10530.2Gdlns forResduCtrlPgmbyMOU8/9/89

OPI: REPD
PART 1 OF 2

GUIDELINES FOR THE RESIDUE CONTROL PROGRAM ESTABLISHED BY MEMORANDUM OF UNDERSTANDING (MOU)

PART ONE--BASIC PROVISIONS

I. PURPOSE

The purpose of this directive is to:

A. Ensure that livestock and poultry produced for slaughter do not contain violative levels of chemical residues that would cause the resultant meat and poultry products to be adulterated within the meaning of section l(m) of the FMIA (21 U.S.C. 601(m)) and section 4(g) of the PPIA (21 U.S.C. 453(g)).

B. Establish criteria for an MOU program,

C. Establish procedures for an FSIS application review process of an establishment's residue control program,

D. Provide appeal procedures in the event a program is denied, suspended, or terminated by FSIS, and

E. Assign responsibilities for the program.

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

FSIS Directive 10,530.1, dated 8/11/87.
Federal Food Drug and Cosmetic Act (21 U.S.C. 301 et seq.)
FSIS List of Proprietary Substances and Non-food Compounds.

V. ABBREVIATIONS

The following will be used in their shortened form in this directive:

- AOAC - Association of Official Analytical Chemists
- AS - Area Supervisor
- CAST - Calf Antibiotic and Sulfa Test
- CP - Compliance Program, MPIO
- CS - Circuit Supervisor
- DA - Deputy Administrator
- EPA - Environmental Protection Agency
- FDA - Food and Drug Administration

FMIA - Federal Meat Inspection Act
IIC - Inspector in Charge
LAST - Live Animal Swab Test
MPIO - Meat and Poultry Inspection Operations
MOU - Memorandum of Understanding
PCB - Polychlorinated Biphenyls
PPIA - Poultry Products Inspection Act
REPD - Residue Evaluation and Planning Division, SCI
ROS - Residue Operations Staff, MPIO
SCI - Science Program
SOS - Sulfa On Site Test
STOP - Swab Test on Premise

VI. DEFINITIONS

As used in this directive, the following terms mean:

A. Animal. Livestock, poultry, or any other animal species raised for human consumption subject to the jurisdiction of the FMIA or PPIA.

B. Animal Drugs/Medications. Animal drugs regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C 301 et seq.).

C. Animal Feed. An article that is intended for use as food for animals, that is intended for use as a substantial source of nutrients in the diet of the animal, and that is not limited to a mixture intended to be the sole rations of the animal. Such articles include oats, hay, or grass.

D. Animal Feedstuffs. All animal feed, animal feed ingredients, finished animal feed, medicated animal feed, medicated water, and water.

E. Animal Feed Ingredients. Substances or products in animal feed which are fed to livestock for the purpose of fulfilling the nutritional needs of such livestock. Such ingredients include hay, grains, protein supplements, fats, minerals, vitamins, chemical supplements (such as salt, amino acids, and iron compounds), and byproducts (such as dried beet pulp and rice hulls.)

F. Applicant. An official establishment or person, firm, or corporation affiliated with an official establishment that applies to FSIS for participation in an MOU program or a person, firm, or corporation that is currently operating under the MOU program and has responsibility for, and control over, the conditions under which an animal is raised for slaughter.

G. Approved Residue Testing Procedures. Analytical procedures that are conducted using the Association of Official Analytical Chemists methods or an equivalent method.

H. Contaminant. Substances which cause violative levels of chemical residues in animals, including drugs, pesticides, or other chemicals such as PCB that are banned from use around a food animal.

I. Finished Animal Feeds. A mixture of animal feed ingredients that provides all or nearly all of the nutritional requirements of livestock. A finished animal feed may be the only product fed to such livestock or it may be fed with one or two supplements such as corn and/or a mineral mixture. A finished animal feed, with the intended supplement(s), is manufactured to

contain all the nutritional requirements for the type of livestock to which it is to be fed.

J. Fomite. Substances other than animal feedstuffs that come in contact with livestock and poultry that in themselves are not harmful but may harbor residues of animal drugs, pesticides, biological products, and other chemicals and that may transfer such residues between or to such livestock and poultry. Fomites may include such items as bedding and manure.

K. Inventory Control System. Records maintained on a monthly basis to show total amount in stock, source, and use of animal feedstuffs, animal drugs, and other chemicals. The inventory also includes the total amount of each animal drug that is used as approved in the producer's protocol.

L. Letter of Guaranty. A letter certifying a particular claim, with the issuer assuming liability if that claim is found to be false. M. Lot. A group of animals confined in the same production unit. Each animal is treated in the same manner as other animals in the group for a minimum of 100 days prior to slaughter or for the life of an animal, whichever is shorter. In a lot, all animals receive the same animal feedstuffs, medications treatment, and are subject to the same fomites. For the purposes of testing, any animal can be regarded as representative of all animals in the lot.

N. Medicated Animal Feeds. Finished animal feeds manufactured to contain prophylactic or therapeutic concentrations of animal drugs, biological products, or other chemical substances to affect infectious or parasitic agents or the physiological state of any livestock. Medicated animal feeds are regulated under Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360 (b)) and the Virus-Serum-Toxin Act (21 U.S.C. 151-159).

0. Medicated Water. Water to which prophylactic or therapeutic concentrations of animal drugs, biological products, or other chemical substances have been added to affect infectious or parasitic agents or the physiological state of any livestock.

P. MOU Program. A voluntary residue control program in which an applicant ensures that an animal produced for slaughter at an official establishment is not adulterated. The MOU program is a voluntary agreement between FSIS and an applicant, with the applicant accepting responsibility for the execution and recordkeeping of procedures developed to control the exposure of an animal to drugs, pesticides, and chemicals so that meat and poultry products from animals raised under a MOU are not adulterated with violative levels of drugs, pesticides or other chemicals. An element of the MOU program is the protocol as defined in Paragraph VI. R. of this directive.

Q. Official File. All documents maintained in FSIS that relate to an MOU program including recommendations by program reviewers and other documentation generated after approval of the MOU.

R. Production Control Protocol. An operational description of the

methods an applicant uses to control the exposure of an animal to drugs, pesticides, or other chemicals that may produce violative levels of chemical residues in meat and poultry products derived from animals raised under an MOU. Each protocol contains the necessary general elements that apply to each applicant as well as a description of methods unique to a particular applicant. For the purposes of this directive, the production control protocol will be referred to as "protocol."

S. Production Unit. A feedlot, farm, house, pen, or subunit of any of the above with its own feed, water, and fomites which is separated from other units by a barrier such as a fence or stall and in which an animal is raised for a minimum of 100 days prior to slaughter or for the life of an animal if less than 100 days.

VII. POLICY AND BACKGROUND

A. As a result of findings of poultry adulterated with chemical residues, a voluntary, cooperative residue program began in 1976 between FSIS and one poultry establishment to help ensure that an animal presented for slaughter at an official establishment does not contain violative levels of chemical residues that might result in the product being adulterated.

B. Eligibility to participate in the program requires that an official establishment be legally or economically integrated with the facility that raises the animals. The applicant agrees to either conduct its own feed testing and flock monitoring or make arrangements to have the feed tested and flocks monitored, as necessary, and takes action when an agreed-upon level of certain residues are found. This type of a voluntary agreement is known as an MOU. Because of the success of the initial MOU program, additional poultry establishments obtained FSIS approval to operate under the MOU program. In 1985, the MOU program was extended to cattle feedlot operations and in 1987, to swine operations.

C. To participate in the MOU program, the applicant develops a protocol to ensure that an animal raised by the participating production facility does not contain any violative levels of chemical residue when presented for slaughter. The protocol covers only those drugs, pesticides and other chemical residues which present a significant risk of causing violative levels of chemical residues in meat and poultry products from animals slaughtered under an MOU agreement. A protocol contains an operational description of the testing programs and control systems, if any, that will be utilized by the producer.

D. The types of tests, if any, performed and the combinations thereof, vary with each MOU. The following are examples of testing programs that may be part of an MOU agreement:

1. Testing of individual animal feed ingredients or medicated animal feed either by the feed company or the MOU applicant. Early test results may identify animal feed ingredients or medicated animal feed with the potential to cause a residue problem.

2. Testing of the finished animal feed or medicated animal feed

prior to or while such feed is being fed to livestock or poultry.

3. Testing samples of individual lots of animal feed ingredients or medicated animal feed held in the event retrospective testing is required.

4. Testing of animals prior to slaughter (i.e., LAST).

D. The control provisions to be used by each applicant in describing the protocol are provided in Paragraph VIII. of this directive.

E. Upon the presentation of official credentials by any duly authorized representative of the Secretary of Agriculture, access must be given to the applicant's operating records and production units to assure compliance with the MOU program.

F. The MOU program can be terminated immediately by telephone by FSIS or the applicant and must be confirmed by a letter within 5 days of the oral notification.

G. Applicants electing to operate under the MOU program must follow the guidelines outlined in this directive.

VIII. CRITERIA

A. Completion of Protocol. The applicant prepares and submits a protocol that describes how the applicant will control the exposure of an animal to drugs, pesticides, or other chemicals that may produce violative levels of chemical residues. Each significant route of exposure to drugs, pesticides, or other chemicals must be addressed in the protocol. The criteria of the protocol must meet the following provisions:

1. General Operating Provisions.

a. Production Facilities. Production facilities must be constructed and operating procedures implemented so that contamination risks are minimized. Specifically, the following areas must be covered in the protocol as described.

(1). Animal holding pens must be constructed so that an animal fed medicated feed cannot contaminate other animals. In some cases such contamination may occur if an animal which has been fed medicated feed eats from the same food or water bins as an animal which has not been fed medicated feed or water, or if the animal contacts fomites associated with a medicated animals. Facilities must be available for segregating a medically treated animal when necessary to prevent cross-contamination.

(2). Animal feedstuff transport machinery must be utilized in a manner that prevents medicated feed or water from contaminating feed or water fed to animals which are not on medicated feed and/or medicated water. If transport machinery is used for both medicated and non-medicated feed, cleaning procedures must be implemented to prevent contamination This may require separate transport systems when machinery cannot be effectively cleaned.

(3). Storage of animal feedstuffs, fomites, drugs, pesticides, or other chemicals, and water must be arranged to prevent possible contamination. Such contamination of storage materials could result in violative levels of chemical residues in meat and poultry products derived from animals raised under the MOU. In particular, no grease or oil, fuel, pesticide, paint, spray, medication, fomite, or any potentially contaminating drugs, pesticides, or other chemicals will be kept in any place used for storage, processing, or feeding of rations and water, or any other area where animals are raised. Animal feedstuffs in contact with the open air or the ground may be susceptible to contamination and such a storage practice may result in the disapproval of the protocol unless appropriate control or testing practices are implemented.

b. Recordkeeping. The following must be carried out in maintaining records:

(1). Maintain records for 2 years from the date the information was received.

(2). Provide written documentation about the following activities:

(a). The source of all animal feedstuffs, drugs, pesticides and other chemicals that were purchased or produced.

(b). All animal feedstuffs, drugs, pesticides and other chemicals that were used or consumed by the identified animal.

(c). The date the animal feedstuffs was fed to an animal.

(d). The services performed by a licensed veterinarian, as necessary and/or appropriate.

(e). The method by which the applicant determines that animal feedstuffs, fomites, drugs, pesticides, or other chemicals are being used appropriately.

(f). The method by which the applicant records inspection findings, resulting from the on-site monthly inspections .

(g). The procedure by which the applicant corrects deficiencies found during the monthly on-site inspections .

(h). The condition of storage and transportation of all animal feedstuffs.

(i). The formulation of all animal feedstuffs.

(j). The amount and type of bedding or fomites purchased and when they were used in an animal pen.

(k). The written results of laboratory tests, if any.

(l). Medical Treatment. A record of therapeutic treatment must be maintained at the production unit for all treatments given to an individual animal or any lot of animals. These records must describe

the following for a minimum of 100 days prior to slaughter or for the life of the animal, if less than 100 days:

(i). The individual identification of a treated animal or a lot of animals.

(ii). The generic name and amount of the medication given, the approximate body weight of a treated animal at the time of treatment, and how the treatment was administered.

(iii). The reason for treatment.

(iv). The date the treatment was given, the earliest permitted date for presentation for slaughter of an individually treated animal or lot of animals, and the date an animal was sent to slaughter.

(v). The name of the person(s) supervising and/or administering the treatment.

(vi). The method of disposal of the unused medication used in the treatment of an animal, if any.

(vii). The inventory control system maintained for each individual medical treatment or drug used, if the product is stored by the applicant.

(m). The records of the consulting veterinarian that records the dates and results of his/her review.

(n). Drugs, Pesticides, or Other Chemicals. The record of any drugs, pesticides, or other chemicals used on an animal or lot of animals, on areas where the animal is raised, or on any other area or article an animal comes in contact with, such as animal feedstuffs or fomites, must be maintained at the production unit. The name, date, amount, method and source used, and the reason for use must be included.

c. Management and Supervision. Management of MOU production facilities requires that employees have the appropriate skills for the jobs that are assigned. In particular, the following are required:

(1). Skill requirements for all employees must be determined by the applicant, and appropriate methods must be used to assess employee skills. If, when assessed, employees lack required skills or training, the applicant must document what training has been provided.

(2). Supervisory responsibilities must be described and assigned to appropriate positions in the organization. The applicant must have a current list of the names of all personnel assigned to supervisory positions, as well as a list of names and job titles of the person(s) to be contacted on site at each production facility.

(3). Implementation of procedures required by the MOU program must be checked through on-site inspections at least on a monthly basis. The applicant must determine the method of recording inspection findings and the procedure for correcting deficiencies.

d. Individual Medical Treatment. When medical treatment is administered to an animal or lot of animals, the following procedures must be undertaken:

(1). Where necessary to prevent cross-contamination of other animals, an individual animal requiring medical treatment must be isolated.

(2). Material and equipment used for treating an animal must be kept in a sanitary and orderly manner.

(3). An individually-treated animal must be identified by an ear tag, a back tag, a tattoo or brand, depending on the species of animal. For poultry, a group identification system must be maintained for each flock.

(4). Injections must not be given in those areas of a live animal, which will be the primary commercial cuts of the carcass, during the last 100 days prior to slaughter or life of an animal if less than 100 days.

e. Drugs, Pesticides, or Other Chemicals Use. Only FDA-approved animal drugs, EPA-approved pesticides, or other USDA-approved chemicals are allowed in the MOU program. In particular:

(1). No drugs, pesticides, or other chemicals may be used on animals or on areas where an animal is raised, or on any other area or article in which an animal may come in contact with, without the approval of the consulting veterinarian.

(2). The approved animal drugs, pesticides, or other chemicals will only be used in compliance with the labeled use on an animal or on anything with which they may come in contact, or, only in strict accordance with FDA's extra-label use policy.

(3). All pesticides, or other chemicals used in or around production facilities, establishments, and animal transport vehicles must be used in strict accordance with label instructions.

(4). All animal drugs, pesticides, or other chemicals must be stored in original containers that are clearly labeled.

f. Animal Identification. The MOU program is intended to help prevent and eliminate contamination that may result in violative levels of chemical residues in meat and poultry products derived from animals raised under an MOU. Therefore, it is necessary to know the specific conditions under which an animal is to be raised. This requires that an animal or lot of animals be identified as follows:

(1). An animal or bird raised in accordance with the requirements of the protocol must be identified at the production unit;

individually or by lot, respectively,

(2). A code must be used that identifies the particular production unit of the applicant, and

(3). A method of identification must be used that is consistent with marking agents described in the current edition of the FSIS publication, List of Proprietary Substances and Non-Food Compounds, in addition to any other animal identification required for a particular species.

g. Required Consulting Veterinary Practices. Because of the complexity and sophistication required in the design and operation of an MOU production facility, a licensed veterinarian must accomplish the following:

(1). Periodically visit each production unit participating in an MOU program and examine the operations and records of each unit.

(2). Record the dates and results of the reviews and give a copy of these records to the production unit manager for filing on site.

(3). Communicate with each unit regarding compliance with the MOU program and report any deviations from the protocol to the applicant who, in turn, notifies FSIS.

2. Animal Feedstuffs Provisions

a. Animal Feedstuffs. Animal feedstuffs given to an animal are a primary source of violative levels of chemical residues in meat and poultry products. To prevent adulteration, animal feedstuffs must be checked periodically to assure proper formulation. This requirement can be met as follows:

(1). No lot of animal feedstuffs will be used until the applicant has accomplished one of the following:

(a). Provided a written record of test results of random, representative samples from each lot for specific contaminants such as PCB. The samples must have been tested at a laboratory that FSIS has accepted in that the laboratory uses testing methods such as AOAC, quality assurance samples, and positive methods of sample identification.

(b). Provided a letter of guaranty from the supplier of the product that states that the animal feedstuffs do not contain drugs or other chemicals that will cause meat and poultry products derived from animals raised under an MOU to be adulterated. When a letter of guaranty is used as proof of proper formulation, reference samples from each separate lot of animal feedstuffs may be collected if either the establishment or FSIS elects. The lot size will vary depending on the purpose of the production facility. If reference samples are deemed

necessary, they must be collected as follows:

(i). A random sample of the animal feedstuffs must be taken from the lot at the time of delivery.

(ii). The sample must be maintained with clear markings as to date taken and identifying information.

(iii). Such samples may be destroyed 30 days after all animals which have been fed from the lot of animal feedstuffs have been slaughtered.

(2). Soybean meal showing contamination with animal feedstuffs or any other substance must not be used by the applicant.

(3). Any feedstuff bin or other holding or handling equipment that has come in contact with any feedstuff or water suspected or determined to be contaminated with drugs, pesticides, or other chemicals must be emptied and cleaned before it is used for handling or holding any noncontaminated feedstuff or water.

(4). When any animal feedstuffs contain drugs, the consulting veterinarian must be informed and approve its planned use.

b. Water. Contaminants may leak into water supplies because of improperly protected toxic waste dumps, chemical spills or other reasons. Since such contaminants are often colorless and tasteless, they can only be discovered through laboratory analysis. As a preventive measure, water given to an animal must be tested for contaminants twice a year at the expense of the applicant. If the water tested is found to be contaminated, such water must not be used for an animal covered by an MOU. An animal who has consumed contaminated water must not be sent to slaughter until it is determined that the animal does not have any violative levels of chemical residues. The determination is made by testing conducted by the applicant using a methodology approved by FSIS. Because of varying State and local requirements and conditions, water testing needs must be determined on an individual basis.

B. Ownership of Animals. An applicant for an MOU program must demonstrate control of animals by either owning the animals or showing legal or economic integration of the raising, slaughtering, and testing of the animals. Such control may be demonstrated through one or more of the following documents:

1. Partnership Agreements
2. Memoranda of Understanding
3. Contracts
4. Ownership of Cooperatives
5. Articles of Incorporation.

OPI: REPD
PART 2 OF 2

GUIDELINES FOR THE RESIDUE CONTROL PROGRAM ESTABLISHED BY MEMORANDUM OF UNDERSTANDING (MOU) PART TWO--APPLICATION REVIEW PROCESS

I. Application Component. An official establishment may apply to FSIS for approval of an MOU program that ensures that animals presented for slaughter are not adulterated with residues. Several stages of review take place before FSIS signs an MOU. FSIS will make the following determinations: (1). that the applicant has a history of cooperation with the Agency, (2). that the applicant is legally responsible for animals, (3). that the applicant has adequately planned raising procedures and appropriate residue testing procedures, (4). that the applicant has described how effective monitoring will occur, and, (5). that the applicant has described all aspects of the protocol for correct implementation. To make these determinations, the process begins with an applicant's request for an application package, as described below:

A. Request for an Application Package. Any applicant interested in participating in the MOU program may request information telephonically or in writing from the Director, ROS. The application package mailed will contain the following:

1. Standard Application Letter. The letter, when completed and signed by the applicant, is the official request to participate in the MOU program. The signed letter also authorizes any representative of USDA to evaluate and copy records and review operations at slaughter establishments and animal production facilities to determine if procedures meeting the criteria are implemented. The letter is submitted to the Director, ROS.

2. Memorandum of Understanding. The official document to be signed by both the applicant and FSIS official when protocol is approved.

3. Sample Production Control Protocol. An example of a protocol showing how the criteria for an MOU may be addressed.

4. FSIS Directive 10,530.2, Guidelines for the Residue Control Program Established by Memorandum of Understanding (MOU).

5. Instruction Sheet. This sheet describes what materials or forms must be prepared by the applicant and to whom the documents must be submitted.

II. EVALUATION OF APPLICATION

A. Phases. The evaluation of the application includes the following steps:

1. Eligibility Criteria. The applicant, and the official establishment if the official establishment is not the applicant, on the standard application letter, requests that FSIS determine his/her eligibility for participation in an MOU program. Eligibility is determined by a historical review coordinated by the Director, ROS. To be considered

eligible, the information requested in the application must be complete and the applicant must also:

a. Show a history of cooperating with FSIS's missions and goals.

b. Extend a request for any duly authorized representative of the Secretary of Agriculture to examine production facilities and records that are deemed relevant for determination of program implementation.

c. Demonstrate the control of animal raising, testing, and slaughtering.

2. Determination of the Evaluation. When FSIS determines that an applicant is eligible to participate in the MOU program, the applicant will be notified by the DA, MPIO. In the notification letter, a request will be made to prepare a detailed protocol. At that time, the Science Program will be informed that a protocol is being prepared. If an applicant is determined to be ineligible, the DA, MPIO, will notify the applicant of the decision and reasons for the decision.

3. Submission of the Protocol. When an eligible applicant submits a protocol to the Director, ROS, several FSIS offices review the protocol for determinations such as: (1). the necessary timeframe to complete an on-site visit of the production facility, and, (2). if the protocol is operationally feasible. The preparation of a review plan begins as described in Paragraph II. A. 4, of this directive. If the protocol meets the MOU criteria, the applicant is informed as described in Paragraph II., A. 5.

4. Preparation of the Review Plan. If a submitted protocol meets the criteria as described in Paragraph VIII. of this directive, a review plan is prepared. The plan describes what FSIS activities are necessary to assure that the applicant and related producers are correctly operating under the provisions of the MOU. The review plan along with the protocol is forwarded to several FSIS offices for operational and enforcement determinations. The procedures for notifying the applicant is described in Paragraph II., A. 5., of this directive.

5. Inform Applicant of the Approval/Nonapproval of the Protocol. After all program areas complete their review of the protocol, determine it to be operationally feasible, and prepare the review plan, a letter is forwarded to the applicant to advise that the protocol, as approved by FSIS, must not be revised unless changes/additions are approved by FSIS. (See Paragraph II. 8. A. of this directive.) The applicant is also informed that an FSIS on-site visit will be scheduled after formal notification from the applicant that the protocol is fully implemented. If it is determined that the protocol has deficiencies and does not meet the MOU criteria and, therefore, is not approved, a letter will be forwarded to the applicant explaining the reasons for that decision and further advising that the applicant may either submit a revised protocol that corrects the deficiencies

or withdraw the application.

6. On-Site Visit and Report. When the applicant informs FSIS that the protocol is implemented, the appropriate FSIS operations and science personnel will schedule and conduct a joint visit to review all aspects of the protocol. If no deficiencies are found during the on-site visit, the applicant is informed at the exit interview and requested to sign MOU. If deficiencies are found, the applicant is informed in an exit interview that when all deficiencies are corrected, another on-site visit will be scheduled. A report of the on-site visit is jointly prepared by FSIS operations and Science personnel.

7. Notification of Approved MOU Program. An FSIS official signs the MOU and returns a copy to the applicant; one copy of the MOU is placed in the official file. All FSIS personnel with review responsibilities are also notified when an approved MOU program is in operation. The appropriate FSIS personnel are further notified that review tasks should be scheduled and conducted as detailed in the review plan.

8. Proposed Changes/Additions to the Protocol. If an applicant proposes any changes/additions to an approved protocol, the Director, ROS, receives the request and forwards it to the appropriate FSIS offices for review. If, after those reviews, a determination is made that the proposed changes/additions are in accord with the approved protocol on file, the Agency's decision is forwarded to the applicant.

III. MOU APPEAL PROCEDURES

In the event of a decision to either deny or terminate an MOU program by FSIS, the following steps are followed:

a. The DA, MPIO, may terminate an MOU program effective upon receipt of oral notification followed by a written notification within 5 days.

b. The DA, MPIO, submits a letter to the applicant outlining the reasons for the determination.

c. The applicant may appeal the Agency's decision by presenting his/her views in person or in writing to the DA, MPIO, within 30 days of receiving the termination letter. Following the presentation of views, the DA, MPIO, determines whether to reverse or uphold the initial determination.

d. The DA, MPIO, arranges for an oral hearing with the applicant and the Administrator, FSIS, if any facts are in dispute or if the applicant wishes to again appeal the Agency's decision. Following the hearing, the Administrator makes a final determination to approve or deny the application, to revoke the termination of the MOU program or uphold the termination decision.

e. The applicant may reapply for an MOU program after correcting those conditions which resulted in the denial or termination action.

IV. NOTIFICATION OF CURRENT APPLICANTS

In conjunction with the regional offices, the DA, MPIO, will notify current applicants operating in an MOU program of the instructions contained in this document. The applicants will have 6 months, from the date notified, in which to comply with the provisions of this directive.

PART THREE--RESPONSIBILITIES

I. Meat and Poultry Inspection Operations

A. The Deputy Administrator

1. Receives the application package from the Director, ROS, and refers it to the DA, SCI.

2. Receives the MOU, approved protocol and review plan from the DA, SCI, and forwards them to the Director, ROS, to determine if they are operationally feasible.

3. Notifies the applicant that the protocol will or will not be accepted.

4. Returns the approved MOU to the applicant for signature.

5. Signs the MOU once the applicant has successfully implemented the protocol, signs and returns the MOU.

6. Notifies the DA, SCI, of the signed MOU.

7. Forwards copies of approved MOU to the RDs, resulting in copies being forwarded to the AS and CS.

8. Assures that the review plan is implemented.

9. Assures that on-site reviews occur.

10. Assures that reports on the initial and annual on-site visits are completed.

11. Reviews all applicant requests for proposed changes/additions in the MOU and notifies the applicant of the Agency's decision.

12. Reviews all recommendations for suspending or terminating an applicant's MOU program and notifies the applicant when such action is taken and the reasons for the action.

13. Presides over presentation of applicants' views regarding

termination of MOU program.

14. Arranges oral hearing with applicant and Administrator, if necessary.

15. Notifies applicants currently operating under the MOU program of this directive and of the requirement to comply with instructions herein within 6 months.

B. The Assistant DA, CP

1. Receives approved protocol and the review plan from the Director, ROS, to review for enforcement activities and submits appropriate recommendations, if any, to the Director, ROS.

2. Investigates reports of alleged violations of an MOU program as requested by the Director, ROS.

3. Collects and documents evidence necessary to provide the DA, MPIO, through the Director, ROS, with recommendations on suspending or revoking an applicant's approved MOU program.

4. Provides a program for planned reviews of past, present, or suspected violators of an MOU program.

C. The Director, ROS

1. Receives the initial request from the applicant to participate in the MOU program.

2. Sends the application package to the applicant.

3. Determines the compliance history of the applicant and informs the applicant if ineligible. Such determination includes consulting with Regional Directors, MPIO.

4. Reviews documentation of ownership.

5. Submits the completed application package to the DA, MPIO, for distribution to other FSIS units for review.

6. Receives the MOU, approved protocol and review plan from the DA, MPIO, and determines if they are operationally feasible.

7. Forwards a copy of the approved protocol and review plan to the Assistant DA, MPIO, CP, for review.

8. Assures that the review plan is implemented.

9. Coordinates and participates with the Director, REPD, and the Regional Residue Staff Officer in the initial and annual on-site reviews of the production units.

10. Participates with the Director, REPD, in preparing the initial and annual on-site visit reports.

11. Maintains the official Agency file containing the MOU and all related documents for at least 2 years.

12. Maintains for 1 year all documentation generated on unapproved MOU applications, and, thereafter, destroys all such documentation if justification does not exist for maintaining them.

13. Receives applicant's request for proposed changes/additions to the approved MOU or supporting documentation and submits the request to the DA, SCI, through the DA, MPIO, or other appropriate offices for review before approving or denying the request.

14. Evaluates determination to approve or deny protocol changes/additions to an applicant's MOU program by reviewing officials.

15. Submits recommendations on requested proposed changes/additions to the DA, MPIO, and provides necessary paperwork for transmitting the Agency decision to the applicant.

16. Receives requests for MOU terminations and submits such requests to the DAs, MPIO and SCI, for information and initials.

17. Receives reports of actual or suspected violations of the MOU and requests investigation by ADA, MPIO, CP.

18. Reviews investigative documentation collected by CP and/or the Regional Residue Staff Officer and, when appropriate, submits to the DA, MPIO, recommendations on suspending or revoking an establishment's approved MOU program.

19. Notifies other government agencies of investigative documentation regarding actual or suspected violations, as appropriate.

20. Notifies the DA, SCI, through the DA, MPIO, and other concerned FSIS offices of all changes in an applicant's MOU or in the status of an MOU.

21. Provides support to the Regional Residue Staff Officer.

22. Monitors reports of periodic on-site reviews by the Regional Residue Staff Officer and determines if the reviews indicate the MOU program is being executed appropriately in both the production unit and the establishment. Makes recommendations to the DA, MPIO, as necessary.

23. Accompanies each Regional Residue Staff Officer on at least one review annually of production units and establishments operating under an MOU.

24. Generates an annual report on the MOU program for Agency use.

25. Assures that applicants currently operating under the MOU program are notified of this directive and comply with instructions herein within 6 months.

D. The Regional Director

1. Receives from the DA, MPIO, copies of approved MOUs.
2. Copies and forwards approved MOUs to the AS.

3. Assures that the AS and CS oversee the IIC's monitoring of the MOU program which includes maintenance of required logs, files of applicants' production units, and the identification and segregation of MOU animals during ante-mortem and post-mortem inspection.

4. Interacts with managers of production units operating under an MOU program to assure an understanding of responsibilities and goals of the MOU program.

5. Assures that periodic on-site review is completed.
6. Assures that the review plan is implemented.

7. Forwards to the Director, ROS, a report of the periodic on-site review and the completion results of the review plan.
8. Forwards annual status report to the Director, ROS.

E. The Regional Residue Staff Officer

1. Participates with the Directors, ROS and REPD, in the initial on-site review of the production units.

2. Notifies the IIC of establishments under his/her jurisdiction that are approved to operate under an MOU program. Submits a copy of the approved MOU to the IIC.

3. Discusses with the IIC his/her responsibilities under the MOU and assures that necessary resources are available to perform the added duties.

4. Assures that the review plan is implemented.

5. Assures that the IIC maintains records of post-mortem observations required by the review plan. Assures that the IIC receives records of individually medicated animals prior to ante-mortem inspection and maintains records of post-mortem observations required by the review plan of all animals from product units operating under an MOU.

6. Conducts unannounced visits on at least an annual basis of establishments within the region that operate under an MOU program.

7. Conducts unannounced visits on at least an annual basis of a representative number of production units involved in raising animals slaughtered under an MOU program.

8. Assures that managers of the production units and establishments comply with the MOU and protocol.

9. Interacts with managers of production units, establishments, and companies operating under an MOU to assure an understanding of responsibilities and goals of the MOU program and encourages cooperation in achieving these goals.

10. Reports to the Director, ROS, any actual or suspected violations of an MOU program.

11. Ensures that applicants currently operating under the MOU program are notified of this directive and comply with instructions herein within 6 months.

12. Submits to the Director, ROS, through the RD, an annual status report.

13. Submits to the Director, ROS, through the RD, periodic on-site review results.

F. Area Supervisor

1. Receives from the RD copies of approved MOUs.
2. Copies and forwards approved MOUs to the CS.

3. Assures that the review plan is implemented.

4. Assures that the IIC monitors the MOU program which includes the maintenance of required logs, files of applicants' production units, and the identification and segregation of MOU animals during ante-mortem and post-mortem inspection.

5. Forwards to the RD the CS's input for the residue annual status report.

6. Reports to the RD any suspected or actual violations of an MOU.

G. Circuit Supervisor

1. Receives copies of approved MOUs from the AS.
2. Assures that the review plan is implemented.

3. Assures that the IIC monitors the MOU program which includes the maintenance of required logs, files of an applicants' production units, and the identification and segregation of MOU animals during ante-mortem and post-mortem inspection .

4. Assures that unannounced visits of an applicant's production unit within the region are made on at least an annual basis.

5. Assures that the IIC maintains records of post-mortem observations required by the review plan.

6. Assures that the IIC receives records of individually medicated animals prior to ante-mortem inspection and maintains records of post-mortem observations of all animals from product units operating under an MOU program.

7. Interacts with managers of production units, and companies operating under an MOU to assure an understanding of responsibilities and goals of the MOU program and encourages cooperation in achieving these goals.

8. Reports to the AS any suspected or actual violations of an MOU program.

9. Notifies the IIC of applicant operating under an MOU program and provides a copy of the MOU.

10. Discusses with the IIC his/her responsibilities under the MOU and assures that necessary resources are available to perform the added duties.

11. Participates with the Regional Residue Staff Officer in performing the historical review of the applicant for an MOU program.

12. Assures that the IIC maintains copies of all approved MOUs for his/her area of responsibility.

H. The Inspector-in-Charge

1. Participates with the Director, ROS, in performing the historical review of the applicant for an MOU program.

2. Cooperates with the on-site review team during initial review of an establishment applying for an MOU program.

3. Receives notification from the RD of applicants operating under the MOU program.

4. Receives notification from establishment management prior to slaughter of animals raised under an MOU program or production of products from an animal raised and slaughtered under an MOU.

5. Maintains copies of approved MOUs.

6. Receives medical records of individually medicated animals prior to slaughter of animals raised under an MOU program, and returns records to management.

7. Monitors the establishments' programs, such as partial quality control, to maintain identification and segregation of MOU animals during ante-mortem and post-mortem inspection .

8. Interacts with establishment management to promote

understanding of responsibilities and goals of the MOU program and encourages cooperation in achieving those goals.

9. Assures that establishment managers comply with provisions set forth in the MOU program.

10. Reports suspected or actual violations of an MOU program to the Regional Residue Staff Officer.

II. Science

A. The Deputy Administrator

1. Receives from the DA, MPIO, the application package, and refers it to the Director, REPD.

2. Collaborates with the DA, MPIO, in scheduling and reporting the on-site visits.

3. Receives the application package from the Director, REPD, after his/her review, with concurrence from other appropriate Science Division Directors, and reviews and evaluates the scientific evaluation of the protocol, the review plan, and any additional information needs of SCI to assist in the scientific evaluation.

4. Approves, if scientifically appropriate, and returns the package to the DA, MPIO.

5. Follows the same steps with changes in a protocol or informational needs requests.

B. The Director, REPD

1. Receives the application package from the DA, SCI.

2. Evaluates the proposed protocol and documentation for scientific validity.

3. Develops a review plan.

4. Determines any additional information needs of SCI to evaluate the MOU program.

5. Confers with the MOU applicant to ensure that a scientifically satisfactory protocol is prepared.

6. Receives for review the proposed changes/ additions to an approved protocol and returns it to the Director, ROS.

7. Consults periodically with the Director, ROS, the Assistant DA, MPIO, CP, and other divisions in the SCI area, as necessary. 8.

Submits the evaluation of the protocol, review plan schedule and information needs to the DA, SCI.

9. Arranges, in conjunction with the Director, ROS, the initial and annual on-site visits of MOU applicants.

10. Participates with the Director, ROS, in preparing the initial and annual on-site visit report.

11. Files and maintains a copy of the MOU program, evaluation, review plan and additional information needs.

III. Review and Evaluation Staff

A. The Director

1. Serves in an oversight capacity.

2. Develops a plan to determine if the MOU program is operating effectively, if requested to conduct a review by the Administrator.

Lester M. Crawford
Administrator