

Attachment #1. **Second Quarter Progress Report Minor Use Animal Drug Program**
May 8, 2017

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Ivermectin Cattle Fever Tick Project

Information from the field trial on the Texas-Mexico border is presently being assembled into a study report. An additional part-time person has been employed for the summer to assist in preparing the report. Although this remains a major project for MUADP, significant roadblocks remain. An agreement has not been signed between Postive Feeds, Ltd. and Merial, Inc., for the right of reference to the toxicology data belonging to Merial. Merial recently merged with Boehringer-Ingelheim Vetmedica and new scientists have taken over leadership of the project. A signed agreement is necessary for the project to go forward and this has been a significant issue since the beginning of the project. Postive Feeds also needs to complete Chemistry and Manufacturing Component (CMC). The CMC is in its initial stages of preparation but should have been done significantly earlier in the study.. It is ideal to have the CMC approved prior to submission of the efficacy study report.

Efficacy of Chlortetracycline for Sheep Feedlot Pneumonia

A product development conference was requested for this project in January but scheduling has been delayed pending submission of a research protocol and identification of a most likely method to demonstrate efficacy. Drs. Kelly Still Brooks and Paul Plummer at Iowa State University are leading the work on a pilot study to help determine the best approach to demonstrating efficacy. The pilot study is set to start approximately June 10, 2017 and will test a natural exposure model. In this model, lambs are allowed to develop respiratory disease and half of them will be fed CTC at 350 mg/hd/day for 14 days and the other half will remain as untreated controls. Blood will be drawn to determine plasma CTC levels which will be compared to CTC levels in cattle plasma. Ultrasounds and necropsies will be performed to compare lesions and cultures used to identify bacterial pathogens. Results of the pilot study will be used to determine if the natural exposure model or a pharmacokinetic approach (plasma CTC levels) can be used to demonstrate efficacy. Large numbers of experimental animals in the natural exposure model is problematic. A variant of the natural exposure model would be an actual feedlot trial. Dr. John Hallberg (Zoetis) is seeking a veterinarian who works near a lamb feedlot that has the time and ability to oversee a natural feedlot model. However, the FDA/CVM may require multiple feedlots to be involved. Another possible approach is to challenge expose lambs to several strains of *Mannheimia haemolytica* and/or *Pasteurella multocida*. The FDA/CVM may be willing to accept this if other approaches are not acceptable.

Meloxicam in Sheep

Originally ASI did not wish to pursue this project since it would block the use of much less expensive oral formulation which can be used in an extra-label manner for cattle and sheep. However, we have been informed that approval of meloxicam is now a priority. Rather than plan for an additional project at this time, it will be delayed for up to a year. Problems exist with developing a reliable model to measure pain in sheep that would be acceptable to the FDA/CVM.

Zolvix in Sheep

Zolvix™ (monepantel) anthelmintic for sheep is also an ASI priority that is under discussion with the FDA/CVM. Ordinarily a drug needs to be approved in a major species in the U.S. in order to be eligible for approval through the Minor Use Animal Drug Program. Zolvix is not currently approved in a major species in the U.S.

CIDR-g Efficacy in Goats

Dr. Joan D. Rowe at UC-Davis has agreed to help assemble a study report. All data has been transferred to her for statistical analysis.

Human Food Safety of Tulathromycin (Draxxin®) in Goats

A product development conference with ONADE has been requested. Dr. Joseph Smith will be conducting this study as part of his Ph.D. program. Dr. Smith is a clinician in the Department of Veterinary Diagnostic and Production Animal Medicine. He met with his graduate committee on 1/25/17 and received permission from the committee to use this and one or two related studies for his research. Dr. Smith has received the method validation work from UC-Davis and is scheduling the analytical portion of the project with the laboratory supervisor. Initial plans are to determine the pharmacokinetics of tulathromycin in sick goats using a challenge exposure to *Pasteurella multocida*. Subsequently, the tissue residue study will be performed.

Polyanhydride *Haemonchus contortus* vaccine

Dr. Matthew Brewer, Department of Veterinary Pathology at ISU, has obtained a sufficient quantity of *H. contortus* from a commercial supplier. Crude parasite antigens have been prepared and incorporated into polyanhydride. Sufficient numbers of lambs have been identified and housing for them has been arranged. The Iowa State University Institutional Animal Care and Use Committee (IACUC) reviewed the project and approval was received on 5/18/17. The project can begin as soon as lambs can be acclimated for a short period of time.

Sincerely

s/ R. W. Griffith/s

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Attachment #2: Submitted by Drs. Sonny Ramaswamy and Craig Beyroudy (Dean, University of Maryland College of Agriculture and Natural Resources):

The text below represents a two-page summary from the National Institute for Food and Agriculture (NIFA) Call to Conversation on Tactical Sciences for Protection of the U.S. Agricultural Enterprise, hosted by the University of Maryland College of Agriculture and Natural Resources on February 15 and 16, 2017 (Total report is 15 pages and available on request).

***TACTICAL SCIENCES TO PROTECT THE U.S. AGRICULTURAL ENTERPRISE
Building Awareness and Developing a Coordinated Strategy***

In 2017, the National Institute of Food and Agriculture (NIFA) proposed an initiative to focus attention on protecting the integrity, reliability, and sustainability of the U.S. food and agriculture system. These investments enable research, development, and deployment of science-based tactics that are critically needed by the U.S. agricultural sector to detect pests, diagnose diseases, support regulatory systems, and respond to disasters. This report describes current NIFA investments in tactical sciences and summarizes stakeholder opinions from a recent “Call to Conversation” held on the campus of the University of Maryland at College Park on the topic of biosecurity of food systems and the need to strengthen tactical sciences. The report also creates a draft framework for a coordinated, national effort to better protect our food and agricultural systems from existing and emerging threats.

BACKGROUND

Agriculture and agriculture-related industries contribute over 21 million jobs and approximately \$1 trillion to the U.S. gross domestic product (ERS report). Tactical sciences protect the integrity, reliability, and sustainability of the U.S. food and agriculture system from a wide array of known and potential threats from pests and diseases harmful to plants, animals, and/or human health. In the context of the need to feed an estimated global population of over 9 billion by 2050, there is a critical and growing need to strengthen tactical science capabilities and competencies on a scale commensurate with current and future threats to the safety, stability, diversification, and profitability of our nation’s food and agricultural systems. Recent examples of threats that illustrate this point are highly pathogenic avian influenza, which resulted in the loss of nearly 50 million chickens and turkeys and an estimated economic loss of more than \$3 billion in a single year, and citrus greening, which has caused 23 percent yield losses and an economic impact of at least \$1 billion per year.

NIFA INVESTMENTS IN TACTICAL SCIENCES

NIFA's current tactical science portfolio covers three broad functions and consists of multiple small programs distributed across administrative and disciplinary areas (Table 1).

Table 1. NIFA tactical science programs

Function	Programs	Activities
Detection and Diagnostics	National Plant Diagnostic Network	Surveillance and early detection of high consequence pests and diseases; timely deployment of technologies and human resources to respond, manage and recover from outbreaks
	National Animal Health Laboratory Network	
Regulatory Systems Support	Minor Crop Pest Management	Critical research to inform federal regulations ensuring the safety and diversity of agricultural products
	Food Animal Residue Analysis Database	
	Minor Use Animal Drugs Program	
New Tools and Management Strategies for Crop and Animal Production and Protection and recovery	Crop Protection and Pest Management	Research on effective tools to manage pests and diseases and science-based outreach to help producers respond to local and regional threats
	Minor Crop Pest Management	
	Extension Disaster Education Network	

Collectively, these programs offer essential solutions to crop and livestock producers and are critically important to our nation’s trade and economic well-being. Through hard work and good planning, and despite small budgets, these programs have contributed to the protection of our nation’s food and agricultural systems. However, as the global demand for food production increases, the challenge of ensuring adequate protection of agricultural products from emerging pests and diseases is also increasing. To meet this challenge, the elements that contribute to the success of current tactical science programs need to be leveraged and expanded at a national level. Currently these programs function independently, are limited in scope, are not functionally organized to maximize efficiency and impact, and are not viewed by stakeholders as a unified effort. Significant increases in efficacy, effectiveness, and efficiency may be synergized through greater integration and sharing of technical expertise across program areas. Such an integrative effort would require a high level of communication, coordination and mutual trust building among the various functional areas and programs that comprise the tactical science portfolio. Given the very real threats posed by emerging pests and diseases, NIFA believes that a forward thinking tactical sciences initiative is both timely and necessary to enhance U.S. food, agricultural, and economic security.

GOAL OF THE TACTICAL SCIENCES INITIATIVE

The overall goal of the tactical sciences initiative is to create a coordinated national framework of translational and applied science to protect U.S. plant, animal, and food production systems. This framework will significantly strengthen and expand current investments to close existing gaps in food and agricultural defenses through increased capacity to detect pests and diseases, prevent outbreaks, respond to natural disasters, and support containment and recovery operations. Achievement of these objectives will

protect the biosecurity of our nation's food systems, promote U.S. agricultural sustainability and minimize serious disruptions to business and trade. It will also enhance protections for producers, consumers, the food and agricultural system, and the national economy as a whole.