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EPN Comments on EPA's "White Paper:
A Modern Approach to EPA and FDA Product Oversight"
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Founded in 2017,the Environmental Protection Network (EPN) harnesses the expertise of more than 550 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspectives of former regulators and scientists with decades of historical knowledge and subject matter expertise.

I. Introduction

A. Summary of FDA–EPA White Paper

On January 19, 2023, EPA announced the availability and solicitation of oral[1] and written public comments on a document entitled, "White Paper: A Modern Approach to EPA and FDA Product Oversight" (White Paper). The White Paper indicated that the Food and Drug Administration (FDA) and EPA are considering how best to allocate their potentially overlapping responsibilities under the provisions of two laws—the sections of the Federal Food, Drug, and Cosmetic Act (FFDCA) concerning new animal drugs, and the provisions concerning pesticides in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Both statutes potentially apply to products that are used in a manner which affects animals that are considered to be, or that might serve as hosts for, "pests." The stated goals of any reallocation of responsibilities would be to improve transparency and to increase efficiency by aligning each agency's regulatory jurisdiction with its expertise. The triggers identified for undertaking this reconsideration were the emergence of products using new technologies, the "improved scientific understanding" of how animals absorb topically applied products, the importance of "robust animal safety evaluation," and the need to "improve regulatory clarity" over new and existing products.

After laying out this broad framework, the White Paper addresses two related, but distinct issues: 1] the shortage of resources and expertise at EPA to assess whether topically applied pet care pesticides are causing harm to the animals treated with the products, and 2] the lack of clarity about whether EPA or FDA will exercise jurisdiction over new types of products that could be deemed either a "new animal drug" or a "pesticide." The asserted link between the two issues was that both involve a certain element of new scientific information, leading to questions about which agency should take regulatory responsibility. The White Paper offered an idea for addressing EPA's resource and expertise limitations. Specifically, it suggested a "modern approach" for topically applied pet care products would transfer jurisdiction over these products to FDA. (The White Paper is not entirely clear whether the transfer would be limited to products used on companion animals (e.g., dogs and cats) or would also include current pesticides that are applied as impregnated ear tags, sprays, and dips for livestock to control external parasites. Since the public webinar never mentioned pesticides used on livestock, these comments assume the suggested transfer relates only to pet care pesticides.)

[1] EPA hosted a public webinar on March 23, 2023, in which members of the public were invited to make oral comments for two minutes and thirty seconds. A recording of the webinar is available in the public docket.

The White Paper justified the need for a "modern approach" because new science has changed an implicit assumption justifying the 1971 agreement assigning EPA responsibility for topically applied pet care pesticides. (According to the White Paper, the agencies assumed that animals would not absorb topically applied products, although the White Paper did not explain why this justified EPA jurisdiction.) But, in EPN's view, the White Paper's suggestion for transferring jurisdiction appears really to be based on the observation that FDA has far greater expertise than EPA in evaluating the animal health and safety of pet care products. The White Paper did not address the second issue in any depth, other than to acknowledge new technologies are leading to the development of new types of products, such as genetically engineered (GE) animals, that might be regulated either as new animal drugs or as pesticides.

B. The Legal Framework

The statutory definition of "pesticide" in FIFRA precludes dual FDA and EPA jurisdiction over certain types of products. Specifically, a product may not be regulated simultaneously both as a "new animal drug" by FDA and as a "pesticide" by EPA. There is, however, potentially a huge overlap between the definitions of the two terms, and the jurisdictional line between the agencies is far from clear.

The definition of "new animal drug" is very broad. Section 201(v) of the FFDCA defines "new animal drug" to mean "any drug intended for use for animals, other than man, …." In addition, the term, "drug," is defined by the FFDCA, to include ". . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals . . .." See sec. 201(g)(1)(B), (C). The term "animal" is not defined in the FFDCA, but EPN understands that FDA has interpreted the term broadly to encompass any organism in the animal kingdom including humans, non-human mammals, birds, fish, insects, and other invertebrates.[2]

Likewise, the definition of "pesticide" is very broad. Section 2(u) of FIFRA defines "pesticide" to mean "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . .." (The term "pest" means "(1) any insect, rodent, . . . or (2) any other form of . . . animal life . . . which the Administrator declares to be a pest under section [25(c)(1)].") The definition of "pesticide," however, explicitly excludes "any article that is a 'new animal drug' . . .." This statutory exclusion precludes dual jurisdiction over a product as both a "pesticide" and a "new animal drug."

C. EPA and FDA Request for Comments

EPN's comments in Section II of this submission cover four topics:

A. Whether FDA can regulate the potential risks resulting from use of topically applied pet care products more effectively than EPA;
B. The need to explain how FDA and EPA will handle the transition if they agree that a different agency should assume responsibility for regulating a category of products;
C. Given the many types of products that could meet the definitions of "new animal drug" and "pesticide," the need for a principled basis for determining whether FDA or EPA will exercise jurisdiction over a product category; and

[2] In a public webinar on March 23, 2023, the Director of FDA's Center for Veterinary Medicine, Dr. Tracy Forfa, referred to various organisms targeted by pesticides as "pest animals."

D. The need for both agencies to have a formal forum to answer basic jurisdictional questions from regulated entities and the general public.

The agencies specifically requested that the public provide comment on seven questions. The agencies have stated: "[c]omments . . . should be limited to questions/topics posted in the federal register notice," and they "will not review comments outside of this scope." As indicated in the following table, each of the topics on which EPN comments directly addresses one or more of the agencies' seven questions.

Federal Register Questions	**EPN comments**
1. What do you perceive as the strengths and weaknesses of each agency in regulating these types of products?	See sections II. A, B, C, and D.
2. Are there additional or different challenges that EPA and FDA did not identify in the whitepaper?	See sections II. A, B, C, and D.
3. How can EPA and FDA communicate with their stakeholders about the regulation of these products in a clearer and more transparent manner?	See sections II. C, and D.
4. For regulated entities, how have you historically determined which agency to approach first to bring your product to market?	See section II. C.
5. For consumers, do you know who is regulating the products you use on your animal(s)? If you have a concern or complaint about a specific product, do you know which agency to contact?	See sections II. C, and D.
6. How should EPA and FDA modify product oversight to better align with each agency's mission and expertise?	See sections II. A, B, and C.
7. What difficulties would you envision if EPA and FDA were to modify product oversight to better align with each agency's mission and expertise, and how could they be mitigated?	See sections II. A, B, C, and D.

II. EPN Comments

A. FDA and EPA Have Not Demonstrated that FDA Would Regulate Pet Care Products Topically Applied for Pest Control More Effectively than EPA

The White Paper suggests that, because of its greater expertise and resources for assessing the safety of products applied to pets, FDA would be better situated to regulate products topically applied to pets to control fleas, ticks, and other external pests. (Most pet care pesticides currently registered by EPA are either collars impregnated with an insecticidal substance or liquids to be applied to the skin of a dog or cat (commonly referred to as "spot-ons").) EPN thinks a focus on the agencies' relative expertise and resources for assessing animal safety is relevant but too limited. Rather, EPN thinks that the determinative criterion should be which agency will do a better job of regulating the full range of risks that current pet care pesticides might pose. This should start with consideration of the types of risk potentially presented by the category, and then focus on each agency's legal standards, its authority to regulate the products before and

after they have entered the marketplace, and finally the agencies' relative expertise and resources to regulate those risks.

EPN thinks that pet care pesticides/new animal drugs could potentially pose four broad types of risks—risks not only to the treated animals, but also to humans and non-target organisms.

- First, these products may pose a direct risk to the health of the animals to which they are administered. A flea collar or spot-on applied to a pet might make the animal sick, for example.

- Second, the products may pose a risk to the people who apply the products. A spot-on might cause skin and/or eye injury if a person accidentally spilled some of the product on her hands and then rubbed her eyes.

- Third, a product may indirectly expose bystanders or the general public. The use of pet collars and spot-ons could result in unsafe levels of residue on a pet's fur that could be transferred to someone who contacts the animal (e.g., an animal groomer or a child who hugs her dog).

- Fourth, products could pose risks if/when they reach the outdoor environment. Commenters during the March 23, 2023, public webinar voiced concerns that ingredients found in pet care products, whose use is primarily expected to remain indoors, are present as residues in household effluent that violates the Clean Water Act.

FIFRA and FFDCA, and the regulatory frameworks created by EPA and FDA, have strengths and weaknesses for addressing these types of risks. In assessing which agency would regulate pet care products more effectively, the analysis should begin with whether each agency has the legal authority to consider the full range of risks. Under FIFRA, EPA may not register a pesticide unless the agency finds that it will not cause "unreasonable adverse effects on the environment." This term is defined broadly in sec. 2(bb) and clearly gives EPA the authority to consider every type of risk that a pesticide may pose, whether to humans or the environment. Under the FFDCA, FDA considers whether new animal drugs are "safe and effective." See 212 U.S.C. sec. 360b. The FFDCA sec. 201(u) provides "[t]he term 'safe' . . . has reference to the health of man or animal." FDA has applied this standard to include consideration of the safety of treated animals, and clearly it could also encompass consideration of dangers to people. EPN questions, however, whether this standard is as broad as the FIFRA criterion. Does the law give FDA the legal authority to regulate a new animal drug based on its risk to the environment? In EPN's view, if FDA cannot regulate environmental risks and a product category could pose significant environmental threats, EPA—not FDA—should regulate such products under FIFRA when the products meet the definition of "pesticide."

In addition to considering the legal standard an agency uses in regulating a product, EPN thinks it is also important to consider what specific authorities the agencies have over products, both before and after they have approved market entry.

- Pre-market authorization process. Both laws establish requirements for agency review and approval before a regulated article may enter the marketplace. EPA requires registration of all pesticide products sold or distributed in the United States. Similarly, it is unlawful to sell or distribute a new animal drug without FDA approval. Both FDA and EPA require applicants to provide data sufficient to allow the agency to assess the product.

- Post-market surveillance. Both EPA and FDA require companies to report incidents in which their products are alleged to have caused harm. FDA's post-market surveillance system is generally regarded as more comprehensive than EPA's adverse effects reporting system.

- Periodic reassessment. Another important authority is the duty to reassess the safety of previously approved products. FIFRA requires EPA to reassess all previously registered pesticides at least once every fifteen years. EPN is not clear whether FDA has a similar duty. Further, to make any periodic reassessment program meaningful, it is essential that an agency also can require companies holding approvals to develop new data to support a fresh evaluation of their products' safety. EPA clearly has that authority in FIFRA sec. 3(c)(2)(B); EPN is uncertain whether FDA has comparable authority.

- Rescinding approvals. Any analysis of post-market authorities should consider how easily the statutes allow each agency to remove or modify the use of an unsafe product. EPN thinks that the cancellation hearing process in FIFRA is extraordinarily costly and slow, but EPN does not know whether FDA's statute is any better in this regard.

EPN acknowledges that, in assessing the relative merits of FDA and EPA regulation, it is also appropriate to compare the agencies' resources and expertise. As discussed in the White Paper, FDA has greater expertise and resources in assessing the safety of animals treated with anti-flea and anti-tick products. But, as noted above, pet care products may create other dangers. EPA routinely considers the harms that product use might cause to the user of a pet care pesticide, as well as to people who might subsequently contact a treated animal. The White Paper does not address, however, whether FDA has comparable expertise and resources to evaluate such risks. Finally, while most exposure to pet care products occurs indoors, neither EPA nor FDA evaluates the concerns raised about the presence of pet care ingredients in household effluent. Between the two agencies, EPA almost certainly has greater expertise and resources to evaluate the magnitude of the risk from such exposure. EPA could employ the techniques it routinely uses to determine whether outdoor use pesticides pose risks to non-target wildlife—mammals, fish, birds, pollinators—as well as the potential of the pesticides to reach sources of drinking water.

The regulated community will likely offer comments that focus on the relative costs of being regulated by FDA or EPA, as well as the effects of the agencies' regulatory frameworks on competition.[3] As for cost, the regulated entities will care about fees, data generation expenses, and the timeliness of pre-market review and decision-making. In addition, compliance with the regulatory frameworks under FFDCA and FIFRA creates barriers to market entry. FIFRA does so by requiring applicants to generate data or to get permission to cite or pay compensation for reliance on other companies' pesticide data. FFDCA's new animal drug provisions do not establish a similar framework governing the use of one company's data by another company. Thus, the protections created by the patent system and FFDCA's rules affording confidential treatment to applicants' data operate to limit competition among makers of new animal drugs. While these differences

[3] Although regulated entities' comments may not directly address which agency would administer the more comprehensive and rigorous regulatory scheme, industry sectors would likely prefer to be regulated by the less-demanding agency. In fact, in the past, some companies have tried to "game" the jurisdictional system by formulating claims that place their product under the authority of an agency that gives them a more desirable marketing framework—not necessarily the agency which is more carefully assessing product risks.

will matter to the regulated community, EPN contends that they should not have any role in deciding which agency asserts authority over which categories of products.

In sum, EPN thinks the White Paper has not presented a convincing rationale for transferring jurisdiction over pet care pesticides to FDA. Basing an argument for changing the jurisdiction over pet care products primarily on the agencies' relative resources and expertise is unpersuasive because resources and expertise can change. (For example, FDA could assist EPA with the assessment of these products' safety.) In EPN's view, the most important consideration guiding jurisdictional decisions about these products should be which agency has the greater ability, both legally and administratively, to effectively regulate the full range of risks the products might pose. As the foregoing discussion shows, the better jurisdictional home for flea and tick control pesticides used on companion animals is far from clear. In EPN's view, FDA should take on responsibility for pesticidal pet care products only if FDA has the requisite legal authorities, expertise, and resources to protect public health and the environment as well as or better than EPA does.[4]

B. If EPA and FDA agree to change the jurisdictional line, they need to think about how to manage the transition for products that move to a new regulator.

EPN appreciates that the White Paper recognizes FDA and EPA will need to pay close attention to how the two agencies would handle the transition, if they agree to shift regulatory responsibility over a product category. The White Paper states that any decision moving pet collars and spot-ons from EPA to FDA would need to have two essential components. The first is the "flexibility to update and align regulatory oversight of relevant products consistent with each agency's mission and expertise." In addition,

> "[a] second component is one that would then provide a seamless process for the transfer of oversight from EPA to FDA of topically administered products for external parasites of animals, which are currently regulated as pesticides. Importantly, this component should be designed to be minimally burdensome and not require an FDA approval for products previously regulated by EPA, except in the limited circumstance that products raise serious safety concerns."

Unfortunately, however, the White Paper fails to provide any details about the "seamless process" of the transfer. And, although it recognizes the goal of a minimally burdensome transition, it indicates that there will be a different, unidentified process when transferred "products raise serious safety concerns."

In EPN's view, if a product category under FIFRA moves to FDA, it will be easy for EPA to implement the change, but more challenging for FDA. Under current law, as soon as FDA designates any category of pesticides to be "new animal drugs," those products cease to be pesticides. For EPA, that means the agency would no longer have any authority under FIFRA to regulate the products. FDA, on the other hand, will have to figure out what to do about those products previously deemed pesticides. Any such products would be subject to the FFDCA provisions requiring pre-market approval. Currently, under the FFDCA, it is illegal

[4] EPA may also have the mistaken impression that shifting pet care pesticides to FDA will free up all of the resources it currently devotes to such products. EPN notes that, even if the two agencies agree on the transfer, EPA will still need to account for human exposure to such products in the aggregate risk assessment of active ingredients that have food uses as pesticides. EPA will need to assess and include the incidental exposure that people receive when contacting residues on the fur of pets.

to sell or distribute a new animal drug unless FDA has approved it. Despite this provision, the White Paper says, without explanation, that no FDA approval would be needed for a transferred product. In EPN's view, FDA would likely need new legislation to allow the continued sale of transferred products without first obtaining FDA approval to be marketed as new animal drugs.

Further, FDA has requirements concerning labeling of new animal drugs—requirements that transferred pesticide products would likely not meet. Would the pesticide labeling of such products need to change? If so, any transfer of regulatory responsibility to FDA would need to consider and have plans for the pesticides that are labeled and in channels of trade or in the hands of users. Would the companies that made those products have to recall and relabel them? Would the end-users be allowed to apply the products if they followed the existing labeling? Would failure to follow pesticide labeling requirements be illegal under the FFDCA?

An additional set of questions arises with respect to any transfer of jurisdiction over pet care products that "raise serious safety concerns." First, the White Paper does not offer any guidance on what information would trigger "serious safety concerns." Would the concerns be limited to a cursory examination of animal safety reports, or would an agency conduct an in-depth review that took other types of risks into account? Who would make such a decision: EPA, which has had regulatory responsibility for potentially transferred products and has the largest body of information about products, or FDA, which is supposed to have a greater ability to assess pet safety? Second, what alternative process would apply to a product that was deemed to have serious safety concerns? Would the product be removed from the marketplace automatically until it completed some special review? Or, would the company have an opportunity to contest the agency's determination and would the product remain on the market until the dispute was resolved? If a company could oppose an agency determination of "serious safety concerns," in what forum could objections be raised?

In any case, while FDA and EPA weigh whether to reallocate their regulatory responsibilities, EPN strongly recommends that EPA not delay the evaluation of the safety of any pesticidal products that might eventually be transferred to FDA's jurisdiction. If EPA concludes that the registrant of a pet care pesticide needs to modify its product to reduce its risks, FIFRA gives the agency the authority to compel the changes. The sooner any such needed actions are taken, the better.

C. FDA and EPA should agree on a principled basis for determining which agency has jurisdiction over the many product categories, beyond those discussed in the White Paper, that could be called either "pesticides" or "new animal drugs."

EPN recommends that the two agencies establish a principled basis for allocating regulatory responsibilities for such products. Without a principled basis for determining which agency has regulatory responsibility for a category of products, the regulated community and consumers will continue to be confused. Moreover, there is the potential for inconsistent decisions about jurisdiction that could lead to arbitrary and capricious differences in how essentially similar products are regulated. Consequently, EPN thinks that the two agencies must think carefully about how to assign jurisdiction over all types of products that could fall under

both the FFDCA and FIFRA. We think FDA[5] and EPA need a principled approach for making the determination of which agency will regulate which category of products.

Historically, FDA and EPA have not always drawn a clear line delineating which agency will regulate which kinds of products when a category of products could be deemed either a "pesticide" or a "new animal drug." Rather, it appears that FDA and EPA have simply accepted responsibility for certain types of products as regulated entities have approached one of the agencies. Thereafter, regulated entities have, by-and-large, submitted to the jurisdiction of whichever agency already regulated the types of products they intend to market.

Many times, the choice of agency is fairly obvious. In some cases, however, new technologies have led to creation of a new type of product that arguably could fall under either FIFRA or the FFDCA, and there have been no precedents to follow. Then, EPA and FDA have been slow to answer questions about where a regulated entity should go for pre-market approval. As described below, there is little guidance about how FDA and EPA decide which agency will take the regulatory lead, and the absence of a reasoned basis for jurisdictional decisions has been frustrating and often confusing for the regulated community.

The history of the two statutes provides some insight into where to draw the jurisdictional line. FIFRA, originally enacted in 1947, gave USDA jurisdiction over "economic poisons," a term which included rodenticides and insecticides. In 1970, Congress transferred FIFRA authority to EPA. In 1972, Congress comprehensively rewrote FIFRA and, among other things, substituted the term "pesticide" for "economic poison." Since FIFRA became law and has been amended in the same time frame as Congress added and revised the new animal drug provisions to the FFDCA, there has never been any serious consideration that USDA and EPA—not FDA—would regulate products designed to kill rodents and insect pests.

At first blush, the distinction between the two laws appears to turn on whether the products kill or help the treated animal. This distinction between products that are helpful vs. harmful to the treated animal, however, is not useful for pet care products. Whether applied internally or externally, the products are designed to relieve the treated animal of undesirable pests. This may have led to jurisdictional discussions between EPA and FDA shortly after EPA took authority under FIFRA.

In 1971, EPA and FDA entered a Memorandum of Understanding (MOU) that divided responsibility for categories of pet care products based on how the products are applied. The two agencies later updated the MOU in 1973.[6] Under the MOU, EPA and FDA recognized that many types of products could be considered both pesticides and new animal drugs. Because of the overlap, they agreed to exercise dual jurisdiction, with one agency taking primary responsibility for regulation. FDA took jurisdiction over

[5] Because the definition of "pesticide" expressly excludes "new animal drugs" from the scope of FIFRA, FDA's decision about whether a product is a "new animal drug" effectively controls the jurisdictional reach of FIFRA. Rather than FDA making these decisions unilaterally, however, EPN thinks that the interests of good government call for the two agencies to collaborate on a joint position.

[6] Available at: https://www.fda.gov/about-fda/domestic-mous/mou-225-73-8010.

injected and orally applied products, as well as "products topically applied for their systemic action in an animal." EPA had responsibility for other topically applied products.[7]

Although there were some exceptions, overall, the site of a product's expected biological activity (manner of administration) was the determinative criterion, not the mode of action (killing vs. some other (beneficial) effect on "structure or function"). The MOU does not explain why the agencies made this distinction. EPA and FDA, however, have not always recognized, for jurisdictional purposes, a distinction between products that are ingested vs. applied topically, or those that are absorbed vs. those that remain on the surface of an animal. For example, EPA has exercised jurisdiction over contraceptive products used to reduce populations of rats, pigeons, and deer. These products are distributed as baits into the environment where they are eaten by the target pests.

More recently, FDA has drawn a jurisdictional line for another category of products, based on the purpose for using a product. For several years, FDA and EPA deliberated over which law should regulate mosquitoes that had been genetically engineered to prevent successful reproduction. Researchers at the Oxitec company modified a gene in male mosquitoes to produce a lethal effect in their female offspring. Oxitec hopes that, when introduced into the environment, these genetically-engineered (GE) males will mate with wild females, and the female offspring will die before they can reproduce. This, in turn, should lead to reductions in populations of mosquitoes that transmit diseases like West Nile Virus and dengue. In 2017, after lengthy discussion, FDA issued a guidance document in which it determined mosquitoes genetically engineered "for population control purposes" would not be considered a "new animal drug."[8] EPA has regulated such GE insects as a "pesticide."

A principled approach to allocating jurisdiction needs to consider all types of products that might fall under both statutory definitions. Any "pesticide" – a substance intended to prevent, destroy, repel or mitigate any animal pest – is clearly "intended to alter the structure and function of . . . [an] animal[]" and thus could also be called a "new animal drug." EPA's White Paper focuses too narrowly on insect control products topically applied to companion animals and on animals that are genetically engineered for population control of pests.

Setting aside pesticide products that are introduced into the environment to reduce populations of pest animals through lethal effects and the two categories discussed in the White Paper, there are many other products that arguably could fall under either law. Other product categories that the two agencies should consider include:

- Dips, sprays, and ear tags to control fleas, tick, mites and other external parasites on livestock
- Bird and insect repellents
- Mating disruption pheromones
- Contraceptives for deer, rats, pigeons, and other captive, feral, or wild species
- Products administered to animals to interrupt the life cycle of a pest species that is harbored inside the treated animal during one life stage of the pest (e.g., products to kill the eggs of ticks in wild antelopes)
- Products to kill fungus and parasites that attack fish in aquaria and aquaculture (e.g., sea lice)

[7] The MOU further provided that "Neither agency will approve the marketing of a product under the law administered by it if the product would not be in full compliance with the requirements of a law administered by the other." The amendment to FIFRA in 1975 excluding a new animal drug from the definition of "pesticide" effectively nullified this element of the agreement.

[8] https://www.fda.gov/media/102158/download

- Products designed to improve "bee health" by killing parasites on bees (e.g., Varroa mites) or fungus that causes diseases in bees (e.g., *Nosema ceranae*)
- Products that are mixed with animal feed and designed to control flies in and on an animal's feces ("feed-through larvicides").

In EPN's view, the first criterion in any principled basis for allocating jurisdiction should be whether the product is intended to affect a pest animal.[9] Products whose purpose is to improve the health of an individual treated animal by affecting that individual directly without affecting some other animal pest plainly should be deemed a new animal drug. All other products could be considered under either law. As discussed in section II A, EPN thinks that FDA and EPA should then consider a range of factors. Specifically, the two agencies should agree to give responsibility to the one that has the better ability to regulate the safety of a category of products, taking into account each agency's legal authority to regulate the full range of the products' potential risks,[10] and the legal tools to exercise continuing, effective oversight of products after they are approved. Although their relative resources and expertise are also relevant to which agency will do a better job, EPN thinks the fundamental legal framework is more important in the long run.

Applying these criteria, EPN concludes that most pesticidal products that could also be considered new animal drugs—those applied to animals and currently regulated by EPA—should remain subject to FIFRA. EPA not only has clear legal authority, but also the expertise and resources to address the risks such products might pose, even if the purpose of the product is to improve the health of treated animals. Thus, EPN favors leaving GE insects and other GE animals under FIFRA if the purpose of the genetic modification is to address a pest problem. Similarly, EPN favors leaving repellents, livestock treatments, bee health products, feed-through larvicides, and animal contraceptives (particularly those released into the outdoor environment) with EPA.

Finally, although EPN favors a comprehensive approach to determining jurisdiction over products that could be regulated under either statute, EPN recognizes that FDA and EPA may resolve jurisdictional issues on a case-by-case basis as they confront novel types of products. As they have done in the past (e.g., the 1971 MOU concerning pet care products and the 2017 FDA guidance on GE mosquitoes), the agencies can consult and agree on which agency will regulate a new type of product. The decisions can be memorialized using administrative procedures—MOUs, guidance documents, policy statements, or even rulemakings. The agencies do not need new laws to address this issue raised by the White Paper.

D. Both agencies should have a formal forum to answer basic jurisdictional questions

Currently, it can be quite difficult for the regulated community to get timely answers to the question: "who regulates my product?" The MOU delineating how EPA and FDA have divided the universe of pet care products is quite hard to locate, and it does not cover all of the types of products which might fall under both laws. FDA's guidance on GE insects is available from FDA, but not from EPA. Agency guidance addressing other product categories is non-existent or similarly difficult to find. Moreover, the 1973 MOU

[9] FIFRA gives EPA authority only to regulate products intended to control "pests." While the term, "pest," includes "fungus," the definition of that term excludes fungus "on or in living man or other animals." FIFRA sec. 2(k). Thus, a bee product intended to control a fungus in living bees, as opposed to controlling the fungus on surfaces inside a hive, could not be considered a "pesticide."

[10] EPN notes the taxonomy of risks in section II. A. would also apply to other categories of pesticides that might be deemed to meet the definition of a new animal drug.

stated that "If a manufacturer proposing a new product is unable to determine the agency of primary jurisdiction, a presubmission inquiry may be submitted to either agency. FDA and EPA will jointly consider the inquiry and advise the manufacturer of their conclusions in this matter." Notwithstanding the MOU, presubmission inquiries have not yielded timely advice.

In the interests of transparency and more efficient government, EPN recommends EPA and FDA provide a better way for companies to submit questions and get timely answers. Specifically, to ensure timely and coordinated responses, EPN recommends that the two agencies create a single portal, accessed through both EPA's pesticide website and FDA's new animal drug website, where the public can submit questions about where to submit an application to market a product. In addition, FDA and EPA should establish a committee of senior level staff that will provide written answers to inquiries explaining why a product goes to one agency or the other. With consideration of trade secret concerns, these answers should be posted for the public to see. Further, the two agencies should each maintain a website where the relevant jurisdictional guidance documents for both agencies are posted.

These comments were prepared by William Jordan, with the assistance of Jack Housenger, Tina Levine, and Robert Perlis, on behalf of EPN.