DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BIOTECHNOLOGY IN THE YEAR 2000 AND BEYOND
PUBLIC MEETING

Tuesday, November 30, 1999
10:00 a.m.

Cohen Building
330 Independence Avenue, N.W.
Washington, D.C.
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MR. LEVITT: Good morning. My name is Joseph A. Levitt. I am Director of the Center for Food Safety and Applied Nutrition here, at the Food and Drug Administration. It is my pleasure both to be hosting and chairing this meeting, and to be welcoming all of you here today.

This, as you all know, is the second of three public meetings on foods produced by utilizing the tools of modern biotechnology, sometimes called genetic engineering or bioengineering.

As FDA Commissioner, Jane Henney, noted at the Chicago meeting, we knew there would be keen interest in this issue but, to be honest, we really did not anticipate it quite at this level, which explains our need to obtain a facility with a larger seating capacity. I apologize for the inconvenience this change may have caused, but I think if it means we can all be together in the same room it will be well worth it. We tried diligently to contact everybody directly that had signed up for this meeting, either by telephone, by e-mail or by fax, and we hope that we were able to reach everybody. We also have people posted at the other people, if people do go to the wrong place, and we will welcome them here later.

As I mentioned, today's meeting is the second of
three public meetings that FDA has planned on this topic. The first public meeting was held a little more than a week ago, on November 18th, in Chicago, Illinois. That meeting included 11 panelists representing diverse viewpoints, 84 scheduled speakers and 96 press representatives. There is clearly a lot of interest. More than 300 individuals also observed the meeting at the overflow room and, happily, here we have a larger room so we don't have the need for an overflow room here. The third meeting will be held in Oakland, California on December 13th.

By way of introduction, and to ensure consistency between the three FDA public meetings, my opening remarks will mirror those very closely that were provided by Commissioner Henney in Chicago. As she did, I would like to take a moment to stress that we, at the Food and Drug Administration, are very pleased to have this opportunity to share our experience with you and to listen to your views on these very important subjects.

We recognize that there is not only a great deal of interest in this topic, but also that there are widely differing and, admittedly, very strongly held views on the subject of biotechnology. While, at FDA, we wish to listen to everyone, we also ask that we all listen to each other so that the community at large can gain a better understanding of the spectrum of use, and I know that actually in this
room I chaired a number of public meetings and have really
come to really see the value -- as I usually say at the
beginning, "I'll make a deal: I'll listen to each of you if
you all listen to each other" -- and I have found that that
really has helped a lot in terms of sometimes bridging the
views and gaining a better understanding across the board,
and I look forward to that pattern continuing today.

Now, FDA has a long history of public health
protection, as you all know. Our current law dates to the
early part of the century. Over the years, we have faced
many new developments that affect the food supply. For
example, in the 1950s the use of preservatives and other
chemicals in food led to concerns of our food safety. More
recently, FDA has been in the forefront of efforts, as part
of the President's Food Safety Initiative, to reduce food-
borne illness.

Throughout its history, the Food and Drug
Administration has based its regulatory decisions on sound
science with protection of the public health as our foremost
criterion. This is central to FDA's mission and tradition,
a tradition that continues with FDA's oversight of products
developed using modern biotechnology.

Now, let me briefly describe our efforts in the
area of biotechnology, and after I have finished Dr. Jim
Maryanski will speak much more extensively to this. In
1982, FDA approved a new insulin product, the first consumer product developed using modern biotechnology. Since that time the agency has had extensive experience in evaluating the safety of products developed using this new technology. The use of the tools of biotechnology in foods began in the mid-1980s.

FDA completed its review of the safety of chymosin or rennet preparation, the milk clotting enzyme used to make cheese, in 1990. At that time, FDA received no public comments about the safety of this ingredient. Recently, however, the use of the tools of modern biotechnology to produce new varieties of food crops has raised a number of questions about the environmental effects of these crops and about the safety and labeling of foods derived from them.

I should note that some questions, such as those regarding human health and food safety and feed safety, as well as food labeling, fall directly under FDA’s authority. However, others such as those regarding environmental safety and the effects on the plants themselves, generally fall under the authority of other agencies or departments of the U.S. government, such as the Environmental Protection Agency or the U.S. Department of Agriculture. Suffice it to say, today we will be focusing on those issues that fall under FDA’s jurisdiction.

I would like to take this opportunity to briefly
explain how FDA oversees the safety of foods developed using the tools of biotechnology, and to briefly share the experience that we have had in evaluating the safety of these foods over the past five years since the first such whole food, the Flavr Savr tomato, entered the market.

FDA introduced our current policy for regulating foods developed using the tools of biotechnology back in 1992, after an extensive scientific review. The policy was discussed publicly during a joint meeting of FDA’s Food Advisory Committee and Veterinary Medicine Advisory Committee in 1994. Since that time, firms have completed food safety discussions with FDA involving over 40 consultations on new varieties of foods made using the tools of biotechnology.

Now, as Dr. Henney articulated clearly at the Chicago meeting, we believe that our policies and processes in this area are well-grounded in science, and that we have an excellent track record in applying our policy. We believe that our oversight has been substantive, credible and appropriate. We have now had five years of experience with our consultation process. In a few minutes you will hear more from FDA about the specifics of our experience, the testing that has been performed by developers of new varieties, the kinds of information that have been reviewed by the agency, and the regulatory and scientific grounding
for our approach to oversight of these products.

It is our goal to have our review and regulatory processes be as open and transparent as possible. We seek each of your views about whether we need to consider making adjustments to our current system in order to attain those goals.

Now, because of the recent attention that has arisen, we feel it is a very appropriate time to review our experience and solicit views from a variety of interested parties. We want to hear your suggestions on how we might improve our approach to safety assessment as well as how disclosure of information to the public would be best achieved.

Now, let me take a moment to briefly explain the format and logistics for today's meeting. This morning we will focus on issues concerning the safety assessment of these foods and FDA's regulatory oversight of them. There will be a brief overview of our current approach to safety assessment and the experience that FDA has had over the last five years, and FDA representatives will provide that. We will then ask our invited panelists to discuss issues related to questions that we believe will help FDA evaluate its current approach to safety assessment. So, we have both a presentation of what we have been doing as well as views from others on how we have been doing and ways we might
improve and strengthen the system.

This afternoon the focus will shift to issues surrounding disclosure of information to the public. Again, a brief presentation will be provided by FDA, followed by a panel discussion. Finally, we have reserved nearly three hours later this afternoon to hear the views of as many members of the audience that signed up ahead of time as we possibly can. However, due to certain time restraints we do need to conclude our meeting promptly at seven o’clock p.m.

Because we want to ensure that everyone is able to present his or her views, we are asking that all those presentations be limited to two minutes. Again, we did this in Chicago and actually the system really works.

When you checked in this morning, all of those that are presenting this afternoon, you all should have received a folder with a number on it. That number indicates the order in which public presentations will be made, and we will go through the logistics of that this afternoon on exactly how to go about doing that.

Now, because we have limited time for public comment at the microphone, I would like to remind everyone here that we also welcome written comments. We have established a public docket that will display all the information that the agency has received from all its public meetings. The FDA home page highlights these public
meetings and provides the latest registration information, as well as easy access to reviewing pertinent information and submitting comments directly through the Internet. As many of you know, and hopefully all of you will know when you leave today, the FDA home page is very simple: www.FDA.gov. We are also transcribing the three public meetings on this topic. The transcription of each meeting will be made available in the docket and on the Internet as quickly as possible, and our goal is to do that within 15 working days of each meeting. Information about how to access the public docket and submit comments is in your registration packet which you should have received on the way in, if not, you can get one at the break, as well as on the FDA Internet home page that I already referenced.

Finally, just before we begin, I would like to extend a special thank you in advance to the members of both our panels for agreeing to come and share their views with us, with you and with each other. We have attempted to assemble panels with members who represent the spectrum of interested parties. Each, no doubt, has strongly held views and useful information for all of us to consider. We have relied in large part on umbrella organizations, including consumer organizations, professional societies and trade groups, to represent their members or to identify for us panelists for this and future meetings, and for their
cooperation we thank them. We trust that the members of the panels will express a diversity of views, explaining those views and establishing a dialogue among the panelists to ensure that the issues are fully disclosed.

I would also like to add my thanks, along with those of Commissioner Henney, to all of the FDA staff who have devoted a great deal of time and energy to making today's meeting possible. That includes our staff at FDA headquarters and, in particular, our employees in the Office of Consumer Affairs, as well as our field staff, especially those from the FDA Chicago district as well as the Baltimore district offices. Their flexibility regarding the many logistical challenges raised by today's meeting are certainly greatly appreciated. Also, as I mentioned before, I have held several meetings in this room and I can tell you, it has never looked better.

FDA is primarily here, again, to listen and to answer questions. Our goal is not to reach a conclusion by the end of the day. We are engaged in the process of listening, not pronouncing. Therefore, we will not engage in debate on these issues primarily because we want to hear the views of others.

I would also note that FDA is in litigation over this policy, and we need to be respectful of the court decision-making process as well.
Today's discussion and those that will follow will no doubt stimulate our thinking. I welcome your individual input and our collective working together. Again, thank you very much for your attention during these introductory remarks.

Let me now take a moment to introduce my colleagues on the FDA panel. On my right is Mr. William Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation in the Office of the Commissioner. To his right is Dr. Stephen Sundlof, Director of our Center for Veterinary Medicine. To his right is Miss Catherine Copp, senior lawyer in our Office of Chief Counsel. At the far end of the table is Dr. James Maryanski, the Biotechnology Coordinator in my Center, the Center for Food Safety and Applied Nutrition at the FDA. To my immediate left is Mr. Robert Lake who is Director of the Office of Regulations and Policy in that same center, the Center for Food Safety and Applied Nutrition.

Now, since you have certainly heard more than enough from me, I would like to turn to the substantive part of the program and to Jim Maryanski who, as I said, is the Biotechnology Coordinator in my center. Jim will provide, as I mentioned, an overview of really what FDA's policy is and how we have gone about applying that policy, the kind of testing that companies are doing, and how we have gone
through the whole safety assessment process. It is my
pleasure to introduce Jim Maryanski.

FDA Policy: 1994 to the Present

James Maryanski, Ph.D.

DR. MARYANSKI: Thank you, Mr. Levitt. Good
morning, ladies and gentlemen.

This morning I will give you a very brief overview
of FDA’s role in protecting public health and its role in
assuring the safety of foods produced through modern
biotechnology. I will give you a broad-brush picture of the
policy and approach that we have in place for assuring the
safety of these products, and give you a sense of the kind
of testing that is being done for food safety for these
products. I will also share with you some of the experience
that we have had in working with companies over the past
five years so that you have a sense of what we are doing
today, why we are doing it, and how we got to where we are
now.

[Slide]

The Food and Drug Administration, as many of you
know, is an agency in the U.S. government in the Department
of Health and Human Services. There are other public health
agencies that are part of this Department: The National
Institutes of Health, for example, and the Centers for
Disease Control and Prevention and FDA are all public health
The Federal Food, Drug and Cosmetic Act is the federal law in this country that gives FDA oversight over most of our food supply. We have authority over all of the food except for meat, poultry and egg products that are regulated by the Department of Agriculture. So, it is this Act that provides the legal tools for FDA to assure the safety of all of the products under its authority, including foods developed by modern biotechnology.

Our policies are always based on the best science that is available, and that is a very important aspect in our policy and we have spent a number of years studying the science of modern biotechnology and its possible impact on the food supply and food safety.

FDA is responsible for foods that are on the market, in commerce, in the United States and foods that are imported into the United States. So, both domestic and imported foods fall under our authority. Of course, our goal is public health protection. That is our mission. We are here to ensure that the food supply is safe and wholesome.

I would like to give you just a very brief overview of how products produced by modern biotechnology
fit within the broader framework of the U.S. government because there are several agencies that are involved in looking at various issues that are related to the regulation of these products. FDA, of course, is responsible for food safety and labeling for foods that fall under our authority. The Department of Agriculture, and particularly the Animal Plant Health Inspection Service, APHIS, is responsible for ensuring that plants either moved and grown in this country or imported into the country do not pose problems for agriculture. That department has regulations for permitting field testing, as well as for the petitions that allow the commercial growing of plants produced by modern biotechnology.

[Slide]

The Environmental Protection Agency, EPA, also has a very important role because they have responsibility for ensuring the safety of pesticides. So, pesticides must be registered by EPA.

To give you an example of a product and show you how it fits within these three agencies and departments, the BT corn, that is the corn that has its own built in pesticide that you have undoubtedly heard about -- that corn would fall under the Department of Agriculture for consideration of whether it would pose any risk to agriculture under the Plant Pest Act and the Plant Pest Act.
Quarantine Act. That product also would fall under EPA because the BT is a pesticide. So, the BT would be registered as a pesticide by EPA.

The food products and products for animal feeds, such as high-fructose corn syrup that would be used in soft drinks, for example, those products would fall under FDA. So, that product is one for which the company would have to go to all three government agencies to complete whatever regulatory requirements are necessary for that product.

In the late 1980s, the Food and Drug Administration began to receive a lot of questions about the use of recombinant DNA techniques and the possible impact on the food supply. At that time, we were already reviewing petitions from companies for food processing enzymes such as chymosin and alpha amylase, the enzyme that is used to make corn sweeteners -- chymosin, of course, also is known by the name rennet that is used for the milk clotting step in making cheese. We were very familiar with food ingredients produced by this technology.

But, at that time, we began to receive many questions about whole foods -- soybeans, corn, potatoes, tomatoes -- and how would those products be regulated; and what kind of safety testing should be done to ensure the safety of those products. So, we spent a number of years
with our scientists in FDA and working with scientists in other agencies and other governments around the world to work out a system, an approach by which foods could be tested by the firms to establish that they were safe for marketing.

In fact, when Calgene, which was the company that developed the Flavr Savr tomato, approached FDA and asked us to review all of their safety data for the product that they were developing, which was the Flavr Savr tomato, that was the first time really that FDA had been presented with the question of how do we apply modern scientific methods to show that a food, a whole food such as a tomato, is safe to eat. So, we spent a good deal of time looking at that and other questions related to the use of modern biotechnology and its impact on the food supply.

And we published a policy in 1992, in the Federal Register, which was a statement of policy. It was intended to answer the questions that we were receiving at the time. It was essentially a snapshot of the technology based on the kinds of products that were being developed, and how we felt those products could fit within the existing framework under the Federal Food, Drug and Cosmetic Act. The policy that was published applies to all methods of plant breeding. That is, if foods are derived from plants that have been developed by cross-hybridization, the traditional methods in
agriculture, or any of the other number of methods that
plant breeders use to introduce new traits into plants, or
by the new recombinant DNA or bioengineering techniques that
we refer to as modern biotechnology, we felt that all foods
should meet the same standards of safety under the Act and,
therefore, the policy applies to all foods. It applies to
both human foods and products that are used as animal feeds.
So, it covers fruits and vegetables and grains, as well as
the products that are derived from agricultural crops such
as vegetable oils or food starch.

[Slide]
The policy really explains how foods have always
been regulated, and how products that are derived by modern
biotechnology can fit within the framework by which foods
are regulated. FDA has two tools that it uses primarily to
assure the safety of foods under the Food, Drug and Cosmetic
Act. The Act places the legal responsibility for ensuring
the safety of food on the developer of the product and gives
FDA very broad authority to take action against the
developer or to remove the product from the market if it
does not comply with the law.

To give you an example, there was a potato
developed in the 1970s that had an excessive level of a
natural substance that occurs in potatoes. That product
could make people sick. Fortunately, it did not make any
consumers sick; it was discovered before. But FDA and USDA
worked together to remove that product from the market, and
that is what we call our postmarket authority.

We also have authority to assure the safety of
food additives. In fact, a food additive must be approved
by FDA before it can be used in food. There are a number of
exemptions under the law for substances that are added to
foods that are not food additives. For example, pesticides
are exempt from a definition of food additives because they
are regulated by EPA as pesticides.

Substances that are generally recognized as safe, what we call the GRAS, GRAS food ingredients, are also
exempt on the basis that those substances are recognized by
experts familiar with food safety as being safe for use in
food -- salt, vinegar, spices, food-processing enzymes, a
number of things that have been commonly used in food are
considered to be GRAS.

We have applied this to the developments of modern
biotechnology, as well as other methods of introducing new
substances into food, in the context that if a gene is
introduced into a plant and the result of that gene is a new
protein that is present in the food, if that protein is not
generally recognized as safe it would be a food additive,
subject to premarket review by FDA. We have said that most
of the modifications that have occurred to date result in
new proteins in food that are either derived from other food
crops or are very similar to foods that are already safely
consumed in the food supply, and we have said that these
proteins will be presumed to be generally recognized as
safe.

What we have here is the legal tool though to
assure that if this technology, or any other technology, is
used to introduce a substance which is not generally
recognized as safe it would require premarket review and
approval by FDA before the food could be used in the market.

The most important part of the policy that we
published in 1992 was the guidance to industry. The
guidance to industry part of our policy provides information
about the kinds of issues related to food safety that
developers should take into account in bringing new foods to
market. It really provides a yardstick for the developer to
determine whether they are meeting the standards that FDA
expects them to meet under the Act. We consider this to be
a standard of care. When we published the policy in 1992,
this was really the first time that we had put down on paper
what the standards would be for agricultural crops in terms
of food production.

[Slide]

In 1992, when we published this policy, we did ask
for public comments, and one of the comment that we received
from many people was that there should be notification to FDA about foods produced by modern biotechnology. As part of the review of the Flavr Savr tomato, that review was conducted over the period of time that we published the 1992 policy and, as part of our evaluation and determination of whether that policy was an appropriate policy, we had a meeting that was a public meeting of our Food Advisory Committee where we presented our scientific approach to looking at the safety of foods, to that committee, and we used the Flavr Savr tomato as an example of a product produced by modern biotechnology that had been tested by the kinds of methods and approach that we felt were appropriate.

During that committee meeting -- our Food Advisory Committee is a group of experts from outside of FDA that is composed of academic representatives, industry representatives and public interest representatives -- those committee members had an opportunity to look at the approach scientifically that we were recommending to companies, and this product as an example of the kind of testing that would be done under this approach.

The committee members felt that this was an appropriate approach given the characteristics of the product, and many members of the committee, including consumer representatives, suggested to FDA that this product really did not raise substantial food safety issues, and
that if there were to be similar products produced by this
technology, that FDA may need to have a more abbreviated way
to look at these products. We had spent about three years
of very intensive review, looking at all of the data
produced for that particular product. That was a very
useful review for the first product and it helped us in
establishing our policy.

But, we agreed with the committee members that
another approach would be needed for most products. So, we
established what we are now calling our consultation
procedures. These are procedures that are not legally
binding on companies but FDA strongly recommends that
companies follow them in bringing products to market.

We have discussed this approach through this
consultation procedure with our Food Advisory Committee and
our Committee for Veterinary Medicine, and we showed them
seven products that companies had consulted with FDA.
Again, they agreed with us that that seemed to be an
appropriate level of oversight at that time given the nature
of the products that were then coming to market.

[Slide]

There are several principles that I think are
important to keep in mind in thinking about how we approach
looking at the safety of foods. Today in the grocery store,
if you think about the grocery store, meat, poultry and egg
products, of course, are regulated by the Department of
Agriculture but if you visualize yourself walking up and
down the aisles, all of the other products fall under FDA
and those are the fruits and vegetables, the cereals, all
the packaged foods, all the additives that you see on the
label on the ingredient statement of the package. So, there
is a very broad number of foods that fall under our
authority, and it also means that our food supply is very
diverse. Think about the diversity of foods that we have in
our grocery stores today. So, our policy applies to all of
those products.

In asking whether a new product is safe, we ask
whether that product is comparable. Is it similar to its
conventional counterpart? Because the products of modern
biotechnology to date are all derived from common food crops
that have been used in agriculture for many years. So, it
is a process of comparing the new product with the
traditional product. How different is it? How similar is
it? And, are those differences, differences for which
additional testing would be needed?

The approach that we use at FDA for establishing
the safety of food additives is one that we realized would
not work as well for whole foods. Whole foods are complex
mixtures of chemicals. The paradigm that we have for food
additives relies on testing of single chemicals.
So, we had to come up with a different way to look at the safety of foods, and that is a multi-disciplinary approach where we look at many different kinds of scientific information. One of the important pieces of information that is rarely talked about are the considerations that developers do all the time in bringing new varieties to market, looking at their agronomic characteristics and their quality characteristics, and those are very important in determining whether a product can be successfully marketed. Plant breeders have been very successful at avoiding products that FDA would have to remove from the market on the basis of public health.

We also have new tools for safety assessment that are not available through other methods. The tools of molecular biology that are the tools of modern biotechnology also allow the scientist to determine the identity and the function of the substances that are added to foods. This is something that cannot be done by other methods of plant breeding, and so we have a very powerful new tool in not only developing new foods but being able to assess the safety of those products. So, that information, taken along with information that I will show you in a moment, of the composition of the food and assuring that the food is what we expect in terms of its vitamins, its nutrients and other normal components of the food -- this kind of information is
information that we believe generally establishes that the food is as safe as other foods on the market.

There could be circumstances where testing in animals would be warranted but this is not routinely recommended because feeding whole foods to animals can produce very complicated results, and it is very important to design the studies appropriately but generally scientists around the world, including the World Health Organization and the Food and Agriculture Organization, have agreed that this approach is scientifically a sound approach for assessing the safety of foods.

[Slide]

There could be circumstances where we would require testing in addition to what I have just described. For example, if the genetic modification of a crop leads to an unusual protein or a new chemical in the food, or the substance has some similarity to an allergen or a toxin, then additional testing would be required. You may have heard about a potato developed in Europe that contains lectin. Certain lectins are known to be very toxic, and if that potato were presented to FDA we would expect that there would be considerable safety testing that would be required to establish the safety of that product. So, testing is really based on the characteristics of the product on a case by case basis.
I would like to just give you a very broad-brush picture of the kind of issues that breeders take into account for food safety in looking at whether a food can be marketed. This focuses on two aspects. First, of course, there is an intended change in the plant or the food based on the modification that has been made. So, it is important to make sure that if there are new substances that will actually be present in the food that those substances are safe to consume. So, it is important to understand the identity of the substance and its structure and function in the food. That substance should also be assessed, particularly if it is a protein, for whether it would be an allergen. You will hear more about that later this morning.

Of course, it is important that the substance be digestible like other substances in the diet. Dietary exposure is something that is very important in food safety. How much do we eat is the question. Is this something that is a very trivial component of the food, or is it a major component of a food?

Nutrition, of course, is a particularly important issue. If the modification has been done to change the nutritional properties of the food, then an evaluation would have to be done in terms of how would that affect our dietary intake of that nutritional component. Nutrition is
also important in animal feed. Many animals have diets that are primarily one crop and, so, altering the nutrition of that crop could alter the nutritional value for the animal. So, that is an important consideration for the feed that is fed to animals.

We also ask developers to look at whether there have been any unintended or unexpected changes that would be in the food as a result of the change that has been made. All methods of plant breeding are known to result in unintended changes in plants. Plant breeders routinely evaluate a number of agronomic traits to determine whether the plant is performing as it would normally perform.

But in addition to those ways of avoiding unexpected effects, we have asked developers to take some extra steps to minimize or reduce the likelihood that there will be unintended effects that could affect public health. That is done first by ensuring that the genetic material that has been introduced in the plant is introduced in a way that it is stable in the plant; it does not move around in the plant's genome, and that reduces the likelihood of additional unexpected changes.

We also ask developers to do extensive analysis of the food for vitamins, minerals, nutrients and other components of the food that are typical of that food to assure that those components that are important to the food
are present at the levels that are expected. Those levels are known to vary over many conditions of growth. The genetic background of the plant, the environmental conditions under which it is grown, whether it is a year of a lot of rain or it is a year of drought will affect the composition of the food. So, in analyzing these important components in the food it is important to take into account the range that is typical for plants that have been accepted in the commercial market.

[Slide]

I would like to now very quickly give you some examples of the kind of information, using soybean as an example, to show you just a bit of the information that companies are presenting to FDA as they look at these products in terms of food safety.

I have mentioned that agronomic and quality factors are important. Breeders evaluate plants over several generations, in multiple field sites, in different locations. That is to determine whether the plant performs in a manner that is to be expected. I have shown just some examples here. This is plant morphology, flower color, time of flowering, resistance to disease, seed size and quality, percentage composition of oil or protein. These are just a few of the many characteristics that plant breeders typically evaluate for soybeans and bringing a new variety
to market.

[Slide]

Products that have been produced by modern biotechnology are also looked at in terms of the molecular changes that have been made: What genetic material has been introduced? What is new? What are its characteristics? Are there any new proteins that are going to be produced in the food or other substances such as fatty acids or carbohydrates that will be new substances in the food as a result of the change that has been made in the plant? And are those substances safe for consumption? The components of the food in terms of nutrients, anti-nutrients are important in soybeans.

Soybeans also are a food to which some individuals are allergic, and companies are looking at the native allergens in soybeans to be sure that those have not been increased through the genetic change that has been made. Companies are also doing some animal feeding studies with these foods for wholesomeness of the foods before they come to market.

[Slide]

The analyses that are done for typical components of the food are done comparing the new variety, which is called transgenic here, with its parental strain or its appropriate control. What is not shown here is that these
values then are also compared to the range that is typical for that crop for these components. This is showing carbohydrate, fat, protein, fiber analysis -- fiber is very important in looking at whether a feed product is digestible for animals.

[Slide]

Mineral analysis -- minerals are an important component of foods.

[Slide]

Fatty acid analysis for the oils. I am showing here only a few of the fatty acids that are typically analyzed in soybeans. All the data that I am showing you very quickly are composite data that we have derived from the information that has been submitted to us.

[Slide]

The protein quality of the food is very important, and the amino acid profile is an indicator of the quality of that protein.

[Slide]

Soybean has a number of substances that are considered to be anti-nutrients, and developers are also analyzing those substances to be sure they are in the levels that have been accepted as safe.

[Slide]

At this point in time, we have about a little over
40 crops for which developers have completed food safety discussions with FDA. There are ten crops at this time for which we have completed consultations. This is sugar beet, canola, corn -- corn is the largest; there are 12 varieties, cotton, potato, soybean, flax, radicchio, squash and tomato. Those are the crops that have been modified by modern biotechnology and companies have completed food safety discussions with the agency at this point.

As you can see, at this time there is a relatively limited number of food crops that have been developed by this technology. There also is a limited number of traits that have been introduced into these crops in terms of improvements in the crops. These are for herbicide tolerance, insect resistance, viral resistance that provides resistance to common diseases in agriculture. There are tomatoes that have improved ripening, and there are a number of vegetable oils that have been developed. For example, there are two vegetable oils that are different from their traditional counterparts. There is a vegetable oil called high oleic soybean oil, which is a soybean oil that is very different from traditional soybean oil. It has a very elevated level of a fatty acid called oleic acid, and that oil can be used as a high temperature frying oil, whereas soybean oil cannot typically be used as a high temperature frying oil without prior processing of the oil.
I would also like to give you a sense of the time that developers work with the agency before these products come to market. On your left, it says pre-submission. This is the time that companies discuss the kinds of testing that they will do on foods developed from plants through modern biotechnology. This is 15 to 20 months. These are also just examples. I have selected seven consultations at random just to give you a sense of what is typical. It is about a year to two years that companies discuss with FDA the kinds of tests that they will do, and the results of those tests.

This side is post-submission. Post-submission is the time when developers submit to us a summary of the safety and nutritional data that they have developed. That is when they are really saying to FDA, "we feel we have done all the testing that is appropriate and necessary to meet all the provisions of the Food, Drug and Cosmetic Act." FDA then looks at this information to determine whether there is any reason why we would take action against this product if it went to market. In other words, does it contain an unapproved food additive? Will it be mislabeled? Is its nutrient profile something that would not be acceptable in the food? Is there a new allergen in the food? These are the kinds of questions that we are looking at. On the
average, it takes about five months for us to complete that process.

You can see in the yellow boxes that there are some that are very short. There are a number of products which may be the second or third generation of a product where both FDA and the company are very familiar with the kinds of testing that would be needed for that product, and so the consultation process is also very much more abbreviated.

But, I think what is important is that companies do come in a considerable period of time ahead of when they want to market the product. That is very important. Our policy has always been that our door is open, and we encourage companies to come early and often, particularly when a product is a new product that we are not familiar with.

[Slide]

I would just like to close by reminding you of the standard of food safety. Foods developed through the methods of modern biotechnology must be as safe as other foods on the market. That means that the food must not only be safe and wholesome; any substances that are added to the food must either be food additives that have been approved by FDA and regulated by FDA, or they must be generally recognized as safe. There may be pesticides that are
regulated and approved by EPA. But this is the standard that we hold these foods to. We will not accept a lower standard for any new food.

Thank you for your attention.

[Applause]

MR. LEVITT: Thank you very much. We will be making copies of those slides you have seen up there publicly available on the web page and you can be looking for those also.

Let me now take the opportunity to welcome to the stage -- and maybe somebody is going to show you the easiest way to get here -- our first panel. I will introduce you after you are up here as you move to our first panel discussion. It is a little tight up here but we will get to know each other very well today.

Scientific, Safety, and Regulatory Issues

Introduction

MR. LEVITT: Thank you. It is now time to begin the discussion of our first panel on the scientific, safety, and regulatory issues. In terms of logistics, I will ask each panel member to give brief opening remarks, about five minutes worth. These remarks will be followed by discussion among the panel members and questions from the FDA panel.

Let me first review the three questions that we have asked our panelists to address to help us evaluate our
current policy. These were printed in the Federal Register and are in your packets.

The first question reads, has FDA’s consultation process Dr. Maryanski described achieved its intended purpose? Based on experience to date, should this regulatory approach "sunset," should it continue in its current state, should it be made mandatory, or otherwise be revised? So, how should we deal with the consultation process?

Number two says, what newly-emerging scientific information related to the safety of foods derived from bioengineered plants is there, if any? Are there specific tests which, if conducted on such foods, would provide increased assurance of safety for man or animals consuming these foods? So, that is really focused on the kind of testing that is done.

Three, what types of food products derived from bioengineered plants are planned for the future? Will these foods raise food safety issues that would require different approaches to safety testing and agency oversight? If so, what are those approaches? So, for that we ask you to look into your crystal balls and tell us what is coming down the pike.

I am pleased to introduce the members of the first panel. You have in your packets additional biographical
information. If I mispronounce anybody’s name, please
correct me. You ought to have your name spoken correctly.

First is Dr. Peter Day. He is the Director for Agricultural
Molecular Biology at Rutgers University.

Next to him is Miss Carol Tucker Foreman. She is
a Distinguished Fellow and Director of Food Policy Institute
at the Consumer Federation of America.

Next is Dr. Rebecca Goldburg. She is a Senior
Scientist and Manager of the Biotechnology Program at the
Environmental Defense Fund.

Next is Mr. Steven Druker, who is the founder and
Executive Director of the Alliance for Bio Integrity.

Next to him is Dr. Samuel Lehrer, who is Research
Professor of Medicine, Adjunct Professor of Microbiology and
Immunology, and Adjunct Professor of Environmental Medicine
with Tulane University Medical.

Finally, we have Dr. Terry Etherton, who is
Department Head and Distinguished Professor of Animal
Nutrition, College of Agricultural Sciences, Department of
Dairy and Animal Sciences at Penn. State University.

We will go straight to the first panelist, and
again ask if you could try to keep your remarks to about
five minutes, and then we will come back for follow-up
questions. Let’s just start then with Dr. Day.

Panel Discussion
DR. DAY: Thank you, Mr. Chairman. First of all, I would like to congratulate Dr. Maryanski on an elegant and complete introduction. While he was talking I almost thought he was a plant breeder.

Let me just make a few comments about the science. I will try to address the FDA's questions in the course of my comments. First of all, my own position is that the revolution that we are experiencing in the development of new varieties of crop plants is a continuation of a process that began hundreds or thousands of years ago.

We have established a tradition, I think, since Asilomar in 1976, of being concerned about what we are seen to be doing in our laboratory and experimental fields. The NIH guidelines were established. The NIH established a risk assessment research program and, as a result of these activities, we became more and more at ease with what were perceived as risks, sincere risks, 20 to 25 years ago.

The process that the FDA has established, together with the other federal agencies, I think is working very well. I believe that the regulatory approach that is in position works satisfactorily. While I think it could continue in its current state, I think that it needs to be flexible to take account of new situations as they arise.

Now, as I see it, the scientific risks fall into two categories. First of all, the risks to food and the
question of food safety arises, and the FDA, like the other federal agencies, has chosen to focus on the product rather than the process by which it is produced. I think this is sound, and I know of no information that suggests that the process itself is dangerous. The product is what we should focus on. I think because the technology enables us to do things that are new and different we need to continue to focus on the product and to ensure that it is safe.

The second area of concern, which is attracting a lot of attention, is the potential impact of biotechnology on the environment. Now, agriculture has a profound effect on the environment. I don't think any of us would dispute that. I see that biotechnology will have a much less severe effect than agriculture itself. No doubt, during the course of the morning we will be discussing specific instances but let me give you one instance, and that is BT corn -- well, two, I would also like to refer to the herbicide resistant soybeans.

In BT corn one has relieved the farmer of applying conventional pesticides and the untargeted effects that they have. The BT corn also has the advantage of reducing the incidence of mycotoxins in damaged ears fed to animals.

The herbicide resistant soybean has replaced, by using one herbicide, five or six different herbicides that are conventionally used to control weeds in soybean crops.
We can't go back to hoeing. While there are cultural methods that will limit weed development, herbicides are a cheap and effective method of weed control that also have other benefits as far as the soil structure and the question of the number of tillage operations that are applied to fields -- we can economize in fuel.

Are there new things that are ahead? Yes. There is some concern over the horizontal spread of introduced genes and their impact on natural populations of plants. That horizontal spread has been a feature of conventional agriculture, of course. Many weeds in agricultural areas are associated with crops. For example, in Europe the introduction of canola and the spread of the seeds alongside roads has meant that canola has become quite a common weed.

Now, one interesting new technology is the introduction of transgenes into chloroplasts. Chloroplasts are not transmitted in pollen, and some colleagues of mine at Rutgers have developed a method of introducing transgenes into chloroplasts, thereby limiting the spread of transgenes through pollen.

The third FDA question asks what types of food products derived from bioengineered plants are planned for the future. I think what we have seen at the moment has had, unfortunately, rather little impact on the consumer since herbicide resistance and insect resistance don't
really affect the product in the market in terms of its appeal to the consumer. There are a number of new things that are being developed that are more difficult to manage and that I think will be very impressive.

We must also remember that biotechnology doesn't just contribute through the introduction of new genes. There are other technologies that involve, for example, marker-assisted selection and technologies that are based on the growing understanding of the construction of plant and animal genomes that enable plant and animal breeders to work with even greater precision than they do now.

But perhaps what is most important is the potential that biotechnology has for the developing world, and I am thinking of examples like golden rice which has an increased content of vitamin A and an increased iron content, and crops like wheat which has been engineered to grow on aluminum toxic soils which limit production in many parts of the developing world.

I don't think we can afford to ignore and to set aside the potential of this tool to do some remarkably important things to safeguard the world's food supply.

Thank you, Chairman.

MR. LEVITT: Thank you very much. We will just proceed right down the row. Carol Tucker Foreman?

MS. FOREMAN: Thank you very much for conducting
these public hearings on foods derived from bioengineered plants, and for the opportunity to appear on this panel.

Consumer Federation of America is a non-profit association of 260 pro-consumer groups which seeks to advance consumer interests through advocacy and education. Our members include state and local consumer organizations, senior citizens groups, consumer cooperatives and trade unions.

In the past few months, Americans have become increasingly aware of, and increasingly concerned about genetically engineered foods. The concern seems to be driven by a number of factors -- a sudden realization that by next year almost half of the corn, soybeans and cotton planted in the U.S. are likely to be transgenic crops; the vociferous rejection of these products by European consumers; the ongoing debate over the potential for environmental damage and economic concentration resulting from the rapid growth of genetically engineered foods; the utter absence of any direct consumer benefit in any of the products now on the market or anywhere close to being on the market; and, most importantly, the potential for some human health risk arising from the consumption of genetically engineered foods.

The concern about genetically engineered food is in marked contrast to the public's acceptance of genetically
engineered drugs. When faced with serious illness, most of us are willing to take some risks to combat the disease but food is different. Food is special. We eat to sustain life and health. Since food is so basic to us both physically and emotionally, it is really not surprising that consumers are extremely averse to any food-related risk, especially if that risk is perceived as imposed by someone else beyond our individual control and without any countervailing benefit. In short, we eat because it is good for us, not because it benefits those who grow, process or sell food.

Industry and, to a certain extent, the government argue that decisions about the approvals of genetically engineered foods should be based solely on what is described as sound science. Industry and government insist that sound science says GE foods are safe and for many that is dispositive. Consumers aren’t so sure. Good data and sound science are vital elements of good public policy but they aren’t the only consideration. In science there aren’t any final answers. Data are never complete; they are always evolving. The soul of the scientific process is challenge and revision as new data become available. Three years ago sound science told the Food and Drug Administration that it should approve the diet drug fen-fen, and last year’s sound science told the Food and Drug Administration that it was best to withdraw that drug from the market.
Food safety policy should be based on the best data and the best science but, in the end, the policy represents a choice among competing interests and values. Policy makers must balance industry’s desire to bring new products to market and the farmer’s desire to increase yield against the public’s concern about safety.

Public confidence in genetically engineered foods has been eroded by the sense that government has been too sensitive to the needs of industry. We all have to live with the impact of the circumstances governing the original policy on genetically engineered foods. On May 27, 1992 The New York Times reported that Vice President Quayle announced details of a new government policy for streamlining regulation of these foods. Mr. Quayle, according to The Times, told a briefing of industry executives that the policy was part of the Bush administration’s regulatory relief program, and said the U.S. was the world leader in biotechnology and we want to keep it that way.

It is really very difficult to persuade the public, after an introduction like that, that the government’s primary interest is food safety. During Food and Drug Administration’s consideration of an appropriate regulatory structure for GE foods, officials of the agency were extremely aware of the fact that if they required a prior approval of all of these new products it would suck up...
every bit of the agency’s resources and there would be very little to apply to others. FDA now asks the public for its views on the process, and the answer is the process began under a cloud of political influence and managerial bean counting, and FDA has not dispelled that cloud.

I believe that food biotechnology has enormous potential benefits to the world. They are benefits I would like to see realized, but there are none of those benefits to civil society at this point. FDA’s present challenge is to develop a regulatory process that will assure public confidence.

I have some suggestions for it. The government, beginning with the President, should make a clear statement that human safety is the first, second and third most important point in determining whether to approve GE foods, and that the government will assign sufficient resources to do the work required.

Second, FDA should require submission for review and formal approval of all genetically engineered products prior to marketing. Last week, Dr. Michael Jacobson, of the Center for Science and the Public Interest, laid out examples of how the agency might require varying amounts of information depending on the specifics of the products.

Third, consumers must have, and will have, a role in this debate. I propose that the agency create a special
advisory committee on biotech engineered foods. The
committee could help the agency shape the necessary
questions and policy. I am a member of the Department of
Agriculture’s Meat and Poultry Inspection Advisory Committee
which has worked exceptionally well over the past several
years to help that agency shape policy and keep it
transparent.

In a field as new as this one, it may be useful to
establish an independent quasi-governmental research
institution that could raise key regulatory issues and
sponsor research into them. The Health Effects Institute,
which deals with clean air issues and is funded by
government and industry, I think is an excellent model to
look at.

I have gone over my time so I want to just briefly
address labeling. The agency has asked another panel to
discuss that. Two quick points, labeling is not a
substitute for assurance of safety. No food should be
approved unless it is safe. The strong mandatory pre-
approval process that I have suggested should eliminate the
concerns of industry that people would assume a labeled
product is less safe than its traditional counterpart. But
for consumers, access to adequate information to make a
rational decision in the marketplace is absolutely
essential, and I am confident that the public will be more
comfortable with this technology and more prepared to see it move forward if it has the assurance of some premarket review and approval and if the products are labeled. Thank you.

MR. LEVITT: Thank you. Next is Dr. Rebecca Goldburg, Environmental Defense Fund.

DR. GOLDBURG: I would like to begin by thanking the FDA for inviting me to speak today, and before I begin my remarks concerning FDA policy, I want to note that it is unfortunate that the FDA has scheduled this public hearing during the World Trade Ministerial meeting, in Seattle, because as a result a number of public interest representatives who might otherwise be at this hearing are now in Seattle.

Well, to move on, in my brief remarks today I will first comment on food safety and then on FDA regulation of foods derived from genetically engineered crop plants, which I will refer to as genetically engineered foods.

To most consumers, genetically engineered foods are essentially foods with added substances, usually proteins. As Jim Maryanski explained, this is because genes code for proteins. In most cases, these added proteins will likely prove safe for human consumption. Nevertheless, just as with conventional food additives, substances added to foods by genetic engineering may in some instances prove...
hazardous.

One concern about adding proteins to foods via genetic engineering is that they may cause susceptible individuals to become allergic to foods that they previously could safely consume. Food allergies are a serious public health concern, affecting roughly two and a half to five million Americans. Allergic reactions cause discomfort and in some cases can cause life-threatening anaphylactic shock. Since known food allergens are proteins, foods with new proteins added via genetic engineering could sometimes become newly allergenic. This concern is real. One company has already dropped plans to commercialize soybeans with a Brazil nut gene after testing revealed the soybeans were likely to cause allergic reactions in Brazil nut allergic individuals.

Unfortunately, there is currently no predictive methodology for testing the allergenicity of most proteins introduced to foods via genetic engineering. Testing is only possible for proteins from commonly allergenic foods, such as nuts. Proteins from commonly allergenic foods can be screened for so-called antibody-antigen reactions using blood serum available from individuals with common food allergies. However, for most proteins, including those from foods that are not commonly allergenic and those from non-food sources such as bacteria, no such testing is possible.
In other words, most proteins added to foods via genetic engineering cannot be tested for allergenicity. Instead, industry scientists simply screen the biochemical characteristics of proteins to see if they are consistent with the characteristics associated with allergens. It remains to be seen how effective such screening will be in protecting the public health.

Extremely troubling to me, FDA regulators have failed to assume a leadership role in addressing the potentially serious food safety risks from allergens added to foods via genetic engineering. Consider the following three points:

First, although FDA co-sponsored a scientific meeting on food allergy in 1994, the agency has not used its scientific resources to develop and publish guidance to industry on how to assess the allergenic potential of proteins. FDA should develop such guidance. Given the existing uncertainties about assessment of potential allergens, guidance would both be helpful to industry and reassuring to consumers.

Second, FDA’s current policy concerning labeling of genetically engineered foods may not adequately protect public health. FDA at the moment does not generally require labeling of genetically engineered foods, although the agency will require labeling if there is evidence that a
substance added to a food is allergenic. However, should an allergen added to a genetically engineered food not be detected by industry's current screening procedures, allergic consumers will likely not be able to avoid foods containing the allergen.

EDF urges that FDA reconsider its policy for labeling of genetically engineered foods, not only as a matter of public information, the topic of the next panel, but also potentially to help some consumers avoid exposure.

The third point is that FDA does not appear to be taking significant steps to sufficiently improve the scientific understanding of food allergens to develop predictive tests for allergenicity. FDA should assume a leadership role in funding and advocating support for scientific research that may result in the development of predictive testing methodology for food allergens.

I would now like to turn to FDA's policy for regulation of genetically engineered foods, which appears to do more to protect the biotechnology industry than to protect consumers. As I stated earlier, most genetically engineered foods are essentially foods with added substances, at this point usually proteins. FDA's policy gives manufacturers who use genetic engineering to add substances to food considerably more discretion than manufacturers who use other technologies to add substances.
to food.

Under the Federal Food, Drug and Cosmetic Act and FDA’s current regulations, a food is adulterated if it contains an added substance unless either, (a) FDA has approved the safety of the substance by issuing a food additive regulation or, (b) the substance is what is called generally recognized as safe.

The upshot is that FDA requires that manufacturers have scientific evidence to support the safety of substances traditionally added to foods or in food processing, for example, sweeteners or thickeners.

In contrast, under FDA’s 1992 policy, the agency will only require food additive petitions for substances added to foods via genetic engineering, and I quote, in cases where questions exist sufficient to warrant formal premarket review. In other words, FDA will only require data substantiating the safety of genetically engineered foods when there is already reason to believe that the foods might be hazardous.

Thus, FDA’s 1992 policy appears to significantly weaken the long-standing requirement under food safety law that food manufacturers must establish scientifically the safety of new substances added to food before selling them to the public, regardless of whether the manufacturers think they are safe. In other words, FDA’s policy strongly favors
food manufacturers at the expense of consumer protection.

In response to the considerable public outcry that
followed the publication of FDA's policy in 1992, the agency
now recommends that manufacturers voluntarily consult with
the agency before bringing genetically engineered foods to
market. However, because these consultations are outside
the regulatory system, they are not subject to public
scrutiny and are not a satisfactory substitute for a
regulatory program.

The Environmental Defense Fund urges that FDA
revise its 1992 policy to be more protective of consumers.
In particular, we urge that FDA draft a new policy that
would do the following two things:

First, subject substances added to food via
genetic engineering to the same regulatory requirements as
substances added to foods via more traditional means. FDA
should squarely place the burden on industry to substantiate
scientifically the safety of substances added to foods via
genetic engineering.

Second, FDA should require manufacturers to
consult with FDA before bringing genetically engineered
foods to market. FDA does not now require such mandatory
consultations for foods altered by more traditional means.
However, at least for the near future, while genetically
engineered foods are new and their potential hazards are not
fully understood, it behooves FDA to require such
consultations. Thank you very much.

MR. LEVITT: Thank you. Next we have Mr. Steven
Druker, Alliance for Bio-Integrity.

MR. DRUKER: Thank you. I am very pleased to be
here today, and I commend Commissioner Henney and Mr. Levitt
for holding these meetings. I must say that I am still
somewhat surprised to be here because I am one of the
strongest critics of the FDA's current policy on
bioengineered foods, and I have coordinated a major lawsuit
to change it, a lawsuit which is currently pending in U.S.
District Court. The fact that I am here suggests that the
agency truly is open to hearing from all sides and,
hopefully, it suggests that the agency is also open to
change and that is very good because current FDA policy does
require changing.

Although it claims to be science based, numerous
experts criticize it as scientifically flawed, and nine of
these experts are so concerned that the policy is
scientifically unsound and morally irresponsible that they
have taken the unprecedented step of joining as plaintiffs
in the lawsuit that my organization is spearheading to
compel the FDA to institute mandatory rigorous safety
testing of all genetically engineered foods.

These scientist-plaintiffs are eminent, and their
concerns deserve close attention. They include a professor of molecular and cell biology at the University of California, Berkeley, a respected molecular biologist at the State University of New York, and the associate director of targeted mutagenics at Northwestern University Medical School. This latter scientist routinely employs genetic engineering in the medical field, but he is deeply troubled at the extent to which it is being used in food production without adequate safeguards. Also included in our plaintiff group is Prof. Philip Regal, an internationally renowned plant biologist at the University of Minnesota. Dr. Regal has stated, in a sworn declaration to the court, quote, there are scientifically justified concerns about the safety of genetically engineered foods and some of them could be quite dangerous, unquote.

Why do these nine plaintiffs and so many other scientists regard FDA policy as unsound? They think the agency is disregarding the well-recognized potential for recombinant DNA techniques to produce unexpected toxins and carcinogens in a different manner and to a different degree than do conventional methods.

Unfortunately, the FDA's official position ignores this heightened potential for the unknown, for unpredictable negative side effects. Instead, the agency focuses almost exclusively on the factors that are known and are
predictable -- the transferred genetic material and the substances it is known to produce. In effect, it is evaluating each transgenic substance as if it were an ingredient mixed into a preexisting food rather than as a factor that can cause unpredictable deleterious changes in the developmental process of a food organism. As one of our plaintiffs, the respected molecular biologist Prof. Liebe Cavalieri has stated, such an approach is "simplistic if not simple minded."

Although the FDA’s official statements ignore these unpredictable kinds of negative effects of genetic engineering, its own scientists are well aware of them. This came to light when the FDA had to give us copies of its files during the course of the lawsuit. You know, the agency is asking us to bring forth to them any newly emerging scientific evidence. Well, this evidence that I am about to share with you is not new, but it is newly emerging and it is unfortunate it took a lawsuit to pry it out of the government’s own files.

I will only be able to give you a brief summary, a brief taste of some of the memoranda that are from the FDA’s own scientists, in their own files. FDA microbiologist, for instance, Dr. Louis Pribyl stated: "There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering." He added
that several aspects of gene splicing "may be more hazardous."

Similarly, Dr. E.J. Matthews of the FDA’s Toxicology Group warned "genetically modified plants could ... contain unexpected high concentrations of plant toxicants," and he cautioned that some of these toxicants could be unexpected and could "be uniquely different chemicals that are usually expressed in unrelated plants."

Also, the head of the FDA’s Center for Veterinary Medicine wrote in a memorandum to Dr. Maryanski, "CVM" -- that is the Center for Veterinary Medicine -- "believes that animal foods derived from genetically modified plants present unique animal and food safety concerns."

Also, Mitchell J. Smith, who was head of Biological and Organic Chemistry Section at the Center for Disease Control and the Center for Science and Nutritional Safety at FDA, wrote in a letter to Dr. Maryanski that the agency’s proposed policy on genetic engineering turns FDA’s prior practice on its head.

The numerous in-house critiques of the agency’s proposed policy are best summed up by Dr. Linda Kahl, an FDA compliance officer, who protested that the agency was "trying to fit a square peg into a round hole by trying to force an ultimate conclusion that there is no difference between foods modified by genetic engineering and foods..."
modified by traditional breeding practices." She declared, "the processes of genetic engineering and traditional breeding are different and, according to the technical experts in the agency, they lead to different risks."

It is important to note that was not Dr. Kahl expressing her own opinion. She was carefully summarizing the many memoranda from the technical experts that are in the file, and that is a fair summary.

In light of the unique risks, FDA scientists advised that genetically engineered foods should undergo special testing. The Division of Food Chemistry and Technology cautioned, "some undesirable effects such as appearance of new, not previously identified toxicants may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes. This Division, as well as many other FDA experts, recommended that such tests had to include rigorous toxicological testing.

Not only was the agency aware of uncertainties within its own ranks, it also knew there was considerable disagreement about the safety of genetically engineered foods in the scientific community at large. For instance, FDA biotechnology coordinator, Dr. James Maryanski, acknowledged in a letter to a Canadian health official, on October 23, 1991, that there was not a scientific consensus
about safety. He also admitted, "I think the question of the potential for some substances to cause allergenic reactions is particularly difficult to predict."

Nonetheless, the FDA not only disregarded the warnings of many of its own scientists about the unique risks of gene-spliced foods, it covered them up and it has taken a public position that is quite opposite. It's official policy statement declares: "The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way."

Now, I invite the members of this audience to consider the sampling of statements from FDA's own scientists I just shared with you and then to consult our web site, www.biointegrity.org, where we have posted the original versions of these documents, photocopies, along with many other such memoranda, and you consider in your own minds whether you can accept the FDA's claim that it has no information about meaningful differences -- if you can accept that as a good faith attempt to represent reality or whether, instead, it appears to you as a ploy calculated to deceive the public and evade the law.

So, a strong case can be made that FDA policy violates sound science and, therefore, a strong case can be made that it does violate the law, the U.S. Food, Drug and
Cosmetic Act. In this statute, Congress instituted the precautionary principle and definitively decreed that no new substance shall be added to our food unless that substance has been demonstrated to be safe through standard scientific testing.

While the FDA agrees that the foreign genes that get inserted into a plant, along with the substances it produces, are in principle food additives, it maintains they are exempt from regulation because they fall into the exception for substances that are generally recognized as safe, or GRAS. However, as already noted, FDA records indicate such manipulations are not even recognized as safe among the agency's own scientists, let alone by a consensus in the scientific community.

Second, the law is explicit that any recognition of safety must be based on "scientific procedures," and both the FDA and the courts have heretofore consistently interpreted "scientific procedures" as referring to studies published in peer-reviewed literature. Moreover, the FDA's own regulations emphasize that the tests supporting a general recognition of safety "require the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive." This means, in the FDA's own words, that the tests must demonstrate "a reasonable certainty that the substance is not harmful under
its intended conditions of use." Yet, neither the FDA's records nor the scientific literature indicate that such a test exists for even one genetically engineered food.

In fact, the main test that attempted to demonstrate the safety of a bioengineered food through standard toxicology tests failed to do so. That food was the Flavr Savr tomato, the first genetically engineered organism that the FDA reviewed. In commenting on those tests, Dr. Robert J. Scheuplein, director of the FDA's Office of Special Research Skills, stated that the tests raised by failed to resolve a safety issue. He wrote, "the data fall short of a demonstration of safety or of a demonstration of reasonable certainty of no harm which is the standard we typically apply to food additives. To do that we would need, in my opinion, a study that resolves the safety questions raised by the current data." Yet, the FDA approved that product anyway on the grounds it was generally recognized as safe, even though the law requires such recognition to be based on precisely the kind of test that had failed to demonstrate safety. Interestingly, FDA officials claimed that the Flavr Savr passed muster so well that the rigor of its testing will not have to be repeated for other bioengineered foods.

So, although the generally recognized as safe exemption was intended to permit marketing of substances
whose safety has already been demonstrated through sound
testing, the FDA is now using it to circumvent testing and
to approve substances based on inferences drawn from less
rigorous forms of analysis -- inferences that are dubious in
the eyes of several of its own as well as many other
experts.

Moreover, it is very important to make clear that
although government officials repeatedly boast that no
genetically engineered food has ever caused any harm to
human beings, once such food did kill dozens of Americans
and permanently disabled over 1500 others. That was a
genetically engineered food supplement of the amino acid L-
tryptophan. It caused those deaths in the late 1980s. By
the way, only that batch of genetically engineered L-
tryptophan caused that problem. It was later found that
those batches contained some very highly toxic contaminants
at very low levels. They escaped standard pharmacological
testing. The pharmacologic analytic tests showed those
supplements to be pure but they killed people and they
permanently destroyed the lives of over 1500 others.

On July 18, 1991, Douglas L. Archer, then the
Deputy Director of FDA's Center for Food Safety and Applied
Nutrition, was invited to testify before Congress on this
tragedy. In his written remarks he did not once mention the
word genetic engineering or indicate that the L-tryptophan
supplement in question had been genetically engineered. Rather, he blamed the problem on food supplements in general.

Yet, just a few months after his testimony, on September 27, 1991, Dr. James Maryanski, responding to questions from the Government Accounting Office doing an independent study of that tragedy, admitted his own memo in the record, "I said that we have no new information, that we do not yet know the cause of EMS" -- that was the specific ailment that killed the people -- "nor can we rule out the engineering of the organism." It couldn't be ruled out then. The process of genetic engineering was questionable and dubious then and it remains dubious, and many eminent scientists believe that genetic engineering itself is still the most probable cause for those deaths and disabilities.

MR. LEVITT: Excuse me, Mr. Druker, in fairness to the other panelists, if we could try to wrap up --

MR. DRUKER: Okay, I will wrap up --

MR. LEVITT: -- and we will have additional time for questions.

MR. DRUKER: I am sorry, but this information is very important and has not been brought to light, and it should have been by now. I am sorry, I will wrap up.

The FDA says it is now in a listening mode. If its ears are truly opened, then its conscience should have
been touched. You know, we are not involved in some
abstract academic debate. What is at stake is the safety of
the nation’s and ultimately the world’s food supply. All
relevant evidence has to be considered, and the FDA claims
that its processes are transparent and clear and, yet, all
of this evidence I have just brought forth has been
obfuscated, at best, by the agency.

Mr. Levitt and Commissioner Henney, when you hear
my remarks I really implore you to consider very carefully
whether the agency’s current policy is scientifically sound;
whether it is in line with the precautionary principles
mandated by U.S. law; whether it really serves the public
or, as Dr. Goldburg and others have said, better serves the
interests of the biotechnology industry.

If, God forbid -- if genetically engineered foods
do kill and cripple again, those that continue to make
statements that are dubious will have it on their own
conscience. It is time for change. Thank you very much.

[Applause]

MR. LEVITT: Thank you, Mr. Druker. Again, as
with any of the speakers today, if people have additional
written information they would like to submit to the docket
to be sure it gets in the record, we, by all means, are
happy to accept that and, again, we will have additional
time for questioning after all the speakers are done.
Next, we have Dr. Samuel Lehrer of Tulane University Medical Center.

DR. LEHRER: Thank you very much.

[Slide]

My task this morning is to address the issue of genetically modified foods with regard to allergenicity. In particular, I would like to consider the safety assessment of these foods in a very short period of time so that you understand what the process is and address the issues of are we doing enough; is there more that we can do?

[Slide]

First we just need to consider food allergy. Allergies occur in about one to two percent of the adult population and four to six percent of the pediatric population. Almost all food allergies are due to eight foods or food groups.

Symptoms of food allergy can be highly variable, and most food allergies are IgE-mediated immunological reactions, and this is very important because this distinguishes true food allergies from other food intolerances which have a metabolic or toxic basis.

[Slide]

Food allergens generally are proteins, but it is important to remember that not all proteins are food allergens. Generally, plants contain tens of thousands of
proteins, yet, very few of these proteins are allergenic. Most allergens are stable for digestion and processing, and major allergens tend to be abundant proteins within a food. They are in a food in high concentrations. Many food allergens have been cloned and characterized.

[Slide]

Now, when we consider biotechnology's use in terms of improving food supply, as Dr. Day indicated, this has been around literally for thousands of years. But what distinguishes the old biotechnology from the new biotechnology is genetic engineering, and genetic engineering, as some have already said, is a method that facilitates the identification and selection and transfer of genes in coding of a specific protein into the genome of another organism. This method precisely determines which proteins are introduced into the organism and where they are expressed.

Now, most proteins that are introduced into crops are not stable to digestion or processing, and most applications require only minute amounts of new protein or even no protein at all to have the desired effect. So, these last two points, if you remember what I said in the previous slide about allergens, suggest that the likelihood of these proteins being allergenic is minimal.

Interestingly, biotechnology is even being used to
reduce the allergenicity of some foods. For example, a
group in Japan is producing hypoallergenic rice, and I
believe that several groups are attempting to do this with
other crops in the United States.

[Slide]

When we consider the concerns about genetically
modified crops we first need to identify the risks. What
are they? How can these risks be assessed, and how can they
be minimized? This assessment must be based on accepted
scientific principles. This is very important and this is
something the other panelists have said already. Also, the
criteria should be the same as that used for other foods.
Finally, we need to consider how these risks relate to the
benefits provided by the genetically modified food.

[Slide]

To address these issues, as Dr. Goldburg
mentioned, the FDA, EPA and USDA sponsored a conference in
1994 on the scientific issues related to the potential
allergenicity of transgenic food crops, and this was one of
the first meetings to address this issue and discuss some of
the concerns involved.

In 1995, there was a series of meetings on the
allergenicity of genetically modified foods sponsored by the
Allergy and Immunology Institute and the International Food
Biotechnology Council, in Washington, D.C. These meetings
resulted in the publication of a monologue and critical reviews in *Food Science and Nutrition*, in 1996. This monologue addressed allergenicity in general of foods and, in particular, genetically modified foods, and proposed a decision process in which we can address these issues.

This decision tree was based on utilizing immunochemical procedures for testing for allergens, as well as comparing the physical chemical properties of the introduced proteins to known allergens, and this is utilizing the most current technology available. Actually, in response to some of the issues that Dr. Goldburg raised, I might mention that most of the foods that we eat today could not pass this process.

[Slide]

I just would like to review briefly application of this decision process. Dr. Goldburg already mentioned the Brazil nut protein that was expressed in soybean during and it was later shown that this was actually a major Brazil nut allergen. Contrary to what she was saying, to me, this is an example of how the system works because we were able to identify the product; development was stopped and the product was never marketed, in spite of the fact that it was being developed as an animal feed.

[Slide]

So, in conclusion, I believe that the probability
of an introduced protein, that it will be allergenic, is extremely low. There are definitive methods to detect the transfer of known allergens and measure changes in native autologous allergens.

Through the combination of genetic and physical chemical criteria, I believe that it provides assurance that proteins from sources with no allergenic history will not pose significant concerns about allergenicity.

Now, I also want to add, as Dr. Goldburg mentioned, that although we are basing all of these assessments on the available technology, technology can be improved and I think that we should be directing more efforts in terms of developing better models in which we can better assess the allergenicity of new foods being developed by these new technologies. But, based on the current technology, I believe that we are doing everything possible to identify the allergenicity. Thank you.

MR. LEVITT: Thank you very much, and our final presentation will be from Dr. Terry Etherton.

DR. ETHERTON: Thank you, Mr. Levitt. Mr. Levitt, members of the Food and Drug Administration and listening panel, thank you for giving the Federation of Animal Sciences Societies the opportunity to provide comments today on the scientific and safety issues of livestock feeds derived from plants developed using biotechnology.
numerous feeds by livestock, including digestion and absorption of nutrients for milk production and growth.

The Federation of Animal Sciences Societies, or FASS, is a professional organization made up of approximately 10,000 scientists in academia, government and industry which exists to serve society through the improvement of all aspects of food animal product. FASS represents the combined membership of the American Dairy Science Association, the American Society of Animal Science and the Poultry Science Association.

As requested, Mr. Levitt, we will comment on newly emerging scientific information related to the safety of feeds derived from genetically modified crops. It has been estimated that the supply of food required to adequately meet human nutritional needs over the next 40 years in the global village is quantitatively equal to the amount of food previously produced throughout the entire history of humankind. This poses a daunting challenge to the global village for several reasons. First, virtually all land suitable for farming worldwide is being farmed. Secondly,
destruction of tropical rain forest or wildlife habitat is not a viable option for environmental considerations.

Thus, the only feasible solution is to develop new technologies that enhance food product efficiency. Genetic modification of crops for our livestock has been conducted for many years. Plants to supply feeds for livestock have been improved over the years because new plant varieties were developed using conventional techniques of plant breeding and genetic selection.

Crops to supply feed for livestock produce through modern methods of biotechnology are emerging from research and development to the marketplace. Crops developed using modern methods of biotechnology are referred to as genetically modified crops as opposed to crops using conventional plant breeding. Both conventional and biotechnology techniques have benefited agriculture.

Corn grain, whole plant chopped corn and soybeans from the currently genetically modified crops have been fed to livestock and compared with conventional feeds to determine the effects on feed consumption, digestibility and animal responses. Chickens, sheep, beef cattle and dairy cattle have been used in this research.

These data indicate that the chemical composition of the genetically modified and conventional feeds are substantially equivalent, and are well within the normal
range of values reported in the scientific literature. These data indicate that feed consumed, digestibility of feeds, nutrient absorption, growth, milk production, milk composition and health of livestock fed genetically modified and conventional feeds were equivalent.

The digestive process in all livestock breaks down the nutritional components in feeds, including protein and amino acids and DNA and nucleic acids. Because the nutrients in these feeds are broken into smaller components, the plant proteins have not been detected in milk and the plant proteins would not be expected in meat and eggs. These data, and our understanding of nutrient digestion, absorption and metabolism indicate that these genetically modified feeds are safe for livestock to consume. In addition, the food products of livestock consuming these feeds are safe for human consumption, and will be of benefit to the nutrition and well being of the world’s population, especially children in developing countries.

In conclusion, FASS strongly recommends that science be the basis for acceptance of genetically modified feeds for livestock. FASS endorses the use of biotechnology techniques to improve agricultural plants and animal products. FASS also believes that agricultural biotechnology has the capability to improve the supply of livestock feeds and healthful animal and plant food products.
and, thereby, help to meet the nutritional needs of the growing world's population.

In closing, Mr. Levitt, I thank you for the opportunity to provide this testimony. FASS is highly supportive of the existing FDA consultation process, and I would like to leave you with the perspective that we now live in an era where the greatest proportion of people in recorded history have the luxury of dying of old age diseases, and we have the safest food supply that humankind has ever seen. Thank you.

Panel Answers FDA Questions

MR. LEVITT: Thank you. Let me thank all the panelists, and the audience for being so attentive during all of these presentations.

We will now proceed to a little more of a Q&A format. What we will do, so everyone knows what to expect, is I will start with a question and I will just ask everybody down the line to provide an answer to it, and we will just kind of go right in order. We will then go right down the line and, hopefully, magically that will occur about the time we are supposed to take our lunch break. If not, you know, we will watch the time as it goes along.

I will start with something you have already been prepared to answer, as a way of kind of easing into this, and a number of you have answered it directly or indirectly...
but I think it would be nice to just kind of get together the views, if you will, together in the proceedings. That really is the first question the FDA asked in the Federal Register with regard to the current consultation process on how it ought to be modified, if at all.

I will read you the question again which says, has FDA’s consultation process achieved its intended purpose? Based on experience to date, should this regulatory approach "sunset," should it continue in its current state, should it be made mandatory, or would it be otherwise revised? So, I think you have all the potential possibilities there. We will start with Dr. Day.

DR. DAY: My view is that it isn’t broken and it doesn’t need to be fixed. I think that if the FDA is flexible and reactive to new problems as they arise, then they will continue to safeguard our interests in the way they have so far.

I don’t accept the hypotheses as scientific facts. Some of the statements that Mr. Druker made are hypothetical; they have not been shown to occur. So, that is my comment, Mr. Chairman.

MR. LEVITT: Thank you. Miss Foreman?

MS. FOREMAN: Yes, thank you. I think I made it perfectly clear in my prepared statement that I think this system was born under a cloud and that cloud has deterred
public confidence in the system. I don’t think you can
goddly determine that these products are safe any more
than we are goddly going to finish in time for lunch --

[Laughter]

-- and I am hungry! A mandatory approval system
doesn’t cost the agency anything except resources, and the
public ought to be prepared to make those resources
available. It will cost the industry something but not very
much, if one believes Dr. Maryanski about the consultative
process. It rewards the industry by increasing public
confidence in that process, and all you have to do is look
around the country today and see what is happening out
there, and you realize people are not confident with the
process as it exists right now. And, you know, it just
doesn’t work to try to insult people into purchasing your
products. It doesn’t work to sit there and say, "Jane, you
ignorant slut, if you don’t believe this is safe it’s
because you’re stupid." You have to persuade the public
that the government has a process that protects the public’s
interest.

MR. LEVITT: Thank you. Dr. Goldburg?

DR. GOLDBURG: Well, as I made clear in my
statement, I think there is good reason to improve FDA’s
policy so that it is more protective of consumers. As Carol
pointed out, I don’t think that will come at a terrible cost
to industry, and maybe some benefit because consumers might feel more secure about the safety of the food supply. As it now stands, I think that a voluntary system is in the future highly susceptible to problems should companies choose not to go along with crossing t’s and dotting i’s for the Food and Drug Administration. For example, Dr. Lehrer noted the example of the Brazil nut gene in the soybeans as an example of how the system worked; that the problem with the Brazil nut allergen was detected before the product ever reached market. I would like to point out that that example was entirely independent of the regulatory system. The company that created the soybeans, Pioneer Hi-Bred, behaved very responsibly and hired a good scientist to do the analyses, and when the analyses came back chose voluntarily to withdraw the product. There is no guarantee to consumers, however, that in the future all the companies will behave so well, and that is why I think many of us would like a system that more squarely places the burden of proof on industry to demonstrate the safety of the foods it is producing.

MR. LEVITT: Thank you. Mr. Druker?

MR. DRUKER: Mr. Levitt, you asked us to address specifically whether the purpose of the current consulting system has been achieved. It depends on what its purpose is. If its purpose is to give the illusion that the Food, Drug and Cosmetic Act is being followed and that these foods...
have really been established safe before they are marketed, then it is serving its purpose because that is the illusion that is being given.

But if you really want to follow the law and make sure that no genetically engineered food product reaches the market, reaches American dinner tables without having been demonstrated to a conclusive level that it is safe, then there needs to be a change because, as I mentioned, and I would invite Dr. Day or anyone else here to cite one example of a single genetically engineered food that has been established safe through scientific testing, published in the peer-reviewed literature, to the standard required by law.

We have many of our scientific plaintiffs who have signed sworn declarations submitted to the court saying they are not aware of a single such study. As I already mentioned, the FDA's own scientists say that the studies on the Flavr Savr tomato were inconclusive and raised a safety issue that was not resolved.

So, if you want to be in compliance with sound science, as you claim; if you want to be servants of the law, then change the policy. Require mandatory safety testing, and require that every genetically engineered food be established safe to reasonable certainty of no harm before it appears on American dinner tables.
MR. LEVITT: Thank you. Dr. Lehrer?

DR. LEHRER: Yes, I believe that the system is effective now. Can it be improved? Yes. I think that as technology improves, we probably can make better decisions addressing some of these questions. I might be actually overlapping with point two but, in general, I think the system is functioning well.

DR. ETHERTON: Mr. Levitt, as I said in my comments, and would like to emphasize that they reflect those of the FASS membership, we believe that the consultation process has achieved its goal and are supportive of it continuing in its current state. Thank you.

MR. LEVITT: Thank you very much. I will next turn to Mr. Hubbard.

MR. HUBBARD: Dr. Day, it has been well stated that consumer anxiety in Europe is much higher on this issue than in this country, although I think Ms. Foreman mentioned that it is increasing. Can you give us some of your perceptions of why it is higher in Europe? Is it consumer enlightenment? Can you tell us more about that?

DR. DAY: Well, I think there are several reasons. One is that the public's confidence in government science in Britain was severely shaken by the mad cow disease epidemic, particularly the risk of contracting Creutzfeldt-Jakob...
syndrome from the prion that is responsible for that disease.

I think too that the consultative process that we have in this country is better than it is in Britain. I don't know of an agency in Britain that would hold a hearing of this kind, and I think that this kind of meeting is extremely important in allowing people to express their concern so that we can have the kind of discussion that we are having here this morning. That happens to a much less well-developed extent in the U.K.

MR. LEVITT: I think I would like to give the other panelists an opportunity to respond to that question, if you would like, in terms of why consumer concerns appear to be greater in Europe than they are here.

MS. FOREMAN: I agree with Dr. Day in terms of the history of government regulation and the utter failure of the government in Great Britain to deal with mad cow disease responsibly. More recently you had the utter failure of the government in Belgium to deal with the dioxin and, in fact, to mislead the public. That has not been the case here, and the agency is to be applauded for beginning this process of consultation.

But I think the real difference is that this has simply been an issue for a longer period of time in the European countries than it has been here, and maybe on
January 1 we will all wake in concern and genetically engineered foods will have disappeared in the United States -- don't bet on it. I have a feeling that we are in for a long and painful process here that could be cut off if you will decide to take some steps that are reassuring to the public, that is, a mandatory review and approval and, as Becky and I keep saying, doesn't cost the industry an awful lot and may reward them as well.

MR. LEVITT: Thank you. Dr. Goldburg?

DR. GOLDBURG: Well, I think there is a myriad of reasons for the differences, some of which have already been elaborated on and I can't go into completely. I must say though that I have been involved in issues concerning the use of genetic engineering in agriculture for 13 years now at the Environmental Defense Fund, and was involved in the early stages of the development of federal regulations for biotechnology, and at the time those regulations were established biotech products were all in the R&D stage. So, to the extent that what was going on received media attention, the concerns to consumers were all hypothetical. They were in the future. These foods were prospective.

I think the debate in Europe has unfolded in a different way. When regulatory systems started being developed, when consumers started to think about those issues the foods were real -- they were on their table.
Therefore, I think there is a lot more concern.

Agreeing with Carol, I don't think we have seen the last of the issue here. Although the U.S. public to date has not expressed the same kind of concerns we have seen in Europe, I think people are growing in their awareness that many genetically engineered foods are now on their tables, and want some assurance, some independent oversight of the safety of these foods.

Finally, I would like to point out one other difference in biotechnology perception in Europe and the U.S., and I think that has to do with how at least some individuals in the scientific community receive the technology. I think it is important to consider that biotechnology is the baby of the U.S. scientific community and, as such, people in this country -- scientists in this country have all sorts of interests in its development, and that is less true in Europe.

For example, in Europe we saw a very critical report on genetically engineered foods come out of the British Medical Association. I don't think we would see that here. I think there are important cultural differences not only among the public but also in the scientific community.

MR. LEVITT: Thank you. Mr. Druker?

MR. DRUKER: Yes, there are several reasons. One,
as has been mentioned, the FDA has in many respects, over
the last 30-some years, performed very well and admirably,
and gained the respect of the American public. I can think
of the thalidomide drug which many European governments
unwisely approved. The FDA took a precautionary approach
and saved a lot of agony. Tobacco quite recently -- the FDA
has become a great champion of public health when it comes
to wanting to regulate tobacco. So, you have gained some
laurels and I think that transfers to your stance on
genetically engineered food.

Also, of course, there is a difference of media
coverage though within Europe and the U.S. The American
media has tended, by and large, to just report the
promotional statements of the industry spin doctors and of
the government spokespeople who continue to say that there
is really no risk and these foods have been guaranteed safe.
U.S. Secretary of Agriculture, Dan Glickman, has been saying
for years these foods have been proven safe. So, people
believe it. They aren’t aware that they are only assumed to
be safe on the basis of hypotheses, which is not adequate.

Also, of course, the mad cow disease incident in
Great Britain really has I think heightened concern in Great
Britain and in Europe. Relevant to that, I think it is
important to note that the scientist, the main scientist in
Great Britain who predicted that there would be a mad cow
disease type of problem well before it happened, Dr. Richard
Lacey, who has an M.D. and also has a Ph.D. in genetics, and
is professor of medical microbiology at the University of
Leeds in the United Kingdom, predicted that and the British
government ignored him for a long time. Then, lo and
behold, he was right.

    Now, Richard Lacey cannot be a plaintiff in our
lawsuit because he is not a U.S. citizen but he has
submitted a sworn declaration to the court, and he has said
that he believes, along with the rest of our plaintiffs,
that the same potential for widespread problems from
genetically engineered foods exists as it did several years
ago in the mad cow disease episode before the problem became
completely manifest. He reminded the judge that mad cow
disease has about a 12-17 year latency. So, the fact that
we haven't seen people dropping dead in droves yet from
genetically engineered food should not give us great
confidence because things can be building up. And, he is
not a scare monger; he is an eminent scientist. But, he has
said that the claims about the safety of genetically
engineered food rests far more on wishful thinking than on
solid scientific evidence, and he has told the court that
these foods should not be on the market unless they can be
demonstrated safe through rigorous testing, testing which is
currently absent.
DR. LEHRER: I agree with much of what has been said by my fellow panelists, with probably one major exception. First, I think mad cow disease is an important reason why Europeans are somewhat distrustful of what is told to them about their food supply, or are more concerned about their food supply because of their experience with this disease.

In addition, I have several Europeans in my laboratory and we have had extensive discussions on this very topic, and I think there are cultural differences between Europe and the United States with regard to food. I think the Europeans have a very intimate relationship with their foods. Americans do to a degree, but also Americans eat very quickly. Fast food started in the United States. Americans don’t necessarily have the same cultural relationship with food that Europeans do and this may contribute to the process.

Another possibility has been raised in terms of biotechnology being developed in the United States, and a lot of these products that are being developed are being developed by large American corporations that want to market them in Europe, and I think there may be some concerns about that in terms of large American companies marketing these products there. That may have contributed to it.

I do disagree with the issue of media coverage.
Maybe we are reading different articles, but my experience has been that I find the media tends to sensationalize topics. Particularly with genetically engineered foods, many of the articles that I have read, for example, with the Brazil nut expressed in soybean, have titles which suggest problems in the food supply rather than that this has been identified and it is not being marketed. So, at least my experience has been that the media does not downplay this in the United States.

MR. LEVITT: For the record, that was Dr. Samuel Lehrer. Finally, Dr. Etherton?

DR. ETHERTON: My observation reflects several points that Dr. Lehrer shared and Dr. Day. What I would say is that early on scientists, like myself, that were engaged in discovery research in plant and animal biotechnology discovered that an important element of developing products was to become engaged as an advocate to talk about the need for new technologies, their evaluation as far as safety to the consumer. The rate-limiting step in developing these technologies and their implementation is not the discovery or a new technique or the idea, it is eventually to talk to the American public about the need for and safety, and it is very difficult to talk about these because they are complex biologies. A high proportion of people in the United States haven’t had a lot of science education. And, historically I
think American scientists became more engaged earlier --
scientific organizations did, and I think that is built on
the fact that there is a cultural difference. I think the
people who got on a boat and came to North American three or
four hundred years were a different gene pool than those
that stayed behind.

[Laughter]

MR. LEVITT: Thank you. Next we will turn to Dr.
Stephen Sundlof, Director of our Center for Veterinary
Medicine.

DR. SUNDLOF: Thank you, Joe. First of all, I
would like to compliment the panel on a very stimulating
discussion. I learned a lot.

I heard two things and, although they are not
mutually exclusive, I would just like to explore them a
little bit. On the one hand, I heard that using modern
biotechnology you can more precisely transfer specific
characteristics, specific traits to these genetically
modified crops as opposed to through traditional plant
breeding where you may get a number of gene expression
products. So, that is one comment.

The other comment that I heard also was that there
is a potential for unknown expression products to occur.
So, the question that I would like the panel to address is,
first of all, I would like to get some kind of a sense of
the magnitude of the risk. How likely is that occur? The example that was given was the L-tryptophan supplement, dietary supplement. As a follow-up to that, has the technology improved that would make such an expression product less likely to occur now than it did back when that incident occurred?

DR. DAY: I must admit that I have not seen a complete account of the tryptophane story. The most recent one that I read, however, indicated to me that the contaminant problem arose because the company making the tryptophane from a genetically engineered microbe omitted a purification step. I have not seen any evidence confirming that the contaminant was a problem of the genetically engineered organism per se. The genetically engineered organism produced more tryptophane and the company making the product could make a short cut by eliminating the purification step which caused the problem. I am open to be corrected on that by other panelists who may have more up to date information.

We regard to the question of unpredictable effects from introducing transgenes, first of all, the transgene and the associated DNA that carries it into the recipient organism can be characterized, and it is characterized; the DNA sequence is known. There is the possibility, by having flanking sequences of DNA that are homologous to those
already in the organism, of some control over where it is located.

Now, yes, one has to admit that there is the potential that it might have an unpredictable effect. But, when you are comparing that operation with what is quite frequently done in conventional plant breeding of taking plants that have been isolated from each other maybe for hundreds or thousands of years, and they are brought together by plant collectors in gene pools and term plasm banks, and they are inter-crossed, sometimes with great difficulty because there are sexual sterility barriers, and the genetic differences between those individuals are very considerable, much more so than the precisely characterized DNA that is in an insert, then I think you have a much, much greater probability of unpredictable effects.

Jim Maryanski referred to one instance, the product of an unusually high level of solanine in a potato variety called Lenape that was introduced. It was a hybrid, or derived from hybridization of the cultivated potato with a wild Mexican species, and that variety had to be withdrawn. He used it as an example of post-release regulation.

None of our food is one hundred percent safe. It may be contaminated with microorganisms, spoilage organisms.

This is the most important problem that we face in our food
supply. As a biologist, I can't give the critics one hundred percent assurance of anything biologically because of the nature of the materials that we work with. All I can say is that in my opinion, and of many other scientists, the comparative risk is much smaller.

MS. FOREMAN: Well, I was going to pass on this and leave it to the scientists, but since I spend a great deal of my time dealing with microorganisms and their contamination of food products, I just want to say, Dr. Day, that in that case the public has some warning about the presence of danger, and the capacity by handling food products carefully to avoid that danger. That may not be the case when you are dealing with these genetically modified organisms. So, now back to the scientists.

DR. GOLDBURG: I would like to briefly first comment on L-tryptophan. At one point a number of years ago, I spent some time looking at the L-tryptophan problem and came to the conclusion really that no one knows or is likely to ever resolve what caused the problem with L-tryptophan. The manufacturer of the L-tryptophan, a company called Show Denko, changed two steps in the production process for L-tryptophan, both changing a purification step and the genetic engineering of the organism. So, whether the problem was caused by one or both of these process changes is unclear. A researcher at the National Institute
of Health, names Esther Sternberg, invested considerable
time trying to isolate contaminants in problematic L-
tryptophan that might have caused the disease and was left
with a myriad of confusing research results. So, while I
think it would be wrong to say that genetic engineering
causd the L-tryptophan problem, it would also be wrong to
rule it out as a potential cause.

On to the predictability of genetic engineering,
as Dr. Day said, it is absolutely true that the genetic
sequences that are introduced to a food via genetic
engineering, or to a crop plant, are well known or can be
very well known. However, there are some very serious
limits to how precisely genetic sequences can be put into
the chromosomes of plants. It is generally not known or not
controllable where inserted gene sequences land in plant
chromosomes, and there is some potential there for gene
interactions that could have so-called pleiotropic effects.
Certainly, there has been a lot of study of these effects
with genetically engineered flowers, looking at flower
color, and many unexpected effects have been documented.

Whether or not there is more variability in
selective breeding or genetically engineering I don’t think
we know yet. Genetic engineering is still new and I think
we are still finding out to what extent unexpected effects
pose serious health concerns.
I must say, as someone who works to represent environmental and consumer interests, my biggest concerns about genetically engineered foods come from the really unlimited universe of gene products that can be introduced to foods via genetic engineering, and that is what makes them really different than traditionally bred crop plants.

MR. DRUKER: Just to say one more point about the L-tryptophan, or maybe a couple of points, the reason, by the way, that we cannot conclusively rule out genetic engineering or conclusively show it was some lax behavior on the part of Showa Denko in their testing procedure is that all of the relevant evidence was destroyed before the international team of experts could come to the lab and actually make the determination. So, it will remain a mystery.

But the fact is, as Dr. Maryanski admitted to the GAO, genetic engineering as a process cannot be ruled out. It could not be ruled out in 1991 when he made that statement. It still can’t be ruled out. And, the law requires a reasonable certainty of no harm. There is reasonable doubt about the process of genetically engineered itself -- and those strange toxins that were produced are the kinds of unexpected toxins that the FDA scientists were warning about in the statements I read earlier and that many of the scientific experts who are
plaintiffs in our lawsuit warn about.

What is troubling is that the government tries to deny that any genetically engineered food has caused harm. Did then, and recent statements continue to boast that no genetically engineered food is even caused as much as a sniffle or a sneeze. It is just running away from reality.

Now, on the question of whether gene-splicing techniques are more precise, again as has been acknowledged, they are precise to the extent that you know exactly what genetic material you are putting in. They are far less precise in terms of being able to gauge adequately what the ultimate effects are going to be and that, of course, is what most directly relates to the issue of food safety.

I think it is very important just to give a perspective on what is going on from what we already know about information science. Genomes, DNA is an informational code. We already know a lot about informational codes from our own man-made computer software. And what we have learned is that those codes, when they get to a certain level of size and complexity -- we can no longer control what happens when we do input. Even when software engineers make a very well calculated change to a system that they have completely designed and they have the whole understanding of how that system is supposed to interact as a whole, we have learned -- we, meaning the human race --
that we cannot control the unintended effects. In fact, it is to the extent that the standard textbooks on software engineering will say if you find an error in a program, the best procedure is to leave it alone because, by trying to fix that error, the likelihood of creating some unintended effect somewhere else in the system is great enough that it is better to live with an error than you know about than fix it and create one that you don’t yet know about.

Now, compared to even the most complex man-made computer software program the genome of a living organism is far greater and far less understood by the human brain. We know very little about it. We know it is far more unpredictable and, yet, we are intervening and making changes that we should know could make deleterious negative side effects that we cannot predict.

It is very interesting, and then I will end, but I think it is sobering and I would like the FDA officials to consider -- the FDA currently regulates medical devices, and in that capacity it regulates software that runs those devices. If a pacemaker or an x-ray machine -- these are run by software -- if a company wants to make a change in the software code that already is known to be safe, if they make a change the FDA requires them to go through rigorous regression testing to put that system through almost every possible permutation and combination to make sure that no
unintended consequences came out. Why? Because that is the industry standard. We know that that can happen when we change informational systems. Yet, when it comes to food safety, the biotech companies are making semi-random insertions into the most complex informational systems in the universe and the agency says we assume that is the same thing as doing what has been happening in a very holistic, natural way for hundreds of thousands, millions of years.

Go right ahead. You don't need to do any testing. I think that that dichotomy is so gross that it deserves further consideration.

MR. LEVITT: Dr. Lehrer?

DR. LEHRER: I am going to restrict my remarks to allergenicity with regard to unintended or unpredicted effects. In my opinion, with the current assessment methods in place, I think it is highly unlikely that we would have unanticipated allergen being expressed. Certainly, when we are dealing with the transfer of proteins from known food allergens or altering known foods which contain allergens, this is, I would say, almost absolute.

With sources of proteins or genes from foods in which we have no information about the allergenicity, I believe based on the levels of expression, the digestibility of these proteins, and the comparison of properties with known allergens, that it is highly unlikely that there would
be an unanticipated allergen being expressed. Nevertheless, we base this on current technology and, as Dr. Goldburg mentioned, I think we can improve our risk assessment and decision-making process as technology improves, and I think that we need to devote efforts toward that so that we can even minimize an already low or minimal risk.

MR. LEVITT: Thank you. Dr. Etherton?

DR. ETHERTON: Thank you. I would like to share that the probability of their being an unpredictable or unlikely side effect is very, very small. It is important to appreciate, and you heard this morning that there is a very, very extensive regulatory and oversight process that FDA plays out. This is really the flagship organization in the world, and there is a lot of stuff that they require scientists to provide that work for companies. There is oversight by advisory panels and, as you have heard, there are some emerging technologies. We are now standing at the gate where, when a genome is sequenced -- in other words, when we have all of the information for the entire sequence of a plant or animal and know all the genes, we will then be able to evaluate what are called array techniques, that is, a way to look at expression of all these genes to see which are turned on or off.

My point is that when you engineer a plant or animal using very precise techniques, I might add, so we can
target them out to precise locations, then we can look at that effect on all other genes in the animal, whether they are turned on, off or are unaffected. That will be a powerful step forward.

We also know a lot about structure of proteins and function and, as information technologies evolve, we in fact now have very powerful ways to predict function. Then, the obvious point is that you evaluate this in an experimental setting and provide those data to the appropriate regulatory agency to assure that these are as safe as known using existing technologies, which are really very powerful.

Thank you.

MR. DRUKER: If I could just add something to that because on the question specifically you asked about the magnitude of risks. In that memorandum from Dr. Linda Kahl, of the FDA, she mentioned that there is no data that addresses the relative magnitude of the risks. Then she says, are we asking the scientific experts to generate the basis for this policy statement in the absence of any data? It is no wonder that there are so many different opinions. It is an exercise in hypotheses forced on individuals whose jobs and training ordinarily deal with facts.

So, there isn't solid evidence, and I think what you were just speaking about is a hypothetical possibility in the future but, according to all of the scientists who