

# TRANSCRIPT OF PROCEEDINGS

BEFORE THE  
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING  
BIOTECHNOLOGY IN THE YEAR 2000 AND BEYOND

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Pages 1 thru 352

Oakland, California  
December 13, 1999

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BEFORE THE  
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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PUBLIC MEETING  
BIOTECHNOLOGY IN THE YEAR 2000 AND BEYOND

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MONDAY, DECEMBER 13, 1999

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The meeting was convened in the Auditorium,  
Federal Building, Oakland, California, at 9:00 a.m.,  
Sharon Smith Holston, Deputy Commissioner for  
International and Constituent Relations, Food and Drug  
Administration, presiding.

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PRESENT:

L. ROBERT LAKE  
Director, Regulations and Policy  
Food and Drug Administration

MELINDA PLAISIER  
Associate Commissioner for Legislation  
Office of Policy, Planning and Legislation

BERT MITCHELL, D.V.M.  
Associate Director for Policy and Regulations  
Center for Veterinary Medicine

CATHERINE COPP  
Associate Chief Counsel for Foods  
Office of Chief Counsel

JAMES MARYANSKI, Ph.D.  
Biotechnology Coordinator  
Center for Food Safety and Applied Nutrition

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Biotechnology Coordinator  
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SHARON SMITH HOLSTON

P R O C E E D I N G S

9:05 a.m.

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2  
3 COMMISSIONER HOLSTON: I'm Sharon Smith Holston,  
4 and I'm FDA's Deputy Commissioner for International and  
5 Constituent Relations.

6 It's a pleasure to be here and to open the last  
7 of the three public meetings on foods produced by  
8 utilizing the tools of modern biotechnology, a process  
9 sometimes called genetic engineering, or bio engineering,  
10 as FDA Commissioner Dr. Jane Henney noted at an earlier  
11 and also an extremely well-attended meeting in Chicago.  
12 We hoped that there would be interest in this issue, but  
13 the response to our announcement was so overwhelming that  
14 we had to make arrangements for two additional overflow  
15 rooms. I apologize for any inconvenience that this change  
16 may have caused, but I am pleased that, as a result, we  
17 can accommodate our panelists, who represent a diversity  
18 of views; preregistered presenters, who want to contribute  
19 to the discussion; and, of course, the press.

20 Before I go any further, I would like to  
21 announce that we will also have two sign language  
22 interpreters available today to anyone who needs them.  
23 Susan Eadie is here with us now, standing in front of the  
24 auditorium, and Anna Mendess will be here also.

25 As I just mentioned, this is FDA's third public

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1 meeting on this important and timely topic. In the first  
2 two public meetings, in Chicago on November 18, and also  
3 in Washington, D. C. on November 30, the participants  
4 included 23 panelists and 140 scheduled speakers,  
5 representing a broad spectrum of viewpoints. In addition,  
6 there were about 100 press representatives at each  
7 meeting. Altogether, 1,075 individuals attended the  
8 meetings, which received rather full-press coverage.

9 Today, in my introductory remarks, I want to  
10 emphasize the same points that were made by Commissioner  
11 Henney in Chicago.

12 In the first place, we who work for the Food and  
13 Drug Administration are truly pleased to have this  
14 opportunity to listen to your views and share our  
15 experience on this very important issue. We recognize  
16 that this is a topic on which there are widely differing  
17 and very strongly held views. While we at FDA wish to  
18 listen to everyone, we also ask that all of us listen to  
19 one another, so that the community at large can gain a  
20 better understanding of the full range of opinions and  
21 positions.

22 The second point that Dr. Henney made in Chicago  
23 is that FDA has a long history of public health  
24 protection. Our agency's origins go back to the turn of  
25 the century, and the basic law under which we operate

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1 today was passed in 1938. Over the years, we have faced  
2 many new developments that affect the food supply. For  
3 example: in the 1950s, the use of preservatives and other  
4 chemicals in food led to a lot of concerns about food  
5 safety.

6 More recently, FDA has been in the forefront of  
7 efforts, as part of the President's Food Safety  
8 Initiative, to reduce food-borne illness. In short,  
9 throughout our history, FDA has based its regulatory  
10 decisions on sound science, with protection of public  
11 health as the foremost criterion. This is central to  
12 FDA's mission and tradition, and it's a tradition that  
13 continues with FDA's oversight of products developed using  
14 modern biotechnology. A very substantial experience in  
15 this area goes back to 1982 when FDA approved a new  
16 insulin product, a medication that became the first  
17 consumer product developed using modern biotechnology.  
18 Since that time, the agency has had extensive experience  
19 in evaluating the safety of product developed using this  
20 new technology.

21 The use of the tools of biotechnology in foods  
22 began in the mid 1980s. In 1990, FDA completed its review  
23 of the safety of the first food ingredient developed with  
24 the tools of biotechnology, which was caymosun, or a  
25 rennet preparation, the milk clotting enzyme used to make

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1 cheese. At that time, FDA received no public comments  
2 that addressed the safety of this ingredient. Recently,  
3 however, questions have been raised about the safety and  
4 labeling of foods derived from new varieties of crops  
5 developed with the tools of modern biotechnology, and  
6 about the effects these crops have on the environment.  
7 Some of these questions, such as those regarding human  
8 health and food and animal feed safety, as well as food  
9 labeling, fall under FDA's authority. Other concerns, for  
10 example, both about environmental safety and the effects  
11 of genetic modification on the plants themselves,  
12 generally fall under the authority of other agencies or  
13 departments of the U.S. Government, such as the  
14 Environmental Protection Agency or the United States  
15 Department of Agriculture.

16 I want to take this opportunity to briefly  
17 explain how FDA oversees the safety of foods developed  
18 with the tools of biotechnology, and share with you some  
19 of the experience that we have had in evaluating the  
20 safety of these foods, since the first such whole food  
21 product, the Flav'r Savr Tomato, entered the market.

22 FDA introduced its current policy for regulating  
23 foods developed with the tools of biotechnology in 1992,  
24 following an extensive scientific review. In 1994, the  
25 policy was elucidated and discussed publicly during the

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1 joint meeting of FDA's Food Advisory Committee and our  
2 Veterinary Medicine Advisory Committee. Since then, FDA  
3 has carried out over 40 consultations with firms involving  
4 the safety of new varieties of foods made using the tools  
5 of biotechnology.

6 In a few minutes, you will hear from my FDA  
7 colleagues in more detail about the testing that has been  
8 performed by developers of new varieties, the kinds of  
9 information that have been reviewed by the agency and the  
10 regulatory and scientific grounding for our approach to  
11 oversight of these products. We are convinced that our  
12 policies and processes in this area are well grounded in  
13 science, and that we have an excellent track record in  
14 applying our policy. We believe that our oversight had  
15 been substantive, credible and appropriate.

16 We have now had five years of experience with  
17 our consultation process. However, we're committed to  
18 keeping FDA's review and regulatory processes as open and  
19 transparent as possible. And we want to hear from you  
20 whether we need to consider adjustments to our current  
21 system. We want to hear your suggestions on how we might  
22 improve our approach to safety assessment, and how we can  
23 best provide pertinent information to the public.

24 Now, I want to take a minute to explain the  
25 format and logistics for today's meeting.

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1           This morning, we will focus on issues concerning  
2 the safety assessment of these foods, and on FDA's  
3 regulatory oversight. There will be a brief overview of  
4 our current approach to safety assessment and FDA's  
5 experience in this area in the past five years. We will  
6 then ask our invited panelists to address issues and  
7 questions that we believe will help FDA evaluate its  
8 current approach to safety assessment.

9           In the afternoon, we will focus on issues  
10 surrounding disclosure of information to the public; and,  
11 again, a brief presentation will be provided by a member  
12 of FDA's staff, followed by a panel discussion.

13           Finally, we have reserved almost three hours to  
14 hear from as many members of the audience as we possibly  
15 can. However, we have to conclude our meeting promptly at  
16 6:00 p.m. And because we want to give everyone a chance  
17 to present his or her views, we're asking that all  
18 presentations from the floor be limited to two minutes.  
19 When you checked in this morning, each of you should have  
20 received a folder with a number on it. That number  
21 indicates the order in which public presentations will be  
22 made.

23           Because we have limited time for open comments,  
24 I would like to remind everyone that we also welcome  
25 written comments, and that we have established a public

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1 docket that will display all of the information that the  
2 agency will have received at these public meetings. The  
3 FDA web site also provides easy access to pertinent  
4 information on this subject and enables anyone to submit  
5 comments electronically. The FDA internet address is:

6 [www.FDA.gov](http://www.FDA.gov)

7 We're transcribing the three public meetings on  
8 this topic. The transcript of each meeting will be made  
9 available in the docket and on the internet as quickly as  
10 possible, hopefully within 15 working days. As a matter  
11 of fact, the Chicago transcript is up on the internet now.  
12 Information on how to access the public docket and submit  
13 comments is in your registration packet, as well as on  
14 FDA's internet home page.

15 Before we begin, I want to extend special thanks  
16 to the members of our panels for coming and sharing their  
17 views with us and our audience, and with one another. We  
18 have attempted to assemble panels that represent a wide  
19 cross-section of all interested parties, and we've  
20 received much help in that selection from consumer  
21 organizations, professional societies, trade groups and  
22 other umbrella organizations. They have our thanks for  
23 their cooperation.

24 A panelist no doubt has varied but strongly held  
25 views and a wealth of useful information for all of us to

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1 consider. We trust that they will explain their position,  
2 exchange comments, and, in general, make sure that the  
3 issues before us are fully discussed.

4 I also want to join Commissioner Henney in  
5 expressing appreciation to the FDA staff who have devoted  
6 a great deal of time and energy to make today's meeting,  
7 and all of the other meetings, possible. This includes,  
8 in particular, our employees in the Office of Consumer  
9 Affairs and in our Pacific Region, and in our San  
10 Francisco District Offices. Their response to the many  
11 logistical challenges connected with this meeting has been  
12 particularly impressive.

13 As I have suggested earlier, FDA is here  
14 primarily to listen and to ask questions. We're not  
15 trying to reach any conclusion by the end of the day.  
16 Therefore, and because we want to have time to hear the  
17 views of others, we will not be engaging in debating any  
18 points that may be raised.

19 I must also note that FDA's policy is the  
20 subject of litigation, which severely limits our ability  
21 to respond to comments. I expect today's discussion to be  
22 productive and stimulating, and I look forward to our  
23 working together.

24 One final logistical detail: I would like to  
25 ask any of you in the audience who may be carrying cell

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1 phones or audible pagers to please turn them off so as not  
2 to distract our speakers and the rest of the audience. So  
3 I thank you for that.

4 I would now like to introduce our FDA panelists.  
5 To my far left, L. Robert Lake, who is the  
6 Director of our Office of Regulations and Policy, in our  
7 Center for Food Safety and Applied Nutrition.

8 Seated next to me, on the left, is Melinda  
9 Plaisier, who is our Associate Commissioner for  
10 Legislation in our Office of Policy, Planning and  
11 Legislation.

12 On my immediate right is Dr. Bert Mitchell, who  
13 is the Associate Director for Policy and Regulations in  
14 FDA's Center for Veterinary Medicine.

15 Seated next to Dr. Mitchell is Catherine Copp,  
16 who is the Associate Chief Counsel for Foods in the Office  
17 of the Chief Counsel.

18 At the far right, is Dr. James Maryanski, who is  
19 the Biotechnology Coordinator in the Center for Food  
20 Safety and Applied Nutrition.

21 And now Dr. Maryanski will give his  
22 presentation.

23 //

24 //

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1 FDA POLICY: 1994 TO THE PRESENT

2 JAMES MARYANSKI, Ph. D.

3 BIOTECHNOLOGY COORDINATOR

4 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FDA

5 DR. MARYANSKI: Thank you, Ms. Holston. Good  
6 morning, ladies and gentlemen.

7 I'm Jim Maryanski. I have the honor this  
8 morning of explaining to you what we do with foods that  
9 are produced by modern biotechnology, and some of the  
10 experiences that we've had over the past several years.  
11 We'd like to give you a little context for the discussion  
12 that we will be having throughout the day today.

13 If I might have the slides, please.

14 Just to sort of tell you a little bit about who  
15 we are, the Food and Drug Administration, as many of you  
16 know, is an agency in the Department of Health and Human  
17 Services. And just to give you an idea of where we fit in  
18 the scheme of things, there are other public health  
19 agencies that make up this department, including the  
20 National Institutes of Health and the Centers for Disease  
21 Control and Prevention. And, so, FDA and NIH and CDC are  
22 health-protection agencies within this larger department.

23 The law that FDA has responsibility for carrying  
24 out and insuring the safety of the products that it  
25 regulates is the Federal Food, Drug and Cosmetic Act.

1 This is the law that Ms. Holston mentioned has been in  
2 place since 1938, and provides the basis for the oversight  
3 that FDA has for assuring the safety of foods and other  
4 products that we regulate.

5 I think I will explain to you in a few minutes  
6 just what those products are that this law covers. But I  
7 think it's important to understand that this law is very  
8 broad, covers many aspects of consumer protection, and it  
9 is consumer protection that is our mission.

10 Our approach to protecting consumers is based on  
11 the best science that is available. So our policies and  
12 regulations are science-based policies. And we regulate  
13 foods that are interstate commerce. We don't regulate  
14 foods that are in research; but we do regulate foods that  
15 are for sale, both imported into the U.S. and on the  
16 market in the U.S. So it is the commercial part of the  
17 food chain that FDA has responsibility for.

18 I'd like to give you a little sense of how  
19 products of modern biotechnology fit within the broader  
20 federal system in the U.S., because there are a number of  
21 agencies that have responsibilities for various aspects of  
22 the safety of these products. Of course, FDA is  
23 responsible for the safety of foods, and that means we are  
24 responsible for most foods. The Department of Agriculture  
25 has oversight over meat, poultry and egg products, in

1 terms of inspecting those products. But FDA has oversight  
2 over all the other things in the grocery store. And, so,  
3 if you think about the diversity of the products in the  
4 grocery store, and that includes all the substances that  
5 are added to foods, you think about the ingredient package  
6 labeling, all the substances that are added to foods, fall  
7 under FDA's authority.

8           So, in terms of biotechnology products, the same  
9 applies. Those products fall under the act just as other  
10 products produced by other methods. There is no  
11 difference in the way FDA exerts its oversight.

12           The Department of Agriculture is responsible for  
13 many of the issues that relate to environmental concerns.  
14 They, of course, have authority to insure that plant pests  
15 are not introduced into agriculture, both in terms of  
16 plants and seeds that are transported in the U.S., as well  
17 as materials that come into the U.S.

18           The Environmental Protection Agency, or EPA, has  
19 responsibility for pesticides in the food supply and, of  
20 course, elsewhere. So, if a substance is introduced into  
21 food that is a pesticide, EPA is responsible for assuring  
22 its safety, for setting tolerances for its use in food, or  
23 for exempting it from those tolerances. But all  
24 pesticides must be registered by EPA before they're used  
25 in food.

1           So, now, let me give you an example of a product  
2 produced by modern biotechnology, but falls under all  
3 three agencies in some aspects. The BT Corn, the corn  
4 that has been developed to produce its own pesticide  
5 substance. That corn is a product that the company would  
6 discuss and take through the process at USDA, for  
7 consideration of plant pest characteristics and a number  
8 of the environmental issues that would be associated with  
9 that plant. They would also, of course, have to have the  
10 pesticide as produced by that plant registered by EPA  
11 before it could be used in food. And EPA's process for  
12 registration addresses both human safety of exposure to  
13 that pesticide and environmental issues related to the use  
14 of that pesticide. And, of course, FDA has responsibility  
15 for food products that are derived from that corn. So,  
16 for example, high fructose corn syrup is a product that is  
17 produced through the processing of corn that's used in  
18 soft drinks and other products. And, of course, most of  
19 the corn that is produced today from plants developed by  
20 modern biotechnology is used for animal feed. So both  
21 human food products and animal feed products fall under  
22 FDA. As I described our policy for foods today, I will be  
23 speaking of feeds at the same time. We consider them in  
24 the same manner.

25           In the late 1980s, FDA began to receive a lot of

1 questions about the use of modern biotechnology in  
2 agriculture. At that time, as you have heard, we had  
3 already had experience both with pharmaceutical products  
4 and with the first food products, such as the enzyme  
5 rennet, or caymosun, that's used to make cheese. But we  
6 realized that the real large impact of biotechnology was  
7 going to be in agriculture, and really on things that we  
8 think of as whole foods. And, so, FDA convened a group of  
9 scientists within the agency to look at all aspects of  
10 this technology. And these scientists were asked to  
11 consider all possible impacts of this technology on the  
12 food supply. They were not given any restrictions  
13 whatsoever in terms of the law or any other constraints in  
14 terms of bringing the policy together. But they were  
15 asked to look at all possible impacts on health, and then  
16 to consider that within the framework of the Food, Drug  
17 and Cosmetic Act.

18           The purpose of that exercise was so that we  
19 could, first of all, understand the impact of this new  
20 technology on the food supply: How would these foods be  
21 similar, how would they be different from other foods; and  
22 therefore, how should FDA carry out its responsibility of  
23 public health protection? Also to answer the questions  
24 from industry about what kind of safety testing would be  
25 needed for these products, and what kind of regulatory

1 process should be in place for these products to come to  
2 market. In other words, would they be regulated like  
3 other foods that are placed in the grocery store?

4           So the 1992 policy was intended to answer the  
5 questions that we were receiving at the time. It was not  
6 intended to look forward five or ten years later. We  
7 wanted the policy to be flexible. We knew this was a new  
8 technology. We wanted to be able to answer the questions  
9 at the time based on the types of products that were  
10 coming then, and leaving ourselves sufficient flexibility  
11 so that we could adjust if there were changes in the  
12 future. This, of course, is a policy based on the Food,  
13 Drug and Cosmetic Act, and the policy applies to foods  
14 derived from plants developed by all methods of plant  
15 breeding. There are many methods. We're familiar with  
16 cross-hybridization and the sexual processes of mating  
17 plants, but breeders have many other different methods of  
18 introducing, coaxing plants to do things that they would  
19 like them to do that will be beneficial in agriculture and  
20 food production.

21           Our conclusion was that the Food, Drug and  
22 Cosmetic Act applies to all foods, and that all foods  
23 should meet the same standards. So we do not have a  
24 different standard for products of modern biotechnology.  
25 So the policy applies to plants produced by all methods of

1 plant breeding. And it applies to human foods and animal  
2 feeds. This policy explains the regulatory framework and  
3 the scientific approach for assessing safety for products,  
4 such as fruits and vegetables, and cereals, and the  
5 products that are derived from those types of plants, such  
6 as vegetable oils and food starches.

7           The policy that we published in 1992 really  
8 explained how foods have always been regulated, and how  
9 foods that are produced by modern biotechnology can fit  
10 within that framework. FDA has two tools that it uses  
11 primarily to insure the safety of foods in the grocery  
12 store. If a food would pose a health problem to  
13 consumers, if we know something about that food, that we  
14 know that it will be unsafe, we have very broad  
15 enforcement authority to remove that product from the  
16 market. That system works because, of course, companies  
17 do not want to be in that situation, nor do their  
18 customers, who will ask to make sure that the product is  
19 okay with FDA before it goes to market. And, of course,  
20 it works because FDA has very strong enforcement  
21 authority. We, of course, can issue injunctions and  
22 seizures against products, and we can even initiate  
23 criminal prosecution against those who place an illegal  
24 product on the market. So the law is a very strong law in  
25 terms of enforcement.

1 Foods are not required to undergo pre-market  
2 approval by FDA. So new varieties of corn, for example,  
3 or soy beans, do not necessarily — do not come to FDA for  
4 approval before they go to market. But the Act places the  
5 legal responsibility for the safety of these products on  
6 the developer, on the purveyor of the product. And FDA's  
7 job, then, is to provide the guidance to make sure that  
8 these products are safe, to make sure that the purveyors  
9 know what the standards are; and, of course, to remove  
10 products from the market if they do not meet the  
11 standards.

12 There is pre-market approval for substances that  
13 are added to food that are food additives. These would  
14 include substances such as new flavors, thickeners,  
15 preservatives, any substance that is added to food that  
16 isn't otherwise exempt from this part of the Act.  
17 Pesticides, for example, are exempt because they are  
18 regulated by EPA. But there's also a large category of  
19 substances that we call GRAS substances, G-R-A-S,  
20 Generally Recognized as Safe. Congress has established  
21 this exemption because there are many substances that  
22 have been used safely in foods, such as flavors, spices,  
23 vinegars, sugar, food processing enzymes, and so forth,  
24 and did not intend that all of those, that type of  
25 substance, would undergo pre-market review. But this

1 gives us the tool to insure that any substance introduced  
2 into food through modern biotechnology that is not  
3 generally recognized as safe will be reviewed and approved  
4 by FDA before the food goes to market. And we have said  
5 that there are many substances introduced into food  
6 through plant breeding, and that many of those substances  
7 have been safely consumed. And to the extent that a  
8 substance is introduced into food through modern  
9 biotechnology or other means, and it's derived from food  
10 where it's been safely consumed, we will presume that that  
11 substance is really exempt from the Food Additive  
12 requirement.

13           On the other hand, we have also said that there  
14 are many substances that are very similar to substances  
15 found in food, even though they come from very diverse  
16 organisms. And to the extent that that is the case, those  
17 substances are also considered to be, presumed to be,  
18 GRAS. But we have the legal hook. If someone can put a  
19 substance into food using this, or any other technology,  
20 for which there is not a basis for us to presume that that  
21 substance is GRAS, it will be required to undergo  
22 pre-market review. And we've published extensive guidance  
23 for developers.

24           This is really the crux of the 1992 policy: to  
25 make sure that developers know the kind of safety issues

1 that should be taken into account in evaluating new  
2 varieties for commercial food use. And it really is this  
3 part which was new in 1992 in the sense that what we said  
4 wasn't new. We think that there are practices that  
5 breeders normally follow, but we put it down on paper so  
6 there could be no mistake about what the standard is that  
7 FDA expects for these products to meet. And we also set  
8 up a consultation process to make sure that companies had  
9 an opportunity to make sure that they knew all the steps  
10 that need to be taken so that they could meet their legal  
11 duty in bringing these products to market.

12 This was something that evolved after the  
13 publication of the 1992 policy and our review of the first  
14 product, the Flav'r Sav'r Tomato. FDA conducted a full  
15 review of that product at the request of the company.  
16 That review was a review that lasted about three or four  
17 years, and we worked with the company right in the  
18 beginning, helping them design the tests. Because, in  
19 fact, this was the first time that anyone had come to FDA  
20 and said: Well, how do we apply modern biotechnology, or  
21 modern science, rather, to a food? In other words, most  
22 foods have been accepted on the basis of experience and  
23 use. Now the question was: Well, actually, we would like  
24 to provide some additional assurance and use modern  
25 analytical and other methods to assure the safety of these

1 foods. How will we do that?

2           We're very used to looking at the safety of  
3 single chemicals as food additives, that are added to  
4 food. We realized that this was a very different question  
5 because a food is composed of many substances. And, so,  
6 we had to think about that quite hard in terms of  
7 developing a process to assure that this food would be  
8 safe, as safe as other foods in the market. And we  
9 discussed the approach that we presented in the 1992  
10 policy with our Food Advisory Committee in 1994, which is  
11 a committee of experts from outside of FDA and includes  
12 academic, consumer and industry representatives. Those  
13 committee members felt that the approach that had been  
14 used for the Flavr Savr, and that we were proposing for  
15 other similar products, was scientifically sound; but they  
16 also said to us that, given the nature of the Flavr Savr  
17 product, and other products that we were seeing at the  
18 time, they did not, in fact, raise substantial safety  
19 issues, and that FDA might better use its resources by  
20 having some sort of process that was more abbreviated  
21 where we would still have some oversight of this new  
22 technology, but not commit the kind of resources that we  
23 did to this full scientific review of the Flavr Savr  
24 Tomato. And we felt that, given the nature of the  
25 products we were seeing at the time, that was appropriate.

1           We developed what we now call the "consultation  
2 procedures," and discussed those again with our Food  
3 Advisory Committee, and our committee that assists us in  
4 areas on veterinary medicine, such as animal feeds. And  
5 again, the Committees felt that the consultations that we  
6 have in place were an appropriate mechanism given the  
7 nature of the products.

8           The way consultations work is: Our guidance is  
9 there for companies to use and to consult with us on  
10 particular scientific issues, such as evaluation of  
11 nutritional changes, or assessment of possible  
12 allergenicity. What we do ask companies to do is to  
13 provide us a comprehensive summary of the information that  
14 they have developed when they feel they have completed all  
15 the work that they need to do. That information — which  
16 usually is a hundred to several hundred pages in length —  
17 gives the FDA scientists an opportunity to make sure that  
18 all safety issues have been resolved before those products  
19 go to market. And that is the system that has been in  
20 place since 1994, and there are about 45 products that are  
21 now listed on our home page, where companies have  
22 completed their food safety and nutritional assessment  
23 discussions with FDA.

24           I'd like to just give you a little bit of sense  
25 of some of the principles that underlie our approach to

1 safety assessment.

2           The products that we're seeing, of course, are  
3 familiar food crops. They're corn, soy beans, potatoes,  
4 tomatoes. They're not something that we've never seen in  
5 food before. And we felt that, because these are products  
6 that have been modified, but they're based on conventional  
7 crops, that the food that we have today should be the  
8 standard. FDA should not ask developers to prove that  
9 tomatoes are safe to eat, or that corn is safe to eat. In  
10 fact, we know that, if one subjected many of our foods to  
11 the kinds of extensive toxicological testing, they might  
12 not pass because they contain many different substances  
13 that can cause effects in food.

14           What we thought was important is that the food,  
15 as the standard, should be what is used to compare the new  
16 variety. The new variety should be looked at in terms of  
17 what is similar, what is different about this new variety  
18 in terms of food safety, and that we would have to use a  
19 different approach than we normally use for single  
20 chemical, such as food additives. We would have to look  
21 at many different kinds of information. Plant breeders do  
22 extensive evaluations of new varieties over a period of  
23 time during development, and that that agronomic and the  
24 quality characteristics that plant breeders evaluate for  
25 individual crops is a very important process in

1 determining whether a product is suitable to come to  
2 market.

3           We also have some new tools.           Modern  
4 biotechnology gives the tools to develop new products. It  
5 also gives us a way to know more about those products, to  
6 know the identity of the genetic material, to know the  
7 identity and the function of the proteins and other  
8 substances that are new in food as a result of the use of  
9 that technology. And so that that information would be  
10 very important to the assessment of the safety of these  
11 products.

12           In addition, we recommend to companies that they  
13 take some extra steps that are not normally done in plant  
14 breeding. That they develop information to show that, in  
15 fact, the foods have not been changed in the ways that are  
16 important in terms of their nutrients, and other  
17 components of the food, the vitamins, minerals, that I  
18 will show you in a moment. But really to assess whether  
19 the food is, in fact, the same as what is expected in  
20 addition to, of course, whatever change had been made in  
21 that food.

22           There could be circumstances where we would  
23 recommend that further testing be done. And I will give  
24 you some examples. But we don't generally recommend that  
25 animal tests be conducted with these foods, because the

1 tests are very difficult to design, and they cannot be  
2 done in the same way that we do for standard chemical  
3 toxicity testing.

4           Maybe if I could -- it looks a little out of  
5 focus, but there could be situations where we would have a  
6 new protein expressed by a gene introduced into a plant  
7 that would be very different from the proteins that have  
8 been safely consumed. So there would likely have to be  
9 additional tests that would be done for that substance, or  
10 other new chemicals that would be in the food as a result  
11 of genetic alterations. If a new substance showed  
12 similarity to an allergen, or to a toxin, there would have  
13 to be additional testing to assure that that product was  
14 safe.

15           To give you an example, you may have heard in  
16 the news about a potato developed in Europe that contained  
17 a substance called Lectin. Lectin is a substance that, as  
18 a class, there are a number of those substances that are  
19 very toxic. If that product were presented to FDA, there  
20 would have to be extensive toxicity testing in order to  
21 establish that the substance, that the potato, was  
22 actually safe for consumers. So there can be a number of  
23 circumstances where there would be additional testing.  
24 These, of course, are just some examples.

25           I would just like to give you a sense of the

1 kind of information that is being developed on products of  
2 modern biotechnology. This is really our recommendations  
3 for foods derived from all methods of plant breeding. But  
4 it takes into account the change that has been made in the  
5 plant that is the intended change that has been made, and  
6 whether there would be any new substances introduced into  
7 the finished food by that modification, and what would be  
8 the identity structure and function of that substance? Is  
9 it, of course, safe to consume? Will it present allergic  
10 reactions to consumers? Is it a substance that is present  
11 in food at very high levels? To date, most of the  
12 substances, all of the substances, in fact, that have been  
13 introduced into food have been present at very low levels.  
14 They're enzymes.

15 Remember! FDA does not look at the pesticide  
16 substances. EPA has oversight over those. All of the  
17 substances that fall under FDA to date, in terms of new  
18 substances in food, have been enzymes. They're present at  
19 very low levels in the food. They've been shown to be  
20 very readily digestible and not similar to any known  
21 toxins or allergens.

22 There could also be nutritional changes in the  
23 food that would be important. This is an issue that is  
24 particularly important in animal feed, because animals  
25 often have a diet that consists primarily of one crop.

1 And, so, a change in the nutrition of that crop can have  
2 potential ramifications in feed use. But that, of course,  
3 could also be true in humans, a human diet. And we have  
4 to look at changed in nutrition with respect to the  
5 overall diet that people consume.

6 In addition to the intended changes, we ask  
7 companies to consider what unintended or unexpected  
8 changes might occur in the plant and ultimately in the  
9 food. It is well known, of course, that, in plant  
10 breeding, there often are unintended or unexpected effects  
11 that occur, and plant breeders take that into account in  
12 terms of the observations in bringing new varieties to the  
13 market.

14 But we have suggested some additional steps to  
15 minimize the likelihood of unexpected changes. First of  
16 all, by insuring that any inserted genetic material in the  
17 plant is stably inserted so that it's not moving around,  
18 perturbing the chromosome.

19 And secondly, companies are doing extensive  
20 analytical studies to insure that the important, or the  
21 key components of the plant, are what is expected for  
22 commercial varieties of that crop.

23 I would like to just give you briefly some  
24 examples that we have taken from some of the information  
25 that has been submitted to us. I'm going to show you

1 essentially composite information because there's quite a  
2 bit of information that we have, but just to give some  
3 examples of the kinds of things that are looked at in  
4 bringing a product to market.

5           Typically, of course, there are many  
6 characteristics, such as plant morphology, flower color,  
7 time of flowering, resistance to disease, the percent of  
8 oil and quality of protein that are observed for soy  
9 beans. And I'm using soy bean as an example because it's  
10 one of the major crops that has been developed by modern  
11 biotechnology. But these, of course, would be dependent  
12 on the type of crop and where it will be grown, and the  
13 breeder normally will do tests over several years in  
14 several different locations and field sites in order to  
15 assure that this plant is performing in the way that it's  
16 expected to perform. These are just a few of the  
17 characteristics that are taken into account during this  
18 process.

19           There are also, of course, a number of types of  
20 information that are accumulated during development based  
21 on the molecular change, that is, the change using modern  
22 biotechnology techniques. What kind of information has  
23 been introduced into the plant and is it stable? Does the  
24 plant reproduce from generation to generation in the  
25 manner that would be expected? And, of course, I've

1 already discussed the safety of new proteins, nutrients,  
2 anti-nutrients. Soy beans in particular, of course, are  
3 known to cause allergic reactions in some individuals, and  
4 companies have actually done analyses to assure that the  
5 native, or normal, allergens that are present in soy beans  
6 have not been increased in these new varieties. In  
7 addition, companies also do wholesomeness studies in  
8 feeding to animals to be sure that the animals growth, and  
9 so forth, is typical for these new foods.

10 I'm going to go through several slides fairly  
11 quickly, but I would just like to give you a sense of the  
12 kinds of information that companies submit to FDA as part  
13 of a consultation. That, of course, reflects the kind of  
14 testing that they are doing.

15 This shows what is called the proximate analysis  
16 of seed, but this is carbohydrate fat protein, and these  
17 are fiber analyses for digestibility of the seeds. And,  
18 of course, it's typical to control the product of modern  
19 biotechnology with its appropriate counterpart that is not  
20 modified. But these values are also looked at in terms of  
21 the range that is typical for this crop. Because various  
22 parameters vary considerably depending on environmental  
23 conditions, growth conditions, genetic background, and so  
24 forth. And, so, it's very important to look at these  
25 values in terms of what has been accepted commercially,

1 what is typical of this crop. Analyses are done for  
2 minerals that are typical of the crop in the same manner.  
3 Oils, or course, is very important to insure that the  
4 fatty acid composition, the composition of the vegetable  
5 oil, is what is expected.

6           The same for the proteins where the protein will  
7 be an important food ingredient derived from the soy bean.  
8 These are just a few examples of the amino acid analysis  
9 that would be done to assure that the protein quality of  
10 the protein derived from the soy bean will be typical of  
11 what is expected. And there are other substances that can  
12 affect nutrition of both humans and animals that are  
13 typical of soy beans. Analyses are also being performed  
14 on those types of substances.

15           Those are just some of the kinds of information  
16 that companies are generating to assure that these  
17 products are as safe as other foods.

18           To date, there are actually a limited number,  
19 but a growing number of crops that have been produced  
20 through modern biotechnology. There are sugar beets,  
21 canola, corn, cotton, potato, soy bean, flax, radicchio,  
22 squash and tomato. These are the crops that, to date,  
23 companies have completed food safety discussions with FDA.  
24 So you can see that actually there are some major crops,  
25 but it's also a relatively limited number of crops at this

1 time.

2 To give you a sense of what some of the changes  
3 are that are introduced into these crops, they're also  
4 limited in terms of the types of modifications that are  
5 being done. This is just the beginning of this  
6 technology. And, so, many of the crops — in fact, the  
7 majority — are herbicide tolerant; others are resistant  
8 to insects or viruses. Some have altered ripening, such  
9 as the modified tomatoes. And then there are other  
10 products, such as vegetable oils, that have been modified.

11 We have two examples where there are completely  
12 new products, in the sense that they've been modified such  
13 that they are not similar to their traditional  
14 counterpart. One is a product that is a soy bean oil that  
15 has been modified to increase one of the fatty acids  
16 that's typical of soy bean, oleic acid. And that product,  
17 that now has a very high level of oleic acid, as a result  
18 of the genetic change, is very different than soy bean  
19 oil. It's an oil that can be used for high-temperature  
20 frying without processing before it's — soy bean oil  
21 typically has to be processed before it can be used for  
22 high-temperatures. So this product is a very new product.  
23 It, of course, has a different name. It's called High  
24 Oleic Soy Bean Oil.

25 There is a second product called Lauric Canola,

1 which is a variety of canola oil in which a fatty acid  
2 lauric acid has been introduced into the canola plant, and  
3 that again produces a very different product. Lauric acid  
4 is not a new substance in food. It is found in tropical  
5 oils, such as palm oil. But the canola oil that contains  
6 this lauric acid is very different. It's not a vegetable  
7 oil that you typically think of as the bottle on the shelf  
8 in the grocery store. This oil is used in confections and  
9 coffee whiteners. It actually has a relatively limited  
10 use in food.

11 So we have two products that are fairly  
12 different. Most of the products, of course, are more  
13 typical of agriculture. It's typical for plant breeders  
14 to want varieties that resist insects and disease, and to  
15 be tolerant of other agricultural conditions. In the  
16 future, we expect to see a number of different  
17 health-enhanced varieties. But these are the products  
18 that we have seen to date.

19 I'd also like to give you a sense of the time  
20 period, and just what happens when companies bring these  
21 products to market. Usually, it is typical — what we're  
22 showing here is the time frame in months on this side  
23 (indicating), so this is 15 months, for example; and  
24 presubmission is what it says on the bottom. That really  
25 is the time that companies discuss these products with FDA

1 before they complete all of their safety assessment data.  
2 And you can see that, while it varies considerably, it's  
3 not unusual for companies to spend a year, or two years,  
4 talking to FDA. Because, what typically happens is: They  
5 come to the agency and talk to our scientists about the  
6 kinds of test they're planning to do. And that gives our  
7 scientists an opportunity to suggest different tests or  
8 modifications of the kinds of tests. In other words, to  
9 help them design appropriate kinds of testing. For some  
10 products that we have seen before, often the consultations  
11 may be very brief.

12 What we do tell companies we expect is for them  
13 to consult with us, to provide us substantial information  
14 about the testing that has been done when they have  
15 completed it, so that we have a chance to make sure that  
16 all the proper testing has been done. You can see this  
17 time frame is more in the five to several months period  
18 that FDA spends looking at the submission that the company  
19 feels is a complete package.

20 When we are satisfied that the company, in our  
21 view, based on the information we have seen, has answered  
22 all the questions, we do provide the company with a letter  
23 that says not very much. What the letter says is: We  
24 don't have anymore questions based on what we know today.  
25 And we remind the company that it is their continuing

1 obligation to insure that these products meet all the  
2 provisions of the Food, Drug and Cosmetic Act.

3 So this is the process that has been in place.  
4 This process of consultation is described on our home  
5 page. Currently, there are about 45 products that are  
6 also listed there for which companies have completed this  
7 process.

8 So, what do we expect? We expect that new foods  
9 will be as safe as the foods that are in the grocery store  
10 today. And what does that really mean? It means, of  
11 course, that the food cannot have an unimproved food  
12 additive in it. It must -- that would be an illegal  
13 product. So there cannot be a new food additive. It  
14 cannot contain a substance that would be harmful to humans  
15 or the food would be adulterated. FDA would have to  
16 initiate actions to take the product off the market. It  
17 would have to meet all the provisions of the Food, Drug  
18 and Cosmetic Act. This is what we mean when we say that  
19 the food must be as safe as today's foods that are on the  
20 market.

21 Thank you for your attention.

22 [Applause.]

23 COMMISSIONER HOLSTON: Thank you so much, Jim,  
24 for your presentation.

25 All right. We're a little ahead of schedule,

1 which is a good thing. So, right now, we are going to  
2 take a 15-minute break; and, then, when the break is over,  
3 we will begin the panel discussion on the scientific, the  
4 safety, and the regulatory issues.

5 It is now 10 minutes to 10:00 according to my  
6 clock; and, so, we are going to ask that everyone return  
7 and be back in place at 5 minutes after. Let me remind  
8 you of something that I should have reminded about before,  
9 and that is: There are no foods or drinks, including  
10 water, allowed in the auditorium. So please remember that  
11 when you return from the break.

12 Thank you.

13 [Fifteen-minute recess.]

14 SESSION 2.

15 SCIENTIFIC, SAFETY AND REGULATORY ISSUES

16 COMMISSIONER HOLSTON: Thank you very much. It  
17 is now time for our first panel, which will discuss  
18 scientific, safety and regulatory issues. I will ask each  
19 panel member to give brief opening remarks, and they will  
20 be followed by discussion among the panel members and  
21 questions from the FDA panel.

22 These are the questions we have asked to be  
23 addressed by our panelists in order to help us evaluate  
24 our current policy:

25 No. 1: Has FDA's consultation process achieved

1 its intended purpose? Based on experience to date, should  
2 this regulatory approach sunset, continue as it is, be  
3 made mandatory, or otherwise be revised?

4 No. 2: What newly emerging scientific  
5 information related to the safety of foods derived from  
6 bio-engineered foods is there, if any? Are there specific  
7 tests which, if conducted on such food, would provide  
8 increased assurance of safety for man or animals consuming  
9 these foods?

10 No. 3: What types of food products derived from  
11 bio-engineered plants are planned for the future? Will  
12 these foods raise food safety issues that would require  
13 different approaches to safety testing and agency  
14 oversight? If so, what are those approaches?

15 I am pleased to introduce our first panel.  
16 Please note that your information packet has additional  
17 biographical information about each panelist.

18 Dr. Calvin Qualset is the Director of the  
19 Genetic Resources Conservation Program, with the  
20 University of California at Davis.

21 Dr. John Fagan is the Chairman and Chief  
22 Scientific Officer with Genetic ID.

23 Dr. Philip Regal is a Professor of Ecology,  
24 Evolution and Behavior with the College of Biological  
25 Sciences at the University of Minnesota.

1           Dr. Susanne Huttner is Director of the  
2 Systemwide Biotechnology Research and Resource Program,  
3 with the University of California at Berkeley.

4           Dr. R. L. Baldwin is the Sesnon Professor of  
5 Animal Science, with the University of California, and I  
6 don't have — excuse me, one moment. I apologize.

7           Dr. Susan L. Hefle is a Research Assistant  
8 Professor and Co-Director of the Food Allergy Research and  
9 Resource Program at the University of Nebraska, Lincoln.

10           Thank you very much to all of our panelists, and  
11 now I would like to invite Dr. Qualset to open the first  
12 panel.

13           Dr. Qualset.

14           DR. QUALSET: Thank you very much.

15           I want to first congratulate FDA for having the  
16 courage and energy to carry out such discussions as we're  
17 having here, and they've had in Chicago and Washington, D.  
18 C. I think it's very important that the science community  
19 and the public all have a chance to talk about these  
20 issues in a common forum. And it's important that the  
21 regulatory agencies be aware of all of the issues.

22           I'd like just to say one thing about  
23 terminology. This discussion is dealing with  
24 bio-engineering, and is not quite the same as genetic  
25 engineering; but I think I'd like to focus this a little

1 bit more on the genetic side. In other words, that seems  
2 to be the interest here, which is that genes that are  
3 being discussed and the gene products that are produced,  
4 and how those might affect food products.

5 So, bio-engineering, of course, is a very old  
6 field and it involves modifications of biological  
7 materials after harvest. And I think that the genetic  
8 engineering part we think of as beginning with the  
9 introduction of genes into plants that will be used and  
10 expressed in products.

11 The first think I think I want to say is that  
12 all organisms are genetically modified. We have common  
13 genes, or conserved genes, through all of the living  
14 things, and many, many genes are very common in plants and  
15 animals and microbes. So we're, at first instance,  
16 dealing with the continuum of life, that we're talking  
17 about genes that are very similar and that there's no  
18 mystery there about DNA in the sequences of nucleotides in  
19 the DNA that produce, that make up genes, which, in turn,  
20 direct the synthesis of protein. So gene conservation and  
21 genetic modification is a fundamental principle that we  
22 need to remember.

23 I'd like to say something to illustrate a little  
24 more about the continuation continuum that we're working  
25 with. The plants and animals that we use as food products

1 are derived from wild species. They were domesticated  
2 through a series of processes done by early farmers and  
3 protofarmers. These resulted in dramatic changes from  
4 wild species to the domestic species, in terms of their  
5 genetics. But, remarkably, we can identify the  
6 progenitors of many of the important species.

7 The modern farmers have taken those materials  
8 developed by the early farmers and selected and modified  
9 them to suit their needs. Thus, we find different types  
10 of materials within the plants, such as wheat being grown  
11 in Turkey looks different from wheat grown in Canada or  
12 Russia. So we have these changes in genetics of materials  
13 that has been an ongoing process.

14 It was about in the 1700 and 1800s that people  
15 began to be more involved in selection and modifying  
16 plants more systematically to suit their needs. They  
17 worked within land races, which were the early lab types.

18 Then, in the 1900s, and late 1800s,  
19 hybridization was discovered as a possible way to  
20 introduce recombination of genes. And, again, with this  
21 process, you can select recombinant types that represent  
22 new things and they would be adapted to use. So the  
23 hybridization and selection process was going on, and is  
24 still going on, but has been the dominant procedure in the  
25 1900s.

1           After the Second War, when more was known about  
2 mutation and mutigenesis, mutations and induced mutations  
3 by radiation and chemicals, was used as breeding process  
4 to change the genetic material in plants without  
5 recombining through hybridization. So we had an era of  
6 interest in mutation breeding during that period and some  
7 300 or 400 different crop cultivars were developed by  
8 induced mutations.

9           It's the modern era that we need to talk about.  
10 Molecular breeding has become known as the issue of taking  
11 DNA from an organism and studying the genes and isolating  
12 parts of the gene, or all of the gene, and making sure  
13 that gene transferable by putting it into a vector. So  
14 we're know dealing with relatively highly defined genes  
15 that are transferred to crop plants that are being used in  
16 so-called genetically modified organisms. The safety  
17 issue of those genes needs to be considered not for how  
18 they were produced and how the traits were introduced, but  
19 what are the genes doing within the plant, and what are  
20 the genes doing, what do the genes do and produce in a  
21 food product.

22           So the issue of the process, using recombinant  
23 DNA, is not the issue. The issue is what does the gene do  
24 and how does it perform, and is there any inherent risks  
25 involved if we have introduced a new gene to a plant.

1 This is an issue of the safety. This is the safety issue,  
2 and I think any discussions about regulating the process,  
3 and all, are misguided and that we must continue to look  
4 at the products that are produced and how safe they are.

5 This issue of process, for example, how we do  
6 that, the FDA has established, I think, the model for  
7 development of an oversight process. Their consultation  
8 program is working. It is very comprehensive and it  
9 places the responsibility on the developers and others to  
10 make sure that the products they're proposing are safe for  
11 the environment.

12 So those are the few points that I think we  
13 should talk about some more later, but I think my time is  
14 up.

15 COMMISSIONER HOLSTON: Thank you, Dr. Qualset.

16 Dr. Fagan.

17 DR. FAGAN: Thank you for this opportunity. I  
18 really appreciate it.

19 I think that what I'd like to cover is really  
20 not to focus on the arguments regarding safety. I think  
21 you've all heard those by this meeting. You've heard  
22 those from a number of people. I'd like to focus really  
23 on another technical issue that's critical to responding  
24 to the existing situation here in the U.S. And that is  
25 the feasibility, the technical feasibility of segregation

1 and labeling and traceability of these products.

2 Just one comment on the safety is that really  
3 the same database of information is at the hands of those  
4 who think these things are safe, that need experts to say  
5 these are very safe, and the experts who say they're not.  
6 So it really doesn't come down to the science, but the  
7 personal perspective of the individual who is making that  
8 evaluation at this point.

9 There is the key point, though, that there is no  
10 consensus on the issue of the safety of these things.  
11 There's wide range of views on this, and quite  
12 conflicting, as you've experienced in the last three  
13 meetings. And it seems to me that, in the lack of clear  
14 consensus and in light of the fact that this is a highly  
15 novel approach to modifying foods, it makes sense to have  
16 very open introduction of these things. There needs to be  
17 transparency so that consumers can come to terms with  
18 these things on their own ground, instead of wondering  
19 what's out there. And this is critical to, I think, the  
20 implementation of these, that there be choice. That there  
21 be also more rigorous safety testing just, for no other  
22 reason, than to confirm the beliefs of the scientists who  
23 think these things are safe.

24 And third, in the same way, there needs to be  
25 stronger assessment of environmental impact, for at least

1 some period, so that we can really be confident of the  
2 beliefs on that level.

3 But how to respond to the concerns of consumers?  
4 One thing is certain, namely, that, by providing  
5 transparency, we will be able to deal with this in a more  
6 open and effective way, and deal with this in a way that's  
7 going to serve consumers better. What I would like to do  
8 is look at how to provide transparency.

9 First of all, labeling of genetically engineered  
10 crops or foods, all the way through the food chain, is not  
11 some hypothetical theme. It's the reality in most of the  
12 industrialized world. If you look to Europe, you see that  
13 this is the case in virtually every country. There's a  
14 law that requires engineered foods to be labeled, and it's  
15 successfully operating. The same way in Japan and in  
16 south — in Australia and New Zealand, there are laws in  
17 place. In other areas around the world, laws are coming  
18 into being. So it's happening. So it can be done.

19 In terms of the technical feasibility, there are  
20 three things to consider. One is the ability to  
21 segregate; the second is the ability to monitor, which is  
22 testing; and the third is the ability to actually have a  
23 traceability system that allows this process to be  
24 verified. And, as it exists now, all of those are in  
25 place around the world.

1           We have considerable experience in the testing  
2 area. And what we find is that the methods that we use  
3 are common to testing methods that are being in more than  
4 40 laboratories across Europe. The methodology has been  
5 verified by the European Commission as being effective.  
6 Similarly, in Japan, there are a score of labs that are  
7 doing this kind of testing. So the feasibility is there  
8 and it's really part of the market system at this point.  
9 In fact, American food industry is already testing,  
10 segregating and delivering non-GM, verified non-GM, and  
11 verified genetically modified products to Europe and  
12 Japan. In order for them to export, at this point, they  
13 have to do it. So it isn't a question of can it be done;  
14 it's a question of whether we choose to do this in America  
15 in the same way that we're doing for consumers in other  
16 areas of the world. So it's a very feasible thing on that  
17 level.

18           Going on to the key thing here in traceability,  
19 identity preservation systems are the norm in organic  
20 agriculture. They're also what is really put in place by  
21 the biotech agricultural systems in order to segregate the  
22 value-added products that are going to be coming down the  
23 pike right now. There are already some biotech products  
24 being segregated in this way. And, of course, this is  
25 being done now for genetically -- for nongenetically

1 modified things for export around the world. It can be  
2 done here.

3 The common approach is to establish a threshold.  
4 This is the basis of law in Norway, throughout the EU, in  
5 Switzerland, in Australia, Japan, all of these places,  
6 set a threshold. Testing verifies that a product is above  
7 or below that threshold. The testing works very  
8 effectively. I won't have time to go into that, but it  
9 is.

10 There is one critical point here; and that is:  
11 Generally, the thresholds have been in the 1 to 2 percent  
12 range. These are thresholds that are not satisfying to  
13 consumers. And consumers across Europe, for instance, are  
14 now pressuring for lower thresholds in the more, in the  
15 range of 0.1 percent. Just last week, the European  
16 Parliament made an announcement that they will reconsider  
17 legislation in this area looking to lowering the  
18 thresholds and making the system more stringent.

19 So I encourage us, here in American, to really  
20 look to the future and establish a program that's going to  
21 serve consumers.

22 Second, look to the future to a program that  
23 will serve the food industry. What has happened in Europe  
24 is that, because legislation laid far behind the  
25 implementation of the technology and the needs of

1 consumers, the food industry was caught between a rock and  
2 a hard place. If they had had government support,  
3 regulatory support, to allow them more effectively to  
4 deliver what they needed to deliver to consumers, there  
5 would have been hundreds of millions of dollars saved, and  
6 it would have saved a lot of, you know, ulcers and this  
7 sort of thing, as well.

8 So a more rigorous program that serves both the  
9 consumers and the food industry is a thing that's critical  
10 here. And, really, having worked with the food industry  
11 in this testing area, it has become so clear to me that  
12 the industry has been in a very difficult position because  
13 lack of, because of lack of regulation and guidance from  
14 government regarding segregation, testing, labeling, these  
15 sorts of things. If you put something in place long-term,  
16 it will facilitate commerce around the world in this area.  
17 And it will bring America up to the international standard  
18 with regard to this issue, which is the standard requiring  
19 labeling, requiring segregation, and serving the consumer  
20 in a way that hasn't been done here in a manner that is  
21 more transparent.

22 Thank you very much.

23 COMMISSIONER HOLSTON: Thank you, Dr. Fagan.

24 [Applause.]

25 Dr. Regal.

1 DR. REGAL: Thank you very much for the  
2 opportunity to explain why I believe that the mandatory  
3 testing and labeling of genetically engineered foods is  
4 necessary. And also the opportunity to explain why, after  
5 15 years of trying to work with government agencies, I've  
6 recently joined the lawsuit to ask the courts to require  
7 mandatory labeling and testing of genetically engineered  
8 foods. It was not an easy decision for me.

9 I began studying this issue back in 1984. I  
10 organized the first conference that brought together  
11 molecular biologists and leading ecologists and government  
12 scientists, and we held it at Cold Spring Harbor. We had  
13 to Nobel prize winners there, and so on and so forth. And  
14 after that, I organized conferences for the Environmental  
15 Protection Agency, for the National Science Foundation,  
16 for the American Association for the Advancement of  
17 Science, for the Ecological Society of America. I've been  
18 to dozens of other conferences on bio safety, and I've  
19 published key papers in these areas.

20 President Reagan's head of the Basic Sciences  
21 Coordinating Committee, David Kingsbury, asked me to  
22 continue my work and to continue to publish and try to  
23 inform scientists about the various risks. After  
24 Kingsbury left his position, the effort to have in-depth  
25 studies of the risks petered away in Washington, D. C.

1 Basically, there was no continuity on that.

2           So I'd like to say that, what I've seen since  
3 then, and, well, actually, to some extent, even before  
4 that, is a tendency to try to minimize the risks, and to  
5 try to deal with the incredible problems that genetic  
6 engineering presents with slogans and simplifications.  
7 And we've seen an effort, by industry, to get into the  
8 official documents very vague terms, scientifically vague  
9 terms, like familiarity, substantial equivalence, and the  
10 notion that genetically engineered organisms are not  
11 different in their purposes from traditional breeding, and  
12 don't present any additional sorts of problems.

13           What I've seen in this process of simplification  
14 is the industry, and its supporters, painting themselves  
15 into a corner. If you don't, if you oversimplify these  
16 problems, you give the impression that you don't know what  
17 they are; and, then, the public is not going to trust you  
18 to be screening thoroughly. And other scientists, such as  
19 myself, are not going to trust the genetic engineers to be  
20 screening thoroughly. You would not trust a doctor who  
21 says that there side effects are all a bunch of nonsense,  
22 or whatever. You know, if you can't speak intelligently  
23 about side effects, you shouldn't trust that doctor. But  
24 that's what we're getting. We're getting a lot rhetoric  
25 that there are no particular dangers here.

1 I'll just give you a few comments.

2 I consulted for a company that was putting the  
3 genes for spider venom and scorpion venom into corn and  
4 potatoes and soy beans, and so on and so forth. I think I  
5 talked them out of it. But, you know, they had really  
6 convinced themselves that, just because these venoms were  
7 not toxic to mammals, that they didn't present any special  
8 problems. And I think I talked them out of it for  
9 scientific reasons, because there are all sorts of other  
10 problems that need to be considered and not just public  
11 relations. But they had really -- this rhetoric had  
12 worked at their minds and they spent several million  
13 dollars doing this, and it was probably a very big  
14 mistake.

15 This is -- you've heard a lot of science, I  
16 assume, in the previous panels; but maybe I can just  
17 quickly point out that we've already had surprises. Some  
18 remarkable things are happening with this new technology.  
19 Some of them have been in the newspaper and will be  
20 familiar to people. You know, it was a surprise that the  
21 pollen from genetically engineered plants was more  
22 powerful, by 20 to 1, than the pollen from normal plants  
23 in pollinating. There was a competitive advantage. No  
24 one expected that. That was a surprise.

25 It was a surprise to the people at Pioneer

1 Hybrid that the one gene from Brazil Nut would carry the  
2 allergen to soy beans. They didn't expect that. They had  
3 to destroy a lot of soy beans. They found out about that  
4 very late.

5 It was a surprise that the Klebsiella bacteria  
6 that was genetically engineered and they found out that it  
7 turned wheat into slime. It killed the plants. No one  
8 expected that. They were at the verge of releasing it and  
9 they had to do other sorts of tests, by luck, more or  
10 less.

11 We know about all sorts of really odd side  
12 effects in genetically engineered organisms. You've  
13 genetically engineered growth hormones into rats and the  
14 growth hormones produced all sort of brain tissue, but not  
15 the hypothalamus or the pituitary. There are patented  
16 transgenic salmon out there right now that are producing  
17 growth hormones not in their brains like other vertebrates  
18 do, but in their livers. I'm not saying that's dangerous.  
19 But you don't expect these sorts of things with normal  
20 breeding. There's some radical changes.

21 Now I've discussed why the processes are  
22 different in my scientific publications, and some of them  
23 are out there. And we could sit down and, you know, with  
24 a blackboard and I could go through some of these reasons.  
25 But the point is that there are still surprises. It's not

1 — the traditional breeders would not be used to. I think  
2 it was — whether or not the Monarch is endangered, it's a  
3 surprise that toxins are produced by pollen, you know.  
4 And it's very interesting that the different BT types of  
5 corn are producing different levels of this toxin. There  
6 are things out there that — this is still an experimental  
7 technique.

8 Well, in the case of foods, of course, what  
9 we're concerned about is that some of these surprises may  
10 end up with changing biochemical pathways. These are  
11 delicately balanced biochemical pathways.

12 You might — a lot of the examples I've just  
13 given you, you would look at it, and you might say: Well,  
14 this salmon, or this plant looks just like any other  
15 plant; but, when you get into it, there are weird things  
16 going on with its biology. So we need, we need this  
17 testing.

18 Again, I want to stress the fact that the  
19 rhetoric, the basic rhetoric, is dangerous. When we say  
20 things about it being no different from traditional  
21 breeding, it makes the public and the scientific community  
22 doubt that the people who are dealing with it know how to  
23 deal with it. It's really clear to me, as a university  
24 scientist, when I talk with genetic engineers, when I talk  
25 with molecular biologists, they cannot talk knowledgeably

1 about the risks. That's not part of their training. You  
2 can look at their textbook. Their textbooks do not  
3 include — they tell them how to build these things; but  
4 they don't have chapters about safety that are meaningful.  
5 They're very, very thin.

6 So there's nothing in their training, there's  
7 nothing in their public comments, and there's nothing in  
8 their conversation that suggests that there's a community  
9 of people being built out there who are well prepared to  
10 deal with these risks. And, so, I — it's part of their  
11 culture, I suppose you might say, to try to minimize an  
12 impression that there are risks, and they've talked  
13 themselves into that. And I think, if pressure doesn't  
14 come from the government, that that will continue, and I  
15 think it's going to continue a very unstable situation. I  
16 don't want to see that. Genetic engineering for the rest  
17 of our lives, and I just don't want to see the present  
18 situation continue.

19 COMMISSIONER HOLSTON: Thank you, Dr. Regal.

20 [Applause.]

21 Dr. Huttner.

22 DR. HUTTNER: Thank you very much for inviting  
23 me today, and thank you especially for bringing this  
24 meeting to California and the Bay Area. To allow our  
25 remarkably diverse community to address this issue is

1 important. I think you'll know, if you visit our  
2 restaurants and our local fresh markets here in the Bay  
3 Area, food, small farms, and organic farms are an  
4 important part of our culture. It's important that people  
5 have an opportunity to discuss these kinds of issues so  
6 that they can make decisions. So thank you for coming  
7 here to the Bay Area.

8 As Director of the Systemwide Biotechnology  
9 Program at the University of California, I have a couple  
10 of jobs. One is, quite frankly, to promote research in  
11 molecular biology, and a good portion of that is in  
12 agriculture, plant sciences and understanding better the  
13 relationship between plants and diseases and pests.

14 Another important part of my role, though, is to  
15 promote research and communication on issues related to  
16 the impact of biotechnology in the public arena. And in  
17 that context, I've had the pleasure of working with food  
18 leaders in the Bay Area, several years ago, discussing  
19 just this issue about the time when the BST controversy  
20 was really hitting the headlines. What I've learned from  
21 that is that most people in the Bay Area, who are  
22 concerned about biotechnology, have very sound concerns  
23 related to their professional and personal interest in  
24 food safety. And, so, I thank you for allowing them to  
25 talk about this; but, most importantly, to recognize that

1 we're facing a serious information gap.

2           The views about biotechnology becomes so  
3 polarized that people are simply trying to sort it out and  
4 are left without sound information to make decisions.  
5 There's a huge role for the Food and Drug Administration  
6 to play in that context. I wanted to emphasize that at  
7 the very outset, before I address the questions.

8           Your first question was about whether or not the  
9 consultation process achieved its intended purpose. And,  
10 in my view, it has. It will continue to do so, and I  
11 encourage you to continue it as it's currently structured  
12 and implemented.

13           What is important about the current structure is  
14 that it lays out, in the 1992 policy statement, a  
15 scientifically sound and transparent set of guidelines for  
16 food producers. It enables them to understand the key  
17 issues of food safety that they have to address and how to  
18 go about addressing it. I think the decision phase is  
19 particularly important, and I encourage anyone who hasn't  
20 looked at it on the FDA web site to do so.

21           The other thing that's very important about the  
22 1992 policy statement is that it built the appropriate  
23 historical context. It's looking at all genetic  
24 modification techniques. It acknowledges the fact that  
25 all the food that we eat is genetically modified. In

1 fact, all the food we've eaten all our lives, that our  
2 parents have eaten and our grandparents have eaten, and so  
3 on, it's all been genetically modified just by various  
4 kinds of techniques.

5           So, when you're judging the risks associated  
6 with genetic modification, you have to consider it in the  
7 context of what we know about other kinds of genetic  
8 modifications that have been made in food, and what kinds  
9 of risks were involved with them, and what kinds of  
10 benefits were involved with them.

11           If I could have the first slide.

12           In California, we're all used to seeing, during  
13 the summer, semi-truckloads of red, ripe tomatoes. But I  
14 think many consumers would be surprised to find out that  
15 our modern tomato is derived from an ancient predecessor  
16 that was a tiny berry. In fact, it was quite toxic, very  
17 bitter. It took literally hundreds of years of selective  
18 breeding that is genetic modification that we have the  
19 modern tomato.

20           The same thing — next slide — for modern corn.  
21 I'm sure many people don't know that modern corn is  
22 derived from a very fragile grass. It was only through  
23 selective breeding, originally by indigenous people, like  
24 Native Americans, that have brought us the kinds of corn  
25 that we have today, with increased numbers of kernels and

1 large kernel size. This is the kinds of genetic  
2 modification that's going on in virtually all aspects of  
3 our food supply. It's occurred gradually over hundreds of  
4 years. Eventually, plant breeders and scientists came to  
5 understand the molecular basis for this kind of  
6 improvement in plants, and they've been able to take  
7 advantage of it better.

8 Many people also don't understand that genetic  
9 modification is actually a cornerstone of organic farming.  
10 Through genetic enhancement of a plant's ability to  
11 withstand pests and disease, you can reduce the implicit  
12 chemical pesticide. Without genetic modification, it  
13 would be very hard to have organic farming.

14 Even with this broad range of genetic  
15 modification techniques that have been widely used, what  
16 we all know from our personal experience is that the  
17 American food supply is remarkably safe. Yet, today's  
18 biotechnology message, which really fall on a continuum  
19 with these older, more familiar methods, are getting an  
20 enormous amount of attention these days. It's unfortunate  
21 that they're being painted in such stark and contrasting  
22 terms. It makes them seem very new and unfamiliar when,  
23 in fact, when you look at the products that are  
24 development in research laboratories across the United  
25 States, the R&D is quite familiar. They're approaching

1 the same kinds of goals that plant breeders have  
2 traditionally approached in trying to enhance the  
3 production, the quality, of the plant that's going to be  
4 used in farming, or the nutritional characteristic of the  
5 food that's going to be introduced into the marketplace.

6           There are two major differences, though, with  
7 the new techniques. One is precision, and the other is  
8 flexibility. Precision in the sense that you can make  
9 changes one gene at a time, compared to traditional  
10 breeding techniques that randomly intermix hundreds of  
11 thousands of genes from each of two parent plants.  
12 Flexibility in the sense that you can utilize genes  
13 anywhere you find them in nature. Those are the two  
14 issues that really bear our attention when we consider the  
15 FDA's approach to food safety.

16           I'd like to bring to your attention that the  
17 scientific community has been looking at the nature of  
18 risks associated with products made with these new genetic  
19 techniques. More than a decade ago, the National  
20 Academies of Science, then two years later the National  
21 Research Council, convened panels that came to the  
22 conclusion that the risks associated with products of the  
23 new genetic techniques are essentially the same kinds of  
24 risks associated with products of older genetic  
25 techniques. That's not to say that the products of the

1 new genetic techniques are inherently safer. What it  
2 means is that the risks are similar, and, so, we can  
3 manage them using the same kinds of food-safety systems  
4 that we've used for foods that were produced using more  
5 traditional methods, more familiar methods. That's the  
6 foundation on which the Food and Drug Administration's  
7 policy is built, and it's a scientifically sound  
8 foundation.

9 I do not believe that the consultation process  
10 should be made mandatory, for two reasons: (1) is  
11 diminishing returns; and (2) is cost. Because there has  
12 been no evidence of unique risks stemming from genetically  
13 engineered organisms or foods, and because these risks  
14 have been judged the same as those involved in other  
15 genetically modified products, and they can be managed  
16 using our existing system, there can be no incremental  
17 benefits to the public for any additional regulatory  
18 requirement.

19 In addition, we have to consider that regulatory  
20 requirements do add cost to the development of food. Cost  
21 is particularly important to small businesses in  
22 California, to farmers who grow small acreage crops, and  
23 the consumers who are poor. So, for those reasons, I  
24 don't recommend making this process mandatory. It's  
25 working very well the way it is right now, and you have a

1 good deal of information that's available and will  
2 continue to be made available by companies.

3 The second question that you addressed was:  
4 What newly emerging scientific information related to the  
5 safety of foods derived from genetic engineered plants?  
6 Is there any?

7 Well, I consulted with the Centers for Disease  
8 Control, and I couldn't find any evidence of anybody being  
9 made sick by having eaten a genetically engineered  
10 product, or a product containing substances from  
11 genetically engineered plants. Now that's important  
12 because the answer has very broad exposure in the U.S.  
13 food supply. Literally millions of people have eaten the  
14 products of genetic engineering over the last decade, or  
15 so, and there isn't a single instance of someone being  
16 made sick by these products.

17 In addition, the U.S. Department of Agriculture  
18 has undertaken extensive analysis of more than 5,000 field  
19 trials of genetically engineered plants. This is  
20 available on the web, if you're interested, at the USDA  
21 web site. They have the data they've collected. The  
22 problem is it's difficult to read, even if you're a  
23 scientist. Something has to be done to make that more  
24 accessible to the public.

25 In addition, the European Union has invested

1 more than 40 million Euros in biosafety assessments, both  
2 on environmental questions and on food safety questions.  
3 And in none of this research have any unusual problems or  
4 risks been uncovered. Taken altogether, and added to our  
5 experience with literally billions of genetically  
6 engineered organisms used in biomedical research and in  
7 the biopharmaceutical industry, that sets a very high  
8 standard for judging safety issues of biotechnology, and  
9 it lends strong support to the FDA approach.

10 Now what FDA has done, with that as background,  
11 is said: What are the most important issues for food  
12 safety? And they say there's four things, and they make  
13 amino acid a lot of sense: Allergenicity; toxicity;  
14 changing nutrients or fats in the food; and — this one is  
15 specifically related to the flexibility of the new genetic  
16 techniques — the introduction of substances that are new  
17 to the food supply that's something that we don't have a  
18 history of safe use for in the food supply. In that case,  
19 it's going to be treated very rigorously by the agency, as  
20 if it was a chemical food additive, and subject it to  
21 pre-market regulations, as Dr. Maryanski described.  
22 That's a sensible approach to food safety. It addresses  
23 the common issue that are important to all of us as  
24 consumers. And, at the same time, it doesn't add  
25 additional burdens that could in any way distance people

1 from the benefits of our new knowledge in the genetics of  
2 plants and food.

3           The third question is more open-ended, and  
4 that's: What types of new products are going to be coming  
5 forward? What kinds of new plants are going to be made?

6           Well, the fact is, the National Science  
7 Foundation has launched a major initiative called the  
8 Plant Genome Initiative. It's going to, over the next  
9 several years, identify a very large number of important  
10 genes in plants. And, as we gain that information, we're  
11 going to be in a better position to engineer the metabolic  
12 systems of plants to increase their ability to withstand  
13 pests and disease and to make them more nutritious. So  
14 the number of new products that are going to come out will  
15 expand rapidly as our knowledge grows. But I don't  
16 anticipate that you're going to see many new and entirely  
17 novel products that they would introduce new kinds of  
18 risks. But it's worth asking the question repeatedly as  
19 new products are coming forward.

20           The most important role, as I said at the  
21 beginning, for the Food and Drug Administration is not in  
22 regulating risk that people could perceive as being real;  
23 but, instead, recognizing that people know very little  
24 about the fact that genetics plays an important part in  
25 the food supply, and always has. And they deserve to

1 understand better how genetic modification has been  
2 overseen to insure that the food supply is safe, even  
3 though the Food and Drug Administration has never  
4 regulated it, ever. They also need to understand better  
5 the biosafety work that has been done both in the United  
6 States and in Europe, and other countries.

7 Now I, for one, being from the academic  
8 community and the scientific community, am willing to  
9 admit that we've done a lousy job of making this clear to  
10 consumers. We need to work better at that. We need to  
11 make this simpler to understand. These assessments should  
12 not be so opaque that only other scientists can understand  
13 them.

14 In addition, I think it's important that the FDA  
15 acknowledge the important role that other layers of  
16 oversight, outside the government, have played in insuring  
17 the safety of our food supply. In fact, there are  
18 standard practices that have been applied by food  
19 manufacturers and plant breeders for decades, that have  
20 participated in a very meaningful way in insuring safety.

21 And finally, anyone who read the *New York Times*  
22 saw that article on functional foods. As we move into an  
23 era of functional foods, consumers are going to be  
24 increasingly presented all sorts of claims, health claims,  
25 about what kinds of health benefits these functional foods

1 can provide to them. They're going to need much more  
2 information about the role of food ingredients in health,  
3 not just in nutrition, but making them better able to ward  
4 of cancer and heart disease and other important diseases.

5 This is just an incredibly important time in the  
6 life sciences. I think we need to continue the kinds of  
7 dialogue that your opening up here and through this  
8 series, and recognize the public has a right to know.  
9 But, at the same time, we have to be cautious not to  
10 pursue public opinion as the basis for public policy; but,  
11 instead, address risk, given the best scientific attention  
12 we can and explain it.

13 COMMISSIONER HOLSTON: Thank you very much, Dr.  
14 Huttner.

15 [Applause.]

16 Dr. Hefle.

17 DR. HEFLE: Again, thank you very much for the  
18 opportunity to come and speak today.

19 I'm a food toxicologist, and my research areas  
20 are in the interest food allergies and sensitivities and  
21 naturally occurring toxicants in foods. I want to talk  
22 specifically about the safety assessment that's currently  
23 done for genetically modified foods.

24 In my opinion, genetically modified foods are  
25 safe for consumption by anybody and all people. These

1 foods are thoroughly tested by the developers using  
2 appropriate and adequate methods to address safety  
3 concerns. The current FDA consultation process insures  
4 that genetically modified foods are appropriately tested.  
5 The process has been used by every developer, for every  
6 case, even though it is not mandatory. I think this will  
7 continue. The process has worked and worked with success.

8 Now a few comments in particular.

9 The methods used to assess toxicological  
10 concerns of genetically engineered foods are appropriate  
11 and adequate. These methods are the same ones that have  
12 served us very well for many years for food toxicological  
13 concerns, such as testing of preservatives and sweeteners.

14 Toxicological tests targeted to the novel  
15 protein are most appropriate, and those are the ones that  
16 are currently used. Not for whole foods, for example.  
17 Whole food testing is not warranted, is not feasible, and  
18 would be wasteful in terms of laboratory animal resources.  
19 In addition, the inadequacies of single-food animal diets  
20 can cloud the interpretation of results.

21 Now a few comments about the methods used to  
22 address concerns about allergenicity. The current methods  
23 are appropriate and adequate for addressing concerns about  
24 the transfer of known allergens and also possible new  
25 allergenic commodities. If the novel protein is derived

1 from a known allergen, it must be assessed for  
2 allergenicity. The developers are keenly aware of the  
3 obligations to do this assessment and would conduct  
4 appropriate and adequate tests in this situation. My  
5 personal experience with developers is that they are very  
6 acutely aware of the toxicological and allergenicity risks  
7 associated with genetically modified organisms, and do  
8 everything in their power to assure safety.

9 For example, such was the case of the Brazil Nut  
10 protein cloned in the soy beans. Because of the testing  
11 that was done to assess allergenic concerns, the product  
12 development and plans to market were dropped. Plainly and  
13 simply, the system worked. That product, though destined  
14 only for animal feed, was not allowed into the  
15 marketplace.

16 The assessment of novel proteins of unknown  
17 allergenic history is also preformed using appropriate and  
18 adequate methods. To date, all genetically modified  
19 products are of this type and rigorous testing for  
20 possible allergenic concerns has been performed to assure  
21 that these novel proteins are quickly digested and bear no  
22 resemblance to any known allergen, whether it be food,  
23 drug, venom, or inhalant. There are millions of proteins  
24 in food, but only a few hundred of which are allergens.  
25 Given the low expression level of novel proteins in most

1 genetically engineered crops, this makes the risk of any  
2 of these novel protein becoming allergens exceedingly  
3 small.

4           There is no history of increased allergenicity  
5 of traditionally bred crops, and we expect therefore none  
6 was genetically modified crops. It is my opinion that  
7 there is a much greater allergenic risk with traditional  
8 breeding methods, rather than the precise method of  
9 genetic modification. In fact, as Dr. Huttner said, we  
10 have seen no untoward allergenic or toxicologic, for that  
11 matter, responses to the genetically modified foods that  
12 are on the market.

13           It is neither practical nor feasible for FDA to  
14 perform toxicological and allergenicity testing. This  
15 responsibility and obligation should remain with the  
16 developers. The process in place now is adequate, but  
17 needs to be dynamic. As our base of knowledge expands,  
18 and as we know more, the assessment scheme should  
19 encompass and select new pertinent information. For  
20 examples: If validated animal models for allergenicity  
21 become available, they should be considered for possible  
22 exclusion in the assessment scheme. Further discussions  
23 should be encouraged and developed.

24           Thank you.

25           COMMISSIONER HOLSTON: Thank you very much, Dr.

1 Hefle.

2 [Applause.]

3 And our last panelist, Dr. Baldwin.

4 DR. BALDWIN: Thank you very much for allowing  
5 me, on behalf of the Federation of Animal Science  
6 Societies, to present a couple of observations.

7 A bit about myself: I work at the University of  
8 California at Davis in the Department of Animal Science.  
9 I do a lot of work — I'm basically a nutritionist. I do  
10 a lot of work on digestive physiology and metabolism of  
11 animals.

12 The Federation of Animal Science Society is a  
13 professional organization made up of approximately 10,000  
14 scientists in academia, government and industry. This  
15 society exists to serve society through the improvement of  
16 all aspects of food animal production. FASS represents  
17 the combined memberships of the American Dairy Science  
18 Association, the American Association of Animal Science,  
19 and the Poultry Science Association. I will comment on  
20 behalf of FASS on newly emerging scientific information  
21 related to the safety of feeds and animal products derived  
22 from genetically modified crops.

23 It's been estimated that the supply of food  
24 required to adequately meet human nutritional needs over  
25 the next 40 years is quantitatively equal to the amount of

1 food previously produced throughout the entire history of  
2 humankind. This poses a daunting challenge to agriculture  
3 for several reasons:

4 First, virtually all land suitable for  
5 cultivation worldwide, exclusive of environmental  
6 constraints, is currently being farmed. Thus, the only  
7 feasible means of feeding the world population is  
8 development of new technologies that enhance food  
9 production and including the production of livestock  
10 products, which add to the total supply of high-quality  
11 human food.

12 Genetic modification of crops used by livestock  
13 has been conducted for many years, as mentioned by  
14 previous speakers. The livestock feed supply is increased  
15 markedly over the past 40 years because of new plant  
16 varieties and high yielding hybrids were developed.

17 Recently, crops used in livestock production  
18 have been improved using biotechnology. These products  
19 are emerging in the marketplace. Both conventional and  
20 biotechnology techniques have benefitted agriculture.  
21 Corn grain, corn silage, corn stover and soy beans from  
22 genetically modified crops commonly fed to livestock have  
23 been compared with conventional feeds to determine effects  
24 on feed composition, digestibility and animal responses.  
25 Chickens, sheep, beef cattle and dairy cattle have been

1 used in this research.

2 Data collected clearly indicates that the  
3 chemical composition of genetically modified and  
4 conventional feeds are substantially equivalent and are  
5 within the normal range of values reported in the  
6 literature. These data indicate that intakes,  
7 digestibilities, nutrients absorbed, growth, milk  
8 production, milk composition and the health of livestock  
9 fed genetically modified and conventional food are  
10 equivalent.

11 The digestive processes in all livestock break  
12 down the nutritional components of feeds, reducing  
13 proteins to amino acids and DNA to nucleic acids. The  
14 latter are then excreted. In fact, extensive data show  
15 that livestock afford considerable protection for the  
16 human food supply by degrading, detoxifying, or otherwise  
17 discriminating against potential toxicants in foods.  
18 Examples of this include Strontium 90, microtoxins,  
19 phosphorous-based pesticides and undesirable proteins in  
20 feeds. Because components of feeds are broken down into  
21 smaller components during digestion, novel plant proteins  
22 have not been detected in milk and would not be expected  
23 in either meat or eggs. Available data and our  
24 understanding of nutrient digestion, absorption and  
25 metabolism indicate that genetically modified feeds are

1 safe for livestock to consume. In addition, the food  
2 products from livestock consuming these feeds are safe and  
3 often may be safer for human consumption than unaltered  
4 feeds, from animals fed unaltered feeds. This will be a  
5 benefit to the nutrition and wellbeing of the world  
6 population, especially to children in developing  
7 countries.

8 FASS strongly recommends that the scientific  
9 basis of the consultation process for acceptance of  
10 genetically modified feeds for livestock be continued.  
11 FASS endorses the use of biotechnology techniques to  
12 improve agricultural plants and animal products. FASS  
13 believes the agricultural biotechnology has the capability  
14 to improve the supply of livestock feeds and healthful  
15 animal and plant products, and thereby help meet the  
16 nutritional needs of the world's population.

17 Just in closing, I'd like to thank you again for  
18 the opportunity to provide this testimony. I think it's  
19 very important to note that we have the safest food supply  
20 that humankind has ever witnesses. Moreover, we live in a  
21 time when the greatest proportion of our population ever  
22 has the luxury of dying of old age diseases. I think this  
23 speaks volumes about the effectiveness of the agencies  
24 responsible for assuring the safety and wholesomeness of  
25 our food.

1           If we can be of further assistance in the  
2 future, feel free to call upon us. Thank you.

3           COMMISSIONER HOLSTON: Thank you, Dr. Baldwin.

4           [Applause.]

5           COMMISSIONER HOLSTON: I'd like to thank all of  
6 our panelists for their statements. And now I am going to  
7 open the rest of this session to our FDA panel to pose  
8 questions to our panelists. You may direct your questions  
9 to any of them, as individuals, or to the entire panel.

10           Who would like to like to begin? Bob.

11           MR. LAKE: I would like to address this  
12 question, I guess, basically to Dr. Regal. Although, if  
13 anyone else wants to respond to it, that's okay, too.

14           I heard you express a lot of concern about  
15 unexpected effects. I guess one of the questions I have  
16 is to what extent are you concerned about those  
17 bioengineered crops that are currently in the marketplace  
18 versus to what extent are you worried about what might  
19 happen in the future? If you could sort of elaborate on  
20 that a little bit ...

21           DR. REGAL: You know, I have some concerns about  
22 the present crops, but I'm mostly concerned about the  
23 future. Because the techniques are getting more and more  
24 powerful and people are getting more and more ambitious.  
25 They're putting more — you know, this is only the first

1 generation of corn, and they'll take those same strains of  
2 corn and engineer them over and over. Every time the  
3 insects evolve resistance to the BT, they'll put something  
4 else in, and then something else, and then something else.  
5 And, so, we're going to see continual modification of  
6 these and they'll be more ambitious putting in whole  
7 segments of genes.

8 But I am concerned about the present food  
9 supply. I'm concerned about some of the, some of the  
10 comments that I've heard here.

11 You know, we've been told that all of these  
12 foods are thoroughly tested. And then we also have been  
13 told that it would be too expensive to test all foods.  
14 Now there's a contradiction there somewhere, it seems to  
15 me. If they're all being thoroughly tested, then why is  
16 it too expensive to do it?

17 We've also heard that no one has been injured by  
18 the presently genetically engineered foods. Well, how  
19 could we possibly be know that if they're not labeled? I  
20 mean, people are getting allergies and dying and getting  
21 sick all the time. And if you don't know what you're  
22 eating, there's no way to trace that. There's no way that  
23 epidemiologists can work with that.

24 In the case of the L-Tryptophane, those batches  
25 that showed danko produced could be traced, and so the

1 problem could be stopped. But as things are presently,  
2 there's no way an epidemiologist could ever give the kinds  
3 of answers that we would like to have so that we could, we  
4 can improve the process of genetic engineering into the  
5 future.

6 Is that helpful?

7 MR. LAKE: Yes, it is. Thank you. I just  
8 wondered if any of the other panelists wanted to comment  
9 in particular about the existing food, as opposed to what  
10 we might see in the future?

11 Go ahead.

12 DR. FAGAN: It seems to me that the problem of  
13 traceability is a critical thing. Without that, there's  
14 no way to — it would have to be an acutely toxic effect  
15 to be able to identify a problem, or link a problem, to  
16 one of the genetically modified crops that's in the  
17 marketplace right now. When you've got a product that  
18 contains 5 percent soy, you may not see that for some  
19 period of time, or it may be something you eat that you  
20 don't even notice is in the product under normal  
21 conditions, reading labels, and that sort of thing. So  
22 there needs to be better traceability this way.

23 DR. HUTTNER: On the issue of whether or not the  
24 foods should be thoroughly tested, I think one of the  
25 perplexing problems is that the appropriate baseline is

1 all food. It's food produced by other kinds of genetic  
2 methods. And the fact is, because these foods have not  
3 historically been tested for their safety, we lack that  
4 baseline. And it's going to be fairly expensive to  
5 develop it. If you decide to go in that route, that is  
6 the data that you're going to have to collect. The  
7 corollary to that is that moving in that direction would  
8 definitely lead us to a profound difference in the way we  
9 oversee food safety and the role of the federal government  
10 in that. I think you need to take that into  
11 consideration.

12 DR. HEFLE: I'd like to make a comment to Dr.  
13 Regal's comment on food allergies. We are not seeing the  
14 prevalence of food allergies increasing at all, and there  
15 are ways of determining it. For example, if a genetically  
16 modified crop was suddenly responsible for a lot of  
17 allergic reactions, there are ways of figuring that out.  
18 We can figure that out. So that would be traceable.

19 DR. REGAL: I know you don't want a debate, but  
20 I would like to point out that I have seen information  
21 from England that the allergies to sooy beans have  
22 increased 50 percent. And, you know, the article, the  
23 editorial, in the *New England Journal of Medicine* that  
24 warned about allergies in genetically engineered foods,  
25 following the Brazil Nut episode, suggested it's not going

1 to be as easy to test for some of these things as you're  
2 indicating. So I think this worth a deeper discussion.

3 COMMISSIONER HOLSTON: And we would like to have  
4 that discussion —

5 DR. FAGAN: It should be pointed out —

6 COMMISSIONER HOLSTON: — but not here.

7 [Laughter.]

8 DR. FAGAN: Can I just, can I just make one  
9 fairly relevant point here?

10 COMMISSIONER HOLSTON: All right.

11 DR. FAGAN: That is that, as was pointed out  
12 earlier, it should be possible to detect all these  
13 allergens based on the regulations that the FDA now has.  
14 But, in fact, if you look at the system, there's a huge  
15 loophole as it now exists. It says that, if a novel  
16 protein from a known allergen is used, or a gene from a  
17 new allergen, if such a thing is used, it must be — you  
18 must test for allergenicity. But if there is no history  
19 of safe — history of use as a food, we have no evidence  
20 as to whether it's allergenic or not. And according to  
21 the current guidelines that you give to developers, they  
22 actually are not required to assess that. Therefore, I  
23 would say, since a large proportion of the genes that are  
24 being put into foods today are from plants, or from  
25 organisms that are not part of the food supply, we, in

1 fact, have no way of assessing and no regulatory impetus  
2 to assess the allergenicity of these things. This is a  
3 big gap in whether it's mandatory or voluntary, as it now  
4 is. At least that gap should be filled.

5 COMMISSIONER HOLSTON: Thank you. Panelists?

6 COMMISSIONER PLAISIER: I have a question.

7 COMMISSIONER HOLSTON: Melinda.

8 COMMISSIONER PLAISIER: This is for Dr. Baldwin.

9 Dr. Baldwin, I heard you say that animals fed  
10 genetically modified feed may actually be safer for human  
11 consumption than food animals not fed genetically modified  
12 feed. Could you comment a little more about that, please?

13 DR. BALDWIN: Yeah. What I was, what I had on  
14 my mind at that, on that issues, was: I worked for some  
15 time on crops contaminated with microtoxins, apple toxins,  
16 and the like. And insect damage causes a mold growth in  
17 these, you know, in corn and cotton. And the microtoxins  
18 that these molds make are, indeed, deadly materials. It  
19 was my thought that, if the corn plant is protecting  
20 itself, for example, and a corn bore infestation was  
21 reduced, the mold growth would be reduced; and, as a  
22 result, the danger of microtoxins would be reduced.

23 MS. COPP: I'd like to direct this question to  
24 Drs. Fagan and Regal.

25 One thing that the agency is engaged in, not

1 only in this arena but others, is evaluating risk. And in  
2 order to evaluate risk, we need to identify the things  
3 presenting the risk.. Now, Dr. Fagan, if I listened  
4 correctly, you stated in your opening remarks that you  
5 believe there's no consensus on safety. Which, at least  
6 to me, suggests that there are scientists who believe  
7 there are risks with food developed using this technology.  
8 And I think, Dr. Regal, your — the underlying sense of  
9 your presentation is that you also believe there are  
10 risks.

11 I wonder if each of you could be more specific  
12 about the particular risks are so that we could use that  
13 to then evaluate whether appropriate questions are being  
14 asked? So I really want to hear a little more  
15 particularization of the risks presented by the use of  
16 this technology to develop foods.

17 DR. REGAL: Well, some of the, some of the  
18 questions that I have, that I've raised about risk, and  
19 would like to see answered, go back many years. The most  
20 obvious one, I've already mentioned; and that is: If you  
21 disrupt biochemical pathways, can you produce new novel,  
22 toxic compounds? And, of course, you can. I mean, they  
23 evolve and plants are little biochemical factories that  
24 are producing all sorts of nasty things to protect  
25 themselves from viruses and fungi and insects, and so on.

1 We pick the plants that have toxic compounds that are  
2 toxic to insects and not to us, but those pathways can be  
3 changed so that some of them are toxic to us. And we want  
4 to make sure that that sort of toxicity doesn't occur.

5 I had a concern, for a long time, that vectors  
6 were being developed, called "enhanced vectors," that can  
7 go into any kind of tissue because there are species  
8 limitations for the vectors that are being used in many  
9 cases. And those clearly could have carcinogenic  
10 properties if they got into the human -- into animals or  
11 humans. So I think there should be limits placed on the  
12 use of enhanced vectors.

13 Another problem I raised a long time ago was:  
14 Genetically engineered plants are going to be used for  
15 nonfoods. They'll be used to clone drugs and industrial  
16 chemicals, and the pollen will blow into other fields.  
17 And we are seeing that now. Of course, the pollen blows a  
18 lot farther than the agronomists thought it would, or that  
19 the genetic engineers thought it would. And you could  
20 blow some nasty things into a corn field and we'd end up  
21 eating it, simply by contamination. So I asked for a  
22 review of the seed purity standards 10 years ago, and I  
23 was told it would be taken care of. It has not been taken  
24 care of.

25 We've talked about -- I mean, I'm sure you've

1 heard already about antibiotic resistance markers and  
2 promoters that mutate, and that sort of thing. I think  
3 actually some of the, some of the concerns that I have  
4 have come up in the documents from FDA scientists  
5 themselves that have been revealed during the discovery  
6 process and the trial. So if you were to look at, if you  
7 were to look at those court documents, you'd find a lot of  
8 the same concerns that I have some of your scientists also  
9 had.

10 Well, let's see, I could — you know, we could  
11 sit down and talk about it, if you like, but that's a  
12 partial list, and, of course, allergies..

13 DR. FAGAN: Just to add a little bit to what Dr.  
14 Regal has said, one of the points that Dr. Huttner brought  
15 up was that the major -- that risks associated with  
16 genetic engineering are the same kinds of risks; and,  
17 therefore, we don't have to do anything different than we  
18 do with other foods. This is actually not a science-based  
19 statement; this is a legalistic statement. It's based —  
20 it's really operating on the basis of precedent and not  
21 science.

22 Yes, it's true. Allergens, toxins reduce  
23 nutritional value, happen through other approaches, as  
24 well. But, in fact, the processes of genetic engineering  
25 are what we have to look at. And what we see is that the

1 processes of genetic engineering in fact are more likely  
2 to create unexpected, unintended side effects than the  
3 conventional approaches. And this is because you're using  
4 approaches that, in fact, disrupt the existing genome in a  
5 random way. You have insertional mutagenesis every time  
6 you put a piece of DNA into these things.

7           We heard, earlier, that you're putting in one  
8 gene; and, therefore, it's not a problem. But the problem  
9 underlying that is that that's not a surgically precise  
10 process. You're putting it randomly into the genome.  
11 Second of all, we don't know how that gene, once it's been  
12 put in, is going to interact with the other genes, and how  
13 the product is going to interact with the other  
14 biochemicals, biomolecules of that organism.

15           So there are levels and levels of complexity,  
16 interactions, unpredictability that no one, even with a  
17 Ph.D. and 30 years of experience in plant science and  
18 molecular biology, could be able to predict the outcomes  
19 of those things. Without the ability to predict the  
20 outcomes, we need to have a program for assessing the  
21 outcomes in terms of safety. And that's not — that's  
22 what is not in place now. We're saying: It looks like a  
23 tomato; it smells like a tomato, and it's been made  
24 through changing genetics. We've been changing genetics  
25 forever; and, therefore, there's nothing new here and we

1 don't have to do anything other than look at and see that  
2 it's a tomato. Look at gross things like how much  
3 carbohydrate, how much fat is there.

4           Now, what if that tomato had a toxin gene, a  
5 metabolic pathway induced unexpectedly due to the  
6 introduction of a gene? There are tens of thousands of  
7 metabolites that are produced in any tomato. And we  
8 wouldn't have any idea which one of those has been altered  
9 in its levels, which gene was altered, therefore giving  
10 rise to that altered thing. And without knowing what it  
11 is, we can't do the kinds of chemical tests,  
12 chemically-based tests, that are now recommended by the  
13 FDA. We can't choose which test to do. And the basic  
14 principle in science is that you find what you're looking  
15 for. If you don't do an assay for the toxin, or other  
16 problem that's there, you can't detect it. Therefore,  
17 what we need is to use biological testing systems,  
18 long-term, short-term. Not only animal, if we need to do  
19 that, but also human. Because, in fact, there are no  
20 animal models that are appropriate and effective for  
21 assessing allergenicity. There is not such a model, and  
22 there's no chemical model that could be used. Therefore,  
23 the only way we can assess the allergenicity of a novel  
24 product of this sort is by doing human testing. If we  
25 haven't done that, we haven't assured ourselves that

1 novel allergens aren't present.

2 Now, let's look, just for a minute, at one  
3 example of how this can happen.

4 The work that was done in the UK with potatoes,  
5 a lectin gene was put into potatoes. Before that gene was  
6 selected for use, years of research had been done showing  
7 that, when you isolate that protein, that lectin, from its  
8 natural source, it's not toxic to human beings.  
9 Therefore, there should be no problem when you put it into  
10 a potato. And we were working with a food that was not,  
11 quote, "toxic" in an acute sense, either. So what they  
12 did was to put a gene, a "safe gene," into a safe food,  
13 and they came up with a product that was, in fact,  
14 hazardous to rats and, we assume, probably hazardous to  
15 human beings, too.

16 So this illustrates that there's room in the  
17 system for unpredicted side effects to come up. Given the  
18 existence of those, how can we do anything other than do  
19 testing that's broad enough to assess the full range of  
20 unpredictable side effects? And, really, the only way to  
21 cast a broad enough net to do that is to do biological  
22 testing, where you're using the organism itself, and it's  
23 biological processes as the detection system for these  
24 things.

25 These are challenging experiments to do. They

1 take longer than to do a lab test. But without that, we  
2 are not protecting the American people. And because  
3 what's done here in the U.S. is, in fact, legislated as  
4 being the norm other places — what I mean by this is: In  
5 many smaller countries they say: If the FDA has said this  
6 is okay, the USFDA, then we're not going to do testing.  
7 So, when you do testing here, you're testing for a large  
8 portion of the world, developing countries that can't  
9 afford to do this for themselves. We have a huge  
10 responsibility here.

11 Thank you.

12 [Applause.]

13 MS. COPP: I just wondered whether any of the  
14 other panelists — I did direct the question to the two  
15 gentlemen — any of the other panelists wanted to respond?

16 Okay, Dr. Qualset, please.

17 DR. QUALSET: Thank you.

18 Sounds like we're engaged in biological warfare.  
19 What I think we have to think about is that we are  
20 producing products, the developers are producing, directed  
21 towards solving some problem or making an improvement to  
22 our food chain. And I think that the matter of testing  
23 can be taken to an extreme, and you will never, never,  
24 never rule out that there isn't another molecule in there  
25 that you don't know about. And I think that baseline

1 approach, as to our current status of food safety with a  
2 particular product, needs to be the baseline and adjudge  
3 our new products against that.

4 And I think that this matter of testing and  
5 segregation issues need to be discussed. Let me give you  
6 an example:

7 Wheat is a self-pollinating crop, grown widely  
8 in the United States and throughout the world, and  
9 arguable the most important food plant we have. It has  
10 serious problems with diseases, one of which is leaf rust.  
11 There's a gene called LR-31, which is a very good gene for  
12 resistance to leaf rust. We can breed it into the  
13 varieties easily. But what we need to do is isolate that  
14 gene and be able to put it into varieties at will. In  
15 other words, to combine it with other genes.

16 So, what I'm saying is: We bred leaf-rust  
17 resistant wheat with LR-31; and, if we now introduced that  
18 gene to other varieties of wheat, we now have a  
19 genetically modified organism, according to the discussion  
20 here. And now we have to go through testing, *ad nauseum*,  
21 to see that the gene has contributed anything new or  
22 different. We have many ways to test the comparison of  
23 the transgenic and the nontransgenic type of  
24 LR-31-carrying plants, and we can verify that that is  
25 going to be — not going to be an issue.

1           So I think that the speakers downplayed the  
2 value of the testing that we have now. I do think that  
3 there is the baseline. The unpredictable things, I think  
4 that, if someone has a trait that's going into the, into  
5 the plant, that is really unknown to us there will be  
6 sufficient, many more, tests done. More feeding trials  
7 done, biological tests. We use flour beetles, for  
8 example, to look at wheat flour quality where, if the  
9 flower beetles die on eating wheat flour, why we got a  
10 problem, right? Okay?

11           So we have plenty of, a lot of, opportunities  
12 for testing. And I do think that we'll all go hungry  
13 pretty soon if we're going to wait for every last possible  
14 test to be conducted on any modified crop. And I haven't  
15 heard yet that there's anything serious about any possible  
16 problem with the current genetically modified crops. I  
17 haven't heard an example that there's a problem. The  
18 lectin in the potato, I think the research on that was  
19 judged by scientists as a faulty research, for example. I  
20 think that needs to be relooked at.

21           So I'm just saying that we can't throw out the  
22 baby with the bath water here. We got potential for a  
23 great improvement in crops.

24           Just one more example. How many of you know  
25 someone who can't eat wheat gluten, or wheat products,

1 wheat flour? Any of you know people that are sealiac  
2 (phonetic)?

3 [No response.]

4 That's the problem. That's a very important  
5 crop, and we can't — a lot of people can't eat wheat.  
6 They can't eat the gluten. Wouldn't it be good if we  
7 could knock those genes out of that wheat so everybody  
8 could have that wheat. Same with milk, and so forth. So  
9 I think we've got to look for the positives here. I'm  
10 confident on the testing, that we can develop sufficient  
11 testing. Risk benefit, that's what we have to look at.  
12 If the risk is very low, and the benefits very high, go  
13 for it.

14 Thank you.

15 [Applause.]

16 COMMISSIONER HOLSTON: Thank you. Jim.

17 DR. MARYANSKI: Well, I think that I'd like to  
18 hear a little bit more about how one might explore these  
19 unknown effects, in the sense that — I recall hearing a  
20 lecture by Paul Berg a number of years ago, who, of  
21 course, is a Nobel Prize Laureate. He was talking about  
22 how the genome is very plastic. That the genes and  
23 segments of genes move in the chromosome in a way that was  
24 never thought to be the case. At one time, we thought  
25 that chromosomes were this sort of string of beads that

1 kind of stayed in one place unless there was a mutation.  
2 And, of course, it was through the work of Dr. McClintock  
3 in corn that are called transposons -- or, in laymen's  
4 language, jumping beans -- were discovered.

5 I guess what I'm sort of getting at is: What do  
6 we know from plant breeding about changes and  
7 rearrangements that occur in the chromosome during various  
8 methods of genetic alteration? Do we see, are there  
9 always cases where it's only the same gene? Or, when new  
10 traits are brought in, do we see changes in the genome  
11 that really represent, in some cases, new DNA, and,  
12 therefore, newly expressed proteins? Is this very  
13 different in terms, in kind, than what we see with  
14 recombinant DNA techniques where there are, of course,  
15 genes that come from different organisms introduced?

16 I guess I'm somewhat confused in terms of what  
17 really happens in plants? Because this is something that  
18 we've really thought about a lot in trying to understand  
19 just how do the new techniques compare with the changes  
20 that occur through other methods of breeding.

21 DR. QUALSET: Those new traits, new genes, genes  
22 producing new traits, they may be done, as you pointed  
23 out, at random within the genome. We don't know exactly  
24 where they're going to be incorporated. But what we do do  
25 is study the expression of that gene. And if it's

1 expressed, then we know we have the gene incorporated into  
2 the plant. Then we do several generations of testing. In  
3 other words, self-pollinating, growing the progeny, and  
4 growing the progeny, and what we need to find out, then,  
5 is that trait stable. Is it reoccurring as predicted  
6 every generation? And if it is, then it doesn't make any  
7 difference, really, how it got there. And it also says  
8 that it is not moving around. Because, if it's moving  
9 around in the genome, we would have instability. We'd  
10 have altered segregation ratios, and there would be ways  
11 to discover that.

12 So the first criteria are expression, and then  
13 stability of expression through many plant generations.  
14 And I think that's where we get the confidence that the  
15 trait is working as planned.

16 Does somebody else want to —

17 DR. REGAL: You know, there can be some  
18 fundamental differences, and not all of them are going to  
19 lead to safety problems. But it's important, I think, if  
20 we're going to have a scientific discussion, to keep in  
21 mind that there can be some fundamental differences. For  
22 one thing, you're normally limited in plant breeding to  
23 hybridization between members of the — where the whole  
24 genetic network is familiar within a species, or within a  
25 closely related species, closely related genera. And, so,

1 there's some sort of coadaptation of these genes. That  
2 involves things like regulatory systems that keep  
3 everything in homeostasis. And when you take genes from  
4 outside, there's the possibility of adding totally,  
5 totally unfamiliar traffic, biochemical traffic, to the,  
6 to the new organism. Some of that may not be recognized.  
7 They may not recognize, oh, this is something that needs  
8 to be regulated because it's so, it's so foreign.

9           So that's one thing. And, again, you know,  
10 incorporating spider venom genes is obviously very  
11 different from the sorts of things that normally have been  
12 done.

13           Another difference is: We can only breed traits  
14 that vary in a Mendelian fashion, or heterozygous traits.  
15 And I use an example from mammals, because they are more  
16 familiar to most of us.

17           You can breed for height and color and hair  
18 texture and ear shape, and so on. You can't breed people  
19 that have six eyes, or that have long backbones like  
20 snakes, and so on and so forth. A great deal of the  
21 genetics of an organism, a lot of the basic biology, are  
22 fixed. They're genetic, but they're fixed and you can't  
23 get your hands on that with traditional breeding. You can  
24 mess it up with mutations, but you can't get your hands on  
25 it. Now, with genetic engineering, there's the

1 possibility of going in to fundamental parts of the genome  
2 that normally have normally been closed off to us and  
3 altering those. And we have so little experience with  
4 that, virtually none, that this is possibly one reason  
5 that it seems like we're dealing with the unknown in many  
6 of these bizarre cases like, like the salmon that are  
7 expressing growth hormones in their livers. You couldn't  
8 breed that, I don't think. Well, nobody has tried,  
9 but ...

10 Another way in which they're different is that  
11 traditional breeding generally involves trading off  
12 characteristics. In other words, you got to trade off  
13 some wild-type traits in order to get some new traits in.  
14 Because there are only so many sites on the chromosome  
15 where genes can sit. And, generally, when you do that,  
16 you weaken the plant because you're trading off the wild  
17 traits. And, so, corn is not going to compete with wild  
18 relative, for example. With genetic engineering, you can  
19 keep some very potent biological systems in place and  
20 still add new traits. Then the question is: How can  
21 those be disturbed? So that's another difference. It's  
22 pretty fundamental.

23 Another difference is that, normally in  
24 breeding, you're not introducing these vectors. In some  
25 cases, it could be enhanced. You're not introducing these