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2 studies at New York University. Dr. Michael Phillips is the  
3 executive director for food and agriculture for  
4 Biotechnology Industry Organization. Edward Groth is  
5 representing the Consumer Union. Lisa Katic works in  
6 scientific and nutritional policy at the Grocery  
7 Manufacturers of America. And Carl Loop is the vice  
8 president of the American Farm Bureau Federation.

9 Dr. Nestle, if you will open this panel.

10 DR. NESTLE: Thank you, Commissioner Henney, for  
11 the introduction and also for the privilege of being here  
12 today. I have written remarks that I've submitted, and the  
13 copies that were out this morning were lacking the last  
14 page, and I believe that error has been corrected and the  
15 copies that are out there now are complete.

16 Unlike the other members of this panel, I don't  
17 represent any particular organization. I assume I was  
18 invited to speak here because I have credentials in  
19 molecular biology and public health. And I was a consumer  
20 representative to the Food Advisory Committee when it dealt  
21 with the Calgene flavor saver tomato and also when it dealt  
22 with bovine somatotropin. And I'm currently a consumer  
23 representative to the FDA Science Board which is a committee  
24 that reports directly to the Commissioner. I occasionally  
25 write about issues related to food biotechnology.

1 I was asked specifically to address issues related  
2 to consumer perceptions of genetically engineered food. As  
3 an academic this turns out to be extremely easy to do  
4 because consumer acceptance of the products of food  
5 biotechnology is so important to the industry and to the  
6 government, many groups have sponsored research on consumer  
7 attitudes over the last 15 years. And there have been a  
8 number of surveys. They differ in methods. They differ in  
9 study populations, and they differ in questions. But the  
10 results of these surveys in my opinion all say exactly the  
11 same thing. They're remarkably consistent in their views,  
12 and I think they have considerable predictive value for  
13 determining what products of biotechnology are likely to be  
14 accepted and which ones are not.

15 My files contain surveys done by the Office of  
16 Technology assessment, the Department of Agriculture,  
17 Rutgers University, the Grocery Manufacturers of America,  
18 the Food Marketing Institute, the International Food  
19 Information Council, Dietetic Researchers and I also have a  
20 bunch from Europe. I am amazed when I read these, how  
21 similar they are and how indistinguishable their results. I  
22 think they reveal very, very clearly that the public has a  
23 substantial interest in biotechnology. People are curious  
24 about it, and want to know what it will do for them.

25 At the same time the surveys are quite revealing

1 that the public doesn't understand science or biotechnology  
2 very well. For example, if you ask people directly, do they  
3 know anything about biotechnology, they tell you they're  
4 poorly informed about the details and I think this says a  
5 great deal about the science education in our public school  
6 system, which is not something that we're talking about at  
7 this meeting.

8           They express concerns about the unknown risks of  
9 bio-engineered foods. What we heard this morning referred  
10 to as an edginess about it. The surveys report that people  
11 have very high expectations that food biotechnology will  
12 benefit them and will benefit society and they believe that  
13 the benefits will outweigh risks, or they have expectations  
14 that the benefits will outweigh the risks. For example, a  
15 whopping 75 percent of respondents to a recent survey  
16 answered yes to the question, do you feel that biotechnology  
17 will provide benefits for you or your family within the next  
18 five years? 75 percent is a very high percentage in this  
19 type of thing.

20           I think the surveys reveal absolutely  
21 unambiguously that people have preferences for some  
22 genetically engineered foods over others. For example,  
23 people are more likely to prefer those that are useful or  
24 beneficial to health or society, that are safe for people  
25 and the environment and that meet ethical values. For want

1 of a better term, I'm lumping together a lot of value  
2 systems under the heading of ethics.

3           People say they would be likely to buy  
4 bio-engineered foods that protect against insect damage or  
5 require less of pesticides; those that do not involve or  
6 harm animals; and those that do not involve the transfer of  
7 animal genes into plants. There's a certain distastefulness  
8 about doing that that is very clear in these surveys. In  
9 one of the 1997 surveys, for example, only 14 percent of  
10 respondents thought that cloning animals for food was  
11 acceptable.

12           The surveys reveal substantial distrust of the  
13 food biotechnology industry to act in the public interest.  
14 For example, in one survey less than 11 percent of  
15 respondents report that they trust information supplied by  
16 food biotechnology companies. They also distrust government  
17 oversight of food biotechnology, and that is accompanied by  
18 somewhat of a belief that the government favors industry  
19 over the public and that there is a very, very strong need  
20 for strong regulation.

21           And finally, I think the surveys reveal an almost  
22 total agreement that bio-engineered food should be labeled  
23 as such. These views are especially pronounced in Europe  
24 where 96 percent of people polled in Great Britain, for  
25 example, want labels on bio-engineered foods.

1 I think that the surveys show something quite  
2 interesting which is that safety itself, although a very  
3 clearly important aspect, is not the central focus of  
4 consumer concerns about food biotechnology. If consumers  
5 have had to focus on safety as a basis for discussion, it is  
6 because it is the only issue that FDA and the industry will  
7 listen to and take as a basis for discussion. Instead I  
8 think the surveys reveal much more fundamental social,  
9 cultural and religious value systems that underlie public  
10 concerns about food biotechnology and these are not issues  
11 that are provable by standard scientific means.

12 Therefore, when industry or the FDA insist that  
13 scientific proof of safety is the only issue that can be  
14 discussed, and refer to people who have other concerns, as  
15 the industry frequently does, as anti-scientific, Luddite,  
16 irrational, or my favorite which is troglodyte. I think the  
17 point gets completely missed.

18 That point is that the most strikingly useful  
19 conclusion that I draw from the surveys is that acceptance  
20 is product dependent, that it depends on what the product  
21 is. People are more willing to accept products that are  
22 useful, that are safe and that meet their ethical value  
23 systems. When people talk about recombinant insulin and  
24 the enzyme chymasin as being examples of bio-engineered  
25 products that never engendered any public hostility, I think

1 it's because they are demonstrably useful, safe and more  
2 ethical than the products that they replaced, and there's  
3 nothing inconsistent about their acceptance as opposed to  
4 the difficulties over some of the other products.

5           Indeed the survey messages are so clear and so  
6 consistent that I just can't help being utterly astonished  
7 by the industry's response to it. If the report in last  
8 week's New York Times is correct, the industry is organizing  
9 an immense lobbying and marketing campaign to respond to  
10 what it refers to as the rising wave of anti-biotech  
11 hysteria. Once again, the industry is treating consumer  
12 perceptions as a public relations problem, one that can be  
13 fixed by an advertising or education campaign. That did not  
14 work with Monsanto's public relations campaign in England,  
15 and I doubt very, very much that it will work here.

16           If the food biotechnology industry wants to sell  
17 bio-engineered foods to consumers and the FDA wants to help  
18 them do that, it seems to me that the survey results lead to  
19 three very specific suggestions. And these are, number one,  
20 make products that really are useful, beneficial, safe and  
21 ethical. To date the industry has produced expensive and  
22 not very good tomatoes; cow growth hormones; and a variety  
23 of crops that are heavily dependent on herbicides or that  
24 contain toxins of questionable environmental impact. None  
25 of these meets the consumer criteria for acceptability; that

1 is, all three, useful, safe and ethical. And until the  
2 industry starts making foods that do meet these criteria, I  
3 think it's unreasonable to expect that people will want to  
4 buy them.

5 My second suggestion is that to be credible, the  
6 industry needs to -- that if the industry wants to be  
7 considered credible, it needs to be credible. It needs to  
8 bring its rhetoric in line with reality. The industry is  
9 increasingly -- what I find increasingly tiresome mantra.  
10 I'm really quite tired of hearing this. If biotechnology is  
11 the only way we will be able to meet global food needs in  
12 the 21st century, if the industry wants consumers to accept  
13 its products on that basis, it needs to be doing a lot more  
14 work on those kinds of food problems. To date, as we've  
15 heard, most research focuses on what's called temperate zone  
16 agriculture that clearly benefits the industry much more  
17 than it benefits consumers. My suggestion is that the  
18 industry should institute a tithing program and start  
19 putting at least ten percent of its income into research on  
20 problems that would truly benefit humanity. By my  
21 estimation, that would be a couple of billion dollars a year  
22 and research on Third World agricultural problems. It might  
23 be possible to solve some of those very, very difficult  
24 biological problems if that kind of money was put into it.

25 My third suggestion is that if the industry would

1 like to be considered trustworthy, it must be trustworthy.  
2 And it has to label the products. I understand that FDA  
3 considers labeling the L word these days, as well the agency  
4 might, considering its long standing resistance or  
5 discomfort with the idea of disclosure on labels.

6 Surely we wouldn't be here today if it weren't  
7 obvious that labeling has to be a done deal. The only  
8 outstanding issue in labeling, as far as I can tell, is how  
9 it will be done. Labeling is going to happen because of  
10 Congressional intervention, because the people have spoken  
11 and said they wanted it, and not least, because the industry  
12 can't survive without it anymore. Events in Europe have  
13 proven that the industry's opposition towards labeling when  
14 the issue arose in 1994 and FDA's narrow science based  
15 stance taken at the time was a very, very costly mistake.

16 It's time this mistake got corrected. And these  
17 hearings are a very nice opportunity for doing that. I'm  
18 somewhat embarrassed about this, but I cannot resist saying  
19 I told you so. In 1992 when I wrote my first editorial on  
20 this, I started out by saying the labeling issue is really  
21 this simple. Consumers are more likely to buy the food  
22 products of biotechnology if they think the foods are worth  
23 the price and if they trust the producer. Trust requires  
24 disclosure.

25 In the seven years since I said that, I'm even

1 more convinced that more regulation, not less, is better for  
2 industry as well as for the consumers. If bio-engineered  
3 foods are safe, beneficial and ethical and useful, making  
4 sure that they're thoroughly tested and labeled before they  
5 come to market, will only increase trust in the industry and  
6 its products. This conclusion has been evidenced from the  
7 results of 15 years of consumer surveys and I think it's  
8 time to pay attention to what they tell us. Thank you.

9 DR. JANE HENNEY: Thank you. Dr. Phillips.

10 DR. PHILLIPS: Thank you, Dr. Henney. The  
11 Biotechnology Industry Organization is very happy to be  
12 invited, to be a part of this panel. If I may, I've got a

13 --

14 DR. JANE HENNEY: Please turn your microphone  
15 towards you so they can hear you in the audience.

16 DR. PHILLIPS: Sorry. I have prepared written  
17 remarks that I'd like to submit after the panel meeting  
18 today and we'll just be summarizing our comments right now.

19 BIO certainly commends FDA for conducting these  
20 public meetings to explain the agency's policy and the  
21 experience regarding the safety evaluation and the labeling  
22 of food products derived through agriculture biotechnology,  
23 and to solicit views from consumers, industry and academia  
24 on the policy.

25 The Biotechnology Industry Organization supports

1 the consumer's right to have information which allows them  
2 to make informed choices regarding the foods they eat.  
3 FDA's 1992 labeling policy for biotechnology foods and  
4 ingredients is appropriate to provide this information. We  
5 agree with FDA's implementation of the 1992 policy that  
6 requires labeling for significant changes, including  
7 nutrients or the introduction of allergens and specifically  
8 that the common or usual name for the ingredient should  
9 identify the change.

10           The Food, Drug and Cosmetic Act currently allows  
11 food producers to provide choice through voluntary label  
12 statements as long as labels are truthful and not  
13 misleading. If food companies were to pursue voluntary  
14 labeling, FDA, working with the industry, would need to  
15 establish guidelines or criteria to insure that consumers  
16 could rely on labeling for accurate information.  
17 Furthermore, the FDA and FTC must assure that the public is  
18 not misled by packaging or advertising that would in any  
19 way suggest or imply that these products are less safe.

20           The remainder of my remarks I will address your  
21 specific questions, Dr. Henney, that were published in the  
22 Federal Register. Your first question is should FDA's  
23 policy requiring labeling for significant changes, including  
24 changes in the nutrients or the introduction of allergens be  
25 maintained or modified?

1           We say that FDA's policy should be maintained. We  
2 agree that FDA should require the labeling of foods or food  
3 ingredients if there are important changes in the  
4 nutritional content or changes in the safety of the  
5 ingredient or food, such as those that are present of  
6 unanticipated, like an unanticipated allergen for technology  
7 derived enhanced food. And if there's any chance in terms  
8 of the safety of the ingredients, such as a presence of an  
9 allergen that would not be anticipated in the food or if  
10 there is a change in the common or usual name of that food  
11 ingredient.

12           With regards to has this already been implemented.  
13 This has been implemented in the case of foods from  
14 biotechnology derived plants, with improved nutritional or  
15 health benefits which are by definition not compositionally  
16 equivalent to traditional foods.

17           With regard to your second question, should FDA  
18 maintain or revise its policy that the name of the new food  
19 be changed when the common or usual name for the traditional  
20 counterpart no longer applies? And FDA here should maintain  
21 its policy.

22           Food manufacturers and consumers need to be  
23 informed if there had been a significant change in the  
24 product so that the common and usual name no longer applies.  
25 This has already been implemented in the case of foods from

1 biotechnology derived plants with improved nutritional or  
2 health benefits which are by definition not compositionally  
3 equivalent to traditional foods.

4           With regards to question three, have these  
5 policies regarding the labeling of these foods served the  
6 public? These policies have served the public very well.  
7 Labels provide a consumer's first impression of most  
8 packaged food products. Labels list ingredients, they  
9 describe features, they give instructions, explain benefits  
10 and deliver advisories and warnings.

11           Information considered essential to health, safety  
12 and nutrition must by law appear on the label. In addition  
13 to the mandatory labeling discussed above, FDA permits a  
14 voluntary labeling as long as the label is truthful and not  
15 misleading, to provide additional information to those  
16 consumers who desire more information.

17           With regard to question four, should the  
18 additional information be made available to the public about  
19 foods derived from bio-engineered plants, and if so, what  
20 information? Consumers need to be better informed about  
21 foods derived through agricultural biotechnology. More and  
22 better information on the use of biotechnology and food  
23 production should be made available.

24           Consumers need to be made aware of the data and  
25 the experience showing that these foods are as safe as and

1 in many cases, safer than foods derived through traditional  
2 methods. Industry, universities and the developers of these  
3 products need to and are working to provide more information  
4 via a number of different approaches. In addition, we feel  
5 FDA should probably be more pro-active in explaining its  
6 regulatory policy to consumers and its rationale for the  
7 policy. We urge FDA to be more transparent in how it  
8 implements its policy.

9 For example, once a company has completed the  
10 consultation process, information could be posted on FDA's  
11 web site describing the new product, listing the tests  
12 conducted and summary results, results of any review of the  
13 product by FDA advisory committees and information provided  
14 to the company once the consultative process has been  
15 completed.

16 We strongly urge FDA to make its process as  
17 transparent as is possible and of course being careful not  
18 to divulge confidential business information.

19 With regards to your question about who should be  
20 responsible for communicating such information, in general  
21 consumers may wish to obtain additional information about  
22 the safety assessment of foods derived from biotechnology,  
23 the intended purpose and benefits of these plants and those  
24 points in the food or feed chain where these biotechnology  
25 plant products are utilized.

1 Information of food, feed and environmental safety  
2 should be provided by the appropriate regulatory agencies,  
3 the companies who have developed the products and, to a  
4 lesser extent, by the food and feed companies who use these  
5 products. In this regard, we again encourage FDA to be more  
6 transparent in how it implements its policies.

7 And with regards to your last set of questions,  
8 how should additional information be made available to the  
9 public, for example, on the Internet, through food  
10 information phone lines, food labels or by other means?  
11 Clearly more use could be made to provide additional  
12 information through the Internet, toll free numbers and  
13 displays, brochures at point of purchase.

14 Voluntary labeling can also be utilized to provide  
15 additional information. We urge FDA to work closely with  
16 the food industry to develop standards that the food  
17 industry could use in providing voluntary labels, indicating  
18 the use or the nonuse of biotechnology in producing the  
19 labeled food product. A sound labeling policy can and  
20 should recognize the rights of consumers to a safe and  
21 nutritious food supply while facilitating consumer choice  
22 based on clear, meaningful, truthful and non-misleading  
23 information about the product. Thank you.

24 DR. JANE HENNEY: Mr. Groth.

25 DR. GROTH: Thank you very much, Commissioner.

1 The law of conservation of energy or something has shown up  
2 here. Charlie Margulis gained a Ph.D this morning. I've  
3 lost one.

4 DR. JANE HENNEY: Oh, sorry. What kind of degree  
5 would you like?

6 DR. GROTH: I've submitted a written statement  
7 that's part of the packet that was handed out. I'm going to  
8 merely highlight that and then take advantage of what I hope  
9 the time I save, will be to react to some of the things I  
10 heard this morning. First, I want to thank you,  
11 Commissioner and the FDA for holding these very important  
12 hearings. I think one of the major attributes of the  
13 biotechnology debate to date is that the public in many ways  
14 has felt fairly shut out of the decision process. This is a  
15 big step toward openness. I hope it's only the first step.

16 I believe that labeling, as Dr. Nestle said, is  
17 coming. It should be mandatory. Everybody should embrace  
18 it. And I believe it's a matter of self-interest for the  
19 industry. In my statement that I've distributed speaks to  
20 that. So I won't belabor those points.

21 I would like to say that the public interest  
22 sector has been quite frustrated by the complicated  
23 rationale the FDA has come up with to argue that it doesn't  
24 have the authority to require -- is this not working? Maybe  
25 use a different mike.

1           Sorry. We've been frustrated by the complicated  
2 rationale that the FDA has developed over the years to argue  
3 that it doesn't have the legal authority to require labeling  
4 on genetically modified foods. We feel that authority is  
5 there. I'm not a lawyer, as I just made clear. But our  
6 lawyers tell us and others believe that the authority has  
7 been used to require labeling for informational purposes  
8 where there's not a health and safety issue, for instance,  
9 with irradiated food, with previously frozen foods, with  
10 foods made from concentrate and so on.

11           If it's a material fact and important to consumers  
12 and relevant to how they perceive the product, it is  
13 possible, we believe, to require labeling rather than to  
14 depend only on voluntary labeling. We think mandatory  
15 standards for labeling would be far more uniform and fairer  
16 to producers and consumers than relying on a voluntary  
17 system to grow up with market forces driving it.

18           I think that as important as science and safety  
19 are, and they are quite important, the picture is bigger  
20 than that. And I believe the most important concepts right  
21 now are trust, which we heard mentioned this morning. Ralph  
22 Hardy I think was the first to mention trust and I heard  
23 some amens from the choir. And choice, not just trust, by  
24 choice. And I believe labeling is the key to both.

25           The issue of trust is a two way street. I think

1 if the industry and the FDA would like consumers to trust  
2 the science, we need a sign that the FDA and industry trusts  
3 consumers' values and ability to make sound judgments. And  
4 we're not getting that kind of feeling of trust. We're  
5 getting instead what is called public education, and I heard  
6 several people talk about that this morning, which is  
7 designed essentially to make the public think the way the  
8 FDA and the industry think about the issues. That ain't  
9 going to work. It doesn't work.

10 I can't tell you how many industries have had the  
11 experience of finding out that that doesn't work. In fact I  
12 have some examples that I brought with me. They landed in  
13 my office last week. And Lisa, I'm not picking on IFIC.  
14 Lisa is an IFIC alumna. It just happened to come from IFIC.  
15 But the latest issue of Food Insight has a story inside  
16 called Myths and Facts About Food Biotechnology. You can  
17 imagine that everything that consumers think is an issue is  
18 a myth. And then there's a whole lot of facts as to why  
19 consumers don't know what they're talking about.

20 I also saw in the New Yorker, the same week,  
21 almost the same day, a cartoon by Gann Wilson. Gann Wilson  
22 is famous in Chicago. He used to do a lot of Playboy  
23 cartoons. This one is about genetically modified foods, and  
24 it shows the foods taking over and eating the scientists.  
25 I'm sure that a lot of people in this room might not find

1 that very funny. But I would say that this is causally  
2 related to this.

3 If you want more of this, keep doing this. I  
4 think the cynicism and the distrust that is bred by top down  
5 arrogant, if you will, communication that says, consumers,  
6 you don't understand this problem. Let me tell you how to  
7 think about it. That is going to breed more distrust, more  
8 distance between the public, your customers, and the  
9 industry than perhaps the industry can survive. So I think,  
10 as a matter of self-interest, labeling solves a lot of  
11 problems. It gives people a choice.

12 Another aspect of science called risk perception  
13 shows that if risks are voluntary, even if they're very  
14 small risks, which I think many of us would agree most of  
15 these risks we're talking about probably are, if they're  
16 voluntary, people don't worry about them. So putting a  
17 label on a product enables the consumer to choose it or not  
18 choose it.

19 Mike Jacobson said this morning, he listed a  
20 number of reasons why people might choose not to buy  
21 genetically modified foods. And a lot of those have to do  
22 with people's values and their belief of what's good for  
23 society. They may not wish to contribute to intensive forms  
24 of agriculture. They may not wish to support what they view  
25 as tampering with nature. These are perfectly legitimate

1 values for people to hold, and they should be able to  
2 exercise those values in the marketplace.

3           The other aspect of that which Mike didn't mention  
4 and I think is important is that if and when the promised  
5 benefits of biotechnology begin to show up in products in  
6 the stores, things that are better for you nutritionally,  
7 taste better, really do substantially and clearly improve  
8 the sustainability of agriculture, people will want to buy  
9 them. They'll want to know what it is so they can buy it.  
10 Choice works both ways.

11           So labeling gives people a choice and it shows  
12 that the industry trusts consumers to make up their own  
13 minds about the technology with all the information they  
14 have. People have a lot of information and perceptions and  
15 attitudes about biotechnology. Labeling a product  
16 genetically modified is not putting a skull and crossbones  
17 in it. It's not a dire warning that everyone will pay  
18 attention only to that and forget everything else they know.  
19 It's a fact. And they'll put it into the context of  
20 everything they know and think about biotechnology.

21           So if you want trust, give people a choice, label  
22 the products. I really think it's that simple. Thank you  
23 very much.

24           DR. JANE HENNEY: Thank you, Dr. Groth. And now,  
25 Lisa Katic, R.D.

1 MS. KATIC: Thank you, Dr. Henney. And thanks,  
2 FDA. We applaud FDA as well for holding these public  
3 meetings, and appreciate the opportunity to participate.

4 My name is Lisa Katic. I'm the director of  
5 scientific and nutrition policy for the Grocery  
6 Manufacturers of America. GMA is the world's largest  
7 association of food, beverage and consumer product  
8 companies. I want to begin my remarks by addressing the  
9 question of what consumers want to know about foods produced  
10 through modern biotechnology.

11 Studies conducted this summer and fall by the food  
12 industry show overwhelmingly that consumers want truthful,  
13 accurate information about the foods they eat. GMA fully  
14 supports the ability of manufacturers to inform consumers  
15 about these kinds of foods that are produced through  
16 biotechnology. Indeed it has been our experience that when  
17 consumers are presented with balanced accurate information  
18 regarding these foods, they are excited about benefits.  
19 I'll repeat. They are excited about the benefits that these  
20 foods can and will provide.

21 According to Tom Hobin who is a professor at North  
22 Carolina State University, between two-thirds and  
23 three-quarters of American respondents surveyed are positive  
24 about plant biotechnology. The most recent survey showed  
25 that when consumers were provided with information about the

1 benefits of genetic modification, 70 percent said they felt  
2 more positive and hopeful about the genetic modification of  
3 foods.

4           It is clear from our research that consumers want  
5 foods that can provide added health benefits as well.  
6 According to a survey conducted by IFIC, the International  
7 Food Information Council, the vast majority, I'll say 91  
8 percent of consumers, the vast majority of consumers say  
9 they would be interested in learning more about foods that  
10 have added health benefits.

11           Foods and ingredients developed through modern  
12 technology will offer real consumer benefits in the future.  
13 I'll highlight just a few of those right now that are in the  
14 marketplace. We've heard some of these already, and some  
15 that are on the horizon. We're talking about things like  
16 fruits and vegetables that may contain more betacarotene,  
17 vitamin C and E. Probably most of us know that these  
18 components can help to reduce the risk of certain diseases  
19 like cancer and heart disease. We all know heart disease  
20 remains the number one killer in the United States.

21           The rice that was mentioned earlier that will  
22 contain higher amounts of vitamin A, this will help the  
23 leading cause of blindness in children in the developing  
24 world. It was also mentioned that we can perhaps use this  
25 technology to eliminate allergens from foods. Can you

1 imagine we can actually save lives by doing that. Of course  
2 consumers would want something like that.

3 We're talking about healthier cooking oils, corn,  
4 soy bean, canola, and other plants will be modified to  
5 reduce the saturated fat content of cooking oils derived  
6 from these crops. And we all know that saturated fat is one  
7 of the biggest contributors to heart disease. Also better  
8 methods to identify and locate toxins, pathogens and  
9 contaminants in foods. I can't imagine that consumers  
10 wouldn't want that to be done.

11 In addition to nutritional benefits, these kinds  
12 of foods can offer environmental benefits as well. For  
13 example, grains, fruits and vegetables containing pesticides  
14 resistant and herbicide tolerant characteristics can require  
15 fewer chemical applications. These more resilient plants  
16 can tolerate farmers' application of very specific  
17 herbicides for weed control, thus reducing the overall need  
18 for chemical applications and stress to our natural  
19 resources.

20 GMA's Board of Directors recently approved a  
21 position statement strongly supporting the current FDA  
22 labeling policy with respect to foods and food ingredients  
23 derived through biotechnology. This means GMA supports the  
24 labeling of biotech foods where there is a significant  
25 compositional change, where the food is nutritionally

1 different from its traditional counterpart or where  
2 potential allergens have been introduced.

3           The FDA labeling policy also allows for voluntary  
4 labeling statements that are truthful and not misleading  
5 which provides a comprehensive frame work for consumer  
6 protection and choice, two very important words, consumer  
7 protection and choice. Just as some consumers prefer  
8 organic foods, others may want to purchase foods that are  
9 not produced through modern biotechnology. Manufacturers  
10 should be able to satisfy these preferences and competitive  
11 markets will respond accordingly. Competition will deliver  
12 products and information that best satisfies consumer  
13 choice.

14           We support the right of manufacturers to make  
15 claims for their products, including claims about products  
16 made without the use of modern biotechnology. It is  
17 important that these claims, however, not mislead consumers  
18 about the composition, safety or quality of the labeled  
19 product or any other product. We recommend that FDA develop  
20 criteria for claim accuracy and substantiation in relation  
21 to labeling of non-biotech foods or food ingredients.

22           Next question is how to best provide accurate and  
23 adequate information about this technology to consumers. Of  
24 course, you know some groups are urging FDA to mandate the  
25 disclosure of genetic techniques used in the development of

1 a product, even if the food that results is equivalent to  
2 its traditional counterpart and even though it presents no  
3 demonstrated health or safety risk to people. These critics  
4 are not satisfied with FDA's current labeling policy and  
5 seek to mandate special and new labeling requirements.  
6 Special mandatory labeling could mislead consumers into  
7 believing that foods produced through this technology are  
8 either different from conventional foods or that they  
9 present a particular risk, even though FDA has determined  
10 that the food is safe.

11           Such special labeling of foods modified through  
12 modern biotechnology could lead to the very kind of  
13 confusion that FDA has tried to keep out of labels. A label  
14 cannot tell every consumer everything he or she might want  
15 to know about every product. I'm not meaning to be cavalier  
16 by this statement because different consumers care about  
17 different things. If manufacturers try to satisfy the  
18 tastes and preferences of every consumer, the amount of  
19 information that may be useful could literally fill an  
20 encyclopedia. Only a small fraction of this information can  
21 possibly fit on a food label.

22           In addition, sources of information far better and  
23 more comprehensive than labels are readily available to  
24 consumers. This is very important through focus groups and  
25 telephone surveys. Consumers are telling the U.S. food

1 industry that they are able to obtain information about this  
2 technology from the media, from the Internet, from food  
3 companies and academic experts. In fact, a new survey,  
4 another one from IFIC, the International Food Information  
5 Council, found that 81 percent of American consumers agree  
6 that rather than labeling products as containing biotech  
7 ingredients, it would be better for food manufacturers, the  
8 government, health professionals and others to provide more  
9 details through toll free phone numbers, brochures and web  
10 sites. Consumers themselves have told us that.

11           These sources are more informative than the label  
12 because they provide flexibility and a forum to discuss  
13 these issues in detail. For example, GMA along with the  
14 American Farm Bureau Federation and the Food Marketing  
15 Institute and more than 30 other organizations recently  
16 established the Alliance for Better Foods. The purpose of  
17 establishing this alliance was to provide fact based  
18 information to consumers about food biotechnology.

19           The alliance includes farmers, processors,  
20 retailers, scientists, health professionals, medical  
21 experts, academicians, those that are committed to  
22 protecting the environment, those that are fighting world  
23 hunger and those generally who support the development of  
24 biotechnology. The alliance as developed a web site and  
25 publications that address consumers' questions regarding

1 these types of foods.

2           The web site also provides links to government  
3 agencies, including FDA, so that consumers can learn about  
4 the government's role in this technology. They need to know  
5 that there has been regulation and oversight with respect to  
6 these foods.

7           So let me conclude by stressing that GMA and its  
8 members strongly support FDA's existing science based  
9 labeling policy with respect to these foods and food  
10 ingredients. We believe that the FDA policy provides a  
11 comprehensive frame work for consumer protection and  
12 consumer choice and clearly serves the public interest. In  
13 a market system that values consumer choice as the engine of  
14 economic welfare, government regulation should protect  
15 consumers from real risks. And it was mentioned earlier  
16 about my microbial contamination as being a real risk. We  
17 absolutely agree, that they should protect from real risks  
18 and help consumers make informed choices. A policy that  
19 raises unwarranted suspicion of research and development as  
20 mandatory labeling of modern biotechnology could do, might  
21 deny the public the benefits of innovation.

22           It would be unfortunate if misinformation and  
23 unfounded concerns deprived consumers of the information and  
24 the foods that they desire. A sound labeling policy can and  
25 should recognize the rights of consumers to a safe and

1 nutritious food supply, while at the same time facilitating  
2 consumer choice based on meaningful information about the  
3 product itself. By mandating only essential information,  
4 allowing voluntary claims about modern biotechnology and  
5 demanding accuracy in all labeling, FDA's existing labeling  
6 policy has accomplished this goal.

7 DR. JANE HENNEY: Thank you. Mr. Loop.

8 MR. LOOP: Thank you, Commissioner. Good  
9 afternoon. My name is Carl Loop. I'm president of Loop's  
10 Nursery and Greenhouses, Inc. in Jacksonville, Florida.  
11 That's a wholesale plant nursery. I'm also president of the  
12 Florida Farm Bureau Federation and vice president of the  
13 American Farm Bureau Federation. I am pleased to present  
14 the comments this afternoon relative to biotechnology in the  
15 year 2000 and beyond on behalf of our nearly five million  
16 members.

17 Our members are producers of virtually every  
18 commodity produced in the United States and are also  
19 consumers of these products. As such we have a vital  
20 interest in the outcome of these hearings. Any decision  
21 made will affect us in many ways.

22 American farmers and ranchers have long been  
23 innovative developers and adopters of new technology. AFBF  
24 has always been an advocate of research and a supporter of  
25 technology adoption including biotechnology. Research and

1 technology are key to maintaining the competitive advantage  
2 that U.S. agriculture enjoys and the benefits they provide  
3 will guarantee that we continue to produce the safe  
4 nutritional food that consumers desire in an environmental  
5 sensitive manner.

6 American farmers have embraced biotechnology and  
7 made wide use of it in a short period of time. In the  
8 October National Agriculture Statistic Surveys Report, USDA  
9 reported 57 percent of the soy beans, 65 percent of the  
10 cotton and 38 percent of the corn acreage grown in the  
11 United States in 1999 was genetically modified. Producers  
12 have also raised genetically modified potatoes, tomatoes,  
13 canola and alfalfa.

14 The technology has generally worked well for the  
15 producer on the production side but we are currently facing  
16 challenges on the marketing side. Many producers of corn  
17 and soy beans are being told that they need to separate  
18 their genetically modified harvests from that produced from  
19 conventional seed when they market it because many  
20 international and some domestic buyers will not accept  
21 genetically modified products. This indicates that  
22 consumers acceptance, particularly in the international  
23 level, has not matched that of the U.S. producer.

24 We welcome these hearings as an opportunity to  
25 review the oversight of our technology and identify ways in

1 which the public might be provided with needed information  
2 about biotechnology. It is important that all stakeholders  
3 have confidence in the system. Seed companies and producers  
4 need to know what will be expected of them, otherwise no  
5 one, consumer or farmer, will gain the potential benefit  
6 offered by biotechnology.

7           If agriculture and society move forward with  
8 technology we will see crops with enhanced nutritional value  
9 and improved food safety characteristics for both humans and  
10 animals. Others will have improved processing  
11 characteristics. Still other crops will be more  
12 environmentally friendly. Some crops used for feed will  
13 have less phosphorous that is excreted in animal waste.  
14 Other crops will have less need for chemical input for pest  
15 control.

16           You have asked this panel to focus on the labeling  
17 questions that were outlined in the Federal Register notice.  
18 But before dealing with the specific questions, I would like  
19 to share a few excerpts from the Farm Bureau's policies  
20 that relate to them.

21           In our policy on biotechnology we state, and I  
22 quote, "We urge state and national political leaders to  
23 develop a positive national strategy for biotechnology  
24 research and development. Part of this strategy should  
25 include an open and frank dialogue with all interested

1 parties. We support increased efforts through biotechnology  
2 to increase the marketability of our products, to solve  
3 environmental concerns, to increase net farm income by  
4 decreasing input costs and to improve product quality."

5           Later in that same policy we state, "The approval  
6 of new products should be based on safety and efficiency  
7 criteria. Consideration of social, economic criteria should  
8 not be required. We strongly favor patent support to  
9 encourage these new technologies. And we impose imposition  
10 by foreign countries of any import restriction, labeling or  
11 segregation requirements on any genetically modified  
12 organism. Once such commodity has been certified by the  
13 scientific community as safe and not significantly different  
14 from other varieties of that commodity, we support the  
15 maintenance of U.S. export markets by securing foreign  
16 regulatory acceptance of biotech products. Manufacturers of  
17 bio-engineered products should assume major responsibility  
18 for this acceptance as well as making farmers aware of  
19 markets where the products are not accepted."

20           The Farm Bureau policy on labeling states, labels  
21 should not be required to contain information on production  
22 practices that do not affect nutrition or safety of the  
23 product. Severe penalties should be imposed for  
24 intentionally mislabeling of agricultural products. And  
25 agricultural products that are produced using approved

1 biotechnology should not be required to designate individual  
2 inputs or specific technologies on the product label.

3           These policies have come through our policy  
4 development process which starts at the County Farm Bureau  
5 level and continues through adoption by the delegates of our  
6 annual meetings. These policies are very slow, deliberate  
7 and well thought out. As such they represent the policy  
8 direction desired by producers of all commodities from all  
9 across the nation.

10           The FDA has invested considerably time and effort  
11 in the development of product labels that accurately  
12 represent the safety and nutritional value of foods. If the  
13 agency were to change its policy and require special  
14 labeling for biotech foods, this labeling could actually  
15 mislead customers who believe that biotech foods are either  
16 different from conventional foods or present a greater risk  
17 or potential risk greater than other foods. The labeling of  
18 foods as GMO or biotech could lead to a vericon of consumer  
19 confusion that labels are designed to prevent.

20           In addition, the U.S. is engaged in biotechnology  
21 discussions in numerous international forums. It is  
22 critical that U.S. efforts to encourage science based  
23 regulatory regimes globally not be undermined by changes in  
24 U.S. labeling policies.

25           Although the AFBF has no provisions in policy to

1 support any type of GMO or biotech labeling, the fact that  
2 some type of identification is being discussed is an  
3 important development. We do have policy regarding organic  
4 foods that says we support federal legislation to  
5 standardize certification and labeling of foods claimed to  
6 be produced as natural or organic. To the extent there is  
7 reason to differentiate food products, they could be defined  
8 as either non-biotech or non-GMO so that, like organic  
9 foods, an appropriate price premium could be determined by  
10 the market. This premium would allow the development of an  
11 identity preserved marketing system, with premiums from the  
12 system being shared by producers, processors and retailers.

13 While I think these policy statements pretty well  
14 address most of the questions that you have asked, I would  
15 like to respond a little more directly to them.

16 First, should FDA's policy requiring labeling for  
17 significant changes, including changes in nutrients or the  
18 introduction of allergens, be maintained or modified? We  
19 feel the current FDA policy has been very effective and it  
20 is important that this be maintained. Consumers need to  
21 know if a product is different than that which they would  
22 normally expect. If the nutritional quality is changed or  
23 if allergens are present, consumers need to know so that  
24 they can make appropriate decisions relative to the use of  
25 the product. FDA provides a high level of consumer

1 confidence. We all want safe food. Additional FDA labeling  
2 requirements would add cost to consumers and appear unlikely  
3 to provide any additional food safety benefit.

4           Should FDA maintain or reverse its policy that the  
5 name of the new food be changed when the common or usual  
6 name of the traditional counterpart no longer applies? Farm  
7 Bureau policy provides support for the intent of the current  
8 FDA requirement that the name of a food product be changed  
9 if the common name no longer applies due to modification of  
10 the product. Any revisions in these requirements would need  
11 to produce environmental and food safety benefits that are  
12 greater than the increased cost of implementing those  
13 provisions. Vague and undefined risk do not justify policy  
14 revisions.

15           Have these policies regarding the labeling of  
16 these foods served the public? We are unaware of any  
17 problem that had been posed by the current labeling  
18 requirements. The purpose of any labeling should be to  
19 provide potential users of the product with useful  
20 information that is easily understood. It appears that the  
21 current labels have done this. They have served the public  
22 well and because of this, we support maintaining them.

23           Should additional information be made available to  
24 the public about foods derived from bio-engineered plants?  
25 If so, what information? Who should be responsible for

1 communicating such information? In order for the public and  
2 producers to feel comfortable with biotechnology and its use  
3 in food production, it is important that information be  
4 available to those who want to learn more about the  
5 technology. This may include such information as why it is  
6 used, how it relates to other production technologies. It  
7 is also important to provide access to information about the  
8 process that is used to assure the safety and nutritional  
9 value of genetically modified foodstuffs relative to that of  
10 other conventional foods. Relative to providing the  
11 information, the companies involved in the production of the  
12 products as well as the regulatory agencies seem most  
13 appropriate. Farm Bureau is already working in this area  
14 from the producer side.

15           How should additional information be made  
16 available to the public, on the Internet, through food  
17 information phone lines, on food labels or by other means?  
18 The USDA's APHIS web site, as well as that of the Alliance  
19 for Better Foods, represent a good start in providing such  
20 information. The Internet is an increasing useful way of  
21 providing information to consumers. It should continue to  
22 be developed by all parties. Informational phone lines and  
23 traditional publications can also be useful. Current  
24 requirements to identify products of biotechnology that are  
25 different seem to work well, and do not appear to need to be

1 changed.

2 We appreciate the opportunity to provide these  
3 comments to you. Biotechnology has great potential for the  
4 future, but if we are to realize this potential it is  
5 important that the public be comfortable with the processes  
6 that are in place to insure the safety and quality of the  
7 products they consume. We feel like the system has worked  
8 well to date, for it has allowed producers access to the  
9 products and benefits of the technology and it has also  
10 protected the health and well being of consumers. It is  
11 important that the general public be equally comfortable  
12 with the system. We encourage you to seek ways to assure  
13 that the system continues to work as well in the future as  
14 it has to address these concerns. This will allow everyone  
15 to benefit from the potential improvements that can be made  
16 through the availability and use of biotechnology. Thank  
17 you.

18 DR. JANE HENNEY: Thank you, Mr. Loop. And thank  
19 you, each member of the panel, for your presentation. I'm  
20 going to open up the panel for the FDA panel's questions to  
21 you. We'll be running until about 2:30, if I can read the  
22 clock correctly, on this, and let us ask you some questions  
23 first and maybe you'll want to ask each other questions as  
24 well.

25 Quick recap. Thank you to the panel. We're going

1 to be moving to the Q & A part of the session by the FDA  
2 panel of our presenter panel and this will run until  
3 approximately 2:30. We'll take a quick stretch break after  
4 that and then move right to the open mike session. So  
5 members of the panel? Sharon, Ms. Holsten.

6 MS. SMITH-HOLSTEN: We've heard from all of the  
7 panelists about -- is this coming through?

8 DR. JANE HENNEY: No. I think these work better.

9 MS. SMITH-HOLSTEN: We've heard from various  
10 members of the panel about the whole issue of labeling.  
11 Some have spoken to mandatory, some have spoken to  
12 voluntary. I would be interested in hearing from any of you  
13 about how such labeling could be constructed in a way that  
14 it would not in fact be misleading. Do you have ideas about  
15 how to make, if labeling were to be considered, what kinds  
16 of guidelines the agency could use to make certain that that  
17 labeling was not misleading.

18 DR. GROTH: I'll take a crack at that. I'm sure  
19 others will, as well. I think it should be a simple factual  
20 declaration. Simply state in words to the effect that this  
21 food contains or is made with genetically engineered  
22 ingredients. And I believe, as I said, that that's a fact,  
23 it's a simple fact, it's not misleading. It's not dire and  
24 ominous, it's not advertising. It's simply a fact. It's  
25 plugged into the context of everything else consumers know.

1 I'd also like to address the implication that was  
2 in several of the other presentations that we face an  
3 either/or choice here, that we should have either  
4 information on the web site and lots of other places or  
5 labeling. I think we can have both. I think they're highly  
6 compatible and complementary. I think if there's a lot of  
7 information out there on web sites and brochures, etcetera,  
8 the label fact will diminish greatly in terms of its  
9 potential to have a strong impact on consumers.

10 I'd also like to say that I don't believe, but I  
11 believe perhaps Lisa believes, that we can't trust consumers  
12 to understand that factual information, that it would create  
13 all sorts of unjustified fears. I'd sort of like people to  
14 more openly address whether they trust consumers to use that  
15 factual information in a sensible way.

16 DR. NESTLE: I also think that this is a very  
17 simple issue. The British company -- and Safeway had a  
18 genetically modified tomato paste and the can just said made  
19 from genetically modified tomatoes. It was very simple.  
20 Where it gets more complicated is in the corn and soy bean  
21 issue where the ingredients are in the products and because  
22 it's so difficult to do segregation 100 percent. There  
23 would need to be some decision about what percentage of  
24 non-genetically modified ingredients would still allow you  
25 to say that it was mostly one or the other.

1 I don't think you can get zero anymore. It's too  
2 late. I don't think you can get zero anymore. But you  
3 certainly can get it down to a very, very small percentage.  
4 Some decision would need to be made about what that  
5 percentage is. But that's a political decision and it's  
6 just as possible to make that as any other decision about  
7 labeling. I would argue that all labeling is political in  
8 some sense and there were political decisions involved in  
9 every single piece of the labeling that we now have, and  
10 that this is not a very complicated thing to do if people  
11 want to do it. And it also didn't stop people from buying  
12 the tomato paste.

13 MS. KATIC: Actually that's not 100 percent true.  
14 It did start out where it didn't affect in the U.K. the  
15 tomato paste, but when the issue heated up in the media it  
16 very much decreased the sales in the tomato paste, so it did  
17 have a direct effect.

18 I think it does sound like a very simple and  
19 straight forward issue to say, why not just put a statement  
20 on the label? Well, obviously manufacturers are constantly  
21 asking consumers what it is they need to know and want to  
22 know and how best to provide that. We've asked consumers,  
23 would we be able to and if so, how would manufacturers be  
24 able to put a statement on a label that would fully inform  
25 them. And consumers themselves could not come up with a

1 statement that would fully inform them, not mislead them  
2 into thinking that there was some difference in that  
3 particular food or that there was some kind of a safety  
4 issue.

5           So we asked consumers and they themselves could  
6 not come up with a simple statement that would meet that  
7 need. They did tell us that they were satisfied with having  
8 comprehensive information off the label, if it was provided  
9 in another means. And they felt that that was satisfactory.

10           DR. JANE HENNEY: Dr. Maryanski?

11           DR. MARYANSKI: Thank you, Dr. Henney. We've been  
12 hearing a lot of discussion about the labeling of foods. I  
13 would like to hear from the panel their thoughts about what  
14 kind of labeling are we really talking about, in the sense  
15 that we say the terms genetic engineering or modern  
16 biotechnology, and there are a number of technologies that  
17 are used. What is your sense about the kinds of  
18 modifications or the kinds of changes, the kinds of  
19 technology that are really encompassed in this concept of  
20 information on the label, whether it's voluntary or  
21 mandatory?

22           DR. GROTH: I'm sort of winging it here because  
23 this is something we haven't really worked out as an  
24 organization. But clearly, criteria would need to be  
25 developed. I think one fairly obvious one would be if it's

1 a transgenic organism, if it's got genes from something  
2 other than what you think it is; that is, a tomato with a  
3 fish gene or even a tomato with a pine tree gene, something  
4 that is not expected from the perceived identity of the  
5 product, it would probably need to be identified as such.

6 On the other hand, if it's a tomato that has a  
7 gene taken out and reversed and inserted so that it's  
8 permanently shut off, which I think was the technology used  
9 in the Calgene case, that's a tomato. I think Calgene went  
10 much farther than might necessarily be required even under a  
11 fairly strict labeling scheme in disclosing all the details  
12 about what it was, how they had modified it and so on.

13 I don't think lack of labeling was an issue in why  
14 Calgene failed to gain a market on that. But I think  
15 clearly, Jim, you've raised a very important question. What  
16 criteria are needed? Once we got to the stage of deciding  
17 there was going to be labeling, I think we do need uniform  
18 criteria. We need standardization. If we don't have  
19 government mandating the labeling, we certainly need pretty  
20 firm guidelines so everybody is approaching it the same way,  
21 so that producers know what information is needed and  
22 consumers know what information to expect.

23 DR. JANE HENNEY: Dr. Phillips.

24 DR. PHILLIPS: If I could just ask, in the case of  
25 the Flavor Saver tomato then, would you say it needs to be

1 labeled?

2 DR. GROTH: I think that many consumers would like  
3 to know that. Whether it is different enough from a regular  
4 tomato is an interesting question. I said clearly if I had  
5 to put a bin of things that must be labeled, I would put  
6 anything transgenic; that is, it has genes from another  
7 organism in that bin. I'm not sure what I'd do with the  
8 Calgene tomato.

9 DR. PHILLIPS: I think this exactly points out the  
10 problem that we have here. I'm glad you raised the  
11 question, Jim, because this is not just a simple thing to  
12 do. To really put guidelines together that make any kind of  
13 sense and do not mislead consumers, this is an extremely  
14 complicated question. And there is no simple answer to it.

15 You're going to be able to come up to almost any  
16 kind of an exception, no matter how you begin to develop  
17 guidelines. This is going to take a great deal of thought  
18 by the government, by the industry, by consumer groups to  
19 come up with any kind of a system that would truly make  
20 sense. I think we have, if we proceed down this line, which  
21 if the industry is more than willing to work with any groups  
22 in terms of trying to provide information on a voluntary  
23 basis, that it's going to take a lot of time and effort to  
24 really come up with something that everybody could be  
25 satisfied with and answer the kinds of questions that you've

1 raised, Jim.

2 DR. JANE HENNEY: Marion, before you make your  
3 comments, which I'm sure will be on this point, you also  
4 alluded to in your remarks a bit of a concept of a tiering  
5 system or a separation of perhaps the transgenic versus  
6 others. Is this what you had in mind?

7 DR. NESTLE: Yes. I'd like to say I have complete  
8 confidence in FDA's ability to come up with something that,  
9 if it won't please everyone, will at least work. FDA has  
10 just published a 75 page Federal Register notice on  
11 trans-fatty acids. That's not going to satisfy everybody.  
12 But it certainly represents a great deal of thought and  
13 consideration of outside opinion and agency thought. This  
14 is not an impossible task any more than it's impossible to  
15 think up any other labeling scheme that requires a Federal  
16 Register notice. I'm quite confident you people can do it.  
17 I am a great reader of Federal Register notices and I know  
18 what goes into them. They're not going to please everybody,  
19 but they certainly will be something that will at least be a  
20 step forward.

21 I truly believe that this has to happen, and you  
22 might as well start working on it now because if it doesn't  
23 happen the lack of credibility in the industry will make it  
24 impossible for people who are producing corn to produce corn  
25 in this country. That won't do.

1 DR. JANE HENNEY: Next question from the panel?

2 MR. LAKE: Let me sort of pursue this a little bit  
3 more. We are already beginning to see some labeling on  
4 certain products to the fact that this product does not have  
5 any genetically engineered ingredients, and it seems to me  
6 that, you know, this is -- well, we're already beginning to  
7 see it and a good chance we're going to see more of it.

8 One of the questions that I would like the panel's  
9 input, and I like hearing that people have confidence in FDA  
10 to figure out complicated things. But it's nice also to get  
11 some advice or input or people's thoughts. One of the  
12 things, and it's been alluded to here just a little bit, is  
13 there really is no standard for what free really means, you  
14 know, in the real world. I would like to hear from the  
15 panel some thoughts about what the criteria might be.

16 I mean it seems to me, and let me just postulate  
17 this, that at least from I think I'm hearing, that enough  
18 has already happened so that if we insisted on something  
19 that is truly free, free, free, you know, absolutely  
20 nothing, not one molecule, then nothing would actually  
21 qualify as being free.

22 So the question then becomes, well, how small does  
23 it have to be before one calls it free? This is not an  
24 unfamiliar problem either. We faced it with fat labeling.  
25 It is possible to get at it, but I would be interested in

1 hearing from the panelists what your thoughts might be on  
2 that. And we'll just start at this end of the table. What  
3 do you think?

4           And there's a consumer perception component of  
5 this, so maybe from your knowledge of that you have some  
6 thoughts.

7           DR. NESTLE: I mean this is a big issue in Europe  
8 right now. I went to a biotechnology meeting in Brussels a  
9 couple of years ago where they spent the whole meeting  
10 talking to people who were doing genetic tests, trying to  
11 figure out what a lower limit was because there's so much  
12 contamination, corruption and cross pollenization these days  
13 that you really can't keep them separate. Although the  
14 segregation process could be done quite well.

15           I'll just throw it out. Less than one percent.  
16 How's that for a starting place?

17           MR. LAKE: That's a good start. Let's see how  
18 others react.

19           DR. PHILLIPS: Europe indeed, if any place, that  
20 would try to come up with a zero tolerance, Europe would  
21 clearly be the place. And even Europe has come to the  
22 realization that that can't be done. So zero is clearly not  
23 an alternative.

24           As to what it should be in terms of any kind of  
25 tolerance, one percent, two percent, I think you have to

1 take into account what do we have tolerance levels for in  
2 other parts of our food system. We allow, for example, in  
3 bulk corn, number two yellow corn that goes to Europe, we  
4 allow three percent foreign material. So there's some kind  
5 of a benchmark you can begin thinking about. Do you want  
6 something that's less than what we already have for products  
7 that are out there? I think most of us know what foreign  
8 material is, some things you don't want to hear about. But  
9 they're there.

10 So how does something like foods derived through  
11 biotechnology fit into this category? I will clearly say,  
12 it's hard to rationalize why it should be anything less than  
13 something like three percent. I think that's sort of a  
14 beginning point.

15 DR. GROTH: Well, yet another perspective. I can  
16 think of two ways to approach that task, Bob. One would be  
17 to focus on the verifiability of the production process, the  
18 way organic producers do. In organic production, one does  
19 not claim nor expect absolute zero pesticide residues  
20 because we know there's still DDT out there that was applied  
21 30 years ago. But we verify that the production process in  
22 a reliable certifiable way didn't use pesticides.

23 So there are ways of defining things that are  
24 produced in a way that meets the expectation of the consumer  
25 for that product. There are also I think scientific and

1 technical ways of defining it. One way is to say that what  
2 consumers expect is that it's as free as we can reasonably  
3 be sure, as we can verify, of ingredients that are not  
4 supposed to be there. That would depend on the ability of  
5 technology to detect residues of genetically modified  
6 ingredients when the claim was there weren't any. That  
7 unfortunately, from the industry's standpoint, is a shifting  
8 -- the bar keeps getting higher or lower, depending on which  
9 way you're looking at it. But it's not a predictable  
10 standard. It's going to get tougher as methodology  
11 improves.

12           But I would say if you took that route, the  
13 current state of the art is probably closer to a tenth of a  
14 percent than to either one percent or three percent.  
15 Depending again on the food you're looking at, I'm thinking  
16 of soy and corn, and there are probably other foods where  
17 it's nothing like that. So I can think of two generic  
18 approaches. One would be your ability to measure and the  
19 other would be your ability to verify.

20           MS. KATIC: Thank you. Actually Dr. Groth, I  
21 don't think we're very far apart on this particular issue.  
22 The manufacturers have had long discussions about this, and  
23 also have taken the approach that it needs to be a  
24 documentation type system, verifiable throughout the chain.  
25 However, in our discussions we realized that even when you

1 segregate and have a separated system, you know that you can  
2 test and come up with five percent, if not higher. So it is  
3 quite difficult, even when you segregate and have dedicated  
4 systems for these particular types of products to come up  
5 with a very low percentage. So I don't totally disagree  
6 with some of the statements that you made, that people have  
7 to realize that it's what could possibly be done. But the  
8 documentation would be very important.

9 MR. LOOP: We want to be careful that we don't get  
10 caught up in the precautionary principle and think that  
11 there can be no risk anywhere. We can go too far with this.  
12 And where we've got products that are comparable to  
13 traditional produced commodities, the cost benefit and the  
14 practicability of doing some of it, I know we have the  
15 technology to do it, but when I think about how do we police  
16 and enforce this sort of thing and when we look at the other  
17 problems we're facing, you know, how do we balance this out?  
18 I have some real concerns there as to how we go about doing  
19 this and if the scientific community says it's safe, then  
20 how far can we go? I'm not sure that this is the problem  
21 with the public. We've done some surveys, and we're  
22 surprised at the reaction we get from the public, from focus  
23 groups and so forth, that they've got confidence in the FDA  
24 and our food system and what we're doing, when they look at  
25 it compared with the rest of the world. They seem to be

1 very satisfied.

2 I'm afraid if we don't look out, if we -- we've  
3 got farmers out there now that have got products in storage  
4 trying to figure out what to do with it, what is the market,  
5 that it's time to plant and do we plant GMO? If we haven't  
6 got a market, it gets cluttered up, they're not going to  
7 plant. If we pull back away from this technology, when I  
8 think of all the benefits that are there, that could be  
9 available, and you know, we've got risk with the products  
10 we've got now and we can just go too far with this.

11 DR. GROTH: Can I say something more?

12 DR. JANE HENNEY: Certainly. I just want to ask  
13 another twist to the same question.

14 DR. GROTH: I wanted to respond a little bit what  
15 Carl just said. I think what he said is important and I  
16 don't disagree with it. But I think there's more than just  
17 safety involved here. We're really talking about consumer  
18 choice. There are going to be genetically modified products  
19 out there that people really want to buy. If I saw someone  
20 selling peanut butter that would lower my cholesterol level,  
21 I'd buy it. I think there's going to be a lot of products  
22 like that -- well, lower it even more. I think there are  
23 products out there in the future that we keep hearing  
24 promises about, that people are going to want to buy.

25 So I don't think the issue is that everybody is

1 going to want to avoid every genetically modified food  
2 because they think it's unsafe. I think there are going to  
3 be product specific concerns that will make some people  
4 prefer not to buy them, and it might be an environmental  
5 concern, it might be an animal welfare concern, it might be  
6 an ethical concern, a don't mess with nature concern, it  
7 might have nothing to do with safety. But there might be a  
8 good social reason for putting that information on the  
9 label. If it's on the label, it's got to be verifiable.  
10 This is something Bob has taught me over the years. It's  
11 got to be something FDA can insure the public is true. So  
12 that's what we're really talking about, is how do you verify  
13 it if there is a decision made, for whatever reason, to  
14 label it.

15 DR. JANE HENNEY: I appreciate those remarks. I  
16 guess a bit of a twist on Bob's question, when he so boldly  
17 asked you to go ahead and set a level for this, and a few of  
18 you took a shot at that. You came at it more from the bulk  
19 product in terms of one percent, three percent, a tenth of a  
20 percent. We're faced with a bit of a different issue at the  
21 FDA and that is, that product moving through the processing  
22 line and what may be three percent in terms of a corn export  
23 may end up in a taco chip that we would regulate.

24 Does that change your thinking in any way in terms  
25 of sort of how you saw this issue?

1 DR. GROTH: I think I was thinking of end  
2 products. I think the issue of products moving through the  
3 whole chain is quite interesting and I think we're finding  
4 that although many people in the industry sector predicted  
5 huge costs and impossibility essentially of segregation,  
6 that when there's a market demand for GMO free soy, for  
7 instance, from Japan, segregation occurs. It pays for  
8 itself.

9 So I don't think it's really that impossible. If  
10 the decision is made that we want labeling and we can set  
11 reasonable standards, I think the producers will meet them.

12 DR. JANE HENNEY: Margaret?

13 MS. PORTER: I have a question about consumer  
14 research and consultation. A number of the panelists have  
15 mentioned the importance of knowing what consumers think,  
16 and research that they've done, whether it's from the  
17 industry or consumer research or perhaps farmer research.  
18 I'd be interested in knowing, particularly given the  
19 differences in results that I'm hearing, having the various  
20 panelists comment on what's the best way to get at an  
21 accurate sense of what a broad range of consumers think  
22 about these issues and how they will interpret various  
23 statements that might or might not be on the label.

24 MR. LOOP: We did most of ours through polling,  
25 telephone polling with hiring professional pollers to do it.

1 How accurate that is, I guess is anybody's guess. But  
2 you've got to go somewhere and that's the way we have gone  
3 about doing it.

4 DR. NESTLE: There's really a huge social science  
5 research base now for doing this kind of consumer research.  
6 Many of the surveys that were done, were done I think quite  
7 well. Others I think asked extremely leading questions and  
8 got precisely the answer that they wanted. In the amount of  
9 time I had, I didn't have the time to go through it. Some  
10 of the questions are quite hilarious actually in the way the  
11 questions were asked.

12 But you sit down and do focus groups. You do  
13 sample polling. You decide who your audience is.

14 [Interruption from audience.]

15 DR. NESTLE: But you're not a representative  
16 sample. You people have self-selected yourself here. I'm  
17 not saying there's anything wrong with your opinion, and you  
18 represent your opinion. But if you want to get a percentage  
19 of opinion from people in the country, you do a  
20 representative sample.

21 [Interruption from audience.]

22 DR. NESTLE: Oh, I think there's been lots of it  
23 done already.

24 DR. JANE HENNEY: At this point this is a  
25 discussion between the two panels. We'll get to the public

1 input in just a few minutes.

2 DR. NESTLE: I think the public input is very  
3 important. It's very good that you're going to get it. And  
4 you're going to get it. Clearly you're going to get it.  
5 And this is an under-represented group of people who are  
6 heard on this issue.

7 But I don't see anything complicated about doing  
8 this kind of research. You want to know? You ask. Right  
9 now you're asking and you're going to hear.

10 DR. JANE HENNEY: Lisa?

11 MS. KATIC: Actually in particularly ours, and  
12 many others that we've looked at, have tested actual  
13 concepts and messages to see what consumers really think.  
14 It helps you get into the mind of what consumers really  
15 think about this technology. And interestingly, there's  
16 been some people that have talked about the consumers not  
17 being amenable to feeding hungry people and that that's not  
18 a message that's a good one to use. We found with U.S.  
19 consumers that that was a very positive message and that  
20 they thought that that was an important one to communicate.  
21 I think Dr. Nestle brought up a good point, that I think  
22 it's misleading to imply that that's the only way to feed  
23 hungry people. I certainly wouldn't say that that is. But  
24 it certainly is one way that we can feed a developing  
25 population and hungry people in developing countries. And

1 that our consumers do understand that that's important.

2 DR. GROTH: I'd like to endorse what I've already  
3 heard and also add a few perspectives. I think, Margaret,  
4 you asked what's the best way. I think use everything.  
5 Don't pick one way, but put all the pieces together. It's  
6 like the seven blind men with the elephant. You get a  
7 different perspective from each technique, and the truth  
8 emerges somehow from the mixture, not just from any one  
9 particular approach.

10 Also I think we all need to be aware that  
11 consumers are very heterogeneous. We're not talking about  
12 one average person out there who represents everybody.  
13 There are many different groups and types of individuals out  
14 there. And people react to different kinds of technology  
15 and different kinds of choices, different ways. So what  
16 we've learned from examining what are called green consumers  
17 is that there are many different categories.

18 There are people who are totally committed to  
19 living a green lifestyle and want to buy environmentally  
20 safe products. There are people who are what are called  
21 opportunistic greens. If it's just as good as and costs as  
22 much as or less than the other, they'll buy it. And there  
23 are people who think the whole environmental movement is  
24 hokum and they don't want anything to do with any of these  
25 products, and there are people all the way in between.

1           We really can't meet everybody's needs by one  
2 solution. We've got to try to have a system that provides  
3 for choice, so that people can get what they need.

4           DR. PHILLIPS: And I think Ed just made a perfect  
5 case for why you want to go about this in a voluntary way,  
6 because you can't meet every conceivable need that consumers  
7 have. This is where you let the power of the marketplace  
8 speak to the industry. If there is enough demand for this  
9 kind of information, for this kind of food or to be excluded  
10 from eating this type of food, it will represent itself in  
11 the marketplace and that's why voluntary approach to this  
12 makes the most sense.

13           DR. JANE HENNEY: More questions from the panel.  
14 Bob has got one.

15           MR. LAKE: This is a more practical question that  
16 I'm going to challenge the panel with. Let's assume that  
17 FDA decided to take on the challenge of developing one of  
18 our famous Federal Register documents that answers all the  
19 questions and we're on the other side of that, and whatever  
20 the standard is, if there is one. Let's also assume that at  
21 least for some products or some product lines perhaps that  
22 labeling, that this type of product does not contain any  
23 genetically modified ingredients. It turns out to be  
24 positive enough so that there's a marketing advantage to  
25 having that kind of a label.

1           It seems to me, in that situation, that there is  
2 an incentive for people who actually have genetically  
3 modified ingredients to nonetheless label their product as  
4 being free of those ingredients. So that we then face an  
5 enforcement issue or potential enforcement issue. I guess  
6 my question to the panel is, to what extent would you expect  
7 FDA to be engaged in the active enforcement of such a  
8 standard, were it to be developed?

9           MS. KATIC: Actually that's one thing that I, as  
10 you probably heard, said in my comments, that we feel that  
11 up front that is something that FDA should establish,  
12 guidelines and criteria for making those kinds of claims.  
13 So that we don't have chaos in the marketplace and that they  
14 really do have to be substantiated and truthful and not  
15 misleading. And certainly that's difficult and we're still  
16 discussing all of those various issues. But we do think  
17 that that's something that FDA, as well as FTC, need to  
18 discuss as well.

19           MR. LAKE: Assuming we'd done all that, though, my  
20 real question was, to what extent then should FDA be  
21 policing that labeling? That's really my question.

22           MS. KATIC: I guess to the same extent that you  
23 would with any other, no different.

24           DR. PHILLIPS: I think that's exactly right. And  
25 as well as the way you've already gone about this with

1 regards to BST in milk, the type of label that you can put  
2 on, where there must be a disclaimer, so that you are  
3 indicating on that label that the FDA has found that there  
4 is no significant difference between that that is done  
5 synthetically and that naturally through the cow. Same  
6 thing would have to apply here with regards to labeling, as  
7 well as the FTC being involved in the way that the product  
8 is advertised, so that it does not mislead consumers. Those  
9 are, I would say, some of the main things that we would  
10 expect to see from FDA.

11 DR. GROTH: Bob, the question is really how much  
12 police activity should we expect of FDA on this. I think I  
13 agree with Lisa, as much as is necessary, as much as you do  
14 on most issues. But I'd like to also express a little  
15 skepticism about the effectiveness of policing as a way. I  
16 think voluntary labeling works on an honor system, even if  
17 it's mandatory, making sure it's accurate. There's a lot of  
18 honor system in there. FDA can't be everywhere checking  
19 everything all the time. It's just not reasonable to  
20 expect.

21 But there are other ways that this system can be  
22 checked. I remember back nine, ten years ago when apple  
23 growers were promising the public that they weren't using  
24 Alar but in fact, many of them had gone back to it quietly.  
25 Consumers Union and CBS tested apples and found Alar and the

1 whole thing was blown wide open. There are other checks on  
2 the system. I think if the industry were committed to the  
3 labeling, it would want the labeling to be true and there  
4 would be very little cheating going on. If there was,  
5 somebody would probably find out and there would be a hell  
6 of a stink and it would self-correct.

7 MS. KATIC: And I might add, there's already that  
8 system in place with competition. Manufacturers are  
9 definitely paying attention to what each other is doing and  
10 making sure that everything is above board.

11 DR. NESTLE: These things just don't seem very  
12 complicated to me. Consumer Reports has already done an  
13 outing of a group of products. My understanding is that  
14 there's a very simple test that some company is devising and  
15 there is three or four companies that make very simple tests  
16 for this. Lots of people are going to be able to use those.  
17 I think FDA will get a lot of help in its policing.

18 DR. JANE HENNEY: Are there questions you would  
19 like to ask each other?

20 DR. GROTH: I wanted to pick up on something that  
21 Ralph Hardy said this morning and that we also heard from a  
22 couple of people this afternoon. That is the idea of  
23 dialogue. I think, as I said, it's very good that FDA is  
24 having this kind of a gathering. I think it should be done  
25 more often, and I think it should be done more assertively

1 by the interested industries.

2 I would like to appeal to Mike and to others from  
3 the biotech industry and ask them to think about a process  
4 like this, that could be relatively regular, where they  
5 could get together with interested parties, stakeholders.  
6 The government would call them. Sectors of the industry and  
7 of the public and of academia and government could be there  
8 just as citizens perhaps, and talk about some of the issues.  
9 I thought Ralph said something good this morning, and I  
10 would like to expand on it. He said let's get a bunch of  
11 scientists together and try to agree on what the truth is.  
12 I think that would be a very difficult task, Ralph.

13 But I think I would like to see the industry and  
14 the critics of the industry get together and talk about some  
15 of the broader issues, such as what kind of values should  
16 guide society's use of this technology? Who should decide  
17 really which products get commercialized first? I think  
18 that's what a lot of the distrust and debate is about. I  
19 think the industry won't be free of that distrust until it  
20 confronts the issues and talks to the people about those  
21 issues and really tries to reach some sort of a broader  
22 society consensus about this.

23 I'm not saying anything new. The president of the  
24 Rockefeller Foundation said this to the Board of Monsanto a  
25 couple of months ago. I don't know whether that really had

1 much effect, but I'd really like to see that sort of  
2 approach taken. I think if the industry wants the public to  
3 believe that you care about the concerns that are being  
4 raised, you've got to talk to the public about those  
5 concerns. It's really pretty straight forward. I guess  
6 Marion and I just see things in pretty black and white  
7 terms.

8 DR. PHILLIPS: We would certainly embrace that,  
9 Ed. There definitely has to be more dialogue. I think we  
10 all have been guilty of not having enough dialogue and  
11 understanding where each is coming from. I think forums  
12 like this, forums through Ralph's organization or some other  
13 type of group that wants to host, I think it should be on a  
14 neutral site so that no one feels as though they've got any  
15 kind of turf there at all. I think an honest exchange of  
16 views and understanding where each is coming from so that we  
17 can go forward and still keep technology, innovation active  
18 but at the same time safeguarding that indeed we're not  
19 doing harm along the way is in everyone's benefit.

20 MS. KATIC: Yes, I agree wholeheartedly. I just  
21 wanted to make one clarification. Ed, I'm not sure who  
22 exactly you were referring to when you talked about trust in  
23 industry, but I just felt the need and urge to say that if  
24 it was the manufacturers you were referring to, I think we  
25 have absolute trust from consumers because we wouldn't have

1 the successful brands on the market that have been out there  
2 for so long. So that's absolutely important and imperative  
3 to the manufacturers.

4 DR. JANE HENNEY: I want to take this opportunity  
5 to thank you, each member of the panel. You have been very  
6 thoughtful in your comments and your responses to us. We  
7 appreciate the diversity of views and expected to receive  
8 them and glad that we did.

9 I would say we are scheduled for a break, but I  
10 think because we would like to have as much time now for the  
11 public comment as we can, let's just take a quick five  
12 minute stretch break, allow the panel members to leave and  
13 we'll do a quick recess up here, and then we'll get onto the  
14 public session.

15 [Whereupon, a recess was had.]

16 DR. JANE HENNEY: We're now going to hear from  
17 individuals who've requested time to speak at this meeting.  
18 We have had a very large number of requests to speak. We  
19 know, again, that there's going to be a very diverse set of  
20 views on this particular topic that will be presented.  
21 Because we have so many we have asked that each speaker  
22 limit their time to two minutes. We do encourage you if you  
23 can't either squeeze it in those two minutes or other things  
24 occur to you that you would like to say that you make sure  
25 that we hear.

1 We do have our docket open and full written  
2 comments to that docket will be accepted and it's going to  
3 be open through the course of these three meetings. It will  
4 not be closing until January 13th of this next year. So you  
5 have plenty of time to get us any additional thoughts that  
6 you might have.

7 I think I mentioned this morning that when you did  
8 register and received your folder there was a number in it.  
9 That number designated the order in which we will be taking  
10 speakers. And for this particular session I have asked Mr.  
11 Lake to moderate. We won't be, as the agenda originally  
12 called for, taking any breaks. So if you or the other panel  
13 members feel a need to take at least a few moments for  
14 yourself, feel free to do so but we won't have any set break  
15 during the course of this meeting.

16 We will be running until almost 6:00 o'clock but  
17 closing the meeting at that time. So Mr. Lake if you'd take  
18 over with any other instructions you might have.

19 MR. ROBERT LAKE: Okay. In order to get through  
20 the very large number of presenters, and it's basically  
21 everyone in the room who hasn't already had something to  
22 say, so it's a lot of you. We want very much to hear from  
23 each of you. We also want to be sure that each of you have  
24 an opportunity to hear the other people in the room. And  
25 with that in mind, again, we do have to stay within the two

1 minutes. And in order to facilitate that and avoid loss of  
2 time between speakers you'll see that we have a podium  
3 that's actually a dual podium, two sets of microphones.

4 And you will also see sitting on the tops of the  
5 podiums little timing devices with a light. And when you  
6 start you will have a green light. When you get within 30  
7 seconds, that is to say, you know, a minute and a half into  
8 your presentation it'll shift to a caution light for the  
9 final 30 seconds. And when your time is up a red light will  
10 come on and I think there's also a beeper associated with  
11 that. And, also to, you know, we'll be alternating back and  
12 forth between the two mics but also we've got people, you  
13 know, working both sides of the room to line up sort of  
14 aisle by aisle the next set of speakers so that as one sits  
15 down the next one is ready so that we are not losing time  
16 from one to the next.

17 The other thing I would note is that we also are  
18 interested in any written comments that you have either now  
19 or later. If you have some with you now we would receive  
20 those this afternoon, and I believe you can hand them to the  
21 people that we have who are doing the assisting. With that  
22 I guess we ought to go ahead and get started. So if you  
23 want to begin with the first speakers. And the lady we have  
24 over here is actually going to be writing the time and --  
25 okay, do you want to -- are we going which -- which side are

1 we going to do first?

2 PARTICIPANT: Left side first.

3 MR. ROBERT LAKE: Left side first. Okay. And  
4 also, please identify yourself and if you represent an  
5 organization we would appreciate knowing that as part of  
6 your presentation. Thank you.

7 DR. ROGER BEACHY: Thank you for the opportunity  
8 to speak. My name is Roger Beachy from St. Louis the Donald  
9 Danforth Plant Science Center. I want to thank you for the  
10 opportunity to present my enthusiastic endorsement for the  
11 mechanisms that the FDA has put in place for evaluating  
12 foods that have been developed through modern plant  
13 breeding. Having taken part in some of the early successes  
14 of genetic transformation of plants, in this case for the  
15 resistance of virus diseases, I was peripherally involved in  
16 the scientific discussion related to issues of safety at  
17 such plants in the ecological environment and the safety of  
18 foods derived from resistant plants.

19 Indeed, many of the studies that we have done  
20 since that time were in response to the questions raised by  
21 environmental groups. It came as a surprise to me that new  
22 regulations were being implemented in what most scientists  
23 considered to be modern plant breeding and crop improvement.  
24 In light of the fact that plants developed by much less  
25 precise and more genetically disrupting mechanisms were not

1 subjected to similar regulatory oversight. However, like  
2 most scientists I came to realize that oversight is an  
3 important component of acceptance from the standpoint of  
4 consumer assurance.

5           For more than 15 years I've taken great interest  
6 in each of the products of crop biotechnology that has  
7 reached the market place. I watched the development of the  
8 decision tree that must be travelled by the seed companies  
9 that wish to sell the improved seeds to farmers and  
10 producers. Great care has been taken to ensure that  
11 allergens are not included or induced in foods in  
12 genetically modified crops. And that essential vitamins,  
13 minor elements, proteins, carbohydrates, lipids and  
14 secondary metabolites are not substantially different from  
15 those of the parent.

16           Indeed, I consider that most of the requirements  
17 are so complete that it would be difficult for many  
18 university scientists to participate. In fact, we won't see  
19 these used because it's going to be an onerous in  
20 applications in small crops. There will be areas where  
21 we'll continue to have to use a chemical usage and other  
22 forms of crop production simply because we can't meet all  
23 the criteria that are there. Tough luck for the farmer, for  
24 the consumer as well as for the environment. I find it  
25 remarkable that unfounded charges are not built on

1 scientific or credible fact.

2 MR. ROBERT LAKE: Your time is up.

3 DR. ROGER BEACHY: Thank you very much.

4 MR. ROBERT LAKE: Thank you.

5 DR. ROGER BEACHY: Anyway, I appreciate it.

6 MS. JOYCE NETTLESON: Joyce Nettleson, Director of  
7 Science Communications for the Institute of Food  
8 Technologists here in Chicago. The Institute of Food  
9 Technologists, IFT, is a 28,000 member professional  
10 scientific society for food science and food technology. We  
11 commend Dr. Henney and the panel of FDA for reaching out  
12 directly to the public to explain its science based  
13 regulatory process for genetically engineered plants and  
14 receive public comments. We also commend FDA for the  
15 success of its policy which has to date contributed to the  
16 unmarred safety record of at least 40 genetically engineered  
17 plants.

18 IFT believes FDA consultation process has achieved  
19 its intended purpose of ensuring that plant developers  
20 adequately test the safety of genetically engineered plants  
21 with regard to nutrient levels and freedom from potential  
22 toxicants and allergens. While lengthy and costly this  
23 process has increased familiarity with transgenic plants and  
24 provided the basis for U.S., and indeed international  
25 confidence in the healthfulness and environmental safety of

1 bio-engineered plants.

2           FDA's review process has also created a safe track  
3 record for other countries to emulate. And although we  
4 continue to believe that from a scientific perspective  
5 review of genetically engineered plants should be no  
6 different from that of conventionally bred plants which are  
7 not subject to pre-market approval, IFT recommends that the  
8 review process continue on a voluntary and expeditious basis  
9 to maintain public confidence in the safety of  
10 bio-engineered plants and to reassure plant developers that  
11 novel plants can reach the market place in a timely manner.

12           Future bio-engineered foods will be developed  
13 according to agricultural, consumer, manufacturer, public  
14 health and market place demand. Safety evaluation must be  
15 based on the characteristics of the product and not on the  
16 process by which it was produced. This principal must  
17 remain the hallmark of evaluating the risk of all foods  
18 bio-engineered or otherwise.

19           MR. ROBERT LAKE: Your time is up. Thank you.

20           MR. JEFFERY MANDALIS: Good afternoon. My name is  
21 Jeffery Mandalis I am from Eco-Fields which is a retail  
22 store specializing in environmentally correct and  
23 agriculturally based paper and products primarily from  
24 industrial hemp. I am here today because I am quite  
25 concerned personally about genetically modified organisms.

1 I first became aware of these while doing research at the  
2 Board of Trade about two years ago for some of my traders.

3 Now one thing that wasn't discussed today which is  
4 the center of my concerns with GMOs is the terminator  
5 technology developed by the USDA and Monsanto which renders  
6 seeds infertile that are planted of these terminator  
7 hybrids. Now Monsanto will claim it's the only way to  
8 protect their intellectual investment is to have this  
9 terminator technology. But there might be other uses for  
10 this which aren't as disclosed.

11 These companies like Dupont and Monsanto, they're  
12 not life science companies they are death science companies.  
13 They are munitions makers and for over 100 years they've  
14 been creating ways to kill people. Terminator is another  
15 weapon and it would work quite perfectly if it wasn't for  
16 the fact that consumers are just completely rejecting this  
17 as they learn about it. In Europe they learned about it a  
18 little fast although here in America people are catching on  
19 a little slower but they're still catching on.

20 In fact, one of the most interesting things is how  
21 this technology has been already profiled in the 1970's in  
22 the James Bond film On Her Majesty's Secret Service where  
23 the evil chemical banking syndicate Specter creates a  
24 technology which will render all the cattle and plants in  
25 Europe infertile. And I think this same level of let's play

1 with nature type of mentality is on that same sort of James  
2 Bond bad guy level.

3           So, I hope the FDA does realize that consumers are  
4 not willing to be guinea pigs and that they should be  
5 labelled. And maybe the FDA says they can't really label  
6 these things but the Board of Trade hasn't had that problem  
7 and that's why they put a premium on crops that have not  
8 been genetically modified. So please go organic. Thank  
9 you.

10           MR. NEIL LEVIN: My name is Neil Levin I am with  
11 the Fruitful Yield. I am a certified clinical nutritionist  
12 and the purchasing manager for a chain of natural food  
13 stores. We avoid selling GM foods in our stores and our  
14 customers preferred certified organic products. I support  
15 the genetically engineered food right to know acts. Right  
16 now the only voluntary labelling happening is GMO free  
17 labelling.

18           Consumers need to know if their food contains any  
19 genetically engineered material because of concerns over  
20 health and safety risks, environmental protection, religious  
21 and ethically based restrictions. Science has not advanced  
22 enough to guarantee the safety or to warn of unforeseen  
23 reactions. The Center for Food Safety has criticized the  
24 FDA for not requiring pre-market safety testing and  
25 labelling of GMO products. The American Corn Grower's

1 Association has endorsed GMO labelling legislation.

2           The New York Times on November 12th says that an  
3 increasing number of studies suggests that GM plants can  
4 interact with the environment in hazardous ways like  
5 creating super weeds and that regulators are not demanding  
6 the proper studies to assess the risks. The chief executive  
7 at Dupont has said, "Unfortunately many in the industry have  
8 been reluctant to address concerns about the risks of  
9 biotechnology but we have to listen to the people who are  
10 now raising alarms. We don't have all the answers and to  
11 pretend we do or to brush off concern as unfounded is to be  
12 arrogant and reckless."

13           -- in October said that the possibility that a  
14 plant vector in common use in some GM plants can affect the  
15 mucosa of the GI tract, and exert powerful biological  
16 affects. May also apply to GM plants containing similar  
17 constructs such as soya [phonetic] beans. FDA's current  
18 policy of requiring labels of products with known allergens  
19 will not protect people with food sensitivities that are  
20 below the levels sensitive to food allergies. Thank you.

21           MR. ROBERT LAKE: Thank you.

22           MR. MAX GOMBERG: My name is Max Gomberg I'm here  
23 representing University of Chicago student organizations  
24 whose members are concerned with the dangers of  
25 bio-engineered food. We are pleased that the FDA has taken

1 the initiative to solicit public comment on these issues.  
2 However, we are dismayed that what was advertised as a  
3 meeting to listen to public concerns has excluded most of  
4 the public. Commissioner, the federal government needs to  
5 do more to regulate genetically engineered foods.

6 In addition, the government has an important roll  
7 to play in educating people about what goes into foods such  
8 as Newly's [phonetic] Potatoes, Round Up Ready Soy Beans and  
9 hybrid corn. Current approval requirements for genetically  
10 modified foods allow corporations to market plants whose  
11 genetic makeup may be harmful to both people and animals in  
12 many ways. The FDA does not let drugs with potentially  
13 lethal side effects into the market without multiple trial  
14 phases and scientific assurances that those side effects  
15 will be less damaging than the condition for which the drug  
16 is being taken.

17 Why should this cautious regulatory approach not  
18 be the same for genetically modified foods? Humans are  
19 altering ecosystems at such a rapid pace these days that we  
20 barely ever stop to reflect upon the consequences of our  
21 actions. I think I speak for many people when I say that I  
22 worry we are trying to do too much too fast. I read every  
23 day about tragedies caused by overzealous technological  
24 prophets who gave no regard for what their amazing  
25 inventions might do wrong. We do not need biotechnology to

1 feed the starving. We do, however, need to maintain healthy  
2 ecosystems.

3           Labels. Labels should indicate whether a food is  
4 genetically modified to enhance aesthetic or medicinal  
5 properties such as favor and nutrient content or whether it  
6 was given a gene that allowed it to withstand huge doses of  
7 pesticides. It is the latter case that examples the peril  
8 in the bio-food industry. When people design plants to  
9 tolerate massive applications of poison, governments approve  
10 and the rest of the people are unaware that they are  
11 contributing to the destruction of the soil and water that  
12 make life possible it is a sign that things have gone  
13 terribly wrong.

14           Ms. Commissioner, many people believe that all  
15 life on this planet has a special integrity. We have now  
16 reached the point where we can fundamentally alter that  
17 integrity. Let us use our power wisely or let us not use  
18 it at all. Thank you.

19           MR. ROBERT LAKE: Thank you. Next.

20           MR. JOSEPH MENDELSON III: My name is Joseph  
21 Mendelson I'm the legal director for the Center for Food  
22 Safety. We are non-profit, environmental, human health and  
23 sustainable agricultural advocacy organization located in  
24 Washington, D.C.

25           I'm happy that the FDA is finally publicly

1 admitted here today that it has no legal binding regulations  
2 to require any pre-market safety testing or let alone a  
3 pre-market notification system that a genetically engineered  
4 food is coming on to the market. That leaves a purely  
5 voluntary consultation process, defacto-mandatory or not,  
6 that is a giant loop hole that allows potentially dangerous  
7 products to come onto the market.

8 That is something that the American consumers are  
9 in now way going to accept. Contrary to the Farm Bureau,  
10 our organization supports a precautionary principle and in  
11 fact feels it's embodied very much in the Federal Food Drug  
12 and Cosmetic Act. And that's why our organization was  
13 compelled to sue the FDA on its 1992 policy because we  
14 believe that law requires mandatory pre-market safety  
15 testing. It required full environmental review under the  
16 National Environmental Policy Act, which I may add applies  
17 to all agencies and not is just EPA's mandate. And also,  
18 that the act requires mandatory labelling because these  
19 foods are per say materially changed.

20 This should not come as as surprise to the agency.  
21 In fact, in 1992 when it issued its food policy it received  
22 thousands of comments and overwhelmingly the American public  
23 wanted mandatory labelling, pre-market safety testing and  
24 environmental review. You speak of transparency, the agency  
25 has never responded to those comments. It hasn't responded

1 to the comments it received in 1993 as well. It had a 1994  
2 hearing on allergenicity, all that remains from that hearing  
3 is a stack of transcription that has never been taken into  
4 account in other ways by the agency.

5 Frankly, it's time for the agency to act and  
6 listen to the American public. Don't tell us what a great  
7 job you're doing because the fact is there are gaps and loop  
8 holes. It's time for the agency to be the servant of the  
9 American people and not a slave to industry.

10 MR. ROBERT LAKE: Thank you.

11 MR. JOSEPH MENDELSON: Thank you.

12 MS. JANE AKRE: In the interest of saving some  
13 time I'd like to pull the comments of number seven and  
14 number eight. Madam Commissioner, I am Jane Akre appearing  
15 with Steve Wilson. We came to tell you why it would be a  
16 mistake for you to assume that Americans will learn what  
17 they need to know about bio-engineered food from the news  
18 media.

19 We're not media bashers, we're media insiders,  
20 reporters for many years at places like CBS, ABC and CNN.  
21 We came here today from Florida to tell you about the  
22 pressures brought to bear on journalists who simply try to  
23 report on bio-engineered foods and issues of the like. It's  
24 unlike anything either of us has seen in our 50 years  
25 collective experience.

1 We know this because in trying to broadcast and  
2 honest report on bovine growth hormone for Fox Television  
3 viewers it costs both of us our jobs. Two minutes here is  
4 not enough to tell you and to show you how Monsanto  
5 pressured Fox with strongly worded letters attacking us as  
6 unethical, unfair, scientifically stupid reports and claimed  
7 anyone who even dared raise questions was a scientifically  
8 incompetent person.

9 MR. STEVE WILSON: Madam Commissioner, two minutes  
10 is not enough to discuss what Monsanto's New York lawyer  
11 meant to convey when he fired off this letter to Fox  
12 executives saying there is a lot at stake in what is going  
13 on not only for Monsanto but also for Fox News and its owner  
14 Rubert Murdock. Do you think that threat could have been  
15 any more clear when he fired off a second letter and he  
16 wrote that allowing us to report documented facts on  
17 television, some of the same kinds of things you've been  
18 discussing here today, could lead to serious damage to  
19 Monsanto and dire consequences for Fox News?

20 Two minutes is not enough to detail how we were  
21 twice offered large sums of money personally to never report  
22 to the American people facts that we well documented and to  
23 never reveal how the biggest concern at Fox, which by the  
24 way is the owner of the most television stations in America,  
25 was to cover up the facts to avoid trouble with Monsanto and

1 the GM industry.

2 Monsanto, of course, a big advertiser and a  
3 potential litigant. And two minutes is not enough to tell  
4 you about other reports and their editors who we have now  
5 found have been similarly pressured to alter their reports  
6 -- we're sharing our time I believe we have some more here.

7 MR. ROBERT LAKE: That's fine. Keep going.

8 MR. STEVE WILSON: Two minutes is not enough to  
9 tell you about other reports in the mainstream news media  
10 who have been similarly pressured to alter their reports  
11 about GM foods or to just drop stories altogether. And two  
12 minutes is not enough to ask you, Madam Commissioner, why  
13 does it appear sometimes that you and the people who we  
14 depend on to be government watchdogs are more concerned with  
15 promoting and protecting the people you regulate than you  
16 are with informing and protecting we the people.

17 So in the interest of keeping Americans informed,  
18 could you please remember what we just told you, how it  
19 works sometime in the mainstream media? I hope you agree  
20 that when it comes to freedom of information less is not  
21 more. Thank you.

22 MR. ROBERT LAKE: Thank you.

23 MR. RANDY GORDON: Commissioner Henney and members  
24 of the FDA panel, it's a pleasure for the National Grain &  
25 Feed Association to appear before you today with this brief

1 statement. I'm Randy Gordon NGFA's Vice President for  
2 Communications and Government Relations. NGFA is the  
3 largest and most representative agri-business organization  
4 of its kind in the United States. Our 1,000 member  
5 companies are commercial businesses that own and operate  
6 more than 5,000 grain elevators, feed mills and processing  
7 plants throughout the nation.

8 Our member companies handle for than two thirds of  
9 U.S. grains and oil seeds. We commend FDA for having this  
10 series of public hearings to better inform the public about  
11 the procedural safe guards that the agency has in place to  
12 ensure the safety of foods produced from biotechnology. Our  
13 mission statement commits our organization to fostering an  
14 efficient, free market environment that achieves an  
15 adequate, safe and high quality food supply for domestic and  
16 world consumers.

17 Consistent with this mission the NGFA supports  
18 biotechnology and other scientific and technological  
19 innovations that contribute to the availability of an  
20 adequate, safety and high quality food and feed supply. The  
21 NGFA is not aware of any scientific evidence that would  
22 justify FDA changing its science based 1992 regulatory  
23 policy statement which we believe ensures that commodities  
24 produced from biotechnology meet the same safety standards  
25 and labelling requirements as traditional foods produced

1 from conventional grains and oil seeds.

2           Indeed, this generally recognized safe standard  
3 has been the gold standard that FDA has used to govern the  
4 safety of our food supply for more than 30 years, precisely  
5 because it is a science based approach. We believe the GRAS  
6 is dynamic and we believe the FDA could perhaps do a better  
7 job explaining the kind of scientific consensus that is  
8 needed for a substance to be declared GRAS. The Federal  
9 Food, Drug and Cosmetic Act authorizes FDA to require  
10 pre-market review of any substances intentionally added via  
11 biotechnology if they do not meet the GRAS standard.

12           We believe FDA's authority under current law both  
13 pre and post market provisions is sufficient to protect the  
14 safety of the market place and the safety of our food  
15 supply. Thank you.

16           MS. JANE ALEXANDER: Hello. Jane Alexander, I'm a  
17 concerned citizen. In 1975 a conference of molecular  
18 scientists called for a moratorium on genetic engineering  
19 because they found that viruses could recombine in their new  
20 cellular environmental and possibly reactivate their disease  
21 producing ability or create new diseases. The Cauliflower  
22 Mosaic Virus has what's called a hot spot which means it is  
23 prone to break and join with other DNA at that point.

24           It is also used in a naked form which means its  
25 protein coat no longer limits what species it can infect and

1 could therefore possibly be infectious to mammalian cells.  
2 In spite of this, it is used in every GMO. What of the  
3 other bacteria and virus used in this technique? Will the  
4 antibiotic resistant genes in GMOs be passed on to soil  
5 micro organisms or to farm animals feed these crops, to fish  
6 and water or to human?

7 Contrary to all the propaganda put out on  
8 biotechnology we have not been engineering nature like this  
9 for thousands of years it's more like 30. Shooting a  
10 cassette of genes into a chromosome to land we know not  
11 where is hardly the same as mating your best bull with your  
12 best cow or cross pollinating plants. It is a totally  
13 different technique and should not even be compared to  
14 traditional cross breeding.

15 These additives to our food, foreign DNA including  
16 genes from bacteria and virus, are not generally recognized  
17 as safe and these foods are not substantially equivalent to  
18 traditional foods. Thank you.

19 MR. ROBERT LAKE: Thank you, ma'am.

20 MS. CHRISTINE PHILLIPS: My name is Christine  
21 Phillips. I'm a masters student at DePaul University and my  
22 thesis is in the analysis of the dialogue surrounding the GE  
23 issue. The FDA format has leant itself rather to sound  
24 bytes than informed balanced comments so I guess that's what  
25 I'll have to provide.

1           There are several core points I would like to make  
2 and aprapo [phonetic] to the previous testifier I will say  
3 this: There is to date one study of the effects on mammals  
4 of the genetic engineering technology we know besides that  
5 of Dr. Arpad Bustai [phonetic] formerly of the  
6 Rowitt [phonetic] Institute. It was written by Monsanto  
7 Science published in 1996. The study was a feeding trail of  
8 round up ready soil on rats, catfish, chickens and cows.

9           The potato used in most fast food restaurants and  
10 processed foods were developed by Monsanto to produce their  
11 own pesticides genetically engineered with a viral promotor  
12 called the Cauliflower Mosaic Virus. According to Dr. May  
13 Juan Ho [phonetic], Open University U.K., the Cauliflower  
14 Mosaic Virus is a piece of the virus' genetic material, this  
15 is all review, it is a naked form without the viral coat  
16 that normally determines host specificity. Without it the  
17 viral promotor may be taken up, as was said, by mammalian  
18 cells including human beings.

19           According to Dr. Bustai the damage to the stomach  
20 lining of rats and disruptions in the immune system were  
21 most likely caused by the Cauliflower Mosaic Virus. The  
22 Cauliflower Mosaic Virus is spliced into nearly all  
23 genetically engineered crops. These finding are collaborate  
24 by several recent studies if you care to look them up.

25           Most astounding was the finding by Dr. Bustai of

1 the decrease in brain size in rats as a result of his  
2 experiments with GE potatoes. I tried to contact Monsanto  
3 about the Cauliflower Mosaic Virus, they never return my  
4 calls. If anyone is interest I can refer you to two  
5 documents dealing with the manipulation and distortion of  
6 Dr. Bustai's studies and how he was silenced and prevented  
7 from defending them, as is one scientist I know in Chicago  
8 who is afraid to come here and speak out today.

9           Before the U.S. Agriculture Department and the  
10 Research -- at Delta and Pineland make more promises to feed  
11 the world they should clean up 660 tons of toxic waste  
12 containing genetically engineered basilis [phonetic] satilis  
13 [phonetic] B13 modified bacteria most of which was dumped in  
14 a schoolyard in the small farming community of Ranson  
15 Parguai [phonetic]. Thank you.

16           MR. ROBERT LAKE: Thank you.

17           MR. JAMES ROZA: My name is James Roza and I'm  
18 Director of Quality Assurance for Now Natural Foods and I  
19 serve on the board of directors of Citizens for Health a  
20 national consumer based activist organization. As the  
21 global population continues to grow and our natural  
22 resources dwindle mankind is continually searching for ways  
23 to meet the food supplies of future generations. We've been  
24 told that through genetic engineering scientists can improve  
25 yields, reduce herbicide use and preserve our environment.

1 All of these benefits are certainly noble given  
2 the expectations of the future. It's estimated that by the  
3 year 2025 our population will increase by over 50 percent  
4 and that only one percent of the world's land mass will  
5 provide acreage for sustainable agriculture. Couple these  
6 facts with the rise in life expectancy and we will find  
7 ourselves in a position where food production will not keep  
8 pace with demand.

9 Genetic engineering, we are told, allows  
10 scientists to address these concerns by creating new breeds  
11 of crops which have improved characteristics. We are also  
12 told that these modified crops will be identical to their  
13 predecessors with the exception of their genetic code. If  
14 this is true how can something so seemingly benign and  
15 potentially beneficial cause so much controversy? It would  
16 seem that the public would warmly embrace a technology that  
17 would benefit mankind.

18 Quite the opposite, however, is proving to be  
19 true. Public outcry from Europe, Asian and from our  
20 citizens at home have given us pause to the think about the  
21 ramifications of this new technology. Will genetic  
22 engineering live up to its promises or are there unknowns  
23 looming around the bend that could potentially hazardous?  
24 Let's look at the facts. Currently there are minimal  
25 controls in the introduction of new transgenic foods. This

1 leaves rooms for errors and omissions that could prove to be  
2 quite problematic.

3           Unlike the traditional methods of cross breeding,  
4 genetic engineering allows for greater variability  
5 uncertainty that the effects of these foods may have on our  
6 health and environment. To date, no long term studies have  
7 been conducted to ensure the safety of any genetically  
8 engineered food. Without these assurances foods of this --  
9 will always remain suspect until science can prove  
10 otherwise. There is also the issue of potential allergens  
11 being incorporated into the foods that were once considered  
12 safe.

13           The random inclusion of genes from sources  
14 dissimilar to its host could cause problems for millions of  
15 people suffering from allergies or who for religion reasons  
16 must avoid certain foods. Consumers are being done a  
17 disservice if they can't be assured that the food selections  
18 they make at their local supermarket are in accordance with  
19 their health and religious needs. Thank you.

20           MR. ROBERT LAKE: Thank you, sir. Next.

21           MR. LIONEL TREPANIER: Good afternoon my name is  
22 Lionel Trepanier I'm with the Chicago Greens, the Green  
23 Party U.S.A. I have a few comments for the commissioner  
24 regarding how the hearing was held and then I'll condemn the  
25 FDA at the end.

1 I think the fact that the FDA chose not to use the  
2 larger of the two rooms that they had secured for today  
3 indicates a lack of willingness to hear from the public. In  
4 fact, I was over in the other room that had several hundred  
5 people in it this morning when the open ended statements  
6 sounded like martian talk and this went on for about a half  
7 an hour with not a single word was legible.

8 We were informed that the reason that the  
9 broadcast sounded like martian talk to us over there at the  
10 public hearing where we were quite literally put in the  
11 position of hearing was 'cause a media person had stuck  
12 their microphone up near the microphone used for  
13 broadcasting this and it was an unexpected result. And I  
14 think similarly you should consider the technology that you  
15 have here at biotechnology similarly rolled out untested.  
16 But here, rather than just interfering with people how they  
17 hear, they're threatening fish growing out of their heads.

18 So, I have a few other points. When I came into  
19 the room today I estimated 100 empty seats. And again, I  
20 think this points to the lack of the commitment on the part  
21 of the FDA to have a public hearing since they were keeping  
22 out hundreds of the public based on this room being full  
23 when in fact it was quite far from full. In fact, I had  
24 learned in my research prior to this hearing in my attempt  
25 to secure a speaking position here that on November 1st the

1 Chicago Office of the FDA falsely reported that the speaking  
2 list was full. That was an artificial full at 30 persons.

3 I'm glad that the federal office, the Washington,  
4 D.C. office, so fit to pressure the local office here to  
5 keep the comment period for signing up at least open until  
6 November 3rd which was the 15 days.

7 MR. ROBERT LAKE: Thank you, sir.

8 MR. LIONEL TREPANIER: Yeah. And the condemnation  
9 is the revolving door loss of trust.

10 MR. DON FITZ: I am Don Fitz speaking for the  
11 Green Party of St. Louis. At least three developments in  
12 1999 call into question the safety of genetically altered  
13 foods. The best known is the publication in Lancetave  
14 Research [phonetic] by Dr. Busai in feeding genetically  
15 altered potatoes to rats. Dr. Busai's peer reviewed  
16 research demonstrated the rats suffered damage to their  
17 immune systems and digestive systems from eating the  
18 genetically engineered food.

19 Second, Dr. Mark Lapay [phonetic] reported in 1999  
20 that genetically engineered soybeans have developed a 14  
21 percent less phyto estrogens which could protect against  
22 heart disease and cancer. This line of research suggests  
23 that genetic engineering can cause food to lose nutritional  
24 value since it is designed to modify other traits such as  
25 increasing shelf life.

1 Third, since two thirds of genetic engineering  
2 applications are for the purpose of increasing pesticide  
3 resistance, it is not surprising that altered crops have  
4 higher levels of pesticide residues. Dr. Judy Carmen of  
5 Flunder's [phonetic] University is publishing an article on  
6 Monsanto's application to grow Round Up Ready soy in  
7 Australia and New Zealand. Her article will appear in the  
8 winter 2000 issue of Synthesis Regeneration for which I am  
9 the editor.

10 Dr. Carmen writes that the genetic modification in  
11 Round Up Ready soybeans involves incorporating a bacterial  
12 version into the soybean plant giving the soybean protection  
13 from round up. Monsanto claims that cooking the soybean  
14 would deactivate it. Dr. Carmen writes that raw soybeans  
15 will be fed to cattle. Steak is often served medium rare to  
16 rare, therefore, there is a possibility will consume the  
17 still functional enzyme in their diet.

18 Dr. Carmen adds that Monsanto then applied to  
19 permit the allowable level of round up ready glifosate  
20 [phonetic] would be increased 200 fold. However, the  
21 soybeans accessed in application were not treated with round  
22 up. Therefore, they are not equivalent to the soybeans that  
23 will be used for consumption. Concerning the absurd claim  
24 that there's no evidence of the danger of genetically  
25 engineered food, all I want to say is that there are none so

1 blind as those who will not see. And there are none so deaf  
2 who will not hear.

3 The Green Party of St. Louis requests that all  
4 genetically altered food be removed from production and  
5 distribution.

6 MR. ROBERT LAKE: Thank you, sir. Thank you.

7 Next.

8 MR. DAVID SCHMIDT: I'm Dave Schmidt with  
9 International Food Information Council. As in foreign  
10 policy the U.S. and in this case the FDA often finds itself  
11 in a lonely leadership roll on food and agricultural policy.  
12 With this leadership comes responsibility because the FDA  
13 serves as the model for science based regulation around the  
14 world.

15 The vast majority of Americans have great  
16 confidence in the safety of our food supply and in FDA's  
17 regulation of our food as evidenced in a September 1999  
18 Gallop [phonetic] Survey. The International Food  
19 Information Council has also commissioned since 1997 three  
20 surveys of U.S. consumers by Worth and Worldwide, the most  
21 recent October 8 through 10th, 1999.

22 Two out of three consumers support foods produced  
23 through biotechnology and have confidence in the Food and  
24 Drug Administration's policy for labelling biotech foods.  
25 While some surveys have suggested that most Americans demand

1 labelling of biotech foods the Ipic [phonetic] surveys have  
2 been the only public vehicles to test consumer reaction to  
3 the actual Food and Drug Administration labelling policy.

4           Seven out of ten Americans support the current FDA  
5 labelling policy which requires that foods produced through  
6 biotechnology include special labelling only if the food has  
7 been significantly changed. When Americans are given  
8 complete information they endorse the scientifically  
9 grounded approach of the FDA. The Ipic survey found, as was  
10 mentioned, 81 percent of American consumers agree that  
11 rather than labelling products as containing biotech  
12 ingredients it would be better for food manufacturers, the  
13 government, health professionals and others to provide more  
14 details through toll free phone numbers, brochures and  
15 websites.

16           Consumers need the FDA to maintain its focus on  
17 the science of safety rather than of sociology. It's not  
18 small irony that the European Union would like to set up an  
19 FDA-like organization to bring confidence in their own food  
20 regulation to the levels of support that Americans express  
21 for FDA. I will submit our complete survey results for the  
22 record. Thank you for the opportunity.

23           MR. ROBERT LAKE: Go ahead.

24           MS. TAMMY SHEA: Hi. My name is Tammy Shea, I'm  
25 with the Gateway Green Alliance of St. Louis. First I'd

1 like to -- one swift comment, if you really want to instill  
2 trust in American public get Monsanto out of the FDA.

3 [Applause.]

4 The opportunity to comment on the use of  
5 genetically modified organisms to produce food is welcomed  
6 by myself and others that share my concern for the safety of  
7 these foods. However, the timing of the comment period  
8 seems at best to be belated. Offering consumers the chance  
9 to address the multitude of issues that surround the use of  
10 GMOs in food production is to be commended but should have  
11 occurred much earlier in the process, perhaps before these  
12 products were on the market shelves.

13 I would like to take this opportunity to recommend  
14 that FDA not use this comment period as a justification for  
15 proceeding with more approvals of GMOs but rather to realize  
16 that all agencies involved, USDA, EPA, NIH have acted with  
17 gross negligence by failing to solicit or even consider  
18 public response before granting approval for the widespread  
19 commercial use of GMOs.

20 As you've probably realized over the past several  
21 months there's a growing concern about the safety of these  
22 things, their necessity and their impact economically,  
23 ecologically and more importantly the objectivity, or lack  
24 thereof by the governing agencies in their rapid approval.

25 First I think it's important to be very clear

1 about some of the reasons for the opposition to GMOs. We  
2 hear a lot about how the public is just overemotional and  
3 uneducated and they don't understand the science. The  
4 opposition is characterized as being not educated. On the  
5 contrary, the opposition to the current use of GMOs has  
6 resulted from the vast amount of information not corporate  
7 science but independent science that is available on the  
8 internet and between concerned groups.

9 And that information is telling an already very  
10 cynical public that the use of GMOs in agriculture limits  
11 choices for consumers, threatens food safety, does not  
12 promote sustainability and will undermine what is left of an  
13 independent family farms in this country and around the  
14 world. The integrity and the objectivity of the FDA -- is  
15 over.

16 MR. ROBERT LAKE: Thank you, ma'am. Go ahead.

17 MR. JOSEPH GROENKE: My name is Joseph Groenke and  
18 I am representing the Basic Food Group an organization of  
19 hysterical and confused students and faculty from the  
20 University of Michigan who are concerned with food and  
21 agricultural issues.

22 The FDA's policies concerning genetically modified  
23 organisms have not served the interest of voting eaters who  
24 desire a healthy and democratic food production system or  
25 the ecological and economic health of rural communities all

1 but decimated by corporate model farming. Rather they have  
2 served to promote the economic growth of U.S. biotechnology  
3 an escalating corporate control of our food supply.

4           We came up with three false assumptions that we  
5 felt the FDA made in accessing genetically modified  
6 organisms. Number one that genetic engineering is the same  
7 as traditional plant breeding techniques. To say that  
8 splicing genes from distantly related organisms is the same  
9 as interspecific or intergeneric cross breeding is pretty  
10 much like saying that flying from Detroit to Chicago is the  
11 same as walking that same distance. Not only do traditional  
12 breeding techniques take generations of careful selection  
13 they are bounded by ecological and genetic parameters that  
14 exist in nature.

15           Number two, adequate testing has been conducted  
16 concerning human health. In terms of detrimental health  
17 affects it is essential to remember that absence of evidence  
18 is not evidence of absence. Test thus far have been short  
19 term, adhoc, primarily corporately and not publicly funded  
20 and have focused on narrow issues such as known allergic  
21 responses. We should not have to put our bodies at risk to  
22 confirm or negate the safety of GMOs.

23           Number three, the public's desire for labels on  
24 GMOs is not an adequate reason to label. The public's right  
25 to know what they are eating is a justifiable reason for

1 labelling. The Freedom of Information Act and other  
2 disclosure laws allow citizens access to information. In an  
3 age where food has become intellectual property we are  
4 literally being fed biotechnology. Everyone here seems to  
5 be interested in a dialogue but we have to realize that  
6 labelling is an initiation of a dialogue and not labelling  
7 is silence.

8 Citizens in this country have many reasons to  
9 support or not support GMOs and I'm done.

10 MR. ROBERT LAKE: Thank you. Next.

11 MR. KYD BRENNER: Thank you. I'm Kyd Brenner,  
12 Vice President of the Corn Refiners Association which is the  
13 national trade association representing U.S. processors of  
14 corn for food, feed and industrial products. You know, one  
15 of our U.S. senators recently said that everything that can  
16 be said here today has been said but not everyone has said  
17 it so I appreciate the chance to have my two cents on this.

18 Judging by recent press articles there does appear  
19 to be confusion concerning your authority over and policies  
20 concerning food derived from biotechnology. We welcome  
21 these meetings as one method for the agency to ensure that  
22 the widespread trust it enjoys with consumers extends  
23 through its actions on biotechnology. Our association  
24 supports the continued development and implementation of  
25 plant biotechnology. Today we safely process crops that

1 have been designed primarily to help farmers reduce insect  
2 and weed damage. However, research is far along on corn  
3 varieties with improved nutritional profiles for oil and  
4 protein and with changed starch structures that will make  
5 new food ingredients available.

6 It is in all of our interest that there be a  
7 research, legal and business climate that permits this work  
8 to come to fruition. Regarding the consultation process,  
9 while under law this is voluntary, in practical effect it is  
10 mandatory. Put simply, corn growers would not plant and our  
11 members would not purchase new crop varieties that had not  
12 been through an FDA consultation process. We also reiterate  
13 our support for the current FDA labelling policy. We would  
14 support clearer standards from the agency governing the use  
15 of biotech or non-biotech claims on food labels.

16 As with its review process, the agency has  
17 invested considerable credibility in crafting a food  
18 labelling system that provides information useful to make a  
19 balanced diet. We believe any changes considered to this  
20 system should add to this information and not detract from  
21 it. Thank you.

22 MR. ROBERT LAKE: Thank you. Next.

23 MR. ROBERT HASELKORN: I'm Robert Haselkorn, I'm a  
24 professor at the University of Chicago. I'm the chairman of  
25 the plant biology section of the National Academy of

1 Science. I was a member of the recumbent [phonetic] DNA  
2 Advisory Committee. I was co-author of a book in 1988  
3 called Field Testing Genetically Modified Organisms a Study  
4 of the National Research Council whose suggested guidelines  
5 have been followed to the letter by the FDA and I think you  
6 should be commended for that.

7 I also support all of the FDA's actions in this  
8 area to date. I think they are right on the mark. I have a  
9 few little suggestions. If people want labels on everything  
10 that has genetically modified things in them then we have to  
11 label all of our beer and all of our soft drinks because all  
12 of the yeast strains used in the beer fermentation these  
13 days are genetically modified. And the enzymes for  
14 converting corn starch into high fructose syrup are made by  
15 genetic engineering. So, you're going to label every soda  
16 bottle, every beer can in America with contains genetically  
17 modified blah, blah, blah.

18 And also we heard about a label suggesting that  
19 something should say it has genetically modified organisms  
20 in it, but I don't think the Greens would like that label to  
21 say this rice has enhanced vitamin A thanks to genetic  
22 engineering. That's enough.

23 MR. ROBERT LAKE: Thank you. Next.

24 MR. STEVEN DRUKER: My name is Steven Druker,  
25 Executive Director of the Alliance for Bio-Integrity. Our

1 organization coordinated the law suite against the FDA to  
2 gain mandatory safety testing and labelling of genetically  
3 engineered foods. You've heard about the law suit from  
4 Joseph Mendelson earlier who's one of our collaborators.

5           What you need to know, Commissioner Henney, is  
6 that some of the strongest warnings about the risks of  
7 genetically engineered food come from the agencies own  
8 scientists. They're within the agencies own records. I've  
9 seen those records because of the law suit. I probably am  
10 more familiar with them than anybody within the FDA. And,  
11 Madam Commissioner, you need to know what's in there too  
12 because there are warning after warning from numerous  
13 scientists within the agency that recumbent DNA technology  
14 entails a unique set of risks and can generate unintended  
15 and completely unpredictable toxins, carcinogens and  
16 anti-nutritive substances.

17           Just to summarize, because two minutes will not do  
18 justice, but one of the best summaries of this comment came  
19 from Dr. Linda Call [phonetic] of the FDA who objected in a  
20 memo to Dr. Marianski [phonetic] that the agency was "trying  
21 to fit a square peg into a round hole by trying to force  
22 ultimate conclusion that there is no difference between  
23 foods modified by genetic engineering and foods modified by  
24 traditional breeding practices". And then she went on, "The  
25 processes of genetic engineering and traditional breeding

1 are different and according to the technical experts in the  
2 agency they lead to different risks."

3 That was not her personal opinion that was her  
4 summary of what is in the record and that's a very fair and  
5 adequate summary. If you really are wanting to be a  
6 responsible public servant, which I think you are, you will  
7 not only accept what you have heard from those who came  
8 before you, you will look at our website where these  
9 documents, many of these documents are now scanned in in  
10 their original form. You and the rest of the world can see  
11 the extent of the concern within your own agency.  
12 [www.bio-integrity.org](http://www.bio-integrity.org). Thank you very much.

13 MR. ROBERT LAKE: Thank you. Next.

14 DR. COLIN SCANES: I am Colin Scanes. I am the  
15 Director of the Plant Science Institute at Iowa State  
16 University. I'm a biochemist and agricultural scientist.  
17 Thank you for this opportunity to be presenting today.

18 Point one; There is a real need for food to meet  
19 the needs of a growing world population. At the moment  
20 somewhere around 800 million people do not receive  
21 sufficient nutrition.

22 Two; At Iowa State University we are establishing  
23 a comprehensive Plant Science Institute with fundamental  
24 research and accountability to the public. We intend this  
25 to be a leading source of objective research information to

1 the public and policy makers and a forum for dialogue.

2 Three; Public confidence depends on the quality of  
3 information. There maybe a case for public, independent and  
4 third party testing for the ethicacy and safety of  
5 genetically modified foods.

6 Five; There is a question of whether genetically  
7 modified foods should be labelled. On one hand, there is  
8 not evidence of significant changes in the foods due to the  
9 process of genetic modification. On the other hand, there  
10 is significant interest from the public to have labelling.  
11 It maybe questioned if labelling is not based on science  
12 when does the need for labelling begin and when does it end?  
13 Also on labelling we need to ensure it's verifiable and does  
14 not put farmers to undue risk.

15 In conclusion, we all are working to protect food  
16 quality and safety and thereby enhance public confidence in  
17 the safety of the food. Thank you very much.

18 MR. ROBERT LAKE: Thank you, sir. Next.

19 MR. JIM DAVIS: Thank you. My name is Jim Davis.  
20 I'm a member of the Natural Law Party. In the Alliance for  
21 Bio-Integrity's law suit not only are there nine well  
22 credential scientists for plaintiffs but there are also 17  
23 religious leaders from a broad spectrum of faiths including  
24 seven Christian theologians and three Rabbis.

25 They're plaintiffs because they object to eating

1 all GE food on the basis of religious principle. I share  
2 their well founded, sincere beliefs and object to eating GE  
3 foods and agree with them that the FDA is unreasonably  
4 restricting our right to exercise our principles by not  
5 labelling the foods which contain them.

6 Now, my particular faith is based on a pragmatic  
7 not an uninformed basis. I believe that the Creator, the  
8 intelligence of the Creator which created boundaries between  
9 species, that could not be crossed in nature, did this out  
10 of concern for us. It was brought out by Dr. Hardy earlier  
11 this morning that we only have knowledge of about 50 percent  
12 of the parts, the functions that they perform in terms of  
13 the genetic code. Certainly we do not have the holistic,  
14 interactive knowledge which is necessary of the relationship  
15 of each of the parts of the genetic code into making a whole  
16 which is greater than the sum of the parts.

17 We are going headlong without full knowledge and I  
18 feel on the basis of religious principle that we should have  
19 the right to have labelling. And that as each of you ponder  
20 your conclusions, use not only your mind but also your heart  
21 and your soul.

22 MR. ROBERT LAKE: Thank you, sir.

23 MS. LAURIE HARMS: Hello. My name is Laurie Harms  
24 on here on behalf of the Family Farm Defenders. We're a  
25 group of farmers and consumers who were brought together to

1 protest the Stealth introduction, a very common bovine  
2 growth hormone, into our nation's milk supply. Since we  
3 joined with other progressive farmers this past summer we  
4 came out with a list of demands for you.

5 Demand a suspension of sales, environmental  
6 releases and further governmental approvals of all  
7 genetically engineered seeds, agricultural products until an  
8 independent and comprehensive assessment of the social,  
9 environmental, health and economic impacts --

10 MR. ROBERT LAKE: Could you speak into the  
11 microphone a little more? Thank you.

12 MS. LAURIE HARMS: -- of these products is  
13 concluded. Demand a ban on the ownership of all forms of  
14 life including a ban on the patentings of seeds, plants,  
15 animals, genes and cell lines. Demand that agrarian people  
16 who have cultivated and nurtured crops for thousands of  
17 years retain control of natural resources and maintain the  
18 right to use or reuse any genetic resource.

19 Demand that corporate agri-business be held liable  
20 for any and all damages that result from the use of  
21 genetically engineered crops and livestock that were  
22 approved for use without an adequate assessment of the risk  
23 posed to farmers, human health and the environment. Demand  
24 that corporations and institutions that have intervened in  
25 the genetic integrity of life bear the burden of proof that

1 their actions will not harm human health, the environment or  
2 damage the social and economic health of rural communities.  
3 Those corporations must bear the cost of an independent  
4 review guided by the precautionary principle and conducted  
5 prior to the introduction of any new intervention.

6           And six; Demand that consumers in the U.S. and  
7 around the globe have the right to know whether their food  
8 is genetically engineered and a right to access naturally  
9 produced food. This process that we're going through  
10 perhaps the USDA and the EPA will go through another one to  
11 access our opinions on genetically engineered foods and  
12 genetic engineering in general. But it's just a reflection  
13 of the reduction of science that has brought us to this  
14 point and I would like to reiterate what some of my  
15 predecessors have said.

16           We're the youngest species on this planet. We are  
17 enabling some of the oldest and most adaptable species to  
18 cross barriers, to do something they have never ever done  
19 before.

20           MR. ROBERT LAKE: Thank you, ma'am.

21           MS. RHONA APPLEBAUM: Good afternoon. My name is  
22 Rhona Applebaum and I serve as the Executive Vice President  
23 of Scientific and Regulatory Affairs for the National Food  
24 Processors Association, the principle scientific and  
25 technical food trade association for the processed food

1 industry.

2 Food safety concerns related to biotech food  
3 products should be considered and addressed no differently  
4 than other foods with the common goal of continuing to  
5 ensure the safest food supply possible. We've all heard  
6 today about FDA's biotech policy including the consultation  
7 process involved in accessing safety. I won't repeat what's  
8 already been said but I do want to re-emphasize that FDA's  
9 consultation is a process all companies have made use of  
10 prior to the marketing of new products from engineered  
11 plants.

12 Every single company has used this process, but it  
13 is voluntary and this fact has called much criticism. Could  
14 this prior to market process be made more formal and  
15 transparent using already established procedures established  
16 for other FDA regulated food products? Yes, it could and  
17 should. And we would welcome the opportunity to discuss our  
18 ideas further with FDA and others interested in maintaining  
19 consumer's confidence in the safety assessment process and  
20 advancing the science and benefits of food biotechnology.

21 NFPA strongly supports current FDA policy on  
22 labelling requirements for biotech foods. The policy is  
23 science based and is designed to mandate the labelling of  
24 any information which is material or of consequence to the  
25 consumer with respect to safety, health and nutrition. NFPA