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Food Safety Perspectives on Animal Biotechnology

Having been involved in meat and food animal research for a good part of my career, I am aware of the opportunities biotechnology provides in improving the health of food animals and the safety of the meat supply. As the new administrator of the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), I am also aware of the responsibilities we have to ensure the safety of food produced through animal biotechnology. In this paper I will present my perspectives on animal biotechnology by discussing two broad areas. First, the opportunities biotechnology provides in making food safer, and second, the regulatory implications of the new technologies as they relate to the meat and poultry supply.

OPPORTUNITIES TO PRODUCE SAFER FOODS

The Food Safety Inspection Service is a public health agency dedicated to ensuring the safety of the meat and poultry supply. For that reason, any new technology that offers the opportunity to fulfill that mission more effectively and efficiently is of interest to us. While we are addressing the issue of transgenic animals, we are also looking at products such as bioengineered vaccines, bioengineered pharmaceuticals and diagnostic tests. All of these will have a long-term impact on animal health and food safety. Biotechnology offers a number of new tools that will improve the health of food animals. Genetically engineered vaccines may confer immunity more safely and efficaciously than traditional vaccines. With genetically engineered vaccines we can differentiate whether the animal is vaccinated or infected—an important distinction in the fight to control and eradicate animal diseases.

One North Carolina firm recently developed a method of vaccinating chickens inside the shell—even before they hatch. While FSIS does not use these vaccines or regulate them, they affect our mission by improving the health of animals coming to slaughter.

Other tools, such as improved diagnostic tests, are of direct value to us in the meat and poultry inspection program. For instance, researchers with USDA's research arm, the Agricultural Research Service (ARS), are developing a recombinant antigen for the serodiagnosis of bovine cysticercosis. We hope to be able to use this test in the inspection program in the future.

Biotechnology also offers opportunities to improve the microbiological safety of meat and poultry products—our number one priority. In our laboratories DNA probes are being used for detection of *Salmonella* in cooked, ready-to-eat meat and poultry products. We are working to integrate similar DNA probes for *Listeria monocytogenes* and *Campylobacter* into our program in the near future. These tests provide advantages in terms of reducing the time needed to get results and greater specificity in identifying organisms.

Another way to improve microbial safety is by using recombinant DNA to produce a bacteriocin effective against specific foodborne pathogens. The bacteriocin could be added to processed foods to reduce spoilage in a manner similar to the currently approved use of nisin in cheese spreads. Other developments are on the horizon. While we are not currently using these technologies in our microbiology program, certainly the potential is there. For instance, polymerase chain reaction (PCR) technology will allow us to amplify the genetic material from pathogens so we can detect these pathogens without enrichment. This technology will also allow us to look for a specific bacterial genus or species and even a specific virulence gene.

Biosensors are an even newer avenue of biotechnology research. By attaching an antibody, enzyme or nucleic acid to an electrode, these sensors can be used to detect a foodborne pathogen or antibiotic. They have the potential to make shelf life predictions for chilled meat by detecting glucose (an indicator of microbial spoilage flora) at the surface of the meat. While detection is important, the ultimate goal is to prevent contamination in the first place. That is why we hope to see future research directed towards using genetic alteration to produce meat and poultry resistant to pathogenic microbes such as *Salmonella*.

While diagnostic tests that are faster and more effective is a great advantage, producing disease-resistant animals is equally important. For instance, ARS has demonstrated that it is possible to identify swine with a genotype that is resistant to trichinosis. With further research, this genotype could be incorporated into domestic swine populations—conferring trichinosis immunity to all future generations of swine.

At Texas A&M, site of NABC 4, animal geneticists Jerry Taylor and Scott Davis are working on a project funded by the U.S. Agency for International Development to determine if individual genes in goats are associated with resistance to *Haemonchus contortus*, a parasitic disease that affects ruminants throughout the world. While this specific study is more applicable to Third World countries, it certainly has relevance for domestic animal production. If a genetic basis for resistance can be incorporated into livestock production, we can produce healthier animals and reduce the need for animal drugs.

There are also other possible benefits aside from disease resistance that may be realized through genetic modification of animals. Some of these

possibilities include:

- animals with leaner meat;
- animals that use feed more efficiently;
- animals with better growth features; and
- animals that manufacture biopharmaceuticals for human or animal therapy.

The potential benefits from genetically modified animals appears to be increasing all the time.

REGULATION OF TRANSGENIC ANIMALS

Certainly, these new products of biotechnology such as vaccines, diagnostic tests and disease-resistant animals interest us as ways to make the meat and poultry supply safer. We also have another role—to ensure that transgenic animals produced through biotechnology are safe for human consumption. For purposes of this paper, transgenic animals are animals whose genetic composition has been changed by introducing selected genes from other sources into the line from which the animal is derived.

Food-producing animals involved in transgenic animal experiments are currently considered experimental under existing FSIS regulations that affect the meat and poultry industries. The regulations define experimental animals as those treated with experimental drugs, chemicals or biologics. We have not yet approved the slaughter of any transgenic animals and are still in the process of developing our policy. Since the field of biotechnology is changing as we speak, we recognize that our regulatory oversight will have to change to keep pace with technological advances.

In the *Federal Register* of June 26, 1986, the USDA, in conjunction with the Office of Science and Technology Policy in the Executive Office of the President, stated the Department's intention to regulate foods produced by new methods, such as recombinant DNA techniques, within the existing statutory and regulatory framework. This policy is in line with President Bush's federal biotechnology policy, announced in February, 1992, which emphasizes that federal oversight should be based on risk, not triggered simply by an innovative technology.

We believe the existing system will work because we plan to regulate the *products* of biotechnology, not the process itself. Our inspection program is now prepared to handle many diverse animals and many different product types. Our system can handle transgenic animals as well. Under our planned regulatory approach, the investigator must specifically request slaughter of any investigational animals involved in transgenic experiments. Whether or not genetic material was successfully incorporated, the following information must be submitted and reviewed by FSIS before the animals are presented for slaughter:

- species;
- genetic changes being attempted or affected;

- technique used to introduce the genetic material;
- results of appropriate scientific methods for detection of the transgene, such as PCR or Southern hybridization; and
- physical condition and appearance of the animal prior to slaughter.

In addition, for animals that have successfully incorporated the genetic material, the following information should also be provided:

- information on the gene product;
- analytical data/results of the gene product analysis; and
- an assessment of animal health and performance, including a veterinarian's observation and examination, and any clinical laboratory data on the overall health of the animal.

If the information meets the criteria under the experimental animal regulations, the animals would be approved for slaughter. A request for slaughter of these animals must be made indicating the location of slaughter. Each animal from transgenic experiments permitted for slaughter would also receive the required antemortem and postmortem inspection by an FSIS inspector and/or veterinarian. This is important because the way in which an animal grows and functions is a reliable indicator that the change was not detrimental to the safety of these animals. Since we will know ahead of time that the trans-genic animals are to be presented for slaughter, we will have the opportunity to examine their growth and general health before they reach the slaughterhouse.

INTERACTION WITH OTHER AGENCIES

In evaluating the food safety of transgenic animals, we would consult with the Food and Drug Administration (FDA), USDA's Animal and Plant Health Inspection Service (APHIS), or the Environmental Protection Agency (EPA) before making a food safety decision.

The FDA is responsible for assuring food from species other than those inspected by FSIS is safe. They are also responsible for assuring that animal drugs are safe, effective and properly labeled, particularly with regard to the safety of residues remaining in the animal at slaughter. The FDA, along with FSIS, is charged with assuring that food additives added to meat and poultry products are safe for consumers. The FDA, in cooperation with state authorities, also sets standards for the wholesomeness of milk. Pesticide chemicals, used directly on food animals or on animal feed crops, are reviewed prior to marketing for safety by the EPA. Finally, biologic products, such as vaccines and serums used in animal health programs, are subject to oversight by APHIS for potential food safety impacts.

To repeat, FSIS has not approved any transgenic animals for slaughter yet. Our policy on these animals is still being developed and will be considered ready for review as soon as FSIS has come to an understanding with FDA regarding jurisdictional responsibilities of the two agencies with regard to

animal biotechnology. FSIS is planning to publish a paper entitled "Points to Consider" by the end of 1992 that will offer more specific guidance on the requirements for slaughter of transgenic animals. In addition, we plan to have our entire policy reviewed by USDA's Agricultural Biotechnology Research Advisory Committee (ABRAC).

I also want to emphasize that all federal agencies involved in regulating biotechnology are coordinating their efforts in order to secure common guidelines and a clear understanding of jurisdictional responsibilities. In the near future evidence of this coordination as policies on various biotechnology products emerge.

REGULATION OF NONTRANSGENIC ANIMALS FROM BIOTECHNOLOGY RESEARCH

Although no transgenic animals have been approved for slaughter yet, FSIS has authorized the slaughter of nontransgenic animals in Texas. These animals were involved in biotechnology experiments, but they were not genetically modified. These animals were slaughtered after it was ascertained that the criteria announced in the *Federal Register* notice of December 27, 1991, "Livestock and Poultry Connected with Biotechnology Research" (Vol 56, No. 249) was met.

OBSTACLES TO THE USE OF BIOTECHNOLOGY IN ANIMAL AGRICULTURE

Progress has been made in the animal biotechnology arena and the benefits to animal health and food safety are evident. It will not be smooth sailing all the way, however. There are potential obstacles out there that must be brought into the open in order to address them in a constructive manner.

Consumer acceptance of the new technology is a prime example. Just because it is good technology does not mean consumers will accept it. All of us—government, academia and private industry—must work together to address consumer concerns. At FSIS, better communication with the public about biotechnology as well as all other issues concerning food safety, is one of my major priorities. We must not wait until the questions are asked before we provide information. We must not wait until we are attacked to respond. We must be on the offense, not on the defense.

At USDA, we are developing a strategy to get information about biotechnology to the public with the goal of helping the public make informed decisions about the products of biotechnology. Certainly, our agency will have a role in informing the public about our regulatory strategy regarding transgenic animals, but this is just a small part. We must do much more. This is especially important because we will be competing with a number of other groups for the public's attention on this issue.

Short-term, we must focus on educating U.S. policymakers about biotechnology so they can make informed decisions on legislation and policies at the local level. USDA is partially funding pilot studies currently underway to educate local county administrators on the risks and benefits of biotechnology.

Long-term, we must reach the public. USDA's Extension Service plans to set up focus groups with consumers to determine what types of information the public wants and how best to provide them with that information. We must know our audience and we must know *how to* reach them.

The bottom line is this: we must stay in tune with public opinion. I urge you to pay close attention to a survey of consumer attitudes about biotechnology to be released shortly. It was conducted by North Carolina State University and Colorado State University and funded by USDA's Extension Service and North Carolina State.

While the preliminary results show overall support for the use of biotechnology in agriculture and food production, apparently the acceptability of biotechnology will vary with the specific use. People are much more comfortable with the idea of tinkering with plants than with animals, a reflection of public concerns regarding the well-being of animals and moral beliefs regarding genetic modifications in animals.

It is also apparent that the public wants to be involved in decision-making about biotechnology. This interest is a good sign that the public will be receptive to biotechnology education. That is one reason I have been so candid here. Not only must the public be enlightened to enable them to make informed decisions about biotechnology, but they must have confidence in the government's ability to regulate biotechnology. The public must believe us when we say these products are safe. If we do not have their confidence, use of the technology is threatened. That is why we must carefully develop our policies and involve the public in the decision-making process.

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SUMMARY

In summary, biotechnology offers us many opportunities to improve agriculture. I believe biotechnology will have its greatest impact on meat and poultry safety in two ways. First, it will provide us with diagnostic tests that can help us to quickly and effectively detect contamination during the food production process.

Second, biotechnology will enable the production of healthier animals through improved vaccines, improved diagnostic tests and the ability to produce disease-resistant animals. Biotechnology will also potentially provide us with animals with leaner meat, animals that are more feed efficient and animals with better growth potential.

While ensuring the safety of transgenic animals will have an impact on FSIS, I am confident our regulatory structure is equipped to ensure the safety of these new animals.