



Animal and Plant Health Protection Product Evaluation Protocol

*Texas Agricultural Experiment Station, Texas Cooperative Extension,
Texas Forest Service, Texas Veterinary Medical Diagnostic Laboratory*

INTRODUCTION

The Texas Agricultural Experiment Station (TAES), the Texas Cooperative Extension, the Texas Forest Service (TFS) and the Texas Veterinary Medical Diagnostic Lab (TVMDL) (referred to as agencies), are agencies within The Texas A&M University System (TAMUS), that do not receive federal or state funding to evaluate products or devices (chemical and/or non-chemical) for commercial companies, organizations, and/or individuals. However, such evaluation may be performed utilizing funding from other sources. Chemical products, both experimental and those registered by the Food and Drug Administration and the Environmental Protection Agency, to be evaluated include, but are not limited to, plant or animal protectants (antibiotics, antihelminthics, fungicides, herbicides, insecticides and rodenticides) and animal and plant growth regulators. The agencies are responsible for gathering scientifically-based information relative to the effectiveness of these products in order that they may be able to make suggestions to the clientele served.

Evaluation of products or devices by the agencies generally requires outside funding. In most cases, support from commercial industry and/or individuals is necessary to enable these agencies to conduct product evaluations. The level of funding to support product evaluation is determined by the agencies' principal investigators; however, the research contracts will be with the respective agency of TAMUS, not with individual scientists/specialists. Evaluations may take place prior to, during or after a product is labeled by FDA or EPA. Furthermore, products may be evaluated for emergency use, other special needs, or for label expansion.

PROCEDURES

Interested concerns wishing to utilize the assistance of the agencies in evaluating products or devices can be required to develop a mutually agreeable protocol with a collaborating investigator and develop the necessary Memorandum of Agreement prior to establishing an evaluation (Table 1).

Table 1. Sequence and procedure for establishing a Memorandum of Agreement (MOA) with the Texas Agricultural Experiment Station (TAES), the Texas Cooperative Extension, the Texas Forest Service (TFS) or the Texas Veterinary Medicine Diagnostic Lab (TVMDL).

- I. Investigator, working with the private grantor or their representative, establishes a mutually agreeable protocol for product (chemical, non-chemical) evaluation between TAMUS faculty/staff and commercial concern to include appropriate safety measures.
 - II. Investigator processes Memorandum of Agreement (MOA) and other desired documents such as a Propriety Agreement with the commercial concern through the agencies director's office. Note: Some grantors file standardized MOA's with TAMUS to cover multiple projects.
 - III. Material Safety Data Sheets, product use instructions (I.P.A. label) and other required technical information, along with product, is submitted by grantor to TAMUS faculty/staff processing MOA. The forgoing notwithstanding, nothing in this policy shall cause a private grantor to release proprietary data or information not otherwise or here to fore made available to the researcher(s) or to jeopardize property rights.
 - IV. Project evaluation trial is conducted by TAMUS agency's faculty/staff that processed MOA.
 - V. Grantor is allowed an opportunity to review results prior to public release, unless TAMUS is required to release this information under the Open Records Act.
 - VI. A final report containing the results is provided to the grantors and, unless stated otherwise in the MOA or other prior agreements, is the property of TAMUS agency involved.
 - VII. The report is released to the public following an opportunity for review by the commercial concern and/or after the propriety agreement interval has expired.
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Product donated or provided to any TAMUS scientist does not constitute a commitment to perform any type of evaluation or research in regard to the product. If any applied research or product evaluations are conducted using the donated product, the results do not constitute an endorsement of the product.

To initiate a product evaluation through a TAMUS agency, a mutually agreeable protocol must be developed to accompany a Memorandum of Agreement (MOA). The testing agency shall have the right to have all results subjected to "peer review" by department, within the agency or by appropriate scientist in other agencies or institutions. A Proprietary Agreement form is also available to enable a private company or an individual to perform research with release of results restricted to the contracting firm or individual for the time designated on the form. Test design and good laboratory practice (GLP) requirements must be discussed with faculty/staff before an

MOA is developed. The grantor must work closely with faculty/staff to assure proper handling and use of products by well-informed personnel.

All paperwork is usually completed, MOA signed by all parties, and the evaluation approved by the agency, before any trial is initiated. This includes submission of Material Safety and Data Sheets (MSDS), product labels and use instructions, and any other technical information required by faculty/staff. All federal and state regulations applicable to the treatment and evaluation of experimental products must be complied with prior to initiation of any trial.

RESULTS AND RESTRICTIONS

Results are provided to contracting agencies or individuals before public release or other release of the results as may be specified in the MOA. Unless a completed and signed Proprietary Agreement is in place with release restrictions or after expiration of a Proprietary Agreement, results are considered to be public information and available to anyone upon request. Raw data are available to the contractor or other parties upon request.

Results issued by TAMUS are intended for educational purposes only. Reference to commercial products or trade names in reports/publications, etc. is made with the understanding that no discrimination is intended and no endorsement is implied. The agencies within TAMUS assume no liability related to the use or application of the products evaluated. Stated results do not constitute an endorsement of an evaluated product by any agency within TAMUS. Product evaluations are conducted according to conventional scientific methods and results are reported according to the methodology described in the MOA.

The faculty/staff receiving private funding strive to establish trials and conduct research based upon established protocols. Results can not be predicted or guaranteed. In the area of field trials, agreements may be developed separately between the landowner and TAMUS for the land's use. Faculty/staff can not guarantee results of established field trials where field plots or animals are destroyed/compromised by factors out of the control of the faculty/staff member, including field plots destroyed by weather, removal (harvested, plowed), treated with other products or other factors. Funded projects that are not conducted, for reasons out of the control of the agency such as a targeted pest or disease that does not occur in established field plots or animals, are non-refundable. In the event treatments described in the original Memorandum of Agreement need to be modified (i.e., rate, timing, etc.), a new or amended Memorandum of Agreement may be required by the collaborating TAMUS faculty/staff.

Any discoveries made during the product evaluation not directly related to the evaluation of the product being tested are the property of TAMUS and its agencies.

By your signature below, you certify that you and the contracting entity you represent understand and are in agreement with the terms as prescribed herein and that you are an authorized representative of the contracting entity.

Name

Contracting Entity Name

Title

Date