

**UNITED STATES RESPONSE
TO
CRITERIA FOR ASSESSING THE
ADEQUACY OF THE RESIDUE CONTROL PROGRAM**
for Meat, Poultry and Egg Products

Definitions

Residue program: A combination of educational, research and regulatory enforcement activities designed to provide: (1) a structured process for identifying and evaluating drugs, pesticides and other chemical compounds of concern by slaughter class and/or egg product; (2) capability to analyze compounds of concern reliably; (3) appropriate regulatory follow-up of reports of violative tissue residues in meat, poultry and egg products; and (4) collection, analysis, and reporting of the results of these activities.

Residue plan: The anticipated testing regimen to analyze compounds of concern reliably for specific slaughter classes and/or egg products for a specified time period.

I. Background

The purpose of this section is to obtain general information about animal husbandry, availability of drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides. This information will be used to determine equivalency with the United States' residue control program.

A. Provide total population figures of food animal by each species.

Response: In FY 1998, FSIS inspected over 129.1 million head of livestock and over 7.8 billion birds. The 1998 food animal population figures slaughtered for the United States for species are as follows:

<u>Species</u>	<u>Estimated Population</u> (head)
<u>Cattle and Calves</u>	
<i>Cattle (including beef cows, dairy cows, bulls, steers and heifers)</i>	32,531,827
<i>Calves</i>	1,439,868
<u>Swine</u>	91,372,522
<u>Goats, Sheep and Lambs</u>	
<i>Goats</i>	390,677
<i>Sheep and Lambs</i>	3,343,076
<u>Equines</u>	71,173

<u>Other Livestock</u>	10,582
<u>TOTAL Livestock slaughtered under Federal Inspection:</u>	129,159,725
<u>Chickens</u>	
Young chickens	7,415,604,729
Mature Chickens	159,071,989
<u>Turkeys</u>	
Fryer-roaster Turkeys	743,984
Young Turkeys	262,593,144
Mature Turkeys	1,894,150
<u>Ducks</u>	22,426,112
<u>Other</u>	8,857,580

- B. Do animals slaughtered for export to the U.S. originate in another country other than the native country? Are egg products exported to the U.S. produced from eggs originating in other countries?
Response: In the United States, animals are imported from Canada and/or Mexico for slaughter and any animal in the total population is eligible for export. If necessary, animals can be traced back to the grower/country of origin through information provided by the slaughterhouse management. In the case of egg products, eggs can originate in the Netherlands, Israel or Canada.
- C. Describe the husbandry practices commonly used for each species of animals slaughtered for export to the U.S. Information should describe such factors as:
1. Type of housing used for rearing animals; for example, confinement versus pasture (free-range), individual stalls or cages, group pens, etc.
Response: Generally, cattle and sheep are pastured at times during early and mid-life. However, prior to slaughter, approximately 95 percent of the steers and heifers and 65 percent of the lambs are confined to feedlots for intensive feeding to promote weight gain. Approximately 90 percent of the hogs and nearly all poultry in the United States are raised by means of confinement practices.
 2. Unique weather conditions which may require special housing
Response: Generally, climatic conditions in the United States are favorable for constant, year-round food animal production practices. Cattle are usually kept on range or in feedlots unprotected from the weather. On occasion, cattle may be moved to more protected areas during severe storms or periods of prolonged wet weather. Hogs for the most part are furnished shelter in either fully enclosed buildings or in

modified open-front buildings. Some hogs are raised on concrete floors with simple shelters constructed to protect them from severe weather elements or extreme changes in temperature. Sheep are frequently moved to high mountain meadows for summer grazing. In the fall, before heavy snowfall, they are returned to lower elevations where they may be housed and maintained during the winter largely on stored feeds, until well after lambing in the spring. Poultry are housed year-round.

3. Type of feed given to animals (commercial source or farmers mix/grow their own)

Response: Cattle: In the United States, specialized commercial cattle feeding is replacing the traditional enterprise of feeding small lots of cattle on farms producing feedgrains. Cattle producers with lots less than 1000 head capacity are considered farm feedlots, and are usually operated by a farm unit that produces its own feedgrains. Farm feedlots make up about 97 percent of all lots but feed only 19 percent of the cattle. In excess of 80 percent of the cattle produced for slaughter come from large commercial feedlots whose operators purchase the necessary grain and protein supplements.

Hogs: Nearly 95 percent of the hogs produced for slaughter in the United States are grown in the North Central and Southeast regions of the country. The dominant feedstuffs used in hog production are grains (mostly corn) and protein supplements consisting of soybean meal and salt, minerals and vitamins. Grains account for about 80 percent and protein supplements for 20 percent of the total amount of feed used. In the North Central region, approximately 90 percent of the hog producers with farrow-to-finish and feeder pig finishing operations grow their own feedgrain. The remaining 10 percent purchase the grain. In the southeast region, fewer than 50 percent of the hog producers with farrow-to-finish and feeder pig operations grow their own grain. The largest hog producers (50,000 head and over) in this region depend almost completely on purchased grains. Virtually all producers in both regions purchase the protein supplements from commercial sources, which are either premixed or mixed separately with the producers' own feed.

Poultry: Approximately 95 percent of the poultry producers are provided feed rations from nearby feedmills which specialize in formulating feed for local producers.

4. Typical age of animals when slaughtered

Response: In general, livestock and poultry are not slaughtered at a certain age. They are sent to market when they reach a designated weight or size, as with market swine, steers and heifers. Older animals are sent to market when they cease to produce at a desired production level.

Cattle:

Beef cows 5-8 years

Beef cows are sent to slaughter when they have reproductive problems or do not produce a calf.

*Dairy cows 4-5 years
Dairy cow culling rates are 30-40% of the herd each year.*

*Heifers 14-16 months
Steers Heifers and steers are sent to slaughter at about 1,000 pounds live weight to produce a dressed weight of 700-800 pounds.*

*Bulls 2 years or younger
Young bulls are sent to slaughter if they do not have desired breed characteristics or show poor performance such as inefficient weight gain.*

*Over 5 years
Mature bulls are sent to slaughter when they have reproductive problems.*

*Calves Under 9 months
The upper weight for calves (live weight) is 750 pounds, which was modified in 1989. Calves include the following veal classes/types: Bob veal-under 150 pounds, formula fed and non-formula fed veal-151-400 pounds.*

Swine:

*Market hogs 9 months
Market hogs are sent to slaughter between 230-250 pounds.*

*Sows 3-4 years
Sows are sent to slaughter when they have reproductive problems or do not produce pigs.*

*Boars 1-2 years
Young boars are sent to slaughter if they do not have desired breed characteristics or show poor performance traits such as weight gain.*

*Over 3 years
Mature boars are sent to slaughter when they have reproductive problems or do not produce pigs.*

Sheep:

Mutton Over 2 years

Mutton meat comes from mature sheep, including spent ewes and 1-2 year old yearlings. Mutton meat is differentiated from lamb meat based on several criteria, including the degree of calcification of the spool joint (generally occurs at 12-14 months.)

*Lamb 9-14 months
“Spring lambs” may be younger.*

Poultry:

Layers 9-10 months

Broilers 40-50 days

*Turkeys: On the average, 3-6 months
Male “toms” around 5-6 months, female “hens” around 3-4 months.*

5. Treatment for internal and/or external parasites (identify animal diseases or conditions commonly requiring treatment)

Response: In the United States, food animals are routinely treated for certain types of internal and external parasites whenever there is a likelihood that such parasites exist and are known to be a problem. Cattle, hogs and sheep are commonly treated for the prevention of nematodes and other types of internal parasites. Treatment for external parasites such as mites and ticks are also routine. Poultry are commonly given medicated feed supplements for the control of protozoa parasites such as coccidia.

6. Marketing practices

- a. average number of animals in slaughter lot

Response: Cattle: Cattle raised for beef are marketed generally through farm feedlots or large commercial feedlots. The number of beef cattle sent to slaughter from one source can vary between 1-500 head, depending on the type of slaughterhouse and its capacity. The average lot size is typically a truckload, comprising 45 head.

Cull cows/bulls (dairy and beef): These animals are marketed by producers primarily through auctions. Producers generally take between 1 –10 head to auction at a particular time. The average lot size is typically 2 head.

Confinement Fed Fancy Calves: These animals are sold directly from the producer to the slaughterhouse. Depending on the size of the operation, lot sizes can vary between 1 – 50 head.

Swine: Hogs are marketed directly from the producer to the slaughter facility or sent to a buying station, then to slaughter . Lot sizes range

from 1 – 600 head from a single source. The average lot size is typically 40 head.

Sheep: Sheep can be sold directly to the slaughterhouse or marketed through commercial feedlots. Lot sizes range from 1 – 1000 head, with the larger lots representing the producer's entire flock. The average lot size sent to slaughter is typically 200 head.

Poultry: The U.S. poultry industry is predominately vertically integrated, in that the slaughter company owns the birds and has contracted the producer to raise them. Lot sizes for broilers range from 10,000 to 60,000 birds per house, with the average lot size typically 25,000. Lot sizes for turkeys can range from 1000 – 4000 birds per house, with the average lot size typically 2500.

- b. slaughter lots comprised of animals from one farm or from several farms/growers

Response: Composition of the slaughter lot depends on the type of slaughter establishment. Typically, slaughter lots of beef cattle, confinement fed fancy calves, sheep on feed, market hogs, and poultry are frequently from the same grower/feedlot while cull cows/bulls and boars/sows are from several farms/growers.

- D. What measures are taken to prevent exposure of food animals to pesticides?

Response: Commercially produced animal feed is routinely tested for pesticide residues by the company manufacturing the feed; as well as the government regulatory agencies. All pesticides must be registered with the U.S. Environmental Protection Agency (EPA) before they can be distributed or sold in commerce. Pesticide applicators, including animal producers, must undergo training and be licensed before they can purchase and use pesticides.

- E. What measures are taken to prevent exposure of food animals to environmental or industrial contaminants?

Response: EPA has regulations that help prevent contamination of food and feed products through standards for certain chemicals to ensure clean air and clean and safe water. These standards help to keep environmental and industrial contaminants out of the environment, and therefore, to prevent exposure of food animals. Another example of regulations that help prevent contamination is the EPA New Chemicals Program. Under this program, manufacturers and importers of new chemicals are required under the Toxic Substance Control Act (TSCA) to submit certain information on new chemicals. If during EPA's review of this information, it is believed that the use will result in unacceptable exposure or risk, then certain uses may be restricted.

Under TSCA, there is one chemical in particular, polychlorinated biphenyls (PCBs), that has some specific regulations which will help prevent

contamination of meat products. In 1985, the use and storage for reuse of PCB transformers that pose an exposure risk to food or feed was prohibited. This was to prevent the contamination of food products in the event of an explosion or leak in the electrical equipment.

II. Organization and legal authority

The purpose of this section is to describe the specifications of the legal basis and the organization of the government's activities to prevent contamination of food products with chemical residues.

A. Are the preventative measures taken to satisfy the U.S. requirements handled through a central (National), regional (local) or special export residue program?

Response: The FSIS has assumed responsibility for coordinating the efforts behind the National Residue Program (NRP). The NRP consists of a combination of educational, research, and regulatory enforcement activities involving multiple Federal and State agencies. The program is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by slaughter class; (2) capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, analysis, and reporting of the results of these activities. In addition, FSIS is able to coordinate special residue testing programs specific for countries where product is being exported.

B. Identify and summarize the laws and regulations concerning:

1. Approval and use of food animal drugs and agricultural chemicals

Response:

- 1. Federal Food, Drug, and Cosmetic Act (FFDCA) provides for the establishment of tolerances, or maximum legal limits, for animal drug residues in tissues of food-producing animals. Additionally, the law establishes tolerances for pesticide residues in food or feed crops marketed in the United States (Code of Federal Regulations (CFR 21, Part 556.)*
- 2. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) sets forth procedures, requirements and criteria for the registration of pesticide products (CFR 40, Parts 150-189.) The primary focus is to provide federal control of pesticide distribution, sale, and use; as well as to require users to register when purchasing pesticides.*
- 3. Food Quality Protection Act (FQPA) amends the FFDCA and FIFRA to establish a more consistent, protective regulatory scheme, grounded in sound science. It mandates a single, health-based standard for all pesticides in all foods; provides special protections for infants and children; expedites approval of safer pesticides; creates incentives for the development and maintenance of effective crop protection tools for American farmers; and requires periodic re-evaluation of pesticide*

- registrations and tolerances to ensure that the scientific data supporting pesticide registrations will remain up to date in the future.*
4. *Toxic Substances Control Act (TSCA) provides for the protection of human health and the environment from unreasonable risks arising from the manufacture, distribution, use, or disposal of chemicals (CFR 40, Part 700-1517.)*
 5. *Organic Act (OA) provides for the issuance of phytosanitary certificates for plants and plant products and exports (CFR 7, Parts 300-399.)*
 6. *Tariff Act (TA) prohibits the importation of livestock and uncooked meat products from such animals from countries where rinderpest or foot-and-mouth disease exist (CFR 9, Parts 1-199.)*
 7. *Federal Meat Inspection Act (FMIA) provides for the protection of the health and welfare of consumers by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged (CFR 9, Parts 300-335.)*
 8. *Poultry Products Inspection Act (PPIA) provides for the compulsory inspection of poultry and poultry products to prevent the movement in interstate or foreign commerce...of poultry products which are unwholesome, adulterated, or otherwise unfit for human consumption (CFR 9, Part 381.)*
 9. *Egg Products Inspection Act (EPIA) provides for the protection of the health and welfare of consumers by assuring that eggs and egg products distributed to them and used in products consumed by them are wholesome, not adulterated, and properly labeled and packaged (CFR 7, Part 59.)*

Three Federal Agencies play major roles in protecting the public from residue hazards by enforcing the above laws: (1) The United States Department of Agriculture (USDA), including the Food Safety and Inspection Service (FSIS), the Agricultural Marketing Service (AMS) and the Animal and Plant Health Inspection Service (APHIS); (2) the Department of Health and Human Services (HHS) and its Food and Drug Administration (FDA); and (3) the Environmental Protection Agency (EPA).

- a. Provide lists of the following types of substances, specified by chemical names, permitted for use in your country:
 - (1) drugs permitted for therapeutic and preventative use in each species of food animals
Response: See the enclosed copy of FARAD, Food Animal Residue Avoidance Databank, which is a comprehensive compendium of food animal drugs approved in the United States (Attachment 2).
 - (2) prohibited substances
Response: 21 CFR Sec. 530.41 Drugs prohibited for extralabel use in animals. The following drugs, family of drugs and substances

are prohibited for extralabel animal and human drug uses in food-producing animals:

- (1) Chloramphenicol*
- (2) Clenbuterol*
- (3) Diethylstilbestrol (DES)*
- (4) Dimetridazole*
- (5) Iprnidazole*
- (6) Other nitroimidazoles*
- (7) Furazolidone (except for approved topical use)*
- (8) Nitrofurazone (except for approved topical use)*
- (9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxypyridazine).*
- (10) Flouroquinolones*
- (11) Glycopeptides*

- (3) pesticides permitted for use in or on each species of food animals, permitted for crops used in feed processing and storage facilities, or permitted for use in meat processing establishments.

Response: Listings of pesticide registrations by site or by pesticide are available from The Pesticide Programs Information System, which can be downloaded from EPA's website (<http://www.epa.gov/opppmsd1/PPISdata>.) Tolerances, as well as exemptions from the requirement of a tolerance, for residues of pesticides in food animals and in crops, including those used in animal feeds, are listed in 40 CFR 180. This section is updated daily through publication of the Federal Register. It also contains an index to tolerances by commodity, including food animal tissues and an index to tolerances by common name. The Tolerance Index System (TIS) is available on the EPA website.

- b. For each drug and chemical listed in your residue plan, identify:
 - (1) the species;
 - (2) the target tissue used as analytical control;
 - (3) a list of the Maximum Residue Limits (MRL) [tolerance or action limits]

Response: See Attachment 3: Residue Limits for Compounds in the Domestic Residue Program.

2. Specify the procedures used to approve the use of each substance listed in II.B.1.a. (For example, available by veterinary prescription only, limited availability to authorized distributors, detailed directions for use, penalties for misuse, withdrawal times, extra and/or off label use, etc.)

Response: The FDA approves animal drugs, monitors their use and sets tolerances for residues of such drugs in meat and poultry products. Under Section 512 of the FFDC (amended), before a new animal drug may be

used for any purpose, its use for a particular purpose must be approved by FDA. Under the premarketing clearance requirements of the FFDCA, FDA will not approve a new animal drug unless it is adequately demonstrated to be safe and effective for use under the conditions proposed and, if used in food animals, not pose a danger to public health. Anyone who adds drugs to feed is subject to the FFDCA. Just as each label claim for a new animal drug must be approved, so too must the drug be specifically approved for administration in animal feed. FDA requires animal drug residues in meat and milk to be proven safe, and sets a limit or tolerance on the amount of residues allowable in food. FDA may establish a drug withdrawal period before slaughter of an animal, and the animal drug in question may not be administered during the withdrawal period.

- C. Briefly summarize the procedures employed for enforcing the above laws and regulations.

Response: USDA is responsible for enforcing and administering the FMIA, PPIA, EPIA, OA and the TA. Within USDA, FSIS ensures the safety of meat, poultry and egg products intended for human consumption, in part by daily inspection at slaughtering and processing establishments, and by sampling and analyzing tissue samples obtained at or after slaughter. The inspection and analysis are intended to assure, among other things, that meat and poultry do not contain residues of drugs, pesticides, or environmental contaminants that cause them to be adulterated under the FMIA or PPIA. In the case of egg products, FSIS assures compliance with the EPIA. When FSIS finds violative residues of drugs, pesticides, or other contaminants in meat or poultry, the Agency condemns the violative carcasses or organs, depending upon the nature of the residues, and provides information on the violations to the FDA and EPA. In addition, FSIS seizes all available meat, poultry or egg products containing violative levels of residues and eliminates it from the food supply.

The mission of APHIS is to promote the health and well-being of the peoples of the United States and its export customers through the administration, in cooperation with state governments, of the OA and the TA, as they pertain to animal and plant health and quarantine, humane treatment of animals, the control and eradication of pests and diseases, and animal damage control.

Within the HHS, FDA is responsible for administering and enforcing the FFDCA, which among other things, ensures that human foods and animal feeds are safe and do not contain illegal residues. FDA approves drugs used for food-producing animals, establishes tolerances for residues of animal drugs in edible tissues, establishes tolerances and action levels for unavoidable environmental contaminants (other than pesticides), regulates

the processing and distribution of human and animal feeds, and examines samples of these products to assure compliance with the FFDCA.

FDA considers regulatory action against violators when it is determined that they introduced or caused to be introduced into interstate commerce animals containing illegal residues in edible tissues. In addition, “caused to be introduced” charges may be brought against veterinarians, animal dealers, buyers, vendors, auction houses, or other persons who are responsible for having caused the residues, or for introducing animals into interstate commerce without first assuring that the animals are free of illegal residues. FDA conducts follow-up on-site investigations for selected illegal residue findings reported to the districts by FSIS.

EPA is responsible for administering the FIFRA, the TSCA, and limited parts of the FFDCA. Under the FIFRA, EPA is responsible for registering new pesticides in order to provide for the protection of human health and the environment. Pesticide registration is a pre-market review and licensing program for all pesticides marketed in the United States, whether of domestic or foreign origin. EPA is also responsible for establishing tolerances and for revoking tolerances for cancelled pesticides. Following tolerance revocation, EPA can recommend “action levels”, where appropriate, for enforcement by FDA and USDA.

Under the TSCA, EPA is responsible for regulating chemical substances (other than pesticides as defined in the FIFRA) when imported for use as a pesticide. TSCA, unlike FIFRA, does not provide for the establishment of tolerances for industrial chemicals in foods, because their use is not permitted in food production.

Under FFDCA, EPA is responsible for establishing national tolerances for residues resulting from the use of pesticides on agricultural crops and recommending action levels for residues in food to FDA and FSIS.

- D. Provide a simple organizational chart and relationship to the meat inspection system for:
1. compound approval
 2. residue program design
 3. sample collection
 4. laboratory support
 5. enforcement

Response: see Attachment 4 for the organizational chart.

III. Residue Plan Design

The purpose of this section is to obtain information to understand the basis for your annual residue plan and the process used to design the residue plan.

- A. Submit a copy of your annual residue plan, which clearly identifies all sampling plans (monitoring, surveillance or any other special testing programs in place) and identifies the target tissue to be analyzed, by species, for each specific residue compound. Identify whether this is implemented on a calendar year or fiscal year.

Response: The United States National Residue Program (NRP) is implemented on a calendar year basis (January 1 to December 31.) The 1999 plan, including specific compound/slaughter class pairs, target tissue to be analyzed, and sampling frequencies, is enclosed in Attachment 5.

- B. Describe the design of the sampling plan for animals to be tested for residues. Indicate whether the sampling plan is based on random sampling and the statistical significance expected of the residue conclusions or whether the sampling plan is based on non-statistical design principles. In both cases, indicate the objectives of the sampling program.

Response: Testing each animal submitted for slaughter in the United States for all classes of chemicals, including pesticides, animal or human drugs, and environmental contaminants, is not reasonable nor practical. A statistically based residue monitoring program has been developed to ensure that a violation would be detected if the true prevalence rate for violations was 1 percent or greater for a given compound class and production class of animal. Monitoring and exploratory programs are used to detect a threshold level of residues in food animal populations or slaughter classes. In addition to the Monitoring plan, the NRP is comprised of other components including Surveillance and Special Studies each of which are described below:

- ? **Monitoring:** *involves the sampling of specified animal populations to provide information about the occurrence of residue violations on an annual, national basis. Compounds considered usually have established limits, that is, tolerance or action levels. Monitoring information is obtained through a statistically based random selection of specimens of normal-appearing tissues from passed carcasses. Generally, the number of specimens chosen provides a 95 percent probability of detecting at least one violation when one percent of the animal population is violative. In addition to profile information, the results are used to identify producers or other entities marketing animals with violative concentrations of residues. When such producers subsequently offer animals for slaughter, the animals may be subjected to enforcement testing until compliance is demonstrated. The carcass is not held after the sample is taken.*
- ? **Surveillance:** *designed to distinguish components of the livestock and poultry population in which a residue problem exists, to measure the extent of problems, and to evaluate the impact of actions taken to reduce the occurrence of residues in the*

populations. In surveillance, the carcasses and organs may be retained pending test results.

? ***Exploratory Programs:*** *generally used to study the occurrence of residues for which no limits have been established or for which a laboratory testing method has not been validated. There are many chemicals, such as trace metals, industrial chemicals, and mycotoxins, that may be inadvertently present in animals yet have no established residue limits. Their presence in edible tissues and the resulting need for limits to protect public health have not been established. FSIS may conduct studies to develop information on the frequency and concentration at which such residues occur.*

? ***Special studies:*** *may be designed to acquire information about the occurrence of specific residues in livestock, poultry, and/or eggs. A residue may be categorized as a special study if it does not meet the criteria for one of the other type of programs.*

C. What criteria are used to determine whether a compound is included or deleted from your testing program?

Response: FSIS seeks to allocate its resources in the most effective manner to ensure the safety of the U.S. food supply. FSIS selects, from an extensive list of veterinary drugs, pesticides, and environmental contaminants, those compounds and compound classes that are most likely to appear at unsafe levels in meat and poultry. Once the initial list of compounds has been submitted, FSIS seeks to allocate its resources for residue testing to the compounds in the slaughter classes that are of greatest public health concern. Testing each animal submitted for slaughter in the United States for all classes of chemicals, including pesticides, animal or human drugs, and environmental contaminants, is not reasonable or practical. Constraints, such as method availability and laboratory resources, are then applied to the final compound/slaughter class pairs to produce a residue-sampling plan.

D. What is the process for reassessing the residue plan? How are data reviewed and analyzed to evaluate the progress?

Response: Data collection during monitoring and surveillance testing in the National Residue Testing Program is reviewed by FSIS in several ways: (1) on a daily basis as laboratory reports confirming violations and non violative positives are received, (2) on an yearly basis to assess the overall effectiveness of the National Residue program. Every year while planning the residue plan the violation rate of the compound/slaughter class tested during the last several years is taken into account in designing that years plan.

After analyzing the data obtained through monitoring or surveillance programs if a particular problem is indicated, a special study may be initiated

IV. Residue Plan Operations

The purpose of this section is to obtain information on the basis and actual operation of your residue plan.

- A. Describe the implementation of your plan, providing any supplemental information that will help describe what you want to accomplish with the residue plan.

Response: The United States residue program has two purposes: (1) to determine whether illegal residues are present in meat, poultry, and egg products (through monitoring); and (2) to keep products containing illegal levels of residues from being distributed to consumers (through enforcement and surveillance programs.)

National residue monitoring program (including special projects). The Office of Public Health and Science (OPHS) collaborates with the Office of Field Operations (OFO) to generate the sample request forms (See Attachment 6: FSIS Form 10,210-3) from a central database, which is mailed directly to the FSIS Inspector-in-charge (IIC) at the designated slaughter establishment on a monthly basis. The species, tissue, and assigned residue tests(s) are designated on this form. Inspection personnel collect all samples at the time of slaughter in the slaughterhouse.

A checklist, summarizing the sample request forms generated for the establishments within their district is used to monitor sample collection in the time period designated on the sample request form. The Technical Service Center, Slaughter Operations Staff (Residue Operations Staff) coordinates subsequent follow-up action with OPHS to adjust the sampling rates.

Individual Enforcement Testing (including inspector generated samples.) Testing is targeted to detect individual animals or lots of animals with violative concentrations of residues, based on herd history or direct observations. The inspector in the slaughter establishment has the authority to select samples whenever a problem is suspected.

- B. Provide a summary of the instructions that are provided to the field personnel that describe sampling procedures, including but not limited to sample selection, collection, identification and security.

Response: Instructions to field personnel are transmitted through publications of FSIS directives. The following directives are included as reference to procedures related sample selection, collection, identification and security: FSIS Directive 10,210.1, Unified Sampling Form (Attachment 7); FSIS Directive 10,530.2, Guidelines for the Residue Control Program Established by Memorandum of Understanding (MOU) (Attachment 8), and FSIS Directive 10,620.1, revision 1 (Attachment 9.) It should be noted at this time that these directives are currently being revised to reflect procedures to

be followed now that the HACCP/Pathogen Reduction regulations are implemented.

- C. What is the average time it takes from sample collection until final results are available to the inspector (or person responsible for action)?

Response: Every effort is made throughout the system to provide timely results. Sample collection and preparation for mailing to the designated laboratory may take 3 – 7 days. All samples are forwarded overnight mail to the designated laboratory to preserve sample integrity. Analytical time depends upon the type of residue test being performed, ranging from 3 to 21 days. All results are reported to the District Offices and to the Technical Service Center electronically. Negative results are reported electronically to the IIC and to plant management at the official establishment (if so desired.) Total estimated time (on average) is 20 days. Violative positive results are forwarded by facsimile to the FSIS Technical Service Center directly from the laboratory for immediate action.

- D. Describe the control procedures for separating product destined for the U.S. in the case when domestic tolerances are higher.

Response: FSIS maintains an electronic database containing export requirements specific to foreign countries. If a country specifies tolerances for chemical residues different than those imposed upon domestic production, this information can be reflected here.

- E. How are individual animals selected for sampling? How do you select the days on which samples are taken?

Response:

Enforcement samples: The inspector has the authority to select samples from animals presented for inspection, if there is justification for cause through direct observation. In addition, enforcement samples are also identified to follow-up on violators (specific producers, auction markets, dealers, etc.) who have been identified as marketing animals with violative residues.

Monitoring samples: The sample selection date is identified on the sample request form. If the establishment is not working or the species requested is not available on the day scheduled for sample selection, the inspector is advised to select the sample within a week. If this is not possible, the inspector returns the sample request to the designated laboratory, stating the reason for not sampling. Samples are selected at random from healthy (inspected and passed) animals.

- F. Do inspection personnel use in-plant-screening methods? If so, what are these tests and how are they used (monitoring/surveillance, animal selection, etc.)? Describe the validation of these tests for the intended purpose.

Response: Yes.

Sulfa-on-Site (SOS) is a rapid in-plant chemical screening test for detecting residues in market hogs' urine or serum that provides same-day results. The testing protocol is conducted in 42 slaughter plants, which currently process about 95% of the U.S. market hogs. Testing is conducted on one day per week, six samples per day from separate lots.

Swab Test on Premises- (STOP) is an overnight in-plant laboratory microbiological screen test for detecting antibiotic residues in edible tissues, primarily that of cows and/or bulls that are suspect (such as downers, active cases of mastitis, all injection sites, presence of pathology which indicates a likelihood of treatment, or violators with an open residue case file.) STOP tests can be used on other species.

Fast Antimicrobial Screening Test (FAST) is a rapid in-plant laboratory microbiological screen test for detecting antibiotic and sulfa-drug residues in edible tissue of bovine that are suspect.

Manufactured test kits are evaluated by FSIS official laboratories for (1) ease of use and performance when used by inexperienced persons; (2) a measure of false negative and false positive readings; (3) sensitivity; (4) precision; (5) interference or cross-reactivity; and (6) shelf-life stability.

Training is provided to field personnel through hands-on training sessions and through published self-instruction guides. The performance of manufactured test kits is further monitored through the use of internal standards and quality assurance programs, including unknown check samples, to assure that the kits are performing satisfactorily.

V. Compliance and enforcement

The purpose of this section is to obtain information about actions taken to deal with residue findings as they occur.

- A. What actions are taken when positive or violative results are determined for:
- (1) drugs permitted for therapeutic and preventative use in each species of food animals
 - (2) prohibited substances
 - (3) pesticides permitted for use in or on each species of food animals
 - (4) agricultural chemicals permitted for crops used in feed production and in grazing
 - (5) environmental or industrial chemicals that are potential contaminants to food producing animals

Response: Each violation is reviewed by the TSC, and appropriate action is taken as necessary. Such action may include notification of other Agencies such as FDA, EPA, and State regulatory agencies, as well as issuance of a violation letter to the producer or organization that presented the animal for slaughter for food purposes which contained a violative tissue residue concentration of a drug, pesticide, or other chemical. In addition, there may

be additional sampling required at the establishment for enforcement purposes.

FDA and State agencies investigate the cause of the violation and take appropriate corrective regulatory action.

B. What documentation of enforcement actions is maintained?

Response: Upon confirmation of laboratory results, the results are entered into the Microbiological and Residue Computer Information System (MARCIS), which is an FSIS database containing identification information and results related to every sample collected and analyzed by FSIS and FSIS-accredited laboratories. Laboratory results are also electronically filed with the District Offices, as well as the Technical Service Center (TSC). Violative results are recorded into the Residue Violation Information System (RVIS), which is a national, interagency, interactive relational computer system designed by FSIS and FDA to handle pertinent regulatory information related to residue violations in domestically slaughtered livestock and poultry. RVIS integrates information of regulatory actions generated by both FSIS and FDA and tracks appropriate follow-up actions on residue violation investigations by FSIS, FDA and State.

The TSC maintains a case file, which will include a fax copy of the laboratory results, a copy of the violation letter, a copy of the action plan (additional sampling), copy of the analytical results sheet and a case history sheet.

VI. Laboratories

The purpose of this section is to obtain information on the general capabilities of analytical laboratories and their ability to assure the validity and reliability of test data.

A. Organization and characteristics of your laboratory facilities. Provide:

- (1) An organization chart of the laboratory facilities.
- (2) Information on personnel qualifications.
- (3) Information on facilities and equipment.

Response:

Field Services Laboratories

Eastern Laboratory

Patrick C. McCaskey, Director

Tel: (706) 546-3576

FAX: (706) 546-3383

Mailing Address:

*Eastern Laboratory
Russel Research Ctr., Suite 205
950 College Station Road
Athens, GA 30605*

Coordinates and conducts laboratory analytical services in support of the Agency's farm-to-table strategies in the disciplines of chemistry, microbiology, and pathology for food safety in meat, poultry, and egg products.

Midwestern Laboratory

James Hess, Director

*Tel: (314) 263-2680
FAX: (314) 263-2679*

Mailing Address:

*Midwestern Laboratory
Bldg. 105-D, Room 344
4300 Goodfellow Road
St. Louis, MO 63120*

Coordinates and conducts laboratory analytical services in support of the Agency's farm-to-table strategies in the disciplines of chemistry and microbiology for food safety in meat, poultry and egg products.

Western Laboratory

Joseph Chiu, Director

*Tel: (510) 337-5031
FAX: (510) 337-5036*

Mailing Address:

*Western Laboratory
620 Central Avenue
Building 2A
Alameda, CA 94501-3874*

Coordinates and conducts laboratory analytical services in support of the Agency's farm-to-table strategies in the disciplines of chemistry and microbiology for food safety in meat, poultry and egg products.

See Attachment 10 for organizational chart for the Office of Public Health and Science, a list of qualifications of employees at each laboratory, and a list of analytical capabilities of each laboratory.

B. Laboratory procedures

1. Identify the analytical method used for each compound. Include:

- (1) Target analyte(s)
- (2) Target tissue/species
- (3) Performance standards

Response: The analytical methods, minimum proficiency level and target tissues for each compound are listed in Attachment 11.

2. Explain the process to insure that samples and the associated documentation are not interchanged.

Response: The samples are received by the lab from field locations in insulated and sealed boxes. Each sample bears a label, is accompanied by a unique form describing the sample, and analyses requested. During sample box opening, sample label and accompanying forms are checked for consistency. Characteristics such as sample temperature, types of tissues, and seal condition are observed and noted. If all criteria are not met the sample is discarded.

Each sample is given an internal lab number, which serves to track the sample during the time in the laboratory. Once a sample is received at the laboratory, it is accessible only by laboratory personnel.

3. Explain how records are maintained.

Response: Analytical records are maintained by the laboratory, using both paper and electronic files. The electronic records are entered and maintained in the Laboratory Sample Flow System (LSFS), which tracks the sample from receipt to the laboratory until results of the analyses are reported. Analytical records containing new scientific data (chromatograms, spectra, and worksheets) are maintained in the laboratory files. Records are retained according to the FSIS record management handbook requirements.

4. How are test results reported (include content, format)?

Response: As outlined in FSIS Notice 9-98 (Attachment 12), effective April 1997, FSIS laboratories transmit official laboratory results for residues electronically to the Technical Service Center, the inspector in charge at the establishment, as well as appropriate offices in Washington. In addition, establishment management can arrange to receive negative results directly.

5. Are corrective actions conducted for noted deficiencies?

Response: Yes, corrective actions for noted deficiencies are taken in a timely manner and documented on the form included in Attachment 13. Examples from the FSIS Chemistry Quality Assurance Manual, September 1995, pages 46-49 are included as well.

6. Does the laboratory participate in proficiency testing? If yes,
(1) List the proficiency testing programs

Response: FSIS laboratories participate in USDA FSIS Interlaboratory Proficiency Check Sample Programs to monitor analytical proficiency for the following compounds/class:

*Arsenic
Chlorinated Hydrocarbons
Polychlorinated Biphenyls
Nitrosamines
Sulfonamides*

FSIS laboratories analyze Intra-laboratory Proficiency Check Samples for other chemical residues as needed.

- (2) Provide the most recent proficiency test report(s), including whether it passed or failed.

Response: See Attachment 14 for examples of proficiency test reports used by FSIS. Presently, FSIS laboratories meet (pass) the required performance standards. Corrective actions are taken in a timely manner when deficiencies are noted.

7. Is the laboratory accredited? If yes, please provide:

- (1) The name of the accrediting body

Response: The FSIS Accredited Laboratory Program/Quality Assurance Branch, Chemistry and Toxicology Division accredit FSIS laboratories.

- (2) When was the laboratory last accredited?

Response: Laboratories have been accredited for the compounds/class listed in (3) below since 1987. FSIS laboratory analysts are accredited for these and other chemical residues as needed. Accreditation is continuous when the laboratories/analysts maintain the required FSIS performance/proficiency standards for the specific analyses.

- (3) What compound (class of compound) was the laboratory accredited for?

Response: FSIS laboratories are accredited for the following compounds/class:

*Arsenic
Chlorinated Hydrocarbons
Polychlorinated Biphenyls
Nitrosamines
Sulfonamides*

FSIS laboratory analysts are accredited for these and other chemical residues as needed.

List of Attachments

ATTACHMENT NUMBER	SUBJECT
1	Table: Production classes to be considered for each drug/drug class
2	Publication: FARAD (The Food Animal Residue Avoidance Databank)
3	Table: Residue limits for compounds in the domestic residue program
4	Organizational chart relating Federal agencies to the meat inspection system.
5	1999 United States National Residue Plan
6	FSIS Form 10,210-3, Sample Request Form
7	FSIS Directive 10,210.1, Unified Sampling Form
8	FSIS Directive 10,530-2, Guidance for Residue Control Program Established by Memorandum of Understanding (MOU)
9	FSIS Directive 10,620.1, revision 1, Submission of Surveillance Samples for Residue Analysis
10	Organizational chart for the Office of Public Health and Science (OPHS), a list of the qualifications of employees located at each laboratory and a list of the analytical capabilities in each laboratory.
11	Analytical methods, minimum proficiency level and target tissue for each compound.
12	FSIS Notice 9-98, Distribution of Laboratory Test Results
13	Record of deficiencies and corrective actions taken; Excerpt from FSIS Chemistry Quality Assurance Manual
14	Examples of proficiency test reports for arsenic, chlorinated hydrocarbons, polychlorinated biphenyls (PCB), and sulfonamides.

Acronyms and Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
CVM	Center of Veterinary Medicine
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act
FARAD	Food Animal Residue Avoidance Databank
FAST	Fast Antimicrobial Screening Test
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMIA	Federal Meat Inspection Act
FQPA	Federal Quality Protection Act
FSIS	Food Safety and Inspection Service
HHS	Health and Human Services
LSFS	Laboratory Sample Flow System
MARCIS	Microbiological and Residue Computer Information System
MRL	Maximum residue limits
NRP	United States' National Residue Plan
OA	Organic Act
OFO	Office of Field Operations (FSIS)
OPHS	Office of Public Health and Science (FSIS)
OPPDE	Office of Policy, Program Development and Evaluation (FSIS)
PPIA	Poultry Products Inspection Act
RVIS	Residue Violation Information System
SOS	Sulfa-on-site
STOP	Swab Test on Premises
TA	Tariff Act
TIS	Tolerance Index System
TSC	Technical Service Center (FSIS)
TSCA	Toxic Substance Control Act

Attachment 2