USDA RESIDUE TRACKING PROGRAM FOR GROWTH PROMOTANTS

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ABSTRACT

Over 130 million head of livestock and 7 billion birds are slaughtered each year. The vast majority of those slaughtered in federally inspected facilities are free of violative residues. Prevention of chemical residues in the U.S. meat supply is economically important to the meat and poultry industry, not only because contaminated products are destroyed, but also because the market price drops in response to an increased consumer concern about the safety of the meat supply. The U.S. Department of Agriculture, the U.S. Environmental Protection Agency, and the U.S. Food and Drug Administration, are responsible for setting guidelines and residue tolerance levels to ensure the safety and wholesomeness of the U.S. meat supply. In conjunction with regulatory actions, the industry can contribute to the residue avoidance programs by implementing a Hazard Analysis Critical Control Point (HACCP) system approach to preventing violative levels of residues in meat and poultry products.

INTRODUCTION

Over 130 million head of livestock and 7 billion birds are slaughtered each year. According to the U.S. Department of Agriculture (USDA), the vast majority that are slaughtered in federally inspected facilities are free of violative residues. This can be attributed to the education efforts by livestock trade associations in the area of residue control and the monitoring efforts of the USDA's National Residue Program. Prevention of chemical residues and the perception of residues in the U.S. meat supply is important economically to the meat and poultry industry, not only because contaminated products are destroyed, but also because the market price drops in response to an increased consumer concern about the perceived safety of the meat supply. Several federal government agencies are responsible for setting guidelines and residue tolerance levels to ensure to safety and wholesomeness of the U.S. meat supply.

USDA's National Residue Program

The National Residue Program (NRP) is conducted by the USDA's Food Safety and Inspection Service (FSIS) as part of this agency's responsibility to ensure that all USDA inspected meat and poultry products are safe, wholesome, free of adulterating residues and accurately labeled. The goal of USDA's National Residue Program is to help prevent the marketing of animals containing unacceptable or violative residues from pesticides, animal drugs or potentially hazardous chemicals. Residue testing in the United States is divided into two areas: population sampling programs (monitoring, exploratory and surveillance testing) and enforcement testing. Each year, the National Residue Program collects over 400,000 meat and poultry product samples at FSIS and state inspected slaughter facilities. These samples are analyzed for violative residue concentrations; violations are determined by reference to residue limits for pesticides set by the Environmental Protection Agency (EPA) and for animal drugs and environmental contaminants set by the Food and Drug Administration (FDA). In-plant tests are an important part of the National Residue Program because they provide a rapid screening method to detect residues at the plant level.

Monitoring Testing

USDA's National Residue Program monitors specific animal populations to provide yearly information on the occurrence of residues nationally. The compounds considered in the monitoring program have established residue limits and are selected based on the potential hazard and availability of laboratory methods suitable for regulatory purposes. The results are used to identify producers or marketing entities that have animals with violative residue concentrations. In 1994, a total of 38,894 samples were analyzed from all classes of food-producing animals as part of NRP's monitoring activities. The NRP monitoring program sampled and tested for 12

classes of animal drugs and pesticide compounds comprising approximately 42 residues. Of the 38,894 monitoring samples, 70 showed violative residue concentrations. Violations included 23 sulfonamides, 19 antibiotics, 10 chlorinated hydrocarbons and chlorinated organophosphates, seven ivermectin, six levamisole, five arsenic and one morantel tartrate. In most cases, these are not safety hazards but simply residues within the typical tolerance range but for a species with no allowable usage of the test compound. (FSIS, 1994)

Exploratory Testing

Through the NRP exploratory programs, FSIS studies the occurrence of residues for which no residue limits have been set or for which a laboratory testing method has not been validated. The exploratory testing program evaluates chemicals such as trace metals, industrial chemicals and mycotoxins that do not have residue limits and are inadvertently present in animals. FSIS conducts exploratory studies to obtain information on the frequency and concentration of such residues. With this information, FSIS can better evaluate the need for residue limits to protect public health.

Surveillance Testing

Surveillance testing is designed to identify areas of the livestock and poultry populations where residue problems exist and to measure the extent of the problem. Once a residue problem has been identified, the impact of various actions taken to reduce the occurrence of residues in the populations are evaluated. Through this program, carcasses and organs may be retained pending test results. An example of this program is the surveillance for clenbuterol.

Enforcement Testing

As part of its enforcement testing activities, the NRP analyzes specimens obtained from individual animals or lots based on clinical signs or herd history. In 1994, a total of 364,728 enforcement samples were analyzed. According to the 1994 USDA Domestic Residue Data Book, the great majority of the 131.6 million head of livestock and 7.5 billion birds slaughtered in federally inspected plants are free of violative residues.

The National Residue Program's annual plan is developed during the preceding year through discussions among the residue planning staff, the FSIS Science and Technology Program, other FSIS programs and divisions and involved federal agencies. The plan is based on a "compound/slaughter class pair" design concept. The slaughter or production-classes are grouped with compounds that are determined by common production practices for particular animals because these factors impact the animal's exposure and the probability that residues may be present at slaughter. For example, market hogs have an exposure potential profile that differ from profiles for boars and sows. The NRP annual plan is dynamic and can be modified during the year as additional information becomes available or sampling and analytical capabilities change. (Franco, 1990)

Compound Evaluation System

In order to develop and manage the National Residue Plan, residues are given precedence using the Compound Evaluation System (CES). The CES has three elements: residue, hazard and exposure. (FSIS, 1995)

Residue Evaluation

FSIS is able to predict the likely presence of the first element, residue, by knowing the tolerances established by the FDA and EPA for specific compounds and assessing the pharmacokinetic properties of a compound including the rates of absorption, excretion and tissue distribution. Each compound is evaluated for its potential to produce residues in meat or poultry following the criteria that there is a zero-day withdrawal period established by FDA or EPA; the compound is biodegraded rapidly to non-toxic products; the compound is not absorbed; or if absorbed, is excreted rapidly; and the specific compound and its metabolites are physically unstable in the environment.

Hazard Evaluation

Hazard, refers to the inherent toxicity of a compound. Residues producing life-threatening, irreversible or severely debilitating toxic effects are emphasized through the hazard element. Toxicological profiles are based on findings from both clinical and laboratory studies and developed to evaluate the individual critical toxic effects of specific compounds. Once an overall conclusion is reached on the toxic effect of a specific compound, then the compound is assigned to one of five hazard categories:

(A) high health hazard potential, (B) moderate health hazard potential (C) low health hazard potential, (D) negligible health hazard potential, and (Z) insufficient information available.

Exposure Evaluation

Exposure characterization (EC) is the third element of the Compound Evaluation System. Exposure characterization assesses the factors that influence the likelihood of human exposure to chemical residues of pesticides, animal drugs and other contaminant concentrations occurring in meat and poultry that may affect human health. An exposure characterization checklist is used by FSIS to provide uniformity and standardization in the evaluation of many variables known to affect the probability of a chemical residue occurring in meat and poultry. Based on the information in the EC checklist, the compound under consideration is assigned to one of five exposure categories ranging from (1) high probability of exposure, (2) moderate probability of exposure to (3) low probability of exposure and (4) negligible probability of exposure and (Z) designates a substance with insufficient information available.

USDA's Residue Program for Growth Promoting Hormones

Although FSIS has received letters of concern from consumers about hormones in the meat supply, scientific data do not substantiate any cause for concern. USDA does not currently monitor growth promoting hormones because they do not pose a public health risk. Hormones are used by livestock producers to increase lean meat production and improve conversion of feed energy to lean meat products. The majority of cattle entering feedlots in the United States are given hormone implants. Five hormones are approved for use in the United States: estradiol, progesterone and testosterone, three natural hormones, and two synthetic hormones, zeranol and trenbolone acetate. Studies indicate that any increase above the normal level of these hormones in implanted livestock is so minute that it is insignificant. FDA toxicologists have concluded that any increase in the hormone level is insignificant if it does not exceed one percent of the daily production rate of natural hormones in prepubertal children. Furthermore, residues from naturally occurring hormones such as implants cannot be distinguished from naturally present hormone levels in livestock. Residues of natural or synthetic hormones always are well below tolerance levels. Thus, in 1992, hormones were taken out of the National Residue Program plan.

Because synthetic hormones are not produced by humans, zeranol and trenbolone underwent extensive toxicological testing to determine safe levels in meat before they were approved for use in livestock. The tissue residue tolerance levels for beef are 20 parts per billion for zeranol and 50 parts per billion for trenbolone acetate. Zeranol is approved for use in cattle, suckling calves and sheep. Zeranol is ranked as a C-2, which means it has a low health hazard potential with a moderate probability of exposure. Trenbolone, the other approved synthetic hormone, is classified as D, which means it has a negligible health hazard potential. In 1987, the Codex Committee on Residues of Veterinary Drugs in Foods met to evaluate the safety of hormone use for growth promotion and concluded that all five previously named hormones were unlikely to pose a human health hazard. (FSIS, 1993)

The only growth promotant that is currently being studied by the NRP is clenbuterol. Clenbuterol is a beta agonist used in some countries to treat respiratory conditions in livestock and to prevent premature uterine contractions in pregnant cattle. Although FDA has not approved clenbuterol for use in the United States, it has been used illegally in some livestock show circles to increase the muscle mass of animals. As part of its special study, the NRP is taking samples from meat-type show animals and testing them for clenbuterol residues. (FSIS, 1995)

Should Industry or USDA be Monitoring for Current Growth Promotants?

Neither the U.S. meat industry nor the U.S. Department of Agriculture should test for growth promotants. First, there is overwhelming scientific evidence that meat from approved hormone-implanted cattle is completely safe. Second, because livestock producers have access to five approved hormone ear implants, there is no incentive for producers to use illegal growth promotants such as DES. Third, there is no practical way to test animals for the three natural hormones because they naturally occur in all cattle at levels that vary among cattle dependent upon their physiological state. Furthermore, extensive testing has been conducted on the two synthetic hormones to determine that residues always were well below a safe concentration level; thus, no residue tolerance level was required. Initiating test for hormone residues would not only be a waste of economic resources, but

also it would send a negative signal to the European Union that we are not confident in the safety of our meat supply. (Brady, 1992)

What are the Issues and Problems?

On January 1, 1989, the European Union (EU) implemented a ban on red meat imports from animals treated with growth-promoting hormones; this cut off U.S. beef exports to the EU. This ban has cost the United States alone a projected $450 million in reduced red meat exports over the past seven years. Worldwide, this has caused even greater losses as countries have eliminated implants; this has increased costs of producing all beef - for local, as well as export markets. The United States then implemented unilateral retaliation measures. In 1987, the USDA (G.E. McEvoy and G.A. Pastoria) and Texas A&M (F.M.Byers), in a comprehensive assessment study, concluded that the U.S. impact of eliminating these growth regulators would range from $2.4 to 4.1 billion annually, and for the 26 beef producing nations, a 6% reduction in the 60 billion pounds of carcass beef produced; this represents $10 billion less in carcass beef produced alone. Scientific expert panels including the CODEX Committee on Residues of Veterinary Drugs and Foods along with an EEC committee of European scientists and even the EU's Conference on Growth Promotants all have concluded that the use of hormones as growth promotants in cattle are safe for consumers. With the formation of the World Trade Organization (WTO), the EU is now responsible for proving that the ban on U.S. red meat imports is based on sound scientific principles or else the EU must lift the ban. (FSIS, 1987)

In January 1996, the United States requested consultations of the WTO regarding the EU's hormone ban. Consultations were held on March 27, 1996, with Australia, Canada and New Zealand joining the United States in its complaint. However, the consultations were not successful in resolving the trade dispute. At the May meeting of the WTO's Dispute Settlement Body, the United States requested to have a panel examine the EU's ban on U.S. beef, but the EU blocked the request under WTO dispute settlement rules. On May 20, the United States made a second request for a WTO panel examination of the ban on U.S. beef. The United States' main objective is to reopen the EU market for U.S. beef exports.

What Role Can HACCP Play?

As a process approach to identifying, monitoring and controlling chemical, physical and microbial hazards, a Hazard Analysis Critical Control Point (HACCP) system would be the first step in preventing violative levels of residues in beef products. Using the seven HACCP principles, the following illustrates the first steps for chemical residue prevention:

1. Conduct a hazard analysis to identify potential hazards that could occur in the food production process. A chemical residue, potentially from an implant growth regulator, especially on an unapproved compound (i.e., clenbutenol), is a potential hazard in beef cattle operations.

2. Identify critical control points (CCPs), which are points in the process where potential hazards could occur and can be prevented and(or) controlled. An example CCP could be a cattle processing facility or an implant program.

3. Establish critical limits for preventive measures associated with each CCP. The critical limits could be the published and government-approved tissue residue tolerance levels for implants.

4. Monitor each CCP to ensure that it stays within the limits. This can be accomplished by maintaining records documenting proper implant administration of each animal during cattle processing.

5. Take corrective actions when monitoring determines a CCP is not within the established limits. Establish a process to manage animals when records indicate that the implant was not delivered properly and determine an acceptable procedure to follow to neutralize to remove an incorrectly placed implant.

6. Keep records that document that the HACCP system is monitored and working correctly. A HACCP plan might include electronic animal identification tags with appropriate information on implant administration, inventory of implant products and other administrative records.

7. Verify that the HACCP system is working properly through tests and other measures. This can be accomplished by reviewing data from liver and plasma samples to verify the absence residues. If a residue is detected, it could be traced back

through the electronic animal identification system and determined where in the process the problem occurred.

CONCLUSIONS

Although U.S. regulatory agencies and several scientific panels have determined that growth promoting hormones are safe and pose no health risks for consumers, the EU's ban on U.S. beef still stands. Fortunately, the United States has an effective residue tracking program that is scientifically based and not only ensures that the meat supply is free of residues, but also aids in maintaining consumer confidence.

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QUESTIONS & ANSWERS

Question: Shouldn't beef be tested routinely for residues from hormone implants?

A: I don't think hormone testing is necessary because of the low risk to public health. Residue testing for high risk compounds, I fully support. But there is no reason to test for hormone residues in the US because according to the FDA compound evaluation system, implants are safe and the risk is very low. We should not test for hormones simply because the Europeans think we should.

Owens: Wasn't there a problem in Puerto Rico some years back with hormone residues in meat? How was that resolved?

A: Basically what happened in Puerto Rico was connected to advanced puberty in young girls. Beef was blamed initially, but the culprit turned out to be birth control pills.

Question: How should the industry respond to the BSE problem that has plagued England?

A: The FDA has been considering the options and we have expected a response for the last two months. Basically, there are multiple options. One is a total ban on feeding ruminant protein to ruminants. This includes muscle tissue. Other variations including banning use of nervous tissue, spinal cord, brain, etc. I don't know what is delaying the decision. Perhaps the election. We expect a ruling any day. You can argue on either side of a ban. I have serious concerns about the public response to the BSE issue. We eventually will find BSE in the US if we search long enough. Some people are convinced that BSE is linked to the human disease CJD. We need to decide as an industry what we will tell the public in advance of a BSE detection. The first step is to stop feeding ruminant protein back to ruminants. I realize that this has serious ramifications for the rest of the animal industry including pet food. But as far as beef is concerned, we all should stand behind a ban. We also should eradicate scrapies (the sheep disease) in this country. Competitors like New Zealand, Argentina, and

Australia that can make the claim that they don't have scrapie; but we can't make that claim. The most important issue and the highest priority is for dealing with the perception of BSE. Number two is to find a rapid method for detecting the prion that works.

Question: How difficult would it be to eradicate scrapie?

A: It would be expensive and difficult. You need the proper education and commitment from state, federal and private sector groups. This is perhaps the very highest priority for the US sheep industry. The time for action is now. I can't give a dollar figure; we tried once before and it was stopped in the agency, but I think it has to be done.

Question: Is HACCP well perceived by the general public?

A: Are you talking about the consuming public? I think it is not well perceived. It probably shouldn't be. I doubt if we are going to educate the public what HACCP stands for. But we can educate them in a different way. We can educate them on the prevention method of being adapted by the industry. We can educate them on their role in food safety. I am more interested in making sure they are all aware of our industry's initiatives and understand what practicing HACCP can do.

Question: We talked about what we do as far as hormonal implants are concerned. I've heard some horror stories about the use of clenbuterol and other drugs being used in Europe. Can you comment on their drug control programs?

A: Let me answer with an illustration from several years ago. I was doing research with one of the largest retailers in Europe. They showed me the data on abscesses in their carcasses. More than 25% of the carcasses had injection site abscesses. Over 75% of the tissues from those abscesses had violations in use of up to ten different compounds; violations are 2 to 15 times larger than in the United States. This was fairly routine for this company. Universities were having difficulty buying animals for research that didn't have high residue levels. Problems with residues were rampant. Drug testing is Europe is mixed and not that sophisticated.