

MEMORANDUM OF UNDERSTANDING
AMONG THE
UNITED STATES DEPARTMENT OF AGRICULTURE'S
ANIMAL AND PLANT HEALTH INSPECTION SERVICE;
AGRICULTURAL MARKETING SERVICE;
AND
GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

ARTICLE 1 – INTRODUCTION AND PURPOSE

The United States Department of Agriculture's (USDA), Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) is responsible for responding to and investigating potential regulatory violations under authority of the Plant Protection Act. Such violations could include the unauthorized release of a regulated product of biotechnology. Depending on the specific situation, APHIS/BRS investigations may involve obtaining samples of the regulated article and having them tested in accordance with an independently verified analytical method to detect a specific genetic sequence, or a protein expressed by the plant.

Recognizing that USDA's Agricultural Marketing Service (AMS) and the Grain Inspection, Packers and Stockyards Administration (GIPSA) have technical expertise in the areas of commodity sampling, sampling plans, DNA- and protein-based test method verification, and analytical method development, and can provide sample testing services, this Memorandum of Understanding (MOU) provides a mechanism for BRS to rapidly enlist the support of AMS and GIPSA for emerging investigations involving potential regulatory violations.

Description of Services Covered. AMS (or their agent) has the authority and ability to provide sampling and inspection services on cotton, fruits, vegetables, seeds, and tobacco. AMS can similarly provide services for seed sample analyses, storage and germination. GIPSA (or their agent) has the authority and ability to provide sampling and inspection services on grains (including rice and oilseeds), pulses, and legumes.

AMS and GIPSA both maintain laboratories with the shared ability to conduct biomolecular testing of the plant materials described above. Both (alone or in

cooperation with each other) have the ability to (1) verify the efficacy of specific biomolecular test methods furnished by product developers with requisite reference materials and primer sequences; (2) verify commercially developed protein-based test kits, with requisite reference material; (3) develop and/or improve analytical methods when necessary; and (4) work under a single confidentiality agreement with a product developer (with the consent of the developer).

In addition, AMS has the ability to test large numbers of samples (that is, in a “production” environment.)

ARTICLE 2 - AUTHORITIES

APHIS is authorized by the Plant Protection Act, Sec. 431(a), Public Law 106-224, to cooperate with other Federal agencies, the governments of foreign countries, international organizations or associations, states and their political subdivisions, farmer’s associations and similar organizations, and other persons to detect, eradicate, suppress, control, and prevent or retard the spread of plant pests and diseases.

ARTICLE 3 - JOINT RESPONSIBILITIES

The Cooperating parties jointly agree to:

a. APHIS(BRS) will notify AMS and/or GIPSA when a situation arises in which they require assistance and support involving a commodity identified above. Such assistance could involve, but is not necessarily limited to, the following activities:

- (1) Developing a statistical sampling plan
- (2) Obtaining samples according to official AMS or GIPSA procedures, or a modification thereof specified by APHIS
- (3) Providing other assistance to APHIS field investigators relevant to AMS and/or GIPSA expertise
- (4) Verifying the efficacy of an analytical method to detect a specific genetic sequence
- (5) Validating the performance of a commercially developed protein-based test kit
- (6) Providing testing services on samples necessary to conduct the investigation
- (7) One laboratory providing quality control activities over the other

(8) Providing market intelligence on the commodity in question

b. When such a situation arises, APHIS, AMS and/or GIPSA will work together to identify the specific type and scope of services to be provided, the timeframe for completion, and the instrument and mechanism for documenting results. This exercise may involve developing a separate “scope of work” document, depending on the complexity of work, and may include other agencies within and outside of USDA.

ARTICLE 4 - COOPERATOR RESPONSIBILITIES

AMS and GIPSA agree to:

a. The AMS and GIPSA Administrators will each designate an authorized representative who shall be responsible for collaboratively administering the activities conducted under this MOU.

b. AMS and GIPSA understand the urgent nature typically associated with the conduct of an investigation and will strive to provide necessary services in a timely manner. AMS and GIPSA also understand and will respect the need for confidentiality associated with an investigation underway.

ARTICLE 5 - APHIS RESPONSIBILITIES

APHIS agrees to:

a. The APHIS Administrator will designate an authorized representative who shall be responsible for collaboratively administering the activities conducted under this MOU.

b. Reimburse AMS and GIPSA, upon request, for services and materials provided, on a cost-recovery basis. Such costs would be based on hourly rates established in 7 CFR, or negotiated on an a case-by-case basis and could include salary and benefits (including overtime, if requested by APHIS/BRS), travel, equipment, materials, and any other costs, if any, directly related to the services provided. AMS and GIPSA will provide a breakout of costs charged. APHIS may request and receive from AMS and/or GIPSA estimates of such costs prior to or during APHIS investigations that they support. APHIS will effect such reimbursement through a Reimbursement or Advance of Funds Agreement, AD-672.

c. APHIS will communicate any confidentiality requirements that are relevant and appropriate to the work that is requested of the parties to this MOU.

ARTICLE 6 - STATEMENT OF NO FINANCIAL OBLIGATION

Signature of this MOU does not constitute a financial obligation on the part of APHIS. Each signatory party is to use and manage its own funds in carrying out the purpose of this MOU. Transfers of funds or items of value are not authorized under this MOU, but may be transferred through separate agreement as described above in Article 5(b).

ARTICLE 7 - LIMITATIONS OF COMMITMENT

This MOU and any continuation thereof shall be contingent upon the availability of funds appropriated by the Congress of the United States. It is understood and agreed that any monies allocated for purposes covered by this MOU shall be expended in accordance with its terms and the manner prescribed by the fiscal regulations and/or administrative policies of the party making the funds available. If fiscal resources are to transfer, a separate agreement must be developed by the parties, as described above in Article 5(b).

ARTICLE 8 - CONGRESSIONAL RESTRICTION

Under 41 USC 22, no member of, or delegate to, Congress shall be admitted to any share or part of the MOU or to any benefit to arise there from.

ARTICLE 9 - AMENDMENTS

This MOU may be amended at any time by mutual agreement of the parties in writing.

ARTICLE 10 - TERMINATION

This MOU may be terminated by any party upon thirty (30) days written notice to the other parties.

ARTICLE 11 - EFFECTIVE DATE AND DURATION

This MOU will be in effect upon date of final signature and will continue for five years.

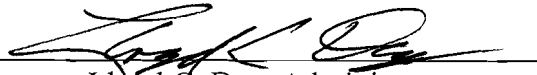
Approved and accepted by:



Cindy Smith, Administrator
Animal and Plant Health Inspection Service



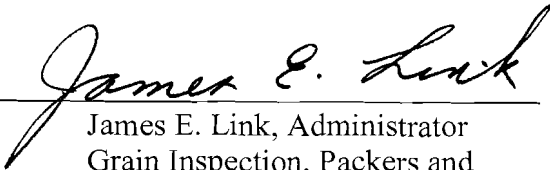
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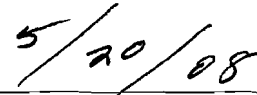
Lloyd C. Day, Administrator
Agricultural Marketing Service



Date



James E. Link, Administrator
Grain Inspection, Packers and
Stockyards Administration



Date