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FSIS *Food Safety Review*

VOLUME 1 • NUMBER 2 • FALL 1991

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FSIS Releases Data Showing Residues in Decline

Agency Updates Veterinarians in Pathology

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Introducing the Second Issue

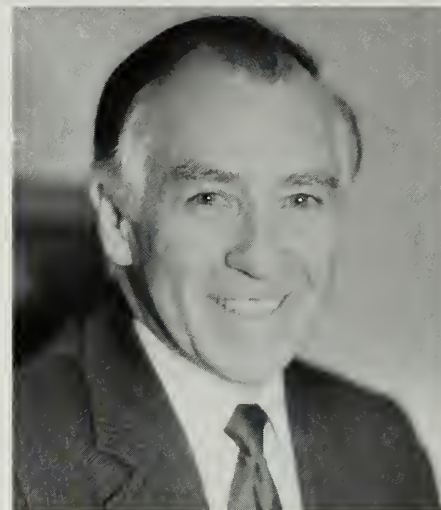
The response to the first issue of *Food Safety Review* reinforced our belief in the importance of pooling our knowledge, so that all of us concerned about and working in the area of food safety can build on scientific advances and on each others' understanding.

The premier issue opened with articles on new methods for detecting microbiological pathogens. This second issue addresses another crucial concern for FSIS scientists—residue control.

Residue control is a major focus of FSIS enforcement activities. You will read in this issue about residue analysis questions FSIS Science and Technology staff are investigating, the list of compounds they test for and update annually based on scientific assessments of risk, and about a new model residue control plan that one company adopted as a result of FSIS enforcement activities.

FSIS is intent on identifying scientific needs in the field of food safety and developing new programs to meet these needs. Among the features in this second issue of *Food Safety Review* is an article on a new pathology correlation center to keep FSIS veterinarians up-to-date on new scientific tools and technologies.

We hope you will use this magazine as a resource for increasing your knowledge of food safety science research and activities. And, we hope to work together with you to address the important food safety concerns that face us all.



Marvin A. Norcross, VMD, Ph.D.
Deputy Administrator, Science and Technology

Fall 1991 Vol.1, No. 2

FSIS Food Safety Review is published by USDA's Food Safety and Inspection Service, the agency charged with ensuring the safety, wholesomeness and proper labeling of the nation's meat and poultry supply. The purpose of the magazine is to inform food science and public health professionals of current science-based initiatives to protect the public health.

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FSIS Food Safety Review is published four times a year. To subscribe, fill out order blank on back cover. Send subscription orders to:
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Results from the FSIS 1990 residue monitoring program are out. Excerpts from a presentation to the press and accompanying charts detail the findings. Among the highlights was a significant decrease in sulfonamide violations in hogs.

7 Enforcement Activities Lead to Model Residue Plan

FSIS regulatory activities prompted a U.S. court to require that a California dairy develop a residue control plan. The model plan is described in this article.

9 Ensuring the Safety of Irradiated Food

The second of two articles about food irradiation shows its high potential for reducing microbial contamination and foodborne illness. This followup story traces a HACCP approach to food irradiation, showing the value of this system for preventing hazardous conditions in food processing.

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Agency veterinarians will update their knowledge about pathology in meat animals and poultry while participating in the rigorous program of the FSIS National Correlation Center in Ames, Iowa.

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*A University of Arkansas researcher is developing a quick and simple test for the detection of *Listeria monocytogenes* in perishable food products.*



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Counting Down on Residues—1990

by Richard A. Carnevale, DVM,
and Sharin Sachs, BS

F SIS conducts the National Residue Program (NRP) to help prevent the marketing of animals containing illegal residues from animal drugs, pesticides or potentially hazardous chemicals. FSIS enforces residue limits established for pesticides by the Environmental Protection Agency and for animal drugs and environmental contaminants by the Food and Drug Administration.

The 1990 Domestic Residue Data Book on NRP results from the past year has just been released. Following are excerpts from a July 1991 statement delivered to the press by Dr. Richard A. Carnevale announcing the release of the book and 1990 NRP findings.

Welcome to our second annual briefing on the FSIS regulatory program for animal drug and pesticide residues in domestic meat and poultry products. You may be familiar with the inspection program of the Food Safety and Inspection Service. FSIS inspectors collected most of the tissue samples that we analyze in the Agency's residue program.

What I have to report today is good news. In the United States, our goal is zero illegal residues in meat and poultry.

Dr. Richard Carnevale is Assistant Deputy Administrator for Science and Technology at the Food Safety and Inspection Service. Sharin Sachs is Chief of the FSIS Information Office.

Our data indicate that the vast majority of the 125 million meat animals and 6.3 billion poultry that enter federally inspected plants each year are healthy and free of illegal residues.

During 1990, in routine, nationwide statistical monitoring, we checked for residues of 133 animal drugs and pesticides. The violation rate was very low, with only about 0.3 percent of the 40,252 samples showing illegal residue levels. That figure reflects all species and subpopulations of food animals monitored. It's on a plateau with 1989 results and reflects a downward trend in illegal residues over time.

All violations detected in the monitoring program represented illegal levels of animal drug residues. There were no pesticide violations uncovered in 1990 monitoring of 10,347 livestock and poultry samples for 42 different pesticides. This is down from 1989, when there were two pesticide violations detected in monitoring. These results reflect the commitment of today's farming community to using pesticides judiciously as part of an integrated farm management system.

Antibiotics and sulfas were the most common drug residue violations in 1990. Most violations detected in 1990 monitoring only slightly exceeded legal limits — which include at least a hundredfold margin of safety.

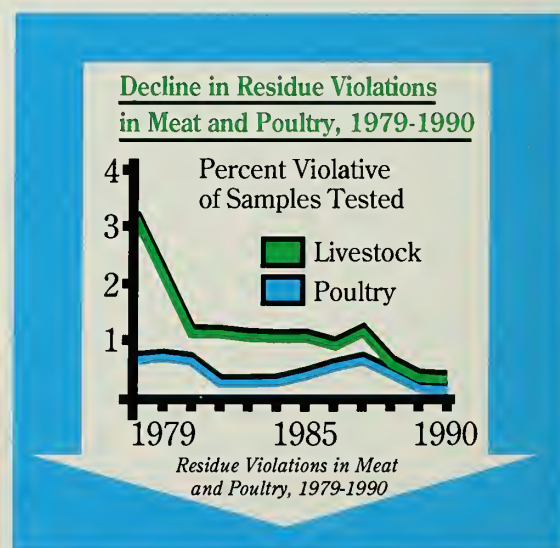
1990 monitoring results echo earlier findings that most antibiotic and sulfa residue violations are confined primarily to food animal classes that make up a rela-

tively small percentage of the total meat and poultry supply.

These animals are more likely to have received veterinary drugs near the time of slaughter to treat serious and life-threatening diseases. (Diseased animals cannot enter the human food supply.) The single most common reason for residue violations is failure to allow adequate time for a veterinary drug to clear the animal's system.

When illegal residues are found, they are usually concentrated in kidney, liver, or fat, rather than muscle meat. In fact, our monitoring program is concentrated on such target organ tissues, as most FDA limits are established in terms of these tissues.

In 1990 testing, we saw improvements



The downward trend continues in residue violations.

in some of the historical problem areas, such as bob veal calves. These improvements reflect successful education, enforcement and, perhaps most of all, acceptance of individual responsibility.

Veterinarians, animal producers, meat and poultry plants, trade associations, regulatory agencies — we all share the responsibility for residue control. We are all accountable to one another and to the public-at-large. Our data suggest more individuals are acknowledging and acting on their responsibility to count down to zero on residues.

We have released the 1991 “Blue Book,” which describes the plan for residue monitoring now underway. Each year, we re-evaluate what compounds need to be included in the testing program, based on informal and formal risk assessment. The FSIS residue program works with the Food and Drug Administration, the Environmental Protection Agency and other groups such as trade associations and the American Veterinary Medical Association on residue safety.

I will now mention other highlights from the *Domestic Residue Data Book*. This report, which we affectionately call the “Red Book,” summarizes the results from our 1990 testing programs.

As you may have noticed, I have used the term “monitoring program” several times. Monitoring data is the only type of information that is representative of the nationwide situation, because it is based on statistically based, nationwide, random sampling.

Monitoring results are not intended to keep individual animals out of the food supply, but to present a “moving picture” of the residue pattern in food animals. In addition, laboratory-confirmed violations are entered into our automated Residue Violation Information System, which can be accessed by FSIS and FDA enforcement staff.

“Surveillance,” or enforcement testing, is designed to keep illegal residues out of the meat and poultry supply. Enforcement testing may cover as limited a scope as one animal, or it can be nationwide.

In enforcement testing, suspect animals are kept out of the food supply until laboratory results confirm they can be marketed or should be condemned. Surveillance testing can be triggered by a trend observed in the monitoring data, because



Dr. Richard Carnevale announces the latest residue results from animal drug monitoring by the Food Safety and Inspection Service.

an FSIS inspector notices a fresh injection site on an animal at the time of slaughter inspection, because FDA test results indicate a problem attributable to animal feed and for a number of other reasons.

Enforcement testing is effective in protecting consumers; it is usually not representative enough to support sweeping generalizations about nationwide trends in residues. Far greater numbers of surveillance samples are taken, particularly with the rapid tests. However, the greater numbers represent the testing of a relatively smaller percentage of the total food animal population.

Following are highlights from our findings.

Antibiotics

Antibiotics accounted for 78 violations among 7,299 samples from all species monitored for antibiotics (1.6 percent violation rate). Twenty-one of the violations were in cull dairy cattle, which are sold for food once their milking days are through. (About 10 percent of the beef supply is cull dairy cattle.) Streptomycin and gentamicin were the most common antibiotics detected in dairy cows.

Penicillin and tetracycline are also detected with some frequency in surveillance samples. Because of concerns with reports of antibiotics and sulfas in milk, with the support of the American Veterinary Medical Association, the National

Milk Producers' Federation — representing milk rather than meat producers — developed for its membership a comprehensive quality assurance program for preventing residues in dairy cows that will later go into the food supply. The Federation could have stopped at a residue control program for milk; instead, it took on responsibility for dairy beef as well. FSIS supports the Milk Producers in this enlightened and innovative program.

On August 1, 1991, FSIS initiated a focused surveillance program for both antibiotic and sulfa residues in dairy and other beef cows. Results from that program will indicate regional incidence of residues and problem populations for this small, but not insignificant, residue problem.

The in-plant rapid CAST test (Calf Antibiotic and Sulfa Test) detects the presence of antibiotics and sulfa in kidneys of bob veal calves — those less than three weeks old and under 150 pounds. Today, FSIS inspectors test almost all bob veal calves using CAST, and violative results lead to immediate condemnation; laboratory confirmation is not required to keep the animals out of the food supply.

In 1990 enforcement testing of bob veal calves, we found 2,070 violative results in 115,403 samples. That's a 1.78 percent violation rate, down from a 2.62 percent violation rate in 1989. Because so many animals were tested in this enforcement

program, we're confident that the new figure reflects a real improvement. However, the American Veal Association should continue to encourage its membership to follow its quality assurance plans for preventing residues.

The FAST test (Fast Antimicrobial Screen Test) being demonstrated here today may one day replace both the CAST test and the "grandfather" of the rapid tests, the STOP test for antibiotics (Swab Test on Premises). FAST detects both antibiotics and sulfonamide drug residues in livers and kidneys, and results can be read in just five hours — often within one inspector's work shift. By comparison, both STOP and CAST plates must be incubated overnight before results can be read. We will soon be pilot-testing the FAST test on cows and calves in several plants.

Sulfonamides

Violation rates for sulfonamides — particularly sulfamethazine — continue to go down. Based on nationwide monitoring, the violation rate for sulfamethazine in hogs is 0.76 percent. In 1984, it was almost 7.0 percent. Last year, we were pleased at the decline from 3.6 percent in 1987 to 1.1 percent in 1989.

We believe these results are the direct result of continuing enforcement efforts by FSIS and FDA, educational efforts by industry trade associations, and more careful usage by animal producers. The National Pork Producers Council deserves a big share of the credit for helping to resolve this residue problem, and we hope their entire membership will follow the recommendations in the NPPC/AVMA quality assurance program to avoid illegal residues.

We plan to continue our enforcement testing program, using the SOS (Sulfa-on-Site) rapid test, implemented in 1988 in the 100 largest hog plants. The test detects residues of sulfamethazine and other sulfonamides in hog urine. In 1990, our inspectors conducted over 108,000 SOS tests, resulting in detection of 281 muscle violations. These are in close correlation with our monitoring data, confirming a significant decrease in violations.

Overall, these results indicate an improving pattern of animal drug use. We are testing more samples for more compounds, and we are finding fewer residues. However, the challenge is to keep count-

NATIONAL RESIDUE PROGRAM DOMESTIC MONITORING PLAN DATA

1990 YEARLY SUMMARY

Total number of samples analyzed = 44,693

Total number of violative samples = 144

COMPOUND	LIVESTOCK	POULTRY
Antibiotics	5972/76	1327/2
Sulfonamides	9057/43	1957/2
Arsenic	1362/4	643/2
Benzimidazoles	2308/0	297/0
Carbadox	915/0	
Carbamates	1222/0	108/0
Chloramphenicol	1396/0	
Chlorinated		
Hydrocarbons	3153/0	1289/0
Chlorinated Organo-		
phosphates	3153/0	1289/0
Diethylstilbestrol	1916/0	
Halofuginone		1285/6
Ivermectin	3446/9	
Melengesterol		
Acetate	331/0	
Nicarbazin		623/0
Nitromidazoles	298/0	314/0
Pyrethins	603/0	
Thiazines	429/0	
TOTAL	35,561/132	9,132/12

ing down to zero illegal residues, and doing that requires concerted efforts by all segments of agriculture.

Hormones and Steroid-like Drugs

Consumers have many questions about veterinary hormone use, and I would like to take this opportunity to mention a few highlights of our findings from hormone monitoring.

Melengesterol acetate (MGA) is a legal hormone added to the feed of heifers to achieve an increase in feed efficiency and the rate of weight gain. No violations were found in 331 heifer samples.

The residue monitoring program showed no violative residues from illegal diethylstilbestrol (DES) in any of the food-producing animals tested.

FSIS will continue testing livers of suspect animals for clenbuterol. A special testing program took place over the past several months on clenbuterol, an unapproved veterinary drug suspected of use in

show animals. Based on information obtained by FDA and Texas livestock officials, including positive urine screening test results, FSIS developed a liver method and analyzed 36 samples from lambs, steers and pigs for the drug. All samples were negative at a sensitivity level of one part per billion. FSIS continues work on a test to detect clenbuterol in muscle tissue. ♦

For a single copy of the *1990 Domestic Residue Data Book (Red Book)* and/or *Compound Evaluation and Analytical Capability National Residue Program Plan 1991 (Blue Book)*, write:

FSIS Information Office
U.S. Department of Agriculture
South Building, Room 1160
Washington, D.C. 20250

Enforcement Activities Lead to Model Residue Avoidance Plan

By Dale Blumenthal, MA
FSIS Science Writer

The government is emphasizing a different approach for keeping illegal residues out of meat and poultry. Prevention programs, in addition to enforcement actions, may help companies remain in the business of producing safe food.

Often, according to Food Safety and Inspection Service compliance officers, there may be hidden reasons—and additional offenses—for every identified violation. Regulatory agencies are encouraging firms to analyze and remedy the cause of problems themselves. In the long run, FSIS believes, such an approach will be more effective in protecting consumers.

The best route to preventing food safety violations and regulatory enforcement actions is for a food company to closely analyze its own processes for potential problems and to adjust the system before violations occur. However, sometimes a firm reviews conditions and develops a quality assurance program only after a regulatory agency has identified violations. Such was the case with DeJong Dairy, Inc., of Hanford, Calif.

Despite years of regulatory letters instructing DeJong to seek scientific information about legal veterinary drugs, FSIS continued to detect violative levels of illegal residues in tissue samples. A complaint for injunction filed by FDA and court negotiations led DeJong to adopt a residue avoidance plan that should keep DeJong Dairy in compliance. The plan

also provides a model for other establishments interested in avoiding residue violations.

Veterinary Supervision

DeJong sought the advice of veterinarians at the University of California, Veterinary Medicine Teaching & Research Center (VMTRC) in Tulare, Calif. Researchers there designed a plan for DeJong that emphasizes veterinary direction and supervision for all purchase, storage, labeling and use of animal drugs.

An attending veterinarian must strictly supervise use of prescription legend drugs and extra label use of either prescription legend or over-the-counter (OTC) drugs, as outlined in the FDA Compliance Policy Guideline 7125.06. All drugs used by the dairy must be administered either by a veterinarian, his or her designated assistant or, in the case of OTC antibiotics, by one of three specified employees (the herder, calf raiser or relief person).

VMTRC veterinarians visit the dairy twice a week in order to:

- 1) diagnose individual ailments or disease processes in the herd;
- 2) review all drug administrations since the previous visit;
- 3) prescribe treatments;
- 4) ensure that animals being treated are in quarantine areas and medical records are being kept for these animals;
- 5) review the medical records of all animals sold off farm;

6) inventory all drugs on the farm and equate drug purchase with use;

7) confirm that all drug labeling and storage conforms to standards outlined in the "Practitioner's Guide to Drug Labeling and Storage on Dairy Farms" (PGDLSDF). This publication was developed by FDA's Center for Veterinary Medicine in collaboration with the American Veterinary Medical Association and the American Association of Boards of Pharmacy.

Drug Purchase and Storage

VMTRC administers the plan and trains and formally approves veterinarians and others involved in the plan. Specialized instruction in the residue control program must cover formal training in drug recognition, proper storage and use of the herd record system for listing all treatments.

The plan limits the number of drug vendors to three until formal training is completed. Only vendors and VMTRC personnel, but not dairy employees, may have keys to the locked cabinets in which all drugs except vaccines must be placed.

VMTRC personnel review and record all drug entries. Each drug container must bear a label, prepared in accordance with the PGDLSDF, that explicitly outlines the conditions of use for each drug.

Since nonveterinarians (such as the dairy owner) and veterinarians are

responsible for complying with the quality control program, the plan identifies compounds such as chloramphenicol, diethylstilbestrol, and dimetridazole as illegal. The plan also notes that sulfamethazine, which is illegal for use in dairy cows, also is not permitted in the dairy.

Secondary storage areas at the dairy include the milking-barn storage areas for lactating and non-lactating cows and the calf-raising area. VMTRC personnel must stock these areas.

Animal Identification and Records

All animals at the dairy receive permanent plastic eartags. Animals treated with drugs requiring withholding are further identified with two additional tags, one a metal eartag and the other a colored "flag" (such as an eartag, legband, or neckchain).

Treatment records for each animal treated must include date, drug used, dose used, route of administration, disease treated, and date of sale, culling or death of the animal. Sale/cull records must show date, animal identifications, and recipient of animals. These steps are consistent with recommendations of the National Academy of Sciences for preventing illegal drug residues.

A daily computerized printout, generated from the treatment records, lists animals that have achieved the proper withholding period and are eligible for return to or removal from the herd. These treatment records show compliance. Just as importantly, they provide the resource for monthly morbidity and mortality reports, which the dairy uses to address health problems, increase productivity and minimize unnecessary drug use.

Quarantine

Lactating animals treated with drugs requiring withholding remain in conspicuously marked quarantine pens until a release date shows up on the computer printout. A similar calf treatment pen houses treated calves, and a "quarantine hutch" is reserved for calves still in a calf hutch.

Animals receiving topical medications



Dairy workers attach a colored legband to a dairy cow—signaling that the animal cannot be legally slaughtered for use as human food.

or intrauterine treatments not requiring withholding for more than 24 hours may remain in their pen, but must be marked with a color identification.

Surveillance and Quality Control

The dairy's regular residue surveillance relies on use of the Live Animal Swab Test (LAST), which is performed on selected animals scheduled for culling. FSIS encourages animal producers and food companies to conduct more of their own residue testing as a check on effectiveness of their residue prevention program. VMTRC personnel use the Delvo P antimicrobial milk assay to establish milk withholding times for extra label use drugs for which milk withholding times are not available.

The plan also requires the dairy to be open at all times for unscheduled visits by state regulatory personnel. All treatment records, drug purchase and inventory records and invoices for animal sales must be made available to inspectors during these visits.

Built into the plan is a requirement that the attending veterinarian review the effectiveness of the program three months after its start and annually thereafter. In addition to records and observations, the reviewing veterinarian must consider feedback from all farm personnel involved in the program. With approval of a designated regulatory official, changes can be made to improve the effectiveness of the plan.

The VMTRC team designed the DeJong Dairy Residue Avoidance Plan to enhance, not replace, regulatory milk and meat monitoring and surveillance. The plan provides a model that individual firms may adapt to their own needs in preventing violative residues in meat, poultry, milk and eggs. Residue control plans protect consumers and also companies, which often encounter extensive legal problems when regulatory officials detect violations.◆

245 Future Inspection Standards— Ensuring the Safety of Irradiated Food

by Lester M. Crawford, DVM, PhD,
Administrator, [FSIS*]
and Susan G. Rehe, MBA
FSIS Science Writer

Editor's Note: The following is based on a previously published article by the authors in the October 1990 edition of Food Control, Butterworth and Co. (Publishers) Ltd., Guildford, Surrey, UK. The previous issue of FSIS Food Safety Review examined regulatory procedure.

**Dr. Crawford is now Executive Vice President for Scientific Affairs, National Food Processors Association.*

Several important areas must be addressed when developing guidelines for meat and poultry products processed using ionizing radiation (Englejohn, 1986a).

First, we must ensure that irradiation does not cover up serious bacterial contamination from inadequate plant sanitation or product mishandling. We must also guard against temperature abuse of irradiated meat and poultry, as fewer of the "indicator" organisms that cause food to spoil will be present. Materials appropriate for packaging foods before irradiation, and staying intact through retail sale, need to be developed and tested.

We must also ensure that products are labeled clearly and accurately at all distribution levels. In addition, methods to determine, after the fact, whether foods have been irradiated should be further developed and validated.

The primary control method for treating meat and poultry with ionizing radia-

tion must be an effective quality control program that incorporates "good radiation practice" and other hygienic practices used to ensure food safety.

The quality control program should include process control procedures based on the Hazard Analysis and Critical Control Points (HACCP) system (National Academy of Sciences, 1985a, 1985b; World Health Organization, 1989).

HACCP is a simple and logical "systems" approach, developed through at least 18 years of operation and fine-tuning. It is designed to prevent problems from occurring, rather than to merely "catch" bad product at the end of the production line. Regular "on-line" checks are made at predetermined critical points in the process where the loss of process control could lead to food safety risks.

In the United States, at least initially, food irradiation will probably be done at multipurpose irradiation facilities rather than in food plants. FSIS has developed two sets of Partial Quality Control guidelines for an irradiation system (Englejohn, 1986a and 1986b). The guidelines are based on work done by the American Society for Testing and Materials and the Codex Alimentarius Commission.

The first set is for food plants preparing product for irradiation, and the second set is for radiation application facilities. Both sets of guidelines emphasize quality control in food irradiation. Applicants are required to provide a detailed

plan of critical control points for each irradiation process to be used.

Product Preparation

The HACCP system plan for a food plant preparing product for irradiation should address the most critical control points in the process, including the following (Englejohn, 1986b):

(a) The uniformity of condition, size, and weight of the raw product must be controlled and documented to ensure an even distribution of the radiation dose.

(b) Packaging materials must be checked to ensure that they comply with FDA requirements and are of uniform size and shape.

(c) After packaging, the product must be checked for consistency (e.g., of size and conformity standards).

(d) Net weight must be controlled through scale calibration, tare and target weight checks, and weight variability checks. These controls relate to proper dose distribution in the product.

(e) Labeling must be checked to determine if the product is properly labeled as a retail, wholesale or second generation product. Final labels must be applied at the plant of origin because the irradiation facility will not be allowed to open cartons or repalletize before or after irradiation.

(f) Distribution plans are required to ensure that the destination plant is aware of labeling and disposition requirements.

(g) Preparation for shipping must

Future choice: non-irradiated or irradiated



include controls for uniform packing configurations to result in uniform bulk density of the product units and a uniform pallet wrapping plan.

(h) Shipping instructions must stipulate segregation of different products before, during and after irradiation.

(i) For transportation control, the product must be shipped under seal. The bill of lading must show product name, net weight, bulk density and dimensions of the product unit.

(j) Constant refrigeration during transport to the irradiation plant must be ensured by the plant of origin.

(k) The plant of origin must also have a recall plan in case a problem occurs after the product leaves the plant.

Irradiating Food Products

HACCP plans for irradiating food products should likely consider the following as critical control points in the process (Englejohn, 1986a):

(a) All quality control requirements imposed on the product ingredients must be verified upon their receipt.

(b) The identity, temperature, condition, weight, bulk density, dimensions, and configuration of all product units must be verified before irradiation to ensure satisfactory dose distribution.

(c) Irradiation procedures must include assurance of source activity, control of process time, documentation of source/product geometry, type and placement of dosimeters, calibration of

the dosimetry system, assurance that the absorbed dose is within limits, and procedures for rework of product that has received only a part of the required dose.

(d) Following irradiation, the food must be stored under specified conditions, means to verify the dose received by the product must be available, and labeling must be checked. The plant must also have a recall plan.

(e) Documentation for each product should include proper commissioning procedures, complete product dose mapping and dosimeter system calibration records traceable to national or international standards. Complete process control records should be on file.

Packaging

Packaging is an important consideration in the regulation of meat and poultry treated with ionizing radiation because products must be packaged before irradiation and the packaging must stay intact through retail sale.

Acceptable materials for packaging foods for irradiation processing are covered in an FDA regulation developed in the late 1960s (Federal Food, Drug and Cosmetic Act). Since the materials specified in the regulation differ from the types currently being used by the meat and poultry industry, FSIS is encouraging packaging manufacturers to ensure that suitable materials are available for irradiation. If industry does not take the lead, more government regulations are likely.

Currently, one preferred method for extending the shelf life is vacuum packaging combined with refrigerated storage at less than 5 degrees Celsius (40 degrees Fahrenheit). The critical control points necessary to ensure safe food with this type of packaging and storage are being examined extensively by the National Advisory Committee on Microbiological Criteria for Foods.

At present, there are no data to support the microbiological safety of irradiated, vacuum-packaged products. For this reason, FSIS would prohibit the sale or distribution of vacuum-packaged irradiated products.

Vacuum packaging retards growth of common aerobic spoilage bacteria, such as *Pseudomonas* species, on refrigerated, fresh meat. Low radiation doses will not destroy *Clostridium botulinum* spores, but will reduce competing microflora. This creates a situation where *C. botulinum* may flourish if the product is not kept at an appropriate temperature.

Labeling

Wholesale and retail labeling is another important area in the regulation of meat and poultry treated with ionizing radiation. FSIS believes that full and complete disclosure of irradiation on wholesale and retail labels, coupled with a sound public information program, is the best way to foster public acceptance of irradiated foods (Engel and Derr, 1988).

For retail labeling of irradiated fresh

products, FSIS will require a statement such as "treated by irradiation," accompanied by the international symbol for food irradiation.

Labels for irradiated wholesale products in commercial distribution channels will include the statements required on retail products, plus the statement, "Do not irradiate again."

Processed meat products, or "second generation" irradiated foods, may contain irradiated meat or other ingredients. The agency is considering a requirement that processed products made with irradiated ingredients bear a label identifying those ingredients. The requirement probably would not apply to ingredients used in minute amounts, such as spices or seasonings.

Determining Irradiation

Currently, no validated test is available to determine if a food has been treated with ionizing radiation. Several testing methods are being developed, but none has been practically and universally applied.

Research conducted for FSIS at the University of Massachusetts at Amherst indicates that the presence of three non-polar lipid fractions in beef, chicken, and pork are excellent indicators of irradiation at doses above 0.25 kiloGray. An international intercomparison study is now underway to determine the feasibility and ruggedness of the method and international application standards.

Another study, to determine the effects of ionizing radiation on the formation of less volatile and nonvolatile radiolytic products from lipids such as cholesterol and phospholipids, is being conducted by USDA's Agricultural Research Service (ARS). ARS has determined that the effects of low-dose irradiation on cholesterol are measurable, dose related and clearly distinguishable. Research on the effects of irradiation on phospholipids indicates that the approach is feasible. However, it poses numerous experimental difficulties.

One detection method showing great promise is being developed by scientists at the National Institute of Standards and Technology and other research cen-

ters. It is based on a phenomenon known as electron paramagnetic resonance (EPR). EPR can be used to detect paramagnetic centers produced in certain foods exposed to ionizing radiation.

Unlike free radicals formed in soft tissue, paramagnetic centers are longer lived, allowing their detection. Quantitative analysis of these relatively stable centers may allow estimation of the dose of radiation absorbed by foods.

EPR detection, though limited to foods containing hard matrices, has many advantages, including small sample size and non-destructive nature. This method is being studied jointly by the Ministry of Agriculture, Fisheries, and Food (Great Britain) and the International Atomic Energy Agency (International Atomic Energy Agency, 1990).

Future of Irradiation

When developing national control and inspection standards for irradiated food, it is essential to keep international requirements in mind. FSIS is working towards this goal by participating in organizations such as the Codex Alimentarius Commission, and the International Consultative Group on Food Irradiation sponsored by the Food and Agriculture Organization of the United Nations, the World Health Organization and the International Atomic Energy Agency.

Many countries have already established rules and protocols for the use of ionizing radiation on a variety of food products. International standards for irradiated foods will serve to strengthen national regulations for irradiated foods, assure consumers and the food industry that the technology is being properly controlled, and facilitate trade (International Atomic Energy Agency, 1989).

Not all foods lend themselves to radiation treatment and some segments of the food industry may find irradiation irrelevant to their needs. However, it may provide new products for the markets in developed countries and also help ensure the availability of staples for the developing countries. Food irradiation is yet another tool for ensuring a safe and wholesome food supply. ♦

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Continuing Education for FSIS Veterinarians

by Jacque Lee
FSIS Science Writer

Veterinarians who look for food animal diseases in 6,500 American meat and poultry slaughter plants are preparing to take refresher courses in pathology to help them better protect the health of consumers.

FSIS established its National Correlation Center (NCC) for pathology in Ames, Iowa, in January 1991. "Correlators" of information, or instructors, have been through an intensive preparatory program. This fall, they are starting to teach FSIS veterinarians currently assigned to slaughter plants. Initial sessions were scheduled in Maryland, Illinois and Idaho.

Over the next three years, each of the nearly 1,200 FSIS veterinarians is expected to complete an intensive three-day course, including lectures and wet-lab, or on-site training. Sessions will be scheduled in each of five FSIS regions throughout the country.

Refresher classes will be offered at each session for various species that FSIS is mandated by law to inspect, under the Federal Meat Inspection Act and Poultry Products Inspection Act.

By law, animals are inspected prior to slaughter to ensure they are healthy (antemortem inspection). During postmortem inspection, each carcass and internal organ is examined for disease, contamination and other abnormalities, such as lesions caused by the injection of drugs. If an inspector finds disease or abnormalities, a veterinarian then examines the carcass in

an effort to arrive at a proper diagnosis before determining whether the carcass can be used for human food. Diseased or otherwise unfit carcasses are condemned or rendered (cooked) into animal feed.

Better Application of Science

"Our goal for the correlation program of continuing education is a standardized interpretation of FSIS regulations," says Dr. Robert (Bud) Voetberg, who directs the new FSIS Correlation Center. Veterinarians will review basic animal diseases, including etiology and pathogenesis. They will also learn how to detect and interpret the significance of any gross lesions, tracing them back to the tissue where the pathology started.

Dr. Voetberg says there is good reason for FSIS to be intent upon standardization. "We don't want to hear about any significant variation in the enforcement of science-based regulations. Correlation through continuing education is one of the best ways to ensure that we are complying with our own standards," adds Dr. Voetberg.

Dr. Voetberg has assembled a Correlation Center staff consisting of four veterinarians. They will complete an intensive instruction program in food animal pathology at the Correlation Center and at Iowa State University in Ames.

The four correlators also attend two seminars each week and benefit from training at the National Animal Disease Center, operated by USDA's Agricultural

Research Service (ARS). In addition, correlators have studied under scientists at six labs operated by USDA's Animal and Plant Health Inspection Service (APHIS).

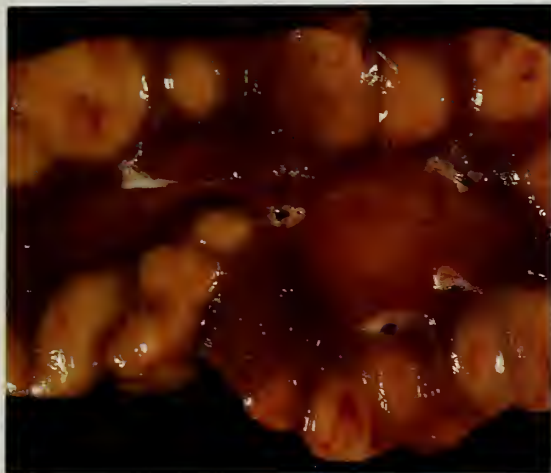
The FSIS Correlation Center concept was developed through the combined efforts of several FSIS branches and divisions under the direction of Dr. Ken McDougall, associate deputy administrator of FSIS Inspection Operations. Dr. Patrick C. McCaskey, director of the FSIS Pathology and Serology Division in Beltsville, Md., and members of his staff lecture at the Correlation Center. Dr. Loraine Cannon of FSIS has also assisted in the presentation of detailed, intense lectures on the diseases of cattle, swine and chickens.

"We have discussed the majority of the disease processes found in each of these species. Lectures have concentrated on gross lesions, etiology, pathogenesis, differential diagnoses and carcass disposition," says Dr. McCaskey. He and Dr. Cannon have presented and discussed over 3,100 slides of the gross pathology of the three species.

Increasing Confidence

Dr. McCaskey thinks continuing education provided through the FSIS Correlation Center program will do more than just add to the knowledge of the individual veterinary medical officer (VMO) at the slaughter plant.

"The VMOs can share what they have learned with the meat or poultry inspectors on the slaughter/processing line," says Dr.



Cut surface of a bovine kidney.

Forty to 50 percent of the kidney has been infiltrated by and replaced with neoplastic lymphocytes. These tumors, known as lymphosarcomas, are soft and appear light tan. Each year, over 12,000 cattle are condemned because they have this disease condition.



Bovine Heart.

The heart contains numerous irregular raised lesions that extend from above the surface into the myocardium. Each of these structures, known in layman's terms as "beef measles," are cysts that contain the parasite *Cysticercus Bovis*, the larval form of *Taenia saginata*, which is a tapeworm of man.



Bovine kidney.

The kidney contains numerous kidney stones. In steers, these stones may cause an obstruction of the lower urinary tract, at times leading to uremia and death.

McCaskey. "Overall, this program should improve morale as well as performance. People gain more confidence about themselves and their job performance when they believe they are well trained."

Work Force Improvement

"Diagnostic technological advances have made it possible to learn more about old diseases as well as new and emerging ones," says Dr. Don Franco, the director of Slaughter Operations for FSIS and of the NCC. "If we didn't assume the responsibility of enhancing our work force, we would be in trouble. No industry or government agency can advance without an agenda to continually improve."

Samples Sought

Regional staff officers will send participants a letter with instructions to: (1) start freezing and saving pathology samples for viewing and discussion during the sessions. These samples will be sent to FSIS pathology labs so that specific diagnoses are known before the discussion; (2) study material on subjects to be discussed; and (3) fill out questionnaires about species a veterinarian is currently working on in a plant.

Dr. Voetberg says the pathology samples collected by veterinarians will be an invaluable part of the refresher course. "We will have the final pathology lab reports on hand with which to discuss

interpretations. Our veterinarians will examine each other's samples, compare their findings, and then see how their reports correlate with the current pathology reports," says Dr. Voetberg.

Another important emphasis of the Correlation Center program will be how to submit pathology samples to FSIS laboratories. This issue was addressed in a National Academy of Sciences report requested by FSIS to help strengthen its scientific base.

Sample submission is a very effective way for the veterinarian to obtain continuing education because it often necessitates direct telephone contact with the pathologist in an FSIS laboratory.

The Important Paperwork

NCC dry-lab sessions will cover the agency's daily and weekly reporting sheets, standard forms veterinarians are required to complete. The National Academy of Sciences also recommended that FSIS improve its knowledge base on animal diseases relative to human health, and the correlation training is designed to carry out this direction.

One section of the daily and weekly sheet contains information for the "animal disease reporting system," or ADRS. The data are useful to FSIS in analyzing trends in the incidence or distribution of animal diseases.

Another key teaching tool in the FSIS continuing education program in pathology for veterinarians will be color slides of diseased tissues in food animals. So far, more than 2,700 slides have been entered into a data base. Eventually, the Correlation Center hopes to build a library of more than 8,000 slides, making it one of the largest of its kind in the country.

Computer programs have been developed to retrieve slides according to organ, specific disease and species. The slides will also be used to develop case studies. For example, slides of the lung, heart and digestive tract may be used to show other lesions associated with liver disease.

Public Health Theme

The Correlation Center also plans to build a color slide library and case histories of so-called exotic animal diseases, such as Bovine Spongiform Encephalopathy (BSE).

"Even though BSE has not been detected in the United States, USDA believes that part of its mission is to make veterinarians aware of clinical findings associated with such diseases," says Dr. McCaskey.

This theme is consistent throughout the Correlation Center's pathology curriculum. Says Dr. Voetberg, "Public health is what we want FSIS veterinarians to think about as they examine every single animal carcass." ♦

Monoclonal Antibodies, Nucleic Acid Probes Speed *Listeria* Testing

by Dr. Michael Johnson
Department of Food Science
University of Arkansas

A 1985 California outbreak of *Listeria monocytogenes* in a Mexican-style cheese killed 47 people. This resulted in the setting of "zero tolerance" levels by both the Department of Agriculture and the Food and Drug Administration for the bacterium in ready-to-eat foods.

USDA's Food Safety and Inspection Service developed its own internationally recognized test to support a monitoring and enforcement program. However, FSIS is always seeking faster and less cumbersome testing methods and has encouraged research by the recently established Food Safety Consortium at the University of Arkansas, Iowa State University and Kansas State University.

Manufacturers of refrigerated ready-to-eat (RTE) foods complain that current testing for the *Listeria monocytogenes* bacterium and holding procedures can take up to one-half of the normal 30-day shelf life of some perishable refrigerated products before they can be distributed. The analysis time and delays associated with the return of test results for the *Listeria* pathogen require a minimum of five to seven days and can easily amount to about 14 days.

This dilemma has spurred food microbiologists to look at more rapid methods to detect, identify, and confirm the presence of the *Listeria monocytogenes* pathogen. More rapid detection methods can shorten the necessary testing/holding times and reduce warehouse storage costs for RTE manufacturers.

Two approaches investigated at the University of Arkansas involve the development of polyclonal/monoclonal antibodies (1,4,7) and of nucleic acid probes (9, 10, 11) specifically for this pathogen. Monoclonal antibodies (MAb) are "engineered" to be specific for just one kind of pathogen. This work was proposed by Dr. Greg Siragusa and the author, and was funded in 1987 by the Southeastern Poultry and Egg Association.

In 1989, the USDA-Cooperative State Research Service Food Safety Consortium provided funding to continue and expand this work to include both MAb and nucleic acid probes.

Dr. Siragusa, now a research microbiologist at the USDA-Agricultural Research Service Clay Center, Nebraska, Meat Animal Research Center, in his Ph.D. dissertation research with the author, published a series of papers on the control, pathogenicity and detection of this organism using MAb. Dr. Siragusa showed that a natural food enzyme, lacto-peroxidase, delayed but did not prevent the eventual growth of this pathogen at refrigerator temperatures(6).

Another interesting finding was that this organism on diagnostic agar media containing the special sugar esculin in 0.5 percent concentration produced smaller or "petite" colonies of *L. monocytogenes*. Cells from these smaller colonies, which some other workers had occasion-

ally observed but not reported, were tested in an immune-compromised mouse model system.

Dr. Siragusa found the cells from the petite colonies to be just as pathogenic as those from normal-sized colonies of *L. monocytogenes*. The toughness of this organism has further been demonstrated by Ayriana Fuad (5). An M.S. degree candidate in Food Science, Fuad found that cells of *L. monocytogenes* are able to survive in frozen tap water at -70 degrees C or -196 degrees F for 30-45 days.

Dr. Siragusa has also reported the development of an MAb, P5C9, for *Listeria* (7). This was more specific than what has been available in commercial test kits. Several inquiries have been received by U.S. companies, and two European firms have asked about this MAb.

To date, samples of the MAb P5C9 have been sent to three U.S. companies for evaluation in their test systems, and a fourth evaluation by a European company is pending.

To make these MAb more useful and rapid to use in processing plant situations, Dr. Arun Bhunia, a post-doctoral research associate working with the author, proposed and obtained funding from the Southeastern Poultry and Egg Association to develop rapid membrane test kits for this pathogen.

Using micro-colony immunoblot (2) or micro-agglutination blot (3) assays, they reported that as few as 20-40 cells of *L. monocytogenes*/g or 500 cells/could be

detected in less than 24 hours, respectively, by these two assays.

Recently, Dr. Bhunia developed another MAb, C11E9, which is more specific than MAb P5C9.

Nucleic acid probes promise to be another very specific means for identifying and confirming the presence of *L. monocytogenes* in foods. To date, however, the probes that are commercially available are not specific for just the pathogenic species of this genus, *L. monocytogenes*. They react with the other *Listeria* bacteria species as well.

Dr. Rong-Fu Wang, a University of Arkansas post-doctoral research associate, and his graduate student, Wei-Wen Cao, have been working to develop probes that are more specific to the pathogenic species of *Listeria*. One important development is the use of a "dry gel hybridization" technique (9) to replace the slower conventional Southern Hybridization procedure.

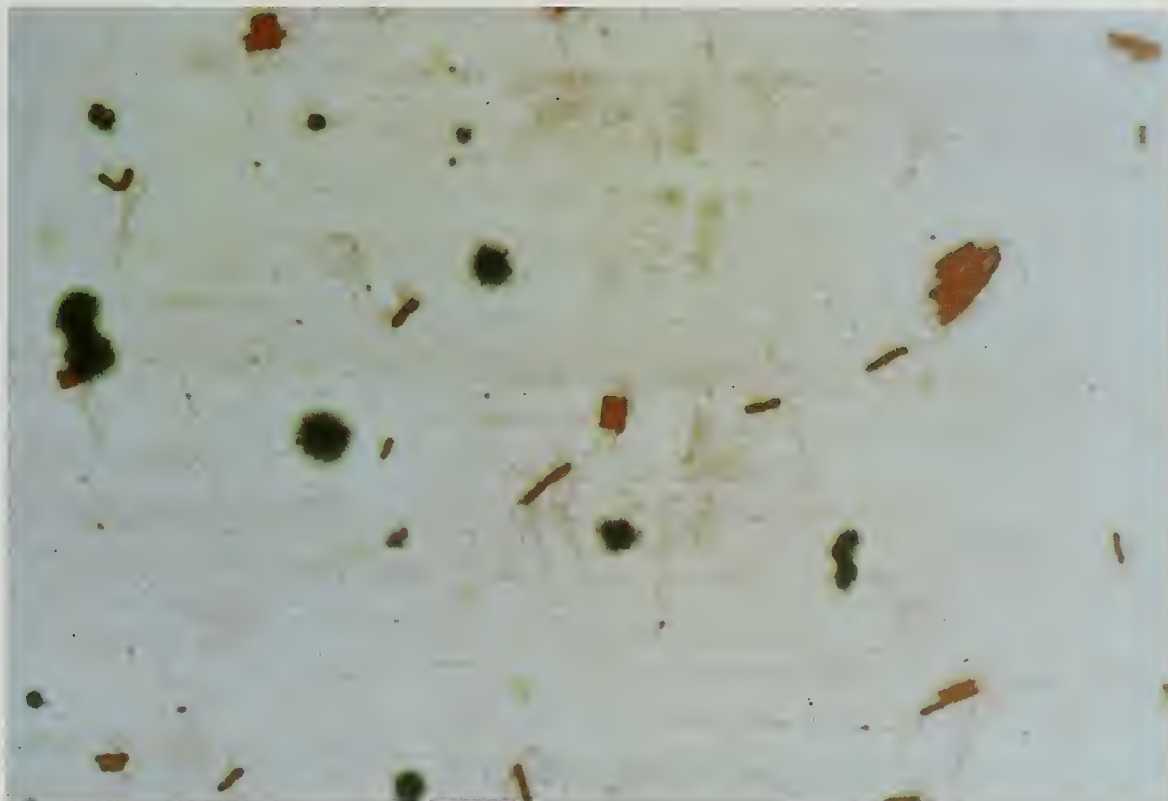
This new dry technique can save 12 to 20 hours of analysis time and is more sensitive. Working with nucleic acids isolated from *L. monocytogenes*, Wang and Cao have developed two new probes (10,11). One is based on a unique DNA sequence, and the other is based on a ribosomal RNA sequence. Both are specific to this pathogen and do not cross-react with other non-pathogenic species of *Listeria* or other bacteria.

Also under study are efforts to make the probes more user-friendly by replacing the radioactive phosphorus label with other chemical labels.

In summary, food microbiology research at the University of Arkansas branch of the USDA-CSRS Food Safety Consortium shows promise of helping to provide government regulators and the food industry with improved tools to confirm the presence in our foods of the important pathogen *L. monocytogenes*. ♦

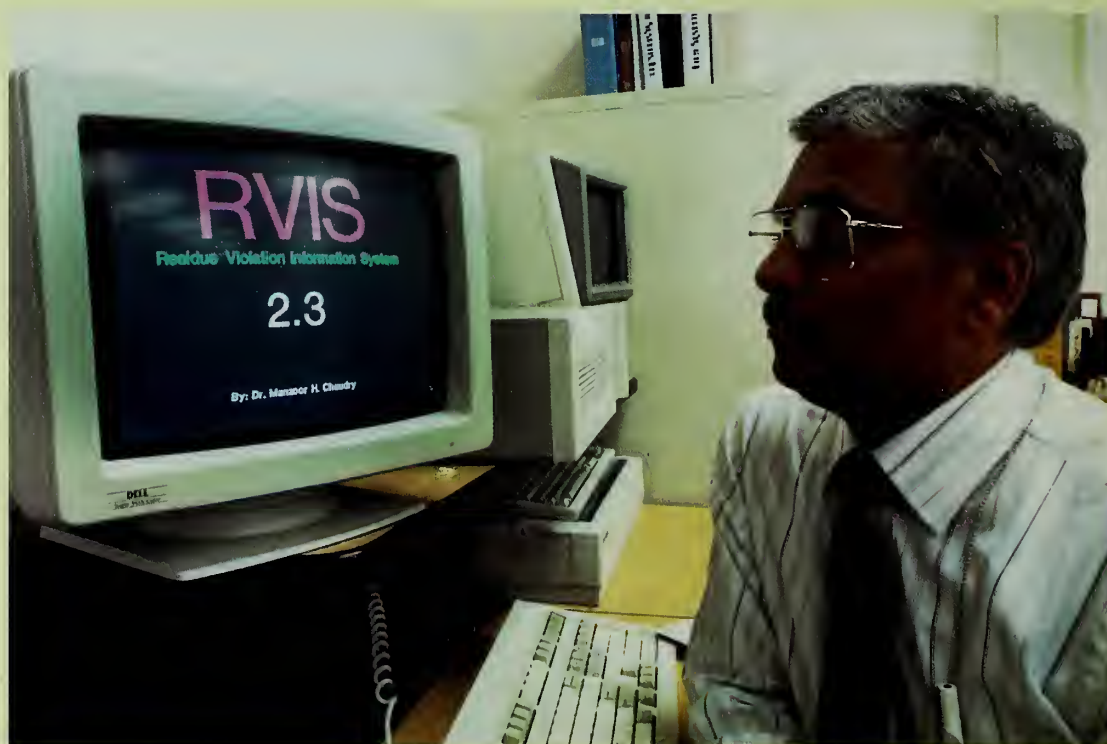
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This is a photomicrograph of the human foodborne pathogen *Listeria monocytogenes*. The photo shows stained flagella, which enable this pathogen to swim around in wet environments in food processing plants.

FSIS Food Safety Review



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Washington, DC 20250

Enforcement staff from USDA's Food Safety and Inspection Service (FSIS) access laboratory-confirmed residue violations through the Residue Violation Information System (RVIS). Story, page 4.