Porcine Zona Pellucida (PZP)

Final Registration Review Decision
Case Number 7801

March 2024

Approved by: _____

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Date: March 12, 2024

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Final Registration Review Decision (FD) for Porcine Zona Pellucida (PZP; PC Code 176603, case 7801-2). In a registration review decision under the Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), [1] the Agency determines whether a pesticide continues to meet FIFRA's registration standard.[2] This final registration review decision addresses all aspects of the registration review, as necessary, including considerations under the Endangered Species Act (ESA) and for the Endocrine Disruptor Screening Program (EDSP) under the Federal Food, Drug and Cosmetic Act (FFDCA)[3] as amended by the Food Quality Protection Act (FQPA). For more information on PZP see EPA's public docket (EPA-HQ-OPP-2022-0153) at www.regulations.gov.

FIFRA[4] mandates the continuous review of existing pesticides. Pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review process in which EPA reviews each registered pesticide every 15 years. Through the registration review process, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and mitigate risks evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects on human health or the environment. For more information on the registration review process, see http://www.epa.gov/pesticide-reevaluation. The Agency is issuing a final decision (FD) in registration review, as required under 40 CFR 155.58.

PZP is a non-lethal immunocontraceptive registered by the Humane Society of the United States for control of wild and feral populations of horses (*Equus caballus*), burros (aka donkeys) (*Equus asinus*), white-tailed deer (*Odocoileus virginianus*) and other cervids. First registered in 2012, PZP is intended to slow down reproduction within herds and, over time, reduce the population.

Historical Context

The Registration Decision for PZP

A registration decision for PZP was issued in 2012.[5] During the decision-making process, EPA did not identify any potential ecological risks of concern. EPA also did not identify potential

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] FIFRA §§ 3(a), 2(bb), 7 U.S.C. §§ 136a(a), 136(bb).
[3] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[5] *Registration of the Contraceptive ZonaStat-H, for Population Control of Wild and Feral Horses and Burros*, June 2012, available at https://www.regulations.gov/document/EPA-HQ-OPP-2009-0800-0017

human health risks of concern. For more detail on how the potential risks and benefits were determined, see the registration decision.

Petition from Friends of Animals (FoA)

A petition was submitted by FoA on May 19, 2015. In the petition, FoA requested, among other things, that EPA conduct a Special Review[6] of PZP based on three arguments: 1) that PZP can result in residues in the environment of non-target organisms that equal or exceed concentrations that are toxic to those organisms; 2) that PZP may otherwise pose a previously undisclosed risk to the environment which is of sufficient magnitude to merit Special Review; and 3) that the use of PZP violates the Wild Free-Roaming Horses and Burros Act (WHBA). A response[7] was provided on June 14, 2023, denying the petition. A copy of this response can be found in in EPA's public docket (EPA-HQ-OPP-2022-0153). No comments were received during the public comment period.

Proposed Interim Decision for PZP

In 2022, EPA issued a proposed interim registration review decision (PID). As presented in the draft risk assessments (DRAs), the toxicity and exposure profile for PZP has not changed, therefore, the PID relied on the findings of the original registration decision and did not propose any additional risk mitigation for PZP.

Proposed Final Decision for PZP

In 2023, EPA issued a Proposed Final Registration Review Decision (PFD). As presented in the DRAs, the toxicity and exposure profile for PZP has not changed, therefore, the PFD relied on the findings of the original registration decision and did not propose any additional risk mitigation for PZP. The four comments received during the PID comment period were addressed in the PFD and no additional comments were received during the public comment period for the PFD.

Organization of this Document

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how and where PZP is used);

[6] 40 C.F.R. Part 154. For nearly three decades, the Special Review process has been largely superseded by other statutorily required reevaluation processes. In 1988, Congress created the Re-registration process, enacted in FIFRA Section 4 (7 U.S.C. § 136a1), which required reevaluation of all pesticides registered before 1984 to determine whether they still met the criteria for registration. That process concluded in 2008. Since the conclusion of Re-registration, EPA has continued to reevaluate registered pesticides through the Registration Review process of FIFRA Section 3(g), (7 U.S.C. § 136a(g)). The last time EPA initiated a Special Review was in 1994. *See* 59 Fed. Reg. 60,412 (Nov. 23, 1994).

[7] EPA's December 15, 2015, initial response to FOA's petition was vacated by the United States District Court for the District of Oregon on March 31, 2020, and was remanded to EPA for further proceedings consistent with the October 24, 2019 findings and recommendation of the Magistrate Judge. *Friends of Animals v. Pruitt*, 2:17-cv-01410-SU (D. Or. 2017).

- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Final Registration Review Decision* (presenting EPA's decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete registration review).

A. Summary of PZP Registration Review

On January 26, 2022, the Agency formally initiated registration review for PZP with the opening of the registration review docket for the case.[8] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of PZP:

- April 2022 – EPA opened the registration review docket for PZP by posting the combined Work Plan and PID in the docket for PZP for a 60-day public comment period. Along with the combined Work Plan and PID, the following documents were also posted to the PZP docket for a 60-day public comment period:
    - *Porcine Zona Pellucida (PZP): Human Health Draft Risk Assessment and Scoping Document in Support of Registration Review* (Human Health DRA) (October 6, 2021)
    - *Porcine Zona Pellucida (PZP): Combined Problem Formulation and Draft Ecological Risk Assessment, Endangered Species Effects Determination, and Drinking Water Exposure Assessment for Registration Review* (Ecological DRA) (January 31, 2022)

- September 2023 – EPA completed the PFD for PZP and made it available in the public docket for a 60-day public comment period. Along with the PFD, EPA plans to post the following documents to the public docket:
    - *Exemption of Porcine Zona Pellucida (PZP) from the Requirements of the Endocrine Disruptor Screening Program*, September 14, 2023.
    - *Petition to Conduct a Special Review of Contraceptive ZonaStat-H, EPA Reg. No. 86833-1*, June 14, 2023.

- March 2024 – EPA completed this FD for PZP and made it available in the public docket.

B. Summary of Public Comments on the Proposed Final Decision

During the 60-day public comment period for the PZP PFD (October 18, 2023, to December 18, 2023), the Agency received no comments from the public.

[8] 40 C.F.R. § 155.50

II. USE AND USAGE

PZP is a non-lethal immunocontraceptive registered for control of wild and feral populations of horses (*Equus caballus*), burros (aka donkeys) (*Equus asinus*), white-tailed deer (*Odocoileus virginianus*) and other cervids. PZP is intended to reduce reproductive capacity for the duration of the contraceptive's length of effectiveness. Over time, the reduction in fecundity, in conjunction with natural death of some herd members, may result in a population reduction. An initial dose of PZP is administered to female herd members via hand dart injection with a second dose (booster) administered at least two weeks later. In both horses/burros and deer, the contraceptive is effective for about 12 months, and herd managers can maintain PZP effectiveness by providing annual booster injections. The vaccine works by causing the target animal's immune system to create antibodies against PZP, subsequently interfering with sperm attachment to the egg.

PZP is a restricted-use pesticide and applications of PZP are limited to use by the Department of Interior and its designated agents; state departments of agriculture/livestock and wildlife, and their designated agents; Federally recognized Indian tribes, and their designated agents; the Department of Defense and its designated agents; the Humane Society of the United States appointed agents; and the United States Department of Agriculture (USDA) and its designated agents.

PZP is registered to control populations of wild and feral horses, burros, and deer capable of causing environmental damage on privately or publicly owned lands. Nationally representative usage data are not available; however, the Department of Interior Bureau of Land Management reported that an average of 557 doses of PZP were used annually from 2017 to 2021 (the last five years of available data) on Bureau of Land Management lands. The National Park Service reported usage of PZP for wild horse control on Assateague Island, Maryland. Usage data for PZP in white-tailed deer are not available.

III. SCIENTIFIC ASSESSMENTS

A. Ecological Risks

The Agency has summarized the 2022 Ecological DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of PZP. For additional details on the 2022 Ecological DRA, see *Porcine Zona Pellucida (PZP): Combined Problem Formulation and Draft Ecological Risk Assessment, Endangered Species Effects Determination, and Drinking Water Exposure Assessment for Registration Review*[9] in EPA's public docket (EPA-HQ-OPP-2022-0153). Ecological effects and environmental fate guideline studies were waived because of a limited exposure pathway to non-target organisms.

1. Risk Summary and Characterization

[9] https://www.regulations.gov/document/EPA-HQ-OPP-2022-0153-0004

The Ecological DRA concluded that because there is no expected environmental exposure pathway to non-target taxa, exposure is limited, and, therefore, there are no risks of concern to non-target organisms. PZP is administered only by direct injection into the tissues of the target animal. The active ingredient is a glycoprotein that is degraded once exposed to the environment and is too large to pass through the membranes of the digestive tract. Digestion into component amino acids and simple sugars would occur prior to absorption. Additionally, label restrictions require that spent darts be recovered, further reducing exposure. Thus, both the chemical properties and labeling for PZP make it unlikely for PZP to transfer into the food web. Therefore, there are no risks of concern for nontarget mammals, birds, reptiles, terrestrial-phase amphibians, terrestrial invertebrates (including honeybees), terrestrial plants, freshwater fish, aquatic-phase amphibians, estuarine/marine fish, freshwater invertebrates, estuarine/marine invertebrates, or aquatic vascular and non-vascular plants.

2. Endangered Species Assessment

EPA has determined that there is no reasonable expectation that any registered use of PZP causes direct or indirect effects to federally listed threatened and endangered (listed) species or designated critical habitat. This is due to the nature of PZP environmental fate properties, application method, and denaturing of the glycoprotein in the environment and animal gut. EPA does not expect direct exposure to listed species because PZP is injected directly into the target animal, leaving no direct exposure pathway to listed species of animals or plants. In the 2022 Ecological DRA, EPA considered the potential for indirect effects and determined that current uses of PZP would not result in indirect exposure to listed species. PZP is broken down in the digestive tract of any animal consuming the target species, so EPA is not concerned that there is a likelihood of exposure to apex predators or scavengers via consumption of treated animals. Therefore, EPA has made a no effect determination for all listed species and designated critical habitat under the Endangered Species Act (ESA) and has concluded that consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service under ESA § 7(a)(2) is not required.

3. Ecological Incidents

EPA reviewed PZP incidents reported to the Incident Data System (IDS). As of EPA's latest search on January 21, 2022, there are no reported incidents for PZP. The Agency intends to monitor ecological incidents for PZP and will conduct additional analyses if necessary.

4. Outstanding Ecological and Environmental Fate Data

The ecological and environmental fate database for PZP is considered complete. Pursuant to 40 C.F.R. § 158.45, EPA granted waivers for both ecological effects and environmental fate guideline studies on the basis of a limited exposure pathway to non-target organisms; accordingly, no additional ecological effects or environmental fate data are needed.

B. Human Health Risks

The Agency has summarized the 2021 Human Health DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in

support of the registration review of PZP. For additional details on the 2021 Human Health DRA, see *Porcine Zona Pellucida (PZP): Human Health Draft Risk Assessment and Scoping Document in Support of Registration Review* in EPA's public docket (EPA-HQ-OPP-2022-0153).

1. Risk Summary and Characterization

The Agency concluded that no human health data are needed for the registration review of PZP. PZP is only available to certified applicators and is delivered in a manner that limits exposure to handlers and bystanders. Toxicology data requirements for PZP were waived based on lack of toxicity to the target animal, history of safe use of the vaccine, the mode of action and fate of the product's metabolites, and lack of immunotoxicity as shown in the published scientific literature. The Agency did not identify any human health concerns.

Dietary (Food + Water) Risks

Use is restricted to feral and wild animals that are not likely to be used in food or feed and thus are not likely to result in dietary exposure. However, even if dietary exposure did occur, there would be little likelihood of human systemic exposure as PZP is a glycoprotein which is too large to pass through membranes of the digestive tract intact. Digestion into component amino acids and simple sugars in the stomach and small intestine would occur before absorption. Even if intact PZP were to be absorbed, it is weakly antigenic and requires an adjuvant to stimulate an immune response when injected.

Residential Handler, Residential Post-Application, and Bystander Risks

There are no registered residential uses of PZP. Therefore, residential exposure assessments were not conducted.

Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. The Agency sums the exposures from these sources and compares the aggregate risk to quantitative estimates of hazard. EPA considers the route and duration of exposure when assessing aggregate risks. For PZP, there are no dietary exposures and no residential uses. Therefore, an aggregate exposure assessment is not needed.

Cumulative Risks

EPA has not made a common mechanism of toxicity to humans finding for PZP and any other substance. PZP does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that PZP has a common mechanism of toxicity with other substances for this assessment.

Occupational Handler Risks

Given the limited exposure potential and lack of toxicity of PZP, the Agency did not identify any occupational handler risks of concern for PZP. Accidental self-injection is possible when handling darts and dart delivery devices and may cause temporary infertility in women. However, the likelihood of self-injection is low because PZP is a restricted use product that is only available to certified applicators who are trained in wildlife management and injection of wild animals. Darts must be recovered after delivery and must be neon orange or green to facilitate recovery. Additionally, long sleeved shirts, long pants, shoes, socks, and chemical resistant gloves are required for applicators and will further reduce the risk of accidental self-injection.

Occupational Post-Application Risks

Based on the limited exposure potential, lack of toxicity, and fate properties of PZP and its metabolites, there are no post-application risks of concern. Additionally, darts that have been shot but missed the target would have their contents discharged when striking the ground or other objects.

2. Endocrine Disruptor Screening Program

As required by the Administrator under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), the Agency has developed the Endocrine Disruptor Screening Program (EDSP) and has begun to assess what EDSP data are necessary to determine whether a pesticide may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."

Additionally, FFDCA section 408(p)(4) authorizes the Administrator, by order, to exempt from the requirements of the EDSP a biologic substance or other substance if a determination is made that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogen, androgen, or thyroid hormone substance.

In September 2023, the Administrator signed an order[10] exempting PZP from the requirements of the EDSP (U.S. EPA 2023). In that order, EPA determined that under currently registered uses, PZP is not anticipated to result in exposure that would produce an effect in humans or other organisms similar to an effect produced by a naturally occurring estrogen, androgen or thyroid hormone.

The EDSP exemption order *Exemption of Porcine Zona Pellucida (PZP) from the Requirements of the Endocrine Disruptor Screening Program* (dated September 14, 2023) is available in the PZP docket.

[10] Administrative Order Exemption of Porcine Zona Pellucida (PZP) from the Requirements of the Endocrine Disruptor Screening Program https://www.regulations.gov/document/EPA-HQ-OPP-2022-0153-0013

3. Human Incidents and Epidemiology

EPA reviewed PZP incidents reported to both the Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR). As of EPA's latest search on January 13, 2022, IDS and SENSOR showed zero incidents reported from January 1, 2016 to January 13, 2022. The Agency intends to monitor human incidents for PZP and will conduct additional analyses if necessary.

3. Tolerances

No tolerances under the FFDCA are necessary because PZP is not registered for any uses that result in residues in or on food.

4. Outstanding Human Health Data

The human health database for PZP is considered complete. The Agency does not anticipate any further data needs for PZP.

C. Benefits Assessment

Wild Horses and Burros
Wild horses and burros in the U.S. are estimated to increase in population by 18-20% per year, potentially resulting in herd population doubling every four to five years.[11] Wild horse/burro populations can exceed the lands' carrying capacity due to several factors including their federally protected status through the Wild Free-Roaming Horses and Burros Act of 1971 (which limits the culling of these animals except as determined by the Secretary of Interior), low predation pressure, and herd reproductive success.. High population densities hurt both the herds' health and the rangelands' ecology.[12]

PZP allows land managers to limit population growth, thereby minimizing the impact that overpopulation of wild horses and burros have on the land and the flora and fauna that use the land. Turner and Kirkpatrick (2002)[13] also reported that treated mares (horse/burros) were healthier and lived significantly longer than non-treated individuals. Treated mare longevity is likely due to the lack of stress associated with conception and birthing a foal.

[11] Tryon, S. 2019. Wild Horse and Burro: Long-Term Management Options for the Bureau of Land Management's Wild Horse and Burro Program. Accessed 12/2021. https://www.doi.gov/ocl/wild-horses-and-burros-0
[12] Tryon, S. 2019. Wild Horse and Burro: Long-Term Management Options for the Bureau of Land Management's Wild Horse and Burro Program. Accessed 12/2021. https://www.doi.gov/ocl/wild-horses-and-burros-0
[13] Turner, A., and J.F. Kirkpatrick (2002). Effects of Immunocontraception on Population, Longevity and Body Condition in Wild Mares. Reproduction (Supplement 60):187-195. Accessed online 12/2021. https://www.wildlifefertilitycontrol.org/wp-content/uploads/2019/02/Effects-of-immunocontraception-on-population.pdf

For horses and burros, the primary non-chemical population control alternative is removal (roundup and adoption), but this is expensive and depends on finding suitable locations to relocate the excess population.

Deer

Deer populations, when unmanaged, can double every four years[14], causing substantial environmental and economic damage. For instance, heavy browsing in forest ecosystems can compromise forest regeneration and decrease plant biodiversity. Economic damage from deer can include agricultural and homeowner losses and damage from deer-vehicle collisions.[15,16] In addition, deer ticks may carry diseases, such as Lyme disease *(Ixodes* spp.). As the deer population increases, so too do tick populations, thereby increasing the likelihood of passing the infection to a human host.[17]

PZP does not immediately reduce the deer population but effectively stabilizes a closed population at the current density during the first few years of treatment.[18] A closed population is geographically isolated from other herds by geographical features (*e.g.*, rivers), fencing, or human development that reduces the likelihood of immigration of deer from nearby herds. Only births and deaths result in population changes when migration is removed from the population equation. As birth rates decrease, so does the future herd density. Field studies reported that population stabilization in semi-open populations with limited migration ability (i.e., residential subdivisions) occurred after 2-4 years of PZP treatment, with population reductions from 6-10% in subsequent years.[19]

In open populations, PZP may not have widespread utility due to the potential for immigration of untreated deer. However, PZP does have utility for managing small, isolated deer populations, especially in suburban areas where human/deer interactions are common. Once deer populations decline, fewer deer result in fewer human/deer interactions (*e.g.*, car accidents), fewer costs to

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[14] Dewey, T. 2003. *Odocoileus virginianus*. Animal Diversity Web. A University of Michigan publication. Accessed 01/2022.
https://animaldiversity.org/accounts/Odocoileus_virginianus/#:~:text=Most%20whitetail%vcsa20deer%20(particularly%20males,as%20young%20as%20seven%20months.&text=White%2Dtailed%20deer%20breed%20once,are%20born%20in%20the%20spring.

[15] Wisconsin Division of Natural Resources. 2021. Deer Harvest and Population Trends. Accessed 01/2022.
https://dnr.wi.gov/wideermetrics/LaunchPage.aspx

[16] United States Department of Agriculture Natural Resources Conservation Service (USDA NRCS). No date. New Jersey Fact Sheet: White-tailed Deer Impacts and Forest Management. A collaborative publication along with the New Jersey Audobon Society. Accessed 01/2022.
https://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs141p2_017804.pdf

[17] Entomological Society of America. 2017. Entomology Today: Could Reducing Deer Populations Reduce Lyme Disease? Accessed 02/2022.
https://entomologytoday.org/2017/09/28/could-reducing-deer-populations-reduce-lyme-disease/

[18] Rutberg. A.T., Naugle, R.E., and F. Verret. 2013. Single-Treatment Porcine Zona Pellucida Immunocontraception Associated with Reduction of Population of White-Tailed Deer (*Odocoileus virginianus*). J Zoo Wildl Med. 44:4. Pgs. 75-83. Accessed 01/2022.
https://www.jstor.org/stable/24551159?seq=1#metadata_info_tab_contents

[19] Rutberg. A.T. 2019. Fact Sheet: PZP Immunocontraception for Deer. A Tufts University, Cummings School of Veterinary Medicine, Center for Animals and Public Policy publication. Accessed 02/2022.
https://avalonnaturepreserve.org/wp-content/uploads/2020/01/Deer-PZP-Fact-Sheet-4-19.pdf

homeowners due to landscape grazing, reduced incidence of deer in nearby agricultural fields, and reduced occurrence of zoonotic diseases passed from deer to human.[20]

Options to reduce deer damage are limited, but some chemicals may be applied to landscape/gardens as a taste deterrent (*e.g.*, thiram and capsaicin) and/or olfactory deterrent (*e.g.*, predator urine). The use of both taste and olfactory deterrents is not practical for large areas, may wash away with rain, and should not be used to protect food crops intended for human consumption. Alternative, non-chemical, deer controls include lethal methods (hunting), habitat modification, scare tactics, and physical exclusion. However, research reports that, besides lethal options, these tactics do not help control wild populations[21] and do not provide the same ecosystem protection that PZP does.

Chemical Side Effects and Contraceptive Alternative

Studies show that application of PZP does not result in abnormal herd behaviors in wild horses/burros[22, 23] but PZP does extend the estrous cycle in deer, which may cause female deer to be more active during an extended estrous cycle. However, differences in energy budgets between PZP-treated and non-treated female deer were found to be insignificant.[24] In addition, research shows that the induced activity during the prolonged estrous cycle does not result in a significant change in the number of deer/vehicle incidents.[25]

One other vaccine-formulated immunocontraceptive is available for controlling horses/burros and deer is gonadotropin releasing hormone (GnRH). The Bureau of Land Management noted that GnRH provides longer-lasting effectiveness compared to PZP; 3-4 years for GnRH compared to 1-2 years for PZP.[26, 27] Limited data available to EPA suggests that the cost of PZP

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[20] Entomological Society of America. 2017. Entomology Today: Could Reducing Deer Populations Reduce Lyme Disease? Accessed 02/2022. https://entomologytoday.org/2017/09/28/could-reducing-deer-populations-reduce-lyme-disease/

[21] United States Department of Agriculture Natural Resources Conservation Service (USDA NRCS). No date. New Jersey Fact Sheet: White-tailed Deer Impacts and Forest Management. A collaborative publication along with the New Jersey Audobon Society. Accessed 01/2022. https://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs141p2_017804.pdf

[22] Kirkpatrick, J.F. 2012. Immunocontraceptive Reproductive Control Utilizing Porcine Zona Pellucida (PZP) in Federal Wild Horse Populations. Accessed 12/2021. https://www.sccpzp.org/wp-content/uploads/PZP-QA-June-6-2012.pdf

[23] The Humane Society of the United States. No date(a). Immunocontraceptive FAQ. Accessed 02/2022. https://www.humanesociety.org/resources/immunocontraception-faq#cost

[24] McShea, W.J., Monfort, S.L., Hakim S., Kirkpatrick, J., Liu I., Turner, J.W., Chassy, L., and L. Munson. 1997. The Effect of Immunocontraception on the Behavior and Reproduction of White-Tailed Deer. Journal of Wildlife Management. 61:2. Pgs. 560-569. Accessed online 02/2022. https://www.jstor.org/stable/3802615?seq=7#metadata_info_tab_contents

[25] Rutberg, A.T. and R.E. Naugle. 2008. Deer-Vehicle Collision Trends at a Suburban Immunocontraception Site. Human-Wildlife Conflicts. 2:1. Pgs. 60-67. Accessed online 02/2022. https://www.jstor.org/stable/24875106?seq=4#metadata_info_tab_contents

[26] Bureau of Land Management (BLM). 2021b. Wild Horse and Burro Program: Highlights from the Fiscal Year 2021. Accessed 02/2022. https://www.blm.gov/sites/blm.gov/files/docs/2021-12/FINAL_WHBhighlightsFY2021.pdf

[27] Bureau of Land Management (BLM). 2021c. Maintaining Range and Herd Health. Accessed 12/2021. https://www.blm.gov/programs/wild-horse-and-burro/herd-management/maintaining-range-and-herd-health

use is comparable to GnRH since most of the cost stems from the labor involved in the application method, not the vaccine itself.[28, 29, 30, 31]

IV. FINAL REGISTRATION REVIEW DECISION

A. Regulatory Rationale

In evaluating potential risk mitigation for PZP, EPA considered the risks, the benefits, and the use pattern of this compound. Given limited human health and environmental exposure and no risks of concern identified, the Agency determined no additional risk mitigation is needed and the 2012 registration decision will be maintained.

B. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. Throughout the registration review process, EPA seeks to include all communities and persons, including minority, low-income, and indigenous populations who may be disproportionately overburdened by the exposure to PZP.

In the PFD, the Agency requested information on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (*e.g.*, as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to PZP compared to the general population or who may otherwise be disproportionately affected by the use of PZP as a pesticide. No such information was submitted to the Agency and EPA has not identified any potentially-disproportionately affected group.

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[28] Kane, A.J. 2017. Currently Available Contraceptives and Sterilization Techniques for Wild Horses and Burros. USDA APHIS Veterinary Services. Accessed 01/2022. https://www.blm.gov/sites/blm.gov/files/wildhorse_2017AdvisoryBoard_Kane.pdf

[29] Kirkpatrick, J.F. 2012. Immunocontraceptive Reproductive Control Utilizing Porcine Zona Pellucida (PZP) in Federal Wild Horse Populations. Accessed 12/2021. https://www.sccpzp.org/wp-content/uploads/PZP-QA-June-6-2012.pdf

[30] Rutberg, A. 2012. Fact Sheet: PZP Immunocontraception for Deer. A Tufts University, Cummings School of Veterinary Medicine, Center for Animals and Public Policy publication. Accessed 01/2022. https://www.townofbethlehem.org/DocumentCenter/View/4427/Deer-PZP-Fact-Sheet-7-12?bidId=#:~:text=The%20porcine%20zona%20pellucida%20(PZP,not%20affect%20other%20body%20processes.&text=PZP%20was%20first%20recognized%20as%20an%20effective%20contraceptive%20in%20the%201970's

[31] United States Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS). 2007. GonaCon™ – Birth Control for Deer: Questions and Answers. Accessed 01/2022. https://www.aphis.usda.gov/wildlife_damage/nwrc/downloads/faq_gonacon_07.pdf

C. Final Registration Review Decision

The Agency is issuing this FD in accordance with 40 C.F.R. §§ 155.56 and 155.58. The Agency has made the following decision: (1) EPA has determined no additional data are required; and (2) EPA has determined that PZP meets the registration standard without any additional mitigation.

The Agency conducted a Human Health DRA and an Ecological DRA. In these risk assessments, EPA did not identify any risks of concern to registering PZP.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration." Here, EPA determined that PZP meets the FIFRA registration standard without changes to the registrations and their labeling.

No tolerances under the FFDCA are necessary because PZP is not registered for any uses that result in residues in or on food.

The Agency made a no effect determination for all federally-listed endangered and threatened species, as well as their designated critical habitat, for the currently registered uses of PZP. Furthermore, the Agency also determined that, based on its lack of exposure, PZP is exempt from the EDSP requirement.

D. Data Requirements

EPA does not anticipate calling-in additional data for PZP's registration review at this time.

V. NEXT STEPS AND TIMELINE

A. Final Registration Review Decision

A Federal Register Notice will announce the availability of the PZP Final Registration Review Decision. This registration review decision closes out the registration review for PZP. The Agency is charged with making sure pesticide registrations keep pace with advancements in science via registration review. PZP will undergo re-evaluation in the future according to the schedule maintained by the Agency.
Fisheries Service under ESA § 7(a)(2) is not required.