual about whom an investigator (whether professional or student) conducting research:
 - (i) Obtains information or biospecimens through intervention or interaction with the individual, or analyzes the information or biospecimens, or
 - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens.”

Further, as part of the definition of “human subject”, the regulation specifies that:

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“Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

“Interaction includes communication between investigator and subject.

“Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record).

“Identifiable private information is private information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.” (40 CFR 26.1102(2)-(6))

3. Intentional exposure. If it was research involving human subjects, did the research involve study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject’s participation in the study?

The use of DQB males in Hawaii meets the definition of research. The applicant is releasing the mosquitoes to gather information in a systematic manner to contribute to the generalizable knowledge on the impact of releasing *Wolbachia*-infected mosquitoes on the local mosquito population.

Moving to the second element of the definition of “research involving intentional exposure of human subjects”, the research does not involve “human subjects” as defined by the regulation. Verily proposes to collect information on how efficacious releases of DQB Males are at suppressing wild *Cx. quinquefasciatus* mosquito populations in the action area. Verily will collect adult and immature mosquito counts from traps placed in forest areas along with the trap coordinates, release numbers and release coordinates. Verily is not proposing to collect any information about individuals in the area of the release or to monitor behavior of individuals. Verily also is not proposing to gather identifiable private information about or identifiable biospecimens from anyone in conjunction with the release or to monitor the efficacy of releasing wild males. None of the information that Verily proposes to gather in the course of this research involving the release of DQB Males involves data about a living individual gathered through interaction with the individual or collecting identifiable private information about or identifiable biospecimens from those who may be present in the area of the release of the DQB Males. Therefore, the research involved with Verily’s release of mosquitoes does not meet the regulatory definition of research involving human subjects. Because the proposed information to be collected as part of this research does not involve human subjects, it is not necessary to evaluate whether the research would constitute intentional exposure of human subjects.

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Because the research does not meet the definition of “research involving intentional exposure of a human subject”, it is not subject to the requirements of 40 CFR 26, Subparts K-L. This means that Verily is not required under EPA’s human studies rule to obtain informed consent of those living in the areas where the DQB Males would be released.

- 4.11 Comment 0053 offered a testimony document titled “Testimony: Oppose Exemption: DQB Males (*Wolbachia pipientis*, DQB Strain, Contained in Live Adult *Culex quinquefasciatus* Males)” which can be found in the public docket, EPA-HQ-OPP-2024-0035 <https://www.regulations.gov/comment/EPA-HQ-OPP-2024-0035-0053>

EPA response to 4.11 – This comment raises the same concerns detailed in this document, as well as the “Response to comment” document from the previously authorized emergency exemption (EE23HI01). The EE23HI01 “Response to comment” document from the previously authorized emergency exemption can be found in the public docket, EPA-HQ-OPP-2022-0896.

- 4.12 Comment 0098 is an anonymous public comment that provided background information regarding the consultation process between the National Park Service, the US Fish and Wildlife Service (USFWS), and EPA. The comment states that “The EPA is legally required to conduct its own Section 7 consultation process with the USFWS and it is not supposed to rely on a previous Section 7 determination since the action has been subsequently modified in a way that effects listed species and critical habitat that was not considered in the initial written concurrence. The EPA is supposed to reinitiate the Section 7 consultation process.” The comment can be found in the public docket, EPA-HQ-OPP-2024-0035 <https://www.regulations.gov/comment/EPA-HQ-OPP-2024-0035-0098>

EPA response to 4.12 – EPA reinitiated the Section 7 informal consultation process with USFWS and received concurrence for this action. EPA came to the same May Affect but Not Likely to Adversely Affect (NLAA) determination as was made with the previous emergency exemption, 23HI01.

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