Regulating Probiotic Use and Improving Veterinary Care to Bolster Honeybee Health

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Summary

One-third of the food Americans eat comes from honeybee-pollinated crops. Honeybees used for commercial pollination operations are routinely treated with antibiotics as a preventative measure against bacterial infections. Pre- and probiotics are marketed to beekeepers to help restore honeybee gut health and improve overall immune function. However, there is little to no federal oversight of these supplements. Apiculture supplements currently on the market are expensive but often ineffective. This leaves unaware farmers wasting money on “snake oil” products while honeybee colonies remain weakened — threatening not just the U.S. agricultural economy, but also the livelihoods of beekeepers and farmers. At the same time, widespread use of antibiotics in apiculture puts honeybees at high risk of spreading antibiotic resistance.

To address these issues, the Food and Drug Administration (FDA)’s Office of Human and Animal Food Operations and the U.S. Department of Agriculture (USDA)’s National Institute for Food and Agriculture (NIFA) should work together to (1) create an FDA review and approval process for pre- and probiotic apiculture products, (2) design educational programs designed to educate veterinarians on best practices for beekeeping health and husbandry, and (3) offer grants to help farmers and apiculturists access high-quality veterinary care for honeybee colonies.

Challenge and Opportunity

Honeybee pollination services are pivotal to the U.S. agricultural economy. It is estimated that about one-third of the food Americans eat comes from crops pollinated by honeybees. Throughout the past decade, beekeepers have suffered colony losses that make commercial apiculture challenging. These colony losses are caused by complex and interconnected issues including the rise of honeybee diseases such as bacterial infections like American Foulbrood or viral infections linked to pests like the Varroa mite, a general increase in hive pests, habitat fragmentation and nutrition loss, and increased use of pesticides and/or pesticide exposure.

The substantial threats posed by bacterial and viral diseases to honeybee colonies have driven commercial beekeeping operations to routinely treat their hives with antibiotics (mainly oxytetracycline). Unfortunately, antibiotic treatment can also (i) compromise honeybee health by wiping out beneficial bacteria in the honeybee microbiome, and (ii) promote antibiotic resistance. Routine use of antibiotics in apiculture hence compounds the challenges mentioned above and further compromises the livelihoods of U.S. farmers and the security of U.S. food systems.

In 2017, the FDA responded to antibiotic overuse in apiculture by amending the Veterinary Feed Directive (VFD) section of the Animal Drug Availability Act of 1996 (ADAA). The 2017 amendment required beekeepers to obtain veterinary approval to treat their colonies with antibiotics against certain diseases. While attractive on paper, the implementation of this policy has encountered challenges in practice. Finding a vet who understands the highly complex dynamics of apiculture has been a
substantial challenge for commercial beekeepers, especially in rural areas. Improvements to the implementation of the VFD are needed to contain the spread of antibiotic resistance in apiculture.

Relatedly, researchers, beekeepers, and companies alike have all been on the hunt for a solution to restore honeybee health after antibiotic treatment. Pre- and probiotic therapy has recently been proposed as a promising and cost-effective strategy to enhance human and animal health, particularly to restore beneficial gut bacteria following antibiotic treatment. Several companies have developed pre- and probiotic supplements targeted at commercial apiculturists. Two popular supplements are HiveAlive™ and SuperDFM®-HoneyBee™. HiveAlive™ is marketed as a prebiotic and is composed of seaweed, thymol, and lemongrass extracts. Although there is some evidence that HiveAlive™ decreases infectious fungal-spore counts and reduces winter honeybee mortality, the value of this supplement as a honeybee prebiotic (i.e., to boost growth or activity of beneficial gut bacteria prior to antibiotic treatment) has not been tested. SuperDMF®-HoneyBee™ is marketed as a probiotic that can restore the honeybee gut microbiome. But SuperDMF®-HoneyBee™ is exclusively composed of microbes — isolated from mammals or the environment — that have never been found in honeybees and therefore are probably incapable of colonizing the bee gut. To date, neither HiveAlive™ nor SuperDFM®-HoneyBee™ has been scientifically shown to protect or restore the honeybee gut microbiome from adverse effects of antibiotic treatment.

A big part of the reason why pre- and probiotic supplements for honeybees (as well as for other agricultural uses) have not been externally validated is that such products are not subject to FDA or USDA regulation. This lack of federal oversight means that beekeepers interested in using such products have only the manufacturer’s word that the products will work as promised. Federal intervention is needed to protect commercial farmers and beekeepers from predatory companies selling expensive “snake oil” products.

Plan of Action

To ensure the long-term sustainability of U.S. apiculture and agriculture, the FDA and USDA should work together on the following three-part strategy to improve the administration of antibiotics in apiculture and to strengthen the regulation of pre- and probiotic supplements marketed to commercial beekeepers.

Part 1. Educate veterinarians in beekeeping to limit misuse and overuse of antibiotics.

For instance, the USDA’s Office of Pest Management Policy (OPMP) and National Institute for Food and Agriculture (NIFA) could collaborate with the U.S. Honeybee Veterinary Consortium on an annual training program, hosted at the USDA’s Bee Research Laboratory, to educate vets working in agricultural areas on the basics of honeybee disease, prevention, treatment, and post-treatment options. The training could also discuss the latest evidence on the efficacy of pre- and probiotic supplements, ensuring that vets can help beekeepers navigate this emerging
marketplace of products. Additionally, for veterinarians who are unable to travel to in-person training, these resources could be made available in an online portal.

**Part 2. Strengthen regulation of pre- and probiotics marketed to beekeepers.**

Currently, the market for pre- and probiotics targeted at beekeepers is a veritable “wild west”: one that allows the marketing and sale of essentially any product as long as the ingredients included are deemed safe per the *Official Publication of the Association of American Feed Control Officials* and are either (i) approved for addition to animal feed (per *part 573 in Title 21 of the Code of Federal Regulations (21 CFR 573)*), and/or (ii) generally recognized as safe (GRAS) for the intended use (including those listed in *21 CFR 582 and 584*). Notably, the *efficacy* of marketed pre- and probiotics does not have to be demonstrated. Therefore, in alignment with an *FDA guidance document* recommending stronger oversight of pre- and probiotics targeted at beekeepers, FDA’s *Office of New Animal Drug Evaluation (ONADE)* should extend its normal *animal drug approval* process to include pre- and probiotic supplements marketed to beekeepers.

**Part 3: Provide apiculturists with better access to high-quality veterinary care.**

USDA could create a new Honeybee Veterinary Services Grant Program (HVSGP) that offers rural farmers and beekeepers funding to obtain vet care for their colonies. This program would be modeled after the American Veterinary Medical Association (AVMA)’s *Veterinary Services Grant Program*, which provides funding to help rural farmers access high-quality vet care for farm animals. The USDA could also consider launching a parallel Honeybee Veterinary Medicine Loan Repayment Program (HVMLRP; again modeled on an AVMA *program*), which would help place vets trained in beekeeping husbandry “in high-need rural areas by providing strategic loan repayment help in exchange for service”. Vets participating in this program would agree to provide the following services:

- Quarterly visits to commercial apiaries in need of vet support.
- Prescriptions of antibiotics as appropriate after colony inspection.
- Collection and reporting of data on health and treatment outcomes of serviced hives

**Conclusion**

Widespread use of antibiotics in commercial beekeeping is a problem for bees, beekeepers, and the larger ecosystem due to the spread of antibiotic resistance and the negative effects of antibiotic treatment on honeybee health. The federal government can mitigate these adverse effects by improving the knowledge and reach of vets trained in best practices for antibiotic treatment in apiculture, as well as by improving regulation of pre- and probiotic supplements purported to restore honeybee gut microbiomes following antibiotic treatment. These actions will
collectively secure the health of honeybees — and the livelihoods of farmers who depend on them — for the long term.

**Frequently Asked Questions**

1. **Why should pre- and probiotics be regulated in honeybees and not humans?**

   Pre- and probiotics should be regulated in both humans and animals. Pre- and probiotic supplements marketed for human use, like those marketed for apicultural use, are poorly regulated and rife with misleading, untested, or simply false claims. While this memo focuses on the apicultural sector, there is certainly a broader need for increased federal intervention with respect to the safety and efficacy of pre- and probiotics.

2. **What would incentivize veterinarians to participate in educational programs like those proposed in this memo?**

   The FDA’s 2017 amendments to the VFD mean that if a beekeeper needs to administer antibiotics to their honeybees, they must obtain a prescription or feed directive from a licensed veterinarian. Therefore, vets have a new professional incentive to better understand the dynamics of beekeeping husbandry.

3. **Why treat the “symptoms” of antibiotic treatment and not the root “cause” of widespread antibiotic use in the first place?**

   In an ideal world, commercial beekeeping would rely on antibiotics only as a last resort. But the reality is that commercial beehives today — due to factors such as a history of intensive antibiotic use in apiculture and the practice of transporting colonies en masse from place to place — are so susceptible to deadly bacteria that imposing major restrictions on antibiotic use in apiculture would seriously compromise U.S. agricultural productivity and the livelihoods of American farmers. Farmers, researchers, and policymakers should continue to collaborate on strategies for phasing out apicultural antibiotic use in the long term. But in the near term, actions should still be taken to promote best practices for apicultural antibiotic treatment and to better regulate supplements that could help minimize adverse impacts of antibiotic treatment on honeybee health.

4. **How retroactive would new FDA regulations on honeybee pre- and probiotic supplements be? I.e., would these regulations apply to products already on the market?**

   Yes, these regulations should apply to existing products as well as products developed in the future.
5. Where will the money come from to support the HBVSGP and new research ventures in pre- and probiotic development for honeybees?

The AVMA’s Veterinary Services Grant Program (VSGP) receives funding annually through Congressional appropriations. This funding was $3.5 million for Fiscal Year 2022 (FY22). The HBVSGP could be launched with a similar amount. HBVSGP funding could come from new Congressional appropriations, and/or from existing USDA programs. For instance, the 2008e Farm Bill designated pollinators and their habitat a priority for the USDA and authorized money for projects that promoted pollinator habitat and health under the Environmental Quality Incentives Program (EQIP). Money could also be earmarked from the USDA National Institute of Food and Agriculture (NIFA), Agriculture and Food Research Initiative - Education and Workforce Development grant program to encourage the research and development of better pre- and probiotic supplements and continuing education programs in honeybee veterinary care.
About the Author

Megan Damico is a Ph.D. candidate at the University of North Carolina at Greensboro (UNCG), where she studies the microbial ecology and evolution of the honeybee gut microbiome. As a microbiologist, beekeeper, and policy advocacy specialist, Megan is an active communicator of science-policy issues and innovations to the public and beekeepers. She is the co-founder and vice president of Spartans for Science and Policy at UNCG and currently serves as the Southern Hub Chair for the National Science Policy Network (NSPN), where she helps new members navigate resources and opportunities available in science policy and advocacy.

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